The American Journal of Surgery 221 (2021) 472–477

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Intraoperative nerve monitoring is associated with a lower risk of recurrent laryngeal nerve injury: A national analysis of 17,610 patients

Jina Kim [a], Claire E. Graves [a], Chengshi Jin [b], Quan-Yang Duh [a], Jessica E. Gosnell [a], Wen T. Shen [a], Insoo Suh [a], Julie A. Sosa [a], Sanziana A. Roman [a, *]

[a] Department of Surgery, University of California, San Francisco, USA
[b] Department of Epidemiology and Biostatistics, University of California, San Francisco, USA

ARTICLE INFO

Article history:
Received 29 April 2020
Received in revised form
21 September 2020
Accepted 8 October 2020

Keywords:
Thyroidectomy
Recurrent laryngeal nerve
Intraoperative nerve monitoring

ABSTRACT

Background: Based on current evidence, the benefit of intraoperative nerve monitoring (IONM) in thyroid surgery is equivocal.
Methods: All patients who underwent planned thyroid surgery in the 2016–2018 ACS NSQIP procedure-targeted thyroidectomy dataset were included. Multivariable regression analyses were performed to examine the association between nerve monitoring and recurrent laryngeal nerve (RLN) injury while adjusting for patient demographics, extent of surgery, and perioperative variables.
Results: In total, 17,610 patients met inclusion criteria: 77.8% were female, and the median age was 52 years. IONM was used in 63.9% of cases. Of the entire cohort, 6.1% experienced RLN injury. Cases with IONM use had a lower rate of RLN injury compared to those that did not use IONM (5.7% vs. 6.8%, p = 0.0001). After adjustment, IONM was associated with reduced risk of RLN injury (OR 0.69, 95% CI 0.59–0.82, p < 0.0001).
Conclusions: Nationally, IONM is used in nearly two thirds of thyroid surgeries. IONM is associated with a lower risk of recurrent laryngeal nerve injury.

Introduction

More than 70,000 thyroidectomies are performed in the U.S. every year, and patients undergoing thyroidectomy face three main complications specific to the procedure: recurrent laryngeal nerve (RLN) injury, hypocalcemia, and neck hematoma.[1–3] RLN injury occurs in 3–11% of cases, and the rate of this complication has been shown to vary with disease-related variables, as well as procedure- and surgeon-related variables.[4–6] RLN injury is an important complication in thyroidectomy because it reduces quality of life for patients,[7] leads to litigation for surgeons,[8] and may serve as an important quality metric for surgeons and hospitals.[3]

In the 1930s, August Bier and Frank Lahey advocated for routine dissection and demonstration of the RLN, in direct contrast to their predecessors Kocher and Billroth, who avoided nerve exposure altogether.[9] However, an anatomically intact RLN did not necessarily equate to intact function. In the 1960s, intraoperative nerve monitoring (IONM) was introduced as a means to identify and confirm RLN function, potentially reducing the risk of injury.[10–12] Since its introduction, use of IONM has grown, but it is still considered an adjunct to the gold standard of direct nerve visualization, and IONM use varies based on location and specialty. For example, IONM is used in the vast majority of thyroid cases in Germany, whereas the rate of IONM use in the U.S. is lower.[13,14] Based on a survey of 42 fellowship trained thyroid surgeons in the U.S., a minority of surgeons lacked access to nerve monitoring technology, and cost was one of a primary reasons for selective (rather than routine) IONM.[14] While IONM may add operative cost, it has been shown to be cost-effective in high-volume settings.[15]

Current studies examining the use of IONM in thyroid surgery present conflicting results and are inadequately powered to demonstrate a statistically significant difference in the rate of RLN injury based on utilization of IONM, given the overall low incidence of RLN compromise.[6,16–28] In 2004, Dralle and colleagues conducted the largest prospective study to date examining IONM in 16,448 consecutive thyroid operations in Germany; they found no statistically significant difference in RLN injury between nerve visualization only and visualization with IONM. However, even in

* Corresponding author.1600 Divisadero Street San Francisco, CA 94115, USA.
E-mail address: sanziana.roman@ucsf.edu (S.A. Roman).

https://doi.org/10.1016/j.amjsurg.2020.10.013
0002-9610/

this study, the authors acknowledged that conclusions were limited by the number of cases.[16]

National datasets such as the American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP) have provided a means for surgeons and hospitals to track perioperative variables and outcomes. Recently, ACS NSQIP created procedure-targeted modules that measure variables and outcomes specific to certain procedures. Using thyroidectomy-targeted NSQIP, our study provides a contemporary perspective on IONM use for thyroid surgery in the United States with the largest patient cohort to date. We also examine the association between IONM use and RLN injury in thyroid surgery.

