Review Article

Clinical practice guidelines on image-guided thermal ablation of primary and metastatic lung tumors (2022 edition)

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ABSTRACT

The main contents of the Clinical Practice Guidelines on Image-Guided Thermal Ablation (IGTA) of Primary and Metastatic Lung Tumors (2022 Edition) include the following: epidemiology of primary and metastatic lung tumors; the concepts of the IGTA and common technical features; procedures, indications, contraindications, outcomes evaluation, and related complications of IGTA on primary and metastatic lung tumors; and limitations and future development.

KEY WORDS: Image-guided thermal ablation, lung cancer, metastatic lung tumor

INTRODUCTION

Approximately, 2.2 million new cases of lung cancer and 1.8 million lung cancer-related deaths were reported in 2020 worldwide. Although the incidence of lung cancer ranks the second in the world, the mortality rate is the highest.[1] Lung cancer is the leading cause of cancer death in both China and the USA. By 2022, China and the USA are expected to have approximately 870,982 and 238,032 new lung cancer cases, and 766,898 and 144,913 lung cancer deaths, respectively.[2] Primary lung cancer is mainly divided into nonsmall cell lung cancer (NSCLC) and small cell lung cancer, which account for 85–90% and 10–15% of total diagnoses, respectively. For early-stage NSCLC, surgical resection with curative intent comprises the primary therapy[3,4]; however, approximately 60% of lung cancers cannot be resected surgically due to various reasons (such as poor cardiopulmonary function or advanced age). Stereotactic body radiation therapy (SBRT) is a good regimen for most patients with lung cancer who cannot undergo surgical resection, but it also has limitations.[5-7] Therefore, many novel local treatment approaches have been developed, including image-guided thermal ablation (IGTA) therapy. IGTA, a precise minimally invasive technique, has been applied on treating early-stage lung cancer. The number of patients with lung cancer treated by IGTA each year is rapidly increasing.[8-16] Pulmonary metastases are widespread in clinical practice, and the lung is the second most common organ to which all tumors metastasize. Nearly one-third of patients who died of cancer had pulmonary metastases. Malignant tumors of epithelial origin (such as colorectal cancer), sarcomas, malignant tumors of the reproductive and urinary systems (such as renal cell carcinoma), malignant melanoma, and other tumors account for 43, 42, 7, 6, and 2% of pulmonary metastasis cases, respectively.[16,17] Currently, IGTA has been shown to be one of the effective methods on treating pulmonary metastases.[18-26]

In 2014 and 2017, two editions of the expert consensus on thermal ablation for primary and metastatic lung tumors (referred to as consensus) were published in China.[27,28] The English version of the consensus was published in 2015 and 2018, respectively.[29,30] The publication of the consensus

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has promoted the development of the thermal ablation on treating lung tumors not only in China but also internationally. To further improve and standardize the technology of the thermal ablation on lung tumor treatment, the Expert Committee on Ablation Therapy of the Chinese Society of Clinical Oncology (CSCO), Expert Group on Tumor Ablation Therapy of the Chinese Medical Doctor Association, Tumor Ablation Therapy Committee of the Chinese Anti-Cancer Association, and Tumor Ablation Group of Chinese College of Interventionalists of Chinese Medical Doctors Association have invited well-known experts in the field from countries along the belt and road to discuss and amend the Clinical practice guidelines of IGTA for primary and metastatic lung tumors (2022 Edition), which aimed to provide a guideline to facilitate the accurate use of IGTA on treating primary and metastatic lung tumors in clinical practice. The level of evidence was based on the CSCO Guidelines Working Committee (http://www.csco.org.cn).

THERMAL ABLATION TECHNIQUES

With the emergence of irreversible electroporation,[31-33] the concept of the tumor ablation has changed considerably. Thermal ablation is one of the energy-based ablation techniques used on treating tumors.[34,35] As a precise minimally invasive treatment technology, it utilizes biological effects of heat to directly cause irreversible injury or necrosis of tumor cells in one or more tumor lesions located in a certain organ. The thermal ablation techniques include radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, laser ablation, and high-intensity focused ultrasound (HIFU) ablation.[34-36] However, the HIFU ablation techniques are rarely used in the ablation of lung tumors.

RFA

RFA is one of the earliest ablation techniques used for the treatment of solid tumors. Inserting radiofrequency electrodes into the tumor tissue and applying alternating current with a frequency of 375–500 kHz can cause mutual friction and collisions of ions within the tumor tissue, which produces thermal biological effects that increase the local temperature up to 60–120°C. When the tissue is heated to a temperature of >60°C, coagulative necrosis may occur. The RFA volume depends on the thermal conduction of local RFA and thermal convection between the circulating blood and extracellular fluid.[34-37]

MWA

MWA typically uses either 915 MHz or most commonly 2450 MHz frequencies. The water, protein, and other polar molecules

within tumor tissues vibrate at high speeds in a microwave electromagnetic field, which results in a collision and mutual friction between the molecules. The temperatures can be raised up to 60–150°C in a short time, leading to coagulative necrosis of the cells.[34-40] MWA has higher convection and lower "heat-sink" effect when compared to RFA. However, MWA still has the following challenges[34,37,41-44]: (1) up-to-date there are limited clinical data and experience because MWA is a relatively new technology; (2) a learning curve is associated with using MWA safely, which is because MWA has larger potential ablation zones compared with RFA; and (3) clinical systems are heterogeneous in terms of antenna design, wavelength, frequency, power, and cooling, which leads to different performance characteristics and confounds regarding the interpretation of clinical results and the predictability of results from different manufacturers' systems.

