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Medico legal aspects on neuromonitoring in thyroid surgery: informed consent on malpractice claims

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SUMMARY: **Medico legal aspects on neuromonitoring in thyroid surgery: informed consent on malpractice claims.**

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Aim. *The purpose of this paper is to provide a forensic profile framework of neuromonitoring in thyroid surgery, regarding the information given to the patient and its classification as part of professional liability in the event of recurrent injury.*

Method. *Evaluation and reflections on the required behaviour of the surgeon on providing details on the operation before the informed consent is given and to outline the possible legal implications regarding professional liability as a result of recurrent injury. In particular, if it is an obligation to inform the patient about using this method and if it is possible for the surgeon to freely choose whether to employ this method, which is still burdened by a certain percentage of error and for that reason it cannot be defined a "standard of care".*

Results. *To recognize neuromonitoring the role of standard of care in surgery of the thyroid means attribute a role of method able to avoid the surgeon to cause iatrogenic damage to the laryngeal nerve. For the foregoing reasons that is not true, determining false positives and false negatives, and this can be a double edged sword for the surgeon.*

Conclusions. *Although the progress in the field of thyroid surgery made in the last decade, currently there is no scientific reassuring evidence to completely avoid the possibility of producing an iatrogenic lesion of the laryngeal nerve. Information given to the patient prior to surgery should respect the requirements of completeness, freedom and honesty in order to allow the patient to self-determination.*

KEY WORDS: Neuromonitoring - Standard of care - Vocal fold paralysis - Informed consent.

Introduction

In the last decades total thyroidectomy has experienced a significant increase becoming, up to now, the most internationally practised endocrine surgery. In 2007 more than 58,00 thyroidectomies were performed in the US, while in Italy, 41.372 thyroidectomies were performed in 2010. Like any surgical procedure, the removal of the thyroid is burdened with a risk of complications, among which the lesion of the recurrent laryngeal nerve is certainly the most feared, either by the patient or the surgeon. The recurrent paralysis shows an incidence of 1-20%. It may be temporary between 3.4% and 7.2% of the cases, or permanent between 0.2% and 0.9% of the cases (1, 2).

Its incidence continues to vary widely in relation to the basic thyroid disease (0.2% -25.0%), the surgical technique (first intervention, 0.6% or reoperation, 3.6%), extent of resection (subtotal / partial or total lobectomy 0.7% versus 1.3%) and the experience of the surgeon (0.6% -1.4%) (3, 4). As regards the economic aspect, in our Country there are sufficient resources from the National Health Service to cover all the costs that the use of these procedures involves; in fact, it appears that 5-7% of the costs arising from hospitalization for thyroidectomy is related to IONM methods (intraoperative neural monitoring) (5).

In light of the results of the most established scientific evidence, according to which the NIM (Neural Integrity Monitor) is not the standard of care (6), theoretically, in case of recurrent lesion, it should not be attributed to a professional misconduct whether surgeons chose to use or not this intraoperative technique.

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However, its use, being more and more widely spread, should be provided as part of the acquisition of informed consent prior to surgery.

The purpose of this paper is to provide a forensic profile framework of NIM in thyroid surgery, regarding the information given to the patient and its classification as part of professional liability in the event of recurrent iatrogenic injury.

Recurrent laryngeal nerve injury

As known, the causes of recurrent paralysis are manifold; among them the most common are represented by simple lesion and/or complete section of the nerve, produced by scalpel blade, electrosurgical thermal lesion, excessive skeletonisation nerve during its isolation, excessive stretching causing axonal damage (particularly frequent in case of substernal goiter), by entrapment in ligatures of vascular pedicles and compression by edema or hematoma wall. While endotracheal intubation, the presence of anatomical variations of the inferior laryngeal nerve, reoperation, malignant tumors, a history of previous irradiation of neck (7-9) are recognized among the less common causes. Iatrogenic injury of the inferior laryngeal nerve may be revealed by a paralysis of both vocal cords (bilateral lesion), potentially fatal to the patient if it caused respiratory failure while in case of iatrogenic unilateral lesion it may be revealed by dysphonia in varying degrees of severity from reversible to irreversible, which is a real disability for the patient and can lead to a deterioration of his/her quality of life because of its adverse impact on the psychological and social-relational and working areas (8).

