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Original research

Interpretation of intraoperative recurrent laryngeal nerve monitoring signals: The importance of a correct standardization

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HIGHLIGHTS

- Intraoperative neuromonitoring is highly predictive of the postoperative nerve function.
- Standardization permits high sensibility and negative predictive value, but also specificity and positive predictive value.
- In selected patients with loss of signal the surgical strategy can be reconsidered.
- This study failed to demonstrate a statistically significant decrease in the nerve paralysis rate.
- Further studies are needed to better evaluate the real benefit of this technique.

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ABSTRACT

Introduction: Despite the increasingly broad use of intraoperative neuromonitoring, review of the literature and clinical experience confirms there is little uniformity in application of and results across different centers. The aim of this study was to evaluate the ability of intraoperative neuromonitoring with a standardized evaluation of the signals to predict the postoperative functional outcome and its role in reducing the postoperative recurrent nerve palsy rates.

Methods: 2365 consecutive patients underwent thyroidectomy by a single surgical team: in 1356 patients (group A) with intraoperative neuromonitoring, in 1009 (Group B) without it.

Results: In group A a loss of signal was observed in 37 cases: we had 29 true positive cases, 1317 true negative, 8 false positive, and 2 false negative. Accuracy was 99.26%, positive predictive value 78.38%, negative predictive value 99.85%, sensitivity 93.55%, and specificity 99.4%. 29 unilateral nerve paralysis were observed (2.13%), 23 (1.69%) transient and 6 (0.44%) permanent. In group B 26 unilateral paralysis were observed (2.57%), 20 (1.98%) transient and 6 permanent (0.59%) Differences were not statistically significant.

Conclusions: Intraoperative neuromonitoring is highly predictive of the postoperative nerve function. We obtained a very high sensitivity and negative predictive value, but also a good specificity and positive predictive value. For these reasons, in selected patients with loss of signal, the surgical strategy can be reconsidered. On the other hand, this study failed to demonstrate a statistically significant decrease in the nerve paralysis rate. Further studies are needed to better evaluate the real benefit of this technique.

1. Introduction

Postoperative dysfunction of the recurrent laryngeal nerve (RLN) is the most serious, sometimes irreversible and life-quality declining, complication in thyroid surgery [1]. Intraoperative identification of the RLN is a well established technique to reduce the incidence of postoperative RLN palsy [1–4].

Numerous methods have been proposed to detect the RLN during thyroid surgery [1,5]. Intraoperative neuromonitoring (IONM) has gained widespread acceptance as an adjunct to the gold standard of visual nerve identification [2,3,6,7].

In general, the technique of IONM can be used in two different

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ways in thyroid surgery: firstly, for detection of the RLN during dissection and, secondly, for IONM of the RLN function [1].

In some studies the use of IONM in combination with visual RLN identification resulted in statistically significant lower post-operative RLN palsy rates than after RLN identification without IONM [1]. An evidence-based literature review of non-randomized studies looking at rates of nerve paralysis with and without monitoring with more than 100 nerves at risk showed divergent results [7]. A randomized study of Barczynski [2] demonstrated statistically lower rates for transient paralysis with IONM as compared to visual identification alone [2,7]. In the meta-analysis by Higgins [8] and in the recent one by Pisanu [9], IONM and identification alone did not demonstrate a statistically significant difference in the incidence of RLN palsy.

Rates of IONM use have recently become more or less equivalent between general surgical and otolaryngology-trained surgeons, with approximately 40%–45% in both groups using IONM in some or all cases [7]. Within the United States, monitoring appears to be used by younger surgeons and surgeons with more than 100 cases per year [5,7,10]. Moreover, IONM is now the standard of care in Germany: 90% of surgical departments were equipped with nerve monitors in 2010 [10,11].

Despite this increasingly broad use of IONM, review of the literature and clinical experience confirms there is little uniformity in application of and results from IONM across different centers [7,10]. A recent standardization of IONM methods and reporting was undertaken in an effort to provide uniformity and to minimize inappropriate variations in the applications of IONM [7,9].

The aim of this study was to evaluate the ability of IONM with a standardized evaluation of the signals to predict the postoperative functional outcome and its role in reducing the postoperative RLN palsy rates.

2. Materials and methods

Between June 2007 and December 2013, 2365 consecutive patients underwent thyroidectomy by a single surgical team. 2038 patients were submitted to a total thyroidectomy, 265 to a total thyroidectomy with VI level lymphectomy, and 62 underwent a completion total thyroidectomy. 1873 were female and 492 male with a mean age of 52.2 years (range 15–87 years).

