Chirurgie assistée par robot: health technology assessment

KCE reports 104B

Federaal Kenniscentrum voor de Gezondheidszorg
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PREFACE

La présence de robots dans nos quartiers opératoires semble relever de la science fiction. Et pourtant, il y en a déjà au moins une vingtaine installés en Belgique, beaucoup plus que dans les pays voisins. De plus, leur répartition géographique est très particulière : souvent plusieurs robots dans la même ville et concentration à l'intérieur de certaines régions.

A quelles fins et pourquoi ces robots sont ils utilisés ? Est il prouvé que les opérations 'assistées par robot' conduisent à de meilleurs résultats ? Des questions auxquelles il fallait apporter une réponse, notamment parce que les robots coûtent très cher, aussi bien à l'achat qu'à l'utilisation. Jusqu'à présent, aucun remboursement supplémentaire n'est prévu. Beaucoup d'hôpitaux demandent donc des suppléments et les patients doivent y aller de leur poche.

Nous espérons que les données et les résultats que nous avons pu rassembler dans ce rapport d'évaluation technologique permettront aux hôpitaux et aux médecins de mieux mesurer s'ils doivent se lancer dans ce genre d'investissement, aux patients de pouvoir poser de bonnes questions, notamment sur ce qu'ils vont devoir débourser et aux autorités de mieux encadrer la prolifération un peu anarchique d'un matériel peut-être promis à un bel avenir mais dont le coût justifie que certaines précautions soient prises.

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Résumé

INTRODUCTION

La chirurgie est invasive par nature. Au fil du temps, des efforts ont été déployés pour réduire les complications et atténuer le traumatisme inhérent à la chirurgie. Pour ce faire, de nouveaux instruments ont été mis au point, ainsi que des techniques plus ingénieuses et des procédures minimalement invasives utilisant des orifices naturels, la voie transcutanée ou encore de petits orifices artificiels lors d'une laparoscopie. On peut considérer les instruments robotiques comme un nouveau jalon dans cette évolution. Ces robots chirurgicaux offrent davantage de flexibilité, plus de stabilité et une meilleure visibilité.

Cependant, toute nouvelle technologie doit être jugée à l'aune de ses performances et de son efficience, et pas seulement à sa force probante au niveau technologique. Le prix d'achat d'un robot avoisine 1,7 millions d'euros, tandis que le coût de maintenance annuel se monte approximativement à 10% de cette somme. En outre, chaque opération individuelle requiert du matériel coûteux, réutilisable un nombre limité de fois.

Le présent rapport porte sur la chirurgie minimalement invasive assistée par robot, dans laquelle le chirurgien qui se trouve dans la même pièce que son patient commande à distance les instruments chirurgicaux. La télémédecine (dans laquelle l'opérateur est séparé géographiquement du patient) n'est pas couverte par le champ d'application du présent rapport. Enfin, ce rapport ne traite pas non plus de la question de savoir s'il est optimal d'intervenir chirurgicalement dans un état pathologique donné.

QUESTIONS ET MÉTHODES DE RECHERCHE

L'objectif de ce *'Health Technology Assessment'* est de déterminer l'efficacité clinique et le bénéfice potentiel des systèmes robotiques chirurgicaux actuellement sur le marché par rapport aux interventions classiques (soit les interventions minimalement invasives par laparoscopie ou la chirurgie ouverte traditionnelle), et ce pour diverses indications. Par ailleurs, et surtout parce que le recours à l'assistance robotique est onéreux, nous évaluerons également le rapport coût efficacité de cette technologie par rapport aux techniques classiques. Finalement, nous avons voulu décrire la pratique actuelle en Belgique et dans le monde, de même que les évolutions prévisibles dans ce domaine et les conséquences pratiques, juridiques et éthiques du recours à cette technologie pour les patients, les hôpitaux et les chirurgiens.

Pour ce faire, nous avons effectué une étude systématique de la littérature existante sur ce sujet. Pour décrire l'utilisation actuelle en Belgique, nous avons en outre envoyé un questionnaire aux hôpitaux belges qui ont actuellement recours à la robotique en chirurgie. S'agissant des aspects éthiques et des problèmes liés aux patients, un panel d'éthiciens a été consulté.

SYSTEMES DE CHIRURGIE ASSISTEE PAR ROBOT

Les tentatives visant à concevoir des systèmes chirurgicaux robotisés ont été multiples. Hormis quelques systèmes expérimentaux, un seul fabricant commercialise avec succès un robot chirurgical à l'heure actuelle. Ce système est doté d'une imagerie haute définition, stéréo et agrandie. Il offre la possibilité d'effectuer des mouvements précis, sans tremblement, et il utilise des instruments articulés intracorporels à degrés de liberté multiples, ce qui permet de remédier partiellement à l'effet de pivot observé avec les instruments rigides de la laparoscopie. Grâce à sa facilité d'emploi alléguée, aussi appelée *'approche intuitive'* on attend de ce système qu'il présente des courbes d'apprentissage plus courtes et qu'il offre des avantages ergonomiques pour le chirurgien.

Ce système présente aussi certains désavantages. L'absence de retour d'effort (feedback haptique) est souvent mentionnée comme problème potentiel dans la dissection de tissus ou dans les interventions de microchirurgie. Par ailleurs, il faut prendre en compte l'expérience à ce jour limitée et le manque de formation. Enfin, force est de constater également le problème majeur de son coût, non seulement à l'achat, mais aussi celui de son entretien et de ses fournitures.

INDICATIONS CHIRURGICALES

Historiquement, la chirurgie assistée par robot a, dans un premier temps, été utilisée en chirurgie générale de l'abdomen dans le but de se forger une expérience. A l'heure actuelle, elle est essentiellement appliquée en chirurgie urologique et plus spécifiquement pour la prostatectomie radicale. Par ailleurs, son utilisation en gynécologie progresse rapidement. Enfin, la chirurgie thoracique, surtout cardiaque, constitue un exemple d'autre usage potentiel de la robotique en chirurgie.

Les données probantes relatives à la chirurgie assistée par ordinateur ne cessent de s'étoffer avec une augmentation exponentielle du nombre de publications ces dernières années. Toutefois, la majorité des données probantes n'est pas réunie via des études comparatives, mais se fonde sur des séries de cas dans des centres importants. On pourrait s'interroger à propos de la pertinence de telles preuves pour un hôpital local qui n'effectue qu'un nombre limité d'interventions. Étant bien entendu que le même doute vaut aussi pour de nombreuses formes de médecine exigeant une dextérité manuelle certaine. Dans la littérature actuelle, on trouve surtout des données portant sur un suivi à court terme. Les données probantes montrent également que les performances et les résultats s'améliorent à mesure que l'équipe chirurgicale engrange de l'expérience.

Des données concernant plusieurs interventions spécifiques ont été réunies dans le présent rapport. Grâce à ces éléments, nous pouvons conclure que la chirurgie assistée par ordinateur est relativement sûre et efficiente lorsqu'elle est pratiquée par des équipes chirurgicales expérimentées. Pour de nombreuses indications, on rapporte également que la chirurgie assistée par ordinateur est moins exigeante pour le chirurgien, tant grâce à une courbe d'apprentissage réputée plus courte qu'en raison d'avantages ergonomiques qui réduisent le stress physique imposé à l'opérateur.

La majorité des données probantes disponibles concernent la prostatectomie radicale assistée par ordinateur, qui constitue du reste l'indication actuellement la plus importante en Belgique et dans le monde. Des éléments indiquent que les pertes sanguines péri-opératoires sont moins importantes qu'avec les techniques conventionnelles. En revanche, les données probantes concernant d'autres avantages escomptés, notamment une réduction de l'incontinence et de la dysfonction érectile ou un séjour plus court à l'hôpital, sont moins cohérentes et largement tributaires de la dextérité et de l'expérience de l'équipe chirurgicale. Même si le niveau des avantages potentiels est variable, ces conclusions valent également peu ou prou pour les plupart des autres indications en urologie, gynécologie, chirurgie thoracique et chirurgie générale de l'abdomen. C'est dans cette dernière que la valeur ajoutée semble la plus faible. En effet, de telles interventions peuvent très souvent être réalisées aisément et plus rapidement avec une chirurgie conventionnelle minimalement invasive et à moindre coût. La chirurgie minimalement invasive pouvant se révéler difficile à pratiquer en gynécologie, les robots pourraient apporter une plus-value en imposant moins d'exigences au chirurgien, tant au niveau de la dextérité que d'un point de vue ergonomique. En chirurgie thoracique, particulièrement cardiaque, l'assistance d'un robot pourrait faciliter les procédures minimalement invasives difficiles à réaliser autrement.

En règle générale, et s'agissant de diverses spécialités chirurgicales, la chirurgie assistée par robot est réputée offrir un maximum d'avantages dans les procédures de reconstruction complexes, avec accès difficile et espace disponible limité à l'intérieur du corps. Toutefois, à l'heure actuelle, aucune allégation de la supériorité de la chirurgie assistée par ordinateur ne peut ni ne devrait être formulée car cela pourrait augmenter les attentes des patients jusqu'à des niveaux irréalistes.

Outre l'aspect coût, un frein important dans toutes les spécialités semble résider en l'absence de données sur les résultats. Une autre contrainte concerne la réalisation de procédures sur des superficies importantes, plus précisément la chirurgie abdominale multi-quadrants, qui exigent actuellement un ré-arrimage (re-docking) du système.

Les études observationnelles actuelles devront être complétées par des études comparatives contrôlées et des bases de données prospectives élaborées sur les enregistrements nationaux. Suite à cet exercice, les données probantes devront faire l'objet d'une réévaluation future. Si l'on met en place des enregistrements prospectifs, il sera essentiel de définir clairement dès le départ les variables nécessaires, y compris les caractéristiques pertinentes du patient, les paramètres péri-opératoires et de résultats, avec un concept d'analyse de données prédéfini.

SITUATION, COUT ET REMBOURSEMENT

Au moins 20 des ces systèmes chirurgicaux assistés par robot sont actuellement utilisés en Belgique. Par rapport au reste du monde, notre pays arrive en deuxième place en nombre de systèmes chirurgicaux assistés par robot par habitant, juste derrière les États-Unis, mais bien avant d'autres pays européens comparables au nôtre. De nos entretiens, nous avons appris que le marketing représente un argument important pour l'acquisition d'un système chirurgical assistés par robot dans certains hôpitaux belges: *« Le robot montre que notre hôpital et nos médecins sont des précurseurs en matière technologique. »* Il ne s'agit pas nécessairement du meilleur argument pour acquérir un matériel coûteux dont l'entretien et l'utilisation sont également onéreux. Dans la pratique, les systèmes installés sont utilisés à des degrés divers et notre enquête a montré que, en Belgique en tout cas, bon nombre d'entre eux ne sont pas employés à pleine capacité.

Le coût supplémentaire associé à une chirurgie assistée par robot ne faisant pas l'objet d'un remboursement spécifique, de nombreux hôpitaux demandent au patient d'acquitter un supplément obligatoire non remboursable, le plus souvent de 1200 euros pour une prostatectomie radicale. Le récent accord national médico-mutualiste demande que le conseil technique des implants transmette au comité de l'assurance une proposition de remboursement du matériel de chirurgie du robot avant la fin mars 2009. Nous avons évalué l'impact budgétaire dans le cas où un remboursement partiel serait envisagé et nous avons pris comme exemple la prostatectomie radicale qui constitue l'essentiel des procédures réalisées actuellement avec assistance robotique. Selon les différents scenarii évalués, l'impact budgétaire pour la seule prostatectomie atteindrait entre 400.000 et 3 millions d'euros, en partant de l'hypothèse que le nombre de prostatectomies radicales resterait relativement constant. Toutefois, il existe un risque de voir la disponibilité de la chirurgie assistée par robot créer une hausse de la « demande » en prostatectomies radicales qui serait induite par l'offre.

Le coût de la chirurgie assistée par robot est en partie fonction du prix d'achat et d'entretien, mais aussi du prix du matériel et des instruments spécifiques qui sont préprogrammés pour n'être utilisés qu'un nombre limité de fois, généralement dix fois. En conséquence, le coût de la chirurgie assistée par robot pour les hôpitaux et la société est tributaire du volume. Sur la base des prix actuels, la chirurgie assistée par robot est aujourd'hui plus onéreuse que la chirurgie conventionnelle dans la plupart des indications. La décision d'installer un système de chirurgie robotisée peut aussi avoir des implications importantes pour la logistique hospitalière, notamment la capacité en salles d'opération.

En l'absence de données probantes cliniques claires, il n'a pas été possible de réaliser des analyses coût efficacité valables. Il existe un besoin fondamental en analyses coût efficacité, conduites conjointement à des études randomisées, incluant des données sur le suivi à long terme et sur la qualité de vie liée à la santé après la chirurgie.

PROBLEMES JURIDIQUES, ÉTHIQUES ET LIES AU PATIENT

D'un point de vie juridique, le consentement du patient et le secret professionnel sont deux principes essentiels de toute activité médicale. Ce qui implique qu'une information claire et complète à propos de l'ensemble de la procédure doive être fournie au patient dans un langage clair, compréhensible pour un profane. En l'absence de tout canevas officiel et opposable, le contenu de cette information sera laissé aux bons soins du médecin. Le patient devrait également être informé des cas où des suppléments non remboursables sont exigés pour une procédure spécifique. Cependant, dans le contexte juridique actuel, il n'existe pas de base claire et fiable permettant de facturer de tels suppléments au patient. En théorie, cela signifie donc qu'une telle politique pourrait être contestée en justice. En termes de responsabilité médicale, les règles de droit traditionnelles sont applicables, comme pour tout acte médical, mais elles ne sont pas spécifiques à la chirurgie assistée par robot.

D'un point de vue éthique, des informations devraient être fournies au patient en ce qui concerne la procédure, les procédures alternatives, la formation et l'expérience du chirurgien dans cette technologie et le supplément à acquitter par le patient. Les patients devraient recevoir une information spécifique à propos du stade de la courbe d'apprentissage de l'équipe chirurgicale. Dans un tel cadre, les chirurgiens ont l'obligation professionnelle de guider et conseiller le patient, dans une relation de confiance, afin qu'il pose le choix adéquat. A fortiori en raison du fait que des allégations de supériorité ne peuvent pas et ne devraient pas être formulées sur la base du simple fait que l'on a recours à une chirurgie assistée par robot.

La position de monopole de l'entreprise au niveau du marketing des systèmes chirurgicaux robotisés nous a amenés à nous pencher sur les règles particulières de l'UE et de la Belgique en matière de concurrence. La législation sur la protection des consommateurs n'est pas applicable à ce système chirurgical. La jurisprudence de la Cour européenne de Justice sur les '*abus de position dominante*' ne l'est pas non plus. Cependant, le concept juridique belge de *'conditions de transaction déloyales'* pourrait être pertinent, surtout dans le cas des instruments à usage limité qui sont préprogrammés pour cesser de fonctionner après 10 interventions.

La formation de base dispensée par le fabricant lors de l'acquisition d'un système ne peut pas être considérée comme officielle. Toutefois, d'un point de vue juridique, il n'existe pas d'exigences particulières pour les chirurgiens : l'utilisation de la chirurgie assistée par robot reste de la responsabilité du chirurgien, celle-ci comprenant, entre autres, les règles du Code de déontologie médicale.

CONCLUSION

À l'heure actuelle, quelque 20 systèmes de chirurgie robotisée sont utilisés en Belgique, principalement en urologie pour pratiquer la prostatectomie radicale. Outre cette indication, la chirurgie assistée par robot est également de plus en plus utilisée en gynécologie et en cardiologie, tandis que pour l'heure, les indications en chirurgie générale de l'abdomen et dans d'autres domaines, semblent limitées.

La chirurgie assistée par robot est une technologie émergente qui pourrait être prometteuse dans des circonstances idéales, à condition que l'équipe chirurgicale qui réalise les interventions ait reçu une formation idoine et possède l'expérience adéquate. En dépit des allégations implicites, voire explicites, de la supériorité de cette technologie, ses avantages manifestes n'ont pas été prouvés et sont largement tributaires de la dextérité chirurgicale et de l'expérience professionnelle de l'équipe pratiquant l'intervention.

Toute allégation d'un avantage réel ne peut être étayée que par des études comparatives contrôlées qui compareraient cette technique aux interventions conventionnelles pertinentes. Pour réunir une expérience valable des performances de cette technique au quotidien, il est nécessaire de rassembler des informations sur ses performances réelles. Ainsi, un enregistrement prospectif des caractéristiques du patient, des paramètres péri-opératoires et du suivi des résultats dans des centres et par des équipes réalisant un nombre suffisant de ces interventions, s'avère nécessaire.

Les patients sont souvent tenus de payer un supplément non remboursable lorsque cette technologie innovante est utilisée. Les patients doivent être informés de cet état de fait et recevoir par ailleurs une information sur la procédure de même que des éléments informatifs objectifs sur les procédures alternatives, dans un langage clair et compréhensible.

RECOMMANDATIONS POLITIQUES

COMMENT ET OU ?

- Il n'existe pas de données probantes claires permettant de valider ou de réfuter la supériorité de la chirurgie assistée par robot. En conséquence, les chirurgiens devraient s'abstenir de présenter cette technique comme étant par nature supérieure, au risque de susciter des attentes déraisonnables chez les patients.
- La sécurité et l'efficacité de la chirurgie assistée par robot ont été raisonnablement établies, mais seulement lorsqu'elle est pratiquée par des équipes chirurgicales dotées de la dextérité et de l'expérience adéquates avec cette technique. Certains éléments indiquent également que les performances et les résultats pour le patient s'améliorent à mesure que l'expérience avec cette technique croît. En conséquence, nous recommandons que la chirurgie assistée par robot ne soit pratiquée que par des équipes chirurgicales spécialisées dans les interventions spécifiques faisant appel à la robotique. En raison du nombre absolu limité d'interventions potentielles en Belgique pour chacune des différentes disciplines, le nombre de ces équipes spécialisées devrait être limité afin de permettre à ces dernières d'engranger l'expérience requise.
- Il est nécessaire de procéder à un enregistrement spécifique obligatoire des interventions réalisées avec la chirurgie assistée par robot, de même que des caractéristiques et des résultats du patient, dans le but de protéger les patients.

INFORMATION DU PATIENT

- En application de la loi relative aux droits du patient, une information claire, objective et complète relative à l'ensemble de la procédure proposée et aux procédures alternatives doit être fournie au patient. Dans le contexte particulier de la chirurgie assistée par robot, il convient que cette information porte également sur la formation et l'expérience de l'équipe chirurgicale dans cette technologie de même que sur les suppléments non remboursables que le patient devra acquitter, le cas échéant.

COUT ET REMBOURSEMENT

- Comme la firme qui commercialise les robots est en situation de monopole, le prix de vente de ses machines et de son matériel disposable est déterminé par ce que les clients sont disposés à payer plutôt que par les coûts réels de production. Dès lors, les autorités publiques devraient demander plus de transparence de la part du producteur en ce qui concerne les coûts réels de développement et les raisons de l'usage limité du matériel.
- En raison des frais supplémentaires inhérents à la chirurgie assistée par robot, de nombreux hôpitaux demandent actuellement un supplément non remboursable aux patients, généralement d'un montant de 1200 euros. Dans le contexte légal actuel, le patient n'est pas suffisamment protégé contre les débours importants liés à l'utilisation de matériels médicaux. Cette absence de protection est particulièrement préjudiciable lorsqu'il n'existe que des données probantes limitées au sujet des matériels utilisés, comme c'est le cas ici. Le KCE recommande une clarification du cadre législatif relatif à la prise en charge du coût du matériel médical.
- Compte tenu des données probantes encore limitées sur les avantages de la chirurgie assistée par robot, un remboursement complémentaire inconditionnel ne peut pas être recommandé pour l'instant. Cette recommandation sera à revoir en fonction de l'évolution de la technique et de ses résultats.
- Si les décideurs, comme implicitement demandé dans l'accord médico-mutualiste, devaient envisager un remboursement complémentaire à charge des deniers publics, une telle décision devrait certainement aller de pair avec la collecte de données prospectives afin de réunir des données probantes supplémentaires permettant de déterminer si oui ou non, la chirurgie assistée par robot présente réellement les avantages allégués. Ainsi, ce remboursement devrait être limité à des interventions spécifiques et à des centres chirurgicaux spécialisés spécifiques, et ce, pour une période limitée. Après celle-ci, il conviendra de procéder à une évaluation comportant un plan d'analyse prédéfini et une collecte des caractéristiques pertinentes des patients et des données péri-opératoires et relatives aux résultats afin d'éviter de réunir des informations inutilisables, non pertinentes ou hors de propos. Il convient d'impliquer les organisations professionnelles intéressées dans la collecte et l'analyse des données, ces dernières devant être rendues publiques.
- De toute évidence, la mise en place d'un tel système de récoltes de données impliquerait des coûts supplémentaires et une décision doit être prise pour savoir qui doit les supporter : la société, les hôpitaux, ou le fabricant.

Scientific summary

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ABBREVIATIONS

AAGL	American Association of Gynecologic Laparoscopists (classification)
ACS	Acute Coronary Syndrome
AHRQ	Agency for Healthcare Research and Quality (US)
AM	Arreté Ministériel (Ministerial Decree) (Belgium)
AMI	Acute Myocardial Infarction
AR	Arreté Royal (Royal Decree) (Belgium)
ASC	Abdominal Sacrocolpopexy
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (Australia)
AUD	Australian Dollar
BiV	BiVentricular
BMS	Bare Metal Stent
CABG	Coronary Artery Bypass Grafting
CAD	Canadian Dollar
CBA	Cost-Benefit Analysis
CDSR	Cochrane Database of Systematic Reviews
CE	Cost Effectiveness
CEA	Cost-Effectiveness Analysis
CI	Confidence Interval
CLF	Conventional Laparoscopic Fundoplication
CMA	Cost-Minimization Analysis
CPB	Cardio Pulmonary Bypass
CRD	Centre for Reviews and Dissemination
CUA	Cost-Utility Analysis
CVZ	College voor Zorgverzekeringen (the Netherlands)
DARE	Database of Abstracts of Reviews of Effects
DBC	Diagnosebehandelingcombinatie (the Netherlands) - Diagnosis Treatment Combination
DES	Drug Eluting Stent
DRG	Diagnosis Related Groups
DVSS	Da Vinci Surgical System
DVT	Deep Venous Thrombosis
EBL	Estimated Blood Loss
EC	European Community (forerunner of the EU)
ECJ	European Court of Justice
ENT	Ear Nose Throat (equals ORL or KNO/NKO)
EU	European Union
FOD/SPF	Federale Overheidsdienst / Service Public Fédéral (FPS) (Belgium)
FPS	Federal Public Service (ministry, see also FOD/SPF) (Belgium)

GERD	Gastro-oesophageal reflux disease
GOÄ	Gebührenordnung für Ärzte (Germany)
GP	General Practitioner
HAD scale	Hospital Anxiety and Depression scale
HAS	Haute Authorité de Santé (France)
HRG	Healthcare Resource Group
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICER	Incremental Cost-Effectiveness Ratio
IMA	Internal Mammary Artery
INAHTA	International Network of Agencies for Health Technology Assessment
ITA	Internal Thoracic Artery
KB	Koninklijk Besluit (Royal Decree) (Belgium)
LAD	Left Anterior Descending (coronary artery)
LIMA	Left Internal Mammary Artery
LITA	Left Internal Thoracic Artery
LOS	Length of Stay
LPR	Law on Patients' Rights (Belgium)
LRN	Laparoscopic Radical Nephrectomy
LRP	Laparoscopic Radical Prostatectomy
LYG	Life-Years Gained
MACE	Major Adverse Coronary Event
MAS	Medical Advisory Secretariat (Canada, Ontario)
MB	Ministerieel Besluit (Ministerial Decree)
MeSH	Medical Subject Headings (NLM)
MIDCAB	Minimally Invasive Direct Coronary Artery Bypass
MIRA	Minimally Invasive Robotic Association
MIRP	Minimally Invasive Radical Prostatectomy
MIS	Minimally Invasive Surgery
MSAC	Medical Services Advisory Committee (Australia)
MV	Mitral Valve
NHS	National Health System (UK)
NHS EED	NHS Economic Evaluation Database
NIH	National Institutes of Health (US)
NIHDI	National Institute for Health and Disability Insurance (RIZIV/INAMI) (Belgium)
NIS	National Institute of Statistics (Belgium)
NLM	National Library of Medicine (US)
NUB	Neue Untersuchungs- und Behandlungsmethoden (Germany)
NZD	New Zealand dollar

OPCAB	Off Pump Coronary Artery Bypass
OPN	Open Partial Nephrectomy
OR	Operating Room
PACAB	Port Access Coronary Artery Bypass
PbR	Payment by Results (UK)
PCI	Percutaneous Coronary Intervention
PN	Partial Nephrectomy
POP	Pelvic Organ Prolapse
PSA	Prostate Specific Antigen
PSM	Positive Surgical Margin
QALY	Quality-Adjusted Life Year
QoL	Quality of Life
RALF	Robot-Assisted Laparoscopic Fundoplication
RALP	Robot-Assisted Laparoscopic Prostatectomy
RARC	Robot-Assisted Radical Cystectomy
RASC	Robot-Assisted abdominal SacroColpopexy
RCT	Randomised Controlled Trial
RD	Risk Difference
RIZIV / INAMI	Rijksinstituut voor Ziekte en Invaliditeits Verzekering / Institut National d'Assurance Maladie - Invalidité (NIHDI) (Belgium)
RP	Radical Prostatectomy
RPN	Robot-assisted Partial Nephrectomy
RR	Relative Risk
RRCP	Robot-assisted Radical Cystoprostatectomy
RRP	Radical Retropubic Prostatectomy
RVU	Relative Value Unit
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons (US)
SD	Standard Deviation
SE	Standard Error
SMD	Standardized Mean Difference
STS	Society of Thoracic Surgeons (US)
TECAB	Totally Endoscopic Coronary Artery Bypass grafting
TRI/CTI	Technische Raad voor Implantaten – Counseil Technique des Implants (Technical Council for Implants (RIZIV-INAMI, Belgium)
TVR	Target Vessel Revascularisation
UK	United Kingdom
UPJ	Uretero Pelvic Junction
US	United States of America
VIP	Vattikuti Institute Prostatectomy

SCOPE AND METHODS

The scope of this report is on robot-assisted minimally invasive surgery (laparo- or thoracoscopic surgery) using instruments remotely controlled by an operator, but explicitly excluding automatic procedures performed solely by the machine. In practice this kind of surgery is performed by a surgeon operating the instruments from a console typically located in the same room as the patient but not within the sterile field, while a 'scrubbed assistant' attends the patient at the table. Technically it is feasible to use telemedicine for this kind of operations but this specific application of the technology is not within the scope of this report. In vivo miniature robots, either fixed-base or remotely controlled movable robots are also excluded. A comparison of surgical techniques with non-surgical alternative treatment modalities, such as watchful waiting, chemotherapy or radiotherapy is not within the scope of this assessment.

The aim of this health technology assessment is to determine the clinical effectiveness and the potential benefit of the currently marketed robotic surgical systems compared to standard interventions, either minimally invasive laparoscopic interventions or conventional open surgery and for several indications. Additionally, and especially because the use of this technology is expensive, we wanted to assess the cost and cost-effectiveness of this technology. Finally, we wanted to determine the current practice in Belgium and abroad, the foreseeable evolutions in this field and the practical, legal and ethical consequences of the implementation of this technology for patients, hospitals and surgeons.

For this assessment we conducted a systematic review of the existing literature on the topic. To describe current utilisation in Belgium we additionally questioned the Belgian hospitals currently using surgical robotic systems. For the ethical aspects and patients issues a panel of ethicists was consulted.

1 INTRODUCTION

Surgery is a medical specialty that is invasive by nature; intentional trauma is induced in patients with the general aim to obtain better outcomes, which could be better functional outcomes, increased survival, less pain and complications or other.

Historically, surgery was therefore a rather aggressive specialty, requiring large incisions to give the surgeon the ability to operate within the body. In recent decades, new techniques and instruments were introduced to make possible the development of so called 'Minimally Invasive Surgery' (MIS). This was originally performed using rigid endoscopic instruments giving the surgeon access to the operation area through small incisions around the surgical target through which the surgeon can see and use his instruments to perform the surgery, with the aim to reduce so-called 'collateral damage'. This evolution was made possible through innovations in optical instruments and miniaturisation, including miniature cameras and enhanced video displays and the development of specific surgical instruments.

This has obvious advantages in many situations, but originally MIS was limited in its possibilities, potential access routes and the complexity of manipulating the instruments through small holes inducing a lever effect. One of the problems is that, until recently, the image presented to the surgeon was two-dimensional, losing natural perspective. Another problem was the difficulty to make complex articulated movements with the original rigid instruments within the body of the patient. Lastly, classical endoscopic operations can be ergonomically demanding on the surgeon.

Since a few years robotic systems have become available that try to overcome these problems. At this moment the market is largely dominated by the da Vinci® surgical system developed and marketed since 1999 by Intuitive Surgical, Inc. (Sunnyvale, CA, USA, www.intuitivesurgical.com). Another player on the market (Computer Motion, Goleta, CA, USA) marketing the ZEUS® surgical system was taken over by Intuitive Surgical in 2003 and marketing of the ZEUS system as a separate device was afterwards abandoned.

The robots currently available have three or four arms, enable three-dimensional visualisation, magnification of the surgical field and tremor-free precise surgery with intra-abdominal articulated instruments that can move with multiple levels of freedom. Patients, surgeons, health care institutions and health payers are attracted to these new systems by several potential benefits such as shorter inpatient length of stay, quicker recovery and less pain after the procedure, and better functional and/or oncological outcomes. However, little evidence exists today that these potential advantages are indeed obtained.

Many hospitals also seem to look at this technology as a way to position their institution as a technological front-runner. In September 2008, 20 da Vinci systems where installed in Belgium, most of them in Flanders, and clustered in specific geographic areas. Eleven of these systems were installed in 2007 indicating a quick expansion of the installed base and for 2008 a similar growth is anticipated. The da Vinci surgical system is expensive, however, both in acquisition (close to 2 million Euro) as in maintenance, training of surgeons and in disposables, also called 'reposables' since most instruments used in the robot have a pre-programmed limited lifetime of typically 10 separate surgical procedures. For these reasons the health economic value of using this technology is unclear.

Cost of disposables and reposables only, disregarding acquisition, maintenance and training costs is estimated to be around €2870 per surgical intervention. Several hospitals in Belgium have therefore decided to charge a non-reimbursable supplement to patients to cover all or part of this cost. This could obviously create important patient issues, possible leading to unequal access to health care based on socio-economic position. It is also unclear how well the patient is informed about the current status of the procedure, including the problems of the learning curve for the surgeons in acquiring this technique.

Robot-assisted surgery is an emergent technology that could be promising if correctly used, and especially the development of robot-assisted radical prostatectomy has received an enthusiastic welcome. But, as with any new gadget, there is the danger of initial uncritical acceptance without much evidence about its use, Therefore, it is important to investigate whether this is only an expensive *'toys for boys'* or whether there is a real benefit in using it. This report will evaluate the existing evidence on effectiveness and costs for the common indications of using robot-assisted surgery. It further explores the potential legal issues and pitfalls of using this technology, the current usage and financing in Belgium, and the potential patient issues that might be at stake. Finally it investigates whether, and for which indications, additional funding from public resources might be desirable.

2 DESCRIPTION OF THE TECHNOLOGY

2.1 HISTORY

The word robot was introduced in modern day language by a play written by the Czech writer Karel Čapek (1890-1938). This play R.U.R. (Rossum's Universal Robots) was first performed in 1920. It is about a factory making artificial people called 'robots' that today would rather be called androids or even clones. These are creatures that could be mistaken for humans and who can think for themselves. This play was probably influenced by the old Prague legend of the Golem, a creature reportedly created by the Jewish Talmud scholar Rabbi Loew in the 16th century. The word robot itself stems from the Check word *robota* meaning 'forced labour' (http://capek.misto.cz/english/presentat.html). The theme of artificially created labour force (using cloning this time) later also came back in Aldous Huxley's *Brave New World*.

This way of looking at robots is far away from today's conception of robots. According to the Oxford English Dictionary (http://www.askoxford.com/?view=uk) a robot is a machine capable of carrying out a complex series of actions automatically, especially one programmable by a computer. This definition still describes a robot as a mechanical device performing pre-programmed repetitive tasks, and corresponds to what is used in industry for mass-production in for example car manufacturing plants.

In minimally invasive surgery, however, robots have a different role, and they are used to provide a human interface to steer the movement of instruments in real-time. The surgeon still maintains control over the operation, although the control is indirect and effected from an increased distance.[1] This is referred to as the *'master-slave relationship'*, whereby the surgeon can control the actions of the robotic arms and instruments directly using the robot to enhance visual control with magnification and a 3-dimensional view, enhancing surgical dexterity enabling him to reach places that are otherwise difficult to access, and surgical precision through the elimination of tremor and the visual magnification. The surgeon directly manipulates intracorporeal instruments that have extended articulation possibilities.

2.2 REGULATORY STATUS AND INSTALLED SYSTEMS

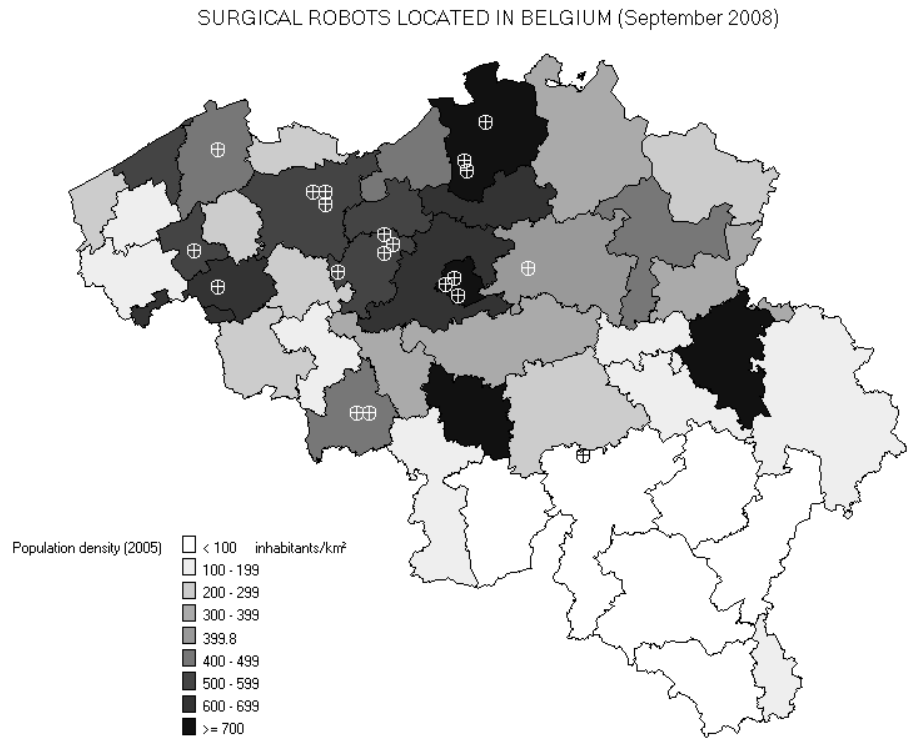
FDA's first approval for the da Vinci® surgical system was granted to Intuitive Surgical in 2000 for use in general laparoscopic procedures such as cholecystectomy and treatment of gastro-oesophageal reflux followed by later approvals for additional indications and subsequent enhancements.[2] Currently, the FDA has approved the da Vinci surgical system for adult and paediatric use in urologic surgical procedures, general laparoscopic surgical procedures, gynaecologic laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures and thoracoscopically assisted cardiac surgery.[3, 4] The da Vinci surgical systems currently available have three or four arms, enable three-dimensional high definition visualisation, magnification of the surgical field and tremor-free precise surgery with intra-abdominal articulated instruments that can move with multiple levels of freedom, replicating the full range of motion of the surgeon's hands, and avoiding the problem of the fulcrum effect seen with conventional laparoscopy using more rigid instruments.[5] In Europe, first CE marking was obtained for the da Vinci system in May 2000 and subsequent improvements such as extra arms, new vision systems etc. received CE marking in subsequent years.

The company Computer Motion received FDA marketing approval for the ZEUS® surgical system in 2001 to assist in endoscopic surgery by grasping and holding, but not for cutting or suturing. This system incorporated an earlier product from the same company, the AESOP® voice controlled robotic arm system for holding the endoscope.

Endoassist®, a head-controlled endoscopic camera manipulator from the company Armstrong Health Ltd (High Wycombe, UK) received original FDA marketing approval in 1997,[2] and has subsequently received new marketing approvals for further versions of its product.[4]

During four years, Intuitive Surgical fought a legal battle against its competitor Computer Motion for an alleged infringement on its voice-recognition technology, an essential component of the Zeus surgical system where the camera was voice-controlled.[6] Computer Motion lost this case, and subsequently in 2003, Intuitive Surgical bought the manufacturer of the ZEUS Robotic surgical system, making the da Vinci surgical system, de facto, the only marketed surgical device of its kind since marketing of the ZEUS system was abandoned.[3] Intuitive Surgical has therefore currently gained a virtual monopoly in robot-assisted minimal invasive surgery. At the end of 2006 there were reportedly more than 400 robotic systems installed in the USA and over 30 000 robotic procedures had been performed.[7] According to Intuitive Surgical (personal communication, Steven Boudrez, November 12th 2008 and www.intuitivesurgical.com) the installed base of the da Vinci surgical system was over 1032 in autumn 2008 (including 776 in the United States and 171 in Europe) and growing fast, corresponding to over 130 000 procedures per year. The total number of robot-assisted surgery systems in Belgium is also expanding rapidly: 6 by the end of 2006, 17 by the end of 2007, meaning that 11 systems were sold in one year (see Figure 1). A similar growth is anticipated in Belgium for the whole year 2008 and the installed base was 20 in September 2008.

Figure 1 : Installed base of Da Vinci surgical robotic systems in Belgium



Source: Intuitive Surgical. Situation in autumn 2008

2.3 APPLICATIONS OF ROBOT-ASSISTED SURGERY

Robotic surgical devices have, in recent years, developed beyond the experimental phase and are nowadays routinely used in minimally invasive general abdominal surgery, in gynaecological, urological and cardiothoracic surgery but also, experimentally, in paediatric surgery and in otorhinolaryngology. The robotic devices and their use are expected to continue to evolve.

The use of these devices, however, continues to be expensive and surgeons need to be trained to work with them. Only recently, a consensus document on robotic surgery was published by the SAGES-MIRA Robotic Surgery Consensus Group.[1] This consensus document not only aims at providing general guidelines for the use of robot-assisted surgery including indications, risks, benefits and costs, but also at providing guidelines for training the surgeons and for credentialing the systems. At the moment, the application of robot-assisted surgery is most popular in urology, mainly for radical prostatectomy. Besides urology, the technology is also increasingly used in gynaecology and cardiology and experimentally in other domains. The use of the technology in abdominal surgery, however, does not seem to continue, since these interventions can easily be done through conventional laparoscopy at a lower price.

We summarize in chapter 3, the evidence on the effectiveness of robot-assisted surgery in different procedures and for several surgical disciplines

2.4 COST OF ACQUISITION, MAINTENANCE AND USE

The current purchase price of the da Vinci surgical system in Belgium, which includes the robot, the video monitor and the surgeon workstation, amounts to approximately €1.7 million, to which the maintenance contract has to be added amounting to about 8-10% of the initial acquisition cost and starting the year after the year of purchase. The maintenance contract includes the software upgrades.

Reported American prices range from $1 million to $1.5 million (€0.67 to €1 million) excluding the yearly 10% maintenance cost. In the UK, current price of the da Vinci system amounts to £700 000 (€0.9 million) plus a 10% yearly maintenance.[8] In Italy, the da Vinci robot costs approximately €1 680 000 to which a maintenance contract of €145 000 (8.6%) has to be added.[9] Also in Germany, the robot reportedly costs approximately €1.6 million plus €150 000 for the maintenance.

Instruments, such as scissors, scalpels, cutters, needle holders and other accessories must be inserted into the robot arms. They are reusable for a specific number of procedures that is pre-defined by the manufacturer and controlled by a memory chip inside each instrument. Beyond this number of uses, unrelated to the instrument wear,[1] usually 10 uses, the instrument is not recognized by the system anymore. This also means that only the instruments available from the manufacturer are compatible with the robot. The required instruments vary with the patient and the type of procedure. Because of this limited number of uses, the term 'reposables' is sometimes used in the literature instead of disposables. Disposables such as sterile drapes for the machine are also sold by the manufacturer.

In the United States, those 'reposables' and accessories, varying with the type of procedures, cost in a range of $1000 to $2500 per procedure. In Italy, additional instruments, drugs and surgical material involved in a robot-assisted operation amount to €1800 to €2500, including €1000 for da Vinci instruments.[9] In Germany, da Vinci instruments are estimated to cost about €1500 per operation.[10] In Belgium, 'reposables' and drapes for a prostatectomy would reportedly amount to €2160 per procedures. With other surgical disposables needed for the procedure, the operative material amount to more or less €2870 in the case of a radical prostatectomy. Those costs obviously differ depending on the number of instruments needed for specific indications.

Published economic evaluations of robot-assisted interventions and organisational issues are discussed in chapters 4 and 5 of this report.

2.5 LEGAL ISSUES

The main potential legal issues in connection with the use of robot-assisted surgery are the ethical rules and patient's rights, the medical liability, the coverage of the additional costs of using robot-assistance, commercial law and consumer protection, legislation on medical devices and specific training issues.

These legal issues are discussed in chapter 6.

2.6 PATIENT AND ETHICAL ISSUES

Patient and ethical issues regarding robot-assisted surgery need to be discussed. Especially the specific need for information provision and informed consent when an emerging technology is used should be considered, together with the problems of social justice regarding the additional out-of-pocket co-payments by the patient. Finally we ask the question whether it is ethically acceptably that society would pay for this alternative form of treatment through additional reimbursement, which is corresponding to rewarding a monopoly position of one manufacturer.

These issues are discussed in chapter 7.

