Cost-effectiveness analysis of PMMA, silicone, or acrylic intra-ocular lenses in cataract surgery in four European countries


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.

Health technology
The authors compared four types of intra-ocular lens (IOL) materials implanted after cataract surgery. The materials compared were hydrophobic acrylic, polymethylmethacrylate (PMMA), hydrophilic acrylic and silicone.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had undergone cataract surgery with phacoemulsification and IOL implantation in the capsular bag. The patients were between 50 and 80 years of age at the time of surgery. Patients with acute post-surgery complications or specific ocular co-morbidities, and thus ineligible for Nd:YAG laser capsulotomy, were excluded.

Setting
The setting was secondary care (surgical centres). The economic analysis was carried out in four European countries (i.e. France, Italy, Germany and Spain).

Dates to which data relate
The effectiveness data were collected on patients who underwent surgery between 1st January 1996 and 31st December 1997. Data on Nd:YAG laser-related complications were derived from studies published between 1984 and 2000. The cost data were derived from sources published between 1996 and 2002. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study, a review and synthesis of published studies and, when data were not available, from expert opinion.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The sample size was not determined in the planning phase of the study. In addition, power calculations were not performed retrospectively. Each centre provided a list of patients who had undergone cataract surgery. Patients from
each centre were randomly selected, based on the type of IOL material used at implantation, in order to achieve even-handed number of IOL material types in each country. The medical records of each patient were reviewed and investigators, or trained clinical research associates, completed equivalent study-dedicated case report forms to ensure that patients met the inclusion and exclusion criteria and had complete follow-up medical record data.

Initially, 14,146 patients were included in the lists of the surgery centres. Of these, 1,952 patients were randomly selected and their medical records were reviewed. Finally a total of 1,525 patients who met the inclusion and exclusion criteria were included in the study. There were 421 patients in the hydrophobic acrylic group, 384 in the PMMA group, 294 in the hydrophilic acrylic group, and 426 in the silicone group. It was reported that 90.2% of patients in the study sample received Nd:YAG laser due to decreased visual acuity, 20.2% due to patients' complaints, and 2.3% to allow for further eye examination. No reasons for Nd:YAG treatment were reported for the remaining 1.9% of patients.

Study design
The analysis was based on a multi-centre (including 16 surgical centres, four per country), retrospective comparative cohort study. Data on the patients were collected for a mean period of 3.2 years. Eighty-five patients had died by the end of the follow-up period.

Analysis of effectiveness
The primary outcomes included:

- the number of patients with PCO in each group,
- the rate of PCO in each group,
- the mean Nd:YAG laser incidence rate, and
- the percentage of patients successfully treated without Nd:YAG therapy.

It appears that all patients included in the study were accounted for in the analysis. It was not reported whether the patient groups were comparable in terms of their demographic and prognostic features. In addition, no adjustments for confounding factors were made.

Effectiveness results
The number of patients with PCO was 37 (PCO rate 8.9%) in the hydrophobic acrylic group, 108 (PCO rate 28.3%) in the PMMA group, 108 (PCO rate 30.0%) in the hydrophilic acrylic group, and 69 (PCO rate 21.6%) in the silicone group.

The mean Nd:YAG laser incidence rate was 7.10 for hydrophobic acrylic, 19.3% for PMMA, 31.10% for hydrophilic acrylic, and 16.20% for silicone.

The clinical success rate (defined as the percentage of patients successfully treated without Nd:YAG therapy) was 92.90% in the hydrophobic acrylic group, 80.70% in the PMMA group, 68.90% in the hydrophilic acrylic group, and 83.80% in the silicone group.

Clinical conclusions
The authors reported that when hydrophobic acrylic is used as an IOL material for implantation, it results in a decreased use of Nd:YAG laser therapy compared with PMMA, silicone and hydrophilic acrylic.

