Transoral Robotic Surgery

Radical Tonsillectomy

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Objective: To describe and show the feasibility of a new surgical technique for transoral robotic surgery (TORS) radical tonsillectomy.

Design: A prospective, phase 1 clinical trial.

Setting: Academic, tertiary referral center.

Patients: A total of 27 participants were prospectively selected using a volunteer sample. All eligible patients agreed to participate in the study.

Interventions: Patients underwent TORS radical tonsillectomy for previously untreated invasive squamous cell carcinoma of the tonsillar region without free-flap reconstruction, staged neck dissection, and adjuvant therapy.

Main Outcome Measures: Outcome measures included final pathologic margin status, need for short- and long-term tracheotomy tube placement, and need for gastrostomy tube feedings among patients with a minimum 6-month follow-up. The incidence of significant postoperative complications was recorded.

Results: No mortality occurred. Final margins found to be negative for cancer were achieved in 25 of 27 patients (93%). Surgical complications included 1 case each of postoperative mucosal bleeding, delirium tremens, unplanned tracheotomy for temporary exacerbation of sleep apnea, and hypernasality and 2 cases of moderate trismus. Twenty-six of 27 patients (96%) were swallowing without the use of a gastrostomy.

Conclusions: Radical tonsillectomy using TORS is a new technique that offers excellent access for resection of carcinomas of the tonsil with acceptable acute morbidity. Future reports will focus on long-term oncologic and functional outcomes.

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METHODS

A human subjects protocol was designed and approved by the Hospital of the University of Pennsylvania, Philadelphia, institutional review board. To be included in the TORS protocol, patients had to (1) be at least age 18 years at the time of treatment; (2) present with indications for diagnostic or therapeutic approaches for benign or malignant diseases of the oral cavity or laryngopharynx; and (3) sign a written informed consent. The exclusion criteria were as follows: (1) unexplained fever and/or untreated, active infection; (2) pregnancy; (3) previous head and neck surgery precluding transoral robotic procedures; (4) presence of medical conditions contraindicating general anesthesia or transoral surgical ap-
approaches; and (5) anatomic characteristics making it impossible for the surgeon to adequately visualize the relevant areas to perform the diagnostic or therapeutic surgical approach transorally.

The major tumor-related contraindications for TORS radical tonsillectomy included (1) unresectability of involved neck nodes; (2) mandibular invasion; (3) tongue base involvement requiring resection of greater than 50% of the tongue base; (4) pharyngeal wall involvement necessitating resection of more than 50% of the posterior pharyngeal wall; (5) radiologic confirmation of carotid artery involvement; and (6) fixation of tumor to the prevertebral fascia. All patients who fulfilled the inclusion criteria, and who were not disqualified based on either the exclusion criteria or the major tumor-related contraindications, were offered TORS radical tonsillectomy as an option. The general practice in most, but not all, patients in our institution is to perform a separate panendoscopy for staging and/or biopsy and percutaneous endoscopic gastrostomy (PEG) on a date prior to primary resection of any head and neck cancer. Our routine was to perform preoperative computed tomography with contrast or a magnetic resonance imaging scan with gadolinium.

The routine approach used for pathologic analysis in this study was a collaborative approach between surgeon and pathologist. The surgeon would bring the primary resection specimen directly to the pathology laboratory for orientation. The specimen was inked by the surgeon with different colors of pathology inks to denote pertinent margins and pinned to cork board and transected to assess the gross extent of the tumor both on the mucosa and in the deep tissues. If the surgeon and pathologist agreed that the margins were grossly negative for cancer, then no frozen sections were obtained, and the specimen underwent processing for permanent margins. If the margins appeared grossly questionable, then either (1) sections were frozen to assess these margins, or (2) no frozen sectioning was performed, and the surgeon returned to the operating room to remove additional soft tissue margin in the area of question. When re-resection was performed, methylene blue was applied topically to the operative bed to ensure proper orientation of the additional margin, and the new specimen was brought to the pathology laboratory by the surgeon for orientation, inking, and pinning prior to processing. When frozen sections were performed and findings were negative for cancer, an additional margin was obtained only if the surgeon believed that the patient would benefit from a wider resection margin.