3 EFFECTIVENESS AND SAFETY

3.1 STRATEGY

The main problem when comparing surgical techniques is that randomisation, the key requirement of randomized clinical trials (RCT), is considered by many surgeons to be difficult or even unethical in surgery.[11] As a result there are only a few RCTs performed comparing robot-assisted surgery to conventional methods. Evidence on robot-assisted surgery is therefore mainly based on observational studies, comparing different techniques in case series compared to temporal or historic controls often operated upon by different surgeons, different hospitals or even different continents.[12] Consequently, it becomes impossible to separate the role of the technology used, i.e. open, laparoscopic or robot-assisted surgery, from the experience and skill of the surgeon and his team.

As a result, the conventional techniques of health technology assessment are more difficult to apply and meta-analyses are hampered by the large heterogeneity of study designs and outcome variables reported.

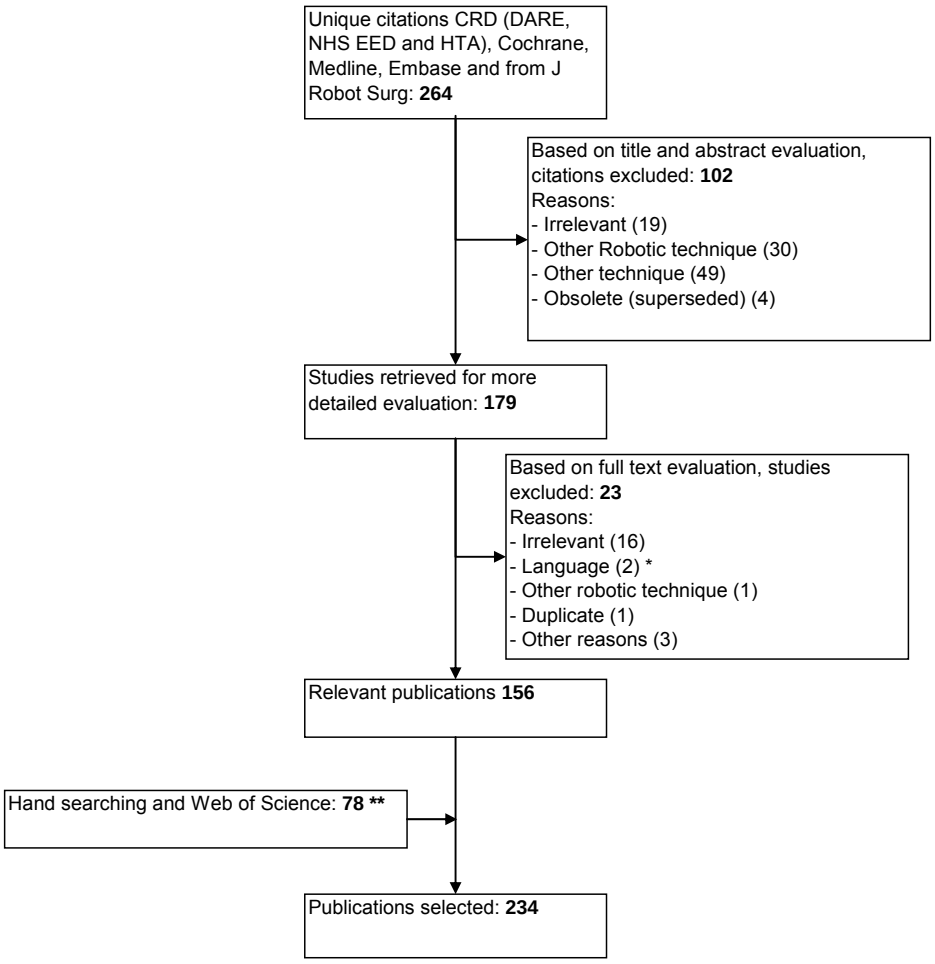
We chose to provide a narrative review of the studies available; HTAs and systematic reviews for those indications where they exist, and primary studies for indications with there are no systematic reviews. However, while interpreting the results of the literature it should be kept in mind that many of the authors of studies reported did declare important potential conflicts of interest.

3.2 LITERATURE SEARCH

We searched the literature for the evidence on the effectiveness of robot-assisted surgery in humans compared to conventional interventions. We primarily searched for systematic reviews, clinical trials, prospective studies, multicentre trials and HTAs using the MeSH terms *'Robotics'* (introduced in 1987) and *'Surgery, computer assisted'* (introduced in 2002) and additionally the keywords (surgery) and [(da vinci) or (davinci)]. We searched Medline, Embase, DARE, EED and HTA through CRD, and the different Cochrane libraries. We also searched individual websites of INAHTA members (http://www.inahta.org/Members/Contact-database/Post.aspx) and browsed through the first two years of the new quarterly Journal of Robotic Surgery (sponsored by Intuitive Surgical) that is not yet indexed in Medline,[13] in search for relevant articles. A preliminary search was performed in April 2008 and updated in October 2008 (see appendix for details). Details about in- and exclusions are shown in Figure 2. We excluded individual case reports, reports on specific surgical techniques or feasibility and on the use of robotic camera assistants only.

Additionally, we queried the INAHTA members through mail to check for recently published or ongoing assessments of robot-assisted surgery. Reference list of key publications were hand searched for references, and a Web of Science search was performed to detect recent articles that referenced those key publications. The combination of these approaches lead to a relatively high number of articles found through manual searches as can be seen in Figure 2.

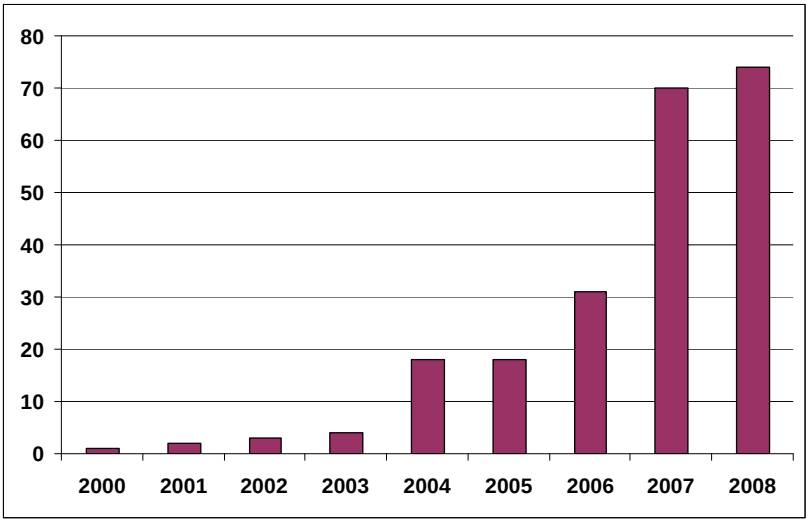
Figure 2 : Flow chart of Identification and selection of publication



*However, 4 studies in Spanish but with an English abstract, and one study in Norwegian only were included because of relevance and references.
**These studies were retrieved at the end of the project to be as complete and up-to-date as possible and did not go through the formal sifting process. Finally, not all were ultimately relevant for this review of effectiveness.

Because robot-assisted surgery is a rapidly emerging technology, we originally decided to limit our search to articles published since 2002 although a few from earlier years were included through the manual search. In practice however, most publications selected were from the most recent years as illustrated in Figure 3.

Figure 3 : Year of publication of selected articles on effectiveness and safety



For 2008 this includes publications up to the last literature search performed mid October 2008.

3.3 DATA SOURCES USED

Of the retrieved studies, 18 were either (rapid) health technology assessments (HTA), systematic reviews or horizon scans, sometimes covering all indications but most often focussing on one specific discipline or intervention. Those are listed in Table 1. The other studies included in this review of effectiveness and cost-effectiveness were reviews of mixed level of detail and quality and specific studies comparing robot-assisted surgery to other treatment modalities in different settings. Some of the earlier publications dealt with robot technology that is not marketed anymore and therefore of less relevance. The effectiveness review in this chapter will therefore mainly be based on selected publications: most recent systematic reviews and technology assessments, and the larger observational case series, again with a preference for the most recent studies to reflect evidence on current state-of-the art technology and experience, the so called 'mature series'.[14] Other publications were used for various aspects, such as less frequent indications, learning curve considerations, ergonomics and logistics and safety issues.

Table 1 : HTAs, rapid assessments, horizon scans and bibliographies

Year	Reference	Scope
2008	Ballini L, Minozzi S, Pirini G. La chirurgia robotica; il robot da Vinci. Bologna: Osservatorio regionale per l'innovazione. 2008, September (167-2008).[9]	All indications (Italian with English abstract)
2007	Llanos Mendez A, Villegas Portero R. Robot-assisted surgery using da Vinci robot telemanipulation in prostatectomy. Seville: Andalusian Agency for Health Technology Assessment (AETSA).[15]	Urology: prostatectomy (Spanish/English)
2007	Australian Safety and Efficacy Register of New Interventional Procedures Surgical. Totally endoscopic Coronary Artery Bypass Surgery (Da Vinci System) - Horizon Scanning 2007.[16]	Cardiac: CABG
2006	Robotassistert kirurgi ved prostatakreft. Quick assessment in Norwegian only without English summary. Nasjonalt kunnskapssenter for helsetjenesten.[17]	Urology: prostatectomy (Norwegian only)
2006	Adams E. Bibliography: Robotic surgery- Update 2006. Boston: Technology Assessment Unit, Office of Patient Care Services, US Department of Veterans Affairs (VATAP).[18]	Bibliography on all indications (update from 2004 report)
2006	CIGNA Health Corporation. Cigna Healthcare Coverage Position: Robotic Surgical Systems (0226).[19]	All indications

2006	National Institute for Clinical Excellence. Interventional procedures overview of laparoscopic radical prostatectomy. 2006.[20]	Urology: prostatectomy
2006	CIGNA Health Corporation. Cigna Healthcare Coverage Position: Robotically-Assisted Coronary Artery Bypass Surgery (0120).[21]	Cardiac: CABG
2005	National Institute for Clinical Excellence. Totally endoscopic robotically assisted coronary artery bypass grafting. London: National Institute for Clinical Excellence (NICE).[22]	Cardiac: CABG
2005	Tooher R, Swindle P, Woo H, Miller J, Maddern G. Laparoscopic radical prostatectomy: a accelerated systematic review. ASERNIP-S report No 48. Adelaide, South Australia: 2005.[23]	Urology: prostatectomy (21 studies comparing open and laparoscopic surgery including 5 studies on robot-assisted laparoscopic surgery)
2005.	Australian Safety and Efficacy Register of New Interventional Procedures Surgical. Robotically assisted left ventricular epicardial lead implantation (update October 2005).[24]	Cardiac: epicardial lead implantation
2004	Ontario Ministry of Health and Long-Term C. Computer-assisted surgery using telemanipulators. Toronto: Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care (MAS).[25]	All indications
2004	Tooher R, Pham C. Da Vinci surgical robotic system: technology overview. Stepney, SA: Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S).[26]	All indications
2004	Adams E. Bibliography: Robotic surgery. Boston: Technology Assessment Unit, Office of Patient Care Services, US Department of Veterans Affairs (VATAP).[27]	Bibliography on all indications (updated in 2006)
2002	Heffner T, Hailey D. Computer-enhanced surgical systems ('robotic surgery'). Ottawa: Canadian Coordinating Office for Health Technology Assessment/Office Canadien de Coordination de l'Evaluation des Technologies de la Sante (CCOHTA).[2]	Short overview of technology, mainly for historic data (French and English)
2002	L'Agence Nationale d'Accreditation d'Evaluation en Santé. Computer Assisted Surgery - Progress Report.(ANAES). 2002.[28]	General description of systems and indications, no review of effectiveness, but focussing on organizational issues and historic information and regulatory status (French)
2002.	National Horizon Scanning Centre. Surgical robots - horizon scanning review Update January 2002. Birmingham: National Horizon Scanning Centre (NHSC).[29]	Overview of then current technology, current indications, without further appraisal of their effectiveness. Update from 2000
2000	National Horizon Scanning Centre. Surgical robots - horizon scanning review. Birmingham: National Horizon Scanning Centre (NHSC).[30]	Overview of then current technology, current indications, without further appraisal of their effectiveness. Updated in 2002

3.4 PARAMETERS FOR EFFECTIVENESS

The hypothetical benefits of robot-assisted surgery derive from the enhanced precision, better visualisation, and easier articulation of instruments and the elimination of tremor. In theory these elements should allow for more precise interventions whereby important anatomical structures such as blood vessels, nerves and other tissues can be spared. Studies directly comparing robot-assisted surgery to either laparoscopic or open surgery, however, are scarce.[9, 18, 25, 26]

Moreover, those studies often compare current interventions to historical controls carried out by other surgeons or in different settings. Therefore, it is unclear whether techniques are compared or whether the comparisons is about the individual skill of surgeons and teams. Another important point is that the studies on robot-assisted surgery are often carried out in large centres with high volumes of robot-assisted interventions and are therefore highly dependent on the skills, experience and organisation of the surgeons and their teams. The validity of the results from those large centres and their generalizibility to smaller centres with less experience can therefore be questioned.[9, 18, 25, 26]

Several types of outcomes have been reported; amount of blood loss (estimated blood loss – EBL) and transfusions needed, complications rates during and after surgery (pain, recovery, re-intervention, …), duration of intervention (skin to skin or total operating room time), length of stay in hospital, immediate and long-term postoperative oncological outcomes (positive surgical margins - PSM, detected lymph nodes, PSA detection during the follow-up), functional short- and long-term outcomes such as continence and return of sexual potency, survival, etc… Another parameter for measuring the success of the operations is the number of unplanned conversions, where an robot-assisted interventions has to be converted into a conventional intervention.[9, 18, 25, 26]

Most studies on the effectiveness and safety of robot-assisted surgery have been relatively small non-randomised observational comparative studies. Depending on indication and study design, different indicators and parameters for effectiveness (and cost-effectiveness) have been reported. Moreover, most of the reported results are short-term outcomes. Little has been reported on long-term parameters such as survival, recurrence of symptoms or recurrence of cancer although recently, there are a few exceptions.[31-34]

3.5 COMPARATOR

Depending on discipline and indications, robot-assisted surgery is sometimes to be compared with open surgery, but in other cases, it should be compared with laparoscopic or other minimally invasive techniques.[1] Few studies compare robot-assisted surgery with other treatment modalities such as watchful waiting, radiotherapy or chemotherapy. This comparison to non-surgical alternatives, however, is outside the scope of this assessment.[9, 18, 25, 26]

3.6 GENERAL EFFECTIVENESS OF ROBOT-ASSISTED SURGERY

Only a few technology assessments evaluated robot-assisted surgery across all indications, while most studies only focused on specific indications. In 2006 the American Veterans Administration compiled a report on robot-assisted surgery across all disciplines,[18] an update on a previous report.[27] In practice, this report dealt only with the da Vinci surgical system as the technology for which most evidence is available. Evidence was graded using the scale from the National Health and Medical Research Council of Australia (NHMRC).[35] At that time, the highest level of evidence was available for Nissen fundoplication with evidence level II (corresponding to evidence obtained from at least one properly designed randomised controlled trial) with evidence from 2 small RCT's.[36, 37] For 3 other indications (adrenalectomy, cholecystectomy and gastric bypass level III-1 evidence was found (pseudo-randomized controlled trials). For the indications prostatectomy, pyeloplasty, mitral valve repair only evidence from comparative studies were found at that time, while for other indications the level of evidence was even lower.

An earlier assessment from ASERNIP-S had similar findings,[26] as did an HTA from 2004 from the Ontario Ministry of Health and Long-Term Care.[25]

Unsurprisingly those three reports came to similar conclusions about robot-assisted surgery in general, concluding that at that time there was insufficient evidence to make many useful comparisons of robotic-assisted and conventional laparoscopic surgery, and as a consequence also for the cost-effectiveness of robotic-assisted surgery.

Although some evidence suggested improvement in functional recovery time, they concluded that safety and efficacy of the procedure depended heavily on the expertise of the surgical team and that long-term information on cancer control and survival outcomes were not available.[18, 25, 26]

Because the available evidence did not show clear advantages of the technique, the VATAP report therefore calls for controlled diffusion of surgical robots and the setting up of monitoring and auditing systems to ensure patient safety, and to concentrate the use of this technology in specialized surgical centres that also offer the conventional surgical techniques to facilitate training and clinical research in the most appropriate indications. They also plead for specific patient selection criteria.[18] At the same time, more and better clinical studies are encouraged.

In 2006, CIGNA healthcare made a technology assessment resulting in a coverage position stating that robot-assisted prostatectomy would be covered but that other indications of robot-assisted surgery, and specifically the robot-assisted coronary artery bypass surgery (CABG) would not, because these were assessed as being experimental only.[19, 21] In 2008, however, CIGNA healthcare issued a new coverage position stating that surgical technique was left to the discretion of the physician but that no additional reimbursement would be provided based on the technique used, including robot-assisted surgery.[38]

In the beginning of 2008, a consensus document on robotic surgery was published by the joint SAGES-MIRA Consensus Group.[1] In this consensus document and in an associated editorial,[39] it is commented that, although the field of robot-assisted surgery is considered promising and with a potential to improve patient outcomes, further study is required to determine the value and role of robot-assisted surgery. Current robotic surgery is assumed to be relatively safe, as documented by clinical case series, and perceived advantages may indeed exist compared to conventional surgical interventions. But, while the literature is rich on case reports, case series and technical details describing specific procedures, level I data on effectiveness and cost-effectiveness are still missing.[1, 39]

As often in discussion about evidence based medicine in surgery, the lack of funding, the fact that those studies are time consuming and the perceived unethical randomisation is given as reasons for the paucity of data.

While the future is difficult to predict, decisions for now need to be made. In making those decisions it is important to recognise that for most indications, the benefits of robot-assisted surgery are not evidence based, and very dependent on surgical skill and experience. As was shown in a specific study comparing open to laparoscopic and robot-assisted prostatectomy,[40] surgical experience and volumes have an important impact on patient outcomes.

Across the various surgical specialties, robotic surgery is thought to offer the greatest advantage in complex reconstructive processes.[1] Limitations of current robot-assisted surgery include lack of haptic (force) feedback, the large footprint of the devices, instrumentation limitations, inflexibility of certain energy devices, and problems for performing multiquadrant surgery that implies re-docking of the robot during the intervention, as current devices are mainly suited for single quadrant interventions.[1]

The SAGES-MIRA consensus states that *'the technically exceptional laparoscopic surgeon may derive little benefit from robotic surgery'*.[1] However, robot-assisted surgery may serve as 'enabling technology' for many surgeons to provide complex minimally invasive procedures to a broad range of patients.

Meanwhile, the main limitations across most specialties are the lack of outcomes data, the training issues and the costs.[1]

An optimal therapeutic robot-assisted surgery system could make minimally invasive procedures accessible to patients for whom the procedures can not be performed using conventional laparoscopic techniques. For this, however, enhancements in precision and tactile feedback are needed.[1]

Finally, in 2008, an Italian HTA report covering the several indications for robot-assisted surgery was published.[9] This report was based on the most recent (since 2004) HTAs and systematic reviews listed in Table 1, supplemented with a series of selected primary studies for indications that were judged promising based on the opinion of an expert panel.

The Italian report concluded that the methodological quality of the systematic reviews and the primary studies is generally poor and that the available trials mainly assessed feasibility and safety issues, and that there were very few real comparative studies.[9] Most studies indeed are observational or comparisons with historical controls. This report concluded that robot-assisted surgery using the da Vinci robot is to be considered an emerging technology for which there are no sufficient data to assess its superiority versus conventional or laparoscopic surgery for any type of surgery.[9] It calls for well designed randomised controlled clinical trials and cost-effectiveness analyses.

3.7 EFFECTIVENESS IN UROLOGICAL SURGERY

The main indication for robot-assisted surgery in urology is in cancer treatment. For several urologic procedures, there are indications of advantages over conventional minimally invasive surgery, although no level I data are available.[1] The few RCTs that have been performed are not relevant for this review since they mainly compare variants of different robot-assisted techniques.[41, 42]

Most comparative studies and case series in this discipline have been done for radical prostatectomy in patients with localised prostate cancer, but other interventions include resection of bladder neoplasms, cystectomy, pyeloplasty, partial or complete nephrectomy and ureteral re-implantation. For most of these other indications mainly feasibility studies and technical descriptions have been published.[9] Generally speaking, specifically the more complex and delicate urologic procedures might benefit most from robot-assisted surgery.[1]

3.7.1 Prostatectomy

The most documented indication for robot-assisted surgery in the urology domain (and for all domains) is radical prostatectomy.

Three specific technology assessments,[15, 20, 23] and several systematic reviews or large series were published.[11, 14, 31, 34, 43-60] In addition, we also used some recent primary studies with large case series for specific outcomes.[50, 61-65] Most of the recently conducted systematic reviews come to similar conclusions, which will be summarized below separately for peri-operative and short-term follow-up outcomes and for the few data available on long-term follow-up. At the moment of going to press, a rapid assessment was published by the Argentine IECS agency,[66] coming to similar conclusions.

Short-term follow-up

From most studies it can be concluded that there are indications that laparoscopic radical prostatectomy is generally associated with a series of perioperative advantages such as decreased blood loss and lower transfusion rates,[11, 15, 20, 23, 43] but other hoped-for advantages, such as reduced length of stay, duration of catheterization, and functional outcomes including a shorter time to recovery of continence and erectile function are less firmly established since they are not consistently found.[11, 15, 20, 23, 43, 67, 68] Low positive SMR and the ability to perform wide pelvic lymph node dissection have been established but data on long-term disease free survival is not available yet.[11, 43] However, shorter-term data appear similar to open radical retropubic prostatectomy (RRP) in these observational studies.[11, 15 20, 43]

In a recent meta-analysis using random effects models and comparing open retropubic, laparoscopic and robot-assisted radical prostatectomy,[43] Parsons et al. included nineteen studies (n=3893 patients) in their analysis. In this study, however, laparoscopic and robot-assisted interventions (7 studies) were pooled to compare them to open surgery.

Compared with those undergoing retropubic prostatectomy, patients undergoing laparoscopic or robotic-assisted prostatectomy experienced less operative blood loss (SMD 1.74, 95%CI 1.74 - 1.49) and were 77% less likely to receive a perioperative transfusion (RR 0.23, 95%CI 0.11 to 0.49). There was no significant difference in overall risk of positive surgical margin (RR 0.88, 95% CI 0.74 to 1.06). There were also no significant differences in 1-year urinary continence (P=0.49) and 1-year erectile function (P=0.09); however, these outcomes were measured using non-validated instruments.[43]

Ficarra et al.[14] reviewed the observational data on robot-assisted laparoscopic prostatectomy (RALP) from 26 case series and found that RALP had in general a relatively short learning curve and interesting postoperative results, especially with regard to reduced hospital stay, reduced blood loss and continence recovery, once the learning curve was completed. However, the available data on recovery of erectile function and oncological follow-up are still incomplete. In the same review, the authors stress the importance of the learning curve effect and they separated data from the initial phase and the so-called 'mature' series. However, they conclude that the learning curve for RALP is shorter than for LRP. This study calls for comparative multicentre trials, preferably randomised, that might allow a more appropriate comparison with the gold standard, represented by RRP.

They recommend that, at that moment at least, the use of this technology should be restricted to high-volume, referral centres, within evaluation studies aimed at precise assessment of the clinical results.[14]

Coughlin et al.[49] reviewed the postoperative erectile function and urinary continence data reported in previous case series for RRP, LRP and RALP. They concluded that functional outcomes provided by larger series of RALP are encouraging with similar potency and continence rates compared to contemporary open or laparoscopic series and a trend toward an earlier return of function in those undergoing robotic surgery. Again, they warn that follow-up is needed in these patients.

Herrmann et al.[44] performed a systematic search and reviewed 23 series of RRP, 22 series of LRP, and 14 series of RALP performed between 1982 and 2007, including comparative studies between the techniques and focusing on oncological outcomes, (i.e. surgical margins, PSA-recurrence and disease-free survival) on functional outcomes (regain of continence, erectile function), and on cost effectiveness. They also conclude that literature on LRP, RALP, and RRP is currently insufficient to favour one surgical technique or to answer whether the laparoscopic approach with or without the help of robot assistance meets quality standards of RRP in the long run. The available biochemical recurrence information is promising for LRP but immature for RALP. Postoperative oncological outcomes seem to equalize the results of RRP by means of PSM for both LRP and RALP. Furthermore, the debate over functional results suffers from a lack of uniformity in methodology, limited follow-up, and a small number of patients.

Nelson et al.[67] specifically compared length of stay between RRP and RALP. They prospectively collected data on 374 patients who underwent RRP and 629 who underwent RALP at the Vanderbilt University Medical Center. Mean length of stay in this specific study on changes in discharge management for the RRP and RALP groups was 1.25 (median 1.09) and 1.17 days (median 1.03), which was similar and not statistically different (p=0.27). Readmission rates were similar in RALP and RRP patients (7% and 5%, respectively, p=0.12). Unscheduled clinic or emergency room visits were the same in the robot assisted laparoscopic and RRP groups (10%, p=0.95). They concluded that patients who underwent RRP or RALP can be treated on the same clinical pathway and a targeted hospital discharge date of postoperative day 1 can be achieved in the majority of patients who undergo radical prostatectomy. Readmission rates or unscheduled hospital visits are necessary in a small proportion of the patients with an early discharge program. The majority of these readmissions were caused by ileus. It should be emphasized, however, that this study was specifically conducted to assess the influence of discharge management, and can not be taken as a typical example of lengths of stay after RRP and RALP.

Rozet et al.[54] compared 133 consecutive patients who underwent RALP with 133 match-paired patients treated with LRP in the same institution. No statistical differences were observed regarding operative time, estimated blood loss, hospital stay or bladder catheterization between the 2 groups. The transfusion rate was 3% and 9.8% for LRP and RALP respectively (p=0.03). Conversion from RALP to LRP was necessary in 4 cases. None of the laparoscopic radical prostatectomy cases required conversion to an open technique. The percentage of major complications was 6.0% vs. 6.8%, respectively (p=0.80). The overall positive margin rate was 15.8% vs. 19.5% for laparoscopic radical prostatectomy and robotic assisted laparoscopic prostatectomy, respectively (p=0.43).

In the study by Boris et al.[55] 150 radical prostatectomies performed by a single surgeon were compared, the last 50 consecutive RRP and LRP, and the first 50 RALP. The groups were comparable with respect to patient demographics. Length of stay, blood loss, and transfusion requirements were significantly better in the RALP group while complications were least in the robot-assisted group. Functional and oncological (PSM) outcomes were similar in the three groups. The authors conclude that prior open and laparoscopic experience facilitates encouraging outcomes for RALP even in a surgeon's initial series of patients.

Hu et al.[40] studied the outcomes for minimally invasive radical prostatectomy (MIRP) using Medicare records. The authors were, however, unable to distinguish whether the robot was used for assistance during laparoscopy because both interventions share a common CPT code. They identified 2702 men undergoing MIRP and open radical prostatectomy during 2003 to 2005 from a national 5% sample of Medicare beneficiaries. MIRP utilization increased from 12% in 2003 to 31% in 2005. Men undergoing MIRP versus RRP had fewer perioperative complications (29.8% vs. 36.4%; P=002) and shorter lengths of stay (1.4 vs. 4.4 days; P=.001); however, they were more likely to receive salvage therapy (28% vs. 9.1%, P=.001). In adjusted analyses, MIRP versus RRP was associated with fewer perioperative complications (odds ratio [OR] 0.73; 95%CI, 0.60 to 0.90), shorter lengths of stay (parameter estimate 2.99; 95%CI 3.45 to 2.53) but more anastomotic strictures (OR 1.40; 95%CI 1.04 to 1.87) and higher rates of postoperative adjuvant therapy (OR 3.67 95%CI 2.81 to 4.81). Patients of high-volume MIRP experienced fewer anastomotic strictures (OR 0.93; 95%CI 0.87 to 0.99) and less salvage therapy (OR 0.92; 95%CI 0.88 to 0.98).

Long-term follow-up

In one of the few long-term follow-up studies, Badani et al,[31] followed 2766 consecutive men underwent RALP at the Vattikuti Urology Institute. Over a 6-year period, data were collected prospectively including demographics, surgical, oncological, and functional outcomes with up to 5-year follow-up. The mean age of the patients was 60.2 years and the mean PSA level at time of diagnosis was 6.43 ng/mL. The mean surgical and console time was 154 minutes and 116 minutes, respectively. Estimated blood loss was 100 ml and 96.7% of patients were discharged within 24 hours of surgery. At a median follow-up of 22 months, 7.3% of men had a PSA recurrence and the five-year actuarial biochemical free survival rate was 84%.

In a smaller and shorter but comparative follow-up study from the Duke Prostate Centre, Schroeck et al.[34] reported on 362 men had RALP and 435 had RRP; the mean follow-up was 1.09 and 1.37 years, respectively. Patients undergoing RALP had a lower EBL but had initially also lower-risk disease. After adjusting for differences in clinical and pathological features, there was no significant difference in early PSA recurrence between patients undergoing RALP or RRP.

In its systematic review of non-randomized controlled studies NICE reported biochemical recurrence free survival after RALP ranging from 92 to 95% (8 months and 3 months) and not significantly different from ranges reported for RRP and LRP.

Discussion

All those comparisons of outcomes between observational case series of different methods of radical prostatectomy have similar limitations. Virtually all case series are single-surgeon or single-institution with differing patient and surgeon characteristics, contain a relatively small number of patients with limited follow-up time, and lack uniformity in measuring subjective items such as continence and potency.[11, 20] Moreover, few studies have incorporated validated instruments to measure patient-reported outcomes and quality of life.[20, 43] Since studies are neither randomized nor blinded, perioperative outcome measures such as estimated blood loss, transfusion rates and length of stay can be subject to bias.[20] But mainly, most reported case series are performed by highly experienced surgeons, treating high-volumes of patients,[69] while in the real world most patients undergoing prostatectomy are treated by many individual urologists, that will never obtain a similar experience. Therefore, the published experience is hardly relevant for the individual patient counseling.[70]

Robot-assisted prostatectomy has been enthusiastically received, but despite uttered claims otherwise, no data exist to support one method of prostatectomy as undeniably better than others. While differences in oncological and functional outcomes may be real (and, if so, appear to be minimal), the lack of properly performed comparative analyses precludes bold proclamations of superiority.[11]

The marketing of a particular approach to RP as ultimately superior to another is not supported by available data.[68] Claims of superiority of the technique might even be counterproductive; Schroeck et al. questioned 400 patient after a median follow-up of 1.5 years after radical prostatectomy about their satisfaction and regret about the procedure.[71] Apart from other predictors, patients undergoing RALP were more likely not to be satisfied and to be regretful compared to patients undergoing RRP, which the authors contribute to the higher levels of expectations associated with being proposed an *'innovative'* procedure.

Ultimately, desired results appear to rely most upon a surgeon's skill and experience than whether the surgeon is looking into the pelvis, at a monitor, or into a robot.[11] As mused by Bradford Nelson during a debate on robot-assisted urology: *"The difference between Tiger Woods and the local club champion is not in the putter, the irons, or the woods, it is in skill and consistency. We, as urologic surgeons need to be more outspoken about the risks of what we do than about the benefits. Dashed expectations add insult to injury and will be the undoing of the public's trust"*.[68]

Conclusion

Although still considered an emergent technology with promising but currently insufficient outcome data, it appears from literature that, when RALP is performed by experienced surgical teams, the peri-operative results of robot-assisted prostatectomy appear to be comparable with results from either RRP or LRP performed by equally experienced surgical teams. The most recent systematic reviews, reported consistently decreased blood loss and lower transfusion rates with RALP compared to RRP or LRP. But other hoped-for advantages such as reduced LOS, shorter surgery time, better functional outcomes and better oncological results are more difficult to substantiate, due to a lack of good comparative data and the heterogeneity of techniques and outcomes reported. Some studies indicate that the shorter length of stay with minimally invasive radical prostatectomy can also be obtained for RRP, depending on the clinical pathway chosen. Available data indicating that the best results are obtained in large case series point to the fact that, although the learning curve for RALP is considered to be shorter than for LRP, also for RALP better results are obtained with increasing experience. All reviews agree that better and randomized trials and long-term follow-up data are needed to further determine the role of RALP in comparison to LRP and RRP.

3.7.2 Nephrectomy

Robot-assistance for performing radical nephrectomy (RN) and partial nephrectomy (PN) for the treatment of benign and malignant disease has been performed in several centres since several years. Case-series, however, are much smaller that for prostatectomy due to the limited number of indications for this intervention.

Radical nephrectomy can be performed using open or laparoscopic techniques (laparoscopic radical nephrectomy – LRN), but also robot assisted LRN.

Nazemi et al. reported on 57 cases of radical nephrectomy using different techniques, including 6 patients where the robot-assisted technique was used.[72] While general patient characteristics of the patients was not significantly different between the techniques, the estimated blood loss, postoperative narcotic use for pain control, and the hospital stay were significantly higher in the open surgery method. However, the median operative time was significantly longer in the robotic group. Operating room costs were significantly higher in the robotic and laparoscopic group, although total hospitals costs were not significantly different among the different groups.[72] It is unclear, however, whether specific costs for robot-assistance were included in the cost-analysis (see also 4.1.2.1 for a description of the cost results).

Rogers et al. retrospectively analysed 42 case of robot-assisted nephrectomy at the Vattikuti Urology Institute.[73] No conversions were needed, surgical margins were all negative and there was no evidence of tumour recurrence after on average 16 months.

The study concludes that robot-assisted nephrectomy is a safe and feasible option but it does not compare results to conventional surgery. No specific long term oncological outcomes are available yet for robot-assisted LRN, but comparing LRN with open nephrectomy, similar 5-year cancer-specific and overall survival were demonstrated.[32]

Rogers et al. report on 148 patients undergoing robot-assisted partial nephrectomy (RPN) in six different centres (9 surgeons) for localized tumours.[73] In this retrospective analysis, there was no evidence of tumour recurrence after a mean follow-up of 18 months. Two patients underwent open-conversion, mean hospital stay was 1.9 days and immediate oncological results and perioperative outcomes were considered comparable with mature laparoscopic series. The study concludes that RPN is a feasible and safe option for partial nephrectomy.

Kaul et al. report on 10 patients that underwent RPN at the Vattikuti Urology Institute. No PSM were detected and no tumour recurrence was observed after follow-up ranging from 6 to 28 months. They also conclude that RPN is a feasible and safe option for partial nephrectomy.

A study reviewing the evidence for open PN (OPN), laparoscopic PN (LPN) and robot-assisted PN (RPN) found similar results for those techniques, although the authors stress that LPN and RPN should only be performed by very 'experienced hands'.[74]

Conclusion

It appears that both radical nephrectomy and partial nephrectomy can be safely performed with robot-assistance, if the surgeon has sufficient experience with the technique. Currently, however, no clear advantages over the open techniques have been demonstrated.

3.7.3 Radical Cystectomy

Again, experience with robot-assisted cystectomy is much smaller than for RALP. Radical cystectomy is the standard of care for patients with invasive, organ-confined carcinoma.[75] Several small case series have been published since the first description of the technique of robot-assisted cystoprostatectomy and urinary diversion by Menon et al.[76] in 2003.[8, 77-80] Studies agree that the intervention is feasible and safe in experienced hands, but long-term outcomes data are lacking.

Conclusion

It appears that radical cystectomy with urinary diversion can be safely performed with robot-assistance, if the surgeon has sufficient experience with the technique. Currently, however, no clear advantages over the open techniques have been demonstrated.

3.7.4 Pyeloplasty

Several case series on pyeloplasty were published.[81-89]

Recently, Patel et al. systematically reviewed the literature on minimally invasive approaches to uretero-pelvic junction (UPJ) obstruction to compare it to the gold standard of open pyeloplasty.[90] They concluded that, where open pyeloplasty achieves results in the range of 90 to 100% success, the laparoscopic results are as good as the open surgery. The problems reside in the difficulty for most urologists in acquiring the technical skills to perform it. In robot-assisted pyeloplasty, results in the range of 88 to 97% are recorded, while reportedly being easier to acquire the necessary skills. Long-term outcome data are currently not available.

Conclusion

Robot-assisted pyeloplasty, in qualified hands, appears to have similar results as those achieved with open and laparoscopic pyeloplasty. The learning curve for robot-assisted pyeloplasty appears to be easier and shorter than for conventional laparoscopic pyeloplasty, which might give it the potential to make the laparoscopic approach accessible to more patients.

3.7.5 Miscellaneous indications in urological surgery

For several other urologic indications robot-assisted surgery has been described. These include vasovasostomy,[7, 91] inguinal herniorrhaphy,[92, 93] adrenalectomy,[7, 94] prolapse surgery,[7, 95-97] bladder diverticulectomy,[98] and ureteral re-implantation,[99]

Conclusion

Although the list of those miscellaneous urologic indications is impressive and early results encouraging, there is currently little evidence that robot-assisted surgery is superior to conventional techniques.

3.8 EFFECTIVENESS IN THORACIC SURGERY

These indications include cardiac and aortic interventions. Additionally, also the resection of solid thoracic tumours, and oesophageal tumours have been reported.[1]

3.8.1 Robot-assisted coronary artery bypass surgery

Coronary Artery Bypass Grafting (CABG) is a procedure performed to relieve angina and reduce the risk of subsequent infarction and death due to coronary artery disease. The procedure consists of the grafting of arteries or veins taking at another suitable part of the patient's body. Traditionally, CABG is performed through a sternotomy giving direct surgical access to the heart and the large vessels, while cardiopulmonary bypass (CPB) and cardiac arrest where regarded as necessary to perform the intervention. Because of the high morbidity associated with traditional open-chest CABG, new techniques were developed to perform CABG through minimally-invasive surgical techniques.[16, 21, 22, 100-103] As with the open-chest CABG, the minimally-invasive techniques can be performed either with or without CPB, so called on-pump or of-pump surgery. Minimally-invasive direct coronary artery bypass (MIDCAB) grafting involves a combination of ports and a small incision (minithoracototomy) over the coronary artery to be bypassed to create one or two anastomoses.[16, 22, 38] Off-pump CABG performed on the beating is carried out using a stabilization device to immobilize the site for anastomosis while the heart continues to beat, thus removing the need for CPB. Port-access coronary artery bypass (PACAB) grafting uses chest ports rather than sternotomy to gain access to the heart.[104] Anastomosis is then performed on the arrested heart with peripheral CPB. Off-pump coronary artery bypass (OPCAB) utilizes medial sternotomy without CPB.

Potential benefits of minimally-invasive surgery include: reduced rate of infection, fewer blood transfusions, less pain, quicker patient-recovery times, shorter hospital stay and less scarring than with traditional operations.[16, 22, 38]

The ultimate goal of minimally-invasive direct CABG surgery would obviously be an total endoscopic procedure on a beating heart without the use of CPB. Although technically feasible this has proven to be difficult due to specific anatomy within the chest, limited space between the heart and the chest wall, and overall technical difficulties of manual microsurgery. Also, the length and fixed-pivot point of conventional endoscopic instruments (the so-called fulcrum effect, see chapter 2) have accentuated the effect of surgeon hand-tremor, which makes completion of an anastomosis difficult and time-consuming.

Robot-assisted totally endoscopic coronary artery bypass (TECAB) could theoretically overcome these limitations of traditional endoscopic instruments, allowing the scaling of movements, freezing of the slave instrument's movements while instruments at the master console can be repositioned into an ergonomic working mode leading to improved ergonomics, and tremor elimination.[16, 22, 38]

Since 2000 several case series of TECAB using robot-assistance have been published, showing encouraging results.[12, 105-110] In its 2006 assessment, CIGNA Healthcare concluded, however, that robot-assisted CABG remained an evolving technology, and that, although some initial outcomes have been positive, the long-term safety and efficacy of the procedure had not been determined and that there were insufficient data to conclude whether robotically-assisted CABG provides outcomes are comparable to those achieved with conventional open CABG or with other minimally invasive revascularization procedures.[21] Robot-assisted TECAB would therefore not be covered. The Australian ASERNIP-S agency evaluated TECAB in 2007, comparing TECAB to conventional CABG, MIDCAB and OPCAB using data from five case series.[16] They concluded that robot-assisted TECAB on the arrested heart had acceptable efficacy and safety and compared reasonably well with MIDCAB and conventional approaches. For TECAB on the beating heart, however, they concluded that the success rate remained low and that the benefits associated with beating heart TECAB did not outweigh the risks. They called however for further studies to substantiate the place of robot-assisted TECAB.

In 2007 a European study conducted in five centres compared robot-assisted TECAB with (n=90) and without CPB (n=74), while an additional 64 cases needed conversion.[12] Perioperative incidence of Major Adverse Coronary Events (MACE), including all-cause mortality, was further compared with a matched cohort from the Society of Thoracic Surgeons (STS) database. This study concluded that both on- and off-pump TECAB are feasible, with a conversion rate diminishing with increasing experience. Overall procedural efficacy was 97% overall and incidence of MACE within 6 months follow-up was 5%. In the off-pump TECAB group the all cause mortality and immediate postoperative myocardial infarction rates were similar to the control group from STS. The re-intervention rates within 30 days however appeared to be higher (4.1% vs. 0.4% in controls) although the numbers were too low for meaningful statistical conclusions. The study concludes that TECAB can safely and effectively be performed.

Conclusion

Robot-assisted minimally invasive CABG is a promising development but is very operator dependent. It should therefore be reserved solely to highly experienced teams. The exact role and the required patient selection for the different methods of robot-assisted minimally-invasive CABG remains to be determined.

3.8.2 Epicardial lead placement

In patients with congestive heart failure and delayed intraventricular conduction, biventricular (BiV) pacing can improve ventricular function, exercise capacity and quality of life.[104] Conventionally, the pacing leads are placed using transvenous approaches, but especially left ventricular lead placement techniques are prone to failure. It is reported that up to 15 to 25% of transvenous implantations fail, at which time surgical intervention is required.[24, 104] Several case series reported on the efficacy of robot-assisted epicardial left-ventricular lead implantation as compared to lead implantation through a limited thoracotomy.[104] In a Horizon Scan from October 2005, the Australian ASERNIP-S, robot-assisted lead implantation was reported to improve vision of the ventricular surface, opening of the pericardium and suturing.[24] In this horizon scan the evaluation of 5 case series and two case reports lead to the conclusion that there is a limited evidence base for the safety and efficacy or robotically assisted epicardial lead implantation for biventricular pacing as an alternative to traditional open surgical procedures, and the studies indicate that the technique may also be effective at reducing morbidity and mortality rates and recovery time.[24] In a recent review, Rodriguez et al.[104] describe this technique as being an attractive one that could become the preferred technique even compared to the transvenous approach, because it allows surgeons to better determine the epicardial site for implantation than through the transvenous approach, leading to increased placement success and improved ventricular function compared with current transvenous approach. An RCT comparing both techniques is reported to be in progress.[104]

Conclusion

This is a potentially promising technique that allows direct placement of epicardial leads difficult to obtain through the conventional transvenous approach. Future research, and an ongoing RCT should provide more definite answers as to the exact place of this technique in cardiac interventions.

