

The effectiveness and safety of thermal ablation for solitary T1bN0M0 papillary thyroid cancer

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Introduction. Thermal ablation guided by ultrasound is crucial in the treatment of thyroid disorders. This study sought to determine whether thermal ablation, an alternative to surgery for individuals with single T1bN0M0 papillary thyroid carcinoma (PTC), is feasible, effective, and safe.

Methods. Retrospective data analysis was done on 172 individuals (38 men and 134 women) who received thermal ablation at 12 hospitals between April 2015 and March 2020. A mean follow-up period of 24.9 14.1 months was used (range, 12-60). The treatment's technical viability, technical success, efficacy, and safety were examined. Comparisons between pre-ablation measures and tumor size at various times following ablation were made.

Results. In the RFA group, local tumor development occurred in 4 patients (4.4%), 3 of whom had persistent PTC and 1 of whom had LNM. Two patients (2.2%) in the surgical group developed LNM; no new or persistent PTC was diagnosed. The development of the local tumor was not significantly different between the two groups. Permanent hypoparathyroidism occurred in four individuals (4.4%) of the surgical group, while there were no major or moderate side effects in the RFA group.

In conclusion, for individuals with isolated T1bN0M0 PTC who are not candidates for surgery or are unwilling to have it done, thermal ablation may be a practical, efficient, and secure therapy option. For some individuals, it can present a brand-new therapy alternative.

Keywords. Papillary Thyroid Carcinoma (PTC), Tumor Size, Radio Frequency Ablation,

Ultrasound-guided Thermal Ablation (RFA)

INTRODUCTION

Papillary thyroid carcinoma (PTC), follicular thyroid carcinoma (FTC), medullary thyroid cancer (MTC), and anaplastic thyroid carcinoma (ATC) are the most common kinds of thyroid cancer (ATC). Evidence suggests that thyroid cancer is increasing in incidence and mortality because of a lack of viable treatment options^[1]. A total of 80 percent of all thyroid cancer cases are caused by PTC, which is the most frequent subtype of thyroid cancer^[2]. Thyroid polycentricity and frequent metastases to nearby lymph nodes characterize PTC, making it more dangerous and deadly for those who suffer from it^[3]. Thyroid polycentricity and frequent metastases to nearby lymph nodes characterize PTC, making it more dangerous and deadly for those who suffer from it^[4]. While most PTCs are benign, their biological characteristics can range from non-progressive/extremely indolent tumors to aggressive metastatic tumors.^[5,6] Therefore, providing a new treatment option for selected patients is the driving force and goal of our research.

Surgery is currently the most common treatment modality for papillary thyroid carcinoma; however, surgery has several drawbacks, some of which can negatively impact the patient's quality of life, including injury to the laryngeal return nerve (RLN), hypoparathyroidism, significant scarring, and the risk of hypothyroidism. Surgery is currently the most common treatment modality for papillary thyroid carcinoma. The treatment of thyroid illness sometimes includes a procedure called ultrasound-guided thermal ablation, which plays a significant part. The purpose of this study was to determine whether or not patients with solitary T1bN0M0 papillary thyroid carcinoma (PTC) who were reluctant or unable to undergo surgery may benefit from thermal ablation and whether or not it was practical, effective, and safe^[7]. As a novel approach to the treatment of thyroid disease, ultrasound (US) guided thermal ablation (such as microwave ablation [MWA] and radiofrequency ablation [RFA]) may play an important part in the modern practice of medicine. This treatment is minimally invasive and requires only a few small incisions. In individuals who have benign thyroid nodules and in certain patients who have recurrent thyroid cancer, radiofrequency ablation (RFA) may be used as an alternative to surgery, as suggested by the Thyroid Radiofrequency Ablation Guidelines of 2017, as well as by the first Italian opinion

statement^[8,9]. Thermal ablation has been shown to have positive results in patients with T1a PTC in some trials^[10, 11].

As a result, the goal of this paper was to investigate the feasibility, efficacy, and safety of thermal ablation in patients with single T1bN0M0 papillary thyroid cancer (PTC) who are either unfit for

surgery or unwilling to go through with it. Finding new therapeutic targets and approaches is therefore vital for the development of future viable treatments for papillary thyroid cancer (PTC), which will address the concerns of patients who have been diagnosed with papillary thyroid cancer.

