



# Awake thoracic epidural anesthesia for uniportal video-assisted thoracoscopic pleural decortication: A prospective randomized trial

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## ABSTRACT

**Background:** Recently, video-assisted thoracoscopic surgery has replaced open thoracotomies. These surgeries are commonly done under general anesthesia with one-lung ventilation. The goal of this trial was to evaluate patient and surgeon satisfaction of awake uniportal video-assisted thoracoscopic pleural decortication under thoracic epidural anesthesia as an alternative to general anesthesia.

**Methods:** This prospective randomized trial included 66 patients who underwent uniportal video-assisted thoracoscopic pleural decortication. Patients were distributed into two equal groups: awake under thoracic epidural anesthesia (group TEA) and under general anesthesia (group GA).

**Results:** Patient satisfaction was significantly different between both groups ( $P < 0.039$ ), as group TEA had higher percentage of the patients who described the procedure as unsatisfactory (33.3%) versus group GA (6.7%). Surgeon satisfaction was, also, better in group GA ( $P < 0.001$ ).

**Conclusion:** Despite being technically applicable, this study showed that awake uniportal video-assisted thoracoscopic pleural decortication under thoracic epidural offers less patient and surgeon satisfaction compared to the same surgical procedure under general anesthesia.

**Clinical trials registry:** This trial is registered in ClinicalTrials.gov (NCT03902470).

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Thoracoscopic; video-assisted; thoracic epidural; decortication; patient satisfaction

## 1. Introduction

During the last few years, video-assisted thoracoscopic surgery (VATS) has replaced open thoracotomies in many thoracic centers due to several advantages that includes less blood transfusion, better pain management, faster recovery, and decreased length of hospital stay [1,2]. Uniportal VATS is a more recent surgical technique in which surgeon only uses one port for insertion of camera, instruments, and delivery of the specimen. It is claimed to have an even better cosmesis and less pain as one intercostal space will be affected only unlike the classic multi-port VATS [3,4].

Classically, VATS is done under general anesthesia (GA) with one-lung ventilation (OLV). Recently, awake, non-intubated VATS under thoracic epidural anesthesia (TEA) or other loco-regional techniques (thoracic paravertebral block, intercostal nerve block, or erector spinae plane block) with or without sedation provided an alternative option in certain patients [5–13]. Awake VATS can provide different advantages including avoiding the airway trauma that occurs frequently with the use of the double-lumen tubes (DLTs), the ventilator-induced lung injury, and the impact of muscle relaxation [14,15]. The absence of positive pressure ventilation allows the surgical incision to induce iatrogenic pneumothorax with

collapse of the non-dependent lung that provide enough space for the surgery [12].

Lung decortication is the surgical procedure performed in cases of chronic stage II/III empyema to evacuate the purulent organized collection and to remove the restrictive fibrous membrane overlying the lung parenchyma to allow complete lung expansion [16]. For long time, decortication was done via open thoracotomy owing to the fact that at stage III empyema, ribs will be crowded, small working space and retracted chest wall would render the procedure difficult to be performed through minimal invasive approach. Recently, several publications investigated the possibility of uniportal VATS decortication with good results but very few of those publication investigate the feasibility of awake uniportal VATS decortication [3,4].

This research was conducted to evaluate patient and surgeon satisfaction of awake uniportal video-assisted thoracoscopic pleural decortication under thoracic epidural anesthesia as an alternative to general anesthesia.

## 2. Patients and methods

This prospective randomized trial was carried out in Assiut University cardiothoracic surgery hospital form

January 2020 to July 2021 after approval from the medical institutional review board of Assiut University, Egypt (IRB no: 17,100,711). Written informed consent was signed by the patients after explaining the techniques used in the study to them. This study is consistent with the Declaration of Helsinki (Revised DOH 2013) and is registered at ClinicalTrials.gov (NCT03902470).

