Malpractice Litigation Involving Iatrogenic Surgical Vocal Fold Paralysis: A Closed-Claims Review With Recommendations for Prevention and Management

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Objectives: We describe the nature of malpractice claims filed involving surgical iatrogenic vocal fold paralysis, review surgical literature for recommendations for prevention of this complication, and suggest management of this complication.

Methods: Data collection was made regarding any closed claims that involved vocal fold paralysis. The results were then analyzed and categorized. The PubMed literature regarding this complication was reviewed, and recommendations on prevention were compiled. Finally, suggestions regarding management based on the current literature and the senior author’s 17-year experience in his laryngeal practice are offered.

Results: From 1986 to 2007, 112 closed claims involving vocal fold paralysis were reported by the 16 largest malpractice insurers. More than US $10 million ($18 million adjusted for inflation [AJI]) has been paid thus far. The average indemnity was $285,000 ($513,000 AJI). The surgical physician defendants were from multiple specialties, including general surgery (31%), cardiothoracic surgery (12%), neurosurgery (12%), otolaryngology (10%), and orthopedic surgery (5%). The most common procedures were thyroid and parathyroid surgery (32%), cervical disc procedures (16%), thoracic procedures (12%), endarterectomy (9%), and open neck biopsy (6%). The most common claims cited were improper performance (61%), failure to recognize a complication (36%), and consent issues (19%).

Conclusions: Vocal fold paralysis is a complication of many different surgical procedures across multiple specialty lines. Closed-claims analysis can offer a unique glimpse on what went wrong and why patients sue. Modification of techniques and incorporation of new technology may significantly reduce this complication. Preoperative written information on potential complications, and early referral to and management by laryngeal specialists, we believe, may significantly reduce malpractice litigation.

Key Words: closed claim, malpractice, surgical complication, vocal fold paralysis.

INTRODUCTION

Vocal fold paralysis can be a devastating occurrence that can complicate many surgical procedures. Several surgical disciplines, including general surgery, neurosurgery, cardiothoracic surgery, vascular surgery, and orthopedic surgery, as well as otolaryngology, typically encounter this complication, yet its detection and management are often delayed. This can result in serious acute respiratory complications, dysphagia, aspiration, and phonatory deficiencies that can significantly impair the return to normal activities of patients. Dissatisfied patients often seek legal redress that can result in costly, time-consuming litigation that has well-documented adverse psychological effects on all concerned. Closed-claims analysis has been performed in a number of other surgical areas, including laparoscopic cholecystectomies, breast cancer, facial nerve injury, and endoscopic sinus surgery. The closed claim is a repository of information accumulated by the insurer during the life of a claim. Closed claims include all claims made, whether they go to trial, are dismissed, or are settled before a trial. The record of a closed claim typically includes a statement of the claim, depositions, interrogatories, risk management evaluations, expert opinions, detailed reports of the plaintiff’s postoperative condition, settlement amounts, and/or jury trial results. It is thought that detailed analysis of closed claims can potentially result in identification of key problem areas that, if they are addressed, may significantly decrease the number of claims made. The goal of this study was to first review closed claims involving vocal fold paralysis and to...
describe their outcome and identify which surgical specialties and procedures are at highest risk for this complication. Second, we analyzed the surgical literature to demonstrate incidences and glean any recommendations on prevention. Third, we examined how best to manage iatrogenic vocal fold paralysis, and identify strategies to help reduce litigation.

METHODS

Physician Insurers Association of America (Rockville, Maryland) is a trade association of more than 50 malpractice insurers that represents more than 60% of physicians currently in private practice. Since 1985, they have systematically collected data relating to all claims filed against their member subscribers. For nonmembers, they will access their closed-claims data banks to obtain general (anonymous) information regarding malpractice claims. Although much of this information is public record, the use of their data bank greatly facilitates its accumulation. The senior author (G.Y.S.) commissioned a data collection study regarding all claims that involved vocal fold paralysis. The results were then analyzed and categorized as follows: associated procedure(s), type of misadventure, surgical specialty, disposition of claim, amount of settlement, results of trial, and claimant demographics.

An English-language literature search was made into the most common surgical procedures complicated by vocal fold paralysis. An initial review of several medical search engines using the key words surgery, complication, and vocal fold paralysis produced several journal articles that were roughly categorized into thyroid and parathyroid surgery, anterior cervical spine surgery, carotid endarterectomy, esophageal surgery, lung surgery, cardiac surgery, and laryngopharyngeal surgery. The complication rates for the various procedures were tabulated and are summarized.

