

HEAD AND NECK

Transoral robotic surgery (TORS) for tongue base tumours

La chirurgia robotica transorale (TORS) nel trattamento dei tumori della base lingua

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SUMMARY

In recent years, transoral robotic surgery (TORS) has been used for the removal of pharyngeal and laryngeal cancers with the objective to improve functional and aesthetic outcomes without worsening the survival. This prospective single-centre cohort study described TORS in selected tumours of the tongue base in order to assess safety, efficacy and functional outcome of the procedure. From October 2010 to February 2012, TORS was performed in 13 consecutive patients affected by T1-T2 tumours of the base of the tongue. This procedure was applicable in all cases. The clinical stage demonstrated 8 T1 tumours and 5 T2 tumours. Neck node metastases were clinically evident in 6 cases (7 N0, 1 N1, 4 N2b and 1 N2c). The final pathology report confirmed malignancy in all cases (11 squamous cell carcinoma and 2 mucoepidermoid carcinoma). Negative-margin resections were obtained in all cases but one with close margins. Synchronous lymph node neck dissections were performed in 7 cases (6 monolateral, 1 bilateral). Patients underwent temporary tracheostomies for a mean time of 6 days. A naso-gastric feeding tube was positioned in 10/13 (76.9%) patients for a mean time of 7.5 days. The average time to carry out the TORS procedure was 95 min (set-up time 25 min; TORS 70 min). No deaths occurred. Surgical complications were observed in 4 cases (postoperative bleedings in 3 cases and intraoperative anaphylactic shock in 1 case). Median hospital stay was 9 days. All patients had good functional outcomes. Adjuvant treatment was indicated in 5/13 cases (35.4%). TORS represents a good tool for staging and treating neoplasm of the base of the tongue. The transoral removal is safe and can radically remove limited oropharyngeal tumours of the tongue base with good functional outcomes. The operating costs can be relatively high but they are related to the number of procedures per year, although the advantages to patients seem to justify the procedure. TORS can represent the definitive treatment in selected T1-T2 cases of base of the tongue tumours without adverse features and allow the possibility for the deintensification of adjuvant treatments.

KEY WORDS: Robotic surgery • Minimal Invasive • Transoral • Oropharyngeal cancer

RIASSUNTO

Negli ultimi anni, la chirurgia robotica transorale (TORS) è stata utilizzata per l'asportazione di neoplasie di faringe e laringe con l'obiettivo di migliorare i risultati funzionali ed estetici senza peggiorare la sopravvivenza. Abbiamo eseguito uno studio prospettico di coorte in soggetti affetti da tumore orofaringeo localizzato a livello della base lingua con l'intento di verificare la sicurezza, l'efficacia e i gli esiti funzionali della procedura. Dall'ottobre 2010 a febbraio 2012, 13 pazienti consecutivi, affetti da tumore T1-T2 della base lingua, sono stati sottoposti a TORS. La procedura è stata sempre tecnicamente eseguibile. Lo stadio clinico era: T1 in 8 casi e T2 in 5 casi. Linfonodi metastatici latero-cervicali erano evidenti in 6 casi (7 N0, 1 N1, 4 N2b and 1 N2c). L'esame istologico definitivo ha confermato la diagnosi di neoplasia maligna in tutti i casi (11 carcinomi squamosi e 2 carcinomi muco epidermoidi). I margini di resezioni sono sempre stati negativi ad eccezione di un caso con margini "close". Uno svuotamento latero-cervicale sincrono è stato eseguito in 7 casi (6 monolaterali, 1 bilaterale). I pazienti sono stati sottoposti a tracheotomia temporanea per un tempo medio di 6 giorni. Si sono alimentati tramite sondino naso-gastrico 10 su 13 (76,9%) pazienti per una media di 7,5 giorni. La procedura è durata mediamente 95 minuti (25 minuti per la preparazione e 70 minuti per la chirurgia TORS intesa dall'incisione al termine del tempo chirurgico). Non si sono verificati decessi. Abbiamo osservato complicanze in 4 casi: sanguinamento nel postoperatorio in 3 casi e shock anafilattico in 1 caso. Il ricovero è durato mediamente 9 giorni. Tutti hanno riportato buoni risultati funzionali. Un trattamento adiuvante nel postoperatorio era indicato in 5 su 13 (35,4%). Dallo studio si può concludere che la TORS rappresenta un valido strumento al fine di stadare e trattare le neoplasie della base lingua. L'asportazione trans orale è sicura e consente di asportare in maniera radicale i tumori di ridotte dimensioni localizzati nella base lingua ottenendo buoni risultati funzionali. I costi possono essere elevati, tuttavia, essi sono legati al numero di procedure annue e i vantaggi per i pazienti sembrano giustificare tale procedura. La TORS può rappresentare il trattamento definitivo in selezionati tumori T1-T2 (≤ 3cm) della base lingua ed in assenza di fattori prognostici sfavorevoli. Questa procedura sembra poter consentire la riduzione dei trattamenti adiuvanti.

