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Postoperative Nausea and Vomiting Between Total Intravenous and Sevoflurane Anesthesia after Peroral Endoscopic Myotomy; A Randomized, Double-Blind

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Abstract | **Original Research Article**

Peroral endoscopic myotomy (POEM) recently has been reported as minimally invasive therapy for esophageal achalasia requires general anesthesia. Postoperative nausea and vomiting (PONV) is one of the most common adverse events after general anesthesia. Although PONV is associated with adverse consequences undergoing POEM, little has been known about the incidence and risk factors. We evaluated the incidence of PONV undergoing POEM as well as the relationship between incidences and anesthetic agents. This prospective double-blind study comprised 60 patients with American Society of Anesthesiologist physical status I or II who were undergoing POEM with inhaled anesthesia or TIVA. Patients were interviewed by two experienced anesthesiologists about incidence of PONV in accordance with a categorical verbal rating scale (VAS) and PONV Intensity Scale. The primary outcome was the incidence of PONV undergoing POEM between the two groups. In addition, we observed postoperative outcomes including bleeding at surgical site, mucosal injury, and patients' satisfaction. The incidence of PONV after POEM within first 6 hours was significant lower in the TIVA group than in the sevoflurane group (46.4% vs 76.7%, p=0.025). Additionally, it was observed that number of patients who experienced postoperative complications, such as surgical site injury, mucosal injury, heart burn, pneumoperitoneum, and emphysema, was higher in TIVA group (44.4%) compared with in sevoflurane group (26.7%), but it was insignificant (p=0.130). These data suggest that TIVA could be considered as a good method to prevent PONV during early postoperative period (within 6 hours) after POEM.

Keywords: Peroral endoscopic myotomy (POEM), Postoperative nausea and vomiting (PONV), Total intravenous anesthesia (TIVA), Sevoflurane, Esophageal achalasia, General anesthesia.

INTRODUCTION

Esophageal achalasia is an esophageal motility disorder characterized by a failure of lower esophageal sphincter relaxation after swallowing and a lack of peristalsis of esophagus [1], which is accompanied by esophageal dilation and regurgitation [1]. Therefore, dysphagia, nausea and vomiting are main symtoms associated with slow gastric emptying in the absence of mechanical obstruction. Treatment options for esophageal achalasia include pharmacological therapy, endoscopic pneumatic balloon dilation and surgical intervention such as laparoscopic Heller myotomy and peroral endoscopic myotomy (POEM). Recently, POEM has been established as the best treatment option for esophageal achalasia, as POEM is safer and less invasive than other surgery [1, 2]. It has been demonstrated that POEM under endotracheal general anesthesia compares favorably to intravenous sedation [3, 4]. Despite impressive advances in the field of anesthesia, postoperative nausea and vomiting (PONV) is one of the most undesirable complications after general anesthesia. The incidence of PONV has been reported between 10% and 30%, but up to 80% in patient with risk factors for PONV [5]. Since Apfel *et al.*, [5] has been developed a risk score for PONV, numerous studies have reported multiple risk factors, including the patient characteristics, anesthetic agent, surgical procedure, and postoperative care, are associated with an increased incidence of PONV [6-8]. Recently, it has been demonstrated that total intravenous anesthesia (TIVA) with propofol can reduce the incidence of PONV compared with sevoflurane anesthesia [6]. Recently, Wengritzky et al validated a PONV intensity scale (Appendix 1) [9], which can be used to identify clinically important PONV. While PONV immediately after

POEM can cause bleeding, damage to the surgical site and esophageal rupture [10, 11], little is known about the incidence of PONV, especially clinically important PONV and anesthetic risk factors such as using volatile anesthetics in POEM. Therefore, we evaluated the incidence of PONV as well as comparing with TIVA prior to inhaled anesthesia using sevoflurane, in patients undergoing POEM procedure.

