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Predictive model of operative time in transoral endoscopic thyroidectomy vestibular approach

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Abstract

Background: Transoral Endoscopic Thyroidectomy Vestibular Approach (TOETVA) has demonstrated excellent safety and is receiving wider use in North America. Understanding which factors lead to operative difficulty, as evaluated by operative time (OT), may help to improve safety and refine indications for this procedure.

Methods: Cases of TOETVA performed at our institution were reviewed. Multivariate linear regression was performed using patient demographics, thyroid characteristics, and operative variables to predict OT.

Results: A total of 207 cases were included for analysis. A multivariate linear regression model, controlling for age, sex, and BMI, was developed from 104 cases with an R^2 of 0.47 ($p < 0.001$). Cross-validation on 103 remaining cases showed root-mean-square error of 46.37. Total thyroidectomy and lobe size were the only significant predictors ($p < 0.001$).

Conclusions: We successfully developed a model to predict OT for TOETVA based on preoperative and operative variables. Lobe size, but not BMI, is a significant predictor of OT.

KEYWORDS

duration, operative time, predictive model, TOETVA, transoral thyroidectomy

1 | INTRODUCTION

Since Kocher's pioneering work in the late 19th century, thyroid surgery has remained relatively unchanged. Given good outcomes and excellent safety, Kocher's transverse cervical incision continues to be the most common approach for thyroidectomy.[1,2] In recent years, however, there has been greater appreciation for the potential of cervical scar formation. Multiple studies have shown that post-thyroidectomy neck scars have a negative impact on patient quality of life.[3-6]

To avoid neck scarring, several remote-access techniques have been developed. Out of these approaches, transoral endoscopic thyroidectomy via the vestibular approach (TOETVA) has emerged as a particularly appealing alternative to transcervical approach thyroidectomy due to its avoidance of any visible incision. Furthermore, TOETVA has been shown to be a safe and feasible technique, providing substantial improvement in cosmesis given its "scarless" nature.[7-11]

However, as interest in this procedure expands to North American surgeons and patients alike, it is important to understand how patient specific factors may impact the difficulty of a given TOETVA case as evaluated by operative time (OT). Good candidates for TOETVA are those with maximal thyroid diameter ≤ 10 cm and a dominant nodule ≤6 cm if preoperative cytopathology is Bethesda II-IV or ≤ 2 cm if

cytopathology is Bethesda V or confirmed well-differentiated cancer.[12] Contraindications include history of prior neck surgery, radiation to the neck, or poorly differentiated thyroid carcinoma.[12] Higher BMI, in particular, has been suggested as a factor that may lead to greater operative difficulty, with excessive body fat and large body habitus recommended as relative contraindications.[12,13]

Although, the relationship between OT and patient outcomes in thyroidectomy is unclear, it has been shown that increased OT is associated with increased complications for several laparoscopic general surgery procedures, including colectomy, cholecystectomy, and inguinal hernia repair, as well as hip arthroplasty and lumbar spinal fusion.[14-16] Understanding which factors are predictive of OT in TOETVA may further improve the safety of the procedure. Additionally, accurate prediction of OT can help to maximize operative workflow and optimize hospital resources.

2 | METHODS

This study was approved by the Johns Hopkins Medicine Institutional Review Board. We performed a retrospective review of patients who underwent TOETVA between September 15, 2016, and February 25, 2020, at a single institution. Written informed consent was obtained and patients were informed of the risks and benefits for each procedure. Cases that were converted from TOETVA to open ($n = 3$) or that involved any additional procedures were excluded. Additionally, the first 11 cases were excluded in order to account for progression on the surgical learning curve to the point of proficiency, as established in our previous study.[17] Either or both of two attending head and neck endocrine surgeons performed each surgery.

Perioperative variables were collected from the patient chart. These variables were: sex, age, BMI, procedure laterality, preoperative diagnosis of Graves' disease, preoperative diagnosis of thyroiditis, preoperative Bethesda classification and cytology on fine-needle aspiration, Afirma gene-expression classifier (Veracyte, South San Francisco, California) testing results, maximum thyroid lobe size (cm), maximum thyroid nodule size if present (cm), OT, surgical pathology results, postoperative diagnosis of Graves' disease, postoperative diagnosis of thyroiditis, requirement of completion thyroidectomy postoperatively, and postoperative complications. Presence of postoperative complications was defined as any of the following: temporary or permanent vocal cord paralysis, hypoparathyroidism (immediate postoperative PTH < 10 pg/ml), seroma, hematoma, or infection. Thyroid lobe size and thyroid nodule size were defined as the maximum dimension as measured on preoperative imaging.

