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ORIGINAL SCIENTIFIC REPORT

A Long, Unnerving Road: Malpractice Claims Involving the Surgical Management of Thyroid and Parathyroid Disease

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Abstract

Background Given their profound emotional, physical, and financial toll on patients and surgeons, we studied the characteristics, costs, and contributing factors of thyroid and parathyroid surgical malpractice claims.

Methods Using the Controlled Risk Insurance Company Strategies' Comparative Benchmarking System database, representing ~30% of all US paid and unpaid malpractice claims, 5384 claims filed against general surgeons and otolaryngologists from 1995–2015 were reviewed to isolate claims involving the surgical management of thyroid and parathyroid disease. These claims were studied, and multivariable regression analysis was performed to identify factors associated with plaintiff payout.

Results One hundred twenty-eight thyroid and parathyroid surgical malpractice claims were isolated. The median time from alleged harm event to closure of a malpractice case was 39 months. The most common associated complications were bilateral recurrent laryngeal nerve (RLN) injury (n = 23) and hematoma (n = 18). Complications led to death in 18 cases. Patient payout occurred in 33% of claims (n = 42), and the median cost per claim was $277,913 (IQR $87,343–$783,663). On multivariable analysis, bilateral RLN injury was predictive of patient payout (OR 3.58, p = 0.03), while procedure, death, and surgeon specialty were not.

Conclusion Though rare, malpractice claims related to thyroid and parathyroid surgery are costly, time-consuming, and reveal opportunities for early surgeon–patient resolution after poor outcomes.

Introduction

As the number of thyroid operations performed annually in the USA continues to increase [1], with an estimated 150,000 thyroidectomies and over 100,000 parathyroidectomies performed annually in the USA [2, 3], postoperative complications and associated malpractice claims related to thyroid and parathyroid surgery remain a concern for both patients and surgeons. The most relevant complications include recurrent laryngeal nerve (RLN) injury, hypocalcemia, and hematoma. While most thyroid and parathyroid operations are relatively low-risk procedures, one of the most feared complications is RLN injury given the associated morbidity.

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For patients, both the circumstances surrounding a malpractice claim and the claim itself can bear an incredible burden. Most patients are not compensated, and when they are, more than half of this compensation is spent on legal and administrative fees [4]. For physicians, malpractice claims can be costly and time-consuming, regardless of outcome, and involvement in a malpractice claim has been associated with depression, burnout, and suicidal ideation [5]. Further, the perceived threat of a claim, highest for invasive specialists such as surgeons [6], perpetuates the costly and potentially harmful practice of defensive medicine.

Given the overall burden of these claims on patients, surgeons, and the health care system, we aimed to evaluate the characteristics, costs, and contributing factors of claims related to the surgical management of thyroid and parathyroid disease. Since most studies focus on claims resulting in a plaintiff payout/indemnity, we also sought to analyze claims resulting in no payout to the patient, given that this outcome is more common and still costly.

Material and methods

We performed a retrospective analysis using the CRICO (Controlled Risk Insurance Company) Strategies' Comparative Benchmarking System (CBS) malpractice claims database, a robust, national repository containing >350,000 claims from >20 insurers and >400 hospitals, representing approximately 30% of all paid and unpaid US malpractice claims. Each claim in the CRICO CBS database undergoes a deep review and detailed coding process by a nurse clinical specialist using a proprietary clinical coding taxonomy to capture specific factors driving patient harm and financial loss.

Twenty years of closed claims (1995–2015) in which general surgery or otolaryngology was the primary responsible service ($n = 5384$) were reviewed and narrowed to include only claims with the diagnosis and/or procedure keywords "thyroid," "parathyroid," "thyroidectomy," and "parathyroidectomy." Each claim was then reviewed individually to isolate claims involving the surgical management of thyroid and parathyroid disease ($n = 128$). For these malpractice claims, systems and clinical factors such as open claim time, associated diagnoses, and associated complications were reviewed. Contributing factors were properties identified during root cause analyses that in aggregate enabled the harm to occur. Each malpractice claim can have multiple contributing factors. The clinical coding taxonomy undergoes robust quality assurance including an auditing process in which 15% of claims are reviewed quarterly. The free-text claim files were also reviewed to better characterize and validate the coded data.

Characteristics were compared on the basis of whether there was a payout to the plaintiff. For univariate analysis, Wilcoxon rank-sum tests were used to compare continuous variables and chi-square tests were used to compare categorical variables. A multivariable logistic regression model evaluating factors associated with plaintiff payout was developed based on prior literature and univariate analysis. Stata/SE 14 (StataCorp LLC, College Station, TX) was used for statistical analysis, and the threshold for significance was 0.05.