Neck dissection was routinely offered to all patients. The neck dissections were staged and performed 1 to 3 weeks following TORS radical tonsillectomy. The rationale for staging the neck dissection was to avoid creating a connection between the pharynx and neck as well as to avoid additional laryngopharyngeal swallowing that might result in the need for a tracheotomy. Lymph node levels I through III were dissected, between the pharynx and neck as well as to avoid additional lateral structures invaded by pathologically involved lymph nodes. The surgeons at the University of Pennsylvania agree with recent literature that supports the use of selective neck dissection followed by irradiation with or without chemotherapy for node-positive disease. Comprehensive neck dissection resecting levels I through V, the sternocleidomastoid muscle (SCM), jugular vein, and accessory nerve was performed when these structures were invaded by pathologically involved lymph nodes. The high-risk features in the primary site and neck that were considered indications for postoperative irradiation without chemotherapy included questionable surgical margins and the presence of 2 or more pathologically positive lymph nodes at the time of neck dissection. Relative primary site indications for postoperative radiotherapy without chemotherapy included T4 disease with infiltrative growth patterns and the presence of peri-

our indications for concurrent radiation therapy with cisplatin follow the recommendations reported by Bernier et al in their combined analysis of the 2 randomized trials conducted by the European Organisation for Research and Treatment of Cancer (RTOG), including (1) positive surgical margins and (2) extracapsular extension (ECE). Since patients with multiple nodes without ECE were included in the RTOG high-risk adjuvant therapy trial, we elected to use this finding as a relative same indication for adjuvant chemoradiation. In addition, while the physicians routinely recommended adding concurrent chemotherapy to postoperative irradiation in high-risk cases, some high-risk patients refused chemotherapy to avoid the incremental acute and chronic morbidity. An intensity-modulated radiation therapy technique was used in all patients to reduce the risk of late xerostomia. All patients (except one, who opted to be treated elsewhere) were treated consistently with a simultaneous in-field boost prescription technique using 6 to 9 coplanar 6-MV photon fields. Subclinical elective irradiation of undissected areas received 54 Gy in 30 daily fractions. The areas of the surgical bed without high-risk features received 60 Gy in 30 daily fractions. Simultaneously, the surgical bed containing high-risk features received 63 Gy in 30 fractions at 2.1 Gy per fraction. Positive and questionable margins received 66 Gy at 2.2 Gy per fraction. Finally, because the TORS approach causes less disruption of normal tissue planes than other approaches (such as transmandibular resections), we were able to minimize the volume of normal tissue irradiated at high doses to reduce the risk of acute and late radiation-related complications.

Although a full speech-and-swallowing evaluation was beyond the scope of this feasibility study, a surrogate for a complete swallowing outcomes analysis was resumption of swallowing function without the use of the gastrostomy tube. The preoperative functional status was assessed using the Karnofsky score. The Charlson Comorbidity Index was used to assess the overall health status of the patient prior to treatment. We used the da Vinci Surgical System (Intuitive Surgical Inc, Sunnyvale, California). To operate this system, the surgeon sits at a console located at a distance from the patient. The other system components are the surgical cart and the manipulator unit comprising 3 laterally placed instrument arms and a centrally located endoscopic arm. The endoscope has 2 integrated video cameras that allow the surgeon at the console to view the images 3 dimensionally. Eight- and 5-mm robotic arms are available with numerous miniaturized surgical tools that mimic traditional surgical instrumentation. The working ends of the robotic surgical instruments are “wristed” and completely controlled by the surgeon’s movement of the handles in the console. Computerized motion scaling allows the surgeon’s movements of the handles in the console to be accurately translated to the wristed end effectors. In addition, the system allows for tremor filtration as well as 6° of motion around the wristed instruments.

Our technique is a modification of the transoral lateral oropharyngectomy described by Holsinger et al. As noted in prior reports, the patient is positioned with his or her head at the foot of the bed to allow room for the base of the robotic cart. The nurse sits to the left of the patient; the robotic cart is positioned on the right side of the patient; and the bedside surgical assistant sits at the patient’s head (Figure 1). A wire-reinforced orodontreacheal tube is sutured to both the contralateral nasolabial fold and the buccal mucosa. A Crow-Davis mouth gag is used to expose the pharynx, and this was suspended to the bed via a Storz

neural invasion. Relative neck indications for postoperative radiotherapy alone included the presence of 1 pathologically positive lymph node at the time of neck dissection, which is consistent with the recent literature for selective neck dissection.
scope is based on the extent of cancer involvement (e.g., styloglossus and stylopharyngeus muscles). The dissection is brought to the level of the constrictor muscles, and laterally the pterygoid muscles are elevated off of the prevertebral fascia using blunt dissection. Numerous transverse veins and arteries are clipped with 3 clips on the patient side and 1 clip on the tumor side using a Storz laryngeal clip applier (Karl Storz) and cautery for smaller vessels. Care is taken to make this cut medially to avoid encountering the carotid arterial system.

