Received: 11 February 2019 | Revised: 19 March 2019 | Accepted: 17 April 2019

DOI: 10.1002/hed.25792

ORIGINAL ARTICLE

WILEY

Positive margin rates and predictors in transoral robotic surgery after federal approval: A national quality study

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Abstract

Background: Purpose of the study is to assess nationwide margin performance in oropharynx transoral robotic surgery (TORS).

Methods: Retrospective review of the National Cancer Database.

Results: Two thousand six hundred sixty-one patients were included. The national positive margin rate (PMR) was 16.9%. High-volume facilities had a lower PMR than low-volume facilities (12.7% vs 21.9%; $P < .001$). Patients with disease of the tonsil had a lower PMR (15.7%) than base-of-the-tongue (18.2%; $P = .14$). PMR increased with T classification (T1 = 13.0%, T2 = 17.1%, T3 = 28.2%, T4a = 45.9%, T4b = 58.3%; $P < .001$). On multivariable regression, factors associated with margin status included only lymph-vascular invasion (1.63[1.13-2.36]; $P = .01$), high volume (0.57[0.36-0.92]; $P = .005$), and T classification (as compared to T1, T2: 1.50[1.03-2.18], T3: 3.11[1.77-5.46], T4a: 7.03[2.95-16.75], T4b: 6.72[1.26-35.93]; $P < .001$).

Conclusions: National PMR is 16.9%, substantially higher than reported in high-volume TORS centers. There is a linear association between positive margins and T classification, with T3 and T4 PMRs exceeding 28%. High-volume facilities are half as likely to yield positive margins compared to low-volume facilities. There was no association between human papilloma virus status, tumor subsite, or academic facility status and positive margins.

KEYWORDS

oropharyngeal cancer, surgical margins, transoral robotic surgery

1 | INTRODUCTION

First described in 2005 and approved by the Federal Drug and Food Administration (FDA) in 2009, transoral robotic surgery (TORS) has become established within head and neck oncology.[1-5] Numerous studies have underscored the exceptional functional outcomes, high rates of locoregional control, avoidance of long-term sequelae of chemotherapy and radiation, and lower cost of TORS as compared to other treatment alogorithims.[2,4,6-8] Because of improved functional outcomes compared to traditional surgery, TORS has re-established the role of primary surgery in oropharyngeal (OP) cancers, and although no definitive data exist comparing functional outcomes to primary radiation therapy, studies have shown similar oncologic outcomes between the two modalities.[2,9,10]

Like any oncologic surgery, margin status is of primary importance in robotic head and neck surgery.[8,11-13] Prior studies have demonstrated negative margin rates comparable to or lower than nonrobotic surgery with TORS; however,

Meetings: This Study was accepted for a Podium at the Combined Otolaryngology Society Meeting 2019.

these single-institution studies have been limited by small sample sizes and very low positive margin rates (PMR), and, therefore, were unable to determine predictors of positive margins.[11,14] A study by Chen et al looked at TORS cases nationally from 2010 to 2011 and included TORS as part of their analysis of margin status in all OP surgical cases, but positive margins exclusively in TORS was not an outcome in their study.[3] Similarly, a recently published study by Li et al examined the same outcomes as Chen et al in a larger cohort, namely survival and positive margins in TORS as compared to other surgical approaches.[15] Although TORS was included as a variable in their analyses for the purpose of comparison with other surgical strategies, factors associated with positive margins exclusively in TORS were not studied. The use of TORS in OP cancer has many distinct advantages as already noted; however, the value of TORS for OP cancer is obviated in cases of positive margins. Therefore, identifying factors associated with positive margins in TORS is critical to appropriate patient and facility selection of TORS candidates. Moreover, because TORS has overwhelmingly targeted low T classification (T1/T2) OP tumors, specifically in the tonsil and base of tongue (BOT) subsites, smaller, single-institution studies have been unable to stratify by T classification and subsite in their analysis of positive margins, which would be possible with a national dataset.[2,8,16]

In this study, we utilized the National Cancer Database (NCDB) to characterize cases of positive margins following TORS in the years since FDA approval in a national sample of patients with OP cancer. The objectives of this study are to (a) describe positive margins with respect to various patient and clinicopathologic variables in TORS patients and (b) identify factors associated with positive margins.

