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Epidural analgesia diminished pain but did not otherwise improve enhanced recovery after laparoscopic sigmoidectomy: a prospective randomized study

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Abstract
Background The primary hypothesis for this study was that epidural analgesia reduces the use of opioids and thus advances bowel function and oral intake and shortens hospital stay after laparoscopic sigmoidectomy performed according to principles of enhanced recovery after surgery.
Methods For this study, 60 patients with complicated diverticular disease were randomized to the epidural anesthesia group or the control group before surgery. Postoperative oxycodone consumption, pain, and recovery parameters were followed for 14 days.
Results The epidural group needed less oxycodone than the control group until 12 h postoperatively. They experienced significantly less pain related to coughing and motion until postoperative day 2. In the epidural group, fewer patients experienced significant pain, and the duration of postoperative pain was shorter. Postoperative oral intake, bowel function, hospital stay, and overall complication rate were similar in the two groups. However, the control group had more postoperative hematomas.
Conclusions Epidural analgesia significantly alleviates pain, reducing the need for opioids during the first 48 h after laparoscopic sigmoidectomy. However, epidural analgesia does not alter postoperative oral intake, mobilization, or length of hospital stay.

Keywords Enhanced recovery · Epidural analgesia · Laparoscopic sigmoidectomy

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To enhance postoperative recovery and reduce morbidity and even mortality, several investigators have sought to optimize the perioperative care of patients who undergo elective surgery for colonic diseases. Their investigations have led to the creation of enhanced recovery after surgery (ERAS, i.e., fast-track) programs, which have been shown to reduce postoperative pain, advance oral intake and bowel function, enhance pulmonary function, and reduce postoperative stay for patients who undergo elective colorectal surgery [1–7].

In a multinational survey of 1,082 patients who underwent surgery for colonic morbidities, those treated according to ERAS criteria were discharged 5 to 8 days earlier than the traditionally managed patients [8]. In ERAS programs, the method of operation (i.e., open or laparoscopic) does not seem to affect the length of hospital stay [1, 8, 9]. However, in a European study involving five centers, laparoscopically managed patients had shorter hospital stays but higher readmission rates than those treated with open surgery [10].

A recommended regimen for colorectal patients with ERAS was published recently by Wind et al. [11]. One of the 17 details listed is epidural analgesia. In a recent randomized trial comparing epidural analgesia and oral medication given to patients undergoing open

sigmoidectomy, and no advantage in favor of thoracic epidural analgesia was found. The proportion of unsuccessful epidurals was 20.6% in this study [12].

One large randomized controlled trial showed that intraoperative epidural analgesia did not reduce major surgical morbidity or mortality in a high-risk population [13]. However, to our knowledge, no prospective controlled trials have investigated epidural analgesia for patients undergoing elective laparoscopic sigmoid resection for diverticular disease in an ERAS setting, with the epidural catheter introduced in the Th 10–11 interspace to secure sufficient concentration of analgesic substance in the lower parts of the thoracic epidural space.

Our study aimed to investigate whether epidural analgesia is needed after laparoscopic surgery for sigmoid diverticular disease among patients receiving care according to the ERAS criteria. We hypothesized that decreased postoperative pain due to epidural analgesia reduces the use of opioids and thus advances postoperative bowel function and oral intake, shortens hospital stay, and decreases complication and readmission rates after laparoscopic sigmoidectomy.

Materials and methods

Between October 2005 and March 2006, 60 consecutive elective patients with complicated diverticular disease (one acute episode in patients younger than 50 years and two in older patients or a preoperative stricture) were randomized either to receive or not to receive epidural analgesia with ropivacaine in conjunction with laparoscopic sigmoid resection. The open randomization was done before the operation using sealed envelopes in blocks of 10.

All the patients underwent surgery at Maria Hospital, Helsinki University Central Hospital, Finland. The inclusion criteria specified an American Society of Anesthesiologists (ASA) physical status score of 1–3, no contraindications for epidural anesthesia, and no allergy for paracetamol, nonsteroidal antiinflammatory drugs (NSAIDs), or local anesthetics. Patients were not eligible for the study if they had bleeding disorders, chronic pain syndrome, bronchial asthma, liver or kidney insufficiency, or diverticular disease presenting with colovesical fistulas. Patients with colovesical fistulas were excluded because they would have required a urinary catheter for several days postoperatively. Previous abdominal operations were not a contraindication for laparoscopy.