### 2.1. Participants

This study included 66 patients of both sexes (aged 18–65 years) and of ASA class I or II who were scheduled for uniportal VATS decortication. Exclusion criteria included patient refusal, coagulation disorders, infection at the site of injection, allergy to local anesthetics, previous thoracic surgery, preoperative PaO<sub>2</sub> < 60 mmHg, preoperative PaCO<sub>2</sub> > 50 mmHg, body mass index (BMI) ≥ 30 kg/m<sup>2</sup>, poor cardiac function (ejection fraction < 50%), renal or hepatic dysfunction, spine deformity, or psychiatric disorders.

### 2.2. Randomization

Using computer-generated random numbers and sealed opaque envelopes, the eligible patients were allocated into two equal groups: awake VATS decortication under thoracic epidural anesthesia group (group TEA) and VATS decortication under general anesthesia group (group GA).

### 2.3. Study protocol

All cases in both groups were operated by the same thoracic surgeon and the same anesthesia team. Preoperatively, the main anesthesiologist explained to all patients how to use the spirometer and how to assess the severity of postoperative pain using the numerical rating scale (NRS) which ranges from 0 (no pain at all) to 10 (the worst pain ever) [17].

In the holding area, thirty minutes before shifting to the operation theatre, nebulization with lidocaine 2% was administered to all patients to suppress the cough reflex in the awake group and to minimize the pressor response to intubation in the anesthetized group. This is followed by administration of 2–3 mg of midazolam and infusion of 500 ml of lactated ringer. In the operative theatre (OR), the patient was connected to the standard monitoring that included pulse-oximetry, non-invasive blood pressure, temperature, and ECG. Later on, capnography was connected.

#### 2.3.1. In group TEA

The patient was placed in the lateral decubitus position where the operation side down. To ensure aseptic condition, back skin disinfection was done twice with chlorhexidine in 70% alcohol. After local infiltration of the skin with lignocaine 2%, an 18-gauge Tuohy needle

was introduced at any level between T4–T6 intervertebral spaces to detect the epidural space using the loss of resistance method then an epidural catheter was advanced in cephalic direction. A test dose of 3 ml of lignocaine 2% was administered first to be followed by 5 ml of bupivacaine 0.5% with 100 µg of fentanyl. Five minutes later, another 5 ml of bupivacaine 0.5% was given to achieve sensory and motor block between T1 and T9 levels to maintain diaphragmatic function. The sensory dermatomal block was mapped with ice.

To start surgery, the position of the patient was reversed where the surgical side became up, then slight flexion of the operative table was done. Additional doses of 5 ml of bupivacaine 0.5% and fentanyl were eventually given one hour thereafter if necessary. Patients were kept sedated but responsive (grade 1 or 2 of the modified Wilson sedation scale) [18] via infusion of low doses of propofol (0.3–0.6 mg/kg/hr). Port site was located at the 5<sup>th</sup> intercostal space at anterior axillary line. After entering the chest cavity, lung drop down with the effect of artificial pneumothorax. Camera inserted into the chest cavity followed by surgical instruments to sweep the lung down, evacuate all infected pus and biofilm, irrigate the chest then remove the thick peel overlying the lung.

To help suppressing the cough reflex, intravenous infusion of lignocaine (1.5 mg/kg/hr) was maintained during the surgery. Oxygen was administered via a non-rebreathing face mask (10 L/min). After finishing the surgical procedure, surgeon ask the patient to do Valsalva maneuver to make sure a full lung decortication then inserting the chest tube from the same stab. Propofol infusion was stopped during wound closure. The epidural catheter was removed in OR before shifting the patient to the post-anesthesia care unit (PACU).

#### 2.3.2. In group GA

The patient was placed in supine position. After pre-oxygenation, induction of anesthesia was done with fentanyl (2 µg/kg), propofol (1.5–2 mg/kg), and cisatracurium (0.15 mg/kg) to facilitate tracheal intubation. An appropriately sized DLT was inserted with direct laryngoscopy and advanced till the endobronchial cuff passed the vocal cords, then the DLT was rotated 90 degrees clockwise or anticlockwise to be advanced either to the right or the left main bronchus. The correct position of the DLT was confirmed by inserting a fiberoptic bronchoscope through the tracheal lumen. Then, the patient was connected to the anesthesia machine. Anesthesia was maintained with isoflurane and maintenance doses of cisatracurium. The patient was placed in the lateral decubitus position where the surgical side up and with slight flexion of the table. Surgery conducted on the same fashion as group TEA except Valsalva maneuver, where surgeon ask the

anesthesiologist to ventilate both lungs and inflate the operated site with a pressure of 35 mmHg. By the end of surgery, neuromuscular blockade was reversed with neostigmine (0.05 mg/kg) and atropine (0.02 mg/kg) to be followed by extubation, then shifting the patient to the PACU.

