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審査学位論文
（博　士）

Original

A comparison of epidural-based and intravenous-based postoperative analgesia in patients undergoing laparoscopic colorectomy

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Abstract

Epidural block is a major analgesic method in patients undergoing open colorectomy, but opioid-based intravenous analgesia may be an alternative technique for laparoscopic surgery.

Forty patients were allocated to two groups: a patient-controlled epidural analgesia (PCEA) group and an intravenous patient controlled analgesia (ivPCA) group. In the PCEA group, 0.25% of levobupivacaine containing fentanyl was administered at a rate of 4ml/h with a bolus of 3ml every hour. In the ivPCA group, fentanyl solution containing droperidol was administered at a rate of 0.6 μg/kg/h with a bolus of 0.6 μg/kg every 30 minutes.

Plasma epinephrine concentrations and pain scores on the morning of postoperative Day 1 were significantly lower in the PCEA group (p= 0.022, 0.036, respectively). However, the values of serum CRP, cortisol and IL-6 concentrations were statistically similar for both groups at all measurement points. Additional analgesic requirements, dietary restart, length of postoperative hospital stay and the occurrence of in-hospital complications also were comparable between groups.

In conclusion, epidural-based postoperative analgesia could suppress the catecholamine response and provided good pain relief, but the proinflammatory response and short-term outcomes were similar to intravenous-based analgesia after laparoscopic colorectomy.

I. Introduction

To date, thoracic epidural block has been used as a major analgesic method in patients undergoing open colorectomy, because it is useful in providing optimal pain relief, early recovery of bowel function and fulfillment of discharge criteria [1,2]. However, operative and anesthetic methods have been changing. The laparoscopic approach has become popular as a less-invasive method that contributes to a better postoperative course, lower hospital costs and shorter hospital stays, with oncological quality of treatment comparable to conventional open colorectal surgery [3-5]. In recent years, it has been reported that epidural analgesia may be replaced by spinal

block or opioid-based intravenous analgesia in laparoscopic colorectomy because of the former's delayed postoperative recovery and longer hospital stay [6]. Remifentanil, an ultra-short-acting opioid analgesic, provides better hemodynamic stability than epidural block during major abdominal surgery [7]. Although epidural block has been useful in reducing stress response and surgery-induced proinflammatory response for open abdominal surgery [8, 9], it has also been reported recently that the remifentanil-based anesthesia was found to be superior to epidural-based anesthesia in cardiac surgery [10]. We performed a prospective controlled clinical trial in patients undergoing laparoscopic colorectomy to assess the effects of postoperative analgesia itself followed by high-dose remifentanil-based general anesthesia on surgical stress response, proinflammatory response and short-term outcomes.

II. Materials and Methods

This study was approved by the Ethics Committee of Iwate Medical University School of Medicine, and written informed consent was obtained from each patient prior to surgery.

1. Patient allocation and exclusion criteria

Patients enrolled in this study were those diagnosed with or suspected to have colon adenocarcinoma from the cecum to the rectosigmoid colon. Subjects were allocated to two groups, a patient-controlled epidural analgesia (PCEA) group and an intravenous patient-controlled analgesia (ivPCA) group, according to their patient numbers, with allocation to alternating groups for consecutively-numbered patients. Patients who had ileus, peptic ulcer, bronchial asthma, any allergies to anesthetics and endocrine diseases, or who were using corticosteroids were excluded. Patients included underwent laparoscopic colorectomy at Iwate Medical University Hospital between September 2011 and February 2013.

