

SUMMARY

RENAL CANCER IN ADULTS: DIAGNOSIS, TREATMENT AND FOLLOW-UP



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■ FOREWORD

Renal cancer is a rather discreet cancer. Not the most common, not so rare: in Belgium, 1 660 new cases were reported in 2012, with a preference for men. Not the kindest but not the most aggressive either: with a five-year survival rate beyond 70%, it closes the top 10 of cancers with the best prognosis. Discreet in its symptomatology: painless, it is often discovered fortuitously, on ultrasound or x-rays performed for other reasons.

This clinical practice guideline summarizes the current scientific knowledge: how to tackle the diagnostic work-up and how to choose the optimal treatment. New surgical techniques, less invasive and more conservative, emerged, which reduce the burden of the intervention and postoperative pain. But the patient will be well advised to end up in the hands of well-trained surgeons to these particular techniques.

For patients with a metastatic disease, these curative surgeries are no longer conceivable. For them, the therapeutic arsenal is rapidly expanding, with promising developments in the field of targeted molecular therapies. Provided that they are actually used in a well-targeted way... because their long list of side effects and their exorbitant price make them absolutely incompatible with an indiscriminate use.

For patients who end up requiring palliative care, the systematic analysis of the scientific literature allows to propose with confidence specific interventions that will increase their quality of life, much better than therapeutic obstinacy, which is often doing more harm than good.

All this without forgetting that, at each stage, informing patients and taking into account their preferences must be at the core of all decisions, if we want to ensure an optimal treatment that fits with their life choices ... particularly at a time life when the days seem numbered.

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■ ABSTRACT

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1. INTRODUCTION

'Renal cell carcinoma (RCC) represents 2-3% of all cancers, with the highest incidence occurring in Western countries. During the past two decades, there has been an annual increase of about 2% in incidence in Europe, although in Denmark and Sweden a continuing decrease has been observed.'¹

In 2012, 1 060 male cases of renal cancer were registered at the Belgian Cancer Registry, corresponding to a crude incidence rate of 19.6 per 100 000 men per year and an age-standardized incidence rate of 15.8 per 100 000 men per year (European standard population). In the female population, 600 cases were registered, corresponding to a crude incidence rate of 10.7 per 100 000 women per year and an age-standardized incidence rate of 7.5 per 100 000 per year (European standard population). Incidence increases with age, with a peak incidence of 80.3 per 100 000 per year for men between 75 and 80 and 45.2 per 100 000 women per year for women between 80 and 85 (Source: <http://www.kankerregister.org>).

'Renal cell carcinoma is the commonest solid lesion of the kidney and accounts for approximately 90% of all kidney malignancies. It comprises different types with specific histopathological and genetic characteristics. Risk factors include lifestyle, such as smoking, obesity, and hypertension. Having a first-degree relative with kidney cancer is also associated with an increased risk of RCC. Due to the increased detection of tumours by imaging techniques such as ultrasound (US) and computed tomography (CT), the number of incidentally diagnosed RCCs has increased. These tumours are more often smaller and of lower stage.

2. OBJECTIVES AND SCOPE OF THIS GUIDELINE

The aim of this guideline is to formulate recommendations for health care providers based on the current evidence on diagnosis, treatment and follow-up of adult patients with renal cancer.

This guideline focuses on the diagnosis, staging, treatment and follow-up of patients with confirmed renal cancer. It does not deal with cost-effectiveness. Screening for and prevention of renal cancer are out of scope.



3. METHODS

3.1. Systematic review of the literature

A search for clinical guidelines was carried out in several databases and institutional websites (OVID Medline, the National Guideline Clearinghouse and the GIN database). The search for systematic reviews, meta-analyses and primary studies was carried out in OVID MEDLINE, Embase and the Cochrane Library (Cochrane Database of Systematic Reviews, DARE and HTA database). Two independent researchers performed the selection, the quality appraisal and the data extraction of the studies. The analysis followed a hierarchical approach:

1. Extraction of the data from the systematic reviews and meta-analyses; in the absence of high-quality systematic reviews and meta-analyses, clinical guidelines of high quality were considered as a starting point.
2. Search for the most recent primary studies to complete the evidence found in the previous step (randomised and prospective controlled trials).

The search covered the period from 2009 to 2015.

