

Robot-Assisted Surgery for Upper Aerodigestive Tract Neoplasms

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Objectives: To assess the feasibility and safety of performing robot-assisted resections of head and neck tumors, and to predict which variables lead to successful robot-assisted resection and better functional outcome.

Design: Prospective nonrandomized clinical trial.

Setting: Academic tertiary referral center.

Patients: Thirty-six patients with oral cavity, oropharyngeal, hypopharyngeal, or laryngeal tumors.

Intervention: Robot-assisted resection of indicated tumors.

Main Outcome Measures: Ability to perform robot-assisted resection, final pathologic margin status, ability to extubate postoperatively, need for tracheotomy tube, and need for gastrostomy tube. Any clinically significant complications were recorded.

Results: Thirty-six patients participated in the study. Eight patients had previously been treated for head and neck cancer. Twenty-nine patients (81%) underwent successful robotic resection. Negative margins were ob-

tained in all 29 patients. Twenty-one of 29 patients were safely extubated prior to leaving the operating room. One patient required short-term tracheotomy tube placement. A total of 9 patients were gastrostomy tube dependent (2 preoperatively, 7 postoperatively). Factors associated with successful robotic resection were lower T classification ($P=.01$) and edentulism ($P=.07$). Factors associated with gastrostomy tube dependence were advanced age ($P=.02$), tumor location in the larynx ($P<.001$), higher T classification ($P=.02$), and lower preoperative M. D. Anderson Dysphagia Inventory score ($P=.04$).

Conclusions: Robot-assisted surgery is feasible and safe for the resection of select head and neck tumors. This clinical series demonstrates that robotic surgery can be utilized successfully in patients with T1 to T4 lesions located in the oral cavity, oropharynx, hypopharynx, and larynx with good preservation of swallow function.

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MINIMALLY INVASIVE SURGERY has gained popularity in multiple different specialties as a means to reduce patient morbidity and mortality. The surgical robot provides 3-dimensional visualization and technical advantages allowing procedures to be performed through a minimally invasive route. Since the introduction of the surgical robot in 1999, robot-assisted cardiac, gynecologic, and urologic procedures have become widely accepted throughout the country. In 2007, approximately 60% of all radical prostatectomies in the United States were performed with robot assistance.¹ Robotic cardiac and urological procedures may result in less blood loss and fewer complications than standard open approaches.^{2,3} Use of the robot in cardiac surgery has also had a favorable impact on operative time, intensive care unit

stays, and overall inpatient care days compared with open procedures.⁴

Excision of upper aerodigestive tract tumors commonly requires a transcervical approach including mandibulotomy and lip-splitting incision and may result in poor cosmesis and dysfunctional speech and swallowing.⁵⁻⁷ Preclinical experimental studies using canine and cadaver models demonstrated the technical feasibility of transoral application of the robot.^{8,9} Subsequent trials in patients have demonstrated both the feasibility and the safety of robot-assisted resection of upper aerodigestive tract neoplasms.¹⁰⁻¹² Robotic surgery in the head and neck offers the possibility of limited surgical morbidity, reduced hospital stay, and improved lesion visualization over open approaches and traditional transoral techniques.

Previous publications, largely originating from a single institution, have docu-

Table 1. Baseline Patient Characteristics

Characteristic	Patients, No. (%)
Sex	
Male	30 (83)
Female	6 (18)
Age, mean (SD), y	61.9 (13.1)
Tumor site	
Oral cavity	3 (8)
Oropharyngeal	22 (61)
Hypopharyngeal	1 (3)
Laryngeal	10 (28)
T classification	
T1	10 (28)
T2	19 (53)
T3	3 (8)
T4	4 (11)
Stage	
1	6 (17)
2	8 (22)
3	3 (8)
4	19 (53)

mented the feasibility of using the surgical robot in the head and neck, although overall numbers remain small.¹⁰⁻¹² We assessed the utility of robot-assisted surgery for the excision of upper aerodigestive tract neoplasms and began to characterize patient and clinical predictors of successful robotic resection and functional outcome.

