Surgery Today (2018) 48:1076–1080
https://doi.org/10.1007/s00595-018-1692-1

ORIGINAL ARTICLE

Thermal effects of the Thunderbeat™ device on the recurrent laryngeal nerve during thyroid surgery

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Received: 8 March 2018 / Accepted: 15 June 2018 / Published online: 9 July 2018
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Abstract

Purpose To investigate the safety of the Thunderbeat™ (TB) device in thyroid surgery by clarifying its thermal effects on the recurrent laryngeal nerve (RLN).

Methods We performed thyroidectomy using TB on four female pigs under general anesthesia. TB was applied 0, 1, and 2 mm from the RLN. The effects of incisions made in tissues in the vicinity of the RLN were evaluated by intraoperative neuromonitoring and pathological examination.

Results The value of the neural integrity monitor (NIM) was unchanged at 2 and 1 mm, but there was loss of signal at 0 mm. The differences between 2 and 0 mm were not clear from the pathological findings.

Conclusions When using the TB device during thyroid surgery, it is recommended that it is visually kept from making any contact with the RLN.

Keywords Thyroidectomy · Energy-based devices · Intraoperative monitoring · Recurrent laryngeal nerve palsy · Thermal effects

Introduction

Since the introduction of 1.1 GBq radioactive iodine therapy for outpatients in 2010, postoperative ablation has been performed following total thyroidectomy and lymphadenectomy in patients at high risk of thyroid cancer. Recurrent laryngeal nerve (RLN) palsy is a common and serious complication of thyroid surgery, particularly after total thyroidectomy. Bilateral RLN palsy requires tracheostomy to prevent suffocation. To avoid bilateral RLN paralysis, it is important to preserve the RLN intraoperatively, as well as to evaluate neurotransmission integrity. Lateral heat diffusion to the RLN has been reported to cause complications of surgery that uses energy-based devices (EBDs). Because thyroid surgery is performed under a narrow hemorrhagic surgical field, EBDs can reduce operative blood loss and operation time and, as a result, have recently replaced hand-tying methods; however, it is imperative not to allow them to inflict heat damage on the RLN [1]. The Thunderbeat™ (TB; Olympus, Japan) is a well-known EBD, introduced in October, 2013. However, its use in thyroid surgery has rarely been reported. Through the simultaneous output of high-frequency current and ultrasonic vibrations, the TB allows for quick incisions with high sealability. Unlike other EBDs, the TB cuts through tissue quickly, but during cutting and coagulation, the blade becomes very hot [2]. To our knowledge, few studies have investigated the safety of the TB during thyroid surgery.

A device that monitors the RLN function intraoperatively, called a neural integrity monitor (NIM), allows us to evaluate the integrity of the RLN as well as to identify its location [3]. The purpose of this study was to investigate the safety of the TB in thyroid surgery. Specifically, this study aims to clarify the thermal effects of the TB on the RLN.

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Methods

Four female piglets (body weight, 40 kg) were used for this study. After intubation with an electromyography endotracheal tube (TriVantage™; ID, 7 mm; Medtronic, Japan), an intraoperative RLN monitoring device (NIM-Response 3.0™; Medtronic) was applied. The tube was inserted via laryngoscopy and its electrode placement was confirmed to be in contact with the vocal cords. Under general anesthesia, the thyroid and RLN were exposed. A muscle relaxant was not used.

The effects of the incisions made in the tissue within the vicinity of the RLN were examined. We used the TB set to the cutting mode to cut tissue located 2 and 1, and 0 mm from the RLN. Tissue 0 mm from the RLN was in contact with the RLN. The activation time was fixed at 4–5 s. The temperature of the RLN was then measured using a thermocouple device (Memory HiLogger™ LR8431; Hioki, Japan). At the same time, the NIM was used to measure the reaction of the RLN to electrostimulation over time. The schema of the experiment is shown in Fig. 1.

The preservation of RLN function in the laryngeal fibers was evaluated by observing the movement of the vocal cords. RLNs after incision were harvested and fixed in formalin. The specimens were embedded in paraffin, sliced, and stained with hematoxylin and eosin and Kluver–Barrera. Immunohistochemical analyses were performed with neurofilament protein antibody (NFP). Immunohistochemistry was performed on 4-μm-thick sections of formalin-fixed, paraffin-embedded tissue using a detection kit (Histofine Simple Stain MAX PO, MULTI; Nichirei Bioscience; Tokyo, Japan) according to the manufacturer's instructions. The tissue sections were incubated with a monoclonal mouse antihuman neurofilament protein (clone 2F11; Agilent Technologies, Inc., Santa Clara, CA, USA) at a dilution of 1:100 as the primary antibody. 3,3′-Diaminobenzidine was used as the chromogen and the tissue sections were counterstained with Mayer's hematoxylin. RLN function was then compared with the pathological tissue.