### 2.3.3. Conversion of patients in group TEA to GA and intubation

This was decided by both the surgeon and anesthesiologist in case of ineffective epidural, persistent hypoxemia ( $SaO_2 < 80\%$ ), persistent severe cough, unstable hemodynamic status or intraoperative uncontrolled air leak or bleeding necessitating thoracotomy. For conversion, the surgical wounds were carefully dressed, the patient was turned to supine position, then induction of general anesthesia was done and followed by intubation using an appropriate DLT.

### 2.3.4. In both groups

By the end of surgery, all patients received paracetamol infusion (1 gram) and anti-emetic prophylaxis in the form of IV ondansetron (4 mg) and IV dexamethasone (0.15 mg/kg).

### 2.3.5. Measurements

- Intraoperatively: heart rate, mean arterial pressure (MAP),  $SaO_2$ , and  $EtCO_2$  were measured before skin incision (baseline measurements); then 15, 30, 60, and 90 minutes after skin incision; and finally at skin closure.
- Postoperatively: pain was assessed by the patient using the NRS [17], patient satisfaction was assessed using a 4-point score (excellent, good, satisfactory, unsatisfactory) [5], and surgeon satisfaction was assessed by asking the main surgeon using the same score.

### 2.3.6. Study outcomes

The primary outcome was patient satisfaction while the secondary outcomes were surgeon satisfaction; intraoperative heart rate, MAP,  $SaO_2$ , and  $EtCO_2$  as measured at different times; and the postoperative pain score.

## 2.4. Statistical analysis

Using G\*Power 3 software, and based on a previous study [5], sixty patients were required as the minimum sample size for detection of an effect size of 0.35 in the rate of patient's satisfaction between two equal groups, with  $\alpha$  error of 0.05 and a study power of 80%. Six patients were added to compensate for dropouts.

IBM-SPSS 24.0 was used for data analysis. Data were expressed as (mean  $\pm$  SD), (median and IQR), or (number and %). Shapiro Wilk test was used for assessing

the normality of data. Chi-square test was used for the comparison of frequencies among the two studied groups, while RM-ANOVA test was used to compare the mean differences of the data that were normally distributed and had repeated measures.  $P$  value  $< 0.05$  was considered significant.

## 3. Results

Out of 137 patients who were screened for the inclusion criteria, 66 patients were finally included in this research and randomly allocated into two groups (33 patients in group TEA versus 33 patients in group GA). The study was discontinued in six patients: three patients in group TEA who were converted to GA (one due to persistent  $SaO_2 < 80\%$  and two due to severe cough), and three patients in group GA for whom open thoracotomy was done (one due to uncontrollable air leak, and two due to surgical technical difficulty). So, the final analysis included 30 patients in each group (Figure 1).

Patients' characteristics including age, sex, BMI, and ASA classification were comparable in both groups. There were no significant differences between both groups in the baseline FVC, or FEV1 as a percentage of the predicted values. The side of surgery and the total surgical time were also comparable in both groups (Table 1).

Regarding patient satisfaction, it was significantly variable between both groups ( $P < 0.039$ ), as group TEA had higher percentage of the patients who described the procedure as unsatisfactory (33.3%) versus group GA (6.7%). Contrary to that group GA had higher percentage of the patients who described the procedure as excellent or good (3.3% and 40% respectively) versus group TEA (0% and 20% respectively) (Table 2). The Surgeon satisfaction was significantly different between both groups ( $P < 0.001$ ) as 100% of the procedures in group GA were assessed as excellent while only 46.7% of the procedures in group TEA were assessed as excellent. The remaining procedures in group GA were assessed as good (30%), satisfactory (13.3%), and unsatisfactory (10%) (Table 2).