2 | MATERIALS AND METHODS

2.1 | Data Source

The NCDB is a national database which collects information on all cancer cases treated at Commission on Cancer-accredited hospitals. It represents over 70% of all new cancer diagnoses in the United States and 34 million historical records.[17]

2.2 | Data Collection

Patients (age ≥ 18) who underwent TORS 2010-2014 for OP squamous cell carcinoma (OPSCC) at the following OP subsites (as coded by the *International Classification of Diseases for Oncology, Third Edition[ICD-O-3]*) were included: C09.0, C09.1, C09.8, and C09.9 (tonsil); C01.9 (BOT); C05.1 (soft palate); and C10.0, C10.2, C10.3, C10.4, C10.8, and C10.9 (other oropharynx). The following ICD-O-3 histology codes were included: 8051-8052, 8071-8076, 8078, 8081-8084, 8094, and 8560. Patients with T0, TX, or metastatic disease and those with missing T classification or margin data were excluded (Figure 1 displays patient selection).

Patient and clinicopathologic factors were categorized as shown in Table 1. Given that extracapsular extension (ECE), via imaging, and lymph-vascular invasion (LVI), via biopsy, are sometimes known prior to surgery (although the latter with less frequency), we included them in the multivariable analysis. Some variables were recoded as shown in Figure 4 to exclude unknown categories in the multivariable analysis. The primary outcome variable was margin status after definitive surgery (the NCDB instructs coders to record the final margin status, which should include re-excisions).

2.3 | Statistical Analysis

PMRs were compared between groups using student's *t* tests and Pearson chi-square tests for means and percentages,

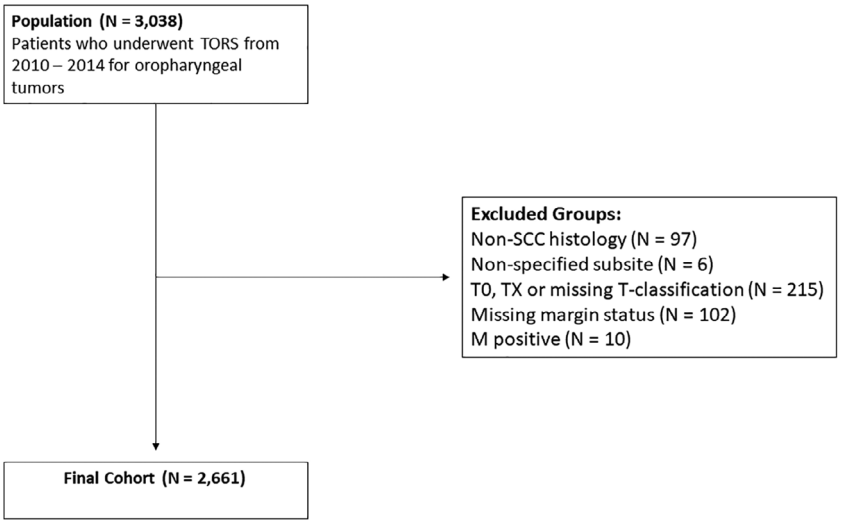

FIGURE 1 Patient Selection. Exclusion criteria are shown in the box on the right. Abbreviations: SCC, squamous cell carcinoma; TORS, transoral robotic surgery

