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C2 Xplore® for Intermittent and Continuous Laryngeal Nerve Monitoring: Technical Note

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ABSTRACT

Due to the direct anatomical relationship between the recurrent laryngeal nerve (RLN) and the thyroid gland, the function and anatomical integrity of the RLN is fundamentally at risk in every thyroid operation. While a RLN morbidity rate of less than 5% is achieved in specialized clinics, the morbidity rates are significantly higher in non-specialized centers. Thus, the aim is to reduce the complication rate by establishing standardized interventions. Exact knowledge of the anatomical course of the RLN, the nerve-sparing dissection technique and the supportive use of intraoperative neuro-monitoring (IONM) to identify anatomical variations are the basis for nerve-sparing surgery. We tested the new C2 Xplore® system (inomed Medizintechnik GmbH, Emmendingen, Germany) as a tool for performing intermittent and continuous laryngeal nerve monitoring during thyroid surgery. The C2 Xplore® helps to enhance surgeon-IONM interaction, and provides comprehensive digital EMG documentation with EMG quantification. EMG artifacts are removed. Image quality and EMG feedback are highly acceptable for intraoperative monitoring. The C2 Xplore® system does not have a deleterious impact on the proper function of other surgical instruments. C2 Xplore® is effective for intraoperative monitoring,

optimizing RLN dissection, and supporting surgical deliberations, and for forensic use and research. A step-by-step C2 Xplore® procedure is described.

INTRODUCTION

Thyroid operations are the most common form of endocrine surgery, with about 40,000 procedures/year in Italy.[1] The leading indication for the operation continues to be bilateral multinodular goiter. In recent years, an increase in more radical resections has been observed compared to previously preferred operations with residual thyroid gland. The rationale here is to avoid the recurrence of nodules and to ensure sufficient radicality in the case of incidental cell carcinomas. The underlying disease, the extent of the resection and recurrent laryngeal nerve (RLN) anatomical variability are directly related to the occurrence of complications. In addition to (permanent) hypoparathyroidism, paresis of the RLN is one of the leading complications. Therapy and avoidance of postoperative complications are specified in the guidelines. Injury of the RLN is one of the most serious complications of thyroid surgery. It is directly related to the surgeon's performance and could lead to a significant deterioration of the patient's quality of life. If unilateral vocal cord palsy can lead to morbidity-related voice changes, as well as potential dysphagia and aspiration, bilateral vocal cord palsy may require tracheostomy.[1] Extensive knowledge of the surgical anatomy, cervical exposure and direct visual identification of the RLN are key points that must be considered during thyroidectomy.[2]

Intraoperative nerve monitoring (IONM) may improve the standards of thyroid surgery. Intraoperative detection of RLN injury by the surgeon′s eye may not be possible, because anatomical integrity may not reflect functional integrity, and only an electromyographic response to an electrical stimulation of the nerve can exclude such injury.[3] There are several potential causes of nerve injury during surgery. However, it is important to note that the major cause of postoperative RLN dysfunction is not transection, but rather non-structural functional nerve damage. Although visual identification of the nerve can help to decrease the rate of RLN injury, it does not completely prevent nerve damage because, as already mentioned, unexpected RLN palsy can still occur despite anatomic preservation of the nerve. In addition, most nerve injuries are not recognized in the operative field, so visualization of the nerve alone does not allow us to determine the degree of injury.(4) Therefore, IONM is expressly recommended for thyroid surgery by most general and endocrine surgery associations.(5,6) Documenting the monitoring process and performing it in the fastest and most intuitive way are crucial in surgery of the thyroid gland.

IONM complements the information offered by direct identification through a functional analysis, which not only improves the recognition of the recurrent nerve and allows differentiation between neural and non-neural structures, but also predicts the functionality of the vocal cords after surgery. With an increase in the safety of this technique and the pursuit of a standardized procedure, the intraoperative prediction of postoperative vocal fold function could be significantly improved. Herein, we present technical notes to illustrate use of the C2 Xplore® system (inomed Medizintechnik GmbH), Emmendingen, Germany in IONM during thyroid surgery.