Methods

Data source

In January 2013, ACS NSQIP initiated a thyroidectomy-targeted module to measure variables and outcomes specifically related to thyroid surgery.[3] Currently, more than 700 institutions participate in ACS-NSQIP, and over 90 hospitals participate in the ACS-NSQIP thyroidectomy-targeted module. This study was deemed exempt from review by the University of California, San Francisco Institutional Review Board as it is based on de-identified data.

Study design

We included patients $\geq$18 years who underwent thyroid surgery in the 2016–2018 thyroidectomy-targeted ACS NSQIP dataset. We used the unique identifier for each case to merge variables included in the thyroidectomy module with the general ACS-NSQIP participant user file. The cohort was grouped by whether IONM was used. The primary outcome was RLN injury, which was defined as symptoms of airway obstruction, hoarseness, weak voice, or change in vocal tone beyond the first postoperative day, whether or not laryngoscopy was performed for confirmation. If voice therapy was implemented postoperatively, this intervention also was considered evidence of RLN injury. Of note, the dataset does not distinguish between temporary and permanent RLN injury. If tracheostomy was performed for RLN injury, this complication could be specified as severe RLN injury in the dataset.

Statistical analysis

Baseline characteristics were compared using non-parametric Wilcoxon (Mann-Whitney) tests for continuous variables and χ^2 tests for categorical variables. Multivariable regression analyses were performed to examine the potential association between using IONM and RLN injury or dysfunction. Co-variates included patient age, sex, race, body mass index, operative time, indication for surgery, clinical evidence of hyperthyroidism, previous neck surgery, extent of thyroid surgery, concomitant central neck dissection, and use of a vessel sealant device. A two-sided p-value of <0.05 was considered statistically significant. Statistical analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC).

Results

In the NSQIP thyroidectomy-targeted module, 17,610 patients met inclusion criteria: 77.8% were female, and the median age was 52 years (Table 1). The most common indication for thyroid surgery was goiter, which constituted 75.5% of all cases. IONM was used in 63.9% of cases. Of the entire cohort, 6.1% experienced RLN injury.

Patients who had IONM were more likely to undergo total thyroidectomy (58.1% vs. 54.2%, $p < 0.0001$), concomitant central neck dissection (27.2% vs. 19.2%, $p < 0.0001$), and longer operations (124 vs. 110 min, $p < 0.0001$) compared to those who did not have IONM (non-IONM group). Cases that included IONM were also more likely to incorporate a vessel sealant device (72.9% vs. 50.9%, $p < 0.0001$). The IONM group also had lower rates of postoperative hoarseness and tracheostomy placement, compared to the non-IONM group (5.6% vs. 6.5%, $p = 0.0001$ and 0.1% vs. 0.3%, $p = 0.0001$, respectively).

After adjustment for demographic, clinical, and pathologic variables, IONM was significantly associated with a lower risk of RLN injury (odds ratio [OR] 0.69, 95% confidence interval [CI] 0.59–0.82, $p < 0.0001$) (Table 2). Several patient demographics were associated with significantly higher risk of RLN injury, including older age (OR 1.01, 95% CI 1.01–1.02, $p < 0.0001$), female sex (OR 1.25, 95% CI 1.02–1.53, $p = 0.03$), and black race (OR 1.64, 95% CI 1.37–1.96, 95% CI < 0.0001). Compared to lobectomy, total thyroidectomy cases were associated with increased risk of RLN injury (OR 1.44, 95% CI 1.20–1.74, $p = 0.0001$).

