AUTOLOGOUS BLOOD PATCH INJECTION VERSUS HYDROGEL PLUG IN CT-GUIDED LUNG BIOPSY: A PROSPECTIVE RANDOMIZED TRIAL

-CRITICAL APPRAISAL-

Presenter: Dr Ahmad Aizuddin Mohamad Jamali

Lecturer in charge: Dr Chandran Nadarajan

Date : 2/8/2021

Radiology

ORIGINAL RESEARCH • VASCULAR AND INTERVENTIONAL RADIOLOGY

Autologous Blood Patch Injection versus Hydrogel Plug in CT-guided Lung Biopsy: A Prospective Randomized Trial

Majid Maybody, MD • Nadim Muallem, MD • Karen T. Brown, MD • Chaya S. Moskowitz, PhD • Meier Hsu, MS • Christina L. Zenobi • Marwah Jihad • George I. Getrajdman, MD • Constantinos T. Sofocleous, MD, PhD • Joseph P. Erinjeri, MD, PhD • Anne M. Covey, MD • Lynn A. Brody, MD • Hooman Yarmohammadi, MD • Amy R. Deipolyi, MD, PhD • Yolanda Bryce, MD • William Alago, MD • Robert H. Siegelbaum, MD • Jeremy C. Durack, MD, MS • Adrian J. Gonzalez-Aguirre, MD • Etay Ziv, MD, PhD • F. Edward Boas, MD, PhD • Stephen B. Solomon, MD

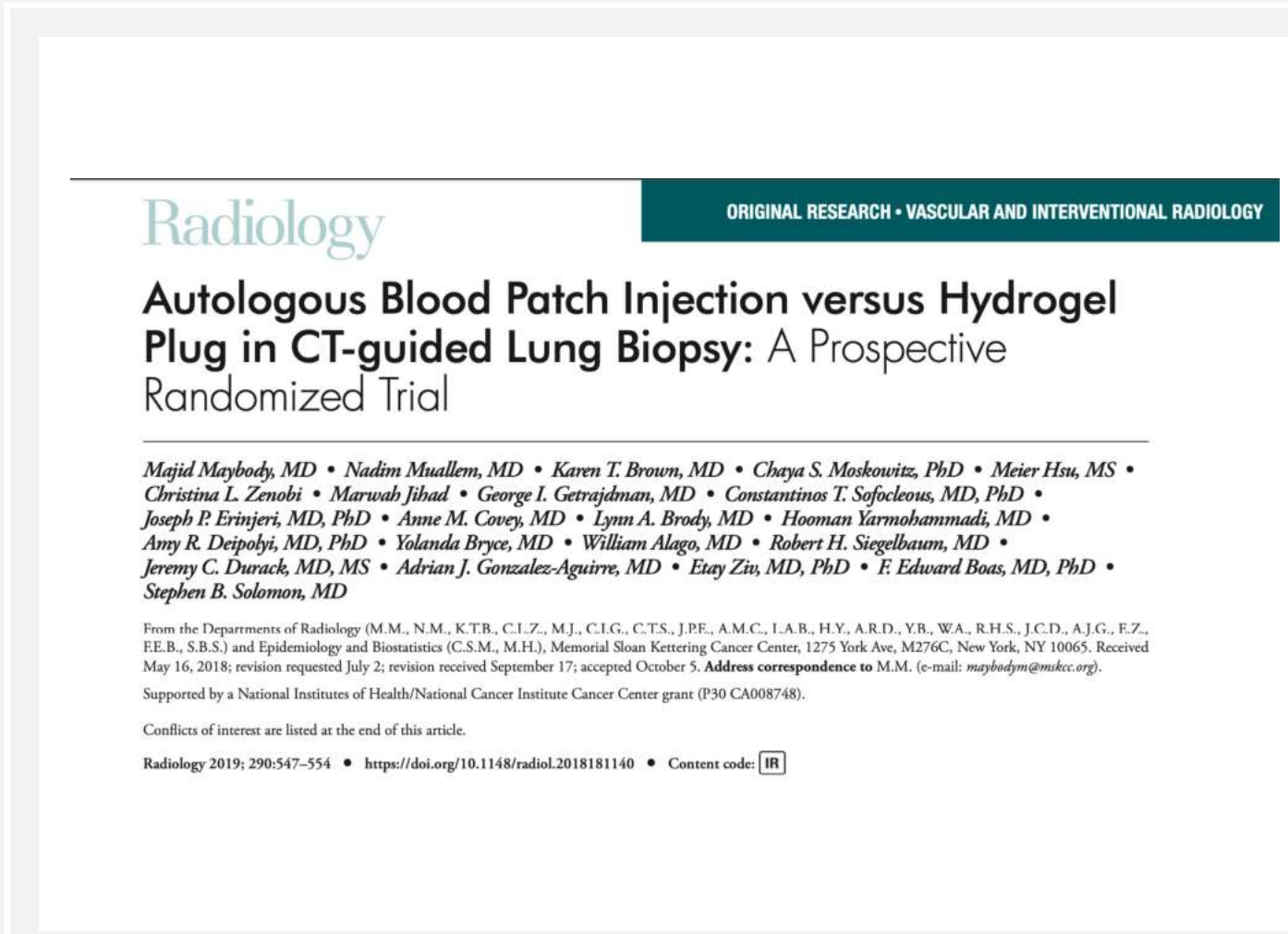
From the Departments of Radiology (M.M., N.M., K.T.B., C.I..Z., M.J., C.I.G., C.T.S., J.P.F., A.M.C., L.A.B., H.Y., A.R.D., Y.B., W.A., R.H.S., J.C.D., A.J.G., E.Z., F.E.B., S.B.S.) and Epidemiology and Biostatistics (C.S.M., M.H.), Memorial Sloan Kettering Cancer Center, 1275 York Ave, M276C, New York, NY 10065. Received May 16, 2018; revision requested July 2; revision received September 17; accepted October 5. **Address correspondence to** M.M. (e-mail: *maybodym@mskcc.org*).

