

Review Article



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Bilateral Vocal Palsy After Total Thyroidectomy: Expert Opinion on Two Malpractice Claims

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ABSTRACT

Two patients complained of hoarseness, respiratory distress and swallowing disorders early after total bilateral thyroidectomy for multinodular goiter and cancer, respectively. Faulty surgical techniques had caused injury to bilateral recurrent laryngeal nerves (RLNs) during thyroidectomy and the associated central lymph node dissection. The operation notes showed no statement regarding the identification, dissection, exposure and/or functional integrity of the RLN on either side of the thyroid and no mention of the first resected lobe. This report reviews the personal experience of the authors in thyroid surgery for use in 2 medical malpractice claims and for future reference.

Keywords: Recurrent laryngeal nerve injury; Vocal cords; Tracheostomy; Nodular goiter; Intraoperative Neurophysiological monitoring; Standards

INTRODUCTION

In this article, we report the case of personal experience of the authors in thyroid surgery for use in 2 medical malpractice claims and for future reference. Two patients complained of hoarseness, respiratory distress and swallowing disorders early after total bilateral thyroidectomy for multinodular goiter and cancer, respectively.

We reviewed various components of these case; complaints of the surgical measures adopted, opinion of the hospital and expert, decision of the courts, methods of nerve monitoring, and the compensation system. we expect it will be resources to assist for similar cases.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

CASES

1. Case 1

A 39-year-old female patient presented with symptomatic, left-dominant, bilateral multinodular goiter with no retrosternal extension. The clinical diagnosis was euthyroid, but the biochemical diagnosis was hyperthyroidism. Therefore, the patient was recommended for a first-time thyroidectomy. The patient had no history of other medical illnesses or previous surgical procedures in the neck area.

Pre-operative video laryngoscopy showed optimal bilateral vocal cord mobility. During thyroid gland surgery, an enlarged thyroid lobe was observed on the left side. Persistent adherence resulting from thyroiditis was also observed during dissection. The medical records show that, after completing surgery on the left dominant side, the surgeon presumed that the left recurrent laryngeal nerve (RLN) had been spared. Therefore, thyroidectomy was also performed on the right side. Again, a persistent adherence was observed, and the right side RLN could not be identified or exposed. Total capsular thyroidectomy was performed. According to the operational report, no enlargement of cervical lymph nodes (LNs) was detected, and no other undue difficulties or unexpected findings were encountered during surgery. Superior parathyroid glands on both sides were identified and preserved with the standard technique, and branches of both inferior thyroid arteries were ligated and divided close to the capsule of the gland. Identification of the superior laryngeal nerve (SLN) was not mentioned in the medical reports. No suction drains were used. Intraoperative neural monitoring (IONM) of the RLNs was not mentioned.

The patient was extubated uneventfully. On the first evening after surgery, however, the patient complained of vocal disorder (hoarseness) and swallowing disorder. No surgical emphysema was noted. The postoperative laryngeal examination findings from postoperative day 1 showed vocal cord palsy on both sides. Vocal cords presented with a sufficient glottal gap in the vocal fold. On postoperative day 1, serum ionized calcium (iCa) level was 3.9mg/dL (reference range, 4.2–5.2), and parathyroid hormone (PTH) was <3 pg/mL. The patient was given 2 ampoules of intravenous (i.v.) calcium gluconate (186 mg of elemental calcium) and then, she started on 3 g oral calcium carbonate (CaCO₃), calcitriol 0.5 µg, and vitamin D3 1,000 IU daily. The final histological examination revealed a benign nodal goiter with a thyroid resection on the left side (34 g; 6.9×3.2×3.2 cm) and on the right side (11 g; 4.0×4.1×1.2 cm). The patient was discharged from the ward on postoperative day 12. Speech therapy was started. At postoperative week 13, cordotomy and arytenoidectomy of the right vocal cord was performed due to increasing dyspnoea and inspiratory stridor during minor physical exercise. The female patient in this case was treated in Italy in 2008.

The patient received €47,000 for the malpractice claim and no compensation for legal expenses. No other legal remuneration has been specified by the hospital or by the patient.

2. Case 2

A 41-year-old male presented with progressively increasing left thyroid swelling for the past 1 year. The patient had an enlarged left thyroid (30×20 mm). No bilateral cervical lymphadenopathy was noted. Fine needle aspiration cytology revealed papillary thyroid carcinoma (PTC). Ultrasonography and computed tomography scans of the neck and upper mediastinum confirmed the left thyroid nodule. No other evidence of disease was observed on the right lobe and isthmus of the thyroid. A slight (1 cm) extension in the mediastinum was also noted.