All the patients had been clinically examined previously, including preoperative colonoscopy. The patients were also informed about intra- and postoperative care including enhanced postoperative rehabilitation, early oral intake, and mobilization, which are essential parts of the ERAS program. The study was approved by the ethics committee of Helsinki University Central Hospital, and a written informed consent was obtained from each patient.

All the patients were given ketoprofen 100 mg, paracetamol 1 g, and diazepam 0.15 mg/kg orally as premedication and anesthetized using remifentanil, propofol, and rocuronium before endotracheal intubation. Rocuronium was administered repeatedly for muscle relaxation during surgery, and muscle relaxation was reversed with neostigmin and glycopyrrone at the end of surgery.

Before their general anesthesia, the patients randomized to receive epidural analgesia were given a 3-ml test dose of lidocaine 20 mg/ml including adrenaline followed by a 10-ml dose of ropivacaine 5 mg/ml via the epidural catheter placed in the Th 10–11 interspace. Ropivacaine blocks sodium ion influx into peripheral nerve fibers. This action is potentiated by inhibition of dose-dependent potassium channels. In isolated animal nerve studies, ropivacaine was more selective for pain (Aδ and C) than for motor (Aβ) nerve fibers compared with bupivacaine. Ropivacaine also is less cardiotoxic than bupivacaine [14]. Thus, ropivacaine is an especially suitable anesthetic for "fast-track" surgery in which rapid mobilization is of the essence. The lower thoracic site was used for the epidural catheter because of the Trendelenburg position used for the laparoscopic sigmoidectomy.

The patients were treated according to ERAS principles [11], and the following ERAS criteria were fulfilled: preoperative counseling, preoperative feeding, intraoperative high-oxygen partial pressure, active prevention of hypothermia, epidural analgesia (according to randomization), minimal invasiveness, no routine use of postoperative nasogastric tubes or drains, enforced postoperative mobilization, enforced postoperative oral intake, no routine use of morphine or other similar opioids, fluid restriction, and early removal of the urinary catheter. Two days before the operation, 3 l of oral purgative bowel preparation (Colonsteril) was given to all the patients.

The nasogastric tube was removed at the end of the operation, and the urinary catheter was removed during postoperative day 1. All the patients received daily doses of ketoprofen including three 100-mg doses administered intravenously (IV) or orally, four paracetamol 1-g doses given IV or orally, and if needed, oxycodone 0.05 mg/kg IV or 0.15 mg/kg administered intramuscularly.

In the epidural group, the epidural infusion of ropivacaine 2 mg/ml (concentration), 4 ml to 10 ml/h (infusion rate of 0.1 ml/kg/h) was continued until the second postoperative morning. The epidural catheter was removed on postoperative day 2.

The patients completed a self-care questionnaire twice a day until postoperative day 14. During the first day, the

questionnaire was completed three times: at 2, 12, and 24 h postoperatively. Pain, fatigue, and nausea were assessed using a visual analogue scale (VAS, 0–10) at rest, during coughing, and during ambulation [15]. Oxycodone was offered if the patient reported significant pain (VAS $\geq$ 3). The patients scored their dizziness (0 = none, 1 = slight, 2 = moderate, 3 = intense) as well as their daily fluid intake, bladder function, and mobility (0 = none, 1 = moderately decreased, 2 = slightly decreased, 3 = normal).

The patients were discharged, according to the routine of the hospital, when they had passed air or stools (assessed in days) and were otherwise well, with pain controlled using oral medication. All patients were seen at the outpatient clinic 1 month after the operation. Possible further examinations, such as colonoscopy, were performed if there were signs of rectal bleeding, constipation, or diarrhea.

Postoperative IV oxycodone consumption was used to calculate the statistical power of the study. A sample size estimate indicated that 30 patients per group would give a power of 80% at the level of 0.05 for detecting a difference of 38% in oxycodone consumption between the control and paravertebral groups (mean consumption, 10.2 $\pm$ 5.8 vs. 6.0 $\pm$ 4.9 mg) using the *t*-test. The power analysis was based on our previous study investigating opioid sparing using single-injection paravertebral block in conjunction with breast cancer surgery [16, 17]. The number of patients was thus prospectively set at 60, with 30 patients assigned to each treatment group.

