

HYPERBARIC OXYGEN THERAPY FOR CHRONIC WOUNDS

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■ KEY MESSAGES

- ➔ Hyperbaric oxygen therapy (HBOT) is the administration of pure oxygen (100%) at pressures greater than atmospheric pressure in a compression chamber. By increasing partial pressure of oxygen to hypoxic wound tissues, HBOT is considered as an adjuvant treatment for chronic ulcers of the lower limb.
- ➔ According to a review published in February 2015 by the Cochrane Collaboration, HBOT significantly improved, in diabetic patients with foot ulcers, the ulcer healing in the short term (up to 6 weeks) but not in the long term. HBOT did not allow to reduce the rate of major amputations in this patient group. In venous ulcers, HBOT may reduce the size of wounds. Overall, safety of HBOT could not be assessed because most trials did not report on major adverse events.
- ➔ The conclusions of the Cochrane's review are in line with those of a previous KCE report published in 2008¹.



■ SUMMARY OF THE PUBLICATION

- *Kranke P, Bennett MH, Martyn-St James M, Schnabel A, Debus SE, Weibel S. Hyperbaric oxygen therapy for chronic wounds. Cochrane Database of Systematic Reviews 2015, Issue 6. Art. No.: CD004123. DOI: 10.1002/14651858.CD004123.pub4..*

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Quality of the publication

Two KCE researchers independently appraised the quality of this review using the AMSTAR tool. The score obtained by the review is 9/11.

Context

The objective of this Cochrane review was to assess the evidence of the benefits and harms of adjunctive hyperbaric oxygen therapy (HBOT) for treating chronic ulcers of the lower limb that failed to heal with other therapeutic strategies.

HBOT is the administration of a 100% oxygen atmosphere at pressures greater than atmospheric pressure in a compression chamber, which allows to deliver a greatly increased partial pressure of oxygen to the hypoxic wound tissues.

This review covered chronic wounds associated with diabetes mellitus, peripheral arterial and venous disease and pressure-related ulcers.

The main outcomes used in the review were proportion of ulcers healed and proportion of people undergoing major amputation (amputation above the ankle). In addition, time to complete healing, wound size reduction, minor amputation rate, quality of life, transcutaneous oxygen tensions, recurrence rate and adverse events were considered as secondary outcomes.

Method

From inception up to February 2015, several databases (Cochrane Wounds Group Specialised Register, CENTRAL, MEDLINE, EMBASE, EBSCO CINAHL) were systematically searched for randomized controlled trials (RCTs).

The quality of the included RCTs was appraised using the Cochrane risk of bias assessment tool. The level of evidence was assessed by means of GRADE.

What is KCE has read for you?

KCE has read for you synthesises a recently published high-quality systematic review or health technology assessment with relevance for the Belgian health system.

The original publication was appraised and contextualised by KCE researchers.

KCE has read for you is not based on original research conducted by KCE.

More details on methodology can be found on the KCE website

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This document includes:



- **Key findings** of the publication under evaluation
- **A contextualisation** within the Belgian healthcare system



Not included:

- Recommendations
- Detailed descriptions



Trustworthy original publication

The methodological quality of the systematic review was assessed with the AMSTAR tool

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Results

Twelve trials, published between 1992 and 2014, formed the body of evidence. Among those, ten trials were conducted in patients with diabetic ulcers, one in patients with venous ulcers and a last one in a mixed ulcers group. No eligible trials were found for the use of HBOT for arterial and pressure ulcers.

The overall risk of bias of these RCTs was judged to be high, due to small samples sizes, featuring diverse wound characteristics and because of discrepancies in trial reporting and in methods.

