

# Transoral robotic surgery in management of oropharyngeal cancers: a preliminary experience at a tertiary cancer centre in India

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## Abstract

**Background** The aim of this observational prospective study was to determine the technical feasibility, safety and adequacy of surgical margins for transoral robotic surgery (TORS) in oropharyngeal cancers.

**Methods** From March 2013 to May 2014, 60 patients with oropharyngeal lesions underwent TORS with or without neck dissection using the ‘DaVinci’ robot. Patients were observed and data recorded on surgical time, blood loss, complications and functional outcome of patients.

**Results** All 60 patients underwent TORS, with neck dissection performed in 45 of the patients. A positive margin was seen in two patients (3.3 %). Intent to treatment was radical in 42 patients and salvage in 18 patients. None of the patients required tracheostomy, and one patient (1.66 %) died postoperatively. Postoperative complications in the form of primary haemorrhage required active intervention in three patients. Average estimated blood loss was  $26.5 \pm 31.1$  ml. Postoperatively, all patients had adequate swallowing and speech function with nasal twang reported in three patients on long-term follow up. Patients started tolerating oral feeds within a week of procedure (mean

3.96 days), with the nasogastric tube removed on the ninth postoperative day (mean 9.19 days). No long-term gastrostomy tube dependency was reported.

**Conclusion** TORS is a safe, feasible, minimally invasive procedure in patients with oropharyngeal cancers. It has the least morbidity and offers benefits in terms of avoidance of tracheostomy tube, prolonged Ryle’s tube and gastrostomy dependency.

**Keywords** TORS · Oropharyngeal cancer · DaVinci Robot · Head and neck cancers

## Introduction

Head and neck cancers are emerging as a major public health problem in India with over 2,00,000 new cases every year [1], with India reported to have the highest incidence of oropharyngeal cancer worldwide [2]. Historically, oropharyngeal cancers were treated by surgical excision and adjuvant therapy. However, increased surgical morbidity and poor cosmesis associated with open surgery led to support for approaches aimed at organ preservation, such as chemoradiation [3]. Chemoradiation in oropharyngeal cancers has achieved excellent local control, but at the cost of greater acute toxicity, with dysphagia being a major concern [4, 5]. Attempts have been made by various researchers to achieve an excellent local control at the cost of minimal functional morbidity. Transoral robotic surgery (TORS) is one such attempt to achieve excellent oncological outcomes with improved speech and swallowing function.

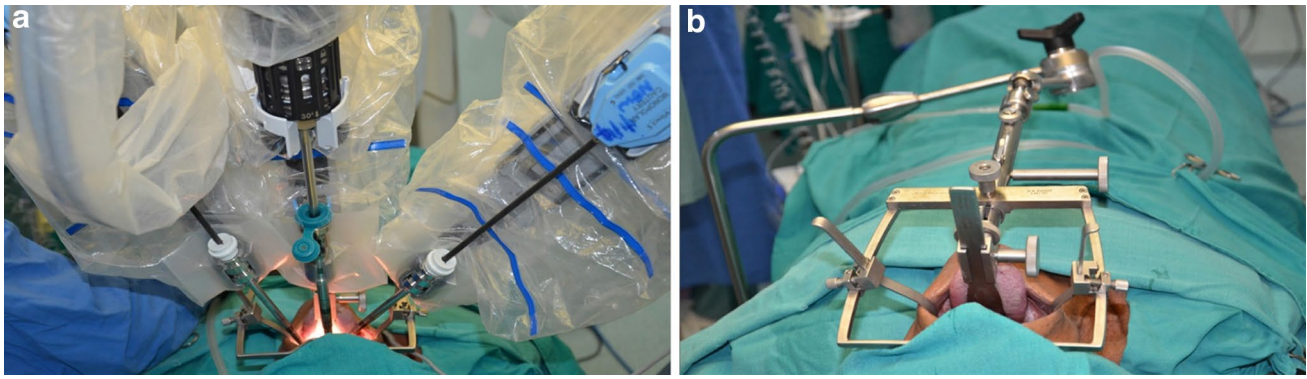
TORS has greatly simplified the surgical approach by providing excellent tumour visualization and magnification. It provides increased maneuverability in a limited

