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Title: Gelfoam slurry tract occlusion after computed tomography-guided percutaneous lung biopsy: does it prevent major pneumothorax?

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INTRODUCTION

Computed tomography (CT)-guided percutaneous lung biopsy is an important procedure in the diagnostic workup of indeterminate or suspicious pulmonary lesions. It is also useful for establishing the histological grading of lung malignancies. In the latest era of personalised therapies, the ability to obtain anatomically intact specimens through lung biopsies also facilitates the identification of specific tumour markers that guide oncological treatments.

Procedural risks following lung biopsy can be significant, with the most notable complications being pneumothorax, pulmonary haemorrhage, and air embolism [1]. Of these complications, pneumothorax is the most common and carries a variable incidence rate ranging from 9% to 54% [1, 2]. The presence of a biopsy-induced pneumothorax is not necessarily an immediate, life-threatening complication [3]. Rather, the progression in the size of the pneumothorax is concerning, especially when it requires insertion of an intercostal drain to prevent the disastrous consequences of haemodynamic instability and cardiorespiratory arrest [4].

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Over recent years, a wide variety of procedural techniques and augmentations have been trialled to reduce its incidence [5]. Some interventions have included changes to patient positioning during the biopsy, post-procedural considerations such as avoiding straining and coughing, lying directly on the biopsy site, and the use of high flow intranasal oxygen [5].

Another category involves interventions at the biopsy site. Such examples include the use of autologous blood clots for both intrapleural and intraparenchymal occlusion [6]. Other techniques have involved tract occlusion using a variety of exogenous agents such as hydrogel, collagen plugs, and saline with varying degrees of success [7, 8, 9].

Gelfoam (Pfizer) is an embolising agent that has been proposed for use in biopsy tract occlusion due to its highly absorbent and expansible properties when applied to tissue. Furthermore, it is inexpensive and can be prepared as a slurry for injection with relative ease. There have been a limited number of studies evaluating its effectiveness as a tract occluding agent after lung biopsy. In 2014, Gelfoam was introduced to our institution for lung biopsy tract occlusion. This was after it was already being utilised by our interventional radiologists for tract occlusion of abdominal viscera biopsies. We postulated that tract occlusion would have a haemostatic effect in preventing the leakage of intrapulmonary air into the pleural cavity.

The aim of this retrospective study was to assess the efficacy of Gelfoam for the purpose of biopsy tract occlusion and the prevention of pneumothorax following CT-guided percutaneous lung biopsy.

MATERIALS AND METHODS

Due to the retrospective nature of the review, ethics approval for data acquisition was waived by our institution's ethics approval committee.

Patients

A retrospective review was conducted on all consecutive adult patients who underwent CT-guided lung biopsy at our institution, a tertiary referral centre, between 1st January 2009 and 30th August 2018.

Our department was adopting the technique of biopsy tract occlusion during the year of 2014 and its utilisation and documentation among our radiologists was variable in that particular year. For this reason, we excluded all cases performed between 1st January 2014 and 31st December 2014. Gelfoam was not administered in any patient before 1st January 2014 while all patients after 31st December 2014 were given Gelfoam for biopsy tract occlusion.

CT-guided lung biopsy

Informed written consent was obtained from all non-Gelfoam and Gelfoam patients immediately prior to performing CT-guided lung biopsy.

All procedures were performed evenly among five procedural radiologists who were experienced with CT-guided lung biopsies and administration of Gelfoam for tract occlusion.

Percutaneous lung biopsies were performed with the patient lying in supine, prone, or lateral decubitus position depending on the anatomical location of the lung lesion and optimal percutaneous approach. A 320 multi-slice CT (Aquilion, Canon Medical Systems, Tokyo) was used for all lung biopsy procedures during this period. Either CT fluoroscopy or a "step-and-shoot" method was used during the biopsy.

Core needle biopsy was performed using a 19-gauge outer core coaxial needle and a 20-gauge inner biopsy needle with either 1 cm or 2 cm throws (Quick-Core Biopsy Needle, Cook Medical). Specimens were sent to the histopathology department for further analysis.