Efficacy

Diabetic ulcers

➔ Healing rate :

- At 6 weeks (5 trials; n=205); Risk ratio (RR) [95% CI]: 2.35 [1.19, 4.62]
- At 6 months (2 trials; n=112); RR [95% CI]: 1.70 [0.90, 3.20]
- At 1 year (3 trials; n=212); RR [95% CI]: 9.53 [0.44, 207.76]

➔ Proportion of patients requiring major amputation :

- (5 trials; n=309); RR [95% CI]: 0.36 [0.11, 1.18]

Venous ulcers (1 trial; n=16)

➔ Proportion of ulcers healed at 18 weeks

- RR [95% CI]: 5.00 [0.28, 90.18]

Mixed ulcers (1 trial; n=30)

➔ Proportion of ulcers healed at end of treatment period (30 days);

- RR [95% CI]: 7.0 [0.39, 124.83]

➔ Proportion of patients requiring major amputation;

- RR [95% CI]: 0.2 [0.03, 1.51]

Safety

Five trials only reported on complications or adverse events. Two of them reported there were no complications or adverse events linked to the usage of HBOT. Three trials reported few adverse events such as discomfort in the ear due to the pressure (barotrauma), claustrophobia, ear pain, tinnitus and headache.

Secondary outcomes

Minor amputation was only reported in four trials dealing with diabetic foot ulcers. There was no statistically significant difference in rates of minor amputation with the use of HBOT compared with sham or control (RR [95% CI]: 0.76 [0.19, 3.10]).

Significant wound size reduction in ulcers treated with HBOT was observed in a mixed ulcer population (1 trial, mean difference (MD) [95% CI]: -61.88% [-41.91, -81.85]) after 30 days and in diabetic foot ulcers (MD [95% CI]: -18.10% [-1.40, -34.79]) after 6 weeks. In venous ulcers, the wound size reduction was observed at 30 days (MD [95% CI]: -33.00% [-18.97, -47.03]), but this benefit was no longer observed at 18 weeks (MD [95% CI]: 29.6% [-23.0, 82.02]).

Finally, quality of life was studied in one trial using the 36-Item Short-form Health Survey in patients with diabetic foot ulcers. No statistically significant difference was observed compared with a control group.

Conclusions

Adjuvant HBOT is beneficial for wound healing in patients with diabetic foot ulcers in the short term (6 weeks) but not in the long term (≥ 1 year). Neither was there a statistically significant difference in amputation rate between the HBOT group and the control group. Finally, no informative conclusion regarding chronic wounds with other underlying pathologies could be drawn due to the scarcity of evidence in the area.

BELGIAN CONTEXT

The conclusions of the above mentioned review are in line with those of a previous KCE report¹ published in 2008. In this report, the authors did not recommend HBOT for chronic wounds. In chronic wounds, the lack of evidence was the main reason not to recommend HBOT. 🖱️

In Belgium, HBOT is available in ten civilian and one military hospital centres. In 2004, the Advisory Committee for Hyperbaric Oxygen in Belgium published a list of clinical indications for which HBOT is recommended 🖱️. This list includes ischemic lesions (ulcer or gangrene) without the possibility of revascularization, or lesions persisting after optimal revascularization (diabetic ulcers and chronic critical ischemia in arteriosclerotic patients [level of evidence B]; selected non-healing wounds secondary to inflammatory processes [level of evidence C]).

REFERENCE

- 1. De Laet C, Obyn C, Ramaekers D, Van De Sande S, Neyt M. Hyperbaric Oxygen Therapy: a Rapid Assessment. Health Technology Assessment (HTA). Brussels: Belgian Health Care Knowledge Centre (KCE); 2008. KCE Reports 74C (D/2008/10.273/15)

What is the Cochrane Collaboration?

The Cochrane Collaboration is an international independent network of researchers, healthcare professionals and users of healthcare, carers, and people interested in health that aims to promote evidence-informed health decision-making by producing systematic reviews.

What is GRADE?

GRADE (Grading of Recommendations Assessment, Development and Evaluation) offers a system for rating quality of evidence in, amongst other, systematic review. More information on GRADE can be found in the GRADE website 🖱️ and in the KCE process book 🖱️.

What are the levels of evidence used by Advisory Committee for Hyperbaric Oxygen?

- **Level A:** At least 2 concordant, large, double-blind, controlled randomized studies with no or little methodological bias.
- **Level B:** Double-blind controlled, randomized studies but with methodological flaws; studies with only small samples, or only a single study.
- **Level C:** Consensus opinion of experts.