Preoperative laryngoscope findings were normal. The patient underwent total capsular thyroidectomy with central node neck dissection. Confluent LNs were noted on the right side. The medical report did not mention RLN identification or exposure on either side and did not mention the parathyroid glands. Additionally, IONM of the RLNs was not mentioned.

The patient was extubated uneventfully after 4.5 hours of surgery. On the night of surgery, the patient complained of rapidly progressing hoarseness and vocal disorders. Laryngeal examination revealed bilateral vocal cord paralysis. The same night, the patient developed acute respiratory distress and required re-intubation under fiber optic guidance. Second and third attempts to extubate on postoperative days 3 and 5 were unsuccessful. Further laryngeal examination confirmed persistent bilateral vocal cord palsy. Surgical exploration of the neck was performed on postoperative day 6. No irregularity was found in the trachea. A 7.5 Fr tracheostomy tube was inserted through the stoma, and the neck wound was closed. The patient was decannulated after 9 days, and the tracheostomy could be closed by the second month after cordotomy of the left vocal cord fold. The final histological examination revealed PTC (PT3, N1). Dissection of 4LNs revealed that all were metastatic. The patient in this case was treated in Italy in 2007.

The patient received €200,000 with no compensation for legal aid and expenses. No other remuneration has been specified.

SUMMARY COMPLAINTS OF THE SURGICAL MEASURES ADOPTED

One thyroidectomy was performed with central node dissection, and one was performed without central node dissection. In both cases, RLN injury resulted from surgical errors. In one case, the errors would have caused problems immediately after surgery, including hoarseness, dyspnoea during exercise, swallowing disorders and acute respiratory distress.

Further operations were necessary: 1 case required tracheostomy, and both required vocal cord surgery. In both cases, the patients complained of additional hospital charges, prolonged hospital stay, prolonged intensive care unit (ICU) stay, unplanned intubation, additional surgery, respiratory failure, readmission, and risk of death. Both patients also documented social and economic problems, including employment disputes.

OPINION OF THE HOSPITAL

The general affairs division and in-house counsel for the hospital has prepared a legal defense of the surgical interventions in collaboration with all involved surgeons (first operator, assistants), endocrinologists, and anesthesiologists. Briefly, the defense can be summarized as follows.

First, the operations were performed according to the standard guidelines of endocrinology, thyroid surgery and oncology in particular. A thyroid capsule dissection was performed to preserve the RLN on both sides, and parathyroid glands were visualized and safely protected during surgery (1-3). Both patients had normal voice function on the day of surgery and during transfer to the surgical ward.

Second, in the opinion of the hospital, the RLN injuries in both cases did not occur during thyroid surgery. Although the surgeons in these cases indicated that IONM would have been desirable, the use of IONM has not shown a significant association with improved thyroidectomy outcomes according to the literature, including a recent meta-analysis (4). According to the surgeons, use of IONM would not have changed the outcome.

Finally, the direct visualization of the RLN during surgery is not necessary if the principle of capsule dissection is satisfied, i.e., if the proximity of the thyroid gland enables avoidance of contact with (and injury to) the RLN during surgery (1-3). Voice function was normal immediately after surgery. The complaint of hoarseness did not occur until later.

EXPERT OPINION FOR PLAINTIFF

The lawyers for the patient have worked up a critique of the surgical interventions. This opinion was written jointly by medical technicians and lawyers for the patient. Briefly the documents can be summarized as follows.

The indications for surgery were correct in both cases, i.e., PTC in the second case and bilateral symptomatic goiter with latent hyperfunction in the first case. Deviation from the routine procedure for identification and exposure of the RLN is difficult to justify, especially in the case of total bilateral thyroidectomy, cancer surgery, re-surgery, or unusual anatomical findings (5,6). If the RLN cannot be clearly identified and exposed during surgery on the first side, surgery should not be performed on the other side. Surgery on the second side should be delayed until vocal cord function is confirmed (5,6). In the present cases, the RLN could not be identified and exposed on the first dominant side. The surgeons noted adhesions, tumor lesions and confluent LNs, which could have made RLN identification and exposure very difficult. The surgeons stated that they carefully preserved the posterior lamina during a preparatory capsular thyroid dissection. Despite their unsuccessful representation of the RLN by total lobe resection on the first side, the second side was also completely removed. Here, too, no representation of the RLN had taken place.

