



## Postoperative Nausea and Vomiting and Postoperative Pain in Patients Undergoing Elective Laparoscopy; Comparison of Total Intravenous Anesthesia versus Inhalational Anesthesia: A Randomized Clinical Trial

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### ABSTRACT

**Background:** Two major complications of surgeries are postoperative nausea and vomiting (PONV) and also postoperative pain (POP). Several studies have compared total intravenous anesthesia (TIVA) with inhalational anesthesia regarding these two complications. Some results have shown a better postoperative recovery conditions, but other contradictory results can also be found.

This study was performed to evaluate and compare the effect of inhalational and intravenous anesthesia in patients undergoing elective laparoscopic surgery, on the incidence and the severity of PONV and POP.

**Methods:** This study was performed as a single-blinded prospective clinical trial. All patients aged 18-65, with ASA class I and II who underwent elective laparoscopy were included. Patients were divided into two groups of intravenous anesthesia and inhalational anesthesia. The incidence and the severity of PONV and POP were examined in 5 separated times after the surgery. The use of a rescue antiemetic and analgesic medication were also evaluated.

**Results:** Overall, 67 patients received inhalational anesthesia and 55 patients received intravenous anesthesia. It was revealed that 47.8% of the patients in the inhalation group and 18.2% of the patients in the intravenous group developed PONV ( $P < 0.001$ ). The severity of PONV was significantly lower in the TIVA group ( $P < 0.001$ ), however, no statistically significant difference was found regarding the severity of abdominal pain ( $P = 0.62$ ).

**Conclusion:** The incidence of PONV and the need for administration of an antiemetic rescue drug are significantly lower in the TIVA group.

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Inhalation anesthesia and total intravenous anesthesia (TIVA) are the most common general anesthesia methods that can be used in all kinds of surgeries [1]. Having the minimum postoperative complication is a favorable desire for both patients and the medical team [2].

Two of the most encountered complications of surgeries are postoperative nausea and vomiting (PONV) alongside postoperative pain (POP) [3].

PONV is known to be one of the most unpleasant side effects of anesthesia and surgery [4].

In other words, it can lead to aspiration, incision site dehiscence, hematoma formation, dehydration,

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electrolyte imbalance, and inability to initiate oral medications which are the main factors contributed to the delayed mobilization and discharge from the hospital [5, 6].

Even though the exact cause of PONV is unclear, multiple factors such as the anesthetic methods, personal characteristics of the patient and the type of surgical operation are reported to play important roles in the occurrence of PONV [7, 8]. Overall, the incidence of PONV is reported to be 25% to 30%, though due to the variety of etiologies these rates are difficult to estimate [9]. Laparoscopic surgery is usually associated with a shorter hospital stay; however, the incidence of PONV is considerably higher (sometimes as high as around 75%) [10-12].

On the other hand, parallel to PONV, POP continues to be a significant problem [13]. A number of studies have suggested that TIVA provides better postoperative analgesia compared with volatiles [14].

Despite the lack of substantial evidence about the exact effect of different anesthetic techniques on the incidence of PONV or POP, it is reported that TIVA has been associated with the earlier recovery and reduced rate of both PONV and POP compared to the anesthesia with inhalational agents in many populations [15, 16]. On the contrary, according to some studies, the effectiveness of TIVA on reducing these complications during the first 24 hours after the surgery is still controversial [17-19].

A thorough understanding of the contributing factors is essential for the management and treatment of postoperative complications and their adverse effects. Therefore, in this study, we compared these two routine anesthetic techniques to evaluate their effect on PONV and POP in patients undergoing elective laparoscopic surgery.

## Methods

After the approval by the Tehran University of Medical Sciences ethics committee with the approval ID "IR.TUMS.IKHC.REC.1397.075", this study was performed as a single-blinded prospective clinical trial between August 2018 and May 2019. Our research was conducted in accordance with the criteria set by the declaration of Helsinki.

All patients aged 18-65, with ASA class I and II who underwent elective laparoscopy, were included. Exclusion criteria included a history of motion sickness or PONV and unwillingness of the patient. The study process was clarified and all patients provided written informed consent.

The questionnaire was adapted from a previous study [20] and was translated to Persian and then modified based on the aim of our study.