The two groups did not differ significantly as regard to the baseline heart rate, or the heart rate at 15, 30, 60, or 90 minutes after skin incision. At skin closure, the heart rate was significantly lower in group TEA ( $P = 0.046$ ). Furthermore, there were no significant differences between both groups in the baseline MAP nor the MAP at 15, 30, 60, or 90 minutes after skin incision, or at skin closure (Table 3).

Despite no significant differences in the baseline  $SaO_2$  between both groups, the  $SaO_2$  values were significantly lesser in group TEA at 15, 30, 60, and 90 minutes after skin incision, and at skin closure (Figure 2a). Similarly, there was no significant difference in the baseline  $EtCO_2$  between both groups. However, the

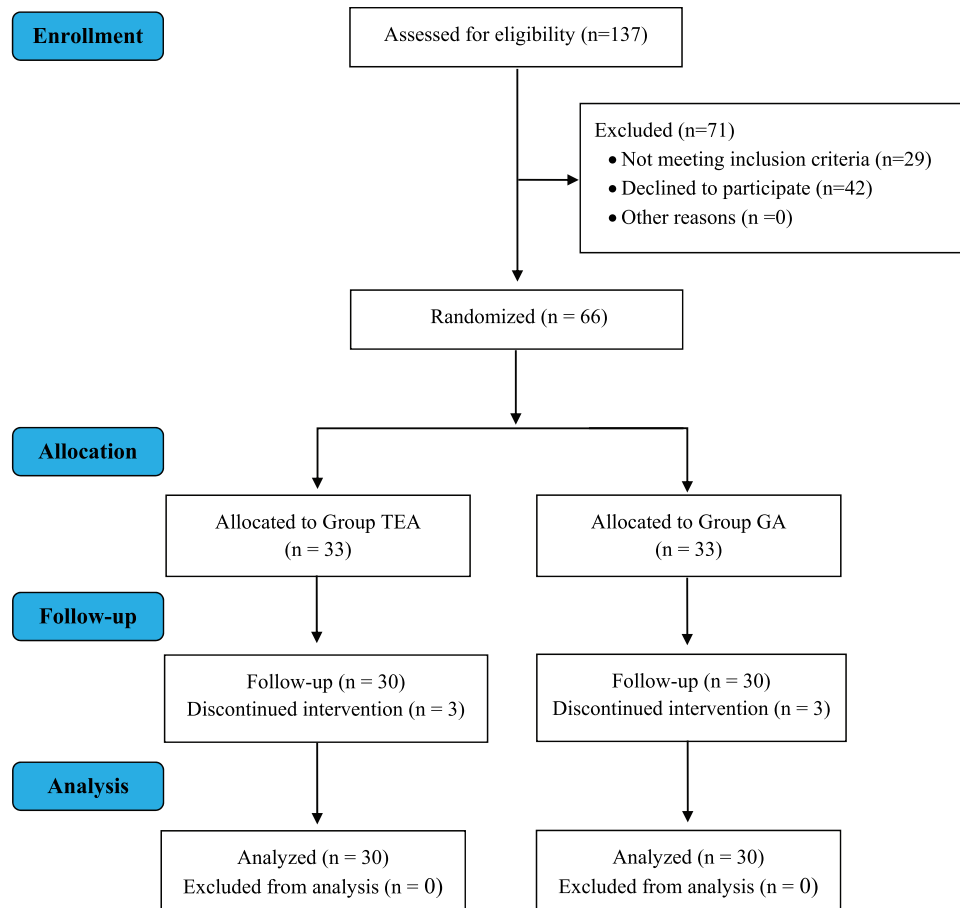


Figure 1. Flow chart of the participants.

Table 1. Patient characteristics and operative data.

