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Standardization of Intraoperative Neuromonitoring of Recurrent Laryngeal Nerve in Thyroid Operation

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Abstract
Background The lack of standardized procedures of intraoperative neuromonitoring (IONM) during thyroid operations may lead to highly variable results, and many of these results can cause misleading information and, conversely, increase the risk of recurrent laryngeal nerve (RLN) injury. Therefore, standardization of IONM procedures is necessary.
Methods A total of 289 patients (435 nerves at risk) who underwent thyroidectomy by the same surgeon were enrolled in this study. Each patient was intubated with EMG endotracheal tube by the same anesthesiologist. Standardized IONM procedures were applied in each patient. The procedures include preoperative and postoperative video-recording of vocal cord movement, ensuring the correct position of electrodes after the neck was placed at full extension, vagal stimulation and registration of EMG signals before and after RLN dissection, and photographic documentation of the exposed RLN.
Results Five patients encountered dysfunction of IONM, which was caused by malposition of electrodes and the problem was detected at once. One patient with non-RLN was detected at the earlier stage of operation. Eighteen nerves experienced loss of EMG signals during thyroid dissection, and the causes of nerve injuries were well elucidated with the application of our standardized IONM procedures.
Conclusions The standardized IONM procedures are useful and helpful not only to eliminate false IONM results, but also to elucidate the mechanism of RLN injury. After ascertaining the surgical pitfalls and improving the surgical techniques, the palsy rate was significantly reduced in this study.

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Introduction

Recurrent laryngeal nerve (RLN) palsy is the most common and serious complication after thyroid operation, and it ranks among the leading reasons for medicolegal litigation of surgeons [1]. Most surgeons have made their best efforts to prevent this complication. Several studies have shown that routine identification of the RLN has significantly reduced permanent palsy rates to <1% [2–8]. However, temporary palsy still occurs at rates of up to 6% [7]. Surgical adjuncts, such as intraoperative neuromonitoring (IONM), are being applied to prevent RLN injury during thyroid operation. IONM has been used as a means not only to localize and identify the RLN, but also to predict cord function and elucidate the mechanism of RLN injury [9–15]. Yet, most studies reported a high negative predictive value of 92–100% but a low and highly variable positive predictive value of 10–90% for IONM [9, 16–21]. This means that patients with an intact IONM signal after thyroid resection would generally have normal vocal function. Conversely, the results of signal loss in these studies were extremely unpredictable, ranging from normal vocal mobility to temporary or permanent cord palsy. These highly variable results not only limit the value of this novel technology, but they also result in misleading information, which may increase the risk of RLN injury. Therefore, in this study, we attempted to standardize our IONM procedures to improve the correlation between the results of EMG signals and the outcome of vocal cord function.

Materials and methods

The study was approved by the Institutional Review Board (IRB) of Kaohsiung Medical University Hospital and the ClinicalTrials.gov (http://www.clinicaltrials.gov; identifier: NCT00629746). Written, informed consent was obtained from each patient. Patients were informed of the intent to use this monitoring system potentially to aid in the localization and identification of the RLNs and assessment of their function during operation. There was no financial or professional association between the authors and the commercial company whose nerve-monitoring product was studied.

From April 2006 to June 2009, 289 patients (435 nerves at risk) who underwent operations for various thyroid diseases—all treated by the same surgeon (FYC)—were enrolled in this study. There were 113 patients with 173 nerves at risk in period 1 (from April 2006 to August 2007) and 176 patients with 262 nerves at risk in period 2 (from September 2007 to June 2009). The patient demographics and technical differences between the two study groups were summarized in Table 1.