Tract occlusion

A Gelfoam slurry was created prior to commencement of the procedure. The equipment used to create this slurry included two 10 ml syringes, a three-way tap, 10 ml of sterile saline, and a single piece of sterile Gelfoam sponge (Figure 1). One quarter of the sponge was cut into smaller 5 mm pieces and inserted into one of the syringes while the second syringe was filled with 10 ml of sterile saline (Figure 2). These syringes were connected using the three-way tap and mixed 10 times until a viscous slurry was produced (Figure 3).

This slurry was injected into the outer coaxial needle at the conclusion of the procedure while the needle was slowly withdrawn from the patient. The volume of Gelfoam slurry injected was dependent on the depth of the lesion.

Patients were asked to hold their breathing during this process to minimise the risk of needle shearing the lung parenchyma. In a small number of patients who received sedation or were unable to comply, breath holding was not mandatory and Gelfoam was injected at a point when the patient exhibited shallow respiration.

Apart from the introduction of Gelfoam slurry injection after 2014, there were no other changes to the biopsy technique before or after 2014.

Post-procedure Imaging

Imaging was performed at two periods as part of standard protocol. Firstly, a low dose CT scan was conducted immediately after tract occlusion to assess for the presence of acute complications including immediate pneumothorax and pulmonary haemorrhage (Figures 4a & 4b).

At the four-hour mark post-biopsy, inspiratory and expiratory plain chest radiographs were performed to assess for the presence of delayed pneumothorax or if there was progression of an existing pneumothorax.

Images were reviewed by a single radiologist prior to discharge.

Patients were kept in the department or admitted into hospital for an extended period of observation if there was progression of pneumothorax on serial imaging or if there was a pneumothorax of significant volume that required further intervention. An intercostal drain was considered for patients that either exhibited haemodynamic instability or developed an acute oxygen requirement, or if there was a significantly progressing pneumothorax.

Data acquisition

Data was collected retrospectively from our institution's electronic medical records. Patients' age, gender, existing diagnosis of Chronic Obstructive Pulmonary Disease (COPD), and radiological evidence of emphysema on pre-procedure CT imaging were recorded.

Details of the procedure including the anatomical location of lesions relative to their respective lobar anatomy and whether they were abutting the pleura (defined as 'peripheral' lesions) or not abutting the pleura (defined as 'non-peripheral' lesions) were recorded.

Primary Endpoints

The two endpoints for our study were the presence or absence of an immediate pneumothorax on CT, as well as the presence or absence of delayed pneumothorax on plain radiograph.

Second Endpoints

The secondary endpoint was to assess if any admissions were required for observation, insertion of an intercostal catheter, or if Video-Assisted Thoracic Surgery (VATS) was necessary in the management of an established or evolving pneumothorax.

Statistical analysis

All data were analysed using the SAS software version 9.4 (SAS Institute, Cary). Comparisons between groups (Gelfoam versus Non-Gelfoam) were made using the Student's T-test or Mann-Whitney U test as appropriate for continuous variables and chi-square or Fisher's exact test as appropriate for categorical variables. The risk factors for development of pneumothorax were determined using logistic regression with results reported as odds ratios (OR) and 95% confidence intervals (95% CI). All calculated p-values were two-tailed and $p < 0.05$ indicated statistical significance.

RESULTS

There were 367 consecutive adult patients who underwent CT-guided percutaneous lung biopsies at our institution during this study period.

We excluded 71 patients for the following reasons: abortion of the procedure before completion (14 patients), use of a different occluding agent other than Gelfoam (2 patients), lack of documentation regarding the use of Gelfoam (16 patients), and no post-procedure chest radiograph being performed (39 patients).

A final total of 296 consecutive adult patients were included for this retrospective analysis (mean age 70 years, age range 20-96 years, 54.5% male & 45.6% female) and are shown in table 1.

Patients with advanced features of pulmonary emphysema (bullae formation) were generally not candidates for lung biopsy due to the higher theoretical risk of pneumothorax. For this reason, the degree of radiological emphysematous changes between both cohorts were not stratified.

Non-Gelfoam cohort

From the period between 1st January 2009 and 31st December 2013, there were 126 patients referred for CT-guided lung biopsy who did not receive biopsy tract occlusion (mean age 71 years, age range 20-96, 53.2% male).

Based on their medical records, 44 patients (34.9%) had an underlying diagnosis of COPD.

Thirty-seven patients (29.4%) were non-smokers while 89 patients (70.6%) were either ex-smokers or active smokers.

In 42 patients (33.3%), emphysema was identified on CT prior to the biopsy attempt.

