

Cost analysis of intraoperative neural monitoring

Alessandro Pontin¹, Antonella Pino¹, Giulia Pinto², Gianlorenzo Dionigi¹, Ettore Caruso¹

¹Division of Endocrine and Minimally Invasive Surgery, ²Division of Oncological and Bariatric Surgery, Department of Human Pathology in Adulthood and Childhood "G. Barresi", University Hospital G. Martino, University of Messina, Messina, Italy *Correspondence to:* Gianlorenzo Dionigi. Division of Endocrine and Minimally Invasive Surgery, Department of Human Pathology in Adulthood and Childhood "G. Barresi", University Hospital G. Martino, University of Messina, Via C. Valeria 1, 98125, Messina, Italy. Email: gdionigi@unime.it.

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Introduction

The recurrent laryngeal nerve (RLN) injury represents one of the most feared complications during thyroidectomy (1). These injuries may cause a temporary or permanent palsy of the RLN and occur, more frequently, monolaterally. If only one side is involved, the palsy results in voice changes, hoarseness, or breathing trouble; in bilateral cases, instead, patients can undergo a potentially fatal airway obstruction needing an urgent tracheostomy (1). This complication, affects the quality of life of the patients, increases the charges for health care, and is the most frequent plea of lawsuits against thyroid surgeons.

The intra-operative neuro-monitoring (IONM) of RLN during thyroidectomy was introduced for the first time in 1990s (2). This technique helps surgeons recognize and preserve the RLN, improving precision during dissection, in order to decrease the risk of RLN palsy. Given the increasing use of IONM, original studies have been conducted to evaluate its effectiveness in reducing the recurrential injury risk. On the one hand, some of these showed that routinely application of IONM did not lower the risk of RLN palsy and three meta-analysis failed to prove any utility (including cost-effectiveness) in the systematic use of IONM during thyroid surgery (3-5).

On the other hand, other studies have indeed demonstrated the validity of IONM in high-risk thyroidectomy, in particular in patients with thyrotoxicosis, retrosternal goitre, who undergo reoperation and thyroidectomy for malignancy. However, only a few studies nowadays examined the advantages of IONM of RLN related to the costs sustained in order to use it (2,4,6). The aim of this review is to highlight these studies and trying to compare the results described.

Search strategy

Studies describing the economic impact of using neuromonitoring during thyroidectomy were retrieved from PubMed and Medline on 1st May 2018. For the research we used the following terms.

- #1 "Neuromonitoring cost"
- #2 "Cost-effectiveness of intraoperative neuromonitoring"
- ✤ #3 "IONM costs"

No methodological or language restrictions were applied during the research.

Studies published dated from 2010 to 2018 were included.

Appraisal

New technologies in surgery frequently mean a higher operative cost because they are more expensive compared to priors treatments and a greater number of patient is treated (7,8). Intraoperative neuromonitoring has been adopted quickly in the last 10 years in the USA as well as in Europe. Horne et al. (9) reported that more of 45% of otolaryngologists use neuromonitoring of the recurrent laringeal nerve and Sturgeon et al. (10). reported that neuromonitoring is used by 37% of general surgeons. This last percentage raised from 7% to 37% between 2001 and 2007 (9,10). In the 2009, in Europe, 5% to 77% of thyroidectomies was done with the Ausilium of neuromonitoring; these numbers varied depending on clinical practice of different countries (11,12). This practice has grown with the introduction of non-invasive tools for neuromonitoring, the publication of randomised prospective trials and with the adoption of guidelines that standardized

the use of IONM (intraoperative neuromonitoring) in thyroid surgery (13-17). In addition, the diffusion of IONM technology may depend on the demand of a single person and not on the decision of a committee. In fact, the decision to buy an IONM system is taken by single centres which compete with each other to attract surgeons and patients (7,8). In the attempt to increase operative volumes and, maybe, get some sort of legal protection by using the IONM, hospitals struggle to deny surgeons requests, even if direct repayment is not enough they are forced to satisfy market demands not to lose patients (18). For these reasons, given the fact that IONM could quickly become the standard practice during thyroid surgery, this review could be really useful to evaluate the cost-efficacy ratio of this technology.

We found only three paper in literature addressing this topic. The first one was published in 2012. In this paper Dionigi et al. (6) evaluated with a monetary approach the patient-care process after thyroidectomy (with and without IONM) by considering the major costs such as equipment, operating room, drugs, staff time, consumables and general expenses. To estimate the impact of the IONM on hospital management they thought of three possible scenarios: (I) traditional open thyroidectomy; (II) thyroidectomy with IONM in a high-volume centre (5 procedures per week); (III) thyroidectomy with IONM in a low-volume centre (1 procedure per week). In this study the authors also evaluated the cost impact of energy-based devices (EBD) used for hemostasis and dissection. They found that all thyroidectomies surpassed the reimbursement of the Italian Healthcare System based on the diagnosis related groups (DRGs) despite the use of IONM (scenario 1: 3.471€). The main expenses came from consumables and technologies (25%), operating room (16%), and staff (14%). Hospitalization costs for a thyroidectomy with IONM range from $3.713 \notin$ to $3.770 \notin$ (scenarios 2 and 3), 5–7% higher than those for traditional thyroidectomy. Even higher economic discrepancies were found when an EBD was used (3.969€).