The identification and rescue of the inferior laryngeal nerve is one of the crucial phases of neck surgery, in particular of endocrine surgery, in relation to the close anatomical relations that exists between the two structures. Various techniques for locating and monitoring the recurrent nerve have been developed in the last decades. They were based on the intraoperative application of an electric current at low voltage directly on the nerve (IONM). The use of these procedures during thyroidectomy has increased significantly thanks to a reduction in costs compared to the past and to an easier access to the necessary equipment, even though a thorough knowledge of the anatomy of the neck cannot forgo an accurate and precise tissue dissection. In order to identify the recurrent nerve and measure the function immediately before and after resection of the thyroid, various surgical devices have been designed to convert the muscle activity in the acoustic signal detectable by an electromyography Once these signals registered, a recording can be often printed to be used for future reference. Availability of such records can have a forensic documentary importance as well as provide a help in the assessment of future vocal cords function (3). The use of neuromonitoring technique involves a prolonged duration of surgery and needs particular support represented by the use of a specific endotracheal tube as well as dedicated people to monitor the nerve during surgery (10).

The intraoperative neuromonitoring techniques currently used are basically of two types: NIM without EMG (electromyographic documentation) which is based on the stimulation of the recurrent laryngeal nerve (RLN), the observation or palpation of the contraction of the posterior cricoarytenoid muscle, the monitoring of the response to the glottic pressure, the intraoperative inspection of the vocal cord function, The second type consists of the NIM with EMG documentation which is based on the recorded stimulation of the laryngeal muscles evoked via endoscopic insertion of electrodes in the vocal cord alternatively the open introduction within the vocal muscles through the cricothyroid ligament or by the use of electrodes inside the endotracheal surface (3).

Despite the increasingly widespread use of this method, as confirmed by the results of the latest studies on the subject (11), the risk of producing such iatrogenic neurological injury is not eliminated but only reduced in terms of frequency, ranging on about 2% (12). This is probably due to the inevitable likely conditions for which, however, the risk of iatrogenic nerve injury may increase, that is to say: anatomical variants, extended lymph node involvement in the case of neoplasia, inexperience of the surgeon (13), wide resection, presence of a relapsed goiter (12) that, just because of the so little encouraging results, are the areas in which it would be justified the use of this intraoperative method (10, 14, 15). The scientific process to standardize the approaches to the neuromonitoring in thyroid surgery through the guidelines drawn by the International Neural Monitoring Study Group has been attempted over the years. At present three methods of application of the IONM standards in Endocrine Surgery (16-18) have been defined: the identification of the inferior laryngeal nerve (many studies suggest, in fact, that IONM is associated with a success in the identification of the nerve rate comprised between 98% and 100%; the prognostic evaluation of postoperative neurological function and the identification of the lesion (especially useful in the prevention of recurrent bilateral paralysis). Moreover, four essential elements for obtaining a really useful IONM that are identified and suggested: preoperative laryngoscopy in all cases; vagus nerve stimulation beyond the threshold limit prior to dissection, allowing to check the operating system features and to accurately map the HLR; vagal stimulation beyond the thre-

shold value at the end of dissection, which allows to have an accurate prognostic evaluation of postoperative glottic capabilities; need for a postoperative laryngoscopy in all cases. The anesthetic standards have also been defined: intraoperative assessment of the parameters of electromyographic signal loss (LOS), which is defined as an EMG change from satisfactory initial values assessed.

Neuromonitoring and standard of care

Despite the strict observation of such claims scientifically supported, therefore, the scientific data obtained from the various centers are not allowed to exclude the risk of recurrent lesion in the candidate subject to thyroidectomy. These results provide a starting point for reflections on the required behaviour of the surgeon on providing details on the operation before the informed consent is given and to outline the possible legal implications regarding professional liability as a result of recurrent iatrogenic injury. In particular, is it an obligation to inform the candidate patient about using this method during the surgery? Is it possible for the surgeon to freely choose whether to employ this method, which is still burdened by a certain percentage of error and for that reason it cannot be defined as a "standard of care"?

A study performed in 1993 concluded that cases of malpractice in Endocrine Surgery concerned a iatrogenic injury of the recurrent laryngeal nerve in 60% of patients. The remaining reasons object of litigations regarded cases of incorrect information about surgery, incorrect surgical technique, delayed diagnosis (19-21). More recent data in relation to this aspect have not been found. However, it is possible to assume that the current widespread use of neuromonitoring in thyroid surgery can have medical-legal motivations, even though such a procedure, according to the results of above studies (1, 5, 19, 20) has so far shown characteristics that can describe it as a true standard of care in the field of thyroid surgery. From a merely medical-legal point of view, the term "standard of care" stands for the conduct of each physician based on the respect of the most common rules of attention, caution and prudence that any other health professional with the same level of preparation and technical skills would use in managing his /her patients (22). Therefore, to recognize neuromonitoring the role of standard of care in surgery of the neck or, in the specific case, in surgery of the thyroid means attribute a role of method able to avoid the surgeon to cause iatrogenic damage to the laryngeal nerve, in any case, either a simple execution or greater complexity. For the foregoing reasons that is not true, since many variables come into play, both technical and anatomical, determining false positives and false negatives, and this can be a double edged sword for the surgeon.

