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Comparison between Intubated Video Assisted Thoracoscopic Surgery and Awake Video Assisted Thoracoscopic Surgery in Management of Recurrent Pleural Effusion in Suez Canal University Hospitals

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ABSTRACT

Background: Pleural effusion is a common clinical disease characterized by pathological fluid accumulation in the pleural cavity. There are many possible causes of pleural effusion, with congestive heart failure, pneumonia, and malignancy being the most prevalent in adults. **Aim of the work:** This research aimed to study the effect of enhancing the accuracy of diagnosis and decreasing post-operative complications on patients with recurrent pleural effusion.

Patients and methods: This randomized controlled clinical trial study was conducted at Suez Canal University Hospitals, Cardiothoracic Surgery Department through the period from August 2021 to March 2023. The study included 100 cases who presented with recurrent pleural effusion of unknown origin. Patients were allocated into two groups. Patients who underwent intubated VATS were in group (A), and those who underwent awake VATS were in group (B).

Results: The intraoperative complications of cardiac arrhythmia and self-limiting subcutaneous emphysema were insignificantly less frequent in awake VATS group. The postoperative complications including loculated effusion, prolonged air leakage and expansion defect, empyema and long pleural drainage were non-significantly less frequent in awake VATS group.

Conclusion: In terms of operative complications and pain after surgery, awake video-assisted thoracoscopic operation was safer, more accurate, and more effective than video-assisted thoracoscopic operation conducted under general anesthesia. Additionally, the duration of the operation was shorter. Consequently, it may be the treatment of choice for all cases, not just those with comorbidities.

Keywords: Intubated and awake Video, Thoracoscopic surgery, Recurrent pleural effusion.

INTRODUCTION

Pleural effusion is a prevalent clinical condition characterized by abnormal fluid accumulation in the pleural cavity. It can develop in various conditions, with congestive heart failure, pneumonia, and malignancy being the most common causes in adults [1, 2].

To determine the cause of pleural fluid, thoracocentesis is performed, which involves analyzing the fluid biochemically, cytologically, and microbiologically. However, this diagnostic procedure only results in approximately 60-75% of cases. Unfortunately, 25-40% of cases with exudative pleural effusion remain undiagnosed even after repeated thoracocentesis attempts [3, 4].

The underlying causes of exudative effusions differ across populations, with malignancy & tuberculosis being the most common undiagnosed causes. Hence, it is crucial to accurately identify the exudative effusions. A definitive diagnosis is typically achieved through targeted biopsy of the pleura [5, 6].

Video-assisted thoracic surgery (VATS) conducted under general anesthesia has traditionally been the standard approach for these patients. However, in recent years, the use of local anesthesia with sedation in video-assisted thoracic surgery operations has been proposed to minimize operative risks & allow patients to breathe spontaneously. This technique enables the treatment of cases with compromised lung function who cannot tolerate endotracheal intubation, as well as those with poor general health [2, 6]. This research aimed to compare the outcomes & complications of the two procedures to determine if there is a clinically significant difference between them.

PATIENTS AND METHODS

This randomized controlled clinical trial study was conducted at Suez Canal University Hospitals, Cardiothoracic Surgery Department from August 2021 to March 2023 and performed on a total 100 patients who presented with recurrent pleural effusion of unknown origin.

Inclusion criteria: Age >18 years**.** Both genders were included in the study.

Exclusion criteria: Patient with chronic illnesses (Uncontrolled diabetes mellitus, liver cell failure, end stage renal diseases & heart failure). Patients with coagulation disorders (INR > 1.5) and bleeding diathesis, or anticoagulant therapy. Presence of bronchopleural fistula. History of immunodeficiency. History tuberculosis. History of intrathoracic malignancy. Autoimmune disease.

