Hyperbaric Oxygen Therapy for Diabetes-Related Chronic Wounds of the Lower Limb: OHTAC Recommendation

Ontario Health Technology Advisory Committee

July 2014
Suggested Citation

This report should be cited as follows:

TBA

Permission Requests

All inquiries regarding permission to reproduce any content in Health Quality Ontario reports should be directed to EvidenceInfo@hqontario.ca.

How to Obtain OHTAC Recommendation Reports From Health Quality Ontario

All OHTAC reports are freely available in PDF format at the following URL: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ohtac-recommendations.

Conflict of Interest Statement

All authors in the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.
About Health Quality Ontario

Health Quality Ontario (HQO) is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario’s health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with advisory panels, clinical experts, developers of health technologies, scientific collaborators, and field evaluation partners to provide evidence about the effectiveness and cost-effectiveness of health interventions in Ontario.

To conduct its systematic reviews of health interventions, the Evidence Development and Standards branch examines the available scientific literature, making every effort to consider all relevant national and international research. If there is insufficient evidence on the safety, effectiveness, and/or cost-effectiveness of a health intervention, HQO may request that its scientific collaborators conduct economic evaluations and field evaluations related to the reviews. Field evaluation partners are research institutes focused on multicentred clinical trials and economic evaluation, as well as institutes engaged in evaluating the safety and usability of health technologies.

About the Ontario Health Technology Advisory Committee

The Ontario Health Technology Advisory Committee (OHTAC) is a standing advisory subcommittee of the Board of Directors of Health Quality Ontario. Based on the evidence provided by Evidence Development and Standards and its partners, OTHAC makes recommendations about the uptake, diffusion, distribution, or removal of health interventions within the provincial health system. When making its recommendations, OHTAC applies a unique decision-determinants framework that takes into account overall clinical benefit, value for money, societal and ethical considerations, and the economic and organizational feasibility of the health care intervention in Ontario.

Publishing Health Quality Ontario Research

When the evidence development process is nearly completed, draft reviews, reports, and OHTAC recommendations are posted on HQO’s website for 21 days for public and professional comment. For more information, please visit: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/professional-and-public-engagement-and-consultation.

Once finalized and approved by the Board of Directors of Health Quality Ontario, the research is published as part of the Ontario Health Technology Assessment Series, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding OHTAC recommendations and associated reports are also published on the HQO website. Visit http://www.hqontario.ca for more information.

When sufficient data are available, OHTAC tracks the ongoing use of select interventions it has previously reviewed, compiling data by time period and region. The results are published in the Ontario Health Technology Maps Project Report.

Disclaimer

This report was prepared by the Evidence Development and Standards branch at Health Quality Ontario or one of its research partners for the Ontario Health Technology Advisory Committee and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to HQO. The analysis may not have captured every relevant publication and relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.

Table of Contents

Background ........................................................................................................................................... 5
Main Findings......................................................................................................................................... 6
Conclusions........................................................................................................................................... 7
Decision Determinants .......................................................................................................................... 8
OHTAC Recommendations .................................................................................................................. 9
References............................................................................................................................................. 10
Background

Patients with diabetes are at increased risk of foot ulcers, which can become chronic, result in decreased quality of life, increased health care resource utilization, amputation, or even death. The standard of care for treating diabetic foot ulcers includes debridement, antibacterials, dressings, antibiotics to control infection, and off-loading. Amputation is the next course of treatment in the event that these interventions fail.

Hyperbaric oxygen therapy (HBOT) has been suggested as an adjunct therapy to standard wound care for improved wound healing and the prevention of amputation. However, there is limited high-quality evidence (in the form of large prospective, randomized, controlled trials) of the efficacy of HBOT for those indications. Despite this lack of evidence, HBOT is being used increasingly as an adjunctive treatment for diabetic ulcers. Physicians in Ontario are reimbursed under the current Ontario Health Insurance Plan (OHIP) payment schedule for use of HBOT to treat diabetic ulcers.

The Programs for Assessment of Technologies in Health (PATH) Research Institute, a research partner of Health Quality Ontario, published a systematic review (1) of the clinical evidence from both randomized controlled trials (RCTs) and observational studies of HBOT for adults with non-healing diabetic ulcers of the lower limb to answer the following research question:

- Does adjunctive HBOT decrease the rate of amputation, improve wound healing, safety, and quality of life compared with standard care alone (i.e., debridement, dressings, antibiotics, and minimization of pressure on the wound) or sham?
Main Findings

- The systematic review included six RCTs and six comparative observational studies that provided data on the efficacy of using HBOT compared with standard wound care for the treatment of non-healing ulcers of the lower limb in patients with diabetes.
- With respect to the RCT evidence on efficacy of HBOT:
  - There was no significant difference in major amputations rates between the two groups (RR = 0.40; 95% CI, 0.07–2.23; p = .29). The relative risk reduction was 77 percent and the number needed to treat to avoid one amputation was 5.
  - There was no significant difference in minor amputation between the two groups (RR = 0.79; 95% CI, 0.19–3.30; p = .75).
  - There was a non-significant reduction in the proportion of unhealed wounds with HBOT treatment (RR = 0.54; 95% CI, 0.26–1.13; p = .10).
- With respect to the comparative observational studies of effectiveness of HBOT:
  - There was a significant reduction in the rate of major amputation for patients who underwent HBOT (RR = 0.39; 95% CI, 0.21–0.73; p = .003).
  - There was a significant reduction in the rate of minor amputation (RR = 0.23; 95% CI, 0.09–0.59; p = .002).
  - There was a significant reduction in the proportion of unhealed ulcers (RR = 0.24; 95% CI, 0.13–0.43; p < .00001).
- With respect to safety, there was limited reporting of adverse events in the available studies. One RCT measured health-related quality of life and found statistically significant differences in favour of HBOT in terms of general health (p = .012) and vitality (p = .018). HBOT-treated patients also showed a significant improvement in depression scores (p = .011).
Conclusions

- There is limited evidence in the form of high-quality RCTs and observational studies that suggests that HBOT significantly reduces the rate of major and minor amputations or improves wound healing in non-healing diabetic ulcers of the lower limb.
- The use of HBOT as a treatment for diabetic foot ulcers has been founded on weak scientific grounds (i.e., few high quality randomized controlled trials).
Decision Determinants

OHTAC has developed a decision-making framework that consists of 7 guiding principles for decision making and a decision determinants tool. When making a decision, OHTAC considers 4 explicit main criteria: overall clinical benefit, consistency with expected societal and ethical values, value for money, and feasibility of adoption into the health system. For more information on the decision-making framework, please refer to the Decision Determinants Guidance Document available at: http://www.hqontario.ca/evidence/evidence-process/evidence-review-process/decision-making-framework.

Based on the decision determinants criteria, OHTAC weighted in favour of clinical efficacy in its recommendations on the use of HBOT for the treatment of non-healing diabetic ulcers of the lower limb.
OHTAC Recommendations

- OHTAC does not recommend the use of hyperbaric oxygen therapy (HBOT) in patients with non-healing diabetic ulcers.
- OHTAC recommends that best-practice wound care be made available to all patients, as well as attention to the quality and accessibility of foot care in Ontario.
- OHTAC is aware of a forthcoming publication based on a field evaluation conducted in Ontario on the effectiveness of HBOT, and is prepared to reconsider its recommendation based on this evidence.
References