TABLE 1 Baseline patient, facility, and clinicopathologic characteristics

Factor	Negative margins (N = 2211)	Positive margins (N = 450)	*P* value
Age, mean (SD), y	59.3 (9.9)	60.9 (10.0)	.002
Distance to facility, mean (SD), miles	69.1 (218.8)	74.0 (216.6)	.66
Sex, No. (%)			.83
Men	1842 (83.2)	373 (16.8)	
Women	369 (82.7)	77 (17.3)	
Race, No. (%)			.31
White	2031 (83.5)	402 (16.5)	
Black	126 (77.8)	36 (22.2)	
Other	32 (82.1)	7 (17.9)	
Unknown	22 (81.5)	5 (18.5)	
Insurance, No. (%)			.05
Not insured	40 (83.3)	8 (16.7)	
Private	1367 (84.7)	246 (15.3)	
Medicaid	129 (78.7)	35 (21.3)	
Medicare	617 (80.7)	148 (19.3)	
Other government	40 (78.4)	11 (21.6)	
Unknown	18 (90.0)	2 (10.0)	
Income, No. (%)			.14
Quartile 1 (<$38 000)	279 (79.7)	71 (20.3)	
Quartile 3	447 (82.2)	97 (17.8)	
Quartile 4	569 (80.9)	134 (19.1)	
Quartile 4 (<$63 000)	906 (86.0)	147 (14.0)	
Unknown	10 (90.9)	1 (9.1)	
Facility type, No. (%)			<.001
Nonacademic	357 (75.5)	116 (24.5)	
Academic	1820 (84.7)	330 (15.3)	
Other or unknown	34 (89.5)	4 (10.5)	
Facility volume, No. (%)			<.001
Low (<3/y)	514 (78.1)	144 (21.9)	
Medium (3-9.9/y)	723 (81.5)	164 (18.5)	
High (>10/y)	974 (87.3)	142 (12.7)	
HPV status, No. (%)			.05
Negative	330 (80.9)	78 (19.1)	
Positive	1329 (84.8)	238 (15.2)	
Unknown	552 (80.5)	134 (19.5)	
Subsite, No. (%)			.14
Tonsil	1266 (84.3)	236 (15.7)	
Base of tongue	793 (81.8)	177 (18.2)	
Soft palate	35 (87.5)	5 (12.5)	
Other oropharynx	117 (78.5)	32 (21.5)	

(Continues)

TABLE 1 (Continued)

Factor	Negative margins (N = 2211)	Positive margins (N = 450)	*P* value
Pathologic T classification, No. (%)			<.001
T1	1052 (87.0)	157 (13.0)	
T2	976 (82.9)	201 (17.1)	
T3	145 (71.8)	57 (28.2)	
T4a	33 (54.1)	28 (45.9)	
T4b	5 (41.7)	7 (58.3)	
Number of positive lymph nodes, No. (%)			.06
0	376 (87.9)	52 (12.1)	
1	691 (85.9)	113 (14.1)	
2	371 (85.1)	65 (14.9)	
3	182 (85.0)	32 (15.0)	
4	96 (83.5)	19 (16.5)	
5+	203 (79.0)	54 (21.0)	
Unknown	292 (71.7)	115 (28.3)	
Extracapsular extension, No. (%)			.72
Negative	1356 (84.4)	250 (15.6)	
Positive	518 (83.8)	100 (16.2)	
Unknown	337 (77.1)	100 (22.9)	
Lymph-vascular invasion, No. (%)			<.001
Negative	1415 (85.2)	246 (14.8)	
Positive	456 (76.8)	138 (23.2)	
Unknown	340 (83.7)	66 (16.3)	
Charlson/Deyo score, No. (%)			.006
0	1775 (84.3)	331 (15.7)	
1	351 (78.5)	96 (21.5)	
2+	85 (78.7)	23 (21.3)	

Abbreviation: HPV, human papilloma virus.

respectively. Univariable and multivariable binary logistic regression was used to identify predictors of positive margins following TORS. All factors with $P < .2$ on univariable regression and all clinically relevant factors were included in the multivariable model. Statistical analysis was performed in SPSS 25 (IBM, Armonk, New York). Statistical significance was determined at $P < .05$. This study was determined exempt by the Yale Institutional Review Board.

3 | RESULTS

3.1 | Patient, Facility, and Tumor Characteristics

Two thousand six hundred sixty-one patients undergoing TORS for OPSCC met inclusion criteria. The mean age was 59.6 years (SD = 9.9), 83.2% were men, and 91.4% were white (Table 1). About 60.6% of patients were privately insured, and 28.7% had Medicare. The largest percentage of cases, 39.6%, was represented by the wealthiest income quartile, whereas the lowest percentage, 13.2%, was represented by the lowest quartile. About 80.8% of operations were at academic centers, and 21.1% were at low-volume facilities, whereas 45.1% were at high-volume centers.

Pathologically, 45.4% were classification T1, 44.2% were T2, 7.6% T3, and 2.8% T4 (Table 1). About 56.4% of tumors had a tonsil subsite, 36.5% BOT, 1.5% soft palate, and 5.6% other OP sites. About 58.9% of patients were human papilloma virus (HPV) positive, although the status of 25.8% was unknown. About 23.2% had ECE on final pathologic review, and 22.3% had LVI. When only patients with known data were included, 27.8% had ECE and 26.3% LVI. The correlation between LVI and T classification was 0.13. About 16.1% of patients had 0 positive nodes, 30.2% had one positive node, and 38.4% had 2 or more.

