







ORIGINAL RESEARCH

Intraoperative nerve monitoring in thyroid surgery: Analysis of recurrent laryngeal nerve identification and operative time

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Funding information

Mahidol University, Grant/Award Number: R01632020

Abstract

Objective: To evaluate the clinical value of intraoperative nerve monitoring (IONM) by comparing the procedure times for thyroidectomies performed with and without IONM.

Methods: A prospective, randomized, controlled study was conducted on 32 patients (representing 41 nerves at risk) undergoing thyroidectomies carried out by two experienced head and neck surgeons (CC & WP). Sixteen thyroidectomies were performed without IONM (the “non-IONM group”), while 16 thyroidectomies were performed with IONM (the “IONM group”). The measured datapoints were setup time, time to visual identification of the recurrent laryngeal nerve (RLN), time to confirm the RLN electrophysiologically, dissection time, and total operative time.

Results: With both surgeons, the IONM group had shorter visual times to RLN identification than the non-IONM group (CC: 3.7 minutes vs 5.3 minutes; WP: 3.4 minutes vs 9.7 minutes). Additionally, the electrophysiological identification time for the IONM group was shorter than the visual identification time for the non-IONM group. The setup times, dissection times, and total operative times of the 2 groups did not significantly differ ($P > .05$). No RLN injuries were observed.

Conclusions: IONM reduces the time needed for RLN identification in thyroidectomies. Functional RLN confirmation can reassure surgeons of the operative results. Moreover, use of IONM does not significantly impact setup and total operative times.

Level of evidence: 2.

KEYWORDS

intraoperative nerve monitoring (IONM), operative time, recurrent laryngeal nerve (RLN), thyroid surgery, visual identification of RLN

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1 | INTRODUCTION

Thyroidectomy is a common head and neck operation that has used steadily improving surgical techniques over the years to reduce its complication rate.¹ Injury to the recurrent laryngeal nerve (RLN) results in vocal fold paralysis, leading to dysphonia, aspiration problems, or even upper-airway obstruction.² The gold standard for RLN protection during a thyroidectomy is visual identification and meticulous dissection of the RLN.³ Despite careful anatomical identification, RLN injury still occurs temporarily in 2% to 8% of cases, and permanently in 0.5% to 3%.⁴ Thus, a visually intact RLN does not necessarily translate into a functionally normal RLN.

Several decades ago, an endotracheal tube (ETT)-based surface electrode was introduced with the potential to become the standard method for intraoperative nerve monitoring (IONM) during thyroid surgery. Advantageously, the technique is non-invasive, has proven reliability and is user friendly. It allows the mapping and localization of the RLN prior to direct visualization, as well as the checking and documenting of the nerve function during and after nerve dissection.⁵ The usage of IONM for thyroid surgery has gained worldwide acceptance.⁶ Still, controversy persists over the clinical value of IONM in thyroid surgery. A study by Barzynski et al found that IONM significantly reduces the rate of transient RLN injuries, but not that of permanent injuries.⁷ Sari et al⁸ demonstrated that the RLN identification time is significantly shortened with IONM, but the impact of IONM

on the total operative time was found to be inconclusive by another study.⁹ On the other hand, the use of IONM by inexperienced surgeons has been reported to be particularly beneficial, especially for high-risk surgical cases.¹⁰ Hence, the current research aimed to assess the efficiency of IONM in thyroid surgery. We hypothesized that IONM would reduce the RLN identification and dissection times, thereby lowering the overall operative time for thyroid surgery.

2 | METHODS

This was a prospective, randomized, controlled study on patients with thyroid diseases who underwent thyroidectomies at the Department of Otorhinolaryngology, Faculty of Medicine Siriraj Hospital. The operations were performed by two experienced head and neck surgeons (CC and WP). The study was approved by the Institutional Review Board, Faculty of Medicine Siriraj Hospital, Mahidol University, and registered with the Thai Clinical Trials Registry.

