The Consistency of Intraoperative Neural Monitoring in Thyroid Surgery

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ABSTRACT

Numerous operating tools and technology transfers are available for thyroid surgery teams performing open, endoscopic and robotic procedures but none, or very few, of them constitutes a mandatory prerequisite. Over the past decade, the choice of intraoperative neurophysiological monitoring (IONM) of the recurrent laryngeal nerve (RLN), has been reached certain consensus, which must at least be selected on an individual basis. Identification and intraoperative assessment of the RLN seems to be more effectively performed with IONM than solely visually or endoscopically. Today, IONM has evolved sufficiently to increase the likelihood of successful functional outcomes in many patients. The transition from the concept of intermitted neural monitoring of the RLN to that of continuous functions evaluation that must be appreciate requires highly skilled knowledge of IONM. This goal will be more likely achieved in centers highly specialized in thyroid surgery.

Keywords: Thyroid gland; Thyroidectomy; Injury; Innervation

INTRODUCTION

Intraoperative neurophysiological monitoring (IONM) has emerged over the last 2 decades, as one of the main avenues of progress within surgery. The idea of applying techniques traditionally used in clinical neurophysiology within the operating room is not novel (1). IONM have been used for many years during neurosurgical procedures, spine surgery, vascular, plastic, Otolaryngology (ENT), etc. (1). Victor Riddel (2) wrote in 1970 on the British Journal of Surgery:

“... It is the author inflexible rule never to resect the second lobe in a bilateral procedure until the integrity of the recurrent laryngeal nerve (RLN) has been proved...”

“... stimulation of the RLN by electrical current will establish its integrity palsy...”

“... stimulation will determine if an unidentified strand of tissue is the RLN or not...”
In the recent past, there has been a renewed drive toward the implementation of these techniques in thyroid surgery, thanks to the advent of new methods, such as non-invasive monitoring throughout dedicated electromyographic (EMG) endotracheal tubes. IONM simplification has allowed for an increase in the indications for IONM and has also expanded clinical and experimental research of the RLN and external branch superior laryngeal nerve (EBSLN) (3). IONM is aimed at either identifying functional structures which cannot be recognized purely on the basis of anatomical landmarks (mapping) or to continuously assess the functional integrity of neural pathways which can be injured during surgery (monitoring) (4).

The rationale and indications for IONM have substantially changed in the last 5 years. Methodologies have to some extent evolved, although the basic principles of monitoring and mapping techniques remain the same. Nevertheless, IONM has undoubtedly become more and more accessible and extensively used than it has been in the past. The growing interest for this discipline is well documented by the increasing number of publications in this field, both in the form of peer-reviewed papers and edited books as well as by the number of scientific meetings dedicated to intraoperative neurophysiologic monitoring (4,5).

There are scientific societies, such as the International Neural Monitoring Study Group (INMSG, www.INMSG.org) and the Korean Intraoperative Neural Monitoring Society (KINMoS, www.kinmos.or.kr), whose members are dedicated to IONM in their daily thyroid practice (6). These and other scientific societies are now facing the need to establish guidelines, credentials, and training requirements for the practice of IONM. The spectrum of expertise and advancements in this field varies quite considerably across different countries, but there is no doubt that the driving force is not limited to Europe, Asia, North America, and involves, to a different extent, virtually all 5 continents.

THE SURGEON AND IONM

IONM is favored by many endocrine surgeons nowadays, but this has not always been the case. In 2007, Loch-Wilkinson et al. (7), wrote that:

“IONM technique cannot never be cost-effective if measured as a cost real for lesion of the avoided nerve”

At same time, false-negative and false-positive results, namely a patient waking up from anesthesia with a RLN deficit in spite of intraoperatively preserved EMG signal or patient waking up from anesthesia without a RLN deficit in spite of intraoperatively changed or loss of signal, could occur, and this detracted from the reliability of IONM (8).

Furthermore, IONM was erroneously considered useful merely for predicting the outcome but not for preventing RLN deficits and this also contributed to its lack of popularity among some surgeons. The feeling of “wasting time” when performing IONM techniques is still a concern for a number of surgeons, as well as the technological, generational hurdle, the personal pride, the lack of audit, absent postoperative laryngeal examination, to still sustain that RLN palsy does not exist in their practice (7,8).
In analogy to the introduction of the laparoscopy in the 1980s, far from being widely accepted at that time, IONM had to find its way to become welcome in the operating room.

