Prospective Randomized Trial

Comparison of Changes in the Optic Nerve Sheath Diameter Following Thoracic Epidural Normal Saline Injection in Laparoscopic Surgery

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Background: Thoracic epidural analgesia is useful for postoperative pain control after upper abdominal surgery. However, epidural analgesia in patients undergoing laparoscopic surgery may potentiate an increase in intracranial pressure (ICP). ICP can be effectively evaluated by measuring the optic nerve sheath diameter (ONSD).

Objectives: The purpose of this study is to investigate changes in the ONSD following thoracic epidural normal saline injection during laparoscopic surgery.

Study design: Prospective randomized trial.

Setting: An interventional pain management clinic in South Korea

Method: This study included 60 patients receiving thoracic epidural catheterization for postoperative pain control following laparoscopic or open gastrectomy. Patients were divided into 3 groups. The open group consisted of patients undergoing open gastrectomy without epidural normal saline injection. The lapa-saline and lapa groups consisted of patients undergoing laparoscopic gastrectomy with and without 10 mL epidural normal saline injection, respectively. The ONSD was measured using ultrasound at 4 time points.

Results: The lapa-saline group showed the most pronounced increase in the ONSD compared to the open and lapa groups at the time points of T1 and T2. Only the lapa-saline group demonstrated 4 patients with ONSD values of more than 5.8 mm. The increase in the ONSD continued even after the deflation of pneumoperitoneum in the lapa-saline group, whereas the ONSD in the lapa group returned to near baseline value after the deflation of pneumoperitoneum.

Limitations: Epidural normal saline was injected instead of a local anesthetic to prevent the occurrence of hypotension. However, the injection of epidural normal saline is considered to be the same physiological condition causing elevation of ICP compared with epidural injection with local anesthetics.

Conclusions: The lapa-saline group showed the most pronounced increase in the ONSD. The ONSD values higher than 5.8 mm were observed only in the lapa-saline group. The increase in the ONSD continued even after the deflation of pneumoperitoneum only in the lapa-saline group.

Key words: Laparoscopy, optic nerve sheath diameter, epidural, analgesia, intracranial, postoperative

Trial registry number: Clinical trial registry information service (NCT04758013)

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Laparoscopic surgery has become a popular and widely performed surgical method because it has many advantages over open surgery, such as enhanced safety, lower mortality and morbidity, quicker return of bowel function, reduction of postoperative pain, and shorter hospital stay (1,2). However, postoperative nausea, vomiting, and headache may be caused by an increased intracranial pressure (ICP) in patients undergoing laparoscopic surgery (3). A previous study demonstrated that special caution is required during laparoscopic surgery in patients with a history of head injuries (4). Therefore, it is important to predict various risk factors that may increase ICP in patients undergoing laparoscopic surgery.

Several studies have reported on situations that can possibly increase the ICP. During laparoscopic surgery, the generation of pneumoperitoneum can cause an increase in ICP (5). The position of the patient undergoing laparoscopic surgery also affects the increase in ICP (5,6). The increase in ICP that occurs during laparoscopic surgery is due to an impaired venous drainage of the lumbar venous plexus subsequent to increased intra-abdominal pressure (7). A previous study showed that the optic nerve sheath diameter (ONSD) was increased after pneumoperitoneum (8).

In order to directly measure ICP, direct pressure measurement at the ventricle or brain parenchyma is required (9). However, since this direct measurement is very invasive, it is useful to measure ICP indirectly using the ONSD. The method of measuring increased ICP using the ONSD has been proven to be simple and reliable in many prior studies (9-12).

Epidural analgesia for postoperative pain control contributes to pain reduction, reduces the need for additional analgesics, maintains the stable hemodynamic status, and attenuates the effect on postoperative cognitive dysfunction (13-15). For adequate pain control, local anesthetics can be injected into the epidural space in patients undergoing laparoscopic surgery. However, there is no study showing that injecting any local anesthetics into the epidural space during laparoscopic surgery can potentiate an increase in ICP.

We hypothesized that the increase in the ONSD would be higher in patients receiving epidural normal saline injection with laparoscopy than that with laparoscopy without epidural normal saline injection.

The primary endpoint of this study was to compare the ONSD values measured by ultrasonography in patients undergoing open or laparoscopic gastrectomy.