Statistical analyses were performed with SPSS for windows, release 15.0 (SPSS Inc., Chicago, IL, USA). The results were analyzed using unpaired Student's *t*-tests for demographic data and basic outcome with postoperative recovery. The Mann–Whitney test was used for intraoperative bleeding because of data skewedness. Analysis of variance for repeated measurements (rANOVA) was used for oxycodone consumption; pain at rest and during coughing, pain, and mobilization; nausea and fatigue; daily fluid intake; dizziness; bladder function; mobility; and bowel function. The chi-square test was used for outcome of ASA. Fisher's exact test was used to calculate the differences in the readmission and complication rates between the two groups.

The number of patients with significant pain was analyzed by forming dichotomized variables. Repeated measurements were assumed to have a first-order autoregressive relationship, and a generalized estimating equations (GEE) model with binomial distribution and logit link function was formed. The data were analyzed on an intention-to-treat basis, which means that patients with unsuccessful epidural analgesia were counted as epidural analgesia patients.

Results

The sigmoidectomy was completed laparoscopically for 60 of the 61 patients. In both groups, 14 patients had previous abdominal operations. One operation in the epidural group was converted to an open procedure because of an unsuspected colovesical fistula, and the patient was therefore excluded from the study. One patient from each group was excluded because of a missing self-care questionnaire. The groups were comparable with regard to sex, age, body mass index (BMI), ASA (Table 1), blood loss, operating time, bowel function, length of hospitalization, and readmission rates (Table 2).

The postoperative oxycodone doses are given in Fig. 1. The patients in the epidural analgesia group rarely needed any oxycodone, and there was a significant time–group interaction between the control and epidural groups ($p = 0.001$, rANOVA). The cumulative oxycodone consumption until the end of postoperative day 1 was statistically higher in the control group than in the epidural group (mean dose, 24.8 $\pm$ 4.3 vs. 9.2 $\pm$ 2.1 mg; $p = 0.009$, *t*-test).

No significant pain at rest (VAS $\geq$ 3) was noted in either group ($p = 0.171$; rANOVA). The mean postoperative pain during coughing was not significant (VAS $\geq$ 3) in the epidural group, whereas the time–group interaction between the groups was significant ($p = 0.001$, rANOVA; Fig. 2A).

At mobilization, the two groups had similar statistically significant time–group interaction ($p = 0.034$, rANOVA; Fig. 2B). Furthermore, the control group had more patients with significant pain (VAS $\geq$ 3). The control patients had more significant pain, and the duration of their pain was significantly longer (i.e., until the end of the follow-up period; $p = 0.001$, GEE), although the epidural catheter was removed on the second postoperative morning (Fig. 2C). The time-group interaction for nausea between the groups, as measured with VAS, was significant during the postoperative stay in the postanesthesia control unit

Table 1 Patient characteristics[a]

	Control ($n = 29$)	Epidural ($n = 29$)
Sex ratio (M:F)	10:19	8:21
Age (years)	55.8 $\pm$ 12.7	58.5 $\pm$ 9.8
BMI	27.7 $\pm$ 4.7	27.1 $\pm$ 4.2
ASA 1	4	9
2	18	16
3	7	4

BMI, body mass index; ASA, American Society of Anesthesiologists

[a] Demographic data (age and BMI) are represented as means $\pm$ standard deviation. The ASA scale is presented in three categories. There were no ASA 4 patients

Table 2 Data for basic outcomes after laparoscopic sigmoidectomy

	Control ($n = 29$) n (range)	Epidural ($n = 29$) n (range)	p value
Operating time (min)	135 (60–165)	120 (85–230)	0.516
Blood loss (ml)[a]	20 (20–800)	20 (20–200)	0.259[a]
Bowel function (air, days)	1 (1–4)	1 (1–4)	0.219
Bowel function (feces, days)	2 (1–7)	2 (1–9)	0.560
Length of hospitalization (days)	3 (2–9)	3 (1–14)	0.810
Readmission rate (no. of patients)	3	1	0.611[b]

