Original Article

Two-Stage Thyroidectomy Driven by Intraoperative Neuromonitoring: Informed Consent Process and Its Effect on Patient Willingness and Consent Rates

Giuseppa Graceffa , Salvatore Vieni , Manfredi Magliulo , Iole Laise , Mario Latteri , Calogero Cipolla

Department of Surgical Oncological and Oral Sciences, University of Palermo, Palermo, Italy

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Correspondence to

Calogero Cipolla

Department of Surgical Oncological and Oral Sciences, University of Palermo, Via del Vespro 129, Palermo 90127, Italy.

E-mail: calogero.cipolla@unipa.it

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ORCID iDs

Giuseppa Graceffa

<https://orcid.org/0000-0002-2608-835X>

Salvatore Vieni

<https://orcid.org/0000-0002-4082-6945>

Manfredi Magliulo

<https://orcid.org/0000-0003-0154-3173>

Iole Laise

<https://orcid.org/0000-0001-8250-3071>

Mario Latteri

<https://orcid.org/0000-0002-2647-1578>

Calogero Cipolla

<https://orcid.org/0000-0003-4396-3563>

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Author Contributions

Conceptualization: Giuseppa Graceffa, Salvatore Vieni, Mario Latteri, Calogero Cipolla; Data curation: Manfredi Magliulo, Iole

ABSTRACT

Purpose: Intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerve (RLN) is a useful technique that can be applied to assess the nerve functionality at the end of the first side lobectomy in a planned total resection to prevent the bilateral injury of the RLN. Here we describe the process of informed consent of patients, who were subjected to a 2-stage thyroidectomy, and its effect on the patients' willingness to be operated on as well as their consent rates.

Methods: A retrospective observational study of patients, undergoing thyroidectomy with standardized IONM, was conducted from January 2019 to December 2019. All patients were preoperatively informed about the possibility of undergoing a 2-stage thyroidectomy. The outcome of this information was evaluated through a specific questionnaire that the patients were asked to fill in.

Results: Eighty patients were initially included in the analysis. The treatment was discontinued in 8 patients, who were originally eligible to total thyroidectomy, due to the detection of a loss of signal in the electromyography. The analysis of the results of the questionnaires highlighted a high compliance of the patients with the expectation of a possible new intervention.

Conclusion: Two-stage thyroidectomy proved to be a reliable surgical approach and appeared to be largely accepted by the patients.

Keywords: Thyroid surgery; Intraoperative neuromonitoring; Nerve injury

INTRODUCTION

The injury of the recurrent laryngeal nerve (RLN) represents the most feared complication of thyroid surgery due to the heavy impact this may have on the patients' quality of life (QoL) (1-3). Indeed, the damage of the RLN may eventually lead to a slight alteration of the voice tone, due to a unilateral vocal cord paralysis (1,2). The incidence of bilateral RLN damage is fortunately very low, in the order of 0.6% (1-5). Bilateral RLN palsy is an uncommon complication, which, although transient, may be life-threatening since it is associated to airway obstruction, which can be potentially lethal for the patient (1-10).

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Intraoperative neuromonitoring (IONM) of the RLN has acquired an increasing importance in thyroid surgery over time (6-10). IONM is a useful technique not only for the identification of the RLN but also for the assessment of the nerve functionality during and at the end of the surgical procedure (11-15). In a planned total resection, to prevent the possible bilateral injury of the RLN, IONM is useful to assess the nerve functionality at the end of the first side lobectomy (15-26).

The aim of this study was to describe the process of informed consent of patients, who were subjected to a 2-stage thyroidectomy guided by IONM and its effect on the patients' willingness to be subjected to an operation as well as their consent rates.

MATERIALS AND METHODS

1. Dataset

We retrospectively examined the records of 90 patients, who were submitted to thyroid surgery in our Division of General Surgery at University Hospital AOUP Paolo Giaccone between January 2019 and December 2019. Ten patients were excluded since they were selected for an elective lobectomy. Eighty patients were, thus, included in the final study.

The Institutional Review Board (IRB21/2019) accepted the revision and confirmed the final dataset. Each patient was informed about the study in detail and asked to give his/her formal written consent to participate.

2. Study design

The study design consisted in a retrospective, descriptive, non-analytic observational investigation. The defined population and outcomes measured were derived from a retrospective review of a prospectively maintained institutional database.

3. IONM equipment

The IONM procedure applied was as previously described in the literature (3,4). The RLN and vagal nerve stimulations were achieved by using a monopolar stimulator probe. Moreover, laryngeal twitching was always checked. Continuous nerve monitoring, instead, was not applied in the present study.

4. Definitions

A signal was defined as unchanged when the V1 and V2 signals were successfully obtained with the same level of stimulation during the operation and no apparent change occurred when measurements were compared (3,4). The loss of signal (LOS), in particular of the V2 signal, was identified as a total loss of the primary normal biphasic waveform with a reduced amplitude response to less than 100 μ V and with a stimulation level intensity of 1 mA (3,4).

