Clinical outcomes of transoral robotic surgery for supraglottic squamous cell carcinoma: experience of a french evaluation cooperative subgroup of gettec

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Abstract. *Clinical outcomes of transoral robotic surgery for supraglottic squamous cell carcinoma: experience of a french evaluation cooperative subgroup of gettec. Background*: Transoral, minimally invasive, organ preservation surgeries are increasingly used to treat laryngopharyngeal carcinomas to avoid the toxicity associated with combined chemoradiotherapy regimens. This study investigated the efficiency, safety, and functional outcomes of using transoral robotic surgery (TORS) to perform supraglottic laryngectomy (SGL).
Methods: This was a multicenter study using a case series with planned data collection from 2009 to 2012 for patients with supraglottic squamous cell carcinomas (SCC) who underwent SGL using TORS.
Results: Eighty-four (84) of 262 patients underwent TORS for supraglottic SCC. Within 24 hours of surgery, 24% of the patients started on an oral diet. The median use of a feeding tube was 8 days for 76% of other patients. Definitive percutaneous gastrostomy feeding was necessary for 9.5% of the patients. 24% of the patients did require a tracheostomy, and the median use was 8 days. One percent (1%) of the patients had a definitive tracheostomy. Aspiration pneumonia was observed in 23% of the patients during the postoperative course, and was responsible for the death of one patient. Postoperative bleeding occurred in 18% of the patients. Based on the pathology results, 51% of the patients received adjuvant radiation therapy.
Conclusion: TORS for SGL in intermediate stage SCC is a safe procedure with good functional outcomes and fast recovery times. However, adverse events can occur. Consequently, this technique requires good patient selection criteria to reduce the risk of postoperative complications.

Introduction

The treatment options for supraglottic SCC include transoral laser microsurgery (TLMS), open surgical resection, and primary chemoradiotherapy (CRT). TLMS has the advantage of improved postoperative function and results in a limited need for tracheotomies and feeding tubes. TLMS appears to have equivalent recurrence rates and survival data as open surgery and nonsurgical treatment.[1-3] The use of TLMS for laryngopharyngeal carcinomas may avoid the acute and late toxicities that can occur with combined CRT in some cases. However, TLMS is a technically difficult procedure, and the endoscopic laser surgeon contends with various technical and spatial challenges. This limits the application of routine TLMS in supraglottic resections.

The da Vinci® Robotic Surgical System has recently made transoral procedures easier for head and neck surgeons, providing a new approach to minimally invasive pharyngeal and laryngeal surgery. In 2007, Weinstein *et al.* reported the first three cases of transoral robot-assisted supraglottic partial laryngectomies and found good oncologic and functional results.[4] The use of the robot improved both the visualization of the surgical field with the three-dimensional imaging system and the dexterity of the surgeon, with the bimanual control of the robotic arms. Moreover with this procedure, the surgical assistant provides additional suction and retraction and thus provides a total of four

dissecting instruments during the resection. By contrast, TLMS leaves only one hand free for manipulation of the tissue.

The main objective of this study was to investigate the efficiency, safety, and functional outcomes of using transoral robot assisted surgery (TORS) to perform supraglottic laryngectomy (SGL) for the treatment of a squamous cell carcinoma (SCC) of the pharynx and/or the larynx.

Patients and methods

This was a retrospective multicenter study using a case series with planned data collection from 2009 to 2012. Seven French independent tertiary care centers participated in this study, which was approved by a local ethics committee. This cooperative group is a sub-group of GETTEC (Groupe d'Etude des Tumeurs de la Tête et du Cou; Study Group of Head & Neck Tumors).

Patients

The eligibility criteria for inclusion in this study were broad and included patients aged 18 years or older that presented with supraglottic intermediate stages of SCC (epilarynx, hypopharynx; T1, T2 and "small" T3) and were judged by the surgeon to be transorally resectable using the robot.

The exclusion criteria included a small mouth opening that would preclude adequate exposure of the operative field. This exposure was checked with a mouth retractor during the initial staging endoscopic examination. Tumors that were judged to be not transorally resectable because of the volume and/or local extension were also excluded.

In each case, the decision to use robotic assistance was approved by a multidisciplinary board following clinical and radiological staging.

All of the patients provided informed consent.

Robot surgical procedures

The surgical intervention was performed under general anesthesia, with a nasotracheal intubation. A tracheostomy was necessary for those patients who had a high risk of airway edema.

The da Vinci® Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA) was set up as previously described by Weinstein *et al*.[4,5] Proper surgical exposure was ensured with the use of a Feyh-Kastenbauer retractor (FK; Gyrus-Medical;

Tuttlingen, Germany). A binocular endoscope set at 0° or 30° of 12 mm diameter was used. This was combined with a Maryland dissector and a monopolar cautery spatula – the arms measuring either 5 or 8 mm in diameter.

