Original Article

Comparing the Incidence of Postoperative Nausea Vomiting (PONV) after Total Intravenous Anesthesia (TIVA) versus Volatile Maintenance Anesthesia (VMA): A Randomized Controlled Trial in Laparoscopic Cholecystectomy or Gynecological Laparoscopic Surgery

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Background: Postoperative nausea and vomiting (PONV) adversely affects the surgical outcome. According to the Apfel score, there is a direct correlation between anesthetic agents and PONV. Currently, it is well-known that PONV is higher in patients receiving volatile maintenance anesthesia (VMA) than those receiving total intravenous anesthesia (TIVA). The present study compared the incidence of PONV in moderate to high PONV risk patients between propofol and sevoflurane anesthesia.

Objective: To study the incidence of early and delayed PONV among the patients with Apfel score ≥2 undergoing laparoscopic cholecystectomy (LC) or gynecological laparoscopic surgery comparing between TIVA and VMA techniques, from June to November 2019. Primary outcome was the incidence of PONV at the post-anesthesia care unit (PACU) and 24 hours after surgery. Secondary outcome was the incidence of intraoperative hypotension, extubation time and fentanyl consumption in PACU.

Materials and Methods: A single-center, randomized controlled involving 75 patients with American Society of Anesthesiologists (ASA) 1 to 3, age 18 to 85 years, Apfel score ≥2 who underwent LC or gynecological laparoscopic surgery. Patients were randomly assigned to receive TIVA (n=36) or VMA (n=39). Intraoperative, TIVA were maintained with propofol 2 to 12 mg/kg/min, and VMA were maintained with exhaled sevoflurane of 1.5 to 2.5%. The bispectral index (BIS) was maintained between 40 and 60. Incidence(s) of early and delayed PONV were recorded.

Results: Patient characteristics were similar in both groups. The incidence of PONV was not significantly different; early PONV: TIVA = 13.9%, VMA = 28.2% (p=0.131); delayed PONV: TIVA = 27.8%, VMA = 28.2% (p=0.967). For the secondary outcomes which are intraoperative hypotension (p=0.343), extubation time (p=0.598), and fentanyl consumption at PACU (p=0.855) were also not significantly different.

Conclusion: There was no significant difference in PONV incidence between TIVA and VMA techniques in laparoscopic cholecystectomy or gynecological laparoscopic operation.

Keywords: Laparoscopic surgery; PONV; Total intravenous anesthesia; Volatile maintenance anesthesia

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Postoperative nausea and vomiting (PONV) are amongst the most common post-anesthetic complications that occur following surgery and anesthesia. PONV can lead to undesirable consequences such as patient dissatisfaction and delayed recovery. Risks of PONV[1-3] include the patient factors (e.g., female gender, younger adulthood, history of motion sickness or PONV), surgical factors (e.g., intraabdominal laparoscopic surgery, middle ear surgery, long operative time) and anesthetic factors (e.g., the use of nitrous oxide, inhalation, opioids, large dose of neostigmine administration). The Apfel score[4], which is a useful and simple tool, was used in this study for stratification of patients with high PONV risk. The risks identification is composed of 4 factors, including female gender, non-smoker, history of PONV or motion-sickness and intraoperative opioids used. Previous studies have been conducted to compare the incidence of PONV between volatile maintenance anesthesia (VMA) and total intravenous anesthesia (TIVA), but in different procedures such as breast surgery, thyroid

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surgery, and laparoscopic surgery, e.g., cholecystectomy, gynecological surgery. The incidence of PONV was about 15 to 70%, with TIVA reporting lesser incidence than VMA[5-16]. The studies of Erk et al[17] and Stosic et al[18] showed the difference but found no statistical significance between TIVA and VMA.