MATERIALS AND METHODS

Clinical patient data sources

We looked at the medical histories of people with T1bN0M0 PTC who had surgery or RFA between April 2014 and May 2019, and we looked at those records. The following will come to a close in the month of May in 2020. The ethics committee at our organization gave their authorization to conduct this retrospective study. If a patient satisfies any one of the following requirements, then they are eligible to take part in this study: The following prerequisites have to be satisfied before an RFA can be distributed: (a) Before the RFA, ultrasound found a single suspicious thyroid nodule with a maximum diameter of >1 cm but less than 2 cm; (b) there was no imaging or clinical evidence of extrathyroidal extension, which is defined as contact with the adjacent thyroid capsule along more than 25 percent of the tumor circumference, destruction of the thyroid capsule, or tumor mass protruding from normal thyroid tissue; lymph node metastasis was found (LNM cN0), Before RFA can be issued, the following prerequisites need to be satisfied: In order for a diagnosis of PTC to be confirmed by US-guided core needle biopsy, there must not be any history of radiation treatment or surgery to the neck in the patient's past, and the patient must be followed for a minimum of one year.

Collected indicators

Before receiving either treatment, it was necessary for every patient to first offer their written informed consent. We compiled data on each patient's demographics, tumor features, length of surgery. The volume of the nodule was calculated by multiplying the length, breadth, and depth values that were based on centimeters by 0.524. This gave the result in milliliters; The RFA

operational time is the amount of time that must pass before the patient can be released from the operating room; The time that was spent under anesthesia was not included in the operating time, which was defined as the period of time beginning at the place where the incision was made and ending at the point when the skin was closed.

RFA Treatment

For each and every RFA treatment, a Siemens Acouson Sequoia 512 scanner, which was also manufactured by Siemens, was utilized. This scanner was fitted with a 6.0 MHz linear array transducer. The CelonProSurge tiny 100-T15, manufactured by Olympus Surgical Technologies, Europe, was the device that we decided to use. It is an 18-gauge straight internal cooled electrode with a 1.5 cm active tip, and it comes equipped with a bipolar RF generator manufactured by the same business (CelonLabPOWER).

Surgical procedure

A surgeon with more than 15 years of thyroid surgery experience will conduct a complete thyroidectomy or lobectomy while the patient is under general anesthesia. American Thyroid Association (ATA) guidelines⁴ and patient preference decide the scope of the surgery. Prophylactic central lymph node dissection is common practice at our hospital.

Postoperative treatment

After operation, the two groups took traditional Chinese medicine routinely to enhance their own immunity. Traditional Chinese medicine ingredients include Astragalus, Pinellia ternata, Atractylodes macrocephala, Cyperus, Prunella vulgaris, etc.

Follow up records

Patients in the RFA group had cervical ultrasounds, which included a CEUS, performed one, three, and twelve months after the therapy, as well as every six months after that. A chest CT with no contrast was conducted on both groups on a yearly basis to rule out the likelihood of distant metastases. The rates of complications and the development of tumors were the key areas of focus.

Statistical analysis

SPSS20.0 software is used for statistical analysis. Quantitative data are expressed by mean \pm standard deviation ($\bar{x} \pm s$), T-test is used to analyze; Qualitative data are described by percentage (%) and chi square test is performed. $P < 0.05$ shows the difference is statistically significant.

RESULTS

Baseline clinical characteristics of the patient

The RFA group included 91 patients in total, 19 men and 72 women, ranging in age from 21 to 62 years, with a mean age of 40.7 ± 9.3 years. General anesthesia was not a viable option for 17 of these patients, including those with renal insufficiency (two patients), poor pulmonary function (four), bronchial asthma (two), damage to the brain's nerves (one patient), hypertension (five patients), and poor cardiac function (three patients). 74 individuals, on the other hand, decided against surgery because of concerns about the possibility of complications and noticeable scars following the procedure; the surgery group included 23 men and 68 women (cN0). The two groups did not differ significantly in terms of age, gender, time of follow-up, PTC diameter, volume, or location. (Table 1).

