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HEAD AND NECK

Feasibility and safety of transoral robotic surgery (TORS) for early hypopharyngeal cancer: a subset analysis of the Hamburg University TORS-trial

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Abstract Over the past 5 years, transoral robotic surgery (TORS) has become well established as one of the standard treatment options for T1 and T2 oropharyngeal squamous cell carcinoma. Besides this main indication, TORS can provide with improved access to other subsites of the upper aerodigestive tract as well, such as the supraglottic larynx and the hypopharynx, with superior visibility and maneuverability to that of transoral laser microsurgery (TOLM). Since September 2011, over one hundred TORS procedures have been performed at our institution, predominantly for oropharyngeal cancer. As part of our first 50 transoral robotic cases making up our initial TORS-trial, five patients underwent TORS for early hypopharyngeal carcinoma. The present case series evaluates its feasibility, safety and the completeness of resection in this well-defined subgroup of patients. Main outcome measures were completeness of resection, the presence or lack of post-operative bleeding, number of days intubated, rate of elective tracheotomy, duration of intensive care and/or intermediate care, speech and swallowing function, and duration of nasogastric and/or gastrostomy tube dependency. All patients have been free of recurrence to date. One patient died of other disease. Four patients are alive and free of tumour, three of them did not need adjuvant therapy. Transoral robotic surgery with appropriate neck dissection is a valid primary treatment option for select early hypopharyngeal carcinoma, especially in cases that did not require adjuvant treatment. In contrast to TOLM, TORS allows a multi-planar en bloc resection in the hypopharynx which makes histopathological evaluation more reliable. In addition to this, its faster learning curve makes the results less dependent on the individual surgeons' capabilities.

Keywords Transoral robotic surgery (TORS) · Hypopharyngeal cancer · Supraglottic cancer · Adjuvant therapy · Treatment-related morbidity

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Introduction

Transoral robotic surgery (TORS) [1] has become well established in recent years, being used primarily for the excision of oropharyngeal squamous cell carcinoma [2, 3], to decrease treatment-related morbidity while maintaining comparable oncological results to that of open surgery and of primary chemoradiation therapy. Since its approval by the Food and Drug Administration in December 2009 in the United States, the transoral application of the daVinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) has remarkably spread in Europe as well [4, 5].

While most published TORS-data focus on the oropharynx and a new paradigm shift is being witnessed regarding the primary treatment of HPV-driven oropharyngeal cancer, there has been much less attention paid to the hypopharyngeal application of TORS so far. Nevertheless, TORS provides with definitive advantages [6, 7] over the tangentionally cutting traditional transoral laser microsurgery (TOLM) in the supraglottic region and in the

Table 1 Patient characteristics

Patient no.	#1	#2	#3	#4	#5
Age (years) median 64 years	64	62	57	64	70
Sex	Male	Male	Male	Female	Male
cTNM (C2)	cT2 cN0	cT1 cN2b	cT2 cN0	rcT1 cN0	cT1 cN0
pTNM (C4)	pT2 pN0	pT2 pN2b	pT2 pN0	rpT1 pN0	pT1 pN0
Stage	II	IVA	II	I	I
Tumour site	PF/AEF	PF	PF/AEF	PF	PF
p16/HPV-DNA	Pos./neg.	Neg./neg.	Neg./neg.	Neg./neg.	Pos./pos.
Alcohol	Abuse	Abuse	Abuse	No	No
Nicotine p/y	40	<10	20	<10	No
HPV-driven	No	No	No	No	Yes

PF piriform fossa, *AEF* aryepiglottic fold, *HPV* human papilloma virus, *p/y* pack years

hypopharynx, those being excellent 3D-HD visualization with a great depth of field and en bloc, multi-planar manual margin control, avoiding piece-meal resections. Its benefits, however, are most obvious when the patient does not need adjuvant therapy. Therefore, appropriate patient selection is of paramount importance [8, 9].

Patients and methods

Patient selection

Since September 2011, we have been conducting a prospective TORS-trial at our institution, which initial part included 50 patients with T1 and T2 malignancies of the upper aerodigestive tract [3]. Among them, five patients underwent TORS and concurrent selective neck dissection for early hypopharyngeal cancer. In the present subset analysis, we summarize and evaluate their clinico-pathological data to determine whether TORS is a suitable first-line treatment for early hypopharyngeal squamous cell carcinoma.

