

Patient Guide

THYROID RADIOFREQUENCY ABLATION

A Leading Edge, Non-Surgical Treatment of Thyroid Nodules.

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BEFORE AND AFTER THE TREATMENT





BEFORE



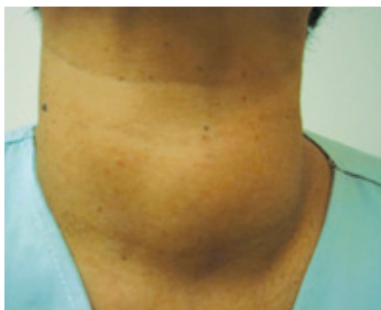
AFTER
2 Months



BEFORE



AFTER
6 Months



BEFORE



AFTER
6 Months

THYROID RADIOFREQUENCY ABLATION

The thyroid gland is small, but it has a big job. While it is primarily responsible for controlling your metabolism, it ultimately affects nearly every part of your body. Like a car battery, we don't usually think about it, until it stops working properly.

Although relatively common, nodules in the thyroid gland can affect how it performs and cause symptoms directly. Even though the vast majority of nodules are benign and not life-threatening, they can still cause problems. Some benign thyroid nodules may cause discomfort, problems with swallowing, produce excess thyroid hormone, or even cause cosmetic concerns.

Traditionally, thyroid surgery or radioactive iodine would have been the only treatment options for problematic thyroid nodules, depending on what the problem is. While either is generally safe, there are drawbacks to both.





Thyroid surgery, while a very safe procedure, is still surgery. It requires a trip to the hospital, general anesthesia, and the risks that come with both of those, to say nothing of the pain and recovery time. Additionally, you have the risks specific to thyroid surgery which include bleeding, scarring, hypothyroidism, damage to the vocal cord nerve, and calcium deficiency. Cosmetically, one often ends up trading a lump for a visible scar

Similarly, radioactive iodine therapy has its challenges. To begin with, special precautions must be taken to protect others from exposure to the radiation, especially children. If you have children, you may need to arrange childcare for several days after you have treatment. Additionally, there are short-term side effects such as nausea, swelling and tenderness in the neck area, dry mouth and a metallic taste that can stay with you for a while. You may need multiple rounds of treatment, and this may inconvenience you by affecting your plan to become pregnant. Finally, some studies suggest a low but increased risk of other cancers following radiation for thyroid nodules.

After treatment with either radioactive iodine or surgery, using thyroid hormone medication to achieve normal blood levels can be a balancing act. If you have hypothyroidism, you may feel sluggish and tired. You'll need to have regular blood tests as the doctor determines the proper thyroid hormone dosage. If you have too much, you feel nervous and shaky. As a result, it may take some time before you feel your best. Managing thyroid medication is a lifelong process.

In the United States, these methods have been the only options for patients dealing with thyroid nodules — until now.

An Easier Option

A common practice in other countries, radiofrequency ablation (RFA) is now available in the United States. Developed over fifteen years ago, this non-surgical alternative shrinks the nodules usually without compromising thyroid function and helps avoid the long recovery times of thyroid surgery.

Radiofrequency ablation of the thyroid was popularized by Professor Baek in South Korea and has since been continuously adopted by many medical practitioners. Worldwide, approximately seven thousand procedures are performed each year in just a few facilities.





What is Radiofrequency Ablation?

Radiofrequency ablation is a medical procedure where dysfunctional tissue is being ablated using heat generated from alternating current, passed from the generator to the tissue via an electrode. Performed under local anesthesia, radiofrequency ablation is relatively painless and does not require general anesthesia. Doctors use guided ultrasound to insert probe into the thyroid nodule. Through selective heating of the probe tip, the nodule is cauterized. The cauterized tissue is then broken down by the body over the course of months.

Advantages of Radiofrequency Ablation of Thyroid Nodules

Compared with surgery, the primary advantages of radiofrequency ablation are:

- ◆ **Increased likelihood of preservation of thyroid function.**
- ◆ **The potential of fewer complications.**
- ◆ **Generally shorter recovery time with a quick return to normal activities.**



The entire procedure takes between fifteen minutes to one hour. Because it is minimally invasive and does not require general anesthesia, you avoid the external scarring of traditional thyroid surgery, and the associated risks of anesthesia. Radiofrequency ablation may also minimize the risk of permanent damage to the vocal cord nerve or to the parathyroid glands.