PAROLE CHIAVE: Chirurgia robotica • Mini-invasiva • Transorale • Cancro orofaringeo

Introduction

Open surgical approaches to the oropharynx can be associated with morbidities such as cosmetic deformity, malocclusion and dysphagia. Therefore, a trend toward using radiotherapy and concurrent chemotherapy as a primary modality in case of oropharyngeal cancer has been observed in the last few decades^{1,2}. However, evidence of a clear advantage of concurrent chemoradiotherapy over using combined treatment (primary surgery followed by radiotherapy or chemoradiotherapy)³ is still lacking, while toxicity of intensive chemoradiotherapy causing severe dysphagia with dependence on a gastrostomy tube has been well documented^{1,4}.

In recent years, transoral robotic surgery (TORS) has been used for the removal of pharyngeal and laryngeal cancers with the objective to improve functional and aesthetic outcomes without worsening survival⁵⁻⁷.

Based on reports in transoral laser surgery (TOLS), the benefits of the transoral approach to the pharyngo-laryngeal lumen are well known^{8,9}. TORS allows a clearer and wider view of the surgical field and better 3D visualization of structures than TOLS, enabling access to the tumour via a smaller approach than the external one. Another advantage of TORS is the use of miniaturized tools. This allows mimicking standard surgical instruments and arm movements, with tremor filtration. In addition, it permits a frontal view and reaches “blind corners” of the pharyngo-laryngeal complex, not-perpendicularly positioned to the visual line due to the possibility to use a 30° telescope¹⁰. One of the objectives of this study is to evaluate whether acceptable overall functional outcomes in case of tongue base tumours are obtained using TORS. Most reports describe the use of TORS in radical tonsillectomy^{5,11} and partial laryngectomy¹². Few authors have focused on tongue base neoplasms, most likely due to the difficulty to recruit eligible cases^{6,13-18}.

The aim of this study was to demonstrate the feasibility, efficacy, functional outcomes and costs in a consecutive series of T1-T2 (≤ 3 cm) patients with tumours of the base of the tongue treated with TORS.

Materials and methods

Patient characteristics

Data were collected from a group of consecutive patients who underwent TORS for tumours of the base of the tongue at the Department of Otolaryngology, Head Neck Surgery of the Regina Elena National Cancer Institute in Rome, Italy. The study was a prospective, single-centre cohort trial. The local ethics committee approval was obtained to perform a clinical trial using the da Vinci Robot (Intuitive Surgical Inc., Sunnyvale, CA) for the resection of head and neck tumours.

Inclusion criteria was the presence of a T1-T2 (≤ 3 cm) oropharyngeal tumour of the base of the tongue, histologically-proven, that was amenable to transoral radical “en bloc” resection. Decision making to treat or not these patients by TORS was made in a tumour board counseling upon clinical evaluation and magnetic resonance imaging (MRI) or computed tomography scan, in case of impossibility to obtain MRI, that was used for detecting tumour extension. Patients with a tumour of the tongue base with superficial extension or infiltration into intrinsic muscles ≤ 3 cm were included in the study, while infiltration of the extrinsic muscle by the tumour (cT4a) represented a contraindication to this surgery. Patients with a mouth opening < 2.5 cm and/or distant metastasis were excluded from the study. Presence of nodal metastasis or previous treatment for head neck malignancy did not influence the procedure on the primary tumour. Neck dissection (ND) was always indicated for patients with squamous cell carcinoma staged as T1 and T2, while ND was not indicated for patients with mucoepidermoid carcinoma (low grade), in accordance with NCCN guidelines¹⁹. Informed consent form was obtained by all patients after attending a counselling session on the alternatives to surgery. Patients were followed up every 2 months for the first year, every 3 months for the second and third year and every 6 months thereafter. At each visit, history and clinical examination were performed, including flexible endoscopy. PET-CT scan and MRI of the tongue base were performed every 6 months for the first two years and every year thereafter.

Tumour management

Surgery started by positioning a temporary tracheostomy and NGFT. A tracheostomy tube was placed at the beginning of surgery before the TORS time for preventing difficulty during intubation and allowing better tumour exposure. When indicated, elective or therapeutic ND was performed during the same procedure, prior to TORS pharyngectomy. The TORS technique applied for tumours of the base of the tongue was the same as described by Moore et al.²⁰.