Equipment set up, anesthesia, and surgical technique

All patients were under general anesthesia and were intubated with Medtronic Xomed Nerve Integrity Monitor (NIM) Standard Reinforced EMG Endotracheal Tube (6.0 mm for women and 7.0 mm I.D. for men). The tube was placed with the middle of the blue-marked region (3 cm of the exposed electrodes) well in contact with the true vocal cords under direct laryngoscopy. The tube was rotated counterclockwise approximately 30° to prevent rotation of the electrodes, and then fixed at right mouth angle. When the patient's head was positioned and the monitor was well set up, we routinely checked the impedance of electrodes. (The impedance of each electrode should be <5 kΩ and the impedance imbalance <1.0 kΩ, and then a normal base line with the waveform amplitudes of approximately 10 μV will be presented on the monitor.) When equipment dysfunction was considered intraoperatively (such as when no EMG signal can be elicited from

Table 1 Comparison of patient demographics and technical difference between the two study groups

Variable	Period 1 ($n = 113$)	Period 2 ($n = 176$)	P^a
Time frames	Apr. 2006 to Aug. 2007	Sept. 2007 to June 2009	–
Age (years), mean (SD)	50.5 (13.5)	50.4 (13.9)	0.93
Sex (female/male)	81/32	132/44	0.53
Procedures			
Total lobectomy (no.)	45 (39.8%)	84 (47.7%)	0.23
Total thyroidectomy (no.)	66 (59.2%)	92 (52.3%)	
No. of nerve at risk (NAR)	173[b]	262[b]	
Disease			
Thyroid cancer (NAR)	53 (30.6%)	69 (26.3%)	0.33
Reoperation (NAR)	7 (4.0%)	13 (5.0%)	0.66
Difference in techniques			
1. Check the proper position of electrodes by laryngofibroscopy	Only when encounter with IONM dysfunction	Routinely after neck extension	
2. Location of intraoperative RLN identification	At the level of Berry's ligament	At the level of Inferior thyroid artery	

IONM intraoperative neuromonitoring, *RLN* recurrent laryngeal nerve, *NAR* number of nerve at risk

[a] Two-sided χ^2 test

[b] Four nerves in period 1 and six nerves in period 2 were excluded due to preoperative nerve palsy

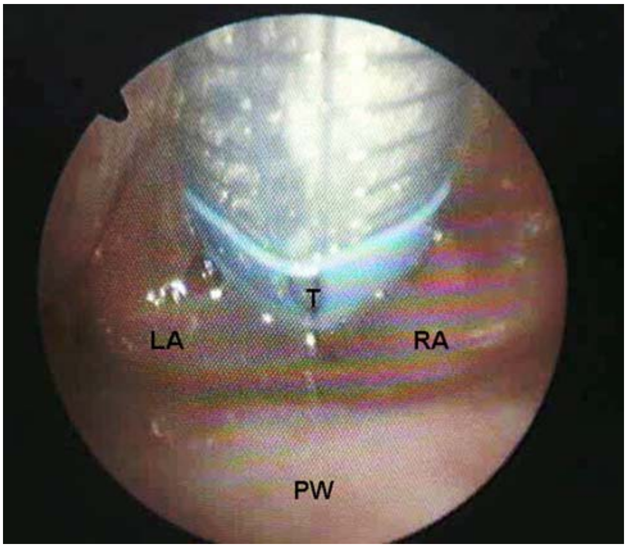

Fig. 1 Proper position of electrodes (depth and orientation) can be checked by laryngofibroscopy after intubation. Through video-laryngofibroscopic monitoring system, the twitch of larynx could be observed synchronically when the vagus nerve or RLN is stimulated during the operation. *T* midline of EMG endotracheal tube; *LA* and *RA* left and right arytenoid cartilage; *PW* posterior pharyngeal wall

the vagus nerve), the proper position of electrodes was rechecked by laryngofibroscopic examination (Fig. 1). During period 2, the position of electrodes was routinely checked by laryngofibroscopic examination after the neck was placed at full extension (Table 1).