Methods

Patients

This prospective and randomized study was approved by the Institutional Review Board (IRB 2020-12-023-003). The potential benefits and risks of this study were fully explained to the participants prior to enrollment, and they provided informed consent. This study was registered before patient enrollment at clinical trials.gov (NCT04758013; date of registration; February 13, 2021).

The inclusion criteria were patients of ASA class I-II undergoing open or laparoscopic gastrectomy with previously inserted thoracic epidural catheter for postoperative pain control. Final enrollment included 60 patients aged between 18 and 75 years (February to August 2021). The exclusion criteria were refusal to participate, coagulopathy, previous history of cerebral infarction, cerebral hemorrhage, brain tumor, and a history of previous thoracic spine surgery.

Induction of General Anesthesia

All anesthetized patients were ASA class I-II and received scheduled gastrectomy by an open or laparoscopic method. Electrocardiography, pulse oximetry, and noninvasive blood pressure monitoring were performed and checked continuously. Cerebral oximeter sensors were attached firmly 2-3 cm above the eyebrow on the left and right sides of the forehead bilaterally. O3 regional oximetry (Root®, Masimo Corp., Irvine, CA, USA) was used to measure rSO_2 continuously.

For the induction of anesthesia, propofol 2 mg/kg and rocuronium 0.8 mg/kg were used. Sufentanil 0.15 mcg/kg was administered to relieve pain during intubation and operation. After successful endotracheal intubation, both lungs were auscultated. Mechanical ventilation with volume control mode was initiated. The tidal volume and respiration rate were adjusted to 8 mL/kg and 12-14 breaths/min, respectively, to maintain an end-tidal CO_2 at 30-40 mmHg.

General anesthesia was maintained with a ventilation of 1 L O_2, 1 L air, and 2.5 volume % of sevoflurane. End-tidal CO_2 and end-tidal sevoflurane concentrations were monitored continuously. A SedLine monitor (SedLineTM, Masimo Corp., USA) was used to maintain an adequate depth of anesthesia. The target range of patient state index was 40-50 during surgery.

After the induction of general anesthesia, patients receiving laparoscopic surgery were injected with CO_2 to generate pneumoperitoneum. Laparoscopic insufflation pressure was 12-15 mmHg. All gastrectomy operations took an average of 3-4 hours. After the completion of surgery, muscle relaxation was reversed using sugammadex 2 mg/kg, and subsequent extubation was performed after confirming that the muscle relaxation was sufficiently reversed.

Group Allocation

This study focused on measuring the ONSD using ultrasonography in 3 groups. The open group was patients receiving open gastrectomy without thoracic epidural normal saline injection. The lapa-saline and lapa groups consisted of patients receiving laparoscopic gastrectomy with and without thoracic epidural normal saline injection, respectively. The open group was assigned by the surgeon. The lapa and lapa-saline groups were randomly assigned using a computer-generated randomization table. All patients in the 3 groups received thoracic epidural catheterization one day before surgery.

Measurement of the ONSD

An experienced investigator with previous studies (16,17) measured the ONSD using captured ultrasound images. This investigator was blinded to the group assignment.

The ONSD was measured by trans-orbital sonography using a hockey stick probe (Logiq S8, GE Healthcare, Milwaukee, WI, USA). We reduced the power output (mechanical index 0.2; thermal index, 0) to minimize the risk of eye injury from ultrasound. To reduce the pressure on the eyeball, the hockey stick probe was placed very gently. After placing the probe on the upper eyelid, the probe was tilted from the anterior to posterior direction to obtain the best orbital axial image in the optic nerve plane, and then the image was captured. An axial image of the orbit was obtained with a depth of 4 cm. The ONSD was measured 3 mm posterior to the optic nerve head (18) (Fig. 1). Each ONSD was measured serially in each eye at the following time points: 10 minutes after the induction of general anesthesia (baseline, T0), 10 minutes after pneumoperitoneum (T1), 1 hour after pneumoperitoneum (T2), and before emergence from anesthesia (T3). For an accurate measurement, the ONSD was measured twice in both eyes. Therefore, the mean value of the 4 measurements was regarded as the ONSD at each time point.

In the open group, since this group of patients did not receive any CO_2 insufflation, T1 and T2 were defined as the time point when an abdominal skin was incised (T1) and 1 hour after abdominal skin incision (T2).

Previous studies have reported that ONSD values greater than 5.8 mm were likely to be associated with an ICP of more than 20 mmHg (19). Therefore, we identified patients with ONSD values of more than 5.8 mm since these patients have a risk of ICP increase.