Sample Size justification:

Sample size was estimated according to the following equation: [7, 8]

$n = [(Z\alpha/2 + Z\beta)^2 \times \{(p1\ (1-p1) + (p2\ (1-p2))\}]/\ (p1 - p2)2$

$n = [(1.95+ 0.83)2 \times \{(0.95(0.05) + (0.75(0.25))\}] / 0.04$

$n = [7.7284 \times \{0.0475 + 0.1875] / 0.04$

$n= 1.816174 /0.04 = 45.4043$

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n=46.06+ 4.540435 (drop out)
n=49.94479 ≈ 50

Where n =sample size. Zα/2= 1.96 (The crucial value is the value that divides the center value of ninety-five percent of the Z distribution from the value that is located in the tail of the distribution). Zβ=0.84 (the critical value that separates the lesser twenty percent of the Z distribution from the upper eighty percent). p1 = proportion of subjects managed by intubated VATS = 0.95 [7, 8, 9]. p2 = proportion of subjects managed by Awake VATS = 0.75 [7, 8, 9]. p1-p2 = clinically significant difference = 0.20.

Utilizing the formula above and accounting for a ten percent dropout rate, a sample size of 100 participants (50 in each arm) is adequate to identify a clinically significant distinction of twenty percent in success rates among the two groups via a two-tailed Z-test of proportions with eighty percent power & a 95% level of significance.

Study procedure:
Patients were allocated into two groups: Patients who underwent intubated VATS were in group (A), and those who underwent awake VATS were in group (B).

Preoperative assessment:
Full clinical examination, full history, & full laboratory investigations (coagulation profile, CBC, liver function test, renal function test, glucose workup, ZN stain in suspicious cases). Radiological assessment of the patient using plain chest X-ray: Postero-anterior (PA) & lateral views before thoracocentesis with CT of the chest with IV contrast preoperative.

Operative preparation:
Awake VATS group:
The patients were positioned on their side, and sedation was administered using 0.05 milligram per kilogram of midazolam. This was followed by a bolus of remifentanil at 0.5 milligram per kilogram & a continuous infusion at 6 mg/kg/hour, or a bolus of propofol at 0.5 mg/kg and a continuous infusion at 3 mg/kg/hour. To provide local anesthesia, 2.5 milliliter of 1% lidocaine was applied to the incision site, while the patient wore an O_2 mask.

Intubated VATS group:
In this group, general anesthesia was induced using the same sedation method as mentioned above for the awake VATS group. Following sedation, in every single patient, general anesthesia was administered, and selective single-lung breathing was performed with the assistance of a double-lumen endotracheal tube. All processes were conducted in the surgery room by the same thoracic surgery team. The case was positioned in a totally lateral decubitus position, & the rib spaces on the side where the operation was to be conducted widening on the operating table through flexion. The surgeon and assistant positions were established according to the predicted location of the pathology. During the surgery, in the event that a potentially fatal heart arrhythmia was discovered, the procedure was immediately discontinued, and the operation was terminated. In the awake VATS group, if patients experienced severe pain, non-compliance, agitation, or hypoxia that hindered the proper completion of AVATS, intubation & conversion to general anesthesia were planned.

A single incision of three to four cm was made for uniportal VATS, based on the computed tomography appearance of the pleural space. Five millimeters or ten millimeters 30° camera & endoscopic and standard instruments were used. The chest cavity was first evaluated, and any remaining effusion was suctioned out. Biopsies were taken from suspicious masses, nodules, or lesions for histopathological examination. If no apparent lesions were found, biopsies were taken from the parietal pleura covering the apex, diaphragm, anterior and posterior chest wall, pulmonary ligament, and any suspicious lesions on the visceral pleura. A chest drain was inserted through the same port into the pleural space. The wound was closed layer by layer, the chest tube was secured to the skin with sutures, and the wound was covered with a sterile dressing and plaster bandage.

No patients in the awake VATS group required conversion to intubated VATS. Decortication or samples from other sites were not necessary as the focus was on pleural effusion cases. The length of the surgery was defined as the time between the start of anesthesia and the end of anesthesia.

