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# Comparative study of geometric localization technique and CT-guided percutaneous localization technique for peripheral GGO in wedge resection: a randomized controlled trial

Xuemin Zhao<sup>1</sup> and Mengjun Bie<sup>2\*</sup>

## Abstract

**Background** Intraoperative localization of ground glass opacity (GGO) is a major clinical challenge. We previously introduced a novel method called geometric localization technique (GLT). We aimed to compare GLT and the mostly common used technique-CT guided percutaneous localization technique (CPLT) in terms of the effectiveness, safety and accuracy.

**Methods** In a randomized controlled trial, patients who were diagnosed with pulmonary GGO and underwent wedge resection were randomized into GLT group (localized using GLT method) and CPLT group (localized using CPLT method). Baseline data, localization related data, successful localization rate, complications, operation related data and pathological results of patients were prospectively collected. Statistical analysis was performed between the two groups.

**Results** A total of 455 patients in our hospital were enrolled in this study from 2022–7-6 to 2024–2-22, including 228 patients in the GLT group and 227 patients in the CPLT group. There were significant differences in terms of the successful localization rate (99.6% vs. 94.3%,  $\chi^2 = 10.667$ ,  $P = 0.001$ ), the rate of sufficient resection margin (99.6% vs. 87.2%,  $\chi^2 = 28.110$ ,  $P < 0.001$ ), and incidence of localization-related complications (0 vs. 17.6%,  $\chi^2 = 114.251$ ,  $P < 0.001$ ) between GLT group and CPLT group. In the GLT group, the distance between GGO and marked visceral pleural point was  $3.9 \pm 3.1$  mm. In the CPLT group, the distance from punctured pleural point to GGO and the distance from anchor to GGO were  $18.3 \pm 11.4$  mm and  $4.1 \pm 3.5$  mm, respectively. In CPLT, one dislocation and thirteen dislodgement occurred. In multivariate regression analysis, only the localization technique was independently correlated with the successful localization rate (OR = 13.105; 95% CI: 1.688, 101.713;  $P = 0.014$ ). Gender (OR = 0.239; 95% CI: 0.099, 0.579;  $P = 0.002$ ), nodule size (OR = 0.864; 95% CI: 0.758, 0.984;  $P = 0.028$ ), depth of nodules (OR = 0.908; 95% CI: 0.861, 0.957;  $P < 0.001$ ) and the localization technique (OR = 40.809; 95% CI: 5.357, 310.855;  $P < 0.001$ ) were independent variables in determining the rate of sufficient resection margin.

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**Conclusions** Compared with CPLT, GLT has at least comparable outcomes in terms of effectiveness and accuracy; good safety profile was the advantage of GLT.

**Trial registration** ChiCTR2200060527 (<https://www.chictr.org.cn>), 2022/6/4, prospectively registered.

**Keywords** Pulmonary nodule, Ground-glass opacity, Localization technique, CT guided percutaneous localization technique, Wedge resection

## Introduction

With the increasing use of CT in screening of lung cancer in recent years, GGO (Ground glass opacity) nodules are easily detected in an early stage [1]. The incidence of lung cancer in GGO nodules has been reported as high as 63% [2]. GGO nodules usually develop slowly, and video-assisted thoracic surgery can significantly improve long-term prognosis [3–5].

Wedge resection is a commonly used surgical procedure for peripheral GGO. The identification of GGO location is very important during wedge resection, which determines the success of the operation. In recent years, the reported localization techniques include CT-guided percutaneous localization technique (CPLT) and bronchoscopic marking method [6, 7]. Electromagnetic navigation bronchoscopy (ENB) and cone-beam CT are used in some large institutions [8, 9]. CPLT is the most widely used localization technique, and the successful localization rate has been reported to be satisfactory [7, 10, 11]. However, CPLT method is an invasive procedure before operation, and location-related complications sometimes occur.

We previously introduced a noninvasive method named geometric localization technique (GLT) for peripheral GGO, which has been used in clinical practice for more than 4 years with good effectiveness and safety [12]. As we know, there is no comparative study of non-invasive and invasive localization technique in literature. We aims to compare GLT and CPLT method in terms of effectiveness, safety and accuracy in localizing peripheral GGO in pulmonary wedge resection.

