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A comparative study between Thoracic Epidural Anesthesia in non-intubated video-assisted thoracoscopes and the conventional general anesthesia with one lung ventilation

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ABSTRACT

Background: Video-assisted thoracoscopic surgery (VATS) refers to the minimally invasive thoracic surgeries performed by video cameras to avoid the invasive conventional open thoracotomy. The majority necessitate one-lung ventilation. Regional anesthesia is involved to avoid the risks of general anesthesia(GA) and one-lung ventilation and promote efficient recovery of these vulnerable populations.

Objective: To assess the feasibility of non-intubated VATS with Thoracic Epidural Anesthesia (TEA) compared to the conventional GA in terms of hemodynamic and ventilatory parameters, postoperative pain control, opiate consumption, ambulation, and length of hospital stay.

Patients and Methods: This study is a prospective randomized clinical study conducted in Ain Shams University Hospitals over 2 years, with a sample size of 40 patients in 2 groups. The GA group, after induction of anesthesia, double-lumen endotracheal tube was inserted to facilitate one-lung ventilation. The TEA group, an epidural catheter was inserted between T3 and T4 orT4 and T5 intervertebral space, local anesthetic dose titrated aiming to achieve sensory and motor block between C7-T7 levels.

Results: The findings revealed no statistically significant difference between groups throughout the perioperative period (p >0.05) regarding ventilatory and circulatory parameters besides opiate consumption. Conversely, in terms of postoperative ambulation and length of hospital stay (LOS), p-value=0.013 and 0.001 respectively for each favoring the TEA group. Similar results were denoted for *postoperative pain control*, there was statistically significant difference between groups in VAS score at 3 hours (P =0.004).

Conclusion: The feasibility of nonintubated VATS with TEA was tested with respect to safety and efficiency compared to the conventional GA. The results of both groups are comparable in terms of hemodynamics and ventilatory parameters. Despite similar overall opiate consumption in both groups, the TEA group demonstrated promising results regarding the enhanced recovery parameters in terms of better early postoperative pain control, earlier ambulation, and decreased length of hospital stay.

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Thoracic epidural; one-lung ventilation; nonintubated VATS

1. Introduction

Awake-regional and non-intubated general anesthesia with spontaneous ventilation are two potential alternatives to conventional single lung ventilation for thoracic procedures including VATS. Regional anesthesia includes both Thoracic Epidural Anesthesia (TEA) and paravertebral local anesthesia. TEA is considered the gold standard technique for pain management after thoracic surgery and is recommended as the first choice in many Enhanced Recovery (ERAS) protocols. TEA provides better pain relief than opioids [1].

Surgical instrumentation causes the characteristic pain following thoracic surgery, which is often severe due to retraction, ribs fracture, and injury to the intercostal nerves. The manipulation of lung and traction of hilar structures can lead to irritation over visceral pleura (which is spared by TEA and intercostal blocks), resulting in *a coughing response* and jeopardizing the surgical intervention. A standardized *multimodal analgesic* strategy is required to keep the patient comfortable. High-intensity postoperative pain can end in post-thoracotomy pain syndrome [2].

Due to technical challenges, such as *surgical pneumothorax, spontaneous breathing, lateral decubitus position, and the effects of sedative and analgesic agents on respiratory physiology*, the effects on perioperative oxygenation and ventilation during nonintubated thoracic procedures are multifactorial. These procedures must only be performed by skilled thoracoscopic surgeons, preferably those with complex cases and bleeding control through uniportal VATS, which may necessitate conversion to GA to secure an open

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procedure. Moreover, TEA may have some limitations, and catheter placement can be challenging. Therefore, adequate skilled care providers are required for their perioperative management [3].

2. Aim of the work

This study aims to assess the feasibility and the effect of *non-intubated VATS with* TEA for awake thoracic surgery to speed up recovery in patients and avoid the complications accompanying GA with one-lung ventilation in terms of hemodynamic and ventilatory parameters, postoperative pain control, opiate consumption, ambulation, and length of hospital stay.