IONM

Numerous studies have shown that the visual representation of the RLN is absolutely necessary and a prerequisite for the use of IONM.[1-5] IONM helps to secure the anatomical structure and the recognition of positional variations, and to secure the function of the nerve. The avoidance of bilateral RLN paresis is of particular importance. To date, the use of IONM has not been associated with any reduction in the rate of paresis compared to a purely visual approach. However, it seems to be useful in surgery for carcinoma and recurrent thyroid gland. Before the start of the operation, a preoperative laryngoscopy is absolutely necessary to assess IONM, since preexisting RLN paresis can be combined with normal stimulation electromyography (EMG). The principle of IONM is the derivation of an EMG of the larynx by stimulating the RLN and the derivation of a muscle action potential at the vocalis muscle. At the beginning of the operation, , the vagus nerve should be prepared and a signal should be derived. A signal above 0.500 mV must be documented. If necessary, a repeated signal derivation must be carried out during the course of the operation, if the effect of the muscle relaxant has not yet subsided. Short-acting relaxants should be used and repetitive dosing avoided. With continuous neuromonitoring (C-IONM), an electrode must be attached to the vagus nerve and an alarm is set after an intact signal has been derived. Whether the use of C-IONM leads to a reduction in the paresis rate has not yet been conclusively clarified. However, it seems that it is most likely to help prevent damage caused by tension on the nerve. Studies have shown a higher probability of RLN palsy with a decrease in EMG amplitude of > 50% and an increase in latency of > 10%. In the case of a nonrecurring laryngeal nerve (NRLN), it is not possible to derive a signal in the caudal nerve portion, so the vagus nerve must be followed cranially to identify branching of the NRLN. A signal with a short latency (<3.5 ms) is to be derived.

Standardization of IONM using the so-called 4-point method is essential for a reliable interpretation of signals. The basic requirement for this is visual representation of the RLN.

After resection of the thyroid lobe and completion of all other measures, it is imperative to derive a signal at the vagus nerve before switching to the opposite side. Here too, a signal of over 0.500 mV must be derived. The final derivation of a signal across the RLN is optional.

Data from multicenter studies have shown that there is a high positive correlation of over 98% between the positive signal derived unchanged at the end of the operation and the normal vocal fold function recorded postoperatively. The correct prediction of signal loss and vocal cord paralysis is much worse, at around 40–70% for temporary paresis and around 10% for permanent paresis.[7,8]

