



Practice patterns for surgical management of low-risk papillary thyroid cancer from 2014 to 2019: A CESQIP analysis

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ABSTRACT

Background: Patients with low-risk-PTC who undergo thyroid lobectomy (TL) have comparable disease-specific survival with lower morbidity than total thyroidectomy (TT). We aim to describe the surgical management of low-risk-PTC using the Collaborative Endocrine Surgery Quality Improvement Program (CESQIP).

Method: CESQIP thyroidectomies of PTC tumors <4 cm were analyzed from 2014 to 2019 (n = 740). Postoperative outcomes were compared. Subgroup analysis examined temporal and institutional trends, and stratified for tumor size. Statistics utilized *t*-test, ANOVA, and *Chi-squared*.

Results: TT patients had greater hypoparathyroidism, operative time, and length-of-stay (all *p* < 0.001). Incidence of TL decreased with increasing tumor size (24.2% for <1 cm, 15.8% for 1–2 cm, 6.1% for 2–4 cm). TL rates increased from 2.0% in 2014 to 21.2% in 2018–19. Completion thyroidectomy was recommended in 12.0% of TL subjects. There was significant variation in TL rate by institution (*p* < .001).

Conclusions: For low-risk-PTC, TT remained the most commonly utilized operation. TL rates increased following release of the new ATA guidelines. TT was associated with higher perioperative morbidity. Further insight is needed to understand factors influencing operative approach.

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Introduction

Papillary thyroid cancer (PTC) is the most common form of differentiated thyroid cancer,¹ and it is most commonly treated with surgical resection of the thyroid gland. PTC is an often indolent tumor, making it amenable to less invasive treatment modalities

Abbreviations: TT, Total Thyroidectomy; TL, Thyroid Lobectomy; ATA, American Thyroid Association; CESQIP, Collaborative Endocrine Surgery Quality Improvement Program; PTC, Papillary Thyroid Cancer; RAI, radioactive iodine; FNA, fine needle aspiration; RLN, recurrent laryngeal nerve; ED, emergency department; LOS, length of stay; SD, standard deviation; BMI, body mass index; CND, central neck dissection; Ca, Calcium.

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with excellent oncologic outcomes. Select PTCs are considered “low-risk”, based on size, location within the thyroid gland, and nodal status.^{2,3}

Surgical management options include thyroid lobectomy (TL) or total thyroidectomy (TT), with or without prophylactic central lymph node dissection. The 2015 American Thyroid Association (ATA) guidelines for the management of differentiated thyroid cancer differed from its 2009 predecessor by placing a strong recommendation for thyroid lobectomy as the preferred surgical approach for cancers <1 cm in size, and either thyroid lobectomy or total thyroidectomy as appropriate surgical approaches for differentiated thyroid cancers between 1 and 4 cm in size⁴ (Table 1). This recommendation is based on several large studies demonstrating no survival benefit for total thyroidectomy in this demographic.^{5–8}

A previous survey study demonstrated a low adherence amongst clinicians to the new guidelines, including some being reluctant to recommend TL for low-risk PTC.⁹ Few data thus far have analyzed trends and changes in clinical practice at the

Table 1
2015 ATA guidelines on surgical management of differentiated thyroid cancer.

T stage	ATA management recommendation ¹	Strength of Recommendation
T1b, T2	(B) For patients with thyroid cancer >1 cm and <4 cm without extrathyroidal extension, and without clinical evidence of any lymph node metastases (cN0), the initial surgical procedure can be either a bilateral procedure (near-total or total thyroidectomy) or a unilateral procedure (lobectomy). Thyroid lobectomy alone may be sufficient initial treatment for low-risk papillary and follicular carcinomas; however, the treatment team may choose total thyroidectomy to enable RAI therapy or to enhance follow-up based upon disease features and/or patient preferences.	Strong recommendation, Moderate-quality evidence
T1a	If surgery is chosen for patients with thyroid cancer <1 cm without extrathyroidal extension and cN0, the initial surgical procedure should be a thyroid lobectomy unless there are clear indications to remove the contralateral lobe. Thyroid lobectomy alone is sufficient treatment for small, unifocal, intrathyroidal carcinomas in the absence of prior head and neck radiation, familial thyroid carcinoma, or clinically detectable cervical lymph node metastases.	Strong recommendation, Moderate-quality evidence

