REVIEW

Percutaneous ablation of low-risk papillary thyroid cancer

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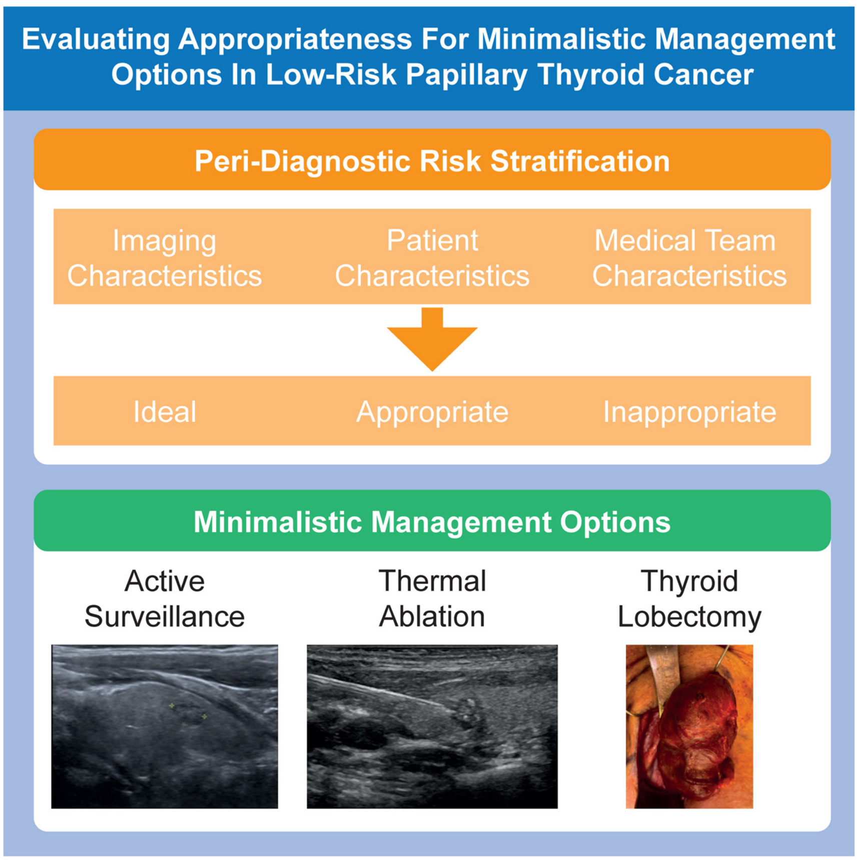
Graphical abstract



Key Words

- thyroid cancer
- thermal ablation
- indications
- safety
- efficacy

Abstract

Minimalistic management options such as active surveillance and thyroid lobectomy are increasingly being accepted as reasonable management options for properly selected patients with low-risk papillary thyroid cancer. Leveraging technologies developed for the treatment of benign thyroid nodules, ultrasound-guided percutaneous thermal ablation is now being evaluated as a potential additional minimalistic management option for small, intrathyroidal, low-risk papillary thyroid cancer. Published retrospective data on

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more than 5000 low-risk papillary thyroid cancer patients treated with thermal ablation indicate that with appropriate training and proper patient selection, these technologies can be safely and effectively applied to papillary microcarcinomas. When compared to immediate surgery, thermal ablation appears to have lower complication rates with similar short-term rates of recurrence. Proper patient selection is facilitated by the use of a clinical framework which integrates imaging characteristics, patient characteristics, and medical team characteristics to classify a patient as ideal, appropriate, or inappropriate for minimalistic management options (active surveillance, thyroid lobectomy, or thermal ablation). While retrospective in nature and lacking randomized prospective clinical trial data, currently available data do support the proposition that thermal ablation technologies reliably destroy papillary thyroid microcarcinoma lesions and are associated with clinically acceptable oncologic outcomes when done by experienced teams in properly selected patients.

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Introduction

For more than 40 years, the prevailing treatment paradigm for well-differentiated thyroid cancer endorsed total thyroidectomy, radioactive iodine therapy, and thyroid hormone suppressive therapy for most patients with papillary thyroid cancer. However, the last decade has seen a shift toward acceptance of more minimalistic management options such as active surveillance or thyroid lobectomy for properly selected patients with low-risk papillary thyroid cancer (Haugen *et al.* 2016, Tuttle & Alzahrani 2019).