3.8.3 Mitral valve surgery

Minimally invasive mitral valve repair has been performed since 1998, first in European centres and later also in the US.[104, 111, 112] By now, several case series have been reported.[111, 113] No systematic reviews comparing this technique to a conventional approach have been performed to our knowledge. There are, however, a few comparative studies.[114, 115] These studies suggest that robot-assisted totally endoscopic mitral valve surgery can be performed safely, and might allow for similar results as conventional approaches, but allowing patients to avoid a sternotomy, requiring less transfusions, and benefit from shorter hospitalization. Investigators express the hope that in selected patients this surgical approach might enable repairs that would otherwise be impossible.[113] However, follow-up duration in most case series is still relatively short and therefore the long-term durability of the repair procedures needs to be evaluated in the future.[111, 113, 115]

Conclusion

In case series robot-assisted minimally invasive mitral valve repair appears to be relatively safe but there are no formal comparisons with conventional and other minimally invasive techniques. Repair longevity remains unclear due to limited follow-up and appears to be very dependent on specific technique and surgeon skill.

3.8.4 Miscellaneous indications in thoracic and vascular surgery

Several other interventions have been described, including congenital cardiac defect, surgery[104] aortofemoral bypass surgery,[116] oesophagectomy,[117] thymectomy,[118, 119] and many other interventions. But number of cases in these case reports and small case series are too low to draw firm conclusions other than the anecdotic proof of feasibility.

Conclusion

Evidence on those miscellaneous indications is mainly sporadic and more evidence is needed before firm conclusions on effectiveness can be drawn.

3.9 EFFECTIVENESS IN GYNAECOLOGICAL SURGERY

Although urologic surgery is currently by far the discipline where robot-assistance is used most frequently, gynaecology comes clearly second (see 5.2.2). Robot-assisted surgery has been performed for hysterectomy for both benign and malignant disease and in myomectomy, in addition to other more anecdotic interventions.[1, 5, 6] It may also provide benefit by allowing minimally invasive fertility sparing operations and in fertility restoring interventions such as tubal re-anastomosis. Also for pelvic reconstructive surgery robot-assisted surgery has been proposed. Although current evidence demonstrates the general safety and feasibility of robot-assisted surgery in gynaecology, the experience is still in its infancy, and as in the other disciplines, prospective trials and RCTs are needed to determine the place of robot-assistance in gynaecological surgery.[5, 6] The da Vinci surgical system received FDA clearance for gynaecological procedures in 2005.[5]

3.9.1 Hysterectomy

The largest body of evidence for gynaecologic applications of robot-assisted surgery is for laparoscopic hysterectomy, specifically the laparoscopic supracervical and total hysterectomy. However, it is recommended that most patients requiring hysterectomy should be offered the vaginal approach when technically feasible and medically appropriate because of the lower morbidity with this approach.[6, 120] Another variant is the laparoscopically assisted vaginal hysterectomy, introduced in the late nineteen eighties.[121]

Conventional totally laparoscopic hysterectomy is reported to have a steep learning curve and it was reported that in the nineties only about 10% of hysterectomies in the US were performed through laparoscopy.[5] Robot-assisted laparoscopic surgery is reported to have an easier learning curve and is therefore believed by some to facilitate minimally invasive approaches.[121, 122] Another argument advanced for robot-assisted surgery is that currently advanced pathology, such as pelvic adhesions, can be a limitation for conventional laparoscopic instruments, a limitation that might be overcome by robot-assisted instruments.[121] Several technical descriptions of techniques to perform robot-assisted hysterectomy have been published.[121-123]

Advincula et al. in a narrative review, appraised 4 observational non-controlled studies including a total of 58 patients.[5] In those small case series, the authors reported similar peri-operative results (EBL, need for transfusion, operative time, length of stay and complications) as obtained with conventional laparoscopic surgery, but without formal control patients. Disadvantages reported are the absence of haptic feedback, the size of the complete system, lack of vaginal access, and obviously the cost.[124]

In a small comparative Sert at al. studied 15 patients undergoing radical hysterectomy for early-stage cervical carcinoma.[125] In the first eight consecutive patients the conventional laparoscopic technique was used; subsequently, in seven consecutive patients a robot-assisted technique was used. Median operating time in the robotic group was lower (241 vs. 300 minutes) and histopathological results were similar in both groups. Less bleeding and a shorter hospital stay were observed in the robot-assisted group.

Boggess et al. reported on 144 oncologically related laparoscopic hysterectomies, including 43 that were robot-assisted.[123] They reported few conversions (none in the robot-assisted group), less blood lost, shorter operative times, more nodes retrieved and overall a borderline significant slightly shorter hospitalization period (1 vs. 1.2 days)for the robot-assisted group when compared to conventional laparoscopy. They also observed a faster learning curve than with laparoscopy, which is ascribed to the more intuitive nature of the system.

Conclusion

Robot-assisted hysterectomy is clearly feasible and results appear to be similar, with indications of better peri-operative parameters. However, there is no evidence to support the claim that it is superior to other methods. The learning curve for the robot-assisted intervention is reported to be shorter and easier than for the laparoscopic intervention.

3.9.2 Myomectomy

Most cases of leiomyomata, in women with a fertility desire are managed through myomectomy, both laparotomic and laparoscopic.[5, 6, 126, 127] Again, one of the reported obstacles for conventional minimally invasive surgery is the steep learning curve and the required surgical skills, since myomectomy involves both precise enucleation work and a multilayer closer requiring extensive suturing.[5] Robot-assisted surgery is considered to be easier to learn and perform, because of the inherent advantages of better visualisation and the stable and precise manipulation of instruments that can move in multiple degrees of freedom.[6] Feasibility of myomectomy through robot-assistance has been demonstrated through a feasibility study,[126] and through a limited case series of 35 cases.[128] Again, specifically the lack of haptic feedback with the robot-assisted intervention is mentioned as a problem in this intervention.[126] Other limited case series point to the feasibility of this intervention with robot-assistance with a limited number of conversions, a relatively short learning curve (10 or more procedures) and good peri-operative results, including short lengths of stay.[6, 129] Long-term outcomes such as recurrence rates, adhesion formation, fertility or uterine rupture have been reported for laparoscopy compared to laparotomy and are essentially similar, but have not been reported specifically for the robot-assisted laparoscopic technique.[6]

Conclusion

Robot-assisted myomectomy is feasible and results appear to be similar to the other methods, but currently there is no evidence to support the claim that it is superior to other methods. The learning curve for the robot-assisted intervention is reported to be shorter and easier than for the laparoscopic intervention.

3.9.3 Tubal re-anastomosis

Tubal re-anastomosis after previous tubal ligation by open microsurgery is an established intervention, and a laparoscopic approach has also been shown to be feasible, albeit difficult and not very ergonomic, and associated with surgeon fatigue and neck, shoulder and back pain.[6, 127] After some preliminary animal studies,[127] one of the earliest applications of robot-assisted surgery performed with the Zeus surgical system (see chapter 2) was tubal re-anastomosis, where tubal patency rate was 89% in a first case series of ten patients, a 50% pregnancy rate, and were the interventions were considered ergonomically much better for the surgeon.[6, 130] More recently, a limited number of case studies with the da Vinci surgical system were published.[5, 131-133] Although surgical results and successful re-anastomosis were encouraging, larger series are obviously needed to assess postoperative pregnancy rates. The lack of haptic feedback was reported to be one of the major problems in the micro suturing needed in this intervention.[124, 127, 132] It is also reported that the robot-assisted procedure resulted in greatly increased operative time when compared with open microsurgery.[127]

Conclusion

Robot-assisted laparoscopic tubal re-anastomosis is feasible and results appear to be similar to the other methods, but currently there is no evidence to support the claim that it is superior to other methods. It may ultimately allow combining the advantages of open microsurgery and laparoscopy providing more comfort to the surgeon.

3.9.4 Prolapse surgery

For serious vaginal vault prolapse, abdominal sacrocolpopexy (robot-assisted abdominal sacrocolpopexy – RASC) is often an good treatment option with success rates ranging from 93 to 99%.[5] However, this procedures is also associated with higher morbidity than vaginal repairs. Case series have been published using a robot-assisted approach to this intervention,[134] reporting early discharge, high patient satisfaction, and few patient developing recurrent prolapse during the limited follow-up period.

Daneshgari et al. reports on 15 women who consented for RASC.[97] 12 underwent successful RASC, with one conversion to laparoscopic ASC, open ASC and transvaginal repair each. Peri-operative result appear to be favorable but although outcomes were not compared to controls the authors conclude that RASC is safe and efficacious and compare favorably to open or laparoscopic ASC.

Conclusion

Early results show that RASC is relatively safe and efficacious and that functional results are similar to the conventional techniques.

3.9.5 Miscellaneous indications in gynaecological surgery

Other indications for robot-assistance in gynaecological surgery have been reported, including vesicovaginal fistula,[6, 134] ovarian cancer staging,[123] ovarian cystectomy,[123] ovarian transposition,[5] oophorectomy,[123] rectovaginopexy for rectal prolapse,[95] and various oncological indications[5, 123, 135, 136]

Conclusion

Evidence on those indications is mainly sporadic and more evidence is needed before firm conclusions on effectiveness can be drawn.

3.10 EFFECTIVENESS IN GENERAL ABDOMINAL SURGERY

Minimally invasive surgery has been pioneered in abdominal surgery since the late seventies, and likewise, many applications of robot-assisted surgery were pioneered in abdominal surgery.[1] Minimally invasive surgery realised many advantages such as smaller abdominal incisions, resulting in quicker recovery, improved cosmetic results and often shorter lengths of stay. The safety, effectiveness and sometimes also the cost-effectiveness have been documented over the lasts 15 to 20 years.[137] As a result, the laparoscopic instruments and techniques for abdominal surgery are well developed for most of the currently performed interventions.

Therefore, it could be expected that robot-assisted surgery would not improve much patient outcomes, although it could potentially improve the surgeons' learning curve and his comfort while performing these interventions.

However, for the more complex operations, the case for laparoscopic surgery remains to be proven.[137, 138] With current technology, robot-assisted surgery appears to be best suited for single-quadrant procedures that present challenging access, especially for interventions requiring fine dissection, micro suturing or reconstruction.[1, 137] For the more straightforward procedures such as cholecystectomy and Nissen fundoplication a substantial cost disadvantage is reported, but these procedures might provide an opportunity for training surgeons in their early robotic learning curve, if this is explicitly the purpose.[1]

In a critical appraisal, Bodner et al. concluded that robot-assisted abdominal surgery is generally feasible and safe, but potential advantages are best obtained in tiny areas difficult of access necessitating dissecting delicate vulnerable anatomic structures.[139] However, although almost all comparative studies report good peri-operative outcomes and few conversions (less than 5%), they also report generally longer operative times with robot-assisted system as compared to conventional laparoscopy, and an increased overall costs due to both the longer operative time as due to the use of more expensive instruments.[36, 37, 96, 138-145]

3.10.1 Anti-reflux surgery

Soravia et al. recently reviewed the literature on robot-assisted Nissen fundoplication and compared the results with 31 robot-assisted Nissen fundoplications for gastro-oesophageal reflux disease (GERD) performed in their centre in Geneva.[140] Peri-operative results were generally satisfying in a total of over 300 cases from 13 studies, with a limited number of conversions and complications and no peri-operative mortality. Length of stay also appeared acceptable but the absence of a control group makes results difficult to interpret.

In a retrospective analysis, Heemskerk et al.[144] compared their first 11 cases of robot-assisted Nissen fundoplication with patients undergoing the same intervention through conventional laparoscopy in the same period. They concluded that results are similar but that the use of robot assistance needed an extra 47 minutes to complete the operation, together with additional costs (see also 4.1.2).

This indication is one of the few where RCTs (not-blinded) have been performed. Morino et al. randomised 50 consecutive patients scheduled for laparoscopic anti-reflux surgery into two groups (25 each) treated either through conventional or through robot assisted laparoscopy. There was no conversion to open surgery in neither of the groups and the pre- and postoperative characteristics were not significantly different between both groups. Length of hospital stay was similar in both groups. Operating time was, however, significantly longer and the mean total cost was significantly higher in the robot-assisted group. In another small RCT, 22 patients with GERD were randomised into laparoscopic versus robot-assisted Nissen fundoplication.[37] Again the robot-assisted procedure was significantly longer, while the length of stay was similar. Short term postoperative complaints were similar but after the 3rd postoperative month the number of recurrent symptoms appeared to be higher in the robot-assisted group in this small study. No clear advantage of using robot-assistance was reported while disadvantages are the prolonged operative time and higher costs. Muller-Stich randomised 40 patients with GERD into robot-assisted and conventional laparoscopic fundoplication.[142] They found similar postoperative outcomes and total length of stay was not significantly different. In contrast to the other two RCTs, they reported a significantly shorter operative time (see also 4.1.2). The authors attribute this difference to a longer experience with the robot-assisted technique. Finally, Draaisma et al. randomised 50 patients with confirmed GERD into robot-assisted and conventional laparoscopic fundoplication.

Long-term outcomes were assessed after 6 months of follow up. This study found no added value of robot-assisted surgery for this procedure up to 6 months after surgery. Parameters such as blood loss, operating time, pain scores or length of stay were similar in both groups.[146]

In a prospective study in a series of over 100 interventions of robot-assisted surgery for GERD, Hartmann et al. reported that with sufficient experience operating times could be markedly reduced.[147]

Conclusion

Robot-assisted Nissen fundoplication is one of the few indications for which evidence from RCTs is available. Evidence shows that this intervention can be performed relatively safely and efficaciously with similar functional results as conventional laparoscopic techniques. However, no clear advantages of robot-assistance are reported while disadvantages are the prolonged operative time and higher costs. There are indications that with increasing experience operative time can be reduced.

3.10.2 Gallbladder surgery

The laparoscopy cholecystectomy has now been performed for over 20 years. Early on during the development of robot-assisted surgery robotic cholecystectomy was performed using prototypes of the machines currently on the market.[137] Cholecystectomy is reported to be relatively easy to perform with robot-assistance.[33, 140, 145] Clear advantages, however, are absent and operative time is often reported to be higher.

Bodner et al. report on the long-term follow-up through analysis of their first case series performed in 2001 and followed since.[33] They conclude that long-term results are excellent and comparable to conventional laparoscopic cholecystectomy without being superior.

Heemskerk et al. compared a series of 12 cases of robot-assisted cholecystectomy to 12 conventional laparoscopy cases.[145] The robot-assisted cases had similar peri-operative results but increased overall operating room stay and increased costs (see also 4.1.2)

Conclusion

Evidence shows that robot-assisted cholecystectomy can be performed relatively safely and efficaciously with similar functional results as conventional laparoscopic techniques. However, no clear advantages of robot-assistance are reported while disadvantages are the prolonged operative time and higher costs.

3.10.3 Colorectal surgery

Soravia et al. recently reviewed the literature for robot-assisted colorectal surgery comparing results to there own 40 consecutive colorectal surgery cases, including 20 sigmoidectomies for different, mainly benign, indications. However, their series also included 6 adenocarcinomata.[140] In general, good peri-operative results were described for 240 patients from 13 case series. There were, however, no control patients in this review, and in a few case series many conversion (up to 40%) were reported. Moreover, many authors do not only perform total robot-assisted intervention but also include hybrid procedures combining laparoscopic and robot-assisted approaches.[140]

Rawlings et al. compare 30 consecutive robotic and 27 consecutive laparoscopic colectomies.[143, 148] The baseline characteristics of both groups were very similar. The operative time for robot-assisted cases was significantly longer for right colectomies (because intracorporeal anastomosis was performed in the robot-assisted cases), but not for sigmoid colectomies. Operating room cost was higher for the robot-assisted cases (see also 4.1.2), while length of stay was not significantly different between both groups.

Conclusion

Evidence shows that robot-assisted colectomy can be performed relatively safely and efficaciously with similar functional results as conventional laparoscopic techniques. However, no clear advantages of robot-assistance are reported. Disadvantages are the prolonged operative time and higher costs.

3.10.4 Miscellaneous indications in abdominal surgery

Other indications for robot-assistance in abdominal surgery have been described in case series, including bariatric surgery,[139, 140, 149] hepatic cyst resection,[140] Heller myotomy (achalasia surgery),[150] para-oesophageal hernia repair,[151] pancreas surgery,[138] splenectomy,[152, 153] rectopexy,[96] and many other indications. Most of these miscellaneous indications appear to be feasible and safe but it is difficult to demonstrate patient-specific advantages due to the small numbers of cases included in these case series.[138]

Conclusion

Most of these miscellaneous indications in abdominal surgery appear to be feasible and safe but there is little evidence for patient-specific advantages.

3.11 MISCELLANEOUS INDICATIONS

A few other domains for robot-assisted surgery have been described, mainly limited to case series. Those include otorhinolaryngology and paediatric surgery.

The otorhinolaryngology domain is currently mainly an experimental indication. Currently data demonstrate feasibility for transoral resections for benign and malignant lesions of pharynx and larynx, with potentially some advantages over traditional approaches. A limitation, as in paediatric surgery is the instrument size and functionality, and the development of smaller and more flexible tools is awaited.[1]

The literature concerning paediatric surgery is mainly composed of case reports and small case series. Over 50 different types of abdominal and thoracic procedures have been performed in paediatric patients.[1] Overall those interventions appear to be safe and have excellent results, but reports remain anecdotic. Their main interest seems to be in complicated procedures requiring reconstruction. An important limitation is the large size of the robotic instruments in relation to the paediatric patient.

Conclusion

Those other indications are, at the moment, mainly experimental and reports are anecdotic. Future experience will determine the importance of these and other additional indications.

3.12 LEARNING CURVE CONSIDERATIONS, EXPERIENCE AND TRAINING REQUIREMENTS

3.12.1 Learning curve and experience

It is generally acknowledged that the use of a robotic interface decreases the learning curve for laparoscopic surgery. It makes minimally invasive intervention more easily accessible to surgeons. But, important training efforts are needed and even with a shorter learning curve, experience is still extremely important.[6, 44, 70, 154] It is considered particularly important for a surgeon to reliably track his/her outcomes, and constantly consider technical or systems modifications to optimize results.[11, 70, 155]

Several studies have emphasized that even for experienced teams performance still improves with growing experience. In their prospective study on robot-assisted fundoplication

Hartmann et al. reported that they were able to reduce median operating time from 105 minutes to 91 min after 40 procedures, and setup time from 24.5 min to 10.4 min after 10 operations.[147] In their review of RALP, Tooher et al. also found that, as experience with the laparoscopic approaches increased, most clinical outcomes also improved, including conversions to open surgery, complications, blood loss, transfusions and operative time. But length of hospital stay did not decrease. There were no clear effects of increasing experience for positive margins rate or continence and potency outcomes.[23]

Badani et al. analyzed results over a 6-year period of 2766 consecutive men underwent RALP at one institution. Data were collected prospectively and the first 200 and most recent 200 patients were compared to determine the impact of experience and quality improvement for patients.[31] Comparisons between the two series showed that, despite a less stringent patient selection in the later series leading to substantially more patients with previous abdominal surgery, performance continued to improve in terms of shorter operative and console times and a decline in PSM.

3.12.2 Training

There are currently no standard criteria for both surgeons and operating room personnel for the use of robot-assisted surgery, although care-givers obviously are aware of the important training requirements to perform those operations using complex machines.[1] The 2008 SAGES-MIRA guidance recommends that, 'at a minimum, the operating room personnel should be trained according to the manufacturer's training guidelines, and should have the opportunity to be 'doubled up' with an experienced nurse or operating room technician during their early experience'.[1] They also recommend that all team members, including industry representatives, should meet on a periodic basis to stay current in their training and to learn about updates and changes in both hard- and software, in order to quickly identify potentially emerging problems.

Surgeons should be adequately trained in the use of surgical robots. Firstly, this requires technical training to have both the knowledge and the practical skills to handle the complex device before using it clinically. In addition to standard operating procedures, this training should also include how to remove the device safely and rapidly in case of a technical failure and the ability to continue the intervention with conventional methods.[1]

Although the company provides some limited skills training in Europe through practicing on a few pigs in Strasbourg (France) this is not sufficient and additional clinical training is considered mandatory (personal communications). Currently surgeons and hospitals have to organise and pay for this themselves.[1, 6, 156, 157] This obviously requires an institutional commitment to develop the field of robot-assisted surgery for one or several disciplines.[157, 158]

Moreover, surgeons need to be trained to use the robot for performing specific operations. This can involve a fully trained and competent laparoscopic surgeon to start using the robot clinically. In this case, it is a matter of adding the specific knowledge of robotic technology to existing laparoscopic skills. However, when the surgeon chooses to start acquiring his minimally invasive surgery skills directly by using the robot, the learning curve may be much more challenging.[1] It is recommended, however, that the surgeon would also be comfortable with the conventional technique of an intervention before attempting robotic surgery. A large enough volume of cases in order to obtain successful results is also recommended.[125]

3.12.3 Use of simulators

Traditional surgical teaching has evolved through a mentorship model. Novice surgeons have typically gained experience and competence gradually, both inside and outside the operating room. With the advent of minimally invasive surgery (MIS) and the development of new approaches to surgical conditions, increased opportunities for transfer of skills outside the operating room have gained popularity.

A wide variety of models have been created ranging from inanimate bench-top trainers to advanced virtual reality simulators. Multiple factors in today's surgical environment have fostered the development of simulators.[159-162] SAGES and MIRA also emphasize the role surgical simulators might play in the future for this type of training.[1] It is recognised though that currently available simulators do not provide a training equivalent to clinical practice.[155] Therefore, they should remain an adjunct in the training of surgeons wanting to perform robot-assisted surgery.

Conclusion

In general, robot-assisted surgery is reported to have a shorter and easier learning curve than conventional laparoscopy, especially for the well-trained laparoscopist. However, studies make it clear that experience of surgeon and team with the specific procedure is still of paramount importance in determining the outcomes of the intervention. Appropriate training should be provided to those surgeons determined to care for a large volume of cases. Surgical simulators, but also didactical tools for teaching while performing a real intervention are expected to receive an increasing role in the near future.

3.13 ERGONOMICS OF ROBOT-ASSISTED SURGERY

Minimally invasive surgery can be a strenuous business and repetitive stress injuries have been reported in surgeons.[163, 164] Because the surgeon operating the machine can sit in a comfortable position at a well designed workstation, it is believed that performing a robot-assisted procedure is more ergonomic.[1, 165] It is less clear, however, how much these benefits also apply to the patient-side assistant.

There are ergonomic differences for the surgeon specific to robotic therapy,[11] and this is especially reported in gynaecological interventions.[6, 127] A pilot study comparing 4 gastric bypass interventions through conventional laparoscopy and four with robot-assistance, however, suggested a mixed picture with indeed less stress to the upper extremities with robot-assistance, but both postural advantages and disadvantages for the neck and back region.[149]

Conclusion

In theory, it could be anticipated that some of the ergonomic stress of performing conventional laparoscopic interventions could be avoided when the surgeon sits more comfortably at a console in a more natural position. However, more research is needed to determine the full ergonomic benefit of robot-assistance.

3.14 SAFETY AND RELIABILITY

Current surgical robots are controlled by the surgeon and do not move autonomously. They do not have independent function or artificial intelligence. As such, they are nothing more than a sophisticated tool used by the surgeon while operating.[1]

The safety issues can be divided into risk deriving directly from the use of a robot, and those associated with the general risks of the intervention itself. The latter have been described previously.

In theory, the lack of 'feeling', called the lack of 'haptic feedback' could lead to increased risk of tissue injury, since the surgeon does not feel the tissues anymore because of the interposition of the robotic system. This risk, however, has mainly been documented in the literature on gynaecologic surgery.[6, 127]

Of course there are also mechanical risks, since all devices are subject to failure. Hardware, software, or even power or connection problems can cause the instrument to stop functioning. Currently available systems are designed to minimize the impact of such failures on patients but nevertheless they do happen.[1]

A few reports on mechanical failures of the robotic surgical systems have been published. Zorn et al. in a single institution experience of 725 consecutive RALP interventions reported no device failures that resulted in case conversions, technical errors in three cases resulting in a surgical handicap and four cases with system failure at initial set-up prior to entrance of the patient in the operating room.[64] Borden, in a similar analysis of 350 RALP procedures found three conversions because of technical failures and six preoperatively.[166] In a case report, Koliakos describes how the articulation joint of an Endowrist® needle driver was broken and positioned such that it could not be removed through the trocar, in which case the robot had to be uninstalled and a bigger incision to be made to remove the instrument.[167]

In a recently published multi-institutional study on robotic surgical system malfunctioning, eleven institutions from the US, EU and Australia participated with a total case volume of 8240 interventions.[168] Critical failures occurred in 34 cases (0.4%) leading to cancelling 24 interventions prior to the procedure, and the conversion of 10 ongoing procedures, two to laparoscopic and eight to open surgery. The reasons for the malfunctioning were the optical systems in one third of cases and the robotic arms in another third of cases; other reasons for malfunctioning included power supply problems, master console and unknown causes.

Conclusion

Robot-assisted surgery, as a technology, appears to be relatively safe and reliable.

3.15 FUTURE RESEARCH AND POSSIBLE DEVELOPMENTS

3.15.1 Information on outcomes

The main issue, at this moment, is the lack of information on outcomes since data from well designed and well executed randomized clinical trials is lacking.

Randomization between two surgical procedures is often thought to be untenable and is discouraged by paternalistic statements such as: "patients are unwilling to surrender their freedom of choice" or "surgeons know which one is better and will not allow their patients to be subjected to an inferior method".[11] Stirrat et al. argue that there are four ethical imperatives when considering surgical randomized trials:[169]

- the interest of patients is paramount
- any recommendation to a patient, colleague, or third party must be supported by the best available evidence
- all new interventions and procedures must be properly compared to the currently accepted method
- those who do not fulfill the previous three must be held to account

In addition to those RCTs that would give information on 'ideal' practice in experienced centres, effectiveness data should be derived from the performance in daily life. This analysis should clarify whether expected advantages are also obtained in reality. Therefore, the setting up of registries of actual practice, including a rigorous follow-up system and comparison with conventional interventions, could help build the knowledge base to decide whether this robot-assisted technology provides additional value worth its additional cost and if so, for which interventions.

3.15.2 Future developments in robot-assisted surgical systems

Robot-assisted surgery is a new domain of surgery and at this moment only one manufacturer is marketing its machine. But a significant amount of research and development is going on to bring smaller, cheaper, faster, and safer devices with improved features such as haptic feedback to the market.[1]

Apart from this, improved instrumentation is needed, including not only smaller instruments but also smarter instruments with capabilities to do smart sensing, informing the surgeon about tissue oxygenation, blood flow, molecular information and even tumour margin information by intraoperative histology.[1, 137]

At this moment imaging is provided with high-definition three-dimensional vision. Future systems might provide additional help to the surgeon with anatomic overlays incorporating information from other sources, or even offering optical biopsy capabilities.[1]

The current monopoly situation, however, is probably not the best incentive for bold new developments since the focus from the producers' perspective is most likely on the development of new instruments that can be used in the conventional robotic systems. Several other research groups are also working on new robotic developments, such as the 'Active Trocar' system (University of Tokyo), the 'Laprotek' (endoVia, Norwood, MA) and the 'hyperfinger' (University of Nagoya).[137]

Apart from miniaturisation, it could also be expected that there will be a paradigm shift from intracorporeal tools attached to an extracorporeal device to entirely intracorporeal devices, made possible by further miniaturization of robotic devices: intra-abdominal cameras and intracorporeal self propelled mobile robots could be used for microsurgery and other applications such as real-time intra-operative anatomy and histology, or for the delivery of new therapeutic techniques such as local phototherapy.[137] Several prototypes of these devices are currently being developed. Only future will tell which of these become successful medical technology.

Some authors express hope that further improvements in technology will result in less expensive equipment, leading to a more universal application of robotics.[6] The current market situation, however, makes this evolution to cheaper robotic systems unlikely in the near future.

Key points

- **Current robot-assisted surgery can be assumed to be relatively safe when used by experienced surgical teams. But, while the literature is rich with case reports, case series and technical details describing specific procedures, level I evidence from RCTs on effectiveness is missing.**
- **The external validity and relevance of studies solely performed in large experienced centres can be questioned. Moreover, except for radical prostatectomy, the evidence available is gathered from relatively small observational case series.**
- **Most observational evidence is available for robot-assisted laparoscopic radical prostatectomy (RALP), compared to laparoscopic (LRP) and open radical prostatectomy (RRP). There is evidence that perioperative blood loss is lower with RALP. For other hoped-for advantages, evidence is less consistent and highly dependent on the skill and experience of the surgical team.**
- **In cardiac surgery, robot-assisted techniques have made possible minimally invasive surgery otherwise difficult to achieve and it is promising technology because of its potential to influence outcomes. However, results are highly dependent upon the skill and the experience of the surgical team.**
- **In gynaecologic surgery the potential advantage of robot-assisted techniques mainly derives from an easier learning curve compared to laparoscopic approaches. Direct outcomes appear to be similar to laparoscopic techniques. Long-term outcomes and evidence from directly comparative randomised studies is missing.**
- **Most gastrointestinal indications appear to be safely feasible but there is little evidence for patient-specific advantages. They generally take longer to perform than conventional laparoscopy. No safety issues are reported. Therefore, these procedures might provide an opportunity for training surgeons in their early robotic learning curve.**
- **Across the various surgical specialties, robot-assisted surgery is thought to offer the greatest advantage in complex reconstructive processes with difficult access and limited space available.**
- **At this moment, no claims of superiority of robot-assisted surgical techniques can or should be made. Making such claims could even be counterproductive as this might induce unreasonable expectations in patients.**
- **Aside from cost, the main limitations across most specialties appear to be the training issues and the lack of outcomes data. Another limitation is in performing procedures that cover large areas, especially multiquadrant abdominal surgery.**
- **Because of the expected rapid growth of experience and the generation of evidence through comparative studies and prospective database, the results of this review will need to be revised in the future.**

4 ECONOMIC EVALUATION

4.1 LITERATURE REVIEW

4.1.1 Methods

Clinical and original economic studies were retrieved simultaneously through the same search strategy (also see chapter 3 and appendix to chapter 3). The studies were classified according the classification of Drummond et al. [170]. Economic evaluation, even partial evaluations such as cost analyses, dating from 2004 were withheld for further review as long as robot-assisted surgery was compared with an alternative. Cost descriptions and break even point analyses were not reviewed here. Data extracted from each study are detailed in the appendix. Length of stay and operative time were considered to be a cost element if no other patient outcome was analyzed. Unless otherwise specified, the mean is given with standard deviation as dispersion parameter.

4.1.2 Results

Eighteen original papers were retrieved, three of which were found by hand-searching. Eleven could be considered as cost-effectiveness studies although no formal incremental ratio was calculated, one as a cost-minimization and five as pure cost analyses. The classification of each study is given in appendix.

4.1.2.1 Robot-assisted urologic surgery (7 studies)

Radical Prostatectomy (4 studies)

In 2004, **Lotan et al.**[171] (USA) compared the costs of 3 alternative techniques for radical prostatectomy: the da Vinci robot-assisted surgery, the laparoscopy and the open retropubic surgery (RRP). Costs included professional fees, equipment and maintenance, operation room occupancy, hospital room, medications and blood transfusions. Length of stay and operative time were obtained from literature, at that time probably for a three-armed robot. The overall costs per procedure were $5554, $6041, $7280 and $6709 respectively for the open surgery, the laparoscopy, the robot-assisted surgery in case of purchase and in case of donation. Robot-assisted surgery was from 22% to 32% more expensive than the open surgery and costs from 11% to 21% more than laparoscopy. The shorter operative time for robot-assisted surgery (140 min versus 160 min. for laparoscopy and 200 min. for open surgery) and its associated shorter length of stay (1.2 days versus 1.3 days for laparoscopy and 2.5 days. for open surgery) did not counterbalance its high equipment costs ($1.2 million or $1705 per case) and the maintenance cost ($100 000 per year), even in case of donation. Robot surgery would only be cost equivalent to open surgery if the robot purchase price decreased to $500 000, the equipment costs to $500 per case and the maintenance contract to $34 000. Cost equivalence would also have been achieved if the length of stay in case of open surgery amounted to 6.3 days instead of 3.6 days or, conversely, in case of an unrealistic outpatient robot-assisted procedure during less than one hour.

In this study, laparoscopic and robot-assisted surgery operative times and lengths of stay were drawn from series operated by surgeons who had performed more than 100 procedures, who were therefore on the right of the learning curve. Moreover, European literature was excluded due to, on average, longer lengths of stay than in American series. Finally, the robot was assumed to be used in 300 cases per year. The cost difference with open surgery would undoubtedly increase with less experienced centres performing those techniques on a smaller number of patients. The selection of mature series also means that, for some parameters, only a single study was considered. Patient outcomes were not considered in the model and patient population was not discussed. However, beside costs issues, patient clinical profile may be determinant in the choice of the technique.

Scales et al.[172] pursued the same objective in 2005 in the USA comparing robot-assisted prostatectomy with open radical retropubic prostatectomy costs. Length of stay and operative time were retrieved from published papers.

Costs included operating room, consumables, anaesthesia, transfusion, professional fees and robot acquisition. Seven cases were assumed to be operated with robot-assistance weekly. Operative times were assumed to be 140 min. for the robot-assisted surgery and 160 min. for the open surgery. As for the length of stay, 1.3 days was assumed in case of robot-assisted operation versus 2.5 days for an open surgery in a specialist centre and 3.2 days in a generalist hospital. According to the base case scenario, the robot-assisted surgery cost $8929 which is respectively 2% and 10% higher than open surgery in generalist setting and in specialist setting. In the specialist setting simulation involving a robot throughput of 14 patients a week, robot-assisted surgery became cost equivalent to open surgery when the robot-assisted operative time decreased from 140 to 90 minutes. Outpatient robot-assisted surgery (< 0.5 day), deemed unrealistic by the authors, was also cost-equivalent to open surgery. The cost equivalence was also attained when the weekly robot throughput reached 15 patients or when the hospital room cost $1200. In the generalist setting, cost-equivalence would require a robot throughput of 10 patients a week. The main factors influencing the competitiveness of robot surgery were thus hospitalization costs (room and board), robot volume and robot operative time. Therefore, authors concluded that, under the cost structure of their academic centre, it is possible to attain cost equivalence between open surgery in a generalist hospital and robot surgery in a high volume specialist centre, underlining the major influence of the cost structure (mainly hospitalization cost).

Unfortunately, the authors mix costs and parameters from different settings. For example; the same hospitalisation costs per day ($840) were used in all settings. Yet, authors insisted on the importance of hospitalization costs, generalist hospitals being cheaper than specialist centres. Authors compared thus one technique in one particular setting versus another technique in a second setting based on the cost structure of the first setting. Nevertheless, this can only reinforce the conclusion that higher costs are incurred in case of robot-assisted surgery. The authors stated that, as robot-assisted surgery matures, it would become economically viable in an increasing number of settings. But the robot-assisted prostatectomy operative times and lengths of stay which they used were already achieved in series operated by surgeons who had performed more than 100 procedures each. In a real world situation, surgeons at the start of the learning curve may perform robot-assisted surgery at increased costs due to longer operative time, longer hospitalizations and even more complications.

The retrospective operative cost analysis by **Joseph et al.**[173] (UK data but costs reported in US$) comparing da Vinci robot assisted prostatectomy (n=106) to laparoscopic surgery (n=57) and open retropubic surgery (n=70) was published in 2008. Three surgeons performed the laparoscopic and open procedures while one surgeon operated with robot-assistance. Costs included were operating room costs including surgical and anaesthesia supplies, nursing and anaesthesia technician labour, operating room occupancy and post anaesthesia care. Varying from one hospital to another, hospitalization costs were excluded from the analysis. Average operating costs per case were $5410, $3876 and $1870 for robot-assisted, laparoscopic and open surgery respectively, including different surgeons performing different techniques. Supplies were the highest operative costs elements, especially for robot-assisted surgery ($4805). Robot-assisted cases were discharged the day after surgery while the mean length of stay was 1.1 day (thus similar) and 2.7 days for laparoscopic and open surgery respectively. Because laparoscopic series were performed earlier than the robot series, authors pointed out that a prospective randomized study is needed in order to take learning curve effects into account.

The exclusion of hospitalization costs and most of all of equipment costs are one of the more serious limitations of this study. Neither initial capital nor maintenance was included in costs although these are major costs drivers in robot-assisted surgery. As robot-assisted surgery is supposed to reduce length of stay, hospitalization costs had also an important role in the comparison.

The evaluation by **Mouraviev et al.**[174] in 2007 was based on the cost comparison of four techniques to operate localized prostate cancer performed by one surgeon: robot-assisted surgery (n=137), radical retropubic surgery (n=197), radical perineal surgery (n=60) and outpatient cryosurgical prostate ablation (n=58).

During the course of the study, perineal approach was used less frequently and robot-assisted surgery was more and more performed. The mean length of stay was 2.79 ± 1.46 days for retropubic approach, 2.87 ± 1.43 days for perineal approach and 2.15 ± 1.48 days for robot-assisted surgery. The direct surgical costs were lower for the conventional procedures ($2471 ± $636 for retropubic and $2788 ± $762 for perineal approach) than for the technology-dependent procedures: $3441 ± $545 for robot-assisted and $5702 ± $1606 for cryosurgery. The total hospital cost differences were lower for those technology dependent procedures: $10 047 ± $3107 for robot-assisted and $9195 ± $1511 for cryosurgery versus $10 704 ± $3468 and $10 536 ± $3088 respectively for the retropubic and the perineal approaches. The authors concluded that there was an off-set of the technology-related expenses by the lower hospitalization costs and the lesser need for blood transfusion. The design of this evaluation is poor, but it included a large number of patients. Cost-effectiveness was not really discussed as outcomes were not balanced (2 cryosurgical ablation failures were not discussed). Follow-up data after hospitalization were not taken into account. Finally, the issue of the capital costs of the robot is not tackled.

A cost-utility analysis published by **O'Malley et al.**[175] in 2007 was not retained because the methodology and data sources used were insufficiently clear.

Pyeloplasty (2 studies)

In 2005, **Bhayani et al.**[81] published preliminary results of a comparison of 8 robot-assisted pyeloplasties versus 13 laparoscopic pyeloplasties (allegedly matched by age, gender and BMI). Patients were operated in 2004 for ureteropelvic junction obstruction. Only operating room time and specific instruments or equipment costs were compared. Disposables, hospitalization, nursing and pharmacy costs were not included, as these were considered to belong to the same standardized pathway. The average operation time was shorter for robot-assisted surgery than for the laparoscopic procedure (105 min. versus 161 min). The total operating room occupancy, including set up, insufflation and take down time, was shorter for the robot-assisted than for the laparoscopy surgery (176 min. versus 210 min.). No complications occurred. Average length of stay was 2.3 days and 2.5 days respectively for the robot-assisted and for the laparoscopic cases. Total costs amounted to $5616 per robot-assisted case and slightly more than $3500 per laparoscopic case. Assuming same hospitalization time, success rate and complication rate, 500 cases per year would need to be operated with robot-assistance, requiring the operating room less than 130 min. to have cost-equivalence between both techniques, which was estimated to be unrealistic. Authors concluded in 2005 that training residents in laparoscopy would be more cost-effective than investing into robot-assisted surgery, awaiting the costs of robot-assisted systems to decline.

Beside the small size of the sample and a weak methodology, resident teaching and participation was provided during the laparoscopies, which lead to an overestimation of the laparoscopic time.

A year later, the comparison of the same procedures in the same Northern American hospital was published by **Link et al.**[84] It is unclear whether cases were common with the previous publication or whether the surgeon was the same. This time, each group included 10 consecutive patients. One single surgeon with an experience of 20 robot-assisted cases performed all procedures. The surgical team had an experience of more than 100 robot-assisted cases as well as in laparoscopy. Costs included only items differing between groups as operative time, anaesthesia professional fees, depreciation of the da Vinci robotic system and laparoscopy video-tower equipment (on 5 years with an annual throughput of respectively 150 and 400 patients), and the cost of surgical supplies including the robotic reposable instruments. Length of stay, blood loss and complications were similar while costs amounted to $5324 per robot-assisted case versus $1990 per laparoscopic case. Even excluding the robotic system capital costs, robot-assisted surgery remained more costly. Contrary to the previous publication, robot-assisted mean operative time was longer than the laparoscopic time (100 min. ± 11 min. versus 81 min ± 22 min) and would be cost equivalent to laparoscopy if laparoscopy lasted at least 388 minutes. Anaesthesia setup and wake times, urethral stenting and positioning times were not significantly different between the 2 techniques.

The authors concluded that, when performed by an experienced surgeon skilled in intracorporeal suturing, the da Vinci robot added little (speed or quality) advantage to the laparoscopic procedure but at greater costs.

Again, the size of the study was very small. The report of this study lacked detailed data especially costs calculation, and presented inconsistencies between tables and text. Docking time and undocking time should have been both included in the analysis. Moreover, no nursing time was valuated, which should further increase the disadvantage for the robot-assisted surgery. Nevertheless, concluding that the robot-assisted procedure is 2.7 times more costly is an overstatement as costs items incurred similarly in both procedures were excluded from the calculation (hospitalization, analgesics, postoperative visits, laparoscopic instruments used in both techniques). Finally, no information was given about the fact that the laparoscopic operative time was half that of that in the previous publication by the same group.

