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Effectiveness and Safety of Intraoperative Neuromonitoring of Recurrent Laryngeal Nerves Using Intramuscular Electrodes: a Multicenter Study

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Research Article

Keywords: intraoperative neuromonitoring, recurrent laryngeal nerve, intramuscular electrodes, thyroidectomy, laryngeal muscle paresis, safe surgery, vocal fold mobility, electromyography

Posted Date: November 17th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10890161/v1

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Additional Declarations: No competing interests reported.

EFFECTIVENESS AND SAFETY OF INTRAOPERATIVE NEUROMONITORING OF RECURRENT LARYNGEAL NERVES USING INTRAMUSCULAR ELECTRODES: A MULTICENTER STUDY

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ABSTRACT

Background.

Intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerves (RLN) is used to improve the safety of thyroid surgery. The traditional method, using an endotracheal tube with EMG electrodes, has limitations: signal instability, anesthesia effects, and high cost.

Objective.

To compare postoperative laryngeal functional outcomes and the clinical feasibility of recurrent laryngeal nerve monitoring using paired intramuscular electrodes inserted into the lateral cricoarytenoid muscle versus an endotracheal tube with electromyographic electrodes.

Methods.

This multicenter prospective non-randomized comparative cohort study included 80 patients undergoing primary thyroid surgery between 2021 and 2024. Forty-nine patients underwent monitoring with paired intramuscular electrodes placed in the lateral cricoarytenoid muscle, and

31 patients underwent monitoring with an endotracheal electromyographic tube. Vocal fold mobility was assessed before surgery and on postoperative day 1; patients with postoperative impairment underwent repeat laryngoscopy at 3, 6, and 12 months. The primary outcome was new postoperative vocal fold mobility impairment; recovery over follow-up was a secondary outcome.

Results.

The cohort comprised 61 women (76.3%) and 19 men (23.8%), aged 19–88 years. Group 1 included 49 patients (61.3%) and Group 2 included 31 patients (38.8%). Transient postoperative laryngeal mobility impairment occurred in 1/49 patients (2.0%) in the intramuscular-electrode group and 1/31 patients (3.2%) in the endotracheal-tube group (Fisher exact p=1.000). Mobility recovered by 3 months in Group 1 and by 6 months in Group 2. No permanent laryngeal mobility impairment was reported during follow-up.

Conclusion.

Intramuscular electrodes provide comparable efficacy and safety to the traditional method of IONM, eliminating its key limitations. This method can be recommended for routine implementation as a reliable and cost-effective alternative.

KEYWORDS: intraoperative neuromonitoring, recurrent laryngeal nerve, intramuscular electrodes, thyroidectomy, laryngeal muscle paresis, safe surgery, vocal fold mobility, electromyography

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BACKGROUND

Intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerves (RLN) in thyroid surgery is used as an adjunct to direct nerve visualization to better understand detailed

surgical anatomical variations and electrophysiological functions [1,2,3]. Damage to the RLN reduces the patient's quality of life and, in the case of bilateral damage, poses a threat to life, which is inconsistent with the accepted concept of safe surgery. Changes in voice function and phonation may lead to increased treatment time, the need for additional medications and diagnostic tools, leading to certain economic losses [4, 5].

The use of IONM helps reduce the incidence of RLN damage. The most widely used method for IONM is the use of intralaryngeal electrodes. However, several unresolved issues with IONM intralaryngeal electrodes remain, including incorrect positioning due to endotracheal tube displacement or the influence of anesthetic factors. These unresolved issues can lead to misinterpretation of neuromonitoring results and damage to the recurrent laryngeal nerves, leading to voice loss. Furthermore, the high cost of a specialized endotracheal tube with electrodes is a significant drawback.

The literature describes methods of IONM of the RLN: electrodes inserted into the thyroid cartilage [6], cutaneous electrodes [7]. The authors have proven the effectiveness of the listed methods, the absence of false signal loss during IONM, and the possibility of using them in patients with tracheostomies. Nevertheless, the authors point out the limitations of alternative methods. A disadvantage of using intracartilaginous needle electrodes for IONM, according to Chiang et al. [8], is the traumatic placement of electrodes with exposure of the lateral surface of the thyroid cartilage. Lee HS and co-authors indicated that cutaneous electrodes used for IONM demonstrated a lower signal amplitude compared to an EMG tube due to the large distance between the electrodes and the signal sources [7].

