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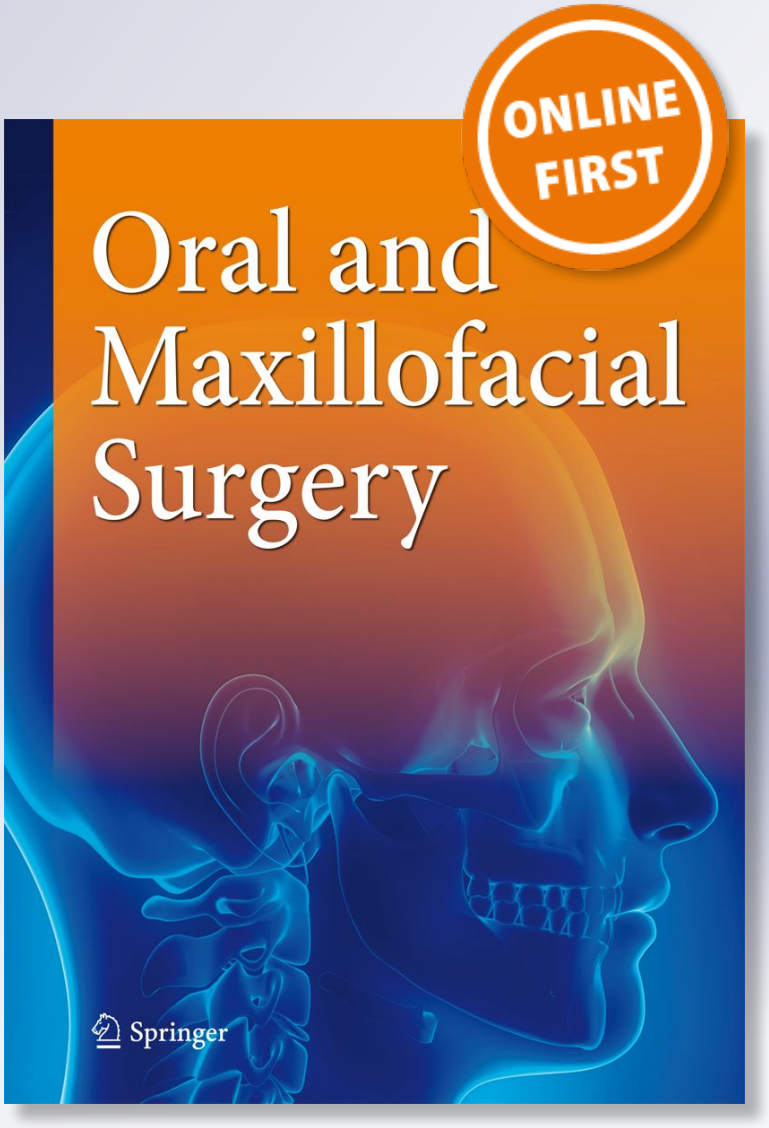

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ORIGINAL ARTICLE

Utility of intraoperative nerve monitoring in thyroid surgery: 20-year experience with 1418 cases

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Abstract
Purpose The efficacy of intraoperative nerve monitoring is controversial in the literature. This study of a single surgeon's experience seeks to determine if the use of intraoperative nerve monitoring influences recurrent laryngeal nerve injury during thyroid surgery.
Methods Six hundred fifty-seven patients with normal preoperative vocal fold function underwent thyroid surgery without the use of intraoperative nerve monitoring from September 1997 to January 2007, while 761 patients underwent thyroid surgery from February 2007 to February 2016 with routine use of nerve monitoring. Patients were followed for a minimum of 6 months after surgery, and postoperative nerve function was determined by fiberoptic laryngoscopy. A Fisher test was used to determine if nerve injury was statistically different between both groups.
Results In patients operated on without nerve monitoring, 21 patients were found to have postoperative vocal fold paralysis with nine regaining functioning. In patients operated on with nerve monitoring, 27 were found to have vocal fold dysfunction with 17 regaining function. Fisher test analysis, both with and without patients regaining function, showed no difference in nerve injury between groups ($p > 0.05$, $p > 0.05$).
Conclusion Intraoperative monitoring during thyroidectomy may not prevent injury to the recurrent laryngeal nerve.