Even though thyroid lobectomy and active surveillance has been shown to be safe and effective management options for low-risk thyroid cancer (Chou *et al.* 2022), many patients who are not interested in active surveillance are seeking an even more minimalistic therapeutic option to destroy the small focus of papillary thyroid cancer without having to undergo thyroid surgery. To meet this unmet need, ultrasound-guided percutaneous ablation technologies, developed as a nonsurgical therapeutic option to decrease the volume of benign thyroid nodules, are now being used to destroy small intrathyroidal papillary thyroid cancer nodules (Hegedus *et al.* 2020, Min *et al.* 2020, Tufano *et al.* 2021, Baldwin *et al.* 2022, Pace-Asciak *et al.* 2022). These percutaneous ablation technologies utilize real-time ultrasound guidance to insert a needle probe that delivers thermal energy into a small thyroid cancer nodule under either local anesthesia or mild conscious sedation in the outpatient setting. With appropriate training, the procedure can be safely and effectively done by clinicians with widely differing training backgrounds including endocrinologist, radiologist, surgeons, and interventional radiologist (Orloff *et al.* 2022). However, it is important to emphasize that most suspicious thyroid cancer nodules do not require fine needle aspiration to establish a diagnosis and do not require immediate thermal ablation or surgical intervention. Thus, it is incumbent upon clinicians to reserve thermal ablation or surgical interventions for highly selected patients with low-risk papillary thyroid cancers who are not candidates for observational management.

In this review, we will describe the efficacy and safety of the ablation technologies currently under investigation and describe a clinical framework for proper patient selection in order to optimize outcomes and minimize complications when considering percutaneous ablation therapeutic options as an alternative to active surveillance or thyroid surgery.

Percutaneous ablation technologies currently under evaluation

The effectiveness of most percutaneous ablation technologies relies on the focused application of intense heat (thermal ablation) to individual thyroid nodules, resulting in coagulative necrosis, protein denaturation, cellular membrane disruption and tissue necrosis with corresponding histologic evidence of fibroblastic proliferation, chronic inflammation, and infarction in the ablation zone (Lu *et al.* 2021). When treating malignant thyroid nodules, the goal is to achieve a thermal ablation zone that encompasses the full volume of the thyroid nodule and a safety margin of at least 2 mm of the surrounding normal thyroid tissue. Inadequate thermal coverage of the edges of the thyroid nodule can lead to the persistence of viable thyroid cells on the periphery and likely puts the patient at risk for a late recurrence (Hua *et al.* 2021). With experience, improved technique, and appropriate use of hydrodissection, studies are emerging suggesting that nodules that are either abutting without invasion or <2 mm away from an intact thyroid capsule can also be safely and effectively ablated (Wu *et al.* 2021, Zheng *et al.* 2022).

Examples of commercially available percutaneous thermal ablation technologies include radiofrequency ablation (RFA), laser ablation (LA), microwave ablation (MA), and high-frequency ultrasound ablation. In the absence of randomized prospective control trials utilizing a head-to-head comparison of these various treatment modalities, it is not possible to determine if one of these technologies is preferable over the others. In most of the published studies, it appears that the choice of thermal ablation technology was probably related to prior experience, expertise, and availability of equipment (Mauri *et al.* 2021).

In addition to the thermal ablation technologies, ultrasound-guided intratumoral administration of ethanol has been used as a chemical ablation method to destroy low-risk papillary thyroid cancer (Baldwin *et al.* 2022). The alcohol injection promotes cellular dehydration leading to protein denaturation, damage to the vascular endothelial and platelet aggregation with fibrin clot formation leading to vascular thrombosis, tissue ischemia, and coagulation necrosis. While widely used in the treatment of predominantly cystic nodules, less data are available regarding the use of ethanol ablation in solid malignant thyroid nodules.

Overview of published case series examining thermal ablation in low-risk papillary thyroid cancer

Most of the data available examining thermal ablation approaches in the management of low-risk thyroid cancer come from single-institution retrospective case series describing carefully selected patients with papillary microcarcinomas (≤1 cm in maximal diameter) who were not interested in active surveillance and declined surgical intervention or who were conisdered high risk for surgical intervention (Cho *et al.* 2019, Choi & Jung 2020, Min *et al.* 2020, Cho *et al.* 2021, Tufano *et al.* 2021, Baldwin *et al.* 2022, Chung *et al.* 2022). Limited data are available for papillary thyroid cancer nodules 1–2 cm (Cao *et al.* 2021, Xiao *et al.* 2021*a*) or 2–4 cm (Xiao *et al.* 2021*b*) in maximal diameter.

