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Review

Unintentional recurrent laryngeal nerve injuries following thyroidectomy: Is it the surgeon who pays the bill?

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HIGHLIGHTS

- Injury of Recurrent Laryngeal Nerve has become one of the most frequent cause of medicolegal lawsuit.
- The incidence of unintentional RLN injury is 1–2% in tertiary referral centers, testifying that, also in experienced hands, it is a predictable but not preventable event at all.
- What is the value and meaning of an informed consent?

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ABSTRACT

Background: Thyroidectomy is one of the most common intervention in general surgery and, after the turn of the century, its rate has sharply increased, along with a worldwide increased incidence of differentiated thyroid cancers. Therefore, injuries of the recurrent laryngeal nerve have become one of the most frequent cause of surgical malpractice claims, mostly following surgery for benign pathology.
Main body: Even if the incidence of definitive paralysis is generally lower than 3%, during the last 20 years in Italy, the number of claims for damages has sharply raised. As a consequence, a lot of defensive medicine has been caused by this issue, and a witch-hunt has been accordingly triggered, so determining mostly a painful and lasting frustration for the surgeons, who sometimes are compelled to pay a lot of money for increasing insurance premiums and lawyers fees. Recurrent laryngeal nerve injury should be considered as a potentially catastrophic predictable but not preventable event, rather than the result of a surgical mistake.
Conclusion: Purposes of the Authors are analyzing incidence, conditions of risk, and mechanisms of recurrent laryngeal nerve injuries, underlining notes of surgical technique and defining medical practice recommendations useful to reduce the risk of malpractice lawsuits and judgments against surgeons.
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1. Introduction

Thyroidectomy is one of the most commonly performed intervention in general surgery and, since the turn of the century, its rate has sharply increased, along with a worldwide increased incidence of differentiated thyroid cancer [1]. The number of thyroidectomies in United States has risen from 48.000 in 1997 up to 58.000 in 2007 and also in Germany, from 2001 to 2006, surgical procedures for thyroid and parathyroid glands have risen from 117.000 up to 160.000 [2]. As a consequence, recurrent laryngeal nerve (RLN) injuries, mostly during surgery for benign pathology, have become the most frequent cause of surgical malpractice claim [3–6]. SS Abadin has reported 143 medical malpractice suits following thyroid surgery throughout 20 years, identifying a RLN injury in about

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10% of cases, with a bilateral damage in about 3% [3]. A literature review of closed malpractice claims has showed that in about 50% of cases a RLN damage has been reported [2] and a median of 974,625 $ has been the jury award granted in the United States, calculated during the years 1989–2009 [3]. Even if the incidence of a definitive paralysis is generally lower than 3%, during the last 20 years in Italy the number of claims for damages has sharply risen. According to the parameters established by the legislative decree n.38 of 2000 by the Italian Ministry of Health (i.e. Balduzzi Decree), a definitive biological damage of 25% has been acknowledged to patient in case of bilateral vocal cord palsy, while the rate of damage is variable from 6% to 25% for unilateral injury. So judges, lawyers, specialists in forensic medicine and insurance agents have spent a lot of time with the aim of better fulfilling the compensation expectations of the patients. A witch-hunt has been triggered, mostly determining a painful and lasting frustration for the surgeons that sometimes are compelled to pay a lot of money for increasing insurance premiums and lawyers fees. Moreover, this issue has raised defensive medicine. As a matter of fact, often the bill is very expensive and surgeons are considered responsible for undue insurance compensations. Nevertheless, injury of the RLN is a potentially catastrophic complication leading to the paralysis of the abductor muscle of the vocal cords, the posterior cricoarytenoid muscle. Symptoms range from a mild hoarseness, in case of unilateral lesion, to stridor and acute airway obstruction in the bilateral damage, with serious and sometimes catastrophic effects on patient social interaction and occupational status [7,8].

Capsular dissection, visual identification and intraoperative nerve monitoring allow to reduce the definitive RLN injury rate to 0.3–3% and, in transient forms, to 6–8% [4,9,10], but unfortunately, they do not prevent vocal cord paralysis to the patient [9]. Most of RLN injuries are not recognized intraoperatively and transection (rarely), clamping, stretching, electrocoagulation, ligature entrapment or ischemia are the main causes. Therefore, especially in patients where a visual nerve integrity has been accurately intraoperatively obtained, it is supposed that sometimes the real cause cannot be identified.

