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Multicenter external validation of a novel aggregated technique for percutaneous CT guided lung biopsy for multiple samplings: the ExtraPEARL study

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Abstract

Objectives To evaluate the reproducibility of the PEARL approach to decrease pneumothorax rates by different board-certified radiologists across multiple medical centers using standard CT units.

Materials and methods This multicenter observational study included four average volume centers in two countries. Data for the PEARL cohort were prospectively collected between January 2022 and May 2023, while the control cohort data were retrospectively collected from procedures performed between June 2021 and April 2022. Patient demographics, lesion characteristics, intraprocedural data, complications, and procedural accuracy were compared.

Results A total of 413 CT-guided lung biopsies were performed (204 PEARL vs 209 Control) without differences in patient demographics, lesion size (26.8 mm ± 20.3 PEARL group vs 27.7 mm ± 19.6 Control, $p = 0.4$), or emphysema rate (34% PEARL vs 27% Control, $p = 0.15$). Adequate pathological yield was observed in both groups (PEARL group 95%, Control group 97%; $p = 0.255$). The overall incidence of pneumothorax was 9% (18/204) in the PEARL vs 23% in the control group (48/209); $p < 0.05$. Chest tube insertion was necessary in one patient in the PEARL group (0.5%), and in nine in the Control (4%); $p = 0.011$.

Conclusions Application of PEARL protocol for CT-guided percutaneous biopsy of lung nodules provides a reproducible method across multiple institutions and physicians to maintain a high diagnostic yield while significantly reducing pneumothorax risk.

Key Points

Question *Reducing the rate of pneumothorax following percutaneous lung biopsy is crucial. The PEARL approach was proposed in an interventional radiology single-center study; external validation still missing.*

Findings *The PEARL approach effectively reduced pneumothorax incidence, with only one chest tube insertion in 204 cases, and both groups demonstrated adequate pathological yield.*

Clinical relevance *The PEARL protocol demonstrated efficiency and cost-effectiveness in minimizing pneumothorax risk during percutaneous CT-guided lung biopsies in a multicenter study, with board-certified radiologists using standard CT equipment in average-volume centers.*

Keywords Pneumothorax, Lung neoplasms, Image-guided biopsy

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Introduction

In the last decade, significant advances have been made in the management of oncological diseases. A personalized therapeutic approach requires adequate tumor sampling to guide the multidisciplinary team [1–3]. Minimally invasive biopsy techniques have evolved to obtain sufficient tumor specimens while minimizing complications.

For lung nodules, transbronchial endoscopic biopsy is the most effective for central lesions, though its diagnostic yield is only 70% for peripheral lesions [4–7]. In comparison, the percutaneous approach achieves a higher diagnostic yield of 83–98% [8–11]. However, percutaneous biopsies carry a higher risk of complications, particularly pneumothorax (PNX), with an incidence of 15–38%, requiring chest tube placement in 5–10% of cases. In contrast, the endobronchial approach has a lower PNX incidence (1–8%) [11–13].

Various techniques have been studied to improve safety and efficacy in percutaneous lung biopsies. For example, removing the biopsy needle during expiration can reduce PNX incidence by 50% [14]. Positioning the patient with the biopsy side down has reduced PNX from 15–27% to 6–10% [15, 16], and a rapid roll-over maneuver has lowered rates from 4–15% to 2–4% [17, 18]. Autologous blood patch sealing and pleural patching have also decreased the need for chest tube insertion by 50–85% [19, 20]. Other tract sealant devices have proven effective but add cost to the procedure [21].

To combine these cost-effective techniques, Najafi et al developed the PEARL protocol (positioning, expiration, autologous sealing, rollover, and pleural patching) [22]. This "all-in-one" method reduced PNX rates from 37% to 16% and chest tube placement from 13% to 1%, without compromising diagnostic accuracy [22]. However, the study had some specificities that limit replicability, including a relatively small cohort, fellows only as operators, and data from a single high-volume interventional radiology center.

Our multicenter study aims to validate these findings in a real-world setting, involving board-certified radiologists in average-volume centers using standard CT equipment.