## Materials and methods

The study was a prospective randomized controlled trial. This study was in accordance with the amended Declaration of Helsinki (<https://www.wma.net/policies-post/wma-declaration-of-helsinki>

-ethical-principles-for medical-research-involving-human-subjects/). The study was approved by the medical ethics committee of the first affiliated hospital of Chongqing Medical University (approval number: 2022–096). Written informed consent was obtained from the patients for the surgical procedure and for the enrollment in this study. The study was registered in the

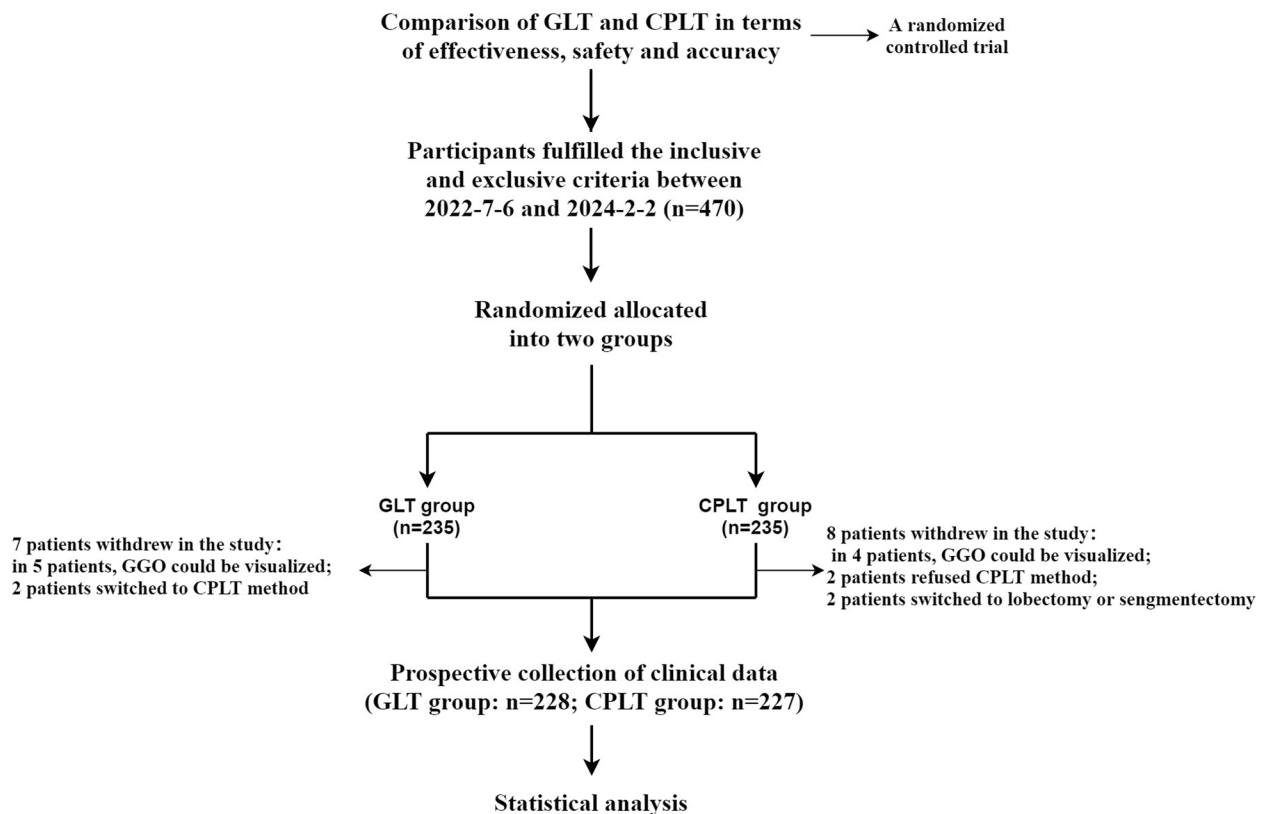
Chinese Clinical Trial Registry (registration number: ChiCTR2200060527, URL: <http://www.chictr.org.cn/>). There was no financial support received for this study. No conflicts of interest are declared.