Gelfoam cohort

There were 170 patients who received Gelfoam between 1st January 2015 and 30th August 2018 (mean age 69 years, age range 27-96 years, 55.3% male).

A diagnosis of COPD was present in 45 patients (26.5%) according to their medical records.

Fifty-two patients (30.6%) were non-smokers while 118 patients (69.2%) were either ex-smokers or active smokers.

The rates of emphysema on CT were similar to the non-Gelfoam cohort with 55 patients having emphysema visualised on CT at the time of biopsy (32.4%).

Immediate pneumothorax

The rates of immediate pneumothorax are outlined in table 2. In the non-Gelfoam cohort, 53 pneumothoraces (42.1%) were detected immediately after the biopsy. This incidence rate was higher compared to that of the Gelfoam cohort which had 51 pneumothoraces (30.0%).

The incidence of an immediate pneumothorax identifiable on CT was 41% lower for patients who received Gelfoam compared to those who did not (OR 0.59, 95% CI 0.36-0.96, p = 0.032).

Delayed pneumothorax

The rates of delayed pneumothorax are shown in table 2. Among non-Gelfoam patients, 33 pneumothoraces (26.2%) were seen on chest radiograph four hours after the biopsy. Again,

the rates of pneumothorax were lower in the Gelfoam group with 32 pneumothoraces (18.8%) detected on plain radiographs.

However, there was no statistically significant difference in the likelihood of developing a delayed pneumothorax (OR 0.65, 95% CI 0.38-1.14, p = 0.13).

There were 20 immediate pneumothoraces that became undetectable on follow-up chest x-ray in the non-Gelfoam group, and 19 immediate pneumothoraces that also became undetectable on chest x-ray in the Gelfoam group.

Major pneumothoraces requiring intervention

The rates of major pneumothoraces needing further intervention are described in table 3.

Only two intercostal catheters were inserted in patients in the Gelfoam cohort (1.2%), but 10 were necessary in the non-Gelfoam group for the management of a significant pneumothorax (8.0%). One patient in the non-Gelfoam cohort ultimately required VATS pleurodesis. There were no deaths. This was a significant difference, with the odds of requiring an intervention (intercostal catheter insertion or VATS pleurodesis) being 86% lower in patients who received Gelfoam compared to those who did not (OR = 0.14, 95% CI 0.03-0.64, p = 0.012).

Comparing peripheral and non-peripheral lesions on the rates of pneumothorax

A comparison of peripheral and non-peripheral lesions is outlined in tables 4 and 5. When Gelfoam was used, the proportion of patients with immediate pneumothorax were similar for peripheral and non-peripheral lesions (28.8% and 30.9%, respectively). This is in comparison to the proportion of patients who did not receive Gelfoam – 28.8% in peripheral lesions but 56.7% in non-peripheral lesions.

A similar pattern was seen with the rates of delayed pneumothorax. In the Gelfoam group, this was 14.1% and 22.7% for peripheral and non-peripheral lesions, respectively. However, in the non-Gelfoam cohort, there was a difference in peripheral and non-peripheral lesions (13.5% and 40.0%, respectively).

There was no significant difference between peripheral and non-peripheral lesions in developing either immediate or delayed pneumothorax when Gelfoam was used for tract occlusion (p = 0.761 and p = 0.141, respectively).

However, when Gelfoam was not used, peripheral lesions were 69% less likely to cause an immediate pneumothorax (OR 0.31, 95% CI 0.15-0.65, p = 0.002) and 76% less likely to cause a delayed pneumothorax (OR 0.24, 95% CI 0.10-0.57, p = 0.001).

Comparison of presence and absence of emphysema on rates of pneumothorax

Rates of pneumothorax for patients with emphysema are listed in table 6 and 7. In the Gelfoam group, the proportion of patients developing immediate pneumothorax was similar in patients with emphysema compared to those without emphysema (27.3% and 31.3%, respectively). This trend was also seen with delayed pneumothoraces (18.2% in patients with emphysema and 19.1% in patients without emphysema).

When Gelfoam was not used, there was a difference between the two groups of patients. The proportion of patients with immediate pneumothorax was 52.4% in patients with emphysema and 36.9% in patients without emphysema. Rates of delayed pneumothorax were also higher in patients with emphysema (38.1%) compared to patients without emphysema (20.2%).

