



# Society of Interventional Radiology Quality Improvement Standards on Percutaneous Ablation of Non–Small Cell Lung Cancer and Metastatic Disease to the Lungs

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### ABSTRACT

**Purpose:** To provide guidance on quality improvement thresholds for outcomes and complications of image-guided thermal ablation for the treatment of early stage non-small cell lung cancer, recurrent lung cancer, and metastatic disease.

**Materials and Methods:** A multidisciplinary writing group conducted a comprehensive literature search to identify studies on the topic of interest. Data were extracted from relevant studies and thresholds were derived from a calculation of 2 standard deviations from the weighted mean of each outcome. A modified Delphi technique was used to achieve consensus agreement on the thresholds.

**Results:** Data from 29 studies, including systematic reviews and meta-analyses, retrospective cohort studies, and single-arm trials were extracted for calculation of the thresholds. The expert writing group agreed on thresholds for local control, overall survival and adverse events associated with image-guided thermal ablation.

**Conclusion:** SIR recommends utilizing the indicator thresholds to review and assess the efficacy of ongoing quality improvement programs. When performance falls above or below specific thresholds, consideration of a review of policies and procedures to assess for potential causes, and to implement changes in practices, may be warranted.

### ABBREVIATIONS

CA = cryoablation, IGTA = image-guided thermal ablation, LM = lymph node, MWA = microwave ablation, NSCLC = non–small cell lung cancer, PET = positron emission tomography, QI = quality improvement, RF ablation = radiofrequency ablation

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## INTRODUCTION

Lung cancer is the second most common cause of new cancer cases in the United States and remains the leading cause of cancer-related death despite decreasing mortality trends over the past 2 decades (1). An estimated 228,820 new cases of lung cancer will be diagnosed in 2020 in the United States (1). In accordance with societal guidelines and common practice, surgical resection remains the primary treatment for early-stage lung cancer (2–4). Despite advances in surgical technique, several patients who present with non–small cell lung cancer (NSCLC) are either medically inoperable for surgery or prefer a nonsurgical minimally invasive local treatment. Image-guided thermal ablation (IGTA) has emerged over the past 20 years as a therapeutic option for early-stage and recurrent NSCLC (5).

IGTA has likewise emerged as an alternative to surgical resection for some patients with metastatic lung disease, since the lungs are a common site of metastatic disease. Surgical resection of lung metastases can be challenging, carrying a degree of morbidity, scar formation from repeat surgeries, and interruption of systemic chemotherapy delivery (6). For these patients, image-guided percutaneous ablation is a safe and effective therapy. The following are the most common ablative modalities: radiofrequency (RF) ablation, microwave ablation (MWA), and cryoablation (CA). These standards are written to be used in quality improvement programs to assess the practice of percutaneous lung ablation. The following are the most significant processes of care: (i) patient selection, (ii) performing the procedure, (iii) monitoring the patient, and (iv) clinical outcomes. For full information about the Society of Interventional Radiology (SIR) Standards Division and Quality Improvement (QI) Document Methodology, please refer to [Appendix A](#).

A comprehensive literature search was conducted in June 2019 in MEDLINE via PubMed using a combination of the following search terms: “non–small cell lung cancer,” “lung tumors,” “NSCLC,” “metastatic lung cancer,” “oligometastatic,” “biopsy,” “thermal ablation,” “radiofrequency ablation,” “cryoablation,” “cryosurgery,” “microwave ablation,” “ablative therapy,” and “ablation.” The search was limited from 1999 to the present, with 1999 representing the publication of the first RF ablation case series of lung tumors. These references are included in a graded evidence table ([Appendix B](#)) and used to update the document. Data from included studies ([Appendix C](#)) were used to calculate appropriate QI thresholds for success and adverse events.

