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Andrea Polistena, Pierpaolo Di Lorenzo*, Alessandro Sanguinetti, Claudio Buccelli, Giovanni Conzo, Adelaide Conti, Massimo Niola, Nicola Avenia

Medicolegal implications of surgical errors and complications in neck surgery: a review based on the Italian current legislation

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Abstract: Aim of the present paper is the review of the principal complications associated to endocrine neck surgery considering how expertise, full adoption of guidelines, appropriate technology and proper informed consent may limit the medicolegal claims at the light of the incoming new regulation of the medical professional legal responsibility. A literature search, using the Medline/PubMed database for full-length papers, was used. Postoperative recurrent laryngeal nerve (RLN) palsy and hypoparathyroidism remain the principal causes of surgical malpractice claims . In the procedure of neck lymphadenctomy intra-operative haemorrhage, thoracic duct injury, injuries to loco-regional nerves can be observed and can be source of claims. After many years of increased medicolegal litigations, the Italian government is proposing a drastic change in the regulations of supposed medical malpractice in order to guarantee the patient's right to a safe treatment and in the meantime to defend clinicians from often unmotivated and prejudicial legal cases. Surgical errors and complications in neck surgery are a relevant clinical issue. Only the combination of surgical and clinical expertise, application of guidelines, appropriate technology and a routinely use of specific informed consent can contain potential medicolegal implications.

Keywords: Malpractice; Medicolegal claims; Complications; Thyroidectomy; Parathyroidectomy; Neck lymphadenectomy

1 Introduction

Safety in care giving is provided by the Italian legislation and legal implications are possible in case of any degree of supposed damage occurred after an health treatment. Since increased malpractice claims, the Italian government has proposed a drastic change in the regulations of medicolegal litigations in order to guarantee the patient's right to a safe treatment and in the meantime to contain prejudicial legal cases [1].

A complication free outcome of the medical treatment, especially of benign diseases, is somehow expected but unfortunately endocrine surgery of the neck is involved with medicolegal implication since the potential surgical complications, among whom the recurrent laryngeal nerve (RLN) palsy and hypoparathyroidism remain the principal causes of surgical malpractice claims [2-4].

This scenario is increasing considering total thyroidectomy and hemithyroidectomy are high rate surgical procedures in Italy. Additionally, they are the most frequent endocrine operations accounting for 37.608 interventions performed in the year 2013 according to the Italian Health Ministry official data [5]. As well others neck endocrine surgical procedures including parathyroidectomy and cervical lymphadenectomy represent, with lower rates, frequent interventions performed in the country. An increasing number of endocrine neck procedures is registered

***Corresponding author: Pierpaolo Di Lorenzo,** Department of Advanced Biomedical Sciences, University of Naples Federico II, Naples, Italy, E-Mail: pierpaolo.dilorenzo@unina.it
Andrea Polistena, Alessandro Sanguinetti, Nicola Avenia, University of Perugia, Medical School, Endocrine Surgery Unit, S. Maria University Hospital, Terni, Italy
Claudio Buccelli, Massimo Niola, Department of Advanced Biomedical Sciences, University of Naples Federico II, Naples, Italy
Giovanni Conzo, Department of Anesthesiological, Surgical and Emergency Sciences, Second University of Naples, Naples, Italy
Adelaide Conti, Department of Surgery, Radiology and Public Health, Public Health and Humanities Section, University of Brescia – Centre of Bioethics Research, Brescia, Italy

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worldwide with similar issues concerning medicolegal claims [3, 6].

Aim of the present paper is the review of the principal complications associated to the endocrine neck surgery considering how expertise, full adoption of guidelines, appropriate technology and proper informed consent may help in containing errors and adverse events, limiting the medicolegal claims at the light of the incoming new regulation of the medical professional legal responsibility in Italy.

2 Analysis of the literature

A literature search, using the Medline/PubMed database for full-length papers, was performed analysing all articles present in the database up to the 31st January 2016. Entry terms were: medicolegal litigation, malpractice, medicolegal claim, informed consent, guidelines, technology, expertise which were each matched with each of the terms: thyroid, thyroidectomy, hyperparathyroidism, parathyroidectomy, cervical lymph node metastases, cervical lymphadenectomy. Out of the retrieved records after preliminary analysis of title and abstracts of the english, italian and spanish language papers available, those pertinent to the objective of the present review were selected. The corresponding full-length articles were examined carefully and those articles considered relevant for the medicolegal implications described or relevant for the description of the surgical procedures and of their complications, were considered for analysis. Non specific criteria of inclusion or exclusion were used. On line documents related to the Parliament and Government acts and to national agencies reports were also included and critically reviewed.

