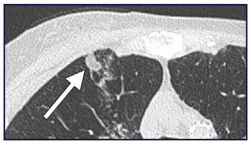
CLINICAL STUDY



Track Sealing in CT-Guided Lung Biopsy Using Gelatin Sponge Slurry versus Saline in Reducing Postbiopsy Pneumothorax: A Prospective Randomized Study

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ABSTRACT

Purpose: To compare the effectiveness of 2 track sealing techniques following computed tomography (CT)–guided lung biopsy using either gelatin sponge slurry (GSS) or saline to reduce the rate of postbiopsy pneumothorax.

Materials and Methods: In this prospective study, a total of 266 patients (median age, 66.2 years; range, 25.5-89.2 years; 150 men) were included between July 2019 and January 2023. The patients referred for a CT-guided lung biopsy, in whom the needle would pass through aerated lung, were randomly assigned to either the GSS sealing technique group (n = 132) or the saline track sealing technique (n = 134) in a 1:1 ratio. All biopsies were performed using a 19-gauge coaxial needle in a tertiary hospital by 1 of 4 interventional radiologists with varying levels of experience (F.C., L.G., P.L., C.V.). The outcomes were pneumothorax occurrence, pneumothorax-related intervention (simple aspiration and/or drainage), and biopsy-related hospital stay length.

Results: Pneumothorax rates were 12.1% in the GSS group and 24.6% in the saline group (P = .008). Hospital length of stay was significantly shorter in the GSS group (P = .003). The need for pneumothorax-related intervention did not reach statistical significance between the groups (6.8% vs 12.7%; P = .107). In the multiple logistic regression analysis, track sealing with GSS was a protective factor for pneumothorax (odds ratio [OR], 0.44; 95% CI, 0.22–0.87; P = .019), and emphysema was associated with higher risk of pneumothorax (OR, 2.67; 95% CI, 1.31–5.44; P = .007).

Conclusions: Track sealing with GSS following a CT-guided lung biopsy is significantly more effective than saline in reducing postbiopsy pneumothorax and results in shorter hospital stay.

ABBREVIATIONS

CT = computed tomography, GSS = gelatin sponge slurry, IRB = institutional review board, OR = odds ratio

Owing to the rise in cancer incidence, implementation of lung cancer screening programs, and the growing need for advanced immunologic and genetic analysis, computed tomography (CT)–guided lung biopsies are increasingly requested and have become a cornerstone procedure in pulmonary lesion management (1). Pneumothorax is the most frequent adverse event of CT-guided lung biopsy, with rates varying widely across studies and ranging from 8% to 52% (2,3). In one third of cases, symptoms require chest tube placement, leading to prolonged hospital stay and therefore additional costs (4,5). Thus, the technique still needs to be optimized and standardized to improve the risk-to-benefit ratio.

Several methods to prevent the occurrence of postbiopsy pneumothorax have been studied. Among these techniques, sealing the biopsy track when removing the coaxial needle has been recognized as one of the most effective maneuvers (6). Indeed, numerous studies have shown that sealing the intrapulmonary puncture channel with different types of materials, such as autologous blood, gelatin sponge slurry (GSS), hydrogel plugs, or saline, significantly reduces the postbiopsy pneumothorax rate and severity (7–10).

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RESEARCH HIGHLIGHTS

- Sealing the biopsy track is effective in reducing pneumothorax after computed tomography (CT)–guided lung biopsy.
- Track sealing with gelatin sponge slurry is more effective than saline in reducing postbiopsy pneumothorax and hospital stay related to the intervention.

STUDY DETAILS

Study type: Randomized controlled trial

Level of evidence: 2 (SIR-B)

Saline injection seems to present several advantages over other sealants: it is an inexpensive, inert, and easy-to-use substance, presenting no risk of solid embolization to the systemic circulation through a pulmonary vein (11,12). However, it is not clear whether saline injection is as efficient as the other techniques. Therefore, to fill this gap, this prospective study aimed to compare the effectiveness of 2 biopsy track sealants, saline and GSS, in reducing pneumothorax and related chest tube insertion rate after CT-guided lung biopsy.