## DEFINITIONS AND TERMINOLOGY

Below are relevant tumor- and therapy-specific terms relevant to this QI standard:

- *Early-stage lung cancer*: Stage I lung cancer for which local treatment (surgical, IGTA, and stereotactic body radiation therapy) can be considered curative without additional systemic therapy (7–9).
- *Metastatic disease*: A lung tumor which has a cell type consistent with spread from another organ system.
- *Tumor ablation*: Direct application of energy to eradicate or destroy focal tumors (10). The method of ablation should be determined by lesion characteristic and risk mitigation and should be left to the discretion of the operating physician. For the purpose of this document, ablation modalities will be considered together as ‘tumor ablation’ unless a detailed discussion of the modalities is needed. In these instances, the ablation modality will be clearly delineated in the text.
- *Image guidance*: Imaging modality used to direct percutaneous tumor ablation. Most ablative technologies can be performed using any one of a variety of modalities, including: computed tomography (CT), ultrasound (US), magnetic resonance (MR) imaging, positron emission tomography (PET), fluoroscopy, CT fluoroscopy, or rotational fluoroscopic guidance (cone-beam CT). CT guidance is most frequently used for lung ablation. For the purpose of this document, the employed imaging guidance will be considered together unless a detailed discussion of the guidance is clearly delineated in the text.
- *Assessment of immediate treatment response*: Imaging used to immediately assess an IGTA procedure once the procedure is completed (11–13). Immediate assessment after IGTA should demonstrate that the ablation zone encompasses the tumor, including a circumferential ablative margin of at least 5 mm, although ideally 10 mm around the tumor (14).
- *Technical success*: Term used to describe whether the tumor was treated according to protocol and covered by the ablation zone (10). Technical success can also encompass the outcome of 2 or more ablation procedures over time if a staged approach is used. Primary technical success should be determined at the first follow-up imaging study after the completion of the predetermined course of treatment (10).
- *Primary efficacy*: Percentage of cases achieving tumor eradication by imaging following the initial procedure or defined course of treatment (10).
- *Secondary efficacy*: Percentage of cases achieving tumor eradication by imaging following the identification of a local tumor progression (10).
- *Retreatment*: Ablation of locally progressive tumor when complete ablation was initially believed to have been achieved (10).
- *Adverse events*: Adverse clinical outcomes related to the procedure. The SIR grading system for complications should be used as previously described (15).
- *Follow-up imaging*: Imaging obtained to assess for residual or recurrent disease (*see below*) and complications. No well-defined guidelines exist regarding either the optimal timing or modality for follow-up imaging (10).

- *Overall survival*: Length of patient survival, regardless of the cause of death. Overall survival (OS) should be calculated both from the time of initial cancer diagnosis and from the start of IGTA therapy (10).
- *Residual disease or tumor*: Term used to describe the remaining viable tumor in the ablation zone on initial follow-up imaging (10).
- *Local tumor progression*: Term used to describe the appearance of viable tumor in the ablation zone after at least 1 follow-up study has documented an adequate ablation with no viable tissue (10).
- *Cancer-specific survival*: Length of patient survival when the cause of death is related to the malignancy. Cancer-specific survival should be calculated both from the time of initial cancer diagnosis and from the start of IGTA therapy (10).
- *Time-to-tumor progression*: Time interval between IGTA and disease progression. Local time-to-tumor progression, the time to local tumor progression in the ablation zone, can be differentiated from time-to-tumor progression, which represents disease progression in any part of the body (10).

## INDICATIONS

### Primary Lung cancer

The primary goal of IGTA of NSCLC is curative intent. As such, patients should be selected who have localized disease, without evidence of intrathoracic lymph node (LN) involvement or systemic spread. The majority of treated patients should be stage IA, since tumors <3 cm in diameter can be reliably treated with a circumferential margin using all ablation modalities (16). While there is an emerging body of evidence supporting IGTA of larger lesions, including stages IB and IIA, sufficient margins are more challenging to achieve (17).

### Recurrent Lung Cancer

Percutaneous thermal ablation plays a role in disease management in selected patients who are deemed inoperable due to poor cardiopulmonary function, medical comorbidities, or those who present with residual or recurrent disease after having undergone other treatments (18).

### Metastatic Disease

Patient selection for IGTA of metastatic tumors to the lungs is more challenging. While the goal of curative intent can be achieved in some patients with isolated lung metastases, the more common goal is local control of disease and cytoreduction of tumor volume. Eligible patients should have a limited number of small lung metastases, controlled disease elsewhere in the body, and a reasonable disease-free interval since prior treatment. All these factors suggest indolent cancer behavior and potential for disease eradication.

## CONTRAINDICATIONS

Relative contraindications to IGTA for lung neoplasms include uncorrectable coagulopathy, active pneumonia, and tumor involvement of a critical structure that would likely be damaged by the ablation (such as motor nerve, central airway or vasculature, esophagus, or bowel).

