A retrospective comparative study of microwave ablation and sublobectomy in the treatment of early subpleural nonsmall cell lung cancer

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ABSTRACT

Objective: Microwave ablation (MWA) is a safe and effective local therapy, however, its efficacy in stage I subpleural nonsmall cell lung cancer (NSCLC) compared to that of sublobar resection (SLR) is unclear. This study aimed to compare the efficacy of the two treatments for stage I NSCLC ≤1 cm from the pleura.

Methods: After propensity score matching (PSM), 70 patients with stage I subpleural NSCLC who underwent either SLR or MWA (35 patients each) from 2014 to 2018 were included. The margin pathology of SLR was negative. MWA reached a sufficient ablative margin. MWA group were stratified according to the minimal ablative margin, with 10 patients each in the 5–10 mm group and the >10 mm group after PSM. The local recurrence-free survival (LRFS), relapse-free survival (RFS), overall survival (OS), and treatment-related complications were compared.

Results: For patients with stage I subpleural NSCLC, the LRFS of patients in the SLR group (35.657 ± 0.338 months, 95% CI: 34.995–36.319) was significantly better than that in the MWA group (31.633 ± 1.574 months, 95% CI: 28.548–34.719, p = 0.021). The RFS was also significantly better in the SLR group (35.629 ± 0.338 months, 95% CI: 34.966–36.292) than in the MWA group (29.387 ± 1.866 months, 95% CI: 25.730–33.044, p = 0.007), but there were no significant differences in terms of the 3-year OS (p = 0.079) and incidence of complications (14.3% vs. 11.4%, p = 0.653). The minimal ablative margin of >10 mm was not significantly associated with the LRFS (p = 0.929).

Conclusion: MWA for stage I subpleural NSCLC showed similar survival outcomes and complication rates to SLR, but poorer local tumor control.

INTRODUCTION

Currently, lung cancer is one of the leading causes of cancer-related deaths in the world and has become a major threat to human health. With the widespread development of lung cancer screening by chest CT, the detection rate of lung cancer is also increasing [1]. According to the GLOBOCAN statistics [2], there were ~2.2 million new lung cancer cases worldwide in 2020, accounting for 11.4% of all malignant tumors. In 2019, there were ~1.8 million deaths due to lung cancer, accounting for 18.0% of malignant tumor-related deaths. Among them, nonsmall cell lung cancer (NSCLC) accounts for more than 80% of lung cancer patients [1], and stage I NSCLC make up of about 15–20%.

To date, surgery is the preferred treatment for early stage NSCLC. Sublobar resection (SLR), which consists primarily of wedge resection and segmentectomy, allows the lesion to be completely removed while maximizing the protection of lung function, has gradually replaced the traditional radical resection of lung cancer (lobectomy + mediastinal and hilar lymph node dissection) and has become the most commonly used surgical method [3].

In clinical practice, however, over 20% of patients cannot undergo surgery due to decreased cardiopulmonary function and other underlying diseases [4]. Therefore nonsurgical treatment plays a greater role in these cases. Thermal ablation (TA), which mainly includes radiofrequency ablation (RFA) and microwave ablation (MWA), has been demonstrated by several studies in recent years as an effective alternative to surgery for early stage NSCLC [5,6]. It is a percutaneous puncture performed under the guidance of imaging technology where an ablation antenna is inserted into the center of the tumor, coagulating tumor proteins and tissue necrosis through high temperature, and ultimately eliminating the tumor [7]. However, issues regarding TA for early stage NSCLC still need to be resolved. For example, the location of the tumor could be an important risk factor affecting the efficacy and major complications, while the subpleural tumor has a special location and is more likely to cause serious complications during and after ablation.
Complications, such as severe pain, pneumothorax, bronchopleural fistula, etc. [8], may affect ablation time, power, and repositioning of the applicator. Changing these parameters will increase the risk of tumor recurrence and lead to incomplete ablation, thereby affecting treatment outcomes. Subpleural tumors are not currently defined [9,10], and were described in this study as tumors ≤1 cm from the pleura. For those patients, when surgical treatment is not suitable, it is worth exploring whether the MWA treatment can achieve the equivalent effect of surgical treatment.

There are currently no relevant studies on the efficacy and safety of MWA and SLR in the treatment of stage I subpleural NSCLC. This study has classified lung tumors according to the locations in the thoracic cavity. This study aimed to compare the efficacy of the two treatments for early subpleural NSCLC.