Authors, analyzing incidence, conditions at risk, and mechanisms of RLN injuries, underline notes of surgical technique and medical practice recommendations useful to reduce the risk of malpractice lawsuits and judgments, as well, against surgeons.

2. RLN anatomy

The RLN is a mixed nerve with sensory and motor fibers, originating from the thoracic portion of the vagus nerve. The right RLN lies in a more superficial plane, along the lateral esophageal edge and is traditionally considered at higher risk of injury. On the contrary, the left nerve, surrounding the aortic arch, is located in the tracheoesophageal groove, more deeply. As a unique segment, or divided in several branches (up to five), it penetrates the crycopharyngeal membrane and innervates the laryngeal muscles. Typically, anastomoses with the superior laryngeal nerve, committed to the innervation of the posterior cricoarythenoideus muscle, are described.

The Zuckerkandl tubercle, a bulge of thyroid tissue from the lateral thyroid lobe, the inferior thyroid artery with its branches, and Berry's ligament, a posteromedial thickening of perithyroid fascia, adherent to thyroid capsule and very hard to dissect, are the main important anatomical neural landmarks [11–13].

In addition, their anatomical variants contribute to precisely define RLNs at risk. Precocious division of RLN extralaryngeal branches is a common anatomical variation [14]. Generally, the anterior extralaryngeal branches are motor fibers that sometimes may be stretched during Berry's ligament dissection. Distortion and elongation of the nerve, caused by large goiter with retrosternal extension, should be considered as another important risk condition favoring RLN palsy [15].The knowledge of highly variable relationships between the RLN and inferior thyroid artery (ITA) is critical to a better neural identification. Moreover, intertwining between RLN and ITA ramifications may complicate dissection and hemostasis [16].

Non-recurrent laryngeal nerve is a rare variant (incidence 0.3–1.6%) observed more frequently on the right side, still representing a surgical challenge. Two types of anomalies are recognized, in type I, the non recurrent laryngeal nerve originates from vagus nerve above the laryngotracheal junction and descends into larynx, mimicking a branch of the vessels of the superior thyroid pedicle. In type II, it arises from vagus nerve below the laryngotracheal junction and runs parallel to the path of the inferior thyroid artery mimicking an arterial branch [17].

3. Nerves at risk

“Nerves at risk” (NAR) should be considered as additional conditions – patient, thyroid pathology or surgery related - increasing the chances of a neural damage [18]. Re-intervention is one of the most important predisposing factor for NAR. Surgical adherences, due to former surgery, and distorted anatomical planes lead to a hard identification of RLN, increasing nerve traction. A risk for permanent RLN palsy up to 30% has risen reported following re-operative procedures [19,20].Thyroid cancer, infiltrating surrounding soft tissue and in some cases the nerve itself, increases the risk of intra-operative damage from 3 to 8 times, if compared to benign disease [4,21–24]. For many years, Graves' disease and retrosternal goiter have been considered NAR conditions but recent studies based on large series showed no increased risk of RLN palsy in such diseases [7,21]. Furthermore, despite the different anatomical routes between left and right RLN, no statistically significant difference in terms of damage rates has been reported in the international literature [25]. Surgeon experience and, of course, the extent of surgery might significantly determine surgical outcomes. Few studies, analyzing surgeon's experience as a risk factor for RLN, showed an increased incidence among surgeons with less than 45 NAR patients per year [21,26–28].

4. Mechanism of RLN injury

RLN injury during thyroidectomy or parathyroid surgery occurs significantly more often “to a visually intact RLN than to a transected nerve” [23]. According to the Evidence data, several mechanisms are advocated as responsible for an unapparent neural lesion.

First of all, during ligation and dissection of the ITA, an unintentional neural clamping might occur, especially in case of neural bifurcation close to Berry's ligament. Actually, during the stretching of the ligament along with the anterior motor branch, the posterior sensory one can be mistaken for the entire RLN, leading to an injury of the anterior fibers [29]. Moreover, a knot too close to the nerve might determine a band of connective tissue constricting the nerve itself.

