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Research Article

Robotic Surgery in Otorhinolaryngology-Head and Neck Surgery: a 5-year experience in a Latin American Center

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Received date: October 06, 2025; **Accepted date:** October 15, 2025; **Published date:** October 30, 2025

Citation: Rivera-Martínez CG, Adelaido L. Chavira, Gabriela R. Arroyo, Jose Granell, Raimundo G. Fonseca, et al, (2025), Robotic Surgery in Otorhinolaryngology-Head and Neck Surgery: a 5-year experience in a Latin American Center, *Clinical Research and Clinical Trials*, 13(4); **DOI:10.31579/2693-4779/300**

Abstract:

Background/Aim: To assess the challenges and outcomes of a newly established ORL-HNS robotic program in a Latin American center.

Materials and Methods: A retrospective study evaluating safety, functional, and oncological outcomes of the initial 39 cases of an emerging ORL-HNS robotic program.

Parameters examined in all cases were age, gender, date of surgery, docking and console times, intra and postoperative (PO) complications, abortion or conversion of the procedure, intensive care unit (ICU) stay, and diagnosis.

For patients with oropharyngeal carcinoma, additional data were obtained, including histology, pTNM stage, time to the resumption of oral feeding and decannulation, surgical margins, and adjuvant treatment, 12-month overall survival (OS), and 12-month disease-free survival (DFS) were also obtained. For OSA cases, a paired-samples t-test was used to compare pre- and post-intervention AHI means. Finally, for patients with thyroid pathology, histology, transient and permanent hypocalcemia, transient and permanent laryngeal nerve injury, and aesthetic results were also obtained.

Results: The conversion rate was 2.5% and the complication rate was 7.6%. All patients treated with transoral robotic surgery (TORS) resumed oral feeding in 24 hours, and none required tracheostomy after surgery. The primary tumor was found in 66% of carcinoma unknown primary (CUP) cases after TORS. The 12-month overall survival (OS) was 83.3% for patients with oropharyngeal carcinoma. For patients with obstructive sleep apnea (OSA), there was a statistically significant improvement in apnea-hypopnea index (AHI) values (from 39.1 ± 23.1 events/hour to 20.8 ± 18.9 events/hour) ($p = .013$). All patients treated with robot-assisted hemithyroidectomy were satisfied with aesthetic results.

Conclusions:

Robot-assisted Surgery (RAS) is feasible and safe. In our experience, it has proven its largest advantage for diagnosing CUP and managing highly selected cases of OSA and OPSCC.

Keywords: transoral robotic surgery; oropharyngeal squamous cell carcinoma; obstructive sleep apnea; robot-assisted thyroidectomy; otolaryngology; carcinoma unknown primary

Introduction

Robot-assisted surgery (RAS) is one of the great medical breakthroughs of the 21st century. RAS has been rapidly adopted in surgical specialties, including urology, gynecology, and general surgery; however, its acceptance in Otolaryngology–Head and Neck Surgery (ORL-HNS) has been more gradual. In 2003, a group at Stanford published a feasibility study of robotic neck surgery in a porcine model [1]. In 2005, a supraglottic partial laryngectomy in a canine model was the first live application of transoral robotic surgery (TORS) [2]. That same year, McLeod and Melder performed the first robotic procedure on a human patient with the resection of a vallecular cyst [3]. In 2007, Weinstein and O'Malley published a prospective series of 27 patients treated with radical tonsillectomy for oropharyngeal squamous cell carcinoma (OPSCC) [4]. In 2009, the first series of robot-assisted thyroidectomies was published [5]. Later that year, the United States Food and Drug Administration (FDA) approved TORS for T1-T2 OPSCC. In 2010, TORS was used for the management of OSA by Vicini et al. [6]. Other indications for RAS, such as parathyroidectomy, neck dissection, laryngectomy, and diagnostic mucosectomy of carcinoma of unknown primary (CUP), have also been described. There are nearly 130 robotic surgery programs in Latin America, 20 of which are in Mexico. There are few published studies on RAS in Mexico [7-10], and to our knowledge, none include ORL-HNS cases. Introducing RAS into clinical practice is challenging, as it is a costly health infrastructure that depends strongly on having adequately trained medical professionals. A standardized model for implementing a robotic ORL-HNS clinical program in developing nations has not been described. This study aims to present the experience of establishing an ORL-HNS robotic surgery program in an academic center and to assess the outcomes of the procedures undertaken since its inception.

