Section A-Research paper

Efficacy of Stapler Use in Bullectomy in Cases of Spontaneous Pneumothorax

Ebrahim Mohamed Metwally ; Ahmed Mohamed Deebis ; Kareem Mohamed Elfakharany; Dina Said Shemais

Cardiothoracic Surgery Department, Faculty of Medicine, Zagazig University, Egypt.

Corresponding author: Ebrahim M. Metwally,
metwallyebrahim2@gmail.com

ABSTRACT

Background: The standard treatment for primary spontaneous pneumothorax (PSP) is thoracoscopic stapled bullectomy. Video-assisted thoracoscopic surgery (VATS) is being used more frequently. **Objective:** This study aimed to evaluate the efficacy of stapler use in bullectomy in cases of spontaneous pneumothorax. **Patients and methods:** A prospective randomized controlled study included 80 cases operated for bullectomy due to clinically and radiologically confirmed complicated bullous lung disease. atients were divided into two groups; Group 1: patients in this group received bullectomy with minimal invasive VATS through 3 ports approach, and Group 2: patients in this group received bullectomy through the traditional open posterolateral thoracotomy approach. The minimum follow-up period was 6 mounth. **Results:** There were statistically significant difference between the two groups regarding post-operative FEV1 % and post-operative FVC %**.** There was statistically significant difference regarding the post-operative pain score at first and seventh day. Higher frequency of recurrence of new bullae in the non-staple line in group 1 compared to group II, with p-value (p=0.004). **Conclusion:** Staplers can be used in bullectomy through open thoracotomy approach with good results.

Keywords: Bullectomy; Staplers; VATS; Spontaneous Pneumothora

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INTRODUCTION

A bulla is a greater than 1 cm3 acquired air-filled area in the lung parenchyma with an oval or circular form and often thin walls with low thickness. Bullous lung disease is characterised by the presence of bullae and emphysematous obstructive airway disease **(1).**

In a patient with bullous disease, the onset of clinical dyspnea is typically accompanied with radiologic bulla progression and an apparent reduction in the volume of the surrounding normal lung. The steady development of relative positive pressure within the bulla, which compresses the surrounding lung or limits its extension, would be one logical reason for this appearance **(2).**

Therefore, the majority of bullae do not significantly contribute to gas exchange, although they do fill and empty synchronously with the rest of the lung. This function would not work with the pressure-induced expiratory filling of a cyst **(3).**

Displacement of the mediastinum, diaphragm, or fissures may serve as incidental evidence of the bulla's impact on the nearby lung. A bulla's appearance on a plain radiograph may be distinct, yet important bullae may not be recognised for a number of reasons **(4).**

Video-assisted thoracic surgery (VATS) can covered all procedures performed with the thoracoscope. The purpose of the procedure is to decrease the amount of pulmonary parenchyma by removing non-functional regions that do not significantly contribute to gas exchange**.** The recurrence rate of primary spontaneous pneumothorax remains high. Some surgical approaches shoud be considered including reinforcing the staple line with synthetic materials**(5,6**).

We conducted this study to evaluate the efficacy of stapler use in bullectomy in cases of spontaneous pneumothorax ,either through VATS or open thoracotomy. Moreover ,we aimed to evaluate the recurrence rate in the staple line and non-staple line in the operated cases.

PATIENTS AND METHODS

This prospective randomized controlled study was conducted in the Cardiothoracic Surgery Department at Zagazig University Hospitals. Assuming that all cases met the inclusion and exclusion criteria were included. An approval of the study was obtained from Zagazig University Academic and Ethical Committee **(ZU-IRB#10361/24-1-2023)**. A written informed consent was obtained from all participants. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria:

All adult patients operated for bullectomy due to clinically and radiologically confirmed complicated bullous lung disease. Multiple small bullae are present.

Exclusion criteria:

Patients who had surgical treatment for other lung pathology, malignancy or having any preoperative disease related to other morbidity were excluded.

Preoperative assessment:

A thorough history was taken in the form of personal history and past history, co-morbidities, or risk factors, history of the disease or any other disorders in the family. Clinical examination that included general and local (cardiac and chest) assessment. Chest computed tomography and plain chest x-rays were both done. Routine haematologic investigations were performed.