Attention is then turned to resection at the level of the tongue base. An incision is made across the posterior floor of mouth to the lateral tongue base mucosa. Unlike nonrobotic transoral tonsillectomy in which the exposure of the tongue base is limited, the robotic optics allow for complete visualization of the tongue base, facilitating the routine resection of a margin of normal tongue base mucosa and musculature as a causal margin. The goal of resection is to have negative final pathologic margins. The extent of tongue base resection is based on the extent of the cancer. However, an important part of the preoperative workup is to be certain that not more than half of the tongue base will need to be resected to avoid a poor swallowing outcome. Care must be taken to avoid transecting the lingual artery. If the artery is encountered and needs to be resected, 3 Storz laryngeal clips are applied on the patient side and 1 on the tumor side prior to transection. If bleeding occurs from the lingual artery, external neck pressure applied by an assistant at the level of the greater cornua of the hyoid decreases blood flow and allows for visualization of the bleeding point and application of Storz laryngeal clips. The base of the tongue is resected to the level of the vallecula. The posterior pharyngeal wall is then resected from the vallecula to the level of the soft palate.

An assistant is seated at the patient’s head. Three robotic arms are inserted transorally. The scrub nurse is seated to the left. Nos. 1 and 2 (left lower corner), 2 optional video inputs not being used. Figure 2. Transoral robotic surgery radical tonsillectomy buccal incision. The blue No. 1 indicates that robotic arm 1 is on the patient’s right; blue No. 2, robotic arm 2 is on the patient’s left; blue camera icon (top center), camera foot pedal is engaged, which allows the surgeon to move the camera arm; gray translucent camera icon (right lower corner) illustrates the position of the endoscope relative to the horizon; white camera icon (left lower corner), telestration function on the bedside video screen is inactive; gray translucent Nos. 1 and 2 (left lower corner), 2 optional video inputs not being used.

A pharyngoplasty may be performed, when significant soft palate resection has been performed, by suturing the posterior palatal mucosa to the posterior pharyngeal wall with 3 or 4 Polydura 3-0 sutures (Synteture division of United States Surgical, Norwalk, Connecticut) using a V-20 needle. In cases of carotid exposure, the option is to suture fascial layers over the carotid or allow healing by secondary intention (Figure 4). The remainder of the mucosal defect is routinely allowed to heal by secondary intention. Bleeding is controlled with suction cautery and Storz laryngeal clips. Surgiflo (Johnson & Johnson, New Brunswick, New Jersey) or Floseal (Baxter, Bloomington, Indiana) is applied to the base of the wound and removed in 120 seconds. If there is no evidence of epiglottic edema, the patient is extubated at the end of the procedure. If there is concern for laryngopharyngeal swelling, the patient remains
intubated and is treated with steroids for 1 to 3 days, followed by extubation.

RESULTS

PATIENT POPULATION

After we obtained written informed consent, which included full disclosure of the risks, benefits, and alternatives to TORS radical tonsillectomy with neck dissection, 27 adult volunteers were included in this prospective study. All 27 TORS radical tonsillectomies were performed between May 2005 and April 2007 by 2 of us (G.S.W. and B.W.O.). The age, sex, pathologic grade, Karnofsky score, and Charlson Comorbidity Index are summarized in Table 1.

All cases were discussed at the Penn Center for Head and Neck Cancer multidisciplinary meeting prior to treatment. The TNM stages were as follows: stage II, 3 patients; stage III, 14 patients; and stage IVa, 10 patients (Table 2). While this study did not prohibit enrolling patients with recurrent tumors, none of the tonsillar neoplasms were recurrent. No patients who were candidates for TORS radical tonsillectomy were excluded from participation in the study.

PREOPERATIVE ENDOSCOPY AND TORS FEASIBILITY

Most patients in this series (17 of 27) underwent a separate panendoscopy under general anesthesia during which a PEG tube was placed. The remaining patients were determined to be candidates for TORS radical tonsillectomy in the outpatient setting, and they underwent panendoscopy and PEG tube placement at the same time as the TORS radical tonsillectomy procedure.

After placement of the Crow-Davis retractor, adequate exposure allowed for appropriate visualization for resection in most cases. The FK retractor (Gyrus ENT LLC, Bartlett, Tennessee) was used in 2 cases.