MATERIALS AND METHODS

This prospective, randomized study was approved by the Institutional Review Board of our Medical Center in January 2019. The 60 patients who underwent POEM at CHA Bundang Medical Center (CHAMC 2018-12-051-003) between March 2019 and February 2020 were enrolled. All patients are aged 20-65 years with an American Society of Anesthesiologists physical status I or II and provided verbal and written informed consent before enrollment. The 3 patients were excluded because one patient was refused, aspiration was occurred prior to endotracheal intubation in one patient, and one patient had a hereditary angioedema. The patients were randomly assigned to two group using a computer-generated number table as follows (Fig 1); (1) volatile anesthesia using sevoflurane [Sevoflurane group] ; (2) TIVA using propofol and remifentanil [TIVA group]. Experienced anesthesia nurses prepared the anesthetic agents before induction of anesthesia, according to direction in an envelope containing the allocation group. The premedication was not received and routine monitorings (electrocardiography, noninvasive blood pressure mearsurement, and pulse oxymetry) were applicated. In the sevoflurane group, anesthesia was induced with propofol 1.5-2 mg/kg intravenously and maintained with 1.5-2% sevoflurane in a mixture of 50% air and oxygen along with continuous remifentanil (0.1-0.15 μg/kg/min). In the TIVA group, anesthesia was induced and maintained with propofol (target effect-site concentration 2.5–3.5 μg/ml) and remifentanil (target effect-site concentration 2.5–3.5 ng/ml) using a target-controlled infusion device (Orchestra® Base Primea; Fresenius Kabi, France). For all patients, tracheal intubation was performed with Macintosh-type laryngoscope after neuromuscular blockage was achieved with intravenous rocuronium 0.6 mg/kg. After endotracheal intubation, mechanical ventilation was applied with a tidal volume of 6-8mL/kg ideal body weight, inspiratory-to-expiratory ratio 1:2, and respiratory rate adjusted to maintain end-tidal partial pressure of carbon dioxide at 30–40mmHg. For reducing complications associated with CO_2 insufflation, low flow CO_2 (approximately 1 ± 0.3 L/min) was applied in our institution [3, 4]. At the end of surgery, ramosetron (Nasea® [HANAH PHARM, Korea, Republic of]), 5-hydroxytryptamin type 3 (5-HT3) receptor antagonist, was intravenously administered for PONV prophylaxis. And neostigmine 0.04 mg/kg plus glycopyrrolate 0.008 mg/kg intravenously were given to all patients for the reversal of the neuromuscular blockade. In order to control postoperative pain, intravenous patient-controlled analgesia (PCA) devices, set to deliver a basal infusion of fentanyl at 20 μg/h with a 5μg bolus and a lock-out time of 15 min, were used during the 24–48 hours postoperative period. Patients were interviewed by two experienced anesthesiologists at 0-6 (early), 6-24 (intermediate) and 24-48 (late) hours postoperatively about incidence of PONV in accordance with a categorical verbal rating scale (VAS) and PONV Intensity Scale. A score was calculated for each patient and 5 score or more of the PONV Intensity Scale was validated as clinically significant PONV [9, 12]. The total dosage of bolus fentanyl and anti-emetic drugs, such as metoclopramide, were also checked up at the same time. The primary outcome of our study was the incidence of PONV especially clinically important PONV according to PONV Intensity Scale within the first 48 hours after anesthesia. Secondary outcomes included the incidence of postoperative adverse events (including bleeding at surgical site, mucosal injury, heart burn, pneumoperitoneum, and emphysema) and patient satisfaction. The sample size was calculated by power analysis while designing the study. By allowing an α error of 5% and a β error of 20%, a minimum of 28 patients would be needed in each group to show a 30% difference in the incidence of PONV [13]. Variables are presented as mean (± standard deviation), median (interquartile range), or frequency (percentage). Intergroup differences were evaluated using Student's t-test for continuous variables, and the chi-square or Fisher's exact test for categorical variables, as appropriate. *P values* < 0.05 were considered significant. All statistical analyses were performed with SPSS (version 26.0, Chicago, IL,. USA).

