Laser office ventilation of ears with insertion of tubes
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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.

Health technology
Two treatment options for serous otitis media (SOM) were compared. One was cold surgical myringotomy and tube placement (M&T), performed in an operating room setting under general anaesthesia. The other was laser office ventilation of ears with insertion of tubes (LOVE IT), performed in an office setting with only topical anaesthesia. LOVE IT was performed with the precise placement of a 2.4-mm laser fenestration of the tympanic membrane.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children with persistent SOM. No further exclusion or inclusion criteria were reported for the patient population studied.

Setting
The setting was secondary and primary care. The economic study was carried out in the USA.

Dates to which data relate
All procedures were performed between 1 June 1998 and 3 July 2000. The price year and the dates relating to resources used were not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
Although not explicitly stated by the authors, 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, and power calculations were not performed retrospectively. After discussing the procedure itself, (i.e. whether the procedure could or would be performed, the anaesthetic technique involved, and the risks and benefits), the parents chose either traditional M&T (group I) or LOVE IT (group II). Forty consecutive patients were included in each group and a survey was sent to the parents of each child.
Study design
The analysis was based on a multi-centred non-randomised controlled trial. It would appear that the duration of follow-up was less than two years. A survey was sent to the parents of each of the children in each group. From the 40 patients in each group, 29 surveys were returned from group I and 35 were returned from group II. The authors did not state any differences between respondents and non-respondents. No statistical analysis was performed to account for possible biases and confounding factors.

Analysis of effectiveness
It was not stated whether the analysis was conducted on the basis of intention to treat or treatment completers only. The primary health outcomes used were:

- satisfaction with the treatment strategy, which was measured with a questionnaire survey addressed to the children's parents;
- time to perform the procedures, which was evaluated using either the time from arrival to departure of the facility, or the time for actual performance of the procedure;
- time interval between referral from the primary care physician to insertion of the tubes;
- time of tube persistence (follow-up); and
- complications.

A chart review was performed to determine the time of each procedure, the time interval from presentation to the otolaryngologist to procedure performance, the tube longevity, and complications. The results were analysed statistically using a chi-squared test and a p-value of less than 0.05 was considered statistically significant. The authors mentioned that of the patients in group I (n=29), 18 were less than 3 years old, 8 were 3 to 6 years old, and 3 were over 6 years old. In group II (n=35), 28 patients were less than 3 years old, 2 were 3 to 6 years old, and 5 were over 6 years old. Thus, 28% (8 of 29) of patients in group I were between 3 and 6 years, compared with only 6% (2 of 35) of patients in group II. This difference approached statistical significance, (p=0.056), but the authors did not make any adjustments for confounding factors. The authors did not state any other differences between the groups in terms of baseline characteristics.

Effectiveness results
The difference in the proportion of patients who made their choice based on anaesthetic technique was highly statistically significant (86% in group II versus 31% in group I; p<0.001).

There was no statistically significant difference between the groups on the question of how well the selected procedure met preoperative expectations.

On the question "Would you choose to do the procedure in the same way?", 79% of group I and 83% of group II said yes, while 17% of group I and 14% of group II said they would choose the alternative method. The differences were not statistically significant.

On the question of whether the parents would have had the procedure done sooner to avoid some of the antibiotic courses, 8% of group II and 4% of group I would not have undergone the procedure at all, but the difference was not statistically significant.

Concerning overall satisfaction with the procedure, 97% and 91% of respondents in groups I and II, respectively, expressed satisfaction (satisfied or very satisfied), (p=0.556).

M&T performed at a free-standing outpatient surgicenter required an average 2 hours from arrival to departure, while M&T performed in a hospital setting averaged 3.5 hours. LOVE IT performed in an office setting required approximately 2.5 hours.
The time for the actual performance of M&T averaged 20 minutes in both the hospital and surgicenter. The time to perform LOVE IT, including application of a topical anaesthetic, laser fenestration of the tympanic membrane and insertion of the tube, ranged from 30 to 90 minutes.

Group II had their procedures performed earlier than those in group I, but this trend was not statistically significant, (p=0.171).

The tubes persisted in all patients for a minimum of 4 months, with a mean time of tube persistence of 8 months for both groups.

Group I had 2 cases of otorrhoea and group II had one case. All of the patients responded to medical treatment with antibiotic drops.

**Clinical conclusions**
The results of the survey showed that patients or parents who selected LOVE IT did so primarily in order to avoid general anaesthesia, an objective which was successfully achieved. The level of patient or parent satisfaction was similar in both groups.