Nephrectomy (1 study)

A comparison of four techniques for nephrectomy performed in a North American medical centre was published in 2006 by **Nazemi et al.**[72]: robot-assisted surgery (n=6), open surgery (n=18), hand-assisted laparoscopy (n=21) and pure laparoscopy (n=12). All surgeries were apparently performed for oncological reasons in consecutive patients in whom age, gender, BMI and tumoral characteristics were not significantly different from each other. There was a statistically significant difference in median operating time between the robot-assisted surgery and the open surgery (345 min. for robot-assisted versus 202 min., p=0.02). Comparing the length of stay, patients operated with robot-assistance experienced shorter hospitalization than patients undergoing open surgery (median=3 days versus 5 days, p<0.01). Nevertheless, there was no statistically significant difference in mean hospital costs (including hospitalization and operating room costs): $35 756 for robot-assisted surgery, $25 503 for open way, $30 417 for hand-assisted laparoscopy and $30 293 for pure laparoscopy (p=0.36). Biochemical outcomes were recorded (such as creatinine level, volume of analgesics) but no clinical patient outcomes.

The study is original in the sense that one single surgeon performed all series, limiting the variability due to different performers. The surgeon was indeed experienced in all four techniques, but the number of previous operations was not reported. Nevertheless, this study presented numerous flaws. The size of the study was insufficient to draw any general conclusions and follow-up was never longer than one month. Costs were given for an unspecified random selection of patients which further restrains the sample size of the study and could induce selection bias. No information was reported on the specific methodology adopted for costs calculation. Finally, the reporting of p values for pair-wise and multiple comparisons was unclear.

4.1.2.2 Robot-assisted thoracic surgery (1 study)

Atrial septal defect closure and mitral valve repair (1 study)

In 2005, **Morgan et al.**[100] published an American retrospective cost comparison between robot-assisted surgery and sternotomy for atrial septal defect closure and for mitral valve repair. Each of the groups included ten patients, including the first patients operated with robot-assistance in that specific medical centre. Operative and postoperative directs costs drawn from the costing system of the hospital were compared. Total costs were not statistically significantly different for both procedures except when robot capital costs per patient were included. In this case, an atrial septal defect closure was 35% more expensive with robot-assistance than by sternotomy ($14 423 versus $10 650, p=0.021). A robot-assisted mitral valve repair costed 25% more than through sternotomy ($17 338 versus $13 894, p=0.004). The method of monetary conversion of operating time, which was one of the main components of operative costs after perfusion costs and supplies, was not given. The main postoperative cost driver was the intensive care unit use, followed by the hospitalization. Generally, the lack of clarity of the methodology and the small size of the study impaired the usefulness of the results.

4.1.2.3 *Robot-assisted gynaecologic Surgery (2 studies)*

Tubal re-anastomosis (1 study)

Rodgers et al.[176] retrospectively compared 26 three-armed robot-assisted tubal re-anastomoses and 41 mini-laparotomies for reversal of tubal ligation, performed between January 2001 and February 2006. One single surgeon performed the robot-assisted cases while three reproductive endocrinologists performed the outpatient mini-laparotomies. Anaesthesia and surgical median times were significantly longer for the robot-assisted technique: anaesthesia lasted 283 min. in case of robot-assisted surgery versus 229 min., surgery took 205 min. in case of robot-assistance versus 181 min. ($p \leq 0.001$). Hospitalization times were similar (99 min for the robot-assisted operation versus 149 min., p=0.14). No conversions from planned robot-assisted surgery towards conventional surgery were needed. No details on costs calculations or details were given. The median costs for the robot-assisted procedure was $1446 higher than for the mini-laparotomy (95% confidence interval: $1112–1812; p<0.001). Follow-up data were collected by telephone between 10 months and 5 years after surgery. The time to return to work was significantly shorter in the robot-assisted surgery group by approximately 1 week (p=0.013). Pregnancy, ectopic pregnancy rates and spontaneous abortion rates were similar. Mainly similar outcomes were thus achieved at higher costs in case of the robot-assisted surgery. Conclusions of the study are that the current available robots should be considered prototypes before smaller, cheaper and easier to use robots become available.

The usefulness of these results, however, is very limited, considering the numerous flaws of the study design: selection bias, recall bias, small sample size, exclusion of robot acquisition costs, exclusion of complications (readmission / reoperation), highly variable follow-up (10 months to 5 years) and heterogeneity of groups (one third patients received some additional infertility treatment).

Myomectomy (1 study)

In the American retrospective charts review of 2007 by **Advincula et al.**,[177] morbidity, amounts charged by the hospital and the surgeons and reimbursements for 29 cases of three-armed robot-assisted myomectomies were compared with those of 29 cases operated by laparotomy, matched on myoma weight, age and body mass index. The robot-assisted myomectomies were performed by one single surgeon while the controls were operated upon by six different surgeons. Two robot-assisted cases were converted into laparotomy (unplanned). None of the robot-assisted surgery patients did required transfusions while two open surgery patients did. Operating room amounts charged by the hospital (excluding surgeons professional fees) amounted to $16 916 ± $2668 in case of robot-assisted surgery versus $2165 ± $429 (p=0.2831) for open surgery, the main cost driver being the $10 570 per case for the robot depreciation on a 5 year period. The postoperative complications rate and the length of stay were lower in the robot-assisted group (length of stay: 1.48 ± .095 for the robot-assisted group versus 3.62 ± 1.50 days for the open surgery group). As a consequence, nursing costs were lower in the robot-assisted surgery group. Professional charges were statistically significantly higher in the robot-assisted surgery group, due to longer operative time (232 min ± 85 min versus 154 min. ± 43 min., p<0.0001). Nonetheless, the third payer reimbursed similar fees for both procedures.

Details on the costs calculations were lacking and costs of follow-up and complications treatment were excluded.

4.1.2.4 *Robot-assisted General Abdominal Surgery (7 studies)*

Fundoplication (4 studies)

The Belgian team of **El Nakadi et al**.[37] reported a small prospective trial in 2006. Attribution of procedure was randomized but not blinded. Twenty patients over 16 years with gastro-oesophageal reflux disease were randomized for Nissen fundoplication into either laparoscopic (n=9) or robot-assisted surgery (n=11), each being performed by an experienced surgeon in the particular technique.

The robot surgery was performed with a three-arms da Vinci surgical system. Exclusion criteria were: achalasia, diffuse oesophageal spasms, brachyoesophagus, and symptom recurrence after previous surgery or previous gastric surgery. Direct hospital medical costs included hospital stay costs (room, routine tests and laboratory costs), operative costs (material, nursing time, surgeons and anaesthesist professional fees) and pharmacy costs. An annual discount rate of 5% was applied over 5 years for the equipment. Operative time was significantly longer in robot-assisted surgery than in laparoscopy (137 +/- 12 min. (mean ± SE) versus 95 ± 5 min), mainly due to the 23 ± 4 min. (mean ± SE) robot set-up time. One conversion was made in the robot-assisted group due to the trocars not being adequate for an obese patient. Length of stay was similar in both groups (4.4 ± 0.2 days (mean ± SE) for robot-assisted versus 4.1 ± 0.3 days (mean ± SE) for laparoscopy). The one-month postoperative complaints were similar in both groups. After three months, four patients complained of temporary digestive disorders while no complaint was observed in the control group. At one year, one patient reported disorder after the robot-assisted operation against two in the control group. Finally, one patient needed laparoscopic surgery six months after the robot-assisted surgery due to gastric torsion. Hospitalization costs and professional fees were similar for both groups. Totals costs amounted to €6973 ± 99 (mean ± SE) in robot-assisted surgery versus €5907 ± 99 (mean ± SE) in laparoscopy. Laparoscopy was more expensive for disposables but cheaper in terms of re-usables, nursing time, investment and maintenance costs. If the robotic surgical system would have not been shared with other disciplines, the costs per case for the nine robot-assisted operations would have been €27 561 ± 99 (mean ± SE). Next to the higher costs of robot-assisted surgery for a similar outcome, authors estimated that the robotic instruments were not adapted enough for digestive surgery (tips too narrow, articulations too distally located) and better adapted for a small surgical field. In addition, the field of vision was reported to be too narrow.

This is the sole Belgian economic evaluation based on a randomized but not-blinded controlled trial. Another advantage of the study is that the same team of two surgeons performed all the procedures, the digestive surgeon specialized in robot-assisted surgery behind the surgeon's console with assistance of the general surgeon specialized in laparoscopy and vice-versa for the laparoscopy. Unfortunately, it is difficult to generalize the conclusion of a study comparing nine patients against eleven patients. Moreover, the maintenance costs represented more than 41% of the annual capital costs per cases, which appears to be extremely high.

The same year, a second randomized controlled trial was published by **Morino et al.**[36] The authors compared 25 gastro-oesophageal antireflux robot-assisted operations to 25 laparoscopies and found no differences in terms of postoperative outcomes at 1, 3, 6 and 12 months using the Gastro-oEsophageal Reflux Disease - Health-Related Quality of Life scale (GERD-HRQoL). Patients were operated by 3 surgeons experienced in laparoscopy. One robot-assisted operation was converted to a laparoscopy but no conversion was done to open surgery. Total operating time was significantly longer for robot-assisted surgery: 131.3 min. ± 18.3 (SE) versus 91.1 ± 10.6 (SE), due to robot set-up time, trocar positioning and longer suture time. Length of stay was similar (2.9 versus 3 days, p=0.588). Costs of disposables were €1454 in case of robot-assisted surgery versus €100. In total, a robot-assisted procedure costs €3157 versus €1527 for a laparoscopy. No decrease in operating time was observed over time.

Beside the cost disadvantage, authors reported technical limitations, yet on a three-arms version of the da Vinci robot, including the lack of haptic feedback, the limited available disposables, their size and laborious switching.

Intermediate data of a third randomized controlled trial comparing robot-assisted versus laparoscopic fundoplication in Germany were published by **Müller-Stich et al**.[142] Both groups included 20 patients with gastro-oesophageal reflux disease. Despite a longer preparation time before the introduction of the first instrument and 2 cases for whom minor technical problems lengthened the operation, the overall operative time was significantly shorter for a robot-assisted operation than a laparoscopic one (88 min. versus 102 min., p=0.033).

Mean length of stay was not significantly different (around 3 days). Even with the exclusion of the initial acquisition and maintenance costs of the robotic surgical system or for the laparoscopy tower, the total costs were 18% higher in case of a robot-assisted surgery than for the laparoscopic surgery (€3244 versus €2743, p=0.003). As complications and patient outcomes at 30 days were similar, authors concluded that 30 days after the surgery, the higher costs induced by the robot-assisted surgery were not justified by any additional benefit. Patient outcomes and quality of life at 12 months were still awaited at the time of publication.

Obviously, the inclusion of acquisition and maintenance costs in the calculation would only worsen the economic inferiority of the robot-assisted fundoplication compared to the open procedure.

In a publication from 2007, **Heemskerk et al.**[144] retrospectively compared 11 laparoscopic Nissen fundoplications performed in a Dutch hospital with their first 11 four-armed da Vinci robot-assisted Nissen fundoplications for gastro-oesophageal reflux. Patients were non randomly assigned between September 2003 and July 2004 and data were matched according to age and gender. Lengths of stay (4 days) and complication rates at 2 weeks were similar. Despite the saving of the presence of 1 assistant during the robot-assisted operations, the longer total operating room occupancy led to similar labour costs. Authors explained the longer operating room occupancy by the robot instruments exchanging and the limited experience of the surgical team. Material additional costs in case of robot surgery amounted to €985. The total costs were 29% higher for robot-assisted operations than for the laparoscopies (€4364 versus €3376, p=0.033). The higher costs of robot-assisted surgery were found to be not justified by benefits for the patient and authors consequently advocated more comparative trials.

Considering the size of the study, it is not surprising that no significant differences in complication rates or in lengths of stay were found. Concerning the costs, no details are given on the calculation. Note that only wages were included to evaluate the costs of operating room time. The difference in favour of the laparoscopy would be even more important if operating room occupancy in itself was also considered a resource to be taken into account.

Colectomy (1 study)

In the Northern American cost effectiveness analysis by **Rawlings et, al.**,[143] 30 robot-assisted (n=17 right + 13 sigmoid) colectomies were retrospectively compared to 27 laparoscopic colectomies (n=15 right + 12 sigmoid). Patients were operated between September 2002 and September 2005 for polyps, cancer, diverticulitis, carcinoid, or Crohn's disease. Complications were estimated unrelated to the robot-assisted surgery and are given in the data extraction sheet in the appendix. For the right colectomies, the operative time was longer for robot surgery than for laparoscopy (219 min versus 169 min), mainly due to the set-up time. No statistically significant difference was observed in length of stay (5.5 ± 3.4 days for robot versus 5.2 ± 5.8 days for laparoscopy). Robot-assisted operating room costs were 34.2% more expensive than laparoscopy ($5823 ± $907 vs. $4339 ± $867), including occupancy costs, personnel costs and supplies, each item being significantly higher in the case of robot-assisted surgery. But added to hospitalization, the difference was not large enough to increase the overall hospital cost significantly ($9255 ± 5075 for robot-assisted surgery versus $8073 ± 2805 for laparoscopy). For the sigmoid colectomies, similar operative time and length of stay were observed between both alternatives (length of stay: 6 ± 8.3 days for robot versus 6.6 ± 7.3 days for laparoscopy). There was a difference in operative costs ($6059 versus $4974) but not statistically significant. Personnel costs and supply costs were significantly higher in the case of robot-assisted surgery. In total, costs for a robot-assisted sigmoid colectomy amounted to $10 697 ± 11 719 versus $12 335 ± 12 162 for the same procedure by laparoscopy. No robot-related complications were observed and patient outcomes after both approaches were similar. Total hospital costs were higher in case of robot-assisted surgery without this difference being statistically significant.

The small size of the sample limited the added value of this study. Moreover the anastomosis was performed extracorporeally in the laparoscopy cases versus intracorporeally with the robot-assistance, which may have biased the comparison.

Rectopexy (1 study)

Robot rectopexy was studied by **Heemskerk et al.**[96] Between January 1st , 2004 and May 1st, 2006, 33 patients with full-thickness rectal prolapse were randomly assigned either to laparoscopic rectopexy (n=14) or to robot-assisted rectopexy (n=19).[a] Exclusion criteria were age below 18 years, unfitness to undergo laparoscopic surgery or hostile abdomen. Costs included hospitalization, outpatient clinics, diagnostic costs, surgical supplies costs and operating room personnel costs. Total costs were higher in case of robot surgery: €3673 against €3116 (p=0.012), due to the longer robot-assisted operative time (152 min. instead of 113 min., p=0.04) and the da Vinci robot use adding €889 more above the €780 common surgical material costs. Conversely, lengths of stay were similar: 3.5 days for robot surgery against 4.3 days for conventional surgery (p=0.527). Complication rates were similar for both groups. Follow-up data were still expected at the time of publication.

The size of this study is rather small and two different techniques were applied during the study due to a change in hospital policy: Wells posterior sling procedure until June, 2004 followed by D'Hoore procedure. Moreover groups included both males and females; the groups were thus too heterogeneous and too small to make the comparison reliable. Finally, no details were available on the methodology to calculate those costs except for personnel costs (wages multiplied by time spent in operating room).

Cholecystectomy (1 study)

In 2005, **Heemskerk et al.**[145] published a comparison of 12 cases of fully robot-assisted cholecystectomies using the four-armed da Vinci Surgical system with 12 cases of conventional laparoscopic cholecystectomies at a Dutch academic hospital. Patients, matched according to age and gender, were operated for symptomatic cholecystolithiasis but without acute cholecystitis. Surgeons had performed from 0 to 3 cases with the robot prior to the intervention. There were neither conversions nor major intra-operative complications but 3 cases of wound infection and one of urinary bladder retention occurred after robot-assisted surgery. Costs items per patient were hospitalization, diagnostic tests, surgical supplies, salary costs (surgeons and nurses), outpatient clinic pre-operative assessment and postoperative follow-up. Total operating room time was significantly longer in the case of robot-assisted surgery (2:30 versus 1:59, p=0.042) from which additional costs were offset by the presence of an assisting surgeon in laparoscopy. Total costs were higher in case of robot-assisted surgery (€3329 versus €2148; p < 0.001) partly due to the €889 robot instruments. Length of the stay was not significantly different (2.5 days for robot surgery versus 2.3 days). Authors thought robot-assisted surgery could only be considered as a learning tool for laparoscopy and advocated more research to define whether increased costs and operating time could be justified in more complex surgeries.

The surgeon operating with robot-assistance was located at the beginning of his/her learning curve. Nevertheless, complications were not correlated to costs. Anaesthesist fees were excluded, which otherwise may have been further unfavourable to the robot-assisted cost calculation.

4.1.2.5 Robot-assisted surgery: Various interventions (1 study)

Prewitt et al.[178] compared 132 cases operated with da Vinci robot-assistance at one academic medical centre in the six most frequent robot-assisted procedures between July 2000 and February 2007 with 1900 open cases for the same procedures gathered by the manufacturer of the da Vinci device, Intuitive Surgical.

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[a] Text and tables figures differing from each other, only figures reported in tables were considered.

The average direct costs per case operated with robot-assistance, including operative costs, hospital stay and staff salaries, was $11 590 compared with the $10 120 per open case. Average net revenue was $15 340 per robot-assisted case against $16 730 per open case. Length of stay was 3.6 days for robot surgery and 6.1 days for open surgery. Unfortunately, the heterogeneity of the groups and the lack of details impede any further reliable interpretation of the results.

4.2 DISCUSSION

The **design** of the studies described previously is generally of poor quality. Comparisons are mostly done retrospectively in one centre only or on small series, impeding the generalizibility of the results. El Nakadi et al.[37] and Morino et al.[36] are the only economic evaluations based on a RCT except for the intermediate German results published by Müller-Stich, et al.[142]

Many studies reviewed combined the hospital **perspective** (costs drawn from the hospital accounting department) with the third payer's perspective (physicians fees). Ideally, the perspective should be that of society, including the amounts charged to the patient as well as the patient's loss of income and time due to recovery. In the studies reviewed, the **time window** exceeds rarely the hospitalization and often the follow-up is not consistent among patients. The treatment costs of postoperative complications or cancer recurrence should in theory be included in the analysis.

Beside of selection bias due to no randomisation, observation bias in the comparison of the clinical results because of non-blinding, and short follow-ups, **costs** calculation methods are not given clearly and often not all cost drivers are included. In some studies, it is unclear whether the operating room time reported is any longer than the time spent by the surgeon at the operating table. The operating time should be defined as the period of time between the patient's entry into the room until his/her exit, including the patient preparation and anaesthesia and the docking/undocking of the robotic system. Moreover, staff members and nurses workload should also be taken into account. Finally, surgeons, assistants and nurses training has never been included in any costs calculations. These should have been incorporated as a capital cost item.

Comparison of operative time and **surgical outcomes** such as complication rates may be biased by the technical performance of each surgeon and his/her position on the learning curve. Answers to this problem have been looked for in the literature. For example, it could be possible to adjust for learning effects by means of a Bayesian hierarchical model,[179] or by stratification (if the sample size is large enough). Nevertheless, according to Brazier in his 2001 article on economic evaluation of surgery, interventions to be compared should be provided in a routine service setting.[180] Moreover, even if robot-assisted surgery may be considered an emerging technology, the Belgian penetration is already high, cost-effectiveness studies should hence analyse costs induced by experienced surgeons already located on the right part of the learning curve. These analyses are needed to base any reimbursement policy on evidence. **Patient outcomes** are poorly reported. Even short term patient outcome are lacking. For example, patient utilities or pain scores could be more useful short term outcome measures than the volume of analgesics used. Depending on the localization and indication, the rate of cancer recurrence, incontinence, impotence, fertility and more generally the long term impact on the quality of life have not been included in the studies so far. Finally, cosmetic results, patient preferences of different approaches may play a role in the choice of the surgical methods.

Sensitivity analyses have been carried in some of the reported studies and are necessary to take different scenarios co-existing in Belgium into account (robot acquisition or donation, various case volumes etc.). Questions on **transferability** of cost studies from abroad are legitimate, especially when costs structure is different. For example, in the Dutch studies,[96, 144, 145] surgeons were paid a salary instead of professional fees, which means that these costs were directly related to operative time.

In Belgium, some surgeons are paid a salary by the hospital where they work but other hospital physicians are independent and receive their fees-for-services from the national health insurance.

On a pure costs aspect and despite their flaws, it generally appears from the reported studies that robot-assisted surgery is more expensive than the other alternatives. Equipment costs but also labour costs are lower in open surgery than using the newer technologies. In the Belgian cost-effectiveness study, robot-assisted Nissen fundoplication appeared to be more expensive than the laparoscopic technique with no better patient outcomes, although indeed on a small number of patients. Most authors reported they were awaiting the costs of robot-assisted surgical systems to decline. For example Bhayani et al. concluded that training residents in pure laparoscopy was economically more interesting than investing in robot-assisted surgery.[81]

Key points

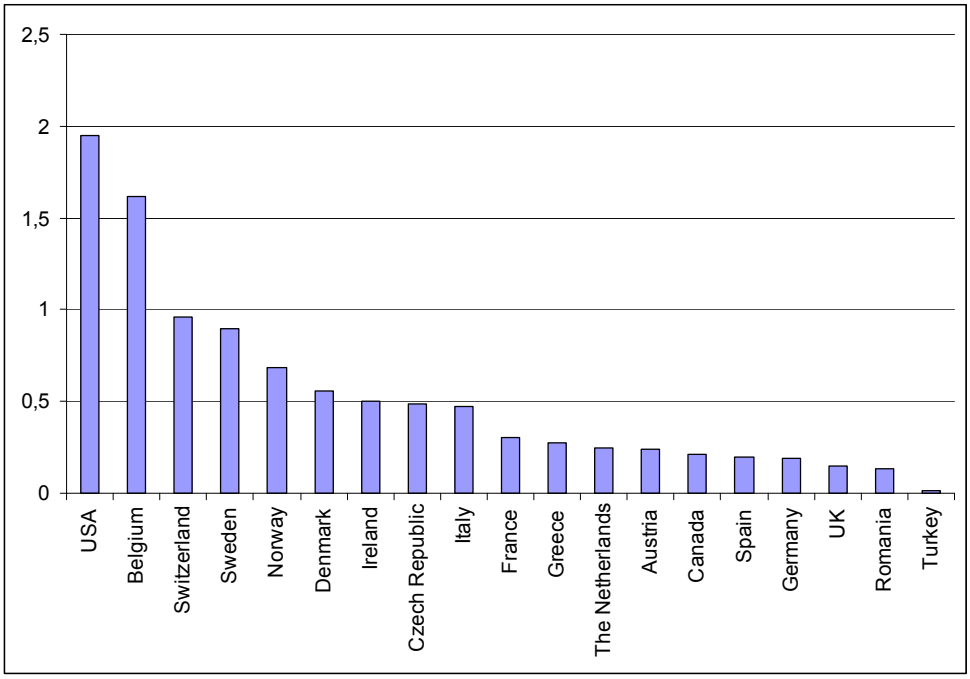
- **Performing surgery with robot-assistance is in general more expensive than using conventional methods.**
- **Costs of robot-assisted surgery for a hospital and for society are obviously volume dependent.**
- **Without clinical evidence, no meaningful incremental cost-effectiveness ratio can be calculated. The only conclusion possible is that, overall, current robot-assisted surgery is more costly than traditional alternatives such as laparotomy, sternotomy or laparoscopic approaches.**
- **There is a fundamental need of cost-effectiveness analyses based on RCTs performed by experienced surgeons and including the long term impact of surgery on clinical outcomes and on health related quality of life.**

5 SITUATION AND ORGANISATIONAL ISSUES

5.1 INSTALLED BASE

According to data from the producer, the installed base worldwide is around one thousand machines. Data from the producer detailing the installed base in different countries (installed base by 4Q 2007) allowed us to rank countries by number of robots per inhabitant. Data in Figure 4 show that Belgium is second in this ranking only being preceded by the USA. The reader should bear in mind that the figure represents the situation at the end of 2007 and that in Belgium (as in other countries) a considerable growth of the installed base is anticipated for 2008.

Figure 4 : Installed Da Vinci Robots (4Q 2007) per million inhabitants



Source: Installed base data from Intuitive Surgical, 4Q 2007. Population data from www.europa.eu, Statistics Canada and US Census.

5.2 CURRENT USE IN BELGIUM

5.2.1 Installed base in Belgium

Installed base in Belgium by end of 2007 (source Intuitive Surgical)

1. Algemeen Stedelijk Ziekenhus - Aalst
2. Onze–Lieve–Vrouw Ziekenhuis – Aalst (first robot)
3. Onze–Lieve–Vrouw Ziekenhuis – Aalst (second robot)
4. Universitair Ziekenhuis Antwerpen
5. Sint Augustinus – Antwerpen
6. AZ Sint Jan – Brugge
7. C.H.U. Saint–Pierre – Bruxelles
8. Europa Ziekenhuizen – Brussel
9. Université Libre de Bruxelles – Hôpital Erasme – Bruxelles
10. AZ Maria Middelares - Gent
11. Jan Palfijn Hospital - Gent
12. St. Lucas - Gent
13. AZ Groeninge - Kortrijk

14. UZ Gasthuisberg – Leuven
15. Heilig Hart Ziekenhuis Roeselare
16. Cliniques Universitaires UCL de Mont-Godinne – Yvoir
17. AZ St. Elisabeth – Zottegem

An update provided by Intuitive Surgical in early November 2008 showed that additional da Vinci robots had been installed in 3 more Belgian hospitals. Those hospitals were not questioned for this report:

18. AZ Klina – Brasschaat
19. C.H.U. Ambroise Paré – Mons
20. C.H.R. Clinique Saint-Joseph – Mons

5.2.2 Questionnaire

5.2.2.1 Methods

A data collection was organized during summer 2008. After a first contact by telephone in the month of June, Medical Directors of the 17 hospitals listed (situation end 2007) above were sent a questionnaire, described in appendix. The form was sent by mail and answers were received by e-mail, post or fax. The objective was to gather enough information to draw a first picture of the practical usage of robot surgery in Belgian hospitals, to identify the specialties using robots and to obtain a rough idea of the volumes treated.

5.2.2.2 Results

Twelve centres (corresponding to 13 robots) answered the questionnaire at least partially. However, some of the hospitals that did not send their questionnaire had given some information during the first telephone interview.

Q1. Number of procedures performed in 2008

An extrapolation was made based on the number of months in 2008 for which the activity was given, generally 9 months until September, in order to estimate the number of procedures performed in the whole year 2008. The responding centres most likely will have realised about 1470 robot-assisted procedures in 2008. Amongst those 85% of the procedures were urologic (70% or the total number were radical prostatectomies), 10% were gynaecologic, followed by cardiac or gastrologic procedures and a few Ear-Nose-Throat (ENT) indications. Taking into account the non-responders and additional information obtained through the telephone, we estimate that the total number of robot-assisted procedures performed in Belgium in 2008 is most likely situated around 1800, from which are 1200 radical prostatectomies. This is a rough estimation and no rule of three as several non-respondents were small centres or centres that had just begun to operate with robot-assistance. In average the yearly volume of a current Belgian centre could be estimated around 100 procedures per year, including 70 radical prostatectomies. The volume by centre, however, is highly variable from a few tens of cases per year to more than 400 procedures per year.

Radical prostatectomy is thus by far the main indication performed with robot-assistance in Belgium. Prostatectomies are today performed on almost all the robots. Approximately 14 to 15 centres use the robot mainly for this indication. Other urological procedures included cystectomy, (partial) nephrectomy and pyeloplasty. About half the robots were also used for gynaecologic procedures such as hysterectomy or tubal re-anastomosis. Digestive surgery included colectomy, Nissen fundoplication, rectum surgery or bariatric surgery such as gastric bypass. Indications in cardiac surgery were mainly totally endoscopic coronary artery bypass surgery (TECAB), cardiac biventricular lead placement and mitral valve repair.

The proportion of a specific procedure performed with the assistance of the surgical robot ranged from 10% to 100%. In other terms, some centres do have abandoned other approaches once robot-assisted surgery was adopted for a specific intervention.

Q2-5. Robot acquisition

In most cases, robots were originally acquired for urologic purposes, followed by gynaecologic indications, abdominal surgery or cardiac surgery. Four hospitals acquired their robots also for cardiac surgery but only two of them reported cardiac procedures in 2008.

The first robot in Belgium was acquired in 1999. Another began its activity in 2000. Most operational robots at the beginning of 2008 had been acquired less than a year before, as can be seen in Table 2.

Table 2 : Number of robots acquired by Belgian hospitals per year

Total	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
17	1	1	0	1	0	0	2	1	10	1*

* 2008 only includes 1 robot on order in 2007 but installed in 2008. Further sales in 2008 are not included in this questionnaire.

Except two cases of (partial) donations and one leasing contract, other robots were purchased. Physicians participated in more than half the robot purchases, contributing from 15% to 100% of the purchase price.

Q6. Inclusion and exclusion criteria

In most hospitals, age of the patient was declared not to have a role in patient selection. In some urology facilities, robot-assisted radical prostatectomy was chosen mainly for young patients to optimally preserve sexual function. In two hospitals patients aged more than 75 years or with less than 10-year life expectation were excluded from robot-assisted surgery.

One hospital reported obesity as an inclusion criterion except when the BMI exceeded 40. Other hospitals excluded patients presenting a BMI above 32 to 40 or did not apply any limit.

Patient socio-economic situation was an exclusion criterion in a few centres when a supplement was charged to the patient.

Anatomic limitations for robot-assisted surgery were: invasive tumours or metastases, T3 prostate carcinoma requiring a large lymphadenectomy (urology), calcified or narrow coronary arteries (cardiac surgery), a need for a complex mitral valvuloplasty (cardiac surgery), multisegment abdominal interventions, or a large uterine volume (gynaecologic surgery). Specific anatomical conditions or previous surgical history could be either inclusion or exclusion criteria.

An often cited contra-indication was the inability to endure a prolonged and extreme Trendelenburg position, chronic obstructive pulmonary disease and a bad cardio-pulmonary condition. Also other general contra-indication for anesthesia were mentioned as for any other form of surgery.

Q7. Operative staff

Generally, one anesthesist participates at the robot-assisted surgery, sometimes two. Beside the assistant surgeon or surgical trainee, the nurse(s) and the main surgeon at the console, another (trainee) surgeon may also be present, especially in the case of the specific training of another surgeon for robot-assisted surgery. In all responding hospitals at least two nurses also participate at the operation, sometimes even three. Generally, there is one surgical nurse amongst them.

Q8. Staff training

In one hospital, the anesthesist devoted to robot-assisted surgery followed 3 days training like the surgeons. Otherwise, only surgeons and nurses received a specific training. Basic 2 days or 3 days training is organized in Europe at Strasbourg (France) by Intuitive Surgical. Other training places in foreign countries like Pittsburgh or Stanford were also mentioned.

Practice training on animals or corpses and observation on-site were also performed in some hospitals. The presence of a biotechnician was cited by one centre.

Q9-11. Use of robot by surgeons

The total number of surgeons currently using a robot in Belgium probably does not exceed 50 surgeons. This figure is the sum of the numbers given by each hospital, but is probably an overestimate since some surgeons are active in more than one hospital. The highest number of surgeons using a robot in one hospital was 6 (in 3 different specialties). Only in 2 surgical services (in 2 separate hospitals) all surgeons were accustomed to use the robot (in urology and in gynaecology).

The practical lifetime experience of the surgeon expressed as number of robot-assisted surgeries performed until now was between 1 and 700 procedures. On average the most experienced surgeon of the service had performed around 85 procedures during his lifetime. The variation between surgeons was important; in 5 services the most experienced surgeon had done only ten procedures or less.

Q12-13.Information to patient

It was always reported that information on the operation was given to the patient, at least during an interview with the operating surgeon and inherent risks of the operation were almost always mentioned. To a lesser extent information on rehabilitation period or hospitalization length were also discussed. In most hospitals, the signature of an informed consent form was required before the operation, in one hospital this informed consent is given orally without formal signoff.

Q14. Waiting list

Only 2 hospitals had waiting list of patients for robot-assisted surgery (respectively in gynaecology and urology).

Q15. Patient supplement payment

Some hospitals reported not to charge the patient while other hospitals asked €150 (for specific gynaecologic procedures), €690 or €1200 (this last amount being asked in 7 hospitals). One hospital declared having a solidarity fund to support the patient when he/she was unable to pay this amount.

5.3 CURRENT REIMBURSEMENT IN BELGIUM AND ABROAD

The different costs for the national health insurance are:

- Surgeon's and assistant's fees
- Anaesthesist's fees
- Lump-sum for endoscopic material

Only operative fees will be discussed as the pre-operative consultation fees will be considered independent from the technique chosen. Two elements can be impacted by the use of a surgical robot: operative time and number of required assistants. In Belgium, only the second one is relevant from the national health insurance perspective.

An actual longer time due to the use of a robot would not increase the reimbursement unlike in other system, such as in the USA, where the anaesthesist reimbursed fees are related to the real operative time.

Nevertheless, if the robot-assisted surgery would require a different staff configuration such as an additional assistant surgeon, this would represent an additional cost. On the contrary, if the number of covered assistants is limited to one, such as for the coverage by the Australian Medicare Benefit Schedule, no incremental cost can occur due to the use of a robot.

5.3.1 Radical prostatectomy

As it appeared from our survey that radical prostatectomy was by far the most frequent procedure performed with robot-assistance in Belgium (about 70% of all robot-assisted procedures), we only examined the reimbursement for this procedure. This was also the example chosen to be able to compare if robot-surgery is covered in different countries.

5.3.1.1 Radical prostatectomy in Belgium

Currently the radical prostatectomy is reimbursed similarly, independently from the technique chosen: through laparotomy, laparoscopy or with robot-assistance. The amount reimbursed is the same, a trainee being reimbursed 75% the amount of the senior specialist. Assistants charge the same code but receive 10% of the fee paid to the operating surgeon.

In case of laparoscopy or robot-assisted surgery, an additional lump sum of €510.93 is charged for the disposables.

Art	Code	Label	K value	Amount	Amount for trainee
14j	261796 – 261800	Prostatectomie totale, y compris l'exérèse du bloc vésiculaire avec suture urétro-vésicale	K450	€927.01	€695.26
35bis	694610 – 694621	Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 261796-261800, par voie endoscopique	U 645	€510.93	
12	200071-200082	Anesthésie pratiquée au cours d'une prestation : Classée dans une catégorie égale ou inférieure à K 450 ou N 750 ou I 850 et supérieure à K 390 ou N 650 ou I 750	K225	€483.42	€362.57

5.3.1.2 Radical prostatectomy abroad

Some details on countries presenting a nomenclature system similar to Belgium are presented in the appendix.

In **France**, there are different fees related to the technique applied. Robot-assistance is not specifically covered and the procedure is reimbursed under the laparoscopic code JGFC001 in the CCAM nomenclature 2008 (Classification des Actes Médicaux).[181]

In the **Dutch** hospital case-mix financing system, radical prostatectomy can be reimbursed through different DBC's (Diagnosebehandelingcombinatie - Diagnosis treatment combination) from the B-segment which groups DBC's that are negotiated between Dutch hospitals and health insurers. Open approach and laparoscopy are differently covered, the reimbursement of the latest being generally slightly higher. There are thus no national tariffs for radical prostatectomy as they are locally negotiated. The authorities and the professional association of Urology is currently studying the possibility of an official registration of robot-assisted surgery in prostatectomy. In the meantime, the procedure is apparently registered as a laparoscopic DBC.

Tariffs for the five hospitals using da-Vinci robot in urology are presented in the appendix, in the case of a patient referred by a physician to the hospital and admitted for more than 1 day. The Jeroen Bosch hospital in 's-Hertogenbosch is the only hospital that applies two different hospital tariffs for the laparoscopic code and charges an additional amount of €3850 when the prostatectomy is performed with a da Vinci robot (€13 000 instead of €9148).

The Dutch Health Care Insurance Board (CVZ - College voor zorgverzekeringen) has recently issued a position in which Da Vinci robot-assisted surgery is declared to belong to the medical state of the art and practice.

The position paper also mentioned that in case the robot-assistance was not available for a patient, open surgery and laparoscopy were equally effective.[182]

The **Italian** hospital case-mix system includes 2 hospital DRG's (Diagnosis Related Groups) for prostatectomy with (306) and without complications (307), tariffs varying from one region to another. The DRG is independent from the type of surgery performed and robot-assistance is not specifically covered. La Società Italiana di Urologia is currently working on a new definition of tariffs for robot-assisted surgery.[9]

In **Germany**, the medical fee schedule (Gebührenordnung für Ärzte, GOÄ) fixes a tariff range per procedure for private insured patients, Two codes exist, depending on the lymphadenectomy needed. There is thus is no specific procedure code for robot-assisted prostatectomy.

For public inpatient care, procedures codes for radical prostatectomy depend on the approach (perineal, laparoscopic, retropubic) and on the possible combination with lymphadenectomy. No specific code exists for robot-assisted surgery. When they are combined to a prostate cancer ICD-10 diagnosis code, the German-DRG 2008 obtained is the same (M01B), reimbursed at €6520 for a public inpatient hospitalization.

There were a few requests from German hospitals to obtain a financing on an individually negotiated basis, considering surgical robot as belonging to NUB, Neue Untersuchungs- und Behandlungsmethoden or "New diagnostic or therapeutic methods" which are new costly procedures not compensated (yet) within DRGs. Four hospitals requested to negotiate an additional financing for robot-assisted cardiac arrhythmia ablation and seven hospitals for robot-assisted radical prostatectomy. The requests did not meet the criteria of the NUB agreement and were rejected.[183] Hence, inpatient robot-assisted surgery is not specifically covered by the statutory health insurance in Germany and many hospitals using the da Vinci robot charge about €3000 to the patient.[10]

In the **British** NHS hospital Payment by Results (PbR) system, robot-assisted prostatectomy has a specific HRG (Healthcare Resource Group) that comes as a surcharge of £1500 (€1790[b]) per case above the open prostatectomy fee. In the private sector it costs about £20 000 (€23 860) per case (personal communication from Professor Prokar Dasgupta, Department of Urology, Guy's and St Thomas' Hospital, NHS Foundation Trust, London).

The reimbursement of the radical prostatectomy differs between the various parts of **Sweden**. In the Stockholm DRG-based system, there is an extra reimbursement for robot-assisted prostatectomy of approximately €1500 per patient (personal communication from Dr. Peter Wirklund, Karolinska Institutet, Stockholm).

The radical prostatectomy in **Québec** is charged under two different codes by the Régie de l'Assurance-Maladie: one for the retropubic approach (06243) and one for the perineal approach (06244) but no specific code exists for robot-assistance surgery.[184]

Generally, **Northern American** health insurers do not apply a differential reimbursement when an intervention is done with robot-assistance; the surgical procedure is considered as a laparoscopic procedure. Nonetheless, some of them require a specific code if the intervention is done with robot-assistance. Some other insurers allow coverage on a case-by-case basis or prior authorization but does not pay anymore than if the surgery was performed by another approach(ex. Health Alliance plans).[185] CIGNA Healthcare requires an add-on (non-reimbursable) code S2900 since July 2005 and covers robot-assisted surgery in the same way as any other approaches.[38]

In **Australia**, there are two procedure codes for a radical prostatectomy, depending on whether a pelvic lymphadenectomy was performed, but there is no different reimbursement for conventional laparoscopy or for robot-assisted surgery. In case of a perineal approach, the anaesthesist fees are reduced.[186]

To our knowledge, robot-assistance during the prostatectomy is thus reimbursed as such by the NHS in England, in someway in the Netherlands and in some parts of

b 2008-11-13: 1£= 1.19321 €

Sweden amongst the reviewed international benefit baskets. In the Netherlands agreement may be made with health insurers to cover robot-assisted surgery at a higher fee than laparoscopy.

5.3.2 Other indications

Other indications than prostatectomy are less well established and performed by fewer institutions. Therefore most countries have not consistently dealt with the financing of those interventions. Currently in Belgium, as described in our survey, radical prostatectomy represents the majority of all robot-assisted procedures in Belgium. Therefore, we only examined the reimbursement specificities for this procedure. Other indications like other urologic procedures, gynaecologic procedures, cardiologic procedures and abdominal or thorax procedures have their own reimbursement specificities. For example, the gastric by-pass codes are different whether performed through laparoscopy or through laparotomy, but fee-for-service is identically set at €818 for both approaches. There is anyway no reimbursement whatsoever the procedure for the robot-assisted surgery approach in Belgium.

5.4 COSTS FOR PATIENTS

The procedure fees, as described under section 5.3, are fully covered by the national health insurance. When a lump sump is billed for endoscopic material, 75% of the cost is covered by the national health insurance and 25% by the patient. In the case of a prostatectomy, the patient's additional cost for laparaoscopy would be €170:

Art	Code	Label	K value	Amount
35bis	694610 - 694621	Ensemble du matériel de consommation et du matériel implantable utilisé lors de la prestation 261796-261800, par voie endoscopique	U 645	€170.30

Beside the out-of-pocket expenses for hospitalization, patients are in many hospitals asked to participate in the robot related costs. The amount is typically around €1200 (see 5.2.2.2). It should be observed, however, that some private hospital insurances cover part or the whole of these additional costs to the patient for those who have such insurance. Some hospitals, however, do not ask the patient to pay a supplement or are more flexible depending on the financial situation of the patient.

Patient incurred costs may be charged or not to a private insurer. Lost time and income incurred by the patient will not be covered here but should ideally be included in any economic evaluation of robot-assisted surgery.

5.5 COSTS FOR THE HOSPITAL

5.5.1 Costs involved

It was not our intention to make a detailed cost analysis applicable to all hospitals since this widely varies between hospitals, depending on funding sources, organisational and financial structure and disciplines involved in using the surgical robot. We wanted, however, to provide a general idea about the different costs items for any hospital induced by robot-assisted surgery. Those are:

- Initial capital acquisition (including robot monitor system, surgeon workstation, cables, operating table in the newest versions)
- Extra costs of fixed assets (floor space, building)
- Yearly maintenance of the robot: repair and update of the robot and its computer program
- Disposable and 'reposable' material (robotic surgical instruments and sterile drapes for the robot) in addition to other consumables used in every surgical procedure such as drapes, gloves, etc.
- Drugs and transfusion blood including the anaesthetics from which the volume depends on the length and the type of the operation

- Nursing and assistant staff salary that are variable costs linked to the peri-operative preparation, the robot manipulation, the anaesthesia and the postoperative care of the patient
- Training costs for the surgeons and the operative staff
- Hospital room and board (depending on length of stay).

Also the use of preoperative diagnostic tests, hospital room and board, nursing care, pain management and postoperative complications treatment may differ or not from a conventional surgical technique.