The idea of a different professional figure (namely the surgeon and the anesthesiologist) working more hand in hand in the operating room and cooperating for the proper EMG tube position, induction and maintenance of anesthesia, the concordance of intraoperative surgical strategy (abort second side surgery in case of loss of EMG signal at first resected side to prevent bilateral RLN injury) became readily acceptable to both professionals.

The reluctance to use IONM has significantly changed today, together with an increasing acknowledgement of the reliability and value of IONM in our endocrine surgery practice. Yet, some resistance to the use of IONM still exists nowadays and relies mainly on the criticism that the use of IONM is not “evidence-based” (1).

**IS IT EVIDENCE-BASED?**

There is discussion about the fact that IONM is not based on class I evidence. Yet, we may ask ourselves what level of evidence we do need to justify the use of IONM. Although the level of evidence for the benefit of IONM is limited to class II and class III studies, it should be recognized that the same level of evidence applies to most of our clinical practice within thyroid surgery and any other technology applied as energy based device utility, intact parathyroid hormone (iPTH), endoscopic or robotic procedures, florescence, etc. (9). From the other surgical procedures using IONM as spinal surgery to that of vascular, brain surgery, even the more accredited analyses (such as Cochrane reviews) fail to demonstrate class I evidence (1,10-12). So, after all, we have to admit that the level of evidence based medicine in IONM is not worse than that found in general surgery generally and in thyroid surgery in particular (1).

It is very unlikely that class I studies will ever occur in the field of IONM (13). There are at least 2 reasons for this. First, the likelihood of preventing a transient RLN deficit using IONM is low that a controlled study where patients are randomly assigned to a control group or a monitored group would be unethical and unacceptable to patient and surgeon alike (13). Moreover, the incidence of severe and permanent RLN complications is even lowest. Thus, IONM would aim at further reducing a number that is already small to begin with (13). A power calculation study would therefore predict that the number of patients needed for such a study would surpass the number of patients enrolled in most single institution and, most likely, multicenter studies (13). We should therefore accept that in the future, the benefit of IONM will continue to be based on good clinical outcomes, historical control studies, and cost-benefit evaluations (1).

One of the concerns relating to guidelines in the field of IONM is related to their medicolegal implications (13-19). Some reports suggest that the courts are applying new clinical practice guidelines in their decision-making processes, it is worthwhile to anecdotally recall a case in which a patient sustained RLN palsy after thyroid surgery, and the plaintiffs’ expert supported the view that IONM was considered the standard of care (13-19).
The Authors of this paper argue that the benefits of the IONM are not legal, but certainly clinical-intraoperative. It is really a pity that the concept of usefulness of the IONM is limited solely to legal medical matters.

**COST-BENEFITS**

A few papers have addressed the issue of costs and benefits in neuromonitoring in thyroid surgery (20-23). A detailed evaluation of the costs of IONM should include not merely those of the equipment and disposables (electrodes, probes, etc.) but also that of training, learning curve, nerve early and definitive identification, the aid in nerve dissection, the continuous nerve function evaluation, cataloging anatomy variability, intraoperative surgical strategy and synchronization of surgical maneuvers, injury mapping, the cost of responding to a IONM warning (false vs. true signals), the EBSLN identification and monitoring, teaching tool, IONM use in less experience surgeons, legal issues and the research imprint (20-23).

From a purely economic standpoint, benefits of IONM generally include the avoidance of RLN complications in terms of both rehabilitation costs, prevention of bilateral nerve injury, severe permanent injury, selective use, and economic compensation for malpractice lawsuits (20-23).

Although most of the papers published conclude that benefits slightly outweigh costs, it is obvious that the cost for each monitored procedure decreases along with the increasing number of cases monitored at a single institution (1,20-23).

The cost-benefit argument is not trivial as it is the one that influences hospital administrators when they decide to invest. The impression is that hospital administrators are increasingly sensitive to the value of IONM as to decrease malpractice claims is one of the goals (1).