Materials and methods

Study design

This is a multicenter prospective observational study (University of Turin, A.O.U. Città della Salute e della Scienza di Torino, A.O.U. San Luigi Gonzaga di Orbassano, Ospedale di Rivoli, ASL TO3—Italy, and CHU Montpellier—France). Approval by the institution's ethics committee was obtained (protocol number 349/2022). Data were prospectively collected (PEARL group) between January 2022 and May 2023. The control group was collected retrospectively and included procedures already performed between June 2021 and April 2022 (Fig. 1). The population included adult patients over the age of 17 years who required biopsies for indeterminate lung lesions as recommended by the Multidisciplinary Tumor Board. All percutaneous CT-guided biopsy procedures were carried out by five Interventional Radiologists with different degrees of experience (between 3 years and 20 years).

"Standard" technique

Biopsies on the Control group were carried out with the "Standard" technique. Biopsy planning was performed with the use of a non-contrast CT scan and the safest direct pathway was chosen to avoid intrapulmonary blood

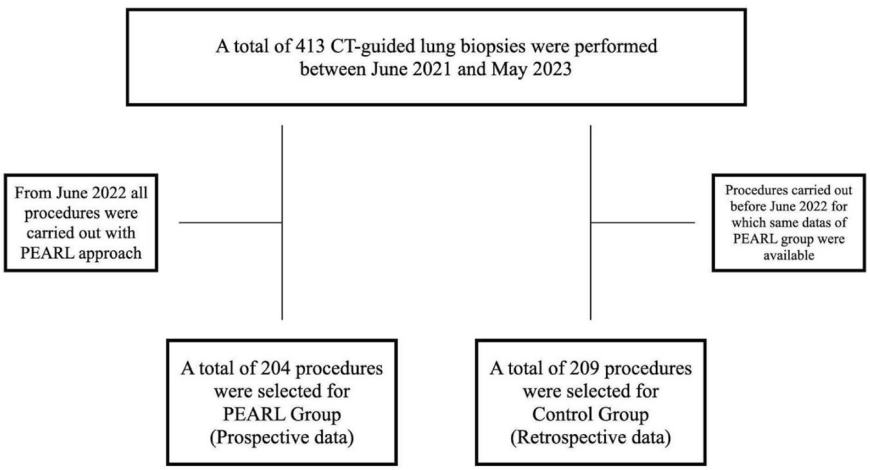

Fig. 1 Flowchart of procedures selected for the study

vessels and pleural fissures. The patient was positioned in the best position designed to facilitate access and safe passage of the coaxial needle, with a goal of only a single pleural transgression. A 17 g coaxial introducer needle was advanced under CT guidance into the tumor. Once the needle was located at or within the tumor, an 18 g core biopsy device with a 1–2 cm sample chamber was passed through the introducer needle. At each sample, patients were asked to breathe slowly or to be in apnea. During the needle exchange, the operator blocked the lumen of the coaxial with his finger to minimize the risk of air embolism. After all samples were obtained, the needle was shortly removed. A control CT scan was performed to evaluate for immediate complications such as PNX, hemorrhage, or air embolism. In the event of an immediate extensive and/or symptomatic PNX, a pleural chest tube was inserted at the same time. Otherwise, the patient was placed on a stretcher in the supine position. The patient was asked to maintain this position for 1–2 h until a chest X-ray or CT was performed to look for delayed PNX and adequate management before discharge.

PEARL protocol

The PEARL protocol [22] is based on three pillars:

1. Positioning: whenever considered safe, the primary position was the one designed to guarantee the positioning of the lesion, and therefore of the needle path, below the left atrium, defined as "biopsy side-down", usually corresponding to the ipsilateral decubitus of patient respect to the target lesion (Fig. 2). Other positions, such as supine or prone, were used only when they simplified the biopsy procedure, for example allowing to avoid pleural fissures or large vessels.
2. Tract sealing: at the end of the procedure removal of the needle takes place after asking the patient to perform a forced expiration. At the same time, up to 10 mL of autologous blood, withdrawn before the procedure, was injected through the coaxial needle. During the biopsy, the syringe was stored vertically on the sterile field, after removing any air present in it. Once the needle was removed and the final CT performed, the patient was quickly (within 10–20 s, "Rapid needle-out patient-rollover") positioned with the access site in a gravity-dependent position ("puncture-site down").
3. PNX management: PNX management depends on the timing of its onset. Particularly, in the case of its onset during the procedure, when the needle was still inserted (hyperacute PNX), the coaxial needle was removed from the pulmonary parenchyma and withdrawn inside the pleural cavity. At this point all the air was aspirated and, once the visceral pleura had been brought back into contact with the parietal pleura, the coaxial needle was removed in forced expiration after injecting 10 mL of autologous blood into the pleural cavity. High-flow oxygen was administered if necessary. Also in these cases, when it is possible, the participant is quickly placed in the "Puncture Side-down position" using the "Roll-over" technique (Fig. 3).