A recent review article by Ou *et al.* examined 40 published studies that evaluated the safety and efficacy of percutaneous thermal ablation in low-risk papillary thyroid cancer (Ou *et al.* 2022). The articles reviewed by Ou included data on percutaneous thermal ablation of 5268 low-risk papillary thyroid cancer nodules in 5074 patients (Table 1). Most of these studies were performed in institutions in China in adults (45 ± 4 years of age at the time of ablation) with small papillary thyroid cancers (6 ± 3 mm in maximal dimension). More than half of the ablations were done using RFA, with about 25% done using MA and 12.5% done with LA. While 73% of the studies restricted ablation to a single thyroid cancer nodule, 27% of the series included patients that had multiple nodules ablation within the same lobe. While the mean follow-up duration in these 40 case series was 3.3 years, a recent study described similar safety and efficacy in a retrospective cohort followed for 5–10 years after percutaneous LA (Kim *et al.* 2021*b*).

Efficacy of percutaneous thermal ablation

In most of the publications, the primary study endpoints focused on ultrasonographic findings during follow-up that confirmed destruction of the thyroid cancer nodule (decrease in size of the ablation zone over time, absence of vascularity, complete resolution of the ablation zone, and no evidence of disease recurrence within the previous ablation zone), while smaller proof-of-principle studies confirmed the absence of viable thyroid cancer cells in the ablation zone on follow-up fine needle aspiration biopsy (Zhou *et al.* 2017, Zhang *et al.* 2018) or core biopsy (Lu *et al.* 2021). Not surprisingly, the very few reported cases that failed thermal ablation had histologic evidence of persistent thyroid cancer within the ablation zone at the time of surgical resection (Ma *et al.* 2018).

When evaluated in meta-analysis, the pooled proportions of complete disappearance of the ablation zone were 57.6% (Choi & Jung 2020). However, the proportion of complete disappearance increases with longer follow-up durations such that by 2 years after ablation, 79.7% of the ablation zones had completely disappeared, while 20.3% demonstrated scar like tissue that revealed no viable neoplastic cells on follow up fine needle aspiration. In a meta-analysis restricted to patients followed for at least 5 years after thermal ablation, the mean pooled disappearance rate was 98.5% (95% CI, 92.8–99.7%) at the time of final follow-up (Cho *et al.* 2021). Even though the most significant decrease in tumor zone volume occurs between 6 and 12 months,

Table 1 Summary data from 40 published case series evaluating the safety and efficacy of percutaneous thermal ablation in low-risk papillary thyroid cancer (Ou *et al.* 2022).

Descriptor	
Number of nodules ablated (*n*)	5268
Number of patients (*n*)	5074
Location of the institution performing the ablation (*n*, %)	
China	36 (90)
Korea	3 (7.5)
Italy	1 (2.5)
Age at the time of thermal ablation (mean ± s.d., years)	45 ± 4
Average tumor size (mean ± s.d., mm)	6 ± 3
Type of thermal ablation	
Radiofrequency ablation (%)	52.5
Microwave ablation (%)	25
Laser ablation (%)	12.5
Radiofrequency or microwave ablation (%)	5
Radiofrequency or laser ablation (%)	2.5
Laser or microwave ablation (%)	2.5
Single or multiple nodules ablated in the same procedure	
Single nodule (%)	73
Multiple nodules (%)	27
Developed hoarseness from the ablation procedure (%)	1.4 (71/5074 patients)
Usual time to recovery of hoarseness (months)	1–6
Follow-up duration after ablation (mean ± s.d. (range), years)	3.3 ± 2.9 (0.7–7.7)
Recurrence in ablation zone (%)	1.2 (65/5268 ablated nodules)
Lymph node metastasis identified during follow up (%)	0.6 (32/5074 patients)

10–20% of percutaneous LA-treated patients have complete resolution of the ablation zone by 6 months (Zhang *et al.* 2018).

