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Early adoption of transoral robotic surgical program: preliminary outcomes.

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Key Words: Transoral robotic surgery (TORS), Oropharyngeal, Squamous Cell Carcinoma

Objective: The objective of this study is to demonstrate the feasibility and safety of establishing a transoral robotic surgical (TORS) program in the post-FDA approval setting. Early outcomes are compared to the previously reported results of pioneering centers.

Study Design: Clinical data from prospective TORS study.

Setting: Academic University Institution

Subjects and Methods: Sixty-one patients treated with 63 TORS procedures. Main-outcome measures: Intra-operative times, margins, complications, time to diet and PEG tube rate. We also report our oncologic outcomes on our first 30 patients.

Results: The spectrum of sub-sites included tongue base, tonsil, parapharyngeal space, retromolar trigone, supraglottis and posterior pharyngeal wall. Surgical console time averaged 79 minutes (±53 min). After re-resection of 4 patients, final negative margin status was 94% (50/53). A subset of 30 patients with squamous cell carcinoma reaching an average of 18 months follow-up had a local regional control rate of 97% with a disease free survival rate of 90%. Peg tube retention rate of 7%. Complications included two readmissions with dehydration, one aspiration pneumonia, and two with minor oropharyngeal bleeding. 91% of patients resumed oral diet by the first postoperative visit.

Conclusions: The initiation of a TORS program in the post-FDA setting can be achieved in a safe and efficient manner. Early results of pioneering TORS centers are reproducible. Continued investigation of TORS as a treatment option for oropharygneal carcinoma is warranted.

Introduction

Transoral Robotic Surgery (TORS) was approved by the United States Food and Drug Administration (FDA) in December of 2009. Cited technical advantages includemagnification and three-dimensional optics along with the ability to visualize and dissect around corners due to angled endoscopes and the maneuverability of the robotic instrumentation[1,2,3,4]. Since then, clinical data from pioneering TORS centers has emerged. These studies report encouraging early outcomes with respect to disease control and swallowing[5,6,7,8,9,10,11,12,13]. In order for a new treatment modality to be safely applied in a widespread manner, however, it must be demonstrated that the results of the pioneering studies are reproducible by adopters of the technology. To date, the majority of published series reflect data collected in a pre-FDA approval protocol setting. The objective of this study is to demonstrate the feasibility and safety of establishing a TORS program in the post-FDA approval setting. Early outcomes are compared to the previously reported results of pioneering centers.

Methods:

Institutional review board approval was obtained from Thomas Jefferson University Office of Human Research. All patients undergoing TORS between March 2010 and October 2011 at Thomas Jefferson University Hospital were included in the study. The senior surgeon (DMC) completed the post-FDA approval TORS clinical training pathway with Intuitive Surgical and the University of Pennsylvania in March of 2010. Intraoperative data including setup, docking and console times, estimated blood loss, margin status, airway status, neck dissection, and reconstruction were collected prospectively. Each patient was further analyzed for post-operative resumption of oral diet, final pathologic margin status and adjuvant therapy. All patients underwent pre-operative MRI or contrast-enhanced CT scan to assess tumor extent and the location of the carotid artery. A pre-operative PET-CT scan was also performed in all patient with confirmed malignancy. Resections were performed in an en bloc fashion. Two specimens

were bisected during dissection to facilitate removal due to size and location of tumor (1 supraglottis; 1 hypopharynx.) Radical tonsillectomy included resection of the underlying constrictor muscle as previously described by Weinstein et al.[11] Preliminary oncologic outcomes and gastrostomy tube retention were reviewed for the first 30 oncologic patients to allow for at least 12-month average follow up.

Results:

Patient population

A total of 61 patients underwent 63 TORS procedures. The average age was 59 and 75% were male. The majority of the cases (88%) were for malignancy. Staging characteristics are reviewed in table 1. Of patients with malignancy, 7 had a history of previous treatment for head and neck cancer. Squamous cell carcinoma (SCC) was present in 52/53 patients with mucoepidermoid carcinoma representing the single other malignancy. TORS resection location is presented in Table 1.