Discussion

The use of intraoperative neuromonitoring technique in neck surgery and in particular in thyroid surgery, presents some medical-legal implications, especially in relation to its usefulness and to the patient and surgeon's expectations on procedures of the intraoperative monitoring of the laryngeal nerve during the thyroidectomy. As it is known, the information time is a fundamental medical act that is performed before any medical-surgical performance, during which the health professional informs the patient about surgery he/she is going to undergo, indicating in particular the diagnostic and treatment options available based on the latest scientific findings and relating on their possible side effects. For the patient, this is an essential prerequisite to enable him/ her to a consciously self-determination; for the surgeon, this aspect becomes relevant in the event of being involved in medical-legal litigation on charge of procuring an iatrogenic recurrent lesion as according to the well-established case-law, he /she is charged of proving that it was a complication (event that even though it was predictable it was not preventable or avoidable in reality) and not of a professional error (ie a preventable event by a different behaviour, adhering to leges artis, to the guidelines accredited by the scientific community and the good clinical practice). Information is a medical act in itself and is a legal obligation of the physician towards the patient (art. 50 C.P. and combined provisions of art. 32 c.p.v. and Art. 13 of the Italian Constitution). Since the era of paternalistic medicine, dominated by the figure of the doctor as the sole holder of scientific knowledge, to whom the patient completely entrusted decisions about his/her own health, up to to the current medicine, which sees a reversal of roles, where patients can exercise their right to self determination only when there is adequate information given before any medical-surgical decision concerning them. This information represents the content of the consensus on which the patient, or the person, who has parental responsibility or guardianship (in case of minor or interdicted person), and the doctor put their signature, formalizing the decision-making process that in bioethics responds to the concept of "shared decision making", ie a shared decision between doctor and patients in relation to the treatment they will receive. The agreement establishes the lawfulness of the surgery (Supreme Court 14.2.2006, n. 11640) but it is not an exonerating responsibility (Supreme Court 7027/2001), even in cases where the doctor must act in emergency conditions (in which the patient is not able to manifest his /her will to be treated). In the latter case in fact, the doctor, by virtue of a state of necessity (art. 54 Penal Code)

can act without consent. Despite the efforts made to improve the act of medical-surgical information, the evidences indicate that information time has a limited impact on the medical care, in so far as patients do not remember much of the information provided by the doctor during the consent acquisition phase, for erroneous or superficial overestimation of the patient comprehension (23). It was also demonstrated that the information process inevitably causes an increase in the level of anxiety in patients (24). Contextualizing the information process to the use of neuromonitoring technique in thyroid surgery, from a merely medical-legal perspective, it is important to linger first on the role that the surgeon attributes to this procedure in the context of the surgery offered to the patient. If he considers that its use is of fundamental help for the operation results of thyroidectomy proposed to the patient, he should inform him/her of the fact that such intervention will be carried out using a method based on electrical stimulation of the nerve, rather than only displaying, explaining the reasons that led to such a move and the relative percentages in terms of nerve rescue. At that point, so that the information provided to the patient is honest and truthful, he should communicate the data reported in the literature, on the basis of which the he believes this method more efficient than those hitherto employed.

Therefore, the surgeon must be able to justify the choice of this method in view of scientific evidence which however, only demonstrates an iatrogenic nerve injury risk reduction to less than 2%, which is identified with the so-called false negatives. Incomplete or generic information about the risk of producing a recurrent lesion would expose the surgeon (in case of producing a recurrent iatrogenic injury) to a medical-legal litigation, in which the patient would criticize him /her for not having been exhaustively and properly informed about the true extent of recurrent lesion risk burdening the surgery the patient was submitted to, despite the use of NIM.

