Cost-utility analysis of tympanomastoidectomy for adults with chronic suppurative otitis media

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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
The study evaluated tympanomastoid surgery. A comparator was not explicitly stated at the outset, although it was likely to be no tympanomastoid surgery. The health technology was compared between two different patient groups. These were patients with wet ear suffering from chronic suppurative otitis media (CSOM) and patients with dry ear suffering from CSOM. The wet-ear group was composed of patients with chronic active otitis media without cholesteatoma (with granulation), chronic active otitis media with cholesteatoma, and chronic inactive otitis media with frequent reactivation. The dry-ear group was composed of patients with chronic inactive otitis media.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised adult patients with CSOM who received tympanomastoid surgery at the Cathay General Hospital (Taipei, Taiwan). No further inclusion or exclusion criteria were reported.

Setting
The setting was secondary care (a hospital). The economic study was carried out in Taiwan.

Dates to which data relate
The patients were enrolled between January 2000 and December 2000. Each patient was followed up for 1 year after surgery. Patients were also evaluated 1 year before surgery. Resource use and cost data were gathered during the first year after surgery. The costs were reported for the price year 2000.

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

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. An unselected sample of consecutive patients who underwent tympanomastoid surgery at the
authors' setting (Cathay General Hospital) were used as the study sample. A sample of 77 patients was recruited. The male-to-female ratio was 20:57 and the mean age of the patients was 43.2 (+/- 12.6) years. The distribution of systemic co-morbidity was 2 (2.6%) patients with hypertension, 2 (2.6%) patients with diabetes and 10 (13.0%) patients with nasal allergy. No patients were reported to have refused to participate and no patients were excluded from the initial sample. Fifty-eight (75.3%) patients were stratified to the wet-ear group. This group comprised 7 patients with cholesteatoma, 8 patients with granulation and 43 patients with frequent reactivation. Nineteen (24.7%) patients were stratified to the dry-ear group. This group comprised 3 patients with retraction pocket, 11 with perforation, 2 patients with ossicular resorption and 3 patients with adhesive otitis media.

Study design
The analysis was based on a single-centre prospective non-randomised cohort study (case series). None of the study participants was blinded. The patients were evaluated 1 year before and 1 year after the tympanomastoid surgery. No patients were reported to have been lost to follow-up.

Analysis of effectiveness
All of the patients included in the initial study sample were considered in the analysis of effectiveness. The primary health outcome was the Chronic Ear Survey (CES) score before and 1 year after surgery. The CES is a statistically validated chronic ear-specific outcome measure. It consists of a 13-item Likert scale survey with 3 sub-scales. The activity restriction sub-scale refers to the impact of chronic otitis media on a patient's daily life. The symptom sub-scale refers to the presence of symptoms (i.e. hearing impairment and drainage). The medical resource utilisation sub-scale refers to the use of medications and office visits. The authors reported that they employed the Chinese version of the CES, which has been validated and was comparable to the CES. The secondary outcomes included mean operation time, average length of hospital stay, reoperation rate and the number of adverse events. It was not reported whether the patient groups were comparable at analysis.

Effectiveness results
Individual CES scores, before and after surgery, were not reported. However, the changes in CES scores were reported for all patients and for each patient group individually (see 'Estimated Benefits Used in the Economic Analysis' section).

No adverse events were reported in either study group.

The mean operation time was 158 (+/- 51.9) minutes for the whole group, 164.59 (+/- 52.74) minutes for the wet-ear group, and 139.23 (+/- 46.22) minutes for the dry-ear group. The difference between the two patient groups was statistically significant, (p<0.05).

The average length of hospital stay was 4.32 (+/- 0.98) days for the whole group, 4.49 (+/- 0.93) days for the wet-ear group, and 3.85 (+/- 0.99) days for the dry-ear group. The difference between the two patient groups was statistically significant, (p<0.05).

The reoperation rate was 5.2% for the whole group, 5.2% for the wet-ear group, and 5.3% for the dry-ear group. The difference between the two patient groups was statistically insignificant.

Clinical conclusions
As CES scores before and after surgery were not reported separately, it was not possible to reach conclusions on the effectiveness of surgery based on the primary outcome (see 'Estimated Benefits Used in the Economic Analysis' section for more conclusive arguments based on benefits). The wet-ear group had longer operation times and longer hospital stays, but there was no statistically significant difference in the reoperation rate and adverse events.

Measure of benefits used in the economic analysis
The authors used health utility, defined as a gain in the change in CES total scores, as the measure of benefit. Individual utility values were not reported, but the changes in CES scores were reported for all patients and for each patient group individually.

**Direct costs**
The health care costs included in the analysis were the up-front admission hospitalisation cost including physician fee, ward fee, nursing fee, laboratory fee, pathology exam fee, image fee, tympanoplasty, tympanomastoidectomy, anaesthesia fee, inpatient dispensary fee, intravenous fluid fee, local treatment fee and material fee. Postoperative outpatient costs included the cost of antibiotics, ear drops, physician fee, registration fee and ENT local treatment fee. All costs were based on actual data and were derived from the hospital claim database. The quantities of resources used were derived retrospectively from medical records. The admission cost was adjusted with reoperation and inflation rates (5%). Discounting was not relevant as the costs were incurred during a short time. All the costs were reported for the price year 2000.