Statistical analysis was performed using Stata/IC 16.0 (StataCorp, College Station, Texas). For all analyzes, a p-value of less than 0.05 was considered significant. Our outcome of interest was OT, defined as the time from skin incision to recorded case finish. First, variables were assessed for association with OT using univariate linear regression. To develop a predictive model of OT, we performed multiple linear regression.

Our total cohort was randomly divided into two samples, with the first sample reserved for developing or training our model. The full multiple linear regression model included the following variables: sex, age, BMI, procedure laterality, preoperative diagnosis of Graves' disease, preoperative diagnosis of thyroiditis, preoperative Bethesda classification, preoperative cytology, maximum dimension of thyroid lobe (cm) (the greatest of anteroposterior, mediolateral, and craniocaudal measurements), maximum dimension of thyroid nodule if present (cm), requirement of completion thyroidectomy postoperatively, and postoperative complications. A sensitivity analysis was performed using either of preoperative cytology or preoperative Bethesda classification, which did not alter our conclusions. These variables have high collinearity as preoperative cytology was defined by grouping Bethesda III and IV as intermediate, and V and VI as suspicious for malignancy or malignant. Afirma testing (Veracyte, South San Francisco, California) was not included as data was available for a limited number of patients ($n = 59$).

Our reduced multiple linear regression model was developed using backwards stepwise selection, with $p > 0.1$ used for exclusion of all variables. Age, sex, and BMI were retained regardless of p-values. To assess variable selection, additional models were developed using lasso and elastic net regularization on the initial multiple linear regression model, with 10-fold cross-validation to select the tuning parameters (candidate values of λ) with the smallest out-of-sample mean squared error (MSE) estimate. These models were then tested on the second sample and compared based on MSE and R^2 values. To assess performance of the reduced multiple linear regression model, leave-one-out cross-validation was performed using the second sample.

3 | RESULTS

A total of 207 cases met criteria. The first surgeon performed 152 procedures and the second performed 29 procedures, with an additional 26 procedures performed jointly. The majority of patients were female ($n = 183$,

TABLE 1 Mean operative time by patient characteristics and preoperative variables

Variable	Frequency, no. of patients = 207 (%)	Mean operative time (min)	Standard deviation
Age (years) (mean = 40.0)			
> = 40	100 (48.3)	146.8	49.8
<40	107 (51.7)	156.4	61.6
Sex			
Male	24 (88.4)	153.4	46.7
Female	183 (11.6)	151.5	57.5
BMI (mean = 27.8)			
Underweight (<18.5)	2 (1.0)	171.5	112.4
Healthy weight (18.5–24.9)	79 (38.2)	143.7	59.2
Overweight (25–30)	55 (26.6)	151.6	48.3
Moderate obesity (30–34.9)	49 (23.7)	163.5	64.1
Severe obesity (35–40)	11 (5.3)	153.0	42.1
Very severe obesity (>40)	11 (5.3)	152.8	36.5
Extent			
Lobectomy	124 (59.9)	129.0	40.2
Total thyroidectomy	77 (37.1)	192.2	57.2
Completion	6 (2.9)	102.3	10.4
Laterality	**(*n* = 204)**		
Right	79 (38.7)	130.4	42.1
Left	48 (23.5)	126.5	34.0
Bilateral	77 (37.8)	192.2	57.2
Preop. Dx of Graves'			
No	175 (84.5)	143.5	47.9
Yes	32 (15.5)	196.6	75.6
Preop. Dx of thyroiditis			
No	187 (90.3)	151.3	57.7
Yes	20 (9.7)	155.8	41.6
Cytology	**(*n* = 201)**		
Nondiagnostic	5 (2.5)	132.8	37.6
Benign	96 (47.8)	168.7	62.3
Indeterminate	74 (36.8)	135.0	47.6
Malignant/suspicious for malignancy	26 (12.9)	148.8	45.4
Max lobe dimension (cm) (mean = 5.5)			
< 5.5	100 (48.3)	137.3	51.5
≥ 5.5	107 (51.7)	165.2	57.5
Max nodule dimension (cm) (mean = 3.0)			
< 3.0	89 (43.0)	140.8	46.2
≥ 3.0	118 (57.0)	160.0	61.8
Required completion thyroidectomy	**(*n* = 201)**		
No	194 (96.5)	153.6	56.8
Yes	7 (3.5)	142.6	46.5
Postoperative complications			
No	174 (84.1)	145.0	51.7
Yes	33 (15.9)	186.9	66.8

