Quality of life in patients with larynx cancer in Latin America: Comparison between laryngectomy and organ preservation protocols

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Abstract

The effect on quality of life (QOL) of laryngectomy and organ preservation protocols is important in decision making. The aim of this cross-sectional study was to evaluate QOL outcomes of patients with advanced laryngeal tumors who were treated with laryngectomy or organ preservation protocols in Latin America. A total of 35 patients from three oncology units were enrolled. Patients with stage III/IV laryngeal cancer who were treated using organ preservation protocols or laryngectomy were assessed with the University of Washington QOL Questionnaire. The most important domains that affected QOL for both groups were speech and activity. In the laryngectomy group, the next most important domains were appearance, taste, pain, and recreation, whereas in the organ preservation group, they were saliva, recreation, mood, and swallowing. There were no statistically or clinically significant differences in the global score or the 7 days of QOL assessments before patients were interviewed. Global QOL assessments were similar when comparing laryngectomy and organ preservation protocols.

Introduction

Laryngeal cancer is one of the most common tumors of the respiratory tract. Chemoradiotherapy and surgery are believed to offer similar final outcomes; however, laryngectomy impairs quality of life (QOL) as a result of definitive tracheostomy and the loss of vocal speech.[1]

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Organ preservation protocols focusing on larynx preservation are widely offered to patients with T3 tumors without massive invasion of cartilage.[2] For patients with more advanced tumors, the effectiveness of chemoradiotherapy compared with total laryngectomy is controversial, with an increasing acceptance of laryngectomy as a more effective strategy.[3] In arriving at a therapeutic modality, most physicians and patients consider QOL concerns to be as important as long-term survival.[4]

One factor favoring organ preservation treatments is the possibility of breathing and talking with natural organs but with a higher rate of adverse effects related to the long-term sequelae of chemotherapy or radiotherapy, such as xerostomia and swallowing disorders. Laryngectomy, therefore, is not usually considered to be the first alternative due to attitudes related to poorer QOL.

Many studies have evaluated QOL outcomes in cohorts of patients who underwent organ preservation or laryngectomy; few randomized controlled trials, however, have compared the results between both strategies. The few randomized comparisons that have been conducted show similar or better results in organ preservation treatments.[5,6] Most of this information comes from QOL assessments in English literature and primarily in patients from developed countries with specific social and economic characteristics.

Data from patients in developing countries and in different cultural settings are lacking. Despite QOL findings coming from Brazilian investigators,[7,8] data are scarce for Spanish-speaking countries.[9,10] Because QOL assessments change according to socioeconomic factors, results are difficult to extrapolate to different populations.

The aim of this study was to evaluate the QOL outcomes of patients with advanced laryngeal tumors who were treated with laryngectomy or organ preservation protocols in Latin America.

Patients and methods

This study was approved by the Ethics in Research Committee of the Hospital Pablo Tobón Uribe, and informed consent was obtained for inclusion. Patients with laryngeal cancer classified as stage III or IV who were treated under organ preservation protocols (including chemoradiotherapy or exclusive radiotherapy) or laryngectomy were included. The choice of treatment was at the discretion of the treating physicians, who were following the guideline established by the National Comprehensive Cancer Network.[11]

All patients must have completed their definitive treatment and were being followed at the Head and Neck Section of the Hospital Pablo Tobón Uribe Oncology Unit, Medellin; Hospital Universitario de Caldas, Manizales; and the Hospital Mederi, Bogotá, Colombia.

Patients with physical impairments that prevented reading, hearing, or understanding the QOL scale, those for whom the last treatment date was more than 5 years ago, and those who did not consent to participate were excluded.

Patient data were collected prospectively during routine clinical visits from February 2013 to January 2015.

To evaluate QOL outcomes, we used the Spanish validated version of the University of Washington Quality of Life (UW-QOL) questionnaire for patients with head and neck cancer, assisting those patients who could not read the instrument to obtain the relevant information. This instrument has been evaluated in many clinical settings and has been translated to and validated in many languages.[12-17]

The UW-QOL has three domains (symptom, priority of symptoms, and global health-related QOL) with separate items (pain, appearance, activity level, recreation, swallowing, chewing, speech, shoulder function, taste, and saliva production) scored on a scale from 0 to 100.