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**Fig. 1** Transoral robotic surgery setup. **a** Patient side cart with positioning of three robotic arms, **b** intraoral exposure obtained via Feyh-Kastebauer retractor (FK retractor)

field of view. Operative time, hospital stay, percutaneous endoscopic gastrostomy (PEG) tube and Ryle's tube dependence have significantly decreased with TORS, without compromise of tumour control [4–10]. We designed the prospective study reported here to evaluate the technical feasibility, safety and adequacy of surgical margins with TORS for oropharyngeal lesions.

## Materials and methods

Between March 2013 to May 2014, 60 patients with oropharyngeal lesions fulfilling the inclusion and exclusion criteria of our prospective study underwent TORS using the da Vinci robotic surgical system (Fig. 1a, b) for resection of their primary tumour at Rajiv Gandhi Cancer Institute and Research Centre, Delhi. The study was approved by the Institutional Review Board, and written informed consent from the participating patients was obtained. Eligibility criteria included patients aged  $\geq 18$  years with oropharyngeal lesions. Contraindications of TORS included decreased mouth opening (maximum mouth opening  $< 1.5$  cm) that would prevent adequate exposure of the affected areas, presence of American Journal of Critical Care (AJCC) TNM T4 stage disease, invasion of deep tissue lateral to constrictor muscle or posterior invasion of deep vertebral fascia, unresectability of involved lymph nodes, distant metastasis and medical contraindications for general anaesthesia and surgery. Nodal unresectability was defined as carotid artery encasement with deep neck structure involvement that made complete nodal resection difficult and skin involvement with dermal metastasis. The information collected from each patient included a demographic profile, histology, pathological stage, tissue margin status, operative time, perioperative complications, hospital stay, PEG tube dependency and need for adjuvant therapy.

Neck dissection was performed when indicated as either a staged or concurrent procedure. All 60 patients enrolled in this study underwent ipsilateral selective neck dissection (SND)—level II to IV for node negative neck. Patients underwent bilateral SND for tumours crossing the midline. Modified neck dissection was performed in node-positive necks.