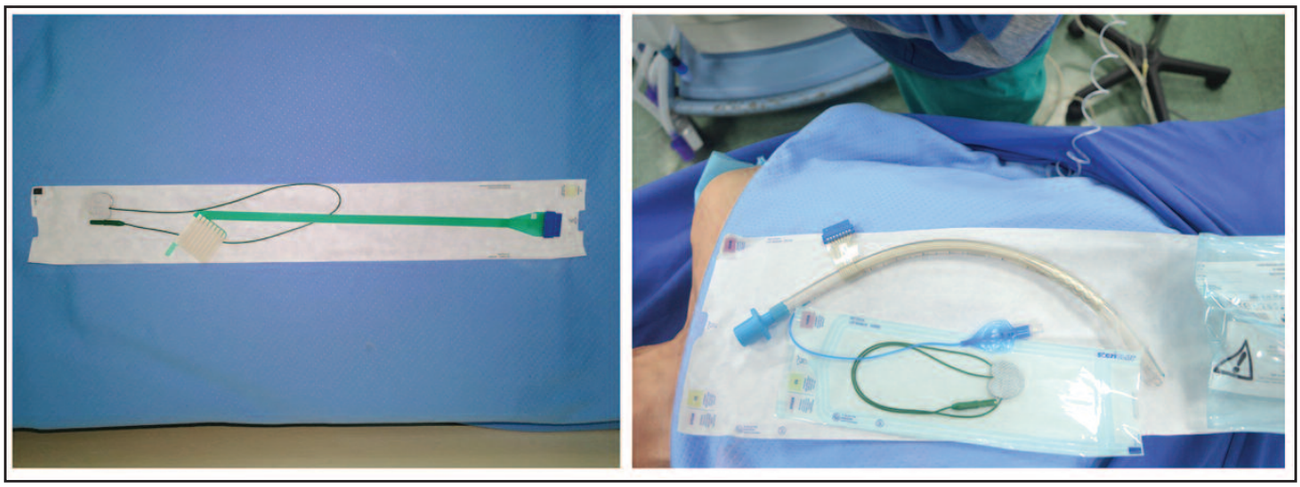

Figure 1. 8-contact Select Laryngeal Electrode (left) and ALM® endotracheal tube (right).

In summary, the intraoperative detection of RLN paresis has been significantly improved through the use of IONM. Without neuromonitoring, only visible damage to the nerve would warrant a change in the operative strategy.

Bilateral paresis is also possible with IONM. We have reported two cases of bilateral paresis despite intact bilateral IONM. A further five patients had paresis with thyroidectomy despite an intermittent signal on the first resected side, and thus also a risk of bilateral NLR paresis.[6]

The procedure in the event of an intraoperative loss of signal should be discussed with the patient preoperatively. The usual procedure is to cancel the operation. However, continuation of the operation by a very experienced endocrine surgeon or partial resection without crossing the border lamella can be justified in individual cases.

DEVICE

The C2 Xplore® system includes:

a. 8-contact Select Laryngeal Electrode for recording the electromyographic signal on the vocal cords;
b. ALM® endotracheal tube;
c. Delta® electrode for continuous monitoring;
d. stimulation probe;
e. C2 Xplore® system (to acquire, select and view the best-registered signal).

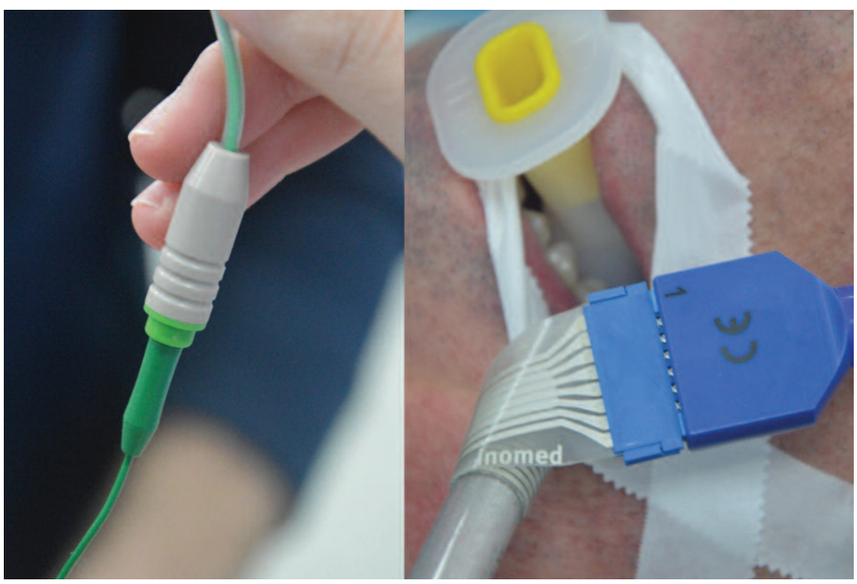

Figure 2. Connection between the endotracheal tube and the interface box.

The documentation process is supported by an integrated database, in which it is possible to store all the records and patient data. ALM® technology provides the most reliable complete solution for monitoring the recurrent laryngeal nerve. With eight long registration contacts, instead of 2 or 4 conventional contacts, the ALM® tube offers an excellent recording signal of the vocal muscle. Moreover, the integrated electrode present on the surface of the tube guarantees maximum signal stability, regardless of rotation of the tube. The Channel Selector selects and displays the strongest signal. All signals are reported both visually and audibly.

