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HEAD AND NECK

Transoral robotic surgery hypopharyngectomy (TORSH): feasibility and outcomes

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Abstract

Purpose With the development of minimal invasive procedure, trans-oral robotic surgery (TORS) is expanding in the field of ENT. Most reviews focus on oropharyngeal and laryngeal (supra-glottic) localization. We report here the feasibility and outcomes of TORS hypopharyngectomy (TORSH) for selected patients with hypopharyngeal tumor.

Methods Between September 2009 and July 2017, 22 patients, retrospectively included, underwent TORSH with curative intent.

Results From 22 successful hypopharyngectomy, no conversion to open procedure was needed. Three patients (13%) presented a post-operative bleeding and were managed by surgical revision. No fistula was encountered. The 3-year overall survival and disease-specific survival rates were 54 and 92%, respectively. Patients started oral feeding after an average of 7 days. Naso-gastric feeding tubes were removed after a median period of 16 days. Two patients (9%) needed a transient gastrostomy (< 1 year). Three patients (13%) received a transient tracheostomy (< 2 months). Median hospitalization stay was 13 days.

Conclusions TORSH is a safe technique. Patients' outcomes are favorable and the post-operative morbidity is reduced compared to open neck approach. Hospitalization length and safe swallowing time are reduced.

Keywords Transoral · Robotic surgery · Hypopharynx · Oncology · Head and neck tumors

Introduction

Head and neck cancers are the seventh most common malignancy in the world [1]. Among head and neck cancers, hypopharyngeal carcinoma has the worst prognosis with a 5-year relative survival at 31.9% (compared to a laryngeal location at 60%) [2]. Indeed, more than 75% of patients have nodal metastatic disease and more than 40% patients also have distant metastasis at the time of diagnosis [3–5]. Furthermore, the majority of patients are heavy smokers and/or drinkers and generally present with multiple co-morbidities. Over the past decades, definitive surgical approach (mostly total pharyngo-laryngectomy) has been the mainstay of treatment. This technique is associated with loss of function as phonation and swallowing. The prognosis is poor with 5-year survival rate of around 40% [4–8]. The development of new chemotherapy drug and radiation techniques brought a revolution in organ preservation protocol, without tracheostomy, but the prognosis remained stable [9]. Furthermore, the swallowing results are poor, and some patients need a permanent gastrostomy [10, 11]. It can be explained by chronic injury and fibrosis induced in the pharyngeal mucosa and muscles. The development of new surgical instruments allows a trans-oral approach. First, with trans-oral laser microsurgery (TLM), this reduces morbidity by avoiding cervical incision and tracheostomy. This technique can preserve some structures, as the pharyngeal sensory nerve plexus and the supra-hyoid musculature. Therefore, the functional outcomes are improved with the same prognosis [12, 13]. The return to oral diet is faster; gastrostomy is rarer, and the hospital stay is lower compared to open radical surgery. However, there are some limitations: because of the linear view from the microscope, the lesion is geometrically

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difficult to evaluate and often removed by piecemeal resection. Also, it is sometimes difficult to accurately assess the tumor margins because of the thermal damage induced to surrounding tissues by the CO_2 laser. This surgical approach is consequently often dedicated to small tumors.

Subsequently, the robotic approach emerged as an evolution of TLM and constituted a real revolution. Many studies revealed the feasibility and the safety of the da Vinci Robotic system for oropharyngeal and supra-glottic tumors [14–18]. It combines the advantage of the trans-oral approach with better functional outcomes, without the need for cervical incision and tracheostomy. The interest is the high-definition 3D view and the dexterity improvement with the 7 ° of freedom articulated arm. The tumor excision is more precise and performed as a one-bloc resection. Some teams started to use the robotic approach for hypopharyngeal carcinoma [19, 20]. During the last years, our institution also acquired expertise in robotic surgery. With the better manipulation and surgeons' experience, we extended its indications to the hypopharyngeal location. The goal of this report is to study the feasibility and the outcomes—oncologic and functional of this approach for hypopharyngeal cancer and share our experience.

Materials and methods

Patients

The study protocol has been approved by the Ethics Review Committee Institution (B039201938846).

Patients with an indication of surgery for a hypopharyngeal squamous cell carcinoma were included in the study from September 2009 to July 2017.

All patients underwent a pre-operative workup: ENT examination with fibroscopy and PET-CT. Patients with distant metastases were excluded. A previous direct panendoscopy under general anesthesia was done with biopsy to confirm the histological diagnosis. No second location was found. An exposure evaluation was performed at the same time with the Laryngeal Advanced Retractor System (LARS; Fentex Medical, Neuhausen, Germany) [21].