3 Complications in neck surgery potentially considered as errors

3.1 Total thyroidectomy, hemithyroidectomy, parathyroidectomy and central neck dissection

The principal complication which might be observed following surgical procedure in the central compartment are: *RLN lesions* in the form of bilateral or unilateral and temporary or permanent palsy and temporary or permanent *hypoparathyroidism*.

Post-operative RLN lesion is, a relatively rare complication of thyroid surgery, the rate of permanent damages occurring approximately between 0.3 and 3% of the cases and transient palsies in up to 8% of the cases. It is generally considered as a transient palsy that recovered up to 12 months after surgery, permanent if unmodified 12 months after surgery [7-15].

The lesion of the main trunk of RLN, or of its smaller motor branches, is responsible for the paralysis of different laryngeal muscles that might be clinically evident as a significant impairment of the voice either in its quality and intensity. Consequent symptoms range from hoarseness in unilateral lesions, to stridor and acute airway obstruction in bilateral damage. Temporary or permanent post-operative vocal changes can have a serious impact on the patient's quality of life.

Less frequently *superior laryngeal nerve* (SLN) lesions are observed. The SLN carries motor fibers to the cricothyroid muscle that tenses the vocal cord by modifying the distance between the cricoids and the thyroid cartilages. Vocal fold tension and thickness influence the frequency of the vibration, which characterizes the voice timbre. Injury of the SLN causes paralysis and or weakness of the cricothyroid, resulting in changes in voice quality, voice projection and production of high-pitched sounds [16-18].

Post-operative haemorrhage: Post-thyroidectomy haemorrhaging is a rare but potentially life-threatening complication of thyroid surgery. It is also associated with an increased risk of RLN and parathyroid lesions at reoperation. It is not an emergency for the entity of the haemorrhage but for the acute respiratory distress, due to tracheal compression, which requires immediate decompression. Minor haemorrhagic events are related to incomplete haemostasis on minor venous vessels, more severe conditions can occur when the branches of the superior or inferior thyroid arteries are interested [19-20].

3.2 Lateral neck dissection (LND)

Intra-operative haemorrhaging can occur after a neck lymphadenectomy, in addition to thoracic duct injury, and injuries to loco-regional nerves and rarer complications. In the procedure of neck lymphadenctomy can be observed intra-operative haemorrhage, thoracic duct injury, injuries to loco-regional nerves and rarer complications [13,21].

Intra-operative haemorrhage: the more severe haemorrhagic events are usually referred to carotid or to jugular vein lesions. They occur during the dissection and require immediate control by direct suture or even vein ligature.

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Post-operative haemorrhage is still possible but it usually is due to minor venous vessels bleeding and the haematoma, in the lateral compartment, less frequently determines compression on the airways, differently from what occurs in the central compartment [13].

Thoracic duct injury: it can follow LND on the left side with consequent chyle leak. The lesion usually occurs at the junction of the left jugular and subclavian veins at the level of confluence with the thoracic duct. In most cases, the injury involves small lymphatic routes with minimal chylous leak [13,22-23].

Nervous lesion: Accessory nerve lesion is the most severe nervous complication following LND, it is usually due to traction or heat damage, more than to a direct section, and determines a clinical condition characterized by decreased neck and shoulder mobility, anesthesia, numbness, neuropathic pain and dysmorphy for hypotrophy of the upper trapezius and sternocleidomastoideus muscles [13-24]. Injury to the *cervical sympathetic nerves* can result in permanent Horner's syndrome characterized by ipsilateral ptosis, miosis, and anhidrosis [13]. *Cervical and brachial plexus* lesion may result in severe functional limitation of the upper limb with limited recovery after corticosteroids therapy and rehabilitation [13].

Phrenic nerve damage, almost asymptomatic on the right side, on the left results in a unilateral paralysis of the diaphragm with a reduction in lung capacity, concomitant shortness of breath, headaches, blue lips and fingers, fatigue, insomnia and overall breathing difficulty [13]. Furthermore a miscellanea of infrequent causes of action after thyroid surgery are reported and include residual thyroid disease, salivary fistula, wound infections and deforming scars [3].