There was no significant difference in the likelihood of developing immediate pneumothorax ($p = 0.59$) or delayed pneumothorax ($p = 0.88$) when Gelfoam was used in both emphysematous and non-emphysematous groups.

In the non-Gelfoam group, the likelihood of developing an immediate pneumothorax was not significant ($p = 0.099$) but the chance of developing a delayed pneumothorax was increased by 2.4 times when emphysema was present (OR 2.43, 95% CI 1.07-5.50, $p = 0.034$).

Rates of admission

There were 28 necessary admissions in the non-Gelfoam group for observation or management of a major pneumothorax (22.2%). This is in contrast with 32 necessary admissions in the Gelfoam cohort (18.8%). However, there was no significant difference in hospital admission with the use of Gelfoam ($p = 0.47$).

DISCUSSION

Biopsy tract occlusion is a technique that has been used in recent times to reduce the risk of pneumothorax and pulmonary haemorrhage after percutaneous lung biopsies. In recent literature, a wide variety of agents such as hydrogel and collagen foam plugs have demonstrated that tract occlusion has some benefit in reducing the rates of developing a pneumothorax [9, 10, 11].

Gelfoam is a cheap, easily accessible, and simple agent to prepare and use for biopsy tract occlusion when compared to alternative methods such as autologous blood patching which is generally considered to be technically more challenging. The results from our study have highlighted several important observations supporting its use as a preferred tract occluding agent.

Firstly, this data demonstrates that Gelfoam was significant for reducing the likelihood of immediate pneumothorax but not for delayed pneumothorax. To the best of our knowledge, there has only been one other study in the literature assessing the efficacy of Gelfoam, but the authors did not demonstrate that Gelfoam resulted in a significant improvement in the overall rate of pneumothorax [8]. An explanation for this could be that, in our study, performing a post-procedure CT increased the diagnostic accuracy for the detection of pneumothorax in comparison to plain radiograph. There were equal proportions of small pneumothoraces seen on immediate post-biopsy CT that were not visualised on plain radiograph (37.7% in the non-Gelfoam group and 37.2% in the Gelfoam group), and this pattern would support this finding.

Secondly, when reviewing the two subsets of patients in our study (emphysema versus no emphysema and peripheral versus non-peripheral lesions), we were able to underscore several crucial findings that have not been reported in the literature. The anatomical location of the lesion (peripheral versus non-peripheral) was not a significant determinant for developing a pneumothorax when Gelfoam was used. However, when it was not used, lesion location significantly influenced the risk of pneumothorax – the odds of peripheral lesions being associated with pneumothoraces were significantly lower compared to non-peripheral lesions ($p < 0.05$). This risk of pneumothorax was not reproducible in the Gelfoam cohort. Previous studies have confirmed that biopsy distance is an established risk factor for developing a pneumothorax due to an increased amount of lung parenchyma being disrupted [12]. Therefore, it is likely that for deeper lung lesions requiring 'high-risk' and longer biopsy tracts, Gelfoam may have an important role in the prevention of pneumothorax.

Similarly, when comparing the subset of patients with and without CT evidence of emphysema, there was no significant difference in the odds of pneumothorax in patients who received Gelfoam. Interestingly, there was a 2.4 times increased likelihood of developing a delayed pneumothorax in emphysematous patients who did not receive Gelfoam ($p = 0.034$).

This suggests that, in patients with established radiological evidence of emphysema, Gelfoam may be critical for preventing pneumthoraces after biopsy.

Thirdly, our data has shown that Gelfoam was significant for the prevention of major pneumothoraces that would require further intervention, namely with an intercostal catheter. The study by Tran et al demonstrated a reduction in rates of intercostal catheters being inserted from 10.7% to 6.9% when Gelfoam was used [8]. In our study, we were able to validate this result with a reduction from 8% to 1.2% ($p = 0.012$). However, the authors of this study did not observe the beneficial effects of gelfoam among when performing a biopsy in patients with two important risk factors (non-peripheral lesions and lungs demonstrating emphysematous change) which we believe to be novel findings further supporting its use in clinical practice.