Cryoablation

Cryoablation systems for tumor necrosis most commonly utilize gases such as argon, argon–helium, or liquid nitrogen. Argon or agron–helium systems are based upon the Joule–Thomson theory, wherein high-pressure argon can cool the target tissue to −140°C and helium can increase the temperature of the target tissue rapidly from −140 to 20°C--40°C. On the other hand, liquid nitrogen can cool the target tissue to −196°C. The cryoablation technique can be used in clinical practice owing to the abovementioned changes in a temperature gradient, which leads to (1) protein denaturation in the target tissue, (2) cell lysis caused by the change of osmotic pressure inside and outside the cells and the "icing" effect, (3) tissue ischemia and necrosis caused by microembolization, and (4) release of tumor antigens and induction of antitumor immunity. The "ice ball" observed by computed tomography (CT) or magnetic resonance imaging (MRI) (0°C isotherm) can directly distinguish the ablating freezing zone from the tumor margin, which can help determine the margin of necrosis (lethal ice temperatures are measures 3–5 mm medially to the visible iceball margin, which actually measures 0°C).[34,45-48]

RFA, MWA, and cryoablation are commonly used ablation techniques in the clinical treatment of lung tumors; each ablation technique has its own advantages and disadvantages. The size and location of the target tumor, status of lung parenchyma, risk of complications, as well as expertise and skills of the professionals must be considered when choosing the appropriate ablation techniques. For tumors ≤3 cm in diameter, the three ablation modalities have remarkable curative effects. Multipolar RFA has good conformability and can be adjusted to protect adjacent organs, but it is more likely to be affected by blood flow and airflow. MWA has several potential advantages over RFA. First, MWA attains higher temperatures, larger ablation zones, and shorter ablation times compared with RFA. Second, MWA is less susceptible to the cooling effect of large blood vessels or airways, not limited by electric impedance. Third, MWA is less sensitive to tissue types and has more consistent results and is relatively insensitive to "heat sinks" compared with RFA. Fourth, multiple MWA antennas can be positioned into the target tissue and activated simultaneously, which maximize the ablation zone size. Currently, RFA is the most commonly used technology in the clinical practice of lung tumor ablation, and physicians have more experience in using it. MWA likely to be used more widely in lung tumor ablation considering its outstanding advantages.[20,49-51] Cryoablation, although slower, is less painful and is ideal for the treatment of tumors along the pleura, chest wall, and bone metastases. Another major advantage of cryoablation is its ability to visualize the low-density ice balls on CT images and outline the exact size, shape as well as the location of the ablation zone. However, cryoablation consumes patients' platelets during ablation. Hence, it is not recommended for the patients with poor coagulation functions.[52]

Laser ablation

Laser ablation for lung tumors is used less frequently than the above mentioned ablation techniques. The most widely used laser ablation technique is the Nd:YAG laser (neodymium-doped yttrium aluminum garnet), which has a 1064-nm wavelength.[34] The principle is that after the laser being introduced into the tissue, the photons are absorbed by the chromophores, then instantly produce high heat, pressure, and other biological effects that degenerate, coagulate, vaporize, or even char tumor cells to kill them. Laser ablation has the following features[53-56]: (1) both the areas of ablation (1.0 cm × 0.5 cm) and damage to surrounding tissue are small; (2) ablation time is extremely short because the laser energy is released instantaneously; (3) optical fiber is so thin that it can hardly be detected on CT images, while often it can be introduced using a 21-gauge Chiba needle, thereby resulting in fewer complications (e.g., hemorrhage). Laser ablation is advantageous for treating tumors with a maximum diameter of <1.0 cm in the lung.

PROCEDURE PLATFORMS

Image guidance

Image guidance techniques for percutaneous thermal ablation therapy include CT, MRI, ultrasound, positron emission tomography (PET)/CT, and cone-beam (CB)/CT. CT is the most commonly used imaging guidance technique for lung tumor ablation, followed by MRI **(level of evidence: 2)**.[30,34] Ultrasound can also guide the ablation of tumors near or attached to the chest wall that can be observed during the entire process. CB/CT is also used in some medical institutions.[57,58] PET/CT can be used for functional imaging but is less frequently used for imaging guidance in clinical practice (especially when pulmonary tumors are concerned).

Other guiding platforms

Thoracotomy or video-assisted thoracoscopic ablation is generally used for treating (1) lung tumors adjacent to vital structures such as large blood vessels, the pulmonary hilar,

or heart; (2) lung tumors found to be unresectable after an open-chest operation.

Bronchoscopic and electromagnetic-guided thermal ablation of lung tumors also have exhibited some advantages.[59-61] Thoracotomy and bronchoscopic thermal ablation of lung tumors is not the focus of this guideline.

INDICATIONS AND CONTRAINDICATIONS

Indications for curative ablation

Curative ablation (A0) refers to the complete necrosis of lung tumors (i.e., complete eradication of all known tumor cells within the indexed tumors and absence of any other known tumor foci in the body).[30,40,62,63] Technical success of the ablation should be addressed per tumor and per procedure by evaluation of local tumor progression-free survival (PFS), time to local (tumor) progression, freedom from local or organ-specific recurrence, primary and secondary or assisted technique efficacy, residual disease, local progression (LP), recurrence rates, and local control.

Primary peripheral lung cancer (according to UICC 8th TNM staging system)[30,64-71]: (1) stage IA, inability to tolerate surgical resection or SBRT due to poor cardiopulmonary function or advanced age (**level of evidence: 2,** Table 1]; (2) stage Ia, refusing to undergo surgical resection or SBRT (**level of evidence: 2**); (3) early primary lung cancer with local recurrence or solitary metastases after the surgery or radiotherapy (maximum tumor diameter ≤3 cm and no other metastases) **(level of evidence: 3)**[72-75]; (4) single lung, with the absence of one lung for various reasons (maximum tumor diameter ≤3 cm and no other metastases) **(level of evidence: 3)**[8,76-80]; and (5) multiple primary lung cancers (maximum tumor diameter ≤3 cm, unsuitable for surgical resection or SBRT, and no other metastatic lesions) **(level of evidence: 2).**[70,81-84]

Fulfillment of one major criterion or at least two minor criteria generally indicate a patient with NSCLC who cannot tolerate surgical lobectomy.[70]

Table 1: Criteria for the intolerance of surgical resection

Major criteria
FEV1≤50%
DLCO≤50%
Minor criteria
Age≥75 years
FEV1 51-60% predicted
DLCO 51-60% predicted
Pulmonary hypertension (defined as a pulmonary artery systolic Pressure>40 mmHg) as estimated by echocardiography or right heart Catheterization
Poor left ventricular function (defined as an ejection fraction ≤40%)
Resting or exercise arterial PO_2 ≤55 mmHg or SpO_2≤88%
PCO_2>45 mmHg