Modelling
The authors reported that en economic model was constructed to estimate the cost-effectiveness of the IOL materials in the four European countries under study. The time horizon of the model was roughly 3 years.
Outcomes assessed in the review
The outcomes were assessed in the review and used as input parameters in the model were the incidence rates of Nd:YAG laser-related complications. Such complications included transient intra-ocular pressure, glaucoma, macular oedema, IOL subluxation, retinal detachment, retinal haemorrhage, cystoid macular oedema, string of pearls, decreased visual acuity, vitreous prolapse, iritis, IOL damage, hyaloid face rapture, papillary block, hyphaema, corneal damage, iris damage and bleeding.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
No criteria were used to ensure the validity of the primary studies.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Overall, the authors used 24 primary studies as sources of effectiveness data.

Methods of combining primary studies
The authors derived a median value and reported the range for each effectiveness estimate.

Investigation of differences between primary studies
The authors do not appear to have investigated differences between the primary studies.

Results of the review
The incidence rates for Nd:YAG laser therapy complications were as follows:

5% for transient intra-ocular pressure,
1.34% for glaucoma,
1.20% for macular oedema,
1.20% for retinal detachment,
0.5% for retinal haemorrhage,
47.60% for string of pearls,
4% for decreased visual acuity,
1.5% for vitreous prolapse,
0.75% for iritis,
18.90% for vitritis,
18.90% for IOL damage,
18.20% for hyaloid face rupture,
0.20% for papillary block,
0.60% for hyphaema,
0.65 for corneal damage,
2.9% for iris damage, and
0.2% for bleeding.

**Methods used to derive estimates of effectiveness**
Due to a lack of data in the literature, some estimates of effectiveness were based on experts' opinion. Expert opinion was derived through a specifically designed questionnaire, which was distributed to four European IOL study group participants in each country.

**Estimates of effectiveness and key assumptions**
Data on two complications of Nd:YAG laser capsulotomy, namely endophthalmitis and IOL subluxation, were not available in the literature. As the experts had not observed such cases, the incidence rate was assumed to be 0%.

**Measure of benefits used in the economic analysis**
The authors used the number of patients successfully treated (i.e. without requiring Nd:YAG laser therapy) as the measure of benefit in the economic analysis. This was derived directly from the model.

**Direct costs**
The health service costs included in the analysis were the mean reimbursement cost per patient by type of IOL material, the cost of IOLs, the weighted costs of Nd:YAG laser therapy, and the cost of Nd:YAG laser therapy complications. The costs and the quantities were not reported separately, and the authors reported only summary costs (e.g. reimbursement cost per patient by type of IOL material). The costs were derived from published sources, while the resources used were based on expert opinion. Although the time horizon of the model was more than 2 years, discounting was not carried out and the price year was not reported. The costs were derived from sources published in different years, but the authors did not report any adjustments for inflation.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
Euros (EUR).
Sensitivity analysis
Although the type of sensitivity analysis was not explicitly reported, it seems that the authors have carried out a multi-way sensitivity analysis to test the robustness of the results to variability in the data. The percentage of patients needing Nd:YAG laser capsulotomy was increased in the hydrophobic acrylic group by 30%, and decreased for all other materials by 30%. In a separate multi-way analysis, the costs of Nd:YAG complications were increased and decreased by 50%.

Estimated benefits used in the economic analysis
The number of patients successfully treated was 291 in the hydrophobic acrylic group, 310 in the PMMA group, 203 in the hydrophilic acrylic group, and 357 in the silicone group.

Cost results
The total costs were reported per patient and per country.

For France, the mean reimbursement cost was EUR 162.84 in the hydrophobic acrylic group, EUR 194.37 in the PMMA group, EUR 224.85 in the hydrophilic acrylic group, and EUR 186.36 in the silicone group.

For Spain, the mean reimbursement cost was EUR 171.73 in the hydrophobic acrylic group, EUR 168.01 in the PMMA group, EUR 2,294.05 in the hydrophilic acrylic group, and EUR 205.66 in the silicone group.

For Italy, the mean reimbursement cost was EUR 324.03 in the hydrophobic acrylic group, EUR 338.03 in the PMMA group, EUR 371.90 in the hydrophilic acrylic group, and EUR 342.18 in the silicone group.