During thyroidectomy, the gland is dissected and medially rotated from its cervical attachment; this maneuver may cause a stretch injury to the distal segment of RLN, adherent to Berry's ligament [30]. These overstretching injuries are divided into two different subtypes: type 1, caused by the direct distress on the nerve by stretching the ligament; type 2, caused by pulling down the distal segment of RLN. The fixed terminal tract of the nerve, above the penetration in the larynx, is the most exposed area which is injured by overstretching [31].

5. Discussion

About 50 years ago H. Bauer, a speech therapist, described the first case of vocal cord palsy caused by intubation, showing that not only thyroidectomy can determine such injuries. As discussed above, RLN injuries are the main advocated cause of medical malpractice litigations in thyroid surgery, and direct trauma, traction, heat and rarely unintentional surgical section are the most frequent mechanisms responsible of the neural damage.

Type of surgery and nature of disease should be accurately considered, because in specific conditions a higher incidence is obviously expected [11]. Evidence based medicine studies show that re-operative and cancer surgery, Grave's disease, retrosternal goiter, surgical extension (lymph node dissection) and surgeon experience are associated to a significant morbidity risk. Moreover, even if a higher incidence is expected on the right side for a more superficial position of right RLN, literature statistical analysis has failed to confirm these data.

Lahey of Boston (1938) and Riddell of London (1956) firstly suggested identification of the RLN [31] to reduce unintentional injuries. Based on a strong Evidence, routine recurrent nerve visualization and dissection is currently the surgical cornerstone for reducing nerve palsy during thyroid and parathyroid surgery. Dralle after comparing, in a large multi-center series, neural visualization and dissection alone to identification plus intra operative neural monitoring (IONM), has confirmed this result [11]. In the order to prevent injuries, no consensus exists regarding the utility of neuromonitoring and its role is still debated. Currently, during a trial process in United States, IONM has not been referenced as a "standard of care", because a systematic review has failed to demonstrate statistically significant differences between visualization alone and visualization plus IONM [3,32]. However, its application can be considered for selected high-risk patients and seems to be very useful to avoid bilateral palsy in case of loss signal on the initial side, forcing to stop the operation [2,19,32–35]. Anatomical variations, comprising nerve distortion by voluminous or retrosternal goiter, precocious division of the extralaryngeal branches, no RLN and intertwining between neural and arterial branches, should be adequately considered during thyroidectomy to reduce unintentional neural and parathyroid damages. Moreover, during dissection, it should be remembered the high risk due to tenacious adherences between tubercle of Zuckerkandl or glandular capsule and nerve or neural branches close to Berry's ligament, that represents a very dangerous anatomical area [36,37]. Actually, most of lesions were determined during the dissection of this short tract (<2 cm) of RLN [23]. In such cases of difficult and risky surgical condition, a near total lobectomy should be preferred, even if this last technique is not supported by a strong evidence in reducing neural damages. Whenever possible, a complete visualization and a nerve dissection from thoracic inlet to larynx is considered a "gold standard", and blindly ligatures or coagulation must be avoided, especially in the area of tracheoesophageal groove. In addition, a precocious neural division of extralaryngeal branches must be suspected and an accurate RLN dissection must be obtained in every patient. Prophylactic or therapeutic neck dissection might be associated to higher incidence of definitive and unavoidably transient unintentional RLN injuries and should be reserved to referral centers [1,36–40]. Surgical neural section is reported only in exceptional cases, while a continuous traction, used to obtain a better exposure of RLN and arterial branch, might be considered as the main cause. Therefore, this should be avoided, preferring an intermittent tension and a cautious dissection, alternating upper and inferior poles. At present an exhaustive Italian series review of medical malpractice claims for RLN injury during thyroidectomy does not exist. By using as keywords "Malpractice claim after thyroidectomy", "Recurrent laryngeal nerve injury after thyroidectomy", "Recurrent laryngeal nerve injury medical litigation" a database research was performed on the two certified Italian lawsuit search engine "De Jure" and "Le leggi d'Italia", finding 23 cases of medical litigations between 2004 and 2014. In the 80% of the reported lawsuits, the patient had won the legal claim in the majority of cases thanks to an inadequate and summary compilation of the surgical notes or of the informed consent, for a delayed communication to the patient of the neural damage and for the inability, by the surgeon, to demonstrate the adoption of a meticulous and gentle surgical technique. In the rare cases of lawsuit victory by the surgeon, the court-appointed physician demonstrate the anatomical and surgical difficulties in determining an unavoidable complication. In our department, approximately 6000 thyroidectomies have been performed during the period 1996–2016. We found 10 lawsuits for RLN injury, in particularly 2 cases of bilateral neural damage and 8 cases of unilateral vocal fold palsy. In 8 cases the surgeon had lose the medico-legal claim and had been compelled to indemnify the patient approximately € 50,000 for a permanent unilateral vocal fold palsy and € 200,000 in case of permanent bilateral palsy. It is a common practice in Italy that the lawyer receives from 5% to 25% of the client refund of injury [41].