While Gelfoam slurry is readily available and easily prepared, some theoretical risks associated with Gelfoam have been proposed, including infection and venous or arterial embolism. However, given the very limited extent to which Gelfoam has been assessed in the current literature, it is difficult to ascertain a true risk profile for these complications. Anecdotal experience from this study suggests that these risks are relatively rare as none of these complications occurred in our cohort of 170 patients who received Gelfoam. Although there is a theoretical risk of embolisation into the pulmonary arterial or venous circulation, pulmonary vessels are commonly avoided during biopsy needle insertion. Furthermore, the amount of gelfoam slurry injected through the coaxial needle is small. Additionally, its use in the therapeutic embolisation of bleeding vessels demonstrates that the effects of embolisation are not permanent and can last only for several weeks to months [13].

LIMITATIONS

The limitations from our study were a relatively small number of patients studied in a single institution. Furthermore, this study did not evaluate other complications following lung biopsy, including pulmonary haemorrhage.

The preliminary findings from our study would benefit from a future prospective study to assess all potential complications of percutaneous lung biopsy with a larger number of patients recruited and randomized for the use of Gelfoam and no Gelfoam – equally distributed between the procedural radiologists.

CONCLUSION

CT-guided percutaneous lung biopsy is an important procedure for the diagnosis and histological grading of suspicious lung lesions. However, pneumothorax is a common complication after lung biopsy, and different techniques have been suggested as methods for reducing this incidence rate. Our study shows that Gelfoam may be a suitable and readily available solution for minimising the risk of pneumothorax in patients with non-peripheral lung lesions and in patients with radiological evidence of emphysema. Without Gelfoam, there is a significant difference in the incidence of pneumothorax between peripheral and non-peripheral lesions (69% less likely for peripheral lesions) and between emphysematous and non-emphysematous lungs (2.4 time more likely for emphysematous lungs). These differences are not present when Gelfoam was introduced. More importantly, there is an 86% reduction in the likelihood of clinically significant pneumothorax requiring the insertion of an intercostal catheter.

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TABLES

Table 1. Patient Demographics

	No Gelfoam (n = 126)	**Gelfoam (n = 170)**
Age in years, mode (standard deviation)	71 (13)	69 (12)
Male (%)	53.2	55.3
History of COPD, n (%)	44 (34.9)	45 (26.5)

Smoking Status:		
- **Non-smoker (%)**	37 (29.4)	52 (30.6)
- **Ex-smoker (%)**	24 (19.0)	41 (24.1)
- **Active smoker (%)**	65 (51.6)	76 (44.7)
Previous lung surgery (%)	1 (0.8)	4 (2.4)
Previous lung biopsy (%)	6 (4.8)	10 (5.9)
Evidence of emphysema on pre-procedure CT (%)	42 (33.3)	55 (32.4)
Number of passes, median (mean)	2 (2.2)	3 (3)

Table 2. Rates of Immediate and Delayed Pneumothorax

	Immediate pneumothorax	**No immediate pneumothorax**	**Total**
Gelfoam used	51	119	170
No Gelfoam used	53	73	126
OR = 0.59 (p = 0.032)			

	Delayed pneumothorax	**No delayed pneumothorax**	**Total**
Gelfoam used	32	138	170
No Gelfoam used	33	93	126
OR = 0.65 (p = 0.132)			

OR odds ratio

Table 3. Rates of Patients Requiring Intervention By Insertion of An Intercostal Catheter

	Intervention required	**No intervention required**	**Total**

Gelfoam used	2	168	170
No Gelfoam used	10	116	126
OR = 0.14 (p = 0.012)			

OR odds ratio

Table 4. Rates of Immediate Pneumothorax in Peripheral Versus Non-peripheral Lesions

	No Gelfoam used		
	Immediate pneumothorax	**No immediate pneumothorax**	**Total**
Peripheral	19	47	66
Non-peripheral	34	26	60
OR = 0.31 (p = 0.002)			
	Gelfoam used		
	Immediate pneumothorax	**No immediate pneumothorax**	**Total**
Peripheral	21	52	73
Non-peripheral	30	67	97
OR = 0.90 (p = 0.761)			

OR odds ratio

Table 5. Rates of Delayed Pneumothorax in Peripheral Versus Non-peripheral Lesions

	No Gelfoam used		
	Delayed pneumothorax	**No delayed pneumothorax**	**Total**
Peripheral	9	57	66
Non-peripheral	24	36	60
OR = 0.24 (p = 0.001)			
	Gelfoam used		