5.5.2 Global cost assessments in the literature

From a hospital point of view, the recent break even point analysis run by the Regional Observatory for Innovation of Emilia-Romagna (Osservatorio regionale per l'innovazione) in Italy calculated that a €1.68 million robot could only become profitable if the volume treated was beyond the threshold of 548 radical prostatectomies a year.[9] Capital, maintenance, instruments, labour costs, materials, hospitalization and indirect costs were put in balance with the tariff of a regional prostatectomy DRG (diagnosis related group).

Steinberg. et al.[187] calculated that the $1.5 million da Vinci S robot was worth acquiring for their American centre if the volume treated increased with 78 patients a year (additional interventions). This was the extra caseload needed to maintain profit and to cover the transitional costs converting the laparoscopic program into a robot-assisted surgery one. In case the robot was donated, only 20 extra cases were needed. Operating time, length of stay and patient outcomes were assumed equivalent between laparoscopy and robot-assistance, considering no additional critical benefits could be made on the already mature laparoscopy program, The authors concluded that the robot purchase was worthwhile (on a pure profit basis) for high-volume hospitals, knowing that only 7% of American hospitals performed more than 54 prostatectomies a year.

5.5.3 Capital costs

Infrastructure

Space must be planned for the robot itself including the operating room table, the surgeon's console and the monitor station. Some authors regretted the lack of robot and operating room table integration of the da Vinci System as a disadvantage for colectomies.[143] In its newest version, the da Vinci S Surgical system integrates the robot, the table and the monitor. The robot itself weights around 635 kg and is hard to fit into small operating rooms.[178] Moreover, free space must be available to rapidly move the robot and the monitor station, in the case when conversion to conventional surgery is needed. Some patients cannot be operated with robot-assistance and therefore an alternative operating room will always need to be available next to the operating room for robot-assisted surgery. This investment in building is a sunken cost as it has to be paid before the start of any robot-assisted surgery program.

Robot acquisition and maintenance cost

Purchasing conditions may depend on the hospital volume of orders of instruments of limited re-use. The choice of different features may also have an impact on the purchasing price, such as an optional extra arm or the 3D high definition vision system, launched in 2007 as an option for the S version or an upgrade for the previous version of the robot.

Capital acquisition costs may be interpreted largely in some institutions and the training costs and possible marketing programs may be capitalized.[1] As an example, marketing by the hospital may be the development of specific web pages to inform patients of possible risks/benefits of robot-assisted surgery.

There are different possibilities to finance the initial capital investment that have been differently combined in each robot purchase:

- Hospital budget
- Participation by physicians working in the hospital
- Government or local authorities grant (including foreign administration such as the FDA in the US)
- Research funds.

Some hospitals have chosen to lease the robot, awaiting positive results for their patients or future technologic developments, before deciding to definitively acquire the robot.

The accounting method influences the calculation of the cost per case. In Belgium, medical equipment is generally depreciated each year linearly at a 20% rate (5 years base).[188] There are legal exceptions for heavy equipment units such as the magnetic resonance imaging (MRI) unit or the positron emission tomography (PET) unit that are depreciated in 7 years.[189] By analogy to this rule, some Belgian hospitals have chosen a 7 year-period, other hospitals depreciate their machine in 5 years. It is now too early to determine the ideal length of time. Actually, the hospital has to evaluate the replacement rate of the equipment. A shorter depreciation time reflects the belief that (1) the replacement by a newer and better unit might happen relatively early (considering the high costs of the robot) or (2) that the physical lifetime of the machine will not exceed 5 years.

For example, considering a discounting rate of 3%,[190] a robot purchased at €1.7 million with a 10% maintenance contract from the year following the purchase and depreciated on a 5-year basis would cost more or less €900 per case if 500 cases are operated yearly. With 17 functioning robots in Belgium and the capacity still increasing this year, most Belgian centres do not reach such volume. According to our questionnaire, the yearly throughput would be on average around 100 cases, which would lead to €4500 per case on average.

In case of a more pragmatic longer depreciation period such as 7 years, 100 cases per year would cost €3550 each. A maintenance amount would be paid 6 times, but this cost is more than offset by the delayed payment of capital costs. Naturally in case of two robots, the cost of €3550 is reached if the volume is 200 cases per year (notwithstanding any discount obtained from the manufacturer).

For a high-volume hospital (for example 300 cases a year during 7 years), the capital costs would drop to more or less €1200.

5.5.4 Operating costs

Instruments and surgical supplies

Many authors expected a decrease in material costs, especially in the instruments, or so-called reposables.[100, 173] Nevertheless, this is not true for a captive market. From the manufacturer's point of view, there is no need to lower the price in a near future. Once the robots fleet is installed after the broad and fast adoption of the system, revenue is secured for years by the exclusive rights on the reposables. Recurring income including instruments, training and service amounted only to 12% of the sales in 2000, 88% being robots sales. In 2007, this part had reached 46%. On the other hand, the annual robot sales still accelerate even more in dollars than in number of robots (+63% between 2007 and 2006, +42% in number: 241 robots instead of 170), due to the higher price of the new version of the robot.[156] The absence of competition naturally impedes a natural decrease in purchasing price maintaining the robot in the growth phase of its lifecycle. Moreover, the monopoly position of the manufacturer owning numerous patents does not urge technical improvements aiming at increasing the reposables limited number of uses, or even the availability of additional types of instruments. In 2007, the revenue of Intuitive Surgical was $601 million against $373 million in 2006.

Among 2007 expenses, $49 million has been invested in Research and Development, leaving a final net income of $144 million. New gynaecologic instruments were launched in 2006 and hysterectomy emerged soon as their fastest growing procedure increasing with 175% in 2007 (against 65% for prostatectomies).

More than 130 000 da Vinci procedures are expected worldwide in 2008 including more than 70 000 prostatectomies and about 32 000 hysterectomies.

Reposables vary with the type of procedure. In Belgium instruments and drapes in case of a robot-assisted prostatectomy is around €2160 (personal communications from different hospitals). This material cannot be bought by another supplier. Additional non da Vinci operative material may cost around €710 (personal communication). All operative material, therefore, would amount to around €2870. Comparatively, the disposable and reusable (after sterilization) material required by a laparoscopic radical prostatectomy cost about €1860. The extra material compared to a laparoscopy would thus represent more than €1000.

Various surgical disposables	€710
Da Vinci drapes	€260
Da Vinci reposables (10 uses)	€1900
Total	**€2870**

In other procedures such as a ventricular resynchronization in cardiology for example, the 'reposables 'required a might be estimated at €800, while a procedure for auricular fibrillation would require €500 'reposables' and a TECAB between €1000 and €1200. The reposables and disposables cost per procedure in gynaecology has been estimated to $1000 in the literature in USA.[123] Comparatively, this amount was lower than that required by a laparoscopy in a similar case.

Depending on the procedure, there might be cost reductions in other (non da Vinci) disposables. For example, in the case of a TECAB, if a sternotomy can be avoided, savings can be made on the steel thread, etc.

Other consumables

Some supplies (pain reducers) depend on the patient short-term functional and algological outcomes. The volume of anaesthetics and blood transfused may be different or not from the conventional procedure.

Operating room, surgeons and nurses time

The occupancy of operating room is a resource than cannot be used for other procedures during the time it is used in robot-assisted surgery. In other terms, there is an opportunity cost when robot-assisted surgery takes longer than the alternative surgery. To offset the high costs, utilization has to be maximized or preparation and operation time minimized or length of stay shortened to increase efficiency. As a time consuming factor, the robot docking and undocking may been divided by three over time for an experienced team (from 15 min. to 5 min in the gynaecologic department of an American hospital.).[123]

Hospitals able to reduce the length of stay by performing robot surgery may benefit from a prospective payment system in which longer lengths of stay have been previously established for the open procedure.[173] The necessary condition is to perform a sufficient robot-assisted case volume and reduce operative times.

Nursing time will depend on the total operative time (including the time of patient preparation) as well as the care required during hospitalization.

Surgeons and nurses training

The experience of the surgeon is, firstly, the key factor of a safe robot-assisted procedure,[25] but also a warrant to minimize operative time and costs. According to the paper by Benoit et al. from 2001, the surgeon impacted the cost through factors such as surgical time and volume of blood transfused but patient factors such as age or co-morbidities had no significant correlation with total hospital costs.[191]

Set aside a better care for the patient, hospitals hope to offset the extra costs induced by a robot-assisted program by reducing the length of stay, the operative time for some procedures and the postoperative care.

In particular in the operating room, well-trained staff is important to gain time in patient preparation and in docking and undocking the robot safely. The set-up of the robot and the operating room varies with the type of procedure and set-up changes between different procedures may be time-consuming.[25]

In the USA, the FDA requires Intuitive Surgical to train surgeons and staff. There is one half-day on-site training and one or 2 day session at the manufacturer training centre.[185] In Europe, some training is given by the company as part of the sales agreement, but physicians generally complain that this training is by far insufficient (personal communications). Most hospitals in Belgium have indicated the need to give additional training to their surgeons and nurses.

5.5.5 Global costs per case

Assuming a hospital performing 100 robot-assisted procedures a year, all radical prostatectomies, the total capital costs per case could be estimated to €3550 per case, as seen in section. 5.5.3. and operative material (disposables and 'reposables') to €2870 as seen in section 5.5.4. Not taking into account hospital room and board, nursing and surgeons time, or other costs drivers that we suppose similar to the case of a radical prostatectomy by another approach, the robot-assisted radical prostatectomy material costs approximately €6420 per case. This amount does not include the additional training costs.

Naturally, those costs heavily depend on the yearly throughput, in the case of a high-volume service (300 cases per year), the global costs would amount to an additional €4070.

Currently, the endoscopic lump sum charged is €510 to the national health insurance and €170 to the patient. If the patient is charged an additional €1200 as done by some hospitals, around €1880 of the robot-assisted radical prostatectomy cost can be considered as covered from the hospital perspective.

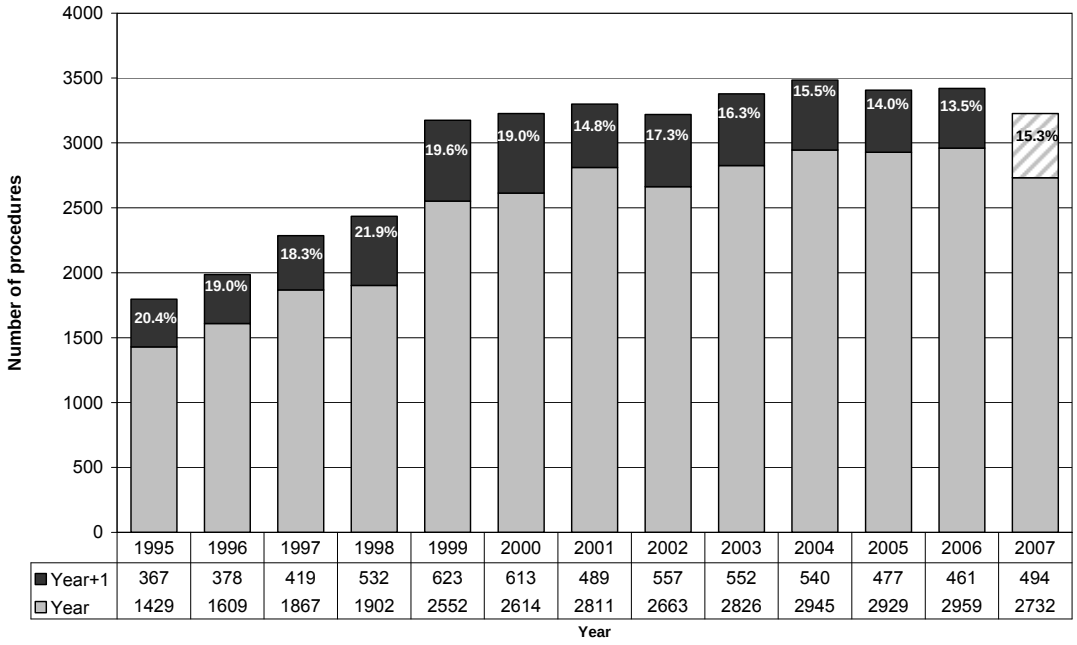
5.6 BUDGET IMPACT FOR ROBOT-ASSISTED RADICAL PROSTATECTOMY

In the recent national agreement between doctors and mutualities, the technical council for implants (TRI/CTI) was asked to present a reimbursement proposal for the materials needed for robot-assisted radical prostatectomy by the end of March 2009.[192] Radical prostatectomy indeed represents the bulk of procedures currently performed with robot-assistance. In this section we evaluate the budget impact if a partial reimbursement of supplies would be considered for this intervention.

5.6.1 Current number of procedures

Belgian reimbursement data available at the time of analysis were until the end of 2007. In the previous period from 2002 to 2006, an average of 15.3% of the radical prostatectomies performed each year was only billed the year after. Therefore, and based on the available number of procedures performed and billed in 2007, the number of prostatectomies performed in 2007 but billed in 2008 was estimated at 494 procedures, which meant that 3226 procedures could be evaluated for 2007, or 3250 to round the figure at the nearest fifty. Figure 5 shows the evolution of the number of radical prostatectomies in Belgium since 1995. From these data it appears that the number of radical prostatectomies is relatively stable in recent years, although there is an obvious risk that this number could increase due to supply induced demand caused by the widespread availability of robot-assisted surgery in this country. It is too early to observe this in currently available data.

Figure 5 : Number of radical prostatectomies in Belgium per year



	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Year+1	367	378	419	532	623	613	489	557	552	540	477	461	494
Year	1429	1609	1867	1902	2552	2614	2811	2663	2826	2945	2929	2959	2732

Source: INAMI/RIZIV doc. N – 2008-06-30. Numbers for radical prostatectomies performed in 2007 and billed in 2008 are preliminary and incomplete.

Based on the answers of our survey (see 5.2.2) mainly related to the first semester of 2008, we estimated that about 1200 robot-assisted radical prostatectomies would be performed in the year 2008, which represents more than a third of all the radical prostatectomies performed in Belgium.

Created in 2005, the lump sum for endoscopic material in case of radical prostatectomy (code 694610 – 694621) was billed in 26.5% of the cases performed in 2005, in 39% in 2006 and in 49.2% in 2007 (=1344/2732). This percentage, which includes laparoscopy but also robot-assisted surgery, could still increase in the future. In the United States, 70% of the radical prostatectomies are performed with the assistance of a da Vinci robot.[193]

5.6.2 Potential scenarios for reimbursement

In the current situation, the patient is often additionally charged twice for robot-assisted surgery; once for endoscopy and again for the usage of robot disposables, but at the same time using the robot still leads to a net loss from the hospital perspective.

In case it is found socially or morally unacceptable to ask the patient for such a large supplement, some alternative scenarios might be made to cover part or all of this extra cost to the patient. A reimbursement under art. 35, §3, category 5, would potentially have the advantage of a clear registration of the robot-assisted radical prostatectomies in Belgium, separately from the pure laparoscopic approach.

Table 3 gives budget estimations needed under different assumptions, from 50% to 100% of the current €1200, and for several assumptions about the proportion of radical prostatectomies performed with robot-assistance.

Table 3 : Simulation of budget impact of reimbursement of da Vinci radial prostatectomy under article 35, §3,category 5

N=3250					
% of robot-assistance		€600	€800	€1000	€1200
	20%	390 000	520 000	650 000	780 000
	30%	585 000	780 000	975 000	1 170 000
	40%	780 000	1 040 000	1 300 000	1 560 000
	50%	**975 000**	**1 300 000**	**1 625 000**	**1 950 000**
	60%	1 170 000	1 560 000	1 950 000	2 340 000
	70%	1 365 000	1 820 000	2 275 000	2 730 000
N=3500		€600	€800	€1000	€1200
% of robot-assistance	20%	420 000	560 000	700 000	840 000
	30%	630 000	840 000	1 050 000	1 260 000
	40%	840 000	1 120 000	1 400 000	1 680 000
	50%	**1 050 000**	**1 400 000**	**1 750 000**	**2 100 000**
	60%	1 260 000	1 680 000	2 100 000	2 520 000
	70%	1 470 000	1 960 000	2 450 000	2 940 000

It is important to note that our estimations rely on a 100% appropriateness assumption for every procedure. Moreover, we assumed that there will be no indication shift towards radical prostatectomy because of the availability of robot-assisted surgery and a supply induced increase in the demand.

In Table 3 we assumed the current level of radical prostatectomies to remain stable in the future but also to be slightly more prudent if we assumed a number of radical prostatectomies somewhat higher, for example 3500 procedures per year, given, for example, the aging of the population or possible indication shifts.

Key points

- **Some foreign countries reviewed have a specific financing: in England, through the hospital HRG financing system, in some parts of Sweden via a DRG-based system and in the Netherlands where a hospital may negotiate a tariff for robot-assisted prostatectomy with health insurers.**
- **The main cost-drivers of the robot-assistance in surgery are the capital acquisition and maintenance, followed by the high costs of limited re-usable surgical instruments.**
- **Considering a $1.7 million capital investment, a 10% maintenance, robot instruments and disposables, one robot-assisted radical prostatectomy would additionally cost from €4070 to €6420 per patient, depending on the hospital volume (300 to 100 cases per year). The da Vinci 'reposables' alone would amount to approximately €1900.**
- **Training costs are not included in this estimate but should also be taken into account.**
- **Surgeon's learning curve and staff experience represent a key factor influencing operating costs.**
- **Supplementary patient charges vary from one hospital to another from €0 to €1200.**
- **In case it is found socially unacceptable to ask the patient for such a supplement and assuming every procedure is performed appropriately, a full reimbursement of the current supplement of €1200 would require a yearly budget of around €2 million assuming that half of the radical prostatectomies would be carried out with robot-assistance.**
- **Reimbursement would allow quantifying robot-assisted interventions.**
- **Policy makers should remain vigilant to avoid potential supply induced demand that could lead to an increased number of radical prostatectomies (or other interventions) in the near future due to the availability of robot-assisted technology or to the reimbursement criteria.**

6 LEGAL ISSUES

6.1 ETHICAL RULES

6.1.1 Importance of ethical rules

Ethical rules are of key importance in Belgium as in any country. As underlined in article 2 of the Professional Code of Ethics, they are applicable to any doctor working on the Belgian territory. For this reason, ethical rules rank first in this part of the report.

6.1.2 The professional code of ethics

As for any clinical act, all the ethical rules are applicable, as set out by the professional code of ethics of the Belgian National Order of Physicians (Orde van Geneesheren – Ordre des médecins).[194]

Rules regarding relationship with patients

Among all the ethical duties set out by the Professional Code of Ethics, some of them are of paramount importance for relationship between physicians and patient

- **Patient consent**: this principle, especially when delivering care with innovative techniques, is of crucial importance, as it is the **prerequisite** for a **lawful and legitimate surgical procedure**. This key issue has been also addressed in detail by the Law on the Patient's Rights (LPR) of 22 August 2002 (see further in this chapter).[195]
- **Professional secrecy**: in Belgium physicians have a deontological duty to respect the confidentiality of the medical information confided to them. Professional secrecy is one of the most important, if not the most important, ethical rule in Belgium as in any country. It is applicable to robot-assisted surgery, as well as to any other medical act. From a legal point of view, professional secrecy is also addressed by article 458 of the Penal Code.[196] In Belgium, as in most western countries, physicians convicted of breach of secrecy are subject to penal sanctions (i.e. fine and / or jail).

Rules regarding quality issues

- Update of knowledge of medical science: Update of knowledge of 'medical science' is defined very broadly by the Professional Code of Ethics, as it entails medical techniques, and may include (inter alia) such techniques as robot-assisted surgery.
- Competence issues: when delivering care, 'physicians must not act beyond their competence' pursuant to article 35 of the Code. In article 141 of the Professional Code of Ethics, a similar rule has been set out: "A physician should be aware of the limits of his own knowledge and skills; he is supposed to act accordingly".
- A large number of cases have been addressed by the National Council of the Order of Physicians. However, the concept of "competence" mainly deals with the problem of the involvement of general practitioners (GPs) in specialized care, especially obstetrics and emergency care. The decisions of the National Order of Physicians have nothing to do with the use of innovative techniques as such (vs. traditional techniques). For all these reasons, the articles of the Professional Code of Ethics on 'competence issues' are legally applicable, but are unlikely to have an impact on robot-assisted surgery as such.

Specific rules concerning surgery

- **Any surgeon is allowed to refuse a surgical procedure** (article 49 of the Professional Code of Ethics) e.g. the use of robot-assisted surgery, if this technique seems to him inaccurate, either from the patient's point of view (danger for the patient) or from his own point of view

(lack of technical skills for instance). Hospital managers have to bear in mind that **therapeutic freedom** of the surgeons is safeguarded by the Belgian Professional Code of Ethics, and thus by the National Order of Physicians. In today's legal context, it is **legally impossible to impose the use of robot-assisted surgery**. The same is true for the patient who can refuse a treatment (surgical or non-surgical).

Key points: main ethical rules applicable to robot-assisted surgery

- **General rules: patient consent and professional secrecy are key principles**
- **Specific rules for surgery: therapeutic freedom is protected by law. Thus, it is legally impossible to impose the use of robot-assisted surgery.**

6.2 PATIENT'S RIGHTS

In the 'Law on patient's rights' from 22 August 2002, the different rights of the patients have been centralized and formalized.[195] This Law on Patient's rights will further be referred to as 'LPR').

Scope: the Law on Patient Rights is applicable to the whole scope of 'health care services' defined as: 'services performed by a health professional with a view to promote, assess, safeguard, restore, or improve a patient's state of health or to perform end-of-life care'. Therefore, it is also applicable to robot-assisted surgery. The key points of this law are:

Right to quality health care services

- Article 5 of the LPR states 'The patient has a right to quality health care services, according to his/her needs, and respect his/her dignity and autonomy, in a non discriminatory environment'. This implies that the health care professional should behave like a '*bonus pater familias*' and should act according to **the standards of carefulness as developed in the medical liability law**. Thus, the practitioners should act according to the applicable standards of the current science. The professional has to know the general accepted techniques and the dangers of obsolete techniques. Important to stress is the fact that this right to a good quality health care service **does not challenge the therapeutic freedom of the physician.** The law uses the terminology 'according to the needs of the patient' which implies that it is not according to his wishes or desires.
- The health care professionals need to know the good standards of care and the generally accepted techniques. Innovative techniques can contribute to an improved quality of care when they are used in an appropriate way.

Freedom of choice

- The patient cannot be imposed a physician, but has the right to choose him/her, unless the law sets out specific limits to this freedom. In emergency cases, for which patient's consent cannot be clearly identified or ensured, it remains the physician's duty to perform emergency care, as required by the patient's state of health and interest. This must be duly reported into the patient notes and 'normal' consent must be obtained as soon as possible whenever further care is required.

Right to be properly informed

- The physician has to give all required information to enable the patient to understand his/her state of health. Information has to be delivered in plain language, and the patient can ask for a written confirmation of this information.
- The patient has the right to refuse information from the physician, except if this refusal can harm his own health or a third person's health.

- Conversely, in exceptional and specific circumstances, the physician is allowed not to deliver information to the patient if this information (or part of the information) is likely to harm the patient's health. However, in this case the physician is compelled to take advice from another physician before taking this decision. Moreover the patient file must be documented accordingly.
- In emergency cases, for which delivery of information is not possible, it is the physician's duty to perform emergency care as mentioned above.

Right to informed consent (or informed refusal)

It is the patient's right to be able to give **free, informed** and **prior consent** to each intervention of a health care professional. The patient can also refuse to give his consent or can withdraw his consent at any moment without motivation. The consent is given explicitly as a rule, but can be implicit if the consent can be deduced from the behaviour of the patient. We can conclude, without doubt, that informed consent is **required for robot-assisted surgery** as for any other surgical procedure.

Jurisprudence on information and informed consent

- **Content of information**: adequate information on foreseeable and normal dangers of surgical procedures has to be delivered to the patient. It is not required that health professionals deliver information on 'exceptional risks'. But given that robot-assisted surgery is part of the surgical procedure itself, it should be recommended to deliver accurate information on robotic surgical techniques as such, or at least to mention it when delivering clinical information to the patient. It must be outlined that the definition of the content itself is left to the physician's discretion, as there is no official and opposable "template" to refer to. Therefore, the content must be defined in such a way that is comprehensive, scientifically indisputable, but also understandable (see below).
- **Wording of information**: it is constant jurisprudence that information has to be delivered in plain language, which means understandable by a *'layman'* (i.e. a non-specialist). Therefore it is recommended to focus on key concepts and to use jargon-free language. Hence, the main difficulty of delivery of information is to strike the right balance between accuracy and intelligibility of information.
- **Legal impact of informed consent**: this principle is the prerequisite for a lawful and legitimate surgical procedure. In other words, any surgical procedure performed without prior informed consent of the patient is considered as illegal and illegitimate. Nevertheless, presumption of consent can be considered especially in emergency cases. Burden of evidence rests on the patient whenever the patient argues that he had not been properly informed and on the physician whenever the latter argues that accurate information had been delivered to the patient. In case of legal action, the problem of delivery of information itself – content and wording as well – is analyzed on a case-by-case basis by the courts. However, in practice, the courts' policy is to sanction physicians' **glaring errors.**

Privacy issues

Article 10 of the LPR states: 'The patient has the right to protection of private life, during each intervention, especially concerning health data and information. The patient has a right to privacy.' This last right implies that only the persons of whom the presence is justified can be present during the intervention, '*within the framework of health care, delivered by a health professional*'. Therefore, if the **presence of technicians or company representatives** is required, the patient should normally give his explicit consent, from a purely legal point of view. Even if it is not always real world practice, this element has to be borne in mind by the stakeholders.

Rights concerning the patient file

The LPR stipulates the right to an accurate and carefully kept patient file by the health care professional and the right to add documents to this file. Above that he has a direct right to have access to the file and to a copy of the entire file or a part of the file. The notion of 'patient file' entails all data concerning health of the patient, documentation of the treatment, concerning a particular patient, kept by the health care professional regardless of its carrier. The LPR also states the modalities of the right to access.

Right to complain

Any patient has the right to complain and to go through a 'mediation procedure' as defined by the LPR (article 11), to ensure the implementation of all the rights set out by the Law on Patient's Rights, *inter alia* patient's consent.

Key points: main patients' rights to be guaranteed

- **Clear and complete information must be delivered to the patient, concerning the whole procedure of robot-assisted surgery.**
- **As for any medical procedure, right to an informed consent is of key importance and must be indisputable. Written information forms should be favoured.**

6.3 MEDICAL LIABILITY

According to the Belgium legislation, three issues to be addressed in case of legal action against a health care provider:

- Harm for the patient
- Mistake committed by the health professional
- Strict connection between the mistake and the harm

The principles mentioned above are applicable to any medical act, *inter alia*, surgical procedures, and underpin any legal action against health care providers. All these principles have been routinely underlined by the *Cour de Cassation/Hof van Cassatie*, especially concerning medical liability, as they are basic legal principles of Civil Law in Belgium.

The most difficult point in legal actions is generally to **prove the connection between the mistake and the harm**. On this point the Case Law of the *Cour de Cassation* is quite strict and demanding, as this connection has to be established as such, irrespective of other points or mistakes, even when existence of harm is unquestionable. On this point, two interesting cases of the Cour de Cassation have to be mentioned:

- V.P. / L.N. Case (17 September 2003).[197] It is mentioned that performing an operation, while being aware of specific or higher risks is not sufficient to involve the health professional's responsibility as this risk, as such, cannot be considered as a 'connection' between a mistake and the harm. In other words, the connection between the harm and the mistake has to be established as such, irrespective of risk/benefit considerations.
- Erasme - Université Libre de Bruxelles Case (12 May 2006).[198] It is clearly reminded that the mistake as such (in this specific case, the absence of the patient's informed consent) is not sufficient to involve the doctor's liability, even if the existence of the harm is legally established and indisputable. Strict connection between this mistake and the harm itself has to be proven.

Burden of the proof

Pursuant to *article 1315, al 2 of the Civil Code*,[199] it is always up to the moving party (i.e. the patient) to bring evidence of the **harm**, the **mistake** and of the **connection** between both elements. This principle is applicable to civil law in general, *inter alia*, medical liability. This principle has been routinely highlighted by *the Cour de Cassation*.

Conversely, the Cour de Cassation (*L / V Case 28 February 2002*) [200] underlined that the existence of the patient's informed consent has to be proven by the health professional, in case of a complex or sensitive surgical procedure, which could be applicable to robot-assisted surgery.

Specific point: use of foreign bodies in surgical procedures

The use of foreign bodies is obviously authorised, when it is part of the treatment procedure. Conversely, misuse of foreign bodies is can be extremely dangerous, and in this case health professionals are subject to sanction.

More precisely, health professionals are bound by **specific legal 'result obligations',** in terms of patient security. The main obligation is not to leave any foreign body (needles, tools, but also small parts or pieces of a machine such as a medical robot) in the patient's body, by error. This rule admits no exception. In this very specific case, liability of the health professionals is automatically involved. Result obligation is defined as a '**non aleatory obligation'** that can be respected, whenever "normal procedures" are used.

Penal liability: 'lack of foresight' and 'lack of care'

Over the last years, the issue of accidental deaths or physical damages caused to patients has been addressed by courts. Liability of health professionals could be considered, for instance, in such cases as accidental death of a patient (or physical damages) caused by the improper use of surgical robots.

Involuntary homicides (or physical damages) are legally within the scope of Articles 418 and 420 of the Penal Code whenever the behaviour can be considered as a '*lack of foresight*' or a '*lack of care*'.[201]

The legal concepts of 'lack of foresight' and 'lack of care' are not specific to surgery but have to be mentioned. In practice, legal actions were taken against physicians whose behaviour was the cause of harms or death e.g. leaving a patient unattended, lack of reaction when facing an adverse event, wrong referral or absence of referral to the accurate department, paying no attention to the patient, etc… Actual behaviour of health professionals is assessed individually and compared to the behaviour that should normally be expected from an attentive and careful professional. The courts' approach is very pragmatic, as it takes context and circumstances into account.

For all the reasons mentioned above, individual liability of physicians has to be mentioned, from a legal point of view. However, this hypothesis is not frequent, as it refers to a dereliction of duty and/or to negligence. Besides, as already explained above, it is not specific to surgery as such.

Key points: main principles applicable in the field of medical liability

- **Legislation and jurisprudence require a very strict connection between the mistake and the harm and are quite protective for health professionals.**
- **Penal liability may be involved individually, in case of 'lack of care' or 'lack of foresight', as for any medical procedure. However, these concepts refer to the behaviour of health professionals, and are not specific to surgery.**

6.4 COVERAGE OF COSTS

Some hospitals that resort to robot-assisted surgery decided to charge the patients in order to cover some of the extra costs generated by using robot-assisted surgery, especially for the reposables. In these hospitals, this charge typically amounts to around €1200. Charging supplements to patients for acute treatment is normally not permitted, as surgery costs are supposed to be covered by the hospital's budget and by the reimbursement rules. However, one must go thoroughly into this question, as similar problems occurred over the last decades for endoscopy costs.

Original legal background (1987-2002)

Originally, article 95 of Law on Hospital of 7 August 1987 had set out the content of hospital budgets very precisely, and drew a specific list of medical acts or products (or health care costs) that are not covered by hospital budgets, and that can justify a specific charge.[202] Originally, this list did not include any endoscopic costs, and for this reason, hospitals that resorted to endoscopic techniques (or other innovative techniques) that were not mentioned in this list, found themselves in a difficult position, as they had to choose between three options:

Option 1: **resorting to these techniques and assuming the additional costs by themselves**. However, this may raise problems in terms of long-term financial sustainability.

Option 2: **renouncing to these techniques** and focusing on techniques funded by *Law on Hospital* only. Considering the pace of medical progress, this would mean that hospitals would not be in the position to keep up with the evolution of techniques.

Option 3: **resorting to these techniques and charging the patients for the additional costs**. In this way, hospitals could keep up with the evolution of medical techniques, without putting the hospital's financial balance in danger.

In the nineties, several hospitals opted for the third option, and decided to charge the patients for the additional costs of endoscopic techniques. However, patients took legal actions against hospitals and the latter were finally condemned by courts, because of the absence of clear legal basis for this charging policy. In practice, hospitals had to reimburse the patients.

This problem was clearly highlighted by the *Cour de Cassation* in 2004 (A. t./l. 29 March 2004).[203] Basically, the *Cour de Cassation* deemed that charging the patient must remain, by definition, an exception, and that such a policy must be implemented within the strict limits of the law. Therefore, charging the patient without clear and indisputable legal basis, i.e. a list of items officially set out by the law (see above) is clearly illegal (due to the duration of the judicial process, the Cour de Cassation referred in *A. t./l. Case* to the *Law on Hospital* as designed before 2002).

The rationale is obvious: ensuring access to the health care system is and remains the corner stone of the system, both from a legal and from the political point of view. Financial problems have to be addressed accordingly by the law maker, to lift financial obstacles.

Today's legal context (since December 2002)

In order to solve the problem mentioned above, the Hospital Law of 1987 was modified by the Loi programme/Programmawet (I) of 24 December 2002 (article 209), enabling to add endoscopy costs to the list mentioned above, but under specific conditions described below. More precisely, hospitals can charge patients for endoscopy costs, under strict conditions:

"*lorsque ceux-ci: soit* ***font l'objet d'une intervention de l'assurance-maladie invalidité,*** *soit* ***figurent sur une liste à établir par le Ministère des Affaires Sociales,*** *après qu'une proposition d'insertion dans la nomenclature des prestations de santé a été formulée conformément à l'article 35§2 , de la loi du 14 Juillet 1994 relative à l'Assurance obligatoire soins de santé et indemnités*".

Once again, the rationale behind this rule is very clear: ensuring access to health care must remain the priority, and charging the patients must remain the exception. Hospitals are allowed to charge patients either when these costs are covered by RIZIV-INAMI or when they are about to be covered thanks to the registration into the national nomenclature of medical acts. From a purely legal point of view charging the patients must rely on a reliable and indisputable basis. Otherwise, the absence of legal basis makes this policy illegal.

Given today's legal context, there seems to be no clear legal basis, to allow hospitals to charge the patients for robot-assisted surgery. Should patients (or patients associations) take legal action against hospitals, these hospitals would probably find them in a similar position as in the nineties, i.e. charging the patients without clear legal basis. As a result they could probably be successfully challenged in court and be obliged to reimburse the patient.

Key points: charging the patients for additional robot-assisted surgery costs

- **In today's legal context there is no clear and reliable basis to charge supplements to the patients**
- **It is legally possible to charge the patients for extra costs, but only under very strict conditions set out by law**
- **Therefore, the hospital's policy to charge patients could be challenged in court, which would oblige hospital managers to reimburse the patient.**

6.5 COMMERCIAL LAW AND CONSUMER PROTECTION

6.5.1 Practices of the company

The firm enjoys a worldwide monopoly in the field of the robot-assisted surgery within the scope of this report. Thanks to this monopoly, the firm is in the position to impose sales conditions on its customers.

A possibly controversial practice of this company is to oblige the purchaser to renew disposable pieces (especially surgical tools) after every ten surgical procedures. Purchasers cast doubt the clinical need of this practice, considering that the wearing effect on surgical tools for the robot is real but in the long-term only.

Therefore, this practice might be considered – at first glance – as an abuse, from a technical point of view but also from a legal point of view. That is the reason why this practice must be analyzed from a legal point of view. Owing to the global dimension of this market and the Belgian EU membership, it is essential to analyze this problem, from a European point of view, to check if EU commercial rules are applicable (or not).

6.5.2 EU competition rules

Legal background: main provisions of the Articles 81&82 of the European Community Treaty

Articles 81 and 82 of the EC Treaty are applicable to **agreements** and **practices** which may "affect trade between Member States".[204] The effect on trade criterion confines the scope of application of Articles 81 and 82 to agreements and practices that are capable of having a minimum level of cross-border effects within the Community. The wording of these articles must be considered with care, as they are **not applicable to all agreements and practices**, but only to those apt to affect trade between Member States.

Case law of the European Court of Justice (ECJ) on related issues

Given the key role of the ECJ in such matters (and more generally in the European Law) it is of great importance to go thoroughly into the ECJ's case law on related issues. Over the last years, one of the most important cases with far reaching consequences was undoubtedly the Microsoft Case in 2007

(Microsoft Corp.Affaire COMP/C-3/37.792 – Microsoft) (JO 2007, L 32, p.23).[205] The explanation below is an interesting illustration of the ECJ position, and can give us interesting clues on **possible parallels that could be drawn with our subject.**

Historical background and Microsoft's practices

Since the nineties, Microsoft has become the most powerful firm worldwide in the field of **client PC operating systems** (market shares over 90%). Since the late nineties, two practices of Microsoft have drawn a lot of criticism from its competitors and the EU Commission.

- First of all, **Microsoft's refusal** to supply its competitors with 'interoperability information' and to authorize the use of that information for the purpose of developing and distributing products competing with Microsoft's own products on the work group server operating systems market.
- Secondly **Microsoft's tying** of the **Windows client PC operating system** and Windows Media Player, which obliges customers to purchase these two products, from two different markets simultaneously.

Summary of the ECJ's reasoning

- **Identification of relevant product markets and geographic market:** the ECJ identified three separate product markets, namely the markets for, respectively, client **PC operating systems, work group server operating systems** and streaming media players. The geographic market is the world (global market).
- **Identification of 'Dominant position':** As regards the client PC operating systems market, the ECJ clearly identified a dominant position: *Microsoft's* ***market shares are over 90%, stability and continuity*** of Microsoft's position is clearly underlined. Moreover, the ECJ identified **significant barriers** to market entry, owing to indirect **network effects**. Those **network effects** derive, first, from the fact that users like platforms on which they can use a large number of applications and, second, from the fact that software designers write applications for the client PC operating systems that are the most popular among users. From all these elements, the ECJ drew the conclusion that Microsoft's Client PC operating systems are **not only dominant products** but also **the '*de facto* standard'** worldwide.
- ***Abuse of a dominant position:*** **the first abusive conduct** in which Microsoft is found to have engaged consists in its **refusal to supply** its competitors with 'interoperability information' and to authorise the use of that information for the purpose of developing and distributing products competing with Microsoft's own products on the work group server operating systems market. This refusal is also identified as part of Microsoft's commercial policy, which has a negative effect on technical development and on consumer welfare. **The second abusive conduct** in which Microsoft is found to have engaged consists in the fact that Microsoft made the availability of the Windows client PC operating system conditional on the simultaneous acquisition of the Windows Media Player software (tying policy)
- **Conclusion drawn by the ECJ:** The ECJ considers that Microsoft's conduct meets the conditions for a finding of a tying abuse for the purposes of Article 82 EC, for the following reasons: First of all, Microsoft has a **dominant position** on the client PC operating systems market. Besides, streaming **media players** and **client PC operating systems** constitute **separate markets**. Thirdly, Microsoft **does not give consumers the opportunity to buy Windows without Windows Media Player.** Eventually, it contends that the tying in question **restricts competition** on the media players market.

Parallels to be drawn with robot-assisted surgery

As far as our subject is concerned, it is clear that there are some similarities between Microsoft's position and the practices of the company producing the surgical robotic system: first of all, it enjoys a dominant position on the global market and is in the position to impose tied purchase of two different items to its customers. However, it is impossible to draw any further parallel between these two cases, for the following reasons:

- **No network effects**: each hospital works separately, for the delivery of surgery.
- The firm is **not in Microsoft's position** as it cannot prevent competitors from launching similar robotic surgical systems on the market: there is no technical prerequisites connected with a 'de facto standard'.
- The **tying in question does not concern two "distinct products"** from separate markets, as defined by the ECJ, as reposables cannot be considered separately from the robot itself.

6.5.3 EU legislation on consumer protection

Over the last years, the European Union has set out a comprehensive legislation (especially Article 95 of the EC Treaty) on consumer protection, on a very wide range of technical subjects: consumer information, labelling, and also improper or unfair practices.[206]

However, it must be clearly outlined that the concept of *'consumer'* is defined as a **natural person only**. Thus, it is **not applicable** to a hospital, as it is a legal entity.

Key points: EU legislation on competition and consumer protection

- **Articles 81 & 82 of the EC treaty on competition are not applicable**
- **Jurisprudence of the ECJ on competition is not relevant to our subject**
- **EU legislation on consumer protection is not applicable**

6.5.4 Belgian law on protection of economic competition

The Belgian law of 15 September 2006 has set out a complete **d**efinition of competition rules and breaches of these rules. Institutions charged to enforce competition rules are the competition council, the competition department, legal actions and processes in the field of competition rules.[207]

Relevance for our subject

Article 3 of this law seems relevant to address our subject as it states that: 'improper practices' can consist of *inter alia* '***imposing directly or indirectly unfair purchase / sale prices or unfair transaction conditions'***.

- Two problems need to be addressed: first of all **scientific evidence** for replacement of surgical tools every ten surgical procedure (as imposed by the company)
- Should this practice not be evidence-based, analysing the company's practice regarding **competition rules** would probably be worthwhile.
- In Belgian jurisprudence, no specific case has been identified in the field of medical devices on that point, but **the idea of "*unfair transaction conditions*" should not be excluded.**

Key points: Belgian commercial law and consumer protection

- **Belgian legislation on consumer protection is not applicable**
- **The company's practices need to be analyzed from a scientific point of view and then from a legal point of view.**
- **The concept of 'unfair transaction conditions' as defined by Belgian legislation could be applicable to our subject.**

6.5.5 Belgian laws on consumer protection

The practices of the company described **do not fall within the scope** of the Belgian law of 14 July 1991, as this law addresses relationship between commercial firms and "consumers", the latter word being defined as a natural person or a legal entity purchasing goods or services, **without any professional purposes.** Therefore it is clear that this issue cannot be addressed by the law of 14 July 1991.[208]

6.6 LEGISLATION ON MEDICAL DEVICES

Legislation on medical devices is mainly addressed by EU legislation. The latter consists of several directives, mainly Directive 90/385/CEE, and Directive 93/42/CEE, recently updated by Directive 2007/47 of 5 September 2007, that is meant to be enforced in all Member States by the end of 2010.[209] The objective of Directive 2007/47 was to clarify some points of the EU legislation, and to set out a few updates, to keep up with the evolution of medical techniques.

Main points of Directive 2007/47

The main objective of the European Union is to build up a common legal framework for medical devices in the EU both for.