FEV1: forced expiratory volume in 1s, DLCO: diffusing capacity of carbon monoxide, pO2: partial O2 pressure, SpO2: O2 saturation

Patients with the following special conditions and without proper histological tumor identification could also be considered for curative intent lung ablation: (1) high-risk factors (middle-aged and older patients, previous history of malignancy or family history of tumor, long-term history of smoking, or history of specific occupational exposure), (2) typical signs of malignancy on imaging (e.g., lesions ≥15 mm, spiculated sign, lobulated sign, pleural indentation, vacuole sign, and vessel convergence sign), (3) huge risk or difficulty in performing biopsy, and (4) patients refusing biopsy. If empiric therapy is considered without performing tissue-based confirmation, a multidisciplinary team (MDT) evaluation is necessary to make a preliminary diagnosis and treatment opinion. Final diagnosis and treatment opinions can be made by shared decision-making (SDM)[40,85,86] on the basis of MDT evaluation. If the outcome of SDM is direct ablation without biopsy or synchronous ablation and biopsy, then the medical staff and patient can follow instructions based on the outcome of SDM. SDM[87,88] is an important auxiliary treatment approach and an important component of evidence-based medicine that should be paid special attention as a new medical model.

Pulmonary metastases: certain biological features suggest a better prognosis for the curative ablation of intrapulmonary oligometastases (e.g., metastases due to breast cancer, sarcoma, kidney cancer, colorectal cancer, melanoma, and hepatocellular carcinoma) **(level of evidence: 2)**.[17,89-93] If the primary disease can be effectively treated, IGTA can be performed for treating pulmonary oligometastases, and comprehensive treatment is necessarily followed by ablation. The maximum number and diameter of pulmonary metastases that may be ablated is still not clearly defined. Most centers prioritize patients with five or fewer pulmonary metastases (≤3 in unilateral lung lesions and ≤5 in bilateral lung lesions), multiple metastases in whom the maximum diameter of the tumor is ≤3 cm, and no metastases in other sites **(level of evidence: 2)**.[16,18-26,30,71,94-98] For patients with bilateral pulmonary metastases, simultaneous bilateral ablation is not recommended **(level of evidence: 3)**.[30,40]

INDICATIONS FOR PALLIATIVE ABLATION

The purpose of palliative thermal ablation is to relieve symptoms caused by the tumor, improve the patient's quality of life, and prolong life as much as possible.[30,63,99,100] It is better to decide the indications for palliative ablation after MDT discussion **(level of evidence 2)**. For patients with a maximum tumor diameter of >5 cm or with >3 cm unilateral lung lesions (>5 cm for bilateral lung lesions), multiple applications at multiple sites in one session, application at multiple sites in multiple sessions, or combination with other treatment methods are required for completing the ablation **(level of evidence 3)**. For refractory pain caused by tumor invasion into the ribs or vertebral body, ablation can be performed at the local bone invaded by the tumor (or combined

with other treatments such as the use of bone cement) so that analgesic effects can be achieved **(level of evidence 2)**.[101-109]

Contraindications

IGTA is a local treatment technique that preserves the lung parenchyma, and patients with lung tumor can tolerate percutaneous IGTA treatment well. Although a temporary reduction in FEV_1 and DLCO may occur after ablation, recovery can reach the baseline levels with little or no effect on lung function.[70,71] Therefore, except for uncorrectable coagulopathies, there are relatively few absolute contraindications for IGTA treating lung tumors.[30,40,71,110,111]

Contraindications: (1) patients with severe hemorrhage tendency, with platelet count of $\leq 50 \times 10^9$/L, prothrombin time of >18 s, prothrombin activity of <40% **(level of evidence 1)**; (2) patients with severe pulmonary fibrosis and pulmonary hypertension **(level of evidence 3)**[30,40,112]; (3) patients with infectious and radiological inflammation around the lesion, poorly controlled skin infection at the puncture site, systemic infection, and high fever (>38.5°C) **(level of evidence 2)**; (4) patients with severe hepatic, renal, cardiac, pulmonary, and cerebral insufficiency **(level of evidence 2)**; patients with severe anemia, dehydration, and severe nutritional and metabolic disorders that cannot be corrected or improved within a short time (within 2 weeks) **(level of evidence 2)**; (5) patients with poorly controlled malignant pleural effusion **(level of evidence 2)**; (6) patients who have used anticoagulants and antiplatelet drugs less than 5–7 days before ablation **(level of evidence 3)** or have used bevacizumab less than 15 days since the last administration **(level of evidence 3)**[30,40,113]; (7) patients with an Eastern Cooperative Oncology Group physical status score of >2 **(level of evidence 2);** (8) patients with combination of other tumors and extensive metastases with expected survival of <6 months **(level of evidence 3)**; (9) patients with episodic mental disorders **(level of evidence 3)**; and (10) patients with implanted pacemakers (RFA is not recommended for patients with implanted pacemakers) **(level of evidence 3)**.[114-116]

PROCEDURE PREPARATION

Imaging

The indications and contraindications of IGTA should be evaluated by carefully reviewing the patient's medical history, physical examination, and recent imaging data. An MDT (thoracic surgery, medical oncology, radiotherapy, interventional radiology, diagnostic radiology, pneumology, etc.) should work together to determine the indications, make the individually personalized decision, and record the discussion of the procedure.[30,34,70] Thoracic contrast-enhanced CT (within 2 weeks) is the key preprocedure imaging assessment. CT can observe the size and location of the tumor as well as its relationship with the vital organs, blood vessels, trachea, or bronchus. Relevant staging examinations such as bone scans and cerebral MRI should be performed. PET/CT scans are recommended if there is a need to exclude or detect distant metastases. The pathological biopsy can be performed for mediastinal lymph nodes with suspected metastasis. For patients eligible for undergoing curative ablation, a PET/CT scan before procedure is recommended for accurate staging **(level of evidence 3)**.[117-119]

Pathological and auxiliary examinations

Pathological examinations

For primary lung cancer, a percutaneous core biopsy of the lesion or fiber optic bronchoscopy should be performed for histological and molecular-pathological diagnosis confirmation of the tumor before performing the procedure **(level of evidence 2)**.[120-126] For pulmonary metastases, a biopsy is usually not required if it shows typical metastatic features on imaging because the pathology of the primary tumor is well defined **(level of evidence 3)**. However, if a second genetic test is needed or if multiple primary tumors are suspected, rebiopsy may be required after the MDT discussion.[30,71]

Auxiliary examinations

Auxiliary examinations may include routine blood, urine, and stool tests; coagulation function; liver and kidney function tests; blood glucose levels; tumor marker levels; blood type; electrocardiography; cardiac ultrasound or coronary CT (may be optional for senior patients). In patients with previous organ transplant minimally invasive therapies are paramount; therefore, auxiliary examinations play an even more important role in the preprocedure assessment.

