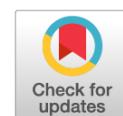


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Experience of Computer Tomography Guided Robot-Assisted Transthoracic Lung Biopsy

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ABSTRACT

BACKGROUND: The sensitivity of computer tomography (CT) guided transthoracic needle biopsy for the verification of lung tumors is reported to range from 74 to 90%. An augmented reality robotic navigation system for CT-guided percutaneous lung biopsy has been developed to facilitate more precise biopsy of lung lesions. The present study describes the authors' experience with the navigation system for transthoracic lung biopsy.

AIM: To analyze the safety and diagnostic value of performing a transthoracic biopsy of lung tumors using a robotic CT navigation system.

MATERIALS AND METHODS: The study included a retrospective analysis of CT-guided robot-assisted transthoracic lung biopsy procedures performed in the Thoracic and Abdominal Surgical Oncology Department No. 72 of the Botkin Moscow General Scientific and Clinical Center between November 30, 2023 to April 04, 2024. A total of 104 patients were included in the study. The biopsy was performed following the developed algorithm.

RESULTS: The specimens obtained were morphologically valuable in 91.8% of cases ($n=101/110$). A total of 1–4 specimens (tissue columns) were obtained from each patient during the biopsy procedure. Specifically, 1 specimen was obtained from 7 patients (6.4%), 2 specimens from 57 patients (51.8%), 3 specimens from 43 patients, and 4 specimens from 3 patients (2.7%). Among the patients for whom morphologically valuable specimens were obtained ($n=101$), the diagnosis of malignant tumor was confirmed in 76 cases (75.2%). In all remaining cases ($n=25$, 24.8%), benign lesions or inflammatory/post-inflammatory changes were diagnosed. Complications of various severity degrees occurred in 17 cases (15.5%). No deaths were reported (0%). The findings revealed no statistically significant differences in the frequency of cases with a verified diagnosis based on the diameter of the biopsy needle ($p=0.124$). Furthermore, the analysis revealed no statistically significant effect of the diameter of the biopsy needle (16G or 18G) on the overall complication rate (18.2 and 9%, respectively; $p=0.266$) and the frequency of pleural drainage for postoperative pneumothorax (10.4 and 6%, respectively; $p=0.72$).

CONCLUSION: The CT-guided robot-assisted transthoracic lung biopsy is a safe and effective technique for the morphological verification of malignant tumors.

Keywords: transthoracic biopsy; lung cancer; computed tomography.

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Опыт выполнения трансторакальных робот-ассистированных биопсий опухолей лёгких под КТ-навигацией

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АННОТАЦИЯ

Обоснование. Чувствительность трансторакальной функционной биопсии под КТ-навигацией в верификации злокачественных опухолей лёгких составляет от 74 до 90%. Роботическая навигационная система с дополненной реальностью для чрескожных биопсий лёгких под контролем компьютерной томографии (КТ) позволяет более точно выполнять биопсию очагов в лёгких. В данной статье мы представляем собственный опыт использования навигационной системы при выполнении трансторакальной биопсии опухолей лёгких.

Цель. Анализ безопасности и диагностической ценности выполнения трансторакальной биопсии опухолей лёгкого с помощью роботической платформы для КТ-навигации.

Материалы и методы. В условиях стационара торако-абдоминального онкохирургического отделения №72 Московского многопрофильного научно-клинического центра им. С.П. Боткина за период с 30.11.2023 по 04.04.2024 мы провели ретроспективный анализ выполнения трансторакальных робот-ассистированных биопсий под КТ-навигацией. Всего в исследование включены 104 пациента. Биопсия выполнялась согласно разработанному алгоритму.

