Determination of an effective dose of intrathecal morphine for pain relief after cesarean delivery

Gerancher J C, Floyd H, Eisenach J

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
Administering intrathecal (IT) morphine along with oral hydrocodone/acetaminophen and other commonly prescribed drugs for pain relief after cesarean delivery. The method of administration of IT morphine was up-down sequential allocation of doses.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Women scheduled for elective cesarean delivery.

Setting
Hospital. The economic study was carried out in North Carolina, the United States.

Dates to which data relate
The dates corresponding to the collection of effectiveness and resource use data were not explicitly specified. 1997 prices were used.

Source of effectiveness data
The evidence for final outcomes was 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 conducted prospectively for the intervention and retrospectively for the comparator.

Study sample
Power calculations were not used to determine the sample size. The intervention group consisted of 40 patients with an average (SD) age of 32 (5) years and with an average (SD) age of 29 (4) years (for failures) who requested spinal anaesthesia and were scheduled for elective cesarean delivery. Four patients were excluded from the study after providing their consent. The PCA group consisted of 15 patients with an average (SD) age of 29 (5) years.
Study design
Non-randomised study with historical controls, carried out in a single centre. Patients were followed up for 72 hours after caesarean section. Dose allocation for the intervention was double-blinded at all times. The duration of the follow-up was 72 hours after cesarean delivery. No loss to follow-up other than those excluded for protocol violations was reported.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only (because of the exclusion of cases with protocol violations). Success rate was the main clinical outcome. The administration of morphine IV at any time before 12 hours after spinal blockade was defined as the criterion for failure. Patients' expectation of postoperative pain, pain intensity, quality of pain relief, complaints of side effects, and willingness to have IT morphine again were assessed by administering a six-question survey within 72 hours of cesarean delivery by one blinded investigator and completed by each patient. Morphine consumption was measures for the first 24 hours. Patient demographic features did not differ across the three groups (success and failures as subgroups of the intervention group and the historical control group).

Effectiveness results
The success rate was 62.5%. Patient survey results were not statistically different between patients who met criteria for IT morphine analgesia success and failure. Patients' expectations of postoperative pain, complaints of pain, and complaints of side effects were not different across the groups. Intrathecal morphine was well accepted by both groups: 80% would choose IT morphine treatment again, and 88% rated their analgesia as 'good' or 'excellent'. The mean (SD) verbal pain score was 3.3 (2.2) for the success cases, 3.6 (2.3) for failure cases, and 4.4 (1.7) for the PCA patients. The authors' best estimate of a 50% effective dose of IT morphine was 22 (+/- 53) microg. Morphine consumption (mg) was 1 (2) for the success cases, 14 (11) for the failure cases, and 54 (29) for the PCA patients.

Clinical conclusions
When used along with oral analgesics, very small doses of spinal morphine provide adequate pain relief after caesarean delivery.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the study. Quantities of morphine consumption and nursing time estimates were reported separately from the costs. The cost analysis only covered the drug costs, and nursing time estimates were reported separately. Acquisition costs for postoperative analgesic therapy were calculated by multiplying 1997 US wholesale drug prices by the actual number of treatments administered to each patient in each group over 24 hours. Nursing time was estimated by the administration of a survey to a sample of 10 nurses. The cost analysis did not cover the costs of equipment and supplies; their acquisition, storage, and maintenance costs; costs of nursing time; or costs of patient comfort or satisfaction.

Indirect Costs
Not included.

Currency
US dollars ($).
Sensitivity analysis
Not performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
Drug acquisition costs for the IT morphine protocol was $15.13 (+/- $4.40) versus $34.64 (+/- $15.55) for the PCA group, (significantly different). Time spent managing patients based on nursing personnel estimates did not differ between IT morphine analgesia, 150 (+/- 57) minutes, and PCA, 148 (+/- 61) minutes.

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors' conclusions
Very small doses of IT morphine, when used in combination with oral analgesics and other commonly prescribed medications, provide time- and cost-efficient postoperative analgesia after cesarean delivery. These results support the use of small doses of IT morphine with oral analgesics and other commonly prescribed medications for analgesia after cesarean delivery.

CRD COMMENTARY - Selection of comparators
reason for the choice of comparator is clear.

Validity of estimate of measure of benefit
internal validity of the study results may be weakened by the use of a non-randomised study design, and the relatively small sample size, as acknowledged by the authors. Given the lack of an explicit benefit measure, the study may be classified as a cost-consequences analysis.

Validity of estimate of costs
ntities of limited items of resource use were reported separately from the costs. Adequate details of methods of cost estimation were given. The study lacked a fully prospective cost analysis.

Other issues
issue of generalisability to other settings was not discussed. In view of the small sample size, absence of a randomised design, and lack of both sensitivity analysis and statistical analysis of the costs, the results need to be treated with some caution.

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