


Oncologic outcomes with transoral robotic surgery for supraglottic squamous cell carcinoma: Results of the French Robotic Surgery Group of GETTEC

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Abstract

Background: Transoral robotic surgery (TORS) is an option to treat supraglottic squamous cell carcinomas (SCCs). We studied the oncologic outcomes after TORS for supraglottic laryngectomy (SGL).

Methods: We conducted a multicenter observational study of SGL using TORS for patients with supraglottic SCC with at least 2 years of follow-up.

Results: One hundred twenty-two patients were included in our study. Mean follow-up was 42.8 months. Local control was 94.3% at 2 years and 90.2% at 5 years. Overall survival and disease-free survival were 86.9% and 95.1% at 2 years, and 78.7% and 94.3% at 5 years, respectively. Sixty-three patients (51.6%) received adjuvant radiotherapy. For 16 of them, this was due to close or positive margins.

Conclusion: Local control rate after TORS SGL was at least equivalent to what has been described in the literature for open or transoral laser surgery, or with radiotherapy. Using TORS seems to be an effective therapeutic treatment of early-stage and intermediate-stage supraglottic SCCs.

KEYWORDS

da Vinci robotic system, head and neck cancer, oncologic outcomes, supraglottic laryngectomy, transoral robotic surgery

1 | INTRODUCTION

Surgical treatment of patients with head and neck squamous cell carcinoma (HNSCC) must, as far as possible, meet the double challenge of performing a complete oncologic resection, while minimizing morbidity as well as functional and aesthetic sequelae.

In the 1970s, the advent of transoral laser microsurgery (TLM)¹ introduced the concept of minimally invasive surgery. Thus, by coupling use of a microscope and a laser, HNSCC could be resected without performing a cervical incision. Over the course of the 1990s and the 2000s, TLM indications, which were previously restricted to small tumors of the true vocal cord, extended to larger tumors as well as other sites, such as supraglottic larynx, oropharynx, and hypopharynx.² Compared to open surgery, TLM, when feasible, allows for a reduced level of morbidity, a faster swallow function recovery, a lower number of tracheotomies, and a shorter hospital stay.³ However, when applied to tumors other than on the true or false vocal cords, TLM is a surgical technique that requires skilled teams, and it has a long and steep learning curve.^{4,5}

The first robotic surgeries took place in the 2000s. This surgical approach was initially intended for laparoscopy, using the da Vinci robot (Intuitive Surgical, Sunnyvale, CA). This robot is suitable for several indications in various surgical specializations, and its use has been extended to resection of HNSCC. The Weinstein et al⁶ team pioneered this area in the United States, performing the first series of 3 resections of tongue base tumors in 2006. Indications became progressively broader, and numerous publications have now shown the feasibility of transoral robotic surgery (TORS) for various head and neck tumor localizations.^{7–9}

In 2009, the U.S. Food and Drug Administration approved use of the da Vinci surgical robot for TORS.

In France, the various surgical groups using this technology have joined the Groupe d'Etude des Tumeurs de la Tête et du Cou (GETTEC) for research purposes and to share of information regarding TORS.

Initial results regarding functional outcomes with TORS supraglottic laryngectomy (SGL) have been published, thereby allowing the feasibility of this technique to be assessed.¹⁰ However, there are few data regarding oncologic outcomes with this technique. Those that have already been published often involved heterogeneous populations, with various tumor sites,¹¹ low numbers of patients, and relatively short follow-ups.¹²

Hence, we performed an observational multicenter study over a 6-year period in regard to oncologic outcomes after TORS SGL. The main purpose of this study was the local control rate after at least a 2-year follow-up. Secondary purposes were the locoregional control rate, overall survival,

and disease-free survival. We also sought to determine possible factors that could influence the occurrence of a relapse.

2 | MATERIALS AND METHODS

We performed a retrospective multicenter observational study that included patients treated by TORS for a supraglottic squamous cell carcinoma (SCC) between December 2008 and January 2015, and who had a follow-up of at least 24 months.

These patients were derived from 9 French independent tertiary care centers at which each operator belonged to the GETTEC.

