Sevoflurane may be more beneficial than propofol in patients receiving endoscopic variceal ligation and endoscopic variceal sclerotherapy: A randomized, double-blind study

LINGHUA TANG, HUIMIN LIU, YANG WU, MEI LI, WEI LI, MENG JIANG, JIABAO HOU, YING JIANG, ZHONGYUAN XIA and QINGTAO MENG

Department of Anesthesiology, Renmin Hospital of Wuhan University, Wuhan, Hubei 430060, P.R. China

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Abstract. The aim of the present study was to evaluate the safety and efficacy of various general anesthesia regimens during endoscopic variceal ligation (EVL) and endoscopic variceal sclerotherapy (EVS). A total of 123 patients with American Society of Anesthesiologists physical status III and IV, aged 40-70 years, undergoing general anesthesia for EVL and EVS were randomly divided into two groups: Sevoflurane anesthesia (group S; n=60) and propofol anesthesia (group P; n=60). Vital signs, particularly heart rate (HR) and mean arterial pressure (MAP), were monitored. The designated time points were as follows: 5 min before induction (T0), and 1, 5, 10, 15, 20, 25 and 30 min after intubation (T1, T2, T3, T4, T5, T6 and T7, respectively). Time intervals were recorded, including recovery time and extubation time. Following surgery, the observer recorded the Ramsay sedation scale (RSS) score and the visual analogue scale (VAS) score. Adverse reactions were noted. Results demonstrated that there were significant differences in MAP between the two groups at T2, T3, T5, T6 and T7 (P<0.05). There was a significant difference in HR between the two groups at T2, T3 and T4 (P<0.05). Recovery time and extubation time in group P were significantly longer than those in group S (P<0.05; 18.38±2.25 min vs. 14.57±1.04 min and 21.70±2.70 min vs. 15.83±0.88 min, respectively). The rate of ephedrine injected was 58.3% (35/60 patients) in group P vs. 28.3% (17/60 patients) in group S (P<0.05). There was a significant difference in the RSS score between the two groups 5 min after extubation (P<0.05). VRS scores demonstrated that anesthetists and patients were significantly more satisfied with the procedure in group S than in group P (P<0.01). In conclusion, the superiority and special clinical value of inhalational anesthesia has been demonstrated during EVL and EVS attributed to stable hemodynamics and high quality of anesthesia recovery in the present study.

Introduction

The population of China has a high rate of chronic liver disease. For example, the prevalence of chronic hepatitis B was 7.18% in 2006 (1) and the prevalence of chronic alcoholic liver disease was 4.3-6.5% in 2003 (2). Different from developed countries, hepatitis B is the most common disease in China (3,4). Globally, >350 million individuals suffer from chronic hepatitis B virus (HBV) infection. At the same time, there are >12 million hepatitis B patients in China and liver cancer and cirrhosis leads to the mortality of 240,000 individuals every year (5). Variceal hemorrhage (VH) is a major and life-threatening complication of chronic liver disease and is associated with significant morbidity and mortality (6). However, the overall rate of survival may be improving with advances in medical technology. In the early 1980s, it was reported that the 6-week mortality following an acute variceal bleed was 40-50%, with rebleeding rates of >33%. Today, overall 30-day mortality is 15%, the rebleeding rate is 26% and the 30-day mortality in those patients who do not rebleed is 7% (7,8). Mortality remains closely associated with failure to control bleeding or early rebleeding (6-8). As one of the most common and lethal complications of portal hypertension resulting from liver cirrhosis, esophageal variceal bleeding may lead to acute hemorrhage shock accompanied by other serious consequences, such as renal failure, infection and even death without timely treatment (9,10). There are a number of methods used to treat variceal bleeding, such as vasoactive drugs, transjugular intrahepatic portosystemic shunt (TIPS) and endoscopic therapy (endoscopic injection sclerotherapy, endoscopic ligation and endoscopic glue obliteration). Endoscopic treatment is the gold standard of care in the management and prophylaxis of variceal bleeding in patients with liver cirrhosis (11). Endoscopic variceal ligation (EVL) and endoscopic variceal sclerotherapy (EVS) are highly