Exposure to the base of tongue was achieved by using a Feyh-Kastenbauer retractor. Radical surgery was assessed by the presence of intraoperative negative margins at the frozen section exam.

Postoperative (p.o.) radiation or concurrent radiochemotherapy were recommended if adverse features were present, including: positive or close (< 0.5 cm) surgical margins, 2 or more metastatic lymph nodes and whether there was extracapsular spread in the cervical lymph nodes.

Outcome measures

Demographic, clinicopathological, and follow-up data were collected. Global time of TORS procedure, TORS setup time, TORS operative time were recorded. Hospital stay was also registered. Intraoperative and p.o. compli-

cations were reported. The recovery to normal breathing (removal of tracheostomy tube) and swallowing (removal of NGFT) were reported. The long-term results were assessed by interviewing each patient about their breathing, speech and swallowing preoperatively at 1 month postoperatively and 3 months after radiotherapy or chemoradiotherapy, when performed. Functional assessment of breathing was done after evaluating a breathing score (BS) (CS 0 = normal breathing; 1 = minor dyspnoea, 2 = gross dyspnoea). Functional assessment of speech was based on a communication score (CS) (CS 0 = normal speech; 1 = minor dysphonia, 2 = gross dysphonia). Functional assessment of swallowing was measured recording a dysphagia score (DS) (DS 0 = normal swallowing; 1 = minor dysphagia; 2 = gross dysphagia). The functional impairment was considered "minor" when it was felt by the patient as abnormality without affecting the daily routine, while as "major" when he/she had to change habits. The role of TORS in reducing or avoiding p.o. adjuvant treatment was also considered. The cost analysis was carried out taking into consideration "Da Vinci" surgical robot-related direct costs.

Results

From October 2010 to February 2012, TORS was performed in 13 consecutive patients affected by T1-T2 (≤ 3 cm) tumours of the base of the tongue at the Department of Otolaryngology Head Neck Surgery of the Regina Elena National Cancer Institute in Rome, Italy.

Mean age of patients was 60.8 years (range 43-76; SD 9.7), 9 patients (69.2%) were male and 4 (30.8%) female. Table I shows the characteristics of patients. TORS represented the primary treatment for the oropharyngeal tumour in all cases, except in one already treated with chemoradiotherapy for squamous cell carcinoma of the base of the tongue. One patient was previously irradiated for an oral cavity cancer and another patient had a previous total laryngectomy for laryngeal cancer.

Preoperative biopsies tested positive for malignancies in all cases evidencing carcinoma. The final pathology report confirmed malignancy in 13 cases with: 11 squamous cell carcinomas and 2 mucoepidermoid carcinomas. Clear resection margins were obtained in all cases except in one with close margins (< 0.5 cm). The average intraoperative blood loss was 105 mL (range 15-420 mL). Blood loss was measured by evaluating the mL of blood present in the aspiration system.

ND was indicated in the 11 patients with squamous cell carcinomas, while it was not performed in case of mucoepidermoid carcinoma as suggested by NCCN guidelines¹⁹. ND was performed only in 7 cases (6 monolaterally and 1 bilaterally) synchronously to the treatment of the primary tumour except in 4 cases (all cN0) for the following reasons: 1 case already dissected, 1 case delayed

for intraoperative arrhythmia, 1 case for intraoperative anaphylactic shock and 1 case for previous irradiation of the neck.

Table II shows clinical staging by TNM classification. Pathological findings were as follows: 7 cases of stage I (7 pT1 cN0), 1 case of stage II (1 pT2 pN0), 1 case of stage III (1 pT2 pN1), 4 cases of stage IV (2 pT1 pN2b and 2 pT2 pN2b).

All patients underwent temporary tracheostomy, except the one with previous total laryngectomy. A NGFT was positioned in 10 (76.9%) patients; it was not used in the patient with previous total laryngectomy and in 2 cases who refused it.

Global time of the TORS procedure averaged 95 min (set-up time 25 ± 7 min; TORS time 70 ± 18 min).

One gram (g) of intravenous paracetamol 2 or 3 times daily was delivered for the first p.o. 48 hours. Antibiotic therapy with amoxicillin and clavulanic acid 2.2 g intravenously, twice a day, was maintained for 1 week after surgery. No deaths occurred. Surgical complications were observed in 4 cases (3 cases of p.o. bleeding on p.o. day 4, 6 and 14 and 1 case of intraoperative anaphylactic shock). The patient with p.o. bleeding on day 6 required surgical revision with transoral cauterization of small vessels of the tongue base for a 250 mL blood loss, while the other 2 patients with p.o. bleeding did not require further surgery because of a 50 and 60 mL blood loss that spontaneously

Table I. Clinical characteristics of patients.