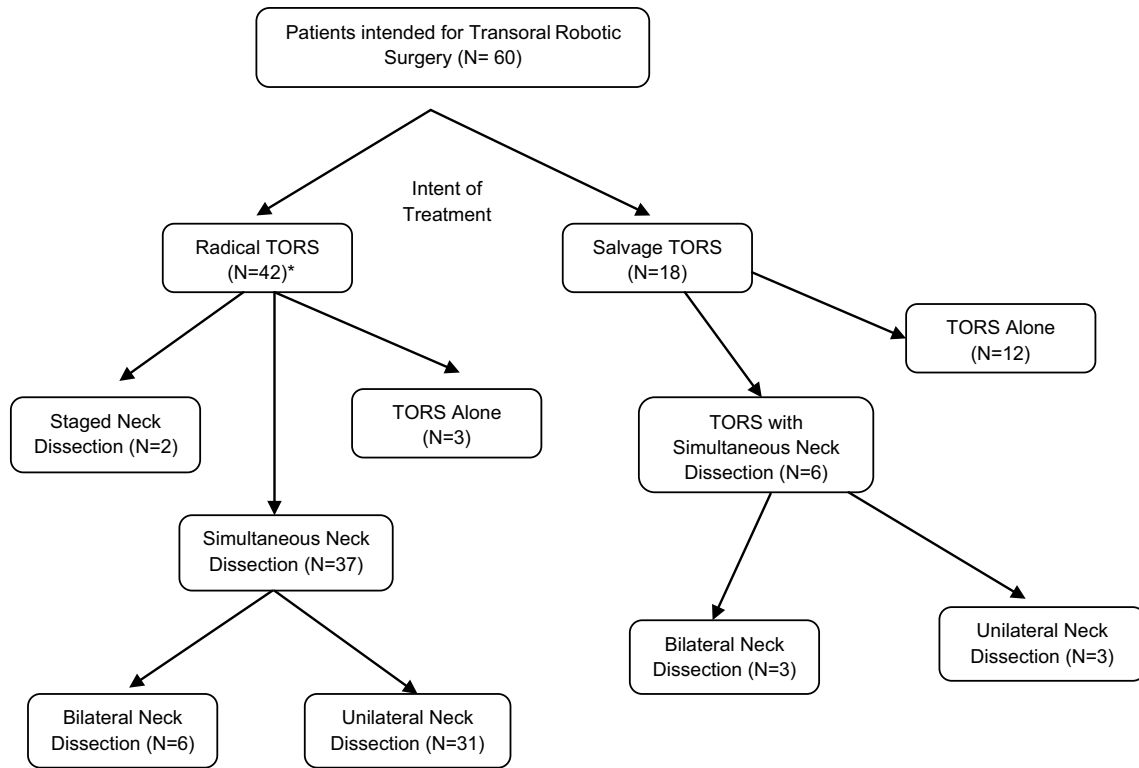
Adjuvant therapy was advocated if adverse pathological features were present, such as pT4 disease, pN2 disease, perineural invasion, lymphovascular invasion, extracapsular extension (ECE) and positive/close margins ( $\leq 2$  mm). Patients received radiotherapy to both sides of the neck and primary site to a dose of 60–66 Gy. Chemotherapy was added to radiotherapy if there was positive margin or ECE. No adjuvant therapy was recommended for previously irradiated patients. Patients were evaluated by means of clinical examination every month for 3 months, followed by a repeat evaluation every 3 months by the surgical team. Follow-up information was also recorded for every patient, including details of recurrence and survival status.

## Results

### Patients and tumour characteristics

A total of 60 patients with oropharyngeal lesions fulfilling the inclusion criteria participated in the study. Figure 2 shows the flow diagram of treatment for patients enrolled in the study. Intent to TORS treatment was salvage in the 18 previously irradiated patients and curative in the 42 naive patients. TORS was successfully performed in all patients, with no necessity for intraoperative conversion to an open surgical procedure.

The average age of the patients was  $55.8 \pm 10.6$  (range 31–88) years. The anatomic location of the oropharyngeal lesions are shown in Table 1. The majority of patients had the tumour originating from the tonsil (24/60). The final



\*includes one patient who underwent diagnostic TORS

**Fig. 2** Flow diagram of treatment for the patients enrolled in the study. TORS Transoral robotic surgery

**Table 1** Patient and tumour characteristics

Characteristics	N (%)
Mean age at diagnosis	55.8 ± 10.6 years
Males:females	56 (93.3):4 (6.7)
Postoperative histopathology	
Squamous cell carcinoma	57 (95)
Non-Hodgkin’s lymphoma <sup>a</sup>	1 (1.66)
Benign	2 (3.33)
Primary tumor subsite	
Oropharynx	60 (100)
Tonsil	24 (40)
Base of tongue	18 (30)
Greater tubercle sulcus	10 (16.6)
Soft palate	5 (8.33)
Vallecula	2 (3.33)
Uvula	1 (1.66)

<sup>a</sup> One patient with previously inconclusive biopsy underwent diagnostic transoral robotic surgery (TORS) and had non-Hodgkin’s lymphoma (Mantle cell lymphoma) on the final histopathology report

histopathological study revealed that 58 (96.6 %) patients had malignancy; the exceptions were two patients with biopsy-proven carcinoma who showed no evidence of

malignancy on the final histopathological study. The pathological tumor and nodal staging of oropharyngeal carcinoma in both curative and salvage setting are presented in Table 2.

Assessment of surgical outcomes

All patients underwent complete resection of the oropharyngeal lesions with TORS. Frozen sections of tumour margin were examined. Of the 60 patients, positive margin was reported in two patients (3.33 %), while a close margin ( $\leq 2$  mm) was obtained in two (3.33 %) patients. Positive/close margins were reported in previously irradiated patients.