RESULTS

We identified 112 closed claims involving vocal fold paralysis from the period from 1986 to 2007. Seventy-six (68%) of the claimants were female, and 36 (32%) were male. The average age was 50.6 years. Of the physician defendants, 104 (93%) were male, with an average age of 49.3 years. Of these claims, 83 involved surgical subspecialties (Fig 1). Of the remaining 29 physicians, 24 were anesthesiologists and the other 5 were medical practitioners performing some type of invasive procedure or missed diagnosis. Forty-three percent (35 of 83) of the surgeon defendants were general surgeons. Cardiothoracic surgeons composed 17% (14 of 83). Neurosurgeons were also named in 17% (14 of 83) of claims. Otolaryngologists were cited in 16% (13 of 83). Orthopedic surgeons were the remaining surgical specialty named in the closed-claims data bank, composing 7% (6 of 83) of all surgeons sued. Thyroid and parathyroid surgery were the most common surgical procedures, comprising 42% of the closed claims (Fig 2). This was followed by anterior surgical spine surgery (20%), cardiothoracic surgery (15%), carotid endarterectomy (15%), lateral neck biopsy (8%), and open laryngopharyngeal procedures (3%). The principal and associated reasons cited for the closed claims included improper surgical performance (70%), consent issues (14%), surgery not indicated (7%), delay or failure to recognize and/or refer for treatment of paralysis (5%), and other (6%; Fig 3). Of the laryngeal nerve injuries, 71% were thought to be permanent, and 29% were temporary (Fig 4).

Analysis of the closed-claims outcomes demonstrated that of the 112 claims, only one quarter went to trial. In 60% of cases (67 of 112), a settlement was reached before trial, and in 15% of cases (17 of
112) a claim was filed but no settlement or jury trial was pursued (Fig 5). Of the 28 claims that went to trial, only 2 (7%) were found in favor of the plaintiff (Fig 6). Overall, only 25% of claims were awarded any payment (Fig 7). The average claim payment was US $285,000 ($513,000 in 2007 dollars adjusted for inflation [AJI; the inflation calculator (www.westegg.com/inflation/) is based on the US Consumer Price Index derived from the annual Statistical Abstracts of the United States]). The largest payment was $875,000 ($1,575,000 AJI), and the mean payment was $240,000 ($432,000 AJI).

DISCUSSION

American medical malpractice is in crisis. Since the early 1980s, there has been a steady increase in malpractice litigation. It is estimated that practitioners pay more than $10 billion in premiums annually, not to mention the increased cost of practicing defensive medicine. More than 50% of claims occurring in hospitals are related to surgical care. A 2002 insurance study showed that surgeons have approximately twice as many claims made against them as nonsurgeons (63% versus 32%). Several studies have estimated that only 1% to 2% of all potential claims made for medical negligence are actually filed. This estimate would seem to be supported by the significant vocal fold paralysis rates in the relatively common surgical procedures cited but the comparably small number of malpractice claims made in our representative sample.

Closed-claims analysis has been shown to be a useful tool in identifying areas in patient care that deserve focused attention to improve patient safety. Chart review and direct observational studies generally are unable to collect sufficiently detailed information about a large enough number of events to discern the underlying patterns and recommend valid interventional strategies. Large-volume closed-claims analysis is advantageous for several reasons. First, because the malpractice insurers represent hundreds of thousands of physicians reflecting the care of millions of patients, they constitute a practical resource for information on patient care errors. Second, by the very nature of the fact that the error in question generated a claim, the data analysis would be able to swiftly elucidate which errors are the most significant to the patient. Third, by pooling all documents related to a claim, including depositions, interrogatories, expert testimony, and often confidential investigations, claims files are a substantially more useful body of information on surgical errors than is chart review alone. Anesthesiology was the first medical discipline to make use of malpractice claims analysis. The American Society of Anesthesiology Closed Claims Project performed for 1990 through 2002 consisted of systematic collection of data from all anesthesia-related claims (excluding dental) from the files of 35 US professional liability insurance companies. Pulse oxim-
etry monitoring, standardized protocols for intraoperative staffing, and a host of other evidence-based safety reforms were direct results of this malpractice claims study. To date, several surgery-related malpractice studies have been undertaken, including those on breast cancer, colon and rectal cancer, and bile duct injury. Others focused on head and neck–related malpractice, including facial nerve paralysis, laryngeal cancer, oral cancer, and thyroid surgery. Although these studies have had significant utility, they all share a common shortcoming of using only cases that actually went to trial. Studert et al, in an exhaustive study of malpractice claims, determined that only 15% of the 1,452 claims went to trial, and 61% of all claims that received compensation were paid as pretrial settlements. This finding would imply that the great majority of malpractice claims used for analysis will be missed if only trial data are obtained. In our study, only 25% of claims went to trial, and nearly 93% of claims that received compensation were paid as pretrial settlements.