2.1 | Study population

The clinical trial was conducted from January 2018 to April 2019. The sample size calculation was based on the study being a superiority trial with a difference of 7 ± 3 minutes in the mean RLN identification

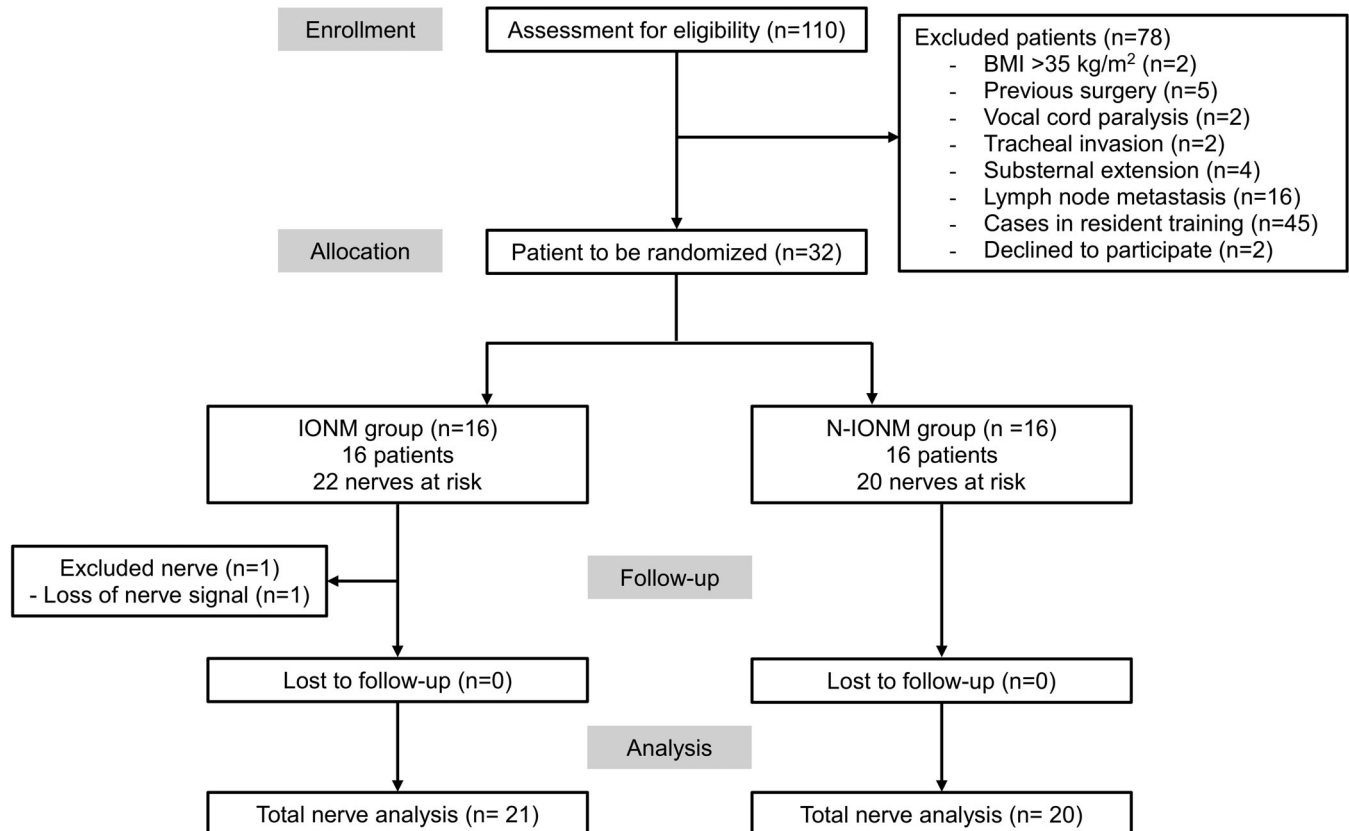


FIGURE 1 Patient enrollment flow based on the CONSORT statement guidelines

times of the IONM and N-IONM groups (as reported by Sari et al—the mean \pm SD times of the IONM and N-IONM groups were 4.1 ± 1.1 and 11.2 ± 2.5 minutes, respectively).⁸ Based on a 2-sample *t*-test, a 2-sided type I error of 0.01, and a 90% power, a sample of 8 patients per group was required. As there were 2 experienced surgeons, a total of 32 patients were needed. In all, 110 adult patients requiring surgical treatment due to thyroid diseases were eligible for enrollment. The inclusion criteria were multinodular goiter, Graves' disease, toxic adenoma, single adenoma, and well-differentiated thyroid cancer. The exclusion criteria were patients with (a) vocal cord dysfunction; (b) a history of previous surgery or radiation at the neck; (c) clinical lymph node metastasis; (d) a possible extension of the carcinoma to the trachea or RLN; (e) obesity class 2 or higher (BMI > 35 kg/m²); or (f) a substernal extension. Also excluded were cases utilized for resident training. All study subjects were fully informed of the treatment options before signing informed-consent forms. Eventually, 32 patients were recruited; they were allocated by stratified block randomization into an “IONM group” (intraoperative nerve monitoring) and a “non-IONM group” (conventional technique), as illustrated in Figure 1. The preoperative and postoperative vocal cord functions of the patients were routinely examined using a 70° or 90° telescope.