Результаты: Информативный морфологический материал получен в 91,8% случаев ($n=101/110$). За одну процедуру биопсии получено от 1 до 4 биоптатов (столбиков ткани) — 1 биоптат получен у 7 пациентов (6,4%), 2 биоптата — у 57 (51,8%), 3 биоптата — у 43, 4 биоптата — у 3 (2,7%). Среди пациентов, у которых получен информативный материал ($n=101$), в 76 случаях (75,2%) верифицирован диагноз злокачественного опухолевого поражения. В остальных случаях ($n=25$, 24,8%) диагностированы доброкачественные или воспалительные/поствоспалительные изменения. Осложнения различной степени тяжести развились в 17 случаях (15,5%). Случаев летальных исходов не отмечено (0%). Не получено статистически значимых различий в частоте случаев с верифицированным диагнозом в зависимости от диаметра используемой биопсийной иглы ($p=0,124$). Также нами не было выявлено статистически значимого влияния диаметра используемой биопсийной иглы (16G или 18G) на общую частоту осложнений (18,2 и 9% соответственно; $p=0,266$) и частоту дренирования плевральной полости по поводу постпункционного пневмоторакса (10,4 и 6% соответственно; $p=0,72$).

Заключение. Выполнение трансторакальной биопсии лёгкого с использованием робот-ассистированной системы КТ-навигации — безопасная и эффективная методика для получения морфологической верификации злокачественных опухолей.

Ключевые слова: трансторакальная биопсия; рак лёгкого; компьютерная томография.

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BACKGROUND

Transthoracic needle biopsy (TTNB) is an invasive diagnosis method for lung tumors, which helps to collect tumor tissue samples for further examination. TTNB provides sufficient material for the subsequent determination of histological type, grade, and molecular genetic characteristics of the tumor [1], which is critical for the selection of treatment strategy and disease prognosis.

TTNB can be performed with ultrasound or computed tomography (CT) guidance. CT-guided TTNB confirms lung cancer with a sensitivity of 74–90% [2–4]. The diagnostic sensitivity of TTNB for the detection of malignancies is lower for small lesions (<3 cm); the reported sensitivity and specificity are 67% and 100%, respectively, with 36% non-diagnostic results [5]. TTNB fails to yield sufficient material in approximately 15–30% of cases, with malignant tumor cells later detected in up to 46% of these patients [2, 6].

TTNB has a number of limitations and potential complications. Pneumothorax is a common complication, with an incidence of up to 10–15% [7–9]. Older patients with chronic obstructive pulmonary disease are at a higher risk of pneumothorax; an increased risk of respiratory failure requiring mechanical ventilation has also been reported in these patients [9]. Hemoptysis is less common (1–9% of cases), whereas intrapleural hemorrhages and other hemorrhagic complications that require treatment are extremely rare [7, 10, 11].

Modern techniques and control methods reduce the risks and improve the efficacy of TTNB. An augmented reality navigation system for CT-guided percutaneous lung biopsy was recently presented [12, 13]. Such systems track the position of the biopsy needle during the procedure, improving the accuracy of lung biopsy and producing adequate, representative tissue samples.

This paper describes the authors' experience with the navigation system in TTNB of lung tumors.

AIM: To assess the safety and diagnostic value of TTNB of lung tumors using a robot-assisted CT navigation system.

MATERIALS AND METHODS

Study Design

A retrospective, single-center study was conducted.

Eligibility Criteria

Inclusion criteria: Satisfactory general condition, good compliance, and withdrawal of anticoagulants (warfarin, rivaroxaban, apixaban, heparin, fraxiparine, enoxaparin) at least 5 days prior to biopsy.

Laboratory findings: Hemoglobin ≥ 100 g/L, platelets $\geq 150 \times 10^9$; coagulation profile: international normalized ratio ≤ 1.3 , activated partial thromboplastin time < 40 s, prothrombin index $\geq 70\%$, prothrombin time > 16 s.

CT findings: Clearly visualized peripheral or central solid masses with a diameter of ≥ 1.0 cm, without the possibility of endoscopic (transbronchial) biopsy, with a safe biopsy needle path; absence of pneumothorax and hydrothorax.

Non-inclusion criteria: Patients who do not meet at least one inclusion criterion.

Exclusion criteria: None.

Study Duration and Setting

A retrospective analysis of CT-guided robot-assisted transthoracic biopsies was performed in the Thoracic and Abdominal Surgical Oncology Department No. 72 of the Botkin Hospital (Moscow) between November 30, 2023, and April 4, 2024. During the implementation stage, we developed the eligibility criteria for CT-guided robot-assisted core needle biopsy of thoracic tumors.

Study Methods

During the pre-planning stage, the proximity to vascular structures (both central and peripheral), mediastinum, and diaphragm was assessed to reduce the risk of intraprocedural complications.