Correspondence to: Professor Zhongyuan Xia, Department of Anesthesiology, Renmin Hospital of Wuhan University, 95 Zhang Zhidong Road, Wuhan, Hubei 430060, P.R. China
E-mail: xiazhongyuannz@hotmail.com

Abbreviations: EVL, endoscopic variceal ligation; EVS, endoscopic variceal sclerotherapy

Key words: intravenous anesthesia, inhalational anesthesia, propofol, sevoflurane, EVL, EVS
accepted by doctors and patients due to minimal trauma, significant effects, fast recovery and notable improvement in patient quality of life (12). Patients who require EVL or EVS often accept general anesthesia, which contains inhalational anesthesia and intravenous anesthesia (13).

Volatile anesthetics have been demonstrated to be more beneficial than propofol for postoperative liver function in cirrhotic patients receiving hepatectomy (14). Furthermore, animal studies had revealed that volatile anesthetics could induce some endogenous protective molecules in the liver (15). However, there is a lack of trials to compare the anesthetic effects of sevoflurane with that of propofol on patients receiving EVL and EVS. The present study aimed to evaluate the safety and efficacy of two general anesthesia regimens on patients receiving EVL and EVS.

Patients and methods

Experimental design and patients. The present study was designed as a double-blind, randomized, parallel-group study. The study was performed in accordance with the International Conference on Harmonization Good Clinical Practice guidelines (16) and was approved by the Ethics Committee of Renmin Hospital of Wuhan University (Wuhan, China). Written informed consent was obtained from all patients prior to initiation of the study. A total of 123 patients with an American Society of Anesthesiologists (ASA) status of III or IV (17) and liver cirrhosis scheduled for EVL or EVS were included in the present study. The patients consisted of 53 females and 70 males, aged from 40–70 years. Study exclusion criteria were as follows: i) Any malignant tumor; ii) hemorrhage shock during perioperative periods; iii) bacterial infection or encephalopathy; iv) large amounts of ascites; and v) a concomitant disease with reduced life expectancy.

In addition to the general laboratory tests, the blood samples of all patients were tested following the manufacturer’s instructions for the presence of hepatitis B virus (Elecys 2010 Immunology Analyzer; Roche AG, Basel, Switzerland), hepatitis C virus (Architect Anti-HCV, Abbott Core Laboratory, Abbott Park, IL, USA) and human immunodeficiency virus (Alere Determine HIV-1/2, Alere Inc., Waltham, MA, USA). A full clinical history, physical examination, electrocardiogram (ECG), chest radiograph, laboratory tests and ultrasonography were performed.

Anesthesia monitoring and methods. Patients were fasted from solid foods and clear liquids for 8 h before the procedure. Routine monitoring was performed during surgery, including ECG, noninvasive blood pressure (BP), pulse oxygen saturation (SpO2) and Bispectral index (BIS; A-2000: Aspect Medical Systems, Inc., Natick, MA, USA). Heart rate (HR) and mean arterial pressure (MAP) were also recorded.

Prior to induction of anesthesia, the 123 patients were randomized into two groups by using a computer-generated random numbers table. A total of 62 patients were in group P (propofol group) and 61 patients were in group S (sevoflurane group). The mean of the last three vital sign measurements prior to induction was the baseline in all patients. All patients received 0.06 mg/kg intravenous tropisetron (Southwest Pharmaceutical Co., Ltd., Chongqing, China) to prevent nausea and vomiting. Anesthesia was induced with intravenous cisatracurium (0.2 mg/kg; Jiangsu Hengrui Medicine Co., Ltd., Lianyungang, China). Etomidate (0.2 mg/kg; Jiangsu Nhwa Pharmaceutical Co., Ltd., Xuzhou, China) was administered intravenously 2 min later. Remifentanil (2 µg/kg; Yichang Humanwell Pharmaceutical Co., Ltd., Yichang, China) and tramadol (1 mg/kg, Grunenthal GmbH, Aachen, Germany) were also administered intravenously 1 min later. On loss of consciousness and when Observer’s Assessment of Alertness and Sedation score was ≤3 (18), breathing was manually supported and tracheal intubation was performed by an attending doctor, which was completed within 30 sec. Following tracheal intubation, the lungs were mechanically ventilated, with volume-controlled ventilation at 6–8 ml/kg and 12 bpm. End-tidal carbon dioxide tension was maintained at 35–40 mmHg. Intravenous fluid management included administration of lactated Ringer’s solution (Shandong Qidu Pharmaceutical Co., Ltd., Shandong, China). Fluid deficit was calculated to be replaced over 8 h, and maintenance fluid was calculated according to patients’ weights.