Surgical protocol

TORSH was performed with the da Vinci Surgical Robotic System Si (Intuitive Surgical, Sunnyvale, CA). A 0° telescope was used in almost all cases, but according to patient anatomy and tumor location, a 30° telescope was needed. Intraoral exposure was obtained in all cases using the LARS.

In this cohort, neck management was plan according to two options:

1. Clinical and radiological N0 patients, a sentinel lymph-node biopsy was performed [22, 23]. This technique consisted in the injection of 1 mCi of 99mTC-albumin nano-colloid dissolved in 1 mL of normal saline, in the sub-mucosa around the tumor (four quadrants of the tumor by suspension laryngoscopy). A PET-CT was performed after 20–30 min of lymphatic diffusion and prior to primary tumor resection. After tumor resection, neck lymph nodes biopsy was performed guided with the help of a hand-held kneed gamma probe (Navigator, RMD Instruments, LLC, Watertown, MA). All the SN were sent for serially sectioned histopathology with immunohistochemistry staining. If the lymph-node biopsy was positive for squamous cell carcinoma metastasis, a cervical neck dissection was performed 2 or 3 weeks after the TORS procedure.

2. Positive lymph-node patients (N +), a *simultaneous* selective neck lymph dissection was performed on the same day as the TORS surgery. We did not perform any preventive vascular ligation if it was not required for neck dissection (as the lingual artery for example).

Concerning the surgical procedure (Figs. 1, 2, 3), we started by mobilizing the lesion to assess its limits and the eventual adherences with adjacent healthy tissues. The surgical resection limits around the tumor were design using the Bovie cautery to obtain free macroscopic tumor margins. First incision was achieved on the posterior pharyngeal wall and extended medially to reach the anterior margin. The tumor was dissected off the posterior constrictor muscles (if they were not invaded). The resection was continued on the anterior and superior margins and carried to the thyroid cartilage. Thyroid cartilage perichondrium was resected if needed. Major vessels were identified and clipped if needed. Finally, the inferior and lateral incision was performed to reach the previous incision all around the tumor. A good retraction of the tumor is helpful to allow the resection through healthy tissues. The tumor was released from its final attachment at the apex of the pyriform sinus.

Intra-operative margins were assessed after tumor resection all around the boarding and analyzed by fresh frozen sections. Surgical trans-oral time was considered as done until all the analyses confirmed negative margins. Final hemostasis was completed if necessary, with Bovie cautery or monopolar suction. Naso-gastric feeding tube was placed and a thin layer of glue (Tissucol®, Baxter, Vienna, Austria) was carefully settled on the tumor bed resection.

Post-operative care

Patients were kept intubated the first night after surgery in Intensive–care Unit. Patients were extubated after fiberscope to assess the airway. Prophylactic antibiotic was continued for 24 h and corticoid during 24–48 h depending on the local edema. Due to the rural location of our institution, patients were kept at the hospital until safe