The surgeon was seated at the console of the da Vinci® system, while an assistant, positioned at the head of the patient assisted with the suction and retractor.

Neck treatment and adjuvant therapy

If a neck dissection was judged necessary by the multidisciplinary board, it was performed simultaneously in all cases during the TORS.

Indication for adjuvant radiotherapy with or without chemotherapy was based on histological results. It was recommended for patients with any of the following conditions: two or more lymph nodes involved, perineural or lymphovascular invasion, extracapsular spread of nodal metastasis and close or positive surgical margins for a tumor at the primary site. Adjuvant radiotherapy was only necessary for close margins and was treated with a dose of 60 Gy.

Outcome measures and statistical methods

The data collected in this study included pre-operative patient characteristics (age and sex), tumor site, clinical and pathologic stage (based on the TNM classification system from the Union for International Cancer Control [UICC], 7th edition of 2009), margin status, type of SGL, perioperative complications, total length of hospital stay, rate and length of tracheostomy, rate and length of feeding tube or percutaneous endoscopic gastrostomy (PEG) tube dependency, and postoperative adjuvant therapy.

The type of SGL was identified according to the European Laryngological Society classification system.[6]

The data were collected and recorded in a secure internet database (capture system, CNIL agreement [Commission Nationale de l'Informatique et des Libertés]).

The data in this paper are summarized as number of patients (percentages). Patients were censored on the date of death or the date of last contact.

The endpoints of the study were determined according to feasibility, safety, and assessment of the surgical margins. Feasibility was measured by

Table 1
Clinical characteristics

Characteristic		*N (%)*
Sexe	Male	68 (81)
	Female	16 (19)
Mean age		59 years (34-82)
Salvage SGL		16 (19)
Type of SGL	I	1 (1)
	II	12 (14)
	III	25 (30)
	IVa	6 (7)
	IVb	40 (48)

Abbreviations: SGL, supraglottic laryngectomy.

the ability to perform TORS without the need for conversion to an open surgery. The safety was assessed by the incidence of perioperative complications, as well as functional outcomes, including the rate of dependency on PEG and tracheostomy. Postoperative swallow function was assessed by a trained Speech and Swallow pathologist and physician with fiberoptic endoscopic evaluation.

Results

Between October 2009 and December 2012, 262 patients were registered in our database. Of these, 84 underwent TORS SGL for a supraglottic SCC.

Patient characteristics

The clinicopathologic data from the patients are shown in Tables 1 and 2. The mean age was 59 years (range, 34-82 years). There were 68 (81%) men and 16 (19%) women. The mean follow-up time was 14 months (range, 1-46 months).

Under the UICC classification, most of the patients were stage T2 (55%) and N0 (64%). Sixteen patients (19%) underwent TORS SGL as a salvage procedure for a recurrence after chemo radiotherapy in 10 patients or solely with radiotherapy in 6.

Details about the types of TORS SGL are reported in Table 1. Large resections were performed in 85% of the patients, with type III and IV SGL. Neck dissections were performed in 67 patients (80%) during the same procedure as the primary tumor removal.

Functional outcomes (Table 3)

Within 24 hours of surgery, 20 patients (24%) were started on an oral diet. For the other patients (76%), a feeding tube was necessary, with a median use of 8 days (range, 0-10 months). Finally, 8 patients (9.5%) underwent definitive percutaneous gastrostomy feeding.

For 64 patients (76%), no tracheotomy was performed. A tracheotomy was performed simultaneously (12 patients) to the TORS SGL procedure because of high risk of postoperative airway oedema, or secondarily (8 patients) because of postoperative dyspnea. From this group, 17 patients were decannulated by 8 days on average. Three other patients (4%) had a tracheostomy for more than 3 months (range, 93-270 days) and only one of them (1%) had a definitive tracheostomy.

The average hospital stay was 15.1 days (range, 3-45 days).

Adjuvant treatment

One patient needed conversion to open surgery due to poor exposure of the surgical field.

Permanent pathologic examinations revealed that 8 patients (9.5%) had positive surgical margins

Table 2
Classification TN

	T1	T2	T3	T4	**Total**
N0	20	28	6	0	**54**
N1	3	7	1	0	**11**
N2a	1	3	0	0	**4**
N2b	4	4	1	0	**9**
N2c	0	4	1	0	**5**
N3	1	0	0	0	**1**
Total	**29**	**46**	**9**	**0**	**84**

Table 3

Functional outcomes

		N (%)
Tracheostomy		20 (24)
	Median	8 days
	Definitive	1 (1)
Feeding tube		64 (76)
	Median	8 days (0-10 months)
	Permanent PEG	8 (9.5)

Abbreviations: PEG, percutaneous endoscopic gastrostomy.

and 44 (52%) had negative margins lower than 3 mm (Table 4).