Surgical Procedures

Under general anaesthesia, double-lumen endotracheal tubes were used for all surgeries.Two thoracic surgeons with over 10 years' experience performed the operations

for the patients included in our study. Patients were randomly divided into two groups; group 1and group 2. The randomization process was performed by one of the authors other than the surgeons who performed the operations, using a computerized randomization program. Patients were allocated to each group according to serial numbers 1,3,5,... in group 1 and 2,4,6,... in group 2. Patients in group 1 received bullectomy using minimally invasive VATS through 3 ports approach and patients in group 2 received bullectomy through the traditional open posterolateral thoracotomy approach. Release of adhesions if found and closure of feeding bronchi using vicryl sutures followed by the stapler to secure the surgical lines. A standardized postoperative carew as introduced to all patients.

Study End Points

The primary end point was the postoperative outcome, post-operative complications and need for re-exploration due to bleeding or for revision. The secondary end points were assessment of postoperative pain for one month postoperative. Additionally, the radiological and clinical follow up for the assessment of recurrent pneumothorax and appearance of new bullae for six months duration postoperatively.

Postoperative follow up:

All patients were followed up during hospitalization period for the detection of the presence of: postoperative air leak in the chest drains, bleeding, pain score, any symptoms or signs of wound infection, pulmonary complications, need for ICU admission and hospital stay duration. After discharge of the patients, they were followed up for the assessment of postoperative pain, follow up chest xray, and respiratory functions after 30 days of the operation. They were followed-up monthly for sixth months duration to detect if there was recurrent pneumothorax or new bullae formation.

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean ± standard deviation and ranges when their distribution was parametric (normal) while non-normally distributed variables (non-parametric data) were presented as median with inter-quartile range (IQR). Also qualitative variables were presented as number and percentages. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk Test. Independent-samples t-test of significance was used when comparing between two means. The Comparison between groups with qualitative data was done by using Chi-square test and Fisher's exact test instead of Chi-square test only when the expected count in any cell less than 5. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: P-value $\leq$0.05 was considered significant, P-value $\leq$0.001 was considered as highly significant, and P-value >0.05 was considered insignificant.

RESULTS

Regarding the demographic data, it was found that the mean (SD) of (group 1) was 29.2±2.6 years and for (group 2) was 29.4±2.4 years. 80% of the group1 were males and in group 2, we found 87% of them males. There was no statistically significant difference between the two groups regarding the demographic data **(Table 1)**. The mean operative time and inta-operative blood loss in VATS groups was statistically lower than Thoracotomy group **(Table 2)**.

Table (1): Comparison between groups according to basic characteristics.

	Group 1 VATS (N=40)	Group 2 Thoracotomy (N=40)	Test value	P value
Age (years)				
Mean±SD	**29.2±2.6**	**29.4±2.4**	**0.357**	**0.7217**
(Min-Max)	**(18-63)**	**(19-52)**		
Sex: **Female** **Male**	 **4 (20%)** **18 (80%)**	 **3 (13%)** **19 (87%)**	**0.702**	**0.402**
BMI				
Mean±SD	**24.9±3.7**	**26.2±2.64**	**1.809**	**0.074**
(Min-Max)	**(20.6-30.3)**	**(23.3-31.2)**		
Comorbidities				
Hypertension	**6 (15.0%)**	**10 (25.0%)**	**1.234**	**0.267**
Diabetes	**10 (25.0%)**	**6 (15.0%)**	**1.234**	**0.267**
Smoking	**10 (25.0%)**	**6 (15.0%)**	**1.234**	**0.267**

Using: t-Independent Sample t-test for Mean ± SD;
x^2: Chi-square test for Number (%) or Fisher's exact test, when appropriate
*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

Table (2) Comparison between groups according to operative characteristics.

