A cost-effectiveness analysis of delayed sphincteroplasty for anal sphincter injury

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
This was an economic evaluation of primary sphincteroplasty (PS) compared with delayed sphincteroplasty (DS). The authors concluded that PS was more cost-effective than DS, regardless of the time horizon and sensitivity analysis. Both treatments fell below the £10,000 per quality-adjusted life-year (QALY) level, but patients in the PS group gained 35% more QALYs compared with those in the DS group. There were a few limitations to the study, so the authors’ conclusions should be considered with a degree of caution.

Type of economic evaluation
Cost-utility analysis

Study objective
The aim was to determine the economic burden and cost-effectiveness of performing primary sphincteroplasty (PS) compared with delayed sphincteroplasty (DS) for patients with faecal incontinence after anatomical anal sphincter injury.

Interventions
Sphincteroplasty is usually performed as a primary (immediate) procedure in order to treat faecal incontinence resulting from anal sphincter injury. DS can be performed if there is significant trauma or soiling, if the primary procedure has failed, or if the injury was not initially recognised.

Location/setting
UK/hospital.

Methods
Analytical approach:
A Markov model was constructed with time horizons of 10 and 15 years and yearly cycles. The authors stated that a payer’s perspective was used in accordance with the National Institute for Clinical Excellence guidance.

Effectiveness data:
The clinical data were obtained from systematic reviews of the literature and expert opinion. MEDLINE, EMBASE, Ovid, and Cochrane database searches were performed (1980 to 2006), without language restrictions, and a manual search of the article references was also completed. The authors searched for comparative and non-comparative studies. These studies were critically appraised by two authors and some were selected on the basis of published recommendations regarding their inclusion in decision analytic models. Four experts were also consulted. A weighted mean was obtained for each parameter, and ranges from experts were used in the sensitivity analysis. The main clinical outcome was failure rates. These were extracted from 12 studies and two systematic reviews including 880 patients in total (103 received PS, and 777 received DS). No other details of the study designs were reported.

Monetary benefit and utility valuations:
Quality-adjusted life-years (QALYs) were derived from SF-36, Gastrointestinal Quality of Life (GIQL), and Wexner incontinence score data using "validated conversion mathematics". The data were obtained from the selected literature and expert opinion.

Measure of benefit:
The measure of benefit was QALYs. Although, a net health benefits (QALYs) versus willingness to pay (threshold at
£10,000) line graph and incremental cost-effectiveness ratio (ICER) scatter plots were also reported.

Cost data:
The costs included those of the surgical procedure, anorectal physiology, endoanal ultrasound, and outpatient appointments. All costs were based on the British National Health Service reference costs for 2004 to 2005, and were expressed in UK pounds sterling (£).

Analysis of uncertainty:
A one-way sensitivity analysis was performed for all variables. The following scenarios were also run: 10- and 15-year time horizons; a subgroup of patients with obstetric anal sphincter injury (OASI) only, with the lowest plausible range of failure probabilities used for the DS group; and a group of patients under 40 years old, with the lowest range of probability failures used for both the PS and DS groups. Each scenario was run for 10,000 iterations and the ranges were reported, but the probability distributions were not.

Results
Over the 10-year time horizon, with PS, 5.72 QALYs were gained at costs of £2,750 and, with DS, 3.73 QALYs were gained at costs of £2,667, creating an incremental cost-effectiveness ratio (ICER) of £487.09 per QALY.

Over the 15-year time horizon, PS was also associated with more QALYs gained and greater costs, and an ICER of £453.08 per QALY.

The results were similar for the OASI subgroup and the younger than 40 subgroup. The 10,000 simulations showed that, at a willingness to pay of £10,000 per QALY, PS dominated DS as the most cost-effective strategy.

Authors' conclusions
The authors concluded that PS was superior to DS as the most cost-effective strategy, regardless of time horizon, and was robust to manipulation of costs and probabilities within the plausible ranges. Both treatments are under the £10,000 per QALY threshold, but patients in the PS group gained 35% more QALYs compared with those in the DS group.

CRD commentary
Interventions:
The interventions were not adequately described. The procedure was not clear for a delayed sphincteroplasty.

Effectiveness/benefits:
The authors performed systematic reviews of the literature so it is likely that the best available evidence was used. However, the authors did not report the quality of the studies utilised. The methods used (“validated conversion mathematics”) to transform non-preference based instruments, such as the SF-36, the GIQL or the Wexner incontinence score, to utilities and then to QALYs were not clearly explained. It is not clear if the utility methods were consistent. No discount rate was stated for the measure of benefit.

Costs:
The cost categories relevant to the study perspective were included, but the resource use and costs sources were not adequately referenced.

Analysis and results:
The authors clearly presented their results both for the base-case and for the other relevant scenarios and the model was adequately described. A probabilistic sensitivity analysis was also performed, but only for one variable.

Concluding remarks:
There were a few limitations to the study, so the authors’ conclusions should be considered with a degree of caution.

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