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## Transoral Robotic Surgery for Oropharyngeal and Tongue Cancer in the United States

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### Abstract

**Objectives**—To compare the clinical and cost effectiveness of TORS versus open procedures following FDA approval in December 2009.

**Study Design**—Retrospective analysis of the Nationwide Inpatient Sample from 2008 to 2011.

**Methods**—Elective partial pharyngectomies and partial glossectomies for neoplasm were identified by ICD-9-CM code.

**Results**—TORS represented 2.1% in 2010 and 2.2% in 2011 of all transoral ablative procedures. Patients undergoing open partial pharyngectomy for oropharyngeal neoplasms (n=1426) had more severe illness compared to TORS (n=641). However, after controlling for minor-to-moderate severity of illness, open partial pharyngectomy was associated with longer hospital stay (5.2 vs 3.7 days, p<0.001), higher charge (\$98,228 vs \$67,317, p<0.001), higher cost (\$29,365 vs \$20,706, p<0.001), higher rates of tracheostomy and gastrostomy tube placement and more wound and bleeding complications. TORS was associated with a higher rate of dysphagia (19.5% vs 8.0%, p<0.001). The lower cost of TORS remained significant in the major-to-extreme severity of illness group but was associated with higher complication rates when compared to open cases of the same severity of illness. A similar analysis of TORS partial glossectomy for base of tongue tumors had similar cost and length of stay benefits, while TORS partial glossectomy for anterior tongue tumors revealed longer hospital stays and no benefit in charge or cost compared to open.

**Conclusions**—Early data demonstrate cost effectiveness of TORS partial pharyngectomy and partial glossectomy for the base of tongue but no benefit in partial glossectomy of the anterior tongue. Anatomic accessibility and extent of surgery likely factor into the effectiveness of TORS.

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## Keywords

Transoral Robotic Surgery; Oropharyngeal Cancer; Tongue Cancer; Nationwide Inpatient Sample; Glossectomy; Pharyngectomy; Robotic Surgery; Cost Effectiveness

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## Introduction

Since the first studies on robotic surgery in the mid 1980s<sup>1</sup>, robotic surgery has become one of the fastest growing areas for surgical innovation. Propelled by general and urologic surgeries in its pre-approval phase, a number of surgical specialties have been compelled to apply robotic surgery to routine and complex cases alike. Robotic surgery boasts a number of advantages including increased dexterity, improved exposure with near-complete elimination of torque on adjacent tissue, and improved motor control leading to smaller volumes of tissue resected, less local tissue injury during harvest and ultimately faster patient recovery. Barriers to its widespread adoption largely center on cost and efficacy.

Increased scrutiny in healthcare costs at the same time as this emergence of robotic surgery has inspired appropriate criticism. Initial cost of the daVinci robot and subsequent maintenance costs are prohibitive to all but a minority of medical centers<sup>2</sup>. A recent perspective on robotic surgery estimates that an additional \$2.5 billion dollars annually would be incurred if robotic surgery was broadly substituted for conventional procedures<sup>3</sup>.

Transoral procedures of the pharynx and larynx traditionally are performed with rigid endoscopic devices within the confined space of the upper aerodigestive tract. In some instances, open approaches to gain adequate exposure are employed to ensure adequate access and resection. Transoral Robotic Surgery (TORS) has attracted early adoption due to the ability to enhance dexterity in the deep regions of the upper airway while continuing to utilize the mouth as a natural orifice. This potential led to the FDA approval of TORS in December 2009.

Early studies in robotic surgery have established the procedure as predominantly safe. While a growing number of studies are establishing the efficacy of TORS, its cost compared to open procedures is unknown. Ultimately, the future application of robotic surgery rests upon an appropriate balance of safety, efficacy, and cost. This study aims to establish the clinical and cost effectiveness of TORS compared to open surgery using the Nationwide Inpatient Sample. To establish comparable procedure-specific cohorts, we limited this study to the two more frequently procedures for TORS: partial pharyngectomy and partial glossectomy.

