Pharmaco-economic evaluation of a disposable patient-controlled analgesia device and intramuscular analgesia in surgical patients

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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
Patient-controlled analgesia (PCA) for managing post-operative pain in surgical patients.

Type of intervention
Treatment.

Economic study type
Cost-benefit analysis and cost-effectiveness analysis.

Study population
Female patients classified as American Society of Anesthesiology physical status I and II, and scheduled for abdominal subtotal hysterectomy.

Setting
Department of Anaesthesiology, Flemish Free University of Brussels Medical Centre, Brussels, Belgium.

Dates to which data relate
The dates were not stated. The study was accepted for publication in November 1997.

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

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
40 female patients (age range: 35 - 69 years), were divided into two groups by computer generated randomisation: PCA group, n=20 and the i.m. group, n=20. No power calculations to determine the sample size were reported. All patients gave written informed consent to the study. No further inclusion or exclusion criteria were reported.

Study design
The study was a prospective, randomised controlled trial, carried out at a single centre. Patients were followed-up for three days post-operatively. No patients were lost to follow-up. The study was unblinded.
Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. Primary health outcomes included pain intensity, sedation scores, functional recovery, nursing time and analgesic efficiency. At analysis, both groups were comparable in terms of age (49.5 years +/-1.9 versus 52.1 years +/- 2.2), weight (67.5 kg +/- 2.6 versus 66.3 kg +/- 2.4), height (161.4cm +/- 1.3 versus 161.2cm +/- 1.0), duration of surgery (145 minutes +/- 7 versus 136 minutes +/- 8) and duration of anaesthesia (178 minutes +/- 8 versus 173 minutes +/- 10).

Effectiveness results
Initial visual analogue scale (VAS) scores were similar in both groups. Pain intensity was reduced by 25% after 3 hours in both groups, but marked differences were observed after 16 hours and subsequently, when the reduction in pain intensity was consistently better in the PCA group at all observation times (p<0.01). Sedation scores were similar in both groups and diminished progressively during the intermediate post-operative period. No patients in either group showed meaningful sedation after 24 hours. The analgesic efficacy of the PCA infusor system was reflected in a significantly higher sum of pain intensity differences (SPID) value (PCA = 4,109 +/- 215 versus i.m. = 2,877 +/-312; p<0.001).

On the day of surgery, the dose of piritramide was similar in both groups. The average amounts of piritramide used were significantly lower in the i.m. group during the first (PCA: 42.9 +/- 2.2, i.m.: 27.5 +/- 4.2; p<0.01) and the second (PCA: 32.7 +/- 2.5, i.m.: 8.9 +/-2.1; p<0.001) post-operative days. The total dose consumed over the three days was significantly lower in the i.m. group (PCA: 134.2 +/- 4.1, i.m.: 84.9 +/- 9.4; p<0.001). No significant differences were observed between the two groups in terms of the times to drinking, eating, flatus, stool evacuation, sitting in chair and discharge from hospital. The i.m. group was able to ambulate earlier in their room and ward (PCA: 88.3 hours +/- 5.5, i.m.: 72.9 hours +/- 4.9 h; p=0.04).

The PCA group consistently needed less nursing time for post-operative analgesia, and for patient aid and general care during the 3-day observation period. Only nursing time for post-operative analgesia at day 0 (PCA: 34.4 minutes +/-3.3, i.m.: 48.6 minutes +/- 2.6), 1 (PCA: 14.8 minutes +/- 1.5, i.m.: 25.8 minutes +/- 2.2), and in total over the 3-day period (PCA: 60.9 minutes +/- 4.3, i.m.: 88.3 minutes +/-4.7) was statistically significantly (p<0.001) shorter in the PCA group. Total nursing time over the 3 days was significantly shorter in the PCA group (PCA: 262.5 minutes +/- 9.4, i.m.: 295.7 minutes +/-12.6; p<0.05).

Clinical conclusions
The results confirmed the superior efficacy of analgesia provided by the non-electronic Basal/Bolus infusor system (PCA treatment).

Modelling
No modelling was undertaken.

Measure of benefits used in the economic analysis
The cost-effectiveness analysis used SPID as its benefit measure. SPID is the sum of pain intensity differences, multiplied by the fraction of time since the previous evaluation, over the entire observation period. The pain intensity difference refers to the difference between the actual pain and the pain intensity at the time the drug is first administered. Pain intensity was measured using a Visual Analogue Scale (VAS). All the patients had practice with the use of the VAS and participated. Pain intensity was measured every 15 minutes for the first hour, hourly for the next 8 hours and every 4 hours until 72 hours after the operation. The cost-benefit analysis used a monetary valuation of nursing time as its benefit measure.