A Pass monopolar stimulation probe (Medtronic Xomed) was used for nerve stimulation during the thyroidectomy procedure. The stimuli were generated from the NIM-Response 2.0 monitor, and the intensity was typically 1.0 to 2.0 mA for vagus nerve stimulation, and 0.8 to 1.0 mA for direct RLN stimulation. The monitor was set to run with a 50 msec time window and an amplitude scale at 0.2 mV/division. Event capture was activated with a threshold at 100 μV. Peak to peak amplitudes of evoked EMG activities were directly read on the monitor screen.

During period 1 of the study, the RLN was identified where it coursed through the Berry's ligament or close to it after medical traction and lateral dissection of thyroid lobe. Because we found that the RLN was prone to injury at the region of Berry's ligament by overstretching the thyroid [14], we changed the RLN approach during period 2 to an early identification at the level of inferior thyroid artery. We localized the RLN at tracheoesophageal groove with a stimulation level of 2 mA. Once the position of the RLN was localized, we identified the RLN and tested it with stimulation current of 1 mA for definite confirmation; then the nerve was dissected meticulously to the entry of larynx.

Four-step procedure of IONM

During the operation, a four-step procedure of IONM was used to test vagus nerve and RLN [14]:

Step 1: V_1 signal—an original EMG signal was obtained from vagus nerve before identification of RLN. Equipment failure was considered if a V_1 signal could not be elicited.

Step 2: R_1 signal—the signal was obtained from the RLN, which was first identified at the tracheoesophageal groove.

Step 3: R_2 signal—the signal was obtained by stimulating its most proximally exposed portion after the Berry's ligament was completely dissected out from RLN.

Step 4: V_2 signal—the final testing of vagus nerve was performed after complete hemostasis of the surgical field. The stimulation level and event threshold of R_1, R_2, and V_2 signals were the same as those of V_1 signal.

Interpretation of signals

Unchanged signal

V_1, R_1 signals and R_2, V_2 signals were obtained successfully with the same stimulation level during the operation, and there was no apparent change between the comparisons: the R_2 signal compared with R_1 signal and the V_2 signal compared with V_1 signal.

Loss of signal

The original signal was obtained from the vagus nerve, but it could not be elicited from RLN or vagus nerve after dissection of RLN.

When R_2 and V_2 signals were lost after complete dissection of the RLN, this meant that the RLN may have been injured during manipulation. An effort was made to identify the disrupted point of nerve conduction and elucidate the mechanism of injury. The disrupted point of nerve conduction would be located by the following procedures: (a) The RLN was tested from the distal portion of RLN at the entry to the larynx. If a signal was obtained, the lower portion of nerve was tested until a response could not be elicited. (b) Conversely, the RLN was tested from the proximal portion of the exposed nerve, and then the upper portion until response was elicited. Thus, the disrupted point of nerve conduction could be located and even pinpointed.

Documentation

Laryngeal examination

All patients received preoperative and postoperative video recording of vocal cord movement with flexible laryngofibroscopy. When asymmetric cord movement was found postoperatively, a comparison with the preoperative recording was performed. When vocal dysfunction was identified, follow-up was each 2 weeks initially and every 4 weeks thereafter until recovery was achieved. Dysfunction was considered permanent if it persisted for 6 months subsequent to surgery. RLN palsy in this study was defined as impaired or fixed cord movement noted by postoperative laryngofibroscopy.

Visual integrity of RLN

All exposed RLNs were photographically documented with a high-resolution camera to show visual nerve integrity during the operation.

Functional integrity of RLN

Functional nerve integrity was documented with the registration of EMG signals (four-step procedures: V_1, R_1, R_2, V_2 signals).

Results

During period 1 of this study, five patients (4.4%) encountered dysfunction of IONM, which was caused by malposition of electrodes, and the problem was detected at once because V_1 signal could not be elicited. After adjustment of tube depth, all patients were finally under successful IONM (Table 2). During period 2, no instance of IONM dysfunction occurred. One patient with non-RLN was suspected at the earlier stage of the operation because V_1 signal could not be elicited. After reconfirming that the IONM system was working, the V_1 signal was finally elicited from the upper neck position and the non-RLN was detected.