RFA treatment effect demonstration

At the end of the study, the tumor volume decreased significantly ($P < 0.001$), and the average tumor diameter also decreased significantly ($P < 0.001$). Both results showed that the tumor was significantly smaller (Table 2). In total, 4.4 percent of patients were found to have evidence of progression of tumors in their immediate vicinity. Six months after the CNB surgery was conducted in the United States, there was a 3.3% chance (three ablated zones) that the patient had cancerous cells. After an ablation had been performed on one patient, the IV region of the ipsilateral cervix showed signs of metastatic lymph nodes three months later (1.1 percent). A second RFA operation performed on these individuals was successful and without incident. The VSR of the patients' remaining ablation zones was between 93.3 and 94.2 percent in both of the patients' cases, and two of the patients' ablation zones completely vanished. (Table 3).

Treatment results of surgery

Four of the patients who received a complete thyroidectomy developed lifelong hypoparathyroidism after more than six months. Thus, it was necessary that they take vitamin D or calcium supplements to keep their blood calcium levels within the usual range. RLN was not injured in the short-term or the long-term. The median follow-up time was 22 months (interquartile range, 13-33 months). No new or persistent lesions were seen in the course of the follow-up. Two

patients, or 2.2 percent of the total, were diagnosed with LNM after surgery. The ablated area was

no longer visible 20 months after a radiofrequency ablation (RFA) surgery was performed on one patient. The other patient was the subject of the second procedure (Table 4).

Comparison of RFA and surgery groups

Complications and local tumor progression rates did not differ significantly between the two groups. Both groups had no evidence of distant metastases. When compared to the surgical group, the RFA group required less time and cost during surgery ($p < 0.001$) than the surgical group. (Table 5)

DISCUSSION

At the moment, thyroid carcinoma is the fifth most prevalent kind of cancer to strike women all over the world. Furthermore, it accounts for 5.1 percent of the estimated overall cancer burden that women face (1). The age-standardized incidence rate of thyroid cancer in China went from 3.21/105 in 2005 to 9.61/105 in 2015, representing a yearly increasing incidence rate of 12.4 percent, according to epidemiological statistics from the country of China^[12]. Ultrasonography-guided percutaneous thermal ablations are a family of minimally invasive local therapies. These therapies, which include radiofrequency ablation (RFA), microwave ablation (MWA), and laser ablation (LA), have been shown to provide promising results for the control of local tumors in a variety of organs, and they are recommended in the guidelines that correspond to each of these therapies^[13, 14]. These methods have also been applied to benign thyroid tumors^[15, 16].

Thermal ablation is widely used in the treatment of diseases of the liver^[17], thyroid gland^[18], prostate gland^[19], as well as other tissues, and the scar left behind on the skin after the operation is not visible. The databases Web of Science and PubMed were thoroughly searched to look for research written in English that were published on or before August 30, 2021. "Hyperparathyroidism" OR "HPT" OR "Hyperplastic parathyroid gland," AND "Radiofrequency ablation" OR "RFA" OR "thermal ablation" WERE THE SEARCH TERMS USED.

RFA was first reported by Hänsler et al.¹^[19] in 2002, followed by scattered case reports^[20-22]. Studies conducted in the past have demonstrated that radiofrequency ablation (RFA) and laser ablation are both viable treatment options that can be used to treat cervical lymph node metastases caused by thyroid cancer^[23]. We believe that the rate at which the tumor disappears is

related to the size of the tumor, the characteristics of the tumor, and the amount of time that is followed up on; as a result, there is a certain amount of diversity in the results of

different research. The rate of post-ablation LNM was observed to range anywhere from 0.6 percent to 2.0 percent, according to the findings of the meta-analysis^[24].

The initial course of treatment for PTC that is advised and carried out at our clinic is surgical excision. RFA, on the other hand, is advised and carried out in situations in which the prerequisites for surgery are not met, such as the patient's refusal to undergo the procedure or their poor overall health. We compared the effectiveness of RFA treatment with that of surgical treatment. The following inferences can be drawn from our findings. The accurate location of the tumor was accomplished in all 91 patients, making the success rate for the ablation procedures one hundred percent. Immediate CEUS following ablation revealed no enhancement in the ablation zone, indicating that the procedure was a complete and utter success from a purely technical standpoint. Two patients reported having moderate pain, which was treated with medicine to alleviate the discomfort. In 4.4 percent of patients, evidence of local tumor growth was found; nonetheless, these individuals were able to have a second RFA procedure carried out without incident. At the moment, radiofrequency ablation is utilized for the parathyroid glands rather infrequently. There is not a significant difference in the number of patients who are cured or the complications that arise after surgery when compared to MWA^[25,26].