3.2. Formulation and validation of the recommendations

Based on the retrieved evidence, the first draft of recommendations was prepared by a small working group (KCE experts and Guideline Development Group (GDG) members). This first draft was, together with the evidence tables, circulated to the guideline development group 2 weeks prior to the face-to-face meetings (October 10, 2014; March 27, 2015; April 28, 2015). Recommendations were changed if important new evidence supported this change. Based on the discussion meetings a second draft of recommendations was prepared and once more circulated to the guideline development group for final approval.

To determine the level of evidence and strength of recommendation, the GRADE methodology was followed (Tables 1 & 2). The strength of recommendations depends on a balance between all desirable and all undesirable effects of an intervention (i.e. net clinical benefit, quality of available evidence, values and preferences, and estimated cost (resource utilization). For this guideline, no formal cost-effectiveness study was conducted. We did not use GRADE for diagnostic clinical questions because the approach is not mature and there is no consensus on how to apply it for diagnosis-related issues.

Globally, 15 experts of the GDG were involved in the evaluation of the clinical recommendations. All invited panellists received the scientific reports for all research questions and were asked to indicate if they agreed or did not agree with the recommendation (the panellists were also able to answer 'not applicable' if they were not familiar with the underlying evidence); this was done using an online survey. If panellists disagreed with the recommendation, they were asked to provide an explanation supported by appropriate evidence. Scientific arguments reported by these experts were used to adapt the formulation or the strength of the clinical recommendations. Patient representatives also played a key role ensuring that patient views and experiences inform the group's work.

The recommendations prepared by the GDG were circulated to professional associations. Each association was asked to assign one or two key representatives to act as external reviewers of the draft guideline. All expert referees made declarations of interest.

Finally, the current guideline was reviewed prior to its publication by 3 independent validators (cf. names in the colophon).

Declarations of interest were officially recorded.

**Table 1 – Levels of evidence according to GRADE^a**

Quality level	Definition	Methodological Quality of Supporting Evidence
High	We are very confident that the true effect lies close to that of the estimate of the effect.	RCTs without important limitations or overwhelming evidence from observational studies.
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies.
Low	Our confidence in the effect estimated is limited: the true effect may be substantially different from the estimate of the effect.	RCTs with important limitations or observational studies or case series.
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect.	

Table 2 – Strength of recommendations according to GRADE^b

Grade	Definition
Strong	The desirable effects of an intervention clearly outweigh the undesirable effects (<i>the intervention is to be put into practice</i>), or the undesirable effects of an intervention clearly outweigh the desirable effects (<i>the intervention is not to be put into practice</i>).
Weak	The desirable effects of an intervention probably outweigh the undesirable effects (<i>the intervention probably is to be put into practice</i>), or the undesirable effects of an intervention probably outweigh the desirable effects (<i>the intervention probably is not to be put into practice</i>).

^a Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011;64(4):401-6.

^b Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. Going from evidence to recommendations.[Erratum appears in BMJ. 2008 Jun 21;336(7658):doi:10.1136/bmj.a402]. BMJ. 2008;336(7652):1049-51.



4. CLINICAL RECOMMENDATIONS

The details of the evidence used to formulate the recommendations and best practice below are available in the scientific report and its supplements. The tables follow the sequence of the chapters of the scientific report.

4.1. Diagnosis

Best practices

The use of the current TNM classification system is recommended.

The use of grading systems and classification of renal cell carcinoma subtype is recommended.

The patient must have the opportunity to be fully informed about his condition, the treatment options, and consequences. Information should be correct, communicated in a clear and unambiguous way and adapted to the individual patient. Patient preferences should be taken into account when a decision on a treatment is taken. Special attention should be given to breaking bad news and coping with side effects.

Psychosocial support should be offered to every patient, from diagnosis on.

4.1.1. Contrast-enhanced CT

Recommendations

- Contrast-enhanced multi-phasic abdominal CT is recommended for the diagnosis and characterization of patients with a renal mass. In case of contraindication to iodine contrast injection, MRI can be used as an alternative.
- Contrast-enhanced multi-phasic abdominal CT or MRI are the most appropriate imaging modalities for renal mass staging prior to surgery.
- For a tumour $\geq T2$ or $\geq N1$ or M1 a contrast-enhanced CT of the thorax is recommended.