[a] The Mann–Whitney test was used for the skewed data

[b] Fisher's exact test was used for the readmission rates; in other instances the t-test was used

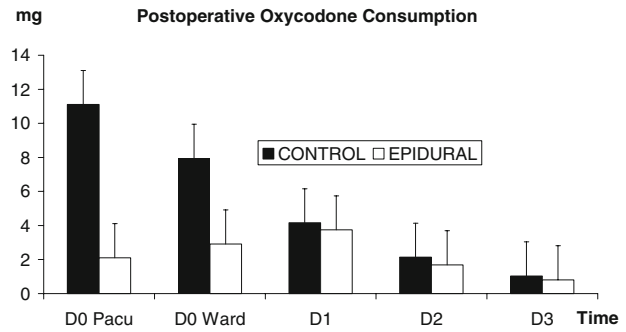


Fig. 1 Mean postoperative oxycodone consumption shows a significant time-group interaction between the control and epidural groups ($p = 0.001$, rANOVA) postoperatively at D0PACU (2 h), D0Ward (12 h), day 1 (D1), day 2 (D2), and day 3 (D3)

(PACU) and until the first postoperative morning ($p = 0.021$, rANOVA). The control patients also had more fatigue during the day of the operation (Table 3).

The patients with epidural analgesia had significantly more postoperative dizziness than the control patients during the PACU and ward periods until the first postoperative morning ($p = 0.032$, rANOVA). They also had more difficulties passing urine after the catheter had been removed ($p = 0.061$, rANOVA). There was no difference between the groups in terms of postoperative eating, drinking, and mobilization.

There was no mortality, but the complication rate was 11/29 in the control group and 6/29 in the epidural group (Table 4; $p = 0.151$, Fisher's exact test). Three patients in the control group had two complications, and one patient in the epidural group had two complications. There were five postoperative hematomas in the control group and none in the epidural group ($p = 0.052$, Fisher's exact test).

One patient in each group had to undergo a Hartmann's procedure because of an anastomotic leakage. Three control patients and one epidural analgesia patient were readmitted for one wound hematoma, one abscess, and two anastomotic leaks (1 in the epidural group). Two postoperative abscesses and three anastomotic strictures occurred in both groups (Table 4). The strictures were dilated endoscopically, and all the other complications except the anastomotic leakages were treated conservatively.