## OVERALL PROCEDURE THRESHOLD

An important part of quality improvement for IGTA should be the assessment of whether procedures are performed for one of these indications. The threshold for these indications is suggested by the authors to be 95%. When fewer than 95% of procedures are for these indications, the department should consider a review of the local process of patient selection.

## PREPROCEDURAL EVALUATION

The decision to proceed with any oncological treatment strategy should ideally be made as a part of a multidisciplinary team. It is best practice for the physician to meet with the patient prior to the procedure to review the patient's medical history, medications, pertinent oncological imaging, and laboratory values. The determination of anesthetic risk should be performed in accordance with guidelines from the American Society of Anesthesiologists (19). The expected outcomes, risks, and timeline for clinical imaging and follow-up should be thoroughly discussed with the patient.

When appropriate, pulmonary function tests are strongly recommended in patients with prior lung surgery and/or comorbid pulmonary disease. Patient selection should be carefully considered for high-risk patients with stage I NSCLC, defined as patients with a single major risk criterion forced expiratory volume (FEV1) or diffusing capacity of the lungs for carbon monoxide  $\leq 50\%$  and/or 2 or more minor criteria (a less depressed FEV1 or diffusing capacity of the lungs between 51% and 60%, advanced age  $\geq 75$  years, pulmonary hypertension, left ventricular ejection fraction  $\leq 40\%$ , resting or exercise partial pressure of oxygen  $< 55$  mm Hg, and partial pressure of carbon dioxide  $> 45$  mm Hg) (20). Patients considered for lung IGTA should undergo accurate staging with contrast-enhanced chest, abdominal, and pelvic CTs or whole body PET/CT within 60 days of the anticipated lung ablation (21). In those patients with primary lung cancer, invasive mediastinal and hilar LN assessment by cervical mediastinoscopy, endobronchial ultrasound-transbronchial needle aspiration, or endoscopic ultrasound is recommended for discrete LN enlargement, fluorodeoxyglucose (FDG) activity in normal-sized LNs, and central location (inner 2/3) of primary tumor (21). Currently, invasive LN sampling is not routinely recommended for peripheral (outer 1/3) T1a, b, and c tumors (21).

## LUNG BIOPSY

Imaging modalities alone cannot accurately distinguish malignant from benign masses. Therefore, percutaneous transthoracic needle biopsy has been used to aid in the diagnosis and management of these lesions, which ultimately reduces overtreatment. Percutaneous biopsy has been proven to be a safe and effective diagnostic modality (22–26). Decisions of when (prior to or during IGTA procedure) and how to biopsy (transthoracic vs bronchoscopic) are best left to the decision of the multidisciplinary treatment team and respective operators. In general, central tumors with suspicious mediastinal LNs are best approached with simultaneous transbronchial biopsy and endobronchial ultrasound mediastinal LN staging; peripheral nodules are best approached with percutaneous transthoracic needle biopsy (27). While the expected pulmonary hemorrhage that occurs during biopsy could potentially interfere with an ablation, simultaneous lung biopsy and ablation can be performed (26).

## PROCEDURAL CONSIDERATIONS

### Devices

Although no randomized clinical trials have compared the various ablation techniques directly to each other, indirect comparisons from systematic reviews and meta-analyses have found that all 3 ablative modalities (RF ablation, CA, and MWA) are appropriate for IGTA of lung tumors. The method of ablation should be determined by lesion characteristic and risk mitigation and should be left to the discretion of the operating physician. Ablative device choices are discussed in detail elsewhere (28), with specific considerations for quality improvement included below.

**RF ablation:** RF ablation is the oldest and most frequently used thermal ablative technique. The limitation of RF ablation in pulmonary ablation is that the lungs have high impedance with poor conduction. Additionally, RF ablation is limited by the heat sink effect from adjacent vessels and large airways (29).

**MWA:** MWA is a thermal/heat-based technique performed at a higher energy and temperature than RF ablation. MWA is less susceptible to the heat sink effect than RF ablation and can theoretically more effectively treat tissues of higher impedance, such as the lungs or close to large vessels. Unlike RF ablation, microwave probes can be simultaneously used in a phased array to generate higher temperatures with synergistic heating (29).