- **Definition of 'medical devices':** *a*s defined by this directive, a 'medical device' is a device whose medical purpose is officially mentioned by the manufacturer. Therefore, we can work on the assumption that this specific legislation is **applicable to robot surgery**.
- **Vigilance Issues**: one of the key obligations of the Member States is to ensure a proper follow-up of adverse events. Whenever adverse events occur (incidents or poor functioning), a report has to be routinely written by the institution and reports are centralised on the European level. However, experience has shown that **actual implementation of vigilance is poor** (see below). In the US, this reporting of adverse events is done through the FDA.

Further development on this subject until 2010

Over the last few years, EU legislation on medical devices has drawn criticism from stakeholders: it is considered as fragmented, complex and sometimes penalizing for the European industry. Besides, Directive 2007/47 is considered as a patch-up of today's legal framework, and thus as insufficient.

For the reasons mentioned above, a Europe wide **Consultation process** has been launched by the EU Commission (DG Enterprise), to collect opinions of all stakeholders on the EU legislation.[210] The stated objective of this consultation process is to simplify the EU legislation, and also to narrow the gap between European and global standards. **Actual vigilance** is one of the key points of this consultation. According to the European legislation, vigilance issues should be routinely reported and centralised into the EUDAMED Database. However, experience has shown that actual enforcement of this legislation is poor. The **EU Commission is deeply concerned about a significant under-reporting of incidents within the EU**. Whenever such adverse events occur, all Member States do not react the same way, and practices vary widely across the European Union. In order to improve vigilance, several solutions have been proposed by the EU Commission. Member States will have to come out in favour of one of these options.

Deadline for contributions was **2nd July 2008**. A short synthesis of these contributions has been published on the European Commission's (DG Enterprise) website on 5 December 2008. Contributions from a large number of respondents were reported, and most of them deemed that today's EU legislation was not utterly satisfactory (i.e. fragmented, too complex and not always comprehensive).

Nevertheless, most of these respondents also argued that an overall recast would probably be premature. Indeed, given the timeframe for the implementation of existing Directives (especially Directive 2007/EC/ due to come into force by the end of 2010), a simultaneous recast or revision of existing regulation would probably throw most people into confusion. This point was underlined by representatives of industry and Member States.

In order to avoid any interference between both processes, most respondents deemed that it would probably be better to wait for these changes to be actually implemented, before assessing the precise need for further changes and considering an overall recast of the EU legislation on that subject (if any).

The key findings of this consultation reflect the opinions of respondents, and not necessarily the point of view of the EC Commission. However, these opinions are apt to be taken into account for a further rethink and revision of the EU legislation.

A **survey** has also been launched on actual **practices concerning disposable material and re-use of medical devices**. A short synthesis of the contributions of the respondents is available on the EC (DG Enterprise) website. It is obvious that no clear Europe-wide concepts have been identified in this field (especially 'single-use' or 'reprocessing') and clarification is expected by most stakeholders, especially on such concepts as 'single use' items, 'reprocessing' practices and 're-usable items'.

All the elements mentioned above clearly show that **EU legislation will probably undergo changes** over the next years. However, one must bear in mind that these legislative processes take much time and are subject to intense lobbying. Should an overall revision process formally be launched, it would then require long-lasting discussions and negotiations. For this reason, we can assume that today's regulation will probably remain the norm, at least for 2009.

Therefore, the priority should be to ensure a clear and reliable follow-up of vigilance issues between all stakeholders: hospitals, FOD/SPF Volksgezondheid/Santé Publique, and the EU level, in line with today's EU legislation.

In the long term, a major rethink and revision of the EU legislation is more than likely, and this issue should come under intense scrutiny.

Key points: legislation on medical devices

- **EU legislation on medical devices, especially Directive 2007/47 is applicable**
- **EU rules on vigilance issues are of key importance and a proper follow-up and reporting of adverse events should be ensured by Belgian authorities, in close connection with the EU level.**
- **EU legislation will probably undergo a major revision over the next years, but the timeframe of this revision remains uncertain.**

6.7 TRAINING ISSUES

Accreditation of training sessions and programmes: regulatory requirements

In the field of training and accreditation, requirements have been defined by a specific agreement signed in 1997 between representatives of health insurance schemes and representatives of health professionals (Accord national medico-mutualiste du 17 février 1997).[211]

Within the framework of this agreement, the Belgian body called "*Groupe de Direction de l'Accréditation – GDA*" is the only institution, that is in the position to accredit training programmes, in the field of medicine.

All institutions that intend to organize training programmes are required to go through a specific accreditation process, as set out by the Belgian legislation (www.riziv.fgov.be).

Relationships between private companies and training organisations or institutions have to be considered with great care. In practice private companies can play a role as sponsor and financial backer of training programmes, but cannot organize training sessions or programmes by themselves. This reasoning is applied to pharmaceutical industry and, by analogy we could work on the assumption that it would be applicable to all medical industry.

For the reasons mentioned above, training sessions organized by a company cannot be considered as official medical 'training programmes or sessions' as defined by the Belgian legislation.

Training requirements for innovative techniques

Today's there is no specific requirement in the Belgian legal framework for the use of innovative techniques in the field of medicine. Each physician is expected to work within the scope of his/her competence and not beyond, pursuant article 35 of the Professional Code of Ethics of the National Order of Doctors. However, the problems of 'competence' addressed by the National Order of Physicians dealt with involvement of physicians in delivery of care (especially emergency care and obstetrics) for which they did not feel skilled or experienced enough, even if legally allowed to deliver this care. The issue of 'competence' did not deal with the ability to use innovative techniques properly in one's own professional speciality.

Moreover, it must be reminded that one of the ethical duties of physicians is **to update his own knowledge of 'medical science',** pursuant article 4 of the Professional Code of Ethics. Given the broad definition of 'medical science', the use of innovative techniques could be considered as a part of this obligation.

Key points: training issues

- **Training sessions organized by the firm cannot be considered as official training sessions or programmes.**
- **No specific requirement can be demanded for the doctors, from a legal point of view: the use of robot surgery is left to the physician's discretion and responsibility.**

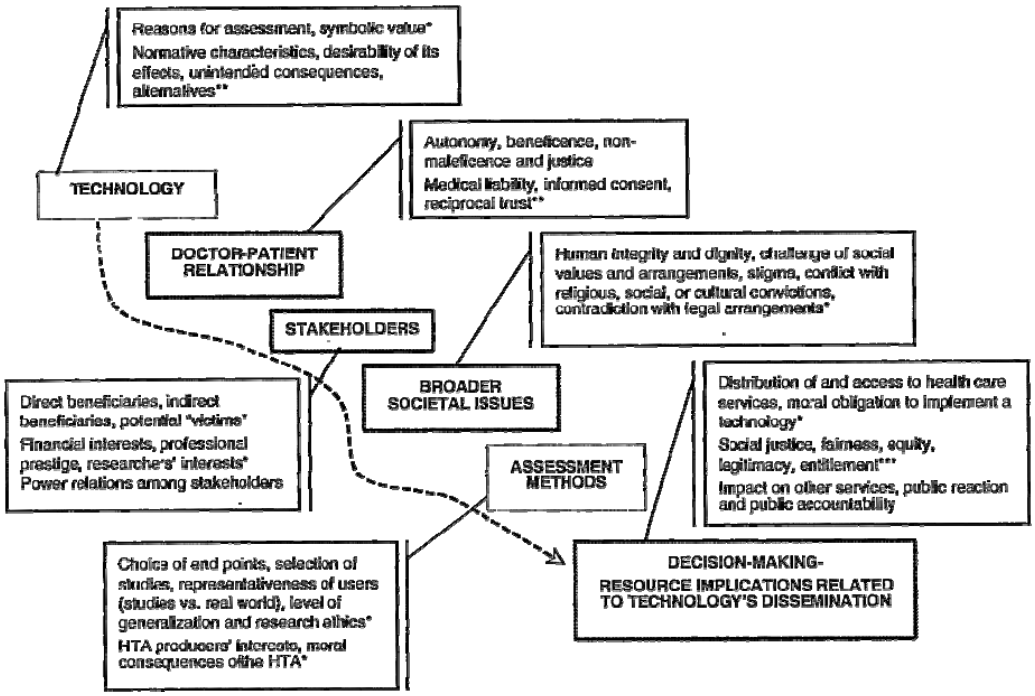
7 PATIENT AND ETHICAL ISSUES

7.1 INTEGRATING ETHICAL AND SOCIAL CONSIDERATIONS

7.1.1 What to discuss?

Every HTA should, ideally, include ethical and social reflections on the use and development of technologies. Giacomini at al.[212, 213] have argued that health technologies should systematically be judged for their moral, social or political value before being able to inform policymakers in a valuable way. Hofmann has produced a checklist of questions for raising the awareness of moral issues which could be reflected upon in an HTA.[214] Hofmann does not aim to present a particular method or procedure but claims that these kinds of questions will increase moral awareness. Lehoux and Williams-Jones,[215] developed a flow chart of ethical and social issues that can be discussed in an HTA

Figure 6 : integrating social and ethical issues in HTA (source [215], page 12).



7.1.2 How to consider ethical and social issues in HTA?

A clear analysis of good practices to incorporate ethical and social reflections and to use the outcomes of ethical and social analysis is currently lacking. Only very view contributions discuss the methodological question of integrating ethics and social topics in an HTA. Three different methodological approaches can generally be used:[216]

- Expert advice from (local) bio-ethicists and social scientists. The results of this round can be integrated or be published as a separate accompanying report to the HTA
- Primary research
- Secondary analysis of previous research on social and ethical issues

Totally different methodological branches are consultative methodologies trying to engage the public in the HTA process (citizen panels, public consultation rounds etc.) However, the methods of these public deliberations are methodologically complex, [217-221] and beyond the scope of HTA as currently performed within most HTA agencies such as KCE.

For the purpose of this HTA on robot-assisted surgery we decided to discuss three selected ethical topics with experts in a panel discussion approach, because data from primary research were not readily available.

7.2 PANEL DISCUSSION WITH ETHICAL EXPERTS

7.2.1 Aim

The main objective was to address and raise awareness whether and to what extent moral and ethical issues should and could be raised with regard to robot-assisted surgery. The panel discussion with ethical experts aimed at introducing the moral reflection with regard to information provision and patient choice, informed consent and social justice (out-of-pocket co-payments).

7.2.2 Participants

We invited several Belgian experts with a professional and academic background in ethics and with a particular interest in health care issues. Four of them attended the expert meeting.

7.2.3 Methods and content

The panel discussion was organised in the form of a single meeting of three hours at the KCE.

The participants received in advance informative notes on the technology, the current use of the technology in Belgian hospitals and on the principles that would be followed by policy makers to advice on reimbursement (see appendix for details). The participants were invited to send possible ethical reflections in a written form to the researchers before the panel discussion took place, but none of the experts used this possibility. After the meeting some additional suggestions were made by one of the experts attending the meeting, mainly on potential sources on ethical principles we could refer to.

At the start of the meeting the researchers of the KCE briefly introduced how the content of the panel discussion would be used in the report. It was explicitly stated that we did not aim to develop consensus statements. It was clearly explained that we wanted to explore, in a pre-selected set of issues related to robot-assisted surgery, how an ethical reflection could be useful to consider for policymakers and for the users of the technology. The moderator focused on the importance of applied ethics. This general introduction was followed by a brief on the technology, the current use and the current reimbursement issues of robot-assisted surgery, mainly explaining the scope of the HTA. After this introduction the panel members were given the opportunity, to ask informative questions on the technology and the current use.

The actual panel discussion was organised around three core topics:

1. Patient related issues and provision of information:
    - What should be done to inform the patient in an ethical way, both regarding content as procedure?
    - What ethical dilemmas do arise related to the "choice" issue of patients and the steering role of the physician in the choice for an intervention? Are patients really capable of choosing themselves for or against a specific procedure?
    - Which elements of information are necessary and what could reasonably be expected to be included in an informed consent form from an ethical point of view?
2. Liability issues and competence development
    - What are the ethical considerations to be made with regard to the learning curve of the professionals in the use of this (and other) technology?

- Is the use of technology (remote manipulation) to be considered within the range of traditional surgical interventions (taking into account liability issues in case of failures of technology and emergency interventions) and do the professional principles still apply to this procedure?
- Which precautionary principles should be followed in order to use the technology? Should patients explicitly be informed on the risks of the intervention, including who is performing the intervention?

3. Equity & the process of reimbursing from publicly funded insurance
   - What ethical or social justice comments can be made on the current practice of imposing non-reimbursed co-payments to the patients consenting for the robot-assisted surgery procedure?
   - The dilemma with the current reality is a situation of an industrial monopoly: is it in these conditions acceptable to introduce specific reimbursement for robot assisted surgery, directly rewarding the monopoly position?
   - Is the current Belgian approach on reimbursement decision making as used within NIHDI (see separate note on the principle of this approach) in line with the ethical principles of good governance?

7.3 RESULTS

7.3.1 General remarks

In general the discussion with the experts was consensual: no major differences in opinions between the experts emerged during the discussion. Some complementary remarks were made on contributions by other panel members, mainly to clarify or to put some additional nuances or emphasis on the arguments.

The ethical experts often reemphasised that most of the ethical issues were not 'robot technology' specific, and that many of the issues raised would also be relevant for other technologies, interventions or pharmaceutical products. As such, the results of this discussion could be regarded as a framework to handle similar questions in future HTAs.

Experts made the remark that issues 1 (patient information) and 2 (surgeon responsibility) are very much entwined. This was felt in the discussion too, as the original distinction between the two topics introduced was not always maintained. Following the experts, information provision should not be reduced to an instrumental issue, but is part of an interaction between the patient and the health professional. One expert considered issue 2 (surgeon responsibility) to be the key issue and should be discussed first in order to be able to discuss the first issue. Another expert expressed that issues 1 (patients information) and 3 (reimbursement and social justice) should be discussed together (linking issues of Information to the patient and reimbursement conditions) to make recommendations to the authorities.

After the expert panel one of the experts called and referred to '*the Barcelona declaration on ethical principles in bioethics and bio law*', in which guiding, mutually connected ethical principles on *autonomy, dignity, integrity* and *vulnerability* of the person are explained, that could be applicable on the topics discussed.[222]

7.3.2 Patient information

During the expert meeting the KCE showed examples of the written information and informed consent forms used by some of the hospitals and services that had responded to the questionnaire (see 5.2.2) These examples mainly illustrated that information provision on robot-assisted surgery was quite divergent between hospitals and that the content of the forms which patients had to sign differed markedly.

First, the remark was made that the forms were not pure *informed consent* forms, but had the basic characteristics of 'contracts' between the patient and the hospital in which conditions were specified on the surgical intervention.

Two experts were satisfied to read that (when applicable) the extra out-of-pocket charge to the patient was broached in the written informed consent documents shown during the meeting. One expert remarked that it seemed that the information sheet was mainly a contract for the hospital to assure that the specific out-of-pocket amount would be paid, rather than patient-oriented information and protection. Two experts expressed their concern that the contract constituted by the informed consent form could be detrimental for the patient-physician trust relationship. These experts warned against a generalization of the compulsory character of the contract combined with a written consent. It was suggested to separate the informed consent on clinical information from the financial agreement.

All experts deplored that the form only stated that "information has been given"– but did not elaborate at all or much on the information content in itself. Experts commented that the available information on interventions often emphasized potential benefits more than potential harms. Neither is it clear whether the patient received information about the alternative procedures. The experts recommended that on ethical grounds a more standardized template of the form, with clear guidelines about the content provided would be useful, in order to guarantee the patients information rights.[c]

The experts argued that in surgery detailed information provision adapted to the patients is generally lacking. According to the medical Deontology and the Law on patient's rights, one could expect however, that patients should be more completely informed on all surgical procedures.[194, 195] The 2002 Law on patient rights states that the patient has the right to ask a written confirmation of the information given orally.[195]

All experts did also agree on the need for information on alternatives. The innovative character, the potential for a shorter hospitalization and currently existing uncertainties concerning the robot-assisted intervention should be communicated, even if this is sometimes considered difficult by surgeons. According to the law,[195] even financial differences between alternatives have to be exposed to the patient. However, the Law makes no provision for sanctions.

During the discussion, the specific question was introduced whether patients should also be informed about the experience the surgeon has with the robot. Experts agreed that this aspect should, from an ethical point of view, also be part of the information provision, especially as the learning curve of the surgeon is an important criterion conditioning the quality of the procedure performed, as is generally the case in surgery.

When a procedure may be considered experimental, information should always be presented in a written form according to one expert. The problem is of course to what extent this robot-assisted surgery is to be considered as *'experimental'*, taken into account the current diffusion of the technology and whether robot-assisted surgery could also simply be seen as an extension of accepted laparoscopic techniques. In this particular case of robot-assisted surgery, at least the information on the level of available evidence and on the expected and known risks should be provided.

According to the experts, the debate on the surgeons experience and standards of care (e.g. number of procedures performed until now, skills of the surgeon etc.) to be communicated to the patients, is an issue that should be developed by the medical professionals themselves, per sub-discipline, in order to improve the patient-professional information and trust relationship.

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[c] In the context of these observations one expert remarked that the discussion on content of the informed consent form is mainly triggered by the fact that issues of out-of-pocket payments of robot assisted surgery came to the fore. It is interesting to observe that this discussion on content of informed consent forms and 'contractual' issues is generally not very well developed, except within the context of clinical research

7.3.3 Trust and patient-professional relationship

The question of trust in the patient-professional relationship was not elaborated upon very much during the discussion. Trust was mainly discussed as a kind of "background" variable against which the issue of information provision and patients should be situated.

The question was introduced to what extent the patient could be considered as a rational decision-maker in taking decisions on a surgical procedure involving himself. One expert considered that in the particular condition of a medical intervention the patient has not sufficient knowledge and is thus *'irrational'* by definition, which implies that he cannot make rational choices by himself. Another expert added that the patient's rationality or perspective is not the same as the medical or scientific rationality. Therefore it can be expected that both physician and patients have a responsibility in developing a choice. Precisely for this reason, one would expect that information is provided about advantages and disadvantages of alternatives too. There is a specific danger to reduce the choice of the patient to issues of out-of-pocket payments only. Especially since innovative technologies are often implicitly perceived by the patients as being 'better'. Without any more information on alternative and more conventional surgical interventions, the argument of an extra out-of-pocket payment for a *'new and innovative surgical procedure'* will have a totally different meaning for the patient and intrinsically become less important as the robot-assisted procedure is implicitly seen as 'offering better quality'.

The summary conclusion on information provision made during the meeting, endorsed by the experts was twofold.

- Patients should be informed in clear language within a trust relationship with the physician; the patient has a right to information and professionals should make efforts to make adequate information transfer also happen in practice.
- Not all responsibility for choice should be put on the patients' shoulders. Professionals have a responsibility to discuss alternatives, and support the patient in making a choice.

7.3.4 Ethical considerations on reimbursement

As a starting point to the discussion one expert regretted that it was not possible anymore to put some fences at the entrance of the robot in the market, as European law does not allow restricting access to the medical equipment market.

As an introduction to the session we briefly explained how the Belgian law on reimbursement nomenclature allows for the possibility of organised *'conditional reimbursement'* (art 35 and 35 bis).[223]

Some form of reimbursement for robot-assisted surgery was ultimately seen as almost unavoidable by the ethical experts, because of its current use. No reimbursement would increase the risk of having a so-called *'class* medicine' with unequal access to health care because of the out-of-pocket payments although there is currently little evidence for this. In this context the question was raised whether private health insurers reimbursed robot-assisted surgery, which is currently indeed the case. This issue, however, was not really elaborated upon. A short comment was made that the redirecting to a private health insurance domain would not resolve the equity question within our West-European welfare approach.

The idea of conditional reimbursement with regular re-evaluations is considered as an ethically acceptable reimbursement approach. The specified conditions to obtain reimbursement would also allow developing more evidence on the effectiveness, the risks, and the costs of using this technology. This evaluation should not only be done for the evidence on robot-assisted surgery, but also for the alternatives, and subsequently weighed against the evidence for efficiency of other interventions in health care.

With regard to the development of this conditional reimbursement model, it was recommended by the experts that a kind of common template should be developed for all types of surgical interventions that can be performed with robot-assistance, specifying the conditions, timeframes of evaluations, etc.

One of the specific conditions for reimbursement that could be enforced is to limit the use of robot-assisted surgery to a number of centres of excellence (per type of intervention), mainly because of the argument of the learning curve and that an adequate level of practice is needed to guarantee interventions meeting high quality standards. Hence, reimbursement would also be an incentive for increasing the experience. Reflections on the geographic distribution of those centres of excellence would obviously be needed in Belgium; not solely a scientific issue but also a political one according to the ethical experts. The limitation to a number of centres is not considered as contradictory to the underlying principle of the free choice of patients in the Belgian health care model.

On the question whether it would be ethically acceptable to 'de facto' pay with public resources a manufacturer in a monopoly position that is setting stringent conditions on the use of its robot and is not opening up its market of reposables, the reactions of the experts were rather pragmatic: they recognise that this monopoly situation imposing rules on the use of reposables is ethically a very difficult issue, and qualified by some as *"shocking"*, especially since this is still only potentially promising but not established technology, but already heavily requesting public resources. But the experts underlined that this question is not unique, and comparable with the often occurring situation with monopoly positions in pharmaceutical industry whose products are also reimbursed.

As a general summary the ethical experts stated that conditional reimbursement is ethically acceptable as it would:

- avoid inequity between patients,
- encourage the search for evidence,
- allow for follow-up.

Key points

- **Ethical experts recommend separating informed consent from the signed financial agreement to pay an out-of-pocket supplement for the robot-assisted intervention.**
- **Ethical experts agree on the need to provide adequate information on alternatives for robot-assisted surgery. The innovative character, the lack of definitive evidence, the potential of a shorter hospital stay and remaining uncertainties concerning the robot-assisted intervention should be communicated. By law, also financial differences between alternatives have to be explained to the patient.**
- **Ethical experts agree that patients should be informed on the experience the surgeon has with the intervention. The criteria used for grading and communicating about the level of expertise should be developed by the medical profession.**
- **Information should be given fairly, together with honest information about alternatives. Patients should be given the opportunity to seek a second opinion.**
- **Patients should be informed in clear language within a relationship of trust with the physician. The patient has a right to this information and professionals should make efforts to make this information transfer happen in reality.**
- **The responsibility for the final choice should not be put solely on the patients' shoulders. Professionals have a responsibility to discuss alternatives, and to support the patient in making this choice.**
- **A conditional reimbursement is considered as ethically acceptable, including the possibility of limiting the number of hospitals (per type of intervention) to centres of excellence, where robot-assisted surgery would be reimbursed, mainly because an appropriate level of practice is needed to guarantee the high quality of the interventions.**
- **Ethical experts recognise that using public resources for rewarding a 'de facto' industrial monopoly situation imposing stringent conditions on the use of its equipment is ethically a difficult issue.**
- **Ethical experts recommended that a kind of common template for a conditional reimbursement model should be developed for all types of interventions that can be performed with robot-assistance, specifying the conditions of use, the conditions to become centre of excellence, timeframes, and method of evaluations.**

8 GENERAL DISCUSSION

8.1 INTRODUCTION

Surgery is by nature invasive. Efforts have been made over time to reduce complications and the trauma inherently associated with surgery, through new instruments, cleverer techniques, and minimally invasive procedures through natural orifices, transcutaneous, or laparoscopically through small artificial holes. Robot-assisted instruments allowing more flexibility, stability and an enhanced vision could be seen as just a further development of this evolution.

New technology, however, should be judged on its performance and cost-effectiveness and not only on its technological persuasiveness. The purchase cost is around €1.7 million while the yearly maintenance cost is approximately 10% of this amount. In addition expensive equipment, with limited reusability, is needed for each operation.

The scope of this report is robot-assisted minimally invasive surgery using instruments remotely controlled by an operator sitting in the same room as the patient. Telemedicine (with an operator sitting at a distance) is not within the scope of this report and neither does it discuss whether a proposed surgical intervention is indeed the best possible treatment for a specific condition.

8.2 THE TECHNOLOGY

There have been several endeavours to design robotic surgical systems. Apart from some experimental systems there is currently only one company successfully marketing such a system. This system allows for enhanced stereoscopic and enlarged high definition imaging. It has the potential for tremor free precise movements and it uses intracorporeal articulated instruments with multiple degrees of freedom allowing partially overcoming the problem of the fulcrum effect seen with conventional laparoscopy using rigid instruments. Because of its claimed ease of use, the so-called *'intuitive approach'*, it is reported to offer shorter learning curves and ergonomic advantages to the surgeon.

The system also has some disadvantages. The lack of force (haptic) feedback is often mentioned as a potential problem when dissecting tissues or performing micro-surgery. Furthermore, the currently limited experience and lack of training with the system needs to be considered. In addition, there is the important issue of cost, not only for the acquisition of the system but also for maintenance and supplies.

8.3 SURGICAL INDICATIONS AND EVIDENCE

Historically, robot-assisted surgery has first been used in general abdominal surgery to gather experience. At this moment it is mainly applied in urologic surgery and more specifically for radical prostatectomy. However, the use in gynaecological surgery is increasing rapidly. Thoracic surgery, mainly cardiologic surgery is an example of other potential uses of this system.

The evidence base for robot-assisted surgery is growing rapidly with an exponential increase in the number of publications in recent years. Most of this evidence, however, is not gathered through comparative studies, but is based on case series from large centres. It can be questioned how relevant this kind of evidence is for a local hospital performing a limited number of interventions, although this is obviously also true for many other forms of medicine requiring skilled handicraft. In the current literature mainly short-term follow-up outcome data are available. Evidence also shows that performance and outcomes improve with increasing experience of the surgical team.

Data for several specific interventions have been gathered in this report. Through this evidence, it can be concluded that robot-assisted surgery is relatively safe and efficient when used by experienced surgical teams. For many indications it is also claimed that robot-assisted surgery is less demanding on the surgeon, both by the reportedly shorter learning curve but also through its ergonomic advantages involving less stress on the surgeon's body.

Most evidence is available for robot-assisted radical prostatectomy, which is also the largest current indication in this country and in the world. There is evidence that peri-operative blood loss is lower than with conventional techniques but evidence for other expected advantages, such as reduced incontinence, reduced erectile dysfunction or shorter length of hospital stay, is less consistent and highly dependent on skill and experience of the surgical team. The same conclusions more or less hold for most other indications in urology, in gynaecology, thoracic surgery and general abdominal surgery, although the level of the potential benefits is variable. In general abdominal surgery the added value appears to be the lowest, as those interventions can very often also be easily and more rapidly performed through conventional minimally invasive surgery and at a lower cost. As minimally invasive surgery can be difficult to perform in gynaecology, robots could have added value by being less demanding on surgeons, both because of required skills and ergonomically. In thoracic surgery, mainly cardiologic surgery, robot-assistance could facilitate minimally invasive procedures that are difficult to perform otherwise.

In general, and across various surgical specialties, robot-assisted surgery is claimed to offer the greatest advantages in complex reconstructive processes and with difficult access and limited space available inside the body. At this moment, however, no claims of superiority of robot-assisted surgical techniques can or should be made, as these might raise patient expectations to unrealistic levels.

Aside from costs, an important limitation across most specialties is the lack of outcomes data. Another limitation is in performing procedures that cover large areas, specifically multiquadrant abdominal surgery that currently requires re-docking of the system.

Current observational studies will have to be supplemented with controlled comparative studies and prospective databases built on nationwide registrations. As a result of this, the evidence will need to be re-evaluated in the future. If prospective registrations are set up, it will be important to define clearly from the start the necessary variables, including relevant patient characteristics, peri-operative and outcomes parameters and with a predefined data analysis design.

8.4 CURRENT SITUATION, COSTS AND REIMBURSEMENT DILEMMAS

At least 20 of these robotic surgical systems are in use in Belgium. Compared to the rest of the world, Belgium comes at second place in the number of robotic surgical systems per capita, only after the US, but far before comparable countries in Europe. From our interviews we learned that an important argument for acquiring a robot-assisted surgical system in some Belgian hospitals is marketing; *"the robot shows that our hospital and our doctors are technological front-runners"*. This is not necessarily the best argument for acquiring expensive equipment that is also expensive in its maintenance and in its use. In practice, the installed systems are used to a various degree and our survey showed that, at least in Belgium, many of them are not used to full capacity.

Because the additional cost for robot-assisted surgery is not specifically reimbursed, many hospitals ask for a compulsory non-reimbursable supplement, most often €1200 for radical prostatectomy, to be paid by the patient. In the recent national agreement between doctors and mutualities the technical commission for implants was asked to present a reimbursement proposal for the disposables needed for robot-assisted radical prostatectomy by the end of March 2009. We evaluated the budget impact if a partial reimbursement would be considered for radical prostatectomy, representing the bulk of procedures currently performed with robot-assistance. Depending on the different scenarios evaluated, the budget impact for prostatectomy alone would amount to between €400 000 and €3 million, assuming that the number of radical prostatectomies remains relatively constant. There is, however, a risk that the availability of robotic surgical system might create a supply driven increase in the 'demand' for radical prostatectomies.

Costs of robot-assisted surgery are partly dependent upon acquisition and maintenance prices, but also on the cost of disposables and of specific instruments that are pre-programmed to be used for only a limited number of times, typically 10 times. As a result the costs of robot-assisted surgery for a hospital and for society are volume dependent. With current prices robot-assisted surgery is more costly than conventional surgery in most indications. The decision to install a robotic surgical system could also have important implications for hospital logistics such as operating room capacity.

In the absence of clear clinical evidence no meaningful cost-effectiveness analyses can be performed. There is a fundamental need for cost-effectiveness analyses performed alongside RCTs, including longer term follow-up data and data on health-related quality of life after surgery.

8.5 LEGAL, ETHICAL AND PATIENT ISSUES

Patient consent and professional confidentiality are key principles in all medical activities from a legal point of view. This implies that clear and complete information concerning the whole proposed procedure should be delivered to the patient in a clear language understandable by a layman. The definition of the content itself is left to the physician's discretion, as there is no official and opposable template to refer to. The patient should also be informed when non-reimbursable supplements are asked for a specific procedure. However, in today's legal context there is no clear and reliable basis to charge those supplements to the patients, meaning that in theory this policy could be challenged in court. In terms of medical liability, traditional legal rules are applicable, as for any medical act, but they are not specific to robot surgery.

From an ethical point of view information should be provided to the patient on the procedure, on alternative procedures, on the training and experience of the surgeon with the technology and on the extra out-of-pocket payment. Patients should be explicitly informed about the stage of the learning curve of the surgical team. Within this framework, surgeons have a professional obligation to coach the patient within a trust-relationship to an appropriate choice, especially since superiority claims cannot, and should not be made based on the mere fact that robot-assistance is used.

The monopoly position of the company in the marketing of the robotic surgical systems led us to investigate the specific EU and Belgian competition rules. Legislation on consumer protection is not applicable to this system. The European Court of Justice's Case Law on *'abuse of a dominant position'* is not applicable either. However, the legal Belgian concept of *'unfair transaction conditions'* might be relevant, especially concerning the instruments of limited usage that are pre-programmed to stop functioning after 10 interventions.

The basic training provided by the company when the system is acquired cannot be considered as official training. However, there are no specific requirements for surgeons from a legal point of view: the use of robot-assisted surgery remains the surgeons' responsibility (the latter including *inter alia* the rules of the Professional Code of Ethics).

8.6 CONCLUSION

At present, at least 20 robotic surgery systems are used in Belgium, mainly in urology for performing radical prostatectomy. Next to these indications, robot-assisted surgery is also increasingly used in gynaecology and cardiology, while indications in general abdominal surgery and other domains appear to be limited right now.

Robot-assisted surgery is an emerging technology that could be promising in ideal circumstances and given adequate training and experience of the surgical team performing the interventions. Despite implicit or even explicit claims for this technology to be superior, clear advantages are currently unproven and are highly dependent on surgical skills and professional experience of the team performing the intervention.

Any claims of real benefits can only be substantiated by controlled comparative studies directly comparing this technique to relevant conventional interventions. Gathering information about the performance of this technology in real life, by the prospective registration of data on patient characteristics, peri-operative parameters and follow-up on outcomes in centres and teams that perform a sufficient number of these interventions is needed to gather additional meaningful experience with the performance of this technique in daily practice.

Patients often have to pay a non-reimbursable supplement when this innovative technology is used. Patients have to be informed about this and information about the procedure together with objective information about alternatives, should be given fairly and in a clear language.

9 APPENDICES

APPENDIX TO CHAPTER 3: EFFECTIVENESS

LITERATURE SEARCH

General strategy

In the systematic literature search, we searched for systematic reviews, clinical trials, prospective studies, multicentre trials and HTAs using the MeSH terms *'Robotics'* (introduced in 1987) and *'Surgery, computer assisted'* (introduced in 2002) and additionally the keywords (surgery) and [(da vinci) or (davinci)]. We initially search from 2002 onwards, but in practice mainly publications since 2006 were included in the review since previous publication often dealt with older techniques that are not available today. Retrieved references were subsequently sifted first on title and abstract, and promising articles were retrieved in full text. The overview of the results of this sifting procedure can be found in the flowchart in chapter 3.

Searches

CRD (Dare, NHS-EED, HTA)

ID	Search (15/10/2008)	Hits
#1	MeSH Surgery, Computer-Assisted EXPLODE 1 2	39
#2	MeSH Robotics EXPLODE 1 2 3	51
#3	#1 or #2	76
#4	da AND vinci	10
#5	davinci	3
#6	#5 or #6	12
#7	#6 or #3	76
#8	#7 RESTRICT YR 2002 2008	61

Those 61 retrieve references included 11 references from Dare, 36 from NHS EED and 29 from HTA.

Cochrane libraries

ID	Search (15/10/2008)	Hits
#1	MeSH descriptor Surgery, Computer-Assisted explode all trees	182
#2	MeSH descriptor Robotics explode all trees	144
#3	'da vinci'	0
#4	da and vinci	32
#5	davinci	5
#6	(#4 OR #5)	36
#7	(#1 OR #2 OR #6)	314
#8	(#7), in 2008	21
#9	(#7), from 2007 to 2008	90
#10	(#7), from 2005 to 2008	200
#11	(#7), from 2002 to 2008	278

Medline through Pubmed

ID	Search (16/10/2008)	Hits
#1	Search Surgery, computer assisted[Mesh]	3722
#2	Search Robotics[Mesh]	5429
#3	Search #1 or #2	8541
#4	Search #3 AND systematic[sb]	78
#5	Search #3 Limits: Meta-Analysis, Randomized Controlled Trial	167
#6	Search #4 or #5	232
#7	Search #6 Limits: Publication Date from 2002 to 2008	218

Embase

The EMTREE term 'Computer assisted surgery' was added in 2003. Synonyms are: computer aided surgery; surgery, computer-assisted.

ID	Search (15/10/2008)	Hits
1	surgery, AND 'computer assisted'	116 173
2	surgery, AND 'computer assisted' AND [2002-2008]/py	67 641
3	'computer assisted surgery'/exp AND [2002-2008]/py	2742
4	'computer assisted surgery'/exp AND ([cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim) AND [2002-2008]/py	154

Journal of Robotic Surgery

We browsed the available first two volumes until volume 2, 3rd issue (September 2008) and the online first publications until 15/11/2008 and selected relevant articles.

Hand searching and Web Of Science

Finally a hand search was performed based on references in retrieved reviews or during meetings that were attended. We also performed an additional upstream manual Web of Science (Thomson – ISI) search for Robot-assisted surgery (limited to reviews) plus specific searches for articles that cited particularly relevant earlier publications to try and capture also the most recent publications. The first search was done on 21/10/2008) and repeated a few times during the final stages of this report.

APPENDIX TO CHAPTER 4: COST-EFFECTIVENESS

CLASSIFICATION OF ECONOMIC STUDIES

Figure 7 : Classification of economic studies

		Are both costs (inputs) and consequences (outputs) of the alternatives examined?		
		No		**Yes**
		Examines consequences only	Examines costs only	
Is there a comparison of at least two alternatives?	**No**	*Partial evaluation*		*Partial evaluation*
		Outcome description	Cost description	Cost-outcome description
	Yes	*Partial evaluation*		*Full economic evaluation*
		Efficacy or effectiveness evaluation	Cost comparison (5)	Cost-utility analysis (CUA) Cost-benefit analysis (CBA) Cost-effectiveness analysis (CEA) (12) Cost-minimisation analysis (CMA) (1)
			Lotan, et al.[171] 2004 Scales, et al.[172] 2005 Joseph, et al.[173] 2008 Morgan, et al.[100] 2005 Prewitt, et al.[178] 2008	Mouraviev et al.[174] 2007 Bhayani, et al.[81] 2005 (CMA) Link, et al.[84] 2006 Nazemi, et al.[72] 2006 Rodgers et al.[176] 2007 Advincula, et al.[177] 2007 El Nakadi, et al.[37] 2006 Müller-Stich, et al.[142] 2007 Heemskerk, et al.[144] 2007 Morino, et al.[36] 2006 Rawlings, et al.[143] 2007 Heemskerk, et al.[96] 2007 Heemskerk, et al.[145] 2005

Adapted from Drummond et al.[170]

ECONOMIC EVALUATION SUMMARIES

Radical Prostatectomy

Author, year	Lotan, et al. 2004[171]			
Title	The new economics of radical prostatectomy: cost comparison of open, laparoscopic and robot assisted techniques			
Country	USA			
Design	Cost comparison (model)			
Perspective	Hospital (+ third payer for the professional fees)			
Time window	Hospitalization			
Interventions	Robot assisted prostatectomy (RAP) versus Laparoscopic prostatectomy (LRP) versus Open radical retropubic prostatectomy (RRP).			
Population	Not specified			
Assumptions	300 cases per year operated with robot in 7 years across specialties No routine blood donation prior to RRP in Mayo clinic and 10% transfusion rate by RRP Experienced surgeons performing LRP and RAP (more than 100 procedures per surgeon)			
Data source for costs	Costs from hospital billing office and OR administration, and literature, length of stay (LOS) and operative time from non European literature.			
		RRP	LRP	RAP
	Operative time (min)	160	200	140
	LOS (days)	2.5	1.3	1.2
Cost items included	OR time ($972+$332/add. half hour) Medicare surgeon's fee (RRP $1593, LRP & RAP $1688), anaesthesist's fee ($112 for 7x15 min + $18 /15 min.) Equipment costs for LRP ($532) and RAP ($1704), robot purchase and maintenance per case ($857 or $286 if the robot is donated). Hospital room and board IV fluids and medications			
Data source for outcomes	Nihil (length of stay was included in the costs elements)			
Discounting	No			
Costs	RRP $5554 LRP $6041 RAP $7280 ($6709 in case of donation)			
Outcomes	nihil			
Cost-effectiveness	nihil			
Sensitivity analysis	1-way	Cost equivalence RRP/LRP if OR time RRP=199 min or LOS RRP 3.6 days, or if OR time LRP=161 min or LOS LRP 0.23 days No RAP LOS or realistic OR time (1 min) decrease made RAP/RRP cost equivalent Cost equivalence RAP/RRP if LOS RRP 6.3 days		
	2-way	Cost equivalence RAP/RRP if OR time RAP<60 min and LOS RAP=0 days Cost equivalence RAP/RRP if donated robot and RAP equipment < $550/case, or if robot=$500000, maintenance=$34000, equip=$500/c. Cost equivalence RAP/LRP if robot=$600000 and RAP equipment=$237/case, or if LRP equipment=$46, or if LRP equipment=$294 and LRP OR time=180 min.		
Conclusions	RRP is the cheapest approach: $487 less than LRP and $1726 less than RAP; mainly due to (laparoscopic and robot-assisted) high costs of equipment (robot purchase and maintenance).			
Remarks	The model conservatively used a shorter LOS for LRP and RAP observed with experienced surgeons and a shorter OR time for RAP versus RRP.			
	Initial capital costs of a laparoscopy program are implicitly included in the initial $972			

	overhead cost for use of the operating room.
	European studies LOS, longer than USA LOS, were excluded
	LOS LRP and OR time RAP source=1 hospital only (large series)

Author, year	Scales, et al. 2005[172]		
Title	Local cost structures and the economics of robot assisted radical prostatectomy		
Country	USA		
Design	Cost comparison (model)		
Perspective	Hospital (+ third payer for the professional fees)		
Time window	Hospitalization		
Interventions	Robot assisted prostatectomy (RAP) versus Open radical retropubic prostatectomy (RRP).		
Population	Not specified		
Assumptions	Transfusion=2U in 15% RRP and 5%RAP Robot is purchased and depreciated during 7yrs Volume robot: 7cases/week		
Data source for costs	Hospital administrators for costs and Medicare reimbursement data Operative time and length of stay were based on literature (a.o. LOTAN et al, 2004)		
		RAP	RRP
	Operative time (min)	140	160
	LOS (days)	1.2	2.5
Cost items included	OR $1265/case + $394/hour Consumables: RAP $1704/case versus RRP:$575/case Anesthesia: $312/case+116/hour Median Post-anesthesia care unit: $295 RAP versus $419 RRP Transfusion: $235/u Professional fees: surgeon: $1594 RAP versus $1212 RRP Anesth:$90/U Robot and maintenance contract $1.2 million+ $100 000/yr Hospitalization $840 daily Avg daily postop pharmacy $122 RAP and $107 RRP Postop lab test =daily $22		
Data source for outcomes	Nihil (length of stay was included in the costs elements)		
Discounting	Not specified		
Costs	RRP $8146 in specialist setting RRP $ 8734 in community setting RAP $8929		
Outcomes	Nihil		
Cost-effectiveness	Nihil		
Sensitivity analysis	1-way	Cost equivalence RAP/RRP	At maximum case volume : 3 patients/day(from Fig 1) if OR time RAP<=90 min in specialist setting, or if OR time RAP<=165 min in generalist setting If LOS RAP <=1days in generalist setting If LOS RAP <0.5 days in specialist setting (outpatient) If RAP volume >= 10 cases/week in generalist setting, If RAP volume > 15 cases/week in specialist setting If hospital room>=$930 daily in generalist setting, If hospital room>=$1200 daily in specialist setting If OR RAP=180 min=> 2 cases/week =>sharp increase in cost per case
	2-way	Cost equivalence RAP/RRP	If LOS RAP <=1 days in specialist setting (outpatient), whatever the volume. If LOS RAP <=1days in generalist setting and

			volume>=7 cases/week (cf. base case) If LOS RAP <=1.5 days in generalist setting and volume>=14 cases/week In specialist setting, if hospitalization = $1200 then LOS RAP must <= 1 day (outpatient) In generalist setting, if hospitalization = $900 then LOS RAP must <= 1 day (outpatient)
Conclusions	A cost equivalence point between RAP and RRP exists at high volume specialist center, the main determinant factor being the hospitalization cost ($840 daily vs $474 in the Study by Lotan, et al 2004), as well as the OR time and the case volume. OR time for RAP must be below 165 minutes. Therefore, the competitiveness is influenced by local costs structure and surgeon volumes and times.		
Remarks	The robot may attract new patients to the hospital.		
	Authors judged the outpatient prostatectomy an unrealistic option.		
	Robot-assisted prostatectomy may become economically viable in more settings as the technology matures.		