## Patients

The software PASS 15.0 was used to calculate the sample size. The successful localization rate of GLT was estimated to be 99% according to our clinical practice, and the successful localization rate of CPLT was about 94% according to previous report [7]. The significance level ( $\alpha$ ) was 0.05 and the power of the test ( $1-\beta$ ) was 80%. Based on these parameters, the sample size of each group was 203 cases. Taking into account the possible withdrawal (15%), 235 subjects in each group were finally required in the study, a total of a minimum of 470 cases of the inclusion of the study subjects.

The inclusion criteria were as follows: (1) age  $\geq 18$  years; (2) solitary GGO with the maximum diameter less than 20 mm and consolidation/tumor (C/T) ratio less than 0.25; Or patients were not candidates for segmentectomy or lobectomy; (3) GGO located at the outer third of lung field; (4) suspicious-appearing malignancy on CT images, or GGO without any changes was followed up for at least 3 months, or malignancy proved by biopsy; lymph node metastasis was not indicated by CT (cN0); (5) The location of GGO could not be visualized; (6) The required resection depth was less than 30mm in order to achieve sufficient resection margin initially evaluated by preoperative CT images [13, 14]. Sufficient resection margin was defined as resection margin  $\geq 2$ cm or the tumor diameter [14]. The required resection depth was calculated as: Required resection depth (mm) = depth (distance from the closest pleura) + [lesion size  $\times 2$  or (lesion size + 20 mm)] [14].

The indication for surgery at our center was GGO size more than 8 mm [15]. For some GGOs which were smaller than 8 mm but were suspicious-appearing for malignancy, surgery was also sometimes considered for those patients in extremely anxiety influencing normal life. For multiple lesions, the GGOs  $< 8$  mm in size were resected synchronously with the main lesion if malignancies were suspected. The indications for wedge resection at our center were: (1) the GGO was smaller than 20 mm in size at its greatest dimension and the C/T ratio was



**Fig. 1** The flow chart of the second part of this study. Note: GLT, geometric localization technique; CPLT, CT-guided percutaneous localization technique; GGO, ground glass opacity

less than 0.25 [16]; (2) sufficient resection margin could be achieved estimated on the preoperative CT imaging [10]; or (3) patients could not fit enough to undergo segmentectomy and lobectomy. The surgical strategy for each patient was determined in consulting meeting.

At the first affiliated hospital of Chongqing Medical University (Chongqing, China) from 2022–7–6 to 2024–2–2, 470 patients who met the inclusion and exclusion criteria were randomized divided into two groups in a 1:1 ratio: GLT group (using GLT method) and CPLT group (using CPLT method). Subsequently, 7 patients in the GLT group and 8 patients in the CPLT group withdrew from the study. A total of 455 patients were finally included in the study, including 228 in the GLT group and 227 in the CPLT. Figure 1 shows the flow chart of the study.

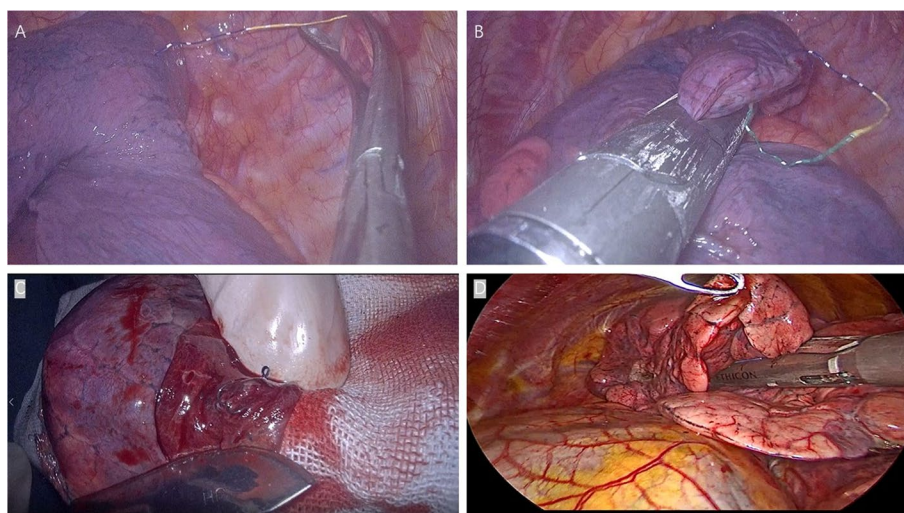
#### Localization technique

For the patients using GLT for localization, geometric parameters were measured in preoperative CT images by the surgeon before operation. The detailed procedure were previously reported [12]. The CPLT method for localization in our hospital is the same as that reported in the literature before [17]. The patient underwent CPLT