2. Anesthesia and preoperative care

No premedication was given on the day of surgery, and preoperative fasting started at 9 p.m. on the day before surgery. Oral clear fluid intake was terminated 4 hours before surgery, and at the same time, infusion of acetated Ringer's solution containing 5% glucose was started at a rate of 100 ml/h. Limb-lead electrocardiograms, percutaneous pulseoximetry, noninvasive intermittent blood pressure and the bispectral index (BIS) were monitored throughout the anesthesia. For PCEA group patients, an epidural catheter was inserted at the level of the Th11-12 intervertebral space before induction of general anesthesia. Thereafter, 3 ml of 1% lidocaine containing 30μg of epinephrine was administered via a catheter before induction to rule out intrathecal and intravascular catheterization. After 5-minute oxygen inhalation, general anesthesia was induced with 1.0-3.0 μg/ml of propofol target controlled infusion (TCI) using a Diprifusor® (Terumo Co., Ltd, Hatagaya, Shibuya-ku, Tokyo, Japan), 200 μg of fentanyl and 0.25 μg/kg/min of remifentanil. Following loss of consciousness, 0.6 mg/kg of rocuronium was administered and the trachea was intubated. Mechanical ventilation was started with 6-10 ml/kg tidal volume, 8-15 breath/min and 3-5 cmH_2O PEEP to maintain the expiratory CO_2 pressure in the range of 35-40mmHg. Thereafter, a nasogastric tube and

urinary catheter were inserted, followed by administration of 1.0-3.0 μg/ml of propofol TCI and 0.5-1.0 μg/kg/min of remifentanil for maintenance of anesthesia. The target concentration of propofol TCI was controlled to keep the BIS value within the range of 40-60, and the infusion rate of remifentanil was increased by 0.1 μg/kg/min when the heart rate or systolic blood pressure rose by 20% compared to the control values recorded before skin incision. When systolic blood pressure fell by 20% compared to the control value, the infusion rate of remifentanil was decreased by 0.1 μg/kg/min, and 4-8 mg of ephedrine or 0.05-0.1 mg of phenylephrine was administered intravenously. Further, 10-20 mg of rocuronium was administered as required. Acetated Ringer's solution was administered at a rate of 5-10 ml/kg/h throughout the entire anesthesia. Epidural analgesia was not used until wound closure. When wound closure started, 200 μg of fentanyl, 50 mg of flurbiprofen and 1mg of droperidol were administered intravenously, after which the following analgesic methods were commenced. In the PCEA group, 5 ml of 0.75% levobupivacaine was administered by bolus, followed by the commencement of administration of 300 ml of 0.25% levobupivacaine containing 700 μg of fentanyl at a rate of 4 ml/h via epidural catheter using a COOPDECH® Balloonjector (Daiken Medical Co., Ltd, Osaka, Osaka Pref., Japan). A rescue bolus of 3 ml per hour was also prepared. In the ivPCA group, administration of 60ml of saline solution containing 36 μg/kg of fentanyl and 5 mg of droperidol was commenced at a rate of 1ml/h intravenously using a COOPDECH® Syrinjector I (Daiken Medical

Co., Ltd, Osaka, Osaka Pref., Japan). The rescue bolus was set at 1ml per 30 minutes. When the operation was finished, administration of propofol and remifentanil was terminated and 2-4mg/kg of sugammadex was administered intravenously. After we were able to confirm spontaneous breathing and recovery of consciousness, the trachea was extubated. The patient was transferred to a recovery room and observed for 30-60 minutes, and then transferred to a ward. The efficacy of epidural analgesia was confirmed as no complaint of pain at movement.

3. Surgical technique

All procedures were performed with 5 ENDOPATH® XCEL™ ports placed at each quadrant of the abdomen and the umbilicus. ENDOPATH® Bipolar Forceps, LIGAMAX™ clips, Harmonic ACE® and EnSeal® (all 5 devices registered by Ethicon Endo-Surgery, LLC, Guaynabo, Puerto Rico, USA) were used for vessel ligation. Anastomoses were performed extracorporeally through a Multiflap Gate (Akita Sumitomo Bakelite Co., Ltd., Akita, Akita Pref., Japan) inserted into the umbilical wound enlarged to 4 cm with ENDOPATH® echelon™ stapler and PROXIMATE® TX stapler (both devices registered by Ethicon Endo-Surgery, LLC, Guaynabo, Puerto Rico, USA). Some patients had 1 or 2 drains inserted in the abdomen for monitoring of postoperative bleeding and/or intestinal leakage.