Keywords Intraoperative nerve monitoring · Thyroid surgery · Recurrent laryngeal nerve injury

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Introduction

Several risks exist with thyroid surgery, including recurrent laryngeal nerve palsy (RLNP), superior laryngeal nerve injury, bleeding, hypoparathyroidism, hypothyroidism, and infection [1]. RLN damage, while rare, is one of the most concerning complications and may have significant adverse ramifications on patients' quality of life. Symptoms encompass dysphonia, difficulty swallowing, aspiration, and severe airway obstruction. The overall incidence of damage varies widely in the literature and has been reported to range from 0.4 to 8% for transient paresis and 0 to 5.2% for permanent paralysis [2–6].

Intraoperative nerve monitoring (IONM) has been shown to be a useful adjunct in achieving the gold standard of surgical dissection and direct visualization of the RLN during thyroid surgery [7]. Three main goals exist for IONM—to verify the functional integrity of the RLN before the conclusion of surgery, to ascertain the location of the RLN during dissection,

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and to provide guidance for the surgeon in difficult situations [8]. IONM is commonly employed during thyroid surgery, with a recent survey suggesting that 53% of general surgeons and 65% of otolaryngologists in the USA use the technique [9, 10]. Marti et al. [11] showed that higher-volume surgeons were more likely to use IONM consistently. Increased surgeon confidence and improved safety were two of the most frequently cited reasons for IONM.

This study sought to analyze the utility of intraoperative nerve monitoring during thyroid surgery by drawing on the extensive experience of a high volume single surgeon. With a total of 1426 patients included in the current study, this data set represents the largest study to date in the English literature dedicated to examining postoperative recurrent nerve injury related to thyroid surgery. Given the cost-benefit considerations of using a nerve monitor as well as the potential for false security, the outcomes of this study may have a significant impact on practice patterns going forward.

Patients and methods

Prior to beginning this study, approval was granted from the institutional review board (IRB) of JPS Hospital in Fort Worth, Texas.

The goal of this study was to analyze whether the use of intraoperative nerve monitoring during thyroid surgery reduced injury to the recurrent laryngeal nerve. The null hypothesis being tested was that nerve monitoring does not affect postsurgical recurrent laryngeal nerve injury, whereas the alternative hypothesis supported that nerve monitoring does indeed decrease nerve injury. This study represents the extensive experience of the senior author (Y.D.) at a tertiary referral center in Fort Worth, Texas, during the period from September 1997 to February 2016.

During the abovementioned 20-year time period, the senior author changed his practice from not routinely using intraoperative nerve monitoring (September 1997–January 2007) to using the nerve monitor for every thyroid surgery (February 2007–Februayr 2016). This change in practice was the impetus behind the current study, as the senior author sought to compare whether the nerve monitor truly influenced nerve injury given the controversy surrounding the subject. The nerve monitoring system utilized was the Medtronic© NIM system (Minneapolis, MN).

Patients that underwent thyroid surgery during this 20-year time period were included in the study. Patients with both benign and malignant disease were included in the study and were followed for a minimum of 6 months postoperatively. Every patient underwent pre-operative and postoperative fiberoptic flexible laryngoscopic examination of vocal fold function. Patients with pre-operative vocal fold dysfunction and those without documented follow-up were excluded from the study. Also excluded were patients undergoing a planned nerve sacrifice, or concurrent tracheal or esophageal resection.

All patient charts fitting the inclusion criteria were analyzed for documentation of nerve monitor use, final thyroid pathology, and postoperative nerve function during the follow-up period. No patients were lost to follow-up. Patients with postoperative vocal fold dysfunction were further evaluated by stroboscopy with a speech language pathologist. In order to compare whether rates of injury differed between those operated on with and without nerve monitor, a Fisher test was employed to determine statistically significant differences using a significance threshold of $\alpha = 0.05$. A desired sample size calculation was then performed in order to determine if the study was sufficiently powered to make a strong conclusion.

