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Original Research

Feasibility and safety of nerve stimulator attachment to energy-based devices: A porcine model study

Sung-Chan Shin[a], Eui-Suk Sung[b], Sung-Won Choi[a], Sung-Dong Kim[a], Da-Woon Jung[a], Seok-Hyun Kim[b], Jung Hoon Ro[c], Jin-Choon Lee[b], Byung-Joo Lee[a,*]

[a] Department of Otorhinolaryngology-Head and Neck Surgery, Biomedical Research Institute, Pusan National University School of Medicine, Pusan National University Hospital, Pusan, Republic of Korea

[b] Department of Otorhinolaryngology-Head and Neck Surgery, Biomedical Research Institute, Pusan National University School of Medicine, Pusan National University Yangsan Hospital, Yangsan, Gyeongsangnam-do, Republic of Korea

[c] Department of Biomedical Engineering, Pusan National University School of Medicine, Yangsan, Gyeongsangnam-do, Republic of Korea

A R T I C L E I N F O

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A B S T R A C T

Background: Recently, several energy-based devices (EBDs) have been developed and applied in the context of thyroid surgery. EBDs can reduce operation time, blood loss, and postoperative pain. Compared to conventional electrocautery, EBDs operate at a relatively lower temperature and produce minimal lateral tissue damage. Yet, during device operation, the tip of the EBD is hot enough to cause thermal nerve damage, increasing the need for surgeons to be cautious about EBD application. To increase the safety of EBDs, we attached nerve stimulators to the tips of two EBDs and compared them to conventional monopolar nerve stimulation using a porcine model.
Methods: Three piglets (30–40 kg) underwent total thyroidectomy after orotracheal intubation with a nerve integrity monitor (NIM) electromyography (EMG) endotracheal tube. Nerve stimulators were attached to two EBDs (Harmonic Focus® + and LigaSure™). After dissection and identification of six recurrent laryngeal nerves in the three piglets, both of the EBDs with attached nerve stimulators and a conventional monopolar nerve stimulator were applied near the nerve and EMG parameters were recorded using the NIM 3.0 system. The stimulus intensity was varied from 5 mA to 1 mA and the maximum distance and amplitude at which nerve detection was achieved were measured.
Results: There were no statistically significant differences between the maximum distance or mean amplitude obtained from nerve stimulators attached to EBDs and those obtained from the conventional nerve stimulator. Additionally, there were no adverse EMG events related to the use of nerve stimulators attached to EBDs.
Conclusions: Attachment of a nerve stimulator to an EBD for nerve detection during thyroidectomy was as safe and effective as attachment of a conventional nerve stimulator. Use of a nerve stimulator attachment may reduce the likelihood of EBD-associated nerve damage during thyroid surgery.

1. Introduction

In recent decades, various energy-based devices (EBD) have been developed and implemented for surgical purposes including thyroidectomy. As EBDs have evolved over time, they have offered increasing convenience to surgeons and gradually replaced traditional operative techniques such as hand tying and electrocauterization [1,2]. EBDs have several advantages: they allow for simultaneous tissue incision and hemostasis, shorten the operative duration, and reduce blood loss as well as postoperative pain [3,4]. Yet, the tip of an EBD can heat up to 200 °C and accordingly produce thermal damage to the surrounding tissue up to 8.6 mm from the target site [5]. During thyroidectomy, recurrent laryngeal nerve (RLN) injury is a principal concern; EBD-related thermal damage to the RLN can be fatal. Recently, intraoperative neuromonitoring (IONM) has been implemented to reduce the likelihood of RLN injury and shown potential as a useful aid for nerve preservation [6]. Although a recent meta-analysis reported that IONM did not significantly reduce the incidence of transient or permanent RLN palsy after surgical intervention, it is lauded for its utility in guiding younger low-volume surgeons in thyroid surgery and can provide additional assistance for preserving the RLN in difficult reoperation cases [6–9]. Additionally, IONM is particularly useful for identifying and preserving the external branch of the superior laryngeal nerve during thyroidectomy [10]. In the present work, we hypothesized

* Corresponding author. Department of Otorhinolaryngology-Head and Neck Surgery, Pusan National University Hospital, Gudeok-Ro 179, Busan, Republic of Korea.
E-mail address: voiceleebj@gmail.com (B.-J. Lee).

