Ultrasound Guided Radiofrequency Ablation (RFA) of the Thyroid Gland

The management of thyroid nodules has changed dramatically in the last twenty years worldwide. With the introduction of fine needle biopsy over 40 years ago, we can characterize nodules as either benign, indeterminate, and potentially malignant with an in-office biopsy. A symptomatic nodule determined to be benign now can be treated with multiple options.

Of course, the most definitive option is surgery, which has the advantage of eliminating the entire nodule completely. The **downside of surgery**, however, is that the entire thyroid lobe is removed, including functional thyroid tissue, thus predisposing to hypothyroidism and a **lifetime of medication**. The hospital charges alone for this procedure are approximately $30,000-$40,000. This does not include the additional surgeon's, anesthesiologist's, and pathologist's charges. Long term costs for management of permanent hypothyroidism is also not factored in these charges. Although surgical risks for thyroidectomy are low, complications are frequent enough to increase the morbidity to the patient and create considerable cost for management and therapy. Most of the thyroid surgery in the United States is performed by low volume surgeons, who have a higher complication rate compared to high volume surgeons. Fortunately, nonoperative approaches are now available for which the complication rate for is easily one tenth or less than for open surgery.[1,2]

Thyroid radiofrequency ablation (RFA) was introduced in Korea in 2002 and has become the most common mode of managing benign thyroid nodules throughout Asia, Europe, and the United Kingdom for the past decade. This treatment modality has become so common that entire sets of guidelines have been established and even updated. An International Multidisciplinary Consensus Statement of the Head and Neck Society states that radiofrequency ablation should now be recognized as the first modality of treatment if available.[3]

Radiofrequency Ablation of soft tissue received U.S. FDA clearance in late 2018 and has been slowly introduced to the endocrine, surgical, and head and neck community of physicians. This intervention requires a water-cooled RF probe which can be specifically directed to the vascular margins of the target nodule. The water-cooled RF probe focused energy safely and effectively destroys the abnormal tissue and vascular supply. The equipment is expensive, and the length of the procedure takes much longer than laser thermal ablation. With the laser treatment, a laser fiber is introduced in the middle of the nodule and the heat dissipates radially.

*The studies comparing the two treatments document the **superiority of RFA** over laser in terms of better outcomes. The nodules decrease more in volume with RFA and the requirement for secondary procedures is only*

5% as compared to 10% seen with laser. This superiority of RFA has been documented in multiple studies including the 12-month Randomized (LARA II Study) Trial.[4]

The significant difference in the procedure regarding skill required, time of the procedure, cost of the equipment, and effectiveness of therapy, makes applying the Category III CPT code assigned for Laser ablation of thyroid nodules inappropriate. **RFA thyroid nodules are equivalent to interventions performed by an interventional radiologist for RF Ablation of liver and renal tumors**.

These procedures require image guided complete thermal ablation of solid tumors in other complex areas of the body. The procedure codes for these procedures are

- 47382 which has a work RVU assignment of 14.9, and
- 50592 which has a work RVU of 6.55.

Hospital charges for these procedures range from $45,000 to $25,000 respectively.

The indications for thyroid RFA are the same as for thyroid surgery. Visual deformity and compressive symptoms (such as foreign body sensation, pressure, dysphagia, hoarseness, and choking sensation) are relieved within weeks of RFA as the ablated nodule shrinks in volume.

Additionally, RFA thyroid has completely changed the management of autonomous thyroid nodules. No longer is costly radioactive iodine exposure necessary. Radioactive iodine not only destroys the specific lesion, but also the adjacent healthy thyroid tissue, more often rendering the recipient hypothyroid. The surgical option of thyroid lobectomy requires removal of healthy thyroid tissue around the toxic nodule. **With RFA thyroid nodules, only the abnormal tissue is treated**, thus allowing for prompt restoration of normal thyroid function.

With the success of RFA in treatment of autonomous thyroid nodules, those of us in the Thyroidology community envision a change in the upcoming guidelines to consider RFA thyroid as the first line of therapy for this disease process.

Thyroid Radiofrequency Ablation (RFA) is an FDA-cleared non-surgical procedure that shrinks the nodules without compromising thyroid function and helps avoid long recovery times of thyroid surgery. Clinical studies in Europe and Asia have demonstrated a durable 50-80 percent reduction in the size of thyroid nodules treated with RFA.

Most thyroid nodules are benign and do not require any specific treatment. The small percentage of thyroid nodules that are malignant are generally treated with surgery and additional therapies in an attempt to cure the

underlying disease and prevent a recurrence. Some benign thyroid nodules do grow to the point of causing cosmetic concerns or compressive symptoms on surrounding structures in the neck requiring treatment. Typically, this treatment has involved surgery.

