



The impact of epidural catheter insertion level on pain control after esophagectomy for esophageal cancer

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Abstract

Background Although the effectiveness of epidural anesthesia on pain control after esophagectomy has been reported, the appropriate insertion level of the epidural catheter remains unclear for adequate postoperative pain control. We investigated the relationship between the epidural catheter insertion level and postoperative pain control after esophagectomy for esophageal cancer.

Methods We analyzed retrospectively 63 patients who underwent McKeown esophagectomy for esophageal cancer between October 2014 and November 2018. The epidural catheter was inserted at the T4–T10 level before general anesthesia induction, and epidural anesthesia was started during the operation. In the analysis, the epidural catheter insertion level was divided into three groups (over T6/T7, T7/T8, and under T8/T9) and determined. Postoperative pain was evaluated a numeric rating scale (NRS) for at least 7 postoperative days, and the first NRS after extubation was used to evaluate the impact of the epidural catheter insertion level on pain control.

Results Ten patients (15.9%) failed pain control. The χ^2 test and a forward stepwise logistic regression analysis revealed that only the epidural catheter insertion level affected pain control ($P < 0.05$). The T7/T8 insertion level significantly decreased postoperative pain after esophagectomy. In the subgroup analysis, epidural catheter insertion under T8/T9 significantly increased postoperative pain after esophagectomy when thoracoscopy/laparoscopy was assisted. No significant differences were observed in the incidence of postoperative complications among the epidural catheter insertion levels.

Conclusions The T7/T8 epidural catheter insertion level contributed to postoperative pain relief and could lead to enhanced recovery after esophagectomy for esophageal cancer.

Keywords Esophagectomy · Epidural anesthesia · Postoperative complication · Numeric rating scale

Introduction

Esophageal cancer has a high malignant potential and poor prognosis and is a common cause of cancer-related death in men and women worldwide (the fifth most common cause in men and eighth most common in women) [1]. The postoperative 5-year survival rate in patients with stage I esophageal

cancer (according to the American Joint Committee on Cancer classification) is approximately 90%, decreasing to 45%, 20%, and 10% in patients with stages II, III, and IV disease, respectively [2]. Although chemoradiotherapy may effectively treat esophageal cancer, esophagectomy remains the most efficient treatment option [3].

McKeown esophagectomy, a common procedure for non-metastatic esophageal cancer, is a cervicothoracoabdominal procedure, and the wound extends to these three regions, making postoperative pain control difficult [4, 5]. Good postoperative pain control enables early rehabilitation and reduces postoperative complications, including pneumonia [6, 7]. Although the effectiveness of postoperative pain control by the combined use of epidural anesthesia has been reported, the appropriate epidural catheter insertion level remains unclear for adequate postoperative pain control after

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esophagectomy [8–10]. We hypothesized that the epidural catheter insertion level affected postoperative pain control after esophagectomy. Therefore, we investigated the relationship between epidural catheter insertion level and postoperative pain control after esophagectomy for esophageal cancer.

Patients and methods

Patients

We retrospectively analyzed the records of 69 patients who underwent esophagectomy for esophageal cancer between October 2014 and November 2018 at Saiseikai Yokohamashi Tobu Hospital. Three patients who underwent resection of other organs at the same time, two who underwent Ivor Lewis esophagectomy, and one who underwent staged operation were excluded from the analysis (Fig. 1). All the patients undergoing McKeown esophagectomy during this period were included for analysis. The study was conducted with the approval of the ethics committee of Saiseikai Yokohamashi Tobu Hospital.

Surgical procedure

We performed esophagectomy with three- or two-field lymph node dissection, depending on the degree of progression and surgical risks. The thoracic procedures were performed through a right thoracic incision with the patient in the left lateral decubitus position or by video-assisted thoracic surgery (VATS) with the patient prone. We performed anterolateral thoracotomy with transection of two costae. For the thoracoscopic approach, a 5-mm port was inserted through the fifth intercostal space on

the posterior axillary line, and 12-mm ports were inserted through the third and the seventh intercostal spaces on the middle axillary line and the tenth intercostal spaces on the posterior axillary line. The abdominal procedures were performed through an upper midline abdominal incision or by hand-assisted laparoscopic surgery (HALS) performed through a mini-laparotomy (7 cm) in the upper abdominal midline, with one port below the navel and two ports in the left abdomen. Reconstruction was performed via a gastric tube and the anastomosis was performed in the neck for all patients. The anastomoses were completed using a linear stapler or were hand-sewn.