However, there has never been a study in Thai patients that clearly compare the incidence of PONV after anesthesia with propofol and sevoflurane. Our study was designed to pick up the patients with moderate to high risk of PONV, as assessed by Apfel score, undergoing high risk PONV surgeries, e.g., laparoscopic cholecystectomy (LC) and gynecological laparoscopic surgery. The anesthesia techniques were adjusted to keep anesthesia related baseline risk of PONV low, including the use of propofol induction and omitting nitrous oxide[19-21]. Prophylaxis antiemetic therapy was exempted in both groups. As proemetic effect of volatile is dose-dependent, incidence of vomiting significantly increases with increased exposure of volatile[22]. According to the study from Katoh and Ikeda[23], the minimum alveolar concentration (MAC) for sevoflurane required to prevent movement in response to surgical incision in healthy patients was 1.71±0.07% (SE). The anesthetic ED_{95} (AD_{95}) that prevented 95% of patients from moving of sevoflurane with oxygen was 2.07%. A depth of sedation monitoring was thus used to modulate the necessary amount of propofol and sevoflurane during anesthesia.

Therefore, the primary objective of this study was to compare the PONV incidence between TIVA and VMA. The secondary objective was to compare the incidence of intraoperative hypotension, extubation time and fentanyl consumption in post-anesthesia care unit (PACU).

Materials and Methods

The protocol has been registered in Thai Clinical Registry (TCTR20210312004). This study is a single-center, prospective, randomized controlled trial. The ethics approval was obtained from the Srinakharinwirot University Ethic Committee (SWUEC-162/61E). The prospective controlled trial was conducted in HRH Princess Maha Chakri Sirindhorn Medical Center, Srinakharinwirot University, Ongkharak, Nakhon Nayok, Thailand from June to November 2019. The sample size was based on the previous study of Singh et al[24], comparison of recovery profile for propofol and sevoflurane anesthesia in case of open cholecystectomy showed the incidence of PONV in VMA 66.67%, TIVA 10% ($p<0.05$). The sample size was calculated by n4Studies program, alpha set to 0.05, power at 80% yielding 32 patients per group. In anticipation of 20% dropout's addition, the total patients collected were 40 per group. Inclusion criteria included the patients who were scheduled for LC or laparoscopic gynecological surgery, e.g., cystectomy, hysterectomy, myomectomy, and lysis adhesion, American Society of Anesthesiologists (ASA) physical status classification 1 to 3, age 18 to 85 years with the Apfel score at least 2 (moderate risk for PONV). We excluded the patients with known allergies or previous adverse reactions to any of the study drugs, severe cardiovascular or pulmonary disease, BMI >35 kg/m^2, vestibular dysfunction, gastroesophageal reflux, pregnancy, and history of antiemetic treatment 24 hours before the operation. Patients who underwent open surgery were withdrawn from the study.

Written informed consents were obtained from all patients before participation. Enrolled patients were randomized by computer. The group assignment was given to the intraoperative anesthesia team verbally by the study team member who did not participate in the postoperative assessment. The patients, surgeons and assessors were blinded. Preoperative preparation was done to every patient according to ASA guidelines for preoperative fasting. All patients did not receive benzodiazepine or H_2 blocker (Histamine H_2 receptor antagonists) for premedication and during our study. All patients were provided general anesthesia with standard monitoring, including oxygen saturation (SpO_2), non-invasive blood pressure (NIBP), heart rate, electrocardiography (EKG). Moreover, the bispectral index (BIS) was monitored. Anesthesia induction was performed using propofol 2 mg/kg, fentanyl 2 µg/kg and intubation with atracurium 0.5 mg/kg in both groups.

In the TIVA group, propofol was infused with the rate of 2 to 12 mg/kg/h after the muscle relaxant was injected. In the VMA group, expired sevoflurane was maintained with the concentration in the range between 1.5 to 2.5%. After intubation with endotracheal tube, suction tube number 14 was placed for gastric decompression. General anesthesia was maintained with oxygen, air (FiO_2 0.5 total flow 1 L/min) and sevoflurane in VMA group and propofol in TIVA group. Further dosage of fentanyl 0.5 to 1 µg/kg/h and atracurium 0.2 to 0.3 mg/kg/dose were administered when clinically needed in both groups. The ventilator settings were adjusted to keep end tidal CO_2 between 35 to 45 mmHg. The adjustment propofol infusion and concentration of sevoflurane were controlled by intraoperative anesthesia team to maintain BIS values between 40 and 60. Standard vital signs monitor was cycled every 5 minutes; in case of hemodynamic changes the assigned intraoperative anesthesia team can provide treatment at their discretion.

