Internal limiting membrane peeling versus no peeling for idiopathic full-thickness macular hole: a pragmatic randomized controlled trial


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 study examined the cost-effectiveness of peeling versus no peeling of the internal limiting membrane of the retina in patients with an idiopathic stage two or three, full-thickness macular hole. The authors concluded that peeling seemed to be cost-effective for these patients. The economic data were only partly described, but the methods were valid and the authors’ conclusions appear to be robust.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of peeling versus no peeling of the internal limiting membrane (ILM) of the retina, for patients with an idiopathic stage two or three, full-thickness macular hole.

Interventions
The two strategies were peeling the ILM of the retina versus no peeling. A combined phacoemulsification and pars plana vitrectomy, including detachment and removal of the posterior hyaloid membrane, followed by fluid-to-air exchange and air-to-gas exchange, was performed with or without peeling.

Location/setting
UK and Ireland/hospital.

Methods
Analytical approach:
The analysis was based on one study, with a six-month time horizon. The authors stated that it was carried out from the perspective of the health service.

Effectiveness data:
The clinical analysis was based on a published pragmatic randomised controlled trial, namely the Full-thickness Macular Hole and Internal Limiting Membrane Peeling Study (FILMS), which was carried out at nine participating centres. Of the 217 patients approached, 141 were randomised, with 71 in the peeling group and 70 in the no peeling group (three were excluded before treatment). The median age was 70.30 years for peeling and 70.58 years for no peeling. The proportion of females was 79% for peeling and 65% for no peeling. Participants and optometrists, who undertook the visual function evaluation, were blinded to the treatment allocation. The length of follow-up was six months. The primary endpoint was the Early Treatment Diabetic Retinopathy Study (ETDRS) distance visual acuity score six months after surgery. Various secondary outcomes were considered. Endpoint data were available for 65 patients for peeling and 62 patients for no peeling.

Monetary benefit and utility valuations:
Health-related quality-of-life estimates were calculated from data collected in the clinical trial, using the European Quality of life (EQ-5D) instrument, using the area-under-the-curve method. The EQ-5D responses were valued using UK population tariffs.

Measure of benefit:
Quality-adjusted life-years (QALYs) were used as the summary benefit measure.

Cost data:
The economic analysis included both primary and secondary care services. The resource quantities were estimated from patient questionnaires collected with case report forms during the clinical trial. The unit costs were from NHS published estimates for health care services or interventions, supplemented with study-specific estimates. All costs were in UK pounds sterling (£).

Analysis of uncertainty:
Bootstrapping of the costs, QALYs, and incremental cost per QALY was conducted to investigate uncertainty. Cost-effectiveness acceptability curves were created.

Results
No statistically significant differences in the primary clinical outcome measure (distance visual acuity) were found between the peeling and no peeling groups, but a statistically significant difference in favour of the peeling group was found for macular hole closure at one-month follow-up (not at three and six months).

The mean cost was £2,550 for the peeling group and £2,974 for the no peeling group. The difference of £424 was not statistically significant. The lower costs in the peeling group were due to fewer subsequent surgeries.

The mean unadjusted QALYs were 0.413 for the peeling group and 0.438 for the no peeling group. When adjusted for minimisation factors, the mean difference of 0.002 was not statistically significant.

Based on the bootstrapped estimates, there was a 90% chance of peeling being cost-effective at a threshold of £20,000 per QALY.

Authors' conclusions
The authors concluded that peeling seemed to be cost-effective for patients with idiopathic stage two or three, full-thickness macular hole.

CRD commentary
Interventions:
The selection of the comparators was appropriate as peeling was compared against no peeling, during surgery. These were the two options available for these patients. The authors provided a clear description of each procedure.

Effectiveness/benefits:
The clinical part of the study was satisfactorily carried out. The randomised design of the trial should have ensured high internal validity for the clinical inputs. The pragmatic design assessed the impact of the two strategies in normal clinical practice rather than ideal circumstances. The inclusion and exclusion criteria for the study participants were reported. An imbalance algorithm was used, in allocating treatment, to reduce the differences between groups in trial centre, distance vision in both eyes, stage of the macular hole, duration of symptoms, and lens status. Statistical analyses were carried out to assess the impact of confounding factors on the clinical outcomes. The analysis used the intention-to-treat principle and power calculations defined the sample size. In general, the study groups were comparable at baseline, except for their EQ-5D scores and gender distribution. QALYs were appropriately used as the benefit measure, as quality of life is a relevant outcome for these patients.

Costs:
The authors stated that the perspective of the health care system was adopted, but the categories of costs were not provided. The pragmatic randomised trial should have ensured accurate and detailed data collection. The unit costs were from standard UK sources and statistical analyses of the costs were conducted. The price year was not reported, but the unit costs were from sources that reported the fiscal year 2008 to 2009. In general, the analysis focused on the clinical data and the economic data were not fully reported.

Analysis and results:
The results were clearly reported, especially for the clinical outcomes. A synthesis of the costs and benefits was not explicitly reported, as the differences in costs and QALYs did not reach statistical significance. The uncertainty was appropriately investigated in a bootstrapped analysis, which calculated ranges of values for most of the outcomes. The pragmatic trial should have ensured good external validity, but the results were specific to the UK and cannot be extrapolated to other countries. More details on the economic data would have been useful.

Concluding remarks:
The methods were valid, but the economic data were only partly described. The authors’ conclusions appear to be robust.

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