

Clinical Outcomes after Pulmonary Cryoablation with the Use of a Triple Freeze Protocol

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ABSTRACT

Purpose: To elucidate clinical variables associated with safety and efficacy in patients after cryoablation of pulmonary tumors with the use of a triple freeze protocol.

Materials and Methods: Percutaneous cryoablation of pulmonary tumors was performed using Galil Medical cryoprobes (Arden Hills, Minnesota) with a triple freeze protocol: 67 nodules in 42 patients were treated at a single institution from 2012 to 2016. Average nodule diameter was 1.6 cm (range 0.4–5.9); 13 nodules (19.4%) were pathologically determined to be a primary lung malignancy, whereas 54 (80.6%) were metastatic nodules of extrapulmonary origin. Average patient age was 68.1 years (range 39.6–89.6), and the male-female ratio was 1.3:1. Ipsilateral thoracic surgery, intervention, or radiotherapy had been performed before the first cryoablation in 18 patients (42.9%). Mean imaging follow-up was 326 days (range 9–1,152).

Results: Pneumothorax occurred in 19 cases (33.9%), 7 (12.5%) requiring chest tube, the likelihood of which was significantly greater in patients with 3 or more cryoprobes ($P < .01$). Local tumor recurrence/residual disease occurred in 6 cases (9.0%). Local tumor recurrence was not seen after ablation of nodules measuring <1.0 cm at the time of procedure, a significant difference from the recurrence rate of 14.3% for nodules measuring ≥ 1.0 cm ($P < .05$). Likelihood of tumor recurrence/residual disease did not correlate with tumor pathology, tumor location, or procedural factors. The estimated marginal probabilities of local recurrence were 11.4%, 11.4%, and 38.1% at 1, 2, and 3 years after ablation, respectively.

Conclusions: Cryoablation of pulmonary tumors with the use of a triple freeze protocol is a viable modality with low recurrence and complication rates.

Percutaneous image-guided cryoablation of pulmonary tumors is a viable treatment modality for select patients (1,2). Recent reports have demonstrated the efficacy of pulmonary cryoablation in cases of primary lung cancer (3,4), recurrent lung cancer (5), and pulmonary metastases (6,7). Moreover, there is potential for cryoablation to deliver results in a cost-efficient manner (8). However, these promising findings must be balanced against rates of complications and tumor recurrence.

One of the more commonly reported complications of pulmonary cryoablation is pneumothorax, ranging from 0% to 38% in recent reports (9,10). Increased number of

cryoprobes has been demonstrated to be a risk factor for pneumothorax, with conflicting findings regarding other risk factors, such as patient sex and previous thoracic procedure (11,12). Published local tumor recurrence rates range from 3% to 44% (3,12). Tumor size has been shown in several studies to influence local recurrence (12,13), whereas other factors, such as distance to major vessels, are more controversial (12,14).

To reduce local recurrence rates, a triple freeze protocol has been proposed as a method to increase ablation effectiveness (15), particularly in the lung, where aerated parenchyma is a poor conductor of thermal energy (16,17). Additional freeze-thaw cycles are thought to induce local hemorrhage, which increases conductivity in later cycles via blood products (18). The theoretic benefits of a triple freeze cycle include minimizing cryoprobe number (thereby reducing complication rate) and maximizing the cytotoxic ablation zone (thereby reducing local recurrence rates). However, there are limited data investigating the utility of triple freeze protocols in a clinical setting, and further evaluation is warranted to ensure safety and efficacy of this approach. The purpose of the present study was to elucidate clinical variables that determine rates of recurrence and complication in patients after cryoablation of pulmonary tumors with the use of a triple freeze-thaw protocol.

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EDITORS' RESEARCH HIGHLIGHTS

- A triple freeze cryoablation protocol, consisting of 3 minutes freeze, 3 minutes passive thaw, 8 minutes freeze, 3 minutes passive thaw, 8 minutes freeze, and 4 minutes active thaw, was used to treat 67 primary and metastatic pulmonary tumors.
- Local recurrence or residual disease occurred in 9% of cases. However, median follow-up time was 248 days, which was less than the 272 day median time to progression, which may underestimate recurrence rates.
- Complication rates were low, pneumothorax being the most common.

