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Complications following transoral robotic surgery (TORS): A detailed institutional review of complications

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ABSTRACT

Objectives: To report the complications occurring following TORS and to identify the factors predictive of complications.
Methods: Following IRB approval a retrospective analysis of all TORS operations at our institution was performed. Postoperative complications within 45 days were collected and graded with the Clavien-Dindo system. Complications were categorized into groups: all complications, not related to TORS and TORS related. Unadjusted odds ratios were calculated to test association between patients with and without a complication.
Results: 122 TORS operations were carried out between June 2010 and August 2015. 77% were male, with a median age of 57. There were 92 primary tumor resections, 10 second head and neck primary resections, 13 salvage procedures and 7 other indications. Surgical resection involved 1, 2 or >3 sub-sites in 36%, 28% and 36% patients, respectively.
Overall, there were 107 complications (66 TORS related, 41 non-TORS related) that occurred in 57 patients (47%). A major complication occurred in 23 patients (18%). 19 patients had a TORS related major complication and 6 patients experienced a non-TORS related major complication. There was a temporal trend in TORS related major complication rate decreasing from 33% in 2010 to 10% in 2015.
Statistical analysis showed that the odds of having any complication were 3 times greater in patients over 60 years old ($p = 0.017$), and 2.5 times greater when there were more than 2 subsites resected ($p = 0.022$).
Conclusions: Age over 60 years and a larger extent of resection were the significant factors predictive of major complications.

Introduction

Since FDA approval of transoral robotic surgery (TORS), the publication of TORS related complications has not equaled reports of oncological outcomes. It is important to know the incidence and severity of complications associated with TORS when counseling patients regarding modality of treatment especially when nonsurgical treatment options are available. The introduction of the da Vinci robot (Intuitive Surgical Inc, Sunnyvale, CA, USA) was initially developed in urology and cardiac surgical specialties. The first reported use of the da Vinci robot in Head and Neck surgery was by Melder et al. in which a resection of a vallecular cyst was performed in 2005 [1]. The first application for a head and neck malignancy was reported by Weinstein et al. at the University of Pennsylvania in 2006 [2]. This group is responsible for the majority of early research and coined the term TORS (Trans Oral Robotic Surgery). Since then, FDA approval for the use in the head and neck was granted in 2009 and TORS has been adopted throughout the world.

TORS has emerged as a transoral approach that offers an alternative to open surgery and primary non-surgical treatments [3]. The advantages of TORS are the ability to operate without line of site restrictions that limits other trans oral endoscopic or microscopic approaches. It also allows resection of tumors that would traditionally require a pharyngotomy or mandibulotomy. Other advantages of this technology include instruments with six degrees of freedom, motion scaling, instrument stabilization and tremor reduction [4]. The binocular and magnified endoscopic vision also allows for accurate 3 dimensional visualization.

TORS has been shown to achieve excellent oncological results across a number of indications and subsite but these are mostly

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from single institutional studies and in the oropharynx [5,6]. There have also been promising functional outcomes of TORS with appropriate adjuvant therapy [7]. A multi-institutional study has recently reported a 3 year survival rate of 92.5% and a 3 year recurrence rate of 88.8% [8].

In contrast to the number of case series reporting outcomes, there are few studies showing detailed analysis of complications. The understanding of complications is important because patients who are suitable for TORS are also good candidates for primary non-surgical treatment and other surgical approaches. To fully inform patients and treating physicians, we aim to report detailed institutional complication rates, types of complications and identify potential predictive factors.

Methods

Patient cohort

Memorial Sloan Kettering Cancer Center institutional review board approval was granted for a retrospective study of all TORS procedures at our institution. All patients receiving a TORS operation were included. Procedures were performed between June 2010 and August 2015. The TORS procedures were carried out by 4 surgeons who had all received adequate training and proctorship.

Data collection

Patients were identified through the institutional operation room database using CPT codes indicating robotic surgery. The patient record was accessed to record demographics, clinical characteristics, health behaviors, oncologic characteristics, surgical details, outcomes and complications. Staging was recorded according to the American Joint Committee on Cancer Staging Manual 7th Edition [9]. Patient data was stored on an institutional network using the oncological database software, Caisis (Biodigital), with access available only to authors.

Complications reporting and analysis

Post-operative complications were defined using the Dindo and Clavien definition, "any deviation from the normal post-operative course" [10]. The process of identification and recording of complications was as described by previous work at our institution [11,12]. All events that occurred in the patient's record within 45 days of surgery, either in medical, nursing, anesthetic or allied health professional documentation was compared to the definition of a post-operative complication. Complications were graded according to the "Clavien-Dindo Classification of Surgical Complication" [13]. A summary of the grading system is shown in Table 1. For analysis, the severity of complications was further summarized as major (grades 3, 4 and 5) and minor (grades 1 and 2).

Complications were also grouped into domains, previously generated from the large study of post-operative complications in oral cancer [12]. This included complications local to surgery, either in the neck (cranial nerve paresis, infection, hematoma, wound breakdown/dehiscence, lymphatic leak, seroma), related to the oropharynx (wound breakdown/dehiscence, hemorrhage, necrosis, infection, burn/trauma and hematoma), in the head and neck (trismus, fistula, orbital complication, hoarseness/stridor, salivary gland infection, epistaxis and TMJ dislocation), resulting from a feeding tube (cellulitis, bowel perforation/necrosis, upper gastrointestinal bleeding, wound breakdown/dehiscence) and from tracheostomy (hemorrhage, fistula, subcutaneous emphysema, displacement).

Systemic complications were grouped into the following domains; pulmonary (pneumonia, pulmonary edema, foreign body, atelectasis, respiratory failure), nervous system (delirium, cerebrovascular accident), cardiac (congestive heart failure, myocardial infarction, atrial fibrillation), hematologic (venothromboembolism, coagulopathy) and infection (catheter, systemic). Long term complications were recorded (tracheostomy, feeding tube, nutritional supplement, trismus, oral intake, aesthetic concerns, mobility, weight loss, osteoradionecrosis, pharyngeal stricture, speech and velopharyngeal insufficiency).

Complications related to local effects of surgery were classified as a TORS related complications and complications unrelated to local effects of surgery were classified as non TORS related complications, see Table 2.

Statistical analysis

Unadjusted odds ratios of clinical and pathologic factors predictive of complications were calculated. Multivariable analysis was

Table 2
TORS and non TORS complications groups.

TORS related complications:	Non-TORS related complications:
Bleeding	Infections outside of oropharynx
Dysphagia	Tube and line complications
Local oropharyngeal	Cardiopulmonary
Aspiration related infections	Haematological
Local pain	Others

Table 1
Clavien Dindo classification.

Clavien Dindo classification	
Grades	Definition
Grade I:	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II:	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included
Grade III:	Requiring surgical, endoscopic or radiological intervention
Grade III-a:	Intervention not under general anesthesia
Grade III-b:	Intervention under general anesthesia
Grade IV:	Life-threatening complication (including CNS complications)‡ requiring IC/ICU-management
Grade IV-a:	Single organ dysfunction (including dialysis)
Grade IV-b:	Multi organ dysfunction
Grade V:	Death of a patient
Suffix 'd':	If the patients suffers from a complication at the time of discharge the suffix "d" (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication