Randomised comparison of remifentanil-propofol with a sciatic-femoral nerve block for outpatient knee arthroscopy


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 alternative anaesthetic procedures for outpatient knee arthroscopy were under evaluation, a regional anaesthetic procedure and a general anaesthetic (GA) procedure.

Under the regional anaesthetic procedure, patients received a combined sciatic-femoral nerve block with mepivacaine 25 mL 2% (Carbocaine; 15 mL for the femoral nerve and 10 mL for the sciatic nerve) using a multiple injection technique aided by a nerve stimulator (Plexival) and a short, bevelled, Teflon-coated stimulation needle.

Under the GA procedure, patients received a continuous intravenous infusion (IV) of remifentanil (0.1 - 0.3 microg/kg per minute) and propofol (Diprifusor; target plasma concentration 2 - 4 microg/mL), and a laryngeal mask airway.

Prior to the administration of the anaesthetic procedures, patients were pre-medicated with IV midazolam (0.05 mg/kg) and ketoprofen (50 mg), followed by an IV infusion of Ringer's lactate solution (5 mL/kg per hour). The GA patients were directly admitted to the operating room, while the peripheral nerve block (PNB) patients were admitted to a block room area and then transferred to the operating room after block placement.

Type of intervention
Other: Anaesthesia.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised ASA I-II outpatients, aged between 18 and 65 years, who underwent ambulatory arthroscopy knee surgery. Patients with diabetes and peripheral neuropathy were excluded. Also excluded were those with contraindications to regional anaesthesia, respiratory or cardiac disease, those receiving chronic analgesic therapy, and those undergoing anterior cruciate ligament repair.

Setting
The setting was tertiary care. The economic analysis was conducted in Milan, Italy.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not stated. The price year was also not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.
Link between effectiveness and cost data

The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample

Power calculations, to assure a certain power, were performed in the planning phase of the study. A sample size of 16 patients in each group was required to assure 0.80 power (two-tailed alpha-error of 0.05 and a beta-error of 0.20) in the detection of a 15-minute difference in the time to discharge from the post-anaesthesia care unit between those receiving the GA and those receiving the PNB.

Forty patients were initially included in the study. These were randomly allocated to receive either a propofol-remifentanil-based GA (n=20) or a combined sciatic-femoral nerve block (PNB group, n=20) The mean age of the patients was 51 years in the GA group and 46 years in the PNB group. There were 7 (GA group) and 9 (PNB group) women, respectively, in the two groups. One patient was excluded from the analysis because of hospital admission for surgical problems. Therefore, the final study sample comprised 39 patients (20 in the GA group and 19 in the PNB group).

The authors did not report any evidence that the study sample was representative of the study population.

Study design

This was a randomised controlled trial that was conducted in a single centre. The duration of follow-up was one day after discharge. The patients were randomised to the groups using a computer-generated random table. The outcome assessment does not appear to have been blinded, although the authors stated that an independent observer was responsible for the evaluation of the patients until discharge.

Analysis of effectiveness

The analysis of the clinical study was conducted on an intention to treat basis. The primary health outcomes assessed were:

- the median preparation time (i.e. time from IV premedication to skin disinfection),
- the median discharge times (and their associated ranges),
- side effects (i.e. hypotension after induction and chest rigidity),
- the number and percentage of patients experiencing pain intensity during surgery, and
- pain intensity using a visual analogue scale (VAS).

After surgery, the modified Aldrete's score and pain intensity were assessed every 5 minutes. When the vital signs remained stable for two subsequent measurements (and the modified Aldrete's score was 9 and the VAS for pain intensity was less than 30 mm), the patients were transferred to the day-surgery unit where they were evaluated every 30 minutes by an independent observer until they were judged ready to go home. The criteria for discharge were: patient alert, stable vital signs, patient able to void and ambulate, nausea and pain controlled by oral medication, and patient had nerve block resolution.

The authors reported that there were no differences between the two groups in terms of demographic variables.

Effectiveness results

The median preparation time was 16 minutes (range: 10 - 28) in the PNB group and 13 minutes (range: 8 - 22) in the GA group, (p=0.015).
Ten PNB patients (50%) versus one GA patient (5%) were directly discharged to the day-surgery unit after the procedure, (p=0.003).

Discharge from the post-anaesthesia care unit (PACU) required 5 minutes (range: 5 - 20) in the PNB group and 23 minutes (range: 10 - 95) in the GA group, (p=0.001).

Home discharge criteria were fulfilled after 277 minute (range: 150 - 480) in the PNB group and 170 minutes (range: 100 - 400) in the GA group, (p=0.005).

Seven patients in the GA group (36%), compared with no patients in the PNB group, showed clinically relevant hypotension after induction, (p=0.013).

Four GA patients (21%) experienced bradycardia, (p=0.11), while one GA patient complained of chest rigidity after being transferred to the PACU.