Postoperative pain control

The epidural catheter was inserted at the T4–T10 levels before induction of general anesthesia. The epidural catheter insertion level was determined at the anesthesiologists' discretion. The standard epidural catheter insertion level was around T7 when esophagectomy was performed. In terms of thoracotomy, patients who underwent VATS tended to receive epidural anesthesia under T7, whereas patients who underwent open thoracotomy tended to receive epidural anesthesia over T7. In terms of laparotomy, patients who underwent HALS tended to receive epidural anesthesia over T7, whereas patients who underwent open laparotomy tended to receive epidural anesthesia under T7. The epidural catheter insertion level was divided as three groups (over T6/T7, T7/T8, and under T8/T9) and determined. A test dose of 3–5 mL 1% lidocaine was administered as soon as the epidural catheter was in place. Epidural anesthesia was administered as a continuous infusion of a 300 mL mixture of fentanyl (5–10 ampules, 0.1 mg/2 mL), droperidol (2 ampules, 2.5 mg/1 mL), and levobupivacaine at a rate of 4 mL/h, starting during the operation, with 3 mL patient-controlled analgesia (Vessel Fuser; Toray, Tokyo, Japan) as rescue analgesia. An intravenous infusion of acetaminophen (Acelio Intravenous Injection®; Terumo Co. Ltd., Tokyo, Japan) was started on the day of operation at 15 mg/kg every 6 h at consistent times every day.

Assessment of postoperative pain control

Postoperative pain was evaluated in 11 steps from 0–10 using a numeric rating scale (NRS). The patient was extubated in the operating room soon postoperatively or in the intensive care unit on postoperative day 1. The first NRS after extubation was used to evaluate the impact of the epidural catheter insertion level on pain control. In this study, successful pain control was defined as $\text{NRS} \leq 2$, and failure

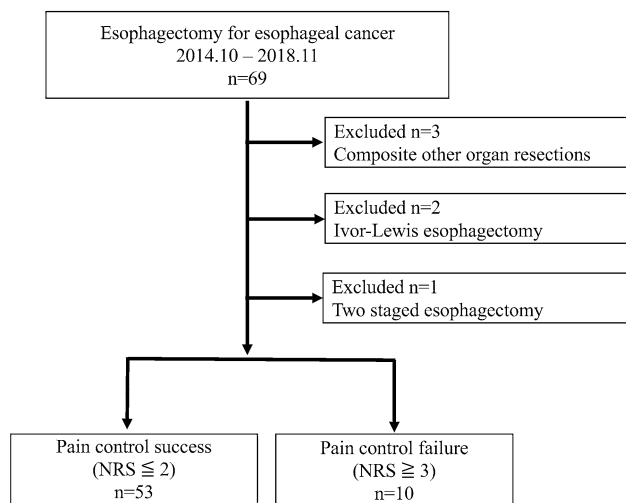


Fig. 1 Study design diagram

as NRS ≥ 3 . The NRS was recorded to at least 7 postoperative days, and maximum NRS was also evaluated.

Data collection methods

A retrospective chart review was used to collect data. Preoperative data included age, sex, neoadjuvant chemotherapy, salvage surgery, and American Society of Anesthesiologists physical status. Disease was staged according to the International Union Against Cancer tumor, nodes, and metastasis grading system, 8th ed. [11]. Perioperative data included tumor location, histology, thoracotomy, laparotomy, surgical field, reconstructed route, operation time, and blood loss. Postoperative complications were graded according to the Clavien–Dindo classification, with Grade \geq II events recorded as complications [12].