Endotracheal tubes

Neuromonitoring tubes can be pre-assembled with electrodes integrated into the endotracheal tube surface, or standard endotracheal tubes can be transformed by attaching a thin adhesive patch containing the electrodes. During the action of fixing the electrodes, the tip of the electrodes is generally positioned 1 cm above the upper edge of the tube cap. The adhesive electrode must be placed and pressed firmly to the tube, ensuring that the electrode does not overlap itself. Whether it is a pre-assembled tube or a tube on which the electrodes have been applied, these must be positioned at the level of the glottis. The electrodes are then connected, via a cable, to an interface system between the recording system and the stimulation system (Figs. 1 and 2).

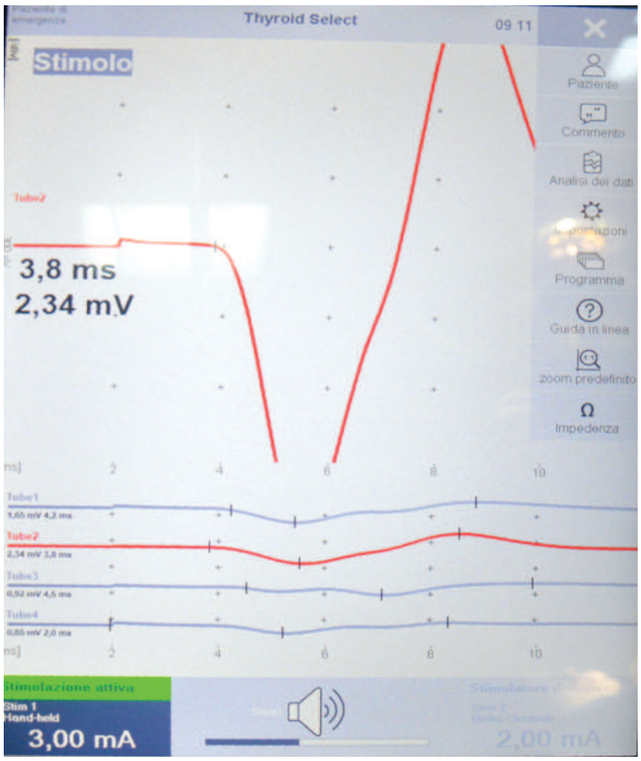

Figure 3. Recurrent laryngeal nerve EMG response.

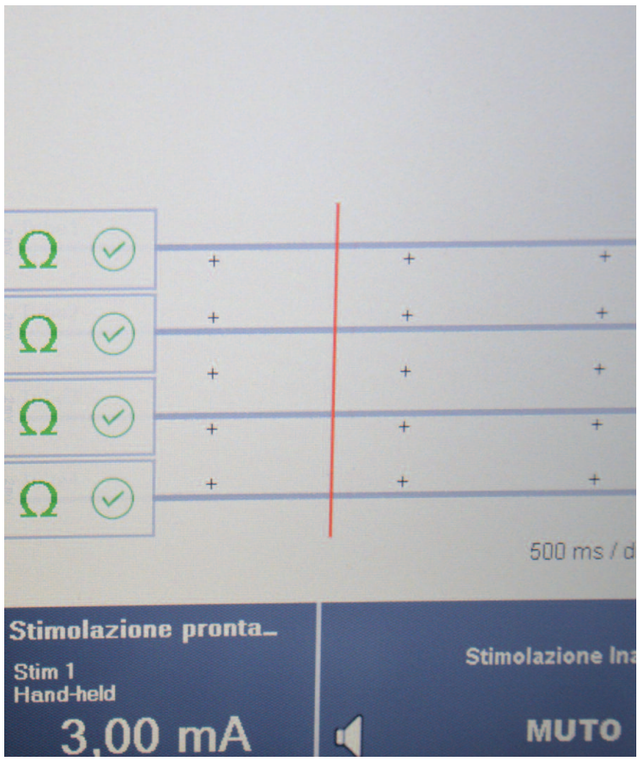

Figure 4. Monitor setting.

