MEDS Clinical Medicine (2024)
Clausius Scientific Press, Canada

DOI: 10.23977/medsc.2024.050417
ISSN 2616-1907 Vol. 5 Num. 4

Bilateral Recurrent Laryngeal Nerve Injury after Ultrasound-Guided Radiofrequency Ablation: A Case Report of Medical Malpractice

Tang Weiyi, Wang Daixin*

Forensic Appraisal Center of Hunan Provincial People's Hospital, Changsha, 410005, China
**Corresponding author*

Keywords: Medical Malpractice; Bilateral Recurrent Laryngeal Nerve Injuries; Ultrasound-Guided Radiofrequency Ablation; Thyroid Nodules; Forensic Appraisal Causative Potency; Informed Consent

Abstract: Here, we report a case of medical malpractice for due to bilateral recurrent laryngeal nerve (RLN) injury caused by Ultrasound (US)-guided radiofrequency ablation (RFA) in China. A patient presented with hoarseness due to bilateral RLN injury following RFA of the thyroid nodules. The appraisal of whether there was medical negligence or malpractice and the causal relationship between the medical treatment and the patient's bilateral RLN injury was entrusted to us by the court. Based on the patient's original medical history, ultrasound and endoscopic examination results, vocal cord dysfunction and informed consent, there was a causal relationship between the patient's RLN injury and the medical treatment, and the causative potency of the medical negligence was the main effect in the case.

1. Introduction

This report discusses a medical malpractice case prosecuted by a court in China, which involved bilateral recurrent laryngeal nerve (RLN) injury after ultrasound-guided radiofrequency ablation (RFA) of the thyroid nodules. RFA, a clinical technology for treating thyroid nodules, has developed rapidly in Chinese medical practices and has been applied to treat benign thyroid nodules and recurrent thyroid cancer over the last decade[1,2]. The basic mechanism of RFA is thermal injury secondary to friction and heat conduction[3,4]. Few reports have been published regarding RLN injury after RFA[5], especially regarding bilateral RLN injury. RLN injury is an important cause of medical malpractice[6]. As a common severe complication of thyroid surgery, bilateral RLN injury is rarer and more serious than unilateral injury. Iatrogenic dysphonia (i.e., hoarseness related to medical treatment) may not be life-threatening, but it can greatly affect a patient's quality of life and result in reduced employment, withdrawal from social life and decreased general health and is thus susceptible to litigation[7]. In China, medical malpractice can involve administrative, civil and criminal liability[8], with civil disputes being more common in judicial practice. This may be because medical malpractice victims and their relatives desire more economic compensation after an accident, and some medical institutions may prefer to pay financial compensation by bearing the civil liability

to end a dispute and reconcile the parties concerned[9]. Medical disputes usually occur after a legal relationship between a patient or their agent and the health unit with whom the legal medical qualification was formed. If two sides disagree on the demand for medical behavior, the diagnostic measures, the implemented treatment, the expected results or the understanding of the powers and obligations, the patient or their agent may demand that the health unit compensate them for the damage[10]. The main duty of the judicial appraiser is to identify the medical fault, the consequences of the damage, the causal relationship between both parties, and the degree of causative potency. China has no specific legal stipulations nor academic treatises regarding causative potency theory[11]. Therefore, the method for assessing the degree of causative potency for RFA-induced bilateral RLN injury in medical malpractice relative to the thyroid gland must be determined. Previous research considered the diagnoses, surgical complications, type of surgical procedures, and informed consent issues[12]such as RLN paralysis and mistakes in making diagnoses from fine-needle aspiration biopsies (FNABs) or frozen-section pathology and whether clinical practice guidelines were obeyed.

In China, patients must sign informed consent before most medical procedures, however, the patient or their family may not fully understand what they have been told regarding the procedure. Three reasons for this are that inadequate information may have been provided, disparities in medical knowledge may exist between patients and doctors, and there may have been insufficient patient/doctor interaction regarding acquiring medical information[13].