In analyzing the data for the reasons for a claim, it is not surprising that the most common was “improper surgical performance.” Studies have illustrated that patients have an expectation of complication-free surgery and are significantly more inclined to sue if they suffer a complication, even if it was discussed before the surgery. Clearly, the first step in preventing a malpractice claim from being filed is to prevent laryngeal nerve injury from occurring. By analyzing the literature regarding iatrogenic laryngeal nerve paresis, several suggestions can be gleaned from the literature to help prevent nerve injury. First, when possible, a left-sided approach is desirable. Second, regular deflation of the endotracheal tube cuff and repositioning of the retractors is reasonable. Third, although no published study discussed intraoperative nerve monitoring, it would seem to be at least a consideration to help prevent nerve injury.

Thyroid Surgery. The literature of the past 20 years supports identification of the recurrent laryngeal nerve during thyroid surgery. This is especially important in cases of large goiters, Graves disease, malignancies, and/or previous thyroid surgery. Most laryngeal injuries appear to be due not to nerve transection, but rather, to traction near the ligament of Berry. Intraoperative nerve monitoring has been recently investigated with the advent of the widely available electrode-bearing endotracheal tube (Nerve Integrity Monitor EMG Endotracheal Tube, Medtronic Xomed, Inc, Jacksonville, Florida) connected to an electromyographic monitor with speakers (Medtronic NIM II). Nerve identification is aided by use of a stimulator probe (Medtronic Xomed Prass monopolar) applying a small current (0.5 to 1.0 mA) and listening for a response. Dralle et al, in the largest prospective series to date, of 16,000 thyroid operations, concluded that nerve identification is the gold standard, but that intraoperative nerve monitoring further lowered the incidence of recurrent laryngeal nerve paresis. This trend was present even in high-volume centers with experienced thyroid surgeons. Despite this finding, a recent survey of 685 members of the American Academy of Otolaryngology–Head and Neck Surgery demonstrated that only about 20% used intraoperative nerve monitors during thyroid surgery. However, those who used a nerve monitor were 41% less likely to experience a postoperative vocal fold mobility problem. Although using a monitor does not ensure freedom from lawsuits, none of the responding otolaryngologists who were sued as a result of vocal fold immobility used intraoperative monitoring.

Anterior Cervical Spine Surgery. Since its introduction 50 years ago, the anterior approach to the cervical spine has been widely adopted. Its rates of vocal fold paresis and paralysis have been reported to be between 2% and 8%. Several mechanisms of injury have been suggested, but the most plausible appears to be traction of the nerve by retractors compressed against an inflated endotracheal cuff. Nettvcrille et al demonstrated that the shorter, more vertical, course of the right recurrent laryngeal nerve made it more susceptible to traction injury. Further, because of the high association of dysphagia and breathy dysphonia, they surmised that the superior laryngeal nerve was also damaged. Several suggestions can be gleaned from the literature to help prevent this complication. First, when possible, a left-sided approach is desirable. Second, regular deflation of the endotracheal tube cuff and repositioning of the retractors is reasonable. Third, although no published study discussed intraoperative nerve monitoring, it would seem to be at least a consideration to help prevent nerve injury.

Carotid Endarterectomy. Carotid endarterectomy is considered the most effective treatment for stroke prevention in patients with carotid artery stenosis. It is estimated that transient laryngeal nerve deficits may occur in up to a third of cases, and permanent damage in 2% to 4%. Vagus nerve damage can be minimized by staying close to the external carotid artery and avoiding excessive manipulation.
of the carotid sheath. Proximal clamping should be performed only when the artery is well isolated from surrounding neural structures. Retractors should be carefully placed not to put excessive tension on the vagus nerve. Once again, it would seem, with the relatively high injury rate, that intraoperative nerve monitoring might be prudent.

**Esophageal Surgery.** Esophageal surgery for cancer appears to have the highest associated risk for vocal fold paralysis — as high as 36%.32,33 This complication is exacerbated by the fact that frequently these patients have compromised respiratory status, and the added risk of aspiration contributes significantly to morbidity.34 The risk is considered greater if either a high node dissection or a high cervical anastomosis is performed. Therefore, if a high resection is contemplated, a deliberate exposure of the nerve, again with the assistance of intraoperative nerve monitoring, would be appropriate. When possible, a low anastomosis is preferred. Clamps placed around the esophagus should avoid incorporation of the nerve. Self-retaining retractors should similarly avoid traction on the nerve.