In Ou *et al.*'s review of 40 retrospective case series (Ou *et al.* 2022), after a mean follow-up period of 3.3 years, recurrence with the ablation zone was identified in 1.2% (65/5268 ablated nodules), while newly identified cervical lymph node metastasis was documented in 0.6% (32/5074 patients) (Table 1). Additionally, in a meta-analysis restricted to patients followed for at least 5 years after thermal ablation, the recurrence within the thyroid gland was detected in only 5 of the 207 patients (2.4%) with none of the recurrences developing in the previous ablation zone (Cho *et al.* 2021).

Safety of percutaneous thermal ablation

When performed by appropriately trained clinicians in properly selected patients, percutaneous thermal ablation technologies are remarkably safe and associated with a very low risk of serious complications (Cho *et al.* 2019, Choi & Jung 2020, Shen *et al.* 2020, Kim *et al.* 2021*a*). Effective pain control can be accomplished using either local anesthesia or light conscious sedation depending on the preference of the patient and the operating clinician. Serious complications such as thermal injury to surrounding structures (trachea, esophagus, major vessels, brachial plexus, or sympathetic chain), significant hematoma formation, hemorrhage, or thyroid nodule rupture are exceptionally uncommon and rarely encountered (Baldwin *et al.* 2022).

The most common complications reported are a sensation of heat during the procedure and or pain/discomfort during or following the procedure (Cho *et al.* 2019, Choi & Jung 2020, Shen *et al.* 2020, Kim *et al.* 2021*a*). These symptoms are easily managed with modifications to the procedure during the ablation and nonsteroidal anti-inflammatory medications following the procedure as needed for a few days.

The most common clinically significant complication is a change in the voice that is associated with thermal injury to the ipsilateral recurrent laryngeal nerve (Table 1). In Ou *et al.*'s review of 40 retrospective case series (Ou *et al.* 2022), transient hoarseness was described in 1.4% (71 of 5074 patients ablated) which resolved within 1–6 months (Table 1). However, most studies assessed potential injury to the recurrent laryngeal nerve through voice exam and not direct documentation of vocal cord function pre- and postprocedure (Cho *et al.* 2019, Choi & Jung 2020, Baldwin *et al.* 2022). Permanent vocal cord dysfunction is exceptionally uncommon, but it may take weeks to months for the voice to return to normal (Ou *et al.* 2022). Meta-analysis of the published data confirms a risk of overall complication of about 3%,

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while the risk of major complications is less than 1–2% (Choi & Jung 2020, Kim *et al.* 2021*a*, Chen *et al.* 2022).

Conflicting data exist regarding the potential that the fibrosis and tissue damage caused by the thermal ablation could impact the technical aspects of a subsequent thyroid surgery (Ma *et al.* 2018, Hua *et al.* 2021, Lu *et al.* 2021).

Clinical outcomes comparing immediate surgery with thermal ablation

While data from prospective randomized trials are not available, several studies have retrospectively compared clinical outcomes between patients who were selected for thermal ablation therapy with patients undergoing standard surgical upfront therapy. Three independent systematic review and meta-analyses (Choi & Jung 2020, Kim *et al.* 2021*a*, Chen *et al.* 2022) and one propensity-matched cohort study (Yan *et al.* 2021) demonstrated similar low recurrence rates during follow-up but significantly higher risk of peri-procedural complications in patients undergoing surgery as opposed to those selected for thermal ablation.

In the Kim *et al.* meta-analysis (Kim *et al.* 2021*a*) comparing standard surgery ($n=314$) with thermal ablation ($n=339$), after a mean follow-up of 3 years, there was no significant difference in the pooled proportion of lymph node metastases (2.6% with thermal ablation vs 3.3% with surgery, $P=0.65$), occurrence of new tumors (1.4% with thermal ablation vs 1.3% with surgery, $P=0.85$), or rescue surgery (2.6% with thermal ablation vs 1.6% with surgery, $P=0.62$). However, the pooled complication rate was significantly higher in the surgery group than in the ablation group (3.3% with thermal ablation vs 7.8% with surgery, $P=0.03$).