4. Postoperative care

Subjects were given 2000 mL of acetated Ringer's solution a day and the dose of infusion was diminished as oral intake increased. Hypotension defined as systolic blood pressure of less than 90 mmHg was

treated with 500 ml of acetated Ringer's solution administered for 2 hours. On postoperative Day 1, the nasogastric tube was removed and clear fluid intake was permitted in the morning. The urinary catheter was also removed and the patient was encouraged to get out of bed and walk. When urinary retention occurred, intermittent catheterization and drainage of urine was performed. Diet was restarted after bowel sound and passage of flatus or feces were confirmed. When the patient tolerated a full diet, intravenous crystalloid infusion was completed. In cases where the rescue bolus was not sufficient for pain relief, 50 mg of intravenous flurbiprofen and 15 mg of intramuscular pentazocine were administered in turn. Postoperative nausea and vomiting (PONV) was treated with 10 mg of intravenous metoclopramide. Continuous epidural infusion was maintained until its empty unless repeated urinary drainage was needed or persistent PONV was observed. Continuous intravenous fentanyl infusion was also maintained unless drowsiness or persistent PONV was observed.

5. Measurements

Intraoperative blood loss, crystalloid infusion, urine output and anesthetic agent consumption were recorded at the end of surgery. Plasma epinephrine, serum C-reactive protein (CRP), cortisol and interleukin-6 (IL-6) were measured at four time points: during anesthetic induction (T1), just before tracheal extubation (T2), on the morning of postoperative Day 1 (T3), and on the morning of postoperative Day 2 (T4). To extract the plasma or serum samples, the venous blood was obtained, left for 120 minutes and

centrifuged at 5000 rpm for 10 minutes at each point. Extracted plasma or serum was quickly frozen prior to the assay. To assess postoperative pain and satisfaction, all patients were interviewed for pain at rest at T3 and T4 using a visual analog scale (VAS), and for satisfaction at T4 with our original 5-level satisfaction scale, on which 1 corresponds to "poor" while 5 is "excellent". Additional analgesic requirements, the day of dietary restart, the length of postoperative hospital stay, the incidence of PONV, urinary retention and drowsiness were also recorded.

6. Statistical Analysis

Continuous data are presented as mean ± SD or medians with 1st-3rd quartiles according to the distribution, while categorical variables are presented as numbers. Statistical comparisons were performed using Fisher's exact test, Chi-square test, Student's t-test or Mann-Whitney's U test. The Kolmogorov-Smirnov test was also used to check the distribution of data. Differences with a p-value of less than 0.05 were considered significant. For statistical analyses, G*Power 3 (Institute for Experimental Psychology, Heinrich-Heine-University, German) and GraphPad Prism® 5 for Windows (GraphPad Software Inc., San Diego, CA, USA) were used[11].

III. Results

Postoperative plasma epinephrine concentration was set as the primary endpoint and a power analysis was performed based on the results for the first 10 patients studied (5 patients in each group). It was calculated that 20 patients were needed in each group to achieve a power of 80 percent and a p-value of 0.05, therefore 30 more cases

Table 1. Demographic data

	PCEA	ivPCA	p-value
Age (years)	66 ± 10	67 ± 12	0.727
Gender (male/female; n)	10/10	9/11	1.000
Height (cm)	160 ± 9	158 ± 8	0.498
Weight (kg)	59 ± 11	59 ± 11	0.977
ASA PS (I/II; n)	5/15	6/14	1.000
Types of resection (ICR/RH/S/HAR; n)	7/2/9/2	3/2/7/8	0.142
Duration of anesthesia (min)	249 ± 45	269 ± 44	0.162
Duration of surgery (min)	187 ± 40	207 ± 42	0.143
Blood loss (gram)	9 (4–19)	9 (4-20)	0.860
Intravenous fluid (ml)	1670 ± 360	1930 ± 530	0.515
Urine volume (ml)	443 (400–663)	345 (216-660)	0.163
Total propofol dose (mg)	798 ± 304	789 ± 273	0.919
Total remifentanil dose (mg)	7.0 ± 2.3	7.5 ± 2.6	0.493