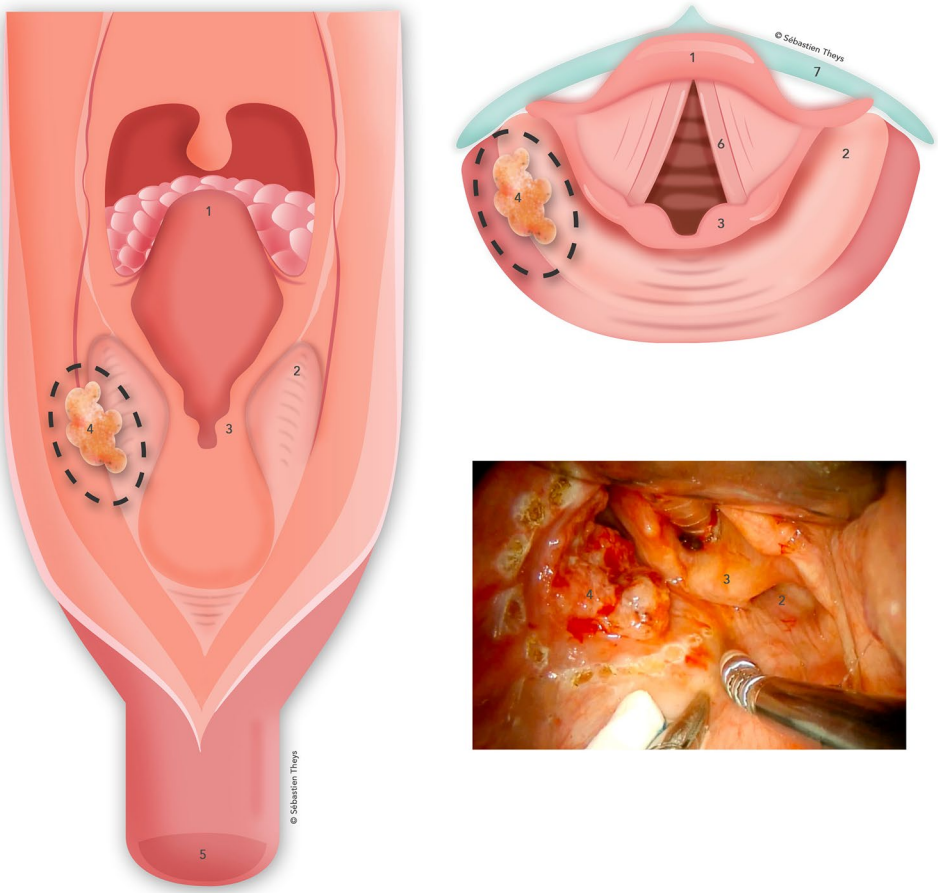

Fig. 1 Tumor location **1** epiglottis, **2** pyriform sinus, **3** arytenoid cartilage, **4** tumor, **5** esophagus, **6** vocal cord, and **7** thyroid cartilage

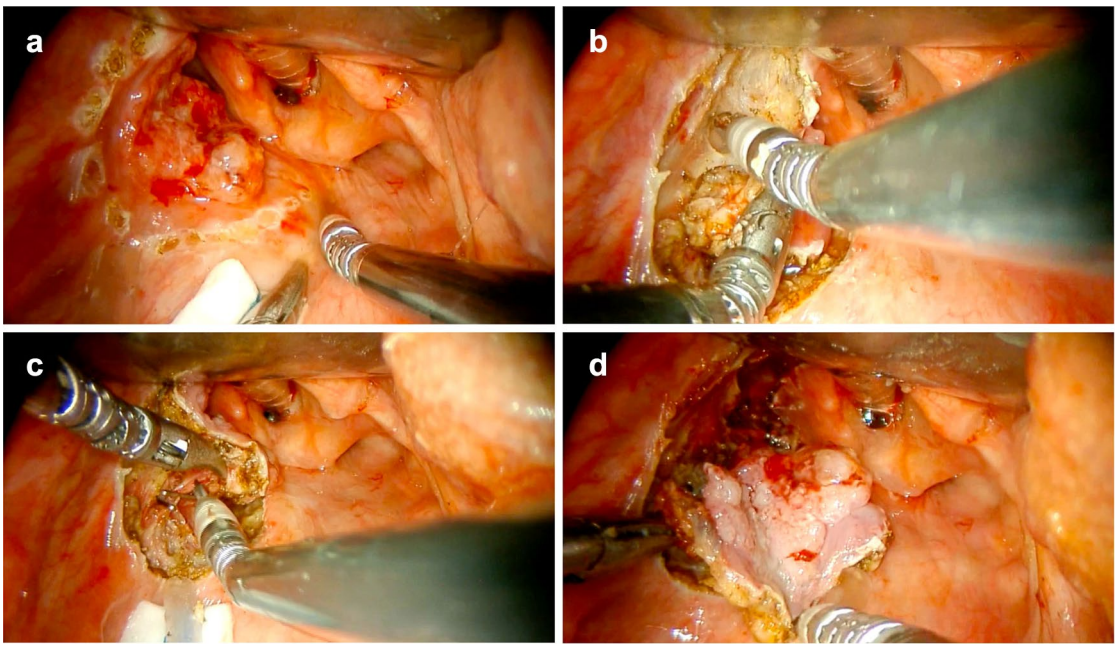

Fig. 2 Tumor excision **a** border tumor surrounding, **b** thyroid cartilage perichondrium resection, **c** vessel clipping, and **d** final view of the tumor resected