Post-operative management:
Pain management began intraoperatively with the local injection of 1% lidocaine (3-5 mg per kg) and 0.25% bupivacaine (1-2 mg per kg) between the ribs. Fluid and electrolyte management was performed in a high dependency unit for 24 hours to monitor any complications such as fever, tachycardia, excessive bleeding, or significant air leak. Once specific discharge criteria were met, the patient was transferred to an inpatient ward. These criteria included normalization of body temperature in case of fever, normalization of heart rate in case of tachycardia, and no post-operative bleeding. Throughout the hospital stay, chest X-rays in the posteroanterior (PA) and lateral views were conducted daily. Patients with limited chest expansion received nasotracheal suction, and lung expansion was achieved after the first session. Patients with prolonged air leaks lasting more than 5 days were placed on low-pressure suction. Patients with malignant pleural effusion underwent pleurodesis using talc powder. The chest tube was removed once the lung fully expanded without any air leaks, and if the drain collected less than 100cc of pleural fluid. Patients were followed up on an outpatient basis for three weeks to monitor wound infection and assess their satisfaction with the operation.

Statistical analysis: The data collected underwent coding, tabulation, and statistical analysis using IBM SPSS statistics software version 22.0, developed by

IBM Corp., Chicago, USA, in 2013, as well as Microsoft Office Excel 2007. To describe the quantitative data, descriptive statistics were employed, including the minimum and maximum values to determine the range, as well as the mean ± SD for normally distributed quantitative data. For qualitative data, the description included the number & percentage of occurrences. Inferential analyses were conducted for quantitative variables.

The Shapiro-Wilk test was used to assess normality, and the independent t-test was employed when the comparison of both separate groups using data that follows a normal distribution. In the case of qualitative data, inferential analyses for independent variables were performed utilizing the Chi-square test to identify variations among proportions. Additionally, Fisher's exact test was utilized when dealing with variables that had small, expected numbers. The significance level was set at a p-value ≤ 0.050, indicating statistical significance, while values above this threshold were considered non-significant.

Ethical Considerations:

The patients provided written informed permissions to participate in the trial. Permission to conduct the research was approved by the Cardiothoracic Surgery Department at Suez Canal University Hospitals Research Ethics Committee of the Faculty of Medicine. For the purpose of conducting research involving human subjects, this study has been carried out in conformity with the Declaration of Helsinki, which is the Code of Ethics of the World Medical Association.

RESULTS

Regarding demographic characteristics, age, sex, comorbidities and ASA, table (1) demonstrated that there were no statistically significant variances among the studied groups as regards demographic characteristics (sex, age, comorbidities & ASA).

Table (1): Demographic characteristics between the studied groups

Variables	Measures	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Age (years)	**Mean ± SD**	57.3±5.6	58.1±5.4	^0.475
	Range	47.0–69.0	47.0–69.0	
Sex (n, %)	**Male**	44 (88%)	42 (84%)	#0.586
	Female	6 (12%)	8 (16%)	
Comorbidities	**HTN**	4 (8%)	5 (10%)	§0.918
	Controlled	3 (6%)	4 (8%)	
	Ischemic heart disease	4(8%)	3 (6%)	
	History of extra thoracic malignancy	3(6%)	2(4%)	
ASA (n, %)	**I**	8 (16%)	6 (12%)	§0.918
	II	20 (40%)	22 (44%)	
	III	19 (38%)	20 (40%)	
	IV	3 (6%)	2 (4%)	

ASA: American Society of Anesthesiologists. ASA I pt. is healthy, ASA II pt. has mild controlled systemic illness, ASA III pt. has fever but not incapacity systemic disease & ASA IV pt. has incapacitating systemic illness. ^Independent t-test. #Chi square test. §Fisher's Exact test.