METHODS

A prospective, nonrandomized study of consecutive patients presenting with upper aerodigestive tract neoplasms from March 2007 through May 2008 was performed at the University of Alabama in Birmingham. Institutional review board approval was obtained to perform a clinical trial using the da Vinci Robot (Intuitive Surgical Inc, Sunnyvale, California) for the resection of head and neck tumors. Inclusion criteria included lesions of the oral cavity, oropharynx, hypopharynx, or larynx requiring surgical resection, biopsy, or invasive treatment. Prior to surgery, an in-depth discussion took place with each patient to ascertain preferences for treatment in the event that robotic resection was not successful. Options available to the patients were not limited or compromised by the initial attempt at robotic resection. Tumors invading bone and those predicted to produce a through-and-through defect requiring free-tissue transfer were excluded. Patients unable to provide informed consent and those with poor mouth opening (defined as a maximal opening of <1.5 cm) were also excluded. Patients with oral cavity lesions were included only in the early aspects of the study as the surgeons gained experience with the setup and use of the robot. Later in the study, unless there was accompanying oropharyngeal extension, patients with oral cavity cancers were no longer enrolled because robotic assistance is not usually required to adequately resect these lesions. All patients in this series had biopsy-proven cancer and were evaluated preoperatively by the attending physician with flexible laryngoscopy and computed tomographic (CT) or positron emission tomographic/CT imaging.

The operating room was arranged with the head of the bed rotated 180° from anesthesia, the surgeon's console approximately 8 feet from the head of bed, and the manipulator unit near the patient's left hip. Exposure was obtained using either the FK retractor, the Crowe Davis retractor, or an Andrews

tongue blade and cheek retractor. Resection was performed with robotic assistance in all patients when technically feasible. When technically not feasible, resection was performed by a standard open or endoscopic approach, or the patient was awoken and treated with primary chemoradiation according to predetermined patient preferences. Neck dissection was performed either at the same operation or in a staged operation. Patients were monitored through their hospital stay and up to 3 months postoperatively.

Recorded demographic and clinical data included patient age, sex, tumor site, tumor stage, and any previous head and neck cancer treatment. Recorded operative data included adequacy of exposure, ability to perform robotic resection, robotic operative time, blood loss, intraoperative complications, ability to obtain negative margins, and ability to extubate postoperatively. Postoperative data included length of hospital stay, the date oral nutrition started, diet at discharge, and any postoperative complications.

The primary outcome measure was successful robotic resection, defined as complete resection with negative margins utilizing the surgical robot. Secondary outcomes included surgical complications, tracheotomy or gastrostomy tube dependence, and subjective swallowing function. The M. D. Anderson Dysphagia Inventory (MDADI) was used to assess dysphagia-specific quality of life. This 20-item questionnaire was given to patients preoperatively and at their first postoperative follow-up appointment. The MDADI was scored according to Chen et al¹³ with a range of 0 (extremely low functioning) to 100 (high functioning).

Descriptive variables were assessed as means (SDs) and categorical variables as percentages. Factors were compared across the outcome groups by *t* test for continuous variables and Fisher exact test or χ^2 test for categorical variables. *P* < .05 was deemed statistically significant. The relationship between baseline and postoperative MDADI scores was assessed by the paired *t* test. Data analysis was performed using GraphPad Prism software (GraphPad Software Inc, San Diego, California) or SAS statistical software (version 9.1; SAS Inc, Cary, North Carolina).

RESULTS

A total of 36 patients were identified as candidates for this study from March 2007 through May 2008. Demographic data and tumor characteristics are summarized in **Table 1**. Although most patients had previously untreated lesions, 8 patients had a history of head and neck cancer treatment (**Table 2**).