Moreover, we developed an inpatient biopsy algorithm:

1. Examination by an oncologist and thoracic surgeon to determine eligibility for biopsy.
2. Hospitalization Physical status assessment.
3. Core needle biopsy under local anesthesia using the PERFINTE MAXIO V2.5.3 robot-assisted navigation system (Perfint Healthcare, India) guided by the synchronized multislice CT scanner CANON Aquilion SP 160 (Canon Medical Systems, USA).
4. Immediately after the procedure: CT evaluation of complications.
5. Transfer to a hospital ward.
6. Follow-up complete blood count after 4 h.
7. Follow-up blood pressure and pulse rate measurement after 1.4 h.
8. Follow-up chest X-ray after 4 h and the next morning to assess the patient's condition.
9. Discharge with recommendations.

Study Outcomes

High frequency of diagnostic histology samples for morphological diagnosis confirmation; low incidence of postprocedural complications.

Ethics Approval

The study used anonymized data and did not require local ethics committee approval. At admission, all patients provided voluntary informed consent for biopsy.

Statistical Analysis

For the statistical analysis, categorical variables are presented as absolute values and proportions (*n*, %), and continuous variables as a mean \pm standard deviation ($M \pm SD$).

The potential effect of categorical factors was assessed using the Pearson's chi-squared test (χ^2). The statistical analysis was performed using the IBM SPSS Statistics software (version 22.0, IBM Corp, USA). All (two-sided) models used a significance level of $p \leq 0.05$.

RESULTS

Study Subjects

The study included 106 patients. Four patients (3.8%) had two biopsies.

The characteristics of study subjects are presented in Table 1.

Each biopsy yielded 1–4 samples (tissue columns): 1 sample in 7 patients (6.4%), 2 samples in 57 patients (51.8%), 3 samples in 43 patients (40.6%), and 4 samples

Table 1. Clinical and demographic characteristics of the patient group

Таблица 1. Клинико-демографические характеристики группы пациентов

Parameter	Value
Age (M±SD), years	66±10.8
Sex (n, %):	—
Male	67 (63.2%)
Female	39 (36.8%)
Tumor size (M±SD), mm	30.4±21.4 (диапазон 9–170)
Tumor location (n, %):	—
Right upper lobe	37 (34.9%)
Right middle lobe	6 (5.7%)
Right lower lobe	25 (23.6%)
Left upper lobe	24 (22.6%)
Left lower lobe	14 (13.2%)
Tumor type (n, %):	—
Primary	95 (89.6%)
Metastatic	11 (10.4%)
Number of biopsy samples (n, %):	—
1	7 (6.4%)
2	57 (51.8%)
3	43 (39.1%)
4	3 (2.7%)
Biopsy needle size (n, %):	—
16G	77 (70%)
18G	33 (30%)

in 3 patients (2.7%). 16G and 18G biopsy needles were used in 70% of cases ($n=77$) and 30% of cases ($n=33$), respectively.

Complications of varying severity were reported in 17 cases (15.5%). The complications are summarized in Table 2.

According to the table, pneumothorax was the most common complication: 12 (10.9%) cases, with 10 (83.3%) requiring thoracostomy. Two (16.7%) cases of clinically and radiologically non-significant pneumothorax required only X-ray guided case follow-up.

No fatal outcomes were reported (0%).

Diagnostic samples were obtained in 91.8% of cases ($n=101/110$). In patients with diagnostic samples ($n=101$), cancer was confirmed in 76 (75.2%) cases. In all remaining cases ($n=25$, 24.8%), benign lesions or inflammatory/post-inflammatory changes were reported. Five of these patients were later prescribed surgical treatment involving pulmonary resection with an immediate morphological examination, taking into account the radiological characteristics of tumors. The examination confirmed the malignant nature of the tumor, and the surgery was expanded to anatomic pulmonary resection. The false negative rate was 4.7%.