One of the most meaningful long-term advantages is that you may not need to take lifelong thyroid medication. The treatment preserves healthy thyroid tissue, which allows the thyroid to continue functioning normally — no ongoing medication management, with the difficulties of achieving the correct thyroid hormone dosage.

Radiofrequency ablation is highly effective for benign thyroid nodules. Depending on the type (solid vs. fluid filled vs. a combination of the two), nodules shrink anywhere between 60-90% after one year, with approximately 80% on average.



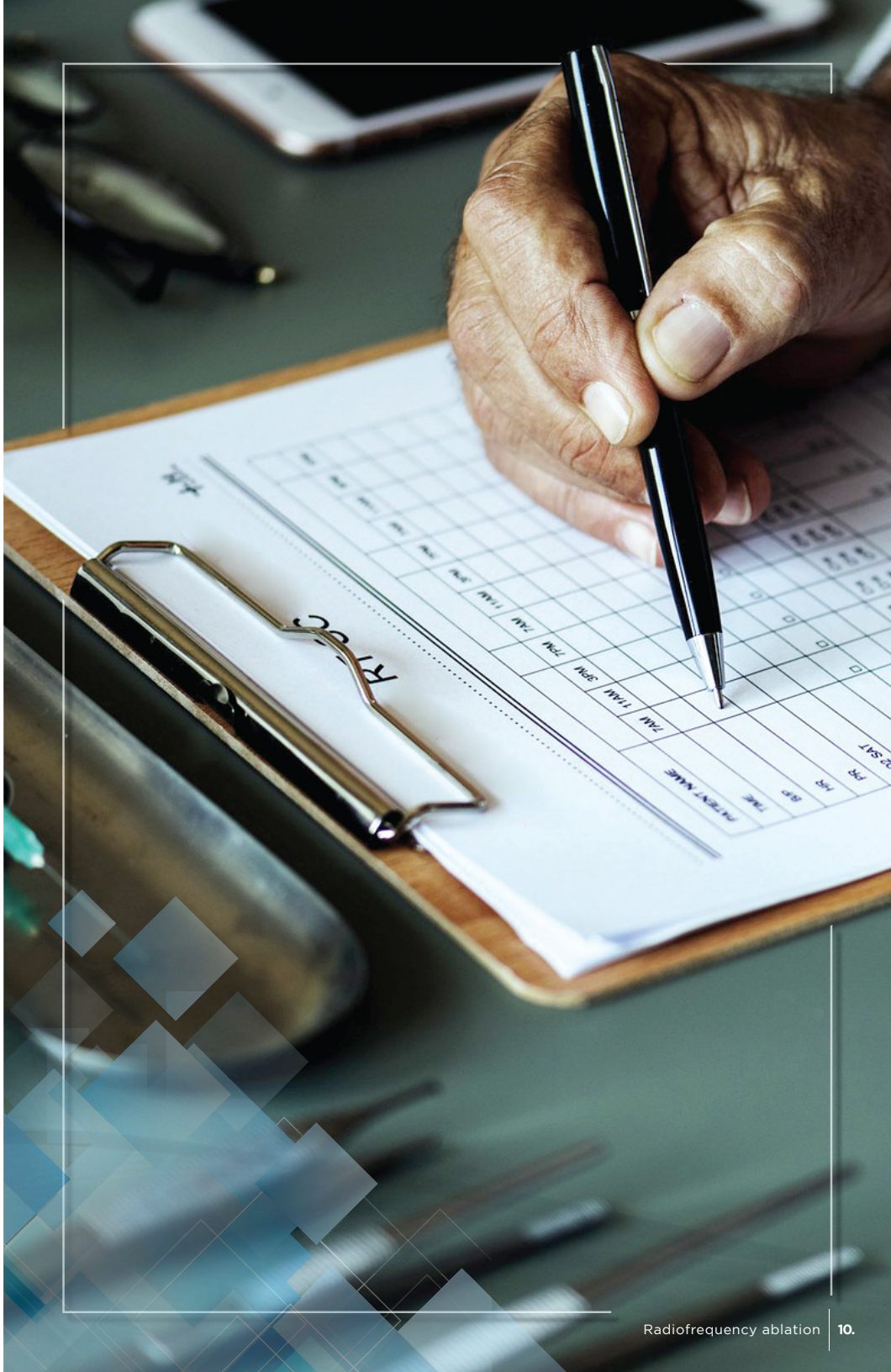
Preparing For Radiofrequency Ablation

Radiofrequency ablation takes place in an outpatient setting. Although you will not be under general anesthesia, you will need to follow some pre-procedural instructions from your healthcare facility.