Here, we report the process of appraising a case of bilateral RLN injury after RFA. Written informed consent was obtained from the patient prior to the enrollment of this case report. The case report was conducted in accordance with the Declaration of Helsinki and which has been approved by the Ethics Committee of Hunan Provincial People's Hospital (Ethics Committee reference number：2024-21).

2. Case report

On June 20 of a certain year, a 58-year-old patient was admitted to a hospital. The patient complained of a 1-week history of gradual thyroid enlargement with pain, nervousness and irritability. Thyroid nodules had been found ~6 years earlier but were untreated. Physical examination revealed multiple palpable nodules in the bilateral lobes of the thyroid with 1 ° of enlargement. On June 18, color Doppler ultrasound of the thyroid gland showed multiple variably sized nodules in the bilateral lobes of the thyroid and an uneven internal echo. The maximum dimension of the largest nodule in the right lobe measured 15 mm × 7 mm, the largest nodule in the left lobe measured 12 mm × 9 mm. A hypoechoic nodule of approximately 10 mm × 5 mm was found in the right neck, with a clear boundary and regular contour. The ultrasound diagnosis was bilateral thyroid intralobar cysts and solid lesions in the right cervical lymph nodes.

On June 19, the thyroid function test results were normal.

On June 23, after the patient signed the informed consent for surgical treatment, RFA of the bilateral thyroid nodules and FNAB were performed under local anesthesia. Per the surgical record, the patient was placed in a supine position, and the thyroid and surrounding cervical lymph nodes were examined via ultrasound to determine the nodular location and size. After administering local anesthesia, the thyroid and carotid space, tracheal space, esophageal space and posterior thyroid space were separated with a mixture of 15 mL 0.9% saline and 5 mL lidocaine to avoid thermal damage during the operation. A small incision was made at the puncture site, and the electrode was placed into the nodule under ultrasound guidance using 30 W of power for multipoint, multilayer ablation until the nodule was covered by a strong echo generated by the thermal energy. Ultrasound was then used to determine whether the nodule ablation was complete and to confirm no active bleeding.

The intraoperative FNAB results showed little thyroid and muscle tissue (left) and fiber and muscle tissue (right). These results showed that the biopsies failed, however, RFA was still performed.

On June 24, the first day after RFA, the patient's voice was hoarse. On the second day, the thyroid function test showed no significant change, and mecobalamin and vitamin B6 tablets were used to treat her hoarseness.

On July 14, electronic noses and the laryngoscopic examination report showed that the bilateral vocal cords could not move, and the glottis could not close. The patient was diagnosed with left and right vocal cord paralysis.

On June 27 of the following year, electronic notes and the laryngoscopic examination report showed bilateral vocal cord fixation with limited activity of the bilateral cricoarytenoid joints, suggesting bilateral RLN paralysis.

3. Forensic medical investigation

On December 26 of the third year, forensic medical experts investigated the case and presented the following results. The patient complained of hoarseness, a choking cough when eating or drinking water, heavy snoring during sleep, walking slowly, and more laborious and heavy breathing when walking upstairs.

She stated that the main content of the preoperative conversation with her doctor was that the doctor told her not to worry because a treatment plan had been developed to treat her condition. Hospital regulations required her to sign an informed consent form before the RFA. Her forensic physical examination revealed that she took 20 breathes per minute, which were slightly heavy. Her speech was slightly hoarse, but her meaning could be fully understood. She drank slowly, but no obvious choking or coughing occurred during the examination.

The patient and her family believed that there was medical negligence in her diagnosis and treatment and that the surgeon and hospital should assume the compensatory liability. Then, the hospital was prosecuted. Whether medical malpractice had occurred and whether the patient's treatment caused her damage needed to be determined.