2.2 | Anesthesia methods

The thyroidectomies were performed under general anesthesia with ETT intubation. With the IONM group, a short-acting muscle relaxant

was applied only at the beginning. The IONM procedures utilized the IONM system, NIM-Response 3.0 (Medtronic Ireland Ltd., Dublin, Ireland), and the NIM Trivantage electromyography (EMG) endotracheal intubation tube (Medtronic Xomed Inc, Jacksonville, Florida). Videolaryngoscopy was used for intubation and confirmation of the ETT electrode position relative to the vocal fold before draping. In all cases, the circuit was confirmed by the production of an appropriate EMG signal.

2.3 | Conventional thyroidectomy (non-IONM group)

A standard collar incision was made through the skin and subcutaneous tissue. The superior and inferior subplatysmal flaps were elevated. The strap muscles were then separated and retracted laterally before the superior thyroid vessels were identified and ligated. The thyroid lobe was bluntly dissected from its investing layer and rotated medially, and the middle thyroid vein was ligated. The RLN was subsequently identified by dissection in the tracheoesophageal groove, and the nerve was gently delineated to its point of entry to the larynx. Following that, the superior and inferior parathyroid glands were identified and preserved, with at least one parathyroid gland with an intact blood supply being preserved in all cases. Finally, the thyroid lobe was removed from its tracheal attachment by dividing the ligament of Berry. Throughout the procedure, only cold dissection, traditional knot tying, and electric cauterization (monopolar and bipolar) were