OPERATIVE DATA

Successful transoral resection using the robot was achieved in 29 patients (81%). One patient could not undergo robotic resection secondary to technical difficulties with the robotic system on the day of operation. Of the 6 patients who underwent unsuccessful procedures, 2 had inadequate exposure (T2, vallecula; T4, base of tongue), and both opted for primary chemoradiation. Early in the series, 1 patient had adequate exposure of the surgical site (T2, epiglottis), but the positioning of robotic arms was inadequate, and carbon dioxide laser resection was performed instead. Two patients had lesions so infiltrative into surrounding structures that the functional benefits of robotic operation would have been lost by necessity for free-flap reconstruction (T2, tonsil; T4, base of tongue). Both of these patients also chose primary che-

Table 2. Summary of Previous Head and Neck Squamous Cell Carcinoma Treatment

Patient	Previous Lesion	Type and Year of Previous Treatment	Current Lesion
1	T3, larynx	Chemoradiation, 2006	T2, oral cavity
2	Tx, pharynx, and T4, larynx	Chemoradiation, 1980s, and resection with free flap, 1999	T1, oropharynx
3	T3, larynx, and T1, oropharynx	Resection with free flap/radiation, 1990, and resection, 2006	T1, oropharynx
4	T3, larynx	Chemoradiation, 2007	Residual T3, larynx
5	T2, larynx	Chemoradiation, 2006	Recurrent T2, larynx
6	T2, larynx	Chemoradiation, 2007	Recurrent T2, larynx
7	T1, oropharynx	Chemoradiation, 2007	Recurrent T2, oropharynx
8	Tx, neck, and T2, oropharynx	Chemoradiation, 2006, and chemoradiation, 2007	Recurrent T2, oropharynx

Table 3. Predictors of Robot-Assisted Resection Success

Factor	No. (%)		P Value
	Successful Resection (n=29 Patients)	Unsuccessful Resection (n=6 Patients)	
Previous RT			.29
Yes	8 (28)	0	
No	21 (72)	6 (100)	
T classification			.01
T1	9 (31)	0	
T2	16 (55)	3 (50)	
T3	3 (10)	0	
T4	1 (4)	3 (50)	
Tumor location			.72
Oral cavity	2 (7)	1 (17)	
Oropharyngeal	19 (66)	3 (50)	
Hypopharyngeal	1 (4)	0	
Laryngeal	7 (24)	2 (33)	
Dentition			.07
Dentate	17 (59)	6 (100)	
Edentulous	12 (42)	0	
Time since study initiation, mo			.37
0-4	8 (28)	3 (50)	
5-8	6 (21)	2 (33)	
9-12	15 (52)	1 (17)	

Abbreviation: RT, radiation therapy.

moradiation. One patient had tumor invasion into the mandible, and the procedure was converted to an open operation (T4, anterior floor of mouth). Patients with unsuccessful resections tended to have higher T stage ($P=.01$), were more likely to have undergone procedures during the early months of the study ($P=.37$), and were more likely to be dentate ($P=.07$) (**Table 3**).

The mean (SD) robotic operative time was 99 (32.6) minutes as recorded in the anesthesia record. Eleven patients (2 with oral cavity lesions, 9 with oropharyngeal lesions) who had robotic resection underwent simultaneous selective neck dissection, whereas 6 patients (5 with oropharyngeal lesions, 1 with laryngeal lesions) underwent selective neck dissection performed at a staged operation. No orocervical fistula resulted from concomitant neck dissection.

Blood loss for robotic resection ranged from 2 to 150 mL (mean [SD], 51 [42] mL). No patient required a transfusion. Adequate hemostasis was achieved intraoperatively in all patients transorally. Two patients had postoperative bleeding. One patient had hemoptysis 3 weeks after surgical resection and required direct laryngoscopy with

Table 4. Tumor Location vs Safe Extubation After Robotic Resection

Tumor Location, No. of Patients	No. (%)	
	Safe Extubation	Intubation or Tracheotomy
Oral cavity, 2	2 (100)	0
Oropharyngeal, 19	15 (79)	4 (21)
Hypopharyngeal, 1	0	1 (100)
Laryngeal, 7	4 (57)	3 (43)

cautery. One patient who was prescribed coumadin experienced oropharyngeal bleeding several days postoperatively, which resolved with medical treatment.

Negative margins by frozen section and confirmed on permanent pathologic findings were obtained for all patients who underwent robotic resection.