Characteristic	Patients, N (%)
Sex	
Female	4 (30.8)
Male	9 (69.2)
Histology	
Squamous cell carcinoma	11 (84.6)
Mucoepidermoid carcinoma (low grade)	2 (15.4)
Neck dissection	
Yes	7 (53.8)
No	6 (46.2)
Adjuvant treatment	
No	8 (61.5)
Radiotherapy	1 (7.7)
Radiochemotherapy	4 (30.8)

Table II. Clinical staging by TNM classification.

Clinical classification	cT1	cT2	Total
cN0	6	1	7
cN1	0	1	1
cN2a	0	0	0
cN2b	1	3	4
cN2c	1	0	1
cN3	0	0	0
Total	8	5	13

stopped in 30 min. No cases of blood transfusion were registered. Median hospital stay was 9 days (range 3-30 days).

The tracheostomy cuff placed at the time of surgery was deflated on the first postoperative day and, then, substituted with an uncuffed tube the second postoperative day. The patient was decannulated when he was able to tolerate the cannula plugged for 24 hours consecutively. The average time of tracheostomy dependence was 6 days (range: 2-14 days). All patients were discharged from the hospital without tracheostomy tube. Breathing was considered as normal (BS = 0) by all patients before and after surgery. Speech evaluation did not show any difference before (CS = 0 in 12 cases and CS = 2 in the case with total laryngectomy) and after treatments (CS = 0 in 12 cases and CS = 2 in the laryngectomized case). The 76.9% of patients had a NGFT for enteral feeding and avoidance of aspiration or bleeding. All patients started nutrition with liquids 48 hours after surgery. The NGFT was removed when patient could tolerate both liquid and soft diet without aspiration. NGFT was placed for a mean time of 7.5 days (range: 3-18 days). Before surgery, DS was 0 in 6 cases, 1 in 6 cases and 2 in 1 case. After treatments (surgery alone or surgery followed by adjuvant treatment), DS was 0 in 9 cases and 1 in 2 cases. Return to oral function and normal diet was achieved in all patients and none of the patients complained of voice or breathing problems after surgery. Adjuvant treatment was indicated in 5 of 13 cases (38.4%) with malignancy: 4 cases had concomitant postoperative chemoradiotherapy (all stage IVa), 1 cases had postoperative radiotherapy alone (stage III). One patient with clinical stage IVa did not receive any adjuvant treatment after he was re-staged as stage II according to the pTNM.

The cost for a single TORS procedure at our Institution was about €2500 per procedure during the period of study, as calculated by the administration of the Institute.

The average follow-up time was 16 months (range, 8-27 months). This period is short for comparison with other treatments, however, all patients are being followed prospectively and oncologic data will be reported in the future as follow-up time increases. At last follow-up, all patients were alive without evidence of loco-regional disease or distant metastasis, except for one who died for causes unrelated to the neoplasia.

Discussion

The use of TORS started in animal models in 2003. It was first applied in humans in 2005 for vallecula cyst²¹. In 2006, O'Malley and colleagues published the first three cases of tumour of the base of the tongue excised by TORS²². They demonstrated that the Da Vinci Robot provided excellent visualization and enabled transoral removal of the tumour while preserving key structures and

nerves. In addition, they showed that it further allowed a complete resection with negative surgical margins and without complications. Recently, many authors published reports using TORS for head and neck cancer. Weinstein and colleagues described the use of TORS in supraglottic laryngectomy²³ and radical tonsillectomy¹¹ in patients with squamous cell carcinoma. Desai et al. reported results in 7 cases with oropharyngeal and laryngeal tumours using the robotic system combined with flexible carbon dioxide laser²⁴.