**CA:** CA is a thermal/cold-based technique involving freezing, in which tissue necrosis rapidly occurs. The ice ball created can be visualized by ultrasound, MR imaging, and CT during ablation, and isotherm maps can be used to spatially arrange probes to achieve a complete ablation. Moreover, CA has an analgesic effect that causes less pain than heat-based ablation, which can result in less sedation being required for the procedure, and decreased pain after ablation, particularly for peripheral lesions (30,31).

A theoretical advantage of CA is that tumor antigen is preserved, which can lead to antibody formation against the tumor as well as an increased T cell-mediated immunity. This may result in tumor death separate from the ablation zone (32). Research involving CA and immune-modulating therapy is ongoing and currently inconclusive.

A theoretical disadvantage to CA is the potential for tumor resistance in the peripheral zone of ablation. Cell death in the peripheral zone is believed to be due to apoptosis (preprogrammed cell death) caused by mitochondrial damage. Tumor cells with altered preprogrammed cell death pathways in this peripheral zone may lead to tumor resistance (33). Another disadvantage to CA is the longer ablation time than heat-based techniques due to repeated freeze-thaw cycles.

**Other:** Several other devices are being studied for use in IGTA, including percutaneous laser ablation, also known as laser-induced thermotherapy, and irreversible electroporation. These techniques are still being investigated for safety and efficacy in lung tumors and are not well studied or documented at the time of this document being prepared.

### Considerations for Device Selection

RF ablation, CA, and MWA are all appropriate modalities for IGTA of lung tumors, and the method of ablation should be determined by the size of the lesion and left to the discretion of the operating physician (34). Across ablation modalities, lesion characteristics and risk mitigation should be the main determinants of energy modality use (18). Ideally, operators will have availability to all 3 modalities as/if requested.

Tumor location is the most significant factor to consider when determining treatment modality. While both CA and MWA are associated with less procedural pain than RF ablation (35,36), lesions that are located in the periphery of the lung or which extend into the pleura and chest wall, may be best treated with CA primarily due to the analgesic effects of the ablation on the adjacent parietal pleura and soft tissues (30,31). CA is also preferred to heat-based thermal ablation for lesions adjacent to central airways, due to the preservation of the collagenous extracellular matrix and decreased opportunity for permanent airway damage (37). Central IGTA, including lesions in proximity of or contiguous with the heart and aorta, can typically be safely ablated without location-specific complications; however, local recurrence rates of the treated lesion are higher when physically touching these sites due to the associated thermal sink effect (38).

Tumors that are located adjacent to the pulmonary vasculature, including several central tumors, are subject to thermal sink effects that can limit the size of an ablation zone and the ability to control the margin of a tumor. This effect has been demonstrated across all thermal ablation modalities, with contact with larger blood vessels predicting tumor recurrence (39). MWA appears to have the ability to overcome some effects of thermal sinks and may

be the preferred modality in this context. There is evidence that the location of the targeted tumor has an influence on the size of the ablation zone, with centrally located tumors in the lower lobes having the highest ablation resistance score (40).

Tumor size is a factor that warrants consideration when choosing an ablation modality. MWA carries a theoretic advantage over RF ablation in the treatment of large tumors, with an increased ablation volume and a decreased ablation time (41–44). Despite this theoretical advantage, a tumor size of >3 cm appears to represent a target size beyond which primary efficacy becomes more challenging to achieve (16). Few studies have included data on patients with NSCLC and metastatic disease with lesions as large as 5 cm treated by ablation (45).

Special note is made of patients with cardiac pacemakers, in whom MWA and CA appear to be safer than RF ablation with regard to pacemaker interference (46).

A final differentiating factor when determining the ablation modality are patient-related issues that may predict an increased chance for pulmonary or pleural hemorrhage. Patients with significant emphysema and fibrosis can have major pulmonary hemorrhage following CA (31,47). Likewise, it would be expected that patients who have an inherent or medication-induced coagulopathy or are on antiplatelet agents that cannot be withheld in the time period before the procedure, could experience an increased risk of hemorrhage following lung ablation. The rates of bleeding complications are generally rare in the published literature. However, it is reasonable to expect that RF ablation and MWA would be associated with decreased rates of hemorrhage compared with CA due to the cauterization of tissue within the treatment zone. It remains to be determined whether recently introduced CA probes with tract cautery functionality may decrease the risk of hemorrhage following CA.