General device settings

A stimulation probe comes from the monitor and is placed sterile on the operating field. The surgeon observes and controls the monitor positioned at the patient's feet. The monitor offers essential visual information and audio tones associated with the electromyographic (EMG) response (Fig. 3). The endotracheal tube is fixed with adhesive tape. The patient's head must be hyperextended. The electrode check should only be performed after the patient's head has been fully extended. The recording electrodes and the stimulation probe require grounding. Therefore, a tiny ground electrode is placed through a small needle placed in the subcutaneous tissue at the patient's shoulder. The primary electrical configuration of the monitoring system is shown in Fig. 4.

Monitoring settings

After the patient is placed in the final position, the monitor is evaluated. Good contact of the tube on the trachea is recognized by reading the impedance, which must not exceed 5 kΩ for each electrode, and the difference between the pairs of electrodes must not exceed 1 kΩ. As guidelines recommend, the optimal current intensity for neurostimulation is 1 mA.[9]

Intraoperative monitoring

The monitor must be checked to ensure the appropriate event threshold at 100 μV, and the probe must be set to a value of 1 mA. A current intensity threshold value greater than 0.3-0.4 mA must be used to achieve sufficient nerve stimulation.[7]

The following standard steps are prerequisites for the correct use of intermittent intraoperative neuromonitoring: preoperatory laryngoscopy, stimulation of the vagal nerve before resection, visual exposure and stimulation of the RLN, stimulation of the vagal nerve at the end of the surgical maneuvers and postoperative laryngoscopy.

Preoperative vocal fold assessment with fiberoptic laryngoscopy in patients undergoing thyroidectomy allows clear documentation of baseline vocal cord function, aids in surgical planning in patients with palsies, and facilitates interpretation of IONM findings.[8] In addition, the final electromyographic signal can predict postoperative nerve function with a high degree of accuracy.[10] In the case of a non-reduced signal, the negative predictive value of IONM can be as high as 97%, while the positive predictive value when signal is lost is only 33-37.8%.[11]

For continuous IONM (C-IONM), the access to the vagal nerve within the carotid sheath could be anterior (midline) or lateral (between the sternohyoid and sternocleidomastoid muscle): the former can be used in small skin incisions, and the latter is generally used in cases of huge goiter, re-do procedures and/or thyroid cancer surgery with the advantage of a lower rate of electrode dislocation.[12] Vagal nerve stimulation by a stimulation probe is necessary to test the integrity and function of the nerve prior to placement of the C-IONM electrode (Delta® electrode): a negative stimulation response should be clarified using a troubleshooting algorithm as for IONM.[13] On the right side, to exclude non-recurrent laryngeal nerve, the vagal nerve should be stimulated distally. At this point, circumferential dissection of a small vagal nerve segment (approximately 1 cm) is done and the electrode is placed. It has been established that the amplitude of the "baseline" reference curve must be ≥500 μV during initial calibration of the C-IONM system to guarantee a stable and reliable EMG signal.[12,13] The electrode is bipolar (Fig. 5), and follows a more focused stimulation.

Once the baseline of C-IONM is obtained, variations in amplitude and

latency are displayed on a timeline. Audible and visual alerts, when threshold values are exceeded, will help the surgeon to identify hazardous maneuvers. Exposure of the thyroid gland, RLN visualization and dissection proceed as in intermittent IONM, using a stimulation probe step-by-step.[14]

RLN functional damage

If there is no intact signal from the vagus nerve and the continuity of the RLN is preserved, it is advisable to check the nerve over its entire prepared stretch. IONM can then be used to attempt stimulation over all sections to detect the point of signal breakdown (type I damage, signal can be derived from sections of the RLN near the larynx, no signal via the vagus nerve). In addition to tension or pressure damage, restrictive ligatures or current marks can be the main cause.

If no signal can be derived from either the vagus nerve or the entire RLN, diffuse damage is assumed (type II damage, no signal via RLN, no signal via N. vagus).