Until recently, available technology for the performance of this procedure required a patient to be placed under general anesthesia to have the treatment performed. The FDA has recently approved newer technology that allows RFA to be performed as an outpatient office procedure under local anesthesia

What is Thyroid RFA?

Thyroid RFA is a minimally invasive percutaneous treatment of benign solid thyroid nodules that results in thermal tissue damage and fibrosis leading to shrinkage of the nodule. We utilize alternating electric current to agitate tissue ions, resulting in ionic friction, which in turn causes heat production. The heat is transferred from the needle (electrode) tip to the surrounding thyroid tissue, at a pre-specified area that is dependent on the type of electrode used (7 mm or 10 mm diameter of the treated area), allowing the operator precision and accuracy. So, basically, we use electricity to generate heat in a small area inside the thyroid nodule.

The doctor inserts the needle under ultrasound guidance using the trans-isthmic approach (from the middle of the neck), and when it is at the target area of the nodule, the RF generator is activated and the procedure starts. The electrode is constantly moving inside the thyroid gland, and that helps to prevent overheating of the tissue – called a “moving shot” technique so that 100% of the nodule is ablated.

At the end of the procedure, all or most of the nodule’s cells are dead, without compromising the cells of the healthy thyroid, and the nodule dramatically shrinks over the following months.

How effective is Thyroid RFA for large benign solid thyroid nodules?

Thyroid RFA is considered successful when the nodule shrinks by >50%. On average, thyroid RFA shrinks solid thyroid nodules by 80%, with a range of 65-94%, so the results are usually really good! Sometimes, the nodules disappear completely. Almost all patients have great symptomatic improvement, with complete or almost complete resolution of their compressive symptoms and/or cosmetic concerns. Significantly more than half the patients (around 90%) will do well with a single RFA session. A minority of patients with very large nodules may require more than one RFA session, to achieve the best outcomes and prevent future re-growth.

For hyperfunctioning thyroid nodules, the volume reduction is similar, and hyperthyroidism eventually resolves in 50-80% of the patients.

It is important to note that thyroid RFA does not lead to these results immediately. There is significant tumor reduction within a month after the treatment, but the nodules continue to gradually shrink for up to a year after the RFA procedure.

If by chance the nodule grows back and there's a volume reoccurrence and becomes symptomatic again, then Thyroid RFA can always be performed again. Having this procedure does not actually preclude having surgery down the line. One can always go back to the traditional approach of surgery if you needed to.

What are the benefits of Thyroid RFA compared to surgery?

- This is a minimally invasive procedure with little to no scarring.
- The procedure lasts 45 - 90 minutes. You only need to take time off work for the day of the procedure. No need for a hospital stay.
- Since healthy tissue is not destroyed during this procedure, the use of thyroid medications is not expected afterward.
- The procedure is highly effective. The reduction in size for a nodule is typically between 60-90% after one year.
- Almost no time needed for recovery. Most patients resume normal activities the next day.
- Much lower complication rates – topical anesthetic only (no general anesthesia)

What are the indications for Thyroid RFA?

Thyroid RFA is indicated for benign thyroid nodules that:

- are causing compressive symptoms (difficulty swallowing, voice change, difficulty breathing, foreign body sensation in the neck, etc.).
- are toxic (over-functioning), causing hyperthyroidism.
- cause cosmetic concerns due to their size.
- form large multinodular goiters.
- a doctor has recommended surgery for their treatment, and the patient is not a surgical candidate or would prefer to avoid surgery.

When is surgery preferred over Thyroid RFA?

Sometimes RFA is not possible, or it is not recommended. The following are some scenarios in that surgery is preferred over Thyroid RFA:

- There is known thyroid cancer, or there is high suspicion for thyroid cancer.
- The thyroid nodule extends to areas that cannot be accessed for treatment with RFA, such as behind the trachea or inside the chest.
- There is a large substernal goiter (a large amount of thyroid tissue getting in the chest).
- There are heavy calcifications in the nodule, which are expected to prevent us from advancing the needle.
- There is concomitant Graves' disease and surgery has been recommended as the best treatment of this disease for the patient.

Am I a candidate for Thyroid RFA?