Estimated blood loss for patients undergoing TORS was  $26.5 \pm 31.1$  ml, with no patient requiring blood transfusion. The average hospital stay was  $4.15 \pm 1.57$  days. The main reason for hospital stay was management of neck drain, and patients were discharged after their neck drains had an output of  $<20$  ml/24 h.

The standard setup time was  $7.34 \pm 8.34$  min and robotic setup time was  $6.71 \pm 5.82$  min. Surgical time averaged  $49.84 \pm 23.93$  min. Mean operating time for TORS was significantly more in previously irradiated cases in comparison to previously untreated cases.

**Table 2** Pathological tumor, node staging among patients treated by TORS with curative and salvage intent

TNM staging	pTx	pT1	pT2	pT3	pT4	NA <sup>b</sup>	Total
Curative intent ( <i>N</i> = 42)							
pNX <sup>a</sup>	1	–	1	–	–	–	2
pN0	–	12	3	2	–	–	17
pN1	–	1	6	–	–	–	7
pN2a	–	2	1	–	–	–	3
pN2b	–	2	6	2	–	–	10
pN2c	–	–	2	–	–	–	2
pN3	–	–	–	–	–	–	0
NA <sup>b</sup>	–	–	–	–	–	1 <sup>b</sup>	1
Total	1	17	19	4	0	1	42
TNM staging	ypTx	ypT1	ypT2	ypT3	ypT4	NA	Total
Salvage intent ( <i>N</i> = 18)							
ypNX <sup>c</sup>	1	4	7	–	–	–	12
ypN0	–	–	–	–	–	–	0
ypN1	1	–	–	–	–	–	1
ypN2a	–	–	–	–	–	–	0
ypN2b	–	–	4	–	–	–	4
ypN2c	–	–	1	–	–	–	1
ypN3	–	–	–	–	–	–	0
NA	–	–	–	–	–	–	0
Total	2	4	12	0	0	0	18

NA, Not applicable;

<sup>a</sup> pNX- A standard American Joint Committee on Cancer (AJCC) abbreviation for patients who underwent TORS alone without any neck dissection

<sup>b</sup> One patient underwent diagnostic TORS (non-Hodgkin's lymphoma)

<sup>c</sup> ypNX, A standard AJCC abbreviation for patients who have had some previous treatment precluding staging (includes 12 patients treated with TORS alone)

No reconstruction was done after primary tumor resection with TORS in any patient.

#### Adverse events

There were no cases of emergency airway compromise, wound dehiscence or oro-cutaneous fistula during the procedure. Of the 60 patients who underwent TORS, five patients (8.33 %) experienced either intraoperative or postoperative bleeding. Three of these required operative intervention, while bleeding resolved in one patient without any active intervention. Secondary haemorrhage caused one postoperative fatality. Four patients who experienced postoperative bleeding were previously irradiated. All events occurred within the first postoperative week following TORS. None of the patients in our study developed orocervical communication.

#### Adjuvant therapy

Adjuvant therapy was provided only to those patients who had not previously undergone radiotherapy. Six patients

were advocated adjuvant radiotherapy, but only four ultimately underwent the therapy (two defaulted). One patient was incidentally found to have a second malignancy, i.e. mediastinal neuroendocrinal tumor, and hence did not receive adjuvant radiotherapy. Twelve patients underwent concurrent chemoradiation in view of positive neck nodes with ECE, while one patient expired due to secondary haemorrhage. Those patients not receiving adjuvant treatment (i.e. had previously received radiotherapy) were closely monitored during the follow-up. In all patients, the primary site was treated to a smaller radiotherapy dose (60–66 Gy) and volumes than would have been used to primarily treat squamous cell carcinoma (SCC). Overall 51.22 % patients (21/41) treated with radical intent avoided radiotherapy.