In multivariate analyses, using IONM was associated with several intraoperative factors, including use of a vessel sealant device (OR 2.10, 95% CI 1.91–2.30, $p < 0.0001$), concomitant central neck dissection (OR 1.46, 95% CI 1.30–1.65, $P < 0.001$), and operative time >2 h (OR 1.96, 95% CI 1.79–2.10, $p < 0.0001$) (Table 3). The threshold of 2 h (120 min) was designated based on the mean operative time of 119 min for the entire cohort. IONM use also was more likely in patients who had undergone prior ipsilateral or bilateral neck surgery (OR 1.50, 95% CI 1.10–2.00, $p = 0.01$).

Discussion

In this contemporary cohort of 17,610 thyroidectomy cases in the U.S., IONM was associated with a lower risk of RLN injury. Currently, the value of IONM in thyroid surgery remains controversial. However, it is important for surgeons to understand how factors such as IONM may aid in the prevention of RLN injury, as this complication has been proposed as a quality metric in thyroid surgery.

To date, most studies examining use of IONM in thyroid surgery have been cohort studies with fewer than 1000 patients, which is far below the numbers expected to be required for adequate statistical power.[16,29] The 2004 multi-center, nonrandomized study by Dralle et al. with 16,448 consecutive operations constitutes the largest study cohort to date. In that study, surgeons performed thyroidectomy via one of three approaches: no attempt at visualization of the RLN (group 1), with visualization of the RLN (group 2), and with both visualization and IONM (group 3). When groups 2 and 3 were compared, there was no statistically significant difference in the rates of RLN injury.[16] Even in this study, the authors acknowledged that due to the low incidence of RLN injury, the study conclusions were limited by the number of cases. In their power calculation, the minimum number of operated sites required to identify significant differences between nerve visualization and nerve monitoring for permanent nerve injury would be 9 million for benign multinodular goiter and 40,000 for thyroid cancer. However, the power calculation by Dralle et al. is not wholly applicable to this study: their calculation used permanent RLN injury as the outcome, whereas the NSQIP-reported outcome does not differentiate between permanent and temporary RLN injury.

In contrast, a 2009 prospective, randomized study of 1000 patients published by Barczynski et al. found that the overall RLN injury rate was significantly lower with IONM compared to visualization alone (2.7% vs 5.0%, $p = 0.007$). Specifically for cases designated as high risk in the study (defined as those with thyroid cancer, thyrotoxicosis, retrosternal goiter, or thyroiditis), the rate of RLN injury was lower by 3.7% when IONM was used ($p = 0.005$). In

Table 1
Baseline characteristics of patients who underwent thyroid surgery in the 2016–2018 ACS NSQIP dataset.