4. Analysis

This case presented a clear causal relationship between the medical treatment and the patient's damage. First, the patient had no hoarseness preoperation, but her hoarseness occurred immediately after the RFA. Second, the electronic notes and laryngoscopic examinations twice revealed typical bilateral RLN injury. According to *The Interpretation by the Supreme People's Court of Certain Issues Concerning the Application of the Law in Cases of Injury Liability and the Guideline for Forensic Judgement Relationship Between Injury and Disease* in the Academy of Forensic Sciences of the People's Republic of China, the causative potency of medical malpractice is divided into the following six grades according to relative proportions from low to high: no effect 0%–4% (average 0%), minor effect 5%–15% (average 10%), secondary effect 16%–44% (average 30%), equal effect 45%–55% (average 50%), main effect 56%–95% (average 70%) and complete effect 96%–100% (average 100%)[2]. To assess the medical malpractice grade assigned to the RFA that caused the patient's bilateral RLN injury, the following five aspects were analyzed: 1) whether the preoperative preparation was adequate, 2) whether the new technology had unavoidable adverse effects, 3) whether the operator's technical level was sufficient, 4) the complexity of the patient's disease, and 5) the informed consent.

First, the preoperative preparation was assessed. *Thermal Ablation of Thyroid Nodules* guidelines in China state that thyroid nodules should be confirmed as benign or malignant before RFA. Several

modern diagnostic techniques enable surgeons to achieve highly accurate preoperative judgements of benign and malignant thyroid nodules to better guide the patient's diagnosis and treatment. In the current case, based on the patient's primary medical history, we considered that the thyroid nodules were less likely to be malignant but that a more complete examination was warranted to be certain. However, in this case, the preoperative assessment was unsuccessful, and we could not determine whether the thyroid was benign or malignant. The Thyriod Imaging-Reporting And Data System (TI-RADS) grades of the thyroid nodules can be determined clinically via B-ultrasound to categorize the thyroid nodules and stratify their malignant risk[14]. Nodules below grade 2 are benign, grade 3 nodules are highly likely to be benign, and nodules above grade 4 have an increased chance of being malignant; therefore, this patient required further puncture biopsies. The preoperative ultrasound report in this case did not include TI-RADS grades, which would have helped diagnose the nodules as benign or malignant. Second, FNABs are the most accurate and standanlized for preoperative evaluations[15, 16] and are especially important for RFA cannot be used to determine the final pathology. Thus, patients was required to undergo an ultrasound-guided FNAB prior to the RFA[4, 17]. In our case, clinicians performed the FNAB during the RFA procedure and obtained no thyroid nodule tissue, indicating that the puncture location was inaccurate and the puncture had failed. However, no additional FNAB was performed, and the thyroid nodule diagnosis was unclear. In this case, the preoperative preparation was inadequate, and RFA was executed despite it not being the best treatment option. This violated the medical principles of RFA for treating thyroid nodules.

In this case, adverse effects of the RFA and the operator's technical level were jointly analyzed because they are closely related. Previous literature has shown that RFA is a safe, minimally invasive treatment[18] and can even be an alternative to surgery for benign thyroid nodules[19]. However, the safety of RFA is questionable because it can cause complications and side effects such as voice changes (RLN injury), nodule rupture, nodule rupture with abscess formation, hypothyroidism, pain, vasovagal reaction, and coughing[20]. RLN injury is one of the serious complications of RFA. Kim et al. showed a 3.3% incidence of RLN injury after RFA, mainly owing to the degree of attention and technical level of the operator during the RFA[21]. The thyroid gland is a small organ and has a complex anatomical relationship with the surrounding tissues. When performing RFA, operators should be aware of the anatomical location of the RLN .The RFA electrode generally maintain a distance of >1 cm from the thyroid capsule to prevent RLN injury during the operation. However, if the operator is too cautious, treatment of the thyroid nodules may be incomplete. Thermal injury to the RLN may be prevented by using the moving shot technique and by undertreating the conceptual ablation undertreating the conceptual ablation units adjacent to the nerve[22]. During the proceduring of RFA, the operator payed attention to prevent injury to RLN[5], and RFA should be performed by an experienced clinician, and its long-term safety and effectiveness must be verified through further follow-up. In our case, the patient's bilateral RLN injury occurred after the RFA. Relevant surgical records showed that the RLN was protected, and the informed consent form stated the possibility of RLN injury and hoarseness postoperation; however, a medical accident still occurred. If the operator had been more attentive during the procedure, the RLN injury may have been avoided. Therefore, the patient's signature on the informed consent did not protect the doctor or hospital from being liable. The medical team failed to fulfill their obligation of risk foresight and avoidance; thus, they were at fault.