In order to be a candidate for Thyroid RFA, the patient must:

- not have thyroid cancer or suspicion of thyroid cancer.
- have had 2 FNA biopsies of the target thyroid nodule that are benign on cytopathology, for inactive (cold) thyroid nodules.
- have had 1 FNA biopsy of the target thyroid nodule that is benign on cytopathology, for overactive (toxic/hot) thyroid nodules.
- be able to get off anticoagulation for the time of the procedure (for patients on blood thinners)

Who is not suitable for Thyroid RFA?

- Someone who has undergone prior surgery, radiation, or sclerosing (scar-forming) therapy to the thyroid or thyroid area of the neck as this causes altered anatomy increasing the risk of damage to non-thyroid tissue.
- Individuals with implantable pacemakers or defibrillators.
- Individuals with extremely small thyroid nodules.
- Individuals who have sonographic features of their nodules that are suspicious for cancer unless additional studies have been performed to verify the benign status of the nodule.
- Individuals who have had previous damage to their vocal cord.
- Pregnant patients.

- Patients with severe heart disease.
- Patients taking chronic anticoagulants or blood thinners that cannot briefly discontinue these medications for the procedure.

What are the complications of Thyroid RFA?

Thyroid RFA is a very safe procedure, with a very low complication rate, much lower compared to surgery. A study of approximately 1500 patients showed an overall complication rate of 3.3%. The major complication rate was 1.4%

The following are the potentially serious complications of thyroid RFA and their frequency, based on the most recent literature review of thousands of patients:

- Temporary voice change: 0.94%
- Permanent voice change: less than 0.17%
- Nodule rupture: 0.17% (usually treated conservatively, surgery is rarely indicated)
- Hematoma: rare, usually disappears within 1-2 weeks
- Hypothyroidism: exceedingly rare
- Other nerve damage: exceedingly rare
- Infection/abscess formation: exceedingly rare
- Life-threatening complications: none reported so far

What can be expected during the procedure?

- The procedure itself takes between 45 to 90 minutes depending on the number or volume of nodules.
- The patient will be able to breathe and talk the entire time and will be able to converse with the doctor during the procedure.
- Two grounding pads will be attached to the thighs (recommend wearing shorts).
- The patient will lay flat on their back with their head and shoulders on a pillow.
- Knees can be bent or a small pillow can be placed under the lower back for comfort.
- Similar to thyroid FNA biopsies, the doctor will use a very thin needle to place a local anesthetic under the skin in the area surrounding the thyroid gland.
- The procedure is so gentle that most people have little to no discomfort. The thyroid gland itself is not sensitive to pain, and the skin and surrounding area of the thyroid gland (including the thyroid capsule) are anesthetized for the procedure. Only 2-3% of patients experience discomfort. This is usually a temporary burning sensation similar to that experienced during dental procedures. Pain tends to happen

only during the procedure when there is energy delivery, with subsequent complete resolution of the pain. In the event of severe discomfort, the procedure will be interrupted and an anesthetic will be injected again until there is no pain.

- Other minor side effects of the procedure are very uncommon and include nausea, vomiting, mild skin burn, parasympathetic/vasovagal reaction (such as temporary slow heart rate or feeling of faint), fever.

What is the follow-up after having Thyroid RFA?

Follow-up visits at our office along with thyroid ultrasound are recommended at 3 months, 6 months, and 12 months after Thyroid RFA.

Is Thyroid RFA experimental?

No. Thyroid RFA received clearance from the FDA and is performed at many prestigious academic institutions across the country such as John's Hopkins, Columbia, and Stanford. Thyroid RFA for thyroid nodules has been performed in Korea for over a decade and throughout Europe and their outcomes are excellent. The published data shows impressive nodule shrinkage rates of more than 80 percent with RFA that is maintained over years of follow-up.

Dr. Richard Harding has performed over 80 RFA procedures at the Thyroid Nodule Treatment Center.

What is the cost of Thyroid RFA?

Currently, the evaluation of the thyroid nodules is covered by insurance companies, however, the radiofrequency ablation of thyroid nodules is not considered a recognized benefit. Some insurance companies do not cover thyroid RFA. In that situation, it would be an out-of-pocket expense for the patient.

Summary

In the final analysis, Thyroid RFA is an attractive alternative for patients who experience problems caused by benign thyroid nodules. It is a safe and FDA-cleared procedure with less pain, less downtime, and no scarring. With its long-lasting effects, RFA is a breakthrough in treating symptoms related to thyroid nodules.

Procedure Video [(48) RF Medical - Radiofrequency Ablation Of Thyroid Nodules - 3D Animation Video]

Each of the following, recent references refer to decades of articles of successful RFA well recognized and accepted in World literature. Where noted, the full article can be downloaded from the Thyroid Nodule Treatment Center website.

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