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Evaluation of recurrent laryngeal nerve monitoring in thyroid surgery

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ABSTRACT

Aim: Thyroidectomy creates a potential risk for all parathyroid glands and nerves. Nerve identification has decreased the rates of nerve injury during thyroidectomy. Intraoperative nerve monitoring (IONM) has been used as an adjunct to the visual identification of the nerve. The aim of this clinical trial is to evaluate the effect of the identification time of RLN during thyroidectomy using IONM.
Method: Two hundred and thirty seven patients and 409 nerves at risk were enrolled in this prospective study. The nerves in Group 1 ($n = 210$) were identified with IONM, whereas the nerves in Group 2 ($n = 199$) were identified without IONM.
Result: The identification time of RLN and the operating time in patients of Group 1 were significantly lower than patients of Group 2. There was not any significant difference between postoperative complications of the groups. According to logistic regression analysis, the use of IONM was found to be the only determinant of the decrease of identification time of RLN.
Conclusion: Although the operating time was lower with IONM than with visualization alone, the shortened surgical time may not seem to have great clinical relevance. However, the shorter the nerve is identified the lower is the surgeon's level of stress. We think that it is important to use IONM to decrease the identification time of RLN in the course of thyroidectomy.
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1. Introduction

Thyroidectomy is one of the most frequent operations performed in iodine-deficient regions. The main postoperative complications are recurrent laryngeal nerve palsy and hypoparathyroidism. Although the overall incidence of nerve palsy is low, when it occurs, nerve palsy is a devastating life-long handicap.[1,2] The reported incidence of recurrent laryngeal nerve palsy varies from 0% to 14%.[1–5] Experienced surgeons can also inadvertently injure the nerve, resulting in persistent nerve palsy in about 1–2% of patients. It has long been accepted that anatomic identification of the RLN is the safest way of reducing nerve injury rates to a minimum.[1–5]

Most surgeons make their best efforts to prevent this complication. Neural monitoring has important uses as an adjunct to the visual identification of the nerve.[6,7] Several methods of nerve monitoring have been described cricothyroid muscle palpation during RLN stimulation, glottic observation of vocal cord movement during RLN stimulation by direct laryngoscopy or through fiberoptic nasopharyngoscopy, glottic pressure response monitoring of the endotracheal tube to stimulation of the RLN, intramuscular vocal cord electrodes and ultimately endotracheal tube surface electrodes that are placed in contact with the mucosa of the vocal cord.[6–11] The principle of the last generation IONM is the electronic registration of a signal of the vocal cord muscle after electrical stimulation of the vagus nerve or the RLN.

Several studies have shown that routine identification of the RLN with intraoperative neuromonitoring has decreased rates of permanent RLN palsy.[9,12–15] However, its role in reducing the frequency of RLN injury and the value of predicting postoperative RLN function remain controversial.[16–19]

The aim of this clinical trial is to evaluate the effect of the identification time of RLN during thyroidectomy using IONM and to suggest that IONM might effect the reduction of identification time of RLN. To our knowledge, this is the first study to evaluate the effect of the identification time of RLN during thyroidectomy using the IONM.

2. Material and methods

2.1. Patients

Two hundred and fifty-four consecutive patients with benign and malignant goiter disorders underwent thyroidectomy at the

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Department of General Surgery, Istanbul Medical Faculty, between September 2007 and September 2009.

The indications for surgical treatment were as follows: multinodular goiter ($n = 92$), multinodular toxic goiter ($n = 34$), Graves disease ($n = 21$), toxic adenoma ($n = 15$), solitary adenoma ($n = 34$), papillary carcinoma ($n = 41$). Exclusion criteria were as follows: the presence of preoperative cord dysfunction, reoperative surgery, retrosternal goiter, monitoring dysfunction (likely electrode displacemant), refusal to participate in this study. Sixteen nerves were excluded from this study (6 nerves had preoperative cord palsy; acoustic signal was not recorded in 10 nerves). Thus, in all, 237 patients and 409 nerves at risk were enrolled in this prospective study (Fig. 1).

Patients were randomly assigned to have RLNs identified by visualization alone or with intraoperative nerve monitoring during surgery. Patients were selected according to the number on the random table for two different groups. Randomization was performed by residents. The nerves in Group 1 ($n = 210$) were identified with IONM, whereas the nerves in Group 2 ($n = 199$) were identified without IONM. The study plan was reviewed and approved by our institutional ethical committee, and informed consent was obtained from all patients.