	Delayed pneumothorax	No delayed pneumothorax	Total
Peripheral	10	63	73
Non-peripheral	22	75	97
OR = 0.54 (p = 0.141)			

OR odds ratio

Table 6. Rates of Immediate Pneumothorax in Emphysematous Versus Non-emphysematous Patients

	No Gelfoam used		
	Immediate pneumothorax	**No immediate pneumothorax**	**Total**
Emphysema	22	20	42
No emphysema	31	53	84
OR = 1.88 (p = 0.099)			
	Gelfoam used		
	Immediate pneumothorax	**No immediate pneumothorax**	**Total**
Emphysema	15	40	55
No emphysema	36	79	115
OR = 0.82 (p = 0.592)			

OR odds ratio

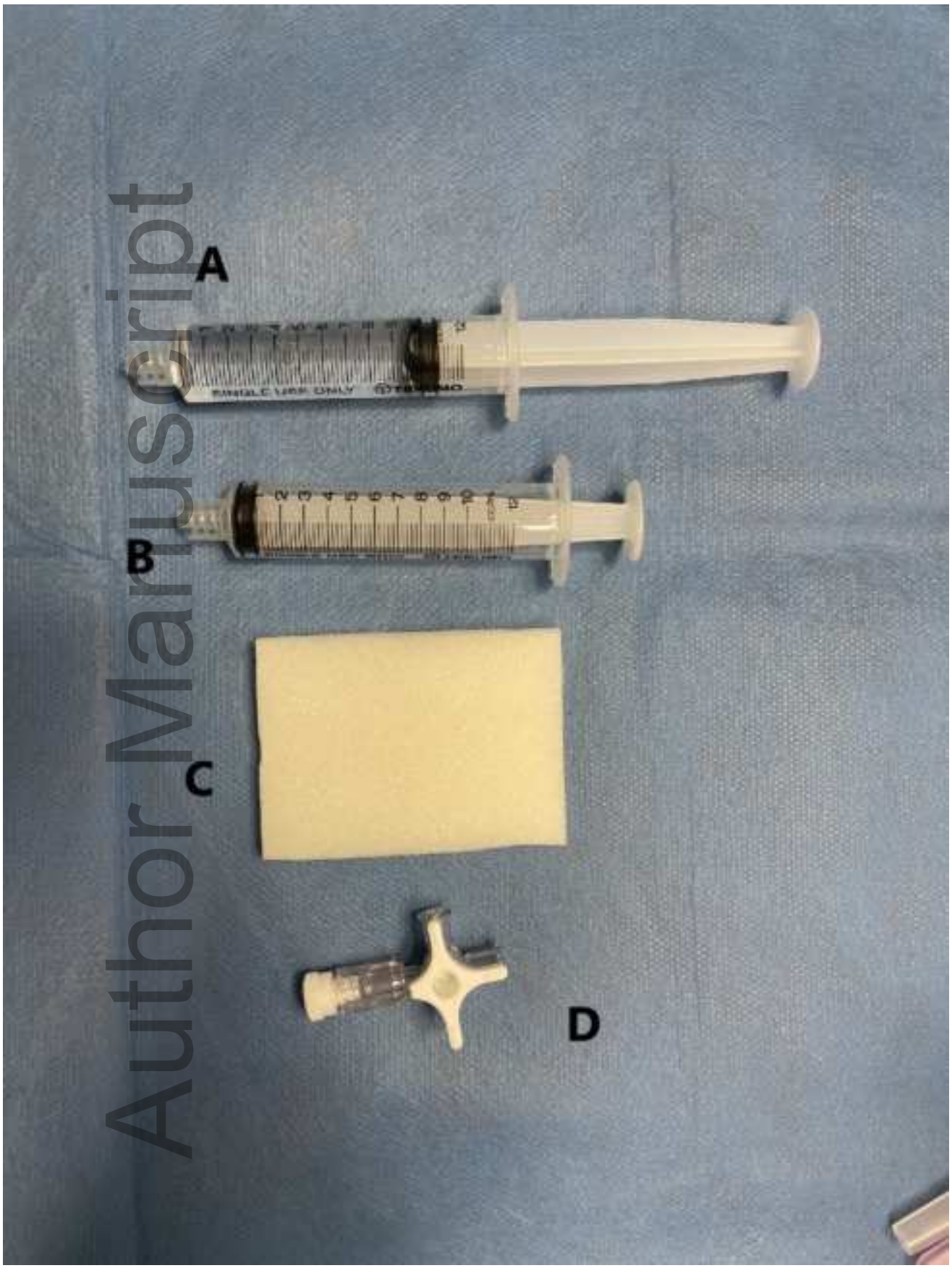
Table 7. Rates of Delayed Pneumothorax in Emphysematous Versus Non-emphysematous Patients