Drugs and monitoring equipment

Drugs for anesthesia and analgesia, antitussives, hemostatics, vasodilators, and antihypertensives as well as rescue medicines and monitoring equipment should be prepared before the procedure.

Patient preparation

The patient and/or guardian are well informed of the benefits and potential risks of the various treatment methods, and the patient and/or entrustee signs the informed consent form. Patients and/or guardians should be involved in SDM when necessary.[40,8,87,127] The patient should fast for 4 h before local anesthesia or abstain from solid food for 12 h and liquids for 4 h before general anesthesia. The patient should also receive surgical skin preparation, take oral antitussive, and receive preprocedure education (such as breathing training) before the procedure. Dentures must be removed before the procedure.

ANESTHESIA AND DISINFECTION

Depending on the patient's condition, the ablation procedure could be conducted using general, sedation, or local anesthesia **(level of evidence: 2)**.[30,40,71,128-131] The puncture site is locally anesthetized using 1–2% lidocaine up to the pleura. General anesthesia is recommended for children, patients who cannot cooperate during the procedure, patients who expect a long procedure time, and patients whose tumors are

close to the parietal pleura that may cause severe pain (unless cryoablation is performed in these locations). During the procedure, standard aseptic techniques should be strictly followed.

PROCEDURE

After choosing the appropriate ablation technique, CT is one of the most commonly used and accurate imaging guidance modalities. The procedure involves thermal ablation applicators (electrodes, antenna, probe, or fiber) that are directly punctured through the skin into the target tissue under CT guidance (percutaneous puncture is one of the core techniques: Appendix). Outpatient procedures are not recommended for lung tumors **(level of evidence 3)**. The ablation procedure is presented in Figure.[30,40]

Planning

Preprocedure planning is critical for the success of the procedure, which mainly includes the following steps: (1) determining the gross tumor region (GTR), which can be defined by the imaging including the location, size, shape, and its relationship with adjacent organs; (2) selecting the appropriate body position and puncture site on the body surface; (3) determining the puncture path from the puncture site to the deepest border of the lesion (target skin distance); and (4) preliminarily determining ablation parameters technique and its parameters (number of applicators, applicators size and length, estimated procedure time and other modality specific settings).

Targeting

After the anesthesia, in accordance with the preoperatively planned GTR, the ablation applicators (electrodes, antenna, probe, or fiber) is used to puncture layer by layer along the preoperatively planned puncture path from the body surface puncture site to the GTR. The CT scans confirmed by the three-dimensional reconstructed image are applied to observe whether the ablation applicator punctures into the target ablation lesion (Appendix).

Ablation

Targeted tissue ablation can be conducted via multimodal depending on the size and location of the tumor **(level of evidence 3)**: (1) at a single site and single session to achieve complete ablation (e.g., tumors diameter ≤3 cm); (2) multisite ablation during one session (e.g., tumors diameter 3–5 cm); and (3) multiapplicator and multisite ablation during one session or multisession ablation (e.g., for tumors with diameter >5 cm or for palliative ablation). The purpose of multimodal ablation is to achieve conformal ablation. Multimodal ablation has to be adjusted to individual tumor size, shape, or location and it also needs to consider patient's condition and their exhaustibility during and after the procedure. Furthermore, the ablation parameters (temperature, power, time, cycle, etc.) vary between different devices.

Monitoring

During the procedure, the applicator is monitored with CT scans to observe any off-target, whether the applicator should be adjusted, whether the preplanning region of ablation is achieved, or whether there are any complications (such as hemorrhage, pneumothorax, etc.). During the procedure, in the lung tissue adjacent to the tumor an opaque, high-density area can be seen, it is called ground glass opacity (GGO) and it reflects the thermal damage of the ablation. When the GGO around the GTR is greater than the GTR before ablation, the applicator can be pulled out. The target tissue at this point is defined as: postablation target zone (PTZ). During the procedure, the patient's breathing, pain, cough, and hemoptysis should be observed and treated symptomatically if necessary.

Intraprocedural modification

The physician can utilize the image-based information obtained during the monitor to modify the treatment as needed to control the procedure. Intraprocedural modification may simply reposition an applicator or adjust the ablation parameters based on physician's experience and imaging findings. Alternatively, it could be as sophisticated as a system that automatically terminates ablation at a critical point during the procedure.

Assessment of immediate treatment response

A repeat large-range (preferably whole-lung) CT scan should be carried out at the end of the procedure to assess immediate response with technical success and ablative margin. (1) Technical success: it addresses whether the tumor was treated according to the protocol and covered completely by PTZ. Tumor coverage can be assessed either during or immediately after the procedure. Thus, a tumor that is treated according to the protocol and determined to be covered completely at the time of the procedure is technically successful.[30,34] (2) Ablative margin: when ablation is performed with curative intent, assessment should demonstrate that the PTZ encompasses the GTR including a circumferential ablative margin (GGO) of at least 5 mm, and ideally 10 mm **(level of evidence 2)**.[71,132-135] For palliative ablation, it is not necessary to achieve the

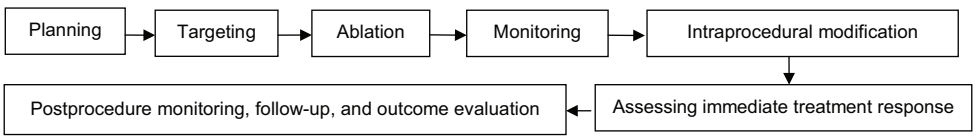

Figure: Ablation procedure

requirements of curative intent ablation in accordance with clinical practice, and it does not require an ablative margin, either (for refractory pain caused by tumor invasion of the ribs or thoracic vertebral body) **(level of evidence 3)**.[30] (3) Identifying any complications: observe the occurrence and treatment of complications if necessary.

