Propofol versus propofol with midazolam for laryngeal mask 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
Propofol with midazolam for laryngeal mask insertion.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Adult patients, ASA grades I-IV, undergoing elective orthopaedic, urological or general surgery and who did not need tracheal intubation as part of their anaesthetic technique. The exclusion criteria were reported as follows: current administration of anti-epileptic medication, significant impairment of renal or liver function, or body weight being outside the normal weight for height by 30%.

Setting
Hospital. The economic study was carried out in Cambridge, UK.

Dates to which data relate
Dates were not stated for the effectiveness and resource use data. The costs of resource use were expressed in 1994 values.

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

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

Study sample
A cohort of 40 adult Caucasian patients were included in the study. Of these, nineteen patients were allocated to the group receiving propofol alone, whilst 21 patients were included in the group receiving midazolam and propofol. The former group included 10 male patients with 16 patients being ASA I and 3 patients being ASA II, whilst the latter group included 13 male patients with 18 patients being ASA I, two being ASA II and one being ASA III. Power calculations to determine the sample size were not given.
Study design
Randomised controlled trial. Patients were contacted within 24 hours of surgery and again by telephone 14-21 days later. The loss to follow-up was not stated.

Analysis of effectiveness
It was not stated whether the analysis of the clinical study was based on intention to treat or on treatment completers only. The primary health outcomes used in the analysis were pain on injection, time in induction room, duration of surgery, duration of anaesthesia, time of recovery, complication rate and patient satisfaction at the last follow-up assessment. The groups were comparable in terms of age and smoking variables.

Effectiveness results
The number of patients who were estimated to have pain on injection were 1 in both groups. The pain score was 3.1 (+/- 0.5) cm SEM in the propofol group and 1.76 (+/- 0.36) cm SEM for the midazolam plus propofol group. (p=0.08). The former group received more morphine while in the recovery area (p=0.02). This was in spite of the fact that 8 and 4 patients, respectively, received local anaesthetic intraoperatively (p=0.08). The time in induction room was estimated to be 5.32 (+/- 4.76) minutes and 5.73 (+/- 2.38) minutes in the propofol alone and propofol plus midazolam group, respectively. The duration of surgery was estimated to be 21.34 (+/- 19.3) minutes in the propofol group and 26.48 (+/- 21.7) minutes in the propofol plus midazolam group. The duration of anaesthesia was estimated to be 34.90 (+/- 19.76) minutes and 40.40 (+/- 23.5) minutes the respective groups. The time in recovery was estimated to be 45.47 (+/- 19.30) minutes (propofol) and 38.91 (+/- 11.28) minutes (propofol plus midazolam). (p>0.05). Nine patients shivered in the 24 hour period after operation (four in the propofol alone group and five in the propofol plus midazolam group). Most patients rated their anaesthetic between 8 and 10 with inter-group differences having p values >0.05.

Clinical conclusions
In practical and clinical terms there were no significant differences between the two induction regimes except for the higher administration of morphine at the recovery area for the propofol group.

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

Direct costs
The costs for the propofol and midazolam anaesthetics were included in the analysis. The quantities of resource use were analysed separately from the costs. The quantity/cost boundary adopted was that of the hospital. 1994 price data were used and the data was obtained from the British National Formulary.

Currency
UK pounds Sterling ().

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The total cost for the propofol alone was estimated to be 65.96 or an average of 3.47 per anaesthetic. The total cost for the midazolam plus propofol group was estimated to be 42.57 or an average of 2.03 per anaesthetic. By combining midazolam with propofol, a cost saving of 1.44 per anaesthetic was estimated.

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
Adding midazolam to propofol allowed a reduced dose of propofol to be used without adverse effects while reducing anaesthetic costs.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was not clearly stated. From the authors' discussion it was not clear whether propofol is used in current practice.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis may be questionable in terms of the underlying power of the study to detect clinically significant effects.

Validity of estimate of costs
The resource quantities were reported separately from the prices. Adequate details of the methods of quantity/cost estimation were given. Important cost items were omitted after statistical analysis showed them to be common to both strategies, but this may not be justified given the lack of power calculations.

Other issues
The authors’ conclusions were justified in terms of the results from statistical tests of effects in several relevant variables. The issue of generalisability to other settings was not addressed, but appropriate comparisons were made with other studies. Results were not presented selectively.

Implications of the study
As the authors recognised, further studies with different dosage calculations are required to refine the strategy of midazolam plus propofol for use in patients undergoing laryngeal mask insertion. In addition, bigger trials would be desirable so as to detect clinically significant differences between the strategies compared.

Source of funding
None stated.

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