Moreover, the surgeon stated that the capsular dissection was safely performed during preparation for surgery, which is not an acceptable standard of care (5,6). This procedure was erroneous and should not have been performed even without IONM and without knowledge of the anatomical integrity of the RLN on the first-operated side. These procedures were not consistent with surgical standards that are applicable in the given situations (5). Surgical standards for RLN management include identification and exposure of the RLNs. Bilateral paralysis of the vocal cords occurred after surgery and led to progressive dyspnea and hoarseness. Both cases required a second operation of the vocal cord, and one case required a tracheostomy. For the second case report (PTC surgery), IONM was mentioned as a standard for the protection of the RLN in difficult thyroid surgery (7). In the case of bilateral thyroid surgery, IONM is a standard procedure for protection of the RLN (8). The technician for the plaintiff referred to another published study (8,9).

Finally, given the type of surgery, final histology (cancer in one patient), follow-up, the evolution of the disease, and the resulting postoperative disorders the disability, the estimated biological damage and financial loss was 15%–25% for the patient in the first case report and 30%–45% for the patient in the second case report (9). However, the disability

in these cases is subject to review after 2–3 years to assess whether the conditions have changed and whether compensation should be revoked.

DECISION OF THE COURTS

In both case reports, the decision of the court was supported by the expert opinion of an experienced thyroid surgeon (Dionigi G, the corresponding author of this paper).

The preoperative investigations and intraoperative findings showed indications for total bilateral thyroidectomy in the case involving goiter and for central LN dissection in the case involving cancer. In both cases, the RLN could not be identified during dissection of the first dominant lobe. A capsular lobe resection in which the RLN nerve was presumed was then performed on the first side by the surgeons in both thyroid surgeries. The surgical report with intraoperative findings and RLN identification was definitely sparse in the second case report presented here (cancer). At the time, the surgeries were performed in these cases (years 2006 and 2008), the standard operating procedure for total thyroidectomy was to visualize the entire cervical length of the inferior laryngeal nerves (6). The course of the anatomical nerve should be visualized and documented before and after resection (6). Specifically, the operative notes should indicate whether the RLN was visualized and intact (IONM) at the end of the procedure, at least on the first operated side (5,6). The surgical reports in both cases did not provide this information. When total thyroidectomy is performed, the RLN often adheres the thyroid gland, especially in the distal part of its course and in cases of adhesion, thyroid cancer and LN metastasis.

Intraoperative monitoring has been available for many years and may have been useful for depicting the course and function of the RLN on the first operated side. Even after resection, a correct positive electromyography (EMG) signal could provide sufficient justification for proceeding with surgery on the contralateral side (5,7). Neuromonitoring facilitates surgery but does not significantly improve outcomes in cases other than cancer or recurrence (7). Regarding the use of IONM, the court again independently confirmed that, if the RLN cannot be clearly identified and exposed during surgery on the first side, then surgery should not be performed on the other side. Surgery on the other side should be performed only after vocal cord function is confirmed.

The statement by the Hospital that no voice disturbance and no dyspnoea had occurred immediately after surgery was incorrect because both patients experienced emergent difficulties of the airway immediately after surgery. The detection of bilateral vocal cord paralysis in the early laryngeal examination can be considered a surgical error (11).

NERVE MONITORING

Even in the most conservative dissection technique, RLN palsy cannot always be avoided. Since the use of IONM cannot prevent paresis, it cannot replace visual identification of the RLNs. The use of IONM does not reduce the rate of paresis in surgery for benign thyroid disease (as in the first case) (7). These facts were also noted by the court authority.

Neuromonitoring can, however, help to avoid bilateral paresis. The surgeon can abort a bilateral operation if there is any doubt about the functional capacity of the RLN on the

initially operated side. Neuromonitoring offers the possibility using a purely morphological assessment to confirm functional integrity (5).

In the years 2006 and 2008, when the disputed operations took place, it is true that routine use of IONM was not considered mandatory according to the guidelines considered valid at that time. However, a surgical technique cannot substitute for an inadequate surgical procedure. In the present cases, therefore, the question is not whether neuromonitoring should have been used. The question is why the simple principle of visual identification of the RLN, which has been considered a standard practice for decades, was not applied in this case. Therefore, RLN paresis is to be regarded as a liability.

Our conclusions regarding these 2 cases are also consistent with the paper by Dralle et al (8).