If the patient has normal blood pressure, heart rate, oxygen saturation, and has no hemoptysis, shortness of breath, chest tightness, chest pain, dyspnea, or other symptoms, they can return to the ward. If the vital signs are unstable, the patient should be admitted to the intensive care unit for observation according to their condition.

POSTPROCEDURE MONITORING

Monitoring vital signs for 12–24 h is recommended, and chest radiograph or CT scan should be performed after 24–48 h to investigate the occurrence of complications (such as asymptomatic pneumothorax or pleural effusion).

AUXILIARY TECHNIQUES

Fluid or gas can be injected between the target and nontarget tissues during ablation to separate them, which is useful for protecting vital nontarget tissues (e.g., the pleura, pericardium, mediastinum, great vessels, etc.) and reducing pain during ablation. These techniques mainly include artificial hydrothorax or artificial pneumothorax **(level of evidence 3)**.[136-141]

CT-GUIDED PERCUTANEOUS LUNG TUMOR ABLATION PROTOCOL

Appendix.

FOLLOW-UP AND OUTCOME EVALUATION

Follow-up

Currently, contrast-enhanced chest CT is the standard method used for evaluating technique efficacy **(level of evidence 2)**. A common protocol for surveillance imaging includes performing contrast-enhanced CT at 1, 2, 3, 6, 9, 12, 18, and 24 months; and every year thereafter [Table 2].[142] The use of PET/CT in combination with contrast-enhanced CT may provide a more accurate assessment of technique efficacy after ablation. Additionally, for patients with renal insufficiency or severe allergy to iodine contrast, a CT or MRI of the chest can be conducted to evaluate the efficacy according to the dynamic changes in tumor size and signal.

Postprocedure imaging features and response assessment

Local response by CT

CT imaging features

Although most ablations conform to a spherical or ovoid shape, there are various factors that influence the shape of PTZ; these include the shape of the original tumor, the number of applicator, close proximity to pleura, and parameters of ablation. After the procedure, the PTZ continues to evolve into a denser air-space opacification and result in an area of consolidation larger than GTR of the original tumor. Even larger areas of consolidation, inflammation, and hemorrhage may coalesce to involve a whole segment or a large portion of the entire lobe. This imaging manifestation can last for 1–2 months, and this finding should not be mistaken for rapid tumor progression.[30,34,142-144] After ablation, CT imaging features include early-, intermediate-, and late-phase changes **(level of evidence 2)**.[30,40,145-148] Early-phase changes occur within 1 month, and three layers are observed: (1) the first layer in which a solid, honeycomb-like or hypoattenuating-bubble structure is observed within the PTZ; (2) the second layer consisting of GGO, which should generally be at least 5 mm (ideally 10 mm) all around the tumor beyond the GTR border, indicating that the tumor has been ablated completely; and (3) the third or outer layer, there is a reaction zone outside the GGO layer, with the density slightly higher than the GGO.[30,142,144] This typical imaging characteristics are called fried eggs or cockade sign, which is more obvious at 24–72 h after ablation. Intermediate phase (from 1 to 3 months): most of the GGO and consolidation resolve, but the PTZ continues to be larger than the GTR. This should not be interpreted as tumor progression. Contrast-enhanced CT images should demonstrate no enhancement within the PTZ. A thin and smooth rind of enhancement may be present, which is known as the egg shell sign (a thin rim peripheral to PTZ, a relatively symmetric and uniform process with smooth inner margin, that can be measured 0.5–3 mm). Late phase (after 3 months): areas of hyperattenuation may be observed within the PTZ, and the size of the PTZ should be the same or slightly larger than the GTR. Over the next 3 months, the PTZ will undergo involution, continuously shrinking in size. By 6 months, the PTZ should be smaller than the GTR. Subsequent follow-up CT results of PTZ may present several different patterns: (1) involuting fibrosis; (2) cavities; (3) disappearance; (4) nodules; (5) pulmonary atelectasis; (6) enlargement (possible recurrence, progression, or hyperplastic fibrosis), etc.[30,142,144,148] The postcryoablation imaging changes are somewhat different compared with those of RFA and MWA. Nonetheless, all changes can be referred to by using the above mentioned change process.[149-152]

Table 2: Post-IGTA follow-up scheme

Pretreatment	1 month	3 months	6 months	9 months	12 months	18 months	24 months	Yearly
CE-CT PET/CT	CE-CT PET/CT	CE-CT	CE-CT	CE-CT PET/CT	CE-CT	CE-CT	CE-CT PET/CT*	CE-CT

CE-CT: contrast-enhanced computed tomography; PET/CT: positron emission tomography/computed tomography. * In case of suspected tumor recurrence

Assessment of local response

After thermal ablation, the PTZ is significantly larger than the GTR of the original tumor due to bleeding, edema, exudation and inflammatory cell infiltration around the GTR, and such imaging findings last for 3–4 months. Therefore, the traditional response evaluation criteria in solid tumors are not suitable for the evaluation of local response after thermal ablation. The response is evaluated based on the lesions 4–6 weeks after the thermal ablation, including complete ablation (A0), incomplete ablation (A1), and LP **(level of evidence 3)**.[8,30,40,71,110]

Complete ablation includes any one of the following patterns: (1) lesion disappears; (2) cavity completely forms; (3) fibrosis or scar (the most common); (4) solid nodule involution or no change, without contrast-enhanced signs on the CT and/or no FDG uptake on the PET/CT; and (5) atelectasis, lesion in atelectasis without contrast enhanced signs on the CT and/or no FDG uptake on the PET/CT.

Incomplete ablation includes any one of the following patterns: (1) cavity partially forms, with some solid parts or liquid components remaining, and with irregular peripheral or internal enhancement signs on the CT and/or intense FDG uptake on the PET/CT; (2) partial fibrosis, with solid residues in the fibrotic lesion, which presents as irregular peripheral or internal enhancement signs on CT and/or intense FDG uptake on the PET/CT; (3) solid nodules with no changed or increased size, which also present as irregular peripheral or internal enhancement signs on CT and/or intense FDG uptake on the PET/CT; and (4) atelectasis, lesion in atelectasis with contrast enhanced signs on the CT and/or intense FDG uptake on the PET/CT.