Result

During the period from September 1997 to January 2007, 699 patients underwent thyroid surgery without the use of intraoperative nerve monitoring. There were 248 males (average age 54.2 years, range 18–91 years) and 455 females (average age 43.1 years, range 18–87 years). The final pathology of the thyroid specimen is as follows:

Compressive goiter- 132 patients (18.8%)
Papillary thyroid cancer- 300 patients (42.9%)
Follicular adenoma- 88 patients (12.6%)
Follicular carcinoma- 52 patients (7.4%)
Metastatic disease to the thyroid- 10 patients (1.4%)
Lymphoma- 8 patients (1.1%)
Benign nodules or cysts- 89 patients (12.7%)
Medullary thyroid cancer- 20 patients (2.8%)

During pre-operative flexible laryngoscopy, it was found that 42 patients had vocal fold paresis or paralysis (18 males, 24 females) and were subsequently excluded from the study. Following this, there were 657 patients in the study with normal pre-operative vocal fold motion.

During the postoperative period, 21 (3.1%) patients were found to have a unilateral vocal fold paralysis. Interestingly, by 8 months, nine of these patients had regained vocal fold motion, while 13 (1.9%) had persistent dysfunction.

During the second 10-year period from February 2007 to February 2016, 801 patients underwent thyroid surgery with the use of intraoperative nerve monitoring using the Medtronic© NIM system. The cohort included 236 males (average age 49.8 years, range 18–79 years) and 569 females (average age 41.9 years, range 18–91 years). The final pathology of the thyroid specimen is as follows:

Compressive goiter- 125 patients (15.6%)
Papillary thyroid cancer- 394 patients (49.1%)
Follicular adenoma- 50 patients (6.2%)
Follicular carcinoma- 42 patients (5.2%)
Metastatic disease to the thyroid- 8 patients (0.9%
Lymphoma- 4 patients (0.4%)
Benign nodules or cysts- 160 patients (19.9%)
Medullary thyroid cancer- 18 patients (2.2%)

During pre-operative flexible laryngoscopy, it was found that 40 patients had vocal fold paresis or paralysis and were subsequently excluded from the study. Following this, there were 761 patients in the study with normal pre-operative vocal fold motion.

During the postoperative period, 27 (3.5%) patients were found to have a unilateral vocal fold paralysis and one patient with bilateral cord paralysis. Interestingly, by 8 months 17 of these patients had regained vocal fold motion, while 11 (1.4%) had persistent dysfunction.

In order to compare both cohorts, a Fisher test was done first comparing all patients with and without paralysis, and then comparing the same group without those patients that regained function. Examining all patients with postoperative vocal fold dysfunction, the fisher statistic was found to be 0.7695 ($p > 0.05$). Excluding patients with regained cord function, the Fisher statistic was 0.52 ($p > 0.05$). Regardless of testing modality or exclusion of patients with regained cord function, there was no statistically significant difference in postoperative recurrent nerve injury between patients operated on with and without intraoperative nerve monitoring.

Granted the low incidence of nerve injury in both groups, a desired sample size was then calculated to evaluate if the study was sufficiently powered to make a strong conclusion. Using a standard type 2 error (β) of 0.2, it was calculated that a study would require approximately 62,600 patients to obtain 80% power, and approximately 83,800 patients to obtain 90% power.

Discussion

This study represents that largest study in the English literature examining the utility of intraoperative nerve monitoring during thyroid surgery for prevention of recurrent laryngeal nerve injury. Preservation of the recurrent laryngeal nerve is of paramount concern during thyroid surgery, and as such, the ramifications of a study of this magnitude could be significant.

During the 20-year period examined in this study where the senior author (Y.D.) changed his practice pattern from performing thyroid surgery without nerve monitoring to routine use of the nerve monitoring, there was no statistically significant difference in nerve injury rates found by statistical analyses ($p > 0.05$). Despite exclusion of patients who regained normal vocal fold function, there was no change in the statistical significance ($p > 0.05$). The findings from this analysis are strongly suggestive of no increased benefit with the use of intraoperative recurrent laryngeal nerve monitoring during thyroid surgery.