2.2. Technique

Thyroidectomies were performed by the same surgeons in all patients. Under general endotracheal anesthesia, the patient is placed in a supine position with the neck extended. A low collar incision is made and carried down through the subcutaneous tissue and platysma muscle. Superior and inferior subplatysmal flaps are developed, and the strap muscles are divided vertically in the midline and retracted laterally. The thyroid lobe was bluntly dissected free from its investing fascia and rotated medially. The middle thyroid vein was ligated. The superior pole vessels were ligated adjacent to the thyroid lobe. RLN was started to dissect in the tracheoesophageal groove. The nerve was gently unroofed from surrounding tissue. Once the nerve and parathyroid glands were identified and preserved, the thyroid lobe was removed from its tracheal attachments by dividing the ligament of Berry.

In IONM group, intubation was performed without aid of neuromuscular blockade. Endotracheal-based monitoring systems (eg, Medtronic NIM, Jacksonville, FL) are used to monitor the bilateral thyroarytenoid muscles for ongoing real-time EMG activity. Neural stimulation was performed with a disposable nerve with the current set at 1.5 mA. An original EMG signal was obtained from the vagus nerve before identification of RLN. Vagal stimulation is used to assess accuracy of tube placement before dissection near the recurrent laryngeal nerve. The stimulation level was set at 1.5 mA as a starting point and the event threshold at 100 mV. The signal was obtained from the RLN, which was first identified at tracheoesophageal Groove and the RLN was dissected completely from Berry's ligament. Equipment failure was considered if a signal could not be received at a level of 2 mA. The final testing of the vagus nerve was performed after complete hemostasis of the operative field. Body mass index (BMI) was calculated as the ratio of weight (kg) divided by height (m^2).

Following the ligation of the middle thyroid vein and superior pole vessels, the dissection of the RLN in the tracheoesophageal groove has been started. The identification time has been defined as the time period between the beginning of the search for the nerve in the tracheoesophageal groove and its complete dissection to the point where the nerve enters the larynx. A resident kept track of the time from the beginning to the ending. Operating time was defined as the time from skin preparation to closure of the skin incisions.

In all patients, indirect laryngoscopic examination was used to evaluate vocal cord motility both before and after surgery. In cases of dysphonia with vocal cord injury, indirect laryngoscopy was also performed 1 and 6 months later. Persistent nerve palsy was defined as persistent dysfunction and clinical dysphonia that lasted for 12 months postoperatively.

Age, gender, BMI, resected thyroid gland weight, the indications for thyroidectomy, thyroid pathology, identification time of RLN, operating time, postoperative complications (persistent or temporary RLN palsy and hypocalcemia) were recorded.

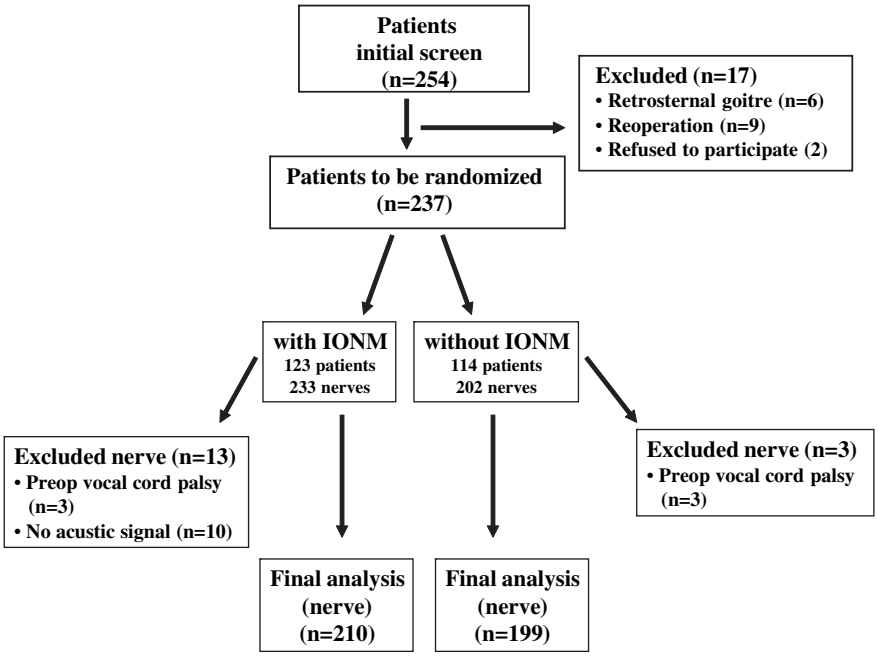


Fig. 1. Flowchart of enrolled and randomized patients.