Intraoperative details

Estimated blood loss was 35 cc ranging from 5-100 cc. The average time spent optimizing exposure and docking the robot was 20 ± 8 minutes with an average total console time (TORS operative time) of 79 ± 53 minutes. Docking to undocking took on average 144 ± 96 minutes, which included the console time as well as awaiting frozen sectioning results and hemostasis. Evaluation of the average console times for subsites demonstrated that radical tonsillectomies required 58 (±26) minutes, tongue base 98 (±59) minutes and supraglottis/hypopharynx 109 (±51) minutes. No trend towards decreased console time was noted in the overall group, but the average time for the last 5 radical tonsillectomies was lower than the first 5 radical tonsillectomies (42 min vs 60 min). Average length of stay was 2.7 days with a range of

1-21 days. The majority (62%) had length of stay 2 days or less with 84% being discharged by POD #3. The patient with the 21-day length of stay underwent staged neck dissections during the same hospitalization.

Complications

There were no peri-operative deaths or major complications. Five patients were re-admitted in the post-operative setting. Two were readmitted for dehydration. Both were managed with supportive care and quickly resumed normal diet. One patient was re-admitted with aspiration pneumonia. In this patient TORS was treatment for a second primary tumor in the base of tongue in a patient who had previously had an ipsilateral radical neck dissection as well as radiation and chemotherapy. He has resumed a partial oral diet. Two were readmitted for minor oropharyngeal bleeding. One patient was observed overnight without further bleeding. The other patient was taken to the operating room and controlled with cautery.

Airway management

All patients were assessed for extubation at the conclusion of the case. Patients were left intubated at the discretion of the surgeon based on intraoperative edema, post-operative bleeding risk, patient anatomy/habitus, and site and extent of dissection. The majority of patients (76%) were extubated at the conclusion of the procedure. Review of the most common subsites demonstrated that only 12% (3/24) of patients undergoing tonsillar resections were left intubated at the conclusion of the procedure, whereas 24% (7/29) of patients with base of tongue resections were left intubated. All patients not requiring tracheostomy tube placement were extubated within 36 hours of the procedure. Two patients had tracheostomy tubes in the perioperative setting. One patient had a tracheostomy tube placed prior to TORS due to a large base of tongue cancer. He was decannulated on post-operative day 20. The second had a tracheostomy tube placed at the time of hypopharyngectomy in part for tumor access and

in part for baseline chronic obstructive pulmonary disease. She was decannulated on post-operative day 9.

Post-operative diet

All patients were evaluated by a speech pathologist prior to discharge from the hospital. Most patients resumed an oral diet on the first or second post-operative day. At the first post-operative visit 52 (83%) of patients were on a strictly oral diet, 5 (8%) of patients were on an oral diet with tube feed supplementation and 6 (9%) of patients were NPO.

Neck dissection

Neck dissection was performed in 39/53 oncologic patients. Neck dissection(s) was performed concurrently with TORS in 18/39 (46%) cases and in a staged fashion in 21 (54%) cases. The median time between operations in the staged group was 12 days with a range from 1 to 50 days. Factors influencing the decision for timing of neck dissection included concern for fistula based on size and site of TORS defect as well as operating room availability. In two patients (1=concurrent, 1 = staged), intraoperative communication between the TORS dissection bed and neck dissection was encountered. Both were managed with fascial closure and re-enforcing local muscle flap. No patients developed post-operative fistulae.

Margin Status

Negative margins were achieved at the initial TORS in 46 (87%) of the oncologic patients (table 2). In 2 patients, an intra-operative negative margin on frozen section was subsequently determined to be positive on final pathology. Re-resection at subsequent operative setting was performed in 4 of the patients with initial positive margins decreasing the overall negative margin rate to 94%. In 3 of these 4

patients, there was no tumor in the re-resection specimen. None of these 4 patients recurred at the TORS site. The management of positive margins with associated outcomes is illustrated in table 2.

Adjuvant therapy

All oncologic patients were discussed at our multidisciplinary tumor board. All patients with extracapsular nodal extention or positive surgical margins were recommended to undergo chemoradiotherapy. Adjuvant treatments for our first 30 oncologic patients are presented in table3. Within the chemotherapy group, 6 patients received platinum based regimen and 5 patients received Erbitux. The chemoradiotherapy group had patients with extensive neck disease (N2a or greater) and primary lesions ranging from T1-T3.