The burden of symptoms was defined following the coding instruction of the UW-QOL instrument, according to the rank that patients gave to each symptom. We also obtained patient demographics and information on stage and European Cooperative Oncology Group functional status from the clinical charts.

The categorical variables are presented as percentages and ranges, and the continuous variables are shown as the means and standard deviation. For the analysis, some continuous variables were categorized. The significance level was set at $p < 0.05$. Between-group differences were assessed with the nonparametric Mann-Whitney and Kruskal-Wallis tests due to the non-normal distribution of variables and the small sample size. We used the Stata statistical software v9.1 (StataCorp; College Station, Texas).

Results

We included 35 patients, 14 of whom were treated with an organ preservation protocol; 21 patients underwent laryngectomy. The demographic data and clinical and treatment characteristics are shown in table 1. The mean age was 61.4 ± 9.5 years (median: 62; range: 41 to 87). A total of 94.3% of the 35 patients were men. Patients were interviewed for symptoms 17.7 ± 21.4 months after diagnosis (median: 10.9).

Ten patients (71.4%) who were treated with an organ preservation protocol needed definitive tracheostomy, and half of the patients in each group had a gastrostomy tube. A total of 22.9% had recurrence at the time of the interview. The only baseline difference between the two groups was that the group that underwent laryngectomy had a lower proportion of adjuvant chemoradiotherapy.

The burden of symptoms on the UW-QOL instrument is shown in table 2. The most important factors on QOL for both groups were speech and activity, respectively. In the laryngectomy group, the next most important factors were appearance, taste, pain, and recreation; for the organ preservation group, the next most important factors were saliva, recreation, mood, and swallowing. The descriptive distribution of domains of the UW-QOL is shown in table 3.

Statistically significant differences were found in activity and speech, with worse scores for the laryngectomy group. Although not statistically significant, more than a 10-point decrement (clinically relevant) was found in the shoulder, anxiety, swallowing, taste, and appearance domains among the patients who underwent laryngectomy, and in the saliva domain among the patients who received an organ preservation protocol. Both social and physical subscales had a dif-

Table 1. Clinical characteristics in patients with advanced laryngeal cancer treated with or without laryngectomy

	Without laryngectomy (n = 14) (n, %)	Laryngectomy (n = 21) (n, %)	*p* Value
Sex (male)	12 (85.7)	21 (100)	0.07
Age (years)*	60.5 ± 10.2 (61)	62.0 ± 9.2 (62)	0.67
T3/4	11 (78.6)	21 (100)	0.16
N2-3	5 (35.7)	11 (52.4)	0.68
Radiotherapy	14 (100)	15 (71.4)	0.02
Chemotherapy	12 (85.7)	5 (23.8)	<0.01
Gastrostomy	7 (50)	11 (52.4)	0.89
Recurrent disease	5 (35.7)	3 (14.3)	0.14
ECOG 2-3	3 (21.4)	5 (23.8)	0.46

**Kruskal-Wallis test*
Key: ECOG = Eastern Cooperative Oncology Group.

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The following Warnings and Precautions have been associated with OTOVEL: Hypersensitivity reactions, potential for microbial overgrowth with prolonged use, and continued or recurrent otorrhea.

The most common adverse reactions are otorrhea, excessive granulation tissue, ear infection, ear pruritis, tympanic membrane disorder, auricular swelling, and balance disorder

For additional Important Safety Information, please see Brief Summary of Prescribing Information on adjacent page and full Prescribing Information available at www.otovel.com.

References: 1. US Food and Drug Administration. Orange Book: Approved drug products with therapeutic equivalence evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/. Accessed February 1, 2017. **2.** Otovel [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC.

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Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

OTOVEL is indicated for the treatment of acute otitis media with tympanostomy tubes (AOMT) in pediatric patients (aged 6 months and older) due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis,* and *Pseudomonas aeruginosa.*

2 DOSAGE AND ADMINISTRATION

- OTOVEL is for otic use only. It is not for ophthalmic use, or for injection.

The recommended dosage regimen is as follows:

- Instill the contents of one single