The study protocol was approved by the Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé (CCTIRS), which is the advisory body regarding the treatment of research matters in the health area.

2.1 | Patients

We included patients over 18 years of age exhibiting a stage T1, T2, or certain selected T3 supraglottic SCCs (medial epiglarynx, lateral epiglarynx, or medial part of the piriform sinus) and treated by TORS regardless of their lymph node status.

We excluded the following patients from our study: (a) patients who did not meet the minimal follow-up period criteria of 2 years at the time of the statistical analysis; (b) patients exhibiting a cancer with a different histological type; (c) patients with a history of treatment by radiotherapy for a prior HNSCC; and (d) patients with distant metastasis at the time of the diagnosis (M1).

The decision to perform TORS was approved by a multidisciplinary board in each center, after histological confirmation and a full assessment. During the initial endoscopy, it was systematically verified that the transoral exposure and accessibility to the tumor were sufficient for TORS with a specific mouth retractor for robotic surgery.

All of the patients received clear, accurate, and comprehensive information regarding the procedure that they would be undergoing.

2.2 | Neck treatment and adjuvant therapy

When raised at the multidisciplinary board, neck dissection was performed. This was performed at the same time as, or subsequent to, the tumor resection, in accord with the procedures in place at each center.

Indications for adjuvant radiotherapy with or without chemotherapy were decided at the multidisciplinary board, based on histological results according to the usual criteria for a poor prognosis. These comprise: more than 1 lymph node

involved, positive margins on surgical sample, extracapsular nodal spread, and perineural or lymphovascular invasion.

Irradiation dose of the larynx for patients with positive tumor margins was 60 to 66 grays.

2.3 | Outcomes measures

The collected data included: preoperative data: age, sex, tumor site, and clinical and pathological stage (based on the TNM classification system from the Union for International Cancer Control [UICC], seventh edition)¹³; perioperative data: neck dissection and the type of SGL performed according to the classification of the European Laryngological Society¹⁴; and postoperative data: adjuvant radiotherapy, occurrence of a local (laryngeal), a nodal (regional), or a distal recurrence, date of death (if this occurred) and its cause; pathological examinations: margin status (tumor margins, and surgical margins, if surgical margins were performed), perineural or lymphovascular invasion, and extracapsular nodal spread. Margins were deemed to be negative (R0) when they were ≥ 3 mm on surgical sample. A margin of < 3 mm but > 1 mm was deemed to be close, and a margin of < 1 mm was deemed to be positive (R1). Surgical margins were not performed systematically, as was the case for frozen margins (according to each center's usual procedures).

The evaluated criteria were local and locoregional control rates, overall survival, and disease-free survival. Disease-free survival corresponded with the percentage of patients who did not exhibit a local recurrence at the end of the follow-up period.

Overall survival was measured as the number of deaths from all causes combined, whereas disease-free survival was determined by the number of deaths linked to local recurrence of the cancer. Patients were censored on the date of death or on the date of the last update.

2.4 | Statistical analyses

Information about the patients were extracted from the digital patient files stored in a secure data base (Commission Nationale de l'Informatique et des Libertés, the National Data Protection Authority [CNIL] accreditation).

First of all, a descriptive analysis of the data was performed. The qualitative variables were reported as values and percentages, and the quantitative variables as averages and the SDs.

The survival rates were calculated according to the method of Kaplan-Meier.

A univariate analysis as well as a multivariate analysis using Cox's model was performed to identify potential risk factors independently associated with a recurrence and with survival. Factors with a P value $< .05$ by univariate analysis

TABLE 1 Clinical and surgical characteristics

Characteristics	No. of patients (%)
Sex	
Male	93 (76.2)
Female	29 (23.8)
Average age, years	60 (41.2-78.3)
Tumor subsite	
Medial epilarynx	68 (55.7)
Lateral epilarynx	41 (33.6)
Piriform recess	13 (10.7)
Type of SGL ^a	
I	1 (0.8)
II	30 (24.6)
III	28 (23)
IV	63 (51.6)
Neck dissection	
Performed	112 (91.8)
Same session that TORS	88 (78.5)
Second session	24 (21.4)
Not performed	10 (8.2)

Abbreviations: SGL, supraglottic laryngectomy; TORS, transoral robotic surgery.