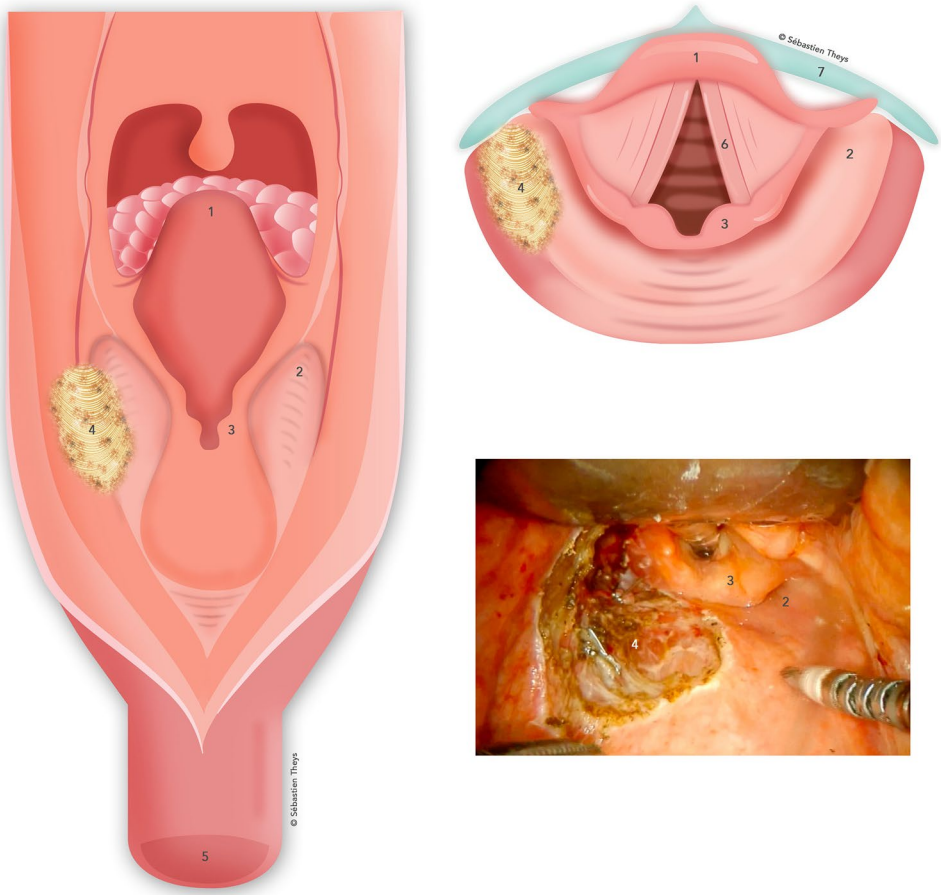

Fig. 3 Post-resection view **1** epiglottis, **2** pyriform sinus, **3** arytenoid cartilage, **4** post-resection bed, **5** esophagus, **6** vocal cord, and **7** thyroid cartilage

swallowing was demonstrated with both solid and liquid diets.

Swallowing function was evaluated with a fiberoptic endoscopic evaluation of swallowing (FEES) and modified barium swallow study (MBSS). Swallow therapy was sometimes needed. A sufficient caloric intake was evaluated before feeding tube removal.

Adjuvant therapy

All patients were discussed in Tumor Board Meeting with the post-operative histological results. Post-operative adjuvant radiotherapy alone was performed in the presence of (a) close margins (< 5 mm), (b) one invaded lymph node (N1), (c) peri-neural invasion, or (d) vascular embolism.

Post-operative adjuvant chemo-radiation was performed in case of positive surgical margins in the definitive histology (R1), more than two invaded lymph nodes (N2 +) and/or extra-capsular nodal spread.

Follow-up

All patients were seen regularly for functional (FEES) and oncologic evaluation.

A non-therapeutic response was considered when the recurrence occurred in a period less than 3 months after treatment. A recurrence is defined as each case of tumor in the same location, no matter the occurrence's duration. A second neoplasia was established in case of cancer in another location (for example, the other side of the pyriform sinus, oropharynx, etc.).

Data and statistics

Data were collected and recorded on the case reports forms. They were analyzed with Excel: MAC 2011 (Microsoft Corp.).

Overall survival (OS), disease-specific survival (DSS), and disease-free survival (DFS) were computed for all patients as the time between surgery and death from any cause, death caused by cancer or an underlying effect, and the first relapse or death caused by cancer or underlying

effect, respectively. Patients were right censored at the time of their last date of physical examination when they were still alive for OS and DSS and when they were still alive and without relapse for DFS. For DSS and DFS, patients who died from other causes were also right censored at the time of death. Kaplan–Meier survival curves were computed for each survival (i.e., OS, DSS, and DFS) using the survival v.2.41-3 package of R v.3.4.0.