4.1.2. Bone scan

Recommendation

- Bone scan is not routinely recommended in the absence of skeletal symptoms or elevated alkaline phosphatase.



4.1.3. Brain imaging

Recommendation

- Brain imaging is not routinely recommended in the absence of symptoms.

4.1.4. PET/CT

Recommendation

- PET/CT is not routinely recommended in the diagnosis, staging and follow-up of renal cell carcinoma.

4.1.5. Biopsy

Recommendation

- Renal tumour biopsy (preferably with a coaxial technique) is recommended before ablative therapy and systemic therapy in the absence of previous pathology.

4.2. Prognosis and prediction of treatment effectiveness

Recommendations

- Prognostic systems are recommended in metastatic disease to evaluate survival.
- In localized disease, the use of integrated prognostic systems or nomograms can be considered for prognosis in addition to TNM.
- No molecular prognostic marker is currently recommended for routine clinical use.



4.3. Treatment of localized renal cancer

4.3.1. Surgery

Recommendations	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none"> Surgery with curative intent is recommended in patients with localized renal tumour. 	Strong	Very low
<ul style="list-style-type: none"> If technically feasible, laparoscopic technique is preferred above open surgery when radical nephrectomy is required. 	Weak	Moderate
<ul style="list-style-type: none"> Partial nephrectomy can be performed, either with an open or laparoscopic approach, the latter being preferably performed in centres with laparoscopic expertise. 	Strong	Very low
<ul style="list-style-type: none"> Laparoscopic radical nephrectomy should not be performed in patients with T1 tumours for whom partial nephrectomy is indicated. 	Strong	Very low
<ul style="list-style-type: none"> Partial nephrectomy is recommended in patients with T1a renal tumours. 	Strong	Very low
<ul style="list-style-type: none"> Partial nephrectomy should be favoured over radical nephrectomy in patients with T1b renal tumour, whenever technically feasible. 	Strong	Very low
<ul style="list-style-type: none"> When partial nephrectomy is not an option for T1 and T2 renal carcinoma, radical nephrectomy should be performed. 	Strong	Low
<ul style="list-style-type: none"> Laparoscopic radical nephrectomy is recommended for patients with T2 tumours and localized renal masses not treatable by nephron-sparing surgery. 	Strong	Low
<ul style="list-style-type: none"> Routine removal of the adrenal gland during (partial or radical) nephrectomy is not recommended in the absence of clinical evidence of invasion of adrenal gland. 	Strong	Very low
<ul style="list-style-type: none"> Lymph node dissection (lymphadenectomy) should not be performed routinely in patients with a localized renal tumour without clinical evidence of lymph node invasion. 	Strong	Low
<ul style="list-style-type: none"> In patients with clinically enlarged lymph nodes, lymph node dissection can be performed for staging purposes or local control. 	Weak	Low
<ul style="list-style-type: none"> Embolization is not routinely recommended before a nephrectomy. 	Strong	Low



4.3.2. Management of RCC complicated with caval thrombus

Recommendations	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none">Excision of the kidney tumour and caval thrombus is recommended in patients with non-metastatic renal cell carcinoma.	Strong	Very low
<ul style="list-style-type: none">To ensure optimal care, patients with a supradiaphragmatic tumour thrombus should be treated in a treatment centre with expertise in cardiopulmonary surgical-technical protocols.	Strong	Very low

4.3.3. Alternative to surgery

Recommendation	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none">Active surveillance of small renal masses can be offered in selected groups of patients: frail elderly and/or patients with comorbidity.	Weak	Low

4.3.4. Ablative therapy

Recommendation	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none">Radiofrequency ablation and cryoablation can be a treatment option in a selected group of patients: frail elderly and/or comorbid patients with small renal masses. For other patients groups, partial nephrectomy is recommended.	Weak	Very low

4.3.5. Adjuvant treatment

Recommendation	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none">Adjuvant therapy is not recommended outside clinical trials.	Strong	Very low



4.4. Treatment of local recurrence/ metastases

4.4.1. Surgery

Recommendation	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none"> Cytoreductive nephrectomy can be considered in patients with metastatic renal cell carcinoma. 	Weak	Low