Materials and Methods

This series comprises all ORL-HNS patients managed with robot-assisted surgery from April 2017 to August 2023 at a publicly funded tertiary care facility in Mexico City. Each case was discussed with the hospital's robotic surgery committee for authorization, and carcinoma cases were also discussed at the tumor board meeting. Written informed consent was obtained from all patients.

Surgical Technique

The da Vinci Surgical Robot, Si version (Intuitive Surgical, Sunnyvale, California, USA) was used for all procedures. All patients were under general anesthesia and all TORS cases were done with nasotracheal intubation. The setup for TORS cases included three robotic arms: a robotic 0°, 8.5 mm camera was placed in the central arm, a 5 mm monopolar cautery was placed in the arm ipsilateral to the tumor, and a 5 mm Endowrist Maryland Forceps was placed in the contralateral robotic arm. Transoral exposure was obtained with either a Davis Boyle or a Davis Meyer retractor. For patients requiring neck dissection, it was performed by an open approach at a different surgical time. Robot-assisted thyroid procedures were performed with orotracheal intubation and laryngeal nerve monitoring with a bilateral axillary-breast approach (BABA). The setup included a robotic 30° 12 mm downward-facing camera positioned in the right breast incision, and an 8 mm hook monopolar cautery was inserted through the left breast incision, which was exchanged with Harmonic Ace Curved Shears as needed. An 8 mm Endowrist Maryland Forceps and an 8 mm Prograsp Endowrist Forceps 8mm were inserted through the axillary incisions.

Variables

All charts were reviewed to obtain the following data: age, gender, date of surgery, docking and console times, intra and postoperative (PO) complications, abortion or conversion of the procedure, intensive care unit (ICU) stay, and diagnosis [7]. Complications were categorized using the Clavien-Dindo (CD) classification [11].

For patients with a diagnosis of oropharyngeal carcinoma, specific additional data were obtained: tumor subsite, histology, pTNM stage, p16 status, whether or not tracheotomy was performed, insertion of a nasogastric tube or gastrostomy, time to the resumption of oral feeding and decannulation, surgical margins, and adjuvant treatment. Recurrence, 12-month overall survival (OS), and 12-month disease-free survival (DFS) were also obtained [12]. The specific variables obtained for OSA cases were the volume resected and pre-operative and postoperative AHI values. Surgical success was defined as a >50% reduction of AHI and a postoperative AHI < 20 events/hour [13]. Surgical cure was defined as a postoperative AHI < 5 events/hour. Finally, for patients with thyroid pathology, histology, transient and permanent hypocalcemia, transient and permanent laryngeal nerve injury [5], and aesthetic results were also obtained.

Statical Analysis

The normality of the distribution for both pre- and post-intervention AHI scores was assessed using the Shapiro–Wilk test. Given that both distributions did not significantly deviate from normality, parametric analyses were performed. A paired-samples t-test was used to compare pre- and post-intervention AHI means. The magnitude of the effect was quantified using Cohen's d for the t-test, with conventional thresholds of .2, .5, and .8 (for d) interpreted as small, medium, and large effects, respectively.

Statistical significance was set at $p < .05$. Statistical analyses were performed using SPSS 26.0 for Windows (SPSS, Chicago, IL).