Similarly, the Shen *et al.* meta-analysis (Shen *et al.* 2020), which included 658 patients followed for a mean of 3.5 years, demonstrated that thermal ablation was associated with significantly lower rates of complication, postoperative length of stay, and cost during the perioperative period when compared to immediate surgery. Furthermore, there was no significant difference in either recurrence or recurrence free survival between the two groups.

Likewise, Chen *et al.* included 1582 patients from a total of 7 articles and demonstrated that the thermal ablation was associated with a shorter hospitalization time, shorter operation time, decreased cost, and reduced peri-procedural complications when compared to immediate surgery (Chen *et al.* 2022). In addition, there was no difference in the recurrence rate or risk of developing local or distant metastasis between the two groups.

Using a propensity-matched cohort analysis comparing 332 patients who underwent thyroid lobectomy with 332 patients who had RFA followed for a median of 48 months, no significant differences were observed in lymph node metastasis (0.6% vs 0.6%, $P=1.00$), persistent lesion (0% vs 0.3%, $P=0.317$), or 4-year recurrence free survival rates (98.2% vs 97%, $P=0.223$) between the lobectomy and thermal ablation patients, respectively (Yan *et al.* 2021). In addition, thermal ablation was associated with lower cost and lower complication rates than thyroid lobectomy.

The findings from these retrospective comparison studies are also consistent with recurrence rates that have been reported in the published case series that did not include a surgical comparison group. For example, meta-analysis of the published data from retrospective case series indicates that the recurrence rate following thermal ablation is approximately 1–2% or less (Choi & Jung 2020). A meta-analysis of patients followed for a minimum of 5 years also confirmed a very low recurrence rate of 2.7% (95% CI, 1–6.5%) (Cho *et al.* 2021). Interestingly, a 1–2% risk of developing newly identified disease during follow-up either within the thyroid gland or in cervical lymph node metastasis is also very similar to what would be expected in patients followed with either active surveillance or upfront thyroid surgery over a similar observation period (Mazzaferri 2007, Nixon *et al.* 2012, Matsuura *et al.* 2022).

Potential role of percutaneous thermal ablation in therapy

Successful integration of any new technology, device, or shift in management paradigms into routine clinical practice requires standardized training, appropriate selection of the treatment modality, careful patient selection, and appropriate informed consent discussions to optimize the effectiveness and patient satisfaction while minimizing the complications of the novel approach (Xu *et al.* 2020, Mauri *et al.* 2021, Jasim *et al.* 2022, Orloff *et al.* 2022). As with any new technology, it is important to obtain and document an informed consent discussion outlining the proposed procedure with the associated risk, benefits, costs, and alternatives (Mauri *et al.* 2021, Orloff *et al.* 2022). While we endorse thermal ablation of benign thyroid nodules as part of the practice of medicine with corresponding clinical consent, when

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these technologies are applied to thyroid cancer nodules at our center, we prefer to perform the procedure as part of a prospective clinical trial with appropriate institutional human use committee oversight. Additionally, it is important to consider the potential cost of the procedure to the patient as thermal ablation of malignant thyroid nodules is often not be covered by private insurance or national health care plans.

If active surveillance is not an acceptable management option, thermal ablation for papillary thyroid microcarcinoma is a reasonable treatment alternative for patients considered to be high surgical risk, who have a shortened life expectancy, with significant co-morbidities that take priority over the treatment of thyroid cancer, or who are unwilling to undergo surgery (Mauri *et al.* 2021, Chung *et al.* 2022, Orloff *et al.* 2022).

Our approach to optimizing patient selection and achieving excellent outcomes is to utilize our peri-diagnostic risk stratification system to systematically evaluate tumor, patient, and medical team characteristics to determine if a minimalistic management approach is ideal, appropriate, or inappropriate (Tuttle *et al.* 2018, Tuttle & Alzahrani 2019) (graphical abstract). We modified our previously published clinical frameworks developed to guide proper patient selection for active surveillance and thyroid lobectomy (Tuttle *et al.* 2018) to address the critical issues that need to be evaluated when considering application of thermal ablation technologies as an alternative to standard thyroid surgery or observation (Table 2). This clinical framework is consistent with the recently published multidisciplinary consensus statement authored by an international panel of surgeons, radiologists, and endocrinologists with expertise in ultrasound-guided ablation procedures (Orloff *et al.* 2022). Our clinical framework relies primarily on ultrasonography of the thyroid gland and cervical lymph node changes to evaluate eligibility criteria for papillary microcarcinomas. Neck CT with contrast is used to provide additional structural imaging information for nodules being considered for ablation in the 1–2 cm size range (Baek & Cho 2021).