For Germany, the mean reimbursement cost was EUR 214.22 in the hydrophobic acrylic group, EUR 162.54 in the PMMA group, EUR 267.54 in the hydrophilic acrylic group, and EUR 212.58 in the silicone group.

Synthesis of costs and benefits
In France, the cost per patient successfully treated (i.e. without needing Nd:YAG) was EUR 175.29 in the hydrophobic acrylic group, EUR 240.85 in the PMMA group, EUR 326.35 in the hydrophilic acrylic group, and EUR 222.38 in the silicone group.

In Spain, it was EUR 184.85 in the hydrophobic acrylic group, EUR 208.19 in the PMMA group, EUR 426.78 in the hydrophilic acrylic group, and EUR 245.42 in the silicone group.

In Italy, it was EUR 348.80 in the hydrophobic acrylic group, EUR 418.88 in the PMMA group, EUR 539.77 in the hydrophilic acrylic group, and EUR 408.33 in the silicone group.

In Germany, it was EUR 230.60 in the hydrophobic acrylic group, EUR 201.41 in the PMMA group, EUR 388.72 in the hydrophilic acrylic group, and EUR 253.68 in the silicone group.

The sensitivity analyses demonstrated that cost-effectiveness ratios in Spain and Germany were sensitive to variations in Nd:YAG laser treatment efficacy. The cost-effectiveness ratios in all countries were also sensitive to the variability of cost estimates. The results of the sensitivity analysis were reported in full.

Authors' conclusions
Hydrophobic acrylic was the most cost-effective option for intra-ocular lens (IOL) material across all countries.

CRD COMMENTARY - Selection of comparators
It was unclear why the authors chose these four materials. You should decide if these represent commonly used technologies in your setting.
Validity of estimate of measure of effectiveness
The analysis was based on a multi-centre, retrospective comparative cohort study. In particular, qualified investigators carried out a retrospective review of patients' medical records, which enhances the internal validity of the study. Although the study sample seems to have been representative of the study population, it was not reported whether the patient groups were comparable at analysis, nor was any statistical analysis performed to account for potential biases and confounding factors. Since no power calculations were reported, it is not known whether the results obtained were powered adequately. In order to fully populate the model some of the effectiveness estimates were derived from the literature. A systematic review of the literature was not carried out, thus the effectiveness estimates used might not represent the best available evidence. The estimates of effectiveness do not appear to have been combined and the authors did not investigate any differences between the primary studies. Some estimates were based on expert opinion, but it was not reported how the panel of experts was selected.

Validity of estimate of measure of benefit
The authors used the number of cases successfully treated as the measure of benefit in the economic analysis.

Validity of estimate of costs
The analysis of costs was performed from the perspective of the health system paying for the health services. As the authors only reported summary costs, it is not possible to comment on whether all the relevant categories of costs were included in the analysis. The costs of IOLs and implantation were omitted as they were assumed to be equal for each material, and it is therefore unlikely that their omission would have affected the authors' conclusions. The costs and the quantities were not reported separately, thus impeding the reproduction of the clinical study in other settings. Quantities of resources used were based on expert opinion, but no sensitivity analysis on the quantities was performed. This may limit the interpretation of the study findings. Although the costs were treated deterministically, sensitivity analyses were conducted to assess the robustness of the estimates used. The authors do not appear to have adjusted cost estimates for inflation and, despite costs being incurred over a 3-year period, no discounting was conducted. In addition, the price year was not reported.

Other issues
The authors did not compare their findings with those from other studies, so it is not known how far their results agree with other published results. The issue of generalisability of the results to other settings was not directly addressed. The authors do not appear to have presented their results selectively. The study enrolled patients who underwent cataract surgery and this was reflected in the authors' conclusions. The authors did not report any limitations to their study.

Implications of the study
The authors did not make any explicit recommendations for changes in policy or practice, nor did they call for specific research topics.

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