88.4%) and the mean age was 40.0 years (95% CI 38.4–41.7). The mean OT was 151.7 min (95% CI 144.0–159.4). Lobectomy was performed in 59.9% of cases ($n = 124$), total thyroidectomy was performed in 37.2% of cases ($n = 77$), and completion thyroidectomy was performed in 2.9% of cases ($n = 6$). Out of six completion thyroidectomies, five followed lobectomy and involved resection of the remaining thyroid tissue, whereas one case was performed following lobectomy for ectopic thyroid tissue. The mean OT was 129.0 min (95% CI 121.8–136.1) (median: 123 min) for lobectomy, 192.2 min (95% CI 179.4–205.1) (median: 182 min) for total thyroidectomy, and 102.3 min (95% CIs, 93.9–110.7) (median: 102 min) for completion thyroidectomy. Mean OT by patient characteristics and preoperative variables are shown in Table 1. Three cases involved patients who did not strictly meet the indications for TOETVA but opted to undergo the procedure anyway. The clinical characteristics of these cases are described in Table S1.

On univariate analysis, each 1-year increase in age ($p = 0.02$) and indeterminate preoperative cytology ($p < 0.001$) were significantly associated with reduced OT. Total thyroidectomy or bilateral resection ($p < 0.001$, $p < 0.001$), preoperative history of Graves' disease ($p < 0.001$), each 1-cm increase in maximum lobe dimension ($p < 0.001$), and surgery having postoperative complications ($p < 0.001$) were significantly associated with increased OT. These results are summarized in Table 2. Postoperative complications occurred in 33 cases (15.9%) and are described in detail in Table 3. No drains were utilized, as is practice at our institution. Given our exclusion criteria, which restricted our study to TOETVA only, this number does not include three cases requiring conversion to open thyroidectomy. In these cases, bleeding, at the superior pole or from friable thyroid capsule, is what prompted conversion to open surgery. These cases are summarized in Table S2.

Our full multivariate model, performed on the first, training sample ($n = 104$), showed female sex ($p = 0.02$) was significantly associated with decreased OT and total thyroidectomy ($p < 0.001$) was significantly associated with increased OT ($p < 0.001$), with no other significant variables. After performing backwards stepwise selection, the reduced regression model showed each 1-year increase in age was significantly associated with decreased OT ($p = 0.04$). Additionally, total thyroidectomy ($p < 0.001$) and each 1-cm increase in maximum lobe dimension ($p = 0.01$) were significantly associated with increased OT ($p < 0.001$), with no other significant variables. Notably, female sex was no longer found to be significantly associated with OT ($p = 0.13$). Lasso regression and elastic net regression were also performed on the full model to compare alternative variable selection approaches and to reduce overfitting. The lasso and elastic net models, with the penalized coefficients, and the full multivariate and reduced stepwise regression models were then performed on the second, testing sample ($n = 103$), resulting in coefficients of determination of 0.16, 0.17, 0.42, and 0.50, respectively. The adjusted-R^2 and RMSE was 0.29 and 38.09 for the full multiple linear model and 0.47 and 44.32 for the reduced stepwise model, hence we chose the latter as our final model ($p_{\text{overall}} < 0.001$).

The results of the reduced stepwise model on the testing sample showed that total thyroidectomy ($p < 0.001$) and each 1-cm increase in maximum lobe dimension ($p < 0.001$) were significantly associated with increased OT. As in the training sample, age was associated with decreased OT, though this association was not statistically significant ($p = 0.06$). These results are shown in Table 4. A scatter plot of the actual versus predicted OTs using the stepwise regression model for the testing sample is shown in Figure 1. Leave-one-out cross-validation of the stepwise model on the testing set demonstrated a mean RMSE of 46.37 and mean absolute error of 33.98.

4 | DISCUSSION

Our analysis demonstrates the importance of maximum lobe dimension in predicting OT for TOETVA. Other than the extent of resection (total thyroidectomy vs. lobectomy), maximum lobe dimension was the only significant and independent predictor for increased OT. Our model explained 47% of the variation in OT for the testing sample.