Propofol and sevoflurane administration was stopped upon completion of the surgery when the surgeon took the endoscope out of the peritoneum. The reversal agents were given when BIS was higher than 80 or ±20% baselines. Tracheal extubation was then performed. At the PACU, nausea vomiting (NV) score as shown in Table 1, was used to assess PONV by an assessor (an anesthetist nurse who did not participate in intraoperative management) every 15 minutes until 1 hour after the patients awoke. Pain score was assessed by verbal rating scale (VRS) every 15 minutes. Fentanyl 0.5 µg/kg/dose was prescribed when visual analogue scale (VAS) ≥5. All patients were discharged from PACU after 1 hour with the modified Aldrete score ≥9. The incidence of early PONV, defined by PONV in the first hour after surgery, was assessed in PACU. PONV incidence that occurred after the first hour until 24 hours postoperative

was reported as delayed PONV. Delayed PONV was assessed by anesthetist nurse who visited patient 24 hours after anesthesia. Nausea vomiting symptom and rescue antiemetic were collected from interview with the patient, drugs administration record and postoperative order. Postoperative pain management was prescribed by the surgeon.

The patient who scored ≥1 was reported as having PONV. At PACU, if the patient reported the NV score ≥2, rescue antiemetic drug, ondansetron 4 mg intravenous was given. If the clinical symptoms did not improve, dexamethasone 4 mg, metoclopramide 10 mg and dimenhydrinate 50 mg intravenous were given in order every 15 minutes. The collected patient data were age, sex, ASA physical status, the Apfel score, intraoperative fluid received, hypotensive events which defined as the blood pressure decrease more than 20% of baseline and required treatment, e.g., vasopressor, operative time, extubation time which defined as the time from reversal agent administration to airway extubation, fentanyl consumption at PACU, VRS for pain, the incidence of PONV at PACU and ward, and rescue antiemetic agents.

Table 1. Nausea vomiting (NV) score[25]

NV score	Clinical
0	No nausea and vomiting
1	Nausea but no vomiting
2	Nausea with vomiting
3	Vomiting more than 2 times in 30 minutes

NV = nausea vomiting

We used program IBM SPSS version 23 for statistical analysis. Continuous data were presented as mean and standard deviation (SD), and categorical data were demonstrated as frequency and percentage. For continuous data, unpaired t-tests were performed to compare between TIVA and VMA. Categorical data were analyzed by Chi-squared test. Relative risk (RR) with 95% confidence interval (CI) for occurrence of PONV after surgery was calculated. The p-value less than 0.05 was considered statistically significant.

Results

A total of 80 randomization assignments were allocated to TIVA (n=40) and VMA (n=40). Five were withdrawn (4 from TIVA, 1 from VMA) because the procedures were converted to open surgery. The data were collected and analyzed from 75 patients, as shown in Figure 1.

Patient demographics and characteristics including age, sex, BMI, ASA physical status, the Apfel score and