The final diagnosis was in 891 patients multinodular goiter (37.67%), in 706 differentiated carcinoma (29.85%), in 480 Hashimoto's thyroiditis (20.29%), in 256 Graves' disease (10.82%), and in 32 medullary carcinoma (1.35%).

Histological diagnosis and surgical procedures are summarized in Table 1.

In differentiated carcinoma, lymph node metastasis were found in 61 patients (9.62%) and micrometastasis in 14 (1.89%). Totally lymph node metastasis were observed in 75 patients (10.16%).

The study was approved by the Bioethics Commitee of the University of Cagliari. All patients provided written informed consent for the intervention and for the storage and use of their data.

All operations were performed by three experienced endocrine surgeons, with a standard Kocher's incision. All patients were submitted to preoperative and postoperative laryngoscopy.

The recurrent laryngeal nerves were routinely identified by visualization and completely exposed. IONM was performed in 1356 patients on the basis of the availability of the equipment (2712 nerves at risk). All these patients undergone general anesthesia and were intubated with Nerve Integrity Monitor Standard Reinforced Electromiography Endotracheal Tube (Medtronic Xomed). 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. When the monitor was well set up, we routinely checked the impedance of electrodes. A Prass monopolar stimulation probe (Medtronic Xomed) was used for nerve stimulation during thyroidectomy. Electromyographic activity was recorded on a NIM-response 2.0 or 3.0 monitor (Medtronic Xomed). No muscle relaxants were used after the skin flaps were elevated.

The neuromonitoring device was used in various phases of the operation: at the beginning a stimulation was done to the level corresponding to the vagus nerve to ensure that the monitoring system was working; after, to the structure believed to be attributable to the inferior laryngeal nerve; at the end, to the level of both the vagus (indirect stimulation) and the recurrent nerve (direct stimulation) after the removal of thyroid and the complete hemostasis of the surgical field and was used for predicting the post-operative outcome.

LOS (Loss of signal) was defined as an electromyography change from initial satisfactory electromyography, no or low response (i.e. 100 μV or less) with stimulation at 1–2 mA with dry field, and no laryngeal twitch and/or observed glottic twitch.

Patients in which the IONM did not function properly were excluded from the study.

We compared patients who have had IONM and patients who have undergone surgery with nerve visualization alone.

Patients in which IONM was utilized (group A) were 1356 (2712 nerves at risk), 322 male and 1034 female. 1171 (86.35%) were submitted to a total thyroidectomy, 40 (2.94%) to a completion total thyroidectomy and 145 (10.69%) to a total thyroidectomy associated to a VI level lymphectomy. In this group diagnosis was benign multinodular goiter in 514 (37.91%) patients, differentiated carcinoma in 413 (30.46%), Hashimoto's thyroiditis in 262 (19.32%), Graves' disease in 150 (11.06%), and medullary carcinoma in 17 (1.25%).

Patients in which IONM was not utilized (Group B) were 1009 (2018 nerves at risk), 170 male and 839 female. 867 (85.93%) were

Table 1
Histological diagnosis and surgical procedures.

	Total n (%)	Total thyroidectomy n (%)	Completion thyroidectomy n (%)	Total thyroidectomy + lymphectomy n (%)
Group A	1356 (100%)	1171 (86.35%)	40 (2.94%)	145 (10.69%)
Multinodular goiter	514 (37.91%)	471 (91.63%)	13 (2.53%)	30 (5.84%)
Differentiated carcinoma	413 (30.46%)	297 (71.91%)	22 (5.33%)	94 (22.76%)
Hashimoto's thyroiditis	262 (19.32%)	245 (93.51%)	4 (1.53%)	13 (4.96%)
Graves' disease	150 (11.06%)	145 (96.67%)	1 (0.67%)	4 (2.67%)
Medullary carcinoma	17 (1.25%)	13 (76.47%)	0	4 (23.53%)
Group B	1009 (100%)	867 (85.93%)	40 (3.96%)	102 (10.11%)
Multinodular goiter	377 (37.36%)	340 (90.19%)	20 (5.31%)	17 (4.51%)
Differentiated carcinoma	293 (29.04%)	218 (74.4%)	7 (2.39%)	68 (23.21%)
Hashimoto's thyroiditis	218 (21.61%)	197 (90.37%)	12 (5.5%)	9 (4.12%)
Graves' disease	106 (10.51%)	103 (97.17%)	1 (0.94%)	2 (1.89%)
Medullary carcinoma	15 (1.49%)	9 (60%)	0	6 (40%)