Supported by a National Institutes of Health/National Cancer Institute Cancer Center grant (P30 CA008748).

Conflicts of interest are listed at the end of this article.

Radiology 2019; 290:547–554 • https://doi.org/10.1148/radiol.2018181140 • Content code: IR

- Recent publication
  - Received :16th May 2018
  - Accepted : 5th October 2018
  - Published : February 2019
- Good impact factor (3.12)
- Original article
- Clearly describe title



Radiology

ORIGINAL RESEARCH • VASCULAR AND INTERVENTIONAL RADIOLOGY

Autologous Blood Patch Injection versus Hydrogel Plug in CT-guided Lung Biopsy: A Prospective Randomized Trial

Majid Maybody, MD • Nadim Muallem, MD • Karen T. Brown, MD • Chaya S. Moskowitz, PhD • Meier Hsu, MS • Christina L. Zenobi • Marwah Jihad • George I. Getrajdman, MD • Constantinos T. Sofocleous, MD, PhD • Joseph P. Erinjeri, MD, PhD • Anne M. Covey, MD • Lynn A. Brody, MD • Hooman Yarmohammadi, MD • Amy R. Deipolyi, MD, PhD • Yolanda Bryce, MD • William Alago, MD • Robert H. Siegelbaum, MD • Jeremy C. Durack, MD, MS • Adrian J. Gonzalez-Aguirre, MD • Etay Ziv, MD, PhD • F. Edward Boas, MD, PhD • Stephen B. Solomon, MD

From the Departments of Radiology (M.M., N.M., K.T.B., C.I.Z., M.J., C.I.G., C.T.S., J.P.E., A.M.C., L.A.B., H.Y., A.R.D., Y.B., W.A., R.H.S., J.C.D., A.J.G., F.Z., F.E.B., S.B.S.) and Epidemiology and Biostatistics (C.S.M., M.H.), Memorial Sloan Kettering Cancer Center, 1275 York Ave, M276C, New York, NY 10065. Received May 16, 2018; revision requested July 2; revision received September 17; accepted October 5. **Address correspondence to** M.M. (e-mail: *maybodym@mskcc.org*).

Supported by a National Institutes of Health/National Cancer Institute Cancer Center grant (P30 CA008748).

Conflicts of interest are listed at the end of this article.

Radiology 2019; 290:547–554 • https://doi.org/10.1148/radiol.2018181140 • Content code: IR

Majid Maybody, MD • Nadim Muallem, MD • Karen T. Brown, MD • Chaya S. Moskowitz, PhD • Meier Hsu, MS • Christina L. Zenobi • Marwah Jihad • George I. Getrajdman, MD • Constantinos T. Sofocleous, MD, PhD • Joseph P. Erinjeri, MD, PhD • Anne M. Covey, MD • Lynn A. Brody, MD • Hooman Yarmohammadi, MD • Amy R. Deipolyi, MD, PhD • Yolanda Bryce, MD • William Alago, MD • Robert H. Siegelbaum, MD • Jeremy C. Durack, MD, MS • Adrian J. Gonzalez-Aguirre, MD • Etay Ziv, MD, PhD • F. Edward Boas, MD, PhD • Stephen B. Solomon, MD

From the Departments of Radiology (M.M., N.M., K.T.B., C.L.Z., M.J., G.I.G., C.T.S., J.P.E., A.M.C., L.A.B., H.Y., A.R.D., Y.B., W.A., R.H.S., J.C.D., A.J.G., F.Z., F.E.B., S.B.S.) and Epidemiology and Biostatistics (C.S.M., M.H.), Memorial Sloan Kettering Cancer Center, 1275 York Ave, M276C, New York, NY 10065. Received May 16, 2018; revision requested July 2; revision received September 17; accepted October 5. **Address correspondence to** M.M. (e-mail: *maybodym@mskcc.org*).