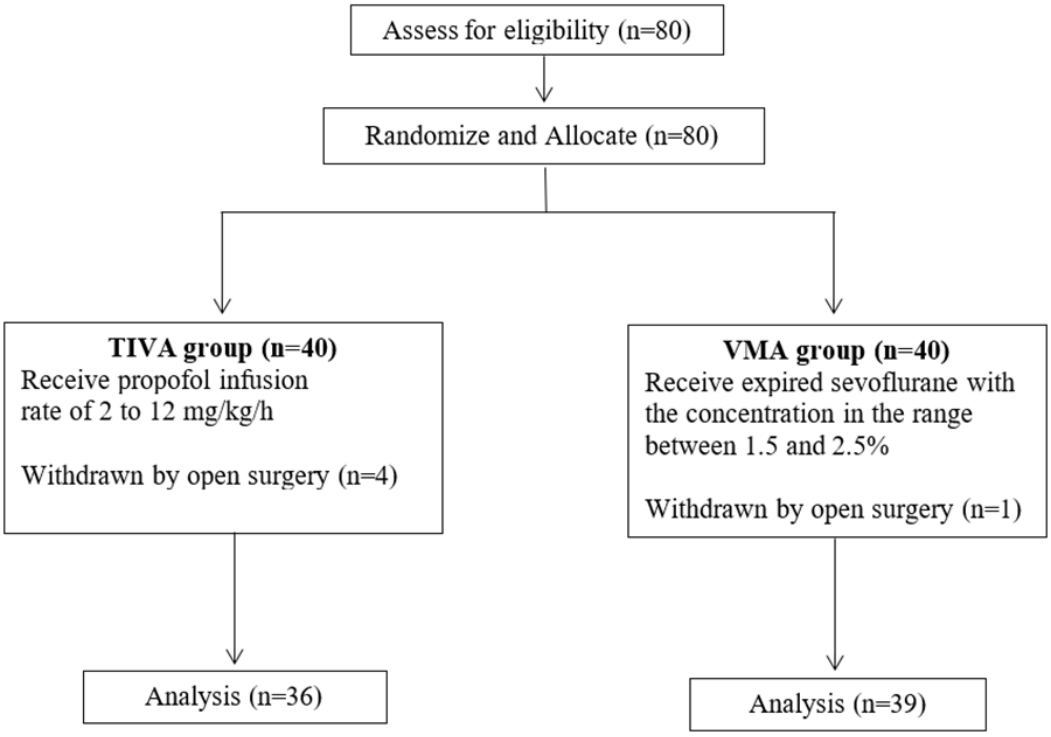

Figure 1. Consort diagram showing the participant flow.

operation performed, were not statistically different (p>0.05) between the two study groups as shown in Table 2.

Intraoperative data with possible effect to PONV incidence including intraoperative fluid received, events of hypotension and duration of surgery, as well as the consequences from anesthetic technique applied, e.g., time for extubation, VRS at PACU and the total amount of fentanyl required at PACU were also collected. All data were compared between TIVA and VMA groups. The intraoperative fluid received and duration of surgery were 471 mL, 73.5 min in TIVA and 514 mL, 80.9 min in VMA. Hypotension was reported less in TIVA (17.1%) than in VMA (25%). The extubation time, VAS at PACU and fentanyl consumption at PACU were nearly similar in both groups, with no statistical difference (p>0.05) between the two groups as shown in Table 3.

At the PACU, NV score was used to evaluate all participants regarding the symptoms every 15 minutes. Patient who scored ≥1 was reported as having PONV. Five patients in TIVA group and 11 patients in VMA group

Table 2. Patient demographics and characteristics

Characteristics	TIVA (n=36)	VMA (n=39)	p-value
Age (years)	48.17±13.96	48.18±12.97	0.172
Female/male	29/7	29/10	0.522
BMI# (kg/m^2)	24.95 (18 to 33)	24.82 (18.6 to 32.8)	0.683
Underweight (<18.5 kg/m^2)	1 (2.8)	0 (0)	
Normal (18.5 to 22.9 kg/m^2)	11 (30.5)	15 (38.5)	
Overweight (23 to 24.9 kg/m^2)	5 (13.9)	5 (12.8)	
Obesity (≥25 kg/m^2)	19 (52.8)	19 (48.7)	
ASA status			0.628
ASA 1	11 (30.5)	9 (23.1)	
ASA 2	23 (63.9)	26 (66.7)	
ASA 3	2 (5.6)	4 (10.2)	
Apfel score			0.707
2	7 (19.4%)	10 (25.6)	
3	18 (50.0%)	16 (41.1)	
4	11 (30.6%)	13 (33.3)	
LC/Gynecological laparoscopic surgery	31/5	30/9	0.308