3. Patients and methods

This study is a prospective randomized clinical study (RCT) conducted in Ain Shams University Hospitals over 2 years, from 2019 to 2021, with a sample size of 40 patients. Patients were randomized by a computer-generated random number table. The sample size was calculated using the PASS 11 program for sample size calculation based on the *Pompeo et al*. study [4]. A sample size of 20 cases per group (total 40) can detect this difference with power 100% and α-error 0.05. Three patients with TEA were converted to GA intraoperatively and thus they were excluded from the study. Recruitment of substitutes was done to abide by the sample size. Therefore, 43 patients were enrolled in the study.

The ethical research committee of the Faculty of Medicine, Ain Shams University, approved the study. In addition, written informed consent was collected from all the participants. The most experienced person on the study team performed the thoracic epidural placement.

3.1. Inclusion criteria

Patients with ASA I and II classification. Age group: 21–65 years old. Patients with pleural pathologies scheduled for VATS procedures restricted to a two-hour time limit were included.

3.2. Exclusion criteria

Patients with expected difficult airway management. Hemodynamically unstable patients. Persistent cough or high airway secretions. Severe emphysema or clinical signs of active infectious disease. Hypoxemia (PaO2 < 60 mmHg) or hypercarbia (PaCO2 > 50 mmHg) Coagulopathy (INR ≥ 1.5). Obesity (BMI > 30 Kg/m^2). Infection at the injection site, allergy to local anesthetics. Neurological disorders: seizures, intracranial mass, or brain edema.

4. Study tools

4.1. Anesthetic plan

In the anesthesia clinic, all patients provided informed written consent before the surgery. The Visual Analogue Scale (VAS) was explained to the patients. The VAS includes a 10 cm straight line with the end-points defining extreme limits of "no pain" and "worst pain". Anesthesia was provided according to the hospital protocol regarding preoperative investigations, fasting hours, intraoperative monitoring, and drugs. In an attempt to facilitate contrasting data, records were taken at fixed intervals perioperatively.

4.2. Study interventions

The study design included two equal groups, each consisting of 20 patients. TEA *Group*: Awake patients who received sole Thoracic Epidural Anesthesia. GA *Group*: Patients who received General Anesthesia with one-lung ventilation.

Patients in the TEA group pre-medicated using Midazolam 3–4 mg intravenous(IV) and Fentanyl 50 mcgIV. Subsequently, patients were placed in the setting position. Under aseptic precautions, an epidural catheter was inserted between T3 and T4 or T4 and T5 intervertebral space. A test dose of 5 ml of 2% Lidocaine was injected in the epidural catheter followed by 7–10 ml of Bupivacaine 0.5% and 50 mcg of Fentanyl. The objective was to achieve sensory and motor block between C7 and T7 levels. At this level, diaphragmatic respiration is maintained. Patients were converted to GA and excluded from the study if they experienced persistent hemodynamic instability or hypoxemia. Hypoxemia is defined as peripheral oxygen saturation (SpO2) < 92% on room air with a need for oxygen supplementation (O_2 mask 5–7 l/min). Postoperatively, the epidural catheter was removed due to technical and logistic limitations.

Patients receiving GA were premedicated by Midazolam 3–4mgIV and Ondansetron 4mgIV. Induction of anesthesia with Propofol (2 mg/kg) and Fentanyl (1 mcg/kg). Double-lumen endotracheal tube insertion was facilitated by Cisatracurium 0.1 mg/kgIV to allow selective lung ventilation. Fiberoptic bronchoscopy was used to confirm its position. Lung isolation enables access into the operative hemithorax. In case of hypoxemia, the objective was to avoid complete collapse of the non-ventilated. Lung protective ventilatory strategies were applied entailing the use of low tidal volumes, moderate degree of positive end-expiratory pressure PEEP, and recruitment manoeuvres

For either groups, postoperative analgesia was offered in regular Paracetamol 1gmIV every 6 h for 48 h. Rescue analgesia given when VAS≥3, in the form of Pethidine 50mgIV given slowly over 10 min.