Fourth, we analyzed the disease complexity. RLN injuries are mostly related to inadvertent traction, hematoma compression, or direct contusion during the operation, as well as difficult separations of adhesion The RFA surgical record in this case showed a small thyroid nodule volume, a complete capsule, and no obvious serious adhesion; thus, the medical fault liability could not be reduced owing to the disease complexity.

Fifth, we analyzed the informed consent. According to Chinese Tort liability law, patients' and

their families' autonomy and the requirement of informed consent should be respected. Medical staff should provide feasible treatments and explain the advantages and risks of different treatments to enable patients and their families to make the best choice. In our case, the surgeon did not inform the patient or her family of alternative treatments to RFA, and they directly signed the informed consent. Surgeons should provide detailed and professional information in a language that the patient can understand until the patient is satisfied with the information and can make an informed decision. Surgeons should offer useful suggestions for patients. In this case, the patient felt that the surgeon did not sufficiently warn her of the potential risks of RFA and that RFA was considered the safest and only treatment. Therefore, the informed consent document only proves that informed consent was obtained prior to the RFA. Generally, this type of consent form is not legally accepted by the courts because some necessary information is lacking. When the FNAB failed, the surgeon should have informed the patient of the result and redetermined the next treatment step but failed to do so. After analyzing the case, we concluded that the patient should have been offered another treatment option and been informed of the FNAB failure; however, the surgeon did not provide this information, and the patient was not fully informed of the risks of RFA. The patient was not provided the opportunity to choose more appropriate treatments that may have prevented or reduced the probability of RLN injury. Forensic experts believed that the surgeon infringed the patient's right of informed consent.

5. Conclusion

In summary, four main medical faults were found in this case: 1) the informed consent before the RFA was unreasonable, 2) RFA was still performed after the FNAB failed, which violated medical principles, 3) the medical team failed to fulfill the obligation of risk foresight and avoidance regarding bilateral RLN injury during the RFA operation, and 4) improper operation caused the RLN injury. Therefore, we concluded that the medical team was at fault and directly caused the patient's bilateral RLN injury. The causative potency of the medical malpractice was 70%–90% in accordance with the relevant provisions of *the Code for Forensic Identification of Injury and Disease*.

ORCID iD

Weiyi Tang https://orcid.org/0000-0002-1055-3077

References

[1] Tufano R, Pace-Asciak P, Russell J, et al. Update of Radiofrequency Ablation for Treating Benign and Malignant Thyroid Nodules. The Future Is Now. Frontiers in endocrinology 2021; 12: 698689. DOI: 10.3389/fendo.2021.698689.

[2] Shin J, Baek J, Ha E, et al. Radiofrequency ablation of thyroid nodules: basic principles and clinical application. International journal of endocrinology 2012; 2012: 919650. DOI: 10.1155/2012/919650.

[3] Papini E, Monpeyssen H, Frasoldati A, et al. 2020 European Thyroid Association Clinical Practice Guideline for the Use of Image-Guided Ablation in Benign Thyroid Nodules. Eur Thyroid J 2020; 9: 172-185. 2020/09/10. DOI: 10.1159/000508484.

[4] Vuong N, Dinh L, Bang H, et al. Radiofrequency Ablation for Benign Thyroid Nodules: 1-Year Follow-Up in 184 Patients. World journal of surgery 2019; 43: 2447-2453. DOI: 10.1007/s00268-019-05044-5.

[5] Shaw G and Pierce E. Malpractice litigation involving iatrogenic surgical vocal fold paralysis: a closed-claims review with recommendations for prevention and management. The Annals of otology, rhinology, and laryngology 2009; 118: 6-12. DOI: 10.1177/000348940911800102.

[6] Ta J, Liu Y and Krishna P. Medicolegal Aspects of Iatrogenic Dysphonia and Recurrent Laryngeal Nerve Injury. Otolaryngology--head and neck surgery: official journal of American Academy of Otolaryngology-Head and Neck Surgery 2016; 154: 80-86. DOI: 10.1177/0194599815607220.