5. Outcomes

Our aim was not to verify if IONM reduced the RLN palsy rate but rather to provide information concerning the process of informed consent of patients submitted to a 2-stage thyroidectomy and its effect on patients' willingness to be operated on as well as their consent rates. All patients were preoperatively informed about the possibility of undergoing a 2-stage thyroidectomy and the outcome of this information was evaluated through a questionnaire (Fig. 1). We, thus, presented each patient to a specific questionnaire in order to establish

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We kindly ask you to answer the following questions: these will help us to understand if the information given to you were adequate and clear and if you expectation regarding the IntraOperative NeuroMonitoring (IONM) were met.

1) Do you feel you were sufficiently informed about the IONM and the two-stage thyroidectomy?

1 2 3 4 5

(1= strongly agree; 2= agree; 3= neutral; 4= disagree; 5= strongly disagree).

2) The information given to you:

A. Were already known to you
B. Were not known to you
C. Were partly known to you, but you wanted to deepen them.

3) The topics covered:

A. Were sufficiently complete
B. Were not sufficiently complete.

4) Was the surgical staff available enough to dialogue and cooperation?

A. Yes
B. No

5) Did you know the advantages brought by the IONM?

A. Yes
B. No

6) The surgical procedure was:

A. Adequate
B. Inadequate

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7) What percentage of the expectations you had before the surgery were met?

0 10 20 30 40 50 60 70 80 90 100 %

8) Do you have suggestions, criticisms to do?

A. Yes
B. No

9) Are there other topics that were not addressed, but you wanted to discuss?

10) Do you feel that the information regarding IONM given to you are needful for the patient's conscious choice and therefore should be given during the outpatient visit?

A. Yes
B. No

11) How did you approach the idea that the surgery could be carried out in two stages?

1 2 3 4 5

(1= strongly agree; 2= agree; 3= neutral; 4= disagree; 5= strongly disagree).

12) Judge your satisfaction with the completeness of the information received on the IONM:

1 2 3 4 5

(1= strongly agree; 2= agree; 3= neutral; 4= disagree; 5= strongly disagree).

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Fig. 1. Model form of the questionnaire submitted to the patients.
IONM = intraoperative neuromonitoring.

whether he/she accepted to be subjected to a 2-stage surgical procedure or not. Only 40 out of the 80 patients examined (50% of our dataset) were willing to answer the questionnaire.

A pre- and postoperative follow-up, which included videolaryngoscopy, was performed 24 hours before the surgery and on the first day following the operation and, subsequently, every 2 weeks up to a period of 6 months from the surgery. The dysfunction was considered permanent if it persisted for 12 months.

6. Data analysis

The measurement of the RLN palsy rate was based on the number of nerves at risk (15). All patients' data was collected in a prospective manner with a dedicated electronic Microsoft Office Access Data Base (Microsoft Corp., Redmond, WA, USA). The database is part of our department's quality-improvement programme.

RESULTS

Eighty patients were included in the final analysis (22 men, 58 women) with a mean age of 55.6 ± 13.1 years (range, 23–63 years). In most cases, prior to the operation, patients were diagnosed with a multinodular goiter. The demographic and pathological characteristics of the eighty patients are summarized in **Table 1**.

All 80 patients were subjected to a thyroidectomy. However, only 72 patients underwent a total thyroidectomy while it was discontinued in the remaining 8 cases (10%) due to a LOS in the electromyography and absence of laryngeal twitching. The latter, thus, underwent a 2-stage thyroidectomy (**Table 1**).

Table 1. The demographic and pathological characteristics of the 80 patients of our dataset subdivided on the basis of the surgery they were subjected to (total vs. 2-stage thyroidectomy)

Characteristics of the 80 patients	Characteristics of the 72 patients who underwent total thyroidectomy	Characteristics of the 8 patients who underwent 2-stage thyroidectomy
Age (yr)		
Mean age	54.8±13.03	54.0±6.32
Range	23–63	45–63
Sex		
Male	20 (27.77)	2 (25)
Female	52 (72.22)	6 (75)
BMI (kg/m ²)		
Normal (≤25)	27 (37.5)	3 (37.5)
Overweight (25–30)	29 (40.3)	4 (50)
Obese (≥30)	16 (22.2)	1 (12.5)
Pathology		
Non-toxic multinodular goiter	50 (69.4)	7 (87)
Toxic multinodular goiter	6 (8.3)	0
Graves' disease	11 (15.27)	0
Plummer's disease	2 (2.7)	0
Differentiated thyroid carcinoma	3 (4.16)	1 (12.5)
Thyroid weight (g)		
≤20	17 (23.6)	2 (25)
21–40	40 (55.5)	4 (50)
>40	15 (20.8)	2 (25)

Data are shown as mean±standard deviation or number (%).

BMI = body mass index.