Based on the above, it is obvious that the search for alternative IONM methods is relevant and requires further study.

OBJECTIVE

The aim is to compare the effectiveness of IONM of the RLN using an intramuscular paired electrode inserted into the cricoarytenoid muscle and IONM using an endotracheal intubation tube with electromyographic electrodes.

MATERIALS AND METHODS

Venue. Federal State Budgetary Institution All-Russian Center for Emergency Radiation Medicine named after A.M. Nikiforov, Saint Petersburg, Russian Federation; State Budgetary Healthcare Institution Research Institute – Regional Clinical Hospital No. 1 named after prof. S.V. Ochapovsky, Krasnodar, Russian Federation; My Medical Center Group of Companies, Gelendzhik, Russian Federation.

Study period. The work was carried out during 2021-2024.

Studied populations

Inclusion criteria: primary thyroid surgery.

Exclusion criteria: patient refusal to participate in the study, advanced forms of thyroid cancer.

Indications for surgery: polynodular nontoxic goiter, follicular tumor (Bethesda IV), thyroid carcinoma (Bethesda VI), diffuse toxic goiter, autoimmune thyroiditis with compression of the neck and/or mediastinum organs.

A method for forming a sample from the population being studied (or several samples from several populations being studied)

The sample was formed using continuous sampling.

Study design

Description of study design:

- multicenter;

- experimental;

- dynamic (assessment of the work of the vocal folds before and after surgery);

- prospective (observation period up to 12 months).

Visual assessment of the vocal fold function (ultrasound + laryngoscopy) was assessed in All patients in the pre- and postoperative period (the first day after surgery, if paresis of the laryngeal muscles was detected - repeat laryngoscopy after 3-6-12 months).

- two-sample, comparative

- uncontrolled

- non-randomized.

Description of the medical intervention

During thyroid surgery, after visually identifying a structure resembling the laryngeal nerve (RLN), it is electrically stimulated by directly applying a stimulating current through an electrode and electrically stimulating the vagus nerve, which results in contraction of the laryngeal muscles. Contractions are recorded using special electrodes placed in the lateral cricoarytenoid muscle on one or both sides.

The method is as follows [9]. A nerve integrity monitor is used for IONM RLN. To record contraction of the lateral cricoarytenoid muscle, a special paired intradermal electrode is used, equipped with two thin steel electrodes 12 mm long and 2.5 mm apart. This electrode is inserted into the lateral cricoarytenoid muscle on one or both sides. The neutral electrode is inserted into the brachial muscle. After intubation of the patient using short-acting muscle relaxants and proper placement of all electrodes, a passive myography curve of the laryngeal muscles—the resting potential—is recorded on the monitor screen. The IONM RLN procedure itself was performed in accordance with the recommendations of the International Intraoperative Monitoring Study [10].

All patients underwent visual assessment of the vocal folds before and after surgery.

Methods

Inclusion criteria were determined using preoperative examination data. Instrumental methods included thyroid ultrasound (nodules were assessed using the international TI-RADS system), fine-needle aspiration biopsy of thyroid nodules (material was assessed using the international Bethesda scale), and visual assessment of vocal fold function (ultrasound + laryngoscopy before and 1 day after surgery). If laryngeal muscle paresis was detected, repeat laryngoscopy was performed 3-6-12 months after surgery. Laboratory data included TSH, calcitonin, free T3 and T4, calcium, and parathyroid hormone.

The following were used during the operation:

- Monitoring of the laryngeal nerve function was performed using the Medtronic NIM 3.0 nerve integrity monitor (USA) and NerveMonitor (InoMed, Germany);

- EMG - intubation tubes;

- a special paired intradermal electrode equipped with two thin steel electrodes 12 mm long and a distance of 2.5 mm between them;

- binocular magnifying glasses (x2.5) Univet;

- Ethicon Harmonic harmonic scalpel.