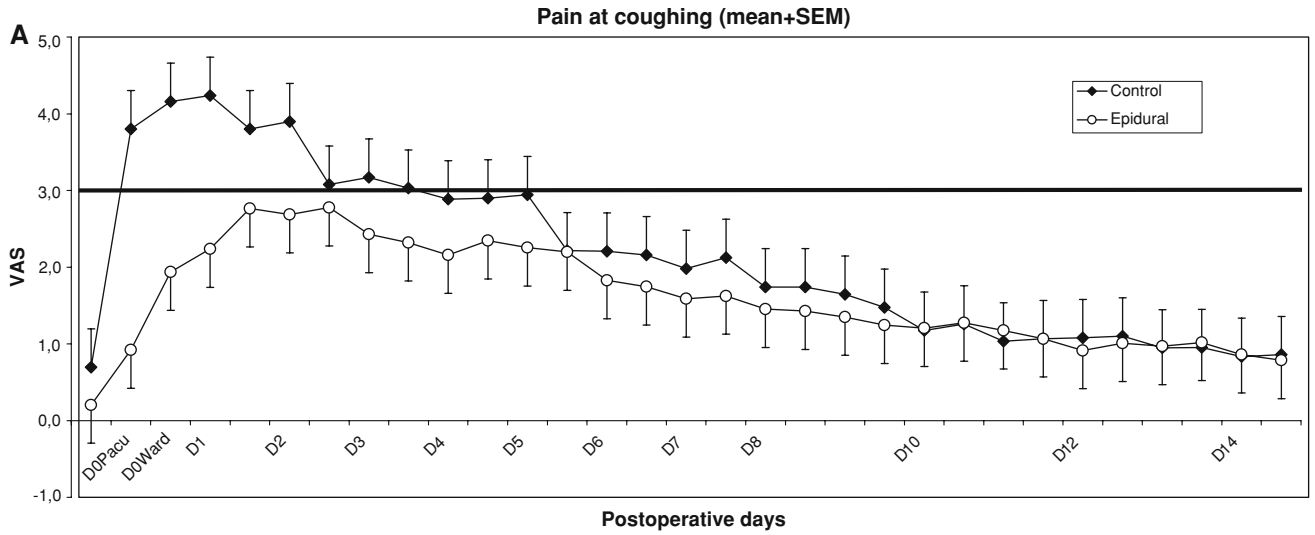
Discussion

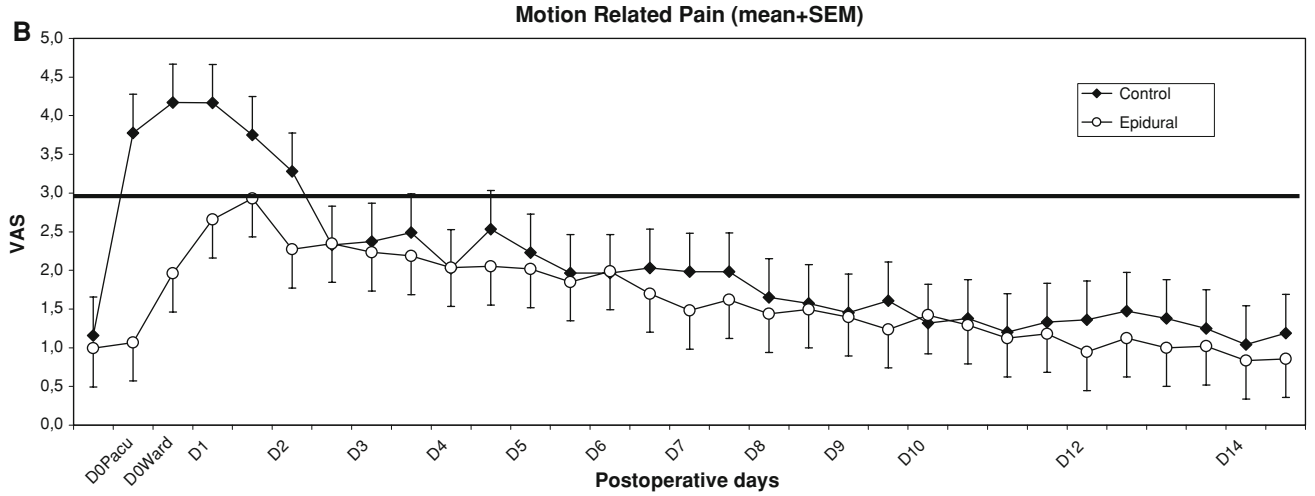
We studied the effect of epidural analgesia on the postoperative recovery of patients who underwent elective surgery for diverticular disease. Patients admitted to the hospital for a laparoscopic sigmoid resection were prospectively randomized either to receive or not to receive epidural analgesia with ropivacaine.

The patients receiving epidural ropivacaine needed less opioid (oxycodone) and had less pain during coughing and mobilization within the first 48 postoperative hours than the control patients. In both groups, the pain during rest was negligible. The number of patients with significant pain (VAS $\geq$ 3) was higher and the pain longer in the control group until the end of the follow-up period. This may have been due to a more pronounced systemic stress response to pain by the control patients during the operation, a response blocked by epidural analgesia. However, we do not know the exact mechanism or mechanisms of the observed prolonged effect after epidural analgesia.

The control patients had more nausea until the end of the operation day as well as fatigue, the intensity of which was significantly greater than in the epidural group until the end of postoperative day 1. Nausea and fatigue are the most likely side effects of opioids, which were needed more frequently in the control group during postoperative day 1.