Variable	No IONM (N = 6362)	IONM (N = 11248)	Total (N = 17610)	P-Value
Patient demographics				
Age (Mean ± SD)	52 ± 15	52 ± 15	52 ± 15	0.01°
Sex				
Female	4878 (76.7%)	8828 (78.5%)	13706 (77.8%)	0.01[2]
Male	1484 (23.3%)	2420 (21.5%)	3904 (22.2%)	
Race				
White	3016 (70.3%)	6721 (73.7%)	9737 (72.6%)	<0.0001[2]
Black	636 (14.8%)	1927 (21.1%)	2563 (19.1%)	
Other	637 (14.9%)	468 (5.1%)	1105 (8.2%)	
BMI (Mean ± SD)	30 ± 8	31 ± 8	30 ± 8	<0.0001°
ASA classification				0.0003[2]
1	420 (6.6%)	755 (6.7%)	1175 (6.7%)	
2	3695 (58.1%)	6347 (56.4%)	10042 (57.0%)	
3	2046 (32.2%)	3882 (34.5%)	5928 (33.7%)	
4	164 (2.6%)	200 (1.8%)	364 (2.1%)	
5	1 (0.0%)	0 (0.0%)	1 (0.0%)	
Indication for surgery				<0.0001[2]
Goiter	4649 (73.1%)	8646 (76.9%)	13295 (75.5%)	
Graves' disease	340 (5.3%)	675 (6.0%)	1015 (5.8%)	
Malignancy	1147 (18.0%)	1653 (14.7%)	2800 (15.9%)	
Other or unknown	226 (3.6%)	274 (2.4%)	500 (2.8%)	
Prior neck surgery				0.10[2]
No	5711 (89.8%)	10086 (89.7%)	15797 (89.7%)	
Yes, contralateral	296 (4.7%)	483 (4.3%)	779 (4.4%)	
Yes, ipsilateral or bilateral	143 (2.2%)	291 (2.6%)	434 (2.5%)	
Yes, midline	99 (1.6%)	146 (1.3%)	245 (1.4%)	
Yes, not specified	113 (1.8%)	242 (2.2%)	355 (2.0%)	
Clinically evident hyperthyroidism	414 (6.5%)	853 (7.6%)	1267 (7.2%)	<0.0001[2]
Perioperative variables				
Extent of surgery				<0.0001[2]
Thyroid lobectomy	2561 (40.6%)	4138 (36.9%)	6699 (38.2%)	
Total thyroidectomy	3423 (54.2%)	6515 (58.1%)	9938 (56.7%)	
Completion thyroidectomy	326 (5.2%)	563 (5.0%)	889 (5.1%)	
Concomitant central neck dissection	1209 (19.2%)	3036 (27.2%)	4245 (24.3%)	<0.0001[2]
Any vessel sealant device used	3222 (50.9%)	8087 (72.9%)	11309 (64.9%)	<0.0001[2]
Total operative time (Mean ± SD)	110 ± 68	124 ± 72	119 ± 71	<0.0001°
Postoperative calcium level checked	3906 (61.4%)	7207 (64.1%)	11113 (63.1%)	0.0004[2]
Postoperative parathyroid hormone (PTH) level checked	2350 (36.9%)	4727 (42.0%)	7077 (40.2%)	<0.0001[2]
Postoperative calcium/vitamin D replacement				<0.0001[2]
None	2735 (45.2%)	4218 (38.6%)	6953 (41.0%)	
Yes, both oral calcium/vitamin D	1569 (25.9%)	3923 (35.9%)	5492 (32.4%)	
Yes, oral calcium only	1391 (23.0%)	2013 (18.4%)	3404 (20.1%)	
Yes, oral vitamin D only	353 (5.8%)	760 (7.0%)	1113 (6.6%)	
Complications				
Readmission	154 (2.4%)	272 (2.4%)	426 (2.4%)	0.99[2]
Postoperative neck hematoma	122 (1.9%)	200 (1.8%)	322 (1.8%)	0.50[2]
Unplanned reoperation	92 (1.4%)	158 (1.4%)	250 (1.4%)	0.82[2]
Hypocalcemia requiring ER visit, readmission and/or IV calcium	273 (4.3%)	424 (3.8%)	697 (4.0%)	0.09[2]
Hypocalcemia prior to discharge	5946 (95.0%)	10490 (95.9%)	16436 (95.6%)	0.01[2]
Hypocalcemia within 30 days	5834 (93.4%)	10048 (93.8%)	15882 (93.7%)	0.25[2]
RLN injury				0.0001[2]
No	5932 (93.2%)	10608 (94.3%)	16540 (93.9%)	
Yes, hoarseness beyond POD#1	412 (6.5%)	632 (5.6%)	1044 (5.9%)	
Yes, required tracheostomy	18 (0.3%)	8 (0.1%)	26 (0.1%)	

° based on unequal variances t-test
[2] based on Chi-square test

addition to high risk cases, the authors also noted that IONM may be especially helpful in identifying RLN variants, such as a bifurcated RLN which is prone to injury near the ligament of Berry or inferior thyroid artery.[6]

In the past decade, several meta-analyses and systematic reviews have aggregated data from published studies to examine use of IONM in thyroid surgery with larger cohorts.[30–39] Again, conclusions were mixed. Some meta-analyses suggested that IONM was associated with reduced risk of transient RLN injury,[35–37] while others demonstrated reduced risk of permanent RLN injury with IONM.[39] Others have found no difference in RLN injury risk with IONM.[30–32,34]