	No Gelfoam used		
	Delayed pneumothorax	**No delayed pneumothorax**	**Total**

Emphysema	16	26	42
No emphysema	17	67	84
OR = 2.43 (p = 0.034)			

Gelfoam used			
	Delayed pneumothorax	**No delayed pneumothorax**	**Total**
Emphysema	10	45	55
No emphysema	22	93	115
OR = 0.94 (p = 0.882)			

OR odds ratio



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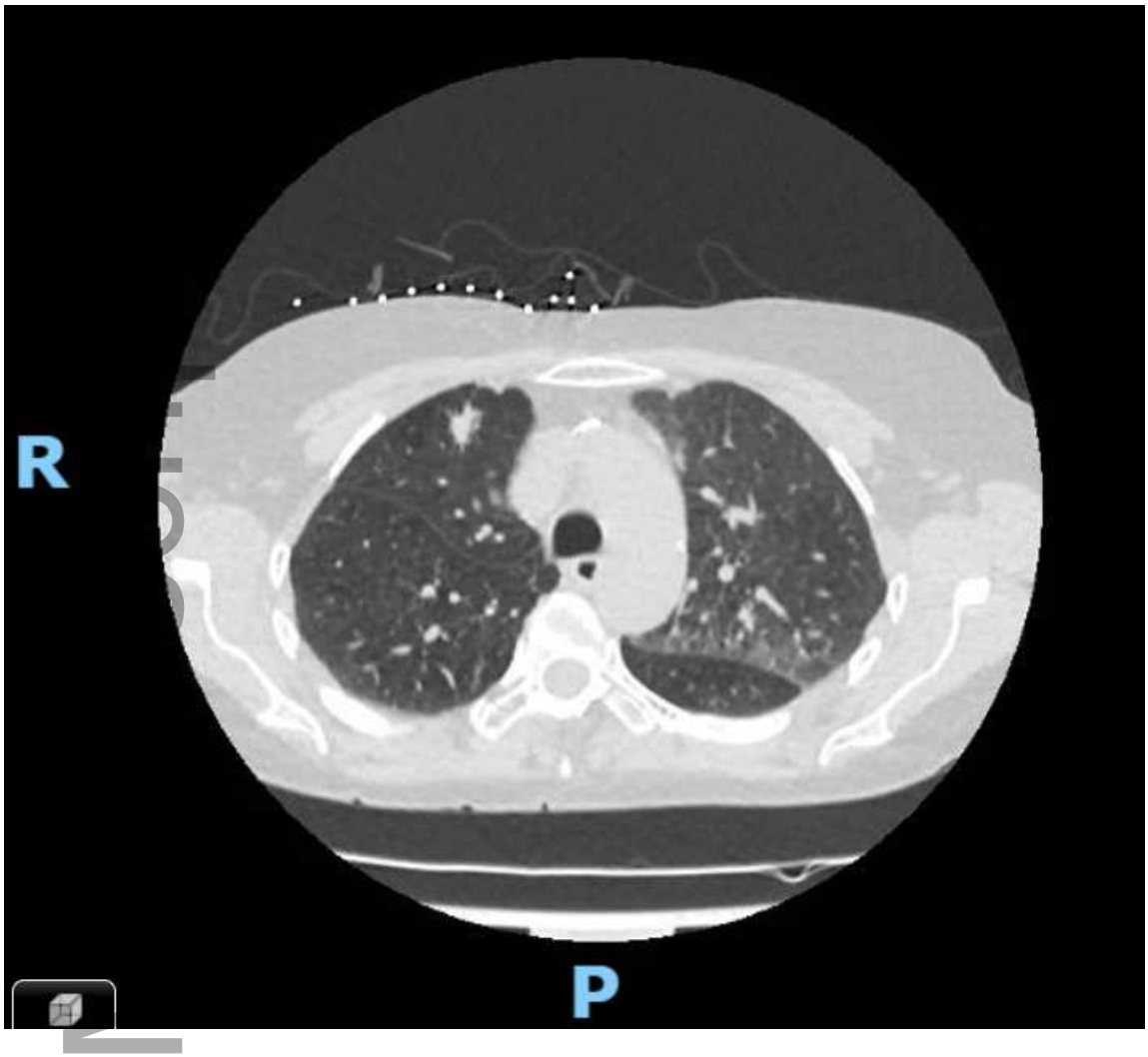