for GGO localization by experienced radiologists on the day of the operation. The pulmonary nodule localization device (Senscure, Ningbo, China) was used for GGO preoperative localization which consisted of the following five parts: coaxial needle (100 mm in length and 0.9 mm in diameter); pusher; anchor claw and suture; release buckle; protection tube [18]. With the guidance of CT (Siemens, Somatom Definition Flash), the anchor is placed in or around the lesion, and the proximal suture is left in the chest cavity. Another CT scan was performed to confirm that the anchor was in place and to determine whether complications had occurred at last. After CPLT localization, the patients returned to the ward waiting for surgery.

#### Surgical procedure

In GLT group, according to the marked visceral pleural projection and GGO depth, we planned the resected pulmonary areas and then wedge resection was performed using a linear cutting stapler. In CPLT group, wedge resection was planned with the center of punctured visceral pleural point (Fig. 2), and the anchor should be guaranteed to be resected according to the distance between GGO and anchor measured on the CT scan.



**Fig. 2** Schematic diagram of CPLT and GLT localization techniques during operation. **A** The needle punctures into the lung parenchyma through a suitable angle, and the anchor is placed around the nodule, while the wire is left in the chest cavity; **B** After CPLT localization, the visceral pleural punctured point was used to plan the resected area for wedge resection; **C** Anchor was used as a marker for finding GGO after CPLT localization; **D** After GLT localization, the resection area was planned centered by the marked visceral pleura point. Note: CPLT, CT-guided percutaneous localization technique; GLT, geometric localization technique; GGO, ground glass opacity

The sufficient resection margin should be evaluated and guaranteed after wedge resection. Operative field was cut open around the marked visceral pleura or anchor and the targeted GGO could be found. The lesions and resection margin were sent for intraoperative frozen section examination. If the resection margin was not sufficient by visualization or positive surgical margin was indicated by intraoperative frozen section examination, enlarged areas were wedge resected and sufficient resection margin should be evaluated once again.

#### Data collection

Data were prospectively collected for demographic characteristics, GGO characteristics (including location, size, type and depth), intraoperative data (including duration of operation, successful resection of targeted GGO, sufficient resection margin and the distance between GGO and marked/punctured visceral pleural point; and localization and operation related complications, and pathological characteristics.

#### Evaluation

The primary endpoint of this study was the success rate of localization of the targeted GGO. The successful localization procedure was defined as a successful localization of the targeted GGO in the resected lung tissue and the success rate of localization of targeted GGO was calculated as follows: [(number of successful localization of targeted GGOs – number of misses of GGOs in the resected lung tissue)/number of all GGOs localized]

\* 100. The secondary endpoints included the rate of sufficient resection margin, the accuracy of localization techniques, safety, and duration of surgical procedures. The distance between GGO and the marked/punctured visceral pleura point was used to assess the accuracy to localize the targeted GGO. The duration of surgical procedures were measured from the start of intraoperative identification of the targeted GGOs to the removal of the lesions. It didn't include the time of opening and closing of the incision. The rate of localization related complications was used to evaluate the safety of localization techniques.

#### Statistical analysis

The quantitative data were presented as mean  $\pm$  standard deviation. Categorical variable was described as a number and percentage. A two-sided Student's t-test was used for continuous variables, and a Chi-square test or Fisher's exact test was used for categorical variables. Univariate and multivariate logistic regression analyses were performed to determine the associations of GGO related characteristics with the success rate of localization and rate of sufficient resection margin. Statistically significant variables (i.e.,  $P < 0.20$ ) found by univariate regression analysis were included in the multivariate regression analysis. Two-tailed  $P$  value  $< 0.05$  was considered to be statistically significant. All statistical analysis was performed using the SPSS 27.0 software for windows (SPSS, Chicago, IL, USA).