MATERIAL AND METHODS

Study Population

The institutional review board (IRB) approved this prospective study (Comité d'Ethique Hospitalo-Facultaire de Liège; reference number: 2018-130; date of approval: February 5, 2018), and written informed consent was obtained from all patients. All procedures were performed in compliance with relevant laws and institutional guidelines. The study subjects have not been previously reported in other works.

The primary objective of the study was to compare the rates of pneumothorax related to CT-guided lung biopsy between a group of patients receiving saline track sealing and a group of patients receiving GSS track sealing. All patients referred for a CT-guided lung biopsy between July 2019 and January 2023 were screened. Eligibility of the patients was determined during the biopsy planning process by an interventional radiologist (F.C., L.G., P.L., C.V.) before the procedure. The inclusion criterion was patients referred for a lung biopsy during which the needle path was planned to pass through aerated lung. Patients who met the inclusion criterion received detailed information during the prebiopsy appointment and were randomized when they had returned the written informed consent document signed the day of the procedure.

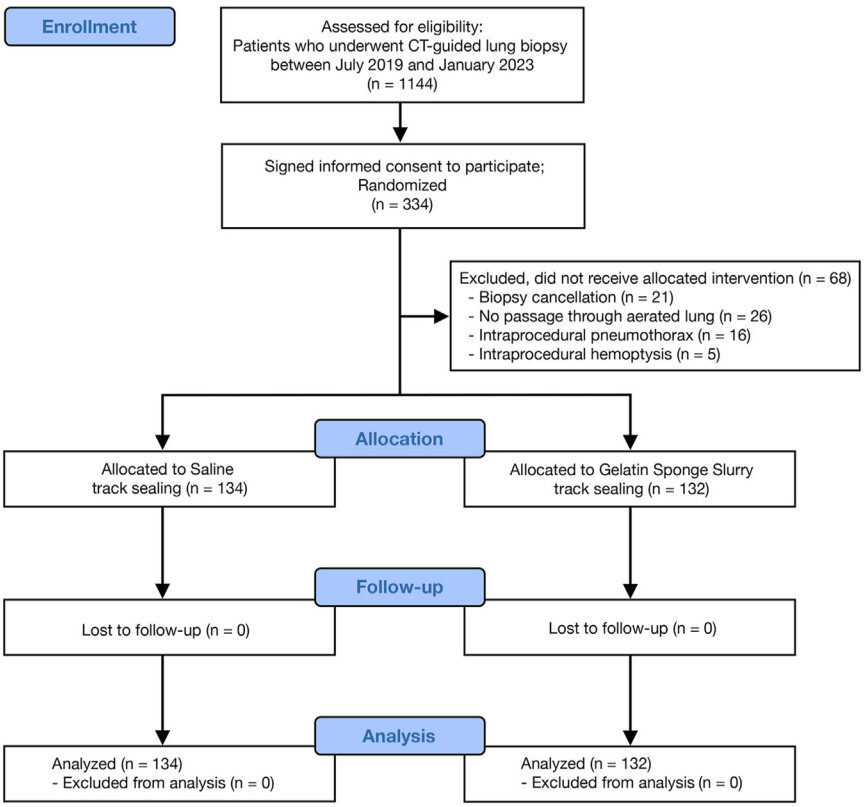

Figure 1. Patient selection flowchart. CT = computed tomography.

Patients were excluded after randomization when (*a*) the biopsy was cancelled, (*b*) the needle path ultimately avoided aerated lung, (*c*) pneumothorax occurred before needle removal, and (*d*) patients presented any adverse event justifying premature interruption of the procedure without track sealing. Patients were not aware of their allocation group.

The patients' clinical and radiologic records were assessed by 1 resident radiologist and 1 board-certified radiologist (S.D., F.C.). Variables relating to the patients (age, sex, smoking history, and presence of emphysema or signs of interstitial lung disease on CT), lung lesions (size and morphology), and procedures (needle path length, patient's position during biopsy, rapid patient rollover after needle removal, and pathology result) were collected.