We analyzed the use of the Da Vinci system for radical treatment of oropharyngeal tumours, localized in the base of the tongue in order to gain an homogeneous group of patients with similar sites and sizes of tumours, whose excision would have previously required trans-mandibular or trans-pharyngeal approach. All the cases consisted of T1 and T2 smaller than 3 cm because we aimed to: (1) verify the feasibility of TORS as primary treatment in case of malignancy, (2) allow "en bloc" resection with free margins, (3) avoid reconstruction and (4) increase the learning curve before approaching more challenging cases. A longer follow-up time is required to confirm the data about the local control published by Weinstein et al.¹⁶. The routine use of tracheostomy and NGFT was the surgeon's first choice before opting for this new surgical approach. It was decided to begin the procedure in the safest way guaranteeing respiration and nutritional status in order to avoid complications such as extubation, haemorrhage and weight loss. Temporary tracheostomy was used in all cases. However, it was not required in patients who already had a total laryngectomy. In the Weinstein study on radical tonsillectomy, 20/27 patients were extubated at the end of the TORS¹¹, Genden did not perform any tracheostomies in 20 cases treated with TORS⁵. The use of tracheostomy in the literature is less frequent than that observed in our study, even though the published papers focused on tonsil tumours and the authors preferred to extubate patients 24-48 hours after surgery. A great advantage in performing a temporary tracheostomy before TORS consisted in obtaining better exposure of the oropharynx. This may not justify routine use of the tracheostomy, but it can be taken into consideration for candidates opting to undergo TORS without good oropharyngeal exposure. We maintained the NGFT in the 77% of cases for a mean time of 7.5 days to avoid that the swallowing movement could facilitate bleeding. All patients started swallowing saliva on the first postoperative (p.o.) day and water on the second p.o. day. No patient complained about swallowing and all were discharged without NGFT. Other authors described discharging patients earlier from hospital and the use of percutaneous gastrostomy for a longer period than the NGFT reported in our study^{15 20 25 26}.

Direct comparisons across these first reported functional outcomes is not straightforward. Performing tracheostomies avoided complications at the moment of extubation

and was useful in 2 of 3 cases of p.o. bleedings (patients bleeding on p.o. day 4 and 6). Conversely, NGFT did not prevent haemorrhage, as expected, but could guarantee enteral feeding as a proper way of nutrition. Complications related to TORS in the present series are not negligible. To date, 3 cases of haemorrhage represented 23% of the risk of complication related to TORS, even if only one case required surgical revision for haemostasis; the case of anaphylactic shock can hardly be related to TORS procedure, since it has never been described before and occurred following intra-operative drug administration.

We registered a global time of TORS of 95 min for the resection of tongue base lesions. A comparison with other statistics is difficult because other authors consider all the oropharyngeal subsites. The mean hospital stay was 9 days ranging from 3 days to 30 days in a patient submitted to excision of the tongue base extended to the supraglottis. The day before endoscopic surgery, external access to the base of the tongue has always required a transmandibular and/or transcervical approach with consequent high morbidity and poor cosmetic and functional outcomes^{2,28}.

TORS for tongue base neoplasms contributed to improving all these aspects offering a substantial advantage for the patient. Future studies should validate the procedure in terms of oncologic outcomes.

One of the main criticisms against using robotic surgery is related to the cost of the procedure. At our hospital the cost per procedure is about €2500, considering that 400 "Da Vinci" procedures a year are carried out in 4 departments (urologic, gynaecologic, abdominal and otolaryngology). When considering this cost alone versus traditional surgical techniques (endoscopic or open), the amount seems excessive, but the true comparison should be done between using a surgical transcervical or transmandibular approach to using non-surgical options like radiation or chemoradiation. Saving hospitalization time itself could be enough to balance the costs of using the robotic system, but the advantages related to the less invasive procedure, the best recovery and the functional outcomes justify the expense. The advantages of TOLS compared to the external approach are already well known. Future studies should confirm whether robotic surgery represents the main field for tongue base cancers because the alternatives (external approach or non-surgical options) seem to be related to a high incidence of complications and sequelae^{2,27-29}.

TORS, as surgical treatment, allowed to assess the pathological staging of the primary lesion in all patients. Neck dissections only added further information on the pathological nodal stage in 7 of 13 cases. TORS and neck dissections permitted the fine staging based on the pathological examination of the specimen. TORS represented the definitive treatment in 8 cases with oropharyngeal tumours of the base of the tongue without adverse events. TORS and neck dissection selected patients for postop-

erative adjuvant treatment sparing radiochemotherapy in one patient with clinical stage IVa who did not receive any adjuvant treatment after he was re-staged as stage II according to the pTNM. A great advantage of TORS is represented by the chance to give another option to patients with T1 and T2 (≤ 3 cm) who would have required more aggressive surgery or chemoradiotherapy as non-surgical treatment.

Conclusions

TORS represents a good tool for staging and treating neoplasms of the base of the tongue. The procedure is safe and can radically remove limited oropharyngeal tumours of the tongue base with good functional outcomes. Costs may be high but are related to the number of procedures carried out per year, although the advantages for patients seem to justify performing the procedure. TORS can represent the definitive treatment in selected T1-T2 cases of oropharyngeal tumours of the base of the tongue without adverse features and allow the possibility to deintensify adjuvant treatments.

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