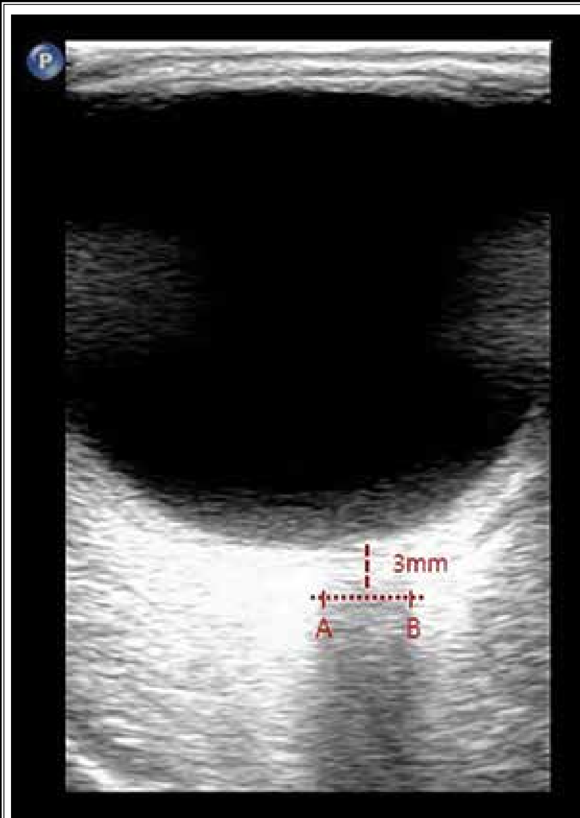

Fig. 1. *Optic nerve sheath diameter (ONSD) measurement by ultrasonography. The ONSD was measured 3 mm posterior to the optic nerve head (A-B) in the axial image of the orbit in the plane of the optic nerve.*

Injection of Epidural Normal Saline

In the lapa-saline group, 10 mL thoracic epidural normal saline was injected via an epidural catheter just following a generation of pneumoperitoneum. The open and lapa groups did not receive any epidural injection of normal saline, although patients of both groups received epidural catheterization.

The presence of possible complications of increased ICP such as blurred vision, dizziness, nausea, vomiting, and headache was checked in the postanesthesia care unit.

Statistical Analysis

This study was designed to identify whether there would be any differences in the ONDS following the injection of normal saline into the thoracic epidural space in the state of laparoscopic or open surgery. Previous study reported that a difference in the ONSD > 0.5 mm

(10% of the mean ONSD in asymptomatic normal adults [mean ONSD 4.9 mm]) would be clinically relevant (20). Twenty patients were required in each group using a 2-sided t-test, significance level of 5%, power of 80%, and dropout rate of 15%.

Continuous variables are presented as mean ± SD or median (interquartile range). Categorical variables are presented as a number (percentile). Demographic data were obtained using an unpaired t-test, the chi-square test, or Fisher's exact test. Repeated measures of analysis of variance (ANOVA) were performed to evaluate the differences between the ONSD values among the 3 groups. An intergroup comparison of the changes in the ONSD over time was performed through group-by time interaction. Post hoc analyses for the ONSD were performed using Bonferroni correction. All statistical values were 2-tailed, and *P*-values of < 0.05 were considered statistically significant. Statistical evaluations were performed using SPSS version 25.0 (IBM Corporation, NY, USA).

Results

A total of 61 patients were enrolled, and 60 patients completed this study (Fig. 2).

Demographic data showed male predominance in all 3 groups. The open group showed a lower body mass index than the lapa and lapa-saline groups (Table 1).

The ONSD values in the open group showed minimal changes from T0 to T3. However, the lapa and lapa-saline groups showed a significant increase in the ONSD at T1 and T2 compared with that at T0. The lapa-saline group showed the most pronounced increase in the ONSD compared with the open and lapa groups at time points of T1 and T2 ($P = 0.006$, $P < 0.001$, Table 2 and Fig. 3).

The lapa and lapa-saline groups showed significant increases in end-tidal CO_2 concentration at the time points of T1 and T2 compared with that at T0. However, the mean arterial pressure, heart rate, rSO_2, and end-tidal sevoflurane concentration did not show any significant changes (Table 3).