Methods

Patients

Our study was a retrospective study. A total of 70 patients with stage I subpleural NSCLC who received only one of the two treatments in Shandong Provincial Hospital from 2014 to 2018 after propensity score matching (PSM) were included, including 35 patients who received MWA therapy and 35 patients who received SLR surgery. The specific patient selection process is shown in Figure 1. Inclusion criteria: (1) NSCLC confirmed by pathology; (2) subpleural lung cancer confirmed by imaging (the distance between tumor edge and pleura ≤1 cm); (3) comprehensive imaging examinations such as CT, MRI, and PET/CT were performed. According to the eighth edition of UICC TNM staging, the clinical staging is consistent with stage I (T1N0M0); (4) age >18 years and ≤80 years old. Exclusion criteria: (1) combined with other important organ dysfunction or system diseases; (2) severe coagulation dysfunction; (3) PS score ≥3; (4) combined with other tumors.

This clinical trial has been prospectively registered in the Chinese Clinical Trial Registry and the registration number was ChiCTR2200059325. The study was approved by the institutional review board and the informed consent requirement was waived, the approved protocol number is SWYX: NO.2022-154.

Treatment and patient follow up

MWA group

MWA was performed using the MTC-3C MWA system (VisonChina Medical Devices R&D Center), the frequency is 2450 ± 50 MHz, the adjustable output level ranged from 0 to 100 W. The effective length was 100, 150, and 180 mm, and an outside diameter of 16, 18, or 19 G was used. The patient was assisted to be in the most suitable position, the puncture point was identified with the help of a metal body surface locator, the local area was disinfected, and layer-by-layer anesthesia was performed with the help of 1% lidocaine injection. The puncture was performed under the guidance of CT. If the location of the ablation antenna was not satisfactory, the ablation was performed after adjustment. The main purpose was complete tumor coagulation and obtaining a sufficient ablative margin (or safety distance). Definition of sufficient ablative margin used in this study was the ablation zone close to the pleural surface covering the pleura, and the minimal ablative margin [11] (the minimum distance from the ablation edge of the nonpleural surface to the tumor edge, Figure 2(C)) was ≥5 mm (guidelines and consensus believe that the safety distance should be at least 5 mm [12,13]). In this study, MWA was completed by percutaneous puncture under the guidance of CT. A total of 35 ablations were performed on 35 lesions. The curative effect was evaluated immediately. All of them achieved complete ablation, and the total ablation time was 7.23 ± 3.14 min. Two of the patients with local recurrence underwent repeated ablation.

SLR group

All operations, performed by the thoracic surgical team of our hospital with prolific clinical experience, were completely resected and the tumor margin was negative, and a sufficient safety distance (≥1 cm) was reserved. All operations were performed by thoracoscopic surgery, and 35 patients received SLR treatment, including 34 cases of wedge resection and 1 cases of segmentectomy.

Patients of both groups generally underwent CT one month after treatments. Patients were followed up with every 6–12 months. Once the tumor recurred, the therapy was based on the preference of patients and the clinical practice of clinicians. All patients were followed up until death, 31 December 2021, or lost to follow-up, whichever came first.

Survival outcome

The primary endpoint of the study was local recurrence-free survival (LRFS), relapse-free survival (RFS), and the secondary endpoint was overall survival (OS).

Local recurrence is defined as tumor progression within the lobe where the tumor is located (medical imaging combined with pathology when necessary). Regional recurrence is defined as ipsilateral lymph node recurrence in the hilum or mediastinum or ipsilateral lung recurrence. Distant recurrence refers to types of recurrence other than local and regional recurrence.

LRFS was defined as the interval from the date of treatment to local recurrence, death, or last follow-up visit. RFS was defined as the interval from the date of treatment to any form of tumor recurrence, death, or last follow-up visit. OS was defined as the time from treatment to death or the last follow-up before 31 December 2021.

MWA with CT monitoring of minimal ablative margin

Two experienced CT experts stratified the ablation group according to whether the minimal ablative margin was
>10 mm based on preoperative and postoperative CT, respectively. When their results are inconsistent, they will have a discussion before making a decision.