After initial presentation, clinical examination and appropriate radiological staging, a panendoscopy was performed in each case by the same surgeon using the same TORS-specific retractor [10] (Laryngeal Advanced Retractor System (LARS) by Fentex Medical, Neuhausen, Germany and/or Feyh-Kastenbauer modified by Weinstein-O'Malley (FK-WO) by Olympus-Gyrus ACMI-ENT, Bartlett, TN, USA) as in the case of the robotic procedures, to be able to accurately assess accessibility with the robotic system [11], as an integral part of the patient selection. In the present subgroup of patients, three tumours were restricted to the lateral wall and apex of the piriform sinus, while the medial wall of the piriform sinus and consequently the aryepiglottic fold was also infiltrated in two further cases. The patients' demographic data and tumour characteristics are listed in Table 1.

TORS procedure

After obtaining informed consent, all TORS procedures and neck dissections have been performed under general anaesthesia with a transoral intubation using a reinforced, metal-coated laser tube both cuffs blocked with air, only to provide protection from the proximity of the monopolar dissection [12]. The surgeries were performed consistently by the same TORS-team [13], licensed according to the official daVinci-TORS-training pathway approved by Intuitive Surgical, Inc. Consistency in the anaesthesia team has also been encouraged but not always achieved due to scheduling issues [12].

In each hypopharyngeal TORS procedure, the Endowrist instrumentation consisted of a 5-mm monopolar permanent cautery spatula and a 5-mm Maryland dissector. These 5-mm instruments allow a significantly higher degree of freedom than the 8-mm instruments do, which is especially beneficial in the hypopharyngeal and supraglottic resections in our experience. A 12-mm stereo-endoscopic camera was used in each case with its 30°-optic looking upwards. The monopolar power generator was used in coagulation mode (blue), set as low as at 15 W, to avoid excessive conducted heat and oedema, as well as to allow accurate histological margin assessment. Surgical technique and outcomes are summarized in Table 2.

As the access to the tumour is of utmost importance, selection of the retractor blade must be individual and appropriate. Currently, there are two major retractor systems on the market, specifically designed for TORS: the Laryngeal Advanced Retractor System (LARS) by Fentex Medical [10], and the Feyh-Kastenbauer modified by Weinstein-O'Malley (FK-WO) by Olympus-Gyrus. The most commonly used blades of both systems are shown on Fig. 1. When performing TORS in the hypopharynx, the working space is much more confined than it is in the oropharynx [14]. Therefore, proper selection of the blade has an even greater impact on the access. On Fig. 1, the longest blades provide with the best access to the piriform

Table 2 Surgical outcomes

Patient no.	#1	#2	#3	#4	#5
Closest margin	4 mm	5 mm	5 mm	5 mm	6 mm
Surgical technique	Monopolar dissection	Monopolar dissection	Monopolar dissection	Monopolar dissection	Monopolar dissection
Endowrist instruments	5 mm monopolar and 5 mm Maryland	5 mm monopolar and 5 mm Maryland	5 mm monopolar and 5 mm Maryland	5 mm monopolar and 5 mm Maryland	5 mm monopolar and 5 mm Maryland
Postop oedema	No	No	Yes	No	No
ICU/IMC days	2/0	5/3	1/1	1/0	1/0
Tracheotomy	No	No	Elective	No	No
NG-tube, days	3	18	7	0 (PEG)	4
PEG-tube	No	Yes, on day 18 postop.	No	Preop.	No

ICU intensive care unit, *IMC* intermediate care, *NG* nasogastric tube, *PEG* percutaneous endoscopic gastrostomy

Fig. 1 Several blades of the FK-WO and LARS retractor systems, from *left* to *right*: FK-WO 1, 2, 3 and 4 for the base of tongue, FK-WO 5 for the piriform fossa, LARS 1 and 2 for the piriform fossa, LARS 3 and 4 for the base of tongue. The longest and narrowest blades are best suitable for hypopharyngeal exposure

fossa, specifically the ones marked here as FK-WO 5 and LARS 1 and 2. Other ones marked as FK-WO 1–4 and LARS 3–4 are designed for the base of tongue.

