ORIGINAL ARTICLE



The role of intraoperative nerve monitoring in tracheal surgery: 20-year experience with 110 cases

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Abstract

Purpose To determine the utility of intraoperative nerve monitoring (IONM) during tracheal resection or slide tracheoplasty to prevent recurrent laryngeal nerve injury.

Methods 110 patients underwent tracheal resection or tracheoplasty between 1997 and 2016. During the first 10-year period, IONM was not used while during the second 10-year period, IONM was used. 49 patients had surgery without IONM while 61 had surgery with IONM. During the post-operative period, patients with nerve injury were compared to determine if significant difference existed between the two modalities.

Results In patients who had surgery without IONM, 7 (14.2%) patients were found to have compromised nerve

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function whereas 8 (13.1%) patients in the group with IONM had nerve injury. 3 patients regained function in the first group while four regained function in the second. A Fisher's exact test was run on the entire cohort and the difference in vocal fold injury was not found to be statistically significant (p > 0.05).

Conclusion Based on this single surgeon experience, there may be no protective benefit with the use of IONM during tracheal surgery.

Keywords Tracheal resection · Intraoperative nerve monitoring · Recurrent laryngeal nerve

Introduction

A visible paradigm shift in the practice of head and neck surgery has occurred since the advent of intraoperative recurrent laryngeal nerve monitoring (IONM). In many institutions IONM has moved from an experimental modality to a commonly employed technology. A recent study quotes IONM with a 99% negative predictive value and 75% positive predictive value of loss of signaling yielding postop vocal cord paralysis [1]. The benefits of IONM have been extensively studied, primarily within the parathyroid and thyroidectomy literature-to date no formal consensus has been made on its utility [2]. With the increased use and availability of IONM, its role has expanded to multiple other surgeries. There does, however, exist a lack of evidence supporting use of IONM in other surgical techniques-tracheal resections and reconstruction will be our focus.

Patients commonly undergo tracheal resection as treatment for specific diagnoses; post-intubation stenosis, idiopathic stenosis, and tracheoesophageal fistula being the most common benign etiologies. Complications of tracheal resection and reconstruction are subdivided into anastomotic and non-anastomotic. In the largest single study on tracheal reconstruction Wright et al. found an overall complication rate of 18% [3]. More recent studies have quoted overall complications in up to 49% of patients, and 20% of complications being non-anastomotic [3–5]. A critical step within tracheal resection involves subperichondrial dissection, allowing the surgeon to protect the recurrent laryngeal nerves without directly visualizing them. During revision surgery this initial step can become challenging, in turn putting nerves at an increased risk for injury [6]. In addition, the closer the resection comes to the vocal cords the higher the risk of injury to the recurrent laryngeal nerves as they enter the larynx [7].

If vocal fold motion impairment is noted immediately after tracheal surgery, it cannot be determined immediately whether nerve function will recover or not. Often times, distinguishing between paresis and complete paralysis may also prove challenging. While there are no studies focusing on vocal fold dysfunction or recurrent laryngeal nerve injury specifically, some have demonstrated a 4-5% rate of dysphagia and dysphonia-possible manifestations of nerve injury [5]. Piazza et al. studied 87 patients who underwent tracheal reconstruction for benign disease, of which 7 patients suffered permanent nerve injury [8]. Unfortunately with multiple studies quoting the complications of tracheal resections, there has yet to be a comprehensive study on IONM during tracheal reconstruction within the current literature. Within IONM moving outside the endocrine surgery realm, there is an abundance of data and knowledge to be gained from surgical experience with these devices in all aspects of head and neck surgery. The challenge still remains to demonstrate its utility, specifically in differentiating actual nerve stimulation from artifact during tracheal surgery [9].

The goal of this study was to determine if rates of nerve paralysis were dependent on the use of intraoperative nerve monitoring during tracheal surgery. This represents the first study of its kind in the literature.

Materials and methods

Institutional Review Board (IRB) approval was granted by JPS Hospital in Fort Worth, Texas prior to beginning the study.

The objective of the study was to determine if the use of intraoperative nerve monitoring affected recurrent nerve injury in patients undergoing tracheal surgery, namely tracheal resection for benign disease or tracheoplasty. The null hypothesis being tested was that IONM does not affect post-surgical recurrent laryngeal nerve injury, whereas the alternative hypothesis supported that IONM does prevent nerve injury. In this context, benign disease included stricture, stenosis, trauma, or previous tracheotomy. Tracheoplasty entailed sliding tracheoplasty with 270-degree mobilization of the trachea. Vertical split tracheoplasty with rib graft was not included in this study.

