



Cost-effectiveness of recurrent laryngeal nerve monitoring in thyroid surgery

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Injury of the recurrent laryngeal nerve (RLN) is one of the most serious complications of thyroid surgery and it is associated with hoarseness, dysphonia, dysphagia, and aspiration. It ranks among the leading reasons for medicolegal claims against surgeons (1). Over the last few decades, there is a significant increase of thyroidectomies performed. In 2011, there were 72,344 total thyroidectomies in USA, which notably was nearly a 60% increase from 2006 (2). Additionally, it has been reported a marked increase of thyroid cancer incidence in high-income countries, including the United States, South Korea, the United Kingdom and several European countries (3).

A systemic appraisal of the literature showed that RLN palsy rates after thyroidectomy vary widely, ranging from 0% to 10% and 0% to 7% for transient and permanent RLN palsy, respectively (4,5). The gold standard of care in thyroid surgery is the routine identification of the RLN and the British Thyroid Association recommends intraoperative RLN identification in all case, in order to reduce incidence of RLN injury (6,7).

Many RLN palsies are unexpected and unrecognized, although the visual integrity of RLN is intraoperatively confirmed. Studies reported that only 10% of RLN injuries were recognized intraoperatively with visual identification and in nearly 75% of transient RLN palsy, surgeons haven't detected visually any damage of RLN (5,7).

Thus, various medical devices have been developed in the last decades to help surgeons identify the RLN and measure its function immediately before and after thyroid resection. These devices convert muscle activity in to audible and electromyographic (EMG) signals. Intraoperative neuromonitoring (IONM) has been advocated as a means to localize and identify the RLN and predict vocal cord function.

IONM has been proposed and applied as a valuable adjunct to standard visual identification of the RLN, aiming at identification and functional control of the RLN. Many studies have shown that IONM can aid RLN identification and reduce the risk of RLN injury (4,5,8). On the contrary, meta-analyses have reported no significant difference in injury rates between IONM use and visual identification alone (9,10).

Although the role of IONM use in thyroid surgery in general remains controversial, most endocrine surgeons agree that IONM is really helpful in cases of enlarged thyroid gland, thyroid cancer, lymph node metastasis, revision operations and in the setting of an existing RLN paralysis (5,7,8,11). The American Academy of Otolaryngology - Head and Neck Surgery guidelines note that IONM could be of value in neural identification, reduction of transient RLN paralysis rates, prognostication of nerve function and avoidance of bilateral vocal cord

paralysis in cases of total thyroidectomy (12).

Unilateral vocal cord immobility can cause significant voice changes in the majority of patients and can also be associated with significant dysphagia and may be associated with aspiration pneumonia.

Postoperative management cost for patients with unilateral vocal cord palsy includes several outpatient clinic visits, multiple laryngoscopic evaluations, voice therapy, one or more vocal cord medialization procedures, vocal cord reinnervation procedures, surgical thyroplasty and of course days of absence from work (12).

Bilateral injury of the RLN is a rare but life-threatening complication following total thyroidectomy. The incidence of permanent bilateral RLN palsy is estimated to be up to 0.6% (5,10,13). Taking into consideration the high and increasing rate of thyroidectomy in the USA, which is estimated to involve more than 90,000 operations per year, this risk translates to a considerable number of patients (14). Many patients with bilateral vocal cord paralysis (VCP) require tracheotomy as an immediate measure to secure their airway. Their airway management also requires additional glottic reconstructive surgery such as arytenoidectomy or cordectomy, which may result both in decannulation and in adverse swallowing and voice outcomes (14).

Intraoperative neural monitoring has been adopted rapidly over the past 15 years in both the United States and Europe and there is a growing number of endocrine surgeons using IONM. Sturgeon *et al.* reported that more than 45% of otolaryngologists and 37% of general surgeons use RLN monitoring in thyroid surgeries (15). This trend necessitates the assessment of IONM value and also a detailed analysis of its cost.