4.4.2. Systemic treatments

Recommendations	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none"> Cytotoxic agents are not recommended in patients with clear cell metastatic renal cell carcinoma. 	Strong	High
<ul style="list-style-type: none"> Monotherapy with IFN-α or high-dose bolus IL-2 is not routinely recommended as first-line therapy in metastatic renal cell carcinoma but can be used in selected patients. 	Strong	High
<ul style="list-style-type: none"> Sunitinib or Pazopanib is recommended as first-line therapy for clear cell metastatic renal cell carcinoma. 	Strong	Low
<ul style="list-style-type: none"> Bevacizumab + IFN-α is recommended as first-line therapy for metastatic renal cell carcinoma in favourable-risk and intermediate-risk clear-cell renal carcinoma. <i>Note: the conditions for a reimbursement by the health insurance are:</i> <ol style="list-style-type: none"> at least one grade 3 or 4 adverse event due to sunitinib; the treatment with sunitinib was stopped for at least 4 weeks; patient has no history of arterial thromboembolic disease or uncontrolled hypertension with standard treatment. <i>In addition, the reimbursement role requires that treatment must be stopped in case of tumour progression assessed by CT-Scan or MRI after 8 weeks of treatment.</i> 	Strong	Moderate
<ul style="list-style-type: none"> Temsirolimus is recommended as a first-line treatment in poor-risk renal cell carcinoma patients. 	Strong	Moderate
<ul style="list-style-type: none"> Sorafenib can be considered as second-line treatment in clear cell metastatic renal cell carcinoma. 	Strong	High
<ul style="list-style-type: none"> Pazopanib, sunitinib or sorafenib can be considered in metastatic renal cell carcinoma patients previously treated with cytokines (IFN-α, IL-2). 	Strong	Low



<ul style="list-style-type: none"> Everolimus can be considered in metastatic renal cell carcinoma patients previously treated with Vascular endothelial growth factor (VEGF)-pathway targeted therapy (<i>i.e. bevacizumab, sunitib, sorafenib,...</i>) or cytokines (<i>IFN-α, IL-2</i>). 	Strong	Low
<ul style="list-style-type: none"> Axitinib is recommended in metastatic renal cell carcinoma patients previously treated with VEGF-pathway targeted therapy or cytokines. <i>Note: Axitinib is only reimbursed after a failure of first line treatment with TKI or cytokine.</i> 	Strong	Low
<ul style="list-style-type: none"> Everolimus or sorafenib can be considered in third-line therapy. 	Weak	Very low

4.5. Palliative care

Additional information regarding the overall cancer population can be found in KCE report 211 (Supportive treatment for cancer – Part 3: Treatment of pain: most common practices) and KCE reports 115 (Organisation of palliative care in Belgium).

Recommendation	Strength of Recommendation	Level of Evidence
<ul style="list-style-type: none"> Embolization can be considered for palliative approach in inoperable patients or patients with metastatic renal cell carcinoma who suffer from severe local pain or massive haematuria. 	Weak	Low

4.6. Follow-up

Recommendations
<ul style="list-style-type: none"> For low-risk disease (pT1, N0, Nx, M0; R0) no routine imaging follow-up is recommended.
<ul style="list-style-type: none"> Moderate to high-risk patients should undergo baseline chest and abdominal scanning (CT or MRI) within three to six months following surgery with follow-up imaging (CT or MRI) every six months for at least three years and annually thereafter to year five.
<ul style="list-style-type: none"> Patients under active surveillance should undergo cross-sectional abdominal scanning (CT or MRI) within six months of active surveillance initiation to establish a growth rate. Follow-up imaging (US, CT or MRI) is recommended at least annually thereafter.
<ul style="list-style-type: none"> After ablative therapy, patients should undergo cross-sectional scanning (CT or MRI) with and without intravenous contrast unless contraindicated at three and six months to assess treatment success. This should be followed by annual abdominal scans (CT or MRI) thereafter for five years.

Best Practices

Patients with a history of a renal neoplasm presenting with acute neurological signs or symptoms must undergo **prompt** (preferably) MRI or CT scanning of the head or spine based on localization of symptomatology.



5. IMPLEMENTATION AND UPDATING OF THE GUIDELINE

5.1. Implementation

Clinical guidelines provide a tool for care providers to consult at different stages of the patient management pathway: diagnosis, treatment and follow-up. KCE formulates recommendations addressed to specific audiences (clinicians, decision-makers, sickness funds, NIHDI, professional organizations, hospital managers...). KCE is not involved in the decision making process itself, nor in the execution of the decisions.