- Well written the authors involved.
- Institution and unit involve clearly written.
- Single center study

ABSTRACT

- Clearly written aim

Purpose: To compare the effect of autologous blood patch injection (ABPI) with that of a hydrogel plug on the rate of pneumothorax at CT-guided percutaneous lung biopsy.

Materials and Methods: In this prospective randomized controlled trial (*https://ClinicalTrials.gov*, NCT02224924), a noninferiority design was used for ABPI, with a 10% noninferiority margin when compared with the hydrogel plug, with the primary outcome of pneumothorax rate within 2 hours of biopsy. A type I error rate of 0.05 and 90% power were specified with a target study population of 552 participants (276 in each arm). From October 2014 to February 2017, all potential study participants referred for CT-guided lung biopsy (n = 2052) were assessed for enrollment.

Study design, method, duration, tools, samples : clearly stated

Results were concisely concluded – measured variables with statistical analysis and significance

Results: The data safety monitoring board recommended the trial be closed to accrual after an interim analysis met prespecified criteria for early stopping based on noninferiority. The final study group consisted of 453 participants who were randomly assigned to the ABPI (n = 226) or hydrogel plug (n = 227) arms. Of these, 407 underwent lung biopsy. Pneumothorax rates within 2 hours of biopsy were 21% (42 of 199) and 29% (60 of 208); chest tube rates were 9% (18 of 199) and 13% (27 of 208); and delayed pneumothorax rates within 2 weeks after biopsy were 1.4% (three of 199) and 1.5% (three of 208) in the ABPI and hydrogel plug arms, respectively.

Conclusion: Autologous blood patch injection is noninferior to a hydrogel plug regarding the rate of pneumothorax after CT-guided percutaneous lung biopsy.

Precise conclusion

Keywords not provided.

INTRODUCTION

Percutaneous image-guided needle biopsy of the lung is a well-established and accurate method used to diagnose pulmonary lesions with 93%–95% diagnostic accuracy (1–3). The demand for lung biopsy is increasing, given the increasing rates of lung cancer, the higher detection rate of asymptomatic lung nodules, and the demand for tissue for new molecular profiling and genomic analysis (4).

The most common complication of percutaneous lung biopsy is pneumothorax. Most series report incidences of 20%–25% for pneumothorax and 4%–8% for chest tube placement, although rates as high as 47% and 22%, respectively, have been reported (5–19). The economic burden of a complicated lung biopsy is substantial, with increased costs of 300%–400% (20,21). There is great interest in reducing the occurrence of iatrogenic pneumothorax, which should translate into a lower rate of chest tube placement and subsequent hospital admission.

Pneumothorax is caused by air leaking out of the lung through the needle puncture site at the visceral pleura once the needle is removed (22,23). Several studies have shown that sealing the pleural puncture site with a variety of materials, including autologous blood, hydrogel plug, fibrin glue, gelatin sponge slurry or plug, or saline, reduces the risk of pneumothorax and chest tube placement (9–19). Two of the best-studied sealants are autologous blood patch injection (ABPI) and a manufactured hydrogel plug called BioSentry, which was formerly known as Bio-Seal (Surgical Specialties, Wyoming, Pa), with proven efficacy based on prospective randomized studies (13,14). ABPI uses the participant's own blood to seal the biopsy track. The hydrogel plug expands on contact with moisture and seals the biopsy track.

We hypothesized that ABPI is noninferior to a hydrogel plug regarding the rate of iatrogenic pneumothorax in CT-guided needle biopsy of the lung. We conducted a prospective single-center randomized controlled trial to test this hypothesis.

- Clearly written introduction
- Prevalence and burden of the pneumothorax explained.
- Brief introduction on pneumothorax.
- Current practice and previous study explained.
- Hypothesis
- Purposed and benefit of current study are not included.
- Previous uses of ABPI not explained

MATERIALS AND METHOD

DESIGN

Study protocol compliance to the regulatory body

Clearly stated study design

Noninferiory trial

Well define control group.

Data collection interval explained.

Our institutional review board approved this prospective investigator-initiated study. Written informed consent was obtained from all participants. Study data were collected in a database that was compliant with the Health Insurance Portability and Accountability Act. The authors had full control over data and information submitted for publication.