^aType of SGL performed as a function of the classification by the European Laryngological Society.¹⁴

were included in this model, as were factors that could be clinically relevant.

A P value of $< .05$ was deemed to be statistically significant.

The analyses were performed using SPSS for Windows software version 19 (Vienna, Austria).

3 | RESULTS

Between December 2008 and January 2015, 153 patients were identified who had undergone TORS SGL using the da Vinci surgical robotic system for supraglottic SCC at any of the 9 participating centers.

Thirty-one patients were excluded, 21 of these because they had a history of HNSCC treated by external radiotherapy, and 10 others because they had a follow-up of < 24 months after their intervention.

A total of 122 patients were included in our study.

3.1 | Patient characteristics

Clinical and anatomopathological data are presented in Tables 1 and 2. The median age was 60.8 years (range 41.2-78.3 years). There were more men (76.2%) than women. The

TABLE 2 T and N classifications

N classification	No. by T classification				Total
	T1	T2	T3	T4	
N0	33	34	9	0	76
N1	6	11	2	0	19
N2a	1	6	2	0	9
N2b	3	6	2	0	11
N2c	0	5	1	0	6
N3	1	0	0	0	1
Total	44	62	16	0	122

median follow-up was 40.6 months (range 0.3-88.9 months), and the average was 42.8 months. Median supraglottic was the most common tumor site represented (55.7%).

Patients with T2N0 classifications were the most highly represented (27.9%), and the majority of the patients were N0 (62.3%; Table 2).

For 112 patients, unilateral or bilateral neck dissection was undertaken according to the location of the tumor (91.8%). The neck dissection was performed at the same time as the laryngectomy in 88 patients (78.5%), and in a different session in 24 patients (21.4%). The median time between the 2 sessions was 9 days.

The most often performed type of SGL was type IV (51.6%).

3.2 | Adjuvant treatment

Pathological examination results are presented in Table 3. Analysis of the surgical specimen's margins revealed that 8 patients (6.6%) had positive margins, 51 patients (41.8%) had close margins, and 63 patients (51.6%) had negative margins.

Surgical margins were performed on 103 patients, or 84.4% of the cases. They were positive for 7.8% of the cases ($n = 8$).

Adjuvant radiotherapy was necessary for 63 patients (51.6%). For 16 patients (13.9%), radiotherapy was performed due to positive margins or positive surgical margins. For 47 patients (74.6%), adjuvant radiotherapy was performed due to a nodal invasion.

TABLE 3 Pathologic examination

Studied data	No. of patients (%)
Presence of lymph node invasion (N+)	60 (53.6)
Margins status	
Positive (R1)	8 (6.6)
Close ($1\text{ mm} < \times < 3\text{ mm}$)	51 (41.8)
Negative ($\geq 3\text{ mm}$)	63 (51.6)
Perineural invasion	22 (20.8)
Lymphovascular invasion	27 (25)
Extracapsular nodal spread	30 (28.6)

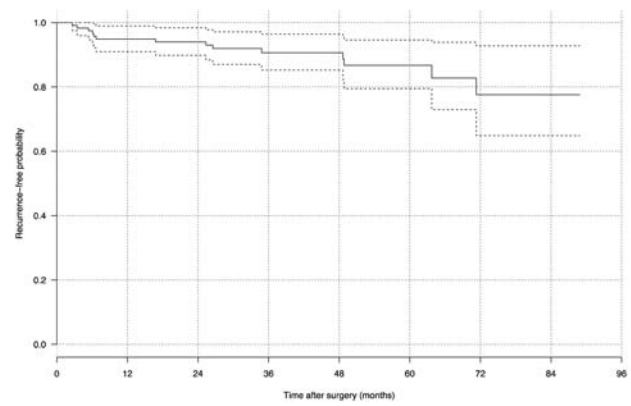


FIGURE 1 Local control for patients treated with transoral robotic surgery for supraglottic laryngectomy. The 2-year and 5-year local control rates were 94.3% (95% confidence interval [CI] 90.2%-98.4%) and 90.2% (95% CI 84.9%-95.5%), respectively

3.3 | Local and locoregional control

At the end of the follow-up period, 14 patients (11.5%) experienced a local tumor recurrence, and for 3 patients a regional recurrence was noted (2.5%). The median time to local recurrence was 21 months (range 2.7-71.3 months).