4 Surgical expertise and clinical management recommended to limit complications

Specialist endocrine surgeons must perform the different procedures respecting the "tips and tricks" that only high volume experience and adequate training can provide, improving the identification and preservation of the crucial anatomical structures involved in the dissection, in order to limit potential complications at risk for medico-legal implications.

4.1 SLN

The SLN is jeopardized when dissecting around the superior pole of the thyroid gland to identify branches of the superior thyroid artery, particularly when the upper portion of the sternothyroid muscle, which is as a landmark for the course of the nerve, is sectioned to improve access to the superior thyroid pedicle in case of large goiters [16].

Due to anatomical variations of the SLN, careful blunt dissection of the superior thyroid pole is recommended and should start from the avascular space located between the medial aspect of the superior pole and the cricothyroid. Blunt dissection of the polar vessels should be operated to gently push up the nerve to avoid its entrapment during ligation. The use of monopolar or bipolar diathermy or other devices for sealing vessels must be limited in order to prevent iatrogenic heat injuries.

4.2 RLN

The RLN injury is extremely rare in high volume centers with adoption of accurate surgical technique. During thyroidectomy and central compartment lymphadenectomy is mandatory a preliminary identification of both nerves which must be controlled during the procedure with protection from traction and heat injury. Patients tolerate quite well unilateral palsy, while although very rare, bilateral true palsy requires urgent tracheostomy to secure the airway [25].

If a monolateral lesion is recognized intra-operatively by direct visualization or by intra-operative nerve monitoring (IONM), it might be considered to limit the dissection in the other side, eventually leaving a minimal glandular tissue around the nerve, at least when treating benign disease.

The active search for and the identification of the LRN is a crucial point of a correct thyroidectomy. The tubercle of Zuckerkandl and the parathyroid are the landmarks that can be used for identifying the RLN, since it generally lies anterior to the nerve which underneath crosses the inferior thyroid artery or it branches with a range of possible anatomical variations [26].

Possible mechanisms of injury include transection, clamping, ligation, traction, thermal injury and ischemia due to extended skeletonization. This imply the necessity of blunt dissection, controlled traction, visual control during clamping and ligation which can be associated to IONM testing and limited use of energy-based devices in the risky area. Laryngoscopy is classically recommended

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preoperativelyand postoperatively in all patient, for evaluation of cordal motility and to asses laryngeal nerve function. It avoids in asymptomatic non dysphonic patients with already present vocal cord paralysis, potential medicolegal implication which can be incorrectly ascribed to thyroidectomy. It is of course mandatory in dysphonic patients, in reoperative surgery or in all cases in which a lesion of the RLN can be present, such as in invasive cancer. A particular attention should be given in those patients presenting a difficult intubation which might determine, after multiple traumatic attempt of positioning the oro-tracheal tube, an arytenoid subluxation which is characterized by a pathological anterior-medial shift of one arytenoid resulting in cord immobility not to be ascribed to the surgeon [27]. The role of IONM can be crucial in the rare condition of non-recurrent laryngeal nerve which is associated to an increased risk of nerve lesion [28].

4.3 Hypoparathyroidism

After the identification of the glands they must be preserved by gentle dissection using ligature or bipolar diathermy to be detached from the thyroid and pushed laterally. To prevent permanent hypoparathyroidism, if an accidental removal or damage with devascularisation is observed at surgery, parathyroid autotransplantation in the sternocleidomastoideus is strongly recommended [13]. Postoperative plasmatic Calcium level monitoring is mandatory in order to support hypocalcemic patients with substitutive therapy, as previously described, to prevent mild symptoms such paresthesia and mainly to avoid tetany [29].

4.4 Post-operative haemorrhage

Only accurate technique and rigorous haemostasis can limit the incidence of post-operative haemorrhage. Arterial bleeding is almost always evident and requires immediate control. The recourse to the Valsava manoeuvre after thyroidectomy, before closure, can guarantee not to leave venous vessels leaking which are otherwise those responsible for the most of the haemorrhagic events in thyroid surgery [29]. Postoperative hypertension, vomiting and straining are significantly related to post-operative haemorrhage. The use of drainage is therefore strongly recommended. Haemorrhage can determine even dramatic outcome if sudden decompression with wound opening is not carried out in the ward, before transferring the patient back to the operative room. The risk of damage to RLN and parathyroids at reoperation for bleeding is high and gentle manoeuvres are therefore always required [13, 29-30].