Outcome of the study was the occurrence of postbiopsy pneumothorax assessed on immediate postprocedural chest CT and chest x-ray at hour (H) 4. Time of pneumothorax occurrence, requirement of a pneumothorax-related intervention (simple aspiration and/or chest tube drainage), and number of hospitalization days related to the intervention were also assessed.

Demographic Characteristics

Between July 2019 and January 2023, 1,144 patients referred for a CT-guided lung biopsy were screened. Study inclusion was temporarily suspended between March 2020 and February 2021 as a result of the COVID-19 pandemic. After application of inclusion and exclusion criteria, 334 patients in whom the needle path would pass through aerated lung returned the written informed consent document signed were randomized. A total of 266 patients were finally included in the analysis: 132 patients in the GSS group (60 women and 72 men; median age, 67.2 years; range, 25.5–89.2 years) and 134 patients in the saline group (56 women and 78 men; median age, 65.7 years; range, 26.7–83.3 years). The study flowchart is presented in the Figure 1, and demographic characteristics of the population are presented in the Table 1. No statistical difference in patient and procedural characteristics was noted between the 2 groups.

Procedures

All procedures were performed under CT guidance using CT fluoroscopy with intermittent single-rotation axial acquisitions on a Somatom Edge Plus scanner (Siemens Healthineers, Erlangen, Germany) by 1 of 4 board-certified interventional radiologists with 2–10 years of experience (F.C., L.G., P.L., C.V.). Patients were positioned in prone, supine, or lateral position during the biopsy, depending on lesion location. No sedation was used. Local anesthesia was performed using 10–20 mL of 1% lidocaine. All biopsies were carried out using a biopsy set comprising a 19-gauge coaxial needle and a 20-gauge semiautomatic needle with a 2-cm cutting area (Quick Core; Cook Medical, Bloomington, Indiana).

Table 1. Comparison of Characteristics between the Saline and Gelatin Sponge Slurry Groups

Characteristics	Saline (n = 134)	GSS (n = 132)	*P* value
Age (y), median (range)	65.7 (26.7–83.3)	67.2 (25.5–89.2)	.275
Sex, n (%)			.547
Male	78 (58.2)	72 (54.5)	
Female	56 (41.8)	60 (45.5)	
Smoking history, n (%)	120 (89.6)	111 (84.1)	.187
Emphysema on CT, n (%)	76 (56.7)	67 (50.8)	.330
ILD on CT, n (%)	1 (0.8)	1 (0.7)	>.999
Lesion size (cm), median (range)	1.8 (0.5–9.3)	1.8 (0.5–9.5)	.948
Lesion type, n (%)			.287
Solid	117 (87.3)	105 (79.5)	
Ground glass	6 (4.5)	6 (4.5)	
Part solid	5 (3.7)	10 (7.6)	
Cavitary	6 (4.5)	11 (8.3)	
Lung track length (cm), median (range)	3 (0.3–7.6)	2.7 (0.2–8.8)	.193
Patient position, n (%)			.871
Supine	61 (45.5)	63 (47.7)	
Prone	65 (48.5)	60 (45.5)	
Lateral	8 (6)	9 (6.8)	
Rapid rollover, n (%)	71 (53)	66 (50)	.626
Pathology result, n (%)			>.999
Diagnostic	131 (97.8)	130 (98.5)	
Nondiagnostic	3 (2.2)	2 (1.5)	
Interventional radiologists, n (%)			.675
1	57 (42.5)	58 (43.9)	
2	28 (20.9)	22 (16.7)	
3	27 (20.1)	33 (25)	
4	22 (16.4)	19 (14.4)	
Pneumothorax, n (%)	33 (24.6)	16 (12.1)	**.008**
Pneumothorax detection time, n (%)			.680
H0	10 (30.3)	7 (43.8)	
H4	22 (66.7)	9 (56.3)	
>H4	1 (3)	0 (0)	
Pneumothorax-related intervention, n (%)	17 (12.7)	9 (6.8)	.107
Other adverse event, n (%)	4 (1.5)	0 (0)	.122
Hospital stay (d), median (range)	1 (1–11)	1 (1–8)	**.003**

Note–Statistically significant results are presented in bold.
CT = computed tomography; H = hour; ILD = interstitial lung disease; GSS = gelatin sponge slurry.

