Efficacy and costs of patient-controlled analgesia versus regularly administered intramuscular opioid therapy


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
Patient-controlled analgesia (PCA) versus regularly administered intramuscular opioid therapy after hysterectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Adult women, classified as American Society of Anesthesiologists’ physical status I to III and scheduled to undergo abdominal hysterectomy. Exclusion criteria were age younger than 18 years or older than 65 years, body mass index more than 30 units, malignant disease, insufficient comprehension of French or English, and history of drug abuse or severe psychological disorder.

Setting
Hospital. The study was carried out at the Centre Hospitalier de l'Universite de Montreal, Hotel-Dieu Campus (HD) and the Royal Victoria Hospital (RV), Montreal, Canada.

Dates to which data relate
The time period during which effectiveness and cost data were collected was not stated. The price year was 1996.

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

Study sample
The study sample comprised 126 adult women meeting the population inclusion criteria. One patient was excluded because of a severe allergic reaction to morphine. Two other PCA patients were excluded: one had a painful pneumothorax that was diagnosed only on the third day after surgery and the other had a defective PCA pump. The authors estimated that a sample size of 70 patients per group was necessary to give the study a power of 0.8 with a type I error rate of 0.05.

Study design
This was a prospective randomised controlled trial carried out at two centres. Patients were allocated to one of two
treatment groups using a table of random numbers. The randomisation protocol was stratified according to study site, and a sealed envelope system was established in each hospital. Patients were followed up for 48 hours after surgery. No patients were lost to follow-up.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. Primary health outcomes included pain assessment (using a visual analogue scale and the McGill Pain Questionnaire), respiratory rate, degree of sedation, use of medication, post-operative recovery time, side effects, and patient satisfaction. No significant differences were found between the two treatment groups in terms of any of the patients’ demographic or clinical characteristics.

Effectiveness results
No significant differences were observed in terms of pain levels or post-operative recovery time. Time to sit in a chair without assistance was significantly longer in PCA patients: 43 hours (+/- 16) compared with 35 (+/- 11), (p=0.003). Time to resumption of a solid diet was 49 (+/- 13) hours for HD hospital and 83 (+/- 28) hours for RV hospital, (p<0.0001). Time to return of bowel function after surgery was 77 (+/- 30) hours for HD hospital and 57 (+/- 16) hours for RV hospital, (p<0.004). Mean visual analogue ratings for the overall efficacy of the analgesic treatment were 8.7 (+/- 1.5) for the PCA group and 8.8 (+/- 1.5) for the intramuscular group, (p=0.79). Patients in the intramuscular group received more morphine than the PCA patients: 132 (+/- 37) mg versus 93 (+/- 50) mg, (p<0.0001). None of PCA patients required rescue medication compared with 30% in the intramuscular group. Dose adjustments were necessary more frequently in the intramuscular group (63%) than in the PCA group (15%), (p<0.0001). Analgesic treatment for more than 10% of study participants was discontinued because of intractable side effects. No difference was found between the two treatment groups in terms of the occurrence of side effects or sedation levels.

Clinical conclusions
Comparable efficacy outcomes were observed with both treatments.

Modelling
No modelling was undertaken.

Measure of benefits used in the economic analysis
Because comparable efficacy outcomes were observed with both treatments, the economic evaluation took the form of a cost-minimisation analysis.

Direct costs
Direct costs were not discounted given the short time frame of the study (less than 1 year). Quantities and costs were reported separately. Direct costs included labour costs (pharmacy, orderly, and nursing time) and non-labour costs (tubing and morphine cartridge costs for PCA, and regular and rescue dose injections for intramuscular injections). The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Wages for staff were estimated as the midpoint in the range of pay scales in the Montreal area for 1996. Non-labour costs were estimated by hospital acquisition costs. The price year was 1996.

Statistical analysis of costs
Not reported.

Indirect Costs
Not included.
Currency
Canadian dollars (Can$).

Sensitivity analysis
Sensitivity analyses were conducted on nursing time and all the cost categories that were unique to PCA.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
Not applicable.

Synthesis of costs and benefits
In terms of labour costs for nurses, PCA treatment was found to be cost saving. PCA treatment was more expensive in terms of labour costs for pharmacy technicians and orderlies. Total labour costs were higher in the intramuscular treatment group. Total non-labour costs were higher in the PCA group. In terms of total costs, intramuscular treatment was cost saving. These results were not sensitive to changes in assumptions.

Authors' conclusions
Compared with regularly scheduled intramuscular dosing, PCA is more costly and does not have clinical advantages for pain management after hysterectomy.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. You, as a user of this database, should verify whether these health technologies are relevant to your setting.

Validity of estimate of measure of benefit
Relevant measures of benefit were used. The absence of differences between the two treatment groups was not due to insufficient statistical power. Contrary to previous studies, this study measured pain at rest and with movement. The authors acknowledged that treatment group differences may reflect differences in surgeons’ practices, hospital policies, social conditions, and geographic realities, as suggested by the significant interhospital differences on several recovery parameters.

Validity of estimate of costs
Only direct costs incurred by the hospital were included. Indirect costs such as those related to lost productivity were not considered but would be relevant for a societal perspective. Costs were derived from local sources and are unlikely to be generalisable to other settings. Purchase costs of PCA pumps and costs related to training and pump maintenance were not included. Inclusion of those costs would be even more favourable to intramuscular injection.

Other issues
Adequate comparisons with other relevant studies were made. The generalisability of the results to other settings or countries was discussed although the authors do not appear to have presented their results selectively. The study enrolled patients undergoing hysterectomy and this was reflected in the authors' conclusions.

Implications of the study
Because of comparable outcomes, the general use of PCA in similar patients should be questioned. The results need to be replicated with other types of surgery and patients. A fruitful area of research would be to identify patient characteristics that best match a particular analgesic method.

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Other publications of related interest


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