Two PNB patients (12%) complained of mild pain during surgery.

Pain measured on the VAS when patients were discharged from the PACU was 7 mm (range: 0 - 30) in the GA group and 0 mm in the PNB group, (p=0.005).

Pain relief at home was adequate in all patients studied.

Six patients in the GA group (30%) and seven in the PNB group (37%) required rescue analgesia during the first 24 hours after surgery, (p=0.74).

Clinical conclusions
PNB provided a faster discharge from the PACU in comparison with GA. A higher number of PNB patients could be directly transferred from the operating room to the day-surgery unit.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic evaluation. The study was therefore categorised as a cost-consequences analysis.

Direct costs
The perspective adopted in the study was not reported. The direct costs were for the acquisition of all drugs administered by the anaesthesia staff, the acquisition of disposable material used during the study period (including needle, syringes, cannulae) and personnel costs (associated with preoperative and postanaesthesia care). The unit costs and the quantities of resources used were not presented separately. The price year was not reported. The resource use data were derived using actual data coming from the sample of patients involved in the effectiveness study. The sources of the unit costs and prices were not reported. Discounting was not relevant and, appropriately, was not carried out. The costs reported were the median costs per patient.

Statistical analysis of costs
A statistical analysis of the costs was carried out using a U-test.

Indirect Costs
The indirect costs were not included.

Currency
Euros (Euro).
Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
The costs of the disposable materials were higher in the PNB group (Euro 15, range: 15 - 22) than in the GA group (Euro 7, range: 7 - 14), (p=0.0005).

The costs of the drugs were lower in the PNB group (Euro 14, range: 14 - 15) than in the GA group (Euro 32, range: 23 - 41), (p=0.0005).

The costs of personnel relating to time spent in the preoperative unit were higher for the PNB group (Euro 30, range: 20 - 44) than in the GA group (Euro 28, range: 16 - 44), (p=0.008).

The costs of personnel relating to time spent in the PACU were lower for the PNB group (Euro 1.10, range: 0 - 22) than in the GA group (Euro 30, range: 0 - 176), (p=0.0005).

There were no significant differences in the median total costs per patient between the anaesthetic procedures. The median cost was Euro 158 (range: 105 - 194) per PNB patient versus Euro 160 (range: 101 - 238) per GA patient, (p=0.61).

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

Authors' conclusions
Compared with a propofol-remifentanil general anaesthetic (GA) technique, the combined sciatic-femoral nerve block was an effective technique in patients undergoing outpatient arthroscopy. The combined sciatic-femoral nerve block may provide similar intraoperative analgesic efficacy to the GA procedure, a shorter length of stay in the postanaesthesia care unit (PACU), and an increased likelihood of bypassing the first phase of postoperative recovery. No conclusion about the costs was drawn.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (combined sciatic-femoral nerve block procedure) was justified as it represented the routine anaesthesia technique used for knee arthroscopy in the authors' setting. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
A randomised controlled study was performed, which was appropriate for the study question. Power calculations were carried out and these justified the size of the sample used in the study. The authors stated that the study groups were comparable at baseline, therefore few confounding factors may be present. It was not reported whether the investigators were blinded to the allocation of the patients to the study groups. Assessment biases could therefore have occurred, and these might have had some impact on the results of the analysis. Since the data came from a single centre, the patients included in this study might not be representative of the study population. This may hinder the generalisability of the results to other settings. Statistical analyses were undertaken to compare health outcomes between the groups.
Validity of estimate of measure of benefit
No summary benefit measure was used as a cost-consequences analysis was carried out. Please refer to the comments in the 'Validity of estimate of measure of effectiveness; field (above).

Validity of estimate of costs
The perspective of the study was not stated, thus it was not possible to assess whether all the relevant categories of costs were included in the analysis. Details on the unit costs and price year were not reported, which limits the transferability of the economic analysis to other settings and would hinder reflation exercises. The cost estimates were derived from the authors' setting, and the authors therefore acknowledged that the results may not be entirely relevant to other hospitals because of the difference in costs. Discounting was not carried out since the costs were incurred during less than 2 years. Sensitivity analyses were not performed on the costs. Statistical tests of the costs were performed when the cost estimates were compared.

Other issues
The authors compared their results with those from other published studies, showing consistent effectiveness results. They also addressed the issue of the generalisability of the study results to other settings. The results were not reported selectively and the effectiveness conclusions reflected the scope of the study. The authors did not report any further limitations of their study. Surprisingly, the authors did not draw a conclusion in terms of both the effectiveness and costs. Sensitivity analyses were not performed to account for variability in the cost or effectiveness data. Consequently, caution should be exercised when extrapolating the study results to different contexts.

Implications of the study
The authors stated that further studies would be required before an extensive modification of guidelines and hospital policies could be recommended.

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None stated.

Bibliographic details

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Other publications of related interest


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Subject indexing assigned by NLM
MeSH
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