Previously, we reported a median OT for TOETVA lobectomy of 201 min, which is substantially longer than the median time of 123 min for lobectomy in our present cohort.[18] This may be understood to be a result of progression along the surgical learning curve, where we previously estimated the point of proficiency to be at 11 cases and Qu et al reported to be at 20 cases.[17,19] In this study, these first 11 cases were excluded in order to assess OT after the point of proficiency, where there is greater stability in OTs. This may explain differences between our overall mean OT of 151.7 min, lower than that of 216.7 min reported by Pérez-Soto et al; additionally, a slightly greater proportion of their cohort underwent total thyroidectomy than did in ours (65% vs. 60%).[20]

On the contrary, our mean OTs of 129 and 192 min for TOETVA lobectomy and total thyroidectomy are approximately 1 h longer than Anuwong et al's respective findings of 77 and 124 min in their series of 422 patients.[7] One reason for this may be the nature of our hospital as a tertiary training institution, with junior or senior resident involvement in the vast majority of our cases. The

TABLE 2 Univariate analysis: linear regression of operative time and patient variables

Variable	β coefficient	*p*-value	95% confidence interval
Age (years)	−0.77	**0.02**	−1.42 to −0.12
Sex			
Male (ref.)	–	–	–
Female	−1.92	0.88	−26.07 to 22.24
BMI	0.71	0.24	−0.48 to 1.90
Extent			
Lobectomy (ref.)	–	–	–
Total thyroidectomy	63.28	**< 0.001**	49.88 to 76.68
Completion	−26.62	0.18	−65.22 to 11.99
Laterality			
Right (ref.)	–	–	–
Left	−3.92	0.65	−20.83 to 12.98
Bilateral	61.79	**< 0.001**	47.00 to 76.58
Preop. Dx of Graves'			
No (ref.)	–	–	–
Yes	53.04	**< 0.001**	32.94 to 73.15
Preop. Dx of thyroiditis			
No (ref.)	–	–	–
Yes	4.46	0.74	−21.70 to 30.63
Cytology			
Nondiagnostic	−35.93	0.15	−85.48 to 13.62
Benign (ref.)	–	–	–
Indeterminate	−33.73	**< 0.001**	−50.43 to −17.02
Malignant/suspicious for malignancy	−19.96	0.10	−43.84 to 3.92
Max lobe dimension (cm)	20.11	**< 0.001**	13.26 to 26.97
Max nodule dimension (cm)	4.5	0.07	−0.31 to 9.31
Required completion thyroidectomy			
No (ref.)	–	–	–
Yes	−11.01	0.61	−53.91 to 31.90
Postoperative complications			
No (ref.)	–	–	–
Yes	41.9	**< 0.001**	21.58 to 62.22

involvement of resident trainees has been shown to be associated with increased operative times for several surgeries, including total thyroidectomy and lobectomy.[21-27] This discrepancy may also suggest further progression is possible beyond the initial point of proficiency and plateau, although further investigation is needed as multiple factors may be involved. Similar differences are found in comparing other studies, with reported mean OT ranging from 60 to 265 min.[28-33]

Although multiple reports have been published establishing the safety of TOETVA, demonstrating a rate of complications comparable to that of traditional, transcervical approach thyroidectomy (TCA), we were not able to identify any prior studies examining the factors predictive of the increased OT of TOETVA.[7-9,34-37] Several studies have examined these factors in TCA, with variable findings. Kwak et al found difficult thyroidectomy, defined as OT above the 75th percentile, was significantly associated with age under 45 years ($p = 0.003$) and male sex ($p = 0.04$), hypothesizing that difficulty could be related to tougher neck tissue in young men.[38] Vieni et al found a composite score considering vascularization,

friability, mobility/fibrosis, and gland size was significantly predictive of OT and able to explain approximately 45% of the variation in OT.[39,40] Consorti et al did not find any correlation between OT and BMI ($R = 0.08$) but did find a weak correlation between OT and neck circumference ($R = 0.33$) and between OT and age ($R = -0.23$).[41]

Similarly, on both univariate and multivariate analysis, we found BMI was not significantly associated with OT. However, we did find higher mean OT (171.5 min) in underweight patients (BMI < 18.5) and overweight or obese patients (151.6–163.5 min) as compared to healthy weight patients (143.7 min), suggesting the relationship may not be linear. We also found younger age was associated with increased OT, though this association was not statistically significant on multivariate analysis. As Kwak et al suggested, this association may be explained by tougher neck tissue in younger patients, with decreased elasticity in older age.[38] Likewise, we found indeterminate cytology to be significantly associated with decreased OT on univariate but not multivariate analysis. This is likely a result of differences in extent of resection, which is a better predictor of OT in the multivariate model. The proportion of lobectomies was 49% among patients with benign cytopathology versus 74% among patients with indeterminate cytology, explaining the significantly lower OT in the latter group.