Anesthesia was maintained with intravenous 4–6 µg/kg/h propofol (Beijing Fresenius Kabi Pharmaceutical Co., Ltd., Beijing, China) by a micropump (Syringe Infusion Pump Model 500, Wuhan Sanfeng Medical Equipment Co., Ltd., Wuhan, China) in group P and 1–1.5% sevoflurane (Abbott Core Laboratory) by inhalation in group S. The concentration of sevoflurane and propofol during the surgery were adjusted by the BIS monitor, which was maintained between 45 and 55 (19). Fresh O2 gas flow of 2.0 l/min was given. Remifentanil (4–6 µg/kg/h) was continuously infused and controlled by a micropump (Syringe Infusion Pump Model 500). At the end of the surgery, O2 flow rate was increased to 6 l/min and the anesthetic regimens were discontinued. The endotracheal tube was removed when patients’ consciousness recovered and respiration was regular and adequate in rate and depth. Boluses of ephedrine or atropine were given if hemodynamic events occurred.

Observed parameters. The designated time points for recording were as follows: The mean of the last three recordings on the vital sign monitor prior to induction was set as the baseline in all patients (T0), and 1, 5, 10, 15, 20, 25 and 30 min after intubation (T1, T2, T3, T4, T5, T6 and T7, respectively). Hemodynamic variables were recorded every min. Hemodynamic events were defined as hypotension (systolic pressure <90 mmHg) and bradycardia (HR<50 bpm).

Recovery time was defined as the time between anesthetic agent discontinuation and eyes opening (either spontaneously or due to verbal commands). The endotracheal tube was removed when patients’ consciousness recovered and respiration was regular and adequate in rate and depth (frequency >8 bpm; tidal volume >6 ml/kg). Extubation time (time from when anesthesia administration was stopped to when the endotracheal tube was removed) was recorded.

A total of 5 min after extubation, the Ramsay sedation scale (RSS) (20) score was also measured. The RSS scores were as follows: 1, anxious, agitated or restless; 2, cooperative, oriented and tranquil; 3, drowsy but responsive to stimulus; 4, brisk response to stimulus; 5, sluggish response to stimulus; and 6, no response to painful stimulus. The goal of sedation in...
the present study was to limit the RSS to a score of 2-3 (20). The visual analogue scale (VAS) score (21) was also measured.

Complications during and after surgery, including hypotension, bradycardia, apnea, hypoxemia (SpO₂<90%) and dizziness were observed. Postoperative nausea or vomiting (PONV), awareness during surgery and postoperative delirium were also recorded.

Patient satisfaction questionnaire. If full recovery was confirmed in the inpatient setting, the anesthetists completed a questionnaire, by using a verbal rating scale (VRS) that inquired about i) overall satisfaction with sedation, ii) difficulty of sedation, iii) patient cooperation and iv) overall satisfaction with the procedure. All patients also completed a questionnaire by using a VRS with the following scores: 0, excellent; 1, good; 2, fair; 3, dissatisfied; and 4, very dissatisfied overall with the procedure, due to factors such as pain, awakening, memory and uncomfortable symptoms during recovery.

Statistical analysis. Measured data were expressed in the form of the mean ± standard deviation. SPSS 13.0 statistical software (SPSS, Inc., Chicago, IL, USA) was used to set up the database and to calculate the results. The patient demographics (age and BMI) and surgical data were compared using unpaired t-test, analysis of variance followed by Tukey’s multiple comparison tests were used to compare the vital signs at different points in the same groups and Bonferroni post-tests were used to compare the vital signs between two groups. The chi-square or Fisher’s test were used to compare the patient demographics (sex and ASA physical status) the complications between two groups. The degree of satisfaction was compared with Mann-Whitney U test between two groups. P<0.05 was considered to indicate a statistically significant difference.