The data presented in this paper represents an expansive group of patients with varying pathology over a significant time period, adding power and credibility to the findings of the study. As the use of intraoperative nerve monitoring has been controversial in the literature, practitioners are often left to their own degree of surgical expertise and comfort with monitoring technology to guide their decision to use intraoperative monitoring. It is important to note that nerve monitoring may give surgeons a false sense of security, influencing their technique of thyroidectomy. More so, lack of signaling or excessive signaling have also been found with the use of this technology, drawing the reliability of the nerve detection into question. The findings of this study may ameliorate those concerns by obviating the need for this technology during thyroid surgery.

Despite the seemingly large sample size, it is important to take into consideration the low frequency of nerve injury that was found in either group. Given the low incidence, approximately 60,000 patients would be needed to generate a study with 80% power at a minimum. Given this vast number of patients required, and the difficulty in obtaining such a data set without multi-institutional collaboration, the results are suggestive of a potential outcome but are not sufficiently powered to make a strong conclusion that is applicable to all.

Studies have shown that IONM in thyroid surgery has high specificity, sensitivity, and negative predictive value (NPV) in predicting postoperative RLNP. Specificity ranges from 90.2 to 99.9%, sensitivity from 82 to 93%, and NPV from 99.1 to 99.8% [12–16]. Positive predictive value, however, is lower and more variable, with ranges from 10 to 90% [13–18]. Low PPV has been attributed to the lack of a standard for defining loss of signal (LOS) and equipment-related problems [13, 14]. IONM has a specific advantage in bilateral thyroid surgery. Goretzki et al. [12] found negative IONM stimulation of the ipsilateral side of dissection specific and sensitive in predicting early RLNP. Thus, IONM has been correlated with a reduction of bilateral paralysis when a LOS occurs on the initial side [12, 19, 20]. Several studies evaluating high-risk cases drew opposing conclusions on the sensitivity and positive predictive power (PPP) of IONM in identifying RLNP. Chiang et al. [21] found that sensitivity and PPP increased in high-risk surgeries, while Hermann et al. [22] suggested that IONM does not reliably predict postoperative outcome in the most severe cases.

The impact of IONM on the rate of RLN injury remains contested, with some experts concluding there is no significant benefit with IONM [23, 24] and other authors advocating its utilization during high-risk settings, such as reoperation or

cancer [17, 21, 24–26]. A recent systematic review [13] determined that there was no significant difference between the rate of RLN injury with IONM versus visualization alone in the majority of included cases [4, 5, 8, 17, 23, 24, 26–31]. The rates of overall RLNP were 3.18% in the IONM group and 3.83% in the control group. Two other systematic reviews [23, 24] similarly found no significant benefit of IONM during thyroidectomy. Several studies differentiated between transient and permanent nerve injury and reported a significant decrease of the latter in the IONM group [32–34]. Dralle et al. argued that for benign goiters, there is a small margin for improving the already extremely low rate of RLNP with IONM. There may, however, be a role for benign disease in Graves' disease and Hashimoto's thyroiditis [17]. For specific high-risk subgroups, studies have again shown conflicting results. Multiple studies, including a large study with 1000 nerves at risk, saw improved rates of RLNP with the use of IONM in revision and complex thyroid surgery [9, 10, 24, 26, 30, 35–37]. However, Robertson et al. [5] and Prokopakis et al. [38] observed only a clinically significant difference between IONM and control groups during revision thyroidectomy, though they attribute this to the studies' low power.

It is clear from the literature that there has been no consensus on the use of intraoperative nerve monitoring, and proponents of each school of thought have been able to substantiate their practice patterns, with some suggesting perhaps a true utility in revision surgery. Although the data from this study is suggestive of no added benefit, future studies should draw on the experience of multiple institutions in order to determine whether the outcomes are consistent among different surgeons, as technique difference may also contribute to postoperative findings. Designing a study that is sufficiently powered to make a robust conclusion would draw on the expertise and volume of multiple institutions. More so, stratification of nerve injury by thyroid pathology, revision status, and a deeper analysis of laterality may allow practitioners to gain a better understanding of specific situations that may benefit from intraoperative nerve monitoring as compared to routine use.

Conclusion

Based on this single surgeon experience of 1426 cases, the use of intraoperative nerve monitoring during thyroid surgery may not confer any additional advantage in preventing injury to the recurrent laryngeal nerve.

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Compliance with ethical standards

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Conflict of interest The authors declare that they have no conflict of interest.

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