Statistical analysis

IBM SPSS, Version 25.0 (IBM Corp., Armonk, NY, USA) was used to perform statistical analysis. Demographic and surgical data (pre-, peri-, and postoperative) were compared between pain control success and failure groups. Categorical data were analyzed using Fisher's exact test or the χ^2 test, as appropriate. Unpaired Student's *t* tests were used to analyze quantitative data. Clinically relevant factors were included in a forward stepwise logistic regression analysis of the impact of epidural catheter insertion level on pain control after esophagectomy. A *P* value of <0.05 was considered statistically significant.

Results

Patient characteristics

The 63 study participants comprised 51 men and 12 women (mean age, 68.8 ± 9.4 years; range 36–83 years). Table 1 shows demographic and perioperative data for all patients. The most common histology was squamous cell carcinoma (93.7%).

Assessment of postoperative pain control

Mean NRS soon after extubation was 0.81 (range 0–8) and pain control failed in 10 patients (15.9%; Fig. 2), all of whom suffered upper abdominal pain. Among all the patients, 52 patients (82.5%) experienced maximum NRS soon after extubation. Among the pain control success group (53 patients), 6 patients (11.3%) suffered from NRS ≥ 3 postoperatively. The χ^2 test revealed that only the epidural catheter insertion level affected pain control ($P=0.015$; Table 1). Pain control failed in 2 (11.1%) of 18

patients whose catheter was inserted over the T6/T7 level, and 7 (35.0%) of 20 whose catheter was inserted under T8/T9. By contrast, pain control failed in only 1 (4.0%) of 25 with catheter insertion at T7/T8. Epidural catheter insertion at T7/T8 significantly decreased postoperative pain after esophagectomy for esophageal cancer. Table 2 shows subgroup analysis of the impact of epidural catheter insertion level for each procedure. We performed VATS/HALS for 23 patients (36.5%), VATS/Open for 17 patients (27.0%), Open/HALS for 2 patients (3.2%), and Open/Open for 21 patients (33.3%). In the subgroup analysis, epidural catheter insertion under T8/T9 significantly increased postoperative pain after esophagectomy when VATS/HALS was performed. A forward stepwise logistic regression analysis considering the impact of thoracotomy, laparotomy, and epidural catheter insertion level revealed that only the epidural catheter insertion level affected pain control ($P=0.042$; Table 3). Table 4 shows the clinical characteristics of 10 pain control failure patients.

Postoperative complications

Table 5 summarizes the postoperative complications according to epidural catheter insertion level. No mortality was observed in this study. No significant differences were observed in the incidence of postoperative complications among the epidural catheter insertion levels.

Discussion

The use of epidural analgesia after esophagectomy has been reported; however, to the best of our knowledge, no report has investigated the appropriate epidural catheter insertion level after esophagectomy [6, 7]. McKeown esophagectomy is a cervicothoracoabdominal procedure, and the wound extends to all the three regions. Where the most pain is located with cervical, thoracic, and abdominal wounds remains controversial. Therefore, the epidural catheter insertion level could not be fixed after esophagectomy, and level was determined at the discretion of the anesthesiologists.

Saeki et al. [7] reported that the patients in whom two epidural catheters were inserted at the T5/T6 and T9/T10 levels to cover the thoracic and abdominal incisions had better pain control than those with one epidural catheter inserted at the T5/T6 level to cover the thoracic incision. Levy et al. [13] reported that the transversus abdominal plane block was equal for pain control after esophagectomy compared to thoracic epidural anesthesia. These reports suggested that upper abdominal pain control led to adequate pain control after esophagectomy. In this study, all patients whose pain control failed suffered from upper abdominal pain, and the T7/T8 insertion level, which targeted upper abdominal pain