The surgeons successfully performed TORS in all cases. All robotic arms functioned optimally during the procedures, and no interference between robotic arms was noted (Table 3). The mean overall operative time to perform the TORS procedure was 1 hour 43 minutes (range, 26 minutes to 3 hours, 53 minutes), including a mean of 9 minutes for exposure and robotic positioning (range, 2-22 minutes). The operative time included the duration of specimen orientation by the surgeon and the pathologist as well as time for frozen section.

EXTENT OF NECK DISSECTION AND PATHOLOGIC FINDINGS

One patient with a clinically negative neck chose not to undergo neck dissection. One patient underwent bilateral neck dissections sparing the SCMs, jugular veins, and accessory nerves, and lymph node levels I through IV were resected. Among the remaining 25 patients, 12 underwent resection of lymph node levels I through IV; 7 underwent resection of lymph node levels I through III. Among the 12 patients who underwent resection of lymph node levels I through IV, 7 underwent resection of the SCM, jugular vein, and accessory nerve; 1 underwent resection of the SCM sparing the jugular vein and accessory nerve; and 4 had sparing of the SCM, jugular vein, and accessory nerve.

Twenty-six of 27 patients had invasive squamous cell carcinoma; 1 had a basalloid squamous cell carcinoma. Perineural invasion was noted in 2 of 27 patients (8%). Six patients had poorly differentiated squamous cell carcinoma, and 6 patients had moderately to poorly differ-

Table 1. Patient Characteristics

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<tr>
<th>Characteristic</th>
<th>Patients, No. (%) (N=27)</th>
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<tbody>
<tr>
<td>Sex</td>
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<tr>
<td>Male</td>
<td>25 (93)</td>
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Abbreviation: SCC, squamous cell carcinoma.

*Patients ranged in age from 46 to 82 years; mean patient age, 58.2 years.
entiated squamous cell carcinoma (Table 1). Among the 9 patients for whom frozen sections were obtained, the final margins were negative in 8 and uncertain in 1 because of cautery artifact. Negative margins were obtained in the 18 patients who did not undergo frozen sections with the exception of 1 patient who had questionable margins.

Of the 4 patients with clinical stage N0, 1 chose to undergo irradiation and not neck dissection; therefore, no pathologic staging was performed. One patient had 2 positive nodes without ECE, and 2 patients had no positive nodes following neck dissection. Among the 26 patients who underwent neck dissection, 2 had no positive nodes; 10 had 1 positive node; and 14 had more than 1 involved lymph node. Eleven patients were noted to have ECE.

ADJUVANT THERAPY

Two patients (staged T2N0 and T3N0) had negative margins (7%), no perineural invasion, and no pathologically involved lymph nodes; they underwent no postoperative irradiation.

One patient had received prior irradiation and chemotherapy for lymphoma. This patient underwent comprehensive neck dissection resecting lymph node levels I through V as well as the SCM, jugular vein, and accessory nerve. This patient had 1 positive node without ECE and therefore would have undergone irradiation alone postoperatively had he not undergone irradiation previously for lymphoma. He followed the recommendations of his medical oncologist elsewhere and was treated with postoperative chemotherapy alone (4%).

OUTCOMES

One patient was lost to follow-up, and among the remaining 26 patients, there were no local or regional recurrences. One of the 26 patients developed widespread distant metastasis.

The mean blood loss during the TORS procedure was 189 mL (range, 0-500 mL). No transfusions were performed.

One patient underwent planned tracheotomy during the TORS radical tonsillectomy because of concerns about airway swelling. Twenty patients were extubated at the end of the TORS radical tonsillectomy. The remaining 6 patients remained intubated for an average of 2.7 days postoperatively (range, 2-3 days). Following extubation, 1 patient underwent unplanned tracheotomy postoperatively for an exacerbation of his sleep apnea.

All patients underwent percutaneous gastrostomy. At last follow-up, 26 of 27 patients were swallowing without the use of a gastrostomy tube (96%).

COMPLICATIONS

No mortalities occurred. The operative complications occurring within 30 days of the TORS procedure are summarized in Table 4. Three complications occurred in 2 patients: one patient, who was hospitalized when he presented for surgery for neck dissection, experienced delirium tremens from alcohol withdrawal; the other patient had transoral bleeding and underwent cautery of minor mucosal bleeding. This patient also had a preoperative history of sleep apnea, which was exacerbated by the postoperative swelling that occurs in TORS. Therefore, a temporary tracheotomy tube was placed to overcome his obstructive sleep apnea. This procedure was per-
formed when the patient was taken to the operating room to control bleeding.