After biopsy completion, the tip of the coaxial needle was withdrawn in the lung to a depth of 1–2 cm from the pleural surface, and the sealant was injected gently into the subpleural lung channel during full needle removal. Needle track sealing was performed using either 3–5 mL of saline (NaCl 0.9%) or 3 mL of saline mixed with GSS, according to a randomization table. The GSS was prepared during the onset time of local anesthesia by cutting an absorbable hemostatic gelatin sponge (Spongostan; Ethicon, Cincinnati, Ohio) into 20 fragments of approximately

identical size (5-mm cubes), which were then loaded into a 10-mL syringe and mixed with saline using a 3-way stopcock to form a thick liquid. No other maneuver to reduce pneumothorax rate such as pleural patching, needle removal during expiration, or dependent lesion positioning during biopsy was used.

Immediately after needle removal, a postprocedural CT scan was performed in supine position to detect any adverse events. After the procedure, patients were transferred to the pulmonology ward for observation, and they were asked to remain in their beds in supine position without coughing. A chest x-ray with erect anteroposterior views in inspiration and in expiration was acquired 4 hours after the biopsy on a digital x-ray machine. If no significant adverse event was detected, the patient was discharged the same day. The decision to keep the patient overnight in the hospital was taken by the referring clinician, who was unaware of the sealing method used.

Definitions

Emphysema and interstitial lung disease were assessed visually on prebiopsy lung CT scans as defined by the Fleischner Society glossary of terms version 2008 and the American Thoracic Society/European Respiratory Society classification of idiopathic interstitial pneumonia, respectively (13,14). Emphysema and signs of interstitial lung disease were assigned as present or absent by 2 radiologists (L.G., F.C.) in consensus, and no quantification tool was used. Needle path length was measured by 1 resident radiologist (S.D.) on the fluoroscopic CT images as the distance covered by the needle through pulmonary parenchyma between the pleural surface and the targeted lesion. Pathology results were classified as diagnostic or nondiagnostic (depending on whether the tissue sample was suitable or not for diagnosis) on the basis of the biopsy pathology report.

Postbiopsy pneumothorax was defined as the occurrence of a pneumothorax of any volume visible on postbiopsy imaging and was assessed by 2 radiologists (L.G., F.C.) in consensus. Pneumothorax was subdivided into 3 categories based on the time of detection: (*a*) H0, if visible on the immediate postprocedural CT scan; (*b*) H4, if visible on the chest x-ray performed 4 hours after needle removal; and (*c*) >H4, if detected later than the H4 chest x-ray if the latter was normal, based on the occurrence of new symptoms. At any time, in cases of complete, progressive, or symptomatic pneumothorax, and according to the Cardiovascular and Interventional Radiological Society of Europe guidelines on percutaneous needle biopsy, chest tube insertion or aspiration were performed using either an 8.5-F pigtail chest tube or a 5-F catheter, respectively (15).

In this study, the rapid patient rollover maneuver, consisting in rapidly rolling the patient in a biopsy-side-down position while remaining recumbent, was not attempted intentionally. However, because the immediate postprocedural CT was performed in supine position in all patients, rapid patient rollover maneuver was taken into account as a variable when the patient was in prone position during the biopsy or, in some cases, in lateral position if the puncture site ended up in a dependent position when the immediate postprocedural CT was performed.

Other adverse events linked to the biopsy or to the track sealing procedure, such as hemoptysis, hemothorax, air embolism, clinical signs of vascular embolization of gelatin sponge fragment, infection, or allergic reaction, were also assessed and graded according to the Society of Interventional Radiology (SIR) classification system (16).

Statistical Analysis

Results are presented as medians and ranges or means and standard deviations for continuous variables and as frequency counts and percentages for categorical variables. The normality of the quantitative parameters was investigated using a mean and median comparison, a histogram, a quantile-quantile plot, and the Shapiro-Wilk test. Comparison of the 2 groups was assessed using a chi-square test (or Fisher exact test) for qualitative parameters and the nonparametric Kruskal-Wallis test for quantitative parameters. Association between quantitative parameters was tested using the nonparametric Spearman rank correlation coefficient.