## Methods

The Nationwide Inpatient Sample is a national database funded by the United States Agency for Healthcare Research and Quality (AHRQ). It is the largest all-payer inpatient health care database in the United States and collects data from a 20% stratified sample of the hospitals around the country. Weight coefficients for each hospital are provided to yield national estimates of inpatient stays. Data from admission to discharge are included for each patient

in this database including charge and cost data. Financial data were inflation-adjusted to reflect 2013 equivalents<sup>4</sup>.

Nationwide Inpatient Sample data were obtained according to the Agency for Healthcare Research and Quality (AHRQ) guidelines. The years 2008 to 2011 were selected due to the introduction of the International Classification of Diseases-9<sup>th</sup> Revision, Clinical Modification (ICD-9-CM) code for robotic-assisted surgery (17.4, 17.41, 17.42, 17.43, 17.44, 17.45, 17.49) in 2010, providing 2 years of data before and after FDA approval. These 4 years were analyzed to determine overall trends in utilization before and after FDA approval of TORS. The remainder of the analysis of partial pharyngectomy and partial glossectomy, however, was restricted to the years 2010 to 2011 in order to compare post-FDA approval cohorts and to exclude investigational cases. Given the lack of an ICD-9-CM code for transoral laser microsurgery (TLM), no specific analysis could be made on this group. Based on coding limitations, the open group includes both conventional open cases and TLM cases.

Patients were identified by ICD-9-CM procedure codes for partial pharyngectomy (29.33) and partial glossectomy (25.1, 25.2) and were restricted to patients with a diagnosis code specifying malignancy of the oropharynx (146.0, 146.1, 146.2, 146.3, 146.4, 146.5, 146.6, 146.7, 146.8, 146.9), base of tongue (141.0), or anterior tongue (141.1, 141.2, 141.3, 141.4, 141.5, 141.8, 141.9), respectively. Given that robotic assistance is unlikely to be considered for emergent cases, the analysis was also limited to elective cases only. Same-stay tracheostomy placement (31.1, 31.2, 31.29) or gastrostomy placement (43.1, 43.11, 43.19) were also identified. Preoperative risk factors including history of alcohol use (305.0, 30.500, V11.3), history of tobacco use (V15.82, 30.51), history of radiation therapy (V15.3), history of chemotherapy (V87.41), HPV diagnosis (079.4), tracheostomy present on admission (V44.0), gastrostomy present on admission (V44.1) were designated for each patient. Same-stay complications including blood transfusion during stay, respiratory failure/insufficiency or arrest, aspiration pneumonia, wound fistula, perioperative hemorrhage, wound breakdown, reintubation, dysphagia and death were identified for each patient. The primary endpoints of this study were any complication, length of stay, and charge/cost.

Sub-group analysis was performed when preoperative risk factors between treatment groups differed. The All Patient Refined Diagnosis Related Groups (APR-DRGs) as defined by the NIS are included for Severity of Illness, which refers to the extent of physiologic decompensation or organ system loss of function, and Risk of Mortality. According to the developers of the APR-DRG, “a high severity of illness or risk of mortality are primarily determined by the interaction of multiple diseases. Patients with multiple comorbid conditions involving multiple organ systems represent difficult-to-treat patients who tend to have poorer outcomes”<sup>5</sup>.

## Results

### Overall Trends in TORS

The percentage of transoral cases performed with robotic-assistance increased dramatically over the first 3 years (0.02% in 2008, 0.2% in 2009, 2.1% in 2010, 2.2% in 2011). During

the 4-year study period, 1,907 (75%) of the 2,538 TORS cases were performed for oncologic indications. This is in contrast to 217,105 open cases of which 32% were performed for oncologic indications (**Table 1**). An increasing proportion of TORS cases were performed for non-oncologic indications, with the largest contributor being tonsillectomy for hypertrophy.