POSTOPERATIVE DATA

Twenty-one of 29 patients (72%) were safely extubated prior to leaving the operating room. Seven patients required postoperative intubation (**Table 4**). Five of these 7 were left intubated in a planned manner (2 epiglottal lesions, 3 with base of tongue lesions). Two patients required emergent reintubation in the immediate postoperative period secondary to airway edema (1 with an epiglottal lesion, 1 with a lesion of posterior pharyngeal wall). Two of the 7 patients were extubated after 24 hours, and 5 were extubated after 48 hours. One patient underwent a planned tracheotomy (T2, tongue base tumor) and was decannulated prior to discharge.

The mean (SD) hospital stay for patients who underwent robot-assisted resection was 2.9 (2.9) days (range, 1-13 days). One patient with a 13-day hospital stay had a second primary lesion detected intraoperatively and opted to undergo a second surgery for resection and staged neck dissection performed during the same hospital stay.

Sixteen of the 29 patients (55%) who underwent robotic resection were tolerating oral nutrition prior to discharge. Oral nutrition was started on the day of surgery in 5 patients, on postoperative day 1 in 10 patients, and on postoperative day 2 in 1 patient. Thirteen patients required tube feeding for nutritional support at the time of discharge. Four patients required short-term nasal tube feeding and tolerated all nutrition orally 2 weeks postoperatively. Nine patients had more severe dysphagia and

Table 5. Predictors of Gastrostomy Tube Dependence Among Patients Who Underwent Successful Robotic Resection

Factor	No. (%)		P Value
	Tube Dependence (n=9 Patients)	No Tube Dependence (n=20 Patients)	
Previous RT			.21
Yes	4 (44)	4 (20)	
No	5 (56)	16 (80)	
T classification			.02
T1	1 (11)	8 (40)	
T2	5 (56)	11 (56)	
T3	3 (33)	0	
T4	0	1 (5)	
Primary site			<.001
Oral cavity	0	2 (10)	
Oropharyngeal	3 (33)	16 (80)	
Hypopharyngeal	0	1 (5)	
Laryngeal	6 (67)	1 (5)	
Postoperative intubation with 48 h			.16
Yes	4 (45)	3 (15)	
No	5 (56)	17 (85)	
Concomitant neck dissection			.10
Yes	1 (11)	10 (50)	
No	8 (89)	10 (50)	
Age, mean (SD), y	69 (8)	58 (13)	.02
Preoperative MDADI score, mean (SD)	67 (20)	82 (14)	.04

Abbreviations: MDADI, M. D. Anderson Dysphagia Inventory; RT, radiation therapy.

were gastrostomy tube dependent. Two of these patients were gastrostomy tube dependent prior to robotic resection owing to prior chemoradiation. Five patients underwent planned gastrostomy at the time of robotic resection, and 2 had gastrostomy tube placement several weeks postoperatively. Three patients who required gastrostomy tubes were tolerating oral nutrition with a functional swallow by 2 months after surgery, and 6 patients had prolonged dysphagia. Factors associated with gastrostomy tube dependence included higher T stage ($P=.02$), tumor location ($P< .001$), advanced age ($P=.02$), and lower preoperative MDADI score ($P=.04$) (**Table 5**).

The postoperative complications occurring within 30 days of robot-assisted resection included dehydration ($n=4$), aspiration pneumonia ($n=1$), delayed postoperative bleeding ($n=2$), and airway edema requiring reintubation ($n=2$). These complications were consistent with transoral excision by any method and were not considered to be directly related to the use of the surgical robot. The need for reintubation of 2 patients prompted a policy change of leaving most patients with tongue base and larynx cancer electively intubated for 24 to 48 hours.

Twenty-eight of 29 patients who underwent robotic resection of their head and neck neoplasm completed the MDADI. The mean (SD) score preoperatively was 77 (17) and at 2 to 4 weeks postoperatively was 61 (16) ($P< .001$).