   Instead, if PNX was discovered at immediate postprocedural CT scan, right after needle extraction (acute PNX) or in the pre-discharge control X-ray or CT 3 h after the procedure (delayed PNX), the patient was placed supine on the CT table and, after positioning a catheter, the air of the pleural cavity was aspirated using a tube extension, three-way

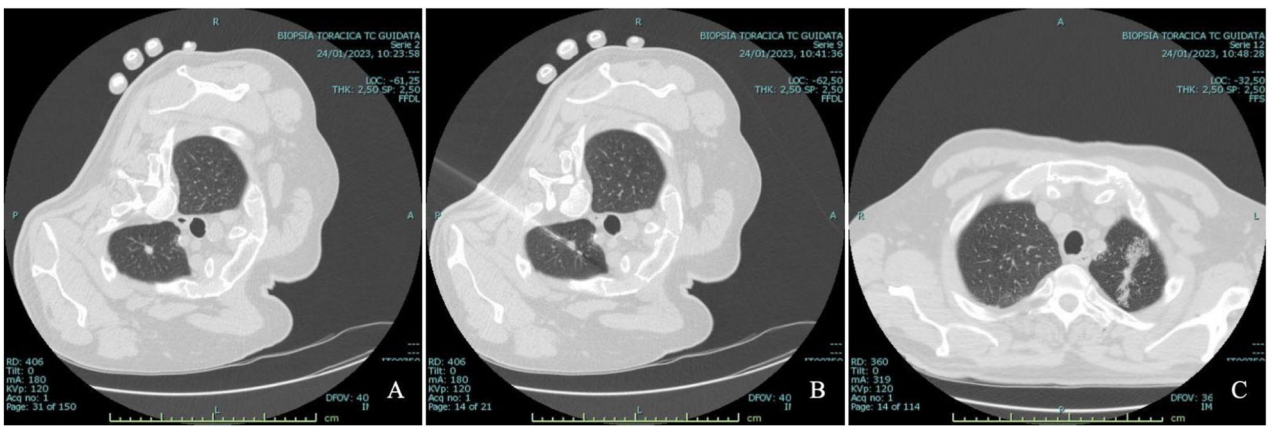

Fig. 2 Biopsy in ipsilateral decubitus position. **A** Unenhanced axial CT scan shows a about 10 mm solid lesion in the left upper lobe of a 71-year-old patient. **B** Unenhanced axial CT scan depicts an 18 G biopsy needle with its style inside the lesion. **C** Unenhanced axial CT scan obtained after the patient's rapid roll-over shows limited hemorrhage on the lesion's front side and blood track sealing on the lesion's posterior side