Although Consorti et al hypothesized that, as in Vieni et al's study, OT may be explained by the technical difficulty of the case, Patoir et al found that these factors—namely, difficulties in locating the parathyroid gland or a recurrent nerve, fibrosis, thyroiditis, invasive cancer, thyroid specimen weight, large goiter, diving goiter, or hemorrhagic goiter—explained only 13% of the variability in

TABLE 3 Complications

Complication type	No. of events
Any complication	33
Temporary vocal cord paralysis	9
Permanent vocal cord paralysis	0
Temporary hypoparathyroidism	13
Permanent hypoparathyroidism	0
Seroma	4
Infection	2
Hematoma	0
Permanent mental nerve injury (> 6 months)	5
Postoperative pneumothorax	1
Other (hyperpigmentation of central neck, submental laceration, mental blister)	5

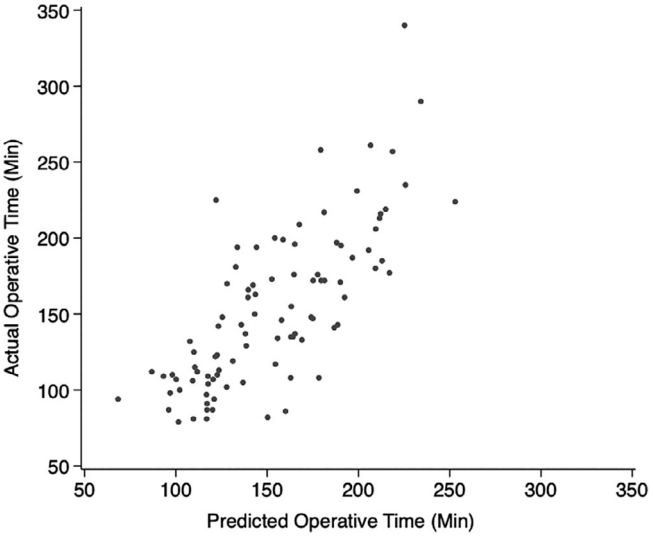

FIGURE 1 Performance of multivariate stepwise model in predicting operative time

TABLE 4 Multiple linear regression, testing sample

Multivariate model—testing sample	β coefficient	*p*-value	95% confidence interval
Age (years)	−0.76	0.06	−1.56 to 0.05
Sex			
Male (ref.)	–	–	–
Female	6.48	0.61	−18.92 to 31.88
BMI	−0.75	0.29	−2.16 to 0.66
Extent			
Lobectomy (ref.)	–	–	–
Total thyroidectomy	57.22	**< 0.001**	37.67 to 76.77
Completion	−21.59	0.42	−74.22 to 31.04
Max lobe dimension (cm)	25.69	**< 0.001**	17.14 to 34.24
Constant	40.33	0.25	−29.09 to 109.75

OT.[40-42] On univariate analysis, we found preoperative history of Graves' to be significantly associated with increased OT; however, this relationship was not significant on multivariate analysis. Preoperative thyroiditis was not significant on either univariate or multivariate analysis. However, our finding that maximum lobe size is a significant and independent predictor of increased operative may be related to unique challenges of TOETVA as compared to TCA, with thyroid size having an outsize effect on optimal surgical approach and the difficulty of resection. Indeed, one of the primary contraindicators with respect to TOETVA is the size of both the thyroid lobe and the nodule to be removed.[12]

This manuscript serves to reinforce the current guidelines and operative indications as defined by our group and others. The predominant feature in all guidelines to date suggests that nodules and lobes above a certain size should not be addressed via TOETVA.[12,35,43,44] Herein, we reinforce that, while larger nodules up to the cutoffs above (10 cm for a lobe and 6 cm for a nodule) may be safely addressed via TOETVA, the operative times will likely increase. Given that other series have associated increased OTs with complications, it is possible that a continuum exists, wherein larger lobes and nodules are associated with increased OTs and increased complications.

The limitations of our study include limited variables, as we did not collect data characterizing the relative mobility, vascularity, or friability of thyroid tissue, or the difficulty of parathyroid or recurrent laryngeal nerve identification and preservation. As Mok et al have shown with the Thyroidectomy Difficulty Scale, as well as Vieni et al with the renovated TDS, these variables may be significantly predictive of OT. Additionally, as our study is retrospective, there may be selection bias limiting its generalizability. Furthermore, our institution is a tertiary center, potentially introducing further selection bias in our patient complexity.

5 | CONCLUSION

We developed a model to predict OT for TOETVA, based on patient characteristics and preoperative variables. This model is able to explain 47% of the variation in OT. Only lobe size and extent of resection were found to be significant and independent predictors of OT, with increased maximum lobe dimension and total thyroidectomy significantly associated with increased OT.

CONFLICT OF INTEREST

This work has never been published or presented anywhere. Ralph P. Tufano is a consultant for Medtronic and Hemostatix. Jonathon O. Russell is a consultant for Baxter Scientific. The authors have no other financial or industry relationships to disclose. There are no sources of funding to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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