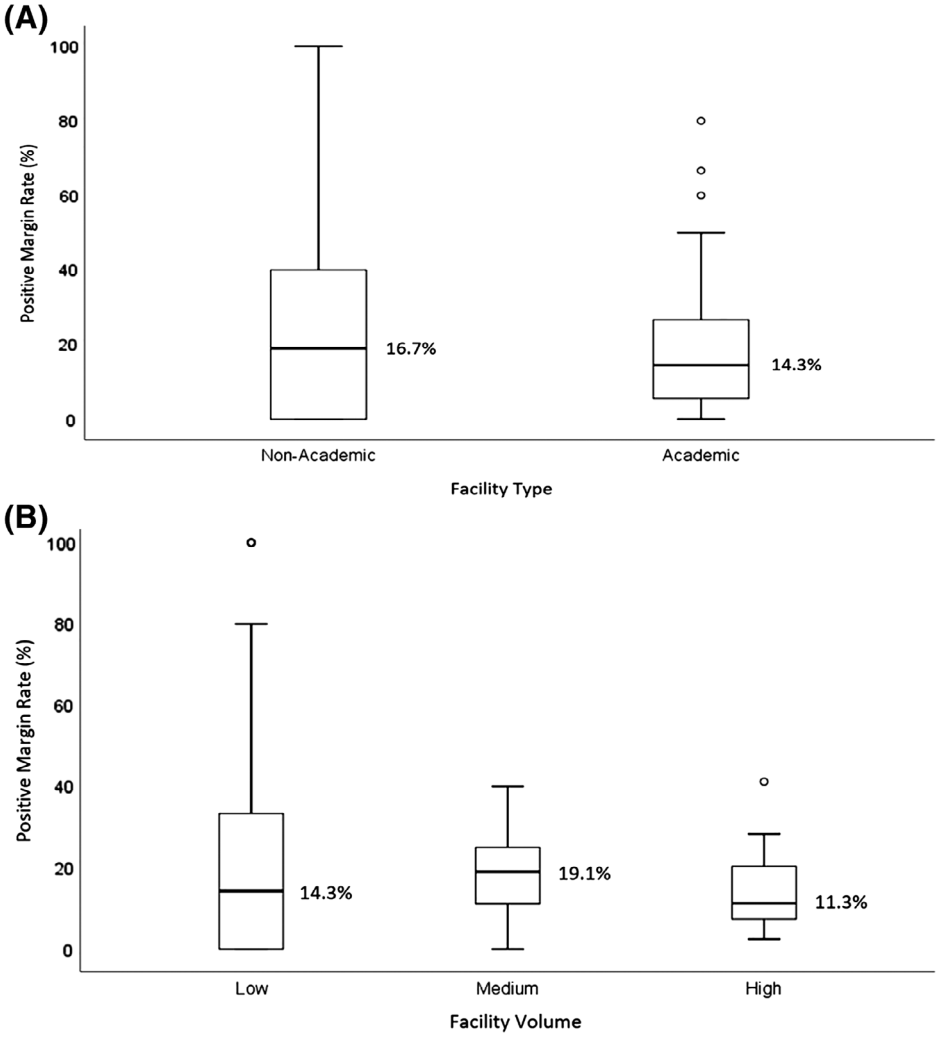

FIGURE 2 Positive margin rate by facility type and volume. Distribution of positive margin rates in transoral robotic surgery patients according to facility academic status (top chart) and volume (bottom chart). The ends of the boxes represent the first and third quartiles. The whiskers display all values within 1.5 times the interquartile range above the third quartile and below the first quartile. The median is displayed adjacent to each plot

3.2 | Margin Status

The overall PMR was 16.9%. Patients with positive margins were, on average, 1.6 years older and lived 4.9 miles farther from the treatment facility than those with negative margins ($P = .66$; Table 1 shows percentages of positive margins for each variable). Men and women had similar rates (16.8% vs 17.3%, $P = .83$), white patients had a PMR of 16.5%, and black patients a rate of 22.2% ($P = .31$). Excepting those with unknown insurance type, privately insured patients had the lowest PMR (15.3%), whereas those with government insurance other than Medicare and Medicaid had the highest, although the difference did not reach significance (21.6%; $P = .05$). Similarly, the PMR decreased nonsignificantly with increasing income (quartile 1 = 20.3%, quartile 4 = 14.0%; $P = .14$). Academic centers had a PMR of 15.3% vs 24.5% for nonacademic centers, and high-volume facilities had a rate of 12.7% vs 21.9% for low-volume centers (both $P < .001$; Figure 2 displays boxplots of the distribution of PMRs among facilities based on academic status and volume).