The 2-year and 5-year local control (laryngeal) rates were 94.3% (95% confidence interval [CI] 90.2%-98.4%) and 90.2% (95% CI 84.9%-95.5%), respectively (see Figure 1).

The 2-year and 5-year locoregional control rates were 91.8% (95% CI 86.9%-96.7%) and 87.7% (95% CI 81.9%-93.5%), respectively (see Figure 2).

3.4 | Survival

At the end of the follow-up period, a total of 28 patients (22.9%) were deceased. Eight patients died as a result of recurrence of their pathology (6.6%). Seventeen died of an intercurrent disease, and 3 from postoperative complications (Table 4).

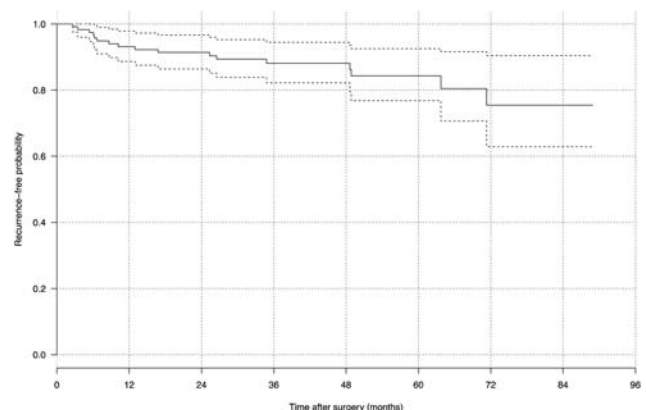


FIGURE 2 Locoregional control for patients treated with transoral robotic surgery for supraglottic laryngectomy. The 2-year and 5-year locoregional control rates were 91.8% (95% confidence interval [CI] 86.9%-96.7%) and 87.7% (95% CI 81.9%-93.5%), respectively

TABLE 4 Death causes

Type of death	No. of patients (%)	Comments
Death linked to the surgery	3 (2.46)	Massive hemorrhage on day 14 (n = 2)
		Pulmonary embolism on day 10 (n = 1)
Death linked to progression of the tumor pathology	8 (6.56)	
Death linked to an intercurrent pathology	17 (13.9)	Bronchial cancer (n = 5)
		Inhalation pneumonia (n = 3)
		Second HNSCC (n = 2)
		Cerebral vascular incident (n = 2)
		Esophageal cancer (n = 2)
		Unknown etiology (n = 2)
		Rupture of esophageal varices (n = 1)

Abbreviation: HNSCC, head and neck squamous cell carcinoma.

The 2-year and 5-year overall survival rates were 86.9% (95% CI 80.9%-92.9%) and 78.7% (95% CI 71.4%-86.0%), respectively (see Figure 3).

The 2-year and 5-year disease-free survival rates were 95.1% (95% CI 91.3%-99%) and 94.3% (95% CI 90.2%-98.4%), respectively (see Figure 4).

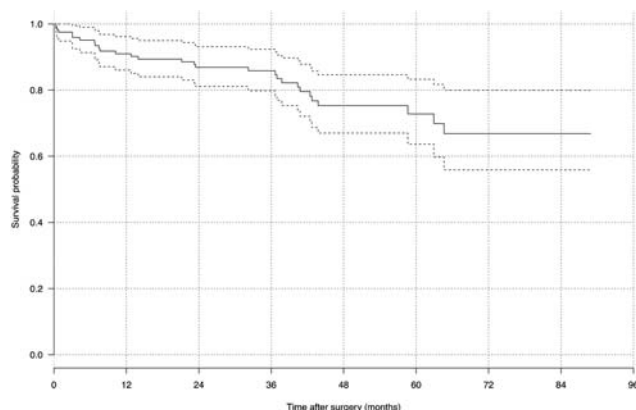


FIGURE 3 Overall survival for patients treated with transoral robotic surgery for supraglottic laryngectomy. The 2-year and 5-year overall survival rates were 86.9% (95% confidence interval [CI] 80.9%-92.9%) and 78.7% (95% CI 71.4%-78.7%), respectively