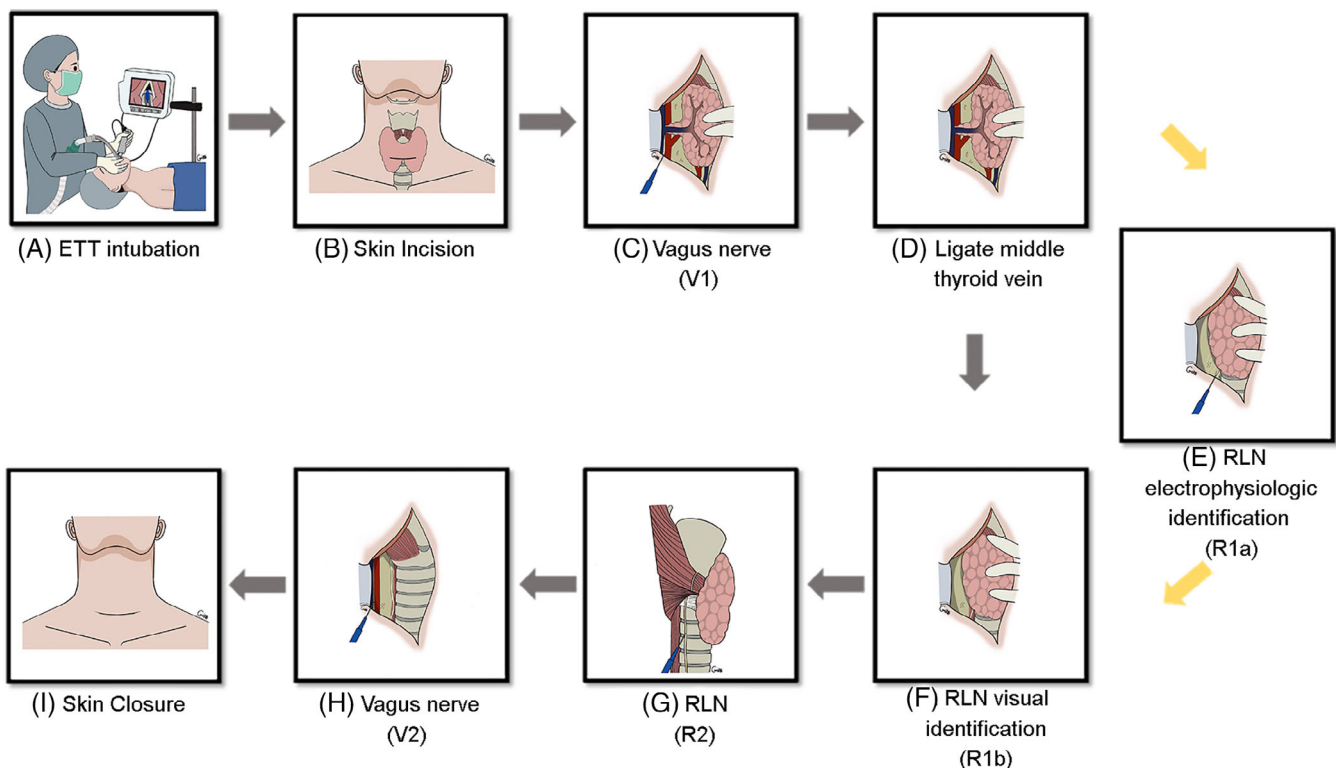


FIGURE 2 Protocol for data collection at specified intraoperative times. ETT, endotracheal tube; RLN, recurrent laryngeal nerve

used. No surgical vessel-sealing devices (such as Harmonic, LigaSure, or Thunderbeat) were used for the dissections.

2.4 | Intraoperative nerve monitoring (IONM group)

The surgical procedures for the IONM group were the same as those for the non-IONM group, other than the following four additional steps being incorporated.¹¹ In the first step (V1-signal), the ipsilateral vagus nerve was stimulated before the middle thyroid vein was ligated and the RLN was identified. As to the second step (R1-signal), the RLN was stimulated to achieve primary identification. This step was newly divided into R1a (in which the RLNs were electrically identified through the tissue surrounding the course of the RLNs by a 2-mA stimulation) and R1b (wherein the RLNs were visually identified and confirmed by a 1-mA stimulation). The third step (R2-signal) involved stimulation of the

RLN once it had been completely dissected. The final step (V2-signal) was to stimulate the vagus nerve after hemostasis. In accordance with the International Neural Monitoring Study Group Guideline,¹¹ an impending adverse EMG event was defined as an amplitude decrease of >50% of the initial baseline value, while an adverse EMG event was defined as an amplitude of <100 μ V. The troubleshooting protocol described in the standard guidelines was also applied in this study.

2.5 | Data collection

Figure 2 presents the protocol for the time points when intraoperative data were collected. The following parameters were collected: setup time (the period from intubation to incision; A to B); electrophysiological identification time (the period from middle thyroid vein ligation to R1a; D to E); visual identification time (the period from middle thyroid vein ligation to R1b; D to F); primary identification time (the period from middle

TABLE 1 Demographic data and characteristics of 32 patients undergoing thyroidectomies