national level following implementation of ATA guideline changes in 2015. A prior study analyzed the National Cancer Institute Surveillance, Epidemiology, and End Results to the new guidelines (2000–2014) demonstrated no increasing trend in TL during the years preceding the guideline release,¹⁰ despite increasing evidence during this period demonstrating equivalent outcomes.^{11–13}

The Collaborative Endocrine Surgery Quality Improvement Program (CESQIP) database is a national, multi-institutional Qualified Clinical Data Registry that tracks and manages quality and outcome data at participating centers.¹⁴ Advantages of utilizing this particular database include a diverse and large patient population and, compared to other databases, improved capture of endocrine surgery-specific outcome variables, such as hypocalcemia and recurrent laryngeal nerve (RLN) injury. This study sought to determine what changes the 2015 ATA guidelines had on surgical management of PTC <4 cm. We hypothesized that following the release of these guidelines that the rate of TL would rise, however that TT would remain the most common surgical approach.

Materials and methods

The analysis of data was considered exempt by the IRB of the primary institution of the first and last author (SMW and AES). A retrospective multi-center analysis of the CESQIP database was performed to answer the clinical question utilizing the thyroid module of the database. The CESQIP data are gathered by abstractors at each unique site with the goal to generate research and to improve quality, with >300 endocrine surgery-specific variables. Research proposals to query the database must be approved by the American Association of Endocrine Surgeons (AAES) CESQIP Committee. A signed data use agreement is signed, all data are de-identified, and data is transferred securely via Arbormetrix.

CESQIP data from the five-year period of 2014–2019 (January 1st, 2014 until March 22, 2019) was specifically requested, with the goal of capturing provider practice patterns both before and after the release of the most recent ATA guidelines in January 2, 2016.⁴ All thyroid surgery patients within the database for the stated time period were initially analyzed, and then based on predefined exclusion criteria (Fig. 1) only those patients who underwent initial oncologic surgery for a <4 cm biopsy-confirmed (Bethesda VI) PTC with no pre-operative evidence of cervical lymphadenopathy were included in the final cohort.

Only subjects with primary diagnosis (*e_pridx_preop_thy*) of “Nodule/Neoplasm” were included. Subjects were only included if they had a pre-operative fine needle aspiration (FNA) consistent with known papillary thyroid cancer (Bethesda VI) (as documented by a “6” in *e_dx_preop_thy_fna_class*). Subjects were only included if their listed procedure (*e_proced_type_thy*) was classified as “Lobectomy” or “Total or Near Total Thyroidectomy”, which would

constitute the independent variable for the investigation. Only T stage of T1a, T1b, and T2 were included (*e_cancer_tstage_thy*).

The following CESQIP dichotomous variables, when answered “true” or “t” by the data abstractor, led to exclusion from the analysis: prior anterior neck surgery (*flg_cmb_thy_ant_neck_sx*), prior thyroid/parathyroid surgery (*flg_cmb_thy_prior_thypara_sx* or *e_sx_type_thy*) prior neck irradiation (*flg_cmb_thy_neck_irradiation*), symptoms of compression (*flg_dx_nod_sxscomp*), substernal thyroid nodule (*flg_dx_thy_nod_substernal*), and resection requiring sternotomy (*flg_proced_thy_lob_stern*). The additional following pre-operative diagnoses were excluded: hyperthyroidism, multimodular goiter, “other”, and lymphadenopathy. Subjects were also excluded if they underwent a therapeutic central neck dissection (*e_proced_thy_nd_ctr_ind*) or a lateral neck dissection (*e_proced_thy_nd_latrl_loc*). In order to include subjects who only had PTC <4 cm in size, subjects were excluded if their diagnosis cancer type was anything other than “Papillary” (*e_cancer_type_thy*). Potential subjects with “M1” or metastatic disease (*e_cancer_mstage_thy*) were additionally excluded. A schematic for inclusion and exclusion criteria of all subjects is demonstrated in Fig. 1.