Parameter	Group TEA (n = 30)	Group GA (n = 30)	P value
Age (years)	33.40 ± 8.8	36.01 ± 10.1	0.293
Sex			
• Male	16 (53.3)	20 (66.7)	0.215
• Female	14 (46.7)	10 (33.3)	
BMI (kg/m <sup>2</sup> )	24.30 ± 2.5	25.15 ± 2.8	0.234
ASA classification			
• I	19 (63.3)	17 (56.7)	0.396
• II	11 (36.7)	13 (43.3)	
FVC (% of predicted)	80.83 ± 8.0	79.60 ± 6.9	0.526
FEV1 (% of predicted)	81.77 ± 6.9	83.03 ± 6.6	0.472
Side of surgery			
• Right	14 (46.7)	12 (40)	0.397
• Left	16 (53.3)	18 (60)	
Total surgical time (min)	112.80 ± 20.1	106.47 ± 13.2	0.155

Values are presented as mean ± SD, or number (%). TEA: Thoracic epidural anesthesia; GA: General anesthesia; BMI: body mass index.

EtCO<sub>2</sub> values were significantly higher in TEA group at 15, 30, 60, and 90 minutes after skin incision, and at skin closure (Figure 2b).

Regarding the postoperative pain at rest, the NRS was significantly lower in group TEA versus group GA after 2 and 6 hours postoperatively ( $P = 0.004$  and  $0.035$  respectively) with no significant difference after 12 hours ( $P = 0.109$ ). The NRS on cough did not differ between the two groups when assessed after 2, 6, and 12 hours postoperatively (Table 4). The time to removal of chest tube, and the length of hospital stay were comparable in both groups (Table 4).

#### 4. Discussion

Several previous studies evaluated the feasibility and safety of awake thoracic surgery under loco-regional anesthesia [5,7,11,12,19–23]. In this study, we evaluated both patient and surgeon satisfaction of awake VATS pleural decortication under TEA as an alternative to the same procedure under GA. Our results showed less patient satisfaction in group TEA as the highest percentage of patients in this group described the technique as unsatisfactory or just satisfactory while in group GA, most patients described the technique as

**Table 2.** Patient and surgeon satisfaction.

Parameter	Group TEA (n = 30)	Group GA (n = 30)	P value
Patient satisfaction			
● Excellent	0 (0)	1 (3.3)	0.039*
● Good	6 (20)	12 (40)	
● Satisfactory	14 (46.7)	15 (50)	
● Unsatisfactory	10 (33.3)	2 (6.7)	
Surgeon satisfaction			
● Excellent	14 (46.7)	30 (100)	< 0.001*
● Good	9 (30)	0 (0)	
● Satisfactory	4 (13.3)	0 (0)	
● Unsatisfactory	3 (10)	0 (0)	

Values are presented as number (%).

TEA: Thoracic epidural anesthesia; GA: General anesthesia.

\*: Significant difference as p value < 0.05.

**Table 3.** Intraoperative hemodynamics.

Parameter	Group TEA (n = 30)	Group GA (n = 30)	P value
Heart rate (beats/min)			
● T0	89.07 ± 7.8	90.53 ± 5.1	0.394
● T1	88.93 ± 7.9	90.20 ± 5.9	0.486
● T2	88.93 ± 11.1	93.01 ± 7.6	0.171
● T3	86.33 ± 11.4	89.13 ± 9.4	0.306
● T4	83.73 ± 10.1	87.01 ± 8.9	0.191
● T5	85.89 ± 12.4	92.67 ± 6.3	0.046*
Mean blood pressure (mmHg)			
● T0	78.01 ± 8.5	81.40 ± 7.1	0.092
● T1	73.20 ± 6.1	73.80 ± 8.5	0.765
● T2	73.73 ± 10.5	76.20 ± 13.6	0.437
● T3	73.60 ± 7.7	72.80 ± 7.4	0.687
● T4	77.53 ± 9.1	77.07 ± 8.9	0.842
● T5	75.78 ± 4.6	78.22 ± 7.3	0.234

Values are presented as mean ± SD.

TEA: Thoracic epidural anesthesia; GA: General anesthesia; T0: Baseline (before skin incision); T1, T2, T3, T4: 15, 30, 60, 90 minutes after skin incision respectively; T5: at skin closure.