Results

The median age of the patients was 64 years. There were four males and one female patient. There were two p16-positive tumours, only one of those being HPV-DNA positive in the same time. The patient presented with the latter tumour was a life-long non-smoker and non-drinker, supporting the theory that HPV can play a role outside of the oropharynx as well. Preoperatively, three tumours were classified as cT1 and two as cT2, and one of the cT1 tumours was pathologically upstaged to pT2 postoperatively. Following their TORS procedure, they all underwent an ipsilateral selective neck dissection including levels IIa, IIb, III and IV in a concurrent fashion; total nodal yield was over 20 in each case. Despite recent recommendations regarding Level IIb in a cN0 neck, we did harvest the entire Level II in these patients to maximize nodal yield and stay oncologically as safe as possible even without adjuvant treatment.

Preliminary oncological outcomes

Completeness of resection (margin status)

Clear resection margins were achieved in all cases. In four patients, the closest margin was ≥5 mm, which we classify as a well clear margin status [9]. In one single case, the closest margin was 4 mm (Table 2).

Need for adjuvant therapy

After having undergone robotic resection followed by their final histopathological staging, all patients were re-discussed at the Tumour Board for adjuvant therapy. Adjuvant treatment was completely spared in 3 cases, based on their favourable pTNM-classification and completeness of resection, including neck dissections with a sufficient nodal yield. One patient received adjuvant radiation alone (60 Gy) for his pT2 pN0 hypopharyngeal cancer, based on adverse features shown in his final histology such as poor differentiation, as well as perineural and lymphovascular invasion. One patient received 66 Gy adjuvant chemoradiotherapy for his pT2 pN2b disease, which may question the necessity of the surgery [15], being almost as much as a primary

Table 3 Oncologic and functional results

Patient no.	#1	#2	#3	#4	#5
Adjuvant th.	No	CRT 66 Gy	RT 60 Gy	No	No
Recurrence	No	No	No	No	No
Follow-up (median 18 months)	28 months	5 months	19 months	18 months	14 months
Current status as of June 2014	Alive, tumour free	Died of other disease (5 months postop)	Alive, tumour free	Alive, tumour free	Alive, tumour free
FEES 1 w. postop.	No penetration or aspiration	Mild aspiration	No penetration or aspiration	Severe aspiration	No penetration or aspiration
FEES 3 m. postop.	No penetration or aspiration	Severe aspiration	Mild aspiration	Mild penetration	No penetration or aspiration
FEES 6 m. postop.	No penetration or aspiration	N/A	No penetration or aspiration	No penetration or aspiration	No penetration or aspiration

CRT chemoradiotherapy, *RT* radiotherapy, *FEES* functional endoscopic evaluation of swallowing

chemoradiation of 70 Gy. In his case, we indicated the surgery hoping to spare him 10 Gy of radiation and the chemotherapy component of the adjuvant treatment, without radiologically suspected nodal extracapsular spread (ECS) in the neck. The latter feature was nevertheless evident in the final histology, so an adjuvant chemotherapy had to be included with the radiation increased up to 66 Gy (Table 3).

Recent follow-up status

At the time of their last follow-up visit (median 18 months), all patients had been recurrent-free and altogether four patients were alive as well as tumour free in the same time. One patient died of other disease (heart attack). Their early oncologic outcomes with their last follow-up status are summarized in Table 3.

Functional outcomes

No conversion to open surgery was necessary. Blood loss was minimal in all cases [16]. Mean robotic setup time was 31 min (range 16–48 min). Because of the rather horizontal retractor angle required for the hypopharyngeal access, edentulous patients were considerably easier to set up. Once the retractor was in position, docking of the robotic arms took an additional 18 min (mean; range 8–22 min). The robotic-assisted resection itself, i.e. the mean console time was 44 min (range 27–59 min) [13]. All patients underwent an ipsilateral selective neck dissection (levels II–IV) in a concurrent fashion.