In this prospective randomized controlled trial (*https://ClinicalTrials.gov*, NCT02224924), we tested the noninferiority of ABPI as compared with a hydrogel plug with respect to the rate of iatrogenic pneumothorax within 2 hours of CT-guided percutaneous lung biopsy. A noninferiority margin of 10% was used based on historic clinical data of a relatively constant pneumothorax rate of 20%–25% and the results of controlled studies where the difference in the rate of pneumothorax between the two arms ranged from 7.3% to 38% (average, 17.7%; median, 14%) (9–19). The secondary objectives were to compare ABPI and hydrogel plug regarding *(a)* the rate of iatrogenic pneumothorax within 2 hours of CT-guided lung biopsy on a per-protocol analysis (without intraoperative exclusions), *(b)* the rate of chest tube placement for pneumothorax up to 2 weeks after lung biopsy, and *(c)* the rate of delayed pneumothorax up to 2 weeks after lung biopsy. In addition, the Data Safety Monitoring Board (DSMB) recommended an analysis to compare the length of hospital stay after pneumothorax between the two

Participants

Eligibility was not restricted based on age, sex, race, body habitus, history of smoking or emphysema, indication for biopsy, number of specimens required, or target lesion characteristics, such as size, location, imaging appearance, or planned participant positioning (Table E1 [online]). No attempt was made to grade emphysema, and only biopsies in which the needle path traversed the lung parenchyma with obvious areas of low attenuation (labeled here as *bullae* and *blebs*) were ineligible (Fig 1). The hydrogel plug was approved by the Food and Drug Administration to be administered only via a 19-gauge Angiotech introducer needle (Argon Medical Devices, Athens, Tex). All participants in whom the hydrogel plug could not be used were excluded at screening. Beginning in October 2014, all participants referred for percutaneous CT-guided lung biopsy were screened. Eighteen board-certified fellowship-trained interventional radiologists participated in both enrollment and biopsy processes (N.M., H.Y., A.R.D, Y.B., A.J.G., E.Z., and F.E.B. had 2–5 years of experience; J.PE. and R.H.S. had 5–10 years of experience; M.M., K.T.B., G.I.G., C.T.S., A.M.C., L.A.B., W.A., J.C.D., and S.B.S. had more than 10 years of experience). Screening and enrollment were performed at the dedicated outpatient clinic of the interventional radiology service. Medical records and imaging studies were screened by a research study assistant (C.L.Z., M.J.; each with 2–4 years of experience) and at least one interventional radiologist. Medical records were reviewed to explore any history of prior ipsilateral chest interventions. CT images were reviewed at a picture archiving and communication system workstation to identify the safest and most practical percutaneous biopsy approach. Participants who met the inclusion criteria were approached by the consenting interventional radiologist.

Our study data were reviewed annually by the DSMB and were reported to the institutional review board. In February 2017, the DSMB closed our study to accrual after the second interim analysis for noninferiority of ABPI on the pneumothorax rate within 2 hours of lung biopsy. For an in-depth discussion of procedures we used in this study, please see the Registration, Procedures, Measurements, and Postbiopsy Care sections in Appendix E1 (online).

Convenient sampling
Exclusion criteria stated briefly
Method of diagnosis stated
Experienced personnel involved

Presumption of penumothorax based on previous studies

Sample size = 552, adequate sample

Selection of statistical method using non inferiority test.

Statistical Analysis

We assumed the pneumothorax rate with the hydrogel plug was approximately 20% based on a study by Zaetta et al (13), and we calculated that a sample size of 552 participants (276 participants in each study arm) would be sufficient to find ABPI noninferior to hydrogel plug with a margin of 10%, 90% power, one interim analysis for noninferiority, and an overall one-sided type I error rate of 5%. We used the Lan-DeMets spending function and set the trial to terminate early for noninferiority if a one-sided nominal z score of -2.54 ($P \leq .006$) was observed. With trial continuation, the final assessment was set to use a z score of -1.662, with an associated P value of .048.

On the basis of the number of lung biopsies performed at our institution, our study was expected to take about 2 years.

The primary analysis was a modified intent-to-treat analysis, in which participants who were randomized but did not undergo biopsy were excluded. All randomized participants who underwent biopsy were analyzed according to the randomized treatment assignment, regardless of actual sealant deployment. The difference between pneumothorax rates for ABPI and those for hydrogel plug was estimated and assessed by using a z test. The same method was used for a secondary analysis in only those participants who had a sealant placed after biopsy without any intraoperative exclusions (per protocol).

The secondary outcomes for comparison of ABPI with hydrogel plug with respect to *(a)* delayed pneumothorax occurring after discharge and within 2 weeks after lung biopsy and *(b)* pneumothorax requiring chest tube placement up to 2 weeks after lung biopsy were also assessed with a z test. Superiority between arms was evaluated by using a two-sided χ^2 test, and differences in the length of hospital stay were assessed by using a negative binomial regression model. All statistical analyses were performed by using statistical software (SAS, version 9.4, SAS Institute, Cary, NC; East 6, version 6.4, Cytel, Cambridge, Mass; and R, version 3.2.4, *www.R-project.org*).