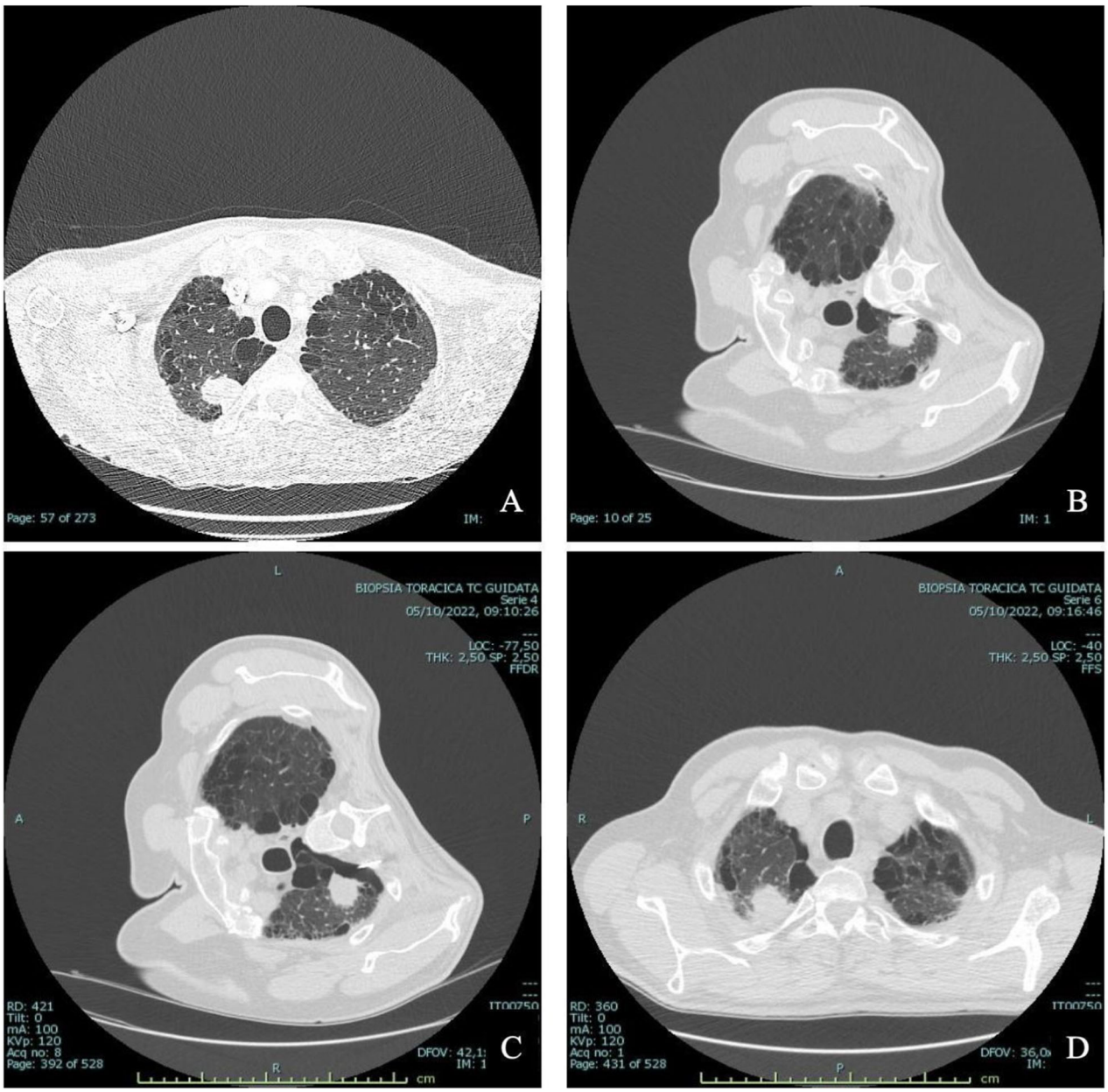

Fig. 3 Biopsy in ipsilateral decubitus position. **A** Axial CT scan performed 5 days before the procedure shows a 30 mm solid lesion in the right upper lobe in a 70-year-old patient with severe emphysema. **B** Unenhanced axial CT scan displays the patient's right decubitus position with an 18 G biopsy needle inside the lesion. **C** Unenhanced axial CT scan shows the occurrence of posterior PNX. **D** Unenhanced axial CT scan obtained with the patient on puncture side-down position depicts PNX resolution, obtained applying pleural blood patch, needle removal during expiration, and rapid roll-over

stopcock, and 60-mL syringe. At this point, the patient was asked to perform a forced expiration and the catheter was removed by simultaneous injection of 10 mL of autologous blood (pleural blood patch).

A video about the most relevant steps of the PEARL protocol is available in the supplementary material session (Supplementary Data 1).

All patients were monitored after the procedure until discharge, at least 3 h after procedure completion. Vital signs, such as saturation and heart rate, were monitored during the procedure and until pre-discharge check-up, performed by chest X-ray and clinical evaluation. PNX management was conducted according to 2010 BTS guidelines [23]. In the absence of complications (no evidence of PNX or in case of asymptomatic small PNX:

defined as a maximum thickness < 2 cm at the apex or the hilum), the patient was discharged. If a PNX was greater than 2 cm or the patient was symptomatic, then a small caliber chest tube (≤ 14 FR) was inserted.