In this study, there were 417 nerves with unchanged R_2 and V_2 signals, and all cases showed normal vocal function postoperatively. The remaining 18 nerves (16 nerves in period 1; 2 in period 2) experienced loss of EMG signals, and the causes of nerve injuries were well elucidated with the application of our standard procedures of IONM (Table 2). One nerve injury in period 1 was due to inadvertent transection, which led to permanent RLN palsy. Among the remaining 17 nerves, one injury was caused by connective tissue constriction, which was detected precisely and released intraoperatively, 2 by inadvertent clamping, and 14 by overstretching at the region of Berry's ligament (6 nerves regained signals before closing the wound, but 2 showed weakened signals and developed

Table 2 Comparison of the equipment failure rate during IONM and the mechanism of EMG signal loss and RLN palsy after thyroidectomy between the two study groups

	Period 1 (n = 113, NAR = 173)	Period 2 (n = 176; NAR = 262)	P[a]
Initial equipment failure (no. of patient)	5 (4.4%)[b]	0 (0%)	–
EMG signal loss (no. of nerve)	16 (9.2%)	2 (0.8%)	<0.001
Mechanism (transection/constriction/clamping/stretching)	(1/1[c]/2/12[d])	(0/0/0/2[e])	
RLN palsy (no. of nerve)	11 (6.4%)	2 (0.8%)	0.001
Mechanism (transection/constriction/clamping/stretching)	(1[f]/0/2/8)	(0/0/0/2[g])	

RLN palsy was defined as impaired or fixed cord movement noted by postoperative laryngofibroscopy

IONM intraoperative neuromonitoring, *RLN* recurrent laryngeal nerve, *NAR* no. of nerves at risk

[a] Two-sided χ^2 test

[b] All were caused by malposition of electrodes, and all patients were finally under successful IONM after adjustment of tube depth and rotation

[c] R_2 and V_2 signals fully recovered after resection of the constricting band; the patient had normal vocal movement after operation

[d] Five nerves experienced loss of signal; four nerves regained the signal completely before closing the wound and show normal vocal function. The other nerves also regained the signal but showed weakened signal and developed impaired cord movement after operation

[e] One nerve regained a weaken signal and developed impaired cord movement after operation

[f] The only nerve with permanent RLN palsy in this study. The nerve was mistaken as the inferior thyroid artery and was transected during dissection of a large goiter at the beginning of our using IONM

[g] One nerve underwent the third operation for large recurrent goiter and another one due to adhesion to thyroid cancer

impaired cord movement. Another 8 nerves did not regain signals before closing the wound; all developed temporary cord palsy).

Although it showed no significant difference between periods 1 and 2 when comparing the difficulty of thyroid operation (Table 1), the signal loss rates after resection of thyroid were significantly reduced from 9.2% to 0.8% ($P < 0.001$) and the RLN palsy rates also were significantly reduced from 6.4% to 0.8% ($P = 0.001$), comparing the patients in period 1 with those in period 2 (Table 2). No permanent RLN palsy occurred in period 2.

Discussion

Similar to EMG monitoring of the facial nerve, which is commonly placed in surgery of temporal bone and parotid gland, IONM during thyroid operations is gaining acceptance. However, several pitfalls and lack of standardization continue to limit the utility of this technology [11, 21]. In this study, we applied our standardized procedures (summarized in Table 3) for patients undergoing thyroid operations with IONM. We found that these standardized procedures are useful and helpful to eliminate false IONM results and to elucidate the mechanism of RLN injury (Table 2). The rates of signal loss and RLN palsy were significantly reduced after ascertaining the surgical pitfalls and improving the surgical technique (Table 2).