Results

Patients

Twenty-two patients underwent TORSH with curative intent, including 18 men and four women. Nine tumors were located on the left pyriform sinus (41%), 12 on the right pyriform sinus (54%), and one on the pharyngeal posterior wall (5%). Patients' characteristics are summarized in Table 1.

Tobacco and alcohol consumption: Four patients had no history of tobacco use, 18 smokers, among which four had stopped some years before the diagnosis. Seventeen patients drank regularly alcohol.

Six patients had another squamous cell carcinoma treated by ENT surgery. Eight patients had a history of ENT radiation: six for squamous cell carcinoma (one right vocal cord, one larynx location, two oropharynx, one oral floor, and one pyriform sinus), one for a thyroid neoplasia, and one for an esophageal tumor. The patient with the esophageal carcinoma was the only one irradiated again after TORSH. Nine patients received chemo-radiation after TORSH.

Based on the guidelines set by the American Joint Committee on Cancer, the patients' staging was analyzed and summarized in Table 2.

Table 1 Enrolled patients' clinical information

Variable	No (%)
Gender	
Male	18 (82)
Female	4 (18)
Age mean, year	60
Range, year	41–83
Stage	
I	13 (59)
II	2 (9)
III	4 (18)
IV	3 (14)
Primary site tumor location	
Left piriform sinus	9 (41)
Right piriform sinus	12 (54)
Pharyngeal posterior wall	1 (5)

No = number

Peri-operative data

Exposure and surgical time were evaluated, respectively, with an average of 19.52 min (range 10–69) and 74.90 min. (range 32–145). This includes the histological time for the fresh-frozen section but not the cervical lymph-node resection. The surgeon's learning curve tended to reduce with the experience of the team, but depends also on the patient's anatomy (Fig. 4).

No complication was reported during surgery, in particular no major bleeding and no transfusion was needed. No conversion to open surgery was required. None of the patient (0%) received tracheostomy prior to the surgery.

Two patients (9%) had positive lymph nodes at the time of diagnosis and underwent neck dissection. Twenty patients were considered clinical and radiology N0 and we performed a sentinel lymph-node biopsy. In this group, the sentinel lymph node has been negative in 13 patients and positive in seven cases for which we performed a neck dissection in a second time.

Surgical margins in all patients are assessed systematically during the surgical procedure by fresh-frozen section analysis. There are positives in seven patients and negatives in 15 patients. For the positives margins, new complementary resections were performed until a negative result is obtained. On the definitive histological examination, one margin was positive, one was close, and 20 were negatives.

Table 2 TNM classification

T stage	*N* classification					Total
	0	1	2a	2b	2c	
1	9	3	0	0	0	12
2	4	1	1	3	0	9
3	1	0	0	0	0	1
4	0	0	0	0	0	0
Total	14	4	1	3	0	22

