Short-term cost-effectiveness analysis of presurgical orthopedic treatment in children with complete unilateral cleft lip and palate

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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
Presurgical orthopaedic treatment (PSOT) in children with complete unilateral cleft lip and palate (UCLP).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Male and female children with complete UCLP who were born at term with no other malformations with both parents being Caucasian and trial entry within two weeks of birth.

Setting
Hospital. The economic study was carried out in The Netherlands.

Dates to which data relate
The main effectiveness data were obtained from a single trial conducted in 1997. Resource and cost data were derived from 1997 sources. The price year was 1994.

Source of effectiveness data
The estimates of the duration of surgical lip closure were derived from a single trial.

Link between effectiveness and cost data
The costing would appear to have been undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The total sample comprised 52 children with UCLP. Forty-three children were included in the effectiveness analysis and randomly assigned to either PSOT (23) or non-PSOT (20) groups by means of computerised balancing of two items (alveolar cleft width and birth weight). The children entered the trial within two weeks after birth. Power calculations to determine the sample size were not reported in this present paper. Further details concerning the clinical effectiveness were reported in a separate study.
Study design
This was a randomized clinical trial carried out at three centres in The Netherlands. The duration of follow-up was up to 18 weeks. There was no loss to follow-up.

Analysis of effectiveness
The analysis of effectiveness was based on intention to treat. The main primary health outcome was the duration of surgical lip closure.

Effectiveness results
The duration of the surgical lip closure procedures was 57.2 minutes for PSOT and 56.4 minutes for non-PSOT, (p>0.05). The 95% confidence interval of the difference in duration of the surgical lip closure was -9.5 to +8.0 minutes.

Clinical conclusions
The duration of the surgical lip closure procedures did not differ significantly.

Measure of benefits used in the economic analysis
The outcome measure was the duration of surgical lip closure.

Direct costs
Medical costs (cost of personnel, cost of PSOT materials, overhead cost) and costs incurred by the parents of the patients (travel costs and out-of-pocket costs) were derived from different sub-sets of the total sample size. The costs of treatment provided to both the PSOT and the non-PSOT patients were considered identical and were not included in the analysis. The cost of personnel was calculated on the basis of regular payment for university workers and 1680 productive hours per year. Overhead costs were calculated on the basis of information for the Rotterdam centre. Travel costs were derived according to guidelines for cost analysis in health care research. Resource and cost data were reported separately. Discounting was not undertaken due to the short period of follow-up. The quantity/cost boundary adopted was society. The price year was 1994.

Statistical analysis of costs
Nonparametric Mann-Whitney U test.

Indirect Costs
Parents’ time costs were included in the analysis based on sub-sets of the total sample. Time for travelling, treatment time, the number of parents accompanying the child to the treatment centre, and parents’ normal daily occupations were used as a basis for calculating the costs of time spent by parents. Resource and cost data were reported separately. Discounting was not undertaken due to the short period of follow-up. The quantity/cost boundary adopted was society. The price year was 1994.

Currency
US dollars ($). Parental expenses were directly recorded in Dutch guilders, but the conversion rate used was not stated.

Sensitivity analysis
A one-way sensitivity analysis was undertaken on the overhead costs.

Estimated benefits used in the economic analysis
The duration of the surgical lip closure procedures was 57.2 minutes for PSOT and 56.4 minutes for non-PSOT, (p>0.05; 95% CI: -9.5 - +8.0 minutes).

Cost results
The total medical costs were $852 and $304 for the PSOT and non-PSOT group, respectively, (p<0.01). Mean travel costs were $128 and $79 for the PSOT and non-PSOT group, respectively, (p<0.05). Mean indirect costs were $231 (PSOT) and $130 (non-PSOT), (p<0.05).

Synthesis of costs and benefits
Using the lower limit of the mean operating time result from PSOT, the incremental cost-effectiveness ratio was $58 per minute of operating time gained. The sensitivity analysis of overhead cost (+/-50%) showed that the difference between PSOT and non-PSOT increased using the upper limit of the range ($1,096 and $402) and became smaller using the lower limit of the range ($611 and $206).

Authors' conclusions
The study shows that PSOT was more expensive than non-PSOT and had an insignificantly lower effect expressed in terms of operating time.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is not clear nor did the authors provide a justification for its choice. However, the reason may have been reported in the trial from which the effectiveness data were derived (Kuijpers-Jagtman and Prahl, 1996).

Validity of estimate of measure of benefit
The estimate of measure of benefit, namely operating room time, used in the analysis is likely to be internally valid. However, the choice of this effectiveness (or benefit) measure has little relation to what might be classified as effectiveness in terms of clinical outcomes. The authors chose this outcome (from several others reported in the effectiveness trial) to illustrate the application of economic evaluation in this area of medicine. The data were used rather selectively in that the lower value of the confidence interval of PSOT was used to determine incremental cost-effectiveness when, in fact extended dominance, had been demonstrated for the non-PSOT group.

Validity of estimate of costs
Resource and cost data were reported separately and adequate details of methods of quantity/cost estimation were given. Important cost items do not appear to have been omitted. However, as stated by the authors, due to missing data, information on out-of-pocket costs was only available for 8 PSOT and 9 non-PSOT patients. Furthermore, as out-of-pocket cost data were influenced by selective response, they were omitted from the statistical analysis. Medical and non-medical costs were obtained from sub-sets of the whole sample. A one-way sensitivity analysis was performed on overhead costs in order to validate the robustness of the findings.

Other issues
The issue of generalisability to other settings or countries was not specifically addressed and appropriate comparisons with other studies were not possible because, as the authors noted, there were no reports on economic evaluation of UCLP or of orthodontic treatment in general.

Implications of the study
Further analysis is required within a long term context. The nature of the interventions considered in this context may constrain the economic evaluation to a cost-consequences analysis.

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Other publications of related interest

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