According to the results of a similar study [21], the incidence of PONV was 66% in the inhalational group,

so considering the parameters of the Table 1 and the standard formula (Figure 1), the sample size of the pilot study (considering 10% of the additional sample to prevent falls) is 50 patients in each group.

**Table1- Sample size parameters?**

$\alpha= 0.05$	$Z1-\alpha/2= 1.961150826$
$\beta = 0.15$	$Z1-\beta= 1.036436077$
$P1= 0.66$	$\bar{P}= 0.5$
$P2= 0.34$	$n= 44$

Randomization was performed on an individual level using 4 number blocks created in excel software. Allocation concealment has been carried out. Given the patient's anesthesia after receiving the induction which is identical in both groups, the patient is blind to the type of anesthesia. The anesthesiologist (PI) and the researcher are not blind to the type of anesthesia and the study is conducted in a single-blinded manner. Data collectors and data analysts have also been blinded.

All patients entered the operating room and were monitored closely, including electrocardiography, pulse oximetry, and blood pressure. Peripheral IV access was established for all of them. Then, before administration of the drug and induction of anesthesia, to provide preoxygenation, patients received 100% oxygen by mask 3 to 5 liters per minute for 5 minutes with normal breathing. Subsequently, all patients received 0.02 mg/kg midazolam and 2 mcg/kg fentanyl intravenously. General anesthesia was administered with 5 mg/kg thiopental sodium as the main anesthetic drug and 0.5 mg/kg atracurium as the neuromuscular muscle relaxant for patients. Patients underwent mask ventilation as the induction medication was administered. Moreover, after ensuring the onset of the muscle relaxant effect and also ensuring the appropriate depth of anesthesia by monitoring, patients were intubated by the anesthesiologist and received isoflurane 0.5-1.2%. Thereafter, the patients were ventilated, with a volume of 10 cc/kg body weight and a respiratory rate of 10-15 per minute. The expiratory carbon dioxide level was set at 35 and FiO<sub>2</sub> was set at 90%. In the inhalation group, Isoflurane %1.5-1.7 in combination with 1cc Fentanyl and 1cc Atracurium were used every 45-60 minutes during the operation. In the intravenous group, 50cc of Propofol 1% was combined with 1-2cc of Remifentanyl and was intravenously infused at the speed of 15-20cc/hr. The incidence of nausea and vomiting alongside the severity of PONV and abdominal pain were evaluated by the 11-point visual analog scale (VAS) and recorded at 0, 2, 6, 12, and 24 hours after the surgery. Rescue antiemetic was given at the request of the patients who had more than one episode of vomiting in the form of 4mg intravenous ondansetron. Also, for pain control, 30mg IV Ketorolac was administered at the request of the patients.

**Figure 1- Sample size formula**

$$n = 2 \frac{\left( z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right)^2 pq}{(p_1 - p_2)^2}$$

Data are shown as mean and standard deviation (SD), or median and range. Demographic and perioperative data were compared using the Student's T-Test. The comparison between the groups was performed using the paired and unpaired T-Test. The relationship between the variables was performed using Fisher's exact test, scoring systems were analyzed using the Wilcoxon's rank-sum test. The dataset was checked for a normal distribution using the Kolmogorov-Smirnov test. P-Value<0.05 was considered statistically significant. The statistical analyses were calculated using SPSS version 21. (SPSS Inc., Chicago, Illinois).

## Results

A total of 131 patients met the inclusion criteria of our study. Six patients had a previous history of either motion sickness or PONV and 3 patients did not want to participate in the study; all of these patients were excluded from the study. Therefore, out of 122 patients who enrolled in our study, 55 (45.1%) patients received TIVA, while 67 (54.9%) patients received inhalational

anesthesia. There were no statistically significant differences regarding the demographic and baseline characteristics of the patients in two groups (Table 2). Table 2 shows that in this study, 6 patients in the inhalational group (9%) and 9 patients in the intravenous group (16.3%) had nausea and/or vomiting before surgery (P=0.44).

Table 3 demonstrates that 47.8% of the patients in the inhalation group and 18.2% of the patients in the intravenous group developed PONV which indicates a statistically significant difference between two groups (P<0.001). Also, the need for antiemetic rescue medication was significantly lower in the intravenous group (P<0.001). However, there was no statistically significant difference between two groups in terms of analgesic administration (P=0.18).

