A cost-benefit analysis of the post-operative use of antibiotic ear drops following grommet insertion

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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
Use of antibiotic ear drops (Sofradex) following grommet insertion in the prophylaxis of otorrhoea.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing bilateral grommet insertion for eustachian dysfunction or otitis media with effusion.

Setting
Hospital. The study was carried out in the Royal Naval Hospital in Gosport, UK.

Dates to which data relate
Not stated. The price year was not clearly stated, although the paper was published in 1995.

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

Link between effectiveness and cost data
Costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
A total of 190 patients undergoing bilateral grommet insertion for eustachian dysfunction or otitis media, and from whom informed consent was obtained, was initially included in the study. Of those patients 25 were withdrawn (13.1%). The mean age was 6.3 years, and 109 patients were male (66%). The right ear was treated in 76 cases (46%). Power calculations were reported and considered the power lost due to withdrawals.

Study design
The study was a randomised controlled trial. Patients were randomised in blocks of ten. In each block, five patients were asked to use the left ear as the treatment ear and the other five to use the right ear. In each case the non-treatment ear was used as a control. The duration of follow-up was 3 months.
Analysis of effectiveness
The analysis was based on treatment completers only. The main health outcomes used in the analysis were grommet function at three months as measured by blockage rates, extrusion rates or improvement in pure tone audiometry whether or not there was an effusion. Since each patient had one ear as the intervention and the other as the control, the groups were comparable in terms of patient characteristics.

Effectiveness results
Fourteen patients had the treatment ears alone functioning, whilst 9 patients had the control ears alone functioning (p>0.05, McNemar’s test). The results for blocked grommets and extruded grommets had differences with p values >0.05. The same was true for the results derived by separating patients with bilateral effusions from those without effusion. Only two cases of persistent otorrhoea were seen at three months and they were both associated with control ears alone. The mean hearing gain after operation was 13.6 dB for the treated and 12.9 dB for the control ears. According to the authors, ”no appreciable effect” was noted for the bilateral effusion cases and the no effusion cases taken separately. The drops had no significant effect upon grommet function at three months measured by blockage rates, extrusion rates or improvement in pure tone audiometry whether or not there was an effusion.

Clinical conclusions
The drops had no significant effect upon grommet function at three months measured by blockage rates, extrusion rates or improvement in pure tone audiometry whether or not there was an effusion.

Measure of benefits used in the economic analysis
Since the effectiveness study showed no difference in clinical benefit between the intervention and control groups, the economic analysis was based on the difference in costs only.

Direct costs
The cost of a bottle of Sofradex and cost of grommet insertion were considered (as calculated by a study from the University of Leeds, 1992). The quantities of resource use were based on the definition of the intervention. Whilst the unit cost of Sofradex was based on the British National Formulary, the price year was not clearly stated.

Currency
UK pounds Sterling (.gb.pn)

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
Although the unit cost of a bottle of Sofradex was given (3.90), the total cost associated with the intervention was not reported.

Synthesis of costs and benefits
Not applicable.
Authors' conclusions
This prospective randomised trial has shown no benefit from the use of prophylactic antibiotic ear drops after grommet insertion whether assessed by grommet function or improvement of hearing thresholds at 3 months, independent of the presence or absence of an effusion and its cost cannot therefore be justified.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear, as this is a widely used technique in the authors’ setting. You, as a database user, should consider if this applies to your own setting.

Validity of estimate of measure of benefit
Data do not appear to have been used selectively to prove a particular point and the choice of health outcomes is justified. Although the results for grommet nonfunction appear to be valid (and were supported by power calculations assuming a 50% reduction in incidence for the intervention group), it should be noted that, for the hearing gain outcome, the study may still lack sufficient power.

Validity of estimate of costs
No adequate details of the methods of quantity/cost estimation were given and it is not clear whether all major cost items were included in the analysis.

Other issues
The cost data may not be generalisable to other settings or countries. Appropriate comparisons with other relevant studies were made. Note that the expected total costs associated with each strategy were not stated.

Implications of the study
Further studies may be needed in order to validate the results of the study, regarding the inefficiency of ear drop prophylaxis in patients undergoing bilateral grommet insertion for eustachian dysfunction or otitis media with effusion.

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AccessionNumber