
Epidural bolus clonidine/morphine versus epidural patient-controlled bupivacaine/sufentanil: quality of postoperative analgesia and cost-identification analysis

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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

The use of patient-controlled epidural analgesia (PCEA) with a combination of bupivacaine and sufentanil (BS).

Type of intervention

Treatment.

Economic study type

Cost-effectiveness analysis.

Study population

The study population comprised patients undergoing pancreatic surgery. Patients were excluded if they were aged over 65 years, had received chronic treatment with corticosteroids, had an allergy to one of the study substances, or had contraindications to epidural puncture.

Setting

The study setting was a hospital. The economic study was carried out in Germany.

Dates to which data relate

The dates during which effectiveness, resource use and cost data were collected were not reported. The price year was not reported.

Source of effectiveness data

The effectiveness data were derived from a single study.

Link between effectiveness and cost data

The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample

Sixty-eight patients undergoing pancreatic surgery were randomised to BOLUS (n=35) and PCEA (n=33). Twenty-seven BOLUS patients and 23 PCEA patients were males. The mean age of patients was 50 years in the BOLUS group and 51 years in the PCEA group. The BOLUS and PCEA patients had mean heights of 173 and 171 cm, respectively, and mean weights of 66 and 68 kg. To demonstrate a 10% cost reduction with a power of 80% and a type I error rate of 5%, a sample size of 58 was needed, with 68 patients needed to account for drop-outs.

Study design

The study was an open design, randomised, controlled trial carried out at a single centre. Patients were followed-up until the fourth post-operative day (PO day). Five BOLUS and four PCEA patients dropped out because of inadequate analgesia with the pre-randomised regimen, occlusion or dislocation of the epidural catheter, or a systolic arterial pressure (SAP) greater than 80 mmHg.

Analysis of effectiveness

Drop-out patients were switched to intravenous patient-controlled opioid analgesia with morphine, and the recording of time and costs was continued; analgesia and side-effects were excluded from the data analysis. The primary health outcomes used were a visual analogue scale (VAS) score at rest and during coughing, heart rate, SAP, incidence of post-operative nausea and vomiting, pruritus, duration of intestinal paralysis, and hospital treatment. Patient groups were found to be comparable by statistical analysis in terms of age, height, weight, gender, diagnosis, incidence of pre-operative abdominal pain, segmental location of the epidural catheter, and duration of operation.

Effectiveness results

Pain intensities at rest were low (VAS score less than 3) and were comparable between groups, ($p > 0.06$). Heart rate was less frequent in BOLUS patients, compared with PCEA patients, on PO days 1 to 4 ($p < 0.013$). SAP was less frequent with BOLUS patients except at 48 and 72 hours, ($p < 0.05$). The incidence of hypotension (SAP less than 80 mmHg) was greater in the BOLUS group (17%) than in the PCEA group (0%), ($p < 0.001$). The incidences of pruritus ($p = 0.7$) and post-operative nausea and vomiting ($p = 0.36$) were comparable. The time required for post-operative pain treatment was longer in the BOLUS group as far as the physician was concerned: 258 versus 182 minutes, ($p = 0.001$). The nurse spent comparable time with patients of both groups: 246 (BOLUS) versus 250 minutes (PCEA), ($p = 0.8$).

Clinical conclusions

An epidural bolus of MC compared with PCEA with BS results in comparable analgesia at rest, inferior analgesia during coughing, and increased incidence of hypotension.

Measure of benefits used in the economic analysis

The authors did not report a summary measure of health benefit and left clinical outcomes disaggregated. Hence, a cost-consequences analysis was conducted.

Direct costs

The direct costs were not discounted since the timeframe of the study was less than 1 year. Some quantities and costs were reported separately, but it was unclear how quantities were related to the final costs. The direct costs were costs for medical personnel, medical supplies and drugs, and for the device for patient-controlled opioid analgesia. The quantity/cost boundary adopted was that of the hospital. The costs and quantities were obtained from the authors' institution. The price year was not reported.

Statistical analysis of costs

The authors used an analysis of variance to detect cost differences between groups. A p-value of less than 0.05 with Bonferroni's correction for multiple comparisons was considered significant. The authors reported total costs for each group.

Indirect Costs

Indirect costs were not included.

Currency

US dollars (\$).

Sensitivity analysis

No sensitivity analyses were reported.

Estimated benefits used in the economic analysis

See the effectiveness results reported above.

Cost results

The costs for pain treatment by the physician were higher with BOLUS patients than for PCEA patients, \$140 versus \$90 ($p < 0.05$). The costs of drugs (\$50 versus \$20, $p < 0.007$) and consumables, ($p < 0.006$) were higher for PCEA patients. The total costs of pain treatment were comparable at \$260, ($p = 0.9$).

Synthesis of costs and benefits

The costs and benefits were not combined into cost-effectiveness ratios as this was a cost-consequences analysis.

Authors' conclusions

An epidural bolus of MC compared with PCEA with BS results in comparable analgesia at rest, inferior analgesia during coughing, and increased incidence of hypotension at comparable total cost.

CRD COMMENTARY - Selection of comparators

A justification was given for the comparator used, namely that it represented a currently employed strategy. You, as a user of the database, should decide if these health technologies are relevant to your setting.

Validity of estimate of measure of effectiveness

The analysis was based on an open design, randomised controlled trial, which was appropriate for the study question. The authors reported the baseline characteristics of the study sample, which allows the reader to investigate whether the study sample was representative of the study population. The analysis of effectiveness was handled credibly. The authors did not explain why the recording of time and costs relating to drop-out patients was continued, while analgesia and side-effects were excluded from the data analysis.

Validity of estimate of measure of benefit

The benefits were estimated directly from the effectiveness analysis.

Validity of estimate of costs

The cost analysis demonstrated several commendable features in that all relevant direct cost categories were included, and statistical analyses were conducted. However, the price year was not reported, some quantities were not reported separately, no sensitivity analyses were reported on quantities or costs and drug prices were not converted into costs.

Other issues

The authors made appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors do not seem to have presented their results selectively. The study considered patients undergoing pancreatic surgery and this was reflected in the authors' conclusions. The dates during which effectiveness, resource use and cost data were collected were not reported. The authors noted that there was a tendency towards prolonged duration of intensive care unit treatment and delayed bowel function in BOLUS patients,

which might have become significant with a larger sample size.

Implications of the study

According to the authors, epidural bolus pain treatment with MC cannot be recommended over PCEA with BS in unselected patients because, although the options produce comparable analgesia at comparable costs, Bolus MC results in a high incidence of severe hypotension. However, in patients with increased sympathetic tone, the side-effects of epidural MC may be desirable. The authors did not select a summary measure of health benefit and the analysis of cost data could have been reported more extensively.

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