Statistical analysis was performed utilizing univariate analysis to compare the cohort based on the independent variable of interest, lobectomy vs total thyroidectomy (*e_proced_type_thy*). Outcome variables of interest within CESQIP are visible on Table 1.

Univariate analysis included *Chi Squared* for comparison of categorical variables and two-tailed (unpaired) *t*-test for continuous variables. Statistical analysis was defined as $p < 0.05$ as per convention. Sub-analysis of the groups was then performed to delineate temporal (yearly and continuous) trends, institutional (site-specific) differences, and stratification by tumor size (as defined by tumor/T stage). To determine temporal trends, a linear model was generated ($y \sim x$) with a 95% confidence interval (CI). Statistical and graphical software utilized include Graphpad Prism (Graphpad Software LLC, Version 8.4.2).

Results

Of the 18,881 thyroidectomies included in CESQIP during the defined study period, the final study cohort consisted of 740 patients. Based on estimates of thyroid surgeries in the United States,¹⁵ this database captures approximately 2.4% of all thyroid operations. Of these, 117 (15.8%) received TL and 623 (84.2%) received TT. A total of 43 unique (de-identified) institutions and 85 unique (de-identified) surgeons were included in the analysis. Patient pre-operative and demographic variables between the TT and TL study populations were compared (Table 2). There were no significant intergroup differences in patient age, gender, BMI, race, RLN monitoring utilization, or pre-operative laryngoscopy. Of note,

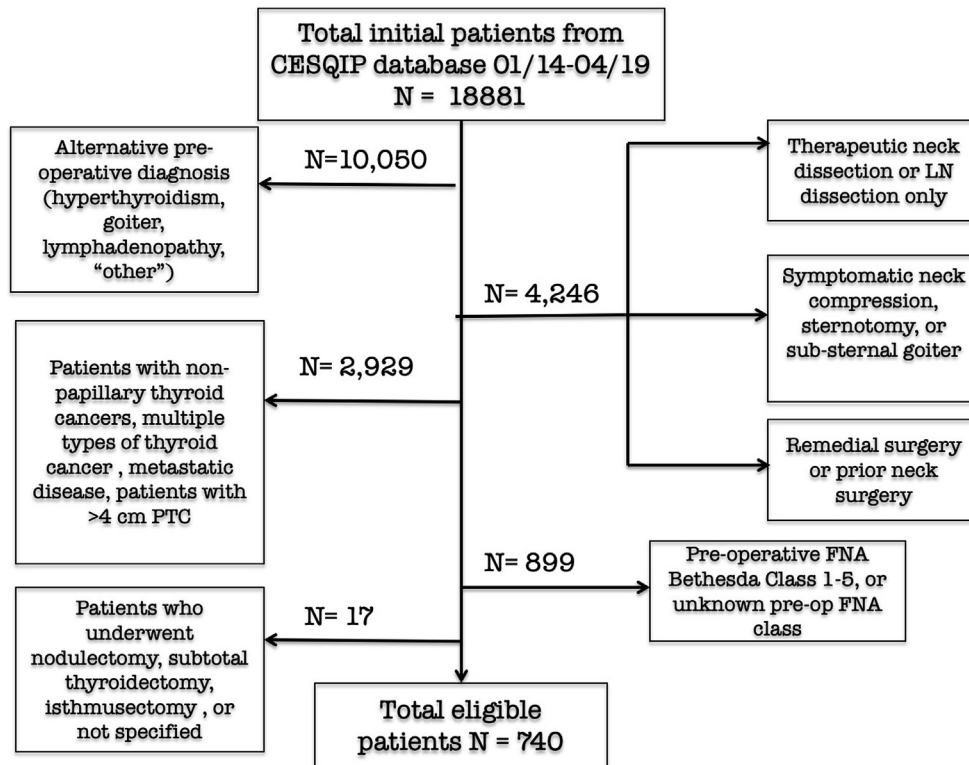


Fig. 1. Schematic for study enrollment including the study's defined inclusion criteria. Utilizing defined variables to determine the inclusion criteria, the study population was narrowed from 18,881 to $n = 740$.