Recently, another study using thyroidectomy-targeted NSQIP in 2016–2017 with 11,370 patients found that RLN injury was associated with older age, diagnosis of malignancy, and total thyroidectomy—similar to our study. However, the authors did not find a statistically significant association between RLN injury and IONM, although there was a trend toward significance in their study (OR 0.9, 95% CI 0.7–1.0, p = 0.06).[40] By including 2018 data, our study included an additional 6240 patients, increasing the sample size by 50%. Since the RLN injury rates from the NSQIP dataset are specific to the U.S. as opposed to Germany, where the aforementioned

Table 2
Multivariate logistic regression model demonstrating association between perioperative variables and recurrent laryngeal nerve palsy among patients who underwent thyroid surgery in the 2016–2018 ACS NSQIP dataset.

Variable	OR	95% CI	P-Value
Age	1.01	1.01–1.02	<0.0001
BMI	1.00	0.99–1.01	0.73
Female sex (ref: Male)	1.25	1.02–1.53	0.03
Race (ref: White)			
Black	1.64	1.37–1.96	<0.0001
Other	1.43	1.09–1.89	0.011
Indication for surgery (ref: Goiter)			
Graves' disease	0.83	0.59–1.16	0.28
Malignancy	1.33	1.04–1.70	0.02
Other/Unknown	0.63	0.31–1.29	0.20
Clinically evident hyperthyroidism	1.04	0.80–1.35	0.79
Prior neck surgery			
Yes, contralateral	0.66	0.37–1.16	0.14
Yes, ipsilateral or bilateral	1.36	0.83–2.2	0.22
Yes, midline	1.76	0.91–3.4	0.09
Yes, not specified	1.44	0.90–2.3	0.12
Extent of surgery (ref: Thyroid lobectomy)			
Total thyroidectomy	1.44	1.20–1.74	0.0001
Completion thyroidectomy	1.21	0.71–2.1	0.49
Concomitant central neck dissection	0.98	0.79–1.21	0.82
Operative time > 2 h	1.63	1.38–1.93	<0.0001
Neck hematoma	2.5	1.70–3.8	<0.0001
Vessel sealing device used	1.05	0.87–1.26	0.60
IONM used	0.69	0.59–0.82	<0.0001

Table 3
Multivariate logistic regression model demonstrating association between perioperative variables and recurrent laryngeal nerve monitoring among patients who underwent thyroid surgery in the 2016–2018 ACS NSQIP dataset.

Variable	OR	95% CI	P-Value
Age	1.00	1.00–1.00	0.99
BMI	1.01	1.00–1.01	0.04
Female sex (ref: Male)	1.08	0.98–1.20	0.14
Race (ref: White)			
Black	1.28	1.15–1.43	<0.0001
Other	0.34	0.29–0.40	<0.0001
Indication for surgery (ref: Goiter)			
Graves' disease	0.91	0.76–1.09	0.32
Malignancy	0.79	0.68–0.91	0.001
Other/Unknown	0.84	0.62–1.14	0.25
Clinically evident hyperthyroidism	1.11	0.96–1.29	0.17
Prior neck surgery			
Yes, contralateral	1.21	0.92–1.57	0.17
Yes, ipsilateral or bilateral	1.50	1.10–2.00	0.01
Yes, midline	0.71	0.46–1.10	0.12
Yes, not specified	1.30	0.97–1.76	0.08
Extent of surgery (ref: Thyroid lobectomy)			
Total thyroidectomy	0.85	0.77–0.93	0.001
Completion thyroidectomy	1.13	0.85–1.50	0.42
Concomitant central neck dissection	1.46	1.30–1.65	<0.0001
Operative time > 2 h	1.96	1.79–2.10	<0.0001
Vessel sealing device used	2.10	1.91–2.30	<0.0001

study by Dralle et al. is based, the sample size required for statistical power would be different for the U.S. than Germany. Based on our NSQIP data, 16,715 cases would be needed to detect differences in any RLN injury between the two groups, although we acknowledge the limitations of a post-hoc power calculation.[41,48]