1. The value of IONM in malpractice claims

The use of IONM in thyroid surgery has been the subject of disputes between plaintiffs and defendants at conciliation centers and courts since 2001 (12-14). In most cases of RLN damage that occurred in thyroid surgery performed with IONM (80% of cases in 2001–2007 and 70% of cases in 2008–2014), IONM was not performed according to the recommended procedures published in the literature (12-14). For example, the standard stimulation of the vagal nerve (VN) (V1 and V2) was not performed, or the signal tone was considered only after nerve stimulation.

Given that vocal palsy is usually caused by nonstructural, exclusively functional RLN lesions, which are equally effective in vocal folds, the high rate of bilateral vocal palsy after thyroid surgery performed without neuromonitoring is understandable and expected. However, a major cause for concern is that almost all bilateral vocal palsies occurred during the last reported period (2008–2014) despite the use of neuromonitoring, mostly due to non-compliance with standard procedures for use (12-14).

For evaluating vocal cord palsy after thyroid surgery performed with IONM, the authors argue that the crucial considerations are whether the standard procedure for using IONM was applied and whether intraoperative changes in neuromonitoring and EMG signals were correctly interpreted (12-14).

Therefore, continuous surgical training is needed to ensure that standard neuromonitoring procedures are performed correctly, especially with regard to the indispensable consideration of the EMG as well as the vagal stimulation before and after resection of the first page in all planned bilateral resections (not clear what this means).

The authors of this paper believe that the clinical benefits and applications of IONM (nerve identification, mapping, prognostication, nerve dissection, staged procedures, etc.) far outweigh its (often excessive) legal challenges.

Despite the clinical evidence of the efficacy of IONM, however, we expect that the use of IONM will be increasingly questioned in cases of medical malpractice.

2. EMG documentation

Photographs and videos are important for documenting pre-existing airway impairments or surgical deliberations. Documentation can include thyroid history, preoperative radiologic

imaging, pre-operative symptoms, pre- and postoperative laryngeal examination, and comprehensive surgical reports with intraoperative findings and identification of the RLN. In the second case report, documentation was scarce.

All modern IONM devices can be used to document EMG muscle action potential. For example, IONM can be used to convert muscle activity into electromyographical signals that can be recorded and printed. Documentation of the final normal neurophysiologic signals of the RLNs at the end of the surgical procedure may have important forensic applications because it provides an early indication of whether voice changes are related to the RLN. From a medico-legal perspective, muscle action potential should be recorded and documented at the beginning (V1 and R1) and at the end (V2 and R2) of resection on each side. In a monitored bilateral resection, the minimum requirement is V2 on the first operated side. When using IONM, mandatory documentation includes time-traceable measures of amplitude, latency, waveform morphology and magnitude of stimulating current. The EMG curves can be used to confirm intact nerve function.

3. IONM to prevent bilateral vocal cord injuries

A great achievement in the modern era of thyroid surgery is reduction of major injuries such as bilateral RLN palsy. A potential consequence of a loss of signal (LOS) for the RLN on the first side is a poorly timed contralateral surgery. After an LOS occurs, the surgeon must consider the possibility of at least temporary injury to the ipsilateral nerve and whether surgery on the contralateral side is currently in the best interest of the patient given the intraoperative information indicating ipsilateral paralysis (15). According to Goretzki et al. (15), a failed IONM stimulation of the RLN after resection of the first thyroid lobe is sufficiently specific to reconsider the surgical strategy in patients with bilateral thyroid disease to exclude the possibility of bilateral RLN palsy. In fact, in 85% of patients with known nerve injury and in 56% of patients with negative IONM stimulation at the first side of dissection, the surgical strategy was changed with no occurrence of postoperative bilateral RLN palsy.

After observing LOS on the first side of resection in bilateral goiter, more than 93% of surgeons surveyed indicated that were willing to change the resection plan for the contralateral side to avoid the risk of bilateral RLN palsy, which resulted in discontinuation of surgery in 84% of surgeries and in less extensive resection than originally planned for the other side in 9% of surgeries (12-15). Departments with the heaviest institutional caseloads reportedly change their surgical plans more often than those with a lighter caseloads (12-15). Likewise, departments that routinely perform vagal stimulation and record EMG responses are more likely to discontinue resection on the unaffected side compared to departments that do not (12-15).

Use of IONM is mentioned in the preoperative informed consent form for primary and secondary interventions. Information about the use of IONM should also include the consequences of intraoperative LOS. The possibility of a staged procedure performed after LOS on the first side must be clearly specified in the preoperative informed consent form. Patients should be informed of the possibility of staging the contralateral side in the case of LOS to increase patient autonomy and to encourage shared decision making. In practice, most patients agree with this concept and clearly comprehend the tremendous benefit of continuing resection on the second side in case of LOS on the first dominant side.