Results

A total of 39 procedures were done. Details of the patients treated are summarized in Table 1. The first procedure done was the resection of a vallecular cyst. Two more cases of benign lesions were performed in 2017 and 2018, but then TORS was limited to OSA and cases involving malignant pathology. The number of robot-assisted surgery thyroid procedures diminished over time. The conversion rate was 2.5%, and the complication rate was 7.6%. The ICU stay was minimal, indicated only in an 84-year patient for monitoring. All patients treated with TORS restarted oral diet in the first 24 hours after surgery, and no patient required a tracheostomy after the intervention.

Diagnosis /procedure	Number of patients treated n (%)	Sex n (%)	Age Median (range) Years	Docking Time Median (range) Minutes	Console Time Median (range) Minutes	Conversion rate n (%)	Intra/Postoperative Complications n (%)	ICU stays Median (range) Days
TORS for malignant patholohy	14 (35.9%)	Male 13 (92.9%) Female 1 (7.1%)	55 (38- 86)	6 (2-17)	160 (58-155)	0 (0%)	0 (0%)	0 (0-1)
OSA	14 (35.9%)	Male 10 (71.4%) Female 4 (28.6%)	46 (23-69)	6 (3-15)	53 (30-150)	0 (0%)	2 (14.2%) CD I 7.1%) CD IIIb (7.1%)	0
TORS for benign pathology	3 (7.7%)	Male 2 (66.6%) Female 1 (33.3%)	46 (36-70)	7 (6-8)	35 (26-210)	0 (0%)	0 (0%)	0
RAS hemithyroidectomy	8 (20.5%)	Male 0 (0%) Female 8 (100%)	43 (37-50)	14 (5-29)	210 (158-255)	1 (12.5%)	1 (12. 5%) CD I (12.5%)	0
TOTAL	39 (100%)	Male 25 (64.1%) Female 14 (35.9%)	47 (23-86)	6 (2-29)	83 (26- 255)	1 (2.5%)	3 (7.6%) CD I(5.1%) CD IIIb (2.5%)	0 (0-1)

Table 1: Patients' characteristics treated with robotic surgery

ICU, Intensive Care Unit; OSA, Obstructive sleep apnea; TORS, Transoral robot-assisted surgery; RAS, Robot-assisted surgery; CD, Clavien Dindo.

TORS for management of malignant pathology

Of the 14 patients with carcinoma, 11 were diagnosed with oropharyngeal carcinoma, and three had CUP.

The primary tumor was found after TORS in two of the three CUP cases. One of these CUP patients was diagnosed with OPSCC T1N1M0. The other was diagnosed with hypopharyngeal squamous cell carcinoma during surgical exploration, which was deemed non-resectable, a biopsy was performed and the patient received chemoradiotherapy.

Table 2 summarises the management and follow-up of the 12 patients with oropharyngeal carcinoma. The 12-month OS and 12-month DFS were 83.3% in both cases. Recurrence was distant in all cases, with no case presenting locoregional recurrence.

Patient	Histology / subsite	pTNM	p16 status	Transoperative Surgical margins	Adjuvant Treatment	Follow-up time (Months)	Recurrence	Clinical Status at last follow-up
1	SCC / tonsil	T2N2bM0	NA	Negative	CRT	68	No	Alive, free of disease
2	SCC / tonsil	T3N0M0	Positive	Negative	Neoadjuvant CT/ PORT	69	No	Alive, free of disease
3	High-grade mucoepidermoid carcinoma / soft palate	T2N2cM0	NA	Positive	CRT	8	Diffuse pulmonary disease. After diagnosis of distant disease loses insurance before receiving treatment	Presumed deceased
4	SCC /BOT	T1N2cM0	NA	Negative	CRT	60	Diffuse pulmonary disease diagnosed 56 months after diagnosis, under systemic treatment	Alive, with disease
5	SCC / tonsil	T2N2bM0	Negative	Negative	CRT	51	No	Alive, free of disease
6	SCC /BOT	T1N2bM0	Negative	Negative	CRT	16	No	Alive, free of disease
7	SCC / BOT	T1N3aM0	Negative	Negative	CRT	36	No	Alive, free of disease
8	SCC (sarcomatoid variant) / BOT	T3N3bM0	Negative	Negative	No*	11	Mediastinal adenopathy. Receives systemic treatment	Deceased
9	SCC / Tonsil	T3N2bM0	NA	Negative	CRT	50	14 months after treatment presents with a focal pulmonary recurrence managed with thoracoscopy with control for 35 months. Since progression of the disease, the patient has been under systemic treatment	Alive, with disease
10	SCC / BOT	T1N1M0	Positive	Negative	No	12	No	Alive, free of disease
11	SCC / Tonsil	T2N2bM0	Positive	Negative	CRT	13	No	Alive, free of disease
12	SCC / Tonsil	T2N1M0	Positive	Negative	CRT	18	No	Alive, free of disease