Additionally, considering that IONM may become standard practice in thyroidectomy in the near future, an extensive cost analysis is both necessary and useful. The cost of IONM use is calculated taking into consideration all direct costs such as equipment (purchase of IONM system and regular services) and consumables per patient (endotracheal tube with EMG electrodes, patches and probes).

Only few studies have investigated the cost-effectiveness of IONM in thyroid surgery. In 2007, Loch-Wilkinson and colleagues suggested that IONM could never be cost-effective even if we make the assumption that every RLN injury could be preventable (16).

Rocke *et al.* examined the cost-effectiveness of routine IONM (use in every case) *vs.* selective IONM (use only in

high-risk cases) *vs.* no IONM (visual identification only), using decision-tree model without human participants. Their results showed that visual identification of the RLN is more cost-effective than any use of IONM. They found that the selective IONM use in high-risk cases could be most cost-effective, only if a surgeon can decrease the rate of RLN injury, with the use of IONM, by 50.4% or more compared with visual identification (17).

In an interesting study, Al-Qurayshi *et al.* reported that IONM would be a cost-effective measure to prevent and protect the patient from the rare but significant disability and costs associated with bilateral RLN injury. Their study also strongly suggested that neural monitoring has a cost-effective advantage in total thyroidectomy, and that IONM information should be incorporated in thyroid surgery to guide the intraoperative decision-making process, especially in cases of neural signal loss (14).

In their recently published study in *International Journal of Surgery*, Wang *et al.* conducted a prospective, randomized clinical trial, which used a simulation economic modeling to examine the clinical and cost-effectiveness utility of IONM implementation for thyroid surgery in relation to the prevalence rate of RLN injury and the timing of recovery (18). The analysis was based on a state-transition perspective Markov economic model to estimate the long-term costs and the RLN outcomes associated with neural monitoring-based surgery. They excluded patients with preoperative diagnosis of thyroid cancer, reoperations and cervical neck dissection.

The study has a robust and thorough methodology and an interesting point of their protocol is that all patients underwent preoperative and postoperative laryngeal examination and all cases of both symptomatic or asymptomatic RLN injury, promptly referred to otolaryngology department. Examination of vocal cord motility by an otolaryngologist allowed to establish a management plan with speech-language pathologist for voice therapy, and a prompt intervention to optimize the outcome.

Wang *et al.* analysis demonstrated that the importance of IONM is variable depending on the duration, the severity, and the prevalence of the RLN damage, in addition to the clinical setting in which IONM is applied. Authors reported that IONM became cost-effective if the rates of VCP were 33.6% at 1 month, 22.9% at 2 months, 9.8% at 6 months, and 3.8% at 12 months postoperatively, independently of whether phonosurgery was performed. The results suggested that IONM is cost-effective when the prevalence

of transient nerve injury encountered is higher than 38%, a scenario that is rarely reported in a clinical setting. Moreover, IONM appeared to be a clinically cost-effective intervention in those patients who would experience definitive, permanent VCP when the incidence is estimated at about 3% of cohort population simulated (18).

A previous study showed that the use of IONM in thyroid surgery has an impact on the overall hospital budget, accounting for 5–7% of the total hospitalization costs for a thyroidectomy procedure. Dionigi *et al.* found that the net per-procedure cost of IONM vary according to the frequency with which IONM is used and the additional total cost of using an IONM procedure declined to about 5% of the cost of these procedures (19).

Wang *et al.* also highlighted in their study that this scenario was cost-effective only in a high-volume setting with >5 IONM procedures/week (18). This is a very interesting finding showing that the impact of surgeon's experience, as well as the experience with IONM use and the duration of training are of paramount importance in surgical outcomes. Previous studies reported that IONM successful rates were affected considerably by the extent of surgical and anesthesiological experiences. Dionigi *et al.* suggested that there is a learning curve of at least 50 patients before surgeon becomes familiar with IONM technique and increases significantly intraoperative RLN identification and preservation (20).