The procedures entail Uniportal VATS, whereas the surgical incision in the 8th intercostal space at the posterior axillary line. No gas insufflation needed. A wound protector was applied ensuring induced open pneumothorax to enable deflating the operated lung. Continuous communication with the surgical team ensured satisfaction and technical feasibility to access the operated hemithorax in the TEA group. A shared decision was taken intraoperatively in three patients to convert to GA due to either hemodynamic instability or technical difficulty for the surgeon to complete the procedure.

5. Measured outcomes

5.1. Primary outcome

Perioperative changes in the ratio of arterial oxygen tension to fraction of inspired oxygen (PaO_2/FiO_2) and arterial carbon dioxide tension ($PaCO_2$). [Time Frame: baseline, intraoperative 1 h, immediate postoperative and postoperative at 6, 12 and 24 h].

5.2. Secondary outcomes

Perioperative changes in *heart rate* (HR in beats per minute bpm) and *mean arterial pressure* (MAP in mmHg) [Time Frame: baseline, intraoperative 1 h, immediate postoperative and postoperative at 2, 6, 12 and 24 h]. *Postoperative pain* using the VAS Score [Postoperatively at 3,12, and 24 h]. *Postoperative Pethidine consumption* (dose in mg) [Time Frame: Postoperative 24 h]. *Hospital stay* (in days) [Time Frame: 1 week from operation to discharge. The *onset of ambulation* (in hours) [Time Frame: Postoperative 24 hours]

6. Statistical analysis

Data were analyzed using Statistical Package for Social Science (SPSS) version 22.0, Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

6.1. The following tests were used

The independent-samples t-test **(t)** of significance was used to compare two means. Chi-square (X^2) test of significance was used in order to compare proportions between two qualitative parameters. Mann Whitney U-test (Z): for two-group comparisons in non-parametric data. The confidence interval was set to 95%, and the margin of error accepted was set to 5%. Therefore, the *p*-value was considered significant if probability (*P* value): *P*-value<0.05 was considered significant (Figure 1).

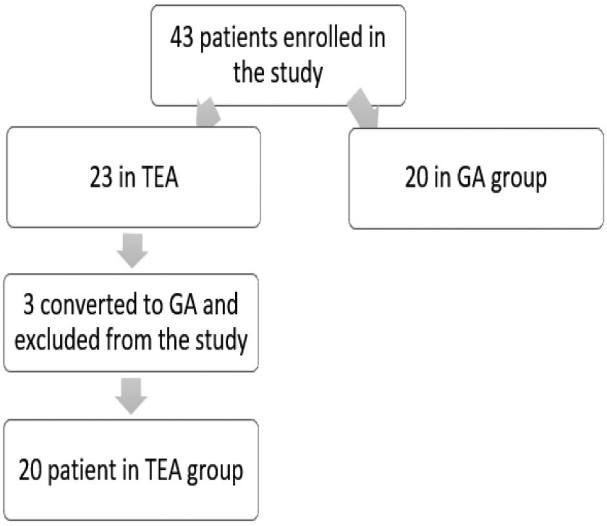

Figure 1. Flow chart for the study.

7. Results

Forty-three patients were enrolled in the study, 20 patients in the GAgroup and 23 in the TEA group. Three patients converted to GA intraoperatively after starting the operation with TEA, so they are excluded from the study (Table 1).

Groups were comparable in demographic data (in terms of age, sex, BMI and ASA classification), concomitant comorbidities and surgical variants (duration and side of surgery). There was no statistically significant difference between groups ($p > 0.05$). Considering *the type of operation*, no statistics were computed because the operation is a constant, i.e., pleural biopsy and drainage (Table 2).

Table 1. Comparison between groups concerning demographics and operative data.