They will review the list of your current medications and provide instructions. In most cases, your medications will not affect the procedure. If you take medication for diabetes or high blood pressure, you will most likely be instructed to keep taking it.

If you're on blood thinning medication, you will probably need to stop taking it for a few days prior to the procedure.

Be sure to inform your physician if you have a pacemaker, implants, are pregnant, or on any medication (especially for blood thinning). Don't wear makeup, lipstick, or any metal jewelry on the day of the procedure.





What to Expect During the Procedure

You will be able to breathe, swallow and talk normally the entire time. Two grounding pads will be attached to your thighs.

Your neck will be cleaned and head will be placed on a small cushion with your neck extended. The doctor will administer local anesthesia in the area surrounding the thyroid.

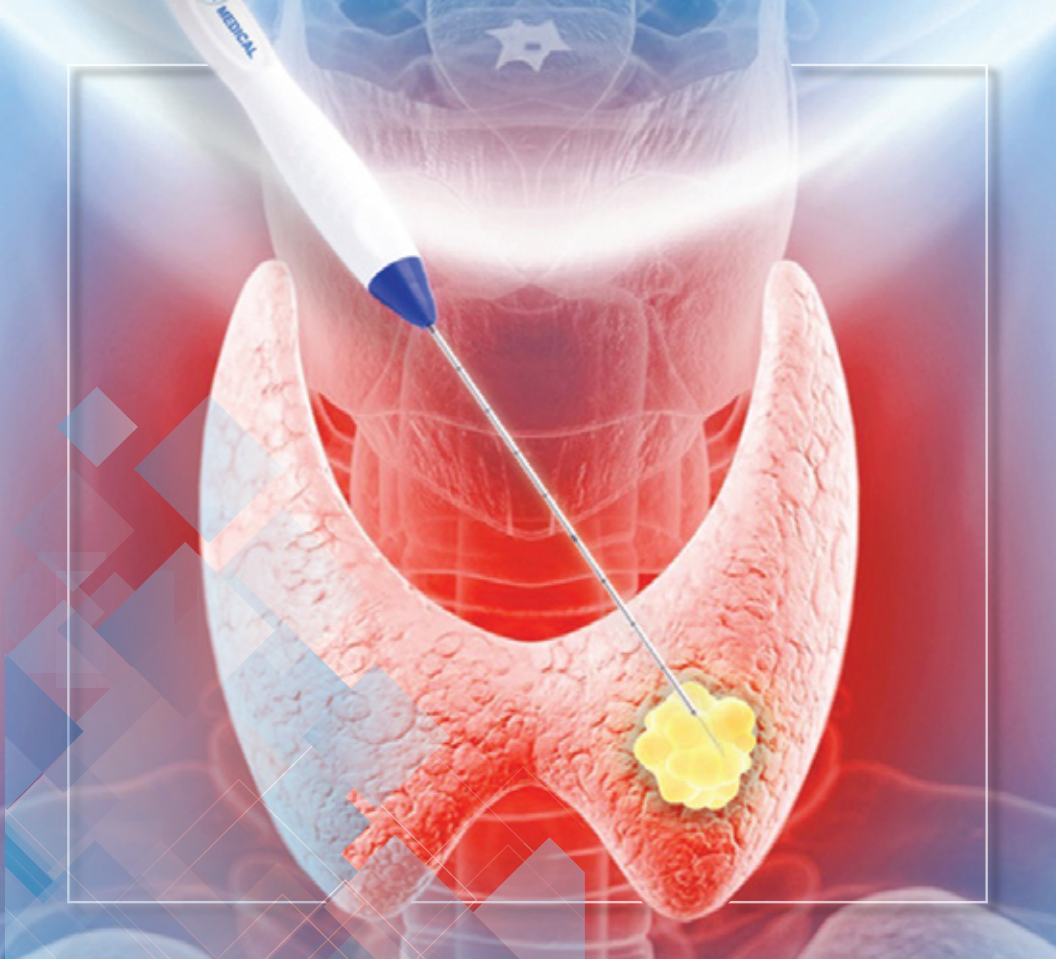
The doctor will ask you several times during the treatment how you are doing and whether you feel pain, and can easily give you more if you are uncomfortable at any time.