	Surgeon: CC		P-value	Surgeon: WP		P-value
	N-IONM (n = 8)	IONM (n = 8)		N-IONM (n = 8)	IONM (n = 8)	
Age ^a (year) (min, max)	41.5 (20, 55)	49.5 (28, 60)	0.234	36.5 (18, 65)	47 (27, 61)	0.279
Gender (female:male)	7:1	7:1	1.00	5:3	8:0	0.200
BMI ^a (kg/m ²) (min, max)	22.6 (17.4, 30)	23.4 (17.1, 30.4)	0.574	26.4 (19, 35)	26.1 (19.4, 35)	0.959
Operation						
Hemithyroidectomy	5	6	0.931	7	4	0.788
Total thyroidectomy	3	2	0.200	1	4	0.400
Nerves at risk						
Right	6	7		4	3	
Left	5	3		5	8	
Thyroid gland weight ^a (g) (min, max)	20.5 (9, 76)	16 (9, 36)	0.574	47 (18, 116)	119 (10, 179)	0.234
Largest diameter of each lobe ^a (cm) (min, max)	5.4 (4.5, 8)	5.2 (3.8, 6)	0.468	6 (5, 8)	7.5 (4.5, 9.5)	0.056
Blood loss ^a (mL) (min, max)	40 (20, 100)	27.5 (20, 50)	0.382	17.5 (5, 30)	40 (10, 200)	0.051
Pathology						
Benign	2	4		4	2	
Graves' disease	-	-		-	1	
PMC	1	3		2	3	
PTC	4	1		1	2	
FTC	1	-		1	-	
Complications						
Nerve paresis	0	0		0	0	
Nerve paralysis	0	0		0	0	
Hypoparathyroidism	0	0		0	0	
Transient hypocalcemia	1	0		0	1	
Permanent hypocalcemia	0	0		0	0	

Abbreviations: FTC, follicular thyroid carcinoma; IONM, intraoperative nerve monitoring group; N-IONM, non-intraoperative nerve monitoring group; PMC, papillary microcarcinoma; PTC, papillary thyroid carcinoma.

^aMedian.

thyroid vein ligation to either R1a in IONM or R1b in non-IONM; D to E or F); dissection time (the period from R1b to R2; F to G); and total operative time (the period from skin incision to skin closure; B to I).

2.6 | Follow-up

Both groups received the same postoperative management and follow-up. The initial postoperative laryngoscopy was performed within 2 weeks of the surgery. The minimum follow-up time was 6 months. A “transient RLN injury” was defined as a vocal cord paresis or paralysis that recovered within 6 months of the surgery. A

“permanent RLN injury” referred to a vocal cord paralysis persisting beyond 6 months from the surgery.

2.7 | Statistical analysis

Demographic data are presented using descriptive statistics. The Mann-Whitney *U* test was applied to test the differences in the time frames of the IONM and non-IONM groups for each surgeon. Pearson's correlation was used to test the association between the size of the thyroid gland and the operative time. A multiple linear regression was conducted to assess the relationship between the operative time and

TABLE 2 Results of various intraoperative times

Time ^a (min)	Surgeon: CC		P-value	Surgeon: WP		P-value
	N-IONM (n = 8)	IONM (n = 8)		N-IONM (n = 8)	IONM (n = 8)	
Setup (min, max)	15.3 (12, 18)	16.1 (13.8, 19.9)	.574	13.6 (9.8, 17.5)	14.6 (9.3, 19)	.574
Visual identification (min, max)	5.3 (1.5, 8.2)	3.7 (1.2, 6)	.050*	9.7 (4.6, 27.4)	3.4 (0.8, 19.3)	.002*
Primary identification (min, max)	5.3 (1.5, 8.2)	1.1 (0.6, 2)	<.001*	9.7 (4.6, 27.4)	1.6 (0.3, 9.3)	<.001*
Dissection (min, max)	25 (9.6, 45.1)	24.1 (13.9, 58.9)	.705	3.1 (2, 18.3)	6 (3.2, 14.3)	.065
Total operative						
Unilateral	116.8	113.7	0.931	86.6	74.4	0.788
(min, max)	(98, 131.1)	(99.2, 152.1)		(57.1, 98.5)	(58.5, 122.3)	
Bilateral	180.1	131.9	0.200	129 ^b	105.1	0.400
(min, max)	(154.5, 187.3)	(124.1, 139)			(95.8, 124.7)	

Abbreviations: IONM, intraoperative nerve monitoring group; N-IONM, non-intraoperative nerve monitoring group.

*P-value less than .05 considered statistically significant.

^aMedian.

^bNo min, max as there was only one data item for that category.

	Surgeon: CC		Surgeon: WP	
	R	P-value	r	P-value
<i>Correlation analysis: various intraoperative periods and largest diameter of each lobe</i>				
Visual identification time, largest diameter	-0.140	.545	0.073	.761
Primary identification time, largest diameter	-0.326	.149	0.034	.887
Dissection time, largest diameter	0.314	.166	0.780	<.001*

Abbreviation: r, correlation coefficient.