RESULT

- Large screening sample with large sample size.
- Clearly

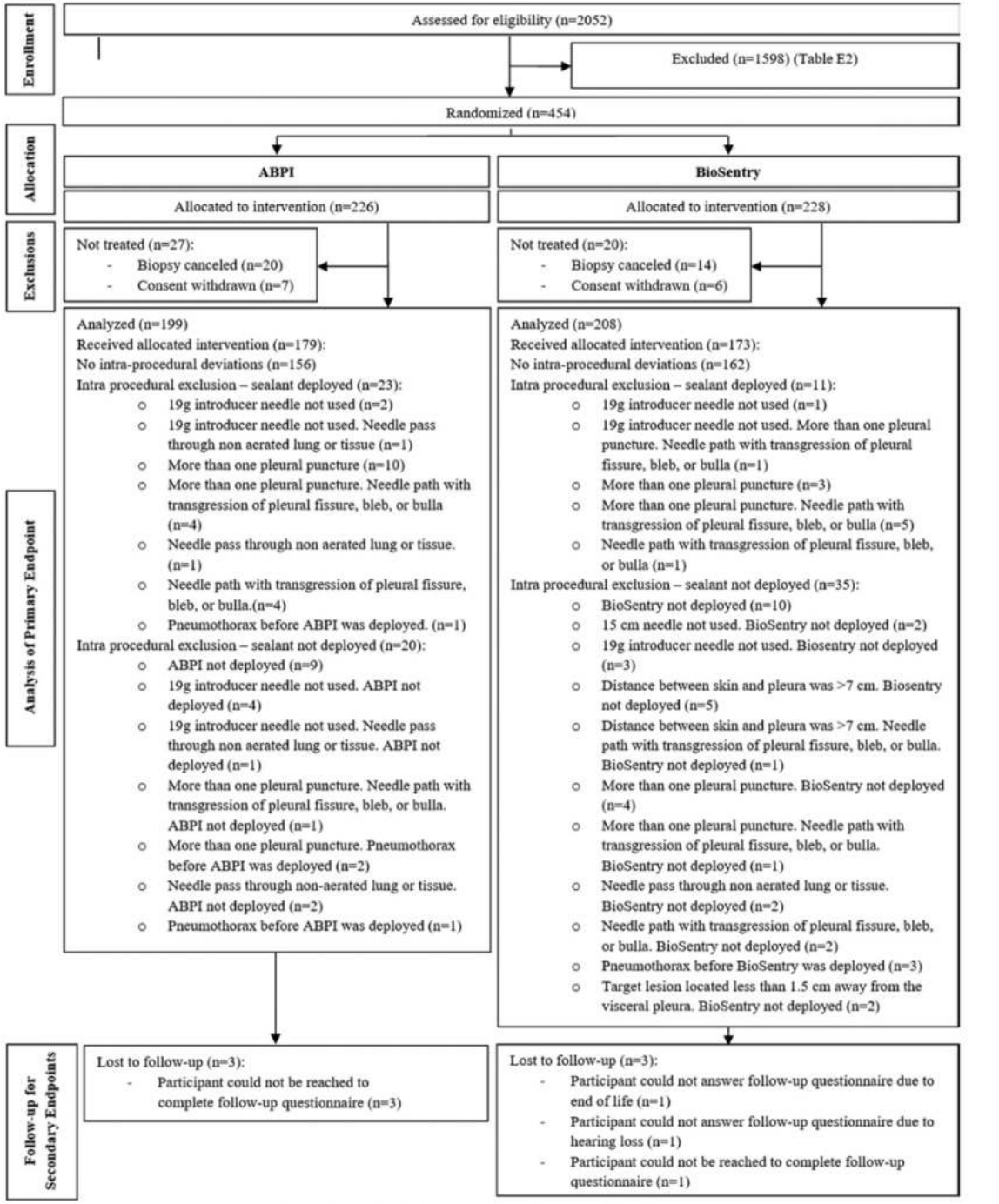


Figure 2: Consort diagram. *BioSentry* refers to the hydrogel plug. *ABPI* = autologous blood patch injection.