Data collection

Collected data were as follows: patient age and sex, previous lung surgery or radiation therapy on mediastinum or lung, tobacco habit, presence, and severity of emphysema. The severity of emphysema was defined as mild and severe. According to Fleischner classification [24], we categorized trace and mild stages of centrilobular emphysema, along with mild paraseptal emphysema, as mild. Moderate and confluent centrilobular emphysema, as well as panlobular emphysema, were classified as severe. Additional data collection included characteristics of lesions (size, localization (lobe and position within the parenchyma, such as central, parenchymal, or hilar lesion), presence of cavitation within the lesion, intrapulmonary biopsy tract length (distance from pleura to the edge of the lesion), patient positioning, onset and timing of PNX, size and severity of PNX, intervention for PNX, other complications (perilesional bleeding, hemoptysis, hemothorax, gas embolism), and tumor histological diagnosis.

Statistical analysis

Kolmogorov–Smirnov test was performed to evaluate the normal distribution of the variables. Continuous variables were expressed as mean and standard deviation. Categorical variables were expressed as frequencies and percentages. The association and the statistical significance of the categorical variables have been verified with Chi-square or Fisher's exact test, as appropriate. The *t*-student test has been used to compare continuous variables with normal distribution. A bilateral value of $p < 0.05$ was considered statistically significant. Statistical analysis was carried out using SPSS software, version 29.0 (IBM Corp).

Results

Population's characteristics

A total of 413 CT-guided lung biopsies were enrolled for the study. Of these, 204 were carried out in a consecutive manner with the PEARL approach, whereas 209 consecutive biopsies using the standard technique were included for the Control Group. No significant differences were found in lesion and patient characteristics between PEARL and the Control Group (see Table 1). In particular, lesions size (PEARL group, 26.8 mm ± 20.3 vs Control group, 27.7 mm ± 19.6, $p = 0.4$) and biopsy tract length (PEARL group, 18.3 mm ± 14.8 vs Control group, 16.6 mm ± 17.1, $p > 0.05$) were not significantly different. Also, tobacco use (PEARL group, 137/204 (72%), Control group, 136/209 (68%), $p = 0.6$) and emphysema rate (PEARL group, 69/204 (34%), 13/69 (19%) graded as severe; Control group, 57/209 (27%), 10/57 (18%) graded as severe, $p = 0.15$) were not significantly different. In all cases, only one pleural puncture was performed.

Table 1 Group's characteristics

	Control group ($n = 209$)	PEARL group ($n = 204$)	*p*
Age (years)	68 ± 11	69 ± 10	0.94
Sex			> 0.05
Males	111 (53%)	122 (60%)	
Females	98 (47%)	82 (40%)	
Localization (lobe)			
RUL	57	63	
ML	18	7	
RLL	34	64	
LUL	68	35	
LLL	32	35	
Parenchymal localization			0.28
Peripheral	142	120	
Parenchymal	47	58	
Central	20	26	
Tobacco habit (y/n)	136/63 (68%); 10 na	137/54 (72%); 14 na	0.60
Emphysema on CT	57 (27%)	69 (34%)	0.15
Mild	47	56	
Severe	10	13	
Previous lung surgery (y/n)	17/186 (8%); 6 na	9/191 (5%); 4 na	0.24
Previous lung radiotherapy (y/n)	11/192 (5%); 6 na	5/195 (3%); 4 na	0.27
Lesions' size	27.7 mm ± 19.6	26.8 mm ± 20.3	0.4
Presence of cavitation	11 (5%)	17 (8%)	0.22
Biopsy tract length	16.6 mm ± 17.1	18.3 mm ± 14.8	> 0.05
Patient positioning			< 0.05
Biopsy side-down	17 (8%)	131 (64%)	
Supine	90 (43%)	49 (24%)	
Prone	64 (31%)	17 (8%)	
Lateral	38 (18%)	7 (3%)	

Differences in patient positioning during the biopsy were reported. For the PEARL group, the biopsy position called "biopsy side-down" was the choice in 131 of 204 participants (64%), whereas supine, prone and lateral positions were utilized in 49/204 (24%), 17/204 (8%), and 7/204 (3%), respectively.

In all patients in the PEARL group, coaxial needle removal was performed at the end of a forced expiration,

administering 10 mL of autologous blood through the coaxial needle. Furthermore, at the end of the procedure, rapid roll-over was performed (194/204, 95% patients), and all patients were placed in a decubitus position with the needle entry side in a gravity-dependent position (i.e. in contact with the bed).

Differences between centers are summarized in Table 2.