### Partial Pharyngectomy

There were a total of 1,426 open partial pharyngectomies and 641 robotic partial pharyngectomies performed electively for oropharyngeal neoplasm during 2010 to 2011. Open patients were the same age (59.3 vs 59.1 years,  $p=0.547$ ) and female sex (21.2% vs 23.1%,  $p=0.357$ ) as the TORS group but had more chronic conditions (4.7 vs 4.2,  $p<0.001$ ), more diagnoses (8.3 vs 7.0,  $p<0.001$ ), worse APR-DRG severity of illness, were more likely to have a history of radiation therapy, alcohol abuse and a tracheostomy on admission.

In order to compare similar groups, both treatment groups were stratified into mild-to-moderate and major-to-extreme APR-DRG Severity of Illness groups. This yielded a stratification that better grouped cohorts by their disease state and other comorbidities. Among mild-to-moderate cases, TORS was associated with significantly fewer respiratory, bleeding, and wound complications (**Table 2a**). No deaths occurred in either treatment group. However, TORS cases did have higher rates of dysphagia. TORS also had shorter hospital stays (3.7 vs 5.2 days,  $p<0.001$ ) and substantially lower hospital total charge and cost. TORS also afforded a greater proportion of patients to be discharged home.

Among major-to-extreme cases, the open group had more comorbidities including a history of alcohol, history of radiation therapy, and more chronic conditions. Length of stay, charge, and cost data favored TORS (**Table 2b**). However, TORS had increased dysphagia and pulmonary complications, while open cases had more wound complications. Of note, tracheostomy placement and gastrostomy placement were significantly higher for open cases. There was no difference in disposition to home within the major-to-extreme partial pharyngectomy group.

### Partial Glossectomy

The large majority of elective partial glossectomies for tongue neoplasm were performed with open surgery (95%). In order to compare similar groups, we separately analyzed anterior tongue and base of tongue neoplasms.

The TORS and open cohorts for base of tongue neoplasms had similar comorbidities (**Table 3**). The TORS group was younger, consisted of more men, had more history of radiation, and less smoking history. TORS again achieved a shorter length of stay (4.8 vs 7.8 days,  $p<0.001$ ), significantly lower cost and charge. In addition, TORS patients while they had higher rates of existing tracheostomies on admission, had fewer tracheostomy placed. In this cohort, however, TORS had higher respiratory complications, higher rates of dysphagia, but fewer wound or bleeding complications.

For the anterior tongue cancer cases, we restricted the analysis to mild-to-moderate severity of illness due to the low number of major-to-extreme cases. Among partial glossectomies for

anterior tongue cancer, TORS patients continued to have higher comorbidities but had comparable severity of illness (**Table 4**). Length of stay was longer for TORS patients while charge and cost data were not significantly different from open cases. TORS also had higher gastrostomy placement rates, reintubation rates, and dysphagia. High rates of discharge to home were achieved across both treatment groups.

## Discussion

There was exponential growth of TORS in its first year following FDA approval in late 2009 with a subsequent plateau. Its early implementation has been predominantly for oncologic indications. TORS for partial pharyngectomy and partial glossectomy for the base of tongue were associated with shorter hospital stays, lower charge and lower cost compared to open partial pharyngectomy. TORS for partial glossectomy of the anterior tongue, however, was inferior to open surgery in both clinical and cost measures. This parity suggests that the utility of TORS is in accessing challenging anatomic sites such as the oropharynx and base of tongue. In contrast, the anterior tongue can be readily accessed with or without a robot and subsequently demonstrates no benefit with a TORS approach.

Our results may also suggest that the extent of the surgery relates to the efficacy of TORS. While TORS for mild-to-moderate disease had fewer complications than open cases, TORS for major-to-severe disease had more complications than open cases of the same severity. Interestingly, this higher rate of complications does not diminish the length of stay, charge/cost and disposition to home benefits realized by TORS.