Local progression includes any one of the following patterns: (1) enlargement by 10 mm, with enlarged irregular or internal enhancement signs on the CT and/or enlarged intense FDG uptake on the PET/CT; (2) local newly developed lesion, with newly enhancement signs on the CT and/or newly developed intense FDG uptake on the PET/CT; and (3) biopsy shows the presence of tumor cells.

Local response assessment by PET/CT

PET/CT is one of the most accurate assessment methods of the local response after ablation, and it is useful for finding tumor residues, progression, recurrence, and distant metastasis **(level of evidence 2)**.[153,154] PET/CT provides a high false-positive imaging features within 3 months after ablation because of the inflammatory response after ablation. Thus, PET/CT examination at this stage could be used to detect distant metastases and new lesions but has limited effect on determining whether there is local residue and progression.[155,156] PET/CT can objectively reflect the metabolic activity of the tumor in 3 months after ablation because of the reduction or regression of the inflammatory response in the ablation zone. If there is no FDG uptake in the tumor observed by PET/CT after ablation, then it indicates that the tumor is completely ablated. If there is intense FDG uptake in the tumor observed by PET/CT after ablation, then it indicates tumor residue or progression caused by incomplete ablation or local tumor progression. A variety of patterns on the PET/CT image can reflect the metabolic activity of the tumor.[157] Sometimes, it is difficult to determine whether the enlargement of the hilar or mediastinal lymph nodes is caused by metastasis or an inflammatory response. If there is no FDG uptake or significantly lower FDG uptake observed in the enlarged lymph node 3 months after ablation, then it indicates an inflammatory response and the opposite indicates metastasis.

Clinical outcome evaluation

Regular follow-up should be performed based on the assessment of local response. The following measurements should be assessed during the longitudinal follow-up: (1) data of technical success and early safety at minimum 6-month follow-up; (2) preliminary clinical outcomes at minimum 1-year follow-up; (3) intermediate-term data at minimum 3-year follow-up; and (4) long-term data at minimum 5-year follow-up.[158] Overall survival (OS) is the most important indicator for clinical outcome; therefore, OS of patients in 1 year and 2, 3, and 5 years are recorded.[159] For patients with palliative ablation, quantification of outcomes should be evaluated by assessment tools, such as quality of life indices and medication usage (e.g., morphine-equivalent doses).

COMPLICATIONS AND SIDE EFFECTS

Percutaneous lung tumor ablation is a relatively safe local therapy, despite this, complications are reported according to the classifications of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) criteria[160] [Table 3]. According to the time of occurrence, the complications are classified into the following three types: (1) immediate complication (<24 h), (2) perioperative complication (24 h–30 days), and (3) delayed complications (>30 days).

Table 3: Definition and classification criteria of CIRSE complications

Grade	Description
1	Complication during the procedure which could be solved within the same session; no additional therapy, no postprocedure sequelae, no deviation from the normal post therapeutic course
2	Prolonged observation including overnight stay (as a deviation from the normal posttherapeutic course <48 h); no additional postprocedure therapy, no postprocedure sequelae
3	Additional postprocedure therapy or prolonged hospital stay (>48 h)required; no postprocedure sequelae
4	Complication causing a permanent mild sequelae (resuming work and independent living)
5	Complication causing a permanent severe sequelae (requiring ongoing assistance in daily life)
6	Death

SIDE EFFECTS

Pain

Some patients experience mild to moderate peri-procedural pain during or immediately after the ablation. If the pain is severe during the procedure, the dosage of analgesics (such as sufentanyl) can be increased. Postprocedural pain is usually mild, which can last for several days. Pain can be managed with nonsteroidal antiinflammatory drugs (NSAIDs, such as flurbiprofen axetil).

Cough

Coughing is a common symptom during the procedure. Severe cough can aggravate pneumothorax or subcutaneous emphysema, or even cause ablation applicators "off target." Some patients might not be able to tolerate the procedure due to severe cough. Postprocedure cough is caused by inflammation of the tumor tissue necrosis and heat injury around the lung tissue. Oral codeine can prevent coughing if given 1 h before the procedure. The procedure will not be affected by a mild cough. For the postprocedure cough, antitussive and expectorant as well as the necessary antibiotics should be given as appropriate.

Postablation syndrome

Postablation syndrome may occur in about one-fourth of patients, which is caused by the absorption of necrotic material and release of inflammatory cytokines. This syndrome is a transient and self-limiting symptom/sign consisting of low-grade fever (<38.5°C), nausea, vomiting, and general malaise. NSAIDs and glucocorticoid can be applied for short-term if necessary.

Nonmassive hemoptysis

Due to the local reaction caused by puncturing intrapulmonary vessels with the ablation applicators or by ablation injury, some patients may have blood in the sputum or nonmassive hemoptysis after the procedure, which can cause panic in patients. The nonmassive hemoptysis is usually brief and self-limiting that does not require treatment.

COMPLICATIONS

Pneumothorax

Pneumothorax is the most common complication that occurs after ablation and has an incidence rate of 10–60%.[30,40,71,161,162] Pneumothorax is more commonly associated with the following conditions: emphysema, male, age >60 years, tumor <1.5 cm, tumor located in the lower lobe of the lung, puncturing a single lung tumor tissue for more than three times, use of multiple ablation electrodes (antennas, probes, or fiber optic), ablation of multiple tumor puncture sites for a high number of times, and long ablation routes through lung tissue or large interlobular fissures.[30,149,163,164] Most cases of pneumothorax are self-limiting or can be easily treated. Chest tube placement for drainage is available for pneumothorax with >30% lung compression or patients with remarkable symptoms **(level of evidence 3)**.[30,162,165] It has recently been reported that sealing the needle tract with a gelatin sponge after ablation can prevent and treat pneumothorax.[166] If the patient still has gas leakage after chest tube placement for drainage, then continuous negative pressure suction, pleural fixation, sclerosing agent injection, and endotracheal valve insertion can be performed **(level of evidence 3)**.[167,168] Additionally, attention should be paid to the occurrence of delayed pneumothorax. Pneumothorax that occurs 72 h after ablation is generally considered as delayed pneumothorax.[169-171]