Only the lapa-saline group demonstrated 4 patients with ONSD values of more than 5.8 mm (Table 4). When the difference in ONSD changes was evaluated, the lapa and lapa-saline groups showed a significant increase in the ONSD at T1 and T2 compared with that at T0. However, such increase in the ONSD was still sustained in the lapa-saline group even after the deflation of pneumoperitoneum (T3-T0), whereas the ONSD in the lapa group returned to near baseline value after the deflation of pneumoperitoneum (Table 5 and Fig. 3).

None of the patients complained of nausea, vomiting, headache, blurred vision, and dizziness.

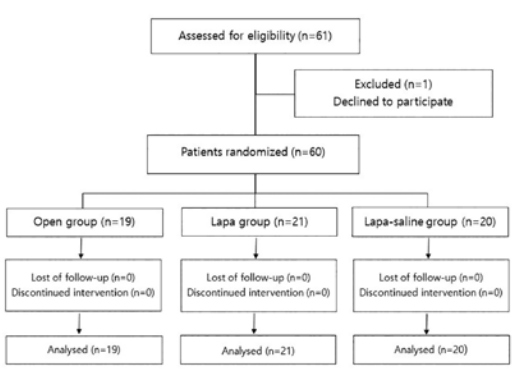

Fig. 2. *Flowchart showing patients who participated in this study.*

Table 1. *Demographic data.*

	Open group (n = 19)	Lapa group (n = 21)	Lapa-saline group (n = 20)	*P* value
Gender (male/ female)	16 (84.2)/3 (15.8)	16 (76.2)/5 (23.8)	14 (70.0)/6 (30.0)	0.598
Age (years)	58.4 ± 9.3	62.5 ± 12.3	59.7 ± 11.1	0.485
Body mass index (kg/m^2)	21.9 ± 3.2	25.6 ± 3.1	23.8 ± 2.4	0.003

Values are presented as mean ± SD for quantitative variables and N (%) for qualitative variables.

Table 2. *Mean values of the optic nerve sheath diameter (ONSD) at each time point.*

	Open group (n = 19)	Lapa group (n = 21)	Lapa-saline group (n = 20)	Adjusted *P* value
ONSD (mm)				
T0	4.69 ± 0.39	4.56 ± 0.25	4.60 ± 0.46	0.530
T1	4.74 ± 0.44	5.07 ± 0.32†	5.27 ± 0.67†	0.006
T2	4.72 ± 0.43	5.13 ± 0.30†	5.37 ± 0.59†	*P* < 0.001
T3	4.75 ± 0.42	4.61 ± 0.20	4.82 ± 0.65*	0.310

Values are presented as mean ± SD. The adjusted *P*-value indicates the Bonferroni-corrected *P*-value. *$P < 0.05$ vs. T0; and †$P < 0.001$ vs T0; in each group. T0, 10 minutes after induction of anesthesia (baseline); T1, 10 minutes after pneumoperitoneum; T2, 1 hour after pneumoperitoneum; T3, before emergence from anesthesia.

Discussion

This study investigated whether there could be a difference in the changes in ONSD under 3 different operative conditions. As reported in previous studies, we could observe an increase in the ONSD in lapa group (8,18,21). We hypothesized that the change in the ONSD would be higher in the lapa-saline group than in the lapa group due to an additional epidural normal saline injection. Consequently, the lapa-saline group showed the most pronounced increase in the ONSD compared with the open and lapa groups at time points of T1 and T2. This study showed that when an epidural normal saline injection was combined to laparoscopic surgery, this could potentiate the increase in the ONSD.

Using ultrasound to measure the ONSD is a useful method to measure ICP indirectly. The correlation of ultrasonography and invasive ICP measurement has been validated in various studies (12,22). The background that ONSD measurement using ultrasound can reflect ICP is that the subarachnoid space surrounding the retrobulbar optic nerve is distensible, and therefore, the optic nerve sheath can expand as a reflection of ICP elevation (19). Previous studies have reported that an ONSD enlargement greater than 5.8 mm was likely to be associated with an ICP of more than 20 mmHg (23). According to the result of this study, 4 patients with ONSD values of more than 5.8 mm were found only in the lapa-saline group. Although there were no patients complaining of serious complications due to an increased ICP in this study, special caution may be needed when a laparoscopic surgery is performed combined with an epidural injection in patients with a history of cerebral hemorrhage, infarction, and other brain lesion.