Results

Patients. A total of 140 patients were assessed for study eligibility. Of these patients, 17 did not meet the inclusion criteria and so 123 patients were finally enrolled. During anesthesia, 1 patient experienced vascular rupture in group S prior to intubation, which led to reflux aspiration. In group P, 2 patients experienced vascular rupture during surgery. Despite the fact that following treatment for vascular rupture the prognosis was good, all of these patients were excluded. Therefore, 120 patients were finally included in the statistical analysis (Fig. 1). Patient data, basal BP, HR were similar in the two groups at T0 (P>0.05; Table I).

Hemodynamic variables. Results demonstrated that there was a significant decrease in HR and MAP following induction of anesthesia in all patients. Compared with T1,
TANG et al: SEVOFLURANE IS MORE BENEFICIAL THAN PROPOFOL IN EVL AND EVS

Table I. Patient demographics.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>P (n=60)</th>
<th>S (n=60)</th>
<th>P-value</th>
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<tr>
<td>Age, years</td>
<td>60.6±8.35</td>
<td>58.8±9.35</td>
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<td>Sex (male/female), n</td>
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<td>27/33</td>
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<td>Body mass index</td>
<td>19.79±1.15</td>
<td>19.59±1.12</td>
<td>0.32</td>
<td></td>
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<tr>
<td>American Society of</td>
<td>48/12</td>
<td>50/10</td>
<td>0.63</td>
<td></td>
</tr>
<tr>
<td>Anesthesiologists status</td>
<td></td>
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Data are expressed as the mean ± standard deviation where appropriate. S, sevoflurane; P, propofol.

MAP was significantly decreased at T2, T3, T5, T6 and T7; Compared with T2, MAP was significantly elevated at T4, T6, T7; compared with T3, MAP was elevated at T4, T6, T7; compared with T4, MAP was decreased at T5, T6, T7; compared with T5, MAP was elevated at T6, T7. Data are presented as the mean ± standard deviation. \(^*\)P<0.05 vs. T0; \(^\#\)P<0.05 vs. T1; \(^\&\)P<0.05 vs. T2; \(^\downarrow\)P<0.05 vs. T3; \(^\downarrow\)P<0.05 vs. T4; \(^\downarrow\)P<0.05 vs. T5. MAP, mean arterial pressure; group P, propofol group; T, time point.

Figure 2. MAP of group P at different time points. MAP of group P was significantly decreased at all time points after induction compared with the baseline (T0). Compared with T1, MAP was lower at T2, T3, T5, T6, T7; compared with T2, MAP was elevated at T4, T6, T7; compared with T3, MAP was elevated at T4, T6, T7; compared with T4, MAP was decreased at T5, T6, T7; compared with T5, MAP was elevated at T6, T7. Data are presented as the mean ± standard deviation.

Figure 3. MAP of group S at different time points. MAP of group S was significantly decreased at all time points after induction compared with the baseline (T0). There were significant differences in MAP in group S between T1 and T5, T1 and T6, T4 and T5, T4 and T6, and T4 and T7 after induction. Data are presented as the mean ± standard deviation. \(^*\)P<0.05 vs. T0; \(^\#\)P<0.05 vs. T1; \(^\&\)P<0.05 vs. T2; \(^\downarrow\)P<0.05 vs. T3; \(^\downarrow\)P<0.05 vs. T4; \(^\downarrow\)P<0.05 vs. T5. MAP, mean arterial pressure; group S, sevoflurane group; T, time point.

Figure 4. Comparison of MAP in groups P and S. Compared with group P, MAP was significantly higher in group S, except for at T0, T1 and T4. Data are expressed as the mean ± standard deviation. \(^*\)P<0.05 vs. group P. MAP, mean arterial pressure; group S, sevoflurane group; group P, propofol group; T, time point.

Recovery time in group P was 18.38±2.25 min vs. 14.57±1.04 min in group S (P<0.05). Exeutation time in group P was 21.70±2.70 min vs. 15.83±0.88 min in group S (P<0.01; Table II). The RSS score was significantly higher in group P than in group S (2.42±0.50 vs. 2.12±0.32, respectively; P<0.05) 5 min after extubation (Table II). The VAS scores given by the patients in the two groups were not significantly different (P>0.05; Table II).