Pleural effusion

A small amount of pleural effusion is often seen after ablation (incidence rate: 1–60%).[30,40,172] The occurrence of pleural effusion is associated with increase in pleural temperatures during the procedure, which may indicate that pleural effusion is related to pleuritis induced by thermal injury. Significant risk factors for the development of pleural effusion are the use of a cluster applicator, distance <10 mm (from the tumor to the pleura), ablation of multiple lesions at one session, a decrease in the length of the aerated lung that is traversed by the applicator, and long ablation time.[118] Nevertheless, aseptic pleural effusion after ablation can usually be treated conservatively. For 1–7% of pleural effusion cases, chest tube placement for drainage is required **(level of evidence 2)**.[173,174]

Hemorrhage

The incidence of hemorrhage during ablation is 3–8%.[30,175-177] Hemorrhage may present as hemoptysis, hemothorax, hemorrhagic shock, and acute respiratory failure but mainly as hemoptysis and hemothorax. (1) Hemoptysis: The incidence of massive hemoptysis during ablation is low. Risk factors for intraparenchymal hemorrhage include[30,40,177]: a. lesions with a diameter <1.5 cm for which the applicator will be adjusted when inserting into small target lesions; b. occur of lesions in the middle and lower lung, where they are more easily influenced by respiratory movement and more difficult to puncture. In addition, blood vessels are more easily damaged by the movement of the applicator tip; c. the path of the applicator to penetrate the lung tissue is >2.5 cm, wherein these lesions are closer to the hilum and surrounded by large blood vessels; d. the pulmonary vessels are penetrated through the ablation path; e. prior radiation therapy. Approximately, 80% of pulmonary hemorrhage can be avoided by not passing the applicator through the blood vessels. The applicator can be inserted parallel to the blood vessels so that risk factors of pulmonary hemorrhage can be avoided; e. use of multipolar ablation applicator. If there is moderate hemoptysis, ablation should be performed immediately with intravenous administration of hemostatic drugs. Because ablation itself can induce blood coagulation, the hemorrhage will gradually stop during ablation. During puncture, larger blood vessels or atelectasis in lung tissue should be avoided.

Most cases of postprocedure hemoptysis are self-limiting and only last for 3–5 days. For patients who are not suitable to undergo conservative treatment, interventional embolization or thoracotomy can be performed. (2) Hemothorax: The internal thoracic artery, intercostal artery, or other arteries are damaged during puncture, which should be avoided. If there is hemothorax, the patient should be closely monitored and actively treated using conservative treatment. For unstable patients, interventional embolization or thoracotomy can be performed (level of evidence 3).[30,40]

Infection

The incidence of lung infection caused by ablation is 1–6%.[30,162,165,172,178] However, patients with lung tumors especially NSCLC are primarily older patients who cannot tolerate surgical treatment and often have underlying pulmonary disorders wherein lung infection and inflammation can cause a dramatic decline in lung function and even death. Antibiotics can be administered prophylactically 30 min to 1 h before surgery and again within 24 h.[179] Administration duration can be extended to 48–72 h after ablation in the following cases: older patients aged >70 years, long-term chronic obstructive pulmonary emphysema, poorly controlled diabetes, tumors >4 cm, more than three unilateral lung tumors, and immunocompromised patients **(level of evidence 3)**.[30,40] If the body temperature is still >38.5°C at 5 days after the procedure, lung infection should be suspected. Antibiotic dose should be adjusted according to sputum, blood, or pus culture results. Pulmonary or chest abscesses can be drained using a chest tube. In addition, ablation increases the risk of secondary infection because interstitial pneumonia often occurs after radiotherapy.

Cavitation

Cavitation of the PTZ after lung ablation is common, which may be regarded as a natural consequence after the procedure but can lead to serious complications such as infection and hemorrhage. The incidence of the cavitation is about 14–17%.[30,161,180] Cavitation often appears 2–4 weeks after ablation and then gets absorbed as a shrinking fibrosis 2–4 months later. Tumors adjacent to the chest wall, excessive ablation, and tumors associated with emphysema are more likely to develop cavities. Cavitation infection and abscess formation should be considered when there is a fever and weakness. Additionally, the presence of *Aspergillus* infection should also be investigated.[181-184] Cavitation-induced recurrent hemorrhage can be treated using interventional embolization if patients are not suitable to undergo conservative treatment.

Other rare complications

There were rare cases of complications reported such as bronchial pleural fistula; acute respiratory distress syndrome; bronchiolitis obliterans organizing pneumonia; nontarget thermal injury or frostbite; rib fractures; cold shock; thrombocytopenia; needle tract seeding; injury of the brachial plexus, intercostal, phrenic, or laryngeal nerves; pulmonary embolism; systemic air embolism; and pericardial tamponade. These cases should be treated individually.[30,171,185-194]

Ablation-related mortality

Although thermal ablation of lung tumors is generally safe, it may cause significant complications. Most complications can be treated conservatively or with minimal therapy. However, certain incidences of serious or even fatal complications have been reported. According to the current literature, the mortality rate associated with lung tumor ablation was reported to be 0–2.6%.[30,162] National (Nationwide) Inpatient Sample from United States reported an in-hospital mortality rate of 1.3% for 3344 cases of lung tumor ablation **(level of evidence 2)**.[195] The main causes of death are as follows: various pneumonia (including fungal pneumonia), lung abscess, massive hemorrhage/massive hemoptysis (including pulmonary artery pseudoaneurysm rupture), bronchial pleural fistula, air embolism, and acute respiratory distress syndrome.