Patients over a 20-year time period, September 1997 to February 2016, were included in this study. During the first 10 years of this period, September 1997 to January 2007, the senior author (Y.D.) did not use nerve monitoring intraoperatively while during the second 10-year span, January 2007–February 2016, he routinely used IONM using the Medtronic© NIM system (Minneapolis, MN, USA). During the period when the nerve monitor was routinely used, dissection was often guided by alarm signals from the nerve monitor. When the monitor presented an alarm signal, dissection was approached from a different direction and tissue traction was also evaluated and appropriately addressed.

All patients underwent fiberoptic flexible laryngoscopy prior to the procedure as well as during the post-operative period to study vocal fold function. Examinations were performed by the senior author (Y.D.) throughout the minimum follow-up period of 6 months. Stroboscopy was not performed, and the examinations were not blinded. No patients were lost to follow-up and all were compliant with the prescribed follow-up regimen. Patients with previous vocal fold paresis or paralysis, those with any parathyroid or thyroid malignancy, or patients with malignancy within the trachea were excluded from the study.

Following collection of data, nerve injury rates were compared using a Fisher's exact test with a significance threshold of p = 0.05. To determine if the results of the comparison would be sufficiently powered to make a strong conclusion, a sample size calculation was performed based on a desired power of 80% and a standard type 2 error (β) of 0.2. Using a reported recurrent nerve injury rate of 8% based on a recent 2014 study on tracheal surgery [8] and a reduction goal of 50% (4%), the ideal sample size was calculated to be 1104 patients. If the desired power was decreased to 50%, then 542 patients would be needed to show a true difference, and if the power was further decreased to 20%, then 178 would be needed.

Result

At the completion of the study, there were a total of 110 patients included. During the period when nerve monitoring was not used, 49 patients had undergone tracheal surgery, 28 female (mean age 52.6 years, range 18–82) and 21 male (mean age 56.1 years, range 19–76). All patients had normal pre-operative vocal fold mobility. During the post-

operative period, seven patients were found to have recurrent nerve injury (14.2%). Of these seven patients, three patients had surgery due to old tracheotomies, one from a previous airway trauma, and three from tracheal stenosis. At 3 and 5 months post-operatively, three patients regained normal vocal fold function, while the remaining four patients had long-term paralysis (8.1%).

During the following 10-year period when intraoperative nerve monitoring was used, 61 patients had undergone surgery, 34 male (mean age 52.9 years, range 18–84) and 27 female (mean age 57.7 years, range 20–86). Endoscopic exam prior to surgery revealed normal vocal fold motion on all patients. After surgery, it was found that eight patients had recurrent nerve injury evidence by compromised vocal fold motion (13.1%). Of these eight patients, five were operated on for stenosis, two from previous airway trauma, and one patient for an old tracheotomy. At 1, 4, 6 and 7 months, four patients regained normal vocal fold function, while the remaining four patients had long-term paralysis (6.5%) The nerve injury data from both groups is summarized in Table 1.

To perform a statistical comparison a Fisher's exact test was carried out first analyzing all patients in each group with post-operative nerve injury, followed by only patients who had not regained vocal fold motion after the follow-up period. When comparing all patients with post-operative nerve injury, The Fisher's exact test was found to be 1, with p > 0.05, suggesting a lack of difference between the two groups. After patients that regained function were removed, the Fisher's exact test statistic was still 1 with p > 0.05, again suggesting a lack of significant difference.

Discussion

This represents the first study in the literature examining differences in recurrent laryngeal nerve injury in patients undergoing tracheal surgery with and without intraoperative nerve monitoring. As preservation of the recurrent laryngeal nerve is a major focus in tracheal surgery, especially so for benign disease, the results of this study may have significant implications. The current study found that comparing rates of recurrent nerve injury between the two 10 year periods when the senior author (Y.D.) changed his practice from initially not using intraoperative nerve monitoring to routinely using nerve monitoring, there was no statistically significant difference in nerve injury rates as evidenced by Fisher's exact test analysis (p > 0.05). Even after the exclusion of patients who regained normal vocal fold function, there continued to be a lack of difference between the two groups (p > 0.05, p > 0.05). The results from this study suggest that the use of intraoperative recurrent laryngeal nerve monitoring during tracheal surgery for benign disease or tracheoplasty, may not yield any additional benefit in regards to nerve injury.

