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Post-Biopsy Pneumothorax Incidence in Patients Treated with Biosentry™ Plug Device

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ABSTRACT

Introduction. This study aimed to determine if the Biosentry™ Plug Device (BPD), a prophylactic sealant used to prevent pneumothorax after lung biopsies, reduced post-lung biopsy pneumothorax rates, and other complications compared to no device utilization.

Methods. This single institution, retrospective cohort study included patients who received a lung biopsy in the Department of Interventional Radiology from May 1, 2015 to August 31, 2017. Data such as sex, race, ethnicity, chronic obstructive pulmonary disease status, degree of lung bullae if present, smoking status, and use of BPD were recorded. Decisions to use BPD were based on operator preference. A chi squared analysis was used with a p value greater than 0.05 considered significant.

Results. The study included 521 patients who underwent a lung biopsy during the study timeframe. Of these, 74 (14.2%) received the BPD, while 447 (85.8%) did not. One-hundred ninety (36.4%) had a pneumothorax within one month of the lung biopsy. Of the total 190 that experienced pneumothorax, 36.7% of non-BPD biopsies resulted in pneumothorax, while 35.1% of BPD biopsies resulted in pneumothorax (p value = 0.7970; degrees of freedom = 1).

Conclusions. These findings indicated that BPD may not reduce pneumothorax incidence nor limit the severity of complications in patients.
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INTRODUCTION

Transcutaneous lung biopsies, performed in Interventional Radiology, are the gold standard for diagnosing suspected lung malignancies that cannot be reached bronchoscopically.[1] This type of biopsy is important both for diagnosis and detection of tumor receptor type, which can influence treatment options.[2] Pneumothorax is a common complication that occurs after 8 - 54% of all lung biopsies.[3] Many pneumothoraces are small and can resolve with time, although others can require additional clinical monitoring, hospital admission, chest tube placement, or surgery. Therefore, reducing the rate of pneumothoraces could improve patient outcomes and decrease cost.

Most lung biopsies require immediate pre- and post-biopsy computed tomography (CT) chest scans to assess for biopsy feasibility and complications. A treatment for pneumothoraces is frequently chest tube placement. Published rates of chest tube placement vary between 2 - 18% of patients who have had a pneumothorax post-biopsy, which requires hospital admission.[5-8]

At the end of the biopsy procedure, a Biosentry™ Plug (BPD; AngioDynamics, Latham, New York, USA), a hydrogel plug that expands and forms an airtight seal in the lung pleura and cutaneous biopsy tract, can be placed where the biopsy was performed to prevent pneumothoraces from occurring.[4] In study, the BPD demonstrated a 16% absolute risk reduction in pneumothorax rate post-biopsy, although the study was not powered to analyze the association of the use of the plug and other important outcomes, such as admission rates, chest tube placements, or cardiothoracic surgery consultation. Another study documented a significant reduction in post-procedure chest tube insertions associated with the BPD and a near significant reduction in length of hospital stay.[9] Few studies have examined the benefits of BPD on preventing post-biopsy pneumothorax and chest tube placement, but no other studies have focused on admission and surgery consult rates.

This study aimed to determine whether the BPD is efficacious in decreasing post-lung biopsy pneumothorax rates compared to cases where no device was used at one institution. Secondary aims were to determine whether inpatient admission, chest tube placement, and surgery consultation rates differ between patients who received the BPD and those who did not.

METHODS

Institutional review board approval was obtained, and patient medical records were reviewed in compliance with Health Care Portability and Accountability Act guidelines. This retrospective cohort study included patients who received a lung biopsy from May 1, 2015 to August 31, 2017 and had at least one follow-up image after biopsy to document presence or lack of pneumothorax. Patients who met any of the following criteria were excluded from this study: were under 18 years of age, had an existing pneumothorax when undergoing the lung biopsy, had no available post-biopsy imaging, or had a history of extensive bullous emphysema.