Continuous data and categorical data were presented as mean±SD and frequency and percentage, respectively.
# Data were presented as mean (min-max)
TIVA = total intravenous anesthesia; VMA = volatile maintenance anesthesia; BMI = body mass index; ASA = American Society of Anesthesiologists physical status; LC = laparoscopic cholecystectomy

Table 3. Intraoperative and post-anesthesia care unit details

Intraoperative and PACU details	TIVA (n=36)	VMA (n=39)	p-value
Intraoperative fluid# (mL)	471 (150 to 1,300)	514 (100 to 1,200)	0.337
Hypotension	6 (17.1%)	10 (25.0%)	0.343
Operative time# (min)	73.56 (30.0 to 152.0)	80.92 (26.0 to 169.0)	0.450
Extubate time (min)	8.14±4.50	7.41±3.57	0.598
VRS at PACU	4.75±1.34	4.92±1.69	0.334
Fentanyl at PACU (mg)	74.44±32.73	76.03±34.07	0.855

Continuous data and categorical data were presented as mean±SD and frequency and percentage, respectively.
# Data were presented as mean (min-max)
TIVA = total intravenous anesthesia; VMA = volatile maintenance anesthesia; PACU = post-anesthesia care unit; VRS = verbal rating scale.

reported early PONV. However, the NV score was ≤2 in both groups. None of the patient experienced severe symptoms (NV score = 3). According to Table 4, the incidence of early PONV in TIVA group was lower than the VMA group, but not statistically significant (13.9% in TIVA and 28.2% in VMA, RR = 2.436, p-value = 0.131). The need for rescue antiemetic was higher in VMA (RR = 6.364, 95% CI = 0.727 to 55.721). Rescue ondansetron improved the symptom for all patients. Therefore, the need for the second dose antiemetic at PACU was obviated. The incidence of delayed PONV was nearly the same in both groups (27.8% in TIVA and 28.2% in VMA, RR = 1.021, p-value = 0.967).

Discussion

Our study demonstrated the incidence of PONV associated with TIVA and VMA techniques. The incidence of PONV in early postoperative period (in the first hour) was not significantly different (p>0.05) in TIVA group compared to VMA group. The delayed PONV incidence, however, was nearly the same in both groups. There was no statistically significant difference (p>0.05) between TIVA and VMA techniques. The incidence of early PONV in our study was lower than that from the study of Tseng et al[26] showing 59% of PONV in patient who underwent inpatient gynecological laparoscopic surgery without antiemetic prophylaxis. The study from Fujii[27] reported the PONV incidence for LC of 50 to 70% after the first hour to 24 hours after surgery. This study supported the evidence that the incidence of PONV can be reduced in both TIVA and VMA modifying by adjusting anesthesia factors such as using propofol induction, short acting opioids, avoiding using nitrous oxide, proper intraoperative fluid management and gastric decompression after intubation.

Emetic effect of volatile anesthetic is dose-dependent and most prominent in the first 2 hours after surgery[21]. The study of Apfel et al[22] explained that increase exposure to volatile was associated with significantly increased incidence of vomiting. The degree of exposure was defined as applied concentration x duration of volatile anesthesia[28]. To maintain adequate depth of anesthesia with the optimum dosage of sevoflurane and propofol, BIS monitoring was applied in our study. The consumption of propofol was 292.17±344.87 mg in TIVA. The total amount of sevoflurane was recorded by selecting the anesthesia consumption from anesthetic machines (Drager Primus® and Drager Perseus®). In VMA, the total amount of sevoflurane consumption was 6 to 31 mL (average was 13.845 mL). The delayed emergence was not found in this study. In TIVA group, early PONV occurred in 5 patients and only 1 patient needed antiemetic treatment, while early PONV in VMA group occurred in 11 patients and 6 patients needed the treatment. This showed that even though modified anesthesia technique could reduce the incidence of early PONV. Delayed PONV incidence was not significantly different (p>0.05) between both groups.