Author, year	Joseph ,et al. 2008[173]			
Title	The cost of radical prostatectomy: retrospective comparison of open, laparoscopic, and robot-assisted approaches			
Country	UK			
Design	Cost comparison by retrospective chart review			
Perspective	Hospital and third payer (costs + professional fees)			
Time window	Hospitalization			
Interventions	Robot assisted prostatectomy (RAP) (n=106) versus Laparoscopic prostatectomy (LRP) (n=57) versus Open radical retropubic prostatectomy (RRP) (n=70).			
Population	Not specified			
Assumptions				
Data source for costs	Hospital (perioperative services and operating room database)			
Cost items included	OR costs: supplies, nursing labor, OR time, post anesthesia care, anesthesia supplies and anesthesia technician labor. Monitors, cameras, lighting units, central carbon dioxide supply, cost of OR table and anesthesia machine are considered capital costs and allocated across all surgical disciplines.			
Data source for outcomes	Hospital chart reviews			
Discounting	Nihil			
Costs		RAP	LRP	RRP
	Labor cost	$494	$832	$330
	Supply cost	$4805	$2933	$1429
	Anesthetic supply cost	$111	$111	$111
	Total operative costs	$5410	$3876	$1870
le	Length of stay: RAP:discharge the day after surgery (98% <24h) LRP: mean 25.4 hours (95% CI 5.3 hours) RRP: mean 64.5 hours (95% CI 1.7 hours)			
Outcomes	Nihil			
Cost-effectiveness	Nihil			
Sensitivity analysis	Nihil			

Conclusions	Intraoperative costs higher for RAP and LRP compared to open surgery but statistically significant advantage in LOS reduction for RAP and LRP.
Remarks	Initial costs for starting the minimally invasive program were not included.
	95% calculation CI method not stated (non-normal distributions)

Author, year	Mouraviev, et al. 2007[174]				
Title	Financial Comparative Analysis of Minimally Invasive Surgery to Open Surgery for Localized Prostate Cancer:A Single-Institution Experience				
Country	USA				
Design	Cost-effectiveness based on large case series and controls				
Perspective	Hospital				
Time window	Hospitalization				
Interventions	Laparoscopic robotic prostatectomy (LRP) (n=137) versus cryosurgical ablation of the prostate (CAP) (n=58) versus Radical retropubic prostatectomy (RRP) (n=197) versus radical perineal prostatectomy (RPP) (n=60) Interventions were chosen by physician recommendations and patient preferences.				
Population	Between January 2002 and July 2005, 452 consecutive patients with prostate cancer in stage T1-T2, able to tolerate anethesia and without local and systemic spread. Exclusion criteria were neoadjuvant chemotherapy or hormonal therapy, prior transurethral resection/laser prostatectomy, salvage prostatectomy, or multiple surgical procedures. Patients undergoing CAP were older and had a higher ASA score.				
Assumptions	Nihil				
Data source for costs	Not stated				
Cost items included	Direct costs (OR time surgical supplies, anesthesia, post-anesthesia, nursing, pharmacy, cardiac services, respiratory therapy, radiology, lab/transfusion services and medical/surgical supplies), global hospital costs (direct+indirect+pathology professional fees)				
Data source for outcomes	Not stated				
Discounting	Nihil				
Costs	*Mean ± SD (range) $*	**Retropubic (RRP)**	**Perineal (RPP)**	**3 Robot (LRP)**	**CAP**
	Surgery	2471	2788	3441	5702
	Nursing	1013	1104	752	110
	Pharmacy	593	578	570	199
	Cardiac services	10	12	6	2
	Respiratory	24	30	20	0
	Radiology	55	64	45	17
	Laboratory	620	609	345	204
	Blood transfusion	409	158	37	0
	Total Direct costs	5259	5273	5386	5595
	Total costs	**10704**	**10536**	**10047**	**9195**
Elements influencing costs	Length of stay (p<0.0005) except RRP vs RPP (p=0.54)	2.79 ± 1.46	2.87 ± 1.43	2.15 ± 1.48	0.16 ± 0.14
Outcomes		**Retropubic (RRP)**	**Perineal (RPP)**	**3 Robot (LRP)**	**P value**
	Total extension (%)	197	60	137	
	Extracapsular extension (%)	19.3	14.9	13.7	P<0.0001
	SV invasion (%)	7.6	9	2.2	0.0115
	Gleason sum > 7	13.7	11.9	3.6	P<0.0001
	Positive margin (%)	20.3	25.4	30.2	P<0.0001
	PSA recurrence (%)	9.6	10.4	8.6	0.0821
	Two men (3.4%) were considered to have treatment failure because of positive findings on postcryotherapy prostate biopsy.				
Cost-	No formal ICER				

effectiveness	
Sensitivity analysis	Nihil
Conclusions	The higher direct costs of CAP and robot-assisted surgery were offset by the lower nonsurgical hospital costs. Long term follow-up for CAP and LRP are needed.
Remarks	During the study, LRP became more commonly performed, RPP was used less. RRP and CAP Were used evenly throughout the study...
	The 2 treatment failure of CAP were not discussed in the article.

Pyeloplasty

Author, year	Bhayani, 2005[81]		
Title	Complete daVinci versus laparoscopic pyeloplasty: cost analysis		
Country	USA		
Design	Cost-minimization study based on prospective data collection and retrospective medical reviews and model-based costs estimations		
Perspective	Hospital and third payer (costs + professional fees)		
Time window	Not stated (hospitalization)		
Interventions	Dismembered da Vinci robot-assisted (n=8) vs laparoscopic pyeloplasty (n=13) for ureteropelvic junction obstruction		
Population	All patients with primary ureteropelvic junction. Exclusion: patients with previous ipsilateral renal surgery. Laparoscopic patients were chosen to match (approximatively) robot-assisted cases in comorbidities and BMI.		
Assumptions	Robot was used in 150 cases / yr in a 5-yr period Laparoscopy video tower and AESOP robot camera holder=400 cases / yr in a 5-yr period. Operating room=$16 / min. after first hour. Total room time=total surgery time + set up time+ insufflation time+ take down time		
Data source for costs	Not stated (probably hospital administration.)		
Cost items included	Except the Endostitch (for laparoscopy), disposables, hospitalization, nursing and pharmacy were not included, as the same pathway was followed by both groups of patients.		
Costs	*Mean / case*	Robot (n=8)	Laparoscopy (n=13)
	5 Endowrists	$800	
	Robot	$2000	
	Endostitch		$200
	Video tower		$10
	Costs (total per case)	$5 616	$3 500 (not accurately reported)
Elements influencing costs	Total operative time (min)	105 min.	161 min.
	Total room time (min)	176 min	210 min
Data source for outcomes	Hospital		
Discounting	Nihil		
Outcomes	Blood loss: 107 ml (robot) vs 129 ml, length of stay: 2.3 days (robot) vs 2.5 days, no failure in any group		
Cost-effectiveness	Costs in case of robot-assisted surgery higher than laparoscopy.		
Sensitivity analysis	One-way sensitivity analysis: laparoscopy operative time must increase to 388 minutes (6.5 hours) before robot surgery becomes cost-equivalent to laparoscopy.		
	Even if robot volume was 500 cases /yr , robot OR time should be < 130 min for robot to reach cost-equivalent to laparoscopy (unrealistic at John Hopkins, Baltimore).		
Conclusions	Assuming no difference in outcomes, raining residents in laparoscopy is less costly than using robot surgery.		
Remarks	Resident teaching and participation in laparoscopy precludes appropriate comparison.		
	The staff, that was the same for all cases, experience with> 100 computer-assisted surgical cases. A representative from the company was available and aided in setup in all cases.		
	Longer terms follow-up were expected		

Author, year	Link, 2006[84]
Title	A prospective comparison of robotic and laparoscopic pyeloplasty
Country	USA
Design	Cost-effectiveness study based on prospective data collection from consecutive case series and model-based costs estimations
Perspective	Hospital and third payer (costs +professional fees)
Time window	Hospitalization with a mean follow-up of 5.6 +/- 2 months (mean +/- SD)
Interventions	da Vinci robot-assisted (n=10) vs laparoscopic pyeloplasty (n=10) for ureteropelvic junction obstruction
Population	All patients with primary ureteropelvic junction obstruction scheduled for laparoscopic dismembered pyeloplasty. Exclusion: patients with previous ipsilateral renal surgery.
Assumptions	Robot was used in 150 cases / yr in a 5-yr period Laparoscopy video tower and AESOP robot camera holder=400 cases / yr in a 5-yr period. 1 Operative time= $12/ min.
Data source for costs	Anesthesiologist's professional fees from 2004 Medicare reimbursement rates. Direct and indirect operating room costs for the second half of 2004 provided by hospital administration.
Cost items included	Only costs items that differ between both surgeries=operative room occupation, anesthesia professional fees, da Vinci robot acquisition costs, laparoscopic equipment, and consumables as long as these were not standardly used in both cases..

Costs	*Mean ± SD*	Robot (n=10)	Laparoscopy (n=10)	P value
	Consumables	$933.61	$72.70	
	Costs (total per case)	$5 323.81	$1 989.87	
Elements influencing costs	Total operative time (min)	100.2 ± 9.1	80.7 ±21.9	0.018
	Total room time (min)	173.8 ±15.4	134.8 ±20.6	<0.001

Data source for outcomes	Hospital
Discounting	Nihil
Outcomes	No difference in blood loss, no difference in length of stay, no failure in any group
Cost-effectiveness	No ICER reported
Sensitivity analysis	One-way sensitivity analysis: laparoscopy operative time must increase to 388 minutes (6.5 hours) before robot surgery becomes cost-equivalent to laparoscopy.
	Depreciation of capital equipment represents 46% of the total robot projected cost. If da Vinci depreciation was eliminated from the model, robot-assisted surgery was still 1.7 times more costly than laparoscopy based on increased consumables and operative time costs
Conclusions	Robot-assisted surgery had longer mean operative (by 19.5 minutes) and total room (by 39.0 minutes) times than the laparoscopic cases. Anesthesia setup and wake times, ureteral stenting and positioning times, age, and body mass index were not significantly different between the 2 techniques.
	For surgeons facile with intracorporeal suturing, dependence on the da Vinci robot adds little speed or quality advantage to the laparoscopic procedure and results in substantially greater costs
	Nondisposable standard laparoscopic instruments were excluded from depreciation analysis either because they are used in both pyeloplasties or because their long lifespan (ie, needle drivers, nondisposable trocars) made their per-case cost negligible.
	The performer was 1 surgeon experienced with the da Vinci system (20 cases) and just prior to starting the da Vinci arm of the study, performed 3 robot-assisted pyeloplasties to define steps and optimal port placement. The surgical team had an experience of more than 100 robot-assisted cases and a laparoscopic experience.
	Mean follow-up of 5.6 ± 2.2 months was too short to assess pyeloplasty success rates.

Nephrectomy

Author, year	Nazemi, et al. 2006[72]					
Title	Radical Nephrectomy Performed by Open, Laparoscopy with or without Hand-Assistance or Robotic Methods by the Same Surgeon Produces Comparable Perioperative Results					
Country	USA					
Design	Prospective collection of data of consecutive patients in one single centre (CEA)					
Perspective	Not stated (hospital charges and costs)					
Time window	Hospitalization and follow-up going from 1 day to 31 days. (median=15, 4, 5, 7 days in respectively open, robot-assisted, hand-assisted and pure laparoscopic methods).					
Interventions	Robot-assisted (n=6) versus Open (n=18) versus pure Laparoscopic (n=12) and laparoscopic with hand-assistance (n=21) nephrectomy for renal tumor.					
Population	Consecutive cases operated between September 2000 and July 2004, from early open cases, hand-assistance then pure laparoscopy to robot-assisted surgery. Age, sex, BMI, pathological diagnosis and tumor characteristics were similar between groups.					
Assumptions	Nihil					
Data source for costs	Not stated					
Cost items included	Operating room charges and total hospital costs from randomly selected patients in each group.					
Data source for outcomes	Not stated					
Discounting	Nihil					
Costs	***Mean (range)***	Robot (n=6)	Open (n=18)	Pure laparoscopy (n=12)	Laparoscopy w/ hand-assistance (n=21)	P value
	Operating room	$ 10 252	$ 4 533	$ 8 432	$ 8 432	0.007
	Overall hospital costs	$ 35 756	$ 25 503	$ 30 293	$ 30 417	0.36
Elements influencing costs	***Median (range)***	Robot (n=6)	Open (n=18)	Pure laparoscopy (n=12)	Laparoscopy w/ hand-assistance (n=21)	P value
	Operative time, min.	345 (246-548)	202 (116-382)	237.5 (181-34)	265 (129-402)	0.02
	Estimated blood loss, ml	125 (25-1500)	500 (75-3000)	125 (50-300)	100 (10-1000)	0.01
	Blood transfusion (%)	1 (16%)	3 (16%)	2 (17%)	5 (24%)	0.9
	Length of stay, days	3 (2-5)	5 (3-11)	4 (3-12)	4 (1-61)	0.03
Outcomes	Postoperative change in creatinine, mg/dL	0.3 (-0.4-0.8)	0.15 (-1.0-2.9)	0.4 (0.1-0.8)	0.4 (0-3.8)	0.11
	Postoperative drop in hemoglobine	-1.4 (-3.5 -0.1)	-2.1 (-7.4 - 0.5)	-2.3 (-3.5 - 0.6)	-1.7 (-4.2-1.1)	0.30
	Postoperative patient-controlled analgesia pump	0	6 (75%)	2 (17%)	3 (14%)	0.004
	Postoperative morphine equivalent use for analgesia, mg	19.0 (2-212)	5.5 (1-10)	30 (0-58)	16 (0-210)	0.37
	Perioperative complications	1 (18%)	3 (17%)	2 (17%)	4 (19%)	1.00
		Stapler failure resulting	Clostridium Difficile	Perforated duodenum,	Wound dehiscence,	

		in renal vein bleeding and conversion to hand-assisted laparoscopic method	Colitis, Pneumonia Pneumothorax	Brachial plexus injury, Enterocutaneous fistula, Pneumonia	myocardial infarction	
	There were no positive margins in patients with malignancy					
Cost-effectiveness	No formal ICER					
Sensitivity analysis	Nihil					
Conclusions	Radical nephrectomy can be safely performed by one of the 4 techniques studied (by a surgeon familiar with the techniques). Results need to be confirmed by research on larger cohorts with a longer follow-up period.					
Remarks	Pairwise comparisons unclear					
	Operations were performed by rotating urology residents and available but well trained ancillary staff.					

Atrial septal defect closure and mitral valve repair

Author, year	Morgan, et al. 2005[100]						
Title	Does robotic technology make minimally invasive cardiac surgery too expensive? A hospital cost analysis of robotic and conventional techniques.						
Country	USA						
Design	Cost comparison based on a retrospective review of cases (consecutive for atrial septal defect, not specified for mitral valve repair))						
Perspective	Hospital						
Time window	Hospitalization						
Interventions	a. Atrial septal defect closure: robot-assisted surgery (n=10) versus sternotomy (n=10) b. Mitral valve repair : robot-assisted surgery (n=10) versus sternotomy (n=10)						
Population	See remark						
Assumptions	Robot is purchased and depreciated during 5 yrs, in 100 cases / yr						
Data source for costs	Hospital cost accounting system						
Cost items included	Direct costs only. In the direct costs, operating room time, material costs, drugs, lab tests and respiratory services were included but pre-operative costs were excluded, such as pre-operative hospitalization costs and diagnostic tests						
Data source for outcomes	Nihil						
Discounting	No						
Costs	Costs of robot was $ 1 000 000 + 100 000 annual maintenance = $ 2800 / case "Reposables" were valued at 4x200=$800 / case						
		Atrial septal defect closure			Mitral valve repair		
	Mean ± SD ($)	Robot (n=10)	Sternotomy (n=10)	P value	Robot (n=10)	Sternotomy (n=10)	P value
	Drugs	162±92	157±83	0.179	151±110	296±240	0.327
	Lab	133±67	87±46	0.239	203±181	268±192	0.593
	OR time	2358±1952	1773±887	0.328	3231±1887	1906±1116	0.072
	Perfusion	4037±1593	3865±1016	0.753	3855±1420	3775±1068	0.893
	Respiratory	278±198	263±188	0.938	341±298	409±259	0.672
	Supplies	1489±1390	1268±994	0.676	3218±1693	2853±1258	0.437
	Operative costs	**8457±2623**	**7413±2581**	**0.409**	**10999±1186**	**9507±1598**	**0.029**
	Drugs	279±254	218±138	0.716	240±188	455±316	0.306
	ICU	1763±586	1936±776	0.610	2004±675	2256±1044	0.531
	Lab	81±55	190±144	0.238	141±68	207±198	0.349

	Other tests	73±55	29±17	0.122	33±22	52±44	0.326
	Physical therapy	50±34	62±40	0.787	51±48	52±37	0.969
	Radiology	66±25	49±31	0.234	57±22	94±67	0.124
	Hospitalization	1127±335	1278±509	0.558	1126±378	1490±574	0.139
	Postoperative costs	**3164±656**	**3237±876**	**0.847**	**3539±839**	**4387±1690**	**0.173**
	Total costs	**11622±3231**	**10650±2991**	**0.518**	**14538±1697**	**13894±2774**	**0.539**
	Difference		+ $972	0.518		+$644	0.539
	+ $ 2800 /case		+$3773	0.021		+$3444	0.004
Items influencing costs	length of stay	4.3±1 days	7.3±6.4 days	0.203	5.3±1.2days	7.8±4.8 days	0.124
Outcomes	Nihil						
Cost-effectiveness	Nihil						
Sensitivity analysis	Nihil						
Conclusions	Costs were significantly higher for robotic operations only when capital costs were included, for both types of procedure (atrial septal defect closure and mitral valve repair).						
Remarks	Small size - though not statistically significant (n=10), there were large differences in gender, hypertension, CVA, peripheric vascular disease and diabetes mellitus history between groups for the mitral valve repair.						
	Indirect costs not included						
	No method reported for calculating operating room costs (very similar postoperative mean costs while length of stay is 4.3 for robot-assisted atrial septal defect versus 7.3 days for same procedure by sternotomy)						

Tubal re-anastomosis

Author, year	Rodgers, 2007[176]			
Title	Tubal anastomosis by robotic compared with outpatient minilaparotomy			
Country	USA			
Design	Retrospective case-control study (CEA)			
Perspective	Not stated (Hospital and third payer)			
Time window	Minimum 10 month follow-up to 5 years.			
Interventions	three-armed da Vinci robot-assisted tubal re-anastomosis (n=26) vs outpatient minilaparotomy (n=41),			
Population	Women with a prior tubal ligation and a minimum of 4 cm tubal segments, operated between January 2001 and February 2006 according to the surgeon the patients presented to for reversal of a prior tubal ligation for pregnancy prevention. Cases operated with the Zeus system or by laparoscopy were excluded. Groups were similar in age (mean around 34 yr), BMI (between 22 and 30), gravidity (mean 2.9), parity (around 2.5) and percentage of bilateral tubal anastomosis (24 % for robot-assisted cases versus 36%)			
Assumptions	Nihil			
Data source for costs	Not stated			
Cost items included	Operating room, anesthesia and physician fees, nut not the $1.5 million robot price + $130 000 maintenance			
Costs	*Mean (interquartile range), except costs (median)*	Robot (n=26)	Laparotomy (n=41)	P value
	Costs (Medians difference)	$1446 (95% IC : 1112-1812)		<0.001
Elements influencing costs	% Blood loss < 100 ml	73%	80%	0.48
	Surgical time (min)	229 (205-252)	181 (154-202)	0.001
	Anesthesia time (min)	283 (267-290)	205 (170-230)	<0.001
	Hospitalization (min)	99 (72-159)	142 (82-349)	0.14

	Weeks to go back to work	0.8(0.5-2.9)	2.8(1-3.4)	0.013
Data source for outcomes	Retrospective review of hospital data and interviews of patients by telephone			
Discounting	Nihil			
Outcomes after surgery	Time to conceive (months (IQR))	2 (0-9)	4 (1.6-10)	0.13
	N of patients conceiving	61%	79%	0.10
	% of pregnancies	19	47	
	% of ectopic pregnancies	11%	13%	0.70
	% of spontaneous abortions	16%	38%	0.26
	% Viable intrauterine pregnancies	74%	49%	0.31
	Tried other infertility treatments	30%	31%	0.82
	No conversion, similar pregnancies rate in both groups, similar rates of ectopic pregnancies Complications=1 readmission for tachycardia in the robot-assisted cases versus 6 complications including postoperative fever, cellulitis, wound separation, readmission for abdominal pain, reoperation for an incisional hernia, and excessive nausea and vomiting.			
Cost-effectiveness	No formal ICER			
Sensitivity analysis	Nihil			
Conclusions	There do not seem to be any advantages of robot-assisted surgery compared with outpatient minilaparotomy for tubal anastomosis. The role of the robot may be better reserved for patients that are not good candidates for outpatient minilaparotomy (obesity e.g.) The current robot-assisted technology should be considered prototypes before smaller, cheaper and easier to use robots are available			
Remarks	This study shows many flaws: selection bias, recall bias, small sample size, exclusion of robot acquisition costs, complications costs were excluded (readmission/reoperation.), no details on costs calculations. Highly variable follow-up (10 months to 5 years) Heterogeneity of groups (1/3 patients received some additional infertility treatment)			
	One surgeon performed all robot-assisted operations, while three experienced reproductive endocrinologists performed the open mini-laparotomies.			
	Assitants had difficulties maneuvering around the robot.			

Myomectomy

Author, year	Advincula, et al. 2007[177]			
Title	Robot-assisted laparoscopic myomectomy versus abdominal myomectomy: a comparison of short-term surgical outcomes and immediate costs.			
Country	2007			
Design	Retrospective case-control study (CEA)			
Perspective	Hospital and third payer (hospital costs + reimbursement fees)			
Time window	Hospitalization			
Interventions	da Vinci robot-assisted myomectomy (n=29, 3 arms)versus traditional laparotomy (n=29)			
Population	58 patients with symptomatic leiomyomata, operable by laparoscopy, matched according to myoma weight, BMI and age, operated between May 2000 and June 2004. Patients with leiomyomata too large for safe laparoscopy were excluded.			
Assumptions				
Data source for costs	Hospital cost accounting system and reimbursement fees.			
Cost items included	Hospital charges included, among other item non stated, operating room occupancy, anesthesia, nursing staff, lab tests, pharmacy, recovery department. Professional charges were reported. separately. Complications care was excluded.			
Data source for outcomes	Hospital charts			
Discounting	No but costs were converted in constant June 2004 $..			
Costs	*Mean ± SD*	Robot(n=29)	Laparotomy (n=29)	P value

	a.Professional charges ($)	5946 ± 1447	4664 ± 642	0.0002
	b. Hospital charges ($), including	30 084 ± 6689	13 401 ± 7747	<0.0001
	Operating room($)	16916 ± 2668	2165 ± 429	0.0005
	Anaesthesia($	445 ± 109	364 ± 69	<0.0001
	Nursing staff ($)	1332 ± 1057	2371 ± 1715	0.1663
	Lab($)	114 ± 92	139 ± 148	0.2078
	Pharmacy ($)	256 ± 184	322 ± 299	0.938
	Recovery department ($)	445 ± 101	474 ± 182	0.0005
	Total charges ($)=(a)+(b)	36 031 ± 6946	18 065 ± 8006	<0.0001
	Professional reimbursements ($)	2263 ± 1355	1842 ± 828	0.2831
	Hospital reimbursements ($)	13 181 ± 10 752	7015 ± 3468	0.0372
	Total reimbursements ($)	15 444 ± 11 639	8857 ± 3771	0.0205
Elements influencing costs	Operative time	231 ± 85 min	154±43 min	<0.0001
	Blood loss	196 ± 229 ml	365 ± 473 ml	0.0112
	Length of stay	1.48 ± 0.95 days	3.62 ± 1.5 days	<0.0001
Outcomes	Intraoperative complications	Cardiogenic shock due to vasopressin (1)	none	
	Postoperative complications	Aspiration pneumonia (1), port site cellulitis (1), chest pain (1)	Blood loss & anemia requiring transfusion (2) Respiratory arrest + DVT with Greenfield filter placement + a ute renal failure (1), hypertension (2), fever (4), hematoma (2), wound dehiscence (1)	
Cost-effectiveness	No formal ICER			
Sensitivity analysis	Nihil			
Conclusions	Complication rates were higher in the open group. Robotic approach to myomectomy currently costs more than a traditional laparotomy. Reimbursement rates were similar despite a higher operative time in the robot-assisted surgery.			
Remarks	Three-armed da Vinci surgical system. (period 2000-2004)			
	One single surgeon performed the robot-assisted surgery versus 6 senior obstetricians or gynaecologists for the laparotomies. All cases involved a resident or fellow as a first assistant.			
	Follow-up and complications treatment were not included in the cost comparison.			

Nissen Fundoplication

Author, year	El Nakadi et al. 2006[37]
Title	Evaluation of da Vinci Nissen Fundoplication Clinical Results and Cost Minimization
Country	Belgium
Design	Cost-effectiveness analysis based on a prospective trial with randomization of the procedure (no blinding)
Perspective	Hospital (costs + professional fees)
Time window	1 year after surgery
Interventions	Robot Nissen Fundoplication (n=9) versus Nissen fundoplication by coelioscopy (n=11)
Population	20 patients
Assumptions	Operation room occupation was 20 procedures / 500 per year (4% of the robot availibility)
Data source for costs	Hospital clinical trial
Cost items included	See below "Costs"
Data source for outcomes	Hospital clinical trial

Discounting	5%			
Costs	*mean±SEM*	Laparoscopy	Robot	P-value
	Hospital stay	2,242 ± 141	2,249 ± 82	0.965
	Pharmacy	167 ± 22	202 ± 17	0.242
	Surgical procedure	1,525 ± 35	1,553 ± 40	0.601
	-disposables	1,079	828	< 0.001
	-reusables	76	1214	< 0.001
	-Nurse salary	€48 ± 3	€69 ± 6	0.01
	-Investment	545	15175	< 0.001
	-Maintenance	225	6271	< 0.001
	Total	5,907 ± 168	27,561 ± 99	< 0.001
	Total (OR use 4%)	5,167 ± 168	6,973 ± 99	< 0.001
Elements influencing costs	Operation time	96 ± 5 min	137 ± 12 min.	0.01
	Length of stay	4.1 ± 0.3 days	4.4 ± 0.2 days	0.284
Outcomes	Alimentation day	1.81 ± 0.18	2.11 ± 0.11	0.21
	Complaints at 1 month: cases of dysphagia for solids and 2 cases of flatulence in the laparoscopic group, and 1 case of dysphagia for solids, 1 case of epigastric pain, and 1 case of flatulence in the robot group. Complaints at 3 months: 1 case of dysphagia for solids, 2 cases of epigastric pain and 1 case of flatulence; Complaints at 12 months: In the robot group, 1 patient complained of soft stools. In the laparoscopic group, 2 cases of flatulence were observed. At 6 months: laparoscopic procedure with reduction of the torsion and fixation of the anterior gastric wall to the abdominal wall for 1 patient from the robot group presenting with a gastric torsion.			
Cost-effectiveness	Nihil			
Sensitivity analysis	No			
Conclusions	The robot-assisted Nissen procedure was longer and more expensive than the laparoscopic one. Robot instruments appeared not adapted to the digestive surgery.			

Author, year	Morino, et al. 2006[36]
Title	Randomized clinical trial of robot-assisted versus laparoscopic Nissen fundoplication (CEA)
Country	Italy
Design	Cost-effectiveness analysis based on a RCT
Perspective	Not stated (hospital)
Time window	Postoperative follow-up of 6 months
Interventions	Robot-assisted (RALF) (n=25) versus conventional laparoscopic fundoplication (CLF) (n=25) for gastro-esophageal reflux disease (GORD)
Population	50 patients were randomized (1:1) between February 2002 and February 2004, with GORD requiring surgery. Exclusion criteria were giant hiatal hernias, ASA score III-IV, previous upper abdominal surgery and contraindications to pneumoperitoneum. Patients were similar in terms of age, sex, BMI and 24-h pH data.
Assumptions	Nihil
Data source for costs	Not stated
Cost items included	Use of the operating room (367€/hour), costs for surgical devices (disposables, trocars and wires) and robot maintenance, length of hospital stay (300€/day). Initial acquisition costs for da Vinci robot or laparosopic tower were not included.
Data source for outcomes	Personal interviews at 1, 3, 6 and 12 months, functional results were analyzed at 3 and 6 months. Manometry, pH monitoring at 3 months and endoscopy at 6.
Discounting	Nihil

Costs	*Mean ± SEM (range)*	Robot (RALF)	CLF	P value
	Disposables	1454 €	100 €	
	Total operative costs	803 €	557 €	
	Length of stay costs	900 €	870€	
	Total costs	**3157 €**	**1527 €**	
Elements influencing costs	Set-up time	23.1 ±*6.5 (12-39)*	-	-
	Effective operative time (skin-to-skin time)	*78 ± 17.5 (48-104)*	*63.5 ± 13.3 (46-84)*	0.001
	Total operative time	*131.3 ±18.3 (90-162)*	*91.1 ±10.6 (72-106)*	<0.001
	Length of stay	2.9 (2-6) days	3.0 (2-7) days	0.588
Outcomes	No conversion to open			
		1 conversion to CLF		
	Mild transient dysphagia	3 patients at 1 month	3 patients at 1 month	
	No intraoperative nor postoperative complication in neither group			
	No clinical differences between groups using the GORD-HRQOL scale at 3, 6, 12 months.			
Cost-effectiveness	No formal ICER			
Sensitivity analysis	Nihil			
Conclusions	Operating times were significantly longer in case of robot-assisted surgery, costs were higher while no differences was observed in terms of outcomes.			
Remarks	Robot used was a three-arms one. Operations were performed by 3 surgeons experienced in laparoscopy. No learning curve was observed.			

Author, year	Müller-Stich, et al. 2007[142]			
Title	Robot-assisted versus conventional laparoscopic fundoplication: short-term outcome of a pilot randomized controlled trial (CEA)			
Country	Germany			
Design	Cost-effectiveness analysis based on a RCT			
Perspective	Not stated (hospital)			
Time window	Postoperative follow-up of 30 days			
Interventions	Robot-assisted (RALF) (n=20) versus conventional laparoscopic fundoplication (CLF) (n=20) for gastro-esophageal reflux disease (GERD)			
Population	Forty patients were enrolled between August, 2004 and December 2005, aged at least 18 years, with history of more than 6 months of symptomatic GERD requiring acid suppressive therapy of a minimal standard dosage of the applied proton pump inhibitor (PPI) for at least 3 months in the preceding year. Exclusion criteria were previous major upper abdominal surgery, hiatal hernias with paraesophageal involvement, obesity with a body mass index of over 40 kg/m2 and evidence of primary esophageal disorders such as achalasia, sclerodermia or malignant diseases. Eleven patients refused and one additional was not enrolled due to a BMI>40.			
Assumptions	Nihil			
Data source for costs	Not stated			
Cost items included	Staff, use of the operating room and costs for surgical devices (disposable and reusable instruments, covers and trocars), length of hospital stay. Initial acquisition costs for da Vinci robot or laparosopic tower were not included.			
Data source for outcomes	Documentation at discharge and postoperatively at 30 days			
Discounting	Nihil			
Costs	*Mean ± SD (range)*	Robot (RALF)	CLF	P value
	Total operative costs	1534 ± 111 (1363 – 1896)	763 ± 115 (603-1059)	0.001
	Length of stay costs	1710 ± 488 (600-2400)	1980 ± 481 (1200-3000)	0.086

	Total costs	**3244 ± 512 (1511-3970)**	**2743 ± 483 (1892-3763)**	**0.003**
Elements influencing costs	Set-up time (OR door to 1st instrument introduction)	23 ±5 *(14-35)*	*20 ± 3 (15-30)*	0.050
	Effective operative time (1st instr. introduction to last suture)	*65 ± 18 (40-130)*	*82 ± 18 (55-130)*	0.006
	Total operative time	*88 ±18 (60-150)*	*102 ±19 (75-152)*	0.033
	Length of stay	2.9 ± 0.8 days	3.3 ± 0.8 days	0.086
Outcomes	Mild operative dysphagia	16 patients (80%)	18 patients (90%)	1
	Continuous operative dysphagia	5 patients (25%)	5 patients (20%)	1
	Dysphagia score (*Mean ± SD)*	1.3 ± 0.6	1.3 ± 0.7	0.809
	Reflux score (*Mean ± SD)*	1.3 ± 0.7	1.6 ±1.3	0.064
	Proton pump inhibitors resumed due to at least mild reflux at 30 days (*Mean ± SD)*	2 patients (10%)	3 patients (15%)	1
	=> no conversions, no major complications in any group.			
Cost-effectiveness	No formal ICER			
Sensitivity analysis	Nihil			
Conclusions	While operative time can be shorter for RALF than CLF if performed by an experienced team, costs are higher and short-term outcome is similar. Based on perioperative outcome, RALF cannot be favoured over CLF..			
Remarks	The paper gives the perioperative secondary endpoints of a pilot for a multi-centric randomized controlled trial designed to obtain estimates of symptomatic outcome and quality of life in the mid-term follow-up after 12 months. .			
	After a learning phase of 30 procedures, 1 surgeon performed the RALF was performed by 1 surgeon who had already passed a learning phase of 30 procedures. CLF was performed by 3 different surgeons including the RALF surgeon, all with at least 30 CLF procedures performed before			

Author, year	Heemskerk, et al. 2007[144]			
Title	Robot-assisted versus conventional laparoscopic Nissen fundoplication: a comparative retrospective study on costs and time consumption (CEA)			
Country	The Netherlands			
Design	Retrospective study of consecutive cases and historic cases, matched according to age an sex			
Perspective	Not stated (hospital)			
Time window	2 weeks after surgery			
Interventions	Robot-assisted Nissen fundoplication (n=11) versus conventional laparoscopic fundoplication (n=22),			
Population	Between September 2003 and July 2004, patients with gastro-oesophaegal reflux were non randomly assigned to da Vinci four-armed robot-assisted surgery (n=11) or conventional laparoscopy (n=11). Exclusion criteria were: age < 18 years or a Nissen fundoplication for oesophageal disupture			
Assumptions	Nihil			
Data source for costs	Not stated (hospital)			
Cost items included	Hospital admission, diagnostic costs, material costs and wages per hour for staff, multiplied by total operating room stay.			
Data source for outcomes	Prospective recording of time during surgery, examination and reassessment at the outpatient clinics 2 weeks after surgery.			
Discounting	Nihil			
Costs		Robot (n=11)	Laparoscopy (n=11)	P value
	Admission costs	€2244.00	€2244.00	0.405

	Diagnostics costs	€22.84	€21.87	0.430
	Materials costs	€1765.00	€780.00	< 0.001
	Wage costs	€331.98	€330.48	0.669
	Total costs	**€4363.82**	**€3376.35**	**0.033**
Elements influencing costs	Anaesthesia time (min)	16 min.	10 min.	0.210
	Preparation time (min)	15 min.	20 min.	0.166
	Operating time (min)	176 min.	135 min.	0.094
	Anesthesia recovering time (min)	13 min.	8 min.	0.236
	Total operating room time (min)	**220 min.**	**173 min.**	**0.028**
	Length of stay (days)	4 days	4 days	0.928
Outcomes	Number of complications	3	3	0.901
	Early dysphagia	1	1	0.867
	Late dysphagia	1	2	0.893
	Number of complications	3	3	0.901
	There were no intraoperative complications, bleeding or conversion. 1 laparoscopic case needed a partial posterior Toupet fundoplication			
Cost-effectiveness	No formal ICER ratio			
Sensitivity analysis	Nihil			
Conclusions	There were no difference in length of stay or complications suggesting robot-assisted surgery is safe and feasible but its operating room time and its total costs (€987.47 more) were significantly higher. Further research is needed to justify the increased costs and time in robot-assisted surgery compared to laparoscopy.			
Remarks	The laparoscopic team included 1 surgeon, 2 assisting residents and a scrub nurse. The robot team included 1 surgeon, 1 assisting resident and a scrub nurse.			
	A non statistically significant decrease in time was observed between the 5 first cases operated with robot and the last 5 ones (total room occupancy=266 min to 197 min, p=0.115 and operative time=222 min to 150 min, p=0.059).			

Colectomy

Author, year	Rawlings, et al. 2007[143]						
Title	Robotic versus laparoscopic colectomy						
Country	USA						
Design	Cost effectiveness analysis based on a retrospective review of consecutive colectomies at 1 tertiary hospital						
Perspective	Hospital						
Time window	Not stated (the later complication was recorded 12 days after surgery and one readmission occurred 5 days after surgery).						
Interventions	Colectomy : robot-assisted vs laparoscopic (right and sigmoid)						
Population	30 patients with polyps, cancer, diverticulitis, carcinoid, or Chrohn's disease from septembre 2002 to Septembre 2005						
Assumptions							
Data source for costs	Hospital billing system						
Cost items included	Total operating room (OR) cost, OR personnel cost, OR supply cost, OR time cost, and total hospital cost						
Data source for outcomes	Hospital data						
Discounting	No – costs were adjusted to 2005 $.						
Cost items included	*mean ± SD*	Right colectomy			Sigmoid colectomy		
		Laparoscopy	Robot	P	Laparoscopy	Robot	P
	OR personnel	1,340 ± 402	2,048 ± 309	<0.0001	1,621 ± 617	2,134 ±	0.024

	costs					432	
	OR supply costs	1,841 ± 518	2,950 ± 475	<0.0001	2,137 ± 905	3,159 ± 637	0.003
	OR time costs	990 ± 300	1,521 ± 321	<0.0001	1,348 ± 681	1,500 ± 461	0.519
	TOTAL OR ($)	4,339 ± 867	5,823 ± 907	<0.0001	4,974 ± 1,596	6,059 ± 1,225	0.068
	TOTAL ($)	8,073 ± 2,805	9,255 ± 5,075	0.430	10,697 ± 11,719	12,335 ± 12,162	0.735
Elements influencing costs	Operative time (min)	169.2 ± 37.5	218.9 ± 44.6	0.002	199.4 ± 44.5	225.2 ± 37.1	0.128
	Estim. blood loss (ml)	66.3 ± 50.7	40.0 ±24.9	0.067	65.4 ± 52.1	90.4 ± 60.0	0.280
	Length of stay (days)	5.5 ± 3.4	5.2 ± 5.8	0.862	6.6 ± 8.3	6.0 ± 7.3	0.854
	Conversion	2	0		0	2	
Outcomes	Complications for right surgery: 1 anastomotic leak in the robot group and 1 postoperative bleed + prolonged ileus in the laparoscopic group. Complications for sigmoid surgery: 1 prolonged left hip paresthesia, 1 cecal injury, 1 patient who slid off the operating room table after the robot portion of the case, 1 transverse colon injury, and 1 patient returned to the office with urinary retention in the robot group and 1 anastomotic leak, 1 wound infection in the laparoscopic group.						
Cost-effectiveness	Nihil						
Sensitivity analysis	Nihil						
Conclusions	Right colectomies: Longer OR time for robot surgery (219 min versus 169 min.), especially the set-up time but no statistically significant differences neither in blood loss nor in length of stay. OR Robot costs were 34.2% more expensive than laparoscopy: $5823 vs $4339. Personel costs, supply costs and OR time were all significantly higher in the case of robot surgery. But the difference was not enough to increase the overall hospital cost significantly ($9,255 ± 5,075 for robot-assisted surgery versus $8,073 ± 2,805) Sigmoid colectomies: Similar OR time, blood loss and length of stay. Similar total costs£. OR costs were higher for the robot group ($6059 versus $4974) but not statistically different. Personel costs and supply costs were significantly higher in the case of robot surgery.						
Remarks	Demographics were similar between robot-assisted and laparoscopic groups.						
	Laparoscopic anastomosis was extracorporeal while intracorporeal anastomosis was achieved in robot-assisted surgery.						

Rectopexy

Author, year	Heemskerk, et al. 2007[96]
Title	Robot-assisted vs. conventional laparoscopic rectopexy for rectal prolapse: a comparative study on costs and time (CEA)
Country	NL
Design	Cost effectiveness analysis based on a retrospective review of consecutive non-randomly assigned cases
Perspective	Hospital (Maastricht University Hospital)
Time window	Hospitalization and short-termfollow-up (unspecified)
Interventions	Robot-assisted laparoscopic rectopexy (n=19: 7 Wells rectopexies+12 D'hoore rectopexies) versus conventional laparoscopic rectopexy (n=14: 4 Wells rectopexies+10 D'hoore rectopexies)
Population	33 patients (22 females) with full-thickness rectal prolapse (mean age=52 years) treated between January 2004 and May 2006. Exclusion criteria: <18 years, unfit to undergo laparoscopic surgery, or Bhostile abdomen. Previous simple abdominal surgery was not

	considered a contraindication, nor previous antiprolapse surgery.			
Assumptions	Nihil			
Data source for costs	Not stated, (probably hospital cost allocation system). Salary costs are given by time in operating room multiplied by wages.			
Cost items included	Hospital admission and treatment, surgical material costs, salary costs.			
Data source for outcomes	Patients outcome in the hospital			
Discounting	Nihil			
Costs		Robot (n=19)	Conventional (n=14)	P value
	Costs (salary)	€519.87	€386.35	0.040
	Costs (instruments)	€780.00	€780	1.000
	Costs (use of da Vinci)	€889.18	€0	0.000
	Costs (lab/x-ray etc)	€18.73	€18.04	0.700
	Costs (outpatient clinics)	€47.80	€47.80	1.000
	Costs (admittance)	€1417.26	€1883.36	0.441
	Costs (total)	**€3672.84**	**€3155.55**	**0.012**
Elements influencing costs	Admission (days)	3.5	4.3	0.527
	Conversion (%)	5%	0%	0.383
Outcomes		Robot	Conventional	
	First defecation (days)	1.8	1.9	0.857
	Postoperative constipation>5 days	16%	14%	0.905
	NB: Mortality was assumed to be 0% (not reported). NB: Incontinence scale was recoded in Gr 0, Gr 1, Gr 2 (instead of 1,2,3,4) with no mapping given. Results were thus not extracted. NB: Tables were assumed to be correct (19 robot surgeries versus 14 conventional ones)			
Cost-effectiveness	No ICER reported			
Sensitivity analysis	Nihil			
Conclusions	Robot-assisted laparoscopic rectopexy is a safe and feasible procedure but results in increased time and higher costs than conventional laparoscopy.			
Remarks	Inconsistencies between tables and texts (number of patients and group labels + Parks-Browning scale 1-4 mapped to 0-2).			