Table 2: Characteristics, management and follow-up of Patients Diagnosed with Oropharyngeal Carcinoma

*The tumor board advised PO CRT; yet, before treatment was delivered the patient lost follow-up due to COVID-19 disease, and treatment was delayed.

SCC, Squamous cell carcinoma; BOT, base of tongue; NA, not available; CRT, Chemoradiotherapy; CT, chemotherapy; PORT, Postoperative radiotherapy

None of the patients with oropharyngeal carcinoma required a tracheotomy or gastrostomy during follow-up. Some patients complained of mild and transitory dysphagia during follow-up, yet all of them managed a full oral feeding. Hence, no further evaluation was performed.

Obstructive Sleep Apnea (OSA)

Five patients (35.7%) had undergone previous surgery. Base of tongue management was performed in all cases with resection of a median volume of 6 cc. In three cases (21.4%), a partial epiglottectomy was performed simultaneously. There was a statistically significant improvement in AHI values (from 39.1 ± 23.1 events/hour to 20.8 ± 18.9 events/hour) ($p = .013$). Cohen's $d = 0.77$, denoting a medium-to-large effect size.

Surgical cure was achieved in 4 patients (28.5%), surgical success in 4 patients (28.5%), PO AHI improved without reaching surgical success in 2 patients (14.2%), PO AHI had minimal changes in 2 patients (14.2%), and PO AHI worsened in 2 patients (14.2%). Two patients (14.2%) presented PO bleeding and only one required surgical management. The remaining patients did not present PO complications.

Robot-assisted Thyroid Surgery

Of all the patients treated surgically for thyroid pathology at our ORL-HNS Department, only 0.7% were robot-assisted. Eight patients were programmed for robot-assisted surgery. Robot-assisted hemithyroidectomy was performed successfully in seven patients; in the remaining patient, who had a T3bN0M0 papillary carcinoma, the procedure was converted. Of the patients that had robot-assisted hemithyroidectomy, six had benign histology, and one was classified as T2N0M0 papillary carcinoma; the patient underwent an open complementary hemithyroidectomy. Vocal cord function was normal in all patients. No patients had transient or permanent hypocalcemia. All the patients treated entirely by robot-assisted surgery were satisfied with the functional and aesthetic results.

Discussion

The conversion and complication rates are comparable to previous studies. The most prevalent complication was PO bleeding [12]. Oral intake was resumed earlier, and tracheostomy and gastrostomy rates are lower than in series treating patients with OPSCC [14-16]. This represents a reduction in short-term morbidity without affecting safety, which is one of the reasons to advocate in favor of robotic surgery. Console time was longer in our series compared to that reported by high-volume centers [17]; yet, there were anesthetic complications related to longer surgical times. On the other hand, this is likely to reduce as the team gathers more experience.