Table 4 Potential advantages of four-step procedure for IONM during thyroid surgery

(1) It can confirm the monitoring system is working and normal pathway of RLN as V_1 signal was elicited[a]

(2) It provided original data by stimulating vagus nerve[b,c]

(3) It provided data that would be very useful to compare the signals before and after dissection of RLN

(4) It can elucidate where and how the nerve was injured by testing the vagus nerve and RLN at each step

(5) It can confirm a functional RLN in which RLN identification is frustratingly difficult and dangerous

[a] Equipment failure or non-RLN should be considered if V_1 signal could not be elicited

[b] Such as the stimulation level and the intensity of evoked potential of V_1 signal

[c] Stimulation level used to elicit an EMG response from vagus nerve can definitely elicit response from RLN and the intensity of signal would generally be greater than that from vagus nerve

In this study, we routinely used the four-step procedure of IONM [14], and we find that it has several advantages (summarized in Table 4). For example, five patients who encountered equipment failure in period 1 and one patient who had non-RLN in period 2 of this study were all detected early by testing the vagus nerve at the beginning of the operation (step 1). One of the other advantages of the four-step procedure is that it can help to elucidate the surgical pitfalls and help to improve the surgical

Table 3 Standard of procedures for IONM begins with the preoperative and ends with the postoperative video-recording of cord mobility

Procedures	Remarks
Preoperative video-recording of cord mobility	With flexible laryngofibroscopy
Assuring the functional setup of the monitor system	
Check the impedance and impedance imbalance	Impedance <5.0 kΩ and impedance imbalance <1.0 kΩ
Check the presence of normal base lines	Waveform amplitudes around 10 μV
Check the proper position of electrodes	Laryngofibroscopic examination after neck extension
Four-step procedure	
Step 1, V_1 signal	Signal was obtained from vagus nerve before identification of RLN
Step 2, R_1 signal	Signal was obtained from the RLN at the tracheoesophageal groove
Step 3, R_2 signal	Signal was obtained from the proximal portion of RLN after complete dissection
Step 4, V_2 signal	Signal was obtained from vagus nerve after complete hemostasis
Interpretation of signals	
Unchanged R_2 and V_2 signals	Functional integrity of the RLN
Loss of R_2 and V_2 signals	RLN may have been injured during manipulation
	Identify disrupted point and elucidate the mechanism of injury[a]
Photographic documentation of the exposed RLN	Visual integrity of the RLN
Postoperative video-recording of cord mobility	If asymmetric cord movement is found, compare with preoperative recording

1. Check the twitch of larynx by laryngofiberscopy during nerve stimulation

2. Retest the vagus nerve and RLN before closing the wound

[a] Confirm the true signal loss if no disrupted point could be detected

techniques. In this study, there were 18 nerves (16 nerves in period 1; 2 in period 2) with loss of EMG signals, and the causes of nerve injury were well elucidated by this four-step procedure (Table 2). Among the 16 nerves with injury in period 1, 12 (75%) were caused by overstretching the RLN at the region of Berry's ligament. Thus, we changed the RLN approach to an early identification at the level of inferior thyroid artery in period 2. All RLNs were localized and early identified at the tracheoesophageal groove before lateral dissection of thyroid lobe. Using this approach, excessive traction on the thyroid can be avoided, and we found that the signal loss rate and RLN palsy rate was significantly reduced compared with period 1 of this study. Only two RLNs (0.8%) developed temporary palsy and both were associated with inevitable stretch injury: one nerve which underwent the third operation for large recurrent goiter, and another one due to adhesion to thyroid cancer. No permanent RLN palsy occurred.