RESULTS

In all, 60 patients with esophageal achalasia underwent POEM and of those 3 patients were excluded from the analysis. There were no significant differences between two groups with demographic data, Apfel score and operative data, as described in Table 1. The incidence of PONV after POEM within first 6 hours was significant lower in the TIVA group than in the sevoflurane group (46.4% vs 76.7%, p=0.025). In contrast, during intermediate and late postoperative period, no significant differences were founded (p=0.439 and p=0.586, respectively) between the two groups (Table 2). Additionally, incidences of clinically important PONV according to PONV Intensity Scale were 21.1% (12/57) and 7% (4/57) within postoperative 6 and 24 hours, there were not significant differences among the two groups (p=0.546 and p=0.347, respectively). Secondary outcomes were summarized in Table 3. According to our result, the postoperative hospital stay are 7 days, there was no difference between two groups. It was observed that number of patients who experienced postoperative complications, such as surgical site injury, mucosal injury, heart burn, pneumoperitoneum, and emphysema, was higher in TIVA group (44.4%) compared with in sevoflurane group (26.7%), but it was insignificant (p=0.130).

Furthermore, the number of patients who were satisfied with PONV after general anesthesia was superior in TIVA group, but with no significant difference between the two groups (p=0.656). Of the patients, 20 (35.1%) had complications before hospital discharge (Table 4). The patients who experienced postoperative complications was significantly associated with higher PONV Intensity Scale within early postoperative period (2.6 ± 2.2 and 1.2 ± 2.0, p=0.025). Additionally, patients with complications had longer postoperative hospital stays (8.2 ± 3.2 vs 6.9 ± 1.2, p=0.035).