This study affords a unique view of national charge and cost data for open and TORS cases across the entire inpatient stay. One early study examining cost using the NIS for years prior to FDA approval do support the notion that TORS can be performed successfully while maintaining low cost<sup>6</sup>. While the data do support selective use of TORS in partial pharyngectomy in patients with low comorbidity, it should be noted that cost also correlates with covariates that likely affect such as number of procedures, number of diagnoses, and death during hospitalization. This makes isolating causes for lower comparative cost of TORS challenging. It is possible that the severity of the complications may be higher in open surgery despite the overall rate being lower. Severity of complication has been demonstrated to correlate with additive cost<sup>7</sup>. When viewed in an aggregate, however, the data supports the notion that TORS partial pharyngectomy affords shorter hospital stays and lower hospital costs<sup>8</sup>.

Another intriguing contribution to cost efficacy is that TORS appears safe despite the absence of adjunctive tracheostomy and gastrostomy procedures. Prior studies do demonstrate low tracheostomy and gastrostomy placement rates with TORS<sup>9</sup>. To this point, prior studies on charge and cost correlate postoperative respiratory failure as a significant contributor to postoperative costs<sup>10</sup>. Furthermore, gastrostomy placement and subsequent care has been shown to be cost-efficient or costly depending on the prophylactic or emergent context of its placement<sup>11</sup>. While the NIS does not specify the context of gastrostomy placement, the data demonstrates that TORS can be performed with drastically lower rates

of tracheostomy and gastrostomy placement within the same hospital stay. This is a finding that bears further study and may reshape the approach to these supportive procedures.

Charge and cost data must be carefully interpreted given that the NIS provides data on the index admission alone. Therefore, uncomplicated discharges that later develop into complicated cases would not be incorporated into these data. In addition, while our control of severity demonstrates comparable subgroups, further analysis to ensure appropriate control of other biases such as cancer stage is warranted.

One important aspect of TORS that our study does not address is margin assessment. While TORS confers short-term clinical and cost benefit, tactile feedback during resection is diminished with this technique. A recent multicenter TORS study reported a positive margin rate of 4.3%<sup>12</sup>. Other smaller series report positive margin rates from 0% to 7% among varied cohorts<sup>9,13-17</sup>. Longer-term oncologic studies that are ongoing will clarify the ability to achieve locoregional control with TORS.

Due to the limitations of code availability, a direct comparison of transoral laser microsurgery (TLM), the best modern era comparator group for TORS, was not possible using the Nationwide Inpatient Sample. It stands to reason that the less invasive modality of TLM might yield cost and clinical outcomes closer to that of TORS. However, there is little available data on the comparative cost of TLM. Future studies that included TLM as a discrete comparison group to TORS would be highly informative with regards to decision-making on surgical modality.

Finally, an important limitation of this study is the inherent bias of retrospective analysis of a national database. While we controlled for severity of illness in this study, the control for selection bias between two different treatment groups is not possible, particularly at this early stage of TORS adoption. The adoption of any new technology may be biased towards patients who would be able to tolerate a less known entity. We do believe the results provide novel insight on how TORS may be safely and effectively implemented in its early phase of adoption.

## Conclusion

Our findings demonstrate cost effectiveness of TORS partial pharyngectomy and partial glossectomy for the base of tongue but no benefit in partial glossectomy of the anterior tongue. Anatomic accessibility and extent of surgery likely factor into the effectiveness of TORS. While cost is perceived as a major barrier to adoption of TORS, our results support the length of stay and financial benefits associated with robotic surgery in the oropharynx. As more cases are accrued nationally, studies that investigate oncologic outcome, surgical outcome and overall cost will help guide how we apply TORS going forward.

