Segurança na cirurgia da tiróide: neuromonitorização e selagem vascular

Artigo Original

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Resumo

Introduction: Thyroid surgery carries significant risks and complications such as recurrent laryngeal nerve paralysis and postoperative suffocating hematoma. The most recent advancement providing safety is intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerve (RLN) and the advances in hemostasis systems.
Objective: The main objective of the study was to explore our experience regarding safety measures and the reduction of complications in thyroid surgery.
Materials and Methods: We present a review of 400 neck surgeries performed by the same surgeon, from September 2011 to February 2020. The main variables studied were intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerve and vascular sealing hemostasis systems.
Results: Out of the total 400 patients, a total of 625 RLNs were studied, using IONM. Thirteen unilateral vocal cord paralyses were recorded, 8 of which were temporary and only 5 definitive. The predominant hemostasis system utilized was the vascular sealing system and bipolar clamp 87%, and in 13%, ligation of a thyroid artery. Only 1 patient experienced postoperative hemorrhage, which was resolved without incidents.
Conclusions: Intermittent intraoperative neuromonitoring of the RLN and advances in hemostasis systems have proven to be valuable in thyroid surgery, improving safety and saving surgical time.

Keywords: Neuromonitoring, thyroidectomy, vascular sealing, hemostasis.

Introduction

Thyroidectomy is a surgical procedure not without its share of complications, and among them, the most dreaded is the injury to the recurrent laryngeal nerve (RLN). Traditionally, visually identifying the RLN and tracking its entry into the larynx has been hailed as the "gold standard" for preventing nerve injuries. However, intraoperative neuromonitoring (IONM) has proven to be a valuable tool in anatomical identification by providing neurophysiological data. This is particularly important as anatomical integrity alone does not guarantee functional integrity. The practice of neuromonitoring in thyroid endocrine surgery has roots dating back to 1970 and has seen significant advancements in the last two decades, drawing insights from the fields of neurosurgery and neurophysiology[1]. The key advantage of neuromonitoring lies in its ability to aid in anatomical identification and provide insights into the functional status of the RLN.

The most commonly adopted neuromonitoring technique is intermittent due to its ease, but continuous neuromonitoring can also be used by placing an electrode on the X pair, allowing the surgeon to assess continuous nerve stress during dissection[1,2]. Some studies find no significant differences in nerve injury rates with and without IONM, while others show a significant decrease in paralysis rates[3]. In a trial of 686 patients, the paralysis rate decreased from 7.6% to 4.7%, and it increased the accuracy of surgeons during nerve dissection[4]. Zheng in 2013 published a meta-analysis with 36,487 patients where IONM reduced the rate of temporary paralysis but not the rate of definitive paralysis[5]. Some studies propose tailoring the use of IONM based on the surgeon's experience, suggesting that in those with less experience (<25 thyroidectomies), IONM would be performed in all patients, improving permanent paralysis rates. In surgeons with extensive experience (paralysis rates <1%), neuromonitoring is only done in complex cases[6].

The intermittent IONM system works through an electrical stimulus using a stimulation electrode (1 milliampere) on the RLN or the X pair. This electrical signal produces a muscular contraction of the intrinsic laryngeal muscles, which stimulates two surface electrodes attached to the endotracheal tube. The electrical signal is converted into an acoustic signal, and the potentials are recorded on a monitor.

On the other hand, advances in hemostasis systems have reduced hemorrhagic complications and shortened surgical time. Historically, until the introduction of arterial hemostatic forceps in 1870, thyroid surgery was questioned by eminent surgeons like Billroth or Samuel Gross, who considered it "reckless or butchery"[7]. Postoperative bleeding is one of the most feared complications, requiring immediate or extremely urgent reinterventions and jeopardizing the RLN and parathyroid glands. Currently, appropriate surgical techniques, selective or minimally invasive approaches, careful hemostasis, as well as the introduction of novel hemostasis systems, have significantly decreased hemorrhagic complications. Vascular sealing devices can use different types of energy and can be divided into three types (ultrasonic systems, electrosurgical bipolar systems operating with radiofrequency, and hybrids)[8].

Therefore, the main objective of the study is to determine whether IONM and vascular sealing hemostasis systems improve safety and reduce complications in thyroid surgery.

Materials and Methods

A retrospective clinical study was conducted at the ENT Department of the University Clinical Hospital of Valladolid, covering the period from September 2011 to December 2020 (9 years and 3 months). Authorization for the study design was obtained from the Research Ethics Committee for Medicines (CEIm).