How It Works

A generator creates an electric circuit. The electrode is designed to optimally deliver energy to the area that is being treated.

During the procedure, the doctor will place the tip of the probe into the thyroid nodule. The generator creates a high frequency wave and sends it directly to the end of the probe. Your doctor can then adjust the area being treated as needed to ensure that you achieve the desired results.

You will often hear background noise and “mild popping” sounds throughout the procedure. These sounds are normal and signify an appropriate response is taking place.



How long does the procedure last?

While the procedure itself takes less than an hour, the entire process may take 2-3 hours. Pre-procedural care and post procedural monitoring takes an additional hour. When the procedure is complete, a small bandage will be placed on the treatment site and the neck may be cooled with ice packs.

Is Radiofrequency Ablation Painful?

The procedure is so gentle that most people have little to no discomfort. This is because the thyroid nodule itself is not sensitive to pain. Other than the initial injection of numbing medication, the only remaining sensation is generally pressure. Intermittent sensations of discomfort thereafter can be treated with additional doses of pain medication or adjustment of the probe tip.

Radiofrequency ablation does not cause any scarring to the external neck. In many cases, one puncture of the skin is sufficient to treat the entire thyroid gland.

What to Expect After the Procedure

After monitoring for a short period of time, you will be discharged. Please check with your doctor before you drive, as you may need someone to drive you to and from the procedure. You should be able to return to most of your regular daily activities almost immediately.

Your doctor may provide temporary limitations, however. These may include avoiding the following:

- ◆ **Lifting heavy objects (over 10 pounds.)**
- ◆ **Strenuous physical activities.**
- ◆ **Any activities that cause pain or discomfort in your neck (such as massage or acupuncture).**

In general, radiofrequency ablation will not affect your energy or strength. If you feel any abrupt changes after treatment, you should notify your physician immediately.





What Happens to the Nodules After Treatment?

In the weeks following the procedure, the cells of the treated thyroid nodule are removed by the body's immune system. Most patients notice the nodule has already become smaller in just two to three weeks, with solid nodules taking longer than cystic nodules.

Part or all of targeted thyroid nodules may be permanently destroyed during the procedure. Immune cells of the body then break down the affected areas, which shrinks the nodules. The percent reduction depends on the original size and nature of the nodules, with around 40–60% after three months and about 60–90% after one year.

In the years after the procedure, all that remains in the treated area is scar tissue. While some of the nodule around this scar may remain, it is generally significantly smaller than the same nodule before treatment. The surrounding healthy thyroid gland remains unharmed and can continue to produce thyroid hormone.

Often, difficulty swallowing, feelings of pressure or tightness of the throat, or even the bulky appearance of the nodule is usually significantly decreased or no longer detectable.

Can I Be Treated With Radiofrequency Ablation?

The Korean Society of Thyroid Radiology (KSThR) introduced its first guidelines in 2012, with a revision in 2017. According to the 2017 guidelines, radiofrequency ablation for treating benign thyroid nodules is recommended for patients with:

- ◆ **Benign thyroid nodules that produce symptoms or cause cosmetic concern.**
- ◆ **Nodules that produce excess thyroid hormone. There are known as autonomously functioning, or “hot” thyroid nodules (AFTN).**

Radiofrequency ablation is not recommended for patients with:

- ◆ **Thyroid cancer, thyroid nodules with a biopsy result that is uncertain as to whether there is cancer present**
- ◆ **A nodule that meets U.S. criteria of cancer, despite FNAb (fine needle aspiration biopsy) or CNB (core needle biopsy) results.**

Before undergoing radiofrequency ablation, doctors will want to make sure your thyroid nodule is benign. This is confirmed through ultrasound guided fine-needle aspiration (FNA) or core needle biopsies (CNB). In some cases, a single benign diagnosis may be sufficient, while other nodules require two treatments.