Fig. 2 (**A**) Postoperative pain during coughing experienced by patients with and without epidural analgesia. Curves represent mean postoperative pain in terms of visual analog scale (VAS) + standard error of the mean (SEM). Until postoperative day 2, pain was significant (VAS $\geq$ 3, thick horizontal line), and there was significant time-group interaction for pain between the control and epidural groups ($p = 0.001$, rANOVA) at D0PACU (2 h), D0Ward (12 h), day 1 (D1), day 2 (D2), day 3 (D3), and so forth, postoperatively. (**B**) Postoperative pain during mobilization of patients with and without epidural analgesia. Curves represent mean postoperative pain in VAS + SEM postoperatively. Until postoperative day 2, pain was significant (VAS $\geq$ 3, thick horizontal line), and there was significant time–group interaction for pain between the control and epidural groups ($p = 0.034$, rANOVA) at D0PACU (2 h), D0Ward (12 h), day 1 (D1), day 2 (D2), day 3 (D3), and so forth postoperatively. (**C**) Proportion of patients with significant postoperative pain (VAS $\geq$ 3) in the epidural and control groups. More patients had significant pain and longer duration of pain in the control group than in the epidural group until the end of the follow-up period ($p = 0.001$, GEE)


A
Pain at coughing (mean+SEM)
VAS
5,0
4,0
3,0
2,0
1,0
0,0
-1,0
Control
Epidural
D0Pacu
D0Ward
D1
D2
D3
D4
D5
D6
D7
D8
D10
D12
D14
Postoperative days


B
Motion Related Pain (mean+SEM)
VAS
5,0
4,5
4,0
3,5
3,0
2,5
2,0
1,5
1,0
0,5
0,0
Control
Epidural
D0Pacu
D0Ward
D1
D2
D3
D4
D5
D6
D7
D8
D9
D10
D12
D14
Postoperative days

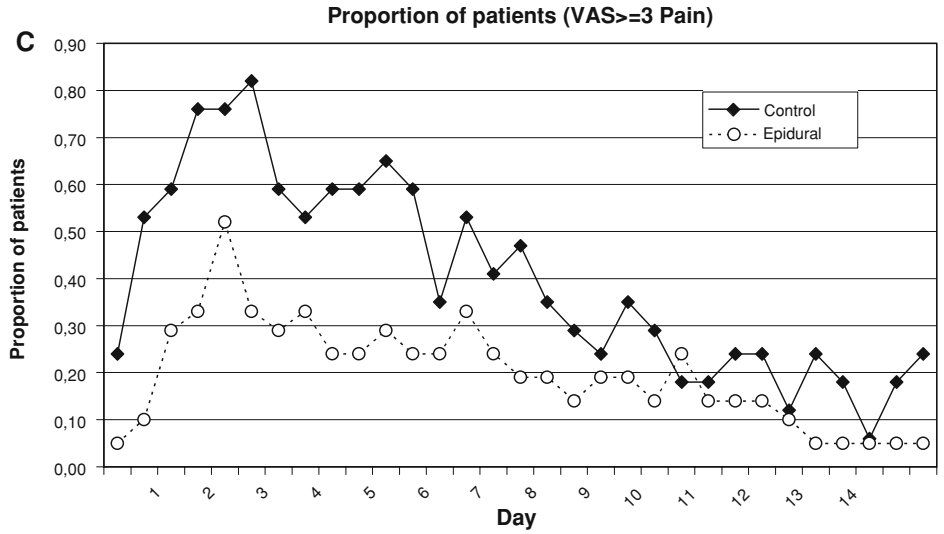

C
Proportion of patients (VAS>=3 Pain)
Proportion of patients
0,90
0,80
0,70
0,60
0,50
0,40
0,30
0,20
0,10
0,00
Control
Epidural
1
2
3
4
5
6
7
8
9
10
11
12
13
14
Day

Table 3 The level of postoperative fatigue[a]

	Operation day (recovery room)	Operation day (evening)	Day 1 (morning)	Day 1 (evening)	Day 2 (morning)	Day 2 (evening)
Epidural	2.1 ± 0.4	2.6 ± 0.5	2.5 ± 0.4	2.4 ± 0.4	2.0 ± 0.3	1.9 ± 0.3
p value	0.001	0.004	0.115	0.715	0.074	0.342
Control	4.9 ± 0.6	5.0 ± 0.6	3.6 ± 0.5	2.7 ± 0.5	3.1 ± 0.5	2.4 ± 0.4