4.5 Chylous fistula

At the level of the confluence of the thoracic duct with the left jugular and subclavian veins the dissection must be extremely accurate. Ligatures must be preferred to diathermy or other energy devices to guarantee sealing of lymphatic branches. Chyle leak lesion evident at surgery must be treated, at the same time, by suture ligation with non-absorbable material. In case of extended dissection in level IV-V with suspicious lesion and risk of late fistula evidence, maintenance of the drainage tube and starving is usually sufficient. In case of evident fistula artificial feeding is required or at least a fat free diet and pressure dressing are suggested [13, 22-23].

4.6 Nervous lesions

All the nerves involved in the dissection, especially the spinal accessory nerve should be preserved with careful isolation during LND and even traction, potential thermal injury, extensive dissection and skeletonization, devascularisation and ischemia must be limited. For the spinal accessory nerve identification, the use of IONM is recommended for a safe dissection and in the meantime it provides a record of the pre- and post-dissection signal which certify the correctness of the procedure [13, 24].

5 Guidelines and evidence based medicine

The adoption of guidelines is the fundamental issue to limit eventual medico-legal implication. Any surgical procedure must be planned according to recognized guidelines which define the correct indication to surgery.

Neck endocrine surgery was deeply investigated by national and international scientific societies which designed the guidelines of treatment for benign and malignant thyroid and parathyroid diseases and cervical lymph node metastases with indication to surgical treatment [29, 31-32].

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6 Technology

6.1 IONM

IONM has been developed to facilitate the identification of RLN, to map its route, to avoid its iatrogenic injury and to obtain prognostic information about postoperative vocal cord functions during thyroid and parathyroid operations. The technique of IONM was previously described [33]. The identity of an intact RLN would be confirmed through a series of audible acoustic signals that were generated by the machine. The functional integrity of the nerve once again would be confirmed at the end of the thyroidectomy by the testing of the most proximal exposed portion of the nerve.

6.2 Magnification

Magnification of the operative field by 2.5x glasses might help during the dissection of RLN and parathyroids adding precision to the surgical manoeuvres hence keeping the morbidity at a low level. According to previous experiences the microsurgical approach with magnification is feasible, reduces surgical time, and improves the outcome in total thyroidectomy [34].

6.3 Energy-based devices

Energy based devices including bipolar vessel sealing system and ultrasonic technology are modern options for haemostasis and dissection during thyroidectomy and neck surgery. They offer a safe dissection and the rate of nerve lesions, post-operative hypoparathyroidism, bleeding, drainage, and operative time are usually no significantly different considering the different instruments used or in comparison to traditional knot and tie ligation technique. They are safe and effective device when applied to a correct surgical strategy as above reported [35-36].

6.4 Minimally invasive technique

Video-assisted endoscopic techniques offer a magnified visualization which might be useful in dissecting crucial anatomical structures [37-38]. In all cases, however, the identification and preservation of the RLN, of the SLN and of the parathyroid glands are still key points of the operation which must be carried out with regards to the principles of classical technique and require adequate training in high volume centres. Intra-operative parathormone dosage together with radioguided technique and minimally invasive approach reduced the rate of recurrent hyperparathyroidism after parathyroidectomy for primary hyperparathyroidism thus containing the rate of reoperation with the related increased morbidity [39-40].

7 Informed consent

The Italian Constitution defend the personal liberty (article 13) and the right for health and provide for every citizen appropriate cure which is free of charge for poor people, but in the meantime states that nobody is obliged to a medical treatment with the except of isolated case when prescribed by the law as in case of severe mental illness or of under-age patients with no parents or no relatives in charge (article 32) [41]. The Medical Deontological Code (articles 33 to 39) states that any invasive diagnostic or therapeutic medical procedure constitutes a contract between the patient and the healthcare professional [42]. This contract is essential to ensure a consensual medical practice. This contract also requires the preliminary information of the patient and this information is considered as the key to achieve the patient's informed consent. The patient also became a partner whom the physician must prospect the most appropriate management of his condition after having explained the various treatment options and their respective advantages and risks, possible degree of urgency and the expected consequences in the event of refusal of the treatment. The only exception is the case of therapeutic necessity when it is impossible to obtain the patient's consent. It usually deals with emergency surgery and trauma and it is extremely rare for the elective endocrine surgery of the neck. Following complications and delayed diagnosis, failure to provide information about the risks involved in the case of an invasive diagnostic or therapeutic medical procedure has become the third leading cause of malpractice litigation against healthcare professionals in the USA [6, 43].