Direct costs
Direct costs included the cost of therapy (such as the costs of piritramide use, infusor set and tubing, ancillary...
equipment per injection), personnel costs (nursing costs for aid and general care), and hospitalisation costs. Quantities and costs were not reported separately. Costs were not discounted. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Cost figures were obtained from the hospital.

**Statistical analysis of costs**
The data were analysed by one-way analysis of variance (ANOVA). A p-value less than 0.05 was considered to be statistically significant.

**Indirect Costs**
Some indirect costs were included under the heading "hospitalisation costs".

**Currency**
Belgian francs (Bfr). No conversion was performed.

**Sensitivity analysis**
No sensitivity analysis was undertaken.

**Estimated benefits used in the economic analysis**
Taking the benefit measure for the cost-benefit analysis, total nursing costs were significantly higher in the i.m. group (PCA: Bfr4,110 +/- 138, i.m.: Bfr4,725 +/- 196; p<0.05). Taking the benefit measure for the cost-effectiveness analysis, SPID in the PCA group was significantly higher (PCA = 4,109 +/- 215 versus i.m. = 2,877 +/- 312; p<0.001).

**Cost results**
Total analgesic therapy costs were significantly higher in the PCA group (PCA: Bfr4,580 +/- 68, i.m.: Bfr1,676 +/- 80; p<0.001). Total nursing costs were significantly higher in the i.m. group (PCA: Bfr4,110 +/- 138, i.m.: Bfr4,725 +/- 196; p<0.05). Total direct costs in the PCA group exceeded those in the i.m. group (PCA: Bfr7,716 +/- 138, i.m.: Bfr4,989 +/- 204; p<0.001). There was no significant difference between the two groups in terms of hospitalisation costs.

**Synthesis of costs and benefits**
The cost-benefit analysis indicated a higher cost-benefit ratio for the PCA group (PCA: Bfr1.1, i.m.: Bfr0.35). The cost-effectiveness ratios in both groups were similar (PCA: Bfr1.9, i.m.: Bfr1.7).

**Authors' conclusions**
The cost-benefit analysis showed that PCA had a higher cost-benefit ratio. However, because of the more efficacious analgesia of PCA, cost-effectiveness was similar for both analgesic treatments.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear.

**Validity of estimate of measure of benefit**
The measure of benefit in the cost-effectiveness analysis seems to be valid. No justification was given for the choice of the 3-day observation period. It could be argued that there was no well-founded reason for choosing nursing time as a benefit measure and for carrying out a cost-benefit analysis. Essentially, the analysis was concerned with two cost figures (costs of therapy and nursing time) which make up total costs: they should be treated as such and not translated.
into an "artificial" benefit measure.

**Validity of estimate of costs**
The cost figure was made up mostly of direct costs. No sensitivity analysis was conducted, which makes it difficult to assess the robustness of the results and the generalisability of the cost results to other settings or countries.

**Other issues**
The reader's attention is drawn to a possible flaw in the study: the unblinded study design may have introduced bias in the VAS scores and nursing times. Additional problems may arise from the small sample size. The results of this study may not be generalisable to other settings due to differences in surgeons' practice, hospital discharge policies and social conditions. It is considered that a cost-effectiveness analysis would have sufficed, since the cost-benefit analysis is artificial and provides no additional relevant information.

**Implications of the study**
The results of this study need to be validated by other research carried out preferably in other settings and countries.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
9649988

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Activities of Daily Living; Adult; Aged; Analgesia, Patient-Controlled /economics /instrumentation /nursing; Analgesics, Opioid /administration & dosage /economics /therapeutic use; Analysis of Variance; Cost-Benefit Analysis; Direct Service Costs; Disposable Equipment /economics; Drug Costs; Economics, Pharmaceutical; Evaluation Studies as Topic; Female; Follow-Up Studies; Humans; Hypnotics and Sedatives /administration & dosage /economics /therapeutic use; Hysterectomy; Infusion Pumps /economics; Infusions, Intravenous /economics /instrumentation; Intramuscular /economics /instrumentation /nursing; Male; Middle Aged; Pain Measurement; Pain, Postoperative /economics /nursing /prevention & control; Piracetam /administration & dosage /economics /therapeutic use; Prospective Studies; Receptors, Opioid, mu /agonists; Time Factors

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