TT patients were less likely to receive an endoscopic or remote-access approach (1.44 vs 5.13%, $p = .009$) and more likely to receive a prophylactic central neck dissection (35.47 vs 10.26%, $p < .0001$).

Postoperative outcome variables between the two study groups were then compared (Table 3). TT patients had a significantly higher parathyroid auto-transplantation rate (20.2 v 5.1%, $p < .001$), and higher rates of clinical concern for postoperative hypoparathyroidism (9.8 v 0.0%, $p < .001$). TT patients also had longer operative times and longer hospital length of stay (both $p < .001$). Vocal cord dysfunction was 2.1% in TT, and 0.0% in TL ($p = 0.11$). Observed differences in long term outcomes between TT and TL groups, including long term hypocalcemia and vocal cord dysfunction, were not significant ($p = 0.11$ and $p = 0.19$, respectively). A completion thyroidectomy was recommended in 12.0% of TL cases.

Temporal trends over the course of the study period can be viewed in Fig. 2 and Fig. 3. The incidence of TL for PTC tumors <4 cm prior to the release of the ATA guidelines (2014–2015) was 3.7%, and following the guidelines (2016–2019) was 21.9%. Yearly and continuous trends can be viewed in the figures, including a statistically significant trend towards more TL during the study period ($p < .0001$). Fig. 4 further stratifies the subjects by CESQIP institution and notes a significant variances in TL rate by institution (ANOVA, $p < .001$).

The rate of TL by tumor size was then analyzed, to determine if surgeons were treating larger (T2, or 2–4 cm) tumors differently than smaller (T1a and T1b, or 0–2 cm) tumors. We noted that while TT remained the preferred surgical approach for all categories (T1a, T1b, T2), there was a decreasing utilization of TL as tumor size increased (24.2%, 15.8%, and 6.1% respectively) (See Fig. 5).

Discussion

The 2015 ATA guidelines, which were released in January 2016, created a sea change in thyroid surgery by stating that papillary thyroid cancers under 1 cm *should* receive TL, and that tumors 1–4 cm could safely undergo either TL or TT. However these guidelines remain highly controversial, and this study suggests that CESQIP surgeons have not fully embraced TL for low-risk PTC.

The decision regarding the extent of surgery for low-risk PTC (here defined as T1 and T2 tumors with no evidence of lymph node metastasis) is a complex one, in which providers must factor in risk of disease recurrence, procedure morbidity, patient preferences, and additional tumor prognostic factors (molecular analysis, tumor position/extra-thyroidal extension, cytologic features, radiologic features, etc.).¹⁶

Potential advantages of TT include ability to administer radioactive iodine (RAI) postoperatively, more reliable monitoring of serum thyroglobulin (Tg), and ability to address synchronous tumors or nodules. The TT group did feature *statistically* significant higher rates of incidentally found papillary microcarcinomas, however the clinical significance of these is likely minimal.¹⁷ There is also the concern for the myriad of unanticipated pathological findings that may upgrade an apparent “low-risk” PTC into a higher risk category and ultimately require completion thyroidectomy, such as extrathyroidal extension, vascular invasion, tall cell variant histology, positive lymph nodes, or positive margins.¹⁸

As confirmed with previous studies, TL patients had lower perioperative morbidity including lower concern for hypocalcemia, shorter operative time, and shorter hospital length of stay. Patients that received TL were significantly more likely to return to the Emergency Room for reasons not immediately related to their surgery (4.3% vs 1.4%), suggesting that these patients might have

Table 2
Baseline characteristics of study population.

