

Complications Encountered in the Treatment of Benign Thyroid Nodules with US-guided Radiofrequency Ablation: A Multicenter Study¹

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Purpose:

To evaluate clinical aspects and imaging features of complications encountered in the treatment of benign thyroid nodules with radiofrequency (RF) ablation.

Materials and Methods:

Institutional review board approval was obtained for this retrospective study, and informed consent was waived. From June 2002 to September 2009, 1459 patients underwent RF ablation of 1543 thyroid nodules with an RF system with internally cooled electrodes at 13 thyroid centers, which were members of Korean Society of Thyroid Radiology. Numbers and types of major and minor complications were assessed.

Results:

The authors observed 48 complications (3.3%), 20 major and 28 minor. The major complications were voice changes ($n = 15$), brachial plexus injury ($n = 1$), tumor rupture ($n = 3$), and permanent hypothyroidism ($n = 1$). The minor complications were hematoma ($n = 15$), skin burn ($n = 4$), and vomiting ($n = 9$). All patients recovered spontaneously except for one with permanent hypothyroidism and one who underwent surgery.

Conclusion:

Although the complication rate of RF ablation is low, various complications may occur; comprehension of complications and suggested technical tips may prevent complications or properly manage those that occur.

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Radiofrequency (RF) ablation is a promising technique for treating various tumors, especially for focal liver cancers (1–4). Multicenter studies in patients with liver cancer have assessed the types and incidence of various complications associated with RF ablation and methods to prevent or resolve these problems (4–6).

RF ablation has also been shown to be an effective treatment modality for benign thyroid nodules (7–11). However, several complications have been reported, including voice changes, skin burns, hematoma formation, and transient hyperthyroidism (8,9,12,13). These complications may be prevented by the use of the “moving shot” technique for RF ablation of the thyroid nodules (7,8,10,11,14). Although the type and incidence of complications and techniques for prevention have been assessed, previous studies were limited by the small numbers of patients and the lack of systemic evaluation (7,8,10). Therefore, the Korean Society of Thyroid Radiology (KSThR) performed a retrospective multicenter study to evaluate complications of RF ablation in a large series of patients. By using the KSThR survey data, we evaluated the clinical aspects and imaging features of complications encountered in the treatment of benign thyroid nodules with RF

ablation and assessed technical tips to avoid complications and better manage those that occur.

Materials and Methods

The study protocol was approved by the institutional review board of Asan Medical Center and informed consent for each procedure was obtained from all patients before the procedure; informed consent was waived for this retrospective investigation.

Preparation and Participation

In November 2008, the KSThR organized a task force team, consisting of 12 working committees, to evaluate the complications of thyroid RF ablation. The task force team established a list of complications by reviewing published articles and by discussion (3,4,6,15–27). The team finally collected complication data, from 13 Korean hospitals, on patients who had undergone RF ablation of benign thyroid nodules from June 2002 to September 2009. All patients had pressure symptoms or cosmetic problems; had benign nodules greater than 2 cm in largest diameter, as confirmed at two separate ultrasonography (US)-guided fine needle aspirations, and no malignant US findings according to the guidelines of the KSThR (28,29); had serum thyroid hormone levels within normal limits; and refused or were ineligible for surgery.

Procedures and Equipment

All hospitals involved had experience with 10 or more cases of thyroid RF ablation. All procedures were performed by thyroid radiologists who were

trained in thyroid RF ablation by training programs of the KSThR. The treatment protocol has been described previously (7–10). RF ablation was performed with an RF generator (Cool-Tip, Covidien, Boulder, Colo; SSP-2000, Taewoong Medical, Gimpo, Korea; M-1004, RF Medical, Seoul, Korea) and an internally cooled electrode (Cool-Tip, Well-Point, and Big-Tip, respectively), with an active tip of 1.0, 1.5, or 2.0 cm, depending on the size of the nodule. All procedures were performed with percutaneous US guidance. Before RF ablation, operators divided thyroid nodules into multiple small conceptual ablation units to minimize thermal injury to surrounding critical structures. An electrode was placed in the thyroid nodule using a transisthmus approach method, followed by ablation using the moving shot technique (7,8,10,11). Although the electrode has been fixed during ablation of liver malignancies (3,22,23,27), this technique is not appropriate for treatment of thyroid nodules. Because the thyroid gland is a relatively small organ compared with the liver, prolonged fixation of the electrode is dangerous for surrounding normal structures. To resolve this problem, we designed the “moving shot technique” and conceptual ablation units (14,30). We divide thyroid nodules into multiple conceptual ablation units, and perform



