Cost-effectiveness and budget impact of adjunctive hyperbaric oxygen therapy for diabetic foot ulcers
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The study examined the clinical and economic impact of hyperbaric oxygen therapy (HBOT) as an adjunct to standard care, compared with standard care alone, for the treatment of diabetic foot ulcers in a typical 65-year-old patient. The study used both a cost-utility framework and a budget impact analysis. The authors concluded that HBOT was a cost-effective treatment in the Canadian health care setting. Despite the limited reporting of some aspects (most details were presented in the full report), the authors’ conclusions are likely to be robust.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective of the study was to examine the clinical and economic impact of hyperbaric oxygen therapy (HBOT) as an adjunct to standard care, compared with standard care alone, for the treatment of diabetic foot ulcers (DFUs) in a typical 65-year-old patient. The study used both a cost-utility framework and a budget impact analysis. This analysis formed part of a project by the Canadian Agency for Drugs and Technologies in Health, supported by health ministries.

Interventions
The study examined HBOT plus standard care versus standard care alone.

Location/setting
Canada/hospital.

Methods
Analytical approach:
This economic evaluation was based on a published decision model on the treatment of DFUs, which was adapted to the Canadian setting. The time horizon was 12 years. The authors stated that the perspective of the Ministry of Health was adopted.

Effectiveness data:
A systematic review of the literature was undertaken in common bibliographic databases to identify controlled trials comparing the two strategies. The quality of the selected studies was validated using an approach that considered both study design and study performance. The probability of minor or major lower extremity amputations (LEAs) and of healed ulcers with and without adjuvant HBOT, which represented the key clinical outcomes, was taken from 7 clinical trials. The data on mortality after LEAs or unhealed ulcers were obtained from a published study conducted in the USA.

Monetary benefit and utility valuations:
The utility valuations were derived from a published survey of Swedish DFU patients using the EuroQol EQ-5D measure.

Measure of benefit:
The summary benefit measure was the quality-adjusted life-years (QALYs). These were estimated using the decision model. The use of discounting was not stated.
Cost data:
A breakdown of the cost items was not given, the costs being presented as macro-categories. The authors stated that HBOT costs included overhead and amortised machine costs. In addition, the costs of minor LEAs, major LEAs and unhealed ulcers were considered in the analysis. The unit costs and resource quantities were derived from Canadian provincial data supplemented with data from published studies. The costs were in Canadian dollars (CAD). The price year was 2004. The use of discounting was not reported, although it would have been relevant given the long-term horizon of the analysis. In the budget impact analysis, data on the prevalence of DFUs eligible for HBOT were derived from Canadian sources, while information on HBOT came from the Misericordia Hospital in Edmonton and the Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé in Quebec.

Analysis of uncertainty:
The issue of uncertainty was addressed in a sensitivity analysis. First, probability rates were changed to make them more favourable to routine care. Second, the cost of HBOT was increased until the intervention was cost-neutral (the costs of the two strategies were the same). In the budget impact analysis, different assumptions about treatment length were made.

Results
The expected QALYs were 3.64 with HBOT and 3.01 with standard care. The cost of HBOT was CAD 40,695 versus CAD 49,786 for standard care alone. Thus, HBOT was a dominant strategy because it was simultaneously more effective and less expensive than standard care alone.

The sensitivity analysis confirmed the dominance of HBOT. The break-even point for cost-neutrality was observed when the cost of HBOT was above CAD 17,000 (CAD 3,652 in the base-case analysis). This further supports the superior economic profile of HBOT.

The budget impact analysis indicated that the cost of treatment of all prevalent DFU cases in Canada would range from CAD 14.4 million to CAD 19.7 million every year over 4 years. The most influential data were the number of years it would take to treat the group of eligible patients. The analysis also highlighted the substantial investment required compared with the existing capacity (from 19 to 35 new machines).

Authors' conclusions
The authors concluded that HBOT as an adjunct to standard care for the treatment of DFUs was a cost-effective treatment in the Canadian health care setting. The study results support the implementation of HBOT in Canada. However, it was noted that additional HBOT capacity would be needed to adopt this option as the standard of care throughout Canada.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear, the new treatment being compared with standard care. However, the authors did not provide a definition of what they included under the label "standard care". This might be problematic in terms of relevance to other settings, particularly given the variety of technologies (i.e. dressings) available for the treatment of DFUs.

Effectiveness/benefits:
The approach used to identify the clinical estimates was appropriate since the use of a systematic review of the literature ensures the inclusion of the best available evidence. The restriction to clinical trials further enhances the quality of these sources. Most details of the characteristics of these studies were presumably presented in the full report that was published separately. The derivation of the benefit measure was appropriate. The use of patient preferences for utility weights represents a validated approach, although data were taken from Swedish patients; this was acknowledged as a limitation of the analysis.

Costs:
The categories of costs included appear to have been appropriate to the perspective adopted, but a breakdown of the cost items was not given. As in the analysis of the clinical data, the bulk of the analysis was presumably presented in the...
full report. The cost estimates were derived mainly from regional sources, which reflect the typical Canadian accounting system. The authors noted the poor quality of some cost estimates, which represented a drawback to the analysis. The cost estimates were treated deterministically.

Analysis and results:
The use of an incremental analysis to combine the costs and benefits was appropriate. The results of the analysis were presented clearly. The issue of the sensitivity analysis was addressed only with respect to some specific assumptions made in the model. The use of a probabilistic sensitivity analysis would have further clarified some uncertain areas. In general, the authors stated that some of the estimates used in the decision model were derived from foreign studies, which might not be applicable to the Canadian setting.

Concluding remarks:
The quality of the study methodology appears to have been satisfactory, although the authors noted the limitations of some estimates used in the model. The analysis was characterised by limited reporting around some aspects, although this is understandable given that most details were presented in the full report. Nevertheless, the authors' conclusions appear valid.

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Bibliographic details

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
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