### Periprocedural Management

Periprocedural management should be a case-by-case basis based on the individual's history and risk factors. Discussion and recommendations for antibiotic prophylaxis for lung ablation are provided in the SIR standards for Adult and Pediatric Antibiotic Prophylaxis (48). Full details about anticoagulant and antiplatelet management, risk category, and laboratory evaluation recommendations for lung ablation procedures are detailed in the SIR standards for Periprocedural Management of Thrombotic and Bleeding Risk (49).

The decision to perform the procedure under moderate sedation, deep sedation, or general anesthesia will be based on patient assessment for comfort and cooperation, tumor characteristics, type of ablative modality, and general individual physician practice preferences. Lesion location and modality utilized are the strongest predictors of procedural discomfort. For example, as noted above, CA may be used to mitigate pain during the ablation of peripheral lesions,

allowing most procedures to be performed with moderate sedation (50).

### Patient Positioning, Needle Trajectory, and Imaging

In some cases, >1 needle may be necessary to treat a given lesion. The optimal number and location of the needles will be dictated by tumor size and location, ablation modality, and the manufacturer information. Several principles have been described elsewhere to optimize needle placement and ablation zone formation (51).

The appropriate treatment of the entire extent of the tumor is essential to achieving a complete ablation (52). Obtaining a complete ablative coverage of the tumor plus an additional 10-mm margin has been shown to improve local control (53). Multiple studies have described increased rates of local recurrence in RF ablation and MWA when a ground-glass margin surrounding the targeted lesion is not achieved (45,54). The ground-glass layers surrounding the treated tumor should extend approximately 5 mm beyond that desired therapeutic margin to maximize local control rates (55). Aggressive ablation margins are associated with primary efficacy, including at least 1 study suggesting a complete therapeutic response can be achieved when the ablated area is 4 times larger than the original tumor size (53).

### POSTPROCEDURAL MONITORING

During the immediate period after the procedure, the patient should be monitored with continuous pulse oximetry and regular vital signs checks. A useful strategy for patient positioning and management has been previously suggested (51):

- Place patient in the ipsilateral position with side down to prevent pneumothorax formation and trap any ablation-related blood products within this lung.
- Supplemental oxygen administration via nasal cannula increases oxygen tension within the pleural space in the event of an air leak.
- The head should remain flat after the procedure to prevent the propagation of unseen systemic air emboli.
- Upright portable chest radiograph(s) should be performed prior to patient discharge to ensure no enlarging pneumothorax or pleural effusion that may require further management.

### POSTPROCEDURAL FOLLOW-UP

Upon discharge, appropriate return instructions should be provided for any delayed respiratory symptoms that may indicate the formation of a pneumothorax. While pain following ablation is not typical, some patients will have discomfort, which must be appropriately managed. Anti-inflammatory medications for at least 5 days may help decrease the use of narcotic medications (56).

**Table 1. Imaging Strategies\* (59)**

Timeline	Strategy
Preprocedural imaging	
Within 60 days prior to ablation	Staging with contrast-enhanced chest, abdominal, and pelvic computed tomography (CT) or whole body PET/CT
Postprocedural imaging	
1 wk	Chest radiograph to evaluate for delayed pneumothorax and pleural effusion
1 mo	Chest CT to establish the baseline of ablation zone
Every 3 mo, up to 1 y	Chest CT or PET/CT, when appropriate, to document the appropriate evolution of the ablation zone
Continued care	Imaging and clinical follow-up schedule strategy based on patient presentation and clinical course

PET = positron emission tomography

\*Contrast-enhanced study is preferable whenever possible.

There is no established consensus on imaging modality or time interval after ablation. The clinical and imaging follow-up strategy involves an initial management of procedure-related complications, followed by a transition to monitoring for localized or remote recurrence of disease. A thorough evaluation of imaging findings following RF ablation, MWA, and CA over time have been described (57). In general, it is preferable to use contrast whenever possible (58). A follow-up visit combining imaging and clinical assessment is appropriate. The following strategy has been proposed in [Table 1](#) (59).

CT imaging findings after lung ablation evolve over time. Within the first month, the ablation zone is typically larger than the initial tumor due to surrounding hemorrhage and inflammation in addition to intended coagulation necrosis. Over time, with fibrosis and contraction, the ablation zone undergoes gradual involution and stability. Any enlargement beyond 3 months, particularly nodular growth or enhancement, should be considered suspicious for tumor progression/recurrence or incomplete ablation. PET/CT has been shown to be more sensitive and specific than contrast-enhanced CT in identifying a metabolically active tumor (60). Generally, PET/CT should not be performed within the first 2 months to evaluate the ablation zone due to the confounding inflammatory response from the ablation and confusion for residual tumor.