Advances in Knowledge

- A multicenter trial in a large series of patients found that the complication rate after radiofrequency (RF) ablation of the thyroid nodules was 3.3%.
- All patients, except one with nodule rupture and one with hypothyroidism, recovered from complications without sequelae.
- Newly demonstrated complications included nodule rupture, brachial plexus injury, permanent hypothyroidism, vomiting, and vasovagal reaction.
- This study suggests various technical tips for avoiding complications during RF ablation of thyroid nodules.

Implications for Patient Care

- RF ablation of benign thyroid nodules is a safe procedure.
- Understanding the broad spectrum of complications, knowledge of techniques, and management to prevent complications will minimize complications and sequelae in patients undergoing RF ablation of thyroid nodules.

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Abbreviations:

anti-TPOAb = anti-thyroid peroxidase antibody
KSThR = Korean Society of Thyroid Radiology
RF = radiofrequency

Author contributions:

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Potential conflicts of interest are listed at the end of this article.

RF ablation in a unit-by-unit manner by moving electrode. The conceptual units were smaller in the peripheral danger portion but larger in the central safe portion of the nodule. After insertion of the electrode into the nodule, the electrode tip was positioned in the deepest, most remote portion of the nodule to enable easy monitoring of the electrode tip without the disturbance caused by microbubble. The electrode was moved within the thyroid nodule by tilting it upward or downward. RF power was 30–120 W, depending on the size of the active tip and the internal characteristics of the thyroid nodules. RF ablation began with 30–50 W of power. If the formation of transient hyperechoic zone at the tip of electrode did not appear within 5–10 seconds, we increased RF power in 10 W increments, up to 80–120 W. RF ablation was terminated when all conceptual units of the targeting nodule had changed to transient hyperechoic zone. In most hospitals, patients were not treated with antibiotics before or after ablation.

Questionnaire

Questionnaires were sent to each enrolled hospital to assess total number of patients undergoing RF ablation, total number and size of nodules, total number of treatment sessions, total number and types of complications, types of treatment for complications, time (days) of detection and required for recovery, permanent problems resulting from complications, and technical methods to avoid complications.

Major and minor complications were those defined by the Society of Interventional Radiology (31,32). A major complication was defined as one that, if left untreated, might threaten the patient's life, lead to substantial morbidity or disability, or result in a lengthened hospital stay. All other complications were considered minor. Side effects were defined as untoward consequences that did not require therapy or prescription medications and were regarded as undesired consequences of the procedure that rarely, if ever, resulted in substantial morbidity, although they occurred frequently.

Early complications were defined as those occurring within 30 days after ablation, and delayed complications were those occurring after 30 days (4). Hematoma was defined as any collection of blood in and around the thyroid gland that resulted in inadequate ablation. Pain was defined as any kind of pain that resulted in inadequate ablation despite medication and that persisted for more than 3 days after ablation. Other types of pain were regarded as side effects. Tolerable pain immediately after RF ablation was not regarded as a complication or side effect. Multiple RF applications to the same lesion were considered a single treatment (4). One physician (J.H.B.) collated the data and identified specific complications, treatments, and permanent problems, and then communicated with each hospital via e-mail to obtain specific additional information.

Statistical Analysis

Statistical analyses were performed using statistical software (SPSS version 16.0; SPSS, Chicago, Ill). The χ^2 test was used to assess whether there were differences among institutions with operators who were experienced (more than 100 ablations) and those who were less experienced (less than 50 ablations), and whether there were differences between early and delayed complications. $P < .05$ indicated a statistically significant difference.