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**Table 1**

Annual Trends in TORS

	2008		2009		2010		2011		Total	
	Non-Onc	Oncologic	Non-Onc	Oncologic	Non-Onc	Oncologic	Non-Onc	Oncologic	Non-Onc	Oncologic
# Discharges	39,885,120		39,434,956		39,008,298		38,590,733		156,919,107	
# Major OR Procedures	11,902,905		11,587,089		11,345,859		11,143,990		45,979,843	
# Transoral Procedures	56,025		51,020		58,150		54,458		219,653	
	39,134	16,881	33,477	17,421	37,199	19,742	37,504	15,757	147,314	69,791
Conventional	0	10	5	117	241	968	385	812	631	1,907
TORS										



A-B: Subgroup Analysis by Severity of Illness on Open versus TORS Elective Partial Pharyngectomies for Oropharyngeal Neoplasm in 2010 to 2011

Table 2

Demographics	A. Mild-to-Moderate			B. Major-to-Extreme		
	Conventional N=939	Robotic N=523	P	Conventional N=487	Robotic N=118	P
Mean Age (years)	58.9 ± 10.4	59.0 ± 10.1	0.805	60.3 ± 9.9	59.3 ± 11.4	0.339
Sex-Female	22.9%	23.3%	0.846	18.1%	22.0%	0.359
Hx ETOH	2.6%	1.7%	0.361	7.0%	0	0.001
Hx Tobacco	46.8%	47.2%	0.870	52.7%	43.2%	0.081
HPV	2.7%	1.9%	0.476	4.3%	4.2%	1.000
Hx XRT	5.1%	3.1%	0.082	13.2%	4.2%	0.005
Hx Chemo	2.7%	1.0%	0.033	8.2%	14.4%	0.052
# Chronic Conditions	4.0 ± 2.0	3.9 ± 2.1	0.626	6.2 ± 2.7	5.4 ± 2.0	0.004
Severity 2 (Moderate)	67.7%	61.6%	0.019	29.4%	20.3%	0.051
Trach Status	1.5%	0	0.003	72.1%	14.3%	<0.001
Gastrostomy Status	2.6%	5.2%	0.011	34.1%	13.6%	<0.001
Inpatient Data						
Mean Length of Stay (days)	5.2 ± 3.4	3.7 ± 2.2	<0.001	12.4 ± 10.9	7.6 ± 7.0	<0.001
Mean Total Charges (\$)	98,228 ± 84,889	67,317 ± 39,284	<0.001	204,129 ± 170,540	131,737 ± 73,367	<0.001
Mean Total Cost (\$)	29,365 ± 23,042	20,706 ± 11,520	<0.001	58,904 ± 43,747	44,800 ± 30,318	0.001
# Diagnoses	6.4 ± 3.0	6.1 ± 3.3	0.107	12.1 ± 4.9	11.1 ± 4.3	<0.001
# Procedures	5.3 ± 2.3	4.9 ± 1.5	0.001	8.2 ± 3.8	6.8 ± 3.1	0.022
Trach Placed	26.9%	1.0%	<0.001	72.1%	14.3%	<0.001
Gastrostomy Placed	11.6%	1.7%	<0.001	34.1%	13.6%	<0.001
Discharged Home/Home Health	93.6%	99.0%	<0.001	71.8%	78.8%	0.133
Complications						
Died During Hospitalization	0	0	---	2.1%	4.2%	0.186
Blood Transfusion During Stay	3.1%	0	<0.001	18.7%	21.2%	0.602
Respiratory Failure/Insuff/Arrest	2.7%	2.1%	0.599	48.3%	68.6%	<0.001
Aspiration PNA	0	0	---	6.2%	16.9%	0.001
Fistula	1.1%	1.0%	1.000	4.1%	0	0.019

Demographics	A. Mild-to-Moderate		B. Major-to-Extreme		P
	Conventional N=939	Robotic N=523	Conventional N=487	Robotic N=118	
Periop Hemorrhage	2.8%	3.1%	4.3%	8.5%	0.099
Wound Breakdown	1.1%	0	10.5%	0	<0.001
Reintubation	2.2%	1.0%	2.3%	17.8%	<0.001
Dysphagia	8.0%	19.5%	24.7%	35.3%	0.021

Open versus TORS Elective Partial Glossectomy for Base of Tongue Neoplasm in 2010 to 2011