RESULT

Descriptive statistic clearly elaborated on table

Table 1: Distribution of Target and Technical Characteristics in Per-Protocol Population

Characteristic	ABPI (n = 156)	Hydrogel Plug (n = 162)
History of smoking		
No	47 (30.1)	53 (32.7)
Yes	109 (69.9)	109 (67.3)
History of emphysema		
No	131 (84)	136 (84)
Yes	25 (16)	26 (16)
Laterality or lobe		
Left lower	37 (23.7)	30 (18.5)
Left upper	45 (28.8)	49 (30.2)
Right lower	33 (21.2)	28 (17.3)
Right middle	5 (3.2)	7 (4.3)
Right upper	36 (23.1)	48 (29.6)
Target appearance		
Cavitary	4 (2.6)	3 (1.9)
Ground glass	13 (8.3)	11 (6.8)
Solid	133 (85.3)	143 (88.3)
Solid and cavitary	4 (2.6)	1 (0.6)
Solid and ground glass	2 (1.3)	4 (2.5)
Target long axis (cm)*	1.7 (0.5–15.8)	1.7 (0.5–9.7)
Target short axis (cm)*	1.4 (0.4–9.7)	1.4 (0–10)
Pleura-to-target distance (cm)*	3.5 (1.2–14)	3.8 (1.5–10)
Shortest target-to-pleura distance in any direction (cm)*	0.9 (0–7.1)	0.9 (0–9.4)
Target-to-pleura distance beyond the needle if less than 5 cm*	1.95 (0–8.4)	2 (0–8.4)
Participants whose target-to-pleura distance beyond the needle was more than 5 cm	40	30
No. of core specimens*	3 (0–10)	3 (0–10)
No. of FNB specimens*	0 (0, 3)	0 (0, 7)
Biopsy type		
Core	120 (76.9)	127 (78.4)
Core and FNB	30 (19.2)	27 (16.7)
FNB	6 (3.8)	8 (4.9)
Final pathology and/or cytology result		
Diagnostic	149 (95.5)	154 (95.1)
Nondiagnostic	7 (4.5)	8 (4.9)
Participant position		
Left lateral decubitus	1 (0.6)	2 (1.2)
Prone	85 (54.5)	72 (44.4)
Right lateral decubitus	0 (0)	2 (1.2)
Supine	70 (44.9)	86 (53.1)
CT radiation dose (mGy-cm)*	126.9 (2.09–1868)	122.2 (20.16–1237)
No. of participants without reported CT radiation dose	1	2

Note.—Unless otherwise indicated, data are number of patients, and data in parentheses are percentages. ABPI = autologous blood patch injection, FNB = fine-needle biopsy.

* Data are the median, and data in parentheses are the range.

- Primary objective analysis of immediate complication clearly mention

Table 2: Primary Outcome and Per-Protocol Analysis of Primary Outcome according to Treatment Assignment

Outcome	ABPI	Hydrogel Plug	Difference between ABPI and Hydrogel Plug (%)	95% CI of Difference	p_{NI} H_0: Difference ≥ 10%	p_S H_0: ABPI = Hydrogel Plug
Modified Intent-to-Treat Population (n = 407)						
Pneumothorax within 2 hours of procedure	…	…	−7.7	−16.1, 0.6	<0.0001	0.07
No	157 (79)	148 (71)	…	…	…	…
Yes	42 (21)	60 (29)	…	…	…	…
Per-Protocol Population Who Received Sealant (n = 352)						
Pneumothorax within 2 hours of procedure	…	…	−8.20	−17.2, 0.8	<0.0001	0.07
No	142 (79)	123 (71)	…	…	…	…
Yes	37 (21)	50 (29)	…	…	…	…
Per-Protocol Population with No Intraprocedural Deviations (n = 318)						
Pneumothorax within 2 hours of procedure	…	…	−9.20	−18.3, −0.1	<0.0001	0.05
No	128 (82)	118 (73)	…	…	…	…
Yes	28 (18)	44 (27)	…	…	…	…

