Percutaneous pulmonary needle-biopsy: retrospective analysis of a single center and risk-benefit assessment considering lesions characteristics and 18-FDG uptake.

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Purpose

CT-guided-lung biopsy (CTLB) is a relatively safe and widely accepted procedure for the diagnosis and characterization of several focal lung pathologies, including benign and malignant lesions.[1,8,9] With advances in CT imaging and the growing interest of lung cancer screening, an increased incidence of small lung cancer, especially small adenocarcinoma, has been reported, and the management of lung nodules is becoming increasingly challenging.[2-5] Although observation strategy or direct surgical resection could be proposed if cancer probability is respectively low or high, many decision-making algorithms include a nodule-sampling step. [6,7] C TLB is considered as the standard technique, representing an essential step for diagnosis and treatment planning particularly for peripheral lung lesions and is capable of providing large samples allowing histological and biomolecular analysis. [10-13]

To our knowledge, no important studies have investigated C TLB performance according to nodule and patient characteristics, especially in those nodules showing poor evidence of glucose metabolism at 18-FDG PET examination. The aim of our study is to assess the possibility to select a subgroup of patients, with poor probability of biopsy technical success, who can benefit of different strategies.
Methods and materials

**Data Collection:** Prior to the biopsy, all patients had undergone a diagnostic CT chest scan. Based on these images, a retrospective analysis was performed. Lesion size, localization, morphology and distance from the pleural surface were recorded. The latter was evaluated by an expert interventional radiologist considering the optimal needle trajectory to avoid major vessels, interlobular fissures, visible bronchi and overlapping of bone structures.

SUV (Standardized Uptake Value) were taken from the PET report and a maximum value equal or less than 2.5 was considered the cut-off to mark a nodule as negative. A few cases not reporting the SUV were re-evaluated with the help of a nuclear medicine specialist in order to obtain a numerical value.

Data about each procedure have been extracted from the header DICOM retrieved from our hospital PACS: duration of total session, procedural time for biopsy and Dose-Length-Product (DLP) for each patient were collected. Histopathological reports were examined and results classified in 3 categories: positive for a specific malignant disease, positive for a specific benign disease and not adequate sample. The latter were deemed those which resulted in necrosis, clots, normal parenchima tissue, or those with not enough material for diagnosis. Complications were investigated with peri-procedural CT, 3 hours post-procedural X-ray control or other radiological exams until patient discharge. Complications were classified as minor or major according to the Society of Interventional Radiology (SIR) Guidelines [36]. Minor complications consisted of pneumothorax not requiring intervention, limited parenchymal hemorrhage and transient hemoptysis. Major complications consisted of pneumothorax or iatrogenic bleeding requiring chest tube placement or embolization.

**Statistical Analysis:** All calculations were made using IBM SPSS Statistics for Windows, Version 14.1. Continuous variables were reported as mean +- SD, discrete variables as absolute number and relative frequency. Distribution was checked for normality using the Shapiro-Wilk test. Univariate analysis was performed in order to assess which features correlate with unsuccessful procedures, with a p value cut-off of < 0.1 for statistical significance. When normally distributed, a two-tailed T-test was used; when not normally distributed, the Mann-Whitney test was used. Pearson chi-square was performed to test for dichotomous variables. A multivariate logistic regression model was constructed choosing as independent predictors those features which resulted significant at the univariate analysis, adjusted for the other factors included in the study. Continuous factors included in the model were dichotomized around an optimal cut-off for sensitivity and specificity, by applying Youden’s index on ROC curves. Specifically, we used a cut-off of 18 mm for maximum lesion diameter, and 20 mm for distance from the pleural surface. A Bootstrap internal validation setted at 500 repetition was used to correct for overfitting. Prediction accuracy of our model was estimated using the C-index, and goodness of fit.
via Hosmer-Lemeshow test. Results are reported in odds ratios (OR) with a 95% CI, and a point-based score model for the risk of unsuccessful procedures was developed using variables resulting statistically significant at $p < 0.05$. A normogram was then constructed to help allocating points to each patients, and predicted probability of unsuccess is express as percentages.
• All procedures were performed percutaneously under CT guidance by an experienced Interventional Radiologist with at least 3 years of experience.

• CT images were acquired intermittently using the “step and shoot” technique.

• Needles caliber ranged between 18 – 20 Gauge, with automatic and semi-automatic sampling mechanism, all equipped with Full-Core technology.

Fig. 1: biopsy procedure

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Fig. 2: inclusion and exclusion criteria
Results

Technical success was considered when the tissue sample was deemed appropriate to assess a specific malignant or benign pathology. The overall technical success was 78% (n =250), 68% (n=218) malignant and 10% (n=32) benign. Technical failure occurred in 22% (71 pz) because of inadequate samples (blood cloth, necrosis, normal parenchima or insufficient material for diagnosis).

The mean session duration was 19 minutes and the average duration of needle position and sampling was 10 minutes. The average DLP for the CT fluoroscopy alone was 65.9mGy x Cm2.

Overall complication rate was 35% and major complications rate was 6%, all pneumothorax requiring the placement of a drainage tube.

A wide panel of variables were tested in the univariate setting in order to determine which were the ones most associated with unsuccessful procedures: as an example sex, operator, nodule shape and density failed to show a significant correlation with success, and were thus not taken into account when constructing the score. We believe that some of those features, such as the aspect of the nodule, are likely to be associated with failure, but did not reach the desired significance level out of low presence in the study population (as an example pure GG's nodules, in which CTLB is known for a low diagnostic yield, were just 19 out of 321). The model performances indicates a good discrimination capability (the C - index for the model is 0.71; 95% CI 0.64-0.77) and goodness-of-fit, with an Hosmer-Lemeshow test of p=0.173. Three cluster of low (<50%), medium (50 - 60 %) and high (>60%) risk of technical unsuccess were thus highlighted according to nodule and patient characteristics. When looking at the model we can see how a low 18-FDG uptake in the target lesion resulted as the factor which correlated the most with technical failure: all patients falling into the >50% risk of unsuccess group had this feature. A SUV max value of 2,5 was the threshold to discriminate nodule uptake at 18-FDG PET examination: 251 (79%) lesions resulted "positive" and 70 (21%) "negative". The other key factors determining success were a maximum diameter of less than 18 mm and a basal localization of the lesion.
### Fig. 3: Univariate and multivariate analysis

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Fig. 4: normogram

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Fig. 5: Calibration plot

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Conclusion

The study was successful in identify those variables of the nodules that are more likely to determine a more laborious and complex procedure. Overall success rate of CTLB performed in our court are comparable to those reported in literature, even if it significantly varied between the different clusters of lesions we take in consideration. [37]
Personal information and conflict of interest

E. Ronconi; Rome/IT - nothing to disclose M. A. Tipaldi; Rome/IT - nothing to disclose T. Polidori; Rome/IT - nothing to disclose F. Laurino; Eboli/IT - nothing to disclose A. Pisano; Rome/IT - nothing to disclose A. Zolovkins; Rome/IT - nothing to disclose G. Orgera; Rome/IT - nothing to disclose A. Laghi; Rome/IT - nothing to disclose M. Rossi; Rome/IT - nothing to disclose


