Local anaesthesia and midazolam versus spinal anaesthesia in ambulatory pilonidal surgery

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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
Two anaesthetic techniques were compared, local anaesthesia with sedation versus spinal anaesthesia. Local infiltration consisted of a 50-mL mixture of bupivacaine 0.5% (10 mL), prilocaine HCl 2% (10 mL) and an isotonic solution (30 mL) with 1:200000 epinephrine in combination with intravenous midazolam sedation. The spinal anaesthesia was hyperbaric bupivacaine 0.5% (1.5 mL).

Type of intervention
Palliative care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised ASA physical status 1,2 and 3 patients scheduled for pilonidal surgery with the Limberg flap technique. Patients with clinically significant cardiovascular, respiratory, renal, hepatic or metabolic disease were excluded from the study, as were those with a history of allergic reactions to any local anaesthetic drugs.

Setting
The study setting was tertiary care. The study was carried out at the University Hospital of Pamukkale, Turkey.

Dates to which data relate
The years to which the effectiveness analysis and the cost data related were not stated. The price year was not reported.

Source of effectiveness data
The evidence for the final outcomes 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 study.

Study sample
An a priori power analysis, based on published data, revealed that at least 25 patients in each group would be required to detect a 30% reduction in institutional costs, with a power of 90% at the 0.05 level of significance. This sample size would also be sufficient to detect a 30% difference in visual analogue scale (VAS) scores for pain, with a power of 80% at the 0.05 level. A total of 60 patients were included in the study and randomised to one of the two anaesthetic techniques. Thirty received spinal anaesthesia (group 1) and 30 received local anaesthesia with midazolam sedation.
Group 1 comprised 18 (60%) males and 12 (40%) females, and the mean age was 27.6 (+/- 2.3) years. Group 2 comprised 17 (56.67%) males and 13 (43.3%) females, and the mean age was 28.4 (+/- 1.8) years.

Study design
The study was a randomised controlled trial that was carried out in a single centre. Randomisation was performed using computer-generated random numbers that were kept in consecutively numbered, sealed envelopes. The mean length of follow-up was 26 months. The authors did not report any loss to follow-up. The investigator in charge of assessing pain using the VAS was blinded to the patient's preparation unit.

Analysis of effectiveness
The basis of the clinical study was intention to treat. The primary health outcomes used in the analyses were:

- pre- and postoperative side effects such as nausea, vomiting, headache, backache and urine retention;
- patient satisfaction with the anaesthetic technique, as evaluated by the blinded investigator immediately after operation using a 3-point scoring system (1=poor, 2=good and 3=excellent);
- preoperative VAS pain scores, as evaluated by the investigator using a 10-cm VAS, ranging from 0 (no pain) to 10 (most severe pain);
- postoperative VAS scores, whereby each patient was given a chart to record VAS scores at the fourth postoperative hour and then daily until the seventh postoperative day (all data charts were collected from patients on day 7); and
- anaesthesia, operation, surgery and total hospital time.

The groups were shown to be comparable in terms of their age, gender, height and weight. The authors did not report any confounding variables.

Effectiveness results
No statistically significant difference was found in the frequency of side effects between the groups during the pre- and postoperative periods.

All of the patients were satisfied with the anaesthetic technique. There were no statistically significant differences between the two groups. Patient satisfaction was 2.1 (+/- 0.8) in group 1 and 2.5 (+/- 0.5) in group 2, (p>0.05).

There was no significant difference in preoperative VAS scores between the two groups, (p>0.05).

There was no significant difference in postoperative VAS scores between the two groups, except for the postoperative fourth hour values (3.38 +/- 0.3 for group 1 versus 5.26 for group 2).

Although the anaesthesia time for group 1 was longer, the surgery times were not significantly different between the two groups. However, surgery unit time and total hospital time, were significantly greater in group 1 than in group 2.

Excellent functional results and acceptable scar patterns were obtained in all patients.

Clinical conclusions
Compared with spinal anaesthesia, local anaesthesia with midazolam sedation resulted in a shorter hospital time for pilonidal surgery with no side effects.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences approach was adopted.
Direct costs
The resource quantities and the costs were not reported separately. The direct costs of the hospital were included in the analysis. These were for the anaesthetic drugs and equipment, recovery unit drugs and hourly nursing. The cost data were obtained from the Finance Department of the University of Pamukkale. The total nursing labour costs were calculated on the basis of expenditure of nursing time, while the anaesthetic drug costs were obtained from the pharmacy department. Discounting was not necessary, as all the costs were incurred in less than 2 years, and was not conducted. The price year was not specified.

Statistical analysis of costs
The authors provided mean values and standard deviations for the cost results. The costs were analysed using Student's t-test to test for statistically significant differences between the two groups. The software used was SPSS version 10.0.

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

Currency
US dollars ($). The authors reported no currency conversions.

Sensitivity analysis
No sensitivity analyses were carried out.

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

Cost results
The total mean hospital cost was $12.45 (+/- 0.92) for patients in group 1 and $8.87 (+/- 0.96) for patients in group 2, (p<0.05).

Synthesis of costs and benefits
The costs and benefits were not combined as a cost-consequences approach was undertaken.

Authors' conclusions
The use of local anaesthesia with sedation for ambulatory anorectal surgery resulted in shorter hospital time, lower costs and no side effects in comparison with spinal anaesthesia.

CRD COMMENTARY - Selection of comparators
The use of spinal anaesthesia as the comparator was justified on the grounds that it is a commonly used anaesthetic technique for anorectal surgery. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a randomised controlled trial, which was appropriate for the study question. The study sample appears to have been representative of the study population. The authors performed a power analysis before the study, which ensured that the sample size was sufficiently large to detect any differences in the costs and VAS scores for pain. The patient groups were shown to be comparable at analysis in terms of their age, height, weight and
preoperative VAS scores. The analysis of effectiveness seems to have been handled in a credible manner. Randomisation was carried out in a completely random and concealed fashion, with the investigator evaluating VAS scores and patient satisfaction being blinded to the patient's anaesthetic group. The authors carried out appropriate statistical analyses to detect statistical significance.

**Validity of estimate of measure of benefit**
The authors did not derive a summary benefit measure of the health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
All the categories of cost relevant to the hospital perspective adopted by the authors appear to have been included in the analysis. However, some relevant costs were omitted, for example, the cost of electrocardiograms (ECG), ECG leads, pulse oximeter probes, intravenous catheters and administration sets. The authors deemed these to be common to both alternatives, thus it is unlikely that their omission would affect the authors' conclusions. Appropriate statistical techniques were used to test the significance of any differences in total costs between the two group, and the mean costs were reported along with their standard deviations. However, the costs and the quantities were not reported separately, and the dates relating to the costs and prices were not reported. These two limitations weaken the generalisability of the results and hinder reflation exercises to other settings. A further limitation, which will weaken the generalisability, was that the authors did not quote the exchange rate used to convert the local currency into US dollars.

**Other issues**
The authors made appropriate comparisons of their findings with another study (Li et al., see Other Publications of Related Interest), which used lidocaine instead of bupivacaine for spinal anaesthesia. However, this study also demonstrated that spinal anaesthesia patients needed more nursing time. The authors, however, did not address the issue of generalisability to other settings. The authors do not seem to have presented their results selectively, and they did not report any further limitations of their study.

**Implications of the study**
Even though the study had several limitations, mainly the issue of generalisability to other settings, it appears to have been carried out appropriately and the results seem valid. From the authors' conclusions one can infer that local anaesthesia with sedation should be used in preference to spinal anaesthesia for ambulatory anorectal surgery.

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**Other publications of related interest**


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