		GA (n = 20)	TEA (n = 20)	T/x2	*p*-value
Demographic data					
Age (years)		53±10.88	52.35±11.8	0.18^t	0.85
BMI (kg/m^2)		26.85±3.5	27.75±3.6	0.79^t	0.43
ASA	I	11(55%)	5(25%)	3.75^{x2}	0.053
	II	9(45%)	15(75%)		
Sex	Males	12(60%)	12(60%)	0^{x2}	1
	Females	8(40%)	8(40%)		
Duration of surgery (min)		71±22.3	60.7±16.1	1.66^t	0.1
Side of Surgery	Rt	13(65%)	11(55%)	0.4^{x2}	0.52
	Lt	7(35%)	9(45%)		
Comorbidity					
Medical free		11(55%)	6(30%)	11.1^{x2}	0.35
BA		1(5%)	0(0%)		
DM		1(5%)	2(10%)		
HCV		0(0%)	1(5%)		
HTN		4(20%)	3(15%)		
HTN,DM		3(15%)	5(25%)		
HTN,Goitre		0(0%)	1(5%)		
HTN,HCV		0(0%)	1(5%)		
Hypothyroid		0(0%)	1(5%)		

Data are expressed as Mean ± Standard deviation (SD), t =t-test, X^2=Chi-square

BMI=Body mass index, ASA=American Society of Anesthesiology Physical Status Classification System, BA=Bronchial Asthma, DM=Diabetes Mellitus, HCV=Hepatitis C Virus, HTN=Hypertensive.

Table 2. Comparison between groups concerning hemodynamics and ventilatory parameters.

	GA (n = 20)	TEA (n = 20)	t	p-value
MAP (mmHg)				
Baseline	92.8±11.2	95.2±16.2	0.54	0.59
Intraoperative 1 h	91.6±9	86.85±13	1.34	0.19
Immed. Postop.	94.15±16.4	88±8.5	1.48	0.15
Postoperative 2 h	91.75±12.25	89.85±6.25	0.62	0.54
Postoperative 6 h	90.15±14.3	88.25±8.7	0.51	0.61
Postoperative 12 h	89.65±11.44	86.35±10.62	0.94	0.35
Postoperative 24 h	90.85±14.72	87.15±15.32	0.78	0.44
HR (B/m)				
Baseline	90±14.1	82.25±12.9	1.8	0.08
Intraoperative 1 h	91.35±7.7	89.7±8.03	0.6	0.51
Immed. Postop.	86.15±12.9	79.7±12.1	1.6	0.11
Postoperative 2 h	83.2±11.6	79.95±12.1	0.9	0.38
Postoperative 6 h	77.82±14.05	75.94±13.32	0.43	0.67
Postoperative 12 h	79.33±9.88	77.15±12.68	0.6	0.54
Postoperative 24 h	80.36±10.87	75.54±9.84	1.47	0.15
PCo2 (mmHg)				
Baseline	38.4 ± 6.2	40.85 ± 5.3	1.3	0.18
Intraoperative 1 h	40.85 ± 5.3	44 ± 6.3	1.7	0.09
Immed. Postop.	38.05 ± 5.7	39.5 ± 4.6	0.8	0.38
Postoperative 6 h	37.7 ± 4.3	36.6 ± 3.5	0.8	0.38
Postoperative 12 h	35.5 ± 5.4	36.7 ± 2.9	0.9	0.37
Postoperative 24 h	36.9 ± 3.8	36.3 ± 3.4	0.5	0.6
P/F ratio				
Baseline	323.15 ± 42.2	307.7 ± 41.86	1.16	0.25
Intraoperative 1 h	261.05 ± 46.8	247.25 ± 50.7	1.04	0.31
Immed. Postop.	282.45 ± 66.7	280.45 ± 37.2	0.11	0.9
Postoperative 6 h	322.95 ± 45.3	300.45 ± 37.4	1.7	0.09
Postoperative 12 h	330.15 ± 46.3	310.8 ± 32.98	1.5	0.13
Postoperative 24 h	332.5 ± 57.3	322.55 ± 32.8	0.67	0.51

Data are expressed as Mean ± Standard deviation (SD), t = t-test. Immed. Postop. = Immediate postoperative.