	Group 1 VATS (N=40)	Group 2 Thoracotomy (N=40)	Test value	p-value
Operative time (min)				
Mean±SD	**49.6±2.7**	**79±1.8**	**57.301**	**<0.001****
(Min-Max)	**(64-75)**	**(96-103)**		
Inta-operative blood loss				
Mean±SD	**95.3±3.1**	**173±4.2**	**94.139**	**<0.001****
(Min-Max)	**(89-101)**	**(162-177)**		

Using: t-Independent Sample t-test for Mean±SD;
*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

The bullae characteristics in the patients who were included in our study. We found that 30 % of the patients in VATS groups had one bullae but 70 % of them suffered from more than one bullae among the all bullae 45% were apical, 10% were basal, 5% were in between apical and basal and 40% were another lesions. 35 % of the patients in open thoracotomy groups had one bullae but 65 % of them suffered from more than one bullae, among the all bullae 40% were apical, , 15% were basal, 25% were in between apical and basal and 40% were another lesions. Regarding the size of the bullae 35% of the bullae in

group 1 were 1 cm, 35% of them were 1-3 cm and 30% of them were more than 3 cm. Regarding group 2, we found that 25% of the bullae were 1 cm, 50% of them were 1-3 cm and 25% of them were more than 3 cm **(Table 3)**.

Regarding Post-operative characteristics, we found that there were statistically significant differences between the two groups regarding post-operative chest tube duration, post-operative hospital stay, post-operative need for ICU stay and post-operative wound infection **(Table 4)**.

Table (3) Comparison between groups according to bullae characteristics.

	Group 1 VATS (N=40)	Group 2 Thoracotomy (N=40)	Test value	p-value
Number of bullae/ patient				
One bullae	**12 (30.0%)**	**14 (35.0%)**	**0.057**	**0.811**
Two bullae or more	**28 (70.0%)**	**26 (65.0%)**		
Mean±SD	2.1±0.81	1.9±0.77	1.132	0.259
Site of bullae				
Apical	**18 (45.0%)**	**16 (40.0%)**	**1.318**	**0.725**
Basal	**4 (10.0%)**	**6 (15.0%)**		
In between apical and basal	**2 (5.0%)**	**4 (10.0%)**		
Another lesion	**16 (40.0%)**	**14 (35.0%)**		
Size of bullae				
1 cm	**13 (32.5%)**	**10 (25.0%)**	**2.543**	**0.280**
1-3 cm	**13 (32.5%)**	**20 (50.0%)**		
More than 3 cm	**14 (35.0%)**	**10 (25.0%)**		
Mean±SD	**2.4±1.23**	**2.1±0.97**	**1.211**	**0.230**

Using: t-Independent Sample t-test for Mean±SD;
x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate
*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

Table (4) Comparison between groups according to post-operative course.

	Group 1 VATS (N=40)	Group 2 Thoracotomy (N=40)	Test value	p-value
Post-operative chest tube duration (days)				
Mean±SD	2.5±1	4±0.75	7.589	<0.001**
(Min-Max)	(2-4)	(3-6)		
Post-operative hospital stay (days)				
Mean±SD	5±1	7±0.70	10.363	<0.001**
(Min-Max)	(3-5)	(7-10)		
Post-operative need for ICU stay	(0%)	10 (25.0%)	11.286	0.002*
Post-operative wound infection	0 (0%)	9 (22.5%)	9.764	0.002*

Using: t-Independent Sample t-test for Mean±SD;
x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate
*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

There were statistically significant difference between the two groups regarding post-operative FEV1 % and post-operative FVC % **(Table 5)**.

Pain score was calculated according to the visual analogic pain score. Pain score was recorded from 0 to 10 with 0 score showing no pain and 10 score showing the worst non tolerable pain. There was a statistically significant difference regarding the post-operative pain score at the first and the seventh day, but there wasn't a statistical difference in the post-operative pain score at day 30 post-operative **(Table 6)**.

The higher frequency of recurrence of new bullae in the non-staple line in group1 compared to group 2, with p-value (p=0.004).However, Recurrence of new bullae in the staple line was non-significant, with p-value (p>0.05.There is no statistically significant difference between groups according to Longest length (cm), volume (cm3), duration between the operation and CT follow-up (months) **(Table 7)**.

Table (5) Post-operative pulmonary function tests comparisons between the two groups.