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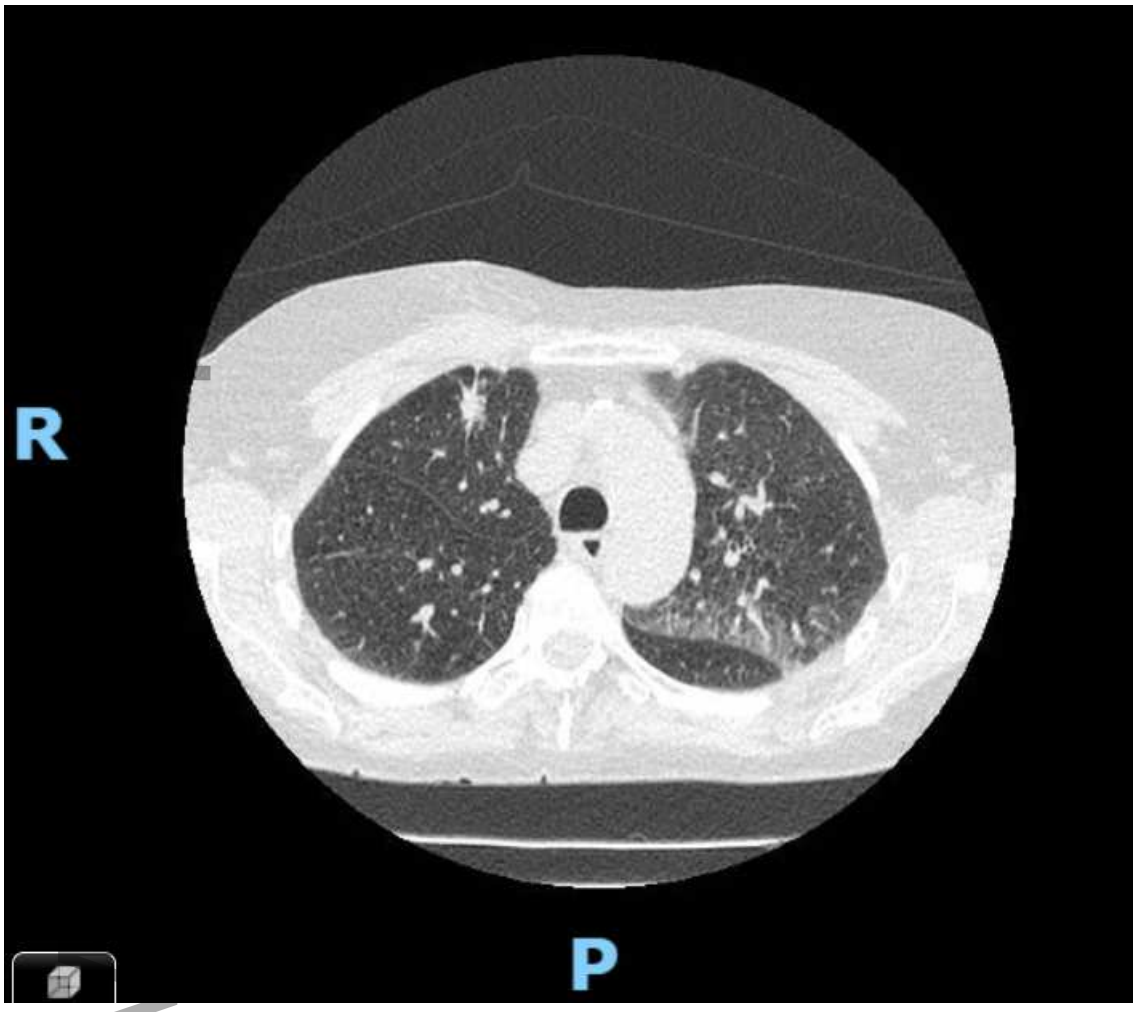

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