Table 3

Demographics	Mild-to-Moderate		P
	Conventional N=747	Robotic N=147	
Mean Age (years)	59.9 ± 3.3	56.5 ± 11.9	0.004
Sex-Female	38.2%	17.6%	<0.001
Hx ETOH	1.5%	3.4%	0.163
Hx Tobacco	44.0%	29.9%	0.002
HPV	2.1%	7.4%	0.002
Hx XRT	8.2%	17.6%	0.001
Hx Chemo	4.6%	10.2%	0.010
# Chronic Conditions	4.01 ± 2.21	3.48 ± 1.82	0.007
Severity 2 (Moderate)	58.2%	61.2%	0.522
Trach Status	0.7%	3.4%	0.014
Gastrostomy Status	1.9%	3.4%	0.221
Inpatient Data			
Mean Length of Stay (days)	5.06 ± 3.95	3.54 ± 2.61	<0.001
Mean Total Charges (\$)	68,605 ± 56,645	52,054 ± 31,134	0.001
Mean Total Cost (\$)	23,414 ± 15,904	19,091 ± 8877	0.003
# Diagnoses	6.54 ± 3.31	5.76 ± 3.55	0.010
# Procedures	4.45 ± 2.89	4.43 ± 2.49	0.955
Trach Placed	27.6%	4.1%	<0.001
Gastrostomy Placed	11.5%	17.7%	0.055
Discharged Home/Home Health	94.8%	96.6%	0.411
Complications			
Died During Hospitalization	0	0	---
Blood Transfusion During Stay	2.3%	0	0.092
Respiratory Failure/Insuff/Arrest	3.6%	10.1%	0.002
Aspiration PNA	0	0	---
Fistula	1.3%	0	0.383

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Demographics	Mild-to-Moderate		P
	Conventional N=747	Robotic N=147	
Periop Hemorrhage	0	0	---
Wound Breakdown	1.3%	0	0.383
Reintubation	1.3%	3.4%	0.084
Dysphagia	6.0%	10.2%	0.071

Open versus TORS Elective Partial Glossectomy for Anterior Tongue Neoplasm in 2010 to 2011

Table 4

Demographics	Mild-to-Moderate			P
	Conventional N=3915	Robotic N=68		
Mean Age (years)	60.1 ± 14.4	59.6 ± 18.2		0.775
Sex-Female	44.8%	27.9%		0.006
Hx ETOH	1.7%	7.2%		0.007
Hx Tobacco	43.2%	64.7%		<0.001
HPV	1.0%	0		1.000
Hx XRT	4.0%	13.2%		0.002
Hx Chemo	1.6%	7.2%		0.006
# Chronic Conditions	3.9 ± 2.2	4.5 ± 2.1		0.044
Severity 2 (Moderate)	45.1%	49.3%		0.542
Trach Status	0.1%	0		1.000
Gastrostomy Status	1.6%	0		0.627
Inpatient Data				
Mean Length of Stay (days)	4.0 ± 3.3	4.8 ± 3.1		0.044
Mean Total Charges (\$)	59,906 ± 51,609	71,478 ± 38,825		0.066
Mean Total Cost (\$)	21,376 ± 17,154	22,111 ± 15,044		0.744
# Diagnoses	6.0 ± 3.6	7.5 ± 3.4		0.001
# Procedures	3.8 ± 2.5	4.2 ± 1.8		0.151
Trach Placed	19.1%	7.4%		0.012
Gastrostomy Placed	5.1%	14.5%		0.003
Discharge Home or Home Health	96.1%	100%		0.113
Complications				
Died During Hospitalization	0	0		---
Blood Transfusion During Stay	2.6%	0		0.419
Respiratory Failure/Insuff/Arrest	1.2%	0		1.000
Aspiration PNA	0	0		---
Fistula	0.1%	0		1.000

Demographics	Mild-to-Moderate		P
	Conventional N=3915	Robotic N=68	
Periop Hemorrhage	0.9%	0	1.000
Wound Breakdown	1.7%	0	0.629
Reintubation	0.7%	7.2%	<0.001
Dysphagia	4.9%	14.7%	0.002