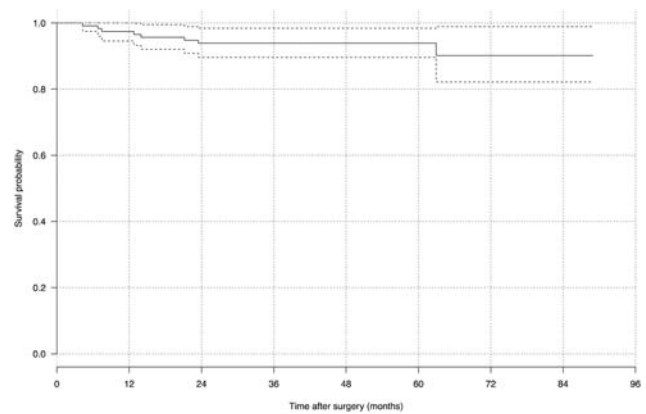


FIGURE 4 Disease-free survival for patients treated with transoral robotic surgery for supraglottic laryngectomy. The 2-year and 5-year disease-free survival rates were 95.1% (95% confidence interval [CI] 91.3%-99%) and 94.3% (95% CI 90.2%-98.4%), respectively

3.5 | Factors influencing local control and disease-free survival

Results of univariate and multivariate analyses seeking prognostic factors that could affect local control and disease-free survival are summarized in Tables 5 and 6.

For local control, only the N classification was significant ($P = .036$). The T classification seemed to be predictive at the limit of significance ($P = .052$).

By univariate analysis, the N classification ($P = .022$) and the presence of extracapsular nodal spread ($P = .043$) were shown to be risk factors affecting disease-free survival.

By multivariate analysis, none of the examined criteria proved to be prognostic factors for local control and disease-free survival.

4 | DISCUSSION

Before the development of robotic surgery for head and neck tumors, slightly more than 10 years ago, treatment of intermediate-stage supraglottic SCC was performed in 1 of 3 ways: “conventional” open surgery, TLM, or radiotherapy with or without chemotherapy. Although no study ever directly compared oncologic outcomes of these 3 procedures, the outcomes seem to be similar,^{15,16} with surgery possibly having a slight advantage in terms of initial local control, albeit with a higher initial postoperative morbidity and cost relative to radiotherapy.^{17,18}

Hence, the choice of 1 technique over another varies depending on the operators’ individual preferences and on the local healthcare resources.¹⁹

Yet surgery, whether open or transoral, offers an important advantage relative to radiotherapy by allowing accurate tumor staging to be obtained, thereby greatly assisting with the decision whether to provide adjuvant treatment. This can allow irradiation to be avoided with patients for whom the

TABLE 5 Prognostic factors associated with local control

Variables	Univariate analysis		Multivariate analysis	
	HR [95% CI]	<i>P</i> value	HR [95% CI]	<i>P</i> value
Age, years		.241		
<60	1.93 [0.64-5.77]			
≥60				
Sex		.226		
Male	0.28 [0.04-2.18]			
Female				
Tumor subsite		.676		
Medial epiglarynx	1.13 [0.63-2.03]			
Lateral epiglarynx				
Piriform sinus				
T classification		.052		
T1	2.21 [0.99-4.93]			
T2				
T3				
N classification		.036		.060
N0	1.42 [1.02-1.97]		1.42 [0.99-2.04]	
N1				
N2a				
N2b				
N2c				
N3				
Adjuvant radiotherapy		.082		
Yes	3.12 [0.87-11.2]			
No				
Margins status		.452		.977
Negative	0.74 [0.35-1.61]		0.99 [0.43-2.28]	
Close				
Positive				
Lymphovascular invasion		.990		
Yes	0.99 [0.27-3.67]			
No				
Perineural invasion		.348		
Yes	2.67 [0.34-20.7]			
No				
Extracapsular nodal spread		.373		
Yes	0.60 [0.20-1.84]			
No				