The outcome measures we used to assess our functional results were swallowing quality represented by the duration of nasogastric tube feeding and/or PEG-feeding, rate of postoperative bleeding, number of elective and emergency tracheotomies, days of intensive care, number of days intubated and days of intermediate care [17] (Table 2).

Swallowing function

Median duration of nasogastric tube feeding was 5.5 days (range 3–18 days). One of the patients (patient no. 4) with a recurrent hypopharyngeal tumour after primary chemoradiation, had a PEG-tube prior to surgery, as she developed severe dysphagia during and after her conservative treatment which made her long-term PEG dependent. In her case, TORS was used for salvage surgery [18]. Another patient (patient no. 2) received a PEG-tube on the 18th postoperative day, because he needed adjuvant chemoradiation and his already impaired swallowing function was expected to deteriorate further during his adjuvant treatment. All other patients resumed full oral diet within the first postoperative week with a reasonable to normal physiological swallowing [19]. Functional endoscopic evaluation of swallowing (FEES) was carried out at 1 week, 3 and 6 months postoperatively (Table 3).

Elective, temporary tracheotomy was performed in one case (patient no. 3) due to postoperative mucosal swelling and difficult intubation in the anamnesis. The tracheotomy was closed on the 6th postoperative day. However, possible arguments for a routinely performed elective tracheotomy in hypopharyngeal and supraglottic TORS cases are detailed in the "Discussion".

Days intubated, intensive and intermediate care

By default, initially all our TORS patients were kept intubated for 24 h and have spent the first postoperative night at the ICU. Extubation followed on the first post-TORS day in the presence of the surgeon, after having observed the resection site and the entire laryngo-pharyngeal mucosa as well as performed a positive leak test.

Postoperative bleeding rate

In this subgroup of patients, there was neither any postoperative bleeding nor need for an emergency tracheotomy.

Discussion

Specifically in the hypopharynx, transoral robotic surgery has several advantages over transoral laser microsurgery. The latter provides with a tangential-only cutting plane because of the known line-of-sight issue, while a constant repositioning of the laryngoscope is often necessary. As a consequence of these limitations, en bloc resection is not possible in many cases and a piece-meal technique is considered to be acceptable by a number of authors. To illustrate the access advantage of TORS over TOLM, Fig. 2a, b show the tumour of patient no. 1, being exposed first with a conventional Kleinsasser-B-laryngoscope, suitable for TOLM. The laryngoscope has to be repositioned to expose either the inferior, or the superior portion of the tumour, on Fig. 2a, b, respectively. In contrast to this, the LARS retractor system, specifically designed for TORS, makes it possible to expose the entire tumour in a single position, shown on Fig. 3.

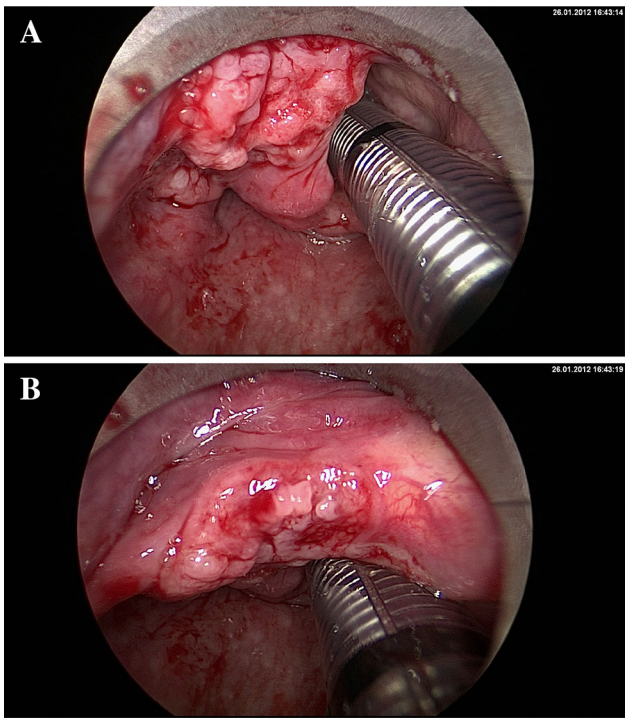

Fig. 2 **a** Patient no. 1 (see Table 1). Left piriform fossa/aryepiglottic fold tumour exposed with the Kleinsasser-B-scope, showing only the inferior portion of the tumour. **b** Patient no. 1 (see Table 1). Left piriform fossa/aryepiglottic fold tumour exposed with the Kleinsasser-B-scope, showing only the superior portion of the tumour