Variable	Entire Population	Total Thyroidectomy	Thyroid Lobectomy	p value
N	740	623	117	
Mean age in years (SD)	46.4 (15.0)	46.2 (15.1)	47.3 (14.3)	0.45
Gender (% Female)	80.0%	80.6%	76.9%	0.36
BMI > 40 (%)	6.8%	6.7%	6.8%	0.96
Pre-op vocal cord dysfunction	0.5%	0.3%	1.7%	0.06
On anticoagulation medications (%)	9.1%	8.8%	10.3%	0.62
Prior neck irradiation	0.0%	0.0%	0.0%	ns
Race (%)				
Black	3.1%	3.1%	3.4%	0.053
Non-black	64.9%	64.4%	67.5%	
Hispanic	19.3%	20.9%	11.1%	
Asian	5.4%	4.8%	8.6%	
Pre-operative FNA	100.0%	100.0%	100.0%	ns
Pre-operative laryngoscopy	17.8%	18.1%	16.2%	0.62
FNA Bethesda Class VI	100.0%	100.0%	100.0%	ns
Nerve monitor use (%)	74.1%	74.2%	73.5%	0.88
Approach				0.009
% open	98.0%	98.6%	94.9%	
% endoscopic access	2.0%	1.4%	5.1%	
Prophylactic CND	31.5%	35.5%	10.3%	<.0001
Pathological Characteristics:				
Incidental microPTC	13.8%	14.9%	7.7%	0.04
Cancer on final path	100.0%	100.0%	100.0%	
Type				
Papillary	100.0%	100.0%	100.0%	ns
Tumor Staging:				
T1	8.5%	8.8%	6.8%	<.0001
T1a	28.5%	25.7%	43.6%	
T1b	41.0%	40.9%	41.0%	
T2	22.0%	24.6%	8.6%	
N0	50.0%	52.5%	36.8%	<.0001
N1	1.5%	1.8%	0.0%	
N1a	18.1%	19.4%	11.1%	
N1b	0.1%	0.2%	0.0%	
NX	26.9%	23.0%	47.9%	
M0	32.7%	36.1%	14.5%	<.0001
MX (unknown) or blank	67.2%	63.7%	85.5%	
Completion Recommended	8.0%	7.2%	12.0%	0.08

been sicker or with higher co-morbidity. The available data were not able to conclusively demonstrate a significant difference in pre-operative co-morbidity.

Temporal trends seem to suggest that the adoption of TL for these tumors initially rose following the guidelines, however now has seemingly plateaued at just over 20% of cases. While the incidence of TL within the study population increased during the time period following the rollout of the most recent ATA guidelines, adoption of TL for PTC <4 cm appears to still be rather low and predominantly in T1 tumors (<2 cm).

Looking at institutional differences, CESQIP-participating centers with higher thyroidectomy volume tended to have slightly higher TL utilization rates, however TT remained the procedure of choice at almost all practice institutions.

Further, subdividing these tumors by size demonstrates even with papillary microcarcinomas (T1a, <1 cm), the vast majority of patients still receive TT. Size stratification revealed an extremely small proportion of 2–4 cm (T2) PTC nodules were addressed with lobectomy alone (6.1%). However, the management of these larger tumors remains an area of controversy despite still being included in the “low-risk” designation.¹⁸ One recent study found a significant survival advantage of TT over TL for classical PTC 2–4 cm in size.¹⁹

While the factors that go into each individual surgical decision are not fully available, it is clear that at a *population* level the guidelines are not being fully embraced or adopted by the providers within CESQIP-participating centers. These data suggest that

further educational work may be needed to encourage the use of TL in low-risk PTC patients. The decision to proceed with TT vs TL is typically multi-disciplinary, and may be dependent on the institutional reliance on radioactive iodine (RAI). It can also be highly patient-centric, with patient-centered preferences for surveillance and follow-up weighing heavily on the decision. Therefore, further research is needed going forward to determine which pre-operative (radiological, cytological, molecular) and post-operative factors (RAI use, surveillance protocols, surgeon or patient fearing need for completion thyroidectomy) are driving the majority of low-risk PTC patients to receive TT over TL.