Values are expressed as mean ± SD, median (1st-3rd quartiles) or the number of patients. The p-values were obtained with 2-group comparisons. ASA PS=American Society of Anesthesiologists physical status, ICR=ileocecal resection, RH=right hemicolectomy, S=sigmoidectomy and HAR= high anterior resection.
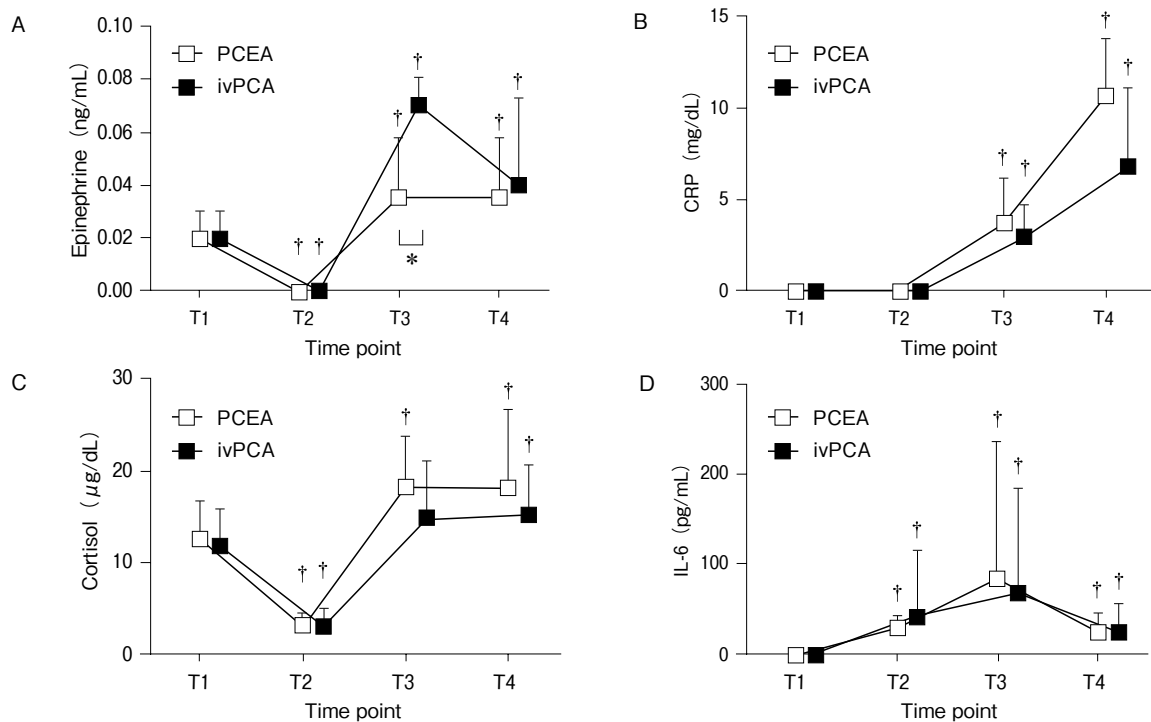

Fig. 1. Profiles of changes in epinephrine (A), CRP (B), cortisol (C) and IL-6 (D).
CRP=C reactive protein. T1=during anesthetic induction, T2=just before tracheal extubation, T3=on the morning of postoperative Day 1, T4=on the morning of postoperative Day 2.
*p=0.022 vs PCEA group, † p<0.05 vs T1.

were recruited. There were no significant differences in baseline data between the two groups (Table 1). In the PCEA group, epidural catheterizations were successfully

Table 2. Postoperative data

		PCEA	ivPCA	p-value
VAS	at T3	23 ± 16	33 ± 14*	0.036
	at T4	25 ± 19	25 ± 11	0.904
Satisfaction score		4 (2-4)	4 (2-4)	0.517
Additional analgesics	until T3 (n)	0 (0-0)	0 (0-1)	0.447
	until T4 (n)	1 (0-1)	0 (0-2)	0.787
Dietary restart (day)		3 (3-4)	4 (3-4)	0.241
Length of hospital stay (day)		8 (7-9)	9 (7-10)	0.162

Values are expressed as mean±SD (range), median (1st-3rd quartiles). The p-values were obtained with 2-group comparisons. VAS=visual analog scale. T3=on the morning of postoperative Day 1, T4=on the morning of postoperative Day 2. Satisfaction scores were measured using a 5-level scale with the levels 1 to 5 corresponding to "poor", "fair", "average", "good" and "excellent". The values of additional analgesics are the frequency of flurbiprofen or pentazocine usage. *p=0.036 vs PCEA group.