Adjuvant CRT was necessary for 43 of the 84 patients (51%), 15 (18%) due to close or positive margins.

There was tumor recurrence in two patients (2%), with a mean follow-up of 14 months.

Adverse events (Table 5)

Following surgery, 15 patients (18%) had secondary bleeding from the tumor removal site. Twelve patients required reoperation with transoral hemostasis. We found the source of bleeding in the primary surgical wound orignating from a small branch of the superior laryngeal artery. We did not find any significant association with patient characteristics and postoperative bleeding. Aspiration pneumonia occurred in 19 patients (23%), and pharyngocutaneous fistula occurred in one patient. There was one death due to aspiration pneumonia, which happened several days after a secondary bleed. The serious adverse events were analyzed at our multicenter morbidity-mortality meeting.

Table 4

Oncologic results

	N (%)
Margins <3 mm	44 (52)
Positive surgical margins	8 (9.5)
Adjuvant CRT	43 (51)
Adjuvant CRT for margins	15 (18)

Abbreviations: CRT, chemoradiotherapy.

Discussion

Organ preservation has long been a consideration in the treatment of supraglottic SCC. Currently, there are two principal approaches to achieve this; SGL, which may be followed by adjuvant radiotherapy, or combined CRT. The main advantage of surgical treatment is the precise staging of the disease, thereby avoiding irradiation of the neck lymph nodes and tumor site. This is important because patients treated for supraglottic SCC usually have a high, five-year survival rate[7] but are also at risk of developing a second primary carcinoma. According to some reports, the risk of developing a second primary carcinoma ranges from 9 to 40%.[8-10] In the event of a second primary tumor, CRT could represent one of the principal treatment options.

One of the drawbacks of classic transcervical surgery, other than possible co-morbidity, is that it occasionally necessitates a lengthy hospitalization. This is due to the inherent requirement for a tracheostomy and enteral feeding tube with this procedure.[11] Consequently, these procedures result in a considerable financial burden to the health care system and medical insurance companies.

For these reasons, many teams recommend treatment by CRT. However, this option is not without its disadvantages, particularly because it can lead to acute and delayed toxicities, in addition to the need for prolonged enteral tube-feeding.[12,13] Furthermore, this approach can limit the available treatment options should a secondary primary carcinoma arise.

To reduce the morbidity associated with CRT and open surgery, LSG using TLMS was developed. For the majority of patients, this approach avoids

		N (%)
Intraoperative adverse events		
	Conversion	1 (1)
	Bleeding	1 (1)
Postoperative adverse events		
	Bleeding	15 (18)
	Pneumonia	19 (23)
	Fistula	1 (1)
	Death	1 (1)

the need for a tracheostomy and shortens the duration of the enteral feeding thereby reducing the hospitalization time. In terms of the tumor burden, TLMS appear to be equivalent compared to open surgery.[1,2,14,15] However, TLMS is a lengthy procedure that requires highly-trained, skilled surgeons. Therefore, in France, few medical teams have adopted this procedure.

The development of TORS has removed some of the drawbacks of TLMS, owing to its ability to operate with "four hands". Additionally, the amount of time needed to master this procedure is relatively short.[16] Unfortunately, the few available reports regarding the use of TORS in SGL are of limited scope. To our knowledge, this multicenter cohort represents the largest study of the feasibility, efficiency, and clinical outcomes of patient undergoing TORS supraglottic laryngectomy.

In this study, we found that the use of TORS to perform SGL was generally applicable for intermediate stages of SCC, and no adverse complications were encountered, with only 1 patient who required open surgery. This case of conversion was due to insufficient exposure of the surgical field. While this is a low number, it is not negligible, and it highlights the need for first performing a rigorous endoscopy examination under general surgery using the retractor designed specifically for robotic surgery.

With regard to enteral nutrition and food intake, 24% of the patients in our cohort did not require a feeding tube. The others were tube-fed for an average of 8 days, and only 9.5% of the patients (8 patients) had to continue with this beyond six months.

The previously published data for this type of procedure are variable, ranging from 0-44% use of

a feeding tube.[17-19] The highest reported permanent gastrostomy is 22%.[17] It must be kept in mind, however, that the number of patients included in these studies were limited.

These results support the concept that TORS SGL allows for a more rapid return to normal food intake than transcervical surgery. A study by Park *et al*. compared patients who had undergone an SGL.[20] Seventeen underwent open surgery and the other 17 underwent robot-assisted surgery. The functional outcomes were better for the patients who received robot-assisted surgery, with normal deglutition achieved, on average, after 8.1 days versus 18.5 days for the patients who underwent transcervical surgery.