Stage I: 59.1%, Stage II: 9.1%, Stage III: 18.2%, Stage IV: 13.6%

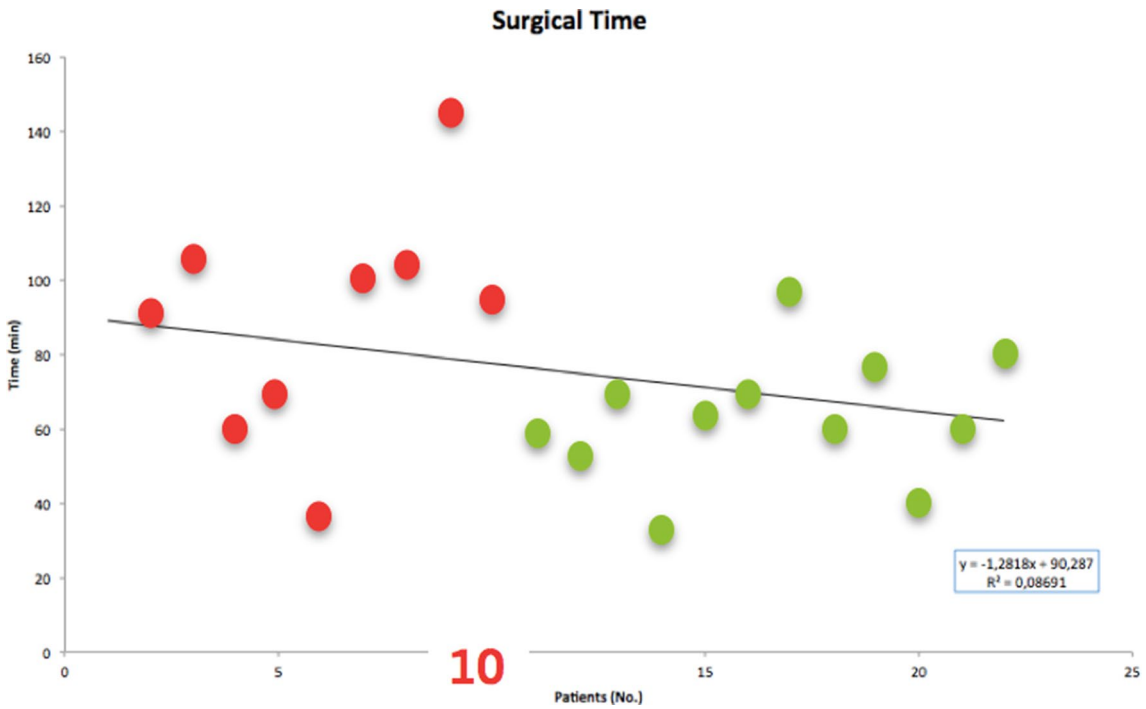

Fig. 4 Learning curve

Early post-operative events

Patients stayed at the Intensive-Care Unit with a mean stay of 3.32 days (median 2 days, range 0–30 days). One patient developed acute alcohol withdrawal and needed a long intubation time of 25 days. The patients were extubated early, after fiberscope, with a mean of 2.1 days (range 0–25 days; median 1 day).

Five patients (22.72%) developed laryngeal edema, well controlled by steroid injection. Only two patients (9.09%) needed a transient tracheotomy for less than 2 months.

There was no fistula (0%).

Post-operative bleeding occurred in three cases (13.63%), all managed by surgical revision, and the origin of bleeding was identified in only one case (clip fell). We managed this bleeding with electro-cautery suction and a preventive transient tracheostomy for safety reasons. For the other two cases, no bleeding was found. No transfusion was needed.

One definitive margin was positive (5%), and the patient underwent post-operative chemo-radiation. Six other patients underwent post-operative chemo-radiation for extracapsular lymph-node expression (two patients) or more than two positives lymph nodes (five patients). Eight patients had a history of radiation in the past (for other locations like oropharynx, thyroid, or esophageal tumor location). In these cases, no post-operative radiation was performed except for the patient with the history of esophageal tumors.

Oncologic outcomes

Average follow-up was 37.21 months (range 3–104 months).

There were four local recurrences (18.18%) and two local and neck recurrences (9.09%). Patients' characteristics and treatment are summarized in Table 3. All patients are alive without recurrence, except one (patient n°3). No clinical or histological factor was found to have a significant association with regional failure.

The 5-year disease-specific survival (DSS) rate is 91.7% and the 5-year overall survival (OS) rate is 53.7%. Six patients (27.27%) died for other causes. The 5-year disease-free survival (DFS) was 57.1%. Figure 5 shows the Kaplan–Meier curves for this rate (OS, DSS, and DFS).

Functional outcomes

None of the patients had a definitive tracheostomy (0%). Three patients (13.64%) needed a transient tracheostomy for less than 2 month swallowing results and hospitalization time are summarized in Table 4. Two patients (9.09%) needed gastrostomy for a short period (less than 1 year).

Table 3 Tumor recurrence following TORS

N°	Primary tumor	Neck treatment	Adjuvant therapy	Site to recurrence	Time (Mo)	Recurrence treatment
1	pT2 N1	SNLB followed by ipsilateral MRND	Yes	Local	11	Surgery
2	pT1 N1	SNLB followed by ipsilateral MRND	No	Local	12	Radiation
3	pT2 N0	SNLB and MRND	No	Local and neck	11	Surgery + radiation
4	pT2 N0	SNLB	No	Local and neck	24	Surgery + radiation
5	pT1 N0	SNLB	No	Local	2	Surgery + radiation
6	pT1 N0	SNLB	No	Local	10	Surgery (in situ)

Mo month, *SNLB* sentinel lymph node biopsy, *MRND* modified radical neck dissection

Discussion

Among head and neck cancers, hypopharyngeal carcinoma has the worst prognosis with a 5-year relative survival at 31.9% (compared to a laryngeal location at 60%) [3, 7, 8]. Indeed, more than 75% of patients have nodal metastatic disease and more than 40% patients also have distant metastasis at the time of diagnosis [4–6]. Almost patients underwent chemo-radiation as the first treatment option [9–11]. For this reason, in the European population, it is difficult to find small tumors without adenopathy, which explains the small number of cases in our study. Eight patients had a history of head and neck neoplasia in the past and were closely followed; in these patients, the hypopharyngeal carcinoma could be diagnosed early and the patient could benefit from a TORS approach.