Table 2 Clinical framework to aid in proper patient selection for percutaneous thermal ablation in low-risk papillary thyroid cancer.

Patient classification	Imaging characteristics	Patient characteristics	Medical team characteristics
Ideal	Solitary thyroid nodule confined to thyroid ≤1 cm Discrete nodule with well-defined boundaries Surrounded by ≥2 mm normal thyroid parenchyma Not abutting the thyroid capsule Previous US documenting stability In nodules greater than 1 cm, neck CT with contrast to confirm the absence of metastatic cervical lymph nodes cN0 cM0	Desires a minimalistic management approach Unwilling to accept active surveillance Willingness to accept a novel therapeutic approach Strong desire to preserve normal thyroid function Strong desire to minimize surgical complications Anxiety that may be improved by thermal destruction of the thyroid cancer nodule Understands that thyroid cancer foci may be identified during follow-up in the remaining thyroid gland or cervical lymph nodes	Experienced team trained in thermal ablation techniques Ready availability of other specialists that may be needed to expeditiously evaluate and manage potential complications Prospective data collection
Appropriate	Multifocal papillary microcarcinoma 1–1.5 cm maximal dimension Nodules that are ill defined or infiltrative into thyroid parenchyma	Strong family history of PTC History of thyroid irradiation High risk for, ineligible for, or declines surgery Does not meet the strict criteria for ideal but is unwilling to accept surgery	Clinician appropriately trained in thermal ablation techniques Clinician with extensive previous experience with ultrasound-guided fine needle aspiration biopsy Access to appropriate thermal ablation equipment
Inappropriate	Location adjacent to RLN/trachea/major vessels > 1.5 cm in maximal dimension Evidence of extrathyroidal extension N1 or M1 disease	Desires surgical intervention Desires active surveillance Unwilling to accept a novel therapeutic approach	Reliable neck US not available Lack of experience with thermal ablation techniques

PTC, papillary thyroid cancer; RLN, recurrent laryngeal nerve; US, ultrasound.

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The ideal patient has a discrete, well-defined, papillary thyroid microcarcinoma with ≥2 mm or normal thyroid parenchyma surrounding the nodule with no evidence of multifocality or cervical lymph node metastasis. The patient is motivated to avoid surgery and unwilling to accept active surveillance and embraces the novel therapeutic management option. Finally, the procedure is recommended and performed within a multidisciplinary management team with extensive experience with the specific ultrasound guided percutaneous ablation technique that will be used.

While not considered ideal, with appropriate patient selection and informed consent, thermal ablation technologies can also be considered for (i) papillary thyroid cancer nodules in the 1–1.5 cm range, (ii) papillary thyroid cancer nodules with ill-defined borders, (iii) patients with a strong family history of papillary thyroid cancer desiring minimalistic management options, (iv) patients with prior history of thyroid irradiation, or (v) patients at high risk, ineligible for or actively declining thyroid surgery. Other than in very exceptional circumstances, thermal ablation technologies are not recommended for patients classified as being inappropriate for minimalistic management (Chung *et al.* 2022).

Conclusions

We consider active surveillance or standard thyroid lobectomy as the most well-established minimalistic treatment options. However, while primarily retrospective in nature and lacking randomized prospective clinical trial data, currently available data do support the proposition that thermal ablation technologies reliably destroy papillary thyroid microcarcinoma lesions and are associated with a complication rate that is likely less than standard surgery while achieving very comparable favorable oncologic outcomes when done by experienced teams in properly selected patients. Currently, we view thermal ablation as a viable management option for properly selected patients who are unwilling to consider active surveillance or immediate surgical intervention or who have significant contraindications to standard surgical therapy. Future studies are needed to optimize patient selection and to differentiate the effectiveness and safety of the various thermal ablation technologies that are currently available.

Declaration of interest
Tuttle: Institutional support was obtained from Elesta for prospective clinical trial. THANC Foundation, Inc. (provision of services); Li: Institutional support was obtained from Elesta for prospective clinical trial; Ridouani: Institutional support was obtained from Elesta for prospective clinical trial.

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