Prospective randomized, controlled trial of thoracic epidural or patient-controlled opiate analgesia on perioperative quality of life

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Background. Perioperative epidural analgesia provides continuous pain control and may have advantages over parenteral opiate administration. This study assessed the impact of epidural analgesia on quality of life (QOL) of patients undergoing major surgery.

Methods. Sixty patients undergoing thoracic or thoraco-abdominal surgery were studied prospectively. Patients were randomly assigned to receive either thoracic epidural analgesia or patient-controlled i.v. opiate analgesia (PCA) after operation. Visual analogue pain and sedation scores were recorded for the period of the study. QOL health surveys at 24 h (SF-8 acute form) and at 1 week (SF-36) were recorded. Results were examined by uni- and multivariate analyses corrected for the effect of multiple comparisons.

Results. Mean pain scores were significantly lower in the epidural group at most time points. Physical and mental scores in the epidural group were significantly better than the PCA group for both SF-8 and SF-36 QOL health surveys (P<0.001).

Conclusions. Epidural analgesia with local anaesthetic and opioid improves QOL and delivers better analgesia compared with PCA in patients undergoing major thoraco-abdominal surgery.

Br J Anaesth 2010; 104: 292–7

Keywords: analgesia, patient controlled; analgesia, postoperative; analgesic techniques, thoracic epidural

Accepted for publication: December 12, 2009
(New York Heart Association Class III–IV), or severe respiratory disease with forced expiratory volume <50% of the predicted value; and those with contra-indication to the epidural catheter placement (e.g. coagulopathy, spinal stenosis, or local infection). A total of 71 consecutive patients were screened and three patients excluded due to severe cardio-respiratory status (n=2) and spinal stenosis (n=1). If there was a failure of TEA, the patient was transferred to a PCA and included in the PCA group for statistical analysis. No patient would be transferred from the PCA group to the TEA group.

All operations were performed under general anaesthesia with neuromuscular block and inhalation agents as standard. Thoracotomy for pulmonary resection and oesophagectomy were performed using the muscle-sparing technique. Before induction of anaesthesia, an epidural catheter was placed at the level T3–10 depending on the level of incision (T3–8 and T4–10 for thoracotomy and upper abdominal surgery, respectively) or the patient was taught to use the PCA device. The epidural analgesia tested and started before the start of the surgery. The opioids were standardized as bupivacaine 0.1% with fentanyl 2 µg ml⁻¹ for epidural infusion at 5–10 ml h⁻¹, and for the PCA, morphine 1 mg ml⁻¹ with a 7 min lock-out. Patients were transferred to a high-dependency unit for the duration of epidural or PCA administration, admission to the intensive care unit was at the discretion of the anaesthetist. The ward nursing staff, specialist pain nurse, and physiotherapists were unaware of the ongoing study, but patients and staff were not blinded to the routes of analgesia. As is standard practice, the vital signs, visual analogue pain scale, and sedation score (Table 1) were recorded at half-hourly intervals for 4 h after operation, hourly up to 12 h, and 2–4 hourly thereafter. In patients with an epidural, motor block (Table 1) was also recorded at these intervals. All scores were recorded by trained high-dependency and specialist pain nurses. The QOL health survey was recorded by a trained high-dependency unit was at the discretion of the anaesthetist. The ward nursing staff, specialist pain nurse, and physiotherapists were unaware of the ongoing study, but patients and staff were not blinded to the routes of analgesia. 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All scores were recorded by trained high-dependency and specialist pain nurses. The QOL health survey was recorded by a physician (who did not participate in patient care) at 24 h (SF-8 acute form) and at 1 week (SF-36), or by post if the patient had been discharged.