Regarding clinical characteristics laterality, table (2) showed that there were no statistically significant variances among the studied groups regarding clinical characteristics laterality.

Table (2): Clinical characteristics between the studied groups

Variables	Measures		Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Laterality (n, %)	**Unilateral**	**Rt**	25 (50%)	26 (52%)	#0.425
		LT	15(30%)	18(36%)	
	Bilateral		10 (20%)	6 (12%)	

Regarding times of thoracocentesis before thoracoscope among the studied groups, table (3) showed that there were no statistically significant distinctions among the studied groups regarding times of thoracocentesis.

Table (3): How many times of thoracocentesis before thoracoscope among the studied groups

Measures	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
One session	**10(20%)**	**9(18%)**	**#0.425**
2 sessions	**30(60%)**	**35(70%)**	
More than 2sessions	**10(20%)**	**6(12%)**	

Before thoracoscope regarding time of operation, table (4) showed that time of surgery was significantly shorter in awake VATS group.

Table (4): Time of operation (minutes) among the studied groups

Measures	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Mean ± SD	40.1±4.3	36.2±4.7	**^<0.001***
Range	33.0–52.0	25.0–43.0	

^Independent t-test. *Significant

In regard to cardiac arrhythmia, self-limiting subcutaneous emphysema and blood loss, table (5) showe3d that cardiac arrhythmia, self-limiting subcutaneous emphysema and blood loss were non-significantly less frequent in awake VATS group.

Table (5): Intraoperative complications among the studied groups

Complications	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Cardiac arrhythmia	4 (8%)	2 (4%)	§0.678
Self-limiting subcutaneous emphysema	3 (6%)	1 (2%)	§0.617
Blood loss	Mean ±SD 200±50	Mean±SD 200±50	0.165
	Range150-250 cc	Range150-250 cc	

#Chi square test.

Concerning postoperative pain score, table (6) showed that there were no statistically significant variances among the studied groups as regards postoperative pain score. Patient was asked to define degree of pain from 0-10 after 4 hours, 8 hours, 12 hours, and 24 hours post-operatively as 0 is no pain & 10 is the worst degree of pain.

Table (6): Postoperative pain management (VAS-10) among the studied groups

Time	Measures	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Hour-4	**Mean ± SD**	4.7±0.9	4.9±0.7	^0.279
	Range	3.0–6.0	3.0–6.0	
Hour-8	**Mean ± SD**	3.6±0.9	3.8±0.8	^0.399
	Range	2.0–5.0	2.0–5.0	
Hour-12	**Mean ± SD**	3.5±0.9	3.5±0.8	^0.645
	Range	2.0–5.0	2.0–5.0	
Hour-24	**Mean ± SD**	2.3±0.9	2.4±0.9	^0.650
	Range	1.0–3.0	1.0–4.0	

^Independent t-test.

Regarding final diagnosis, table (7) showed that there were no statistically significant distinctions among the studied groups.

Table (7): Final diagnosis between the studied groups

Variables	Measures	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Final diagnosis (n, %)	**Non-specific pleuritis**	41 (82%)	43 (86%)	§0.936
	Malignancy	5 (10%)	4 (8%)	
	Granulomatous disease	3 (6%)	2 (4%)	
	Tuberculosis	1 (2%)	1 (2%)	

In regard to loculated effusion, prolonged air leakage, expansion defect, empyema and long pleural drainage, table (8) showed that: loculated effusion, prolonged air leakage, expansion defect, empyema and long pleural drainage were non-significantly less frequent in awake VATS group.

Table (8): Postoperative complications among the studied groups

Complications	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Loculated effusion	6 (12%)	2 (4%)	§0.259
Prolonged air leakage	3 (6%)	1 (2%)	§0.617
Expansion defect	3 (6%)	1 (2%)	§0.617
Empyema	3 (6%)	1 (2%)	§0.617
Long pleural drainage	2 (4%)	0 (0.0%)	§0.495
Death	0 (0.0%)	0 (0.0%)	NA

#Chi square test. §Fisher's Exact test. Not applicable

Regarding ICU and hospital stay, table (9) showed that there were no statistically significant variations among the studied groups regarding.