For this reason national and international scientific societies provide even to endocrine surgeons forms of specific informed consent focusing on the potential complications related to the different procedures, specifying incidence of these events in order at least to fulfil the requirements for a correct medical practice [44-45].

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8 Discussion

The Italian National Agency for Regional Health Services (Agenas) provided data concerning the total amount of the medico-legal claims and legal notifications since 2009 to 2012 showing a stable number of cases over 12.000/year [46]. Similarly the trend of claim for supposed malpractice since 2006 to 2011, according to the official data of Italian national Association of the Insurance Enterprises (ANIA), showed a spike over 14.000 cases between 2008 and 2010 [46].

This scenario was defined as the malpractice chaos, attesting the increasing volume of all the medico-legal litigations with progressive increase of costs for legal defence of the single clinician and of the hospital institutions themselves. Costs also raised for the increase in defensive medicine which is nowadays a frequent trend, adopted in order to attempt the limitation of potential claims, although very often it is not in line to what recommended according to the evidence based medicine protocols. The risk management policy adopted in almost all hospitals with the activity of dedicated professionals, tried to limit the incidence of "errors", analyzing all the "near miss" event and the "sentinel event", mainly by the promotion of clinical audit designated to research, in different fields, all the weakness of the system due to cultural, organizational and clinical problems. Adoption of the current guidelines and the principles of the evidence based medicine are the crucial points of the mechanism.

The proposal of a new regulation [47], whose institutional route is still under evaluation of the Senate at the time in which this paper is written, focuses on many different aspect of the medico-legal regulation in Italy.

In details the articles 1 and 2 promote the safety in the delivery of cure, to fulfil the right to health and welfare. Risk management is considered a key point of the system which must be provided in all the institutions. The right to receive safe cure is guaranteed by an ombudsmen who will be in charge of collecting all the complaints when a damage is supposed after the medical treatment. This organism will transmit data from the local to the national observatory for the safety in the health system with the aim of analyzing all the errors and related costs for medico-legal litigations in order to define guidelines to improve safety (article 4).

Transparency in the data availability and easy access to the personal clinical files on line, with publication of all details concerning the reimbursements after medico-legal litigations in every institution will become mandatory (article 5). The article 6 constitutes one of the more relevant innovation because in case of patients' death or for severe consequences, the clinician risks the penal accuse of murder or of personal lesions offence only in case of severe guilt or fraud. In the meantime the physician cannot be penally accused if the clinical management has been carried out according to appropriate guidelines available. Thus confirming the importance of guidelines applications to contain the medicolegal claims. Therefore in this scenario the litigation moves from the penal code to the civil one, considering only a potential reimbursement.

At this point there is another crucial innovation because (article 7) it has been proposed the inversion of the prove provision, since to find and demonstrate the malpractice and the correlation between the outcome and the clinical management will be in charge to the patient and the physician won't have to defend himself from an already supposed procured damage. In the meantime there is a reduction of the time window in which a medico-legal claim can be promoted from ten to five year before prescription.

The conciliation of a medical arbitration board is provided by the law before the admission to the ordinary court with the aim of limiting the expense and also the overcrowding of the judiciary system. Insurance coverage will be obligatory for every hospital institution (article 8). A special found is constituted to cover all the expense for the patient's refund in case of financial crisis of the insurance company (article 9).

In the light of this new coming legal scenario what can really protect both patients and surgeons from medico-legal litigations is still unclear since at the moment any complication can be considered as the base for a malpractice case.

Expertise in any clinical practice and especially in surgery is the fundament base for an uneventful outcome. In endocrine surgery as for the other specialties it is mainly related to the patients' volume. It was observed that the high volume (at least more than 30 thyroidectomy/surgeon/year) in dedicated centres is associated to better results in terms of complications, length of hospital stay, and cost following thyroidectomy [48]. Although there is no risk zero surgery even in neck procedures, expertise may limit complications and therefore reduce potential medico-legal litigations.

Medicolegal implications are related not only to post-operative complications as events, but also to general malpractice in terms of incorrect surgical indications or lack of basic requirements for surgical practice as the informed consent. An uneventful outcome with correct application of guidelines and all formal requirements is seldom followed by a medicolegal litigation.

