Postoperative pain control after lumbar spine fusion: patient-controlled analgesia versus continuous epidural analgesia

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
The use of continuous epidural analgesia to control post-operative pain in patients undergoing lumbar fusion. The analgesic used was a mixture of local anaesthetic and epidural opioid administered via an epidural catheter placed intraoperatively, using a continuous infusion pump. The mixture was epidural morphine sulphate (0.004%) with bupivacaine (0.0625%).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing lumbar fusion for spinal stenosis, spondylolisthesis, spinal instability and degenerative disc disease.

Setting
Hospital. The economic study was carried out in Charlotte, North Carolina, USA.

Dates to which data relate
No dates were given for either the effectiveness study or costs. The study was acknowledged for publication on March 30 1996.

Source of effectiveness data
Evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
It was not stated whether costing was based on the same patient sample as that used in the effectiveness study nor when it was collected.

Study sample
It was not reported whether power calculations determined sample size. Randomisation was carried out using a random numbers table. 54 patients were randomised to the 2 groups with 26 in the epidural group and 28 in the PCA group. It was not stated whether anyone refused to participate. Exclusion criteria for the study included anaesthetic or opioid allergy, a history of chemical dependence, non-ambulatory status and ASA class IV. The number of exclusions
was not reported.

Study design
The study was a single-centre randomised blinded controlled trial. Follow-up was 3 days. Loss to follow-up was 5/26 (19%) in the intervention and 7/28 (25%) in the control. Reasons for loss to follow-up included 3 in each group (11% of the total) who dislodged the epidural catheter (which was one of the measures of outcome), and 1 additional patient in each group was withdrawn for treatment failure. Other withdrawals were determined to be unrelated to the study protocol including 2 randomised to the PCA group in whom the spinal fusion was not performed. Blinding was achieved by attaching to each patient both an epidural catheter and a PCA delivery system. Patients, surgeons, nursing staff and data collectors were unaware of the active device, however it was difficult to completely blind physicians and nursing staff because of their recognition of the effects of the epidural active agent. Anaesthesiologists of the acute pain service and hospital pharmacy were aware of the active agent used.

Analysis of effectiveness
Analysis was based on treatment completers only, except for measurement of catheter dislodgement, leaving 21 in each group for analysis. Primary health outcomes were:

1. the rate of catheter dislodgement,
2. other mild side effects (including itching, nausea, respiratory depression and transient hypotension),
3. the time taken for the patient to accept liquids and
4. the time taken for the patient to accept solids,
5. the time to ambulation,
6. the length of stay, and
7. pain recorded by a visual analogue scale on postoperative days 1, 2 and 3.

Groups were shown comparable in terms of age, number of levels fused, the use of instrumentation, estimated blood loss and intra-operative complications.

Effectiveness results
Overall the rate of catheter dislodgement was 11%. Minor side effects occurred in 71% of patients in both groups. No major complications occurred. There was no significant difference between groups in times to liquids and solid food, ambulation, length of stay or pain as recorded by visual analogue scale scores.

Clinical conclusions
There was no clinical advantage of epidural opiate/local anaesthetic anaesthesia over systemic opiate by patient-controlled analgesia for spinal fusion patients. The disappointingly high rate of overall catheter dislodgements favours the use of patient-controlled analgesia. It is possible that the low dosage of bupivacaine and the position in which the catheter tip was placed may have prevented adequate delivery of anaesthetic in the intervention group.

Measure of benefits used in the economic analysis
Since the clinical study showed no difference in effectiveness between the strategies the economic analysis was based on costs only.

Direct costs
No details were given of methods of cost collection or analysis. Quantities, prices and total costs were not given. No price date was given. The only figure quoted was the difference in cost between the 2 strategies plus the ratio between them. Costs measured included hospital, physician and pharmacy charges for a 3 day post-operative course of pain relief. The charges were based on management of PCA by the hospital acute pain service rather than by the surgeon. The cost boundary is unclear though use of the word “charges” may indicate that it was the purchaser rather than the hospital.

**Statistical analysis of costs**
Costs were not analysed stochastically.

**Currency**
US dollars ($).

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
Continuous epidural analgesia cost $550 more than PCA for a 3 day course. The relative cost was 1.68 for the epidural compared to 1 for PCA.

**Synthesis of costs and benefits**
Not applicable.

**Authors’ conclusions**
There is no clinical advantage in delivering opiate/local anaesthetic by epidural rather than opiate by patient-controlled apparatus although cost favours the use of patient controlled analgesia.

**CRD COMMENTARY - Selection of comparators**
It is clear why the comparator was chosen.

**Validity of estimate of measure of benefit**
There was a high loss to follow-up and some, at least, of the drop-outs were caused by treatment failure and should have been included in the analysis. The drop-out rate caused by catheter dislodgement was given as 11% overall, 3 in each group, but the comparator group only had epidural catheters in the interests of blinding.

**Validity of estimate of costs**
Details of costing are minimal and no conclusions can be drawn or generalisations made from the economic study.

**Other issues**
Given the lack of details concerning the estimation of costs the findings of the study cannot be applied to other settings or countries.

**Implications of the study**
Further studies are needed to confirm the findings of this particular trial.