The SF-36 is a multi-purpose, short-form health survey with only 36 questions. It is useful for comparing the relative burden of diseases, and in differentiating the health benefits produced by a wide range of different treatments. It yields an eight-scale profile of functional health and well-being scores and also psychometrically based physical and mental health summary measures and a preference-based health utility index. The eight scales are hypothesized to form two distinct higher-ordered, physical and mental health variance. Three scales (physical functioning, role-physical, and body pain) correlate most highly with the physical component and contribute most to the scoring of the physical component summary (PCS) measure. Three scales (mental health, role-emotional, and social functioning) correlated most highly with mental health. Vitality, general health, and social functioning have noteworthy correlations with both components.

Univariate and repeated measures analyses were performed with commercially available software (Windows SPSS Incorporated, Chicago, IL, USA). Assessment of differences in QOL between the groups was performed using analysis of variance with the pain scores treated as continuous variables. χ² tests were used to compare the groups on discrete variables (%). Possible confounding variables such as age, gender, and type of operation were modelled using multi-factorial analysis of variance. Results were corrected for multiple comparisons using a Bonferroni correction factor. All pain and QOL scores are expressed as means with confidence intervals as indicated. A P-value of <0.05 was considered statistically significant.

Results

Patient characteristics

Sixty-eight patients fulfilling inclusion criteria consented to the trial, and 38 were assigned to the epidural group. One patient was transferred to the PCA group at 3 h because of the failure to achieve pain control and epidural leak. Another patient had poor pain control and required additional i.v. opiate and non-steroidal analgesia. Two other patients had epidural leak on day 3, but this did not influence the pain control. Of the 30 patients assigned to the PCA group, six were excluded because of postoperative confusion or were unable to complete the questionnaire (Fig. 1). The median age for the epidural was 59 (SD 14.7) yr and for the PCA group was 62 (17.7) yr. Eighteen of 37 patients in the epidural group were male compared with 17 of 23 PCA patients (Table 2). In the epidural

Table 1 Scoring systems for pain, sedation, and motor block

<table>
<thead>
<tr>
<th>Pain</th>
<th>Sedation</th>
<th>Motor block</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Very mild</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Mild</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>Moderate</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Severe</td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>Very severe</td>
<td>5</td>
</tr>
</tbody>
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group, approximately two-thirds (25/37, 66.6%) underwent thoracotomy alone while the remaining one-third (11/37, 32.4%) patients underwent Ivor-Lewis oesophagectomy with both right thoracotomy and upper midline laparotomy. The corresponding proportions in the PCA group were not significantly different; 18 (78.3%) and 5 (21.7%) (Tables 2 and 3).

Pain scores
Average pain scores were lower in the epidural group at 6, 12, and 18 h and second and third postoperative days (Fig. 2). After adjustment for multiple testing, these values were statistically significant at days 1, 2, and 3 (P-values 0.004, 0.003, and 0.008, respectively).

Quality of life
Patients receiving epidural analgesia showed improved QOL scores (Fig. 3). At 24 h, the SF-8 health survey scores for epidural patients were PCS 46.37, MCS 49.33 for the epidural and PCS 35.56, MCS 31.68 for the PCA groups, respectively, with again an adjusted P-value of <0.001. After adjustment for multiple measures, SF-8 PCS and MCS and SF-36 PCS and MCS for the epidural analgesia were still superior (P-values 0.006, 0.001, 0.016, and 0.001, respectively).

The mean length of stay was shorter for epidural patients (14.5 days) compared with PCA patients (16.9 days), but this was not statistically significant (P=0.383).

Multivariate analysis
Multi-factorial analysis of variance was conducted to test if pain scores and QOL remained significant when patient characteristics were considered. None of the factors (age, gender, and type of operational procedure) had a significant impact on pain or QOL scores (Table 2).
Patient satisfaction

One patient in the epidural group was not satisfied with the mode of analgesia (due to catheter leakage). Overall, patient satisfaction was 97.3% in the epidural group compared with 74% in the PCA group ($P < 0.05$).

Nursing staff satisfaction

Eighty-nine per cent of the nursing staff were satisfied with epidural analgesia. Nursing staff reported that patients with epidurals needed less care because of early physical independence.