A multivariate binary logistic regression model was used to model the occurrence of pneumothorax (yes/no) and pneumothorax-related interventions (yes/no). Odds ratio (OR) and their 95% CIs were reported for each predictor. A negative binomial regression model was used to model length of hospital stay. Regression coefficient (β) and SEs were reported for each predictor. Statistical significance was set at $P < .05$. All statistical analyses were performed using SAS v 9.4 (SAS Institute, Cary, North Carolina) and R v 4.2.2 software (R Foundation for Statistical Computing, Vienna, Austria). Statistical analysis was led by one of the authors with extensive statistical expertise (N.D.).

RESULTS

Groups

Distribution of pneumothorax rates, pneumothorax-related intervention rates, pneumothorax detection times, and hospital stay lengths between the groups are presented in Table 1. The distribution of hospitalization duration showed a peak of values at 1 day of hospitalization in the GSS group, while larger values were observed in the other group (Fig 2a, b). In the saline group, 4 cases of mild adverse events were detected (2 cases of hemoptysis, 1 case of hemothorax, and 1 case of small volume and asymptomatic air embolism in the left ventricle). No other adverse event was observed in the GSS group.

Outcomes

Results of the univariate and multivariate analyses with OR and 95% CI regarding pneumothorax occurrence and

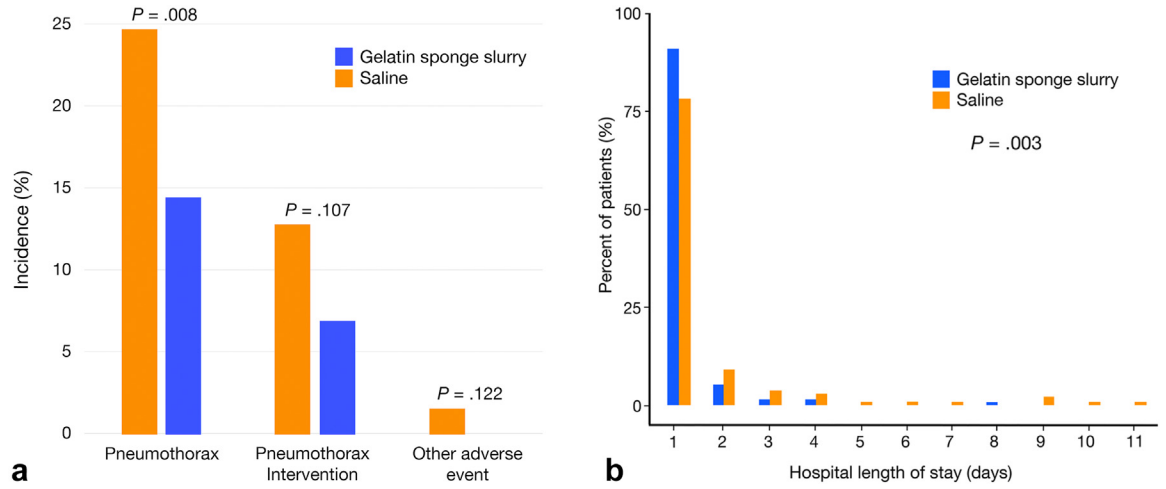

Figure 2. Histograms displaying **(a)** incidences of adverse events and **(b)** length of hospital stay in days for each group.