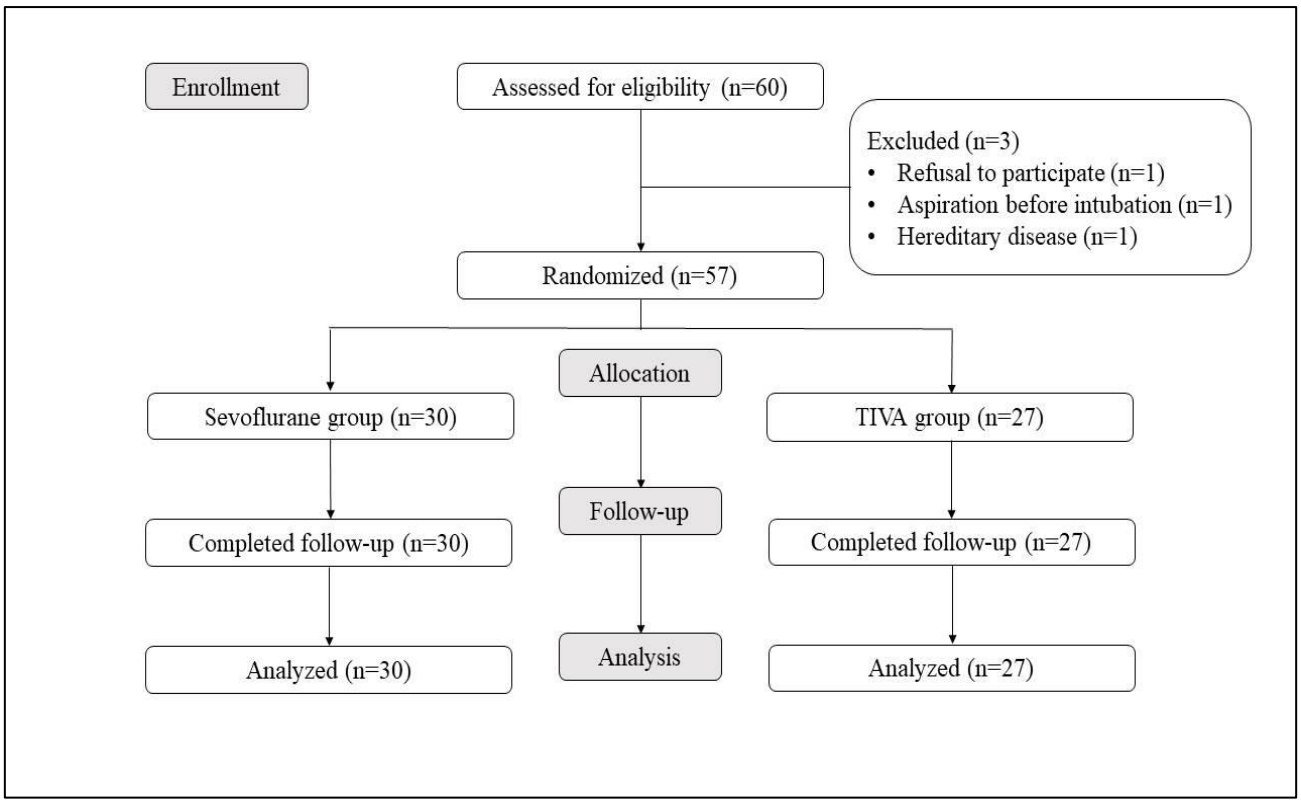

Fig. 1. Patient disposition

Table 1: Demographic characteristics of the two-study group

Characteristic	Sevoflurane group (n=30)	TIVA group (n=27)	p-value
Age, year	40.6 ± 12.8	43.4 ± 12.7	0.905
Male, n (%)	15 (50)	11 (40)	0.796
Height, cm	166.2 ± 8.4	164.0 ± 7.4	0.861
Weight, kg	62.8 ± 11.1	60.0 ± 11.3	0.682
BMI, kg/m^2	22.6 ± 2.8	22.3 ± 3.6	0.741
Apfel score			0.552
0	0 (0)	1 (3.7)	
1	5 (16.7)	6 (22.2)	
2	11 (36.7)	6 (22.2)	
3	8 (26.7)	10 (37.0)	
4	6 (20.0)	4 (14.8)	
No. of Risk factors	2 [2-3]	3 [2-3]	0.647
Duration of anesthesia, min	89.7 ± 24.7	98.8 ± 31.4	0.974
Duration of surgery, min	64.7 ± 22.8	73.3 ± 27.3	0.659
Duration of PACU, min	56.5 ± 11.8	58.7 ± 22.9	0.573

Data are presented as counts (percentages) or mean ± standard deviation or median [25th-75th percentiles]
TIVA, total intravenous anesthesia; BMI, body mass index; PACU, Postanesthetic care unit.

Table 2: Incidence and severity of PONV accordance to VAS and PONV intensity scale, and need for rescue antiemetics after POEM

Time after operation (h)	Sevoflurane group (n=30)	TIVA group (n=27)	*p*-value
0-6			
VAS of Nausea, n (%)	3.8 ± 3.1	2.3 ± 3.1	0.778
Vomiting	4 (13.3)	5 (18.5)	0.430
PONV, n (%)	23 (76.7)	13 (46.4)	**0.025***
PONV Intensity Scale	2.3 ± 2.2	1.6 ± 2.2	0.249
Clinically important PONV, n (%)	6 (20.0)	6 (21.4)	0.546
Rescue antiemetics, n (%)	29 (96.7)	24 (88.9)	0.267
6-24			
VAS of Nausea, n (%)	1.7 ± 2.4	1.5 ± 2.2	0.603
Vomiting	2 (6.7)	1 (3.7)	0.540
PONV, n (%)	15 (50.0)	12 (42.9)	0.439
PONV Intensity Scale	1.6 ± 1.8	0.9 ± 1.4	0.126
Clinically important PONV, n (%)	3 (10.0)	1 (3.5)	0.347
Rescue antiemetics, n (%)	9 (30.0)	3 (11.1)	0.076
24-48			
VAS of Nausea, n (%)	0.4 ± 0.8	0.4 ± 0.8	0.791
Vomiting	1 (3.3)	2 (7.4)	0.460
PONV, n (%)	7 (23.3)	6 (21.4)	0.586
PONV Intensity Scale	0.4 ± 0.9	0.2 ± 0.5	0.191
Clinically important PONV, n (%)	0 (0)	0 (0)	
Rescue antiemetics, n (%)	1 (3.3)	2 (7.4)	0.460

Data are presented as counts (percentages) or mean ± standard deviation
VAS, verbal rating scale; PONV, postoperative nausea and vomiting; TIVA, total intravenous anesthesia.

Table 3: Postoperative outcomes between the two groups

	Sevoflurane group (n=30)	TIVA group (n=27)	*p*-value
Postoperative hospital stay, day	7 ± 2.7	7 ± 1.6	0.332
Postoperative complication, n (%)	8 (26.7)	12 (44.4)	0.130
Patient satisfaction, (%)			0.656
Satisfied	24 (80.0)	24 (88.9)	
Neutral	4 (13.3)	2 (7.4)	
Dissatisfied	2 (6.7)	1 (3.7)	

Data are presented as counts (percentages) or mean ± standard deviation
PONV, postoperative nausea and vomiting; TIVA, total intravenous anesthesia.