**Table 1** Baseline of demographic data and clinical characteristics of patients with pulmonary GGO in two groups

	GLT group (n = 228)	CPLT group (n = 227)	t or $\chi^2$ value	P value
Age (years)	53.0 ± 12.4	52.9 ± 12.0	0.111	0.911
Gender (Male/Female)	83/145	75/152	0.568	0.451
Body mass index	23.4 ± 3.0	23.8 ± 3.3	-1.331	0.184
Smoking	45 (19.7%)	37 (16.3%)	0.910	0.340
Drinking	29 (12.7%)	27 (11.9%)	0.072	0.789
Family history of lung cancer	22 (9.6%)	22 (9.7%)	0.000	0.988
GGO type			0.069	0.793
Pure GGO	42 (18.4%)	44 (19.4%)		
Mixed GGO	186 (81.6%)	183 (80.6%)		
GGO size (mm)	9.9 ± 2.5	9.5 ± 3.0	1.558	0.120
GGO depth (mm)	9.7 ± 6.4	10.6 ± 7.3	-1.369	0.172
GGO location			8.956	0.062
The right upper lobe	84 (36.8%)	102 (44.9%)		
The right middle lobe	16 (7.0%)	11 (4.8%)		
The right lower lobe	38 (16.7%)	25 (11.0%)		
The left upper lobe	61 (26.8%)	48 (21.1%)		
The left lower lobe	29 (12.7%)	41 (18.1%)		
Pathological results			4.453	0.348
Atypical adenomatous hyperplasia	9 (3.9%)	14 (6.2%)		
Inflammatory diseases	26 (11.4%)	29 (12.8%)		
Focal interstitial fibrosis	3 (1.3%)	2 (0.88%)		
Atypical alveolar hyperplasia	2 (0.88%)	3 (1.3%)		
Adenocarcinoma in site	90 (39.5%)	91 (40.1%)		
Minimal invasive adenocarcinoma	84 (36.8%)	82 (36.1%)		
Invasive adenocarcinoma	14 (6.1%)	6 (2.6%)		

GGO Ground glass opacity, CPLT CT-guided percutaneous localization technique, GLT Geometric localization technique

## Results

### Comparison of baselines of demographics and clinical characteristics

From 2022–7–6 to 2024–2–22, a total of 455 patients were included in the study, with 228 patients in GLT group (using GLT method) and 227 patients in CPLT group (using CPLT method). The baselines of demographics and clinical characteristics between the two groups are shown in Table 1. There were no significant differences in terms of demographics, GGO size, GGO depth, GGO location and pathological results.

### Comparison of GLT and CPLT in terms of effectiveness, accuracy and safety

The successful localization rate in GLT group was 99.6% (227/228), while that in CPLT group was 94.3% (214/227), indicating a significant difference between the two groups ( $\chi^2 = 10.667$ ,  $P = 0.001$ ). The rate of sufficient resection margin was 99.6% (227/228) in the GLT group and 87.2% (198/227) in the CPLT group, indicating a significant difference ( $\chi^2 = 28.110$ ,  $P < 0.001$ ). In terms of safety, the incidence of localization-related

complications in the CPLT group was 17.6% (40/227), and 14.6% (41/227) of the patients had pain or discomfort at the puncture point, which was relatively mild and did not receive special treatment (Table 2). While no location-related complications occurred in the GLT group, showing a statistical difference between the two groups ( $\chi^2 = 114.251$ ,  $P < 0.001$ ).

In the GLT group, the distance between GGO and marked visceral pleural point was  $3.9 \pm 3.1$  mm. In the CPLT group, the distance from punctured pleural point to GGO and the distance from anchor to GGO were  $18.3 \pm 11.4$  mm and  $4.1 \pm 3.5$  mm, respectively. Hence, the accuracy in GLT group was significantly higher than that in CPLT group ( $P < 0.001$ ). In CPLT, one dislocation and thirteen dislodgement occurred, and the median interval between localization and operation was 4 h 45 min (range: 50 min–13 h 40 min). In the GLT group, parameters were measured in CT images on the day before surgery. The time for localization in GLT group was  $82.8 \pm 93.6$  s, and the time for localization in CPLT group was  $18.3 \pm 2.7$  min.