Table 2. Factors Influencing Pneumothorax Risk

Variables	Pneumothorax		Univariate		Multivariate	
	Yes (n = 49)	No (n = 217)	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age (y), median (range)	67.7 (29.3–86.5)	66.1 (25.5–89.2)	1 (0.97–1.03)	.933		
Sex (male), n (%)	34 (69.4)	116 (53.5)	**0.51 (0.26–0.98)**	**.042**	0.55 (0.28–1.1)	.091
Smoking history, n (%)	45 (91.8)	186 (85.7)	1.88 (0.63–5.58)	.252		
Emphysema, n (%)	36 (73.5)	107 (49.3)	**2.85 (1.43–5.66)**	**.002**	**2.67 (1.31–5.44)**	**.007**
ILD, n (%)	0 (0)	2 (0.9)		1		
Lesion size (cm), median (range)	1.5 (0.7–5.5)	1.9 (0.5–9.5)	0.79 (0.62–1.01)	.080		
Lesion type				.411		
Solid	40 (81.6)	182 (83.9)	1.03 (0.28–3.74)			
Ground glass	1 (2)	11 (5.1)	0.42 (0.04–4.66)			
Part solid	5 (10.2)	10 (4.6)	2.33 (0.45–12.1)			
Cavitary	3 (6.1)	14 (6.5)				
Track length (cm), median (range)	3.3 (0.9–7.6)	2.8 (0.2–0.8)	**1.26 (1.03–1.53)**	**.027**	1.19 (0.97–1.46)	.093
Patient position				.161		
Prone	28 (57.1)	96 (44.2)	0.95 (0.29–3.14)			
Supine	17 (34.7)	108 (49.8)	0.51 (0.15–1.75)			
Lateral	4 (8.2)	13 (6)				
Rapid rollover, n (%)	19 (38.8)	118 (54.4)	**0.53 (0.28–1)**	**.048**	0.53 (0.27–1.03)	.062
Pathology result, n (%)			0.9 (0.1–8.25)	1		
Diagnostic	48 (98)	213 (98.2)				
Nondiagnostic	1 (2)	4 (1.8)				
Track sealing (GSS), n (%)	16 (32.7)	116 (53.5)	**0.42 (0.22–0.81)**	**.008**	**0.44 (0.22–0.87)**	**.019**

Note–Statistically significant results are presented in bold.
GSS = gelatin sponge slurry; ILD = interstitial lung disease; OR = odds ratio.

hospital stay length outcomes are presented in Tables 2 and 3, respectively. Regarding pneumothorax-related intervention, the univariate analysis showed a significant association with sex (female in 19.2% vs 46.3%; $P = .008$), lesion size (median size of 1.45 cm [range, 0.7–3.5 cm] vs 1.9 cm [range, 0.5–9.5 cm]; $P = .046$), length of pulmonary track (median length of 3.45 cm [range, 0.9–7.6 cm] vs 2.9 cm [range, 0.2–8.8 cm]; $P = .015$), position of the patient (dorsal position in 69.2% vs 44.2%; $P = .034$), and rapid patient rollover (26.9% vs 54.2%; $P = .008$). The track sealing method was not significantly associated with intervention (GSS in 34.6% vs 51.3%; $P = .107$). In the multivariate analysis, sex was the only factor associated with intervention rate. Male patients had a significantly lower intervention rate (OR, 0.48; 95% CI, 0.24–0.94; $P = .034$).

Table 3. Factors Influencing Hospital Stay Length

Variables	Univariate *P* value	Multivariate β* (SE)	*P* value
Age	.627		
Sex (male)	.057		
Smoking history	.213		
Emphysema	**.005**	**0.3 (0.11)**	**.007**
ILD	.234		
Lesion size	.085		
Lesion type	.446		
Track length	**.012**	0.02 (0.03)	.529
Patient position	.116		
Rapid rollover	**.034**	**–0.21 (0.11)**	**.048**
Histology result	.338		
Track sealing (GSS)	**.003**	**–0.34 (0.11)**	**.002**

Note–Statistically significant results are presented in bold.
ILD = interstitial lung disease; GSS = gelatin sponge slurry.
*Regression coefficient.