Results

The most common referring diagnoses were suspicious thyroid nodule ($n = 48$, 38%), thyroid malignancy ($n = 25$, 20%), and hyperparathyroidism ($n = 23$, 18%), and the most common associated procedures were total thyroidectomy ($n = 63$, 46%), thyroid lobectomy ($n = 26$, 20%), and parathyroidectomy ($n = 23$, 18%) (Fig. 1). Top contributing factors (Table 1) included technical issues (70% of claims), clinical judgment issues (49% of claims), communication issues (35% of claims), documentation issues (26% of claims), and behavior-related issues (15% of claims).

Table 2 demonstrates characteristics of the claims cohort. Most plaintiffs were female (74%) with an average age of 50 years. Approximately 33% of claims resulted in a payout to the plaintiff in the setting of a trial verdict or settlement. All claims, regardless of whether there was a payout to the plaintiff, lasted over 3 years. Almost every malpractice claim filed was in the setting of a complication. The most common complications included RLN injury, hematoma, alleged incomplete surgery, wrong-side surgery, and skin injury. After reviewing the individual claim vignettes, we found that when a RLN injury occurred, it was recognized intraoperatively 15% of time and further surgical intervention, such as tracheostomy or vocal cord medicalization, was required 51% of the time. Complications led to death in 18 cases (14%); 11 of these cases involved complications in the setting of a postoperative hematoma. The remaining deaths were in the setting of stroke ($n = 2$), serotonin syndrome, advanced anaplastic cancer, and respiratory distress in the setting of reactive airway, atypical Guillain–Barré Syndrome, and a thyroid mass causing tracheal compression. On multivariable analysis examining factors associated with plaintiff payout (Table 3), bilateral RLN injury was associated with a payout to the patient (OR 3.58, $p = 0.03$), while surgeon specialty (general surgery versus otolaryngology), procedure, and death were not.

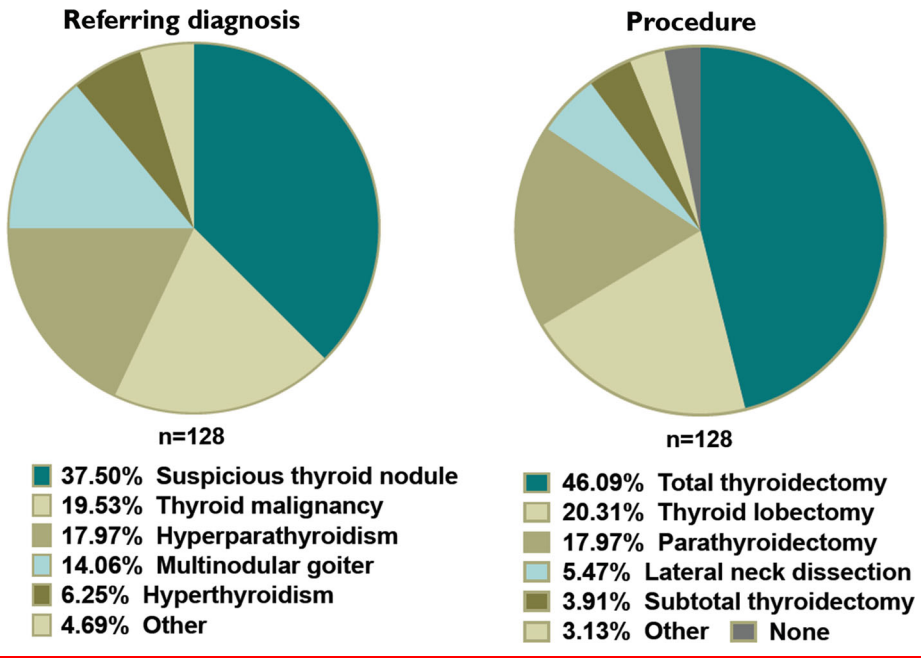

Fig. 1 Top associated referring diagnoses and procedures

Table 1 Top contributing factors deemed to have played a role in reason for a surgical thyroid or parathyroid malpractice claim

Contributing factor	Examples	*n* (%)
Technical	Known intraoperative complication, wrong-side surgery, improperly utilized equipment	89 (70)
Clinical judgement	Failure to recognize a sign/symptoms/test result, delay in selection of appropriate therapy	63 (49)
Communication	Inadequate informed consent process, poor patient/provider rapport including unsympathetic response to patients' concerns, poor communication between providers	45 (35)
Documentation	Delayed, inconsistent, and/or lack of documentation	33 (26)
Behavior-related	Patient non-compliance with clinical recommendations	19 (15)

Qualitative sub-analysis was performed to better understand claims involving bilateral RLN injury. After reviewing these case vignettes, several themes emerged: (1) Most expert witnesses agreed that informed consent should include the risks of both unilateral and bilateral RLN injuries. (2) Incomplete documentation in the operative report (e.g., no mention of identification and preservation of both RLNs during total thyroidectomy) was worse than incorrect documentation (e.g., documenting that all parathyroid glands were seen and preserved when they were not). (3) Over half of bilateral RLN injury patients required tracheostomy with at least 2 ultimately undergoing transverse cordotomy, 1 undergoing medial arytenoidectomy, and 1 requiring yearly Botox injections. (4) When nerve monitoring was not used in the setting of bilateral injury, it was almost always brought up by the plaintiff's attorney. However, in every case there was at least one expert witness who shared that many surgeons do not use the nerve monitor and that routine use is not the "standard of care."