Outcomes

To allow for one-year outcomes data, only the first half of the cohort was included in the survival and PEG-dependence analysis. This included 30 patients with a median follow up of 18.9 months (range 12-22 months. In patients where TORS represented initial head and neck cancer treatment, all were alive at last follow-up. No evidence of disease was present in 24/25 and one was alive with distant metastases. In patients who had a history of prior head and neck cancer and treatment, 3 are alive with no evidence of disease and 2 died of disease. One of these patients had a history of Fanconi's anemia and multiple previous head and neck cancers and died after developing additional primary tumors and regional and distant disease. He died without evidence of disease at the TORS resection site. The second patient underwent TORS for a posterior floor of mouth SCC, which represented a second primary tumor after previous surgery and radiation for an ipsilateral anterior lateral tongue SCC. She developed a deep recurrence at the TORS resection site as well as an additional primary tumor in the contralateral pharynx and refused further intervention. The overall one-year recurrence free survival was 27/30(90%) with an overall local control of 29/30 (97%).

At last follow-up, a total of 2 surviving patients of this group retained a gastrostomy tube. One patient had a history of previous radiation, chemotherapy, and radical neck dissection ipsilateral to the TORS base of tongue resection. Baseline hypoglossal nerve palsy was noted pre-TORS. The other patient resumed oral diet prior to initiating adjuvant chemoradiation and subsequently regressed. Both patients currently maintain a partial oral diet.

Discussion:

Prior to the era of chemoradiation, surgery was commonly used in the management of oropharyngeal tumors. A review of the National Cancer Data Base between 1986 and 1995 demonstrated that surgery alone or with radiation was used in the management of 42.7% of base of tongue tumors[14]. During the same time period, definitive chemoradiation was used in just 14.5% of cases. Gourin and Johnson described the outcomes of the primary surgical management of base of tongue tumors at the University of Pittsburgh for nearly the same time period[15]. The vast majority were open transcervical approaches and most received adjuvant radiation, either alone (91%) or with chemotherapy(26%). Local control rates were 100% for T1 lesions, 97% for T2 lesions, 96% for T3 lesions and 85% for T4 lesions. The disease specific survival for Stage II and Stage IV disease were 62% and 48%. In the retrospective database sample of 16, 188 base of tongue cancers, the inclusion of surgery in the treatment approach was associated with better survival for both early and advanced staged tumors[14].

Despite excellent local control rates with primary surgery, Gourin and Johnson reported that they had begun to offer non-surgical approaches to patients with advanced primary tumors due to poor functional outcomes and limited overall survival[15]. Reflective of this rationale, the past few decades have seen a trend towards CRT as the primary treatment for pharyngeal carcinomas. Indeed, the use of definitive chemoradiotherapy in the treatment of advanced oropharyngeal doubled between 1985 and 2001[16].

To date, there are no randomized trials comparing surgical and non-surgical treatments for oropharyngeal cancers. In 1999, the Groupe d'Oncologie Radiotherapie Tete et Cou (GORTEC) reported the results of a randomized trial of radiation versus radiation combined with carboplatin and 5-fluorouracil for patients with advanced-stage oropharyngeal carcinoma[17,18]. Overall survival, disease free-survival, and locoregional control were all significantly improved in the combined group in comparison to the radiation alone group. At three years, however, these results were only 51%, 42%, and 66%, respectively for the combined arm. It is recognized that the above studies pre-date the impact of human papilloma virus (HPV) on the prognosis of oropharyngeal cancer, but it is evident that the trend away from surgery for the treatment of oropharyngeal cancer was primarily based on concerns with functional outcomes of surgical approaches and not due to oncologic benefit of non-surgical approaches.

More recently, concerns have emerged regarding toxicity and functional outcomes with CRT for treatment of head and neck cancer. Machtay pooled the data from the concurrent CRT arms of 3 randomized RTOG trials to analyze factors associated with severe late toxicity of this treatment approach[19]. Even after eliminating patients with severe laryngopharygneal dysfunction at pre-treatment baseline and patients with locoregional failure or death due to cancer, the rate of severe late toxicity was 43%. As such, it is appropriate that primary surgical approaches are being re-evaluated to address these issues. One advantage of primary surgical approach is pathologic staging, which allows for individualized use of radiation and chemotherapy in the adjuvant setting. Six previous reports in conjunction with this series demonstrated that 8-37% of patients were spared radiation and 48-74% of patients did not require chemotherapy after TORS[2,6,8,12,20,21](table 3). This selective approach has the potential to reduce toxicity and reserve treatment modalities for second primary tumors or recurrences.