According to the Table 4, the mean severity of nausea or vomiting of the study based on VAS at all of the observed time points, from 0 to 24 hours after surgery, was lower in the group undergoing intravenous anesthesia and the difference between these two groups is statistically significant (P=0.02).

Figure 2 illustrates the course of changes in the severity of PONV throughout the first 24 hours after surgery. It demonstrates that in 2 hours after surgery, in both groups, patients suffered the most severe nausea or vomiting.

As seen in table 5, although all time points (except for the 0 hours) the mean VAS for abdominal pain was relatively lower in the TIVA group and the difference was not statistically significant (P=0.62).

**Table 2- Baseline characteristics**

Variable	Groups		P-value
	Inhalation (67)	TIVA (55)	
Mean age, (SD)	41.7 (14.3)	41.7 (12.9)	0.99
Female/Male	43/24	41/14	0.22
Mean BMI, (SD)	27.7 (3.6)	28.7 (5.1)	0.19
ASA I/ASA II	48/19	41/14	0.72
Nausea or Vomiting before Surgery	6	9	0.44
Surgical History	26	18	0.49
Tobacco Addiction	12	7	0.43

**Table 3- Incidence of PONV**

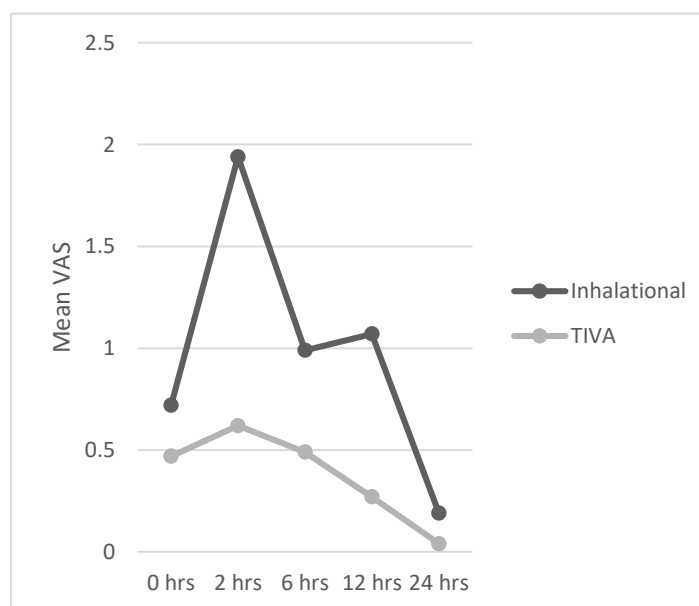
Variable, n (%)		Groups		Total (122)	P-value
		Inhalation (67)	TIVA (55)		
Complication	Only Nausea	15 (22.4)	2 (3.6)	17 (13.9)	0.003
	Nausea with Vomiting	17 (25.4)	8 (14.5)	25 (20.5)	0.14
	PONV	32 (47.8)	10 (18.2)	42 (34.4)	<0.001
Antiemetic		28 (41.8)	5 (9.1)	33 (27.0)	<0.001
Analgesic		37 (55.2)	37 (67.3)	74 (60.7)	0.18

**Table 4- Incidence and severity of PONV divided by time points**

Variable		0 hrs	2 hrs	6 hrs	12 hrs	24 hrs	In group	Between groups
PONV, n (%)	Inhalation	8 (11.9)	24 (35.8)	13 (19.4)	15 (22.4)	6 (9)	<0.001	0.03
	TIVA	4 (7.3)	8 (14.5)	6 (10.9)	5 (9.1)	2 (3.6)	0.13	
VAS, mean (SD)	Inhalation	0.72 (2.07)	1.94 (2.96)	0.99 (2.21)	1.07 (2.23)	0.19 (0.66)	<0.001	0.02
	TIVA	0.47 (1.76)	0.62 (1.84)	0.49 (1.71)	0.27 (0.19)	0.04 (0.19)	<0.001	

**Table 5- Severity of Pain divided by time points**

Variable		0 hrs	2 hrs	6 hrs	12 hrs	24 hrs	In group	Between groups
VAS, means (SD)	Inhalation	4.7 (1.9)	3.3 (1.3)	2.5 (1.8)	2.3 (1.1)	1.1 (1.1)	0.04	0.62
	TIVA	4.9 (1.9)	3.2 (1.5)	2.4 (1.7)	2.1 (1.2)	0.9 (1.2)	0.03	

**Figure 2- The course of PONV severity changes**

## Discussion

The results of this prospective, single-blinded, randomized controlled trial revealed that not only intravenous anesthesia reduced the incidence of PONV, but also decreased the severity of this unpleasant complication compared to the inhalational method.