Although it is a very interesting and innovative study, Wang *et al.* admitted that there are several limitations on its design, presented thoroughly on Table 2 of their article.

The surgical population undergoing total thyroidectomy is usually highly heterogeneous in terms of indications and risks for RLN injury. Further research focusing on specific populations, such as patients scheduled for high-risk thyroidectomies (reoperations, preoperative diagnosis of thyroid cancer, cervical neck dissection, toxic goiter) is suggested to identify patients who are more likely to benefit from IONM use during thyroid surgery.

The authors examined only patients with unilateral RLN injury and excluded all cases of bilateral injury. Although the incidence of permanent bilateral RLN is low, it is a catastrophic complication and patients suffering from considerable impairment of quality of life. The cost for the management of airway, voice and swallowing disorders is much higher for these patients compared to the cost for unilateral VCP management.

Additionally, cost-effectiveness analyses are not clinical analyses and they are performed in the population rather

than the patient level. Although we can calculate the cost of IONM (devices and consumables) and total cost of RLN in terms of work loss days, voice therapy, follow-up office visits with multiple laryngoscopic evaluations, possible surgical procedures (one or more vocal cord medialization procedures, vocal cord reinnervation procedures, surgical thyroplasty for unilateral VCP and arytenoidectomy or cordectomy for bilateral VCP), it is really difficult to estimate, in terms of cost, the impact to all aspects of quality of life of patients with VCP. Authors suggested that future trials should also try to clarify the aspects and characterize the changes in the quality of life that occur during the follow-up. Most surgeons focus on the dysphonia caused by RLN injury and its management. They usually underestimate swallowing process impairment and also the high-risk of aspiration diagnosed in patients with unilateral VCP.

Given the large number of total thyroidectomies performed every year, Dionigi *et al.* suggested that more studies should take into consideration that potential differences introduced by the use of IONM, such as the cost from increased or decreased operation time, changes of transient and permanent RLN injury and also the cost of medico-legal action (20). Additionally, further research should focus on the cost-effectiveness on IONM in high risk thyroidectomies (reoperations, cervical neck dissection, retrosternal goiters, Grave's disease) and also other cases such as parathyroidectomies or cervical vascular procedures.

Finally, another point of interest is the fact of VCP documentation. Symptomatic voice assessment is insufficient and all patients should be examined preoperatively and postoperatively with indirect laryngology in order to evaluate vocal cord motility and confirm an accurate rate of RLN injury. The British Association of Endocrine and Thyroid Surgeons (BAETS) and the German Association of Endocrine Surgeons recommend preoperative and postoperative laryngeal exam as requirements for all patients undergoing thyroid surgery (21).

Although many endocrine surgeons recommend routine laryngoscopy for all thyroidectomy patients, at present only 6.1% to 54% of patients undergo a preoperative laryngeal exam (5). Additionally, if endocrine surgeons want to have accurate information regarding their surgical outcomes, we believe that routine postoperative laryngeal exam is required for all patients undergoing thyroid surgery to have an objective assessment of vocal cord function after the surgical intervention. It is well-known that symptomatic assessment of postoperative patients is inadequate as a postsurgical measure of RLN function. Despite the importance of postoperative

laryngeal exam in surgical outcome quality analysis, the BAETS audit showed that postoperative laryngeal exam was only performed in 21.5% of patients (22).

Taking into consideration that many general surgeons do not routinely perform postoperative laryngoscopy to examine vocal cord function, it is highly likely that the report rate of transient VCP is lower than the actual one. This should be an issue that a future study should address to investigate thoroughly the cost-effectiveness of IONM use in a population undergoing total thyroidectomy where the researchers should know the true incidence of RLN injury and taking into account the impact of dysphonia, dysphagia and aspiration in patients' quality of life.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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