Results

Table 1 shows a summary of demographic data and incidence of complications at each of the 13 hospitals. The number of patients per center ranged from 10 to 892 (total, 1459 patients; including 190 male and 1269 female patients; mean age, 41.2 years) and the number of nodules per center ranged from 10 to 959 (total, 1543 nodules). The mean largest diameter of the treated nodules was 3.8 cm \pm 1.4 (\pm standard deviation) (range, 2–20 cm). Total number of treatment sessions was 2197.

Of the 1459 patients, 48 (3.3%) experienced complications (2.2% per session), including 20 major and 28 minor

complications. None of these complications was life threatening, and 46 patients recovered without sequelae. Of the remaining two patients, one had permanent hypothyroidism and the other underwent left thyroidectomy due to nodule rupture. The major complication rate was significantly lower in patients treated by experienced operators than in patients treated by less-experienced operators (0.7% vs 2.9%, $P = .007$). The total complication rate was also lower for experienced operators than for less-experienced operators, but this difference was not significant (2.0% vs 3.9%, $P = .051$). Early complications were significantly more common than delayed complications (46 vs 2; $P < .001$).

Major Complications

Twenty (1.4%) major complications were reported (Table 2), including voice changes in 15 patients, nodule rupture in three (including one with abscess formation), hypothyroidism in one, and brachial plexus injury in one.

All 15 patients with voice changes had thyroid nodules located close to the recurrent laryngeal nerve (Fig 1). Most voice changes occurred during or just after the procedure. All patients recovered their voice completely, except for two who were lost to follow-up. Most patients recovered their voices abruptly 1–3 months after the procedure. The voice change in one female patient, however, was related not to heat but to hemorrhage. This patient experienced a voice change occurring just after insertion of the electrode (before the start of ablation), and we observed a hemorrhage between the nodule and the trachea (Fig 2). We removed the electrode and compressed her neck for 30 minutes; she recovered her voice completely within 1 hour.

Three nodule ruptures were detected, at 22, 30, and 50 days after RF ablation. Prior to nodule rupture, the ablated thyroid mass had been decreasing gradually; however, these three patients complained of sudden neck bulging and pain at the time of nodule rupture. US images showed breakdown of the anterior thyroid capsule and the formation

Table 1

Demographic Data and Incidence of Complications in 13 Participating Hospitals

Hospital	No. of Patients	No. of Nodules	No. of Sessions	No. of Complications	Incidence of Complications (%)
Daerim St Mary's Hospital	892	959	1494	26	2.9
Asan Medical Center	301	307	383	11	3.7
Mothers Clinic	53	53	62	1	1.9
UNMEC Clinic	39	39	42	1	2.6
Hanyang University Hospital	35	39	40	2	5.7
Seoul St Mary's Hospital	34	37	50	2	5.9
Ajou University Hospital	33	33	36	2	6.1
Samsung Medical Center	20	22	25	0	0.0
Human Medical Imaging & Intervention Center	11	12	21	0	0.0
Yonsei University Hospital	11	12	12	1	9.1
Busan Paik Hospital	10	10	12	1	10.0
BHS Hanseo Hospital	10	10	10	0	0.0
Seoul National University Hospital	10	10	10	1	10.0
Combined hospitals	1459	1543	2197	48	3.3

Table 2

Complications and Side Effects in 1459 Patients Who Underwent RF Ablation of Thyroid Nodules

Complication or Side Effect	No. of Complications	Time of Detection (d)	Time to Recovery (d)
Major	20 (1.4)	1–180	1–90
Voice change	15 (1.02)	1–2	1–90
Nodule rupture	2 (0.14)	22–30	<30
Nodule rupture with abscess formation*	1 (0.07)	50	None
Hypothyroidism*	1 (0.07)	180	None
Brachial plexus injury	1 (0.07)	1	60
Minor	28 (1.92)	1–2	1–30
Hematoma	15 (1.02)	1	<30
Vomiting	9 (0.62)	1–2	1–2
Skin burn	4 (0.27)	1	<7
Side effect	46 (3.15)	1	1–2
Pain	38 (2.6)	1	1–2
Vasovagal reaction	5 (0.34)	1	1
Coughing	3 (0.21)	1	1

Note.—Number in parentheses is percentage of complications per total patients.