As patient-centered care becomes increasingly recognized as a crucial component of effective surgical care, the ability of patients to be informed of the various risks and benefits of TL compared to TT for their cancer treatment is essential. Given the lack of consensus on the best treatment for low-risk PTC, patient considerations and preferences should help guide surgeons' and providers' treatment decisions.

Limitations

Significant limitations to this study include the retrospective nature of the work. Due to the limitations within the data of the CESQIP database, tumor size is based on pathological (post-operative) criteria and not radiological (pre-operative) criteria. The study does not track or compare disease-specific mortality, overall

Table 3
Comparison of outcomes in study populations.

Variable	Entire Population	Total Thyroidectomy	Thyroid Lobectomy	p value
N	740	623	117	
Parathyroid autotransplantation rate (%)	17.8%	20.2%	5.1%	<.0001
RLN transection rate (%)	0.1%	0.2%	0.0%	0.66
Clinical concern for postoperative hypoparathyroidism	8.2%	9.8%	0.0%	0.0004
Postoperative vocal cord dysfunction	1.8%	2.1%	0.0%	0.11
Operative time				<.0001
<1 h	8.5%	4.3%	30.8%	
1–2 h	60.4%	60.4%	60.7%	
2–3 h	24.3%	27.6%	6.8%	
>3 h	6.8%	7.7%	1.7%	
Postoperative ED visit				
Due to hypocalcemia	3.8%	3.7%	4.3%	0.76
Due to hematoma	1.6%	1.9%	0.0%	0.13
Due to other reason	0.3%	0.3%	0.0%	0.54
	1.9%	1.4%	4.3%	0.04
Readmission	1.2%	1.1%	1.7%	0.6
Reintubation (%)	0.3%	0.2%	0.9%	0.18
Hematoma requiring evacuation	0.5%	0.5%	0.9%	0.61
Unplanned return to operating room	0.4%	0.5%	0.0%	0.45
Other complication (nonspecific)	1.2%	1.4%	0.0%	0.19
Surgical Length of Stay (LOS):				<.0001
Outpatient	28.9%	23.6%	57.3%	
1 day	65.3%	69.8%	41.0%	
2 days	4.2%	4.7%	1.7%	
3 days	0.8%	1.0%	0.0%	
4 or more days	0.8%	1.0%	0.0%	
Long term complications				
Vocal cord dysfunction	0.8%	1.0%	0.0%	0.19
Hypocalcemia	1.8%	2.1%	0.0%	0.11

mortality, reoperation, or recurrence. The guidelines mention that decisions regarding TT vs. TL must weigh other considerations,

including (but not limited to) contralateral nodules, family history, previous radiation exposure, and extrathyroidal extension. These