Table 2. Complications after a transthoracic lung biopsy

Таблица 2. Осложнения после проведения трансторакальной биопсии лёгкого

Complications, Clavien—Dindo grade	Number of cases (%)
Grade I	4 (3.6%)
Hemothorax	1 (0.9%)
Pneumothorax	2 (1.8%)
Hemoptysis	1 (0.9%)
Grade II	3 (2.7%)
Hemothorax	2 (1.8%)
Hemoptysis	1 (0.9%)
Grade IIIa	10 (9.1%)
Pneumothorax	10 (9.1%)

Table 3. Indicators of transthoracic biopsy in the verification of the malignant tumor process

Таблица 3. Показатели трансторакальной биопсии в верификации злокачественного опухолевого процесса

Parameter	Value, %	95% CI
Sensitivity	93.83	86.18–97.97
Specificity	100	83.89–100
Precision	80.77	64.25–90.76

Table 3 shows the statistical parameters for the diagnostic value of TTNB in confirming cancer.

There were no significant differences in the incidence of cases with confirmed diagnosis depending on the biopsy needle size ($p=0.124$) (Fig. 1).

Moreover, the biopsy needle size (16G or 18G) had no significant effect on the total incidence of complications (18.2% and 9%, respectively; $p=0.266$) (Fig. 2) or the incidence of thoracostomy for postprocedural pneumothorax (10.4% and 6%, respectively; $p=0.72$) (Fig. 3).

DISCUSSION

One definitive advantage of a robot-assisted CT navigation system is that healthcare professionals performing biopsies are not exposed to radiation. Moreover, available publications indicate that this technique significantly reduces procedure time and radiation exposure for patients [14].

Our study found that lung tumor biopsy using a robot-assisted CT navigation system has a high diagnostic value.

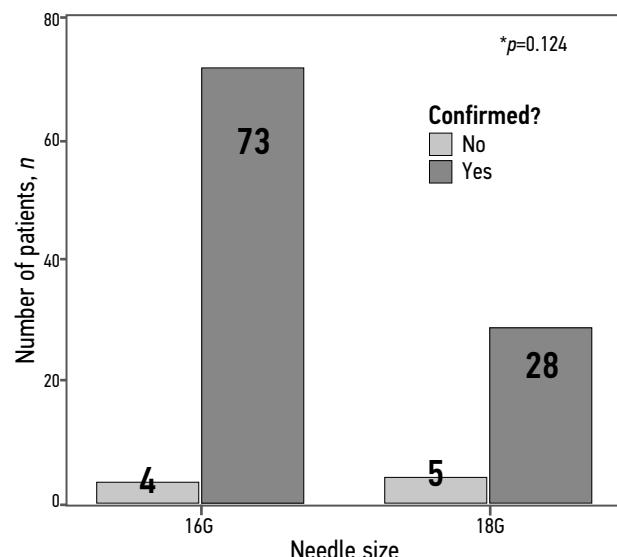


Fig. 1. The frequency of cases with morphological verification of the diagnosis, depending on the diameter of the biopsy needle.

Рис. 1. Количество пациентов с получением морфологической верификации диагноза в зависимости от диаметра биопсийной иглы.

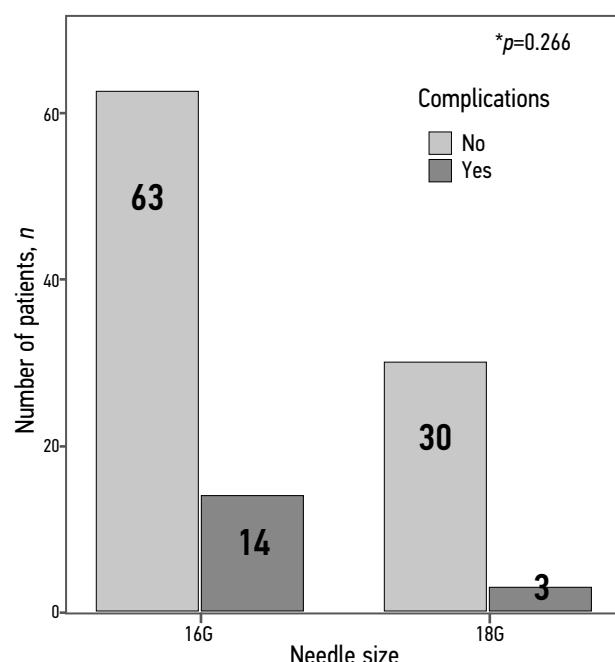


Fig. 2. The overall incidence of complications depending on the diameter of the biopsy needle.