	Group 1 VATS (N=40)	Group 2 Thoracotomy (N=40)	Test value	p-value
Pre-operative FEV1%				
Mean±SD	**65.01±9.68**	**69.00±11.13**	**1.711**	**0.091**
(Min-Max)	**(47-80)**	**(49-88)**		
Post-operative FEV1%				
Mean±SD	**81±9**	**73±10.64**	**3.631**	**0.002***
(Min-Max)	**(61-97)**	**(53-100)**		
Pre-operative FVC%				
Mean±SD	**70.38±7.19**	**70.12±6.12**	**0.174**	**0.862**
(Min-Max)	**(53-78)**	**(59-86)**		
Post-operative FVC%				
Mean±SD	**79±4**	**73±4.5**	**6.303**	**<0.001****
(Min-Max)	**(71-88)**	**(62-81)**		

*Using: t-Independent Sample t-test for Mean±SD; , x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate, p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

Table (6): Postoperative pain score in both studied groups at day 1, 7, and 30 .

	Group 1 VATS (N=40)	Group 2 Thoracotomy (N=40)	Test value	p-value
Post-operative pain score at day 1				
Mean±SD	**3±1**	**6.5±1.02**	**15.497**	**<0.001****
(Min-Max)	**(2-5)**	**(2-8)**		
Post-operative pain score at day 7				
Mean±SD	**2.4±1**	**5±1.08**	**11.172**	**<0.001****
(Min-Max)	**(1-5)**	**(1-5)**		
Post-operative pain score at day 30				
Mean±SD	**2.05±1.00**	**2.00±0.90**	**0.235**	**0.815**
(Min-Max)	**(0-4)**	**(0-3)**		

*Using: t-Independent Sample t-test for Mean±SD; x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

Table (7): Comparison between groups according to Longest length (cm), Volume (cm3), Duration between the index operation and CT follow-up (months), Recurrence in new bullae in the staple line and Recurrence in new bullae in the non-staple line.

	Group 1 VATS (N=40)	Group 2 Thoracotomy (N=40)	Test value	p-value
Longest length (cm)	**6.49±2.16**	**7.31±2.37**	**1.617**	**0.110**
Volume (cm3)	**20.29±12.26**	**22.56±19.98**	**0.612**	**0.542**
Duration between the operation and CT follow-up (months)	**24.62±12.36**	**22.66±10.32**	**0.770**	**0.444**
Recurrence in new bullae in the staple line	**8 (20.0%)**	**10 (25.0%)**	**0.283**	**0.595**
Recurrence in new bullae in the non-staple line	**10 (25.0%)**	**1 (2.5%)**	**8.431**	**0.004***

Using: t-Independent Sample t-test for Mean±SD;
x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate
*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

DISCUSSION:

The most frequent cause of spontaneous pneumothorax is bullous lung disease. In order to do the bullectomy, which was previously done via a normal posterolateral thoracotomy, the care is essentially surgical **(7)**. The majority of patients with bullae have a significant history of cigarette smoking, pulmonary sarcoidosis, 1-antitrypsin deficiency,1-antichymotrypsin deficiency, Ehlers-Danlos syndrome, and inhaled fibreglass exposure have all been linked to emphysematous lung bullae **(8)**.

Finding a balance between sufficient tissue compression time and the risk of increased tissue tearing and excessive tensile strength is essential for the use of staplers in surgery in general **(9,10)**.

The widespread use of VATS is dependent on the usage of staplers, which have been used in thoracic surgery for more than 20 years. However, more adverse events associated with staplers have been observed during the past few years **(11)**.

Our study aimed to evaluate the efficacy of stapler use in bullectomy in cases of spontaneous pneumothorax. There was non-significant difference regarding bullae characteristics.This agree with **Abdullah (12)** who revealed no significant differences between studied groups regarding number, site, and size of bullae (P>0.05).

Several studies have investigated the comparative operative times between open thoracotomy (OT) and VATS for bullectomy.

Wu et al. (10) included eight studies and demonstrated that VATS had a significantly shorter operative time than open thoracotomy (OT), with a pooled mean difference of -46.37 minutes (p<0.001).

Crisco and Colony (13) performed a study on 60 patients who had VATS or thoracotomy procedures for pneumothorax and reported shorter hospital stay, shorter duration of chest drainage, fewer prolonged air leaks and lower total economic cost with VATS procedures. However, there were two recurrent pneumothoraxes following VATS procedures compared to none with the thoracotomy procedures. Also, **Vohra et al. (14)** and **Lin et al. (15)** have demonstrated that VATS results in a shorter hospital stays and post- operative chest tube duration.