HPV positive patients had a lower PMR (15.2% vs 19.1% for HPV negative; $P = .05$). Patients with SCC of the soft palate had the lowest PMR (12.5%), followed by those with disease at the tonsil (15.7%), BOT (18.2%), and other OP sites (21.5%; $P = .14$). PMR increased with T classification (T1 = 13.0%, T2 = 17.1%, T3 = 28.2%, T4a = 45.9%, T4b = 58.3%; $P < .001$) and the number of positive lymph nodes (0 = 12.1%, 1 = 14.1%, 2 = 14.9%, 5+ = 28.3%; $P = .06$). Figure 3 displays the PMRs for all T classifications and tumor subsites. There was no observed difference in the PMR between those positive for ECE and those without ECE (16.2% vs 15.6%; $P = .72$). Patients positive for LVI were more likely to have positive margins (23.2% vs 14.8%; $P < .001$). Finally, patients with 0 comorbidities were less likely to have positive margins as opposed to those with comorbidities (15.7% vs >21%; $P = .006$).

3.3 | Factors Associated With Positive Margins on Multivariable Analysis

On univariable logistic regression, of the demographics, only age and insurance type yielded a P value less than .2. Both facility factors yielded a P value less than .2. On multivariable regression, patients with LVI were 1.6 times as likely to have

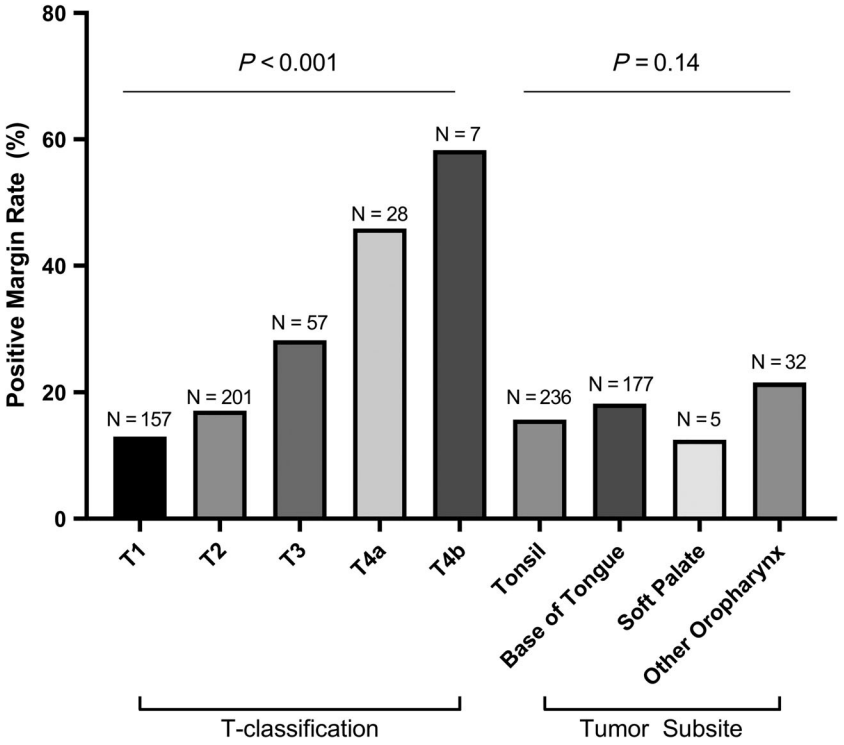

FIGURE 3 Positive margin rates by T classification and oropharyngeal subsite. Bars represent the % of patients within each subgroup who had positive margins following definitive surgery with transoral robotic surgery (absolute number displayed on top of bars). Comparison of proportions between groups was performed with Pearson chi square

positive margins as those without LVI (odds ratio [OR]: 1.63, 95% confidence interval [CI]: 1.13-2.36, $P = .01$; Figure 4). Patients treated at high-volume centers were less likely to yield positive margins as compared to low-volume centers (OR: 0.57, CI: 0.36-0.92, $P = .005$). The likelihood of positive margins increased with higher T classification (as compared