Societal guidelines can provide some framework for the frequency and modality of imaging follow-up following local therapy. American Society of Clinical Oncology recommends diagnostic chest CT with contrast (preferred) or without contrast every 6 months for the first 2 years following treatment (61).

## QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% adverse events), all

physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt the consideration of an internal review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure, such as major adverse events. Individual adverse events may also be associated with adverse event-specific thresholds. When measures, such as indications or success rates, fall below a (minimum) threshold or when adverse events exceed a (maximum) threshold, a review should be performed to determine causes and implement changes, if necessary. As an example, if the incidence of pneumothorax is one measure of the quality of IGTA of lung tumors, a rate that exceeds the threshold should initiate the consideration of a review of policies and procedures to assess for potential causes, and implement changes in practice to lower the incidence of the adverse event. Setting universal thresholds is very challenging, and institutional thresholds may differ from those listed in this document. Departments are encouraged to review the practice of lung ablation within their own institution and alter thresholds higher or lower to meet the quality improvement goals set forth. The thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for an indicator at a particular institution. Therefore, setting universal thresholds is very challenging, and each department is urged to alter the thresholds as needed to higher or lower values, to meet its own quality improvement program needs.

## OUTCOMES

### NSCLC Stage 1A

Stage 1A lung cancers include lesions measuring <3 cm in dimension surrounded by a normal lung or visceral pleura. The goal of treatment of stage 1A lung cancer is the complete eradication of disease. There is a trend of decreased local control rates in the larger T1c lesions (>2 cm and <3 cm) (20).

Local control ranges from 42% to 85% for the study duration up to 5 years, including 77%–85% at 1 year (62,63). When the local control at 1 year decreases to <69%, this warrants a consideration of a review of the operator's performance.

Reported outcomes for IGTA therapy of stage IA lung cancer are impacted by several factors, including varied patient follow-up across studies and overall patient characteristics, including the heterogeneity of the patient population, lack of differentiation between stages when reporting outcomes, and inclusion of only medically inoperable patients in several studies. In those studies that have included patient follow-up to 5 years, OS has ranged from 26% to 91% (17,62–67). One- and 3-year OS rates have ranged from 78% to 91% and 36% to 78%, respectively (17,62–67).

Full outcome data for 1A is provided in [Table 2](#) (17, 62–67), along with recommended threshold values.

**Table 2.** Outcomes of Image-Guided Thermal Ablation for Stage 1A Lung Tumors (17,62–67)

Outcome	Reported rate	Threshold
Local control 1 y (62,63)	78.0% (77%–85%)	70.0%
Local control 3 y (62)	55%	47%
Local control 5 y (62)	42%	30%
Overall survival 1 y (17,62–67)	88.9% (78%–91%)	80.5%
Overall survival 2 y (17,62,65,67)	71.0% (57%–73%)	65.2%
Overall survival 3 y (17,62–64,66,67)	55.7% (36%–78.1%)	43.3%
Overall survival 5 y (17,62,63,66,67)	34.8% (26%–67.8%)	19.4%

### NSCLC Stages 1B and IIA

Patients with larger lung cancers that are LN negative, including stage IB (>3 cm and <4 cm) and IIA (>4 cm and <5 cm), have been predominately studied in retrospective studies of localized NSCLC, including stage 1A patients. Subgroup analysis informs outcomes in these patients with tumors >3 cm. While the complete thermal ablation of lesions measuring up to 5 cm is achievable, local control rates and clinical outcomes generally decrease with an increasing lesion size (17). The limited data on this group of patients does not allow the establishment of thresholds.

### Metastatic Disease

The majority of studies reporting the results of IGTA therapy for metastatic cancer to the lungs have included patients with a variety of cancer subtypes and lesion sizes. Of those studies that

evaluated for OS, the 1-year OS was 58%–100% (17,68–82); the 5-year OS ranged from 31% to 67% (17,69,71,75,78,82).