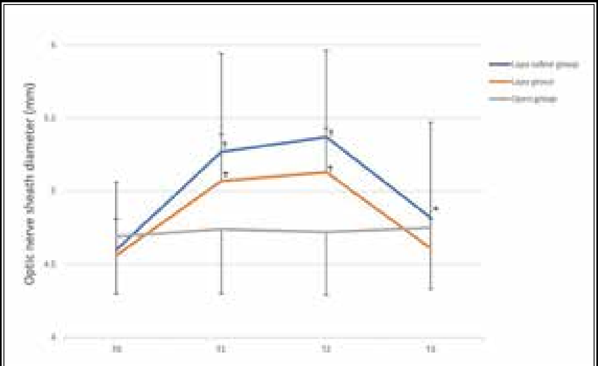

Fig. 3. *Changes in the optic nerve sheath diameter (ONSD) according to time. The lapa and lapa-saline groups showed significant difference in changes in the ONSD at time points T1 and T2 according to time in repeated measures of ANOVA (Pgroup × time = 0.006 T1, P < 0.001 T2). †The lapa and lapa-saline groups showed a significant difference in changes in the ONSD compared to T0 (†P < 0.001 vs T0). *The lapa-saline group showed a significant difference in changes in the ONSD compared to T0 (*P < 0.05 vs T0). Values are presented as mean ± SD. T0, 10 minutes after the induction of anesthesia (baseline); T1, 10 minutes after pneumoperitoneum; T2, 1 hours after pneumoperitoneum; T3, before emergence from anesthesia.*

Table 3. *Mean values of the mean arterial pressure, heart rate, end-tidal CO_2, rSO_2, and end-tidal sevoflurane at each time point.*

	Open group (n = 19)	Lapa group (n = 21)	Lapa-saline group (n = 20)	Adjusted *P* value
MAP (mmHg)				
T0	75.4 ± 8.9	78.2 ± 14.7	78.2 ± 12.6	0.73
T1	85.8 ± 2.3	99.3 ± 14.7	96.1 ± 14.6	0.07
T2	84.6 ± 14.0	88.3 ± 10.4	91.2 ± 8.1	0.19
T3	88.0 ± 13.0	88.1 ± 10.8	89.3 ± 9.0	0.92
HR (beats/min)				
T0	68.9 ± 12.0	66.0 ± 11.0	63.7 ± 9.8	0.34
T1	74.2 ± 11.4	73.4 ± 10.9	71.2 ± 11.1	0.68
T2	74.6 ±11.9	73.8 ± 9.9	72.7 ± 10.5	0.85
T3	77.6 ± 12.7	77.6 ± 10.8	74.1 ± 9.5	0.51
$EtCO_2$ (mmHg)				
T0	34.3 ± 2.0	33.2 ± 3.0	32.6 ± 2.8	0.12
T1	33.5 ± 1.9	35.5 ± 1.9	35.6 ± 2.1	P < 0.01
T2	33.3 ± 1.5	35.0 ± 2.1	34.9 ± 1.7	0.01
T3	35.0 ± 2.3	35.2 ± 2.2	35.5 ± 2.4	0.79
rSO_2 (%)				
T0	65.4 ± 5.6	67.7 ± 6.4	66.2 ± 4.9	0.42
T1	64.5 ± 5.7	67.5 ± 4.7	65.6 ± 7.2	0.27
T2	63.6 ± 6.0	67.0 ± 4.5	66.2 ± 6.3	0.16
T3	65.2 ± 6.8	68.1 ± 4.4	68.0 ± 6.5	0.24
EtSevo (%)				
T0	1.4 ± 0.3	1.5 ± 0.2	1.4 ± 0.3	0.49
T1	1.7 ± 0.2	1.7 ± 0.2	1.7 ± 0.1	0.57
T2	1.7 ± 0.2	1.8 ± 0.2	1.7 ± 0.2	0.41
T3	1.7 ± 0.2	1.7 ±0.2	1.7 ± 0.1	0.86

Values are presented as mean ± SD. The adjusted *P*-value indicates the Bonferroni-corrected *P*-value. MAP, mean arterial pressure; HR, heart rate; $EtCO_2$, end-tidal carbon dioxide; EtSevo, end-tidal sevoflurane; T0, 10 minutes after induction of anesthesia (baseline); T1, 10 minutes after pneumoperitoneum; T2, 1 hour after pneumoperitoneum; T3, before emergence from anesthesia.

