Randomized clinical trial comparing day-care open haemorrhoidectomy under local versus general anaesthesia
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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.

CRD summary
The study compared the costs and effects of two options for open haemorrhoidectomy, the use of either local or general anaesthesia, in patients with third-degree haemorrhoids. The authors concluded that both anaesthetic approaches had similar clinical outcomes in terms of pain and patient expectations, but that local anaesthesia offered cost-efficiencies. The costing methods used in the study were not well reported, therefore the authors’ conclusions should be interpreted with some caution.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The purpose of the study was to compare the clinical effectiveness and costs of day-care open haemorrhoidectomy under local anaesthesia (LA) with those under general anaesthesia (GA), among patients with third-degree haemorrhoids.

Interventions
Patients in the LA group were administered a perianal block (20 mL 1% lidocaine with one in 10,000 epinephrine) injected at four sites outside the external sphincter. An additional 10 mL was injected submucosally following sphincter relaxation. Patients in the GA group received the same perianal block, in addition to propofol (1.5 to 2.0 mg/kg body weight) and fentanyl (10 μg/kg body weight) for induction of anaesthesia and oxygen and sevoflurane for maintenance.

Location/setting
UK/secondary care.

Methods
Analytical approach:
The effectiveness data were derived from a single clinical trial with a follow-up period of 6 months post surgery. The authors did not state the perspective from which the study was conducted.

Effectiveness data:
The primary outcomes were self-reported pain scores and patient expectations based on symptom improvements. A randomised controlled trial of 42 patients was used. The two patient groups had similar demographic and clinical characteristics at baseline. The participants were enrolled consecutively and none were ineligible for day-surgery. One patient randomised to LA refused to participate after randomisation. A single surgeon performed all the surgical procedures. By the 6-month point, one participant from each group was excluded from the analyses because of their surveys being lost in the post. Intention to treat analyses were performed.

Monetary benefit and utility valuations:
None.

Measure of benefit:
The main clinical outcomes were self-reported pain scores and patient expectations based on symptom improvements.
Cost data:
The types of resources addressed in the analysis included suture materials, anaesthesia, day-surgery beds, staff costs, recovery room and postoperative medications. The sources of the resource quantities and values were not stated. Prices were quoted in pounds sterling (£). The price year was not stated.

Analysis of uncertainty:
Sensitivity analyses were not reported.

Results
The mean costs were £285.50 for the LA group compared with £405.50 for the GA group. The difference was entirely due to the cost of general anaesthesia.

Pain scores were significantly higher at 90 minutes in the LA group, but were similar between the LA and GA groups upon reaching home. Pain scores were consistently lower in the LA group from days 1 to 10. Excluding the day of surgery, mean pain and expectation scores were similar in both groups and not significantly different. The results were presented graphically in the report. Journey time was significantly shorter (by approximately 50 minutes) in the LA group.

The cost and effectiveness results were not combined into cost-effectiveness ratios.

Authors' conclusions
The authors concluded that GA and LA have similar clinical outcomes, but that open haemorrhoidectomy under LA should be routinely supported as it produces lower costs and shorter journey times. They also proposed that patients be given a choice between GA and LA.

CRD commentary
Interventions:
The interventions, including dosage and clinical techniques, were reported clearly. The authors provided justification for using the LA option.

Effectiveness/benefits:
The effectiveness data were derived from a small clinical trial in a single setting. Full details of the trial methods were reported and they appear to have been internally valid. The results were presented separately for each effectiveness outcome (pain, expectations, satisfaction and journey time), but in graph format only.

Costs:
The costs included in the analysis appear to have reflected those of the hospital perspective, although this was not explicitly reported. The cost methods were not reported transparently, most likely because the cost component was a small and secondary focus of the overall study. However, this will prevent the reader from fully ascertaining what methods were used for determining resource quantities and valuations and why, for example, the investigators chose not to include resources associated with preoperative counselling or postoperative infections. The price year was also not stated, which hampers any reflation exercises.

Analysis and results:
The health outcomes and net costs were not synthesised into cost-effectiveness ratios. In effect, a cost-consequences analysis was undertaken. The authors discussed their findings generally in relation to other techniques and specifically in comparison with one other study that found similar results when using LA. The authors did not raise any limitations of their study or suggest whether further research would be needed to support their claims.

Concluding remarks:
The reporting and methods used for the effectiveness outcomes were appropriate and clearly reported, whereas comprehensive information was lacking for the cost analysis. Given that the study involved a small sample from a single centre, the results pertaining to the cost components should be viewed with caution.
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