* Complications with remaining sequela.

of a new mass in the anterior neck. Two of these patients showed indications of internal bleeding and one showed delayed abscess formation that initially presented as a hemorrhage. The first patient recovered without treatment. The second patient was admitted to the hospital and treated with antibiotics and analgesics. The third patient underwent surgery, resulting in nodule rupture followed by abscess formation (Fig 3).

In one patient, hypothyroidism was detected 6 months after RF ablation. She complained of gradual neck bulging. US examination showed diffuse enlargement of the thyroid gland without a thyroid nodule. Blood tests showed that her serum thyrotrophin (TSH) concentration was 13.6 mU/mL (normal range, 0.4–4.0 mU/mL) and her serum free thyroxine (FT4) concentration was 0.66 ng/dL (normal range, 0.8–1.9 ng/dL).

Figure 1



Figure 1: Transverse US scan in a 44-year-old woman shows a large left thyroid nodule abutting the trachea (T) and esophagus (E). The recurrent laryngeal nerve, which is usually located in the tracheoesophageal groove, may be damaged by thermal propagation.

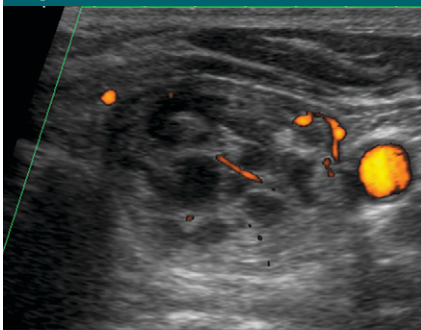
Before and after RF ablation, her serum concentration of antithyroid peroxidase antibody (anti-TPOAb) was more than 1000 IU/mL (normal range, 0–35 IU/mL).

One patient experienced a brachial plexus injury just after ablation. She complained of numbness and decreased sensation in the fourth and fifth fingers of her left hand. She gradually recovered during the next 2 months.

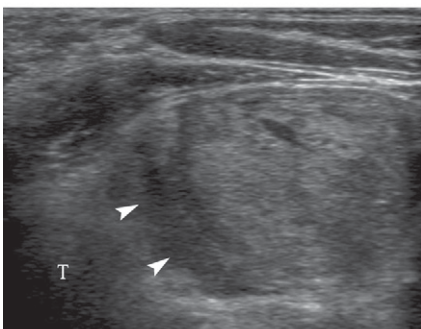
Minor Complications and Side Effects

Twenty eight (1.9%) minor complications were reported (Table 2), including hematoma in 15 patients, vomiting in nine, and skin burns in four.

Figure 2



a.



b.

Figure 2: Voice change resulting from hemorrhage in a 46-year-old woman. Transverse US scans of the left thyroid nodule (a) before and (b) immediately after insertion of the electrode show a hyperechoic hemorrhage (arrowheads) between the trachea (T) and left thyroid nodule.

Figure 3



a.



b.

Figure 3: Abscess formation and ablated nodule rupture in a 46-year-old man. (a, b) Axial CT scans of the left thyroid nodule (a) before and (b) 22 days after RF ablation. The ablated left thyroid nodule decreased significantly in size, but the patient developed new high-density (arrowhead) and low-density (arrow) lesions in the anterior soft tissue and muscle.

Figure 4

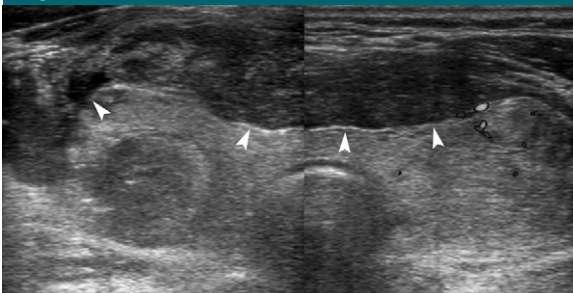


Figure 4: Transverse US scan in a 42-year-old woman shows a large subcapsular hematoma that developed during electrode insertion. Both thyroid glands (arrowheads) were compressed by the hematoma.