Table 4. *Number of patients showing the optic nerve sheath diameter (ONSD) values higher than 5.8 mm.*

	ONSD < 5.8 mm	ONSD ≥ 5.8 mm
Open group	19 (100)	0 (0)
Lapa group	21 (100)	0 (0)
Lapa-saline group	16 (80)	4 (20)

Values are presented as N (%) for qualitative variables.

Table 5. *Difference in the mean values of the optic nerve sheath diameter (ONSD) according to time in each group.*

	Difference in the ONSD value	*P* value
Open group		
T0 - T1	- 0.05 ± 0.02	0.175
T0 - T2	- 0.03 ± 0.03	0.999
T0 - T3	- 0.07 ± 0.03	0.200
Lapa group		
T0 - T1	- 0.51 ± 0.04	*P* < 0.001
T0 - T2	- 0.58 ± 0.05	*P* < 0.001
T0 - T3	- 0.05 ± 0.05	0.999
Lapa-saline group		
T0 - T1	- 0.66 ± 0.07	*P* < 0.001
T0 - T2	- 0.77 ± 0.06	*P* < 0.001
T0 - T3	- 0.22 ± 0.08	0.047

Values are presented as mean ± SD. T0, 10 minutes after the induction of anesthesia (baseline); T1, 10 minutes after pneumoperitoneum; T2, 1 hour after pneumoperitoneum; T3, before emergence from anesthesia.

The first explanation for the increase in ICP was the occurrence of increased intra-abdominal pressure due to a generation of pneumoperitoneum during laparoscopic surgery. Subsequently, increased intra-abdominal pressure impairs drainage of the cerebrospinal fluid (CSF) and venous blood at the level of the lumbar plexus independent of other factors, such as increased $PaCO_2$ and mean arterial pressure (7,24).

Previous studies have reported that the pressure of the epidural space is correlated with ICP (25). In the porcine model, the epidural injection of normal saline increased ICP (26). When normal saline is injected into the epidural space, the movement of the CSF from the subarachnoid space to the cranial cavity develops, which is thought to increase ICP. This movement of the CSF into the cranial cavity is initiated due to the effect of thecal sac compression caused by epidural normal saline injection. Such movement of the CSF toward the intracranial space occurs due to a pressure difference between the spinal and intracranial spaces when an epidural injection is performed. This phenomenon has been demonstrated by a previous study model that revealed a bidirectional movement of the CSF between the cranial and subarachnoid spaces according to the pressure gradient (27,28). In this study, an increase in the ONSD was observed in both groups of laparoscopic surgery. However, in the lapa-saline group, when an additional 10 mL thoracic epidural normal saline was injected following the generation of pneumoperitoneum, a pronounced increase in the ONSD was observed as compared with the other groups. This means that combining an epidural injection during laparoscopic surgery could be a potential risk factor that may enhance an increase in ICP. The lapa group showed that the ONSD returned to near baseline value when a pneumoperitoneum was deflated. However, the lapa-saline group did not show any return to baseline value even after the deflation of pneumoperitoneum, which means that a more sustained effect of ICP increase was developed.

There are several limitations in this study. First, in the open group, due to the occurrence of one patient who did not want to participate in this study, 19 patients were included finally. In addition, patients who wanted to undergo open gastrectomy were few since the laparoscopic method became the main method of surgery. Second, in the open group, we applied different time points of T1 and T2 since this group of patients did not receive any CO_2 insufflation or epidural normal saline injection. Therefore, the time points of T1 and T2 in the open group may be slightly different from those in the lapa and lapa-saline groups. Third, epidural normal saline was injected instead of a local anesthetic. Due to a frequent occurrence of hypotension following epidural injection of local anesthetics, we injected normal saline instead of local anesthetics. However, the injection of epidural normal saline is considered to be the same physiological condition causing elevation of ICP compared with epidural injection with local anesthetics. Fourth, we could not be blinded if the patients were in the open group. However, blinding was possible between the lapa and the lapa-saline groups. The surgical method was decided by the surgeon and patient not by the clinical trial protocol.

In conclusion, the lapa-saline group showed the most pronounced increase in the ONSD. ONSD values higher than 5.8 mm were observed only in the lapa-saline group. The increase in the ONSD continued even after the deflation of pneumoperitoneum in the lapa-saline group. Therefore, special attention is required in patients with a history of brain lesions when laparoscopic surgery is combined with epidural analgesia.

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