Table 1 Clinicopathological characteristics

Variable	All patients	NRS \leq 2	NRS \geq 3	<i>P</i> value
Total	63	53 (84.1%)	10 (15.9%)	
Age (years)	68.8 \pm 9.4	69.1 \pm 9.0	67.7 \pm 12.0	0.681
Sex, n (%)				0.427
Male	51 (81.0%)	42 (79.2%)	9 (90.0%)	
Female	12 (19.0%)	11 (20.8%)	1 (10.0%)	
Tumor location (esophagus)				0.213
Upper thoracic	12 (19.0%)	8 (15.1%)	4 (40.0%)	
Middle thoracic	29 (46.0%)	26 (49.1%)	3 (30.0%)	
Lower thoracic	19 (30.2%)	17 (32.1%)	2 (20.0%)	
Abdominal	3 (4.8%)	2 (3.8%)	1 (10.0%)	
Histology				0.641
Squamous cell carcinoma	59 (93.7%)	50 (94.3%)	9 (90.0%)	
Adenocarcinoma	3 (4.8%)	2 (3.8%)	1 (10.0%)	
Adenosquamous cell carcinoma	1 (1.6%)	1 (1.9%)	0 (0%)	
ASA physical status				0.732
Grade 1	11 (17.5%)	10 (18.9%)	1 (10.0%)	
Grade 2	44 (69.8%)	36 (67.9%)	8 (80.0%)	
Grade 3	8 (12.7%)	7 (13.2%)	1 (10.0%)	
cT category (UICC TNM 8th)				0.568
1	13 (20.6%)	12 (22.6%)	1 (10.0%)	
2	12 (19.0%)	11 (20.8%)	1 (10.0%)	
3	27 (42.9%)	21 (39.6%)	6 (60.0%)	
4a/4b	9 (14.3%)/2 (3.2%)	8 (15.1%)/1 (1.9%)	1 (10.0%)/1 (10.0%)	
cN category (UICC TNM 8th)				0.921
0	25 (39.7%)	21 (39.6%)	4 (40.0%)	
1	22 (34.9%)	18 (34.0%)	4 (40.0%)	
2	14 (22.2%)	12 (22.6%)	2 (20.0%)	
3	2 (3.2%)	2 (3.8%)	0 (0%)	
cM category (UICC TNM 8th)				1.000
0	67 (100%)	53 (100%)	10 (100%)	
1	0 (0%)	0 (0%)	0 (0%)	
cStage (UICC TNM 8th)				0.533
I	13 (20.6%)	12 (22.6%)	1 (10.0%)	
II	17 (27.0%)	14 (26.4%)	3 (30.0%)	
III	21 (33.3%)	16 (30.2%)	5 (50.0%)	
IVA	12 (19.0%)	11 (20.8%)	1 (10.0%)	
NAC				0.627
DCF	16 (25.4%)	14 (26.4%)	2 (20.0%)	
FP	24 (38.1%)	21 (39.6%)	3 (30.0%)	
None	23 (36.5%)	18 (34.0%)	5 (50.0%)	
Salvage				0.955
Yes	6 (9.5%)	5 (9.4%)	1 (10.0%)	
No	57 (90.5%)	48 (90.6%)	9 (90.0%)	
Thoracotomy				0.641
VATS	40 (63.5%)	33 (62.3%)	7 (70.0%)	
Open	23 (36.5%)	20 (37.7%)	3 (30.0%)	
Laparotomy				0.165
HALS	25 (39.7%)	23 (43.4%)	2 (20.0%)	
Open	38 (60.3%)	30 (56.6%)	8 (80.0%)	
Surgical procedures				0.303

Table 1 (continued)