IONM equipment is not particularly expensive when compared to the other tools that we use daily in the operating room for thyroid surgery as energy based devices, robots, endoscopy, etc. An average IONM system ranges between 15 and 20,000 euros. In the majority of Western countries, this does not represent an insurmountable cost.

The true limitation is lack of IONM training with an appropriate IONM curriculum, and what are the appropriate IONM credentials remain a matter of debate (1).

**THE EMG SIGNAL**

In conclusion, we may see the development of IONM during the past 10–15 years in thyroid surgery being well represented by the EMG signal (1). The EMG signal is the graphic representation of the maturity and adoption of IONM technologies (Fig. 1) (1).
Neural Monitoring

A

Technology trigger
Improvement of IONM
Non-invasive devices
EMG tubes
Commercial effort

B

Peak of inflated expectations
Overenthusiasm of IONM

C

Trough of disillusionment
False-negative results, limits, specificity, sensitivity, failures, malfunctions, evidence based medicine lacking

D

Slope of enlightenment
Awareness, research, societies, standardization, reliable goals, extended applications, CIONM, trouble shooting algorithms

E

Maturity
Tertiary care hospitals, academic institutions
perfect knowledge of IONM, neuroanatomy, clinical judgement, endoscopic and robotics application, simplification

Fig. 1. The EMG signal for IONM in thyroid surgery. (A) Technology trigger: This is the first phase, a breakthrough that occurs when IONM is launched on the market generating interest and attraction, due mainly as a non-invasive devices (EMG tubes) and commercial effort. (B) Peak of inflated expectations: This is what happens when overenthusiasm and unrealistic expectations are generated. In this phase, successful applications and failures of a technology occur (first false-negative and false-positive results appearing in the literature). (C) Trough of disillusionment: This is what happens when expectations are not met and technologies become unfashionable. This may correspond to IONM limits evidence, false-negative results, specificity, sensitivity, failures, malfunctions, evidence based medicine lacking. (D) Slope of enlightenment: This is the phase of maturity, when in spite of some failures, research continues to grow, identify reliable goals, and extend applications. Furthermore IONM societies development, standardization, extended applications, CIONM, trouble shooting algorithms application. (E) The plateau of productivity: In tertiary care hospitals and academic institutions where it is performed according to both the highest professional level and standards of care, perfect knowledge of IONM, neuroanatomy, clinical judgement, endoscopic and robotics application, simplification of technology. EMG = electromyographic; IONM = intraoperative neurophysiological monitoring; CIONM = continuous intraoperative neurophysiological monitoring.
REFERENCES

1. Sala F. Intraoperative neurophysiology is here to stay. Childs Nerv Syst 2010;26:413-7.
PUBMED | CROSSREF

2. Riddell V. Thyroidectomy: prevention of bilateral recurrent nerve palsy. Results of identification of the nerve over 23 consecutive years (1946–69) with a description of an additional safety measure. Br J Surg 1970;57:141.
PUBMED | CROSSREF

3. Barczyński M, Konturek A, Cichoński S. Randomized clinical trial of visualization versus neuromonitoring of recurrent laryngeal nerves during thyroidectomy. Br J Surg 2009;96:240-6.
PUBMED | CROSSREF

4. Randolph GW, Dralle H, Abdullah H, Barczyński M, Bellantone R, Brauckhoff M, et al. Electrophysiologic recurrent laryngeal nerve monitoring during thyroid and parathyroid surgery: international standards guideline statement. Laryngoscope 2011;121 Suppl 1:S1-46.
PUBMED | CROSSREF

5. Schneider R, Sekulla C, Machens A, Lorenz K, Thanh PN, Dralle H. Dynamics of loss and recovery of the nerve monitoring signal during thyroidectomy predict early postoperative vocal fold function. Head Neck 2016;38 Suppl 1:E144-51.
PUBMED | CROSSREF

6. Kim HY, Tufano RP, Randolph G, Barczyński M, Wu CW, Chiang FY, et al. (KINMoS). Impact of positional changes in neural monitoring endotracheal tube on amplitude and latency of electromyographic response in monitored thyroid surgery: results from the porcine experiment. Head Neck 2016;38 Suppl 1:E1004-8.
PUBMED | CROSSREF