**Statistical analysis**

All statistical analyses were performed using SPSS 25.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as $x \pm s$ and categorical variables were presented as counts and percentages. Continuous variables were compared by $t$-test, and categorical variables were compared by $\chi^2$ test or Fisher’s exact test. The Kaplan-Meier method was used to compare the survival curves of the two groups, and Cox regression analysis was used to evaluate the effect of multiple factors on survival. Differences of $p < 0.05$ were considered statistically significant.
Results

Patient characteristics

Table 1 shows the baseline characteristics of the two groups of patients after PSM. There was no significant difference in general data between the two groups ($p > 0.05$), which was comparable.

Comparison between MWA and SLR group outcomes

For patients with stage I subpleural NSCLC, the LRFS of patients in the SLR group (35.657 ± 0.338 months, 95% CI: 34.995–36.319) was significantly better than that in the MWA group (31.633 ± 1.574 months, 95% CI: 28.548–34.719, $p = 0.021$, Figure 3(B)). The RFS of patients in the SLR group (35.629 ± 0.338 months, 95% CI: 34.966–36.292) was also significantly better than that of the MWA group (29.387 ± 1.866 months, 95% CI: 25.730–33.044, $p = 0.007$, Figure 3(C)); however, there was no significant difference in 3-years OS between the MWA group and the SLR group ($p = 0.079$, Figure 3(A)).

Factors associated with LRFS and RFS

According to the results of the Kaplan-Meier, there were significant differences in LRFS between the two groups in gender ($p = 0.009$) and smoking history ($p = 0.011$). No significant difference between other variables in LRFS was found (Table 2). Multivariate analyses showed that operation method and gender were independent factors that affected local recurrence ($p = 0.047$; $p = 0.030$). The risk of local recurrence in patients receiving SLR treatment was lower than that in patients receiving MWA, HR = 0.103 (95% CI: 0.029–0.408, $p = 0.003$).

Table 1. Baseline characteristics of the cohort for early subpleural NSCLC.

| Variables                  | MWA group (n = 35) | SLR group (n = 35) | p-Value |
|----------------------------|--------------------|--------------------|---------|
| Gender                     |                    |                    | 0.810   |
| Male                       | 16 (45.7%)         | 15 (42.9%)         |         |
| Female                     | 19 (54.3%)         | 20 (57.1%)         |         |
| Age                        |                    |                    | 0.771   |
| <60                        | 8 (22.9%)          | 7 (20%)            |         |
| ≥60                        | 27 (77.1%)         | 28 (80%)           |         |
| Pathology                  |                    |                    | 1       |
| Squamous cell carcinoma    | 3 (8.6%)           | 3 (8.6%)           |         |
| Adenocarcinoma             | 32 (91.4%)         | 32 (91.4%)         |         |
| Hypertension               |                    |                    | 1       |
| Yes                        | 15 (42.9%)         | 15 (38.9%)         |         |
| No                         | 20 (57.1%)         | 20 (61.1%)         |         |
| CHD                        |                    |                    | 1       |
| Yes                        | 7 (20%)            | 7 (20%)            |         |
| No                         | 28 (80%)           | 28 (80%)           |         |
| Smoking history            |                    |                    | 0.454   |
| Yes                        | 14 (40%)           | 11 (31.4%)         |         |
| No                         | 21 (60%)           | 24 (68.6%)         |         |
| Size                       |                    |                    | 0.881   |
| >1.5 mm                    | 18 (51.4%)         | 17 (48.6%)         |         |
| ≤1.5 mm                    | 17 (48.6%)         | 18 (51.4%)         |         |
| Location                   |                    |                    | 0.869   |
| The left upper lobe        | 9 (25.7%)          | 13 (37.1%)         |         |
| The left lower lobe        | 6 (17.1%)          | 4 (11.4%)          |         |
| The right upper lobe       | 11 (31.4%)         | 10 (28.6%)         |         |
| The right middle lobe      | 2 (5.7%)           | 2 (5.7%)           |         |
| The right lower lobe       | 7 (20%)            | 6 (17.1%)          |         |
| Relationship with pleura   |                    |                    | 0.530   |
| Adhering to the pleura only| 7 (20%)            | 11 (31.4%)         |         |
| Pleural indentation        | 23 (65.7%)         | 19 (54.3%)         |         |
| Visceral pleural involvement| 5 (14.3%)         | 5 (14.3%)          |         |
| Distance to pleura         |                    |                    | 0.725   |
| ≤3 mm                      | 15 (42.9%)         | 14 (40%)           |         |
| >3 mm, ≤5 mm               | 11 (31.4%)         | 14 (40%)           |         |
| >5 mm                      | 9 (25.7%)          | 7 (20%)            |         |
| Pleura                     |                    |                    | 0.392   |
| Cervical pleura            | 1 (4.2%)           | 1 (1.9%)           |         |
| Costal pleura              | 31 (79.2%)         | 31 (87%)           |         |
| Mediastinal pleura         | 3 (14.6%)          | 3 (7.4%)           |         |
| Diaphragmatic pleura       | 0 (2.1%)           | 2 (7.4%)           |         |
CI: 0.013–0.838, Table 2); the risk of local recurrence in female patients was lower than that in male patients, HR = 0.100 (95% CI: 0.012–0.818, Table 2).