For oropharyngeal carcinoma, the achievement of negative surgical margins was comparable to previous series [18]. Nevertheless, the 12-month OS rate was slightly poorer than the series that only included OPSCC cases [19]. However, it must be considered that in our small series, one of the patients had mucoepidermoid carcinoma, and the other had a T3N3bM0 p16 negative, sarcomatoid variant of oropharyngeal carcinoma; both tumors have aggressive behavior. If only early-stage OPSCC patients were considered, OS would be 100% comparable to other series.

The evaluation of functional outcomes has been oversimplified, and an appropriate objective evaluation of dysphagia and patient-reported outcome measures should be obtained in the future. In cases of OPSCC, a comparison of oncological and functional results of patients treated with TORS with or without adjuvant treatment compared to definite radiotherapy or chemoradiotherapy in the future is also needed. The role of TORS in de-escalation protocols in patients with p16-positive tumors is also an interesting area of future research.

Base of tongue reduction using TORS significantly decreases AHI. Overall, the AHI reduction obtained in this series (39.1 ± 23.1 to 20.8 ± 18.9 events/hour) is slightly lower compared to results (44.3 ± 22.4 to 17.8 ± 16.5 events/hour) reported in the systematic review published by Miller et al [20]. Nevertheless, the surgical cure in this series (28.5%) was slightly higher than that obtained in the same systematic review (23.8%); these differences could be explained by the fact that in the latter, TORS was part of multilevel surgery in 83.9% of patients, who also had more severe OSA. This observation supports that TORS is merely a tool and not the sole solution for managing OSA, and surgical decision-making is highly individualized.

About 2% of patients with surgical thyroid pathology evaluated in the service during this period were eligible for robot-assisted thyroidectomy because most patients present with locally advanced disease. Most patients who were offered robot-assisted thyroidectomy declined the procedure and opted for open surgery. The patient's preference likely reflects cultural differences with nations that popularised the technique, such as South Korea. Considering that the most significant advantage of remote access thyroidectomy is the cosmetic result [21] and the low interest of patients in avoiding a visible scar, other robotic neck procedures such as neck dissection and parotidectomy have not yet been introduced in our department.

We recognize this study's limitations, which include the retrospective nature of the data, the relatively small number of patients included, and the heterogeneity of procedures performed.

As described by Secin et al., the development of robotic surgery in Latin America has been slow, and programs are fragile and threatened by affordability [22]. On the other hand, patients with appropriate indications for robot-assisted surgery in ORL-HNS in our setting are still scarce, as most of the patients with OPSCC are diagnosed with locally advanced disease, with thyroid nodules larger than 4 cm, and patients with OSA most times do not meet surgical indications. Furthermore, appropriate certification can only be obtained abroad which adds complexity to successfully overcoming the learning curve. The small number of patients, also hinders the development of well-designed clinical trials able to answer the lingering questions on the role of robotic surgery in ORL-HNS.

Despite the limitations mentioned, this exploratory study is useful for establishing precedent regarding the use of robotic surgery in the ORL-HNS Latin American Department. It is valuable for designing future studies with less methodological bias. It also makes evident that Latin American academic centers should incorporate robotic surgery in their programs, because as a region, we are already falling behind. As clinicians are more familiar with indications of robotic surgery and the infrastructure is more widely available, most of the challenges faced in this initial experience, will fade. On the other hand, the research field in robotic surgery is far from ending as many interesting questions remain unanswered.

Conclusion

Robot-assisted surgery has numerous applications and advantages for patients with ORL-NHS pathology, and it is slowly becoming standard practice worldwide. Academic third-level centers in Latin America should introduce robotic ORL-HNS programs. Although a wide variety of ORL-HNS procedures can be performed safely and with good results, in our experience, robot-assisted surgery has proven its strongest advantage in diagnosing CUP and managing highly selected cases of OSA and OPSCC. Further studies are required to investigate which patients will obtain a significant advantage in quality of life when treated with robot-assisted surgery compared to traditional treatment, despite the high costs of this technology.

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DOI:10.31579/2693-4779/300