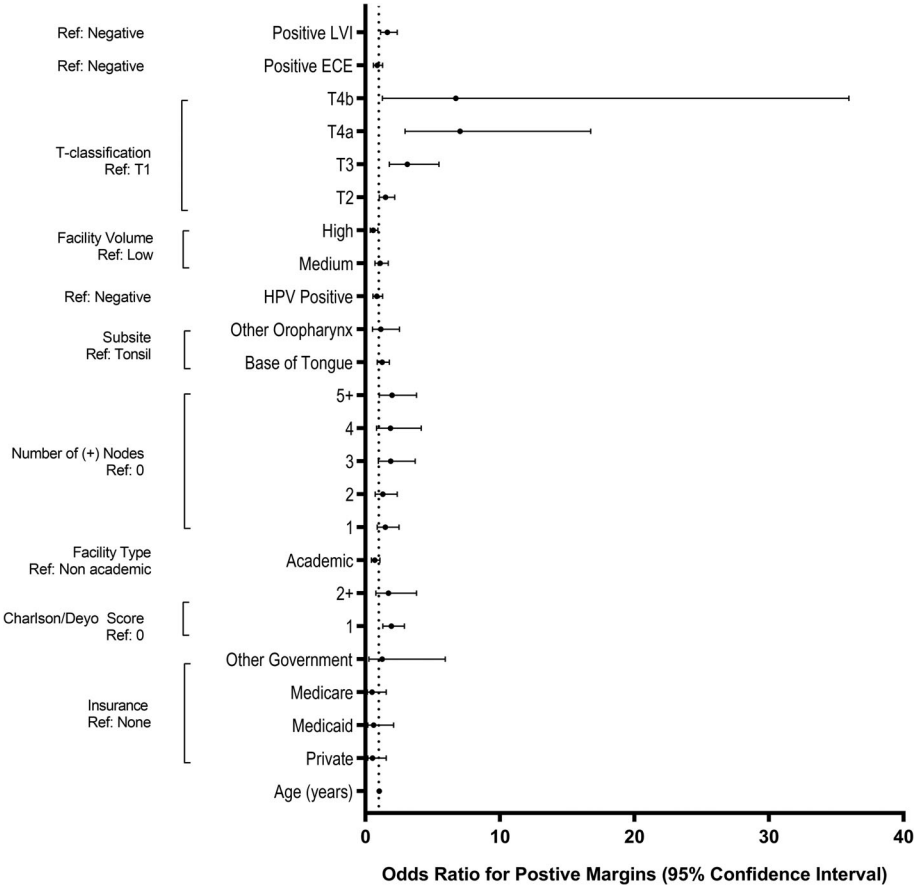

FIGURE 4 Multivariable analysis testing margin status. Univariable and multivariable logistic regression were used to identify predictors of positive margins in transoral robotic surgery patients. Odds ratios (dots) and 95% confidence intervals (error bars) are displayed. Only lymph-vascular invasion, T classification, and facility volume were significant in the model. Abbreviations: ECE, extracapsular extension; HPV, human papilloma virus; LVI, lymph-vascular invasion; Ref, referent

to T1, T2: 1.50 [1.03-2.18], T3: 3.11 [1.77-5.46], T4a: 7.03 [2.95-16.75], T4b: 6.72 [1.26-35.93], $P < .001$). When T4a and T4b were grouped into a single category on multivariable regression, T classification remained a significant predictor of margin status (for T4, OR: 6.94, CI: 3.14-15.30, $P < .001$), and the rest of the model was unchanged.

4 | DISCUSSION

In this study, we characterized patient, tumor, and facility factors in a nationally representative cohort of patients with OP cancer undergoing TORS. We analyzed differences in PMRs by T classification, facility type and volume, HPV status, and tumor subsites, and associated a variety of factors with margin status. To our knowledge, this study, which captures a national cohort of patients rather than one limited to high volume centers, is the largest study of positive margins exclusively in TORS patients to date. As TORS has become routine in the treatment of head and neck cancers, patient selection has become a primary focus of investigation.[2] The advantages of TORS are diminished in cases of positive margins, and, therefore, identifying the factors associated with higher PMRs is critical to its optimal utilization. Although past studies are heavily limited by sample size, this national cohort allowed for sufficient examination of cases of positive margins. Moreover, the use of TORS in less conventional tumors, for example, those of high T classification located in OP subsites other than the tonsil or BOT, was captured in adequate numbers to incorporate analytically.