Cholecystectomy

Author, year	Heemskerk, et al. 2005[145]
Title	First results after introduction of the four-armed da Vinci Surgical System in fully robotic laparoscopic cholecystectomy
Country	The Netherlands
Design	Retrospective case-control study (CEA)
Perspective	Not stated (hospital)
Time window	Follow up 2 weeks after surgery
Interventions	Robot-assisted laparoscopic cholecystectomy (n=12 versus conventional laparoscopic cholecystectomy (n=12).
Population	24 patients (mostly female) matched according to age and gender, operated between September 2003 and February 2004, by cholecystectomy for symptomatic cholecystolithiasis (defined as one or more periods of colic pain in the right upper abdomen in the presence of cholelithiasis objectivated by ultrasound). Patients were without acute cholecystitis at the time of operation.
Assumptions	Nihil
Data source for costs	Operating room time measurements

Cost items included	hospital stay, diagnostic tests, laparoscopic or robot material, accessory costs for sterile draping, salary costs (wages per hour for attending surgeons, residents and nurses, multiplied by overall operating room stay) and outpatient clinics pre-operative assessment and post-operative follow-up			
Data source for outcomes	Not stated (hospital data)			
Discounting	Nihil			
Costs	*Mean (range)*	Robot (n=12)	Laparoscopy (n=12)	P value
	Hospitalization costs,	€1495.5	€1308.8	0.219
	Costs for accessory tests	€582.9	€552	0.567
	Costs for da Vinci system	€889.2	€0	<0.001
	Salary costs	€274.6	€273.8	0.98
	Outpatient follow-up	€47.8	€48.8	1
	Total costs	**€3.329.1**	**€2.148.5**	**<0.001**
Elements influencing costs	Overall operating room stay	2:30 (1:24-3:10)	1:59 (1:09-3:14)	0.042
	Anesthesia time	0:09	0:13	0.280
	Preparation time	0:10	0:15	0.760
	Real operating time	1:55	1:30	0.170
	Length of stay	2.7 days	2.3 days	0.208
Outcomes	Bile spill	42%	33%	0.673
	Wound infection	25%	0%	0.064
	1 patient developed urinary bladder retention in the robot-assisted group			
Cost-effectiveness	No formal ICER – no correlation could be found between complications and costs			
Sensitivity analysis	Nihil			
Conclusions	Fully robot-assisted laparoscopic cholecystectomy is safe and feasible but seems more expensive and time consuming at this moment.			
Remarks				

General

Author, year	Prewitt, et al. 2008[178]			
Title	The patterns and costs of the Da Vinci robot-assisted surgery system in a large academic institution			
Country	USA			
Design	Cost comparison based on retrospective consecutive case studies and open cases data gathered by the manufacturer			
Perspective	Hospital (costs + professional fees)			
Time window	Hospitalization			
Interventions	Da Vinci Robot System surgical procedures: carotid arterial bypass; oesophagomyotomy , nephroureterectomy, radical cystectomy, radical prostatectomy, unilateral adrenalectomy			
Population	224 procedures between July 2000 and February 2007			
Assumptions	Nihil			
Data source for costs	Hospital (University of Nebraska Medical Centre)			
Cost items included	Direct by the hospital related to the operating room use, hospital stay, and staff salaries equipment used for the procedure and patient care supplies..			
Data source for outcomes	Hospital data			
Discounting	No			
Costs	*Mean*	Robot	Open	
	Average direct costs	$11591	$10120	
	Average net revenues	$15344	$16730	
	Average net revenue (received from Medicare/Medicaid and third party payers)			

	Robot: $15 344 / case versus $16730 Length of stay: robot: 3.6 days versus 6.1 days
Outcomes	
Cost-effectiveness	Nihil
Sensitivity analysis	No
Conclusions	Operative costs of robot surgery were higher than those of open surgery but LOS was reduced.
Remarks	Comparison on two series

APPENDIX TO CHAPTER 5: CURRENT SITUATION

QUESTIONNAIRE SUR L'UTILISATION DU ROBOT CHIRUGICAL DA VINCI

Prière de lire avant de remplir le questionnaire

Avant de remplir ce questionnaire, pourriez-vous vous assurer que les données d'identification dans le cadre ci-dessus sont complètes et correctes ?

Les données récoltées par le questionnaire permettront de décrire la pratique en Belgique et d'estimer le nombre de patients traités pour éventuellement effectuer un calcul d'impact financier, actuel ou futur. ***Au cas où vous ne souhaiteriez ou ne pourriez pas répondre à certaines questions, pouvez-vous nous renvoyer le questionnaire même partiellement rempli ?***

Le questionnaire est constitué de deux parties : une partie générale et une partie à faire remplir par chaque service chirurgical utilisant le robot. Le document est un formulaire WORD, vous pouvez le remplir en cliquant ou en cochant une ou plusieurs réponses ou en complétant les cases, selon la question posée. Vous pouvez bien sûr aussi le remplir à la main. Vous pouvez faire autant de copies que de services concernés et nous les renvoyer groupées ou séparément. Certaines réponses ont été brièvement abordées lors de notre entretien téléphonique de juin dernier, les réponses données pouvant donner lieu à confirmation ou modification. Si vous le désirez, vous pouvez entrer des commentaires (de longueur non limitée) à la dernière page En cas de problème ou de question, n'hésitez pas à contacter Cécile Camberlin (02/287.33.15 – cecile.camberlin@kce.fgov.be) ou Chris De Laet (02/287.33.86 – chris.delaet@kce.fgov.be).

Important : Le questionnaire sera traité anonymement, les réponses communiquées seront publiées globalement mais pas individuellement par institution. Seule la liste des institutions disposant d'un robot et leur localisation seront publiées nominativement.

Nous vous sommes très reconnaissants de participer à ce questionnaire.

Merci de renvoyer par mail/faxer ce questionnaire complété aux adresses électroniques suivantes avant le ***15 septembre 2008*** *ou de nous contacter en cas d'impossibilité pour fixer une autre date : cecile.camberlin@kce.fgov.be. chris.delaet@kce.fgov.be. Notre fax est le : 02/287.33.85.*

PREMIERE PARTIE : PARTIE GENERALE

Q 1. Quelles sont les interventions réalisées à ce jour en 2008 avec robot chirurgical dans votre institution ? *N'oubliez pas de préciser le dernier mois auquel se rapporte ce nombre.!*

Période : Janvier 2008 - …..	**Nombre d'interventions**			
	Robot		**Laparoscopie conventionnelle (2)**	**Chirurgie ouverte (2)**
INTERVENTION		**Dont conversions (1)**		
Example: Prostatectomie radicale	*120*	*5*	*150*	*85*
…..	…..	…..	…..	…..

(1) Nombre d'interventions de la première colonne commencées avec le robot, terminées par une autre technique (sans que cela n'ait été planifié) - Dans l'exemple, 5 est inclus dans 120.

(2) hors conversions

Q 2. Pour quelle(s) spécialité(s) le robot a-t-il été acquis au départ (même si l'utilisation a changé) *(Cochez la ou les réponses adéquates)*

Urologie	☐
Gynécologie	☐
Chirurgie cardio-vasculaire	☐
Chirurgie thoracique autre que cardio-vasculaire	☐
Chirurgie abdominale	☐
Chirurgie pédiatrique (*précisez ci-dessous)* ……..	☐
Autres (*précisez ci-dessous)* ……..	☐

Q 3. Quelle est la date d'acquisition du robot?

Mois et année *(ex : 01, 2002 pour janvier 2002)*	01	2008

Q 4. Quel est le mode d'acquisition de ce robot ?

Achat	☐
Leasing	☐
Donation	☐

Q 5. Comment a été financée l'acquisition du robot ? *(plusieurs réponses sont possible : Cochez la ou les réponses adéquates)*

Fonds de l'hôpital	☐
Contribution de la part du corps médical	☐
Donation (par le fabricant)	☐
Donation (par un tiers, personne physique ou morale)	☐
Subside public	☐
Fonds de recherche	☐
Autres (*précisez ci-dessous)* ……..	☐

Commentaires :

……

DEUXIEME PARTIE : QUESTIONS A TRAITER PAR SPECIALITE CHIRURGICALE

IMPORTANT : CETTE DEUXIEME PARTIE DU QUESTIONNAIRE EST A REMPLIR PAR CHACUN DES SERVICES/SPECIALITES CHIRURGICAUX UTILISANT LE ROBOT DE L'HOPITAL (PREVOIR AUTANT DE COPIES QUE DE SERVICES)

LES QUESTIONS Q6 A Q15 NE CONCERNENT QUE LES INTERVENTIONS REALISEES DANS LE SERVICE, ET NON PAS TOUTES LES INTERVENTIONS REALISEES SUR LE ROBOT DE L'HOPITAL

Merci de renvoyer par mail/faxer ce questionnaire complété aux adresses électroniques suivantes avant le 15 septembre 2008 ou de nous contacter en cas d'impossibilité pour fixer une autre date : cecile.camberlin@kce.fgov.be. chris.delaet@kce.fgov.be.. Notre fax est le 02/287.33.85.

Q 6 Pour votre service, quels sont les critères d'éligibilité des patients à la chirurgie robotique *? (Cochez la ou les réponses adéquates)*

	Critère d'inclusion pour le robot	Critère d'exclusion pour le robot
Patient jeune (*précisez ci-dessous)* ……..	☐	☐
Patient âgé ……	☐	☐
Situation socio-économique du patient	☐	☐
Indice de masse corporelle élevé (*précisez* BMI >)	☐	☐
Restrictions anatomiques (*précisez ci-dessous)* ……..	☐	☐
Contre-indications médicales (*précisez ci-dessous)* ……..	☐	☐
Autres (*précisez ci-dessous)* ……..	☐	☐

Q 7. Lors d'une intervention avec assistance du robot dans votre service, combien de personnes **en moyenne** participent habituellement à l'intervention *(précisez un nombre dans chacun des cadres, si possible 0 le cas échéant) ?*

Anesthésiste	
Chirurgien spécialiste	
Chirurgien spécialiste stagiaire	
Infirmier spécialisé en assistance opératoire et instrumentation	
Infirmier	
Autres (*précisez ci-dessous)*	

Q 8. Pour votre service, pourriez-vous précisez, le type de formation relative à l'utilisation du robot reçue par le personnel (y compris dans un autre établissement)?

Anesthésiste	
Chirurgien spécialiste	
Chirurgien spécialiste stagiaire	
Infirmier spécialisé en assistance opératoire et instrumentation	
Infirmier	
Autres (*précisez ci-dessous)* ……..	

Q 9. Quel est le nombre de chirurgiens dans votre service ?

Nombre de chirurgiens	

Q 10. Quel est le nombre de chirurgiens utilisant le robot dans votre service ?

Nombre de chirurgiens ayant recours au robot	

Q 11. Pour votre service, quel est le nombre d'opérations déjà réalisées par chaque chirurgien à la date où vous remplissez le questionnaire (non nominativement) ?

Chirurgien numéro 1	
Chirurgien numéro 2	
Chirurgien numéro 3	
Chirurgien numéro 4	
Chirurgien numéro 5	
Chirurgien numéro 6	
Chirurgien numéro 7	
Chirurgien numéro 8	
Chirurgien numéro 9	
Chirurgien numéro 10	

Q 12. Quel type de canal d'information est utilisé pour informer et orienter le patient ? *(Cochez la ou les réponses adéquates)*

Consultation avec le chirurgien traitant	☐
Consultation avec un autre médecin que le chirurgien traitant	☐
Consultation avec un(e) infirmièr(e)	☐
Remise d'une brochure ou de documentation écrite	☐
Signature d'un formulaire de consentement éclairé	☐
Autres (précisez ci-dessous) ……	☐

Important : *Le cas échéant, pourriez-vous joindre en annexe une copie de la documentation destinée au patient (documentation, formulaire de consentement éclairé) ?*

Q 13. Quel type d'information est donné au patient? *(Cochez la ou les réponses adéquates)*

Informations cliniques (différence entre intervention conventionnelle ou robot, explication de la procédure chirurgicale)	☐
Informations sur les risques éventuels spécifiques liées a l'utilisation du robot	☐
Aspect financiers (contributions personnelles pour le patient : surcoût en comparaison avec la chirurgie conventionnelle)	☐
Information sur la réhabilitation (le suivi ambulatoire)	☐
Information sur la durée de séjour	☐
Autres (*précisez ci-dessous)* ……	☐

Q 14. Le patient doit-il attendre plus longtemps pour être opéré avec robot que dans le cas d'une intervention conventionnelle (sans robot) ?

Oui	☐
Non	☐

Q 15. Le patient intervient-il financièrement dans les coûts de l'utilisation du robot pour son opération?

Oui, tous les patients	☐
La plupart	☐
Non	☐

Q 15.a. Si vous avez répondu OUI ou LA PLUPART à la question Q 15 quel est le montant payé par le patient ?

Commentaires : €

VRAGENLIJST OVER HET GEBRUIK VAN HET CHIRURGISCHE ROBOTSYSTEEM 'DA VINCI'

Gelieve dit eerst te lezen

Zou u, voor u deze vragenlijst invult, de identificatiegegevens hierboven willen nakijken en eventuele fouten verbeteren?

De gegevens die we met deze vragenlijst verzamelen zijn enkel bedoeld om ons toe te laten het huidige gebruik van het chirurgische robotsysteem 'Da Vinci' in België te beschrijven, een schatting te maken van het aantal behandelde patiënten en de potentiële toekomstige behoeften en om de mogelijke financiële impact hiervan in te schatten. ***Indien u bepaalde vragen niet wenst of niet kan beantwoorden, gelieve ons dan toch deze vragenlijst terug te sturen, zelfs indien deze maar gedeeltelijk ingevuld is.***

De vragenlijst bestaat uit 2 delen: een algemeen deel en een deel dat per chirurgische afdeling die de robot gebruikt moet ingevuld worden. Het document is een WORD formulier dat u kan invullen door de vakjes aan te klikken of antwoorden in te tikken. U kan de vragenlijst natuurlijk ook altijd met de hand invullen. U kunt zoveel kopieën maken als nodig voor de betrokken afdelingen. Deze kunnen gezamenlijk of door elk van de afdelingen apart naar ons teruggestuurd worden. Sommige vragen hebben we al kort besproken tijdens onze telefoongesprekken in de maand juni en die antwoorden kunnen met deze vragenlijst ofwel bevestigd worden ofwel veranderd. Indien u dit wenst kan u ook bijkomende commentaren geven (onbeperkte lengte) op de laatste pagina. Indien er iets niet duidelijk is aarzel dan niet om ons te contacteren: Cécile Camberlin (02/287.33.15 – cecile.camberlin@kce.fgov.be) of Chris De Laet (02/287.33.86 – chris.delaet@kce.fgov.be).

Belangrijk: de vragenlijst zal anoniem verwerkt worden en de gegeven antwoorden zullen enkel globaal en niet per ziekenhuis gepubliceerd worden in het rapport of in zijn bijlagen. Wel zullen we een overzicht opnemen van de ziekenhuizen die over een robot beschikken.

We danken u voor uw medewerking.

Gelieve deze vragenlijst terug te sturen via mail of fax voor ***15 september 2008*** *of ons te contacteren indien dit niet mogelijk is: cecile.camberlin@kce.fgov.be. chris.delaet@kce.fgov.be. Onze fax is: 02/287.33.85.*

EERSTE DEEL: ALGEMEEN

Q 16. *Voor welke ingrepen en voor hoeveel interventies werd, sinds begin 2008, het chirurgische robotsysteem in uw instelling gebruikt?*
Gelieve ook aan te geven tot welke maand dit aantal geteld werd.

Periode : Januari 2008 - …..	**Aantal ingrepen**			
	Robot geassisteerd			
INTERVENTIE		**Waarvan conversies (1)**	**Conventionele Laparoscopie (2)**	**Open Chirurgie (2)**
Voorbeeld: Radicale Prostatectomie	*120*	*5*	*150*	*85*
…..	…..	…..	…..	…..

(1) Aantal ingrepen uit de eerste kolom die begonnen zijn met de robot, maar (ongepland) met een andere techniek verder gezet zijn. - In het voorbeeld : 5 is ook inbegrepen in de 120.
(2) Buiten de conversies

Q 17. Voor welk chirurgisch discipline (één of meerdere) werd de robot oorspronkelijk aangeschaft (ook indien het gebruik zich daarna gewijzigd heeft).
(Klik één of meerdere antwoorden aan)

Urologie	☐
Gynaecologie	☐
Cardio-vasculaire heelkunde	☐
Thoracale heelkunde buiten cardio-vasculaire	☐
Abdominale heelkunde	☐
Pediatrische heelkunde *(gelieve te preciseren)* ……..	☐
Andere *(gelieve te preciseren)* ……..	☐

Q 18. Wanneer hebt u de robot aangeschaft?

Maand en jaar (vb.: 01, 2002 voor januari 2002)	01	2008

Q 19. Hoe hebt u deze robot verworven?

Aankoop	☐
Leasing	☐
Schenking	☐

Q 20. Hoe werd deze robot gefinancierd? (meerdere antwoorden zijn mogelijk, klik één of meerdere antwoorden aan)

Fonds van de instelling	☐
Bijdrage vanuit het medisch korps	☐
Schenking (door de fabrikant)	☐
Andere schenking (door derde; fysiek of rechtspersoon)	☐
Subsidie van de overheid	☐
Onderzoeksfonds	☐
Andere *(gelieve te preciseren)* ……..	☐

Verdere commentaar:

……

TWEEDE DEEL: VRAGEN PER CHIRURGISCH SPECIALITEIT

BELANGRIJK: DIT TWEEDE DEEL VAN DE VRAGENLIJST MOET DOOR ELK VAN DE CHIRURGISCHE SPECIALITEITEN DIE HET CHIRURGISCHE ROBOTSYSTEEM GEBRUIKEN APART INGEVULD WORDEN (VOORZIE VOLDOENDE KOPIËN)

DE VRAGEN Q6 TOT Q15 GAAN ENKEL OVER DE INGREPEN BINNEN DEZE AFDELING, NIET OVER ALLE INGREPEN MET DE ROBOT IN DE INSTELLING

*Gelieve deze vragenlijst terug te sturen via mail of fax voor **15 september 2008** of ons te contacteren indien dit niet mogelijk is: cecile.camberlin@kce.fgov.be. chris.delaet@kce.fgov.be. Onze fax is: 02/287.33.85.*

Q 21 Welk zijn, binnen uw afdeling de criteria die bepalen of een patiënt in aanmerking komt voor robotgeassisteerde chirurgie? *(Klik één of meerdere antwoorden aan)*

	Inclusiecriterium voor Robot-chirurgie	Exclusiecriterium voor Robot-chirurgie
Jonge patiënt *(gelieve te preciseren)* ……..	☐	☐
Oude patiënt *(gelieve te preciseren)* ……	☐	☐
Socio-economische toestand van patiënt	☐	☐
Hoge Body Mass Index (*bij* BMI >)	☐	☐
Anatomische beperkingen *(gelieve te preciseren)* ……..	☐	☐
Medische contra-indicaties *(gelieve te preciseren)* ……..	☐	☐
Andere *(gelieve te preciseren)* ……..	☐	☐

Q 22. Hoeveel personen nemen **gemiddeld** deel aan een robotgeassisteerde ingreep *(geef het aantal voor elk van de functies, eventueel 0 indien ze niet participeren)?*

Anesthesist	
Chirurg	
Chirurg/Assistent in opleiding	
OK verpleegkundige	
Andere verpleegkundige	
Andere *(gelieve te preciseren)*	

Q 23. Kan u aangeven welke specifieke opleiding in principe voorzien is voor de medewerkers die deelnemen aan robotgeassisteerde ingrepen (met inbegrip van opleidingen in een andere instelling)?

Anesthesist	
Chirurg	
Chirurg/Assistent in opleiding	
OK verpleegkundige	
Andere verpleegkundige	
Andere *(gelieve te preciseren)*	

Q 24. Hoeveel chirurgen werken er **binnen uw afdeling**?

Aantal chirurgen	

Q 25. Hoeveel chirurgen gebruiken de robot **binnen uw afdeling**?

Aantal chirurgen die de robot gebruiken	

Q 26. Hoeveel ingrepen heeft elke chirurg verricht **binnen uw afdeling** op het ogenblik dat u deze vragenlijst invult (niet nominatief in te vullen)?

Chirurg 1	
Chirurg 2	
Chirurg 3	
Chirurg 4	
Chirurg 5	
Chirurg 6	
Chirurg 7	
Chirurg 8	

Chirurg 9	
Chirurg 10	

Q 27. Hoe wordt de patiënt geïnformeerd en georiënteerd *(meerdere antwoorden mogelijk)*?

Tijdens consultatie met behandelende chirurg	☐
Tijdens consultatie met een andere arts	☐
Gesprek met verpleegkundige	☐
Door een informatiebrochure of andere geschreven documentatie	☐
Ondertekenen van een 'informed consent' formulier	☐
Andere *(gelieve te preciseren)* ……	☐

Belangrijk: *Indien u geschreven informatie hebt voor de patiënt (documentatie, 'informed consent' formulier en dergelijke), zou u deze dan kunnen meesturen samen met de vragenlijst*

Q 28. Welk soort informatie wordt aan de patiënt gegeven? *(meerdere antwoorden mogelijk)*?

Klinische informatie (verschil tussen conventionele ingreep of robotgeassisteerde, uitleg over de chirurgische procedure)	☐
Informatie over mogelijke specifieke risico's verbonden aan het gebruik van de robot	☐
Financiële aspecten (persoonlijke bijdrage voor de patiënt, meerkost in vergelijking met conventionele ingreep)	☐
Informatie over het voorziene herstel (ambulante opvolging)	☐
Informatie over de voorziene verblijfduur in het ziekenhuis	☐
Andere *(gelieve te preciseren)* ……	☐

Q 29. Is er voor de patiënt een langere wachttijd voor een robotgeassisteerde ingreep in vergelijking met de conventionele ingreep zonder robot?

Ja	☐
Nee	☐

Q 30. Draagt de patiënt zelf financieel bij voor de kosten van het gebruik de robot?

Ja, alle patiënten	☐
Meestal	☐
Nee	☐

Q 15.a. Indien u JA of MEESTAL hebt geantwoord op vraag Q 15 wat is het meest courante bedrag betaald door de patiënt zelf?

Verdere commentaar: €

Table 4 : French radical prostatectomy procedure codes (August 2008 - CCAM version 13)

Code	Name of procedure	Fee (€)
JGFA006	vésiculoprostatectomie totale, par laparotomie	692,72 €
JGFA011	vésiculoprostatectomie totale, par abord périnéal	691,07 €
JGFC001	vésiculoprostatectomie totale, par cœlioscopie	777,2 €

Table 5 : Australian radical prostatectomy procedure codes (Australian Medicare Benefits Schedule – August 2008)

Code	Name of procedure	Fee (AUD) 100%	Benefit (AUD) (75%)*	Benefit (AUD) (85%)*
37210	PROSTATECTOMY, radical, involving total excision of the prostate, sparing of nerves around the bladder and bladder neck reconstruction, not being a service associated with a service to which item 35551, 36502 or 37375 applies	$1,439.00	$1,079.25	-
37211	PROSTATECTOMY, radical, involving total excision of the prostate, sparing of nerves around the bladder and bladder neck reconstruction, with pelvic lymphadenectomy, not being a service associated with a service to which item 35551, 36502 or 37375 applies	$1,747.65	$1,310.75	-
20845	INITIATION OF MANAGEMENT OF ANAESTHESIA for radical prostatectomy	$179.00	$134.25	$152.15
20904	INITIATION OF MANAGEMENT OF ANAESTHESIA for radical perineal procedures including radical perineal prostatectomy or radical vulvectomy	$125.30	$94.00	$106.55
51303	Assistance at any operation identified by the word "Assist." for which the fee exceeds $493.35 or at a series of operations identified by the word "Assist." for which the aggregate fee exceeds $493.35	$ 287,8 $ 349,53	$ 215,85 $ 262,15	- -

* treatment for public patents in public hospital is 100%. Private-insured patients are reimbursed 75%.

Table 6 : Québec prostatectomy procedure codes (Manuel de facturation, Régie de l'assurance maladie du Québec, update 71 – July 2008)

Code	Name of procedure	Fee (CAD) All physicians	Fee (CAD) Specialists
	Prostatectomie (incluant la vasectomie, le cas échéant)		
06243	rétropubienne radicale incluant vésiculectomie mais excluant évidement ganglionnaire	$ 672	$ 922
+06244	périnéale radicale incluant vésiculectomie séminale excluant évidement ganglionnaire	$ 713.15	$ 736

Table 7 : Open & laparoscopic prostatectomy DBC tariffs in hospitals using da Vinci robot in the Netherlands (2008)

Declaration Code	Name of procedure Name of Hospital	Total	Hospital Fee (€)	Honorarium Fee (€)
151823 Open	Prostaatkanker / Open operatie met klinische opname / verwijzing			
	Jeroen Bosch ziekenhuis	11726	9679.2	2046.8
	AZ Maastricht	11440	9393	2047
	VU Medisch Centrum	10 303.6	8 256.8	2 046.8
	UMC Utrecht	11 742.5	9 695.7	2 046.8
	Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek	11159.6	8 931.0	2 228.6
151831 Laparoscopic	Prostaatkanker / Kijkoperatie in de buik met klinische opname / verwijzing			
	Jeroen Bosch ziekenhuis **: laparoscopisch**	11447	9148.4	2298.6
	Jeroen Bosch ziekenhuis: **da Vinci Robot**	15299	13000.4	2298.6
	AZ Maastricht	16549	14250	2299
	VU Medisch Centrum	12 612.9	10 314.3	2 298.6

UMC Utrecht	10077.3	7778.7	2298.6
Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek	14470.6	12 000.0	2 470.6

DBC are publicly available on each hospital website.

Table 8 : German private radical prostatectomy fees-for-service (based on GOÄ) (2008)

Code	Name of procedure	Fee range (€)	
1779	Totale Entfernung der Prostata einschließlich der Samenblasen	**150,96**	**347,21**
1784	Totale Entfernung der Prostata und der Samenblasen einschließlich pelviner Lymphknotenentfernung	**204,01**	**469,22**

Table 9 : German radical prostatectomy procedure codes (Operationen- und Prozedurenschlüssel, OPS) (2008)

5-604	**Radikale Prostatovesikulektomie**
	Exkl.: Radikale pelvine Lymphadenektomie als selbständiger Eingriff (5-404.f ff.) Revision nach radikaler Prostatovesikulektomie (5-609.7)
5-604.0	Retropubisch
.01	Ohne regionale Lymphadenektomie
.02	Mit regionaler Lymphadenektomie
5-604.1	Retropubisch, gefäß- und nervenerhaltend
.11	Ohne regionale Lymphadenektomie
.12	Mit regionaler Lymphadenektomie
5-604.2	Perineal
.21	Ohne regionale Lymphadenektomie
.22	Mit laparoskopischer regionaler Lymphadenektomie
5-604.3	Perineal, gefäß- und nervenerhaltend
.31	Ohne regionale Lymphadenektomie
.32	Mit laparoskopischer regionaler Lymphadenektomie
5-604.4	Laparoskopisch
.41	Ohne regionale Lymphadenektomie
.42	Mit regionaler Lymphadenektomie
5-604.5	Laparoskopisch, gefäß- und nervenerhaltend
.51	Ohne regionale Lymphadenektomie
.52	Mit regionaler Lymphadenektomie
5-604.x	Sonstige
5-604.y	N.n.bez.

APPENDIX TO CHAPTER 7: PATIENT AND ETHICAL ISSUES

INFORMATION SHEETS FOR ETHICAL EXPERTS

Background on robot-assisted surgery

Robot-assisted surgery: autumn 2008
Ethical expert panel
Information sheet

The technology

In recent decades, new techniques and instruments were developed to enable the development of so called 'Minimally Invasive Surgery' (MIS). This was originally through developing endoscopic instruments giving the surgeon access to the operation area through small incisions around the surgical target through which the surgeon can see and use his instruments to perform the surgery, with the aim to shorten recovery time and reduce so-called 'collateral damage' caused by large incisions. This evolution was made possible through innovations in optical instruments and miniaturisation, including miniature cameras, enhanced video displays and the development of specific surgical instruments.

Since a few years robotic systems have become available to support this MIS approach even further.

The surgical robots of interest in this assessment are controlled by the surgeon and do not move autonomously. They do not have independent function or artificial intelligence. They are merely a sophisticated tool used by the surgeon while operating.

The robots available enable three-dimensional visualisation, magnification of the surgical field and tremor-free precise surgery with multiple robotic arms.

At this moment the market is largely dominated by the da Vinci® surgical system developed and marketed since 1999 by Intuitive Surgical, Inc. (Sunnyvale, CA, USA, www.intuitivesurgical.com). Another player on the market (Computer Motion, Goleta, CA, USA) manufacturing the ZEUS® surgical system was taken over by Intuitive Surgical in 2003 and marketing of the ZEUS system was afterwards abandoned.

Evidence

Patients, surgeons, health care institutions and health payers are attracted to these new systems because of several potential benefits such as shorter inpatient length–of-stay, quicker recovery, fewer complications, less pain after the procedure, and better functional and/or oncological outcomes.

- However, little evidence exists today that these potential advantages are indeed obtained:
  - Most studies on the effectiveness of robot-assisted surgery have been relatively small non-randomised observational comparative studies. Depending on indication and study design, different indicators and parameters for effectiveness and cost-effectiveness have been reported. The heterogeneous nature of the studies performed make any pooling of results (meta-analysis) difficult.
  - Most of the reported results are short-term outcomes. Little has been reported on long-term parameters such as survival or recurrence of cancer.
  - Few studies compare robot-assisted surgery with other treatment modalities such as watchful waiting, radiotherapy or chemotherapy. This comparison to non-surgical alternatives, however, is outside the scope of this assessment.

- Three technology assessment reports came to similar conclusions about robot-assisted surgery in general: there was insufficient evidence to make many useful comparisons of robotic-assisted and conventional laparoscopic surgery, particularly in regard to the cost-effectiveness of robotic-assisted surgery. Although some evidence suggested improvement in functional recovery time, they concluded that safety and efficacy of the procedure depended heavily on the expertise of the surgical team and that long-term information on cancer control and survival outcomes were not available.

Costs & Patient charges

The da Vinci surgical system is expensive. Currently robot-assisted surgery is more costly than traditional alternatives: open surgery or laparoscopic approaches.

The current acquisition price of the da Vinci surgical system in Belgium, including the robot, the video monitor and the surgeon workstation, amounts to approximately €1.5 million. The additional yearly maintenance contract that includes software upgrades, amounts to about 10% of the initial acquisition cost , starting the year after the year of purchase.

Instruments, such as scissors, scalpels, cutters and other accessories must be inserted into the robotic arms. These disposables (also called 'reposables') are reusable for a specific number of procedures, a number that is pre-defined by the manufacturer and controlled by a memory chip inside each instrument. Beyond this number of uses, unrelated to the instrument wear, usually 10 procedures, the instrument is not recognized by the system anymore and becomes unusable.

- The economic value of using this technology is unclear. The design of the studies is generally of poor quality.
  - Comparisons are mostly done retrospectively in one centre only and on small series, impeding the generalizability of the results.
  - Cost calculation methods are not given clearly and often not all cost drivers are included.
  - Many studies reviewed combined the hospital perspective (costs drawn from the hospital accounting department) with the third payer's perspective (physician's fees). Ideally, the perspective should be that of society, including the amounts charged to the patient as well as the patient's loss of income and time due to recovery.
  - In the studies reviewed, the time window exceeds rarely the hospitalization and often the follow-up is not consistent among patients. The treatment costs of post-operative complications or cancer recurrence should in theory be included in the analysis.
  - Questions on transferability of cost studies from abroad to Belgium seem legitimate, especially when costs structure is different.

Additional cost of disposables and reposables is estimated at around €2000 per surgical intervention.

- Currently there is no particular additional reimbursement for robot-assisted surgery and the use of the device-dependent disposables: for prostatectomy the reimbursement is the one applicable for general surgical interventions with a supplementary fee for endoscopy.
  - Several hospitals in Belgium have therefore decided to charge a non-reimbursable supplement to patients directly to cover all or part of this additional cost.
  - In Belgium there is a demand from professionals (i.c. urologists) to create a specific (higher) reimbursement for robot-assisted surgery in radical prostatectomy for prostate cancer. The Belgian National Institute for Health and Disability Insurance (RIZIV/INAMI) is willing to consider the issue, but has not decided yet.

Use of technology

Robotic surgical devices have, in recent years, developed beyond the experimental phase and are nowadays used in minimally invasive general abdominal surgery, in gynaecological, urological and cardiothoracic surgery but also in paediatric surgery and experimentally in otorhinolaryngology and head and neck surgery.

It is a "technology push" setting in which patients are, to a large extent, positively biased towards the expected added value of the use of this technology, probably also inspired by the messages of industry and surgeons.

Many hospitals also seem to look at this technology as a way to position their institution as a technological front-runner. In early 2008, 17 da Vinci systems where installed in Belgium, most of them in Flanders, and clustered in specific geographic areas. Eleven of these systems were installed in 2007 indicating a quick expansion of the installed base and for 2008 a similar growth is anticipated (current estimate of contacted urologists is that about 25 robots are nowadays operational or on-order in Belgium).

Robot-assisted surgery

Information sheet
Ethical expert panel: autumn 2008
Issue 1: patient information

Key points (see also general documentation sheet):

- **Clear lack of evidence on the added value of robot-assisted surgery compared to more conventional surgery (open or laparoscopic).**
- **Robots for robot-assisted surgery are currently in use in approximately 25 Belgian hospitals, mainly for interventions in urology (mainly radical prostatectomy).**
- **"Technology push" setting in which patients are to large extent positively biased towards the expected added value of the use of technology (cfr first discussion issue)**
- **The hospitals use informed consent form with regard to robot-assisted surgery.**
- **Appropriate use of the robot requires a surgeon learning curve (as for any new surgical technique).**
- **The robot and the disposables market is a monopoly. The conditions of use, price and the imposed replacement after 10 times use are entirely under the control of one firm.**
- **Currently there is no particular reimbursement for robot-assisted surgery and the use of the device-dependent disposables: the reimbursement is the one applicable for general surgical interventions with a supplement for endoscopy.**
- **If a patient consents to a robot-assisted intervention, in a majority of hospitals the patient has to pay an out-of-pocket sum for the robot-assisted procedure (typically around €1200) Some private health insurances do reimburse these additional charges for the patient.**
- **In Belgium there is a demand from professionals (i.c. urologists) to create a specific (higher) reimbursement for robot-assisted surgery**

The ethical problem:

1. What would be ethically required to inform the patient?
   - What kind of information?
     - Should information be given on alternative procedures (and the respective risks and difference in rehabilitation?
     - Should information be provided on the experience of the surgeon with the use of the device?
   - In which form should information be provided?
   - On what ethical grounds/theories/principles?
2. What can one reasonably expect –on ethical grounds- on "content" and "procedural" rules regarding the informed consent form?

Robot-assisted surgery

Information sheet
Ethical expert panel: autumn 2008
Issue 2: trust and professional responsibilities

Key points (see also general documentation sheet):

- **Clear lack of evidence on the added value of robot-assisted surgery compared to more conventional surgery (open or laparoscopic).**
- **Robots for robot-assisted surgery are currently in use in approximately 25 Belgian hospitals, mainly for interventions in urology (mainly radical prostatectomy)**
- **"Technology push" setting in which patients are to large extent positively biased towards the expected added value of the use of technology (cfr first discussion issue)**
- **The hospitals use informed consent form with regard to robot-assisted surgery**
- **Appropriate use of the robot requires a surgeon learning curve (as for any new surgical technique)**
- **The robot and the disposables market is a monopoly. The conditions of use, price and the imposed replacement after 10 times use are entirely under the control of one firm.**
- **Currently there is no particular reimbursement for robot-assisted surgery and the use of the device-dependent disposables: the reimbursement is the one applicable for general surgical interventions with a supplement for endoscopy.**
- **If a patient consents to a robot-assisted intervention, in a majority of hospitals the patient has to pay an out-of-pocket sum for the robot-assisted procedure (typically around €1200) Some private health insurances do reimburse these additional charges for the patient.**
- **In Belgium there is a demand from professionals (i.c. urologists) to create a specific (higher) reimbursement for robot-assisted surgery**

The ethical problem:

1. Can one expect that patients are capable and informed enough to make them personally responsible for making informed choice between robot-assisted surgery and regular surgery (open or laparoscopic)?
2. What can one "ethically" expect from the medical professionals (medical deontology), in their behaviour regarding the use of robot-assisted surgeries? (Cfr the first-order principles often used in bio-ethics: (1) respect for autonomy; (2) beneficence; (3) nonmaleficence; and (4) justice).
    - Is it ethically acceptable to "impose" or lead patients to the use of robot-assisted surgery?
    - What is the ethical border between "personal choice" and "professional coaching" of the patient? (based on what ethical argument)
    - Which role should the physician play /take up (responsibility)? Should one approach/inform/ coach different patients in different ways?
    - Is "trust" an issue to be considered in the context of medical robot-assisted surgery?
        - Can one expect that the "trust-relationship" between patient and medical professional influences the choice for robot-assisted surgery or more conventional alternatives?

- To what extent is the dependency relation between patient and professional an ethical issue?
- Is "Trust" a tool to reduce the need for a patient to search and assess all necessary information to make choices?
- When is a "trustee" working in the best interest of the trustor? Can this be assessed?
- How can interests of trustees (e.g. "toys for boys", technological and clinical innovation, financial interests,…) and capabilities of trustor (e.g. knowledge, dependency, literacy, …) be managed and balanced in practical decisions?

Robot-assisted surgery

Information sheet
Ethical expert panel: autumn 2008
Issue 3: reimbursement

Key points (see also general documentation sheet):

- **Clear lack of evidence on the added value of robot-assisted surgery compared to more conventional surgery (open or laparoscopic).**
- **Robots for robot-assisted surgery are currently in use in approximately 25 Belgian hospitals, mainly for interventions in urology (mainly radical prostatectomy).**
- **"Technology push" setting in which patients are to large extent positively biased towards the expected added value of the use of technology (cfr first discussion issue)**
- **The hospitals use informed consent form with regard to robot-assisted surgery.**
- **Appropriate use of the robot requires a surgeon learning curve (as for any new surgical technique).**
- **The robot and the disposables market is a monopoly. The conditions of use, price and the imposed replacement after 10 times use are entirely under the control of one firm.**
- **Currently there is no particular reimbursement for robot-assisted surgery and the use of the device-dependent disposables: the reimbursement is the one applicable for general surgical interventions with a supplement for endoscopy.**
- **If a patient consents to a robot-assisted intervention, in a majority of hospitals the patient has to pay an out-of-pocket sum for the robot-assisted procedure (typically around €1200) Some private health insurances do reimburse these additional charges for the patient.**
- **In Belgium there is a demand from professionals (i.c. urologists) to create a specific (higher) reimbursement for robot-assisted surgery.**

The ethical problem:

3. Would it be an ethically required and/or ethically acceptable to develop an additional conditional payment (and reimbursement) within the national health insurance system (using public resources)?
4. What "conditions" should be defined if this procedure is used?
    - Considering the knowledge on learning curves, is any service or hospital entitled or can one set conditions regarding:
        - The number of surgeons performing and the number of patients undergoing robot-assisted surgery.
        - A minimal number of operations per surgeon to guarantee skills
        - Recognition of the hospital in an oncology programme
    - Limit to a very specific surgical indication (example prostatectomy)
    - Give a clear and precise description of the technology (ic the type of robot)
    - Imposing the hospitals-surgeons to participate in an electronic registration of surgical activities and patient characteristics & outcomes.
    - Other …

5. Is it ethically acceptable to 'de facto' pay with public resources a manufacturer in monopoly position that is setting stringent conditions on the use of the robot and is not opening up its market of disposables?
    - Would it –inversely- be just from a social justice perspective to deny the right for reimbursement of a technology for which the patient is now charged additional out-of-pocket payments (knowing that private insurers start to reimburse, anyhow)
6. Are there any other ethical dilemmas in this question on reimbursement?

Background information Ad 1:

- A conditional payment & reimbursement would be possible within article 35 of the Belgian nomenclature: Category 5 of article 35 (implants/technologies) of the nomenclature is used for specific clinical indication fields and/or connected to the obligatory evaluation of the technology.
    - Article 35 (category 5 implants) allows to define particular conditions for a temporary payment and reimbursement of the technology: the payment and reimbursement is organized within an agreement stipulating the indication field, the evaluation procedure and organizational prerequisites
    - It is a quick "administrative" procedure, not requiring a publication in the "Belgisch staatsblad/Moniteur belge"?
    - This article is used as a tool to bridge the problem of "no payment and reimbursement at all". By means of a convention a "conditional and time limited reimbursement" is developed, with an obligation to evaluate and (electronically) register the activities and outcomes of the use of the technology. This technique is considered as a tool to allow for the introduction of new technologies within the framework of the public health insurance system. The procedure allows the NIHDI (RIZIV/INAMI) to bridge the period in which there is a lack of evidence on effectiveness and cost-effectiveness of a technology.
    - The time period is generally defined as a 2 or 3 year period.
    - An agreement holds generally that a forfait (lump sum) of 75% is paid, with the clear agreement that the patient is not additionally charged.

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