The 5-year overall survival (OS) rate is 53.7%, partly explained by the significant co-morbidities. The 5-year disease-specific survival (DSS) rate is 91.7%. Park et al. have similar results including 45 patients who underwent hypopharyngeal resection with the da Vinci system. Their 5-year disease-specific survival rate reached 100% on stages I and II, 74% for stage III and IV [24]. Another team, Wang et al., studied ten patients who underwent TORS surgery for hypopharyngeal SCC [25]. They found no local recurrence. Two patients died, one because of distant metastases and the other due to another malignancy. The French GETTEC group (Mazerolle et al.) published a study about 57 patients with sinus pyriform squamous cell carcinoma. They have an overall and a disease-free survival, respectively, at 84 and 74% after 24 months, and at 66 and 50% after 48 months [26].

Adequate exposure is the key of success. Exposure failure can be identified in some anatomical consideration, as in limited mouth opening, large tongue, or retrognathia. Some manipulations can be helpful to improve the exposure as anterior traction of the tongue [27]. Our team also developed a retractor system with several blades (LARS [25]), which reduced the failure. The robotic surgical procedure takes an average time of 74.90 min. Park et al. have a similar result with a mean total surgical time (exposure and resection) of 410 min and found a significant statistical difference compared to open surgery with a mean total time of 911 min [28]. Therefore, TORS can be proposed for some patients with significant co-morbidities, aged or anesthetics contraindications.

The management of the margins is also important. In our population, the use of fresh-frozen sections can avoid definitive positive margins. Only one definitive margin is positive (5%) and one is close (5%); both patients underwent post-operative chemo-radiation. Weinstein et al. have carried a multicentric study of the adequacy of surgical margin in 192 patients with TORS [29]. They found an overall incidence of positive tumor margins in 4.3%, compared to 3.8% in the oropharyngeal tumors, 8% in the laryngeal location, and none for the oral cavity and hypopharyngeal lesions [29]. Furthermore, the surgical approach helps to know the real TNM status of the tumor and the need for postoperative radiation. In some cases, radiation could be reduced or even avoided. It leads to less morbidity, better functional results (mostly in swallowing) and also allows preserving radiation for future potential recurrence or second location (especially when the patient continues its alcohol and/or tobacco habits).

The need for preventive tracheostomy is controversial. Some teams always use preventive tracheostomy [30], first to prevent airway swelling but also to improve the surgical view. Decannulation was done after a mean of 5.3 days. In our study, no intra-operative preventive tracheostomy was needed. Five patients (22.72%) developed local edema, treated by steroid injection. Only two patients (9.09%) needed a transient tracheostomy. One other patient with post-operative bleeding received a preventive tracheostomy. In all cases, the tracheostomy was kept respectively 2 weeks, 1 month, and 6 weeks with no functional impact of the voice. Similarly, Wang et al. did not perform a preventive tracheostomy and did not need it in the post-operative period [25]. The French GETTEC group performed preventive tracheostomy in seven patients with a median decannulation time at 8 days. They have