[a] Mean visual analog scale (VAS) + standard error of the mean (SEM) (*t*-test) scores for fatigue derived from the self-care questionnaires in the epidural and control groups. Scores are given until the second postoperative evening. Thereafter, the scores remained constantly low. The *p* values have been calculated without correction for multiple comparisons. The higher the score, the worse the fatigue

Table 4 Postoperative complications[a]

	Control group ($n = 29$)	Epidural group ($n = 29$)
Anastomotic leakage	1	1
Abscess	2	2
Anastomotic stricture	3	3
Wound hematoma	2	0
Intraabdominal haematoma	2	0
Haemorrhagia ex ano	1	0
Wound infection	1	0
Urinary retention	1	0
Ventral hernia	1	0

[a] Three patients in the control group had two different complications, and one patient in the epidural group had two complications

The patients in the epidural group more frequently had difficulties urinating immediately after removal of the catheter. They reported significantly higher dizziness VAS scores until the end of postoperative day 1. These probably were side effects of ropivacaine originating from the central nervous system (CNS) at the level of the spinal cord or higher and resulting from the block itself [13]. The two groups showed no significant difference in postoperative oral intake, bowel motility, or general mobilization.

Zutshi et al. [12] found no positive effect of thoracic epidural analgesia (in the Th 8–9 or Th 9–10 interspace) on postoperative pain after open sigmoidectomy. Their number of failed epidurals seems considerably high (20.6%). Their result may be due to the failed diffusion of local anesthetic to low enough parts of the thoracic epidural space. The Trendelenburg position used for laparoscopic colon operations probably contributes to this problem. These considerations taken into account, the trend in their study seems similar to our results because they reported a statistically nonsignificant tendency toward less postoperative pain in the epidural group.

The overall morbidity, complication, and readmission rates in our study corresponded well with recent reports of laparoscopic sigmoid resections in ERAS settings [11]. A compromised blood supply in the anastomotic area may cause a stricture or leakage. The most feared complication, anastomotic leakage, occurred for 2 of 58 patients (3.4%), 1 in each group. Three anastomotic strictures manifesting as early as 1 month postoperatively occurred in both groups (10.3%). The relatively high number of strictures could have resulted from a tendency to perform sigmoidoscopy whenever the patient reported even slight obstipation or evacuation difficulty. All the strictures were mild and needed only a single dilation. They all may have healed in time without the dilation.

The four postoperative hematomas and the one hemorrhagia ex ano in the control group compared with none in the epidural group suggest that epidural anesthesia may have a positive effect on the regulation of bleeding caused by surgery, although the intraoperative blood loss was alike in the two groups. Sympathetic blockade followed by secondary reduction in venous pressure may underlie this phenomenon [18]. However, the power of the current study was calculated to show the decreased need of opioids postoperatively and therefore is insufficient to verify the decreased rate of postoperative bleeding complications in the epidural group.

Similar postoperative mobilization in the two groups suggests that pain relief given according to ERAS principles is sufficient for most patients. The need for opioids was minimal even without epidural analgesia. The recovery after laparoscopic sigmoidectomy proceeded similarly in the two groups, and the patients could be discharged from the hospital within 3 to 4 days postoperatively when they felt physically and psychologically well.

We did not observe any beneficial effect of epidural analgesia on bowel motility, although previous investigators have reported such an effect [5, 6, 19]. This discrepancy could be due to the fact that these ERAS studies were performed in conjunction with open colon surgery, which possibly produces a greater pronounced humoral stress reaction, more bowel paralysis, and more postoperative pain than laparoscopic surgery. Consequently, the possible beneficial effect of epidural analgesia also would be more pronounced for patients who undergo open surgery. It also is possible that the power of our study, calculated for detecting differences in postoperative oxycodone use, was insufficient to show small differences in postoperative recovery.

We conclude that epidural analgesia has a favorable effect by decreasing postoperative pain and the need of opioids after laparoscopic sigmoid resection for diverticular disease, especially during postoperative day 1. Epidural analgesia also may decrease the amount of intraoperative bleeding, although the power of the current study was insufficient to prove this. However, epidural analgesia did not shorten the hospital stay or enhance bowel function or oral intake. Neither did it have any effect on the overall complication rate.

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