As tracheal surgery is less common compared to other head and neck procedures, the number of subjects in this study was comparatively large. Although replication of the study with a larger multi-center population is needed, the results are encouraging. When based on the experience of a single surgeon, the advantage lies in the consistency of technique and clinical care amongst all patients.

It is important to understand that both arms of the study had a fairly low frequency of nerve injury. Given the small sample size and low incidence of nerve injury, likely the study was not powered enough to make a true conclusion regarding the data at hand. To achieve 80% power at a minimum, the study would require 1104 patients. However, the current study with 110 patients was underpowered to make a bold conclusion at 80% power if the rate of nerve paralysis was estimated to be 8% without IONM and 4% with IONM. If the paralysis rate was 20% without IONM and with IONM was 2%, then the current study would have been sufficient to make a formidable conclusion at 80% power. Taking this into consideration, the results of the study are suggestive of a potential outcome, and that to for a single surgeon's experience, but are not sufficiently powered to make a strong conclusion that is generalizable. Given that tracheal surgery is not commonly performed at many institutions in large volume, obtaining such a vast patient cohort to perform a higher powered study would prove to be immensely challenging and would certainly require a pooling of data across multiple institutions.

 Table 1
 Tabulated data of patients with and without postoperative nerve injury

	Surgery without IONM	Surgery with IONM
Sex	28 (57.1%) female	27 (44.3%) female
	21 (42.9%) male	34 (55.7%) male
Age range	18-82 years	19-76 years
Pts w/nerve injury	7 (14.2%)	8 (13.1%)
Pts regaining function	3 (6.1%)	4 (6.5%)
Pts w/o any nerve injury	42 (85.7%)	53 (86.8%)
Total patients	49	61

In the literature, there is a lack of dedicated studies examining recurrent nerve monitoring during tracheal resection or tracheoplasty and as such, comparison between our findings and existing data is limited. A study by Cavanaugh et al., attempted to monitor the recurrent laryngeal nerve through trans-cartilaginous nerve leads, but found the results to be misleading owing to the present of artifact [8]. In a study from the thoracic surgery literature, recurrent laryngeal nerve injury during tracheal surgery was reported to be rare, so long as proper technique was used [4]. Authors of that study advocated dissection directly on trachea without routine dissection of the recurrent nerve to prevent injury. A nerve monitor was not used in that study, corroborating the findings of the current study [4]. While studies have quoted complications potentially related to nerve injury, there have been no analyses to elucidate any relationship with the use of nerve monitoring [5, 8].

While not directly examining relationship with nerve monitoring, three prior studies reported recurrent laryngeal nerve dysfunction following tracheal surgery and can serve as a comparison point with the current study. In 1986, Pearson et al. reported a 4.7% nerve dysfunction rate following cricotracheal resection [10]. This rate was similar to that reported by Laccourrye in 1996, 3.1% in a study of 32 tracheal resection cases [11]. In 2014, Piazza et al. reported an 8% nerve injury rate with tracheal surgery, twice that of previous cases [8]. The current study reports an initial 13.1 and 14.3% nerve injury rate in the short-term period following surgery for patient treated with and without nerve monitor, respectively. Taking into consideration patients regaining nerve function, the long-term paralysis rate dropped to 6.6 and 8.2%. Although technical factors and individual pathology may have contributed to the higher nerve paralysis rate, it is also possible that the larger incidence was due to an overall greater number of patients treated in the study.

The limitations of the current study include not only an inadequate sample size to achieve significant power, but also the fact that the data are a single surgeon's experience. The variability of pathology could also add to the differences in intra-operative dissection, affecting the risk of nerve damage as well. In the future, this study should be reproduced between multiple centers and multiple surgeons to determine if the results are similar, and whether surgeon experience may also influence overall outcome. Interestingly, examining rates of nerve injury stratified by pathology could also shed light on inherent anatomic differences. While the findings of this study suggest no additional benefit with intraoperative nerve monitoring, it is the experience of a single surgeon and should not be regarded as a general recommendation as there is no replacement for meticulous surgical technique.

The major strength of this study, and the reason why it adds value to the existing literature rests in the large sample size from a single surgeon's experience. Albeit imperfect, the results from the study provide yet another perspective on the value of nerve monitoring during tracheal surgery while serving as a forum for further research and discussion.

Conclusion

Based on this single surgeon experience of 20-years, there may be no additional benefit in preventing recurrent laryngeal nerve injury with the use of intraoperative nerve monitoring during tracheal surgery.

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Compliance with ethical standards

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Conflict of interest No conflict of interest of financial disclosures to declare.

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