\*: Significant difference as p value < 0.05.

satisfactory or good. Since this was the first experience of thoracic surgery in patients of both groups, the unsatisfied patients in group TEA mentioned that GA would make them more comfortable and offer them better serenity.

A previous prospective observational study showed that patient satisfaction did not differ between the awake group and the general anesthesia group. However, it is worthy to mention that it was a non-randomized trial in which the patients were free to choose their preferred type of anesthesia [21]. Contrary to our result, Pompeo et al., in their randomized trial, reported better patient satisfaction in the awake group [5]. However, this could be attributed to the apparently short durations of the surgeries included in their trial compared to that required for the decortication surgeries in the current study. Moreover, the main surgeon evaluated the procedure of awake VATS pleural decortication as excellent or good in 23 patients out of 30 (76.7%), while he was more comfortable with the general anesthesia group.

The intraoperative hemodynamics including the heart rate and MAP were comparable in both groups

except significant higher heart rate in group GA at skin closure. This might be due to the sympathetic stimulation that might be triggered by minimizing the concentration of the inhalational anesthetic by the end of surgery.

Regarding the intraoperative SaO<sub>2</sub>, apart from one patient in group TEA who had persistent SaO<sub>2</sub> < 80% and so converted to GA and excluded from the follow up and final analysis, all the other patients in group TEA continued the procedure with accepted SaO<sub>2</sub> despite the statistically significant lower values in comparison to group GA. Fortunately, the process of pleural decortication itself and the drainage of the accumulated fluids helps in recruitment of more lung tissues and hence improves ventilation of the non-dependent lung [19]. As well, using a non-rebreathing mask allowed the maintenance of accepted levels of SaO<sub>2</sub> during the procedure.

Despite comparable baseline EtCO<sub>2</sub> in both groups, the intraoperative readings were significantly higher in group TEA. This is consistent with the results of a previous study of Guo Z et al. who reported that the intraoperative peak EtCO<sub>2</sub> was significantly higher in the non-intubated group of patients [24]. Other studies reported high values of PaCO<sub>2</sub> in the patients undergoing non-intubation thoracoscopic surgeries [22,23]. It is worth to mention that, unless contraindicated, permissive hypercarbia is an accepted and well-tolerated technique in many patients and rarely associated with adverse effects except increase of the respiratory rate [20,25,26].

One of the main problems that we had to deal with was the anticipated cough reflex in group TEA. Despite preoperative lignocaine nebulization and intraoperative lignocaine infusion, two patients had severe persistent cough and thus converted to GA and excluded from the final analysis.

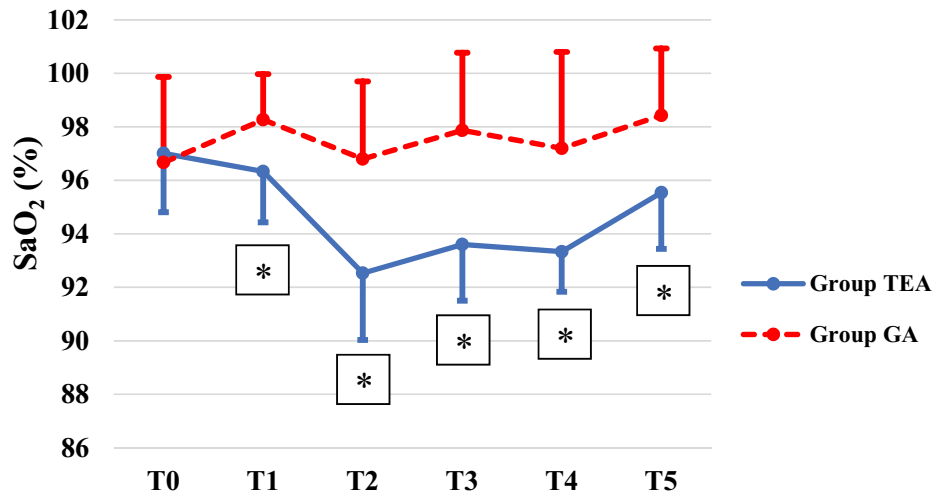
Regarding the postoperative pain, the NRS at rest was significantly lesser in group TEA during the first 6 hours postoperatively which gave an advantage to the postoperative course of this technique in the form of early ambulation.