**Table 2** Comparison of the effectiveness and safety between the two groups

Variables	GLT group (n = 228)	CPLT group (n = 227)	$\chi^2$ value	P value
Surgeons' experience			0.656	0.418
> 10 and $\leq$ 20 years	146 (64.0%)	137 (60.4%)		
> 20 years	82 (36.0%)	90 (39.6%)		
Complications			114.251	< 0.001
Pneumothorax	0	19 (8.4%)		
Haemothorax	0	3 (1.3%)		
Intrapulmonary hemorrhage	0	13 (5.7%)		
Haemothorax and pneumothorax	0	3 (1.3%)		
Haemothorax and intrapulmonary hemorrhage	0	2 (0.9%)		
Discomfort or pain at the punctured point	-	41 (14.6%)	-	-
Dislodgement or dislocation	-	14 (6.2%)	-	-
The success rate of localization	227 (99.6%)	214 (94.3%)	10.667	0.001
The rate of sufficient resection margin	227 (99.6%)	198 (87.2%)	28.110	< 0.001

GLT Geometric localization technique, CPLT CT-guided percutaneous localization technique

**Table 3** Logistic regression analysis between successful localization rate and clinical characteristics

	Univariate logistic regression analysis			Multivariate logistic regression analysis		
	OR	95% CI	P value	OR	95% CI	P value
Age	0.986	0.944, 1.029	0.504			
Gender (Female vs. Male)	0.521	0.179, 1.512	0.230			
Body mass index	0.951	0.809, 1.117	0.539			
Smoking (Yes vs. No)	1.250	0.341, 4.584	0.737			
Family history of lung cancer (yes vs. no)	0.712	0.091, 5.576	0.746			
GGO location	-	-	0.904			
GGO type (mixed GGO vs. pure GGO)	3.104	0.401, 24.055	0.278			
GGO size	0.863	0.740, 1.007	0.062	0.869	0.751, 1.005	0.058
GGO depth	0.933	0.875, 0.994	0.031	0.941	0.882, 1.005	0.069
Localization technique (GLT vs. CPLT)	13.790	1.789, 106.317	0.012	13.105	1.688, 101.713	0.014
Surgeons' experience	-	-	0.996			
Pathological results	-	-	0.982			

OR Odds ratio, CI Confidence interval, GGO Ground glass opacity, GLT Geometric localization technique, CPLT CT-guided percutaneous localization technique

### Logistic regression analysis for clinical characteristics and the success rate of localization or the rate of sufficient resection margin

Table 3 shows the results of logistic regression analysis between the success rate of localization and clinical characteristics. In univariate analysis, the success rate of localization was correlated with GGO size (OR=0.863,  $P=0.062$ ), GGO depth (OR=0.933,  $P=0.031$ ) and GLT method for GGO localization (OR=13.790,  $P=0.012$ ), hence they were included in a multivariate regression model. GGO location, GGO type, surgeon experience and pathological results were not significantly associated with the success rate of localization. In multivariate regression analysis, only the GLT method was

independently correlated with the success rate of localization (OR=13.105; 95% CI: 1.688, 101.713;  $P=0.014$ ).

Table 4 shows the results of logistic regression analysis between the rate of sufficient resection margin and clinical characteristics. In univariate analysis, the rate of sufficient resection margin was correlated with age (OR=0.977,  $P=0.136$ ), gender (OR=0.380,  $P=0.011$ ), GGO type (OR=7.250,  $P=0.053$ ), GGO size (OR=0.856,  $P=0.006$ ), GGO depth (OR=0.915,  $P<0.001$ ), and GLT method used (OR=33.247,  $P<0.001$ ), and then these factors were included in the multivariate regression model. In multivariate regression analysis, gender (OR=0.239; 95% CI: 0.099, 0.579;  $P=0.002$ ), GGO size (OR=0.864; 95% CI: 0.758, 0.984;

