The value-based medicine comparative effectiveness and cost-effectiveness of penetrating keratoplasty for keratoconus

Roe RH, Lass JH, Brown GC, Brown MM

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 objective was to perform a cost-effectiveness analysis of penetrating keratoplasty in one eye or both eyes for patients with severe keratoconus. The authors concluded that penetrating keratoplasty was a cost-effective procedure, which compared favourably with other health care interventions across medical specialties. The study was well presented, but had some methodological limitations and the authors' conclusions should be corroborated by further studies.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to perform a cost-effectiveness analysis of penetrating keratoplasty in one eye or both eyes for patients with severe keratoconus.

Interventions
Penetrating keratoplasty was compared against no treatment.

Location/setting
USA/day-care surgical centre.

Methods
Analytical approach:
The analysis was based on a decision tree model with a lifetime horizon. The authors stated that the perspective of the third-party payer was adopted.

Effectiveness data:
The clinical evidence came from a large, retrospective cohort study that was carried out at three university-based corneal referral centres from 1984 to 1988. This included 140 eyes of 123 patients who underwent penetrating keratoplasty. Life expectancy was assumed to be the same in the penetrating keratoplasty patients as in those who received no treatment and it was based on official statistics. The other data were obtained from other retrospective cohort studies on similar patient populations. The key clinical endpoint was the improvement in visual acuity associated with penetrating keratoplasty.

Monetary benefit and utility valuations:
The utility valuations were estimated using time trade-off methodology on the basis of visual acuity improvements derived from published sources.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and were discounted at an annual rate of 3%.

Cost data:
The economic analysis considered the costs of medications (topical corticosteroids, glaucoma medications, and topical antibiotics), high astigmatism, graft failure, cataract requiring surgery, and penetrating keratoplasty. The last item
included the initial consultation, surgeon's fee, facility fee, anaesthesia fee, eye bank charge, postoperative drugs, and follow-up visits. The analysis excluded the costs for contact lenses and spectacles. The source for the resource use data was not clearly reported, but it appeared to be the same study as was used for the clinical effectiveness data. The drug costs were based on average wholesale prices, while other costs were derived from Medicare fee schedules. All costs were in US dollars ($) and a 3% annual discount rate was applied. The price year was 2006.

Analysis of uncertainty:
One- and two-way sensitivity analyses were carried out on the key model inputs, such as the discount rates, utility estimates (varied by published confidence intervals), treatment costs (varied by ± 50%), and graft rejection rates and other complication rates (varied using arbitrary ranges of values). Both the discounted and undiscounted results were presented.

Results
In comparison with no treatment, penetrating keratoplasty led to a gain of 3.05 discounted QALYs (2.50 for the second eye and 5.55 for both eyes) and an additional cost of $5,914 ($5,569 if repeated or performed in the second eye). Thus, the incremental cost per QALY gained with penetrating keratoplasty in the first eye was $1,942 ($2,228 for the second eye and $2,003 for both eyes).

An interesting finding of the sensitivity analysis was that, even in the worst-case scenario that used the most unfavourable utility gains, the incremental cost per QALY was $22,256, and was below the commonly used thresholds for cost-effectiveness. In general, relatively small changes from the base-case results were observed in the other scenarios.

Authors' conclusions
The authors concluded that penetrating keratoplasty was a cost-effective procedure, which compared favourably with other health care interventions across medical specialties.

CRD commentary
Interventions:
No intervention was selected as the comparator to determine the active value of penetrating keratoplasty. Other interventions may have been available for patients with severe keratoconus. The authors justified the exclusion of deep lamellar keratoplasty due to the lack of long-term, validated data.

Effectiveness/benefits:
The clinical evidence was mainly derived from a retrospective study. This study may have had methodological limitations not only due to its retrospective nature, but also because it appears that only patients undergoing penetrating keratoplasty were included. It was, however, based on a relatively large sample, which appears to have been representative of the patient population. Supplementary data were based on other studies, the methodological characteristics of which were not presented. The details of the conversion to utility from vision were reported. QALYs were a valid benefit measure, as the study focused on the impact of the surgical procedure on the quality of life, which is a relevant dimension of health for this patient population.

Costs:
The authors provided extensive information on the items included in the cost analysis and the sources used to derive the unit costs. The exclusion of some cost categories was justified. The price year and the use of discounting were clearly reported. In general, the economic analysis was well presented, but little information on the sources of data on resource consumption was provided. The key cost estimates were varied in the sensitivity analysis.

Analysis and results:
The approach used to combine the costs and benefits was appropriate as an incremental analysis was performed. The costs and benefits of the comparator (no intervention) were not reported and only the incremental impact of penetrating keratoplasty was assessed. A one-way deterministic sensitivity analysis was conducted on some of the model inputs, but a more comprehensive analysis could have confirmed that the findings were robust. The authors acknowledged some of the study limitations that have been reported.
Concluding remarks:
The study was well presented, but had some methodological limitations. The authors’ conclusions should be corroborated by further studies.

Funding
Supported by Research to Prevent Blindness, Inc; the Center for Value-Based Medicine; and the Eye Research Institute.

Bibliographic details

PubMedID
18812762

DOI
10.1097/ICO.0b013e31817bb062

Original Paper URL
http://journals.lww.com/corneajnl/Abstract/2008/10000/The_Value_Based_Medicine_Comparative_Effectiveness.7.aspx

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Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Cost-Benefit Analysis; Evidence-Based Medicine; Health Care Costs; Humans; Keratoconus /pathology /physiopathology /surgery; Keratoplasty, Penetrating /adverse effects /economics /standards; Multicenter Studies as Topic; Quality of Life; Quality-Adjusted Life Years; Retrospective Studies; Severity of Illness Index; Treatment Outcome; Visual Acuity

AccessionNumber
22009100384

Date bibliographic record published
31/03/2009

Date abstract record published
24/02/2010