#### Functional outcomes: swallowing and speech function

Patients tolerated the TORS procedure well, and oral feeding was started as early as the second postoperative day in 20 patients (3.96 ± 2.7 days). The mean duration of Ryle's

tube use in all patients, previously irradiated patients and previously untreated patients was  $9.19 \pm 5.7$ ,  $12.89 \pm 8.23$  and  $7.39 \pm 2.81$  days, respectively. Only two previously irradiated patients required PEG tube insertion in view of persistent nasal regurgitation, and the tube was removed after 30 days of use. Thus, there was no long-term PEG tube dependency in patients undergoing TORS. Nasal twang following TORS was noted in three (5 %) patients postoperatively on long-term follow up.

#### Follow-up

The average follow up of the patients was 8 (range 1–18) months. At 18 months of follow-up, the overall survival (OS) of the patients was 93 % and the recurrence-free survival (RFS) rate was 64 %. The OS for patients treated with radical and salvage surgery was 98 % at 17 months and 81 % at 18 months, respectively ( $p = 0.051$ ). The RFS for patients treated with radical and salvage surgery was 70 % at 17 months and 49 % at 18 months, respectively ( $p$  value 0.038).

#### Discussion

The primary goal of head and neck cancer treatment is local control and organ preservation. Historically, surgical excision followed by adjuvant therapy was the treatment of choice for oropharyngeal cancers. Various studies have shown a 70–84 % local control rate, with 5-year survival ranging from 49–55 % with this treatment option [11]. Based on the results of the PENN (University of Pennsylvania) study (1980–1990s), Machtay et al. [12] recommended that open surgery followed by adjuvant radiotherapy for base of tongue (BOT) lesions achieved excellent local control. However, these open surgical approaches were associated with high rates of surgical morbidity in terms of speech and swallowing function, with 29 % of patients having either long-term PEG tube or tracheostomy tube dependency. Denittis et al. [13] also evaluated surgical and functional outcome in oropharyngeal cancer patients treated with primary surgery followed by adjuvant radiotherapy and concluded that despite excellent locoregional control (73 % at 3 years), patients had a high rate of distant metastasis (29 %) with suboptimal functional outcome. Parsons et al. [11] compared functional outcomes with surgery versus radiotherapy for oropharyngeal cancers and reported higher complication rates in the surgical arm. Despite surgery providing excellent locoregional control, the high morbidity led many surgeons to abandon this approach for this specific site [3].

In view of the high surgical morbidity, the PENN group conducted a subsequent study in which they evaluated the role

of chemoradiation in advanced oropharyngeal carcinomas; the results showed a lower rate of distant metastases in patients receiving chemoradiation (15 %) than in the surgical series [14]. However, the PENN chemoradiation study revealed significant acute and chronic toxicity in the patient cohort [15]. In their 1997 study, Machtay et al. reported that chemoradiation was associated with significant speech and swallowing dysfunction, along with varying degrees of xerostomia [12]. Nguyen et al. showed that concurrent chemoradiation had an adverse impact on patients' quality of life [16]. Taken together, it would appear that although organ-sparing approaches help to preserve vital organs, a large number of patients develop treatment-related toxicity. Numerous reports have shown that a radical dose of radiotherapy (70 Gy) together with concurrent chemotherapy leads to a high rate of acute toxicity [17].

Various attempts have been made to achieve excellent local control at the cost of minimal morbidity. This concerted effort has led to evolution and worldwide acceptance of TORS. However, few centers have committed themselves to TORS to decrease surgical morbidity and maintain the benefits of complete local control [18–20]. Laccourreye et al. [18] demonstrated 89 % local control with a combined transoral surgical resection of tonsillar cancer, neck dissection and adjuvant radiotherapy in 166 patients. Steiner et al. [19] and Grant et al. [20] demonstrated similar rates of preservation of speech and swallowing function without compromising on disease control by using transoral laser microsurgery for BOT lesions. Several other studies have found TORS to be an effective alternative to open surgery for oropharyngeal carcinoma [8–10, 21]. Weinstein et al. [22] demonstrated preservation of oropharyngeal function and adequacy of tumour removal with TORS for tonsillar SCC.