There was no statistically significant difference between groups perioperatively ($p > 0.05$) neither in hemodynamic data (in terms of MAP and HR) nor ventilatory ABG parameters (in terms of $PaCO_2$ and PF ratio). (Figure 2) (Table 3)

There was a statistically significant difference between groups in VAS score at 3 h favoring the TEA in terms of postoperative pain control ($p = 0.004$). However, it was insignificant at 12 h, 24 h and overall postoperative pethidine consumption ($p > 0.05$)

7.1. Postoperative complications

In terms of postoperative ambulation and length of hospital stay (LOS), p-value = 0.013 and 0.001 respectively for each. Patients in GA group started ambulation after 4.5 ± 1.5 h with average stay 3.7 ± 1.3 days, in contrast to the TEA group who ambulated after 3.3 ± 1.5 h and stayed for 1.9 ± 1.6 days (Figure 3).

8. Discussion

Twenty-three patients were enrolled in the TEA group, three patients (15%) were intubated and *converted to general anesthesia* intraoperatively and excluded from the study, which could be attributed to the inadequate TEA block and intractable irritative cough that caused patients' discomfort. This was a slightly higher conversion rate than the results of *Hung and colleagues* [5], concluded that the conversion rate was 2.3–10%. Other causes reported suggesting immediate transfer to tracheal intubation if; respiratory acidosis where pH < 7.1, resistant hypoxemia (PO_2 < 60 mmHg) after high-flow oxygen inhalation and non-invasive ventilation, anxiety attack and invalid sedation, hemodynamic instability, and massive uncontrolled hemorrhage.

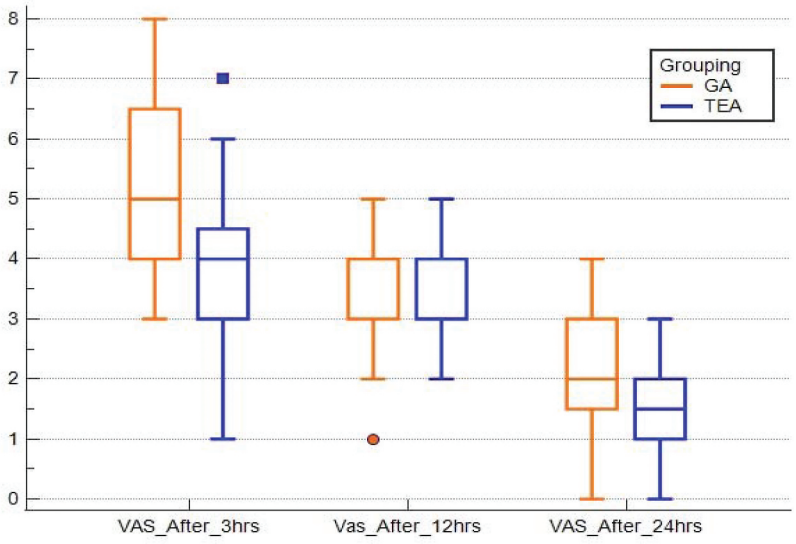

Figure 2. Box and whisker graph for postoperative VAS score. Data are expressed as *horizontal line* in the box = median, *box* = interquartile deviation, *vertical lines* extending to the range of values, *dots* = outliers.

Table 3. Comparison between groups as regards postoperative pain control and VAS score.

	GA (n = 20)	TEA (n = 20)	Z/t	p-value
VAS				
Postoperative 3 h	5(4–6.5)	4(3–4.5)	2.8^{z}	0.004
Postoperative 12 h	4(3–4)	3(3–4)	0.23^{z}	0.82
Postoperative 24 h	2(1.5–3)	1.5(1–2)	1.9^{z}	0.05
Pethidine Consumption(mg)	22.5 ± 25.5	25 ± 30.3	0.28^{t}	0.78

Data are expressed as Mean ± Standard deviation (SD), t = t-test, Z = Mann Whitney U test.