Local control rates have been well studied. Over the course of multiyear follow-up, the rate of local control for the treatment of lung metastases ranged from 90.8% to 94.6% at 1 year (70,80). When the local control at 1 year falls below 70%, this warrants a review of the operator's performance. Full outcome data for metastatic disease is provided in Table 3 (17,68–82), along with recommended threshold values. For outcomes with limited data, no thresholds are recommended. Studies of IGTA for metastatic disease are impacted by a heterogenous patient population with comorbidities that impact overall OS outcomes. The authors recommend that metastatic disease outcomes for IGTA should be evaluated in future research.

### ADVERSE EVENTS

Published rates for individual types of adverse events (Appendix D (15)) are highly dependent on patient selection and may be based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Generally, the adverse event-specific thresholds should therefore be set higher than the adverse event-specific reported rates listed in Table 4. In addition, it is recognized that a single adverse event can cause a rate to cross above an adverse event-specific threshold when the adverse event occurs within a small patient volume (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program. In Table 4 (17,68,69,71,74,75,79,82–91), all values are

**Table 3.** Outcomes of Image-Guided Thermal Ablation for Metastatic Disease (17,68–82)

Outcome	Reported rate	Threshold
Not stratified by histology		
Overall survival 1 y (68–70)	93.6% (92.4%–97.6%)	88.4%
Overall survival 2 y (68,69)	80.7% (79.4%–86.6%)	73.5%
Overall survival 3 y (69)	67.7%	No recommendation
Overall survival 4 y (69)	58.9%	No recommendation
Overall survival 5 y (69)	51.5%	No recommendation
Colorectal cancer		
Overall survival 1 y (17,72,74,75,79–82)	90.4% (76.9%–96%)	78.7%
Overall survival 2 y (17,72,74,75,79,80,82)	68.8% (50.8%–85.5%)	47.6%
Overall survival 3 y (17,72,74,75,80,81)	56.7% (46%–61%)	45.4%
Overall survival 5 y (17,75,82)	47.5% (43.6%–67%)	34.1%
Sarcoma		
Overall survival 1 y (69,73,76,77)	88.8% (58%–94.1%)	55.9%
Overall survival 3 y (69,73,76,77)	59.8% (29%–85%)	19.6%
Overall survival 5 y (69)	41.5%	No recommendation
Renal cell carcinoma		
Overall survival 1 y (69,71,78)	94.9% (10%–100%)	87.8%
Overall survival 3 y (69,71,78)	74.7% (52%–100%)	40.7%
Overall survival 5 y (69,71,78)	62.8% (52%–100%)	23.9%

**Table 4.** Adverse Events for Image-Guided Thermal Ablation of Lung Tumors 4 (17,68,69,71,74,75,79,82–91)

Outcome	Reported rate	Threshold
Pneumothorax requiring chest tube insertion* (17,68,69,71,74,75,79,82,84–86,88,89)	20.7% (6.7%–46.6%)	46.2%
Pulmonary hemorrhage† (79,83,86)	6.4% (6%–9.3%)	9.2%
Hemorrhage requiring intervention (83,86)	1.7% (1.6%–2.9%)	3.0%
Pleural effusion‡ (71,79,82,85–89)	6.0% (2%–49.2%)	36.9%
Pneumonia/abscess (83,86,87,89)	4.7% (1.8%–5.7%)	7.6%
Empyema (87)	0.3%	1% <sup>§</sup>
Nerve palsy (83)	0.3%	1% <sup>§</sup>
Systemic air embolism (68)	0.6%	2% <sup>§</sup>
Death (17,79,82,83,86–88)	0.9% (0%–2.2%)	2.5% <sup>§</sup>

\*A simple pneumothorax requiring chest tube is an expected outcome of the procedure and may not require additional therapy; it, therefore, may not be considered a complication of the IGTA procedure unless an escalation of care is required.

†It is notable that of the modalities, cryoablation has the highest rates of pulmonary hemorrhage and hemoptysis following treatment, a natural consequence of melting ice within the pulmonary parenchyma (63,85,90,91).

‡Pleural effusion is impacted by ablation modality, and the majority do not require therapy.

§This adverse event is infrequent and, in some cases, carries morbidity and mortality; a peer-review of each case is recommended.

supported by the weight of literature evidence and panel consensus. Pneumothorax has been reported in 18.7%–45.7% of cases following IGTA therapy and is an expected, predictable, and self-limited outcome of the procedure. A simple pneumothorax not requiring a chest tube is not considered a complication unless an escalation of care is required; therefore, no threshold will be set.

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