The use of TORS has increased dramatically in the last decade, as already corroborated in a smaller national sample by Chen et al.[3] From 2010 to 2014, in this particular cohort of patients with OP cancer, TORS usage increased from 293 in 2010 to 686 in 2014 (increase of 234%). Given current practice patterns and the potential for improved functional outcomes and reduced costs, we expect TORS utilization will continue to increase in coming years.[18]

The overall rate of positive margins in this study was 16.9%, which is less than the overall PMRs found in prior studies of patients with OP cancer in the NCDB, especially compared to cohorts including nonrobotic surgical patients.[3,19,20] Chen et al found an overall PMR of 20.2% in TORS patients as opposed to 31.0% in patients treated with nonrobotic surgery (for all T classifications) and found TORS to be associated with a decreased likelihood of positive margins on multivariable analysis.[3] Li et al reported a PMR of 16.5% in T1/T2 patients, which was lower than both nonrobotic surgery and transoral laser microsurgery (28.4% and 21.4%, respectively).[15] Zevallos et al demonstrated a PMR of 16.8% for TORS patients of all T classifications as compared to 28.3% for other transoral, nonrobotic approaches, although this difference was not significant in their multivariable model.[21] A study of low-classification (T1/T2) OPSCC in the NCDB by Cracchiolo et al yielded an overall PMR of 24% for all primary surgical patients.[20] Finally, a 2017, single-institution study of patients undergoing primary surgery for OPSCC reported a PMR of 38%.[22] These reports suggest that TORS may yield lower PMRs than nonrobotic surgery, although we emphasize that it is difficult to directly compare the PMRs found here to other studies given the high proportion of early-classification tumors in this cohort.

In accordance with FDA specifications, the large majority of TORS operations in the oropharynx are performed for T1 and T2 tumors (45.4% and 44.2%, respectively).[5,16] However, it is notable that a significant number are performed off-label in T3 and even T4 tumors (7.6% and 2.8%, respectively). Given that TORS is being utilized outside of the conventional context, the impact of T classification on margin status is particularly relevant for the expansion of the scope of TORS. In this study, the rate of positive margins dramatically increased with successively higher T classifications. Patients with T1 and T2 cancer had a PMR less than 20% (13.0% and 17.1%, respectively), whereas patients with T3 cancer had a rate of 28.2%, and almost half of patients with T4 cancer were positive after surgery (47.9%). The difference among T classifications was statistically significant and was a significant predictor of margin status after controlling for relevant demographic and clinicopathologic features. T3 tumors were three times more likely than T1 tumors to have positive margins, and T4 tumors were seven times more likely to result in positive margins following TORS. These results suggest that it may be exceptionally difficult to achieve positive margins with high T classifications in TORS. Further research is needed regarding the functional and oncologic outcomes of TORS patients with T3 and T4 cancer to understand the utility of TORS in these patients.

This study found that TORS procedures yielded a PMR of 15.3% at academic centers as compared to 24.5% at nonacademic centers, a difference which was not significant on multivariable analysis. PMRs at academic facilities vary in the literature. Pooled data from three clinical trials in a study by Weinstein et al yielded a PMR of 3.8% for OP tumors of all classifications, and a retrospective review of 11 academic institutions revealed a rate of 9.9%.[8,23] Two single-institution studies, by Moore et al and Persky et al, reported rates of 2% and 10%, respectively, for T1 and T2 tumors.[24,25] These rates are lower than the PMRs of academic facilities in this study, even when limited to low-classification tumors (13.9%). The disparity between the PMR demonstrated here and those of smaller studies indicates that publication bias may be influencing the PMR reported in the literature and that the actual PMR of TORS nationwide in academic facilities is closer to 15%, in contrast to the lower rates previously reported. It is notable that the study with the largest number of institutions mentioned above reported a PMR closest to that found in this study.

Although there was no difference in the PMR between academic and nonacademic centers, it is notable that the large majority of TORS operations (81%) occurred at academic institutions, consistent with previous studies, and that their share of the caseload did not change during the study period (81.9% in 2010 vs 81.6% in 2014, $P = .74$).[3,26] Moreover, when facility volume was removed from the multivariable model, academic facilities became significantly less likely to yield positive margins that non-academic (0.54 [0.36-0.80]; $P = .002$). Therefore, our results suggest that the volume of TORS operations is the driver of PMR variations among cancer centers.