Regarding of pulmonary function; we found that there was a statistically significant difference between the two groups regarding post-operative FEV1 % and post-operative FVC %.

However, **Waller et al. (16)** studied two groups of 30 patients undergoing surgery for bolus lung diseases by VATS and open thoracotomy. They reported that the operating time was significantly longer for the VATS group but that the postoperative analgesic requirement, hospital stay and lung dysfunction (as measured by reductions in FEV1, FVC) were reduced for this group compared to the thoracotomy group.

In a study of **Lone et al (17)** the mean postoperative dyspnea score in those with underlying diffuse disease (19 patients) improved from a preoperative value of 2.45 ± 0.62 to 1.66 ± 0.72. The mean postoperative dyspnea score in those without underlying diffuse disease (25 patients) improved from a preoperative value of 2.05 ± 0.5 to 1.05 ± 0.61.

Wang et al. (18) conducted a nonrandomized comparison, 359 patients received lung volume reduction surgery by median sternotomy, and 152 patients received lung volume reduction surgery by video-assisted thoracoscopy. They also showed significant improvement in dyspnea index following VATS bullectomy.

Schipper et al. (19) in their study showed increase in FEV1 from 34% of predicted value to 55% of the predicted value at six months of postoperative period. However, they included only patients who had giant emphysematous bullae in their study. **Lin (20)** showed that hypoxemia and hypercapnia improved after surgery and FEV1 increased moderately.

Our results are confirmed by a previous studies, **Pala et al. (21)** aimed to evaluate patients who had undergone elective surgery, early and late mortality following surgery, the early and late reappearance of bullae, and the early and late modifications of clinical and functional data. They had observed significant improvement in FEV1, FVC and FEV1/FVC values in postoperative period.

Regarding post-operative pain score we found a statistically significant difference at first and seventh day, but there were statistically no significant difference regarding the post-operative pain score at day 30 post-operative between two groups.

Our finding agree with **Jiménez-Merchán et al. (22)** compared complication rates for VATS and thoracotomy procedures for spontaneous pneumothorax. They found higher rates of complications with VATS procedures, but they attributed these results to lack of surgical experience with their early cases, as the most recent 60 VATS procedures had much lower complication rates.

On the contrary, **Ben-Nun et al. (23)** demonstrated that VATS approach has the benefits of less postoperative pain, better wound drainage, better functional recovery, better short- and long-term patient satisfaction, and equivalent cost- effectiveness to the open approach.

Page's et al. (24) showed a higher recurrence rate of pneumothorax after management by VATS: 3.8% of patients in VATS group vs 1.8% in thoracotomy group.

Also, **Barker et al. (25)** reported that a four-fold increase in the recurrence of pneumothorax following VATS as compared to open surgery has been reported in a meta-

analysis with 4 randomized and 25 non-randomized studies, although a second meta-analysis of only the randomized trials did not show this difference.

In thoracic surgery, certain features of the lung tissue whose peripheral and central regions differ significantly in their contents of solid and more plastic elements directly affect the stapling procedure. Additionally, lung cancer and pulmonary fibrosis are known to cause increases in lung tissue thickness. The effectiveness of staplers is also impacted by these changes, along with pulmonary emphysema **(12).**

On other hand, **Yano et al. (26)** revealed that the adverse events mostly occurred during lung surgery and included heavy bleeding, air leakage, and oozing because staplers malfunctioned when utilised for vascular, bronchial, and/or parenchyma division. However, it has never been documented before for a stapler to become caught on lung tissue.

Landreau et al. (27) and **Yim et al. (28)** showed significantly less postoperative pain in VATS group as compared to thoracotomy group.

Further, **Vallejo et al. (29)** reported that after the surgical treatment, the next step is to prevent the recurrence of spontaneous pneumothorax, which is estimated from 23 to 50% of all the patients. The highest risk occurs in the first 30 days, and, during this time, patients must avoid activities which involve acute variation of the pressure in the lungs, like flying or diving; these activities increase the risk of recurrent spontaneous pneumothorax.

CONCLUSION:

Staplers can be used in bullectomy through open thoracotomy approach with good results. It is an opportunity to revise the idea of resecting bullae with a suitable margin and develop other methods for reducing the stress at the stapling line.

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Author contribution: Authors contributed equally in the study.

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