Discussion

This study found better pain control in the epidural group to be consistent for the period of observation and significant at 1, 2, and 3 days after operation. This is in keeping with the findings of two prospective, randomized trials that found improved analgesia with thoracic epidural compared with the intercostal block and superiority of intra- plus postoperative epidural rather than just postoperative. However, the time of starting TEA (pre-incision or at closure) does not influence long-term post-thoracotomy pain.

Patient age, sex, or type of procedure had no significant influence on scores. However, alterations in procedure types may influence degree of pain. A recent randomized trial of 60 patients comparing muscle-sparing thoracotomy with standard posterolateral thoracotomy found the former to be significantly less painful, although there was little difference in pulmonary function. Similarly, the technique of rib closure has been shown to affect the level of discomfort, with pericostal sutures implicated in post-thoracotomy shooting pain. In this study, surgery was performed with a standardized muscle-sparing thoracotomy and upper midline laparotomy incisions with similar, defined anatomical exposure and method of fascial/cutaneous closure. The epidural catheters were placed at thoracically rather than at lumbar levels with the aim of providing segmental analgesia and sparing lumbosacral segments to minimize urinary retention, motor block, and hypotension.

The QOL measures in the epidural group were significantly better than the PCA group at all time points; however, it is unlikely that improved analgesia alone decreases perioperative morbidity and improves QOL. We suspect that the differences in QOL are due to less nausea, vomiting, pain, and possibly, sleep deprivation. However, this cannot be proven specifically as the QOL instrument is not able to break down the reason for the enhanced score. Regional analgesic techniques provide additional physiological benefits by enhancing gastrointestinal motility and mucosal blood flow by inhibiting sympathetic outflow and facilitating parasympathetic drive.

Although epidural analgesia promotes patient well-being, faster recovery of bowel function, and patient mobility, it does not alter length of stay in hospital when compared with PCA. Better analgesia and faster return of bowel activity has been shown for TEA compared with PCA in elective open surgery for colectomy, but calorie/protein intake or overall stay was unaffected. This may reflect persistent protein catabolism despite smoother glycaemic changes with epidurals.

A randomized study of 38 patients undergoing laparoscopic colectomy found TEA provided better analgesia without altering length of stay. Our study assessed patient attitude and mental state and also physical well-being by self-appraisal and QOL measurement. TEA improved both physical and mental scores in addition to producing better analgesia and patient satisfaction.

Patients undergoing major surgery are at risk of pulmonary complications due to impaired diaphragmatic, intercostal, and abdominal muscle function and, if analgesia is inadequate, tidal volumes reduce resulting in...
inadequate responses to physiotherapy.\textsuperscript{20} \textsuperscript{35} \textsuperscript{34} Compared with PCA, epidural analgesia may improve pulmonary function and tissue oxygenation by attenuating spinal reflex inhibition of diaphragmatic function, lowering pain and sedation scores, and facilitating patient participation in physiotherapy.\textsuperscript{20} \textsuperscript{35} \textsuperscript{36} A weakness of this study is the failure of the block randomization to achieve equal numbers of patients in the two groups. We felt that block randomization would help in maintaining the double-blinding of the study. The study terminated when the anaesthetists, specialist pain nurse, and nursing staff became aware of the study.

In conclusion, the use of epidural analgesia is associated with better pain control and better short-term QOL for patients after major surgery compared with patients receiving PCA. Although the reasons for the QOL improvements were not independently assessed, it seems they are due, at least in part, to better mobility, less sedation, improved compliance with physiotherapy, and more effective analgesia.

Acknowledgements
The authors would like to acknowledge statistical advice and assistance from Mr P. O’Kelly of the Department of Nephrology and Transplantation, Beaumont Hospital, and Ms J. O’Brien, pain specialist nurse in the Department of Anaesthesia, Beaumont Hospital.

References
7. McHorney CA, Ware JE, Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care 1993; 31: 247–63
10. Ware JE, Kosinski M, Keller SD. SF-12®: How to Score the SF-12® Physical and Mental Health Summary Scales, 2nd Edn. Boston, MA: The Health Institute, New England Medical Center, 1995