In another study published in 2015, Sanabria and colleagues (4) created a decision analysis to assess the costeffectiveness of recurrent laryngeal nerve monitoring. To measure outcomes probabilities, they borrowed data from a meta-analysis and utility was quantified using preference values. The authors did not find differences in utility between arms. Recurrent laryngeal nerve injury rate was 1% in the neuromonitor group and 1.6% for the standard group. Thyroidectomy without monitoring turned out to be the less expensive option and the incremental costeffectiveness ratio was 9,112,065 COP\$. In conclusion they established that routine neuromonitoring in total thyroidectomy with low risk of recurrent laryngeal nerve injury was neither cost-use full nor cost-effective.

Finally, in 2017 Wang et al. (19) published a paper addressing cost-effectiveness ratio for IONM during thyroid surgery with a meticulous analysis of the cost versus utility of this technology for 5 different groups of patients: (I) no RLN injury, (II) vocal fold palsy (VCP) recovery within 1 month, (III) 2 months, (IV) 6 months and (V) after 12 months. In the model used to design this study the average patient consisted of a young female patient, 40 years old, employed, daily voice user, who underwent elective, conventional total thyroidectomy via cervical incision using a standardized intermittent IONM technique, for an operable benign, bilateral, diffuse, multinodular, non-toxic, non-retrosternal goiter. IONM was cost-effective if the rate of VCP was 33.6% at 1 month, 22.9% at 2 months, 9.8% at 6 months and 3.8% at 12 months, independent of phonosurgery. An important note was that the scenario described was cost-effective only in a high-volume setting. From these results the authors concluded that IONM was cost-effective for permanent RLN injuries.

During the history of thyroid surgery many types of monitoring of the recurrent laringeal nerve were proposed and adopted: laryngeal palpation, glottal observation, monitoring of the glottal pression, intramuscular electrodes endoscopically placed on the vocal cord, intramuscular electrodes placed trough cricothyroid membrane, endotracheal tube-based surface electrodes and postcricoid surface electrodes. For different reasons, including safety and ease of use, systems based on endotracheal tubebased surface electrodes are today the most used tools for neuromonitoring worldwide. Further research is necessary to analyze the costs related to the use of these technologies. The costs of the equipment and of consumable materials could lower with the increase of the competition in the machinery market or the sales of consumable material needed for neuromonitoring.

These reviews, however, were focused only on the economic aspects related to the use of IONM in thyroid surgery, without considering its clinical benefits (14,17). Loch-Wilkinson *et al.* (20) reported that IONM technology cannot be cost-efficient if measured in terms of real cost for nerve lesion avoided. In this contest comparative analysis of effectiveness could have a crucial role. In addition, in the majority of works, none of the possible consequences

Annals of Thyroid, 2019

of nerve lesion (for example medical therapy, reiterated laryngeal exams, surgery of the vocal cords, legal costs or compensation) was evaluated or included in the total cost. As of today, in thyroid surgery, only a single randomized trial was conducted on the use of IONM; the limited clinical evidence shows that transitory lesions of the nerve are far less common if neuromonitoring is used during the procedure (14,15,17). However, the objective of this study was not proving the clinical benefits of using the IONM. Barczynski et al. (17) demonstrated that the prevalence of transitory palsy of the RLN in high and low risk patients was respectively less than 2.9% and 0.9% during surgery with IONM. A multiple linear regression analysis confirmed that IONM system significantly lower the rate of transient and permanent palsy of the RLN from a factor of 0.58 and 0.30 respectively (14). These results may be used in future for a cost-efficacy and a costbenefit analysis to be conducted when the use of IONM will be more widely used. It's important that selection centres evaluate prospectively the potential benefits that thyroidectomy with IONM could produce. Moreover, in order to identify patients that could benefits more from the use of IONM instead of a traditional approach we need more evidences based on large multicentric studies and non-randomized careful evaluations (14,15,17). In high risk thyroid procedures the IONM proves himself safe and guarantees significantly better outcomes for the nerve when compared to traditional thyroidectomy (14,15,17). Currently, the selective application of neuromonitoring is the most common strategy in centres where thyroid surgery is practiced. Hospitals could use these information in response to the pressures of surgeons more prone to technology, whereas surgeons could use them to choose which option of treatment propose in high risk patients. These notions could be useful for the patients to choose the preferred treatment and for the payer in the negotiation of refunds. An efficient Health care System should valorize the ability of surgeons and their patients to make welldocumented decisions about the adoption and the use of new technologies even if this means no adequate refund form insurances or DRG systems.

Lastly, surgeons must perform at least 50 to 100 procedures with IONM to become experts in its utilization (21). The use of IONM systems could stretch operative time if compared to traditional surgery without IONM resulting in an increase of total costs. Furthermore in the aforementioned studies, the benefits of the intraoperative neural monitoring of the recurrent laringeal nerve such as the reduction of nerve lesion and its associated costs, are not considered.

All of the reported studies do not consider that the costs of neuromonitoring could possibly be justified with its use in other procedures such as parathyroidectomies, cervical lymphadenectomy, and maybe some vascular procedures on the neck. Spread the cost of IONM on other procedures may change the results of its cost-efficacy analysis. Further research is needed to establish the correct indication for the use of this technology in patients undergoing thyroidectomy.

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Footnote

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Page 4 of 4

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