Neural damage is therefore an unavoidable complication, reported in all worldwide series, and in order to decrease the risk of malpractice claims several recommendations may be highlighted. First of all, a gently and meticulous surgical technique with visual identification of the nerve should be always adopted. Moreover, a precise and sufficiently comprehensive filling of the surgical report, testifying RLN identification and its integrity at the end of the procedure, and demonstrating that intervention has met the standard of practice performed by a qualified surgeon, is of paramount importance. An informed consent form, containing an accurate description of all complications, including RLN injuries, must be clearly discussed and signed by the patient. A pre-operative flexible laryngoscopy should be always performed with the aim of identifying any previous possible vocal folds alterations, and it should immediately required in every patient with a suspect of laryngeal malfunction in order to obtain a precocious diagnosis of vocal cord palsy. In this last condition, a multidisciplinary and cohesive team (including an otolaryngologist and a speech therapist) plays a determining and central role in the postoperative care and rehabilitation of the patient. At last, empathetic relationships, reassuring the patients about the outcomes is of paramount importance. Therefore, unintentional RLN injury is a predictable but not preventable event and unfortunately bilateral palsy still represent a dramatic clinical condition around the globe, for both surgeons and patients [42–44]. It should not be considered a "surgeon mistake", but rather an unavoidable complication due to the surgical operation itself, required and indicated according to the thyroid disease and the endocrinologist. It is very strange and somewhat inexplicable that a proposed possible surgical complication, RLN injury, discussed and accepted by a signed informed consent, could become a cause of request for reimbursement of the damage. What is the value and meaning of the informed consent? Jurisprudence should carefully consider this issue and, consequently, try to mediate the laws.

6. Conclusions

In the last decades, especially thanks to the large diffusion of US-guided FNAC, the incidence of differentiated thyroid cancer has been sharply increased and much more thyroidectomies are worldwide performed. As a consequence, RLN injuries have become one on the main cause of medical litigations and a lot of resources

are spent with the aim of better resolving the expectations of compensation of the patients. Visualization, dissection and intra operative nerve monitoring have reduced the incidence of unintentional RLN injury to 1–2% in tertiary referred centers, testifying that, also in experienced hands, it is a predictable but not preventable event. Sometimes, neural damage must be considered as an unavoidable complication rather than a "surgical mistake". Moreover, it should be remembered that complications are proposed by the surgeon and subscribed by the patient, during an unmissable informed consent.

In Italy, frequently, surgeons are forced to spend a lot of money for lawyers and insurance premiums, which rise more and more as a consequence of claims for damages received. In some cases, surgical complications have become a true business rather than an unpleasant event following treatment. Unfortunately, such phenomena have become source of surgeon frustration for surgeons and of defensive medicine, in turn associated to higher public health costs. The surgical community is still claiming a careful analysis by national Government and Ministry of Health, in order to put surgeons in a strong position to accomplish their risky but very important social mission in taking care of the patients and healing them, whenever possible. In addition, a national fund for compensation for damage should be established.

Ethical approval

Is only a review article of literature and dosen't need any ethical approval.

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Author contribution

Claudio Gambardella: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Andrea Polistena: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Alessandro Sanguinetti: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also participated substantially in the drafting and editing of the manuscript.

Renato Patrone: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Salvatore Napolitano: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

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Pier Giorgio Calò: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Nicola Avenia: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Giovanni Conzo: Partecipated substantially in conception, design, and execution of the study and in the analysis and interpretation of data; also partecipated substantially in the drafting and editing of the manuscript.

Conflicts of interest

Authors have no conflict of interest.

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List of abbreviation

RLN	Recurrent Laryngeal Nerve
ITA	Inferior Thyroid Artery
NAR	Nerves At Risk
IONM	Intra Operative Neural Monitoring

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