Table 3. Postoperative complications

	PCEA	ivPCA	p-value
PONV (n)	12	8	0.343
Urinary retention (n)	4	0	0.106
Drowsiness (n)	0	1	1.000

Figures are patient numbers. The p-values were obtained by 2-group comparisons. PONV = postoperative nausea and vomiting.

performed in all patients, without any intravascular or subarachnoidal placement. Plasma epinephrine concentrations in the PCEA group at T3 were significantly lower than in the ivPCA group (p=0.022, Fig. 1A). On the other hand, the values of CRP, cortisol and IL-6 were statistically similar in both groups at all measurement time points (Fig. 1B-D). The pain score VAS at T3 was significantly lower in the PCEA group (p=0.036), but satisfaction scores, additional analgesic requirements, dietary restarts and lengths of postoperative hospital stay were comparable (Table 2). In terms of postoperative in-hospital complications, there were no statistical differences between the groups in the occurrence rate of PONV,

urinary retention and drowsiness (Table 3). There were no other surgical complications such as anastomotic leakage, wound infection, intraabdominal abscess or hematoma.

IV. Discussion

It has been reported that epidural analgesia is superior to intravenous analgesia with respect to pain relief, recovery of bowel function and length of hospital stay in patients undergoing colorectal surgery[1, 2]. Moreover, this method can also protect against pneumonia, prolonged mechanical ventilation, reintubation and myocardial infarction after thoracic and abdominal surgery[12]. Therefore, epidural block is highly recommended for open colorectomy in the

enhanced postsurgical recovery guidelines [13]. On the other hand, these guidelines also indicate that spinal anesthesia or opioid-based patient-controlled analgesia (PCA) may be an alternative method in laparoscopic surgery. Transition of recommended analgesic methods may consist of two components: changing the surgical method, and the opioid analgesics used. With respect to the former, laparoscopy is an emerging technique that provides earlier tolerance of diet, bowel movement, flatus and stool canalization, mobilization, suction drain removal, cessation of analgesic drug administration, fewer perioperative complications, lower hospital costs and shorter hospital stays, without deterioration of the oncological quality of treatment relative to conventional open colorectal surgery [3-5]. In a recent randomized trial, it was reported that epidural analgesia was found to provide better pain relief on the evening of surgery, but caused delayed recovery of bowel function, a higher incidence of PONV and longer hospital stays, and can be replaced by spinal block or opioid-based intravenous analgesia in laparoscopic colorectomy [6]. Epidural block may also increase the incidence of intra- and postoperative hypotension and urinary retention after urinary catheter removal [2, 12]. Fluid overloading in treatment for hypotension during and after surgery may cause gastrointestinal edema, ileus and subsequent delayed recovery of bowel function and mobilization [14, 15]. With respect to the latter, remifentanil is also an emerging ultra-short-acting opioid. It may provide better hemodynamic stability and have fewer requirements for neuromuscular blockade than epidural block during major abdominal

surgery [7]. It has been reported that epidural-based anesthesia attenuated stress response, surgery-induced proinflammatory response and typical postoperative transient immuno-suppression compared with remifentanil-based anesthesia in conventional open colon surgery and major abdominal surgery [8, 9]. In contrast, it has also been reported that high-dose remifentanil-based anesthesia was superior to epidural-based anesthesia in terms of its modulatory effects on the inflammatory response in cardiac surgery with cardiopulmonary bypass [10]. On the basis of the above background, we hypothesized that high-dose remifentanil-based intraoperative anesthesia combined with epidural-based or opioid-based postoperative analgesia may be a potent technique for providing favorable outcomes in patients undergoing laparoscopic colorectomy.