Ear, nose, and throat (ENT) specialists investigated the anatomical and functional integrity of the vocal cord in these 8 patients by means of a videolaryngoscopy, which was performed 24 hours after the surgery and, subsequently, every 2 weeks up to a period of 6 months from the operation. The RLN damage was ascertained in 6 out of 8 cases (75%). In these patients the average recovery time of vocal cord palsy was of 37.6 days (range, 28–98 days). The ENT follow-up, which was conducted in these 6 patients, showed an improvement of the RLN damage up to a complete recovery. In the remaining 2 cases, in which also laryngeal twitching was absent, the postoperative videolaryngoscopy did not reveal any damage 24 hours following the thyroidectomy. These 2 patients, in whom no RLN damage was observed, were thus immediately subjected to a contralateral lobectomy, as already explained in the preoperative informed consent. Thus, the bilateral damage of the RLN was null when patients were exposed to a 2-stage thyroidectomy.

Of the 80 patients examined, only half (n=40, 50%) were willing to answer the questionnaire. Concerning the questionnaire, patients were fully satisfied with the information they received prior to the operation, as is shown in **Table 2**.

DISCUSSION

Studies on the standardized use of IONM have shown that its application in thyroid surgery has a highly negative predictive value, ranging from 90% to 100% (1,7,8). On the other hand, the positive predictive value shows a wide range, from 10% to 90%, because of the high number of false positive results (11).

We used IONM and no case of permanent RLN damage was observed in all the 80 patients included in the study. Based on our experience, the risk of bilateral RLN permanent damage

Table 2. Questionnaire replies

Question		Answer				
1		1	2	3	4	5
No. of patients		39 (97.5%)	1 (2.5%)	0	0	0
2		A		B		C
No. of patients		0		40 (100%)		0
3			A		B	
No. of patients			40 (100%)		0	
4			Yes		No	
No. of patients			40 (100%)		0	
5			A		B	
No. of patients			0		40 (100%)	
6			A		B	
No. of patients			0		40 (100%)	
7		0%-30%	40%-70%	80%	90%	100%
No. of patients		0	0	2 (5%)	1 (2.5%)	37 (92.5%)
8			A		B	
No. of patients			40 (100%)		0	
9			Open-ended question			
No. of patients			No patients answered			
10			A		B	
No. of patients			40 (100%)		0	
11		1	2	3	4	5
No. of patients		36 (90%)	2 (5%)	2 (5%)	0	0
12		1	2	3	4	5
No. of patients		40 (100%)	0	0	0	0

was null when patients were subjected to a 2-stage thyroidectomy. In fact, in the 8 patients (6 ascertained) described above, the 2-stage thyroidectomy procedure applied avoided the bilateral RLN damage, cutting off long-term complications.

The routine use of IONM in thyroid surgery has led to 2-stage operations to prevent bilateral RLN palsy. By following this approach, the removal of the thyroid gland occurs in 2 stages. In the first stage, surgery is limited to the main lobe, while the remaining gland is excised only at a later stage, in a second intervention. In fact, in case of LOS following excision of the first lobe, the surgeon can evaluate the opportunity to delay the removal of the second lobe. Thus, a LOS during first lobectomy should lead to a waiting time before the contralateral lobectomy is performed.

In line with previous findings, we recommend to consider some key points when applying the 2-stage approach to thyroid surgery (3,4,26).

First of all, it is crucial that a 2-stage thyroidectomy is performed by a team of physicians, having different competences. We suggest that ENT experts perform pre- and post-operative laryngoscopy, that anesthesiologists should be guided in the correct placement of the endotracheal tube and to avoid the use of long-term muscle-relaxant.

As indicated in the International Neural Monitoring Study Group guidelines, the procedure should start from the dominant thyroid lobe. Only if a LOS occurs should you recur to a 2-stage approach in order to avoid the risk of bilateral vocal cord paralysis and its implications in the patient's QoL (2,4).

Secondly, but equally important, is the fact that all patients must be aware and accept to undergo a 2-stage thyroidectomy in order to avoid any risk of bilateral RLN damage.

This decision should take into account several elements, including, in particular, thyroid pathology. Over the years, oncologic radicality, in cases of a 2-stage thyroidectomy, has been a matter of debate. In this respect, we should consider that differentiated thyroid carcinomas have a good prognosis, even in cases of local or distant metastases, and that radioablative therapy with iodine-131 can be delayed safely (26). In case of thyroid carcinoma, the thyroidectomy should preferably start from the tumor side. In case of thyroid carcinoma with preoperative ipsilateral vocal cord paralysis, the surgery can even start from the contralateral side, proceeding towards the invaded side in the absence or after intraoperative recovery of LOS (27). Thus, a 2-stage thyroidectomy seems to be adequate also in cases of thyroid carcinoma. Alternatively, a near-total lobectomy could be performed on the second side to preserve the contralateral RLN.

CONCLUSION

In this scenario, it is necessary to underline once again the importance of a correct standardization of IONM to reduce false positive results, which may lead to an unnecessary 2-stage thyroidectomy. When a 2-stage thyroidectomy is performed, contralateral lobectomy should be carefully planned following the recovery of the vocal cord motility, typically 6–8 weeks after surgery, or, in case of permanent palsy, after the demonstration that there is enough respiratory space.

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