Variable	All patients	NRS ≤ 2	NRS ≥ 3	P value
VATS/HALS	23 (36.5%)	21 (39.6%)	2 (20.0%)	
VATS/Open	17 (27.0%)	12 (22.6%)	5 (50.0%)	
Open/HALS	2 (3.2%)	2 (3.8%)	0 (0%)	
Open/Open	21 (33.3%)	18 (34.0%)	3 (30.0%)	
Reconstructed route				0.464
Posterior mediastinal	47 (74.6%)	40 (75.5%)	7 (70.0%)	
Retrosternal	4 (6.3%)	4 (7.5%)	0 (0%)	
Antesternal	12 (19.0%)	9 (17.0%)	3 (30.0%)	
Surgical procedures				0.430
3FLND	26 (41.3%)	23 (43.4%)	3 (30.0%)	
2FLND	37 (58.7%)	30 (56.6%)	7 (70.0%)	
Operation time (min)	563.5 ± 86.0	559.7 ± 79.2	584.0 ± 119.0	0.416
Blood loss (ml)	424.0 ± 409.9	435.7 ± 436.1	362.1 ± 231.3	0.606
Epidural catheter insertion level				0.015
Over T6/T7	18 (28.6%)	16 (30.2%)	2 (20.0%)	
T7/T8	25 (39.7%)	24 (45.3%)	1 (10.0%)	
Under T8/9	20 (31.7%)	13 (24.5%)	7 (70.0%)	
pT category (UICC TNM 8th)				0.144
0	3 (4.8%)	1 (1.9%)	2 (20.0%)	
1a/1b	5 (7.9%)/17 (27.0%)	5 (9.4%)/15 (28.3%)	0 (0%)/2 (20.0%)	
2	6 (9.5%)	5 (9.4%)	1 (10.0%)	
3	28 (44.4%)	24 (45.3%)	4 (40.0%)	
4a/4b	3 (4.8%)/1 (1.6%)	2 (3.8%)/1 (1.9%)	1 (10.0%)/0 (0%)	
pN category (UICC TNM 8th)				0.226
0	36 (57.1%)	29 (54.7%)	7 (70.0%)	
1	13 (20.6%)	11 (20.8%)	2 (20.0%)	
2	12 (19.0%)	12 (22.6%)	0 (0%)	
3	2 (3.2%)	1 (1.9%)	1 (10.0%)	
pM category (UICC TNM 8th)				0.661
0	62 (98.4%)	52 (98.1%)	10 (100%)	
1	1 (1.6%)	1 (1.9%)	0 (0%)	
pStage (UICC TNM 8th)				0.146
0	3 (4.8%)	1 (1.9%)	2 (20.0%)	
IA/IB	5 (7.9%)/11 (17.5%)	5 (9.4%)/10 (18.9%)	0 (0%)/1 (10.0%)	
IIA/IIIB	3 (4.8%)/18 (28.6%)	2 (3.8%)/14 (26.4%)	1 (10.0%)/4 (40.0%)	
IIIA/IIIB	3 (4.8%)/17 (27.0%)	3 (5.7%)/16 (30.2%)	0 (0%)/1 (10.0%)	
IVA/IVB	2 (3.2%)/1 (1.6%)	1 (1.9%)/1 (1.9%)	1 (10.0%)/0 (0%)	

NRS numeric rating scale, ASA American Society of Anesthesiologists, UICC International Union against Cancer, TNM tumor, nodes, and metastasis, NAC neoadjuvant chemotherapy, DCF docetaxel, cisplatin, and 5-fluorouracil, FP 5-fluorouracil and cisplatin, VATS video-assisted thoracic surgery, HALS hand-assisted laparoscopic surgery, FLND field lymph node dissection

Data are shown as mean ± standard deviation or number (percent)

control, significantly decreased postoperative pain after esophagectomy. These results also suggested that an upper abdominal wound causes the most pain after esophagectomy. It is possible that an abdominal wound is more painful than a cervical or thoracic wound because patients use abdominal muscles most after esophagectomy. The reason why the chest pain was at low-to-negligible level could be explained by two factors. First, epidural catheter insertion at the T7/

T8 level covered the thoracic incision. Second, patients did not suffer from chest pain because patients used not thoracic muscles but abdominal muscles when breathing.