Our study provides a contemporary view on IONM use in thyroid surgery that is specific to the United States. Surgeons across the world have reported different rates of IONM utilization, suggesting that surgeons' expertise with IONM may vary based on their geographic region.[42] For example, from the German StudDoq/Thyroid database, IONM was used in 98.4% of patients undergoing thyroid surgery (compared to 63.9% in our U.S. dataset).[43] Therefore, thyroid surgery outcomes related to IONM for one country may not be generalizable to another. IONM use in the United States is less prevalent and may be related to surgeon training and experience. While 63.9% of thyroid surgery cases in NSQIP reported IONM use, the rate of IONM has been reported to be higher among fellowship-trained surgeons in the U.S. In a 2016 survey of 42 endocrine and head and neck surgeons who underwent fellowship training in the past 10 years, 81% performed >25 thyroid surgeries per year, and 95% used IONM for some or all of their cases.[44] Sturgeon et al. surveyed members of the American Association of Endocrine Surgeons on their use of IONM and found that high case volume of >100 thyroid operations per year was associated with IONM use.[45]

In the United States, these reported variations in IONM use based on surgeon training and thyroid case volume suggest that IONM ultimately may be a surrogate marker for these surgeon-specific variables, which have been demonstrated to be important for surgical outcomes, but currently are not captured by NSQIP.[4,46,47] In the 1998–2009 Health Care Utilization Project-National Inpatient Sample, Adam et al. found that a surgeon volume threshold of >25 total thyroidectomies per year was associated with improved outcomes, but median surgeon volume in the U.S. was just seven thyroidectomies performed per year.[46] As discussed previously, surgeons with specialty training and higher thyroid case volume are more likely to use IONM routinely as part of their practice. Put together, these studies suggest that surgeon training, case volume and familiarity with procedure-specific technologies are interrelated and are associated with patient outcomes in the U.S.

With the retrospective nature of this study, associations—but not causation—can be made between IONM and RLN injury. And as with many national databases, there are limitations to the NSQIP thyroidectomy-targeted module that preclude a deeper understanding of how IONM is related to RLN injury. Currently, NSQIP does not distinguish permanent vs. temporary RLN injury, continuous vs. intermittent IONM, or high vs. low surgeon case volume. It also would be important to report whether the RLN was visualized intraoperatively or not, since nerve visualization remains the gold standard in thyroidectomy. In future iterations of thyroidectomy-targeted NSQIP, greater granularity of data would enrich outcomes analysis.

Whether IONM is associated with patient outcomes or acts as a surrogate for surgeon experience, it is important for surgeons to understand the factors that contribute to RLN injury, as this outcome has been proposed as a quality metric in thyroid surgery. In a 2018 NSQIP study by Liu et al., the authors analyzed 14,540 patients who underwent thyroidectomies at 98 hospitals in the U.S. When hospital performance was profiled by RLN injury using mixed effects regression models, eight hospitals were low outliers and 14 were high outliers. When hospital performance was assessed with the addition of RLN injury as a variable, performance status changed for four hospitals. This study demonstrated that RLN injury can be applied as a quality outcome metric, as there were significant performance differences based on this variable.[3] To this end, it is valuable to study patient- and surgeon-specific variables that may contribute to RLN injury.

Conclusion

In summary, this is a contemporary perspective on the use of IONM during thyroidectomy in the United States. Of 17,610 patients, IONM was used in nearly two thirds of cases, and IONM use was independently associated with reduced risk of RLN injury. Patients at higher risk of RLN injury, such as those with cancer and/or undergoing concomitant central neck dissection, may experience greater benefit from IONM. Further investigation is required to understand the impact of IONM in these subgroups, as well as more nuanced outcomes such as permanent vs. temporary RLN injury and bilateral RLN injury. Understanding perioperative factors that may contribute to thyroidectomy outcomes will be important, as outcomes such as RLN injury could be applied as a procedure-specific quality metric in future surgical care.

Disclosure

The American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Declaration of competing interest

Julie A. Sosa is a member of the Data Monitoring Committee of the Medullary Thyroid Cancer Consortium Registry supported by GlaxoSmithKline, Novo Nordisk, AstraZeneca and Eli Lilly. She receives institutional research funding from Exelixis and Eli Lilly.

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