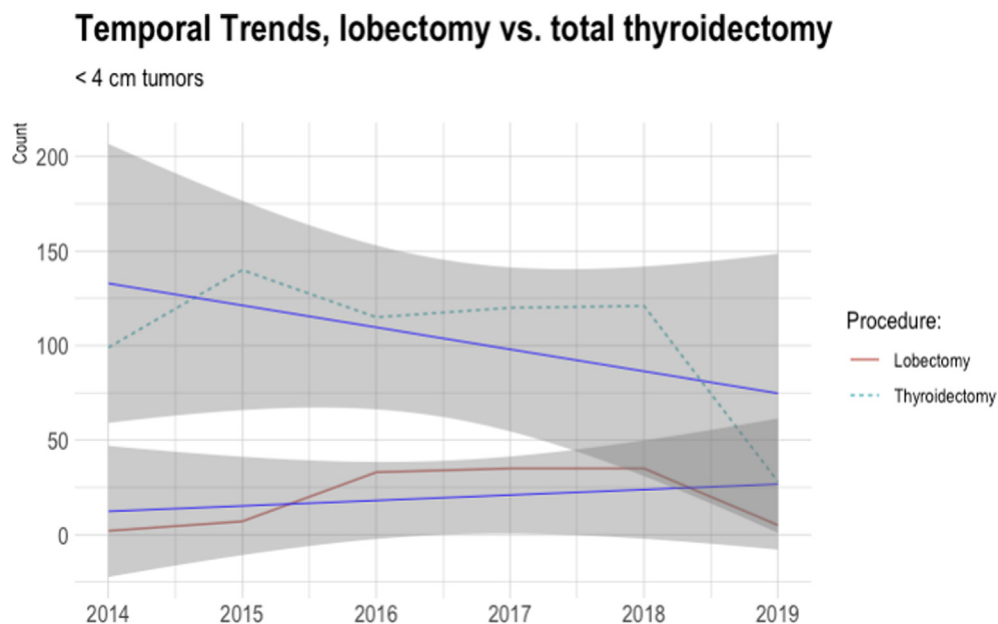


Fig. 2. Temporal trends for surgical management of low risk papillary thyroid cancers. The study included data from 2014 to 2015 (prior to release of latest ATA guidelines) as well as 2016–2019 (after release of the guidelines) to infer a causal effect from the guideline release. The X axis depicts time, and the Y axis the total number of each procedure for the given year (either thyroid lobectomy or total thyroidectomy). A trend (purple line) was generated using a linear model ($y \sim x$) with the shading representing the 95% confidence interval (CI). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Temporal Trends, lobectomy vs total thyroidectomy

< 4 cm tumors

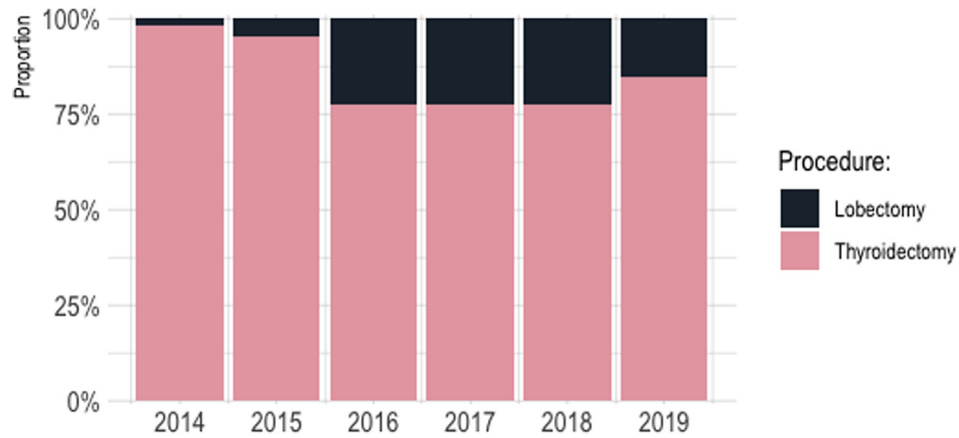


Fig. 3. Temporal trends for surgical management of low risk papillary thyroid cancers. Relative proportion of both measured procedures, thyroid lobectomy (lobectomy) and total thyroidectomy (thyroidectomy) are stratified by the year procedure was performed (X axis).