This study had some limitations as being a single-center study, the strict exclusion criteria of the participants, and the absence of the long-term outcome such as satisfactory lung expansion and pulmonary function. We recommend further studies to evaluate awake VATS decortication in high-risk patients such as elderly patients or those with other co-morbidities.

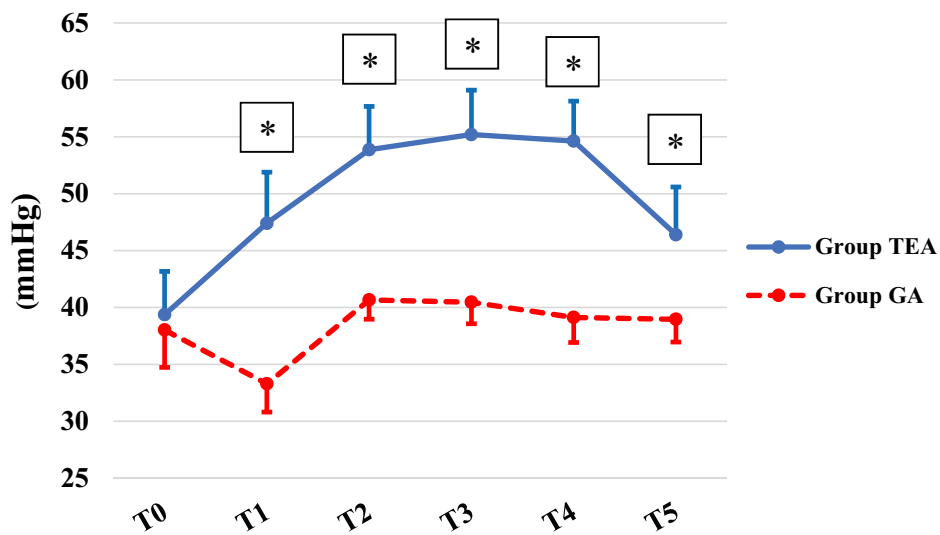
## 5. Conclusion

Despite being technically applicable, this study showed that awake uniportal video-assisted thoracoscopic pleural decortication under thoracic epidural offers less patient and surgeon satisfaction compared to the same surgical procedure under general anesthesia.





A. Intra-operative oxygen saturation.



B. Intra-operative EtCO<sub>2</sub>.

**Figure 2.** (a) Intra-operative oxygen saturation. (b) Intra-operative EtCO<sub>2</sub>. Values are presented as mean ± SD. TEA: Thoracic epidural anesthesia; GA: General anesthesia; T0: Baseline (before skin incision). T1, T2, T3, T4: 15, 30, 60, 90 minutes after skin incision respectively; T5: at skin closure. \*: Significant difference as P value < 0.05.

**Table 4.** Postoperative data.

Parameter	Group TEA (n = 30)	Group GA (n = 30)	P value
NRS at rest			
• After 2 hours	2 (1,2)	2 (2,3)	0.004*
• After 6 hours	2 (1,2)	2 (2,3)	0.035*
• After 12 hours	1 (1-1)	1 (1-1)	0.109
NRS on cough			
• After 2 hours	3 (2,3,4)	3 (2,3)	0.658
• After 6 hours	2 (1,2,3)	2 (2,3)	0.645
• After 12 hours	2 (2-2)	2 (2,3)	0.813
Time to removal of chest tube (days)	1.67 ± 0.7	2.01 ± 0.9	0.162
Length of hospital stay (days)	2.73 ± 0.8	3.07 ± 0.9	0.177

Values are presented as median (interquartile range), or mean ± SD. TEA: Thoracic epidural anesthesia; GA: General anesthesia; NRS: numeric rating scale. \*: Significant difference as p value < 0.05.

## Disclosure statement

No potential conflict of interest was reported by the authors.

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