*P-value less than .05 considered statistically significant.

TABLE 3 Correlation analysis of various intraoperative times and the largest diameter of each thyroid lobe

TABLE 4 Multiple linear regression analysis of various intraoperative times

	Surgeon	Visual identification time		Primary identification time		Dissection time	
		b	P-value	b	P-value	b	P-value
Surgeon	CC	—	—	—	—	—	—
	WP	2.453	.193	3.169	.053	-22.659	<.001*
Technique	N-IONM	—	—	—	—	—	—
	IONM	-4.949	.002*	-6.946	<.001*	0.868	.775
Largest diameter of each lobe (cm)		0.805	.173	0.560	.268	1.320	.258

Abbreviations: b, linear regression coefficient; IONM, intraoperative nerve monitoring group; N-IONM, non-intraoperative nerve monitoring group.

*P-value less than .05 considered statistically significant.

several independent variables. A *P*-value of $<.05$ was considered statistically significant. The statistical analyses were performed using PASW Statistics software (version 18; SPSS Inc, Chicago, Illinois).

3 | RESULTS

In all, 32 patients (27 women and 5 men), aged 18 to 65 years (mean 43.3 ± 12.5 years), were included. There were 41 nerves at risk (20 right-RLNs and 21 left-RLNs). Statistical analyses were conducted separately for each of the two surgeons. The baseline demographic data, operation techniques, patient characteristics, and cytological and pathological results are detailed in Table 1.

3.1 | Operative times

Both surgeons required less visual identification time for the IONM group than the non-IONM group (CC: 3.7 minutes vs 5.3 minutes; WP:

TABLE 5 Multiple linear regression analysis of total operative time

	Total operative time	
	<i>b</i>	<i>P</i> -value
BMI (kg/m ²)	1.112	.270
Surgeon		
CC	—	—
WP	−47.148	<.001*
Technique		
N-IONM	—	—
IONM	−10.580	.149
Operation		
Lobectomy	—	—
Total thyroidectomy	38.146	.001*
Weight (g)	0.1	.383
Blood loss (mL)	0.009	.940
Pathology		
Benign	—	—
PMC	−2.518	.783
Malignant	1.701	.871

Abbreviations: *b*, linear regression coefficient; IONM, intraoperative nerve monitoring group; N-IONM, non-intraoperative nerve monitoring group; PMC, papillary microcarcinoma.

**P*-value less than .05 considered statistically significant.

TABLE 6 Electrophysiological data

Side	Amplitude (μV): median (min, max)				
	V1	R1a	R1b	R2	V2
Right (n = 10)	554 (300, 1248)	986 (411, 2114)	927 (289, 1811)	601 (295, 1621)	361 (268, 1031)
Left (n = 11)	540 (386, 1249)	898 (316, 1437)	952 (444, 1358)	849 (240, 1255)	492 (282, 1560)

3.4 minutes vs 9.7 minutes), and less primary identification time for the IONM group than the non-IONM group (CC: 1.1 minutes vs 5.3 minutes; WP: 1.6 minutes vs 9.7 minutes). The setup times, dissection times, and total operative times of the IONM and non-IONM groups did not differ significantly ($P > .05$; Table 2). Pearson's correlation was applied to determine the dependence of the operative time on the size of thyroid gland. While the largest diameter of each lobe demonstrated no correlation with either the visual identification or primary identification times, there was a correlation with the dissection time for surgeon WP ($r = 0.780$; $P < .001$; Table 3). Table 4 presents the factors found by a multiple linear regression analysis to be related to the operative time. Significantly, IONM reduced the visual identification and primary identification times by around 5 and 7 minutes ($P = .002$ and $P < .001$), respectively. As to the dissection time, surgeon WP was 23 minutes faster than CC ($P < .001$). Nonetheless, IONM yielded no effect on the dissection time ($P = .775$).

The multiple regression analysis showed that not only the surgeon but also the type of operation significantly affected the total operative time (Table 5). Surgeon WP was 47 minutes faster than CC ($P < .001$), while the total thyroidectomies took 38 minutes longer, on average, than the hemithyroidectomies ($P = .001$). Although IONM reduced the total operative time by 10.6 minutes compared with that for the non-IONM procedure, the difference was not statistically significant ($P = .149$).