What legal consequences would the use of the NIM have in defensive medicine? When the NIM is used in easy surgical management (interventions that apparently do not have a particularly high risk of iatrogenic injury) one wonders whether it should indeed be used in order to reduce theoretically likely adverse events (considering also the amount of information to be provided to the patient prior to surgery, about a procedure that can not be considered a standard of care). In fact, in cases where despite the use of NIM an iatrogenic nerve injury would occur, the surgeon could even see his responsibility getting worse, as the judge could consider his conduct blameworthy as having had the opportunity to identify the course of the nerve, he or she has not been able to preserve its anatomical and functional integrity. It would constitute, in this situation, medical malpractice. However, should the surgeon choose not to use this method as he/she might consider the case of easy technical execution and almost void the possibility of damaging the nerve since he/she believes in his/her technical capabilities as well as the local anatomical situation and would instead occur an iatrogenic injury, the operator would incur in an imprudent or even negligent practice. Therefore, what should be done? We believe that the key point lies in complete and truthful information of the patient in order to share the choice of technology and technical solutions to be adopted. Indeed the patient may come to a conclusion only after being informed of the theoretical probability of preserving the nerve when using the neuromonitoring method and especially clarifying the patient that this method cannot completely reset the risk. Moreover, it is important to fill in the clinical documentation especially the description of the operation in the surgery logbook, accurately indicating the general status of the surgical field as well as the steps of the surgery process, in order to provide the Judge, in case of litigation, the evidence of good surgical practice and to demonstrate that the lesion occurred to the patient did not depend on a technical fault but an unforeseeable event.

However, a different scenario is provided by cases burdened with a higher risk of iatrogenic damage (cancer, inflammation, previous irradiation of the neck, reoperation), that make the thyroidectomy practicable in two stages (an option that has to weigh the least risk of bilateral recurrent lesion, compared to a higher risk of complications related to a double surgery performed under general anesthesia and a possible therapeutic delay in case of malignant neoplasia). Indeed, in such a case it would be better to use IONM methods being the surgery burdened by a greater risk of producing a bilateral iatrogenic injury and the resort to this method can be a valuable aid for both the surgeon and the patient, notwithstanding the obligation and the duty to inform that the surgeon has to accomplish. This could also play into the hands of the surgeon in case of a neurological intraoperative injury, for he/she could see resized his/her responsibility as the particularly complex surgical situation had burdened the surgery with a greater risk despite the use of the NIM. For this reason it should be noted that the current jurisprudence (Supreme Court., Sec. III, 2334/11; Supreme Court., Sec. III, 4852/99) is reluctant to recognize in these cases the "special difficulties" provided in art. 2236 of the Civil Code which would occur only in cases not adequately known yet or not studied and experienced enough, or when a lack of doctrinal debate with reference to therapeutic methods and techniques to follow is manifested.

Conclusions

Although the progress in the field of thyroid surgery made in the last decades, currently there is no scientific reassuring evidence to completely avoid the possibility of producing an iatrogenic lesion of the laryngeal nerve, which still represents the real Achille's heel of this procedure. Information given to the patient prior to surgery, even in case of thyroid surgery should respect the requirements of completeness, freedom and honesty in order to allow the patient to self-determination. Therefore, the surgeon must comply with the patient's will even whether to use or not the NIM techniques whereby this will is the result of an adequate preliminary information. Indeed, in case of increased risk circumstances, it should be necessary to convert the surgery into a two-stage thyroidectomy. The currently most performed neuromonitoring procedures, although generating in the surgeon an increased sense of security doing an operation, have led to less than 2% reduction in the number of recurrent lesions, which a percentage rate far too high compared to the number of surgical interventions on the thyroid annually performed all over the world. For this reason it is important and necessary to draw up protocols for the use of NIM internationally applicable, providing uniformity of approach in the management of the information phase, the patient management and use of such techniques in thyroid surgery.

From a medico-legal standpoint, given the large number of malpractice cases that involve surgeons who perform thyroidectomies, the crucial element is represented by the quality and quantity of information provided to the patient about the procedure before the surgery. As long as surgeons will rely on the neuromonitoring techniques believing to be legally protected in the event of neurological injury, he/she will fall into error, since the protection can derive only from an adequate and complete information to the patient also in relation to the use of such techniques, especially documenting the aforementioned and explaining that there are no absolute guaranties to be able to preserve the laryngeal nerve, but to be able to obtain a reduction of the risk of iatrogenic damage, which is currently just below 2%.

Thereby the patient will be able to decide whether to undergo the surgery and whether or not to choose this procedure, which can find real justification in selected cases (recurrent goiter, substernal goiter, tumors), characterized by an increased risk of iatrogenic injury, making the neuromonitoring a useful aid for the surgeon and not a mere tool of defensive medicine as it can be considered in routine cases, where the NIM could become counterproductive for the surgeon relying thereon.

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