Complications during surgery and following extubation. The rate of ephedrine injected was significantly higher in group P than in group S (58.3% [35/60 patients] vs. 28.3% [17/60 patients]), respectively (P<0.05; Table III). The occurrence of SpO\(_2\) <90% was significantly higher in group P (9.7%) than in group S (0%; P<0.05; Table III). The occurrence of dizziness in group P was significantly higher than that in group S (P<0.05; 13.3 vs. 0%, respectively). There were no significant differences between the two
groups in the occurrence of PONV (6.7% in group P vs. 10% in group S), awareness during surgery and postoperative delirium (P>0.05; Table III).

Anesthetist and patient satisfaction. The VRS score by the anesthetists and the patients between the two groups were significantly different (P<0.01; Table IV). The number of VRS scores of 0 and 1 given by patients and anesthetists was significantly higher in group S than in group P (P<0.01). The number of VRS scores of 3 and 4 given by patients and anesthetists was significantly higher in group P than in group S (P<0.01). Notably, the main reasons for their dissatisfaction were the complications listed in Table III.

Discussion

The ideal non-operating room anesthesia should ensure that the patient falls to sleep rapidly, the sedation is sufficient, the circulation is steady, the recovery is quick and that there are minimized complications (22). The results of the present study demonstrated hemodynamic stability, minimal respiratory depression and minimized complications for patients undergoing EVL and EVS when using sevoflurane. The findings of the present study demonstrated the unique characteristics of sevoflurane on minimal respiratory depression, reduced side effects, rapid recovery of awareness and high levels of satisfaction provided compared with the use of propofol.

Partially due to its rapid recovery profile, propofol is currently the most frequently used intravenous anesthetic (23). However, the most notable undesirable effect of propofol is its marked depression on cardiovascular and respiratory parameters, particularly for patients with liver cirrhosis or shock, elderly patients and patients with an ASA status of III or IV (24,25). The crucial question is how to maintain the stability of hemodynamics during the perianesthesia phase. Of all currently used anesthetics, the pharmacokinetic properties of sevoflurane come closest to that of the ideal anesthetic. That the pharmacological characteristics of sevoflurane include inherent stability, low flammability, lack of irritation to airway passages, low blood: gas solubility allowing rapid induction and emergence from anesthesia, minimal cardiovascular and respiratory side effects and minimal end-organ effects (26,27), means it has a wider margin of safety for patients with marked risk factors, including an ASA III/IV status and being elderly.

The aim of the present prospective study was to determine, in a series of consecutive patients with liver cirrhosis and an ASA status of III or IV, the safety, efficacy and the satisfaction of the use of propofol and sevoflurane. Furthermore, the present study aimed to evaluate the advantage on the post-sedation activity of patients who underwent EVL and EVS with propofol anesthesia compared with patients who received sevoflurane anesthesia.

Hypotension is a common side effect associated with propofol use due to vasodilation and negative inotropic effect (28,29). The present study demonstrated that, compared with propofol, sevoflurane kept hemodynamics stable. MAP and HR had smaller fluctuations in patients in group S than those in group P. Patients for EVL and EVS in the current study often have acute or chronic blood loss. Propofol may be associated with diminished myocardial contractility, decreased cardiac output, reduced ability of the cardiovascular system to respond to stress (30) and preoperative fasting, all of which lead to relative or absolute hypovolemia (31). Therefore, in the present study, more ephedrine was used in group P than...
Following fluid infusion and ephedrine injection, patients' MAP was gradually increased and began to stabilize. The maintenance of MAP was better with sevoflurane compared with propofol. Although the difference may be of limited significance for healthy patients, the relative hypotension associated with propofol may be detrimental in elderly patients and patients with coronary artery disease (32-35).