**Statistical analysis of costs**
The unit costs were treated deterministically. The authors used the Mann-Whitney U-test to compare cost-differences between the two groups. The analysis was conducted using the SAS software package (SAS Institute, Cary, NC).

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

**Currency**
New Taiwan dollars (TWD). In cases where the costs were reported in US dollars ($), the appropriate conversion rate was used (TWD 33.5 = $1 at the 2000-01 average exchange rate).

**Sensitivity analysis**
Although not explicitly reported, the authors conducted a one-way sensitivity analysis to test the robustness of the results to variability in the data. The parameters that were varied were the length of stay (reduced by 1 day) and the reoperation rate (reduced by 1%). The method used to select the ranges used in the sensitivity analysis was not reported.

**Estimated benefits used in the economic analysis**
The average utility gain for all patients was 24.7 (+/- 3.0) for the change in CES total scores. It was 37.6 (+/- 3.4) in the wet-ear group and 24.4 (+/- 2.2) in the dry-ear group. The difference between the two patient groups was statistically significant, (p<0.05).

**Cost results**
The total costs per patient were reported.

The average cumulative cost including surgery and 1-year follow-up costs was TWD 45,716.30. It was TWD 48,163.20 for the wet-ear group and TWD 38,419.70 for the dry-ear group.

**Synthesis of costs and benefits**
The cost-utility ratio (defined as cost per utility gain, TWD/utility gain) was TWD 1,850.9 for all patients, TWD 1,280.90 for the wet-ear group and TWD 1,574.60 for the dry-ear group. The difference between the two groups was statistically significant, (p=0.0001).

The sensitivity analysis showed that reducing the length of stay by 1 day would decrease the average cost-utility ratio by
TWD 73.1 for the whole group. Improving the reoperation rate by 1% would reduce the average cost-utility ratio by TWD 15.1.

Authors’ conclusions
Treating continuous or intermittent chronic draining ear is the more cost-effective option compared with treating a quiescent infection, because of its favourable utility gain and relatively reasonable cost. "However, the efficacy of surgery for dry chronic otitis media should not be discouraged by these cost utility data; patients in the dry-ear group still proved to benefit from surgery by showing significant improvement in their quality of life."

CRD COMMENTARY - Selection of comparators
The authors evaluated tympanomastoid surgery for the treatment of CSOM. They did not discuss the existence of alternative therapies. If there are any, which is likely, it makes this study only a partial analysis.

Validity of estimate of measure of effectiveness
The analysis was based on a single-centre prospective non-randomised cohort study, which seems to have been appropriate given the study question. The study sample seems to have been representative of the study population but, since details of the patients were not provided, it was not possible to ascertain comparability between the patient groups. The length of the study and follow-up were reported, and an appropriate statistical analysis was undertaken to detect statistically significant differences in health outcomes. However, no power calculations were conducted. Thus, it was not possible to ascertain whether the results obtained were due to the intervention or to chance. In addition, the main outcome (i.e. CES scores before and after surgery) was not reported for each sub-scale. Only changes in the CES total score were reported.

Validity of estimate of measure of benefit
The authors used health utility, defined as the gain in the change in CES scores measured 1 year before and 1 year after surgery. There were few details on the methodology used to derive utility gain from each CES sub-scale score. It appears that the health utility measure included the medical resource utilisation score and, therefore, quantities of resources used were counted both in the numerator and denominator of the cost-utility ratio. Consequently, the approach used to measure the benefit and the cost-utility ratio in the present study may be questioned, and this limits the internal validity of the results.

Validity of estimate of costs
The perspective adopted in the economic analysis was not reported, but it could not be societal since the indirect costs were not included in the analysis. All the unit costs were reported, thus enhancing the reproducibility of the results to other settings. The quantities of resources used were derived from medical records, and a statistical analysis was undertaken to compare resource use between the two patient groups. In addition, some parameters of resource used were tested in a sensitivity analysis, which strengthens the interpretation of the study findings. All costs were based on actual data, but were treated deterministically, and no sensitivity analysis on the cost estimates was conducted to assess the robustness of the estimates used. The authors only carried out their statistical analysis to compare cost-differences between the two patient groups. The authors reported that they used charges to proxy prices because of the lack of available cost data. It is possible that the costs were overestimated. Appropriate currency conversions were conducted and the price year was reported, which will aid any future reflation exercises. Discounting was unnecessary as the costs were incurred during a short time.

Other issues
The authors compared their results with those from other studies, and generally found consistency. The issue of the generalisability of the results was not directly addressed. The authors do not appear to have presented their results selectively. The study enrolled patients with CSOM who underwent tympanomastoid surgery and this was reflected in the authors’ conclusions. The authors stressed, as a limitation to their study, the fact that they used hospital bills instead
of actual costs. In addition, the study lacked appropriate power because of its small sample size.

**Implications of the study**
The authors did not make any explicit recommendations for changes in policy or practice, or for further research. However, the discussion highlighted areas where more information is required.

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