To conduct this study, we reviewed the data from the clinical records (both physical and electronic) of patients. A descriptive analysis of the selected variables was performed. All the statistical analyses were conducted using the software IBM® SPSS® Statistics and Microsoft Excel®. The study included 400 patients who underwent thyroid and parathyroid surgery by the same surgeon. All patients underwent preoperative videolaryngoscopies, surgery under general anesthesia by an experienced surgical team, and the same surgical technique. The standard surgical technique involved extracapsular dissection with or without sectioning of the prethyroid muscles. Crucial steps of the surgery included ligating the middle thyroid vein if present, ligating the superior thyroid pedicles with anatomical preservation of the external branch of the superior laryngeal nerve (identified in only 5.2% of cases), identification and dissection of the RLN up to its entry into the larynx with and without neuromonitoring, and ligating the inferior thyroid pedicle. Hemostasis was achieved through vascular sealing with a bipolar system, bipolar clamp with or without traditional ligation.

The NMIO system used was intermittent neuromonitoring with recording electrodes attached to the endotracheal tube and a stimulation electrode (NIM 3.0, *Medtronic*). The applied electrical stimulus was 1 milliampere (mA), and electrical signals from the RLN were recorded pre-dissection (R1) and post-dissection (R2) with a positive record (in the presence of an electrical signal) or a negative record (in the absence of an electrical signal).

A protocol for anesthesia and surgical management was established. In case of signal loss (R1+/R2-) or absence of signal (R1-/R2-), a verification protocol was implemented (chek for tube position, electrode contact, connections, monitor parameters, patient relaxation grade, stimulation probe, etc.). If the loss or absence of signal persisted after verifying the protocol and occurred on the first side of total thyroidectomy, the second lobectomy was deferred. During the first 3 years (2011-2014), neuromonitoring was performed in selected cases (large cervical goiters, retrosternal extension, associated oncological nodal surgery, revision surgery, and contralateral laryngeal paralysis). From 2014 onwards, NMIO was systematically performed in all patients.

Postoperative laryngoscopy was performed on all patients, and in those with neuromonitoring, the electrical signal result was compared with the postoperative laryngoscopy, establishing four events: true negative (positive R2 record, no paralysis), true positive (negative R2 record, unilateral paralysis), false positive (negative R2 record, no paralysis), and false negative (positive R2 record, paralysis).

Results

A total of 400 patients were collected. The mean age was 56 years, ranging from 19 to 83 years. The majority were female 81.8%, and the remaining 18.2% were male. Approximately 43% had no significant medical history, while hypertension (HTA) was the primary personal history, observed in 124 patients. In 32%, there was a family history of thyroid pathology, and only 9.5% had risk factors for thyroid cancer (iodine-deficient salt, family history, and previous radiation). Table 1 outlines the surgical indications, with bilateral euthyroid multinodular goiter being the main indication, occurring in 109 patients, followed by a single thyroid nodule, unilateral multinodular goiter, and papillary thyroid cancer, all with a frequency of 12%.

Table 1
Surgical indication based on thyroid pathology

	Frequency	Percentage
Thyroid nodule	51	12,8%
Unilateral non-toxic multinodular goiter	51	12,8%
Bilateral non-toxic multinodular goiter	109	27,3%
Toxic multinodular goiter	23	5,8%
Graves-Basedow desease	18	4,5%
High suspicion of thyroid cancer	23	5,8%
Papillary carcinoma	48	12%
Carcinoma + lymph node metastasis	21	5,3%
Primary hyperparathyroidism	27	6,8%
Secondary hyperparathyroidism	3	0,8%
Medullary carcinoma	2	0,5%
Multinodular goiter + hyperparathyroidism	24	6%

Table 2 illustrates the types of surgeries performed, with total thyroidectomy in 175 patients, hemithyroidectomy with or without isthmectomy in 133, isolated isthmectomies in 2, isolated parathyroidectomies in 19, bilateral parathyroidectomies in 2, subtotal parathyroidectomies in 2 and doble unilateral parathyroidectomies in 3 patients. The association of total thyroidectomy with parathyroidectomy in 15 and hemithyroidectomy with parathyroidectomy in 16 cases, Therapeutic lateral neck dissections were associated in 23 patients, and selective central neck dissections in 10 cases. Preoperative radiological tests included ultrasound in 62%, ultrasound and computed tomography (CT) in 17%, ultrasound and scintigraphy in 12%, and isolated CT in 5.8% of cases. In the 400 patients studied, 625 nerves were dissected, with 325 on the right and 300 on the left. A total of 620 recurrent laryngeal nerves (NLR) were identified, of which 6 right nerves were non-recurrent inferior laryngeal nerves (0.9% of the total NLR). The 5 NLR that were not identified were due to isolated isthmectomies and selective parathyroidectomies. Neuromonitoring was not performed in 128 patients (32%), being carried out in 272 (68%). Out of the total 625 dissected NLR, 462 (73.9%) were monitored. Thirteen unilateral vocal cord paralyses were recorded, 8 of which were temporary (1.2%), recovering in less than 6 months, and 5 were definitive (0.8%). Of the 8 temporary paralyses, 6 occurred with neuromonitoring (1.29%) and 2 without neuromonitoring (1.22%), while of the 5 definitive paralyses, 4 (1%) were with neuromonitoring and 1 (0.2%) without neuromonitoring (Table 3). Of the 5 definitive paralyses, 4 were due to oncological pathology and 1 to a parathyroidectomy. There were no bilateral paralyses. In the 272 neuromonitored patients, after performing postoperative

