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Intraoperative stimulation neuromonitoring versus intraoperative continuous electromyographic neuromonitoring in total thyroidectomy: identifying laryngeal complications

Charilaos Koulouris, M.D., Theodossis S. Papavramidis, M.D., Ph.D.*, Ioannis Pliakos, M.D., Nick Michalopoulos, M.D., Michalis Polyzonis, M.D., Konstantinos Sapalidis, M.D., Ph.D., Isaak Kesisoglou, M.D., Ph.D., George Gkoutzamanis, M.D., Ph.D., Spiros T. Papavramidis, M.D., Ph.D.

3rd Department of Surgery, AHEPA University Hospital, Aristotle University of Thessaloniki, 6 Aigaiou Str., 54655 Thessaloniki, Greece

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Neurostimulation;
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Abstract

BACKGROUND: Laryngeal complications occur in thyroidectomies as a result of several factors, but especially because of nerve damage. We compared intraoperative stimulation neuromonitoring (IONM) with intraoperative continuous electromyographic neuromonitoring (IEM) to evaluate their ability to identify postoperative laryngeal complications.

METHODS: This prospective clinical trial included 174 patients (348 nerves) who had both IONM and IEM. We recorded age, sex, pathology, vocal fold motility, and complications.

RESULTS: IONM identified 334 nerves, whereas IEM identified 348. Five patients had transient laryngeal complications, 2 bilateral, and 3 unilateral recurrent laryngeal nerve paresis. In addition, in 2 patients IEM showed placement of the tracheal tube balloon on the vocal folds, which led to correction. Sensitivity and specificity were 96.48% and 100% for IONM and 100% and 100% for IEM, respectively. IONM had a positive predictive value of 100% and a negative predictive value of 36.84%. The positive and negative predictive values of IEM were 100%.

CONCLUSIONS: Both techniques identify recurrent laryngeal nerve injuries; however, IEM seems to have an advantage concerning the nonsurgical laryngeal complications and may play a role in preventing morbidity.

The major aim of the modern thyroid surgeon is to provide surgery with the lowest possible complication rate. Surgical experience is mandatory for the surgeon to achieve anatomic identification and preservation of the recurrent laryngeal nerves (RLNs) and the parathyroids.[1] Although the morbidity and mortality of thyroid surgery have decreased dramatically,[2] complications still occur as a result of several factors.

Iatrogenic injury of the RLN during thyroidectomy is a well-documented serious complication of thyroidectomy inducing the greatest morbidity.[3,4] The incidence of tempo-

* Corresponding author: Tel.: +(00) (30) 6944536972; fax: +(30) 2310420293

E-mail address: Papavramidis@hotmail.com

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rary and permanent vocal cord palsy after thyroid surgery, based on the number of nerves at risk, were reported to range from 3.4% to 7.2%% and .2% to .9%, respectively.[5,6] Although not all postoperative voice disturbances are surgically related,[7,8] this does not change the fact that symptomatic RLN paralysis constitutes a major cause of impaired quality of life and a factor of job incompetence postoperatively.[9]

The aim of the present prospective study was to compare intraoperative stimulation neuromonitoring (IONM) with intraoperative continuous electromyographic neuromonitoring (IEM) concerning the intraoperative identification of postoperative dysfunction of the vocal cords. Finally, we wanted to assess whether IEM could identify the nonsurgically related palsies of RLN: all malfunctions of the vocal cords related to intubation, placement of the tracheal tube balloon, or other anesthesiology-related complications.

Materials and Methods

This prospective clinical trial was approved by the AHEPA University Hospital Research Ethics Board and was performed over an 8-month period. Written informed consent was obtained from all patients.

The inclusion criteria for this study were as follows: (1) age older than 18 years, (2) acceptance to participate to the study, and (3) scheduled total thyroidectomy using a harmonic scalpel. The exclusion criteria were as follows: (1) previous neck surgeries, (2) irradiation of the neck, (3) patient participating in another clinical trial that may affect this study's outcome, and (4) pre-existing palsy of at least 1 vocal cord.

All patients underwent preoperative and postoperative fiberoptic laryngoscopy to assess vocal cord motility. All procedures were performed by a surgical team dedicated to thyroid surgery. Anesthesia was standardized following the protocol proposed by Andrieu et al[10] and applied also by our team to previous studies.[11] The data for all patients have been collected prospectively and recorded in a database.

Given that RLN transient palsy is between 3% and 7% according to the literature[5,6] and that in our previous studies we showed no palsies,[2,12] the sample population calculation was made taken as mean RLN palsy percentage 1%. In addition, based on our previous studies, we expected to have .1% of RLN palsies occur in the present series. The α error level was set at 5% and the β error level was set at 50%. Based on the earlier-described data the minimal sample size calculated was 331 nerves. After sample size calculation we prospectively evaluated 348 nerves at risk (174 patients). All patients had both IONM and IEM. The following data were recorded: age, sex, pathology, preoperative and postoperative vocal motility, and complications.

The xltek Protector IOM device (xltek, Ltd, Ontario, Canada) was used for RLN intraoperative monitoring. Patients were intubated with an endotracheal tube bearing 2 electrodes imbedded in the tube wall and placed up against each vocal cord. Two grounding electrodes were positioned bilaterally in the subcutaneous tissue of the shoulder, to the area corresponding to the median portion of the deltoid muscle. Electrode and groundings wires, along with the hand-held nerve stimulator, were connected to the monitoring device (xltek Protector IOM), recording a wave spike originating from each vocal cord muscle contraction. Electrodes for continuous background muscle activity monitoring were adjusted to the xltek Protector IOM device (IEM). The RLN was identified at the tracheoesophageal groove during dissection and stimulated by the application of a bipolar probe evoking an electric current ranging from .5 to 1.5 mA at a frequency of 30 Hz. Intact RLN identification was confirmed by a sequence of potentials visualized on a laptop screen, and was previously estimated by an expert trained technician. IONM and IEM application did not result in any alteration of either the established thyroidectomy procedures or the involved surgical field.

Any postoperatively recorded vocal cord hypomotility was considered a vocal cord paresis. In patients with documented postoperative vocal cord palsy a flexible fiberoptic laryngoscopy was performed at the first, the third, the sixth, and the 12th month after surgery. Persistent vocal cord palsy for a period longer than 12 months after surgery was considered a permanent paralysis. For both techniques, every test that showed normal vocal cord function and normal vocal cord motility were considered true positive, whereas every test that showed abnormal vocal cord function and vocal cord paresis was considered true negative. False positive was when normal vocal cord function was identified by nerve monitoring but vocal cord paresis was present. False negative was when abnormal vocal cord function was identified but vocal cord motility was normal. The term prevalence describes the ratio of the true test results (positive or negative) over the total number of tests performed.

Statistical analysis was performed with SPSS for Windows (SPSS, Inc, Chicago, IL).

Results

The patient epidemiologic characteristics, as well as indications for surgery, are summarized in Table 1. As expected, there was a female predominance in the population. The main surgical indication was nodular goiter, followed by thyroid carcinoma and Graves' disease.

IONM was supposed to be applied to 348 nerves at risk, however, only 334 nerves were identified successfully (96.55%). By contrast, IEM was applied successfully to all cases. Among the 174 patients, 5 patients had laryngeal complications. Two patients had bilateral nerve palsy, and 3 patients had unilateral RLN paresis. All of these complications were transient and complete recovery was obtained within 3 months after surgery. The 2 patients with bilateral palsy had urgent tracheostomies and the tracheostomy tube