Abbreviations: CI, confidence interval; HR, hazard ratio.

risk of developing a second primary carcinoma can range from 9% to 40%.²⁰⁻²² Radiotherapy can in fact lead to complications, particularly in the long-term,^{23,24} and it limits the options for reirradiation in case of a second primary tumor.²⁵

Compared to open surgery, transoral surgery is more pre-servative in regard to structures involved in swallowing mechanisms.²⁶ In the majority of cases, a tracheotomy can be avoided, which decreases postoperative morbidity²⁷ and allows for a

TABLE 6 Prognostic factors associated with disease-free survival

Variables	Univariate analysis		Multivariate analysis	
	HR [95% CI]	P value	HR [95% CI]	P value
Age, years		.953		
<60	1.04 [0.26-4.20]			
≥60				
Sex		.816		
Male	1.21 [0.24-5.99]			
Female				
Tumor subsite		.806		
Medial epilynx	1.10 [0.51-2.35]			
Lateral epilynx				
Piriform sinus				
T classification		.273		
T1	1.77 [0.64-4.94]			
T2				
T3				
N classification		.022	1.51 [0.96-2.39]	.076
N0	1.63 [1.07-2.46]			
N1				
N2a				
N2b				
N2c				
N3				
Adjuvant radiotherapy		.166		
Yes	56.9 [0.18-17457]			
No				
Margins status		.141	0.68 [0.23-2.00]	.488
Negative	0.48 [0.18-1.28]			
Close				
Positive				
Lymphovascular invasion		.522		
Yes	2.00 [0.24-16.6]			
No				
Perineural invasion		.422		
Yes	27.9 [0.008-94470]			
No				
Extracapsular nodal spread		.043		
Yes	0.23 [0.05-0.95]			
No				

Abbreviations: CI, confidence interval; HR, hazard ratio.

shorter hospital stay.²⁸ It seems that TLM offers oncologic outcomes that are at least equivalent to those of open surgery.²⁹

The advent of the da Vinci robot and its development for head and neck surgery has, among other things, allowed some technical difficulties encountered with TLM to be

overcome, such as line-of-sight limitations. The learning curve with TORS is such that practitioners already skilled in endoscopic surgery can quickly learn to use it,³⁰ unlike TLM, which requires a long and difficult learning process for use at sites other than the vocal cords.⁵

In regard to functional outcomes, several studies have already shown the feasibility of TORS for the treatment of supraglottic tumors.^{10,12,31} The outcomes in terms of the delay in swallow function recovery, of decannulation in case of a tracheotomy being performed, and the reduced hospitalization time are consistent across the various publications in the literature.

The purpose of our study was to determine the oncologic outcomes after TORS SGL. Functional outcomes have already been reported in another publication by the GETTEC group, which involved almost the same cohort of patients.¹⁰

To our knowledge, there is little data available in regard to oncologic outcomes of TORS SGL. Our study provides the largest published series of patients operated on with TORS for supraglottic SCC sites only. The first series in the literature regarding oncologic outcomes after TORS SGL was established by Ozer et al³¹ in 2011, who encountered 100% local control, an overall survival of 66.7%, and a disease-free survival of 87.5% (9 patients). In 2013, with a series of 18 patients, Mendelsohn et al¹² found a 2-year locoregional control rate of 83%, a disease-free survival rate of 100%, and an overall survival rate of 89%. The same year Park et al³² carried out a prospective study involving 16 patients who had undergone TORS SGL; in which the 2-year disease-free survival rate was 91%. Hence, in terms of local control, our results seem to be close with those of other studies.

In our series, the 5-year overall survival rate was 78.7%. This number is explained by the majority of deaths being due to intercurrent causes, which reflects a patient cohort with a history of heavy alcohol and tobacco use in most of the cases. In this regard, we found that the number of second primaries was not insignificant ($n = 9$ or 7.4%; Table 4), and this is also being comparable with what has been reported in other publications.²² We also observed 2 deaths because of postoperative hemorrhage (1.6%). This rate is higher than what was reported for the series of Mandal et al,³³ with 0.9% of severe hemorrhage that led to death.