The limitation of our study was that we did not show the correlation between sevoflurane consumption and early incidence of PONV. We needed to collect end tidal sevoflurane concentration to calculate the degree of exposure[28]. This could possibly explain why the results of our study showed no statistically significant difference (p>0.05) in PONV incidence between TIVA and VMA techniques. A systematic review and meta-analysis conducted by Amirshahi et al[29] found PONV incidence to be higher in Europe than in other continents. The MAC of sevoflurane significantly differed as a function ethnicity[30]. It was greater in Caucasian Jews, less in Oriental Jews, and even less in European Jews. We raised the possibility that Thai population might require minimal amount of sevoflurane to maintain anesthesia, thus the emetogenic potency of volatile would be less too. Moreover, some patients might not be fully awake during the first postoperative hour, making the assessment of NV score inaccurate and contributing to the low incidence of early PONV reported. The sedation score record will solve this error. Our study focused on different surgeries, i.e., laparoscopic cholecystectomy, and laparoscopic gynecological surgery, that possibly had effect on tissue trauma pain and incidence of PONV.

Regarding delayed PONV, there was also no statistically significant difference (p>0.05). Because the

Table 4. Primary outcome PONV and rescue antiemetic used in an early PONV (at PACU) and in delayed PONV (at ward)

	TIVA (n=36)	VMA (n=39)	Relative risk	95% confidence interval	p-value
Early PONV					
PONV	5 (13.9%)	11 (28.2%)	2.436	0.753 to 7.880	0.131
Rescue antiemetic	1 (2.8%)	6 (15.4%)	6.364	0.727 to 55.721	0.061
Delayed PONV					
PONV	10 (27.8%)	11 (28.2%)	1.021	0.372 to 2.802	0.967

Categorical data were presented as n (%)
PONV = postoperative nausea vomiting; TIVA = total intravenous anesthesia; VMA = volatile maintenance anesthesia

postoperative factors that affect PONV including pain, opioids, and ambulation were similar in both groups. The anesthetic technique mostly affected early postoperative period. The study of White et al[31] concluded that the patients with Apfel risk score of three or four were associated with higher incidence of emetic sequelae in the first 24 hours after surgery. Our study did not involve postoperative analgesia order as analgesic agents were prescribed by surgeon. The difference in pain control regimen would affect the incidence of PONV as well. The review of medical record showed that opioid such as morphine was the most frequency prescribed. If possible, multimodal analgesia with opioid free should be applied in order to see the effect solely from TIVA- and VMA-treated groups. The incidence of delayed PONV was collected from the patient interview and medical administration record. We did not use NV score at ward, which could possibly lead to inaccurate report of delayed PONV.

Conclusion

It is true that using TIVA results in lower PONV incidence as compared to using VMA. However, when combining the adjusted anesthesia techniques along with good monitoring, the incidence of PONV can also be reduced. Preventable factors such as avoiding nitrous oxide, using an optimal dose of volatile and propofol while keeping an intraoperative depth of sedation monitored can be applied to decrease the incidence of PONV. From this study, it can be concluded that early PONV was lower in TIVA than VMA but there was no statistical difference ($p>0.05$).

What is already known on this topic?

To prevent PONV, we needed to evaluate the patient at risks and establish interventions to reduce incidence. Anesthesia preventable factors and antiemetics prophylaxis can improve PONV. Intravenous anesthesia can reduce the risk of PONV better than volatile anesthesia.

What this study adds?

Our anesthesia protocol in this study focused on the effects of propofol and volatile in PONV. All participants allocated in both intervention arms had PONV risks. It was found that when using the adjusted anesthesia technique, the PONV incidence was not statistically different ($p>0.05$) between TIVA- and VMA-treated groups. Our protocol can be applied for practical care. The cost of BIS monitor should be discussed further.

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Potential conflicts of interest

The authors declare no conflict of interest.

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