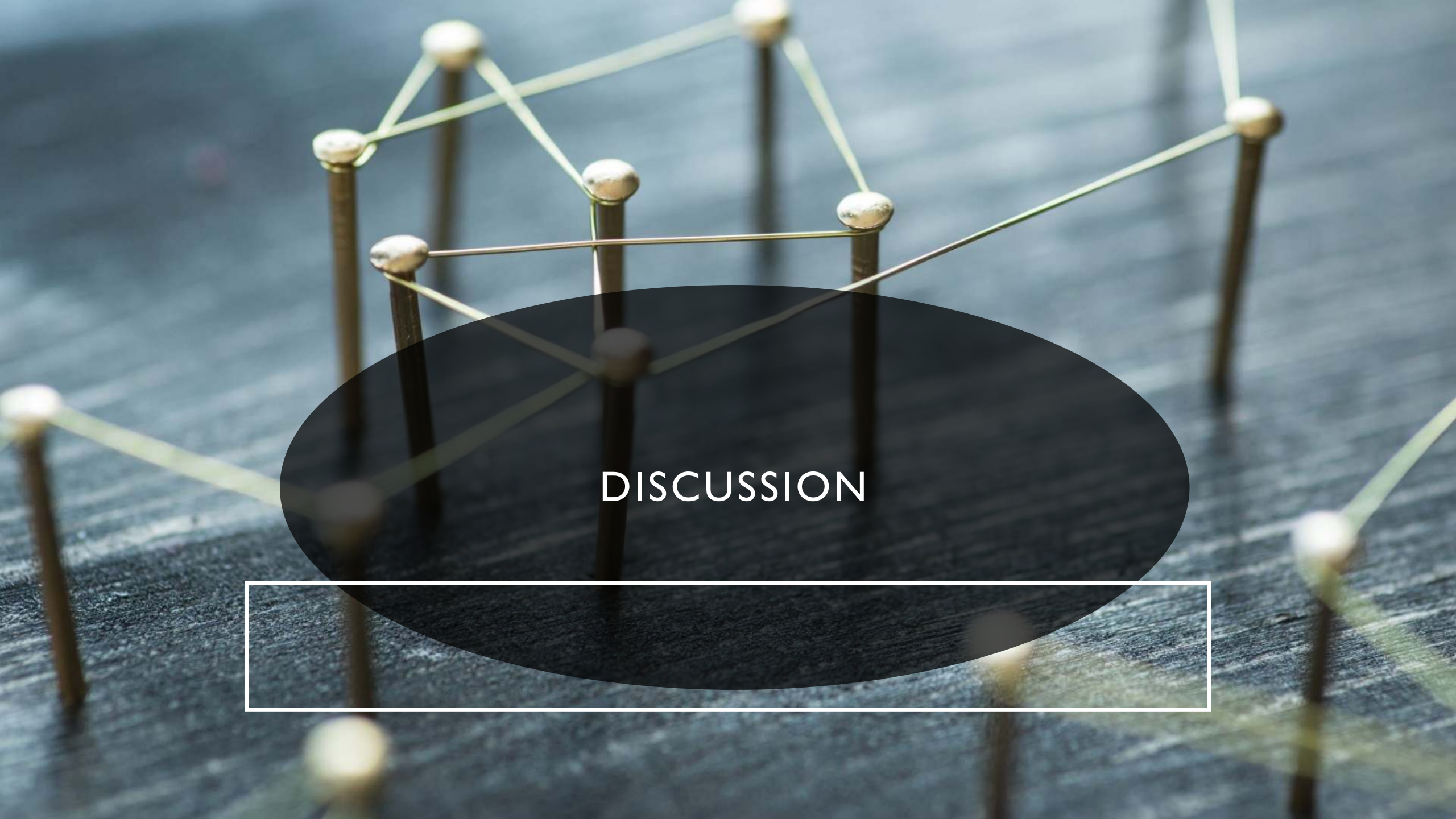
Note.—Unless otherwise indicated, data are number of patients, and data in parentheses are percentages. ABPI = autologous blood patch injection, CI = confidence interval.

- Study involve secondary outcome or delayed pneumothorax within 2 week post procedure.

Table 3: Secondary Outcomes according to Treatment Assignment

Outcome	ABPI (n = 199)	Hydrogel Plug (n = 208)	Difference between ABPI and Hydrogel Plug (%)	95% CI of Difference
Chest tube placed within 2 weeks after procedure	…	…	−3.90	−10.0, 2.1
No	181 (91)	181 (87)	…	…
Yes	18 (9)	27 (13)	…	…
Delayed pneumothorax within 2 weeks after procedure	…	…	0.10	−2.3, 2.4
No	196 (99)	205 (99)	…	…
Yes	3 (1)	3 (1)	…	…

Note.—All data were obtained in the modified intent-to-treat population (n = 407) and, unless otherwise indicated, are number of patients with percentages in parentheses. ABPI = autologous blood patch injection, CI = confidence interval.



DISCUSSION

- Immediate complication cause explained.

when ABPI or hydrogel plug were used as the track sealant. From October 2014 to February 2017, 2052 potential study participants were assessed for enrollment. A total of 453 participants were randomly assigned to the ABPI (n = 226) or hydrogel plug (n = 227) arm. A total of 407 participants underwent treatment without intraoperative exclusion (ABPI, n = 199; hydrogel plug, n = 208). Pneumothorax rates within 2 hours of biopsy were 21% (42 of 199) and 29% (60 of 208); chest tube rates were 9% (18 of 199) and 13% (27 of 208); and delayed pneumothorax rates within 2 weeks after biopsy were 1.4% (three of 199) and 1.5% (three of 208) in the ABPI and hydrogel plug arms, respectively. The DSMB recommended the trial be closed to accrual after an interim analysis met prespecified criteria for early stopping based on noninferiority. We concluded that ABPI is noninferior to hydrogel plug in regard to the rate of pneumothorax after CT-guided percutaneous lung biopsy.

The most commonly accepted mechanism for iatrogenic pneumothorax from percutaneous needle biopsy is leakage of air from the puncture site at the visceral pleura after needle removal.

Since lung biopsies are performed with increasing frequency and because complications such as pneumothorax lead to more costs and resources, substantial interest persists in decreasing the rate of iatrogenic pneumothorax (4,20,21).