2.3. Statistics

Data were analyzed using SPSS 11.0 for Windows. Results were expressed as mean ± SD. Comparisons of data were done by Wilcoxon-Signed ranks and the chi-squared test and logistic regression analysis. Logistic regression analysis was performed with operating time and identification time of RLN as the dependent variable. The following continuous variables were selected for the logistic regression model: Age, gender, BMI, resected thyroid gland weight, the indications for thyroidectomy, thyroid pathology, postoperative complications. Results were considered statistically significant when the two tailed p value was less than 0.05.

3. Results

3.1. Patients

In whole group, the mean age, F/M ratio, BMI, thyroid gland weight, identification time of RLN, operating time were 47.7 ± 13 years, 195/42, 27.1 ± 3 kg/m^2, 71.3 ± 39 g, 7.7 ± 4.6 min, and 71.9 ± 31 min, respectively. There was no operative mortality. The incidence of transient vocal cord paralysis and hypoparathyroidism were 2.5% and 10.1%, respectively. Persistent vocal cord paralysis and hypoparathyroidism were not encountered in our series. In all, 49 lobectomies, 178 total thyroidectomies, 10 total thyroidectomies and central neck dissection.

3.2. Evaluation of the patients according to with/without IONM

There were not any significant difference between age, gender, BMI, resected thyroid gland weight, the indications for thyroidectomy, the type of operations, thyroid pathology, postoperative complications of the groups ($p > 0.05$) (Table 1). The identification time of RLN and the operating time (4.05 ± 1.1 min and 65.4 ± 31 min) in patients of Group 1 were significantly lower than patients of Group 2 (11.2 ± 2.5 min and 79.1 ± 30 min) ($p = 0.001$) (Fig. 2).

3.3. Correlations

There was a negative correlation between the use of IONM and operating time ($r = -0.265$, $p = 0.04$), the identification time of RLN ($r = -0.857$, $p = 0.0001$). There was a positive correlation between thyroid gland weight and operating time ($r = 0.806$, $p = 0.0001$) (Fig. 3).

Table 1
A comparison of the features in the groups.

Parameters	Group 1 ($n = 123$) with IONM	Group 2 ($n = 114$) without IONM	p
Age (year)	47.2 ± 14	48.3 ± 12	NS
Female/Male ratio	104/19	91/23	NS
BMI (kg/m^2)	26.9 ± 3	27.3 ± 3	NS
Surgical indications (n)			
MNG	49	43	NS
MNT	18	16	
Graves disease	11	10	
TA	7	8	
SA	16	18	
Carcinoma	22	19	
Surgery (n;%)			
Lobectomy	100	88	NS
Total thyroidectomy	23	26	
Thyroid gland weight (g)	73.6 ± 41	66.8 ± 37	NS
Complications (n)			
Nerve palsy	3	3	NS
Hypoparathyroidism	11	13	

BMI: body mass index; MNG: multinodular goiter; MNT: multinodular toxic goiter; TA: toxic adenoma; SA: solitary adenoma