There were significant differences in RFS between the two groups in tumor size (p = 0.049) and location (p = 0.041). No significant difference between other variables in RFS was found (Table 3). Multivariate analyses showed that the operation method was an independent factor that affected the recurrence (p = 0.017). The recurrence risk of patients receiving SLR was lower than that of patients receiving MWA, HR = 0.164 (95% CI: 0.036–0.750, Table 3).

### Complications

The main complication after ablation was pneumothorax (14.3%), and the main complication after surgical treatment was pneumonia (11.4%); there was no statistical difference in the incidence of complications (p = 0.653, Table 4).

### Ablative margin

We stratified the ablation group (n = 35) according to minimal ablative margin, with 18 patients in the 5–10 mm group and 17 in the >10 mm group. After PSM, 10 patients in each group were included (Table 5). The local tumor recurrence rate in both groups was 20.0% (2/10), and there was no significant difference in LRFS between the two groups according to the Kaplan–Meier analysis (p = 0.929, Figure 4).

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**Table 2.** Factors associated with LRFS of the cohort for early subpleural NSCLC after PSM.

| Variables             | Univariate analysis (Kaplan-Meier) | Multivariate analysis (Cox) |
|-----------------------|-----------------------------------|-----------------------------|
|                       | x²      | p-Value     | HR (95% CI)     | p-Value     |
| Group                 | 5.355   | 0.021       | 0.120 (0.015–0.975) | 0.047       |
| Pathology             | 3.801   | 0.051       | –               | NA          |
| Gender                | 6.901   | 0.009       | 0.098 (0.012–0.799) | 0.030       |
| Age                   | 0.445   | 0.505       | –               | NA          |
| Hypertension          | 0.227   | 0.633       | –               | NA          |
| CHD                   | 2.061   | 0.151       | –               | NA          |
| Smoking history       | 6.393   | 0.011       | –               | 0.309       |
| Size                  | 2.354   | 0.125       | –               | NA          |
| Location              | 7.508   | 0.111       | –               | NA          |
| Relationship with pleura | 0.051   | 0.975       | –               | NA          |
| Distance to pleura    | 0.778   | 0.678       | –               | NA          |
| Pleura                | 0.979   | 0.806       | –               | NA          |

–: no data; CI: confidence interval; LRFS: local recurrence free survival; NA: not applicable.
stage lung cancer who are less willing to undergo surgical resection. For such patients, nonsurgical treatment plays an important role. In recent years, nonsurgical treatment methods have been increasingly used in clinical practice, such as TA, stereotactic radiation therapy, etc. [18], as they provide patients with more options and have achieved good therapeutic effects [19,20]. Among them, TA has the advantage that it can completely destroy the tumor while reducing the damage to the surrounding normal tissue, which is very attractive for patients. Kim SR’s [21] study showed that RFA can provide comparable survival to lobectomy for stage I NSCLC patients. Another study [22] comparing MWA and lobectomy in the treatment of stage I NSCLC showed that the two groups had similar OS and DFS, but MWA had shorter hospital stays and lower costs. For RFA and MWA, numerous studies have shown that the effects of the two are similar for lung cancer [23,24]. However, MWA allows larger ablation volumes, which should reduce the chance of local recurrence, but such an outcome has not been completely demonstrated in clinical practice. In the past 5–10 years, MWA has been used on a wider scale for NSCLC [25].