. Transoral laser microsurgery (TLM) has been shown to have outstanding local control without the morbidity of open approaches. A multi-center trial of TLM for advanced-stage oropharyngeal cancer demonstrated 3-year overall, disease-specific, and disease-free survival of 86%, 88%, and 82%, respectively[22]. To date, TLM has not been widely adopted. One proposed reason for this is a steep perceived learning curve[4]. TORS has been proposed to overcome access issues with a shorter learning curve[4,23]. Imperative to the success of TORS is the ability of adopting institutions to match the outcomes of the pioneering centers that achieved FDA clearance. Outcomes of a controlled protocol setting cannot be assumed to be directly transferrable to the general treatment setting. An example of this is the treatment of advanced laryngeal cancer in the United States over the past 20 years. In 1991 and 2003, The Department of Veterans Affairs Laryngeal Cancer Study Group and RTOG 91-11 demonstrated reasonable survival rates with laryngeal preservation in a subgroup of patients.Since then, there has been a marked trend towards CRT for the treatment of advanced laryngeal cancer[26,27]. However, large database reviews have shown a decrease in survival for patients with advanced laryngeal cancer concurrent with the increased use of CRT[28,29]. This raises questions regarding patient selection and application of technique in the general population.

The current study compares favorably with previously published results of TORS in both execution and efficacy. Our average setup time of 20+/- 8 min is similar to that reported by Lawson et al (24 +/- 14 min) and Hurtuk et al (23 +/- 9 min)[20,23]. Our average console time did not trend lower with time, likely due to the variability in case site and increasing complexity. Anatomic subsite did effect the console time and reflects the increasing complexity with inferior location in the pharynx. Radical tonsillectomy is likely the most reproducible and least anatomically challenging TORS procedure. Analysis of our first 5 cases of radical tonsillectomy compared to our last 5 cases did show a decrease in console time for this procedure from 60 min to 42 min. Our average console time for supraglottic laryngectomies (109 min) compared with previous published data from Lawson (122 min) and Weinstein (92-178min)[23,30].

A negative resection margin is an important prognostic for surgically managed oropharyngeal tumors[15,31]. Margins were deemed negative on the final pathology report of the first TORS procedure for 46/53 (patients treated for malignancy in our series.) In 2 patients, the margins were unclear based on specimen processing and were presumed to be positive. To ensure an accurate margin, the patients underwent re-resection at a second operative setting. In both of these patients, the re-resection specimen did not have tumor. Neither patient received adjuvant therapy and both remain disease-free.

In 2 patients, margins were not cleared intraoperatively at the initial TORS setting. One was cleared with a second TORS procedure and one was treated with adjuvant CRT on the basis of advanced neck disease. In 3 patients, deep margins that were reported as negative on frozen-section returned positive on final pathology. All were deep anterolateral margins in patients with glossotonsillar sulcus involvement. One patient underwent transcervical resection at the time of staged neck dissection and all required adjuvant chemoradiotherapy on the basis of neck disease. After re-resection, negative margins were achieved in 50/53 (94%) patients treated for malignancy. This is comparable to previously reported results (table 3)[2,6,8,12,20,21].

The impact of TORS on airway control and swallowing function is considered less than then impact of open surgical approaches, which frequently require tracheostomy and feeding tube placement. Most patients were extubated at the conclusion of TORS. The location of the tumor resection affected the likelihood of intubation post-operatively. Only 3/21 (14.3%) tonsillar resections remained intubated, whereas 7/22 (31.8%) base of tongue resections and 5/8 (62.5%) supraglottic/hypopharyngeal resections remained intubated. All intubated patients were extubated within 36 hours, with the majority being extubated the morning of POD 1. Our immediate extubation rate of 76% compares favorably with the rate of 68.5% reported by Iseli et al[8]. Most of our patients resumed oral intake by post-operative day 1 with 91% of patients tolerating PO intake at the first post-operative visit. In the

patients who were taking an oral diet with tube feed supplementation, the feeding tube had been placed for anticipated adjuvant therapy with chemoradiation based on clinical staging. The patients who were strictly NPO at the first post-operative visit had undergone either supraglottic laryngectomy (n = 3) or hypopharyngectomy (n = 3) and were NPO at the surgeon's direction due to anticipated risk of aspiration.

Long-term gastrostomy tube (G tube) dependency is often used as a marker of treatment-related late toxicity. In those patients with at least 12 month follow-up, two continued to have a G tube. One patient had a history of previous radical neck dissection, hypoglossal nerve paralysis, and radiation. A G tube remains due to aspiration concerns. The second patient required the G tube during chemoradiation. Both have attained partial oral diets with the greater percentage by mouth. Our series of 7% PEG recidivism is consistent with previously published data from the pioneering TORS centers of 0-17% PEG dependence (Table 3)[2,6,8,12,20,21].