COMMENT

This study further demonstrates the feasibility and safety of robot-assisted resection of upper aerodigestive tract

tumors. The surgical robot has several advantages over traditional endoscopic and open approaches, including 3-dimensional visualization, tremor filtration, and greater freedom of instrument movement. These advantages were appreciated in this study and offered good lesion visualization, short hospital stay, and good functional preservation. Traditional endoscopic approaches with an operating microscope and/or carbon dioxide laser are limited by smaller operative fields and line-of-sight manipulation. Following traditional open approaches requiring lip-splitting incision and mandibulotomy, patients are often left with considerable cosmetic deformity, malocclusion, and dysphagia.⁵⁻⁷ Furthermore, open approaches often result in large contiguous defects requiring complex free-flap reconstruction resulting in prolonged hospital stays, prolonged dysphagia, and tracheotomy. This study, as well as other reports in the literature, demonstrates a mean hospital stay of approximately 3 days for patients undergoing robotic resection.¹¹ Twenty of the 29 patients who underwent robotic resection in this study (69%) were tolerating all nutrition orally by 2 weeks after surgery. Only 1 patient in this study required tracheotomy and was decannulated prior to discharge. Other reports in the literature¹⁰⁻¹² have demonstrated the safety of delayed neck dissection performed at 1 to 3 weeks after surgery. To our knowledge, there have been no reports of concomitant neck dissection with robotic resection. Of the 11 patients in this study who underwent concomitant neck dissection, no orocervical fistula or increase in complication rate was seen, demonstrating that neck dissection at the same procedure is safe in selected patients.

The surgical robot was not designed for transoral use and does have several limitations. Introduction of the robotic arms into the oral cavity can be a challenge, and not all patients are currently candidates. However, with experience, the challenges of access can be overcome for many patients. A separate preoperative examination under anesthesia to assess robot feasibility helps eliminate candidates with poor access. Many patients in this series had previously undergone staging endoscopy in our institution by another physician, and the senior author (W.R.C.) felt unjustified in repeating this examination prior to robotic resection. Three patients in this study were unable to undergo robotic resection secondary to inadequate access. Contributing factors to this problem were narrow arched mandible, full dentition, retrognathia, trismus, and the learning curve associated with robotic surgery. Two patients (T2, posterior pharyngeal wall, and T2, epiglottis) in this study had clinically significant airway edema postoperatively requiring reintubation within 24 hours of their operation. Other studies have shown no increase in airway edema following robotic resection.¹⁰ However, Weinstein et al¹¹ reported that 23% of patients remained intubated for a mean duration of 2.7 days following robotic radical tonsillectomy. Whether monopolar cautery causes more tissue injury and edema than carbon dioxide laser in the oropharynx and larynx is unclear.¹⁴⁻¹⁶ Further studies are necessary to predict which patients can be safely extubated following robotic resection of their head and neck neoplasm.

No clinical guidelines have been established for robot-assisted resection of head and neck tumors. In this study,

previous head and neck radiation did not preclude the ability to perform successful robotic resection. Edentulous patients had a higher percentage of successful robotic resection than dentate patients, likely secondary to easier exposure. A higher percentage of successful robotic resections were performed in the last 4 months of this series, demonstrating that robotic surgery is associated with a learning curve.

Several clinical variables were significantly associated with gastrostomy tube dependence, including age, T stage, tumor location, and preoperative MDADI score (see Table 5 for *P* values). The mean age of patients requiring gastrostomy tube feeding was 13 years older than patients not requiring gastrostomy tube placement. Tumors occurring in the larynx and those with higher T stage were also more frequently associated with gastrostomy tube dependence. Patients who were gastrostomy tube dependent also had lower preoperative MDADI scores.

To date, the number of reported robot-assisted resections of upper aerodigestive tract neoplasms remains limited.^{10-12,17-19} This study adds 29 successful robot-assisted resections of tumors located in the head and neck, further demonstrating that this technique is both technically feasible and safe. This study also begins to enumerate clinical guidelines of successful resection and swallow preservation. Further studies are necessary and are currently under way to test this technique in a larger number of patients over a longer period of time to assess both long-term functional and oncologic outcomes of robotic resection and to compare these results with traditional techniques.

This technology is already widely available. The da Vinci Surgical Robot is approved by the US Food and Drug Administration for use in other surgical specialties and is now operational in more than 850 academic and community hospitals. This project assessed the feasibility of robot-assisted surgery to resect head and neck tumors. This study does not confirm oncologic or functional superiority to any standard method of treatment. Further studies are needed to define the indications, advantages, limitations, and outcomes of robotic surgery for head and neck applications.

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