Analysis of costs demonstrated that of the third of claims that were paid, the median cost per claim was $277,913, with a total incurred cost of $26.5 million over the study period (Table 2). For unpaid claims, there was a median cost of over $9954 per claim in legal and administrative fees, with a total incurred cost of $3.9 million dollars over the study period.

Discussion

This study demonstrates that claims involving the surgical management of thyroid and parathyroid disease are overall rare, but when they do occur, are time-consuming and expensive. Even for the majority of claims in which there was no payout to the plaintiff, the legal and administrative fees for surgeons totaled over 3.8 million dollars over the study period. Most thyroid and parathyroid claims were filed in the setting of an alleged complication. While RLN injury is a known but infrequent complication after thyroid

Table 2 Univariate analysis, characteristics compared across paid and unpaid thyroid and parathyroid surgery claims

	All thyroid/parathyroid claims (n = 128)	Indemnity payout		
		Yes (n = 42, 32.8%) Plaintiff verdict and settled cases	No (n = 86, 67.2%) Defense verdict and denied/dropped/dismissed cases	p value
Plaintiff age (years ± SD)	49.7 ± 15.1	49.7 ± 13.3	49.7 ± 16.1	0.99
Plaintiff sex, female, n (%)	93 (74.4)	31 (77.5)	62 (72.9)	0.59
Event to assert time, mo., median (IQR)	16.8 (8.6–24.8)	17.1 (4.8–24.1)	16.3 (10–25)	0.31
Event to claim close time, mo., median (IQR)	38.7 (24.4–55)	42.2 (30.9–55.1)	34.6 (21.1–55)	0.18
Surgeon specialty				0.21
General surgery, n (%)	63 (49.2)	24 (57.1)	39 (45.4)	
Otolaryngology, n (%)	65 (50.8)	18 (42.9)	47 (54.7)	
Procedure				0.37
Total thyroidectomy, n (%)	59 (46.1)	16 (38.1)	43 (50)	
Thyroid lobectomy, n (%)	26 (20.3)	10 (23.8)	16 (18.6)	
Parathyroidectomy, n (%)	23 (18)	10 (23.8)	13 (15.1)	
Main associated complication, n (%)				0.08
Recurrent laryngeal nerve injury	39 (30.5)	14 (58.8)	25 (29)	
Unilateral injury	16 (12.5)	3 (7.1)	13 (15.1)	
Bilateral injury	23 (18)	11 (26.2)	12 (14)	
Hematoma	18 (14.1)	9 (21.4)	9 (10.5)	
Alleged incomplete surgery	16 (12.5)	4 (9.5)	12 (14)	
Hypocalcemia secondary to parathyroid removal/compromise	10 (7.8)	2 (4.8)	8 (9.3)	
Wrong-side surgery	5 (3.9)	4 (9.5)	1 (1.2)	
Skin laceration, electrocautery injury, or retractor injury	5 (3.9)	1 (2.4)	4 (4.7)	
If unilateral or bilateral RNL injury, recognized intraoperatively?				0.89
Yes	6 (15.4)	2 (14.3)	4 (16)	
No	33 (84.6)	12 (85.7)	21 (84)	
If unilateral or bilateral RNL injury, further surgical intervention required?				0.88
Yes	20 (51.3)	8 (57.1)	12 (48)	
No	16 (41)	6 (42.9)	10 (40)	
Not specified	3 (7.7)	0	3 (12)	
Death, n (%)	18 (14)	8 (19.1)	10 (11.6)	0.26
Resident or Fellow named in claim, n (%)	12 (9.4)	3 (7.1)	9 (10.6)	0.53
Expense paid, $, median (IQR)	23,379 (2970–75,084)	38,127 (16,031–79,534)	9954 (1402–45,439)	<0.0001
Indemnity, $, median (IQR)	0 (0–75,000)	197,500 (85,000–700,000)	0	<0.0001
Total incurred, $, median (IQR)	37,886 (4530–253,858)	277,913 (87,343–783,663)	9954 (1402–45,439)	<0.0001
Total incurred costs over study period, $	30,386,582	26,512,055	3874,527	<0.0001

and parathyroid surgery, occurring in <1–5% of cases, it was the top complication associated with thyroid and parathyroid malpractice claims, both in our analysis and in prior studies [7, 8]. In our cohort, when a unilateral or bilateral injury occurred, it was not recognized intraoperatively a majority of the time. On adjusted analysis, bilateral RLN injury was associated with plaintiff payout.