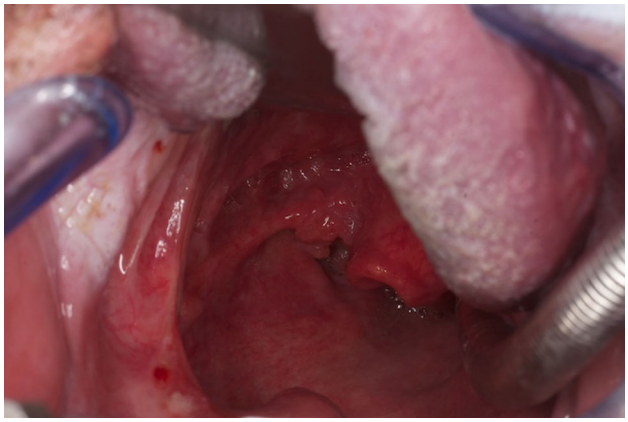

Fig. 3 Patient no. 1 (see Table 1). Left piriform fossa/aryepiglottic fold tumour exposed in its entirety with the LARS retractor system. No need for intraoperative repositioning

As a consequence of this, TORS enables the surgeon to perform multi-planar en bloc tumour resections under a magnified-3D-HD view even in confined spaces like the hypopharynx, which allows a more accurate assessment of the resection margins. The greater degree of freedom of the Endowrist instrumentation makes the margin safety of the resections equally sound to conventional open surgery, but on a much lower cost of surgical morbidity. This allows TORS to match the oncological safety of open surgery with the low morbidity of endoscopic laser surgery.

Among our first fifty TORS cases, consisting of predominantly oropharyngeal cancer patients but also including this subset of five hypopharyngeal cases presented here, there were two postoperative bleedings that required intervention under re-intubation (4 %), and neither of those occured from the hypopharynx. Although elective tracheotomy was not performed routinely in our series, the authors would like to emphasize that any bleeding in the hypopharynx or in the supraglottic larynx can be potentially life-threatening by preventing re-intubation and blocking the airway. Therefore, performing an elective tracheotomy in hypopharyngeal and supraglottic TORS cases may be reasonable in our opinion, especially if no neck dissection is done during the same session.

In our series, all patients underwent an ipsilateral selective neck dissection at the same time, with subsequent ligatures of the ascending pharyngeal and lingual arteries, to reduce the risk of postoperative bleeding from the hypopharyngeal primary TORS resection site. However, in cases with a staged (delayed) neck dissection, we would recommend performing an elective tracheotomy even before starting the robotic resection, to remove the endotracheal tube from the surgical field for a better access as an extra benefit, in addition to securing the airway postoperatively.

Conclusion

From a functional point of you, numerous clinical studies have shown improved post-TORS swallowing function compared to other surgical modalities and to primary chemoradiation therapy [17, 19], along with shorter hospital stay and faster recovery, as well as a more efficient return to work after completion of therapy [20, 21].

We found TORS to be an oncologically safe, technically feasible surgical modality for select T1 and T2 hypopharyngeal squamous cell carcinomas [22], with excellent margin control and minimal morbidity. Paired with an equally low-morbid selective neck dissection with sufficient nodal yield, the goal is to spare adjuvant treatment for a select group of low-risk patients.

However, in cases where adjuvant therapy cannot be completely omitted, we find a reduction of at least 10–12 Gy in radiation (from 70 to 72 Gy of first-line conservative treatment to 60 Gy of adjuvant treatment) and sparing the chemotherapy component of adjuvant therapy, are worth indicating TORS and selective neck dissection for well accessible T1 and T2 hypopharyngeal carcinomas [22, 23], to improve their functional outcomes compared to first-line chemoradiotherapy [24, 25].

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