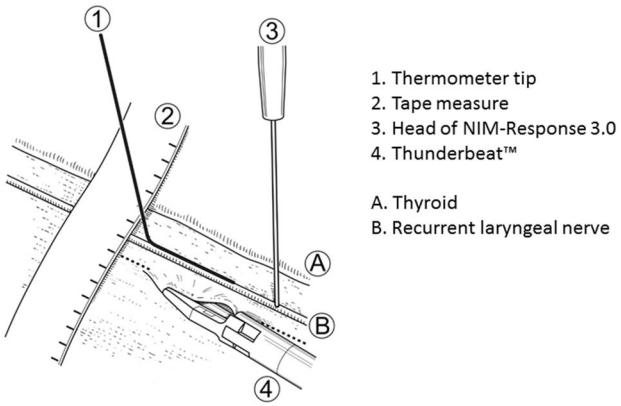

Fig. 1 Experimental layout

Results

RLN function

The international guidelines for intraoperative neuromonitoring (IONM) define RLN damage as a loss of signal (LOS) on the NIM of < 100 μV. Tissue incisions made 2 and 1 mm away from the RLN did not result in any change in NIM values. LOS was observed when the TB was in contact with the RLN; however, although improvement (as movement of the vocal cords) was noted after 40 s in the tissue 0 mm from the RLN ①, sustained LOS was observed ② (Fig. 2).

In the laryngeal fibers, tissue incisions made 2 and 1 mm away from the RLN resulted in normal movement of the vocal cords. In the tissue cut 0 mm from the RLN ①, the vocal cords were temporarily paralyzed, although the they recovered movement in accordance with the outcomes determined by the NIM. In the tissue cut 0 mm from the RLN ②, the vocal cords were paralyzed.

Histological findings

The maximum temperature of the RLN was 41.6 °C, and LOS and vocal cord paralysis were not observed in tissue cut 2 mm from the RLN. All histological images remained unchanged. On the other hand, the maximum temperature of the RLN reached 82.6 °C and resulted in LOS after incision in the tissue cut 0 mm from the RLN ②. The histological findings of these two nerves were comparable. There was no denaturation by heat and the histological structure was maintained (Fig. 3).

Discussion

RLN injury is one of the most serious complications of thyroidectomy and preventing bilateral RLN paralysis is of the utmost importance. However, RLN surgical injury and postoperative vocal cord paralysis still occur in approximately 9% of patients undergoing thyroidectomy [4]. According to Dionigi et al., the most frequent cause of RLN injury is traction (71%), then thermal injury (17%), although the rates of temporary and permanent vocal palsy were 98.6 and 1.4% for traction lesions and 72 and 28% for thermal injury. The rate of permanent vocal palsy associated with in thermal injury is high [5]. Therefore, it is important to prevent thermal injury in thyroid surgery.

