Double-blind comparison of sevoflurane vs propofol and succinylcholine for tracheal intubation in children


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 use of two anaesthetics intended to assist tracheal intubation in children undergoing adenotonsillectomy. One was propofol (3 to 4 mg/kg) plus succinylcholine (2 mg/kg), given by an intravenous induction procedure. The other was sevoflurane, given by an inhalation induction procedure using 8% sevoflurane in nitrous oxide and oxygen.

Type of intervention
Other: anaesthetic technique.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children (ASA I-II) aged 3 to 10 years, who were undergoing adenotonsillectomy. Children were excluded if they presented with a history of significant airway, cardiac, respiratory, renal, hepatic or central nervous system disease. They were also excluded if they had a history of sensitivity to the drugs used.

Setting
The setting was a hospital. The economic study was carried out at the North Staffordshire Hospital, Staffordshire, UK.

Dates to which data relate
The period during which the effectiveness and resource use data were collected was not reported. No price year was given.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

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

Study sample
Power calculations were performed to detect a statistically significant difference of 25 to 30% in the proportion of excellent intubation scores. The method used to select the sample was not reported. Overall, 64 eligible children were enrolled. There were 33 children in the propofol-succinylcholine group and 31 children in the sevoflurane group. The mean age in the propofol-succinylcholine group was 5 years (range: 3 - 10) and 11 were boys. The mean age in the sevoflurane group was 5 years (range: 3 - 9) and 21 were boys.
Study design
This was a randomised, double-blind clinical trial that was carried out in a single centre. Randomisation was carried out using computer-generated random allocation and sequentially numbered sealed envelopes. The anaesthetists who performed the tracheal intubation (after 150 seconds) were blinded to the anaesthetic technique. The effectiveness of the blinding was then assessed by asking the anaesthetists to guess the anaesthetic technique used. The children were not followed up after the operation. No loss to follow-up was reported.

Analysis of effectiveness
All the children included in the study were accounted for in the analysis, thus the basis of the clinical study appears to have been intention to treat. The health outcomes were time to start of IPPV, start of intubation, intubation time, duration of the operation, extubation time after the end of anaesthesia, and time to eye opening after the end of anaesthesia.

The intubation conditions were assessed using the Krieg score and the Copenhagen Consensus Conference (CCC) score. These grade the quality of tracheal intubation according to ease of laryngoscopy, position of the vocal cords, cough, and movement of the limbs. The children completed a questionnaire about throat soreness, limb pain, nausea, pleasantness of the intervention, and confirmation of the technique for future interventions. This was conducted in conjunction with an attending nurse or parent.

The study groups were comparable at baseline in terms of their age, weight and ASA status. However, there were statistically significantly more boys in the sevoflurane group.

Effectiveness results
In the propofol-succinylcholine group:
- the time to start of IPPV was 57 (+/- 24.9) seconds;
- the start of intubation was 152.4 (+/- 3.3) seconds;
- the intubation time was 16.3 (+/- 11.5) seconds;
- the duration of the operation was 22 (+/- 6.3) minutes;
- the extubation time after the end of anaesthesia was 5.9 (+/- 4) minutes; and
- the time to eye opening after the end of anaesthesia was 10 (+/- 5.1) minutes.

In the sevoflurane group:
- the time to start of IPPV was 74 (+/- 43.6) seconds;
- the start of intubation was 158 (+/- 16.3) seconds;
- the intubation time was 24.3 (+/- 25.6) seconds;
- the duration of the operation was 19.1 (+/- 4.9) minutes, (p<0.05);
- the extubation time after the end of anaesthesia was 4.3 (+/- 2) minutes; and
- the time to eye opening after the end of anaesthesia was 7.2 (+/- 1.7) minutes, (p<0.05).

The Krieg score was excellent for all children (100%) in the propofol-succinylcholine group and for 91% of the those in the sevoflurane group. The score for the remaining children (9%) in the sevoflurane group was good.
The CCC score was excellent for 82% of the children in the propofol-succinylcholine group and for 55% of those in the sevoflurane group, (p<0.05). The score was good for 18% of the children in the propofol-succinylcholine group and for 45% of those in the sevoflurane group.

The data from the questionnaires (obtained from 48 of the 64 children) showed no significant difference in terms of the incidence of nausea, vomiting or pain between the groups.

Fifteen children (75%) in the propofol-succinylcholine group found induction pleasant, compared with 12 children (43%) in the sevoflurane group.

Twelve children (69%) in the propofol-succinylcholine group stated that they would have the same anaesthetic again, compared with 13 children (46%) in the sevoflurane group. However, this difference did not achieve statistical significance.

Clinical conclusions
The effectiveness analysis showed that both anaesthetics were generally equally effective for tracheal intubation, although the scores were slightly better for the propofol-succinylcholine group than for the sevoflurane group.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. A cost-consequences analysis was therefore carried out.

Direct costs
Discounting was irrelevant due to the short time horizon of the study. The unit costs and the quantities of resources used were reported separately. The items included in the cost analysis were the drug costs. The cost/resource boundary adopted was that of the NHS. The costs were estimated using actual drug acquisition costs, while the quantities of resources were obtained from the trial. No dates were reported and no price year was given.

Statistical analysis of costs
Statistical analyses of the total costs were carried out to test for statistical significance of the results.

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

Currency
UK pounds sterling (€).

Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
The total cost with sevoflurane was 3.62 (+/- 0.55). This was significantly higher than the cost with propofol-succinylcholine when based on the actual amount of drug used (2.04 +/- 0.54), but significantly less than the cost based
on whole ampoules (4.38 +/- 0.05).

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
Sevoflurane proved to be a clinically and economically acceptable alternative to propofol-succinylcholine in the support of tracheal intubation in children undergoing adenotonsillectomy in UK.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. Succinylcholine represented a commonly used intervention, while sevoflurane was a more recent anaesthetic offering potential advantages. You should assess which anaesthetic is currently used in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness analysis was enhanced by the randomised and double-blinded design, which eliminated potential biases and confounding variables. In addition, power calculations were performed in the preliminary phase of the study, and the study groups were generally comparable at baseline (with the exception of gender). Finally, the blind assessment was validated using a questionnaire and the analysis was carried out on all children included in the study. These features of the study design enhance the validity of the effectiveness results.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis, and a cost-consequences analysis was therefore performed. It is worth noting that the two anaesthetics were similar in terms of most of the outcome measures used in the analysis.

Validity of estimate of costs
The perspective of the study was that of the UK NHS, and only the categories of costs strictly related to the interventions were included in the analysis. Statistical analyses of the total costs were carried out. In addition, the unit costs and the quantities of resources used were reported separately. The dates during which the resource use data were collected, and the price year, were not reported. Thus, reflation exercises to other settings would be difficult. The cost estimates appear to have been somewhat specific to the study setting, and sensitivity analyses were not carried out.

Other issues
The authors made few comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed. In addition, sensitivity analyses were not carried out, although it is unclear whether there would be variability in the unit cost data used. Consequently, the external validity of the analysis was quite low. The authors enrolled a specific paediatric population and this was reflected in their conclusions.

Implications of the study
Sevoflurane represents a valid alternative to propofol-succinylcholine in terms of tracheal intubation conditions during anaesthesia, in children undergoing adenotonsillectomy. The authors acknowledge that one potential disadvantage of sevoflurane is the lack of established intravenous access. The results regarding satisfaction with the technique may have been influenced, as outlined by the authors, by the parents’ attitudes to the use of a facemask in the sevoflurane group. This may have been more distressing for parents to observe and may have influenced the satisfaction scores completed by the children.
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