The hematomas were in the perithyroidal, subcapsular, and intranodular locations and were caused by mechanical injury due to the electrode. Hematomas were found to result in the gradual enlargement of hyperechoic mass lesions and sometimes in the compression of thyroid parenchyma (Fig 4). Most hema-

tomas completely disappeared within 1 or 2 weeks. Although nine patients experienced vomiting after ablation, none complained of vomiting or nausea during ablation. Treatment with antiemetics resulted in improvements within 1–2 days. All four cases of skin burn were at the puncture sites and were first-degree

burns. Patients complained of skin color change, mild pain, and discomfort (Fig 5). All patients recovered from pain and skin color changes within 7 days without sequelae.

Side effects of RF ablation included mild pain ($n = 38$), vasovagal reaction ($n = 5$), mild fever up to 38°C ($n = 4$), and coughing ($n = 3$) (Table 2). Vasovagal reactions included sweating, difficulty breathing, and hesitation. Elevation of the patient's legs and stopping the ablation resulted in normalization within several minutes. Coughing was induced by thermal propagation to the trachea and was managed by stopping the ablation. Coughing usually lasted 10–30 seconds, with symptoms associated with heat injury to the trachea detected during follow-up.

Discussion

This multicenter study revealed several new complications not previously reported, including nodule rupture, brachial plexus injury, permanent hypothyroidism, vomiting, and vasovagal reaction (Table 3). None of these patients experienced any life-threatening complications related to RF ablation, and the major complication rate was lower for patients treated by experienced operators than for those treated by less-experienced operators, indicating that RF ablation is a safe procedure when performed by well-trained operators.

Although image-guided interventional procedures have many advantages, their performance entails risks. Comprehension of complications and methods to prevent complications are extremely important during the establishment of new interventional procedures. A multicenter study of patients undergoing RF ablation for liver tumors revealed rarer complications and objectively quantified the complication rate expected when RF ablation is performed by a skilled physician (4,5).

Voice change is a serious complication of RF ablation. We identified four patients with voice changes, likely due to injuries to the recurrent laryngeal nerve (8,9). Moreover, voice changes may be caused not only by thermal injury

Table 3

Summary of Published Data on Complications of RF Ablation in Patients with Benign Thyroid Nodules

Study	No. of Patients	Hematoma	Skin Burn	Pain	Transient Hyperthyroidism	Hypothyroidism	Edema	Fever	Voice Change
Kim et al (9), 2006	30	1	1	1	3	1
Jeong et al (8), 2008	236	5	...	13	3	3
Deandrea et al (20), 2008*	31	Few	3
Spiezia et al (19), 2009*	94	13	5	...
Baek et al (7), 2009*	9	1
Baek et al (10), 2010	15
Lee et al (11), 2010	27	1
Total	442	7	1	27+Few	6	1	3	5	4

* Including autonomously functioning thyroid nodules.

Figure 5



Figure 5: Neck of a 47-year-old woman shows first-degree skin burns at the electrode puncture site immediately after RF ablation.

but also by hemorrhage. Thermal injury to the recurrent laryngeal nerve may be prevented by using the moving shot technique and by undertreating the conceptual ablation units adjacent to the nerve (7,8,10,11). Another possible cause of voice changes in patients undergoing RF ablation is variation in vagus nerve injury. The vagus nerve is usually located between the common carotid artery and internal jugular vein, but may also be located adjacent to the thyroid gland (33,34) (Fig 6). Therefore, when performing RF ablation, operators should be aware of possible injury to the vagus nerve located near the lateral margin of the thyroid nodules as well as injury to the recurrent laryngeal nerve near the inferomedial portion of the thyroid.

Three of our patients experienced nodule rupture, a previously unreported

Figure 6



Figure 6: Transverse US scan in a 50-year-old man shows the anterior variation of the vagus nerve (arrowhead), which is located adjacent to the left thyroid nodule. In this position, the vagus nerve may be damaged during RF ablation.

complication of thyroid RF ablation, although a similar situation has been observed after laser ablation of the thyroid nodules (35). In that study, patients experienced pseudocysts with fasciitis owing to leakage of the fluid into the neck muscle fascia; these lesions were treated with anti-inflammatory drugs and were reabsorbed spontaneously in 3–6 months. All three of our patients with thyroid nodule rupture presented with sudden neck bulging and pain during follow-up. Nodule rupture may have been caused by acute volume expansion of a nodule due to hemorrhage, suggesting that patients with nodule rupture be managed conservatively, including with antibiotics and/or analgesics, rather than by invasive procedure

such as aspiration, which may increase the risks of infection and/or abscess formation.