In 1974, on the basis of the observation that pneumothorax was rare in patients whose lung lesions "bloomed" (bled) at fluoroscopic-guided biopsy, McCartney et al concluded that bleeding might have sealed the pleural puncture site. They published the first report on the use of ABPI after lung biopsy in 25 patients (25). Early case series and controlled studies showed mixed results but poor study design, including fluoroscopic guidance, participant selection methods, number of operators, and sample size, limited the relevance of their findings (7,8,26). Since 1992, a total of 11 controlled studies on use of track sealant in lung biopsies have shown significant benefits in both pneumothorax and chest tube rates (Table 4).

In 2010, Zaetta et al published the results of a prospective multicenter randomized controlled clinical study of 339 study participants allocated to either a hydrogel plug arm or a no sealant arm. They demonstrated significantly fewer pneumothoraxes (18% vs 31%) and fewer chest tube placements (4% vs 11%) in participants in the hydrogel plug arm as compared with those in the no sealant arm (13). In 2013, Malone et al published the results of a prospective randomized controlled clinical study of 242 study participants allocated to either an ABPI arm or a no sealant arm. They showed a trend toward reduction of pneumothorax (26% vs 35%), and a significant reduction in chest tube placement (9% vs 18%) associated with ABPI (14).

ABPI has several advantages over hydrogel plug: it is essentially free; it does not require a specific introducer needle type, gauge, or length; it can be deployed for lesions closer than 1.5 cm to the pleura; and it is proven to be absorbed shortly after deployment.

Our study had limitations. Results are based on an oncologic population in a comprehensive cancer center and may not necessarily be representative of results in other populations. The 10% noninferiority boundary is based on clinical historic data and results of prior relevant studies. We allowed freedom in choosing the type of 19-gauge introducer needle used in the ABPI arm. Such deviation is not expected to change our results significantly, as most controlled studies on this topic

- History of clot role explained.
- Previous study limitation stated.
- Control group study history clearly mention
- Advantage and benefit of studies explained

LIMITATION

- Studies only involved oncologic population.
- Single size biopsy needle used: 19G

CLINICAL IMPORTANCE

- Cheap
- Safer
- Not require specific equipment or deployment device
- Temporary sealant

CONCLUSION

Further prospective randomized clinical trials will be needed to evaluate the effectiveness of other track sealants. The fact that the overall rates of iatrogenic pneumothorax in percutaneous image-guided needle biopsy of the lung have not grossly changed since earlier reports in the 1970s despite advances in technology indicates potential gaps in our knowledge about risk factors such as emphysema, the physiology of respiration, and the mechanisms of iatrogenic pneumothorax. Until these risk factors are better understood, our study suggests that autologous blood patch injection can be as effective as a hydrogel plug in reducing the risk of pneumothorax and subsequent chest tube placement after percutaneous needle biopsy.

Brief and concise summary

CONFLICT OF INTEREST

- All of the the authors disclosed no conflict of interest.

- Overall, this is a good article. Good comparison with control group.
- Strength of this study
  - Prospective study
  - Large sample size
  - Appropriate follow up, up to 2 week.
- Potentially can be practice in our department because of availability of the material, cheap and does not require special apparatus.

FUTURE RESEARCH

- No meta-analysis found to this date that compare among sealant post biopsy to prevent pneumothorax.

Review | Published: 12 March 2019

Post-Biopsy Manoeuvres to Reduce Pneumothorax Incidence in CT-Guided Transthoracic Lung Biopsies: A Systematic Review and Meta-analysis

Ya Ruth Huo, Michael Vinchill Chan ✉, Al-Rahim Habib, Isaac Lui & Lloyd Ridley

CardioVascular and Interventional Radiology **42**, 1062–1072 (2019) | Cite this article

- Prospective RCT comparing the sealant available in the market.

REFERENCE:

- Maybody M, Muallem N, Brown KT, Moskowitz CS, Hsu M, Zenobi CL, Jihad M, Getrajdman GI, Sofocleous CT, Erinjeri JP, Covey AM, Brody LA, Yarmohammadi H, Deipolyi AR, Bryce Y, Alago W, Siegelbaum RH, Durack JC, Gonzalez-Aguirre AJ, Ziv E, Boas FE, Solomon SB. Autologous Blood Patch Injection versus Hydrogel Plug in CT-guided Lung Biopsy: A Prospective Randomized Trial. Radiology. 2019 Feb;290(2):547-554. doi: 10.1148/radiol.2018181140. Epub 2018 Nov 27. PMID: 30480487; PMCID: PMC6357949.
- Hahn, Seokyung. "Understanding noninferiority trials." *Korean journal of pediatrics* vol. 55,11 (2012): 403-7. doi:10.3345/kjp.2012.55.11.403