As mentioned, the exact cause of PONV is not thoroughly understood. However, the patient-related, surgical and anesthetic factors are described as contributing factors [22].

Despite the very high incidence of PONV associated with laparoscopic surgeries and the evidence that TIVA

reduces PONV, inhalational anesthesia remains popular among anesthesiologists for a variety of reasons [23-25].

In our study, the incidence of PONV was significantly lower in the TIVA group, 47.8% in the inhalational group and 18.2% in the intravenous group which is to some extent in line with the results of the study conducted by Shinn et al. [26]. In the study of Shinn et al. the incidence of PONV was reported to be 15.8% in the intravenous group and 75% in the inhalation group. Also, in the study of Won et al. [27] 10.2% of the TIVA patients and 55.9% of the Inhalation patients suffered from PONV and the difference reported being significant.

Nevertheless, in a study conducted by Wong et al. [28], no differences were reported between the number of

patients suffering from nausea and/or vomiting between two groups of TIVA and inhalational anesthesia. Moreover, Yoo et al. [29] reported that although TIVA is associated with the lower incidence of PONV in the early post-operative stage, the difference between intravenous anesthesia and inhalational anesthesia 6-48 hours postoperative in terms of incidence of PONV is not significant. Additionally, according to the study of Erk et al. [30] the incidence of PONV in the first 12 hours after surgery is not significantly different between TIVA and Inhalation anesthesia. Also, Voigt et al. [31] reported that in patients who received no antiemetic prophylaxis, the incidence of PONV was 48.2% in patients given inhalational anesthetics and 43.8% in those who received intravenous anesthesia and this difference was not statistically significant. Since the PONV is a multifactorial complication the difference in the reported incidence rates is expected. A comparison between different groups should be performed with equal conditions in order to reduce confounding and prejudice factors.

The present study showed that the need for an antiemetic rescue drug was significantly lower in TIVA than in inhalation anesthesia. Won et al. [27] reported that 5.1% of TIVA patients and 18.6% of the inhalation group needed an antiemetic drug which is inconsistent with our study. Whereas, Joe et al. [32] reported a non-significant difference between the two groups concerning the need for antiemetic medication between 6-24 hours post-surgery. As the type of antiemetic drug or the applied dosage may differ in various researches, the present disagreement is predictable. So, this should be considered when comparing different search results. The result of our study revealed that there was no significant difference regarding the administration of analgesic drugs between two groups. Similarly, Fassoulaki et al. [33] showed that the consumption of analgesic medication did not differ between TIVA and inhalational anesthesia. Nonetheless, according to a study conducted by Fu-hai Ji et al. [34], TIVA patients required less pain control drugs compared to the inhalational group.

This study along with the study of Arslan et al. [8], showed that the severity of PONV up to 24 hours after surgery, in the intravenous group was significantly lower compared with the inhalational group. On the contrary, according to the reported results by Won et al. [27], despite the lower VAS range in patients undergoing intravenous anesthesia, the difference between the two groups was not statistically significant. In addition, Park et al. [35] showed that for 24 hours after the surgery, the severity of nausea was similar in both groups of TIVA and inhalational. In line with the study by Fassoulaki et al. [33], our study showed no difference in the severity of POP between two groups in the first 24 hours after the surgery. In contrast, the results of the study by Fu-haj ji et al. [34] indicates more severe abdominal pain in

patients who underwent inhalational anesthesia. Differences in the demographic characteristics of the study population as well as the sample size, and type of surgery could be the causes of the disagreement in the results of different studies.

## Conclusion

To conclude, due to serious adverse effects of PONV after laparoscopic surgeries and also the difficulties that are caused by POP for both patients and medical staffs, it is important to determine the appropriate anesthesia method to minimize the complications and improve the satisfaction level and recovery condition post-surgery. Our study provides a basis for the future studies and different populations with different conditions.

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