**Cardiac Surgery.** Vocal fold paralysis from cardiac surgery is derived from 3 major sources. First, indirect injury may be caused by the larger, double-lumen endotracheal tubes and/or transesophageal probes. Second, cooling during cardioplegia has been associated with phrenic nerve injury and may also contribute to vagal nerve injury. Third, there may be excessive traction on the nerve during sternal retraction. Direct injury may occur predominantly during harvest of the internal thoracic arteries for coronary bypass.35 As in esophageal surgery, patients in the immediate postoperative period are prone to significant respiratory morbidity with this complication.

**Informed Consent.** The issue of inadequately informed consent appeared as the second most common basis of a claim (Fig 3). Although specific causes were not available, it is clearly an important duty for the physician or other health care worker to explain potential significant complications. Nevertheless, studies have shown that patients typically remember less than 50% of what is told to them.36 Written explanations of surgical risks have been shown to increase patients’ understanding, and can potentially reduce the chance of legal redress if a bad result occurs.37

**Laryngologist Referral.** Failure to recognize the complication of vocal fold paralysis or lack of appropriate referral was not listed in many claims (8 of 112). However, this may be a significant contributor to the attitude of the patient whose voice and/or swallowing complaints are ignored. Patients’ complaints of dysphonia and dysphagia should not be disregarded, however slight they may be. Subtle injuries to the recurrent laryngeal nerve are often missed by the surgeon, as vocal fold function is not routinely evaluated by many physicians.19 Postoperative documentation of vocal fold status should be routinely performed in any patients who undergo procedures with significant potential of laryngeal nerve injury and who have any change in voice or swallowing. If vocal fold mobility impairment is suspected, early referral to a trained laryngologist offers many advantages. Precise assessment with documentation, typically with videostroscopy, is usually performed. Videostroscopy allows for careful assessment of vocal fold movement in order to detect suspected motor abnormality, as well as identify other causes of vocal fold movement disorders, such as arytenoid dislocation. A second useful technique often performed by laryngeal specialists is laryngeal electromyography. By placing electrodes typically into the thyroarytenoid and cricothyroid muscles, the integrity of the recurrent and superior laryngeal nerves, respectively, can be evaluated. This can be invaluable in assuring the patient that the nerve was not transected during surgery. Often, a rough idea of prognosis can be inferred.38 The laryngeal specialist and his or her speech pathologist colleagues usually also perform computerized acoustic analysis of the voice in conjunction with perceptual analysis.

Once the patient has been referred to the laryngologist, several palliative measures can be undertaken. Patients who have undergone major cardiothoracic and esophageal surgery who have sustained vocal fold paralysis are at high risk for life-threatening pneumonia.39 Early management with vocal fold medialization has been shown to significantly decrease the rates of morbidity and mortality.40,41 In patients who may not be at great risk for aspiration but have more typical phonatory problems, several options exist. If there is a chance of functional return, then a temporary medialization can be performed. This has historically been performed with Gelfoam (Pharmacia and Upjohn Company, Kalamazoo, Michigan) and would usually last for 8 to 12 weeks. It has the distinct disadvantage of requiring a large-bore needle for injection and usually requires a general anesthetic. A newer product, Voice Gel (Bioform Medical Incorporated, San Mateo, California), composed of water, glycerin, and carboxymethylcellulose, can be injected in the office in a relatively simple procedure. Studies have demonstrated that it has approximately the same longevity as Gelfoam.42 In the senior author’s 18-year laryngology experience, prompt attention, precise diagnosis, and temporary medialization mea-
sures have a great salutary effect on patients who have sustained laryngeal nerve injuries. Their acute voice and swallowing concerns are alayed, their immediate deficits are improved, and their sense that they have been wronged is often eliminated. The risk of litigation by these patients can potentially be avoided.

CONCLUSIONS

Injury to the laryngeal nerves is a well-described complication of many different surgical procedures crossing multiple specialty disciplines. Closed-claims analysis can offer a unique glimpse into what went wrong and what steps can be undertaken to avoid both the complication and subsequent costly and emotionally draining litigation. Modification of techniques, incorporation of new technology, written information on potential complications provided before operation, and early referral to and management by laryngeal specialists, the authors believe, could significantly reduce the rates of both surgical complications and resulting malpractice litigation.

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