Table 2
Type of surgery performed

	Frequency	Percentage
Hemithyroidectomy	133	33,25%
Total Thyroidectomy (TT)	175	43,75%
Isthmectomy	2	0,5%
TT + Central Compartment Neck Dissection	10	2,5%
TT + Lateral Compartment Neck Dissection	18	4,5%
Lateral Compartment Neck Dissection	5	1,25%
Isolated parathyroidectomy	19	4,75%
Bilateral parathyroidectomy	2	0,5%
Subtotal parathyroidectomy	2	0,5%
Doble unilateral parathyroidectomy	3	0,75%
TT + parathyroidectomy	15	3,75%
Hemithyroidectomy + parathyroidectomy	16	4%

Table 3
Postoperative unilateral laryngeal paralysis

Patients n= 13	Temporary (8)		Definitive (5)	
	Frequency	Percentage	Frequency	Percentage
IONM	6	1,29%	4	1%
Without IONM	2	1,22%	1	0,2%

Intraoperative neuromonitoring (IONM)

Table 4
Relationship between neuromonitoring and postoperative laryngoscopy

	Frequency n=272	Percentage
TN (record + / No paralysis)	239	87,8%
TP (record - / Unilateral paralysis)	10	3,6%
FP (record - / No paralysis)	23	8,4%
FN (record + / Paralysis)	0	0%

(True Negative: TN, True Positive: TP, False Positive: FP, False Negative: FN)

laryngoscopy, 239 true negatives (TN) were recorded with a rate of 87.8%, 10 true positives (TP) with a rate of 3.6%, 23 false positives (FP) with a rate of 8.4%, and 0 false negatives (Table 4). The negative predictive value (NPV) was 100%, and the positive predictive value (PPV) was 30%. The sensitivity and specificity of neuromonitoring were 100% and 91%, respectively. On the other hand, the pretiroideal muscles were not sectioned in 248 patients (62%), unilateral in 110 (27.5%), and bilateral in 42 patients (10.5%). The predominant hemostasis system used was bipolar sealing with a vascular sealing system and bipolar clamp in 348 patients (87%), associated with traditional ligature in 52 patients (13%). Muscle section and traditional ligation were reserved for pedicles of large cervical or substernal goiters. Only 1 patient (0.25%) experienced postoperative bleeding, which was resolved without complications.