7. Loch-Wilkinson TJ, Stalberg PL, Sidhu SB, Sywak MS, Wilkinson JF, Delbridge LW. Nerve stimulation in thyroid surgery: is it really useful? ANZ J Surg 2007;77:377-80.
PUBMED | CROSSREF

8. Sietes-Serra A, Fontané J, Dueñas JF, Duque CS, Lorente L, Trillo L, et al. Prospective study on loss of signal on the first side during neuromonitoring of the recurrent laryngeal nerve in total thyroidectomy. Br J Surg 2013;100:666-6.
PUBMED | CROSSREF

9. Carlander J, Wagner P, Gimm O, Nordenström E, Jansson S, Bergkvist L, et al. Risk of complications with energy-based surgical devices in thyroid surgery: a national multicenter register study. World J Surg 2016;40:117-23.
PUBMED | CROSSREF

10. Whitfield PC, Kirkpatrick P. Timing of surgery for aneurysmal subarachnoid haemorrhage. Cochrane Database Syst Rev 2001:CD001697.
PUBMED

11. Tator CH. Review of treatment trials in human spinal cord injury: issues, difficulties, and recommendations. Neurosurgery 2006;59:957-82.
PUBMED | CROSSREF

12. Wilson L, Lin E, Lalwani A. Cost-effectiveness of intraoperative facial nerve monitoring in middle ear or mastoid surgery. Laryngoscope 2003;113:1736-45.
PUBMED | CROSSREF

13. Dralle H, Sekulla C, Lorenz K, Brauckhoff M, Machens AGerman IONM Study Group. Intraoperative monitoring of the recurrent laryngeal nerve in thyroid surgery. World J Surg 2008;32:1358-66.
PUBMED | CROSSREF

14. Kim HY, Liu X, Sun H, Wu CW, Chai YJ, Chung WY, et al. Medico-legal issues of intraoperative neuromonitoring in thyroid surgery. J Endocr Surg 2017;17:42-56.
CROSSREF

15. Dralle H, Schneider R, Lorenz K, Phuong NT, Sekulla C, Machens A. Vocal cord paralysis after thyroid surgery: current medicolegal aspects of intraoperative neuromonitoring. Chirurg 2015;86:698-706.
PUBMED | CROSSREF

16. Dralle H. Surgical assessment of complications after thyroid gland operations. Chirurg 2015;86:70-7.
PUBMED | CROSSREF

17. Dralle H, Lorenz K, Machens A. Verdicts on malpractice claims after thyroid surgery: emerging trends and future directions. Head Neck 2012;34:1591-6.
PUBMED | CROSSREF
18. Dionigi G, Bartolo V, Rizzo AG, Marullo M, Fabiano V, Catalfamo A, et al. Improving safety of neural monitoring in thyroid surgery: educational considerations in learning new procedure. J Endocr Surg 2018;18:21-36.

19. Dionigi G, Sun H, Chai YJ, Catalfamo A, Mangraviti A, Rizzo GA, et al. Bilateral vocal palsy after total thyroidectomy: expert opinion on two malpractice claims. J Endocr Surg 2017;17:139-48.

20. Wang T, Kim HY, Wu CW, Rausei S, Sun H, Pergolizzi FP, et al. Analyzing cost-effectiveness of neural-monitoring in recurrent laryngeal nerve recovery course in thyroid surgery. Int J Surg 2017;48:180-8.

21. Sanabria Á, Ramírez A. Economic analysis of routine neuromonitoring of recurrent laryngeal nerve in total thyroidectomy. Biomedica 2015;35:363-71.

22. Rocke DJ, Goldstein DP, de Almeida JR. A cost-utility analysis of recurrent laryngeal nerve monitoring in the setting of total thyroidectomy. JAMA Otolaryngol Head Neck Surg 2016;142:1199-205.

23. Al-Qurayshi Z, Kandil E, Randolph GW. Cost-effectiveness of intraoperative nerve monitoring in avoidance of bilateral recurrent laryngeal nerve injury in patients undergoing total thyroidectomy. Br J Surg 2017;104:1523-31.