However, a major problem associated with TA is the destruction of adjacent key structures. When TA is performed on subpleural tumors, it is more likely to cause damage to the chest wall and intercostal nerves, causing severe pain, and more likely to damage the pleura resulting in pneumothorax or other complications, which may force the operator to change the ablation plan (e.g., reduce microwave power and ablation time). Such altered planning may affect the ablation zone and ultimately local efficacy. Although intra-vascular anesthesia and artificial pneumothorax [9,26] can reduce intraoperative pain, they undoubtedly increase the difficulty and risk of operation. Therefore, for patients with subpleural lung cancer who are not suitable for or refuse surgery, whether MWA is still a good alternative to surgery deserves further exploration.

The findings of our study show that there was no significant difference in OS between MWA and SLR, but the latter has improved LRFS and RFS. The difference in local tumor control may be related to the greater and clearer safety
distance that can be achieved with surgery. In terms of the complications we observed, there was no significant difference in the incidence of complications between the two groups, which is aligned with the findings of other studies [27,28], which proves that both methods are considerably safe. Therefore, for NSCLC patients with tumor margins ≤1 cm from the pleura, as long as the patient’s condition allows it, surgical treatment remains the preferred treatment; however, MWA is a good alternative when surgery is refused or not suitable. This finding is consistent with the conclusion of Zhao H’s [29] comparative study of the two surgical methods. In other studies [19,28,30], SLR was not only associated with better local tumor control rate, but also with better OS. This difference may be related to our short follow-up time. Alexander et al. [31] suggested that the poorer OS in the ablation group was related to the fact that patients who underwent ablation tended to be older, and that ablation remained a good alternative to surgery.

In our study, gender was an independent risk factor for LRFS, with males having a higher risk of local recurrence than females. There is insufficient research on local recurrence and prognostic factors in the comparative study of the two surgical methods, but some studies addressed gender differences in postoperative recurrence. In Tao H’s study [32], male patients were more prone to recurrence and metastasis than females after early stage NSCLC, while in Sakurai H’s study [33], female patients with adenocarcinoma had better postoperative prognosis than males but there was no significant difference in nonadenocarcinoma patients, and most of the pathological types of lung cancer in this study were adenocarcinoma. In Zhao H’s [29] comparative study of SLR and ablation in patients with early stage NSCLC, the Cox regression model also showed that the prognosis of women was better than that of men (p = 0.007). However, some scholars believe that gender is not directly related to the prognosis of lung cancer [34]. Although there are differences in biological behavior, hormones, genes, and other aspects between males and females, whether they have an impact on the occurrence and development of lung cancer remains to be further studied.

Additionally, in this study, according to the position of the tumor in the thoracic cavity, it was classified according to the lobe of the lung where the tumor is located, the close pleura, and the distance from the tumor edge to the pleura [8]. Univariate analysis found that the above factors did not affect local tumor control and survival. Therefore, it is not considered an independent influencing factor of the two surgical methods in this study. However, this conclusion needs to be further confirmed in future multicenter large-sample clinical studies.

Some studies have confirmed that local recurrence can be significantly reduced when the surgical margin is ≥1 cm [35,36] in SLR. In our study, the safety distance of the SLR group is > 1 cm, and the pathological results show that the surgical margin is negative. For subpleural NSCLC treated by MWA, it is more difficult to grasp the safety distance (5–10 mm [12,13]). In the MWA group, all patients achieved sufficient ablative margin mentioned earlier, and complete ablation was achieved. However, studies [13,37,38] show that the larger the safety distance, the lower the risk of local recurrence. Therefore, we stratified the ablation group according to the minimal ablative margin, but there was no significant statistical difference in our study. This could be due to the limited number of samples in the study. Increasing the ablative margin [37–39] or developing and applying image registration and fusion software [37] to calculate the ablative margin better may prove promising in improving local tumor control. Multicenter large-sample studies are needed to confirm this view in the future.

This study is not without limitations. First of all, it is a retrospective study, and there is inevitable information bias to some extent, which is not conducive to data integrity. Secondly, the sample size of this study was relatively small and it was a single-center study, which may result in some data bias. Therefore, prospective, multicenter, and big data studies are still needed to obtain more accurate local control and survival results.

In conclusion, SLR has better tumor control than MWA in patients with stage I subpleural NSCLC, but there is no significant difference in OS and major complication rates between the two. In clinical practice, surgery should be the first choice for the majority of patients. However, for patients who refuse or are not suitable for surgery, MWA could be an effective alternative treatment modality.

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