Conclusion

The initiation of a TORS program in the post-FDA setting can be accomplished in a safe and efficient manner. Local regional control of 97% and disease free survival of 90% support strong preliminary oncologic outcomes consistent with pioneering TORS centers. An early return to PO intake without enteral supplementation in 83% of TORS patients, in additional to only two retained G-tubes after adjuvant treatment, supports good functional outcomes. Although these findings require longer follow-up, these results support continued investigation of TORS as a treatment option for oropharyngeal cancer.

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Table 1: Patient Characteristics

Characteristics	**Patient No (%) N=61 Patients**
Pathology	
Squamous cell carcinoma	52 (85%)
Mucoepidermoid carcinoma	1 (2%)
Benign	8 (13%)
Subsite	
Oropharynx	
Tonsil/Tonsillar pillar	21 (33%)
Base of Tongue	22 (34%)
Posterior oropharyngeal wall/soft palate	3 (5%)
Hypopharynx	4 (6%)
Supraglottis	4 (6%)
Oral Cavity	3 (5%)
Parapharyngeal Space	6 (10%)
	TORS for Malignancy (N = 53 patients)
T Stage	
T1	25 (47%)
T2	22 (42%)
T3	6 (11%)
N stage	
N0	20 (37%)
N1	4 (8%)
N2	26 (50%)
N3	3 (5%)
AJCC Stage	
Stage I	11 (21%)
Stage II	11 (21%)
Stage III	2 (4%)
Stage IV	29 (55%)
P16 status	
Positive	32 (62%)
Negative	20 (38%)

Table 2: Margins

Margin status after 1st TORS resection (n=53 cancer cases)	Patient No (%)
Negative	46 (87%)
Positive	7 (13%)

Management of close/ positive margins

Primary	Location	Re-resection	Adjuvant Tx	Outcome
BOT	Deep	2nd TORS	None	DOD (distant)
Glossotonsillar sulcus	Deep	Pharyngotomy with ND	Chemorads	NED at 14 month
Parapharyngeal		2nd TORS	None	NED at 16 months
Tonsillar Pillar	Lateral	Transoral with ND	None	NED at 12 months
BOT	Deep GTS	None	CRT	NED at 12 months
Tonsil	Lateral	None	CRT	NED at 6 months
Tonsil/BOT	Deep GTS	None	CRT	NED at 4 months

Margin status after close/positive margin management (n = 53 cancer cases)	
Negative	50 (94%)
Positive	3 (6%)

Table 3: Study Comparison

	Cognetti Thomas Jefferson (N=30) ¥	Weinstein[2] UPENN (N=31)	Cohen[21] UPENN (N=50)	Iseli[8] Alabama (N=54)	White[12] Mayo/Alabama (N=89)	Hurtuk[20] Ohio State (N=54)	Genden[6] Mt Sinai (N=30)
Adjuvant Treatment							
None	8 (26%)	7 (22%)	9 (18%)	20 (37%)	33 (37%)	5 (9%)	5 (17%)
Radiation alone	11 (37%)	12 (39%)	12 (24%)	17 (31%)	13 (15%)	15 (28%)	11 (36%)
Chemoradiation	11 (37%)€	12 (39%)	27 (54%)	17 (31%)	43 (48%)	34 (63%)	14 (47%)
Retained G tube	2 (7%)	0 (0%)	Not reported	9 (17%)	0 (0%)	4 (7.5%)	0 (0%)
Final Negative Margins	29 (97%)	31 (100%)	47 (94%)	Not Reported	89 (100%)	49 (91%)	30 (100%)
Local Regional Control	29 (97%)	30 (97%)	(98%)	Not Reported	79 (89%)	53 (98%)	27 (91%)
Disease Free Survival	27 (90%)	30 (97%)	(92%)	Not Reported	77 (86%)	52 (96%)	23 (78%)
Average Follow up	18 months	24 months	24 months		24 months	10 months	18 months

¥ Current study: To allow for one-year outcomes data, only those patients that made it to 12 months follow-up were included in the survival and G-tube dependence analysis

€ Six of eleven patients received platinum based chemotherapy with the remaining 5 patients receiving Erbitux.