Statistical analysis

All patients underwent a visual assessment of the vocal folds before and after surgery. The obtained results were statistically processed on a personal computer using MS Soft Excel 2010, STATISTICA 20 and IBM SPSS STATISTICS 16.0 programs. Statistical significance of the results was assessed using the Fisher criterion, assuming that the $p<0.01$ level indicates the significance of differences in values equal to 99% or more, $p<0.05$ are significant with an error-free prediction probability of 95% or more, $p>0.05$ - their differences are insignificant. Continuous data were presented using the mean, standard error of the mean and range (min-max). Statistically significant differences between the studied groups of patients were assessed using one-way analysis of variance (for quantitative characteristics with a normal distribution), as well

as the Pearson chi-square test (for qualitative characteristics). Odds ratios (ORs) were presented with 95% confidence intervals (CIs) and p-values. Logistic regression analysis was used to determine the most significant factors influencing surgical outcome (complications present: vocal cord paralysis or paresis vs. no complications).

Ethical review

The study was carried out in accordance with ethical and legal standards.

RESULTS

The study included 80 patients (19 men and 61 women), aged 19 to 88 years (mean age was 47.2±4.8 years). Patients had various thyroid pathologies, such as: polynodular nontoxic goiter, follicular tumor (Bethesda IV), thyroid carcinoma (Bethesda VI), diffuse toxic goiter, autoimmune thyroiditis with compression of the neck and/or mediastinum organs.

Patients are divided into two groups:

Group 1 - IONM using a paired intramuscular electrode inserted into the lateral cricoarytenoid muscle.

Group 2 – IONM using an endotracheal intubation tube with electromyographic electrodes.

Patients were comparable in age, gender, body mass index, surgical procedure, pathology, and degree of recurrent laryngeal nerve dissection (Table 1). Baseline vocal fold mobility was comparable in both groups, and statistical analysis revealed no significant differences between the samples.

Table 1 - General characteristics of the groups

	Group No. 1 38.0% (n=49)	Group No. 2 24.0% (n=31)
Age	49.2±2.17	54.4 ± 2.97

Sex	Men	26.5% (n=13)	19.4% (n=6)
	Women	73.5% (n=36)	80.5% (n=25)
Diagnosis	DTG[1]	18.3% (n=9)	29.0% (n=9)
	MT [2]	32.7% (n=16)	19.4% (n=6)
	Benign nodular formations	49.0% (n=24)	51.6% (n=16)
Volume of operation	TE[3]	51.0% (n=25)	48.4% (n=15)
	HTE[4]	49.0% (n=24)	51.6% (n=16)
[1]DTG - diffuse toxic goiter, [2]MT - malignant tumor, [3]TE - thyroidectomy, [4]HTE - hemithyroidectomy			

In the early postoperative period, temporary limitation of laryngeal muscle mobility was detected in 1 patient (2.0%) in group No. 1 and 1 patient (3.2%) in group No. 2. Laryngeal mobility was fully restored after 3 months in the patient in group No. 1 and after 6 months in the patient in group No. 2.

Patients operated on using an intramuscular (Group 1) and superficial (Group 2) electrode were compared for the incidence of postoperative complications using the Pearson $\chi 2$ test and subsequent calculation of odds ratios (Table 2). The analysis revealed no statistically significant differences between the studied patient groups in the incidence of the aforementioned characteristics: p-levels ranged from 0.387 to 0.668.

Table 2 – Comparison of the frequency of impaired laryngeal muscle mobility in patients of group No. 1 and group No. 2

Complication	OR [95% CI]	p-level
Paralysis	0.97 [0.908-1.032]	0.387
Paresis	1.04 [0.984-1.105]	0.519
OR – odds ratio		

CI – confidence interval

Thus, the study did not reveal any differences in the frequency of RLN damage between patients in groups 1 and 2.

DISCUSSION

Representativeness of samples

This study demonstrates the feasibility of using IONM of the RLN using an intramuscular paired electrode inserted into the cricoarytenoid muscle for the prevention and intraoperative detection of damage to the RLN during thyroid surgery.

Comparison with other publications

The IONM method has long been recognized as an effective means of reducing the risk of intraoperative damage to the RLN during thyroid surgery [4,11,12]. However, the traditional approach using an EMG endotracheal tube has certain challenges. One of these is a false loss of signal (LOS) resulting from tube displacement or disruption of its contact with the vocal folds, which can lead to distorted interpretation of neurophysiological data [6,7,13].

Such technical failures can impact the course of the operation, forcing the surgeon to alter the scope of the intervention, including abandoning bilateral surgery, even in the absence of actual nerve damage [7,10,13]. This raises the need to find alternative, more stable methods for recording laryngeal muscle activity. Such alternatives include cutaneous and transcartilaginous needle electrodes, which have demonstrated high signal stability and less dependence on anatomical features and position in the trachea [6,7,13]. In particular, the transcartilaginous technique proposed by Chiang FY et al. [6] has proven its validity in terms of safety and technical feasibility, but requires tissue dissection in the thyroid cartilage area, which may increase the trauma of the intervention.