ABLATION IN COMBINATION WITH OTHER THERAPIES

The combination of ablation with other methods is one of the major directions of many current tumor studies, including the combination of ablation with surgery, radiotherapy, chemotherapy, molecular targeted agents, and immunotherapy, etc. (1) The combination of IGTA with radiotherapy can improve the local control rates of tumors and prolong the survival of patients without a substantial increase in side effects **(level of evidence 3)**.[196,197] (2) For advanced-stage NSCLC, IGTA combined with chemotherapy provides some benefits such as improving local control rates of tumors and prolonging the survival of patients **(level of evidence 2)**,[198-205] Therefore, this combination may be used as a new approach for treating advanced-stage NSCLC. (3) Tyrosine kinase inhibitors (TKIs) are currently one of the main approaches used for treating NSCLC with EGFR mutations or ALK-EML4 fusion mutations. The administration of TKIs in such patients can achieve an objective response rate of approximately 70% and PFS of approximately 10–19 months. However, most patients ultimately develop acquired resistance to TKIs after 1–1.5 years. Therefore, it is important to distinguish among these patterns as different therapeutic strategies may apply. Considering the growth rate of the tumor and the number of growing tumor lesions, progressive disease during TKI treatment can be generally distinguished into three patterns—intracranial disease progression, development of one or few distant metastatic sites while the patient remains asymptomatic, and systematic and/or symptomatic disease progression. The first two patterns fall into the general term of oligoprogressive disease. Typically, the definition of oligoprogressive disease refers to the presence of less than five discrete metastatic sites. Local ablation with continued EGFR inhibition has shown efficacy in treating patients with oligoprogressive disease and is associated with long PFS and OS. Local ablation with continued TKI treatment can be used as a treatment strategy for advanced-stage NSCLC in which extracentral nervous system oligoprogressive

disease has developed during EGFR TKI treatment.[30,70,206-213] (4) For patients with pulmonary metastases after ablation, systemic combination therapy, such as combined systemic chemotherapy, targeted therapy, or immunotherapy, must be administered according to patients' condition.

CONCLUSIONS

Minimally invasive therapy, especially IGTA technology, is one of the future directions of lung tumor treatment. For patients with early-stage NSCLC who cannot tolerate surgery, IGTA (for tumors with a diameter of 2–3 cm) may provide 1-, 3-, and 5-year survival rates of 97.4, 72.9, and 55.7%, respectively, with a mortality rate of <1%.[214] Additionally, IGTA has some advantages in treating lung cancer cases with GGO.[40,215] The 3-year OS of patients with pulmonary oligometastases from colorectal cancer treated with percutaneous IGTA can reach 82.2%.[16,23] Clinical evidence indicates that IGTA has become the third major local tumor treatment modality after surgery and radiotherapy,[70] and the use of IGTA in the comprehensive treatment of lung tumors is expected to increase in the future.

Currently, there are still some limitations associated with IGTA techniques used for treating primary and metastatic lung malignancies[162,216-220]: (1) IGTA has the potential to become one of the primary treatments; however, there is a lack of multicenter, randomized, prospective clinical studies on IGTA; (2) there are few clinical trials on the combination of IGTA with other treatment methods (such as radiotherapy, chemotherapy, and molecularly targeted therapy); (3) it is one of the future directions for improving the rate of complete local ablation and reducing local recurrence; (4) the role of palliative ablation in the comprehensive treatment of lung cancer still needs to be further explored; (5) more work needs to be done to search for new heat sources, develop hyperthermic sensitizers, and upgrade ablation equipment; and (6) basic research is relatively insufficient, such as the distribution of complex thermal fields and the effect on the body's immunity, and how to combine the IGTA technology with immunotherapy, which still need to be continuously explored in the future.

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Conflicts of interest

There are no conflicts of interest.

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APPENDIX

Procedure for CT-guided percutaneous thermal ablation of thoracic tumors

For patients with indications of the use of IGTA for treating thoracic tumors, the following procedure steps are recommended:

1. Place the patient in a comfortable and stable (prone, supine, lateral, etc.) position on the CT scanner table. Advise the patient to perform some calming breathing exercises.
2. Use a marker to mark the potential applicator insertion site and perform a CT scan (3–5-mm thickness).
   (a) Assess target lesion location, size, shape, and relationship with neighboring vital organs.
   (b) Determine the puncture path: the "target skin distance" (the distance from the skin puncture site to the target lesion) should generally be >2 cm. No vital organs (bone, blood vessels, trachea, etc.) should be blocked along the puncture path.
   (c) Measure the angle of trajectory (the distance from the skin puncture site to the pleura the lesion and the distance from the vital anatomical structures on the puncture path).
   (d) Select a larger intercostal space for the procedure in order to facilitate an appropriate adjustment of puncture direction. If necessary, an auxiliary ablation technique may be used, such as artificial hydrothorax or pneumothorax.
3. Administer 1–2% lidocaine as the local anesthetic. Pleural anesthesia is necessary. Leave the syringe needle subcutaneously as a marker or insert a 22-gauge spinal needle up to the pleura and adjust the angle (the spinal needle will serve as a guide for the applicator). Perform CT scan to adjust the ablation applicator angle.
4. Under CT guidance, insert an ablation applicator through the preset path to the target lesion. It is recommended to follow the three steps described below:
   (a) Use CT to observe the puncture direction and all vital anatomical structures before the ablation applicator penetrates the chest (for patients with a thicker chest wall) and before the applicator punctures the lung parenchyma (for patients with a thinner chest wall).
   (b) When the ablation applicator is close to the target lesion, perform a CT scan to observe any complications, such as hemorrhage or pneumothorax. Evaluate the angle of the ablation applicator and presence of any possible vital organs on the puncture path.
   (c) After the ablation applicator penetrates the target lesion, perform a CT scan (3D reconstruction if necessary) to confirm the precise position of the applicator tip and its relationship with important surrounding anatomical structures.
5. Start ablation according to the recommended parameters. Ablation parameters (temperature, power, time, cycle, etc.) vary between different devices. During the procedure, monitor the applicator using CT to observe whether the applicator is "off target," if it needs to be adjusted when the preplanning range of ablation has been achieved, or for any possible complications (e.g., hemorrhage or pneumothorax).
6. At the end of the procedure, perform a CT scan to assess technical success. The ablation applicator can then be pulled out. Ablate the withdrawal path and avoid injury to the pleura and skin.
7. Perform a whole-lung CT scan to detect immediate complications and preliminary efficacy. Severe pleural effusion or pneumothorax should be treated immediately.