**Table 4** Logistic regression analysis between sufficient resection margin rate and clinical characteristics

	Univariate logistic regression analysis			Multivariate logistic regression analysis		
	OR	95% CI	P value	OR	95% CI	P value
Age	0.977	0.948, 1.007	0.136	0.994	0.958, 1.032	0.770
Gender (Female vs. Male)	0.380	0.179, 0.804	0.011	0.239	0.099, 0.579	0.002
Body mass index	0.943	0.843, 1.055	0.305			
Smoking (Yes vs. No)	1.725	0.739, 4.024	0.207			
Family history of lung cancer (yes vs. no)	0.651	0.150, 2.083	0.567			
GGO location	-	-	0.391			
GGO type (mixed GGO vs. pure GGO)	7.250	0.974, 53.979	0.053	6.769	0.829, 55.227	0.074
GGO size	0.856	0.767, 1.957	0.006	0.864	0.758, 0.984	0.028
GGO depth	0.915	0.874, 0.957	< 0.001	0.908	0.861, 0.957	< 0.001
Localization technique (GLT vs. CPLT)	33.247	4.488, 246.297	< 0.001	40.809	5.357, 310.855	< 0.001
Surgeons' experience	-	-	0.979			
Pathological results	-	-	0.645			

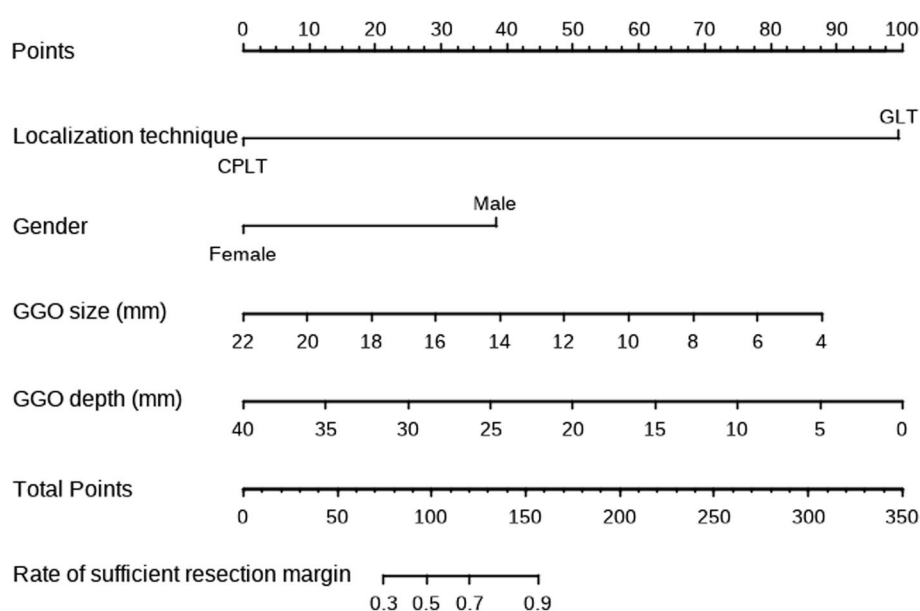
OR Odds ratio, CI Confidence interval, GGO ground glass opacity, GLT Geometric localization technique, CPLT CT-guided percutaneous localization technique

$P=0.028$ ), GGO depth (OR=0.908; 95% CI: 0.861, 0.957;  $P<0.001$ ) and GLT method used (OR=40.809; 95% CI: 5.357, 310.855;  $P<0.001$ ) were independent variables in determining the rate of sufficient resection margin. Incorporating four independent risk factors into the prediction model, we developed an alignment diagram prediction model for whether the resection margin was sufficient (Fig. 3).

## Discussion

The study showed that GLT method is at least comparable with CPLT method in terms of effectiveness and accuracy. Good safety profile was the advantage of GLT due to the noninvasive character. GLT technique might be expected to be used as an alternative to locate peripheral GGO.