The decision to use BPD was determined by the attending physician's preference. Four interventional radiologists conducted the biopsies with 8 - 24 years of experience. The BPD was used according to its instructions for use.

Patient demographics, clinical history (chronic obstructive pulmonary disease (COPD), bulla, and smoking status), and imaging information were obtained from the electronic medical record and Picture Archiving and Communications Systems (PACS). Pre- and post-procedure CT and chest radiographs were analyzed and clinical notes were checked for mention of the presence of a pneumothorax, COPD, and bullous disease as per regular post-biopsy protocol. Post-procedure complications that occurred within one month of the biopsy and resulted in pneumothorax, surgical consults, chest tube placements, and admissions were recorded.

Patients were grouped based on use of BPD and a chi-squared test of independence analysis was conducted to determine the association of pneumothorax incidence and BPD use. SAS 9.4 was the analytic platform used to analyze the data sets. A p value of greater than 0.05 was considered statistically significant.

RESULTS

Six-hundred forty-eight patients initially were identified as having undergone a lung biopsy and 127 were excluded for having a pre-existing pneumothorax, no available post-biopsy imaging, or having a history of extensive bullous emphysema. In total, 521 patients were included in the study. Of these, 74 (14.2%) received the Biosentry™ Plug device, while 447 (85.8%) did not. Other patient characteristics are found on Table 1. Two-hundred eleven patients (40.5%) had some degree of COPD. Five patients (< 1%) had some history of lung bulla. Three-hundred eighty-four patients (73.7%) had a smoking history.

One-hundred ninety (36.4%) suffered a pneumothorax within one month of the lung biopsy. Of these 190, 187 (98.4%) had pneumothorax occur within one week and 185 (97.4%) occurred within 24 hours of biopsy. Of the total 190 that experienced pneumothorax, 36.7% of non-BPD biopsies resulted in pneumothorax, while 35.1% of BPD biopsies resulted in pneumothorax (p value = 0.7970; degrees of freedom = 1; Table 2).

Of the 190 pneumothorax patients, 48 (25.3%) were admitted as inpatients due to pneumothorax. There was no difference in admission rates between those who did and did not have the device (p = 0.5555). Fifty-three (27.9%) patients had chest tubes inserted. There was also no statistical difference between those that did and did not have the device (p = 0.2121). Of the 521 total subjects, 17 (3.3%) required a cardiothoracic surgery consultation and no statistical difference was found between the two groups who did and did not have the device (p = 0.4887; Table 3).

DISCUSSION

This study found no association in BPD use and pneumothorax rates within one month of biopsy. Additionally, the data showed no significant differences in rates of chest tube placement, admission for pneumothorax, or cardiothoracic surgery consultations sought between those who received the BPD and those who did not. However, the rates were lower in the BPD group for all outcomes studied (36.7% versus 35.1% for overall incidence of pneumothorax, 28.7% versus 23.1% for chest tube placement, 26.8% versus 15.4% for admission rate, and 3.6% versus 1.4% for cardiothoracic consults). Future studies with larger sample sizes should explore whether the BPD lowers rates for these two complications.

Though this study did not find a statistically significant difference in outcomes between those who received and did not receive the BPD, a lower rate was seen for the BPD group in all outcomes studied including pneumothorax, chest tube placement, admission rates, and cardiothoracic consults. This trend compared with the findings from other studies. Of four other studies that explored the efficacy of BPD in preventing pneumothorax, three[4,9,10] found a significant decrease in post-biopsy pneumothorax and all studies noted significant decreases in chest tube insertion for patients treated with BPD.[4,9,10,11] Like our study, Grage et al.[11] also found that there was no statistical significance in pneumothorax reduction with BPD use. An increase in sample size for this study, particularly the group that received BPD, may have resulted in different findings.

Table 1. Patient characteristics.