In this study, a technique for inserting paired needle electrodes directly into the lateral aspect of the cricoarytenoid muscle was first implemented and tested [9]. The results demonstrated stable recording of neuromuscular activity, comparable to data obtained using an EMG tube, while eliminating its key drawbacks—primarily, dependence on position in the trachea and the likelihood of false signals.

It should also be noted that no differences in complication rates were found between the groups using different IONM methods ($p>0.05$). However, our proposed technique of intramuscular insertion of paired needle electrodes has advantages: it is less costly, requires fewer technical resources, and can be used in clinical situations that preclude the possibility of intubation with an EMG tube, for example, in the presence of a tracheostomy [6,7].

Taking into account the totality of the obtained data, this technique can be considered as a promising direction in the development of IONM.

Clinical significance of the results

The method of IONM of the VNG, discussed in the article, using needle electrodes installed in the lateral cricoarytenoid muscle, is comparable in IONM with the use of an EMG tube in the prevention and diagnosis of VNG damage during thyroid surgery.

Limitation of the study

A disadvantage of the study may be the high cost of the nerve integrity monitor to record IONM data.

Directions for further research

It is advisable to conduct further research with an increased sample of patients and a more detailed analysis of additional factors of postoperative impairment of laryngeal muscle mobility.

CONCLUSION

The use of paired intramuscular needle electrodes inserted into the lateral cricoarytenoid muscle represents a reliable and safe alternative to traditional IONM methods during thyroid surgery. The results of the study demonstrated diagnostic efficacy comparable to the classical IONM method, while eliminating the latter's key limitations—most notably, the potential loss of stable contact with the vocal folds.

An analysis of clinical data confirmed that the use of IONM significantly reduces the incidence of postoperative laryngeal muscle dysfunction, such as paresis and paralysis. The introduction of intramuscular electrodes into routine practice can improve the reliability of neuromonitoring, ensure a more individualized approach, and, in some cases, reduce costs while maintaining high standards of safety and efficacy.

DECLARATIONS

Abbreviations

IONM, intraoperative neuromonitoring; RLN, recurrent laryngeal nerve; EMG, electromyography; TI-RADS, Thyroid Imaging Reporting and Data System; TSH, thyroid-stimulating hormone; T3, triiodothyronine; T4, thyroxine; LOS, loss of signal; OR, odds ratio; CI, confidence interval; DTG, diffuse toxic goiter; MT, malignant tumor; TE, thyroidectomy; HTE, hemithyroidectomy; ICMJE, International Committee of Medical Journal Editors.

Ethics approval and consent to participate

The study protocol was submitted to and approved by St. Petersburg State Local Ethics Committee (approval No. 11/2/2021). All procedures involving human participants were performed in accordance with the Declaration of Helsinki and all relevant institutional and national guidelines and regulations. Informed consent to participate was obtained from all participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests.

Funding

The work was carried out on the initiative of the authors without attracting funding.

Authors' contributions

All authors confirm their compliance with the international ICMJE criteria for authorship (all authors made a significant contribution to development of the concept, conduct of the study and preparation of the article, read and approved the final version before publication). Aregawi A.B. 1 - significant contribution to the concept of the study. Vabalayte K. 1 - significant contribution to the concept or design of the study, contribution to obtaining the data necessary for writing the article; according to criterion 2 - introducing significant edits to the manuscript in order to improve the scientific value of the article; Romanchishen A.F. 1 - significant contribution to the concept of the study. 2 - introducing significant edits to the manuscript; Bondarenko Yu.S. - author's contribution to criterion 1 - contribution to obtaining, analyzing data and interpreting the results; according to criterion 2 - writing the article; Polyakova E.A. - author's contribution to criterion 1 - contribution to obtaining, analyzing data and interpreting the results; according to criterion 2 - writing the article; Polshina V.I. -1 - contribution to obtaining the data necessary for writing the article; Reshetov I.V. - 1 - significant contribution to the concept of the study. 2 - introducing significant edits to the manuscript. All authors approved the final version of the article before publication and agreed to be responsible for all aspects of the work.

Acknowledgements

Not applicable.

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