One patient developed permanent hypothyroidism 6 months after RF ablation. This patient showed persistent elevation of serum anti-TPOAb before and after RF ablation. Patients who developed hypothyroidism after ethanol ablation (36) also had increased anti-TPOAb and/or antithyroglobulin antibody levels before ablation. Although the risks of hypothyroidism are very low and its cause is unclear, patients with elevated anti-TPOAb before ablation should be told about the risks of hypothyroidism after RF ablation.

Because the brachial plexus is located deep in the neck, thermal injury is unusual, but this complication has been reported during the ablation of apical lung cancer (37). Continuous moving of the electrode without tracing the electrode tip and echogenic microbubbles that prevent the electrode tip from being clearly visualized may result in penetration of the RF electrode beyond the thyroid capsule. This may result in damage to nerve structures located around the thyroid gland, including the sympathetic chain, phrenic nerve, vagus nerve, and brachial plexus nerve. Operators should therefore always pay attention to the electrode tip by viewing the entire length of the electrode on real-time US images.

Hematoma can usually be controlled by means of mild compression of the neck for several minutes. Intranodular hemorrhage caused by an RF electrode

can usually be well controlled by means of direct ablation of the hemorrhagic focus. Serious perithyroidal hemorrhage may be prevented by examining the perithyroidal vessels and/or anterior jugular vein before insertion of the electrode. In addition, modified small-bore electrodes (18-gauge) may decrease the risk of hemorrhage when compared with large-bore electrodes (7,10).

Two types of skin burn have been observed in liver RF ablation, at the sites of electrode punctures and pad attachment (4,5). In thyroid RF ablation, only skin burn at the electrode puncture site has been reported (9). The risk of burns at the pad attachment site is relatively low because RF energy in the thyroid is lower (30–120 W) than in the liver. Application of an ice bag during the ablation may prevent skin burns at the electrode puncture site. A bipolar electrode may prevent skin burn at the pad attachment site.

Pain is the most common complaint during RF ablation. Most patients complained of various degrees of pain in the lower neck, sometimes radiating to the head, ears, shoulders, chest, back, or teeth. Pain, however, was relieved rapidly when the generator output was reduced or turned off. Although total procedure time was longer in patients with than in those without severe pain, no patient was incompletely treated due to pain. Pain was usually self-limited and all patients were prescribed analgesics for less than 3 days. No patient complained of intractable pain or required admission for pain.

Several possible serious complications of RF ablation have not previously been reported. For example, esophageal injury, a life-threatening complication, may be prevented by maintaining a safety margin between the esophagus and the tip of the RF electrode. Operators should consider the expected ablation zone and strictly trace the tip of the RF electrode during RF ablation of nodules near the esophagus. In addition, patients should be asked to swallow cold water during the ablation of a conceptual unit adjacent to the esophagus. Bowel adhesion to the liver has been shown to increase thermal injury to the

bowel by decreasing bowel peristalsis (4,5). We believe that both cold water and esophageal peristalsis can prevent thermal injury to the esophagus.

Heart problems have also been reported during the RF ablation of liver cancers (4,6). Because RF current passes through the heart during thyroid RF ablation, heart attacks and arrhythmias may be possible complications. Bipolar electrodes may therefore be helpful for the patients with heart problems.

There were several limitations in the present study. First, the evaluation of the data was dependent on the chart review and investigator's opinions. Another limitation was the lack of systematic follow-up. Retrospective analyses have a tendency to underestimate the true complication rates because patients are lost to follow-up. In addition, a single author analyzed all complications, which increases the risk of individual bias.

In conclusion, this multicenter study in a large series of patients who underwent RF ablation of the thyroid nodules demonstrated that the complication rate is low, but various complications may occur during thyroid RF ablation. We suggested techniques to prevent some of the complications that may occur during and after RF ablation. These findings may help in the early detection, prevention, and proper management of complications of thyroid RF ablation.

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