A device error, electrode dislocation or neuromuscular blockage can be excluded by stimulating the contralateral vagus nerve.

If the continuity of the RN is intact and there is no mechanical compression of the nerve, there is a higher probability of recovery of the vocal cord paralysis.

LOS and troubleshooting

In case of loss of signal (LOS), a troubleshooting algorithm must be applied to ensure that it is not due to a system malfunction. The surgeon and anesthesiologist should collaborate. With a normal preoperative laryngoscopy, the following must be checked: endotracheal tube placement, possible grounding electrode detachment, interface box problems, monitor setting problems, initial electromyographic signal (satisfactory if vagal nerve stimulation >500µV), laryngeal twitch, and dosage and "disposal" of non-depolarizing neuromuscular agents (rocuronium) used for the induction of narcosis. If LOS occurs, defined as an EMG change from an initial satisfactory EMG to no or low (≤100 µV) response with stimulation at 1 to 2 mA in a dry field and no laryngeal twitch,[5] it is crucial to define the type of injury (1= segmental; 2= global). An injured nerve requires a minimum wait of 20 minutes following LOS to recover ≥50% of its baseline amplitude before moving on with completion thyroidectomy on the unaffected side.[5] If the nerve amplitude fails to recover at least 50% of its baseline amplitude after 20 minutes, there is a high risk of postoperative vocal fold palsy. In case of LOS on the first side of resection in a planned bilateral surgery, the surgeon must reconsider the surgical plan. A loboistmectomy can be considered, with a completion lobectomy after the complete recovery of vocal fold function.

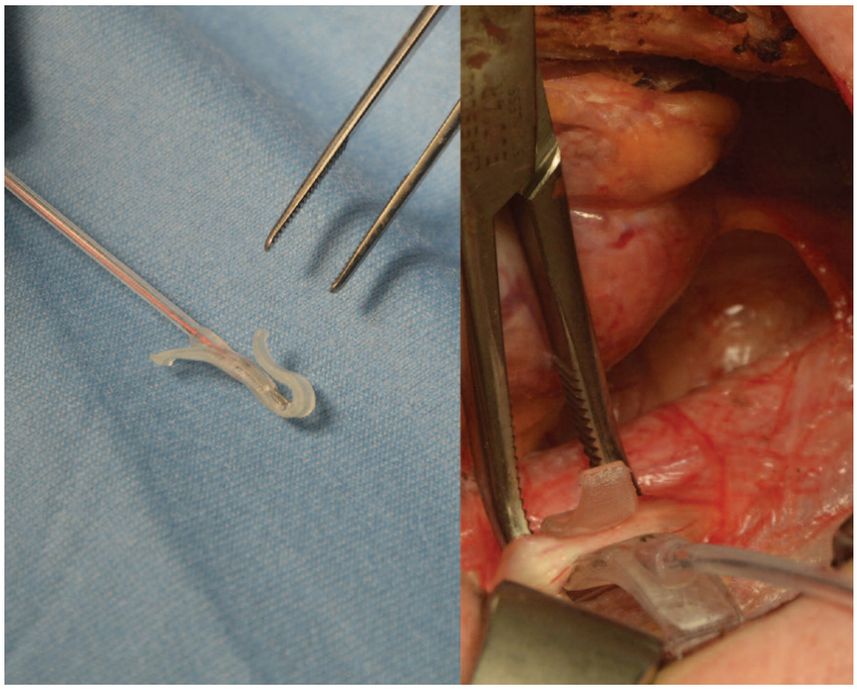

Figure 5. Delta® electrode and its application to the vagal nerve.

Medicolegal considerations

When using IONM, all patients must be informed about the possibility of a stage thyroidectomy if LOS occurs.