**Measure of benefits used in the economic analysis**
The authors did not estimate a summary measure of benefit. The study was, in effect, a cost-consequences analysis.

**Direct costs**
The costs were incurred during a short time period, thus discounting was not relevant. The quantities and the costs were not analysed separately. The costs of surgeon's fees were excluded from the analysis because they were common to both alternatives, regardless of the procedure (M&T or LOVE IT) or facility. The costs included in the analysis were facility fee and anaesthesia fee for each of three settings. More specifically, M&T in surgicenter, M&T in hospital, and LOVE IT performed in the senior author's office. Both the quantities and costs were estimated from actual data, but the source of the costs for the M&T procedure (surgicenter or hospital) was not explicitly stated. The price year and the dates when the quantities of resources were measured were not reported. The costs appear to have been reported per case.

**Statistical analysis of costs**
The costs were treated as point estimates (i.e. the data were deterministic).

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis was not carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The cost of hospital M&T was $3,040, the cost of surgicenter M&T was $2,375, and the cost of LOVE IT was $240.

**Synthesis of costs and benefits**
The estimated benefits and costs were not combined.

**Authors’ conclusions**
Laser office ventilation of ears with insertion of tubes (LOVE IT) is a potential alternative to traditional cold surgical myringotomy and tube placement (M&T) in the treatment of serious otitis media (SOM). LOVE IT is most likely to be selected by those patients who wish to avoid general anaesthetic. LOVE IT provides a level of satisfaction similar to that of traditional M&T. In terms of cost, LOVE IT is less costly than M&T for one-time procedure performance.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparator used. M&T has been regarded as the "gold-standard" for the treatment of SOM. You should decide if this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a multi-centred non-randomised controlled trial. It would have been more appropriate had a randomised controlled trial or prospective cohort study with concurrent controls been undertaken, as these studies, if well conducted, are considered to be the 'gold'-standard study design when comparing health interventions, as they are less prone to bias. No power calculations were reported. Since the study sample was small, the study might have had insufficient power to detect statistically significant differences in the outcomes. For the same reason, it is unclear whether the study sample was representative of the study population. As the parents chose the intervention, they may have been reluctant to admit that they had made a suboptimal choice for their child's care. With the exception of age, no differences in baseline characteristics between the study groups appear to have been assessed. Group differences may be considerable and attributable to self-selection bias. The authors did not undertake an appropriate statistical analysis to account for potential biases and confounding factors.

**Validity of estimate of measure of benefit**
There was no summary measure of benefit. The study was, in effect, a cost-consequences analysis.

**Validity of estimate of costs**
The authors did not report the perspective adopted, which makes it difficult to assess whether all the relevant categories of costs were included in the analysis. Surgeon's fees were excluded from the analysis, because they were common to both treatment strategies. The cost of the equipment was also not included and it is possible that it might have had a great impact on the results. The costs and the quantities were not reported separately. There were no statistical or sensitivity analyses of the quantities. This may limit the interpretation of the study findings. Some prices were taken from the authors' setting, but no statistical analysis of the prices was performed. It was unclear whether charges were used to proxy costs. The source of the costs for M&T procedure (surgicenter and hospital) was not reported. In addition, the use of summary costs makes it impossible to know what aspects of costs were included within the categories. Discounting was unnecessary since all the costs were incurred during a short time. The date to which the prices related was not reported, which will prevent any possible inflation exercises.

**Other issues**
The authors did not make appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not explicitly addressed. The authors reported some limitations of their study. First, their study included too few children in the 3- to 6-year-old age range to permit meaningful statistical comparisons between those undergoing each type of procedure. Second, patient satisfaction data should be interpreted with caution, given that parents may be unwilling to express dissatisfaction to their child's physician, or to admit that
they had made a suboptimal choice for their child's care. LOVE IT requires the purchase of rather expensive equipment for the physician. This was not accounted for in the analysis, although it was suggested that this cost could be recouped over a reasonable period of time and that the same equipment may be used for a variety of other office-based procedures.

**Implications of the study**
The authors explicitly reported that their study is not a statement that LOVE IT should replace traditional M&T, and that these procedures are complementary. In addition, both offer an opportunity to dramatically decrease the use of antibiotics, bacterial antibiotic resistance, hearing loss, and the tremendous health care costs associated with middle ear disease. The authors suggested that patient selection is the most important factor for deciding the procedure, and that with proper patient education many patients may have tubes placed sooner using LOVE IT, with far fewer antibiotics. They also suggested that further studies are necessary to compare LOVE IT and M&T in terms of long-term cost-effectiveness, including the need for repeat procedures, the cost of antibiotic courses, and the incidence of persistent perforations.

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