PEARL group vs control group

The overall incidence of PNX was 9% (18 patients out of 204) in the PEARL cohort vs 23% in the control group (48 patients out of 209); $p < 0.05$. PNX onset in the PEARL group was hyperacute in 11 (61%), acute in 5 (28%), and delayed in 2 (11%). In the control group, 22 cases were hyperacute (46%), 15 acute (31%), and 11 delayed (23%); $p = 0.001$. In referral to PNX grade in the PEARL group: 13 were mild (72%), 4 were moderate (22%), and 1 severe (6%), whereas in control: 27 were mild (56%), 11 were moderate (23%), and 10 severe (21%) ($p = 0.001$).

Chest tube insertion was necessary in one patient in the PEARL group (0.5%), and in nine in the Control group (4%); $p = 0.011$. These findings are summarized in Table 3.

Other complications, such as hemothorax and hemoptysis, occurred in 3 patients (1%), and 7 patients (3%), respectively in the PEARL group, and 3 (1%) and 10 (5%) in the control group, $p = 0.976$ and $p = 0.879$, respectively. Air embolism was not observed in either group. Adequate pathological yield was observed in both groups: 95% (194/204) for the PEARL cohort and 97% (203/209) for the control group ($p = 0.255$).

Discussion

The findings of this multicenter study corroborate the findings of the preliminary study published by Najafi et al [22] that promote the PEARL protocol as an effective means to provide protective benefits of positioning and autologous blood tract sealing to significantly reduce the PNX and chest tube insertion incidence ($p < 0.05$ and $p = 0.001$, respectively) after percutaneous CT-guided lung biopsy. The benefits of the PEARL technique can be explained by many small but additive modifications to the "standard" technique that integrate seamlessly into the normal routine without added cost or significant changes to procedural workup.

Injection of autologous blood provides a cost-free method for tract sealant, particularly when compared to manufactured plug material such as Gelfoam pulp, hydrogel plug, fibrin glue, and heamocoagulase [25]. Our results are in line with a recent meta-analysis that showed the efficacy of autologous blood patches in preventing PNX in patients with or without emphysema, but also in reducing chest tube insertion [26]. While biopsy site closure devices have been developed with good outcomes, not all institutions or patients may be able to gain access to or afford these devices [21].

In the same way, the biopsy side-down position has been proven by various studies to reduce the incidence of PNX

Table 2 PEARL group heterogeneity

	Country 1 (Italy) ($n = 254$)	Country 2 (France) ($n = 159$)	p
Cases			
Control	125	84	
Pearl	129	75	
PNX			
Control	34 (27%)	14 (17%)	0.07
Pearl	18 (14%)	0	0.002
Surgical chest drainage			
Control	6 (5%)	3 (4%)	0.74
Pearl	1 (0.8%)	0	
Hemothorax			
Control	3 (2%)	0	0.28
Pearl	3 (2%)	0	0.30
Hemoptysis			
Control	7 (6%)	10 (12%)	0.12
Pearl	2 (2%)	5 (7%)	0.10

Table 3 Results of the PEARL group vs the control group

	Control group ($n = 209$)	PEARL group ($n = 204$)	p
PNX			
Global	48 (23%)	18 (9%)	< 0.05
PNX grade			
Mild	27 (56%)	13 (72%)	0.001
Moderate	11 (23%)	4 (22%)	
Severe	10 (21%)	1 (6%)	
Timing of PNX onset			
Hyperacute	22 (46%)	11 (61%)	0.001
Acute	15 (31%)	5 (28%)	
Delayed	11 (23%)	2 (11%)	
Surgical chest drainage	9 (4%)	1 (0.5%)	0.011
Air embolism	0	0	
Hemothorax	3 (1%)	3 (1%)	0.98
Hemoptysis	10 (5%)	7 (3%)	0.88
Technical success	203/209 (97%)	194/204 (95%)	0.26
Histological diagnosis	203 of 209 (2 na)	194 of 204 (4 na)	
Primary lung cancer	139	137	
Metastasis	32	27	
Non-cancer	32	30	

[15, 16], likely due to the weight of the ipsilateral lung causing compression of the alveoli surrounding the needle during the biopsy and increased apposition of the pleural layers [27]. In our study, the biopsy side-down position was achieved in only 64% of cases, compared to the 92% reported by Najafi et al [22]. The choice of patient positioning—specifically the "biopsy side-down" approach—was applied "as much as technically feasible," according to the original paper. Technical feasibility was determined by the operators, which may have led to some variability in assessments. However, we successfully performed a rapid rollover in most of the patients (94% vs 87% of the original paper) and autologous blood injection was performed in all cases (100% vs 95% of the original paper).