In this study, we also found that the loss of EMG signals caused by overstretching can regain full, partial or no recovery, and the outcome of cord mobility can be normal, weakened, or fixed. Among 14 nerves with stretch injury, 4 nerves (29%) regained full recovery of EMG signal and showed normal vocal function after operation; another 2 nerves regained partial recovery and showed weakened cord mobility; the other 8 nerves, which did not regain the signal before closing the wound, all showed fixed vocal cord. In our experience, the nerve with a disrupted point of nerve conduction must be a cord paralysis. If the nerve lost EMG signal and no disrupted point could be detected, the first thing we would do is check the monitoring system to exclude the possibility of equipment dysfunction, and then check the twitch of larynx by laryngofiberscopy (Fig. 1) to ensure the true loss of EMG signal. Before closing the wound, we will retest the vagus nerve and RLN to detect the possible recovery of EMG signal (Table 3).

Several potential pitfalls of IONM have been reported, such as equipment malfunction (defect in the device or electrodes), improper setup of equipment, misuse of muscle relaxant, anatomic variations of RLN, shunt stimulus, which can cause misleading information, among them monitoring setup problems are the most common cause of false IONM results [22–24]. In the series by Beldi et al. [16], the monitoring failed in 39 (23%) procedures among 296 operations. In the series by Chan and Lo [17], there were five patients with equipment failure and these patients were excluded from their study. In Snyder and Hendricks's series [11], there were nerve monitoring setup problems in 3.8% of cases (7/185), and four of these instances were of unknown causes.

In this study, malposition of electrodes was the main cause of equipment failure. The position of the electrodes could be displaced and not be detected when the patient's neck is changed from sniff position for tracheal intubation to full extension for thyroid operation. The presence of normal baseline, impedance <5.0 kΩ and impedance imbalance <1.0 kΩ, only suggests proper connection of wires and good electrode-mucosa contact; however, this does not mean that the IONM is working [25]. Five patients (4.4%) of period 1 encountered dysfunction of IONM that was caused by malposition of electrodes, although all patients had normal baseline and impedance. These patients were finally under successful IONM after adjustment of tube depth. No patient in period 2 encountered dysfunction of IONM after we routinely checked the electrodes position with laryngofibroscopy as the neck was placed at full extension. Thus, being certain of the correct position of electrodes before using IONM is extremely important.

In this study, we found that preoperative and postoperative video-recording of vocal movement is essential to evaluate the vocal function before and after operation. We experienced two instances of asymmetric cord movement after operation, but, after comparison, it showed the same as the preoperative condition. Furthermore, two patients with weakened cord mobility in this study both were asymptomatic. Therefore, symptomatic assessment of vocal cord paralysis is notoriously inaccurate, as noted previously. Variability of symptoms in patients who have unilateral paralysis is well known. It is generally believed that up to 30% or 40% of patients with unilateral RLN paralysis are asymptomatic [26, 27], and many patients with postoperative hoarseness may not have vocal cord paralysis [6]. Recognition of preoperative vocal cord paralysis is essential if the surgeon is to reduce the risk of contralateral injury and bilateral cord paralysis [28]. Therefore, all patients need to have preoperative and postoperative laryngeal examination, best assisted with video-recording, if the true rate of RLN injury is to be appreciated.

Intraoperative verification of functional and anatomical RLN integrity is a prerequisite for a safe thyroid operation. In this study, all exposed RLNs were electromyographically documented with intraoperative neuromonitoring (IONM) to show functional nerve integrity, and all nerves were photographically documented with a high-resolution camera to show anatomical nerve integrity during the operation. In addition, we revealed several anatomical variations of RLN in the form of high-resolution photographs, which were very informative for ascertaining the surgical pitfalls and improving our surgical techniques.

Conclusions

The standardized IONM procedures are useful and helpful not only to eliminate false IONM results but also to elucidate the mechanism of RLN injury. After elucidating the mechanism of RLN injury and changing the way of RLN approach, the palsy rate was significantly reduced in this study. Standardized IONM procedures include pre- and postoperative video-recording of cord mobility, ensuring the correct position of electrodes with laryngofibroscopy after full extension of the neck, vagal stimulation, and registration of EMG signal before and after dissection of RLN, and photographical documentation of exposed RLN.

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