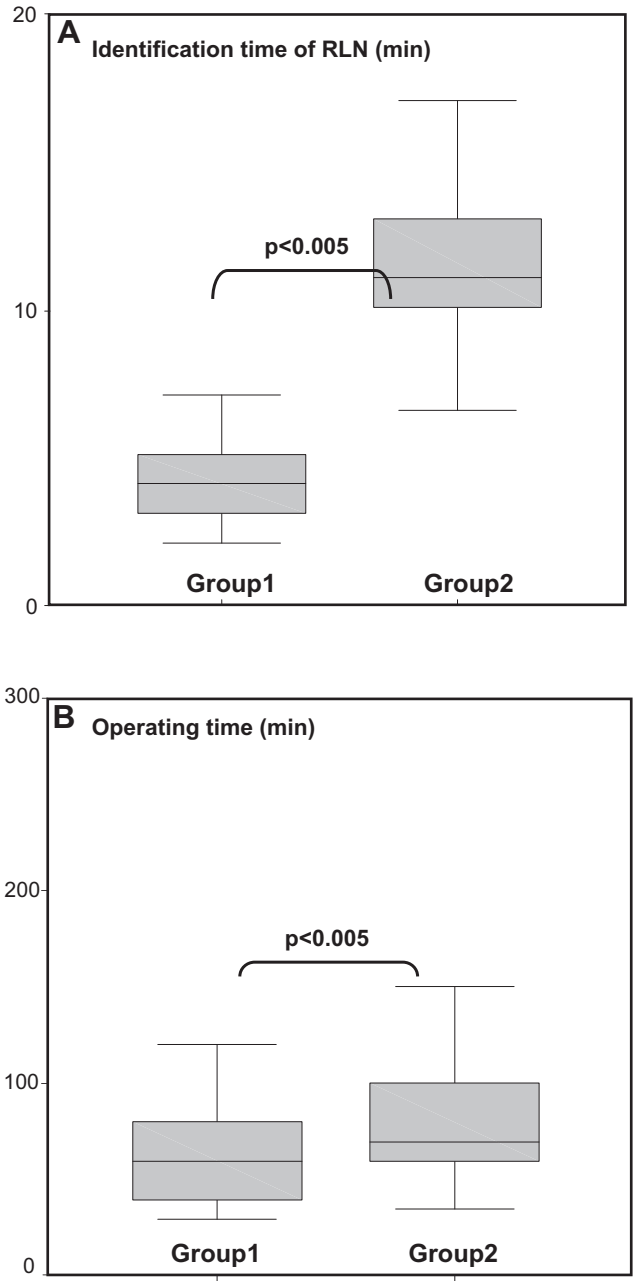


Fig. 2. Evaluation of the operating time and the identification time of nerve according to with/without IONM

3.4. Logistic regression analysis

When the operating time was included as dependent variable, thyroid gland weight more than 70 g resulted in a 21-fold increase in the operating time (OR 21.6, 95% CI: 12.4–37.7, $p = 0.03$) whereas the use of IONM resulted in a 3-fold decrease in the operating time (OR 3.3, 95% CI: 1.9–5.6, $p = 0.03$).

When the identification time of RLN was included as dependent variable, the use of IONM (OR 553, 95% CI: 182.9–1674.72, $p = 0.0001$) was found to be the only significant independent determinant of the decrease of identification time of RLN. The use of IONM resulted in a 553-fold decrease in the identification time of RLN.

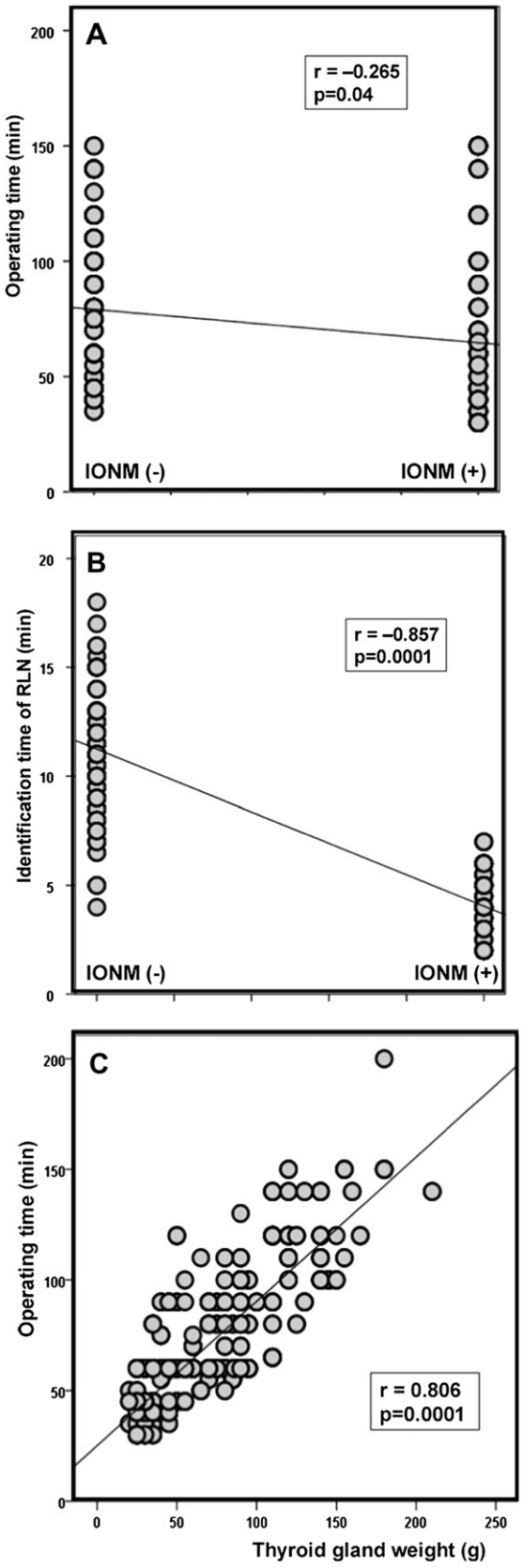


Fig. 3. Relationship between the use of IONM and operating time (A) and identification time of nerve (B) operating time and thyroid gland weight (C).