Saeki et al. [7] reported that two epidural catheters contributed to better pain control than one epidural catheter. However, two epidural catheter insertions demanded more induction time and had higher risk related to epidural puncture. One epidural catheter was superior to two

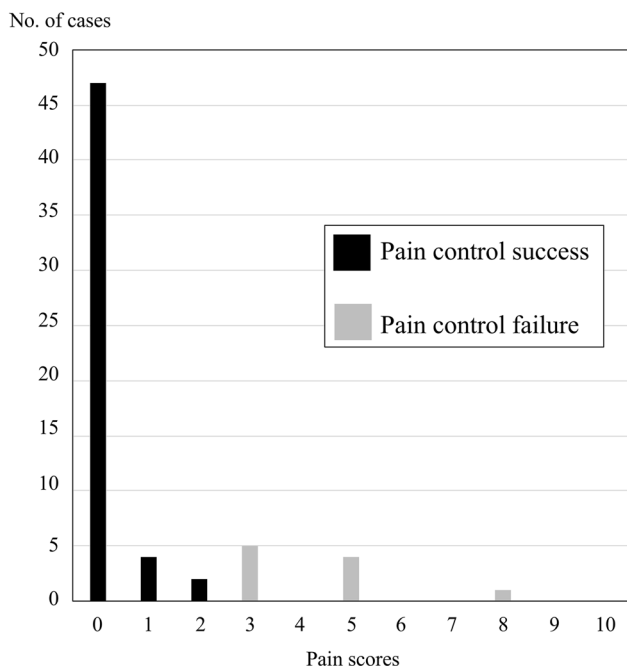


Fig. 2 Overall pain scores

epidural catheters in terms of induction time and safety if the same pain control could be obtained. In this study, an insertion level under T8/T9 was worst for pain control after esophagectomy, and 35% patients suffered from upper abdominal pain. The under T8/T9 insertion level was considered inadequate for upper abdominal pain control after esophagectomy. On the contrary, pain control failed in only 4% of patients after esophagectomy at the T7/T8 insertion level. The T7/T8 insertion level was considered equal to

insertion of two epidural catheters to cover thoracic and abdominal incisions in terms of pain control.

Esophagectomy was a highly invasive procedure and required not only epidural anesthesia but also combined anesthesia [14, 15]. Postoperative scheduled intravenous acetaminophen reportedly was useful for pain control after esophagectomy, and in our study, scheduled intravenous acetaminophen was administered in all patients [15]. The NRS soon after extubation was used to assess the impact of only epidural anesthesia and exclude the impact of intravenous acetaminophen on pain control after esophagectomy [13]. To the best of our knowledge, our study is the first to recommend appropriate epidural catheter insertion level after esophagectomy, when one catheter insertion was performed.

No significant differences were observed in the incidence of postoperative complications among the epidural catheter insertion levels. In terms of postoperative complications, the T7/T8 insertion level was at least safe compared to other insertion levels. Adequate pain control after esophagectomy reportedly enabled early rehabilitation and contributed to decreased postoperative complication rates [7, 16]. To investigate whether the T7/T8 epidural catheter insertion level had an advantage other than pain control required a larger sample size and, moreover, randomized control trials.

There are two important limitations of our study. First, we used a retrospective design at a single institution with a small sample size and, therefore, this study was exposed to selection bias as with all retrospective studies. Second, we used NRS to assess pain control, and NRS could be subjected to each patient. However, NRS currently is considered to be one of the most reliable and reasonable pain assessments.

Table 2 Subgroup analysis of the impact of epidural catheter insertion level for each procedure

Procedure (Thoracotomy/ Laparotomy)	Pain control	Over T6/T7	T7/T8	Under T8/T9	P value
VATS/HALS (n = 23)		7 (30.4%)	10 (43.5%)	6 (26.1%)	0.045
	NRS ≤ 2	7 (33.3%)	10 (47.6%)	4 (19.0%)	
	NRS ≥ 3	0 (0%)	0 (0%)	2 (100%)	
VATS/open (n = 17)		3 (17.6%)	4 (23.5%)	10 (58.8%)	0.970
	NRS ≤ 2	2 (16.7%)	3 (25.0%)	7 (58.3%)	
	NRS ≥ 3	1 (20.0%)	1 (20.0%)	3 (60.0%)	
Open/HALS (n = 2)		0 (0%)	2 (100%)	0 (0%)	NA
	NRS ≤ 2	0 (0%)	2 (100%)	0 (0%)	
	NRS ≥ 3	0 (0%)	0 (0%)	0 (0%)	
Open/open (n = 21)		8 (38.1%)	9 (42.9%)	4 (19.0%)	0.058
	NRS ≤ 2	7 (38.9%)	9 (50.0%)	2 (11.1%)	
	NRS ≥ 3	1 (33.3%)	0 (0%)	2 (66.7%)	