A predominant aim of management for patients undergoing EVL and EVS is to minimize risk factors of myocardial and cerebral ischemia. In order to effectively reduce the likelihood of potential adverse neurological or cardiovascular events, it is essential to maintain adequate cerebral perfusion and continually adjust cardiovascular variables (36). The majority of clinicians aim to maintain arterial BP as close to the preoperative level as possible (37,38). During the perioperative phase, episodes of ischemia occur in close association with marked fluctuations in BP (36). From the present study, it may be concluded that the maintenance of anesthesia with sevoflurane in patients resulted in more stable hemodynamics, but a less substantial decrease in MAP in comparison with propofol. Research has demonstrated that propofol induces a reduction in BP and HR in humans (39), and inhibition of sympathetic nerve activity is believed to be one of the major mechanisms underlying propofol-induced hemodynamic depression (38). These results are similar to those of the present study.

The present study demonstrated that the recovery time and extubation time in group S were significantly shorter than those in group P. Furthermore, there was less individual variation between patients in the recovery time or extubation time in group S than in group P. Patients undergoing EVL and EVS usually have low serum albumin levels and hypovolemia due to liver dysfunction and bleeding (40,41). Compared with propofol, sevoflurane is metabolized independent of liver and renal function; therefore, it is more controllable (42).

The present study also demonstrated that the RSS score of patients 5 min after extubation in group S was significantly lower than that in group P. As brain damage related to respiratory events is the leading cause of morbidity in group S. Following fluid infusion and ephedrine injection, patients' MAP was gradually increased and began to stabilize. The maintenance of MAP was better with sevoflurane compared with propofol. Although the difference may be of limited significance for healthy patients, the relative hypotension associated with propofol may be detrimental in elderly patients and patients with coronary artery disease (32-35).

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The present study also demonstrated that the RSS score of patients 5 min after extubation in group S was significantly lower than that in group P. As a non-operating room anesthesia, patients need to wake up quickly and be aware without untoward effects including respiration depression and drowsiness. Therefore, the goal of sedation in the present study was to limit the RSS score to 2 or 3. According to the present study, anesthesia with sevoflurane is one of the best choices.

Propofol has been demonstrated to produce a higher incidence of apnea, with a duration >30 sec, which exposes the patient to the risks of a decrease in SpO₂ (43). As brain damage related to respiratory events is the leading cause of morbidity
in anesthesia-related events, the safety of anesthesia is critical. Research has demonstrated that propofol is associated with a 9.7% incidence of apnea (44,45). Additionally, the present study demonstrated that the incidence of dizziness in group S was significantly lower than that in group P. However, due to side effects such as PONV and postoperative delirium, sevoflurane was disliked by some anesthetists. In the present study, no significant difference was observed between the occurrence of PONV or postoperative delirium existed between the two groups. There is a high incidence of PONV in gastrointestinal surgery, and it is known that propofol may reduce the occurrence of PONV (46,47). Research has indicated that sevoflurane may effectively decrease awareness during surgery (48). However, the present study did not show any significant difference in the occurrence of PONV, the occurrence of postoperative delirium or awareness during the surgery between the two groups, maybe because the sample was not large enough.

The results of the present study demonstrated that, when compared with use of propofol, compound use of sevoflurane and remifentanil may induce less side effects, including blood fluctuation, respiration depression, dizziness and awareness of patients. Therefore, the anesthetists and patients were much more satisfied with the sevoflurane anesthetic in the present study. In the present study, 3 patients were excluded because of reflex aspiration and hemorrhage shock. This occurred prior to induction in 1 patient and during the surgery in the other 2 patients. Gastrointestinal bleeding is a major risk that may occur at any time for patients undergoing EVL and EVS. Therefore, it is essential to minimize the risks of perioperative reflex and aspiration, such as the preparation of the aspirator or suction apparatus and rapid sequence intubation. If this occurred, it should be ensured that the airway is unobstructed and then the hemorrhage shock should be dealt with. In conclusion, the present study preliminarily demonstrated that endotracheal intubation and sevoflurane inhalation anesthesia are more effective and safer for patients undergoing EVL and EVS compared with propofol anesthesia. Sevoflurane greatly reduced BP fluctuation and reflux-aspiration risk. In terms of recovery of postoperative respiration and consciousness, sevoflurane inhalation and remifentanil anesthetic regimens have more advantages, and may be the ideal anesthetic drugs and methods to use for EVL and EVS surgery. However, as the sample size of the present study was not large, further research is required to further verify the results of the present experiment.

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