TORS can be challenging in terms of tumour visualization, tissue manipulation in minimal space and functional preservation by securing surrounding structures. The aim of the feasibility part of our study was to investigate whether TORS would meet these challenges. We measured this by recording the ability to expose the tumor and complete the surgery successfully with TORS without conversion to open surgery, as well as by evaluating the safety and adequacy of surgical margins with TORS.

The feasibility of TORS was clearly demonstrated in our study, with 100 % of our patients successfully undergoing TORS without the need for intraoperative conversion. In contrast, Moore et al. [23] attempted nonrobotic transoral surgical resection in 102 patients with SCC of tonsil, of whom 5.9 % ultimately required conversion to an open procedure. Preuss et al. [24] reported open conversion in 3.6 % (10/275) of patients who underwent transoral laser resection of oro-laryngeal tumours, and Genden et al. [8] reported achieving adequate surgical exposure in 90 % of cases using TORS.

Operative time, as an indicator of surgical efficacy, may be influenced by multiple factors, including surgeon experience, tumour size, site, previous history of irradiation, among others and is considered to be a cost-effective and safe indicator. Mean operative time for TORS in our study was  $49.84 \pm 23.93$  min, with the operating time decreasing with increasing surgeon experience. TORS may thus allow for shorter operating times than open surgery, which could be beneficial for elderly patients.

The overall incidence of positive and close tumour margins was the same (3.33 %) in our patient cohort, with positive/close margins found in previously irradiated patients. These rates are similar to those reported for other transoral approaches. Moore et al. [23] observed positive surgical margins in 3.9 % tonsillar tumor cases ( $n = 102$ ) resected by conventional transoral techniques, and Grant et al. [25] reported positive surgical margins in 3.4 % of individuals who underwent transoral laser resection of BOT tumours. Weinstein et al. [26] evaluated the oncological and functional outcomes of TORS in advanced oropharyngeal cancer and reported a 2 % positive margin rate. Thus, in terms of the adequacy of surgical margins, the TORS approach appears to be at least comparable to other transoral minimally invasive approaches, and at par with open surgery.

TORS in combination with neck dissection facilitated the identification of patients with favourable histological features, thereby allowing us to decrease the radiotherapy dose, and even to omit chemotherapy in a few cases, which resulted in deintensification of the overall treatment. Based on pathological reports, postoperative radiotherapy doses are given to a much smaller surgical bed, rather than to a larger original tumour volume. Deintensification of treatment significantly reduces the long-term swallowing dysfunction which has been reported with chemoradiation [27, 28]. Among our 60 patients, 19 were prescribed adjuvant radiotherapy with or without chemotherapy. Overall, 51.22 % of our patients (21/41) were not given radiotherapy, and no radiation was advocated in previously irradiated patients. Similar to the prospective single arm study by Weinstein et al. [29], ipsilateral SND at the time of TORS for primary oropharyngeal carcinoma allowed us also to “deintensify” adjuvant therapy in many patients. Weinstein et al. [30] showed that while most patients in their study had advanced clinical stage, almost all were found to have favourable pathological features. These authors also reported pathological downstaging at both the primary site and neck in the majority of the patients. More et al. [31] reported a lower swallowing dysfunction with the lower dose or deintensified adjuvant radiotherapy in patients undergoing TORS followed by adjuvant radiotherapy in comparison to chemoradiation for advanced oropharyngeal malignancies. Thus, while our data supports deintensification of radiation treatment for oropharyngeal

carcinomas, future trials would be required for validation of these results.