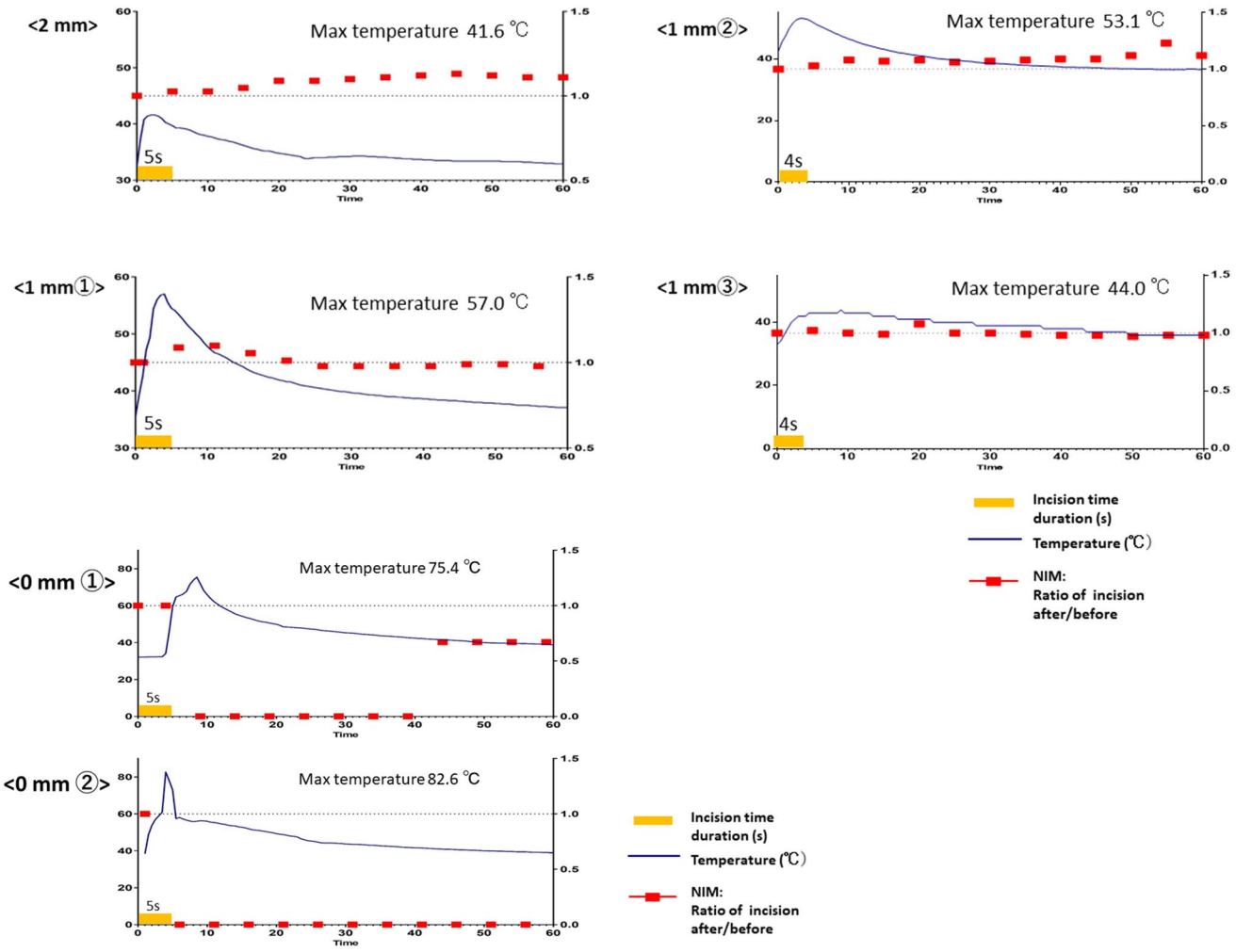

Fig. 2 Temperature changes in the recurrent laryngeal nerve (RLN) and neural integrity monitor (NIM) values (ratio of after incision/before incision) at distances between the Thunderbeat (TB) and the RLN of 2, 1, and 0 mm. The NIM values were unchanged at the incision distances of 2 and 1 mm from the TB, but there was loss of signal (LOS) at an incision distance of 0 mm

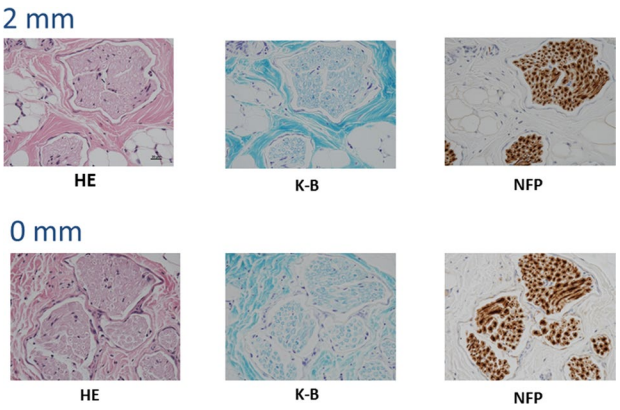

Fig. 3 Histopathological comparison. There were no clear differences in the pathological findings of tissues incised 2 vs. 0 mm from the RLN

EBDs, such as the Harmonic Scalpel™ (HS; Ethicon Endo-Surgery; Tokyo, Japan) and LigaSure™ (LS; Medtronic Japan; Tokyo, Japan), are used widely in thyroid surgery. EBDs are associated with shorter operative duration, hospital stay, less blood loss, postoperative drainage, pain, and hypocalcemia than traditional methods [6–11]. The Harmonic Scalpel™ system consists of a current generator, an ultrasonic transducer, and an instrument to direct the tissue effect. Ultrasonic energy controls bleeding through the process of coactive coagulation, thereby sealing vessels with a protein coagulum. The LigaSure™ utilizes a combination of pressure and current to melt the collagen and elastin contained within the blood vessel walls, thereby sealing the vessels. The TB is a newer instrument, introduced for use in Japan in October, 2013, which simultaneously applies ultrasonically generated frictional heat energy and electrically generated bipolar energy. The TB is multifunctional,

enabling the surgeon to coagulate large blood vessels while cutting and dissecting during surgery [12]. Unlike other EBDs, the TB characteristically cuts through the tissue quickly; however, the temperature of its blade becomes very high, and the safety margin with respect to the RLN was until now, unknown. The use of the TB, which is an EBD characterized by its ability to perform quick incisions, is anticipated to spread in the field of thyroid surgery. Thus, a clearer understanding of its safe application duration and distance from the RLN is critical.

Traditionally, clamp-and-tie techniques, suture ligation, and monopolar or bipolar electrocautery have been used for controlling bleeding in thyroid surgery. However, several reports advocate the usefulness of EBDs in thyroid surgery. Our experiment was conducted on live animals under general anesthesia in an environment close to that of practical clinical settings. Reports of RLN injury in actual experiments using live animals are rare. Some investigators have reported an increase in the temperature of the RLN associated with the use of EBDs. In one experiment, the tissue surrounding the RLN was cut with a harmonic scalpel, and vocal cord paralysis and pathological changes to the RLN reportedly occurred within 2 mm of the incision [13].

In recent years, special electrode-equipped endotracheal intubation tubes have been used to monitor nerves in thyroid and parathyroid surgeries intraoperatively by stimulating the recurrent laryngeal and vagus nerves and observing vocal muscle activity. It is also helpful to predict the outcome of vocal cord function during the operation. This practice is spreading internationally.

In the present study, the temperature reached its maximum value immediately and then decreased gradually wherever it was applied. When it was applied 1 and 2 mm from the RLN, the temperature dropped below the startup value. This infers that the cut tissue around the nerve caused a decrease in the blood flow, resulting in a decrease in temperature. Lin et al. established that 60 °C is a critical temperature causing RLN thermal injury [4]. Thus, the results may be affected by the highest temperature being more than 60 °C. The NIM helps to detect the early phases of nerve injury immediately after a potential injurious maneuver. RLN injury did not occur when the site of TB application was at a distance of ≥ 1 mm. The maximum temperature reached when the tissue was cut 1 mm from the RLN was 57 °C. These results suggest that the lateral thermal damage from the TB is minimal and that it can be safely applied at a distance > 1 mm from the RLN. According to Hee Yong Kwak et al., the TB can be used safely at a distance of 3 mm from the RLN, but it must be applied for < 8 s at more proximal locations [14]. In the present study, LOS was not seen at 1 mm and there was no damage histologically. A shorter activation duration of $\leqq 5$ s may be acceptable at 1 mm.

To the best of our knowledge, this is the first study to evaluate thermal damage to the RLN by conducting IONM and pathological tissue examination. The previous reports provided no details on points heated by an energy device. In our study, the point was specifically identified in line with clinical practice. There are some membranes surrounding the RLN in piglets, similar to humans. During surgery, the membrane can be cut by an energy device and this is one of the most anxiety-provoking events in thyroidectomy. Incisions made 1 mm away from the RLN did not result in changes in the measured NIM values before or after cutting, and the movement of the vocal cords was normal. The fact that vocal cord paralysis did not occur at 2 mm and RLN paralysis occurred as a result of heat from the TB suggests that histological changes might not be concomitant.

In the present experiment, the RLN was harvested immediately after the TB incision and fixed in formalin. There were no histological changes, even if the RLNs were paralyzed. Karla V. Chavez et al. conducted an experiment using HS in a porcine model, from which paralyzed RLNs were harvested 2 days after surgery and evaluated. They also reported that histological and immunohistochemical examinations of the paralyzed RLNs did not reveal significant changes attributed to thermal injury [15]. These results may suggest that thermal damage caused by EBDs does not always result in pathological change. On the other hand, these changes are reported to arise 12 h after traumatic injury to the nerves. Nerve degeneration can take 4–7 days [16]. If thermal damage to the nerves follows traumatic injury, the timing of harvesting the RLNs might be too early in these experiments. Moreover, fixing the RLNs in formalin may have prevented the histologic confirmation of heat-induced protein denaturation.

Our study has some limitations. First, the sample size was small. Second, other EBDs were not evaluated. Third, because of species differences, the data from this study may not translate to human surgery. Fourth, the period of observation was limited. Thus, our study warrants further investigation to establish the clinically acceptable distance and safety margin for the application of an EBD.

Conclusion

Iatrogenic RLN injury is a serious complication potentially associated with using the TB in thyroid surgery. Our findings suggest that the RLN can be preserved by ensuring at least a 1 mm margin when using the TB during thyroid surgery. In clinical practice, to ensure a more stable and secure procedure, taking into consideration the tissue shrinkage by heat, it is recommended that the site of TB application should be visually kept from coming into contact with the RLN.

Declarations

All animal experiments were approved by the Institutional Animal Care and Use Committee (IACUC) of Tokyo Medical University and were performed in accordance with the institutional, science community, and national guidelines for animal experimentation.

Acknowledgements We thank Olympus Co., Ltd. and Medtronic Co., Ltd. who cooperated in this experiment.

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