Discussion

The main limitations of thyroid surgery for decades have been its serious complications. Therefore, the idea of the study is to increase surgical safety based on two fundamental aspects: IONM and the use of vascular sealing systems. Firstly, IONM of the RLN was introduced in the 1970s with the aim of reducing rates of laryngeal paralysis. Since then, there have been several studies focused on IONM, trying to clarify whether this tool really helps and reduces laryngeal paralysis, as results in many individual clinical studies are contradictory, and meta-analyses have not established acceptable conclusions (9). Most reviews state that IONM reduces the rates of transient unilateral laryngeal paralysis but not permanent unilateral or bilateral paralysis[10]. The main limitation in study design is the low paralysis rate, which requires a larger sample size and the heterogeneity of samples. There are numerous arguments in favor of IONM, such as assistance in difficult situations (reinterventions, locally advanced tumors), nerves with anomalous pathways or branches, facilitating dissection through successive checks, providing information about nerve functionality after lobectomy, and therefore aiding decision-making in case of signal loss on the first side. It increases the surgeon's confidence, is useful in teaching, medicolegal aspects, aids in data recording, and is better interpreted with increased usage[11]. Therefore, it enhances patient safety. The American Academy of Otolaryngology and Head and Neck Surgery recommends performing IONM since it reduces the identification time of the RLN, the incidence of transient paralysis, and helps prevent bilateral paralysis[12]. However, there are also arguments against it, such as the fact that the rate of permanent paralysis is not reduced, the relatively high rate of false positives that interferes with the normal development of surgery, and the risk posed to the patient by false negatives. All of this, combined with the cost of the equipment, lack of consensus, and heterogeneity in its use, makes IONM limited for some[13]. A consensus document was established in 2018 by members of the thyroid commission of the Spanish Society of Otolaryngology (SEORL) on the use of IONM, recommending its use in all cases and should be performed in high-risk surgeries. In cases of signal loss in the first lobectomy of a total thyroidectomy, it allows decision-making and contributes to reducing bilateral paralysis, increasing patient safety. The sequence would be to stimulate the vagus predisection (V1), RLN predisection (R1), RLN postdisection (R2), and finally, the vagus postdisection (V2)[14,13] In our study, we performed IONM in 462 (73.9%) of all operated nerves. During the first 3 years, we performed it in high-risk surgeries, and from 2014 onwards, we did it systematically in all patients. We only collected electrical signals R1 and R2 at the proximal end of the recurrent (reducing excessive dissections and avoiding the risk of false negatives), and in cases of oncological surgery with associated neck dissection or very voluminous goiters, we also collected V1 and V2. The rate of temporary unilateral laryngeal paralysis was 1.2%, and permanent paralysis was 0.8%. According to most studies, temporary paralysis ranges from 1.4% to 30%, and permanent paralysis ranges from 0.3% to 5%[15-18] [14,15,16,17]. The incidence of temporary paralysis with and without IONM was 1.29% and 1.22%, respectively, and permanent paralysis was 1% with IONM and 0.2% without IONM. As in most studies, conclusions cannot be drawn since the paralysis rate is low, and the study is heterogeneous (the group of patients with IONM is larger, and in addition, in the early years, complex cases with a higher risk of paralysis were monitored). This is the main limitation of the study. The second major factor that interferes with the safety of thyroid surgery is postoperative bleeding. The incidence of bleeding and its complications has decreased with the introduction of new sealing and vascular closure devices based on different types of energy. However, the risk of thermal injury to the RLN can increase if not used correctly. To avoid increasing nerve injuries, it is necessary to know the mechanism and functioning, the safe distance from important structures, and proper learning. Therefore, it should not be used in the vicinity of the RLN without first identifying it, and the distance should not be less than 2-3 mm [8]. In our study, we used the same vascular sealing system (Ligasure TM small jaw) in all patients. It was used not only for sealing but also in dissection and pretiroideal muscle section. Sealing was systematically performed on the upper and lower pedicles and anterior jugular veins if the pretiroideal musculature was sectioned. Hemostasis was carried out with sealing and bipolar in 348 patients (87%), and traditional ligation was added in the remaining 13%.Conventionally, systematic pretiroideal muscle section contributed to increase the risk of bleeding. Out of 400 patients, we did not section the pretiroideal muscles in 248 (62%). Unilateral section was necessary in 110 (27.5%), and bilateral section in 42 (10.5%). The incidence of postoperative bleeding was 0.25%, indicating that the systematic use of vascular sealing associated with the preservation of the pretiroideal musculature contributes to the reduction of bleeding risk. Similar to IONM, results with vascular sealing systems are difficult to compare and extrapolate due to the scarcity of randomized clinical trials and sample biases (type of surgery, surgical experience, etc.). In general terms, these hemostasis systems offer clear advantages by reducing time, simplifying the surgical procedure, minimizing blood loss, facilitating surgery in confined spaces, and eliminating or reducing the number of traditional ligatures, thus eliminating human error[19]. The main limitation of our study, like most others, is the low rate of laryngeal paralysis and heterogeneous samples.

Conclusions

In the thyroid and parathyroid surgery, IONM associated with the latest hemostasis advancements has demonstrated its utility, enhancing safety along with other benefits such as reduced surgical time, decreased hemorrhagic risk, and consequently, shorter hospital stays. It remains unclear whether IONM globally decreases laryngeal paralysis due to the lack of well-designed studies. It appears to decrease temporary unilateral laryngeal paralysis and also contributes to the reduction of bilateral paralysis through intraoperative decision-making in signal loss situations. Therefore, IONM aids in the identification and dissection of the RLN, provides information on functional status at the end of surgery, and allows decision-making in the event of signal loss on the first side of a thyroidectomy. It is also useful in legal and educational contexts.

Given all the aforementioned points, both tools are essential in this surgery, improving safety and helping reduce complications, which in some situations can be extremely serious.

Conflict of interest

The authors declare that they have no conflicts of interest related to this article.

Data confidentiality

The authors declare that they followed the protocols of their work in the publication of patient data.

Protection of people and animals

The authors declare that the procedures followed are in accordance with the regulations set by the directors of the Clinical Research and Ethics Committee and in accordance with the Helsinki Declaration of the World Medical Association.

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Availability of Scientific Data

There are no publicly available datasets related to this work.

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