Our results are comparable to those obtained using TLMS. Indeed, the functional outcomes reported by Canis *et al*.[1] for 277 patients who had undergone TMLS SGL are quite similar to those of the present study. Seventy-seven percent (77%) of the operated patients relied on a nasogastric feeding tube for an average of 7 days, 5% had a gastrostomy lasting 2 to 42 months and a further 2% had a permanent gastrostomy.

Similarly, the duration of enteral feeding tube found in our study was shorter than when CRT was administered. In CRT, enteral feeding is often used systematically during, and occasionally long after treatment - thereby resulting in a significant number of permanent gastrostomies. In the meta-analysis by Machtay *et al*., an enteral feeding tube for more than 2 years was required for 20.4% of the patients.[12]

In relation to perioperative tracheotomy, 24% of our patients had a temporary tracheostomy for an average of 8 days. For 1 patient (1%), tracheostomy was permanent. Results from other studies indicate that the use of tracheostomy ranges from 0-78%.[17-19] However, it should be noted that Mendelsohn *et al*. left their patients intubated for 24 hours following the operation, and did not perform a perioperative tracheotomy.[18] Therefore, these results also support the use of TORS relative to open surgery to perform SGL. Indeed, following transcervical surgery, most patients require a tracheostomy which remains longer than with TORS. According to the study of Park *et al*.,[20] patients were decannulated by 9.2 days on average in the TORS group versus 13.7 days on average in the conventional transcervical surgery group.

Compared to TLMS, our results on tracheostomy rates seem to be similar. Camarillas *et al*.[21]

highlighted that 11.5% of patients treated with TLMS required perioperative tracheotomies and 7.7% required permanent tracheostomies.

Compared to TLMS or open surgery, TORS does not appear to increase the risk for postoperative pneumonia, even if avoiding a tracheostomy does, in theory, increase the risk of aspiration. In our investigation, we encountered a 23% incidence of aspiration pneumonias - which is slightly higher than the 2 to 11.5% reported with TLMS.[1,21,22] However, this complication also occurs with trans-cervical surgery for which aspiration pneumonias can occur in as many as 40% of cases.[23]

The margins for our tumor resections were less than 3 mm for 52% of the cases, and they were positive in 9.5% of the patients. These numbers differ from those published in the literature, where negative margins were obtained for all patients.[17-19,24] There may be several reasons for this difference. The definition of a negative margin is not always clarified in publications (i.e. tumors margins, surgical margins, or frozen section margins). Furthermore, the French medical centers involved in our study are not geared to systematically perform frozen section. Lastly, some of the positive margins may be the result of initial user limitations. Indeed, all of the initial patients for each surgical team were included in this study. The tumor resection by TORS is performed using a monopolar electrosurgical instrument that results in carbonization and retraction of the excised tissue, which can make it difficult to determine the margins. This issue was initially unclear to the French surgeons who were used to open surgery. In light of this, the surgeons now routinely include very large surgical margins to afford a better analysis of the margins. Despite these issues, we found that 49% of our patients did not require adjuvant therapy. Thirty-three percent (33%) of patients received adjuvant therapy for positive lymph nodes and 18% for close or positive margins.

These results are similar to those of Olsen *et al*.[17] and Mendelsohn *et al*.,[18] for whom adjuvant treatment was employed in 67% and 50% of the cases respectively.

The frequency of secondary bleeding was an unexpected complication with an occurrence of 18%. This complication has been previously reported, although to a lesser extent. The multicenter study by Weinstein *et al*.[25] found that for a range of otorhinolaryngology sites, TORS resulted in post-

operative bleeding in 5% of the patients. We were unable to correlate this complication with a pre-operative condition. Over time some surgeons elected to ligate the superior laryngeal artery. We cannot comment on this practice because of insufficient data. However, it is pertinent be aware of this issue because it probably does occur more frequently than with TLMS where it has been reported in 9-11.5% of cases.[1,21] It is therefore necessary to inform the patient and medical support staff so that the issue can be addressed in an appropriate and timely manner.

Conclusion

This study has demonstrated the benefit of transoral surgery compared to open surgery. Indeed, the use of TORS to perform SGL in intermediate stages of SCC is a safe procedure with good functional outcomes and fast recovery. However, adverse events are possible. Consequently, this technique requires good selection criteria for patients to reduce the risk of postoperative complications. In our opinion, compared to TLMS, TORS offers better surgical comfort and enhances the possibilities of transoral resection. In France, TLMS is not standard for large resections of supraglottic tumors because of the difficulties associated with this surgery. For this reason, TORS is becoming popular. Unfortunately, the additional cost of this procedure is significant compared to TLMS or open surgery. Future investigations should examine the oncologic outcomes of TORS to treat supraglottic SCC. However, because encouraging preliminary oncologic results have been reported in the literature[26] and based on our promising functional results we believe there is sufficient reason to continue the evaluation of this type of robot-assisted surgery for suitable patients.

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