TORS allows for organ preservation and a better functional rehabilitation with decreased morbidity. We were able to reduce the dose and volume of the radiation field based on the final histopathology tests. The most commonly used indicators of preservation of swallowing function in our study were duration of Ryle’s tube use and PEG tube dependency. PEG tube insertion was performed in two (3.33 %) previously irradiated patients and the tube was removed after a duration of 30 days. Thus, there was no long-term PEG tube dependency in our study, and the PEG tube insertion rate was lower than that reported for other surgical and nonsurgical therapies [28]. The results were similar to those reported by Weinstein et al. [29] and White et al. [32]. In contrast, PEG tube dependency rate was 9.1 % in the PENN chemoradiation series [14, 15]. Greven et al. [33] reported complete dysphagia for solids/liquids and PEG tube dependence in 18 % patients treated with chemoradiotherapy in advanced oropharyngeal cancer. Recent studies evaluating the role of intensity-modulated radiotherapy in oropharyngeal cancer have reported 9–38 % PEG tube dependency rates after treatment [34–36]. The mean duration of Ryle’s tube use for all patients enrolled in our study was  $9.19 \pm 5.7$  days and was significantly longer in previously irradiated patients. Oral feeding was started as early as the second postoperative day in 20 patients (mean 3.96 days). Resumption of normal diet was observed on average on the 14th postoperative day, thereby indicating rapid swallowing rehabilitation.

Nasal twang following TORS was noted in three patients (5 %) in the immediate postoperative period. Moore et al. [13] reported hypernasality in 4/45 patients (8.88 %) after TORS for oropharyngeal cancer, which rapidly resolved in all 45 patients postoperatively by the first follow-up. In a similar study, Leonhardt et al. [37] found speech function to be moderately affected by TORS. Weinstein et al. [22] reported hypernasality in one patient following transoral robotic tonsillectomy, with subsequent transoral scar resection leading to its resolution. Genden et al. [8] however did not notice any significant velopharyngeal insufficiency in his study.

Rapid speech and swallowing rehabilitation in our patients was accompanied by a shorter hospital stay. The mean hospital stay of our patients was shorter than that of patients who would have otherwise undergone an open surgery or would have been admitted for supportive care in view of acute toxicity due to concurrent chemoradiotherapy. In the study by Moore et al., all 35 patients were discharged from the hospital within 6 days [9]; while Boudreaux et al. [10] and Weinstein et al. [7] reported a mean hospital stay of 2.6 and 5–7 days, respectively.

Of the 60 patients who underwent TORS, five experienced postoperative bleeding, among whom three required

operative intervention; one patient expired due to secondary haemorrhage. The incidence of postoperative transoral bleeding requiring intervention among our patients is comparable to the range of 0.5–10.4 % reported in patients undergoing transoral surgical resection. None of the patients in our study experienced carotid artery injury; in comparison, the observed rates of carotid artery injury is 1.2–3.0 % after open procedures or radiation treatment [38–42]. Wound dehiscence did not occur in any of our study subjects compared to 2 % reported after transoral surgery and 2–14.3 % following open surgical procedures [42, 43]. No patient in our study developed orocervical communication. Aubry et al. [44] and Moore et al. [45] also reported a low incidence of orocervical communication in their respective studies evaluating the role of TORS in head and neck cancer. Both groups of researchers came to the conclusion that a higher rate of orocervical communication occurred in patients undergoing simultaneous rather than sequential neck dissection. None of the 60 patients in our study required tracheostomy or had airway compromise. In a similar study by Genden et al. [8], tracheostomy tube use or prolonged intubation was not reported in any patient.

Overall, TORS represents a new innovative minimally invasive approach in the treatment of oropharyngeal cancers. It is a safe, feasible and effective alternative to open surgical or standard nonsurgical treatment in patients with oropharyngeal cancer and promotes a decrease in morbidity and achievement of a better functional outcome. The rates of positive surgical margins achieved with TORS in our study are at least equivalent to those reported for other surgical modalities. The limitations of the study include nonrandomization of our patients, small number of patients and a short follow-up period. Additionally, objective assessment of swallowing and speech functions was not done in our study. Instead, we relied on PEG tube dependency, duration of Ryle's tube use and tracheostomy dependence as indicators of functional outcomes. However, this study represents a unique single institution study experience in India with TORS. We hope that the promising results from our study can serve as a treatment arm for comparisons in future prospective randomized trials examining the role of robotic surgery for treating head and neck cancers.

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**Conflict of interest** None.

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