[7] Zhuo P, Gao D, Xia Q, et al. Sciatic nerve injury in children after gluteal intramuscular injection: Case reports on medical malpractice. Medicine, science, and the law 2019; 59: 139-142. DOI: 10.1177/0025802419851980.

[8] Min Z and Peng T. Current Status and Legal Treatments of Medical Disputes in China. Springer Berlin Heidelberg, 2013. Pellerin v. Humedicenters, Inc. (1997) 969 So. 2d 590, La. App. LEXIS 1636.

[9] Wentao. X Guangyou Z and Xiaopin Y. Expertise and precaution of medical malpractice. Beijing, P.R. China:

Beijing Science Press, 2015, pp. 42-43.
[10] Zhang X. On the Causative Potency Theory in Tort Law.In: Legislation of tort liability law in China.Singapore: Springer, 2018, pp.233–253.
[11] Lydiatt D. Medical malpractice and the thyroid gland. Head & neck 2003; 25: 429-431. DOI: 10.1002/hed.10254.
[12] Gong N, Zhou Y, Cheng Y, et al. Practice of informed consent in Guangdong, China: A qualitative study from the perspective of in-hospital patients. BMJ Open 2018; 8: e020658.
[13] Kwak J, Han K, Yoon J, et al. Thyroid imaging reporting and data system for US features of nodules: a step in establishing better stratification of cancer risk. Radiology 2011; 260: 892-899. DOI: 10.1148/radiol.11110206.
[14] Wang C, Friedman L, Kennedy G, et al. A large multicenter correlation study of thyroid nodule cytopathology and histopathology. Thyroid: official journal of the American Thyroid Association 2011; 21: 243-251. DOI: 10.1089/thy. 2010.0243.
[15] Cibas E and Ali S. The 2017 Bethesda System for Reporting Thyroid Cytopathology. Thyroid: official journal of the American Thyroid Association 2017; 27: 1341-1346. DOI: 10.1089/thy.2017.0500.
[16] Crippa S, Mazzucchelli L, Cibas E, et al. The Bethesda System for reporting thyroid fine-needle aspiration specimens. American journal of clinical pathology 2010; 134: 343-344; author reply 345. DOI: 10.1309/ajcpxm 9wirq 8jzbj.
[17] Mauri G, Cova L, Monaco C, et al. Benign thyroid nodules treatment using percutaneous laser ablation (PLA) and radiofrequency ablation (RFA). International journal of hyperthermia: the official journal of European Society for Hyperthermic Oncology, North American Hyperthermia Group 2017; 33: 295-299. DOI: 10.1080/02656736. 2016. 1244707.
[18] Na D, Lee J, Jung S, et al. Radiofrequency ablation of benign thyroid nodules and recurrent thyroid cancers: consensus statement and recommendations. Korean journal of radiology 2012; 13: 117-125. DOI: 10.3348/kjr. 2012. 13.2.117.
[19] Baek J, Lee J, Sung J, et al. Complications encountered in the treatment of benign thyroid nodules with US-guided radiofrequency ablation: a multicenter study. Radiology 2012; 262: 335-342. DOI: 10.1148/radiol.11110416.
[20] Kim YS, Rhim H, Tae K, et al. Radiofrequency ablation of benign cold thyroid nodules: initial clinical experience. Thyroid: official journal of the American Thyroid Association 2006; 16: 361-367. 2006/05/02. DOI: 10.1089/thy. 2006. 16.361.
[21] Baek J, Kim Y, Lee D, et al. Benign predominantly solid thyroid nodules: prospective study of efficacy of sonographically guided radiofrequency ablation versus control condition. AJR American journal of roentgenology 2010; 194: 1137-1142. DOI: 10.2214/ajr.09.3372.
[22] Ugurlu MU, Uprak K, Akpinar IN, et al. Radiofrequency Ablation of Benign Symptomatic Thyroid Nodules: Prospective Safety and Efficacy Study. World Journal of Surgery 2015; 39: 961-968.