Few studies have stratified the PMR by subsite in TORS. Our study found that the differences in PMRs between OP subsites was neither significant on univariate analysis nor a significant predictor of margin status in multivariable analysis. Persky et al in a single-institution study of 140 patients, found that PMRs were significantly higher at the BOT (19.6%) as compared to the tonsil (4.5%) and that procedures at the BOT were six times as likely to result in positive margins as compared to tonsil on multivariable analysis.[25] In contrast, we found PMRs of 15.7% and 19.4% in the tonsil and BOT, respectively, and found that this was not significant in multivariable analysis. Persky et al only controlled for HPV status and T classification in their analysis, which was also limited to a single institution. This study, in contrast, includes a national cohort within which we controlled for a variety of patient, tumor, and facility characteristics. Therefore, we suggest that tumor subsite may be less likely to influence final margin status than suggested by their study. We note that the final determination of margin status is at the pathologist's discretion and methods and definitions may vary between institutions; this may also contribute to the discrepancies observed. Previous studies have not included nontonsil, non-BOT subsites in their analysis. Here, we found that there was no difference in PMR between these other, less common subsites as compared with BOT and tonsil, which suggests that TORS is a viable option in a carefully-selected group of patients with other OP tumor subsites.

Finally, we found that LVI was significantly associated with positive margins in the multivariable model but that ECE and HPV status were not. Importantly, there was potentially a relatively low rate of ECE (23.2%) in this study as compared to other reports in the literature.[27] However, a minority of patients were missing data for ECE; of those with known data, the rate of ECE was 27.8%, similar to some other oropharynx studies.[28,29] It is still possible that there is selection bias to not operate on those with obvious ECE preoperatively; however, we do not believe that such selection bias would affect margin rates. Processes occurring at lymph nodes are separate from the primary tumor, and, therefore, a bias against ECE would likely not affect margin rates either positively or negatively. Moreover, one of the goals of this study was to understand the impact of clinicopathologic features like ECE on surgical margins in oropharynx cancers treated with TORS, and, as already mentioned, no association was found between margin status and ECE.

There was a substantial difference in the PMR between patients who had LVI and those who did not (23.2% vs 14.8%, respectively; $P < .001$). It is possible that the association between LVI and larger tumor size is driving the difference in the PMR; however, this difference remained significant in multivariable analysis, which controlled for pathologic T classification. Moreover, there was only a weak correlation between T classification and LVI in our cohort (0.13). It is interesting that this study demonstrated no association between HPV and margin status in TORS, consistent with a single institution study by Cohen et al which demonstrated no difference in margin status between HPV positive and negative patients undergoing TORS for OPSCC.[30] One explanation, similar to that suggested by de Almeida et al, for the lack of influence of HPV on margin status in TORS may be the low tumor volume in TORS cohorts irrespective of HPV status.[8]

There were several limitations to this study, namely the retrospective design and dependence on the quality of data in the NCDB. Furthermore, the NCDB, although capturing the majority of newly diagnosed cancer cases, is not nationally representative and therefore the data provided here may differ meaningfully from national trends. Finally, clinicopathologic differences between patients not captured by the data may confound our results. T classification alone does not capture all gross characteristics of tumor morphology, some of which may affect margin status. For example, resecting an endophytic tumor presents a different scenario from a highly exophytic mass, regardless of T classification. Similarly, higher volume surgeons may be more comfortable achieving negative margins as size and invasion of surrounding structures worsen, which may or may not be reflected in the T classification. Therefore, caution should be taken when interpreting these results in light of these types of clinicopathologic confounders.

5 | CONCLUSION

In the years since FDA approval, national PMRs for OP TORS operations has been 16.9%, substantially higher than that reported in high volume TORS centers. There is a linear association between positive margins and T classification, with T3 and T4 tumors having rates exceeding 28%. Furthermore, high-volume facilities were half as likely to yield positive margins as compared to low-volume centers in TORS for OP cancer in multivariable analysis. Finally, there was no association between HPV status, tumor subsite, or academic facility status and positive margins. Further work is needed to understand the

utility of TORS in patients with high T classification and to decrease variability in the PMR among facilities.

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How to cite this article: Hanna J, Morse E, Brauer PR, Judson B, Mehra S. Positive margin rates and predictors in transoral robotic surgery after federal approval: A national quality study. *Head & Neck*. 2019;41:3064–3072. https://doi.org/10.1002/hed.25792