Surgery is currently the standard treatment for primary thyroid cancer. However, in patients with primary thyroid cancer who refuse surgery or who are unsuitable for surgery, radiofrequency ablation may be considered as an alternative to surgery. For those patients who refuse surgery or who are at high surgical risk, radiofrequency ablation can also be performed for recurrent thyroid cancers in the thyroid gland area or lymph nodes located in the neck.

Radiofrequency ablation is not an absolute alternative to thyroid surgery, however. Your physician will first rule out thyroid cancer and will need to determine if you're a suitable candidate.

The following thyroid conditions are generally considered to be treatable with radiofrequency ablation:

- **Benign or “hot” nodules (those that produce excess thyroid hormone)**
- **Thyroid cysts that produce excess thyroid hormone**
- **Rapidly growing benign nodules or cysts**
- **Visually disturbing nodules or cysts**
- **“Hot” nodules when radioactive iodine therapy is not preferred**
- **Patients who refuse surgery**
- **Patients who are at high risk for anesthesia**

Radiofrequency ablation is not performed during pregnancy or on patients with implanted pacemakers or defibrillators.

How Effective Is This Procedure?

Clinical trials have measured the rate of reduction, therapeutic success, changes in symptoms and cosmetic improvement of benign thyroid nodules.

For “cold” benign nodules (those that do not produce excess thyroid hormone), clinical trials have shown a mean reduction rate of 32.7 to 58.2% at one month, and 50.7 to 84.8% at six months. In most patients, nodule related symptoms and cosmetic problems also significantly improved or disappeared. In a long term follow-up study, radiofrequency ablation was effective over a four year period with the nodules consistently decreasing by 93.5%.

For “hot” benign thyroid nodules (those that do produce excess thyroid hormone), clinical trials have shown volume reduction rates of 52.6 to 70.7% at six months, and improved or normalized thyroid function in most patients. In a multi-center study, hyperthyroidism caused by “hot” nodules improved in all patients and was completely normalized in 81.8% of patients. This led to the conclusion that radiofrequency ablation can be considered as an alternative to thyroid surgery or radioactive iodine therapy.



How Many Treatments Are Necessary?

For most nodules less than 4 cm, one treatment will sufficiently decrease the size of the nodules and improve symptoms. When nodules are close to vocal cord nerves, or with very large nodules, repeated procedures may be necessary.

Untreated areas of “hot” nodules may interfere with the improvement in thyroid function. In these instances, complete ablation may be required. For this reason, more than one treatment session may be necessary to successfully treat “hot” nodules.

Are There Any Side Effects or Complications?

In a multi-center study of 1459 patients organized by the Korean Society of Thyroid Radiology, the overall complication rate following radiofrequency ablation was 3.3%. The major complication rate was 1.4%.

While uncommon, complications can be:

- **Temporary voice changes, such as hoarseness.**
- **Slight bleeding — usually disappears on its own within one day, or at the most, up to three months.**
- **Wound infections**
- **In rare cases, vomiting, cough, or seared skin at the treatment site may occur.**
- **Patients with AFTN (“hot” thyroid nodules) have the possibility of hypothyroidism after the procedure.**

Although rare, a complication may require an inpatient hospital stay or follow-up treatment

Is There Any Follow-Up Care?

Following radiofrequency ablation, your physician may monitor the treated nodules with ultrasound scans or lab tests.

Is This Procedure Reimbursed By Insurance?

Although this procedure is FDA cleared for soft tissue, currently there is no insurance reimbursement. The out of pocket cost will be provided by your provider and/or institution.

However, as a patient you have the right to submit to insurance for reimbursement after the procedure has been completed. Your physician's office can help guide you in this process.

Leading Edge Option for Benign Thyroid Nodules

In the final analysis, radiofrequency ablation (RFA) is an exciting alternative for patients who experience problems from benign thyroid nodules— offering the potential for less pain, less downtime and less external scarring than with surgery and without the risks of RAI. It is a safe and validated procedure that is now available in the United States. With its long lasting effects, radiofrequency ablation is a breakthrough in treating the symptoms of thyroid nodules. Ultimately, your physician can help determine the most effective treatment option for you.



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