In a malpractice analysis, IONM provides important prognostic information regarding ipsilateral vocal cord function after surgery on the first side is completed. Using IONM to

stage contralateral surgery when RLN damage is diagnosed can reduce the potential for bilateral vocal cord paralysis. If IONM is used, the surgeon must consider the results and eventually decide when to stop the operation on the first side. If not otherwise stated, the operation should be stopped in the case of benign disease. Surgery should proceed only when it is clearly justified by malignant bilateral disease, severe co-morbidity, etc.

4. IONM in difficult thyroid surgeries

In a difficult case (i.e., if an injury has occurred), the surgeon should carefully examine arguments and justify the decision to perform surgery without monitoring (16). In 2009, we tested our hypothesis that RLN identification during thyroid surgery reduces injury and that intraoperative nerve monitoring may be of additional benefit (7). That study is the only randomized prospective trial that has compared outcomes of thyroid surgeries performed with and without IONM. In this study, 1,000 consenting patients scheduled to have bilateral thyroid surgery were randomized to a standard protection group or an additional nerve monitoring group. The primary outcome measure was prevalence of RLN injury. Of 1,000 nerves at risk in each group, transient and permanent RLN injuries occurred in 38 and 12 nerves without RLN monitoring ($P=0.011$) and in 19 and 8 nerves with RLN monitoring ($P=0.368$), respectively. Use of RLN monitoring significantly decreased the prevalence of transient RLN paresis by 2.9% in high-risk patients ($P=0.011$) and by 0.9% in low-risk patients ($P=0.249$). The negative and positive predictive values of RLN monitoring in predicting postoperative vocal cord function were 98.9% and 37.8%, respectively. The authors concluded that, although it did not decrease the incidence of permanent RLN paresis, nerve monitoring decreased the incidence of transient RLN paresis compared with visualization alone, particularly in high-risk patients (7).

THE COMPENSATION SYSTEM

Although all cases described here occurred in Italy, they provide a useful medicolegal reference. Notably, the compensation system has been substantially modified by the 'Accidents at Work and Occupational Diseases Insurance (Amendment) Regulations 2000', which introduced compensation for biological damage (9). Compensation for impairments caused by biological damage is already a well-established medicolegal concept in civil litigation (9). Previously, generic working capacity was considered to obtain the percentage of impairment. Currently, however, this evaluation is based on the damage to the biological and relational capacities of the person. While the medical premise is to calculate a percentage of biological damage, the National Institute for Insurance against Accidents at Work (INAIL) system in Italy is integrated with the system of civil law. Therefore, the economic evaluation highlights the difference between the 2 compensation systems. Along with compensation for biological damage, the system as modified by the regulations provides compensation for financial losses caused by psycho-physical impairment, i.e., impaired working capacity. The legal instruments provided by parliament to implement compensation for both biological damage and financial loss were passed by the 'Secretary of State for Employment with Approval of Tables of Impairments, Biological Damage and Coefficients Regulations' (9).

DISCUSSION

According to the literature, the frequency of bilateral palsy of the vocal folds after thyroid surgery is 0.08%–0.4% for benign thyroid gland disorders and 0.34%–4.8% for malignant

thyroid gland disorders (10). In contrast with unilateral paresis, which is asymptomatic in up to 60% of cases, bilateral paralysis of the vocal folds is associated with significantly reduced quality of life (11). Therefore, the guideline is to discontinue surgery in the event of suspected intraoperative nerve injury or a non-mandatory contralateral indication (i.e., benign goiter) (5).

In both of the considered cases, the RLNs were not visualized and exposed during resection of the first side. The surgeons stated that they performed capsular dissection technique, which would not have injured the RLN. However, many studies show that the risk of RLN injury in thyroid surgery increases by up to 12% when the RLN is not visualized (5,6). In contrast, the data in the literature clearly show that the rate of RLN injury is lowest when the nerve is visualized and exposed (5,6).

On the other hand, stress on the RLN is possible and even expected (preserved anatomical, visual integrity of the nerve, not clear); for example, due to traction, compression or thermal injury (5,6).

In conclusion, failure to visualize the RLN in the cases considered here substantially increased the risk of nerve injury, and indications for resection of the second side should have been re-evaluated intraoperatively.

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