Рис. 2. Количество пациентов с наличием или отсутствием осложнений после биопсии в зависимости от диаметра биопсийной иглы.

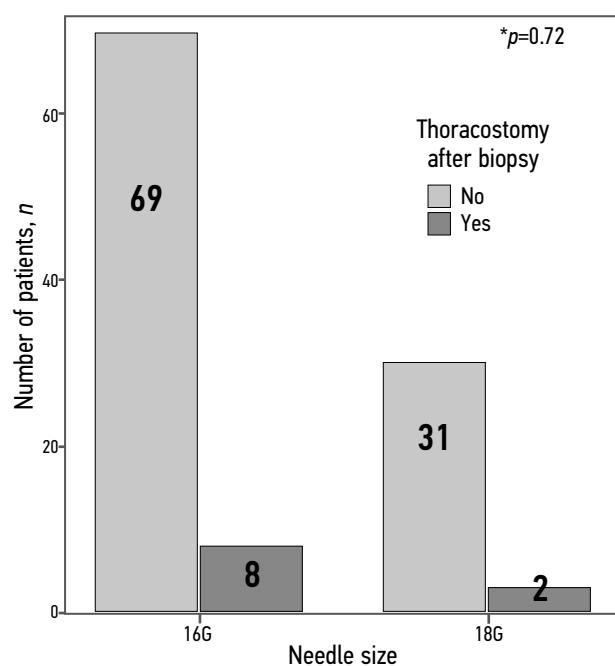


Fig. 3. The frequency of drainage of the pleural cavity depending on the diameter of the biopsy needle.

Рис. 3. Количество случаев дренирования плевральной полости в зависимости от диаметра биопсийной иглы.

The sensitivity, specificity, and precision in our study were 93.83, 100, and 80.8%, respectively, which is comparable to international findings [15–17]. Our data on biopsies in 106 patients is representative when compared to other published research. For example, Iannelli et al. [18] performed needle biopsy in 100 patients; Grasso et al. [19] used a robot-assisted navigation system in 197 patients; and Lanouziere et al. [20] described the procedure outcomes in 60 patients. This indicates that methods for using robot-assisted CT navigation systems in TTNB are still being developed.

Given that false negatives, which accounted for 4.7% in our study and reach 10–14.5% in other studies [15, 17], cannot be completely eliminated, we consider it necessary to continue follow-up in cases where cancer was not confirmed by biopsy. The first follow-up CT in these patients must be performed no later than after 3 months.

In our study, the incidence of complication was 15.5%, with 9% requiring thoracostomy, which is consistent with published data [7–9]. Previous comparisons revealed that real-time needle path tracking using 3D modeling allowed selecting the safest and shortest needle path, reducing the incidence of complications [14]. We found no significant differences in the incidence of complications depending on the biopsy needle size (16G and 18G); thus, both needle sizes are considered acceptable.

Study Limitations

The study is non-randomized in terms of biopsy needle size selection and the number of collected biopsy samples (tissue columns). Furthermore, this is a single-center study, with all procedures performed by two surgeons.

CONCLUSION

Robot-assisted CT-guided lung TTNB is a safe and effective technique for morphological confirmation of cancer.

ADDITIONAL INFORMATION

Authors' contribution. Z.A. Bagatelia — research concept, research design development, scientific guidance; D.N. Grekov — research concept, research design development, scientific guidance; S.S. Lebedev — research design development, scientific editing, critical review, scientific guidance; A.K. Chekini — research concept, writing the text of the manuscript, scientific editing, critical review; V.N. Yakomaksin — data collection, scientific editing, critical review; V.E. Bugaev — literature review, data analysis, statistical data processing, writing the text of the manuscript; R.A. Mkrtumyan — data collection, data analysis, editing text of the manuscript; K.S. Titov — research concept, data analysis, scientific editing; M.P. Onishchenko — data collection, data analysis, development and conduct of research; V.B. Rumer — data collection, data analysis, development and conduct of research. All authors approved the manuscript (the version for publication), and also agreed to be responsible for all aspects of the work, ensuring proper consideration and resolution of issues related to the accuracy and integrity of any part of it.

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