On the other hand, our outcomes for 2-year and 5-year disease-free survival are good (95.1% and 90.2%, respectively), and they are at least equivalent, if not better, than results found in the literature. For TLM, these results range from 72% to 80% at 5 years,^{29,34,35} and for open surgeries from 73% to 78% at 5 years.^{17,36} For equivalent stages (T1/T2), the 5-year disease-free survival obtained by radiotherapy (70% to 91%^{37,38}) is equivalent, if not slightly worse, than what that we obtained with TORS (90.2%). Care must be taken when comparing these numbers, as the patients treated in this study were highly selected. Thus, they were mainly early-stage and intermediate-stage, and, hence, they are not comparable in all regards with patients who could be treated by open surgery or by radiotherapy. It can nonetheless be discerned that TORS SGL of selected patients offers cure

rates that are at least equivalent to radiotherapy and other surgical techniques.

In our study, the final pathological analysis of margins revealed that 8 patients (6.6%) had positive margins, whereas 63 patients (51.6%) had margins that were ≥ 3 mm. Our results are not as good as those found by other studies of the same topic.^{8,12} This could be due to the fact that, in our study, tumor resection was done with a monopolar scalpel, leading to a retraction and carbonization of margins of the surgical sample, although their macroscopic presentation may appear satisfactory to the operator. It should be noted that the nature of margins is not always specified in some series (specimen margins? Surgical margins, frozen margins?), and that the distinction between positive and close margins often differs from one center to the next.³⁹

In our series, only 63 patients (52%) underwent adjuvant radiotherapy, and only 16 of them were due to positive margins. For the other 48% of the patients, radiotherapy could thus be avoided. A similar level was found in the series of Mendelsohn et al,¹² with 55.6% of the patients receiving adjuvant radiotherapy due to advanced neck disease.

By univariate analysis, only the N classification seemed to have an impact on local control and disease-free survival. Yet, no factor stood out as being statistically significant by multivariate analysis. This can probably be explained by the low number of events that occurred, which may have been insufficient to identify certain factors as being statistically significant. Additionally, we found that the margin status was not a prognostic factor, which could corroborate our clinical impression that our margins may at times be false-positive results due to a degree of retraction linked to the use of a monopolar scalpel, and that more weight should perhaps be given to the surgical margins. Furthermore, in a series of 410 patients (88% involving the oropharynx) operated on by TORS, the margin status did not emerge as a prognostic factor for locoregional control and disease-free survival.¹¹

Despite these encouraging oncologic outcomes, we are aware that TORS has a major drawback, which is the associated financial cost. The Belgian team of Dombree et al⁴⁰ has compared the financial costs of the following 3 techniques: open surgery, TLM, and TORS. The TORS was found to be the procedure for which the cost of the surgery itself was highest, although it should be pointed out that, relative to TLM, TORS allows for a reduction in the time that the operating room is used.⁴¹ The length of hospital stay is also significantly shorter than with open surgery.^{42,43}

It should also be noted that, in light of the rise in robotic surgery for numerous surgical specialties, some authors consider that the financial amortization may be easier for multidisciplinary health centers that want to acquire this surgical device.^{8,44}

5 | CONCLUSION

This multicenter study has shown that oncologic outcomes with TORS SGL were at least equivalent to those obtained by open surgery, TLM, and radiotherapy, which, until now, represented the 3 main therapeutic options for the treatment of early-stage and intermediate-stage supraglottic SCC.

The TORS seems to be a good alternative to other surgical techniques. In our series, we have seen that when the tumor could be resected with sufficiently safe margins there was no need for adjuvant radiotherapy in close to 50% of the cases. This therapeutic downscaling seems to be of particular relevance in terms of sequelae, as well as for patients susceptible of developing a second carcinoma.

The usefulness of TORS, which has already been shown for other localizations, such as the oropharynx, is, hence, clear for supraglottic SCC selected at an early-stage of disease.

Although questions regarding the financial cost of TORS are warranted, validation of our results by performing a larger scale prospective study seems to be required in order to further address this cost issue.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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