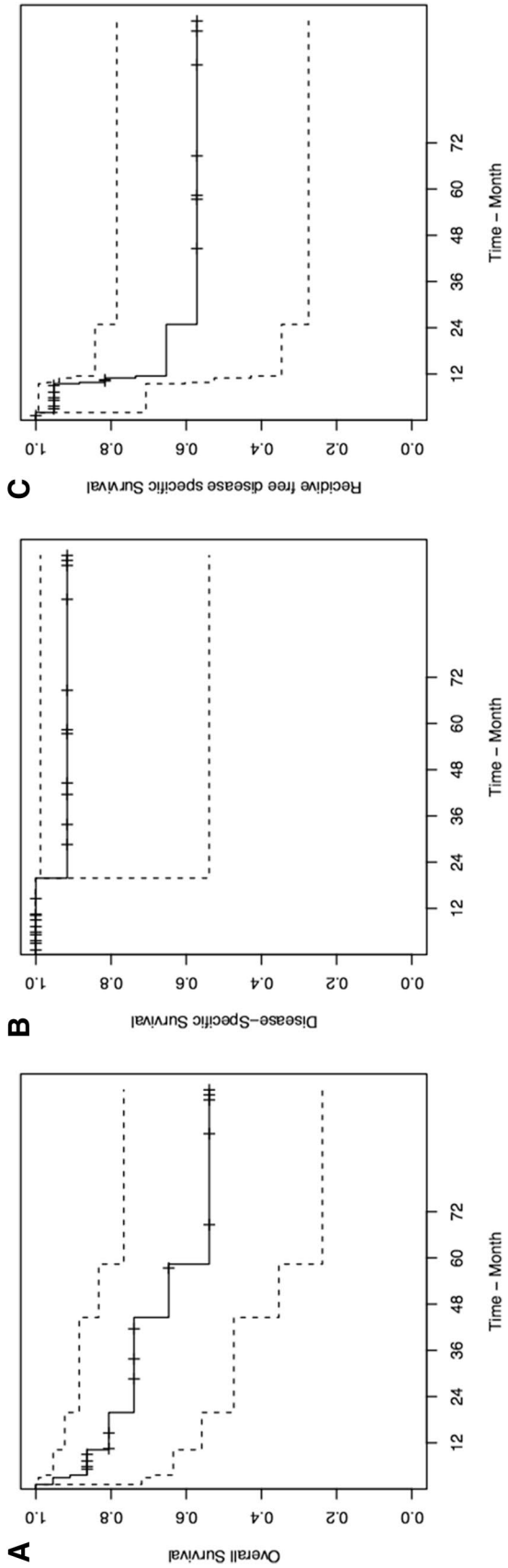

Fig. 5 Kaplan–Meier curves. **a** Overall survival. **b** Disease-specific survival. **c** Recurrence-free disease-specific survival

Table 4 Functional outcomes

	Mean (days)	Median (days)	Range (days)
Extubated	2.1	1	0–25
Feeding tube	35.17	16	0–183
Oral diet	7.95	6	0–30
Hospitalisation time	17.48	13	3–61

also noticed adecrease of the tracheostomy need with their surgical experience [25].

Post-operative bleeding occurred in three cases (13.63%). All received a surgical revision, but the origin of bleeding was identified in only one case (a clip fell down). No prophylactic lingual artery ligation was performed. Asher et al. published a study about hemorrhage after trans-oral robotic-assisted surgery (in all locations) [31]. They found that the only relative bleeding risk is due to the use of antithrombotic medication. No significant difference was found with the treatment by chemo-radiation. Each case of bleeding was managed by trans-oral approach (mostly laryngoscopy). They state the hypothesis to prevent it by prophylactic lingual artery ligation during the neck dissection. In our cases, sentinel lymph nodes contributed to reduce morbidity and we performed neck dissection only for a few cases. In our hands, preventive lingual artery ligation is not necessary to minimize surgical morbidity, especially when the bleeding can be controlled by trans-oral approach.

Concerning swallowing results, patients started oral feeding after a mean of 7.95 days after surgery and naso-gastric feeding tubes were transient for a mean period of 35.17 days. We worked together with nutrition and dietetic medical staff, so a good oral caloric intake and BMI were required before feeding tube removal. Furthermore, many patients suffered from malnutrition before surgery and needed more feeding supplementation time. Two patients (9.09%) needed gastrostomy for a short period (1 month and less than 1 year). They were both also previously treated by radiation, explaining in part their swallowing difficulty. Our results are comparable to the study of Park. Their patients could start an oral diet at an average of 15.9 days after surgery (range 2–170 days), and one definitive gastrostomy was needed [27]. Mazerolle et al. have also good functional results with an oral re-feeding possible for 93% after a median of 5 days and for 96% at the end of the follow-up. Only two definitive gastrostomies were required [26].

Finally, regarding hospital stay, the mean time was 17.48 days (range 3–61 days, median 13 days). Park et al. carried out an interesting comparison study between the trans-oral robotic surgery and the radical surgery for the hypopharyngeal cancer [27]. They found an average hospital stay of 26.1 days for TORS and 43.4 days for open surgery, with significant differences ($p=0.045$).

Some limitations can be found in our study: the experimental design (retrospective reports) and the small group of patients. To better confirm our results and increase the statistical power, prospective inclusion of patients is still ongoing.

Conclusions

TORSH is a safe and reliable technique. Patients' outcomes are favorable, and the post-operative morbidity is reduced compared to the open neck approach. Hospital stay was reduced, and patients required a shorter period for safe swallowing.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by HS, VS, and LG. Statistical analysis was done by AJ. The first draft of the manuscript was written by HS and all authors commented on the previous versions of the manuscript. All authors read and approved the final manuscript.

Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflict of interest.

Ethics approval Ethics Review Committee Institution of the CHU Namur approved the current research protocol: B039201938846.

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