DISCUSSION

In this prospective study, patients receiving GSS track sealing after CT-guided lung biopsy presented a significantly lower rate of postbiopsy pneumothorax compared with patients receiving saline track sealing. In the meta-analysis of Huo et al (6) comparing the results of studies using different methods of reducing pneumothorax rates, saline track sealing was found to be the most effective technique in decreasing overall pneumothorax incidence when compared with controls with an OR of 0.11 (95% CI, 0.02–0.48). However, all studies included compared patients receiving track sealing with patients receiving no sealing. Owing to its gelatin-based spongy structure, GSS has the ability to absorb up to 45 times its weight in liquid and expand when released in the lung (17). The hypothesis is that GSS, owing to its properties, induces a more efficient mechanical obstruction of the puncture site when compared with saline, which is more fluid and disperses rapidly when injected in the lung parenchyma (Fig 3a–h). Moreover, as a consequence of the rapid resorption and diffusion of saline in lung tissues, compared with GSS sealant, concerns could be raised regarding the appearance of delayed pneumothorax (>4 hours after needle removal) in the saline population. However, no statistical difference in pneumothorax detection time between the 2 groups was observed.

Beside GSS and saline, other types of sealant have proven their effectiveness in reducing postbiopsy pneumothorax, with the most widely studied being autologous blood and hydrogel plugs (9,18–22). The question whether GSS outperforms these sealants in this specific indication remains unsolved. However, GSS has several advantages compared with manufactured hydrogel plugs such as its low cost, its ease of use, and its wide availability. The main advantage of GSS over autologous blood is its ability to expand when released in the lung parenchyma, as explained earlier, which may theoretically induce a better sealing effect. Moreover, GSS has the ability to induce hemostasis

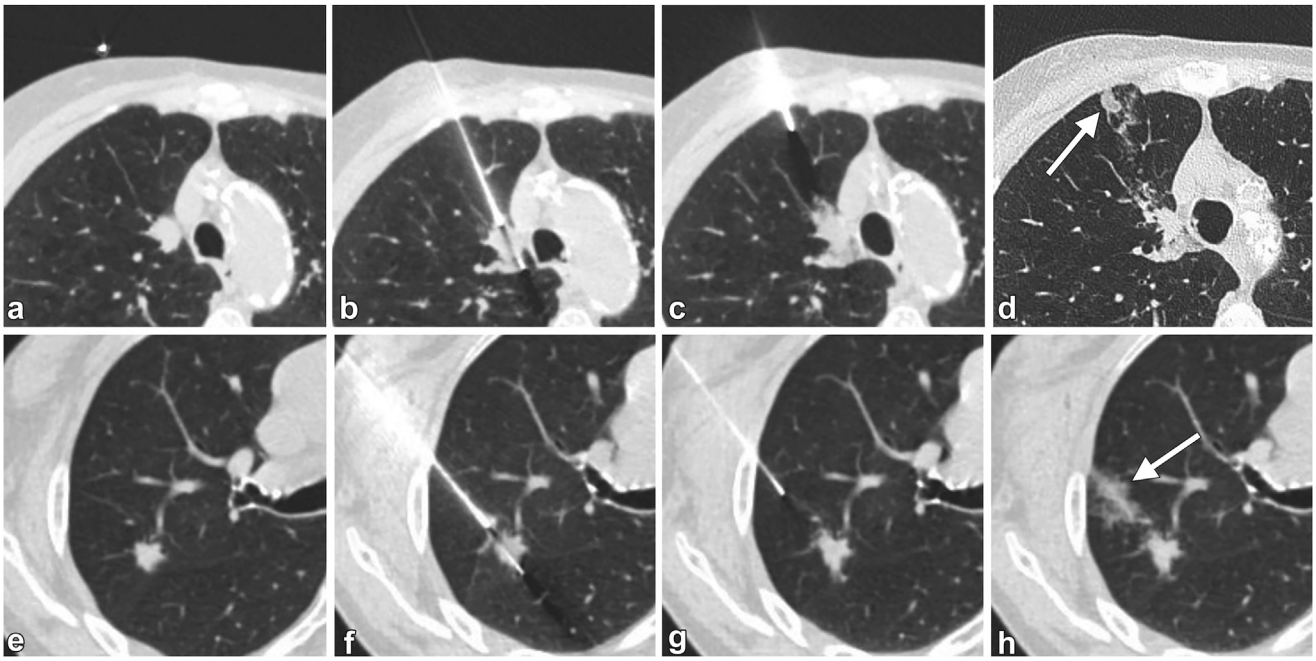

Figure 3. Axial computed tomography (CT) fluoroscopic images (single-rotation) of 2 lung biopsy procedures with track sealing. **(a, e)** Both patients presented with a suspicious right upper lobe lung lesion. **(b, f)** Procedures were performed using a 20-gauge core-needle biopsy system. **(c, g)** After biopsy completion, the tips of the coaxial needles were withdrawn to 1–2 cm of the pleural surface. Track sealing was performed using **(d)** gelatin sponge slurry, forming a well-defined subpleural opacity (arrow), or with **(h)** saline, forming a more diffuse ground-glass opacity (arrow).