Two patients had moderate trismus.

One patient had hypernasality of his voice severe enough to undergo surgical resection. A scar band that had formed between his soft palate and his tongue base was removed during this procedure, and the hypernasality resolved.

ROBOTIC ARMS

Early in the study, 5-mm robotic instrumentation was not available at our institution. The most common instruments used were the 8-mm Cadiere forceps and the 8-mm permanent cautery spatula. When 5-mm robotic instrumentation became available, the most common instruments used were the 5-mm Maryland dissector and the 5-mm monopolar cautery with disposable spatula tip. The 8-mm atrial retractor was used with the third arm for cheek retraction in 1 case. Table 3 lists the variety of robotic arms used for the TORS radical tonsillectomy procedures as well as their frequency of use.

With this report, to our knowledge, we add a description of a new procedure to the literature, TORS radical tonsillectomy, which may have benefits over existing approaches. In our experience using either an operative microscope with laser or a headlight with electrocautery to perform nonrobotic transoral surgery, the view of the oropharynx is limited. This is because the line of sight begins at a viewpoint very far from the tonsil, and this limits the view laterally toward the great vessels, superiorly toward the palate and nasopharynx, and inferiorly toward the tongue base. Recently, in cases of limited transoral surgical access, open approaches via mandibu- lotomy with free-flap reconstruction have been advocated.14 However, with improvements in access afforded by the open approach comes an increase in acute morbidity, including the routine need for tracheotomy, complex reconstruction, and prolonged rehabilitation.

The TORS procedure has the advantage of having the tip of the double video endoscope in the patient's mouth, very close to the cancer. When this intraoral viewpoint is coupled with the option of a 30° scope, the limitations imposed by the standard transoral approaches are handily overcome. In addition, since the surgeon now has excellent visualization in all directions, TORS radical tonsillectomy has increased the indications for transoral resection. In particular, TORS allows for concurrent tongue base resection under direct visualization. In addition, the improved lateral view, when coupled with a magnified 3-dimensional view, allows the surgeon to identify small and large vessels for either transection or preservation.

Although the focus of this report is the feasibility of a new surgical technique without long-term oncologic findings, it should be noted that there were no early local or regional recurrences and only 1 distant oncologic failure. These results are encouraging, especially because approxi- mately 90% of the cohort had advanced clinical stage disease (stages III and IV) at the time of TORS. In addition, the Charlson Comorbidity Indexes and the Karnofsky scores were similar to those of patients reported elsewhere undergoing either head and neck surgery or concurrent chemoradiation treatment.15,16 The acute morbidity in terms of surgical complications and swallowing rehabilitation was acceptable.

While the absolute number of acute complications in this series was 5 of 27 (19%), most resolved without significant sequelae (Table 4). The early complication rate is comparable to the rates reported for the alternative therapies of nonrobotic transoral surgery, open surgical resection, and concurrent chemoradiation treatments.12,16 Of interest, a number of acute sequelae reported in the literature for these alternative treatments, including death, pneumonia, and/or fistula, did not occur in our TORS radical tonsillectomy group.12,16

One additional benefit of a primary surgical approach was that the pathologic assessment allowed for almost half of the patients in this series to avoid chemotherapy and 2 to avoid irradiation and chemotherapy entirely. Nonetheless, long-term analysis of this new surgically based, multimodality treatment approach, including evaluation of longer-term swallowing and speech function, degree of neck and shoulder disability, general quality of life, and oncologic outcomes, is needed to assess the risks and benefits of this approach compared with the variety of other surgical and nonsurgical alternatives. Therefore, while the present study proves the feasibility of TORS radical tonsillectomy, further long-term study of this cohort of patients is warranted.

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Author Contributions: Dr Weinstein had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Drs Weinstein and O’Malley are joint first authors. Study concept and design: Weinstein and O’Malley. Acquisition of data: Weinstein, O’Malley, and Snyder. Analysis and interpretation of data: Weinstein, O’Malley, Sherman, and Quon. Drafting of the manuscript: Weinstein, O’Malley, and Sherman. Critical revision of the manuscript for important intellectual content: Weinstein, O’Malley, Snyder, Sherman, and Quon. Administrative, technical, and material support: Weinstein, O’Malley, Snyder, and Quon. Study supervision: Weinstein and O’Malley.

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Additional Contributions: Devraj Basu, MD, assisted in this project.

REFERENCES