VATS video-assisted thoracic surgery, HALS hand-assisted laparoscopic surgery, NRS numeric rating scale, NA not assessed

Table 3 Forward stepwise logistic regression analysis of the impact of epidural catheter insertion level on pain control after esophagectomy

Variable	β	SE	Wald	Df	P value	Adjusted odds ratio	95% CI
Thoracotomy VATS (vs. open*)	0.268	0.919	0.85	1	0.771	1.307	0.216–7.910
Laparotomy HALS (vs. open*)	– 1.034	0.960	1.162	1	0.281	0.356	0.054–2.331
Epidural catheter insertion level T7/T8 (vs. over T6/T7 or under T8/T9*)	– 2.369	1.166	4.126	1	0.042	0.094	0.010–0.920

SE standard error, df degrees of freedom, CI confidence interval, VATS video-assisted thoracic surgery, HALS hand-assisted laparoscopic surgery

* Reference group

Table 4 Clinical characteristics of pain control failure cases

Patient	Age (years)	Sex	Thoracotomy	Laparotomy	Epidural catheter insertion level	First NRS	Maximum NRS	Pain site
1	57	M	Open	Open	T9/T10	5	5	Abdominal
2	49	M	VATS	HALS	T8/T9	5	7	Abdominal
3	68	M	VATS	Open	T7/T8	8	8	Abdominal
4	56	M	VATS	Open	T4/T5	3	3	Abdominal
5	79	M	Open	Open	T6/T7	3	3	Abdominal
6	80	M	VATS	Open	T8/T9	5	5	Abdominal
7	82	M	Open	Open	T8/T9	3	3	Abdominal
8	77	M	VATS	Open	T8/T9	3	3	Abdominal
9	72	M	VATS	HALS	T8/T9	3	3	Abdominal
10	57	F	VATS	Open	T9/T10	3	3	Abdominal

VATS video-assisted thoracic surgery, HALS hand-assisted laparoscopic surgery, NRS numeric rating scale

Table 5 Postoperative complications among the epidural catheter insertion levels

Variable	All patients	Over T6/T7	T7/T8	Under T8/T9	P value
Total	63	18	25	20	
Morbidity (CD Grade II or higher)	39 (61.9%)	11 (61.1%)	19 (76.0%)	9 (45.0%)	0.104
Anastomotic leakage	20 (31.7%)	4 (22.2%)	10 (40.0%)	6 (30.0%)	0.457
Chylothorax	6 (9.5%)	2 (11.1%)	3 (12.0%)	1 (5.0%)	0.703
Pyothorax	3 (4.8%)	2 (11.1%)	1 (4.0%)	0 (0%)	0.268
RLNP	11 (17.5%)	3 (16.7%)	6 (24.0%)	2 (10.0%)	0.467
Pneumonia	19 (30.2%)	5 (28.6%)	9 (36.0%)	5 (25.0%)	0.703
CD Grade III or higher	26 (41.3%)	11 (61.1%)	10 (40.0%)	5 (25.0%)	0.077
Mortality	0 (0%)	0 (0%)	0 (%)	0 (0%)	1.000

CD Clavien–Dindo classification, RLNP recurrent laryngeal nerve paralysis

In conclusion, we showed that the T7/T8 epidural catheter insertion level for epidural analgesia could reduce postoperative pain after esophagectomy. We recommended the T7/T8 epidural catheter insertion level to relieve postoperative pain and enhanced recovery after esophagectomy.

Compliance with ethical standards

Ethical Statement All procedures were performed with the approval of the Ethics Committee of Saiseikai Yokohamashi Tobu Hospital and in accordance with the Helsinki Declaration of 1964, and its later versions. Informed consent, or an appropriate substitute for it, was obtained from all patients before inclusion in the study.

Conflict of interest The authors declare that they have no conflicts of interest associated with this study.

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