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In the USA unnecessary or inadequate surgery account each for 9% of malpractice litigation source, similarly delayed diagnosis for 6% [49]. These conditions include the incorrect pre-operative study especially when there is a delayed cancer diagnosis and the overtreatment when a complicated outcome is registered for a benign disease or as opposite a too limited resection when a cancer is finally detected, thus requiring reoperation with increased risks. This impact support a clear role of guidelines either in the making decision process and in the choice of the proper surgical treatment without risks of under- or over-treatment. In the light of the above consideration and of the new incoming regulation, only with strict adoption of guidelines promoted by scientific societies, the clinical practice can be somehow protected from medico-legal litigations at least for diagnostic malpractice or incorrect indications to the surgical treatment.

Technology has been significantly imported into neck endocrine surgery since many years. In terms of improved safety with reduced morbidity few innovations had really contained the rate of surgical complications especially in term of RLN palsy and hypoparathyroidism. Among them the use of IONM really represents a novelty in terms of limitation of potential medico-legal claims. Far from being IONM substitutive of clinical evaluation and expertise in identification and preservation of the nerve, its main advantage is related to the certification of nerve recognition before dissection and the registered proof of its integrity by vagus nerve signal detection after dissection. The report of IONM became an integrant part of the patient clinical file and can be even used for any sort of litigation if a voice defect is observed post-operatively. It must be highlighted that when available in the hospital, IONM must be routinely adopted in all the procedure since there could be potential claims in case of LRN lesions if not used.

Evidence-based date coming from randomized prospective trials testify the safety and efficacy of the minimally invasive thyroidectomy. But a real advantage in terms of safety is not evident compared to conventional thyroidectomy, being the major difference the improved cosmesis and less postoperative pain in comparison to increased costs compared to the classical technique [37-38].

The correct adoption of the informed consent strengthen the safety for both patients and clinicians when a good medical practice is carried out according to the principles of the evidence based medicine delineated by the guidelines. As described in section 6 [43-45] a clear, easy understandable information on the features of the clinical condition, with extended clarification of all the alternative treatments with their pro and cons, with clear explanation of all the potential complications, with their rates related to the experience of the surgeon, with the possible long term sequels and the methods to face them, is strongly recommended for all medical treatment especially for invasive ones such as surgery. The undersigned informed consent is a must of the correct and ethic medical practice but it is not itself sufficient to prevent medico-legal implications in case of persistent sequels which may be the base for a claim for supposed malpractice, but its lack could increase medico-legal consequences in case of claims.

In strict correlation to the informed consent, another relevant aspect to be focused on is the general surgeon-patient relationship. Now considered an important mechanism to avoid medical legal implications is part of the necessary attitude in the medical practice. It can show the honest conduct of the health professional, independently from the outcome and usually limits the patient's concerns. Patients and mass media sometimes tend to consider all medical errors to be preventable adverse medical events, but for the nature itself of medicine and human physiopathology, it is not always possible to prevent and contain neither simple nor critical complications. Patients can present post-operative sequels as consequence of errors of commission or an adverse outcome, due to errors of omission when something that should have been done to prevent a damage was missing [50]. Negligent actions should be always persecuted by the Law and be clearly distinguished from honest unpredictable and unpreventable mistakes. The balance between doctors and patients honesty with theoretical embrace towards the common aim of the cure is the key of the doctor/patient relationship in the setting of the medicolegal implication. When this relationship is missing in one or both side of the join, an increase in potential medicolegal claims must be expected. Timely and candid disclosure should be standard practice. Honesty about error may lessen, rather than increase, the medicolegal liability of the surgeon and may help to reduce the patient's concerns.

9 Conclusions

Surgical errors and complications in neck surgery are a relevant clinical issue which might induce medicolegal litigations. In neck surgery, application of guidelines and a routine use of specific informed consent are strongly recommended according to evidence based medicine and health legislation to guarantee optimal care to

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patients and to avoid the base for a supposed malpractice. Furthermore only the combination of surgical and clinical expertise with high volume activity and appropriate use of the available technology can help in reducing surgical complications which are worldwide the source for patient's complains and for the following potential medicolegal implications. The efforts in creating and maintaining an honest surgeon-patient relationship is an ethical and professional duty which furthermore, in the clinical practice, might help in lessening patient's complains and following sequels.

List of abbreviations

RLN recurrent laryngeal nerve
SLN superior laryngeal nerve
LND lateral neck dissection
IONM intra-operative nerve monitoring

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