Moreover, all stimulation responses, automatically stored in the C2 Xplore® memory, can be selected for reporting during or after monitoring and the surgeon can also add a comment to a curve. At the end of the procedure, a complete patient report can be created to be archived in the patient medical report. Reports can be generated with or without a trend chart. To facilitate the reporting process, the system offers an LED scanner which quickly reads patient data from the bar code and also from the QR code of the medical record, enclosing the stimulation responses selected.

DISCUSSION

Intraoperative visual representation of the RLN and gentle preparation are decisive prerequisites for protecting it. This requires exact knowledge of the anatomy and its variants. Intraoperative monitoring allows the anatomical structure and the functional integrity of the nerves to be safeguarded, and can detect otherwise invisible damage. If damage to the recurrent nerve is determined intraoperatively, the operative strategy should be reconsidered and adjusted. The average rate of permanent and temporary paralysis of inferior laryngeal nerves after thyroidectomy is high, and stands between 2.3% and 9.8% respectively.[15] For this reason, it is crucial for the surgeon to adhere to a carefully standardized intraoperative technique that minimizes the possibility of damage that could lead to worsening of the patient's quality of life and to an increased medicolegal liability. Although IONM is considered to be feasible and safe when used in addition to traditional visualization of the nerves, there is no clear consensus in the literature on the use of IONM during thyroid surgery.

Recent guidelines from the American Academy of Otolaryngology-Head and Neck Surgery recommend the use of IONM in thyroid surgery to ensure voice protection. The German Associa-

tion of Endocrine Surgeons practice guidelines and the International Neural Monitoring Study Group guidelines both support the use of IONM in all thyroid surgeries, while the American Head and Neck Society endorses its use in cases of thyroid cancer, and particularly in patients with RLN palsy.[16,17]

In addition, while IONM is considered safe, it has some limitations: i) EMG signal can be affected by anesthesia and manipulation of the trachea, and ii) it is not easy to differentiate between nerve injury and loss of contact between the recording electrodes and the vocal folds in case of EMG amplitude reduction or LOS. While intermittent IONM allows the detection of a change in the EMG signal only after damage has occurred, C-IONM allows continuous stimulation that can produce sentinel events to detect dangerous surgical maneuvers. It examines the whole course of the RLN by continuous stimulation of the vagal nerve to detect proximal injuries that can be missed by intermittent stimulation distal to the injury.[18] It gives feedback about nerve function in short intervals. If the EMG signal decreases or becomes weak, indicating imminent nerve injury, an adverse condition may be reversed before nerve damage is persistent.[19] However, C-IONM also has some limitations. For example, the surgical positioning of the vagal electrode is more difficult than in other procedures with IONM or without monitoring because of the dissection of the carotid sheath. Various methods of approaching the vagal nerve have been proposed, and several probes that help simplify the procedure are available. Despite the increasing number of centers using this procedure, no standard method has been proposed.[20]

In our experience with the C2 Xplore® system, we have found that some IONM-related problems can be overcome. First, it is beneficial to use adhesive electrodes with eight contacts that the anesthetist can adapt to the endotracheal tube, thus reducing the possibility that a malfunction may be the result of a lack of contact between the tube and the vocal cords. In addition, the Delta® electrode supplied for C-IONM is easy to apply and remove once the procedure is complete.

CONCLUSION

At the Policlinic Hospital of Messina, in the Division of Endocrine and Minimally Invasive Surgery, we have tested the new C2 Xplore® system for IONM during thyroidectomy.

Today, the use of IONM is encouraged due to the possibility that it may help to control the functional integrity of the RLN. The goal of monitoring modalities is to detect surgical or physiological insults to the RLN while they are still reversible or, when prevention is not an option, to minimize the damage done to these structures during thyroidectomy.[21,22] All the advantages related to its use, as reported in this technical note, can explain the increasing number of monitored procedures and the indication, according to various guidelines, of its use in standardized procedures.

The C2 Xplore® intraoperative monitoring system offers good reliability of the signal quality in intraoperative monitoring of the RLN and is an innovative solution for monitored procedures. STI

AUTHORS' DISCLOSURES

The authors declare that there are no conflicts of interest.

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