	No Biosentry™ Plug used 447 (85.8%)	Biosentry™ Plug used 74 (14.2%)	All 521 (100%)
Age, mean (SD)	65.4 (12.3)	67.3 (12.1)	65.7 (12.3)
Sex, n (%)			
Male	234 (52.35%)	36 (48.65%)	270 (51.82%)
Female	213 (47.65%)	38 (51.35%)	251 (48.18%)
Race, n (%)			
American Indian/ Alaskan Native	2 (0.45%)	0 (0.00%)	2 (0.38%)
Asian/Pacific Islander	1 (0.22%)	1 (1.35%)	2 (0.38%)
Black	34 (7.61%)	7 (9.46%)	41 (7.87%)
White	385 (86.13%)	61 (82.43%)	446 (85.60%)
Other	5 (1.12%)	1 (1.35%)	6 (1.15%)
Unknown	20 (4.47%)	4 (5.41%)	24 (4.61%)
Ethnicity, n (%)			
Non-Hispanic/Latino	433 (96.87%)	73 (98.65%)	506 (97.12%)
Hispanic/Latino	12 (2.68%)	1 (1.35%)	13 (2.50%)
Unknown	2 (0.45%)	0 (0.00%)	2 (0.38%)
COPD status, n (%)			
None	262 (58.61%)	48 (64.86%)	310 (59.50%)
Mild	103 (23.04%)	13 (17.57%)	116 (22.26%)
Moderate	67 (14.99%)	10 (13.51%)	77 (14.78%)
Severe	15 (3.36%)	3 (4.05%)	18 (3.45%)
Bulla status, n (%)			
Unknown	1 (0.22%)	0 (0.00%)	1 (0.19%)
None	443 (99.11%)	73 (98.65%)	516 (99.04%)
Mild	3 (0.67%)	1 (1.35%)	4 (0.77%)
Moderate	0 (0.00%)	0 (0.00%)	0 (0.00%)
Severe	0 (0.00%)	0 (0.00%)	0 (0.00%)
Smoking status at time of biopsy, n (%)			
Current	103 (23.04%)	11 (14.86%)	114 (21.88%)
Former	228 (51.01%)	42 (56.76%)	270 (51.82%)
Never	116 (25.95%)	21 (28.38%)	137 (26.30%)

Table 2. Pneumothorax rates with and without Biosentry™ plug device use.

	No Biosentry™ Plug used 447 (85.8%)	Biosentry™ Plug used 74 (14.2%)	p Value	Degrees of freedom
Is pneumothorax present within one month after biopsy?*			0.7970	1
Yes	164 (36.69%)	26 (35.14%)		
No	283 (63.31%)	48 (64.86%)		

*97.4% of pneumothoraxes occurred within 24 hours of biopsy.

Table 3. Differences in pneumothorax inpatient admission, chest tube placement, and cardiothoracic surgery consultation related to Biosentry™ Plug Device use.*

	No Biosentry™ Plug used	Biosentry™ Plug used	p Value
Was a chest tube placed within one month after biopsy? (After pneumothorax)			0.5555
Yes	47 (28.66%)	6 (23.08%)	
No	117 (71.34%)	20 (76.92%)	
Was patient admitted because of the pneumothorax?			0.2121
Yes	44 (26.83%)	4 (15.38%)	
No	120 (73.17%)	22 (84.62%)	
Was cardiothoracic surgery consulted?			0.4887**
Yes	16 (3.58%)	1 (1.35%)	
No	431 (96.42%)	73 (98.65%)	

*The initial two questions include the 190 patients with pneumothorax, while question three incorporates all 512 patients.
**Fisher's exact test was used because of small expected cell count.

Limitations to this study included a lack of randomization and unequal sample sizes in the BPD and non-BPD groups. Another limitation may be that different patient characteristics may have played a role in who received the BPD and who did not, biasing the results. However, the decision to use the BPD was not based on patient characteristics, but on operator preference (two operators preferred to use the device and two did not).

This study found that there was no statistically significant association between BPD use and pneumothorax and chest tube placement rates within one month of biopsy. Though this was on trend with other studies, future studies may want to explore use of the BPD further.

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