In addition to primary methods for avoiding nerve injury including intraoperative visualization and knowledge of the

Table 3 Multivariable logistic regression model examining factors associated with plaintiff payout

Factors	Odds ratio	95% CI	*p* value
Claimant age	1.00	0.98–1.04	0.67
Female	1.30	0.46–3.66	0.62
General surgery specialty (vs otolaryngology)	1.62	0.67–3.90	0.28
Procedure			
Total thyroidectomy	0.71	0.19–2.58	0.60
Thyroid lobectomy	2.87	0.66–12.37	0.16
Parathyroidectomy	2.54	0.58–11.12	0.22
Associated complication			
Bilateral RLN injury	3.58	1.10–11.8	0.03
Unilateral RLN injury	0.34	0.07–1.56	0.17
Hematoma	2.62	0.69–9.88	0.16
Death	1.21	0.30–4.87	0.79

normal and variant anatomy of the RLN, RLN monitoring (RLNM) has become an increasingly popular adjunct in thyroid and parathyroid surgery. The efficacy of RLNM has been studied extensively, both retrospectively and prospectively, and still no study has demonstrated a significant difference in transient or permanent RLN injury rates with RLNM use [9]. That said, given the significant association with bilateral RLN injury and plaintiff payout in this study, an area in which RLNM may prove useful and potentially cost-effective [10] is in the prevention of bilateral RLN injury. Specifically, if a stimulated signal is diminished or lost on one side during a planned total thyroidectomy, one can consider stopping the operation rather than proceeding and thus putting the contralateral nerve at risk. It is unclear whether such a strategy would have ultimately altered the outcome of these claims or for the patients. Unfortunately, data regarding the use of RLNM were not uniformly available in the CRICO CBS database; in the future, inclusion of detailed information regarding RLNM use would be informative. Given that total thyroidectomy carries greater morbidity compared to thyroid lobectomy, including increased risk of RLN injury, it would also be informative to ascertain whether malpractice claims in the setting of bilateral RLN injury have decreased since adoption of the 2015 American Thyroid Association thyroid nodule and differentiated thyroid cancer management guideline recommendations which suggest lobectomy alone is a reasonable surgical approach for management of low-risk differentiated thyroid cancer [11].

The impact of surgical trainee involvement in thyroid and parathyroid malpractice claims warrants further study. In the USA, it has been estimated that residents and fellows are named in approximately 30% of lawsuits [4]. In this surgical thyroid and parathyroid claims cohort, a trainee was named in 9.4% of claims. Further, while a prior study examining cholecystectomy claims using the same database demonstrated that a trainee being named in a malpractice claim was protective of plaintiff payout, [12] in this cohort there was no significant difference in percent of paid claims when a trainee was named versus not. These differences may be secondary to sample size and/or reflect whether there exist differences in the number of teaching hospitals within each group, data not uniformly available in the database. Importantly, whether or not a trainee is named in a claim may not directly reflect whether or not they were involved in the harm event. In a study of all-specialty trainee malpractice claims, [13] trainees were named as defendants in only a minority (32%) of claims in which they were directly involved in the harm event, yet named in 9% in which they were deemed not to have been involved in the harm event. This discrepancy often represents differences in state law (e.g., in Florida trainees cannot be named as defendants unless they are practicing "outside their scope" whereas in Massachusetts, where there are hospital "charitable caps," lawyers may be more motivated to name as many medical providers in a claim as possible). Better characterization of resident and fellow involvement in the harm events that lead to thyroid and parathyroid malpractice claims may better guide opportunities for harm prevention and quality improvement.

Limitations of this study include selection bias, given that malpractice claims only represent a fraction of patient harm events, and gaps inherent to the database, such as lack of information about provider factors (e.g., clinical experience and prior claim history), patient factors (e.g., consistently coded comorbidities), and location factors (e.g., population served and state tort law variation). In addition, the number of surgical thyroid and parathyroid claims over time cannot be tracked given that the total denominator of claims at any given time is unavailable since insurers and organizations join and depart the database at different times. Lastly, the data do not capture the psychological

burden associated with the malpractice claims process and do not capture patient expenses.

Despite the limitations, this work highlights the significance of strategies that decrease the risk and help with early detection of thyroid and parathyroid surgery complications, while also demonstrating the substantial burden of these claims. As we strive to improve our liability system and optimize our approach to communicating with patients after unanticipated outcomes, leveraging data on past performance can guide current improvement efforts in a more informed way.

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