According to the existing studies^[27,28], ablation of all hyperplastic glands at once can not only save money and cut down on the amount of time spent in the hospital when treating hyperplastic glands that were detected through imaging, but it can also produce superior therapeutic results. Patients who have a residual lesion with a diameter of less than 30 millimeters may benefit more from RFA's effect^[29]. In conclusion, the RFA was well tolerated by each and every patient. We did not notice any major or minor issues during the procedure, such as a change in the patient's voice, hypoparathyroidism, hematoma, or skin burns. In the course of our research, the extended term of follow-up offered ample time to accomplish the full absorption of the ablated region. The treatment of papillary thyroid carcinoma with thermal ablation is one that is both safe and successful.

LIMITATION

There are very few studies that have been done on the severity of papillary thyroid cancer and

thermal ablation at various levels, and the number of patients treated has been quite low. Consequently, one of our constraints is that we do not have a sufficient number of high-quality

experimental research and analysis. In addition, the duration of our follow-up period is just five years, which is a rather limited time frame; hence, the monitoring of long-term efficacy as well as long-term problems warrants additional research.

CONCLUSION

In a nutshell, the purpose of this study was to investigate the practicability, viability, usefulness, and absence of risk associated with the treatment. The size of the tumor was measured before and after the ablation procedure to compare it with the measurements taken at various time periods after the procedure. Patients who suffer from papillary thyroid cancer respond favorably to treatment based on the principles of RFA thermogenesis (PTC). Thermal ablation is an alternative treatment for papillary thyroid cancer in patients who do not satisfy the indications for surgery or who refuse to have surgery. Compared to surgical treatment, thermal ablation can minimize hospital stays, reduce costs, and is an effective treatment for the disease.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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Table 1 Baseline clinical characteristics of the patient

Characteristics	RFA (n=91)	Surgery (n=91)	t	P
Mean age	40.7±9.3	40.2±10.4	0.342	0.733
Sex (n,%)			0.120	0.729
Female	70(76.9)	68(74.7)		
Male	21(23.1)	23(25.3)		
Volume (ml)	810.6±646.5	789.1±601.2	0.232	0.817
Maximum Diameter (mm)	13.4±2.8	14.1±2.5		
Primary tumor location (n,%)			0.607	0.436
Left	34(37.4)	29(31.9)		
Right	57(62.6)	62(68.1)		

Table 2. RFA treatment effect demonstration

Items	Pre-thermalablation	Pro-48months	t	P
Maximum Diameter (mm)	13.4±2.8	3.1±4.4	18.840	<0.001
Volume (mm ³)	810.6±646.5	82.7±126.1	10.542	<0.001

Table 3. The VSR of the patients' remaining ablation zones

Variable	Patient 1	Patient 2	Patient 3
Sex	F	F	F
Age (years)	40	64	40
Primary tumor location	L	L	L
Distance (mm)	1	2	1
MD (mm)	15	11	15
Volume (ml)	628	332	1297
CEUS mode	Hypo	Hypo	Hypo
Diagnosis	FNA	FNA	FNA
Initial Treatment	MWA	MWA	RFA
Second treatment	MWA	Surgery	RFA

Table 4. Treatment results of surgery

Patients	Sex	Age (y)	Diagnosis	CEUS mode	Treatment	Ablation Time (s)	Tumor Location	MD (mm)	Volume (mm ³)
1	F	50	FNA	Hypoa	MWA	267	Left	11	276
2	M	64	FNA	Hypoa	MWA	157	Right	11	466
3	M	58	CNB	Hyper	MWA	382	Right	19	1810
4	F	30	CNB	Hyper	MWA	301	Right	16	1524
5	F	22	FNA	Hyper	MWA	148	Right	11	633
6	F	57	CNB	Hypoa	MWA	127	Left	20	1633
7	F	64	CNB	Hypoa	MWA	120	Right	12	565
8	F	50	CNB	Hypoa	RFA	405	Right	20	3391

Table 5. Comparison of RFA and surgery groups

Characteristics	RFA	Surgery	t	P
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Local tumor progression (n)	4	2	0.689	0.406
Complication	4	2	0.689	0.406

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