The implementation of this guideline will be facilitated by the College of Oncology and the professional associations involved in this guideline. The scientific material of this guideline is intended to be disseminated by scientific and professional organisations. They can transform this material into attractive and user-friendly tools tailored to caregivers groups. They will also play a key role by a dissemination that makes use of diverse channels such as websites or sessions of continuing education.

5.2. Monitoring the quality of care

This guideline could be considered as a starting point to develop quality improvement programs that target all caregivers concerned.

It can be used as a tool to support health policies to improve the quality of care, e.g. through the support of actions to increase caregivers' awareness and to improve their practice, or through the development (or revision) of sets of process and outcome quality indicators.

KCE previously recommended to set up an integrative quality system in oncology, covering the development and implementation of clinical practice guidelines, the monitoring of the quality of care with quality indicators, feedback to health care providers and organizations and targeted actions to improve the quality if needed.

Accordingly, supplementing this guideline with an appropriate set of quality indicators would provide an opportunity to systematically assess the quality of renal cancer care delivered in Belgium. However, while quality indicator sets covering the diagnostic and therapeutic options have been developed for other cancer types, this is yet not the case for renal cancer.

5.3. Guideline update

In view of the rapidly evolving evidence, this guideline should be updated every 5 years. If, in the meantime, important new evidence would become available, this should be taken into consideration.



COLOPHON

Title:	Renal cancer in adults: diagnosis, treatment and follow-up – Summary
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Acknowledgements:	Nicolas Fairon (KCE): information specialist
Other reported interests:	<p>Membership of a stakeholder group on which the results of this report could have an impact: Ward Rommel (Kom op tegen Kanker), Elisabeth Van Eycken (BVRO-VBS), Axel Feyaerts (Société Belge d'Urologie)</p> <p>Consultancy or employment for a company, an association or an organisation that may gain or lose financially due to the results of this report: Axel Bex (Advisory Board Pfizer), Bertrand Tombal (Amgen, Astellas Pharma, Bayer, Sanofi, Ferring Pharmaceuticals)</p> <p>Payments to speak, training remuneration, subsidised travel or payment for participation at a conference: Axel Bex (Pfizer symposium October 2014), Nicolaas Lumen (consultance for Ipsen, Janssen, Lilly and Bayer), Bertrand Tombal (Amgen, Astellas Pharma, Bayer, Sanofi, Ferring Pharmaceuticals), Sylvie Rottey (GSK, Pfizer, Bayer, Novartis), Dirk Schrijvers (post ESMO)</p> <p>Presidency or accountable function within an institution, association, department or other entity on which the results of this report could have an impact: Elisabeth Van Eycken (Kankerregister), Nicolaas Lumen (Board member BAU working group oncology), Geert Villeirs (president Belgische Vereniging voor Radiologie)</p> <p>Participation in scientific or experimental research as an initiator, principal investigator or researcher: Axel Bex (EORTC 30073 Surttime study, partially sponsored by Pfizer), Sebastien Hotte (grant-in-aid for Novartis in a trial using dovitinib for head and neck cancer), Bertrand Tombal (Amgen, Astellas Pharma, Bayer, Sanofi, Ferring Pharmaceuticals), Dirk Schrijvers (studies about renal cell carcinoma)</p>
Layout:	Ine Verhulst, Joyce Grijseels

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- The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.
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Publication date: 05 October 2015
Domain: Good Clinical Practice (GCP)
MeSH: Kidney Neoplasms, Practice guidelines
NLM Classification: WJ 358
Language: English
Format: Adobe® PDF™ (A4)
Legal depot: D/2015/10.273/85

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How to refer to this document?

Benahmed N, Robays J, Stordeur S, Gil T, Joniau S, Lumen N, Renard L, Rorive S, Schrijvers D, Tombal B, Van den Eynden B, Villeirs G, Rottey S. Renal cancer in adults: diagnosis, treatment and follow-up – Summary. Good Clinical Practice (GCP) Brussels: Belgian Health Care Knowledge Centre (KCE). 2015. KCE Reports 253Cs. D/2015/10.273/85.

This document is available on the website of the Belgian Health Care Knowledge Centre.