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Original research

Double probe intraoperative neuromonitoring with a standardized method in thyroid surgery

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ABSTRACT

Introduction: The purpose of this study was to evaluate the effectiveness of intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerve (RLN) and the vagus nerve (VN) with a standardized approach in thyroid surgery.

Methods: Retrospective study with an experimental group with which IONM was used, both with the RLN that the VN, and a control one, each consisting of 300 total thyroidectomies. Each patient underwent a pre-and post-operative videolaryngoscopy. The number of RLNs identified and the number of transient and permanent RNL injuries for each group were assessed, and then compared with χ^2 tests. In the experimental group Sensitivity, Specificity, Positive Predictability, Negative Predictability and Accuracy of IONM were evaluated, depending on the number of true positive results, false negatives, true negatives and false positives obtained by comparing the results of IONM with the post-operative videolaryngoscopies.

Results: The results obtained for the experimental group vs. the control group were: RLNs identified 595 (99.1%) vs. 552 (92%) -P Value <0.0001; Permanent RLNs injuries 4 (1.33%) vs. 5 (1.67%) -P Value 1; transient RLNs injuries 1 (0.33%) vs. 8 (2.67%) -P Value 0.044.

The IONM system, for the RLN and VN showed respectively: Sensitivity 66.7% vs. 83.3%; specificity 97.6% vs. 99.5%; Positive Predictability 22.2% vs. 62.5%; Negative Predictability 99.6% vs. 99.3%; Accuracy 97.3% vs. 99.3%.

Conclusions: Our study highlights that using IONM with a standardized method in thyroid surgery, improves the ability to identify the RLN and a reduction in the incidence rate of transient RLN injuries.

1. Introduction

Damage to the recurrent laryngeal nerve (RLN) is the most severe specific complication that can occur in thyroid surgery, and underlies major medical-legal controversies among endocrine surgeons [1–3].

The incidence of RLN damage in thyroid surgery is highly variable depending on operator experience, with rates of incidence ranging from as low as 0.2% in specialized centers to as high as 20% in settings where thyroid surgery is infrequent [2,4,5].

Two main factors can reduce the risk of RLN injury: operator experience and a systematic search to allow visualization of the RLN [1,2,4,5]. Nevertheless, the incidence rate of RLN damage is never zero even in the most expert hands. RLN localization is considered the most reliable means of minimizing the incidence rate of RLN damage. Hence, several intraoperative neuromonitoring (IONM) systems have been introduced in recent years including that of the continuous monitoring of the vagus nerve [6–11].

One IONM system available on the market, the Avalanche XT (Dr. Langer Medical GmbH – Waldkirch – Germany), involves the application of current pulses to tissues that induce a release of muscular action potentials from muscles innervated by the pulsed nerve. This system is equipped with two probes; a unipolar probe with a detection radius that is sufficiently wide to allow one to search for nerves that are not visible even after lobe dislocation, thus guiding dissection maneuvers, and a bipolar probe with a smaller detection radius that allows one to identify structures (such as nerves or other structures) by recording electrical conduction. The Avalanche XT system was purchased by the 5th Division of General Surgery and Special Surgical Techniques of the Second University of Naples in July 2010.

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2. Methods

We conducted a retrospective case–control study including all the total thyroidectomies performed between 1 October 2009 and 31 October 2011 at the 5th Division of General Surgery and Surgical Special Techniques of the Second University of Naples.

The only criteria for exclusion from the study was the diagnosis, during pre-operative videolaryngoscopy, of a pre-existing vocal cord paralysis (every patient who is subjected to total thyroidectomy in our Department is subjected to both a preoperative and postoperative videolaryngoscopy undertaken by otolaryngologists of the Otorhinolaryngology Clinic of the Second University of Naples).

Each operation was performed by the same surgical team.

Between 1 October 2009 and 31 July 2010, 306 total thyroidectomies without IONM were carried out: 6 patients were excluded from the study for vocal fold paralysis due to previous thyroid surgery preoperatively so the control group consisted therefore of 300 total thyroidectomies.

Between 1 September 2010 and 31 December 2010, 100 total thyroidectomies with IONM Avalanche XT were carried out: these patients were not included in the study because they were considered as part of a "learning curve".

Between 1 January 2011 and 31 October 2011, 302 total thyroidectomies were carried out using IONM with Avalanche XT: 2 patients were suffering from paralysis of one vocal cord due to previous thyroid surgery and were excluded. The Avalanche group consisted of 300 total thyroidectomies.

In each group 600 nerves were therefore considered to be at risk.