The most common complication for nonintubated patients is cough, which is stimulated by the surgical manipulation of the hilum, lung, and bronchi. It may interfere with lymph node dissection around the hilum and trachea. *Gelzinis* [6] proposed this reflex can be abolished by placing topical anesthesia directly onto the surface of the lung or by a surgical intrathoracic vagal blockade. Anesthetic adjuncts that may ameliorate coughing include dexmedetomidine and sevoflurane.

In this study, there was no statistically significant difference regarding *the duration of operation* between both groups (P = 0.1). Similarly, *Pompeo and Dauri* [7] found the operation time of non-intubated thoracoscopic surgery was comparable to GA patients (P = 0.64). However, this contrasts the results of *Liang and colleagues* [8], who studied Mediastinal tumor resection, found operation time was shorter in the nonintubated group (P < 0.001) facilitating a rapid recovery.

As primary outcomes (*ventilatory and ABG parameters)* for the study, there was no statistically significant difference between groups throughout the perioperative period (p > 0.05). Aiming to facilitate contrasting data, records at fixed intervals perioperatively are denoted in Table 2. Surgical pneumothorax is inevitable, but oxygenation and ventilation during nonintubated VATS are manageable and clinically tolerable. Moreover, *Zhang and colleagues* [9] included 1426 patients, with 707 patients in the non-intubated group documented less respiratory complications (P = 0.0006) for this group.

On the other side, *Pompeo and colleagues* [10] noted paradoxical breathing *(Pendelluft effect)* may develop between both lungs (when air is sucked interchangeably between the ventilated the non-ventilated lungs), increasing the risk of intraoperative hypercapnia and hypoxemia. In most cases, hypercapnia resolves spontaneously, and postoperative $PaCO_2$ is lower than after conventional anesthesia.

In addition, both groups were comparable in *hemodynamic data*, no statistically significant difference between groups could be noted (p > 0.05). Comparable results with conventional GA, ensuring hemodynamic stability, are advantageous for the less invasive nonintubated VATS as an evolving efficient safe alternative.

Wink and colleagues [11] investigated TEA in 1209 records concluded the effects on HR and MAP are mild and not uniform. Changes result from the complex interaction between direct cardiac sympathetic blockade and cardiovascular reflexes that occur secondary to altered preload and afterload. In healthy patients, the cardiodepressant effects of TEA is well tolerated with preservation of cardiac output (CO). The impact of cardiac sympathectomy in patients with limited cardiac reserve has not been studied specifically. Only if extensive neural blockade or cardiac unstable patients, *Missant and colleagues* [12] noted reduction of preload that can evoke hypotension and bradycardia (p < 0.05) attributed to impairment of the baroreflex.

Taking into consideration the *length of hospital stay (LOS)*, we found significant decrease compared to GA patients (1.9 ± 1.6 to 3.7 ± 1.3, respectively, P = 0.001).