3.2 | Electrophysiological data

The median amplitudes of V1, R1a, R1b, R2, and V2 were recorded for each side of the RLNs (Table 6). No impending adverse EMG or adverse EMG events were observed.

3.3 | Complications

No intraoperative RLN injuries were observed. There was only one case of EMG signal loss during a total thyroidectomy. As the time needed to solve the technical difficulty was longer than 15 minutes (the time specified for the withdrawal of a case from the study), the data for the affected side was excluded. After correction of the ETT placement, the time for the other side of the thyroid gland was successfully monitored, and the related time frames were included in the study. The postoperative laryngoscopies demonstrated normal vocal cord functions in all cases. The mean follow-up time was 18 months. Two subjects (1 CC and 1 WP) experienced transient hypocalcemia with a normal parathyroid hormone level; a small dose of a calcium supplement was prescribed for each patient. Both hypocalcemia cases

completely recovered within approximately 1 month, following which the calcium supplements were discontinued.

4 | DISCUSSION

The use of IONM in thyroid and parathyroid surgery is well established and is becoming increasingly accepted worldwide.^{12,13} The utilization of IONM with a stimulation probe and an ETT-based surface electrode has been found to be convenient and safe.¹⁴ According to the 2015 guidelines of the American Thyroid Association, IONM can be used to facilitate nerve identification and confirm intact neural function.¹⁵ Moreover, the American Head and Neck Society has recommended the use of IONM on patients with thyroid cancer.¹⁶ In the current study, we performed a standard thyroidectomy for both the IONM and non-IONM groups, and we employed identical surgical steps to ensure that the time measurements were consistent and accurate (Figure 2). As per the conventional technique, four-step nerve monitoring (V1 + R1 [R1a and R1b] + R2 + V2) was utilized for the IONM group. The “identification time” was subclassified into the “electrophysiological identification time” (R1a) and “visual identification time” (R1b). With both surgeons, the electrophysiological identification time and the visual identification time were significantly shorter for the IONM group than the direct visualization time for the non-IONM group (Table 2). Thus, it can be safely concluded that the use of IONM beneficially facilitated RLN identification.

Despite the efficiency of IONM in shortening the operative time for thyroid surgery having been assured by several studies, it remains inconclusive. Sari et al⁸ conducted a prospective, randomized, controlled study on 237 patients (409 nerves at risk) using a single group of surgeons. The results demonstrated that the identification and total operative times for the IONM group (4.05 ± 1.1 minutes and 65.4 ± 31 minutes, respectively) were significantly shorter than the corresponding times for the non-IONM group (11.2 ± 2.5 minutes and 79.1 ± 30 minutes). In that study, the term “identification time” was defined as the duration from the beginning of the RLN dissection in the tracheoesophageal groove to the completion of the dissection, while “total operative time” was defined as the period from skin preparation to skin closure. However, the extent of the surgeries (unilateral and bilateral thyroidectomy) was not clearly stated.

In another retrospective study on 82 patients by Zhao et al, the identification time was defined as the period needed between the V1 and R1 signals to achieve RLN identification; the IONM-identification-time range was 0.5 to 2 minutes.¹⁷ A meta-analysis by Pitsanu et al⁹ found that the mean total operative time for total thyroidectomies in the IONM group (97.6 minutes) was longer than that for the non-IONM group (94.6 minutes), but without a statistically significant difference. Even though the operative time for the IONM group was longer (due to extra time being needed by the anesthesiologist to position the ETT electrode), less than 5 to 10 minutes was required for setting up and troubleshooting. Miller et al¹⁸ found that the setup time was minimized when the RLN was routinely monitored; moreover, those researchers found that, with experience, the setting up of the system could be as quick as with the conventional technique. This

is likely why IONM yielded no significant effects on the total operative times in the previous studies. Our results showed that as the team gained experience in preparing the monitoring system, the reductions in the setup time were comparable with those of Miller.