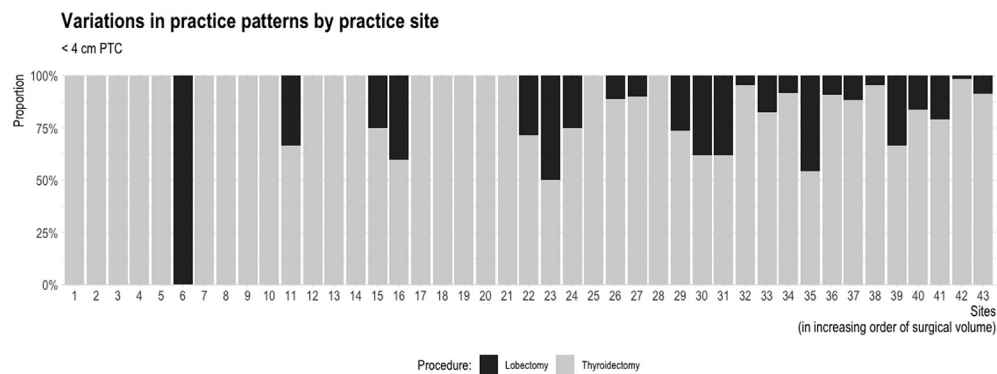


Fig. 4. Variation in practice patterns by practice site, <4 cm Papillary Thyroid Cancer (PTC). Each of the 43 unique sites (institutions) that reported at least one included case in the CESQIP database were included on the X-axis, placed in sequence according the procedure volume (total # of included cases), with site 43 here representing the highest volume. The Y-axis denotes proportion of total thyroidectomy and thyroid lobectomy for each site. Differences between institutions was statistically significant via ANOVA ($p < .001$).

Changes in Utilization of Thyroid Lobectomy in Papillary Thyroid Carcinoma by Tumor Size

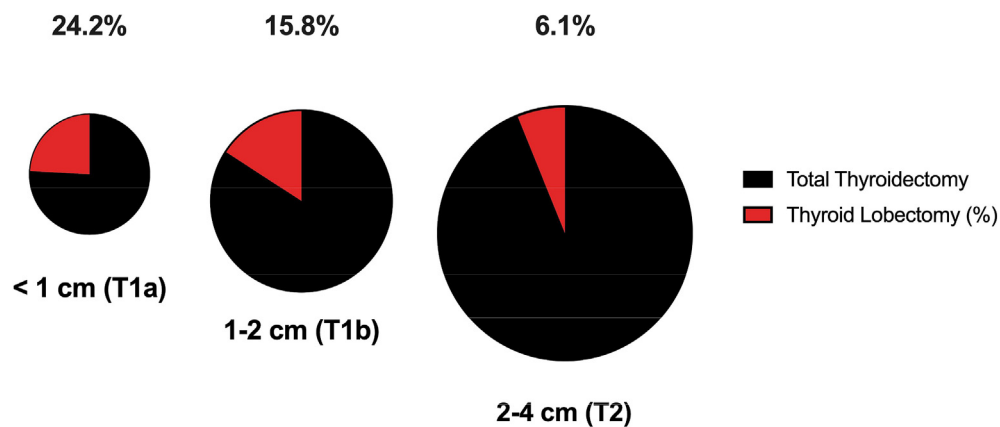


Fig. 5. Thyroid lobectomy rates as stratified by tumor size (T stage). An inverse relationship was observed between rates of lobectomy and increasing tumor size. Total thyroidectomy remains by far the most common surgery utilized at each tumor stage for known Papillary Thyroid Cancers. Note: the differences in total size/area of each pie chart is meant to demonstrate the differences in the tumor size, and not the total quantity of nodules in each subgroup.

variables are not tracked within the database and thus not considered in our study. Further, molecular analysis is increasing being studied in the pre-operative setting to help determine extent of surgery, and these data were not considered. Prior studies have suggested that Bethesda VI FNA biopsies tend to reflect more aggressive histological cancers than indeterminate (Bethesda III, IV, V) cytologies.^{18,20} Thus the exclusion of indeterminate biopsies in this study may bias the study toward more aggressive PTC subtypes. We also do not have longitudinal data on the re-operative (completion thyroidectomy) rate of the TL group, which is an important factor for many surgeons and patients when deciding between the two approaches. Finally, we were not able to track low-risk PTC patients that ultimately were treated with active surveillance or non-operative management, as the CESQIP database is limited to surgical patients that underwent thyroidectomy.

Conclusions

This study demonstrates that TT remains the operative procedure of choice amongst CESQIP participating surgeons for low-risk PTC, despite a modest trend towards higher rates of.

TL following the newest edition of ATA guidelines. Further studies should investigate the reasons for ongoing low adoption of TL for these cancers. This will help elucidate the optimal operative approach, with a goal to minimize patient morbidity and maximize patient quality of life and oncologic outcomes.

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Declaration of competing interest

The authors (SMW, TSW, AT, CMK, CCS, AES) each report no relevant disclosures or conflict of interest related to the submission of this manuscript.

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