Table (9): ICU and hospital stay among the studied groups.

Variables	Measures	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
ICU stay (days)	**Mean ± SD**	1.7±0.6	1.5±0.5	0.165
	Range	1.0–3.0	1.0–3.0	
Hospital stay (days)	**Mean ± SD**	3.2±0.8	3.0±0.7	0.173
	Range	2.0–5.0	2.0–4.0	

^Independent t-test.

Regarding post-operative fellow up of patient, table (10) showed no statistically significant differences concerning wound infection and satisfaction of operation.

Table (10): Fellow up of patients among the studied groups

Variables	Intubated VATS (N=50)	Awake VATS (N=50)	p-value
Wound infection	4 (8%)	2 (4%)	§0.678
Satisfaction of operation	48 (96%)	49 (94%)	§0.617

DISCUSSION

Pleural effusions, which are common in different types of malignant diseases, are often a sign of a poor prognosis. Managing pleural effusions is crucial for improving the quality of life for people who have complications that are symptomatic, as they are associated with significant morbidity and mortality [(10)]. Due to the complications and re-accumulation of pleural effusions associated with various surgical approaches, there is a need to evaluate the safety & feasibility of non-intubated video-assisted thoracoscopic surgery (VATS) compared to intubated VATS for the treatment of thoracic diseases. This study aimed to enhance the diagnosis of recurrent pleural effusion without subjecting patients to the complications of intubated thoracoscopy [(11)].A randomized controlled clinical study was conducted at a tertiary care hospital from August 2021 to March 2023, involving patients with recurrent pleural effusion of unknown origin. Out of 120 assessed patients, 100 were involved in the research, with 50 within every group. Eleven cases were excluded in accordance with the inclusion criteria, & nine patients refused to participate. The analysis included the data of 100 patients who underwent either intubated VATS (Group A) or awake VATS (Group B). The term "awake VATS" was used in this study to describe the surgical procedure performed without general anesthesia. The study found no statistically significant distinctions among the groups as regards demographic characteristics, comorbidities, laterality of pleural effusion, and final diagnosis. These findings align with previous studies, such as **Kocatürk *et al.*** [(12)] study, which compared the accuracy in diagnostics & safety of awake and intubated VATS for the detection of pleural illnesses. That study found that pleural disease was unilateral in 83% of patients and bilateral in 17% of patients. Regarding the duration of the operation, our research found that in the intubated VATS group, the average time was 40.1 ± 4.3 minutes, compared to 36.2 ± 4.7 minutes in the awake VATS group. There was a statistically significant distinction among the two groups (p value <0.001). Similarly, a study by **Kocatürk *et al.*** [(12)] demonstrated that both the anesthesia and surgery times were significantly decreased in the awake VATS group (p0.001 for both). **Gokce *et al.*** [(7)] also found that the duration of the operation was significantly shorter in the AVATS group compared to the VATS group (p < 0.001). This difference was attributed to the intubation and positioning requirements in the VATS group. In line with our results, **Zhang *et al.*** [(13)] conducted a systematic review and meta-analysis and found that non-intubated VATS (NIVATS) had a significantly shorter overall operating time compared to intubated VATS (WMD: −35.96 min; 95% CI, −48.00 to −23.91; P<0.00001). Previous studies by **Klijian *et al.*** [(14)] and **Katlic and Factor** [(15)] also support the idea that with advancements in AVATS surgical techniques and VATS devices, both the duration of the operation and hospital stay have significantly decreased, allowing for a wider range of procedures.