CPLT is the most commonly used localization technique in clinical practice, such as hookwire, microcoil, injection of dye and ENB, etc. [10, 11, 19]. Hookwire is effective when the tumor is located close to the visceral

**Fig. 3** A nomogram predicting the rate of sufficient resection margin in multivariable logistic regression model

pleura. The microcoil method has the advantage of being able to visualize the lesion under the fluoroscope during operation [8]. Each localization technique also has its own disadvantages. Hookwire and microcoil localization techniques have the disadvantages of dislodgement and migration [6, 7, 20]. Radiation exposure and requirement for protective clothing during surgery are the major weakness of lipiodol localization; dye staining tends to diffuse easily and thus leads to over-resection [10]. Barium injection may interfere with pathological diagnosis due to severe inflammatory reaction [20]. The optimal localization technique for small pulmonary nodules has not been determined and new localization techniques still should be introduced into the field.

Recent studies have shown that both hookwire and microcoil can achieve satisfactory successful localization rate (97.7% and 95.3%, respectively) [10]. A meta-analysis enrolled 46 studies reported that hookwire, microcoil and lipiodol localization could yield similarly high successful operative field targeting rates (94%, 97% and 99% respectively) [7]. It has been reported that successful localization rate of methylene-blue is 97.9% [11]. In the study, the successful rate of CPLT localization was 94.3%, which was comparable with previous report, while the success rate of localization using GLT method was 99.6%, indicating that the effectiveness of GLT and CPLT method was both satisfactory.

In the GLT group, the rate of sufficient resection margin (99.6%) was also significantly higher than that of the CPLT group (87.2%). Because of the punctured angle in CPLT method, the punctured needle is often not perpendicular to the lung surface, thus the distance between the visceral pleural puncture point and the nodule is sometimes large, possibly resulting in insufficient resection margin. In the study, the distance between GGO and marked visceral pleural points in GLT group was  $3.9 \pm 3.1$  mm, while the distance from nodule to punctured visceral pleural point and anchor in the CPLT group were  $18.3 \pm 11.4$  mm and  $4.1 \pm 3.5$ , respectively. The wedge resection was planned with the center of the marked visceral point in the GLT group, while the resection area was usually planned according to the punctured visceral pleural point in CPLT group. Hence, the distance from GGO and the marked visceral pleural point in GLT group of the punctured pleural point could represented the accuracy of the localization technique. The study indicated that GLT might have better accuracy than CPLT method.

CT-guided percutaneous localization techniques are preoperative invasive procedures and may lead to some complications with relatively high incidence, such as pneumothorax, hemothorax and intrapulmonary bleeding [7, 10, 11, 21]. A rare case has been recently reported

that hookwire was slid into pulmonary artery threatening the patient's life [22]. A recent comparative study found that the incidence of complications for hookwire and coil microcoil were 31.0% and 15.5% [10]. In the study, the incidence of localization related complications for CPLT was 17.6%, which was comparable with previous reports, and about 14.6% of the patients complained of pain or discomfort at the punctured point. Compare with CPLT, GLT was advantageous and patients might have better medical experience.

There were several limitations in this study. Our study was a single-center design, and the sample size was relatively small. We didn't compare GLT method with some other localization techniques. And there were no special instruments like other localization techniques. We will further improve this technique to make it more accurate and invent some special instruments.

## Conclusions

Compared with CPLT, GLT has at least comparable outcomes in terms of effectiveness and accuracy; good safety profile was the advantage of GLT.

## Abbreviations

GGO	Ground glass opacity
ENB	Electromagnetic navigation bronchoscopy
CPLT	CT-guided percutaneous localization technique
GLT	Geometric localization technique
C/T	Consolidation/tumor

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The authors thank all patients who consented to the enrollment in this study. No one else than the authors have participated in the design, data collection and analysis, data interpretation, and preparation of this article.

## Authors' contributions

MB planned the study. MB and XZ collected the data, performed the statistical analysis and drafted the manuscript. MB and XZ convinced of the study, and participated in its design and coordination. All authors read and approved the final manuscript.

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None.

## Data availability

The datasets used and/or analyzed in this present study are available from the corresponding author on reasonable request.

## Declarations

### Ethics approval and consent to participate

This study was carried out following the international ethical recommendations for medical research in humans. Both authors were sure that this study was conducted in accordance with the standards set out in the Declaration of Helsinki. Before starting the study, the Ethical Committee of the first affiliated hospital of Chongqing Medical University approved the study protocol. All participants provide written informed consent before enrollment.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.



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