MATERIALS AND METHODS

Subjects

Institutional Review Board approval was obtained, and the study was conducted in compliance with the Health Insurance Portability and Accountability Act. Subjects were included if they had undergone percutaneous image-guided cryoablation of pulmonary tumors with the use of a triple freeze-thaw protocol from February 2012 to June 2016. The diagnosis of pulmonary malignancy was determined either after histologic sampling of the pulmonary nodule or, in the case of a pathology-proven extrapulmonary malignancy, the presence of a new or enlarging pulmonary nodule. Subjects were excluded if the documented purpose of the procedure was for palliation or pain management. All procedures were performed after discussion at a multidisciplinary thoracic tumor board.

Sixty-seven nodules were ablated during 56 unique procedures in 42 patients (Table 1). 46/56 procedures involved cryoablation of 1 nodule, 9/56 procedures involved cryoablation of 2 nodules, and 1/56 procedures involved cryoablation of 3 nodules. Thirty-two out of forty-two patients underwent a single procedure, 7/42 patients underwent 2 separate procedures, 2/42 patients underwent 3 separate procedures, and 1/42 patients underwent 4 separate procedures. Generally, multiple nodules were ablated in a single procedure when located unilaterally, multiple procedures were performed when nodules were located in both lungs or following identification of new tumors.

The average patient age at the time of first procedure was 68.1 years (range 39.6–89.6) and the male-female ratio was 1.3:1. Ipsilateral thoracic surgery, intervention, or radiotherapy had been performed before the first cryoablation in 18 patients (42.9%). Preablation scans in 7 patients (16.7%) demonstrated mild emphysema; no patients exhibited advanced emphysematous disease.

Nodule size and location with respect to the pleura and a blood vessel measuring ≥ 3 mm in diameter are reported in Table 1. Of all nodules ablated, 13 (19.4%) were pathologically determined to be a primary lung malignancy and 54 (80.6%) were metastatic nodules of extrapulmonary origin (Table 2).

Table 1. Patient Demographics, Procedural History, and Nodule Size

Characteristic	Value
Age, y	
Mean \pm SD	68.1 \pm 11.9
Range	39.6–89.6
Sex	
Male	24 (57.1%)
Female	18 (42.9%)
Imaging follow-up	
1 mo	62 (92.5%)
3 mo	55 (82.1%)
6 mo	48 (71.6%)
1 y	19 (28.4%)
2 y	6 (9.0%)
3 y	2 (3.0%)
Emphysema	7 (16.7%)
Previous ipsilateral thoracic treatment	18 (42.9%)
Lobectomy	8 (19.0%)
Wedge resection	8 (19.0%)
Microwave ablation	3 (7.1%)
Radiation therapy	7 (16.7%)
Previous chemotherapy	65 (97.0%)
Cryotherapy	
Nodules ablated per procedure	
Mean \pm SD	1.2 \pm 0.4
Range	1–3
Total nodules/procedures	67/56
No. of procedures per patient	
Mean \pm SD	1.3 \pm 0.7
Range	1–4
Total procedures/patients	56/42
Nodule size	
Volume, mean \pm SD, cm ³	2.7 \pm 1.1
Volume, range, cm ³	0.03–6.2
Axial diameter, mean \pm SD, cm	1.6 \pm 1.1
Diameter, range, cm	0.4–5.9
<1 cm	25 (37.3%)
1–2 cm	25 (37.3%)
2–3 cm	9 (14.9%)
>3 cm	7 (10.5%)
Nodule location	
>1 cm to pleura	33 (49.3%)
≤ 1 cm to pleura	34 (50.7%)
Contacting pleura	16 (23.9%)
>3 mm to vessel	60 (89.6%)
≤ 3 mm to vessel	7 (10.4%)

Note—Values are presented as mean \pm SD, range, or n (%).

Procedures

Cryoablation was performed with the use of the Galil Medical Visual-ICE Cryotherapy System with IceRod 1.5 Plus (17-gauge) cryoprobes (Arden Hills, Minnesota). The patient was positioned prone or supine per operator preference, and a sterile field was prepared. Computerized

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