In this study, plasma epinephrine and serum cortisol concentration were well-suppressed during anesthesia in both groups. Compared with a previous report, high-dose remifentanil was found to be able to effectively control surgical stress [8]. Nevertheless, plasma epinephrine concentration increased during the postoperative period, particularly in the ivPCA group. Further, epidural block was found to be superior to intravenous-based analgesia in controlling surgical stress response postoperatively. Although the consumption of additional analgesics and patient satisfaction scores were similar between the two groups, lower pain scores on postoperative Day 1 in the PCEA group also provided evidence of the superiority of epidural-based analgesia.

In terms of other stress response and proinflammatory response, there were no

statistical differences between the groups in serum CRP, cortisol and IL-6. This result is similar to that of previous reports in which epidural block was found to suppress increases in plasma epinephrine and norepinephrine concentrations but could not suppress increases in serum CRP, cortisol, IL-6 and other cytokines in patients undergoing radical esophagectomy [16]. It is believed that IL-6 has the role of being a prime mediator in glucocorticoid release, and can directly stimulate the adrenal gland to increase serum cortisol concentrations [17]. In this study, remifentanil-based anesthesia combined with epidural-based analgesia was not sufficient to suppress the proinflammatory response and the subsequent increase in serum cortisol concentration postoperatively.

Our study has several limitations. Firstly, it was not based on the recent fast-track, enhanced recovery protocols which contain many detailed perioperative management recommendations, but on the conventional method [13]. In particular, these guidelines state that avoidance of nasogastric drainage and fluid overload are useful for preventing postoperative ileus, early recovery of bowel function and shorter hospital stays. Epidural analgesia has shown superiority over opioid-based intravenous analgesia in early postoperative recovery in several trials following enhanced recovery guidelines [3, 6]. Secondly, the sample size may be too small to prove any differences in other outcomes except for plasma epinephrine and pain relief, because the power analysis was performed focusing on the concentration of epinephrine, indicating the severity of surgical stress response. Specifically, although four cases of urinary retention occurred only in the PCEA group, the statistical power was insufficient to find a statistical difference.

In a future study, we intend to also investigate the influence of regional analgesia such as transversus abdominis plane block or thoracic paravertebral block. These emerging techniques are also effective for postoperative analgesia after abdominal surgery [18].

In conclusion, epidural-based analgesia was found to have several advantages over intravenous-based analgesia, in terms of postoperative catecholamine response and early postoperative pain relief for laparoscopic colorectomy. Nevertheless, in the present study it did not affect the proinflammatory response, occurrence rate of in-hospital complications or length of postoperative hospital stay. Intravenous-based postoperative analgesia may be able to replace epidural-based postoperative analgesia for patients undergoing laparoscopic colorectomy.

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腹腔鏡下大腸切除術患者における術後鎮痛法としての
硬膜外鎮痛と経静脈的鎮痛薬投与との比較

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要旨

　硬膜外鎮痛は開腹手術後の主たる鎮痛手段であったが，腹腔鏡手術では経静脈鎮痛で代替できる可能性がある．対象は腹腔鏡下大腸切除術を受ける患者 40 名．硬膜外鎮痛群 (PCEA) と経静脈鎮痛群 (ivPCA) とに分けた．PCEA 群ではレボブピバカイン・フェンタニル混合液を，ivPCA 群ではフェンタニル・ドロペリドール混合液をそれぞれ投与した．第 1 病日朝における血漿エピネフリン濃度および疼痛スコアは PCEA 群で有意に低かった (順に p = 0.022, 0.036).　しかしながら，血清 CRP，コルチゾール，IL-6 濃度に関してはいずれの観察時点においても有意な群間差を認めなかった．追加鎮痛薬の使用回数，経口摂取再開日，術後在院日数および院内合併症発生率は両群で同等であった．硬膜外鎮痛は経静脈鎮痛に比してカテコラミン抑制効果と鎮痛効果に優れていたが，炎症反応抑制効果，短期アウトカム改善効果を示さなかった．