As for postoperative pain, our study showed no statistically significant distinctions among the groups in terms of pain management assessed by the visual analog scale (VAS) score. Similarly, **Kocatürk *et al.*** [(12)] found no noticeable variations in pain intensity as assessed by VAS at different time points after surgery (4, 8, 12, or 24 hours). However, **Zhang *et al.*** [(13)] reported lower postoperative pain in the NIVATS group compared to the control group, but this discrepancy may be due to the larger sample size of the studies included in their meta-analysis. **Regarding complications,** our study showed that the awake VATS group had a non-significantly lower frequency of intraoperative complications such as cardiac arrhythmia and self-limiting subcutaneous emphysema (p value= 0.678, 0.617) compared to the intubated VATS group. Similarly, postoperative complications including loculated effusion, prolonged air leakage, expansion defect, empyema, and long pleural drainage were also non-significantly less frequent in the awake VATS group (p value= 0.259, 0.617, 0.617, 0.495). Consistent with our findings, **Kocatürk *et al.*** [(12)] reported that both groups had no complications noted during surgery. Complications following surgery such as fluid drainage & pneumonia were identified in one patient (0.6%) who underwent awake VATS, & in the same patient (0.6%) who received intubated VATS. [(12)]. **Gokce *et al.*** [(7)] found that complications occurred in 13.3% of cases in the VATS

group and 9.8% in the AVATS group, with no statistically significant difference in complication rates between the groups. These results are in line with previous studies that have demonstrated the safety of video-assisted thoracoscopic surgery in cases at elevated likelihood of problems as a result of factor such as advanced age, comorbidities, & performance status. In contrast, **Zhang *et al*. [(13)]** found that the complication rate was significantly lesser in the non-intubated VATS group compared to the intubated group. Our findings are also consistent with previous studies by **Kocatürk *et al*. [(12)]** and **Gokce *et al*. [(7)]** which showed that nonspecific pleuritis was the most common postoperative diagnosis, followed by malignancies, tuberculous necrotizing pleuritis, and non-necrotizing granulomatous pleuritis, with no significant variance among the awake VATS & intubated VATS groups in terms of comorbidity presence. These results align with a study by **McDonald *et al*. [(16)]** in which the identification of pleural effusion was compared between awake VATS and intubated VATS & found that non-specific pleuritis was diagnosed in a higher percentage of cases in the awake VATS group compared to the intubated VATS group. It was noted that within 24 months of follow-up, ten to twenty percent of cases diagnosed with nonspecific pleuritis were found to have malignant disease, highlighting the importance of clinical follow-up.

The strength points of this study:

This study's strengths are its controlled clinical design, its location at a singular tertiary care center, and the absence of any patients who were lost to follow-up throughout the duration of the study. It is the first study in Egypt to compare the diagnostic utility of non-intubated VATS and intubated VATS in recurrent pleural effusion. Furthermore, the research was conducted exclusively at a single institution, employing the identical surgical team & anesthetic protocol, factors that most likely contributed to the validity of our findings.

The limitations of the study: The study was limited by its comparatively small sample size in comparison to previous research and its lack of multi-centricity, which significantly raises the risk of publication bias. The comparatively limited duration of postoperative patient follow-up was an additional constraint. Transformative to malignant or specific illnesses did not occur in any patients who received clinical follow-up for a minimum of twenty-four months. It is significant that a longer period of clinical follow-up could have resulted in the identification of specific diagnoses in cases with nonspecific pleuritis.

CONCLUSION

In terms of operative complications and pain following surgery, awake video-assisted thoracoscopic operation was safer, more accurate, and more effective than video-assisted thoracoscopic operation conducted under general anesthesia. Additionally, the duration of the operation was shorter. Consequently, it may be the treatment of choice for all cases, not just those with comorbidities.

DECLARATIONS

- **Consent for publication:** I confirm that every author has given their consent to submit the work.
- **Availability of data and material:** Available.
- **Competing interests:** None.
- **Funding:** No fund.
- **Conflicts of interest:** no conflicts of interest.

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