The usage of inconsistent definitions for operative times poses a challenge. For instance, the definition of “identification time” used in the studies by Sari and Zhao were not identical. Also, “total operative time” was sometimes employed for both hemithyroidectomies and total thyroidectomies, without distinguishing between the type of operation. By contrast, each period and surgery type were clearly delineated in our study, thereby enabling the various time frames to be applied to each surgery type in the IONM and non-IONM groups. In this study, we used the ligation and division of the middle thyroid vein as the starting time point for the identification of the RLN because that vein was a constant landmark. Dividing this vein before RLN identification is a standard operative technique in thyroid surgery¹⁹ as it provides good exposure in the tracheoesophageal groove, thereby enabling safe nerve dissection. However, electrophysiological identification might be performed at the beginning of a thyroid dissection in some situations, as described by Chiang et al.²⁰ This method could be beneficial in preventing injury to a RLN that is aberrantly located due to, for instance, a nonrecurrent laryngeal nerve or a distorted location resulting from an extrathyroidal invasion.

The results of the multiple linear regression showed that the RLN dissection time for surgeon WP was 23 minutes faster than that for surgeon CC, mainly due to the utilization of different techniques to preserve the parathyroid. Surgeon CC identified all possible parathyroid glands and performed the capsular dissection with preservation of the supplying vessels. In contrast, after parathyroid glands were identified and dissected laterally, surgeon WP focused on conducting the dissections along the tracheoesophageal groove to the point where the RLN entered the larynx. Nevertheless, the rates of postoperative hypoparathyroidism for the two surgeons did not differ. When other independent variables were controlled, there was a significant decrease in both the visual and primary identification times with IONM. Consequently, the surgeons were more confident about the early recognition of the RLN with IONM.

The multiple regression analyses also found that the total operative time of surgeon WP was 47 minutes faster than that of surgeon CC. The durations of the dissection times determined the total operative times of both surgeons. Moreover, the IONM had no effect on the dissection times of each surgeon, and it tended to decrease the total operative times by approximately 10 minutes; nonetheless, the differences were not statistically significant. The total operative and dissection times were within a time-frame range that could be affected by factors such as the parathyroid preservation techniques employed, the tumor characteristics, and the wound- and skin-closure techniques utilized. Hence, we propose that the visual and primary identification times were shortened following IONM for nerve identification and mapping.

While only a single case of EMG-signal loss was observed in this study, monitoring could still be continued on the other side of the thyroid gland after the ETT was repositioned. Thus, surgeons need to be fully familiar with the troubleshooting protocol to cope with

unexpected situations that may arise and to competently collaborate with the anesthesiology team.

There were a few limitations of the present study. Firstly, the sample size was smaller than those used by previous studies because it was based on work by Sari et al⁸ to determine the RLN identification time. In addition, the different techniques used by the two surgeons for the identification and preservation of the parathyroid glands may have affected their respective dissection times. To offset this limitation, the data analyses took the differences in the techniques into consideration.

5 | CONCLUSIONS

IONM is a promising tool for the identification and protection of the RLN during a thyroidectomy. Our findings showed that IONM significantly decreases the time needed to identify the RLN, and that IONM does not change the set-up and overall operative times. Early recognition of the RLN via IONM increases the confidence of surgeons, reduces the operative time for a thyroidectomy, and improves the safety of the procedure.

ACKNOWLEDGMENTS

The authors gratefully acknowledge Dr. Chulaluck Komoltree, PhD, of the Division of Clinical Epidemiology, Department of Health Research and Development, Faculty of Medicine Siriraj Hospital, Mahidol University, for her assistance with the sample size calculation and statistical analyses; Dr. Pariya Pinkaew, MD, of the Department of Otorhinolaryngology, Police General Hospital, for the medical illustration; and Jeerapa Kerdnoppakhun of the Department of Otorhinolaryngology, Faculty of Medicine Siriraj Hospital, for secretarial support.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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How to cite this article: Maneepprasopchoke P, Chongkolwatana C, Pongsapich W, Iwata AJ, Kamani D, Randolph GW. Intraoperative nerve monitoring in thyroid surgery: Analysis of recurrent laryngeal nerve identification and operative time. *Laryngoscope Investigative Otolaryngology*. 2021;6:354-361. <https://doi.org/10.1002/lio2.543>