The two groups were homogeneous in terms of age, sex, and type of pathology necessitating this operation (Table 1). Each group was in turn divided into a low-risk class, which included only non-toxic multinodular goiters (LR Avalanche subgroup and LR Control subgroup), and a high-risk class, which included all risky conditions represented by reoperation due to bilateral recurring goiters, thyroid cancers (in these cases we performed total thyroidectomy and bilateral prophylactic central-compartment neck dissection and, when necessary, therapeutic lateral neck compartmental lymph node dissection) [12–17], toxic multinodular goiters, Graves' disease, thyroiditis associated with non-toxic multinodular goiter and substernal goiters [3,18–22] (HR Avalanche subgroup and HR Control subgroup).

The Avalanche Group was composed of 152 low-risk patients (LR Avalanche subgroup) and 148 high-risk patients (HR Avalanche subgroup), including 234 women and 66 men; they had a mean age of 50.57 years (range 17–80 years old).

The Control Group was composed of 157 low-risk patients (LR Control Group) and 143 high-risk patients (HR Control Sub-group), including 227 women and 73 men; they had a mean age of 50.10 years (range 22–78 years old) (Table 1).

Although the influence of curarizing drugs with a long half-life on the evoked muscular action potential is not totally clear [4,23,24], to reduce the potential for bias, patients in the Avalanche group were subjected to general anesthesia in the absence of long half-life curarizing drugs and intubated with traditional oro-laryngeal tubes onto which an adhesive electrode was applied before the intubation. During the operation, we used a unipolar probe on each side until one or more structures considered to be the RLN were detected. To ascertain their nature, the structures were then examined using a bipolar probe while recording. Once each RLN was located, the electrical conduction of the RLN was tracked before completion of the lobe dissection (R1) and again at the end of the operation (R2).

On each side, the neurovascular bundle of the neck was prepared for a 2-cm span, and the vagus nerve conduction track was recorded using the unipolar probe before starting the lobe dissection (V1) and then again at the end of the operation (V2). The action potential evoked from vagal nerve stimulation should reduce the risk of false negatives (FNs) that can be caused by stimulation of the RLN at a distal point with respect to the site where the damage might have occurred. Stimulation was performed at a pulse current of 1 mA and a frequency of 3 Hz.

The frequency with which the recurrent nerves were located was compared between the groups. We carried out a $\chi 2$ test on two independent samples because this test allows nominal variables to be compared; hence, it is considered the only valid test for the comparison of frequencies. We created contingency tables characterized by m lines (nominal variables) and n columns (samples being examined). The nominal variables are represented by the number of recurrent nerves located, the number of permanent RLN paralyzes observed, and the number of temporary RLN paralyzes that occurred. The two samples are represented by the Avalanche Group and by the Control Group respectively. The null hypothesis H0 for this study was that the samples and variables examined were independent. Our alternative hypothesis was that the samples and the nominal variables were inter-dependent. The lower the probability is of rejecting H0 when it is true, the more significant is the test result. The adopted level of significance (α) was 5%.

Modification or disappearance of electrical conduction at R2 and V2 was evaluated relative to that at R1 and V1 for the RLNs and vagus nerves respectively. Subsequently, we evaluated the correspondence or non-correspondence of the eventual modification of the intra-operative electromyographic signal and vocal cord motility detected during the post-operative videolaryngoscopy.

The cases where a reduction or loss of the signal was recorded were considered to have a positive test result: a true positive (TP) if the post-operative videolaryngoscopy documented paralysis of the vocal cords, and a false positive (FP) if the videolaryngoscopy excluded alterations in the vocal cord motility. When no signal modification or loss was recorded, the test result was considered to be negative: a true negative (TN) when the videolaryngoscopy

Table 1
Demographic data, indication for surgery and details of groups and subgroups.

		Avalanche group ($n = 300$)	Control group ($n = 300$)	Statistical test	*P*-value
	Age	50.57 (range 17–80)	50.1 (range 22–78)	Z- test	0.628
	Sex (F/M Ratio)	234 F/66 M (3.55/1)	227 F/73 M (3.11/1)	$\chi 2$	0.498
	Disease				
Low risk patients	Non toxic multinodular goiter	152 (50.67%)	157 (52.33%)	$\chi 2$	0.682
	Thyroid carcinoma	44 (14.66%)	49 (16.33%)	$\chi 2$	0.572
High risk patients	Substernal goiter	39 (13%)	34 (11.33%)	$\chi 2$	0.532
	Toxic multinodular goiter	38 (12.67%)	31 (10.33%)	$\chi 2$	0.37
	Graves' disease	8 (2.67%)	11 (3.67%)	$\chi 2$	0.484
	Thyroiditis	12 (4%)	8 (2.67%)	$\chi 2$	0.362
	Recurrent goiter	7 (2.33%)	10 (3.33%)	$\chi 2$	0.46