Table 4: Postoperative PONV intensity Scale by three postoperative periods according to presence or absence of complication

	No Complication (n=37)	Complication (n=20)	*p*-value
Postoperative PONV Intensity Scale			
0-6 hr	1.2 ± 2.0	2.6 ± 2.2	0.025*
6-24 hr	1.1 ± 1.5	1.7 ± 1.8	0.219
24-48 hr	0.4 ± 0.7	0.3 ± 0.7	0.612
Postoperative hospital stay, days	6.9 ± 1.2	8.2 ± 3.2	0.035*

Data are presented as mean ± standard deviation
PONV, postoperative nausea and vomiting.
TIVA, total intravenous anesthesia

DISCUSSION

In this present study, we founded that TIVA could reduce the incidence of PONV compared with sevoflurane anesthesia within first 6 hours after POEM. POEM has been known as an effective and safe treatment for esophageal achalasia and is recommended under general anesthesia rather than sedation [3, 4]. Because PONV is the most unpleasant side effect of general anesthesia, prevention of PONV remains a challenge for anesthesiologists. Patient characteristics, anesthetic

methods, surgical procedure, and PCA were known risk factors for PONV [8]. It has been demonstrated that the Apfel's score, including female gender, prior history of PONV, nonsmoking, and the use of postoperative opioids, was independent risk factor for PONV undergoing inhalational anesthesia [5]. According to Apfel's score, the risk factors affecting PONV were well balanced except anesthetic methods. Since then, many studies show that TIVA with propofol is associated with a lower incidence of PONV compared with volatile agents [14-17]. Although the triggering mechanism of PONV remains unclear, Apfel *et al.*, [18] reported that the pro-emetogenic effect of volatile anesthetics could be strong risk factor of PONV in the postoperative period as well as anti-emetic property of propofol could be associated with low incidence of PONV. Similarly, our study showed that the incidence of PONV seems to be significantly lower in TIVA group undergoing POEM compared with sevoflurane group especially within postoperative 6 hours (Table 2). Although PONV intensity scales were low in TIVA group during postoperative 48 hours, but there were not significantly differences between two groups. Also, to our surprise, there was no statistically significant interaction of postoperative antiemetics with anesthetic agents. Of note, esophageal rupture, heart burn, pneumoperitoneum, and emphysema have been associated with PONV [19, 20]. These adverse effects of PONV immediately after POEM could cause bleeding at surgical site, mucosal injury and damage to the surgical site. Therefore, prevention of PONV is one of the most important considerations for patients undergoing POEM. According to our result, TIVA with propofol seems to be safer and more favorable anesthetic technique than volatile anesthetics, such as sevoflurane. Our results suggest the volatile anesthetics would be considered as one of the causes of PONV especially, in the early postoperative period (within 6 hours) undergoing POEM. However, inhaled anesthetics had no influence to delayed PONV (6-24 and 24-48 hours) after POEM. Although 35.1% patients had experienced complications in the hospital stay after POEM, there was no significantly difference between two groups. However, patients with postoperative complications showed significantly higher PONV Intensity Scale within early postoperative period than those without complications (Table 4). Additionally, development of complications was associated with prolonged postoperative hospital stays. To our knowledge, if high PONV Intensity Scale was observed within 6 hours after POEM, incidence of complications could be increased and postoperative hospital stays could be prolonged.

There were several limitations to this study, First, because data were collected from a single center, intraoperative and postoperative routine management may have influenced the PONV. Therefore, further large-scale, multicenter studies are necessary to confirm the difference in the incidence of PONV undergoing POEM between TIVA and volatile anesthesia. Additionally, all of the patients were received opioid-based intravenous PCA for postoperative pain control, which was known an independent risk factor of PONV. Although PCA may have had an influence on PONV, but since PCA was applied to all of the patients therefore there was no difference between two groups. Therefore, further studies will be needed to take these limitations into consideration.

In conclusion, our study suggests that TIVA could be considered as a good method to prevent PONV during early postoperative period (within 6 hours) after POEM. In addition, patients with high PONV Intensive Scale within 6 hours after POEM seemed to develop complications, therefore it is necessary to observe carefully during early postoperative period undergoing POEM.

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