These variations, however, did not compromise the overall efficacy of the PEARL technique. In fact, this finding highlights that the PEARL approach, with its combination of techniques, can achieve overall good outcomes even when there are minor differences in the individual steps.

Our study design with a multicentric real-world comparison group allows comparison to prior studies that have evaluated percutaneous lung biopsy. The incidence of PNX and chest tube insertion is in line with the meta-analysis performed by Heerink et al [12] in which the reported average incidence of pleural chest tube placement was 6% after a total of 8133 percutaneous biopsies. In the comparison between the centers of the two countries, at Country 2 (France) lower PNX rate was observed, likely due to the long-term expertise of the operator (15 years) of the center; however, the drop in PNX rates between control and PEARL group was similar among countries (13% vs 17%, see Table 2). Of note, the overall incidence of chest tube insertion in our control group (4%) is inferior to the 13% reported by Najafi et al in their control group [22]. Although differences in the level of experience of the operators (our study was conducted by board-certified radiologists with more than 3 years of experience vs fellows with up to 2 years of experience) could play a role, the difference could be explained by the lower prevalence of emphysema in our patient's cohort compared to that of Najafi et al (27% vs 47%) and by other differences among study populations.

The implications are important when considering the multidisciplinary approach to lung biopsy. Prior comparison studies have shown a higher PNX incidence after percutaneous biopsy as opposed to an endobronchial approach, in particular a meta-analysis that evaluated endobronchial biopsies for PNX and chest tube placement described rates up to 3% and 0.56%, respectively [7, 28].

The overall incidence of PNX for the PEARL group was 9%, which is remarkably decreased in comparison to 23% for the control group. In addition, the majority of the cases of PNX did not require placement of a pleural chest tube, with only one case out of 200 (0.5%) in the PEARL group, compared to 9 cases in the control group (4%). These data, considering the differences correlated to lesions' sites, suggest that the PEARL approach is reaching the endobronchial technique regarding chest tube placement rates.

Lastly, the application of the PEARL protocol did not affect the accuracy of the biopsy procedure (95% in the PEARL group vs 97% of the control group), maintaining the superiority of percutaneous biopsy over endobronchial biopsy (approximately 90%) [5, 6, 29].

We do acknowledge some limitations to our experience. First, the evaluation of imaging and comparison of biopsy procedures was performed by different board-certified radiologists across the involved centers, which can factor in variability in data collection. Secondly, there is uncertainty as to which step(s) of the multi-staged PEARL protocol was the most relevant to decrease PNX risk. The design of the PEARL protocol compiled several techniques that separately have been reported upon [14–18] with the idea that the combined effect might be more beneficial than each separately.

Furthermore, no precise data are still available about radiation dose differences among the two groups, and further studies are awaited. Lastly, while our study cohort included 413 procedures between the PEARL and control groups combined, more than doubling the single-center experience of Najafi, we do acknowledge that evaluation within larger cohorts would provide further support to establish this protocol as the reference standard approach for lung biopsies.

In conclusion, this multicenter study confirms that the application of the PEARL technique during percutaneous CT-guided biopsy of lung cancers decreases the risks of PNX and pleural chest tube placement to similar complication rates seen with endobronchial biopsies while maintaining a high diagnostic yield. The application of the PEARL protocol does not involve significant pre-treatment considerations, cost, time, or skill requirements compared to the standard percutaneous approach.

Considering these benefits, the PEARL protocol should be considered as an efficient and cost-effective measure to minimize PNX risks during percutaneous CT-guided lung biopsy.

Abbreviation

PEARL	Positioning biopsy-side down, needle removal during expiration, autologous blood patch sealing, rapid rollover, and pleural patching
PNX	Pneumothorax

Supplementary information

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Data availability
Data generated or analyzed during the study are available from the corresponding author by request.

Compliance with ethical standards

Guarantor
The scientific guarantor of this publication is Marco Calandri.

Conflict of interest
The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

Statistics and biometry
One of the authors has significant statistical expertise. No complex statistical methods were necessary for this paper.

Informed consent
Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval
Institutional Review Board approval was obtained.

Methodology

- Prospective
- Case-control study
- Multicenter study

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