at the site of injection. To date, only 1 study has directly compared the effectiveness of 2 different types of sealant in reducing postbiopsy pneumothorax (autologous blood and hydrogel plugs), and in it, no significant difference in terms of effectiveness was observed (23).

Some authors have also used GSS prepared with iodinated contrast agent instead of saline to obtain a more viscous slurry (24). This GSS with contrast also permits to assess the extent of the sealing, but only retrospectively.

Injection of GSS into the lung parenchyma includes a theoretical risk of paradoxical embolism, as it has been described with fiducial markers (25). To reduce the risk, the needle tip was systematically withdrawn to the subpleural lung area before injecting the sealant in order to avoid large pulmonary veins. No nontarget embolization, systemic air embolism, or other adverse event linked to the track injection procedure was observed in the GSS arm of the study. Furthermore, as the sealant was prepared during the onset time of local anesthetic, the use of GSS adds no additional time to the procedure as a whole.

In the present study, the rate of patients requiring a pneumothorax-related intervention was almost half as high when GSS was used when compared with saline. However, that difference was statistically not significant, partly explained by the low number of interventions in the whole population.

Track sealing with GSS was also an independent factor associated with shorter hospital length of stay. Although no direct causality can be determined, this could be explained primarily by the higher proportion of pneumothorax in the GSS group. In fact, the referent clinician had to make the decision to keep fragile patients overnight for monitoring in cases of pneumothorax, even if no drainage was performed. Second, although not significant, the chest tube rate was higher in the saline group, which could have led to a significantly longer hospital stay.

The rapid patient rollover technique is an easy-to-use method, which has previously demonstrated its effectiveness in reducing the rate of postbiopsy pneumothorax and chest drainage (26,27). However, in this study, rapid rollover was significantly associated with lower pneumothorax rates in the univariate analysis but did not remain significant in the multivariate analysis. Nevertheless, patients who underwent rapid rollover had statistically lower hospital stay length, and this could be an indirect effect of the effectiveness of the maneuver, which may, when associated with track sealing, require a more considerable sample size to reach statistical significance on pneumothorax rate.

Finally, besides the type of track sealing method, the presence of emphysema was the only other predictor significantly associated with pneumothorax rate following the multiple logistic regression analysis. In addition, it was an independent factor associated with longer hospital length of stay, which is in line with recent literature (28,29).

This study has some limitations. First, this is a monocentric study, and results should be validated externally in a multicentric study to be applied more widely. Second, in case of intraprocedural pneumothorax, subpleural track sealing is still feasible, followed by pneumothorax aspiration using the same needle. However, in this study, patients with intraprocedural pneumothorax were excluded because this could have masked the effect of the sealant in case of incomplete aspiration. As a consequence, pneumothorax incidences reported in this study do not truly reflect the real-life situation. In addition, the decision to proceed with aspiration or chest tube insertion was predominantly taken by the radiologist who performed the biopsy (F.C., L.G., P.L., C.V.) and who was therefore aware of the sealant material used. Even if that decision was based on detailed criteria described in the Material and Methods section, this could have led to bias. Finally, no adverse event linked to GSS use was detected during the study, but rare adverse events may not have been observed owing to the low number of patients in the GSS arm.

In conclusion, the results of this study have demonstrated that the track sealing technique using GSS is more efficient than saline in reducing the rate of postbiopsy pneumothorax. The use of GSS was also associated with shorter postbiopsy hospital length of stay.

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None of the authors have identified a conflict of interest.

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