4. Discussion

We investigated the effect of IONM on identification time of RLN in the patients performed thyroidectomy. Although there was no significant difference between postoperative nerve palsy of the groups, we found that the use of IONM decreased identification time of RLN and operating time. According to logistic regression analysis, the use of IONM was found to be the only determinant of the decrease of identification time of RLN.

The most frequent complications of thyroid surgery are nerve palsy and hypoparathyroidism. Several factors influence the likelihood of injury to the nerve, including the underlying disease (i.e., substernal goiter, malignancy, Graves disease), the extent of resection, and the experience of the surgeon.[1–3] Even experienced surgeons report inadvertent injury to the nerve and persistent RLN palsy in about 1–2% of patients.[1–6] Causes of nerve palsy include: damage to the nerve's anatomic integrity; thermal lesions; excessive nerve skeletization; axon damage caused by excessive strain, edema, hematoma, and difficult tracheal intubation; and neuritis caused by scar tissue and viral neuritis. The reported incidence of nerve injury has decreased over the last several decades due to the identification of the nerve during surgery. This approach is accepted by most endocrine surgeons.[1–7]

It was Theodor Kocher who brought his operative mortality of thyroidectomy from 14.8% in 1882 to an eventual level of less than 0.18% in 1898. His meticulous technique resulted in an incidence of recurrent nerve injury similar to that of surgeons today.[20] Later, in 1938, Lahey[21] dissected the recurrent laryngeal nerve in virtually every case. He wrote that careful dissection decreased the number of injuries to the recurrent laryngeal nerves.

Despite significant improvements in RLN dissection, the incidence of RLN palsy varies from less than 1 per cent to as high as 20 per cent.[1–3] Nerve identification in certain types of operations may be very difficult. These difficult cases include reoperations, cancer excisions, anatomic distortion with large tumors, anatomic anomalies (nonrecurrent laryngeal nerve), and a history of irradiation or inflammation.[1–6]

To help identify the RLN and measure its function immediately before and after thyroid resection, various medical devices have been developed over the past two decades for intraoperative use.[7] Several methods have been described for RLN monitoring including finger palpation of the cricoarytenoid muscle during nerve stimulation, vocal cord observation by direct or fiberobtic laryngoscopy, the use of intramuscular vocal cord electrodes.[9–11] The most widely used method of RLN monitoring has been the use of nerve integrity monitor (NIM).[14,15] NIM system uses a special endotracheal tube with the vocal cord electrodes embedded in to the wall of the tube. Because the electrode is on the endotracheal tube itself, the particular skill or experience is not required of the surgeons. It is required that the anesthesiologist accurately places the electrode in contact with the vocal cords.[7,8,14,15]

Recent studies have shown that intraoperative neuromonitoring can aid RLN identification.[8,9,12–16] However, its role in reducing the frequency of RLN injury and the value of predicting postoperative RLN function remain controversial.[17–19] Dralle et al.[8] reported a multi-institutional prospective study of 16,448 patients with 29,998 nerves at risk who underwent thyroidectomy. The patients were divided into 3 groups: no RLN identification, visual RLN identification, and visual identification combined with neuromonitoring. They found no significant difference between visual identification alone and combined visualiation with RLN neuromonitoring. However, for less experienced surgeons, nerve monitoring resulted in a reduced rate of permanent RLN palsy. Some authors have believed that neuromonitoring can aid in anatomic identification of RLN and aid in resident training.[12–16] In our study,

the benefit of RLN monitoring is assistance in nerve identification, resulting in a significant decrease in the identification time of RLN and operating time.

The use of these devices in thyroid surgery seems to be more expensive than the conventional technique. This is probably the major disadvantage of these devices. In our study, although the operating time was lower with IONM than with visualization alone, the shortened surgical time may not seem to have great clinical relevance. The major benefit of RLN monitoring is assistance in nerve identification, resulting in a significant decrease in the identification time of RLN.

Many intraoperative stressors such as rising intolerance for physician error, potential legal issues, and medical insurers can increase intraoperative stress. Kern et al.[22] pointed out those surgical injuries accounted for the greatest number of cases and the highest cost of litigation.

5. Conclusion

Most surgeons aim to preserve the nerves and parathyroid glands under the potential risk during thyroidectomy. The shorter the nerve is identified the lower is the surgeon's level of stress. We think that IONM is not alternative to visual nerve identification. IONM may lend itself as a routine adjunct to the gold standard of visual nerve identification. It is important to use IONM to decrease the identification time of RLN in the course of thyroidectomy.

Conflict of interest

We have no conflicts of interest.

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Ethical approval

The research is approved by the ethical committee of the Faculty of Medicine, University of Istanbul.

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