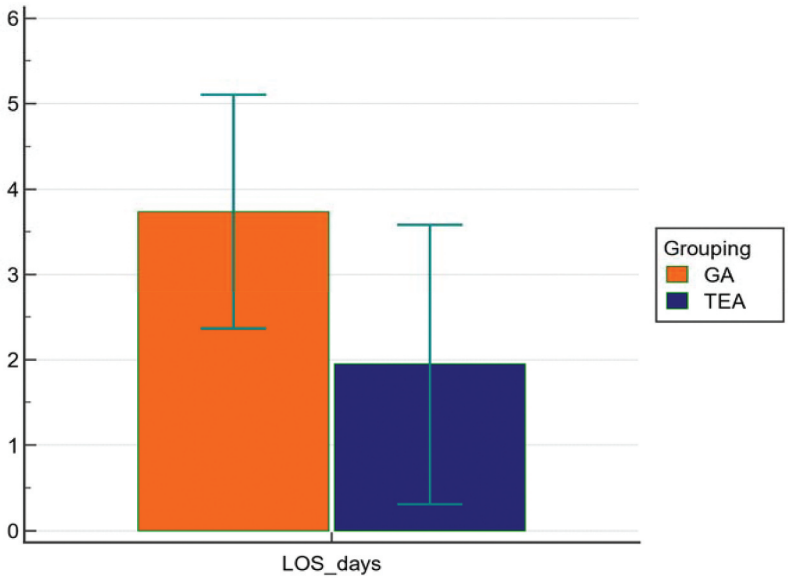

Figure 3. Bar charts for postoperative length of hospital stay. Data are expressed as *height of bar* = mean, *vertical lines* extending to the range of values.

Zhang and colleagues [9] included 14 random controlled trials RCTs that reported LOS, but the heterogeneity was vast ($P < 0.00001$, I2 = 97.0%). The random effects model demonstrated that the LOS in the nonintubated group was significantly shorter ($P = 0.01$).

Wang and colleagues [13] concluded that in addition to the type of operation, the postoperative chest-tube dwell time and the application of antibiotics can also affect hospital stay length and ambulation. Furthermore, a patient's discharge may depend on the subjective assessment of a patient's rehabilitation status. Therefore, further large-scale studies are requested.

Both groups were assessed for *postoperative pain control*, there was statistically significant difference between TEA and GA groups in VAS score (3–4.5 to 4–6.5, respectively, $P = 0.004$) at 3 h. These results cope with *Kocatürk and colleagues* [14]; whereas revising in similar studies, the fixed effects model showed that the VAS scores were significantly lower than those in the VATS group under GA. Conversely, a notable side effect for TEA was detected by *Tacconi and Pompeo* [15]; the increased incidence of TEA-related back pain. Additionally, the reported improper control of ipsilateral post-thoracotomy shoulder pain (not uncommon in VATS also) by TEA alone due to phrenic nerve irritation. Adjuvant non-steroidal analgesics have proven efficiency in either cases.

Conversely, both the *postoperative pethidine doses* (25 ± 30.3 mg to 22.5 ± 25.5 mg) and frequency for TEA to GA groups ($P = 0.78$) were statistically insignificant. This could be attributed to the finding that no statistically significant difference between groups could be noted at 12 and 24 h regarding postoperative pain control, i.e., long after discontinuation of TEA due to technical and logistic limitations ($p > 0.05$).

Considering the onset of postoperative ambulation, there was statistically significant difference between both groups, 3.3 ± 1.5 and 4.5 ± 1.5 h for TEA and GA groups, respectively, $p = 0.013$. This finding is consistent with *Batchelor and colleagues* [2] for the proper post-surgical pain control promoting enhanced recovery. That why TEA (even combined to GA) is strongly recommended as a part of the evidence-based thoracic ERAS guidelines. However, in another small RCT by *Pompeo and colleagues* [16] concluded no difference in morbidity observed on postoperative day 1 among young healthy subjects in either groups ($p > 0.05$) for spontaneous Pneumothorax, despite few minor side-effects including dizziness, vomiting and transient urinary retention occurred in the nonintubated group.

The limitation of the current study is the authors` scope for minor thoracic surgeries for patients having relatively stable comorbidities. Further studies needed to generalize the results for major surgeries and critical patients.

9. Conclusion

The feasibility of nonintubated VATS with TEA was tested in terms of safety and efficiency compared to the conventional GA. The results are comparable between both groups, in terms of hemodynamics, ventilatory parameters, yet favorable supporting the TEA group, in terms of postoperative pain control, decreased opiate consumption, ambulation and length of hospital stay. Thus, nonintubated VATS can be considered as a potent alternative for the selective one lung ventilation in cautiously selected patients and procedures, provided both the thoracic anesthesist and surgeon are familiar with this technique and the associated challenges. The literature backs up these findings convinced by the unique available physiological explanations for this variant technique dedicated for the special population with the thoracic concomitant pathologies.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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