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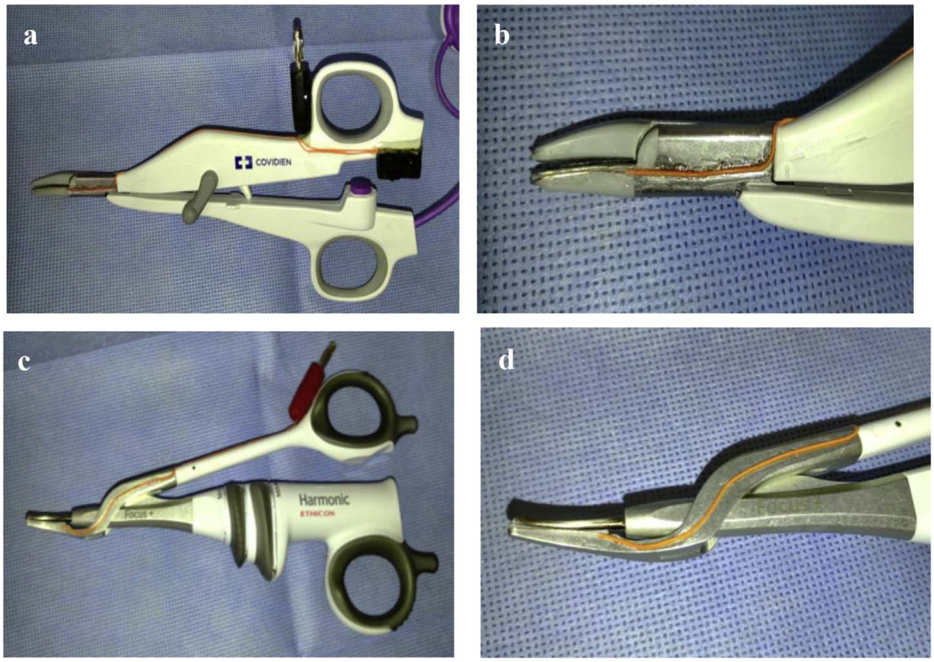

Fig. 1. Nerve stimulators attached to energy based devices.
Nerve stimulators were attached to the lower jaw of the LigaSureTM (a, b) and the inactive arm of the Harmonic Focus® + (c, d).

that EBD-related nerve damage could be more conveniently prevented by attaching a nerve stimulator to the tip of an EBD and monitoring the status of the RLN in real time with intermittent IONM during thyroidectomy. To verify the safety and utility of this approach, we assembled two prototype nerve stimulator-EBDs, evaluated the maximum distance and evoked amplitude for nerve detection in accordance with stimulation intensity, and compared results to those obtained with a conventional monopolar nerve stimulator in a porcine model.

2. Materials and methods

2.1. Animals

Three Yorkshire-Landrace-Duroc female piglets (30–40 kg) underwent total thyroidectomy. All animal experiments were approved and performed as per the guidelines of the Institutional Animal Care and Use Committee (IACUC) at our institute. After overnight fasting, all three piglets were anesthetized with a mixture of ketamine (20 mg/kg, i.m.) and xylazine (2 mg/kg, i.m.) and maintained under anesthesia with 3% isoflurane. The piglets were placed in a supine position on the operation table and monitored with pulse oximetry, electrocardiography, and a blood pressure cuff. After securing the intravenous line, a veterinarian performed intubation with a nerve integrity monitor (NIM) electromyography (EMG) endotracheal tube (6.0 mm internal diameter, Medtronic Xomed, Jacksonville, FL). After visual verification of the tube position, a total thyroidectomy was performed.

2.2. IONM

The stimulating intensity was varied from 5 mA to 1 mA and the maximum distance for nerve detection and amplitude were recorded with NIM Response 3.0 system (Medtronic, Xomed, Jacksonville, FL) using a conventional monopolar probe (Prass standard tip, Medtronic, Xomed, Jacksonville, FL) and nerve stimulator attached to an EBD. Detailed monitoring settings followed the international standards guideline statement [6]. The adverse event threshold was set to 100 μV, and stimulating current was set at a frequency of 4 Hz for 100 ms with a 2.1-ms rejection period.

2.3. Nerve stimulator-EBDs

We developed a prototype device by attaching nerve stimulators to the tips of two EBDs (Harmonic Focus® + and LigaSure™). After stripping the sheath from an electric wire, we attached the wire to the tip of an EBD and plugged into the EBD so that the wire could deliver current and act as a nerve stimulator. The nerve stimulator was attached to an inactive arm of the Harmonic Focus® + and the lower jaw of the LigaSure™ (Fig. 1).

2.4. Study design

To verify the nerve detection ability and safety of our nerve stimulator-EBDs compared to a conventional monopolar nerve stimulator, we determined the maximum distance and amplitude at which nerve detection was achieved while lowering the stimulus current from 5 mA to 1 mA (Fig. 2).

2.5. Statistical analysis

All values are presented as the mean and standard deviation. Kruskal-Wallis tests were used to compare the maximum distance and mean evoked amplitude of nerve detection among the three devices. Statistical analyses were performed with the SPSS software package (version 19.0, SPSS, Inc., Chicago, IL, USA).

3. Results

3.1. Adverse EMG events

There were no adverse events recorded in the NIM 3.0 system associated with use of the nerve stimulator-EBDs; RLN function was maintained even when the stimulation intensity was increased to 5 mA, indicating device safety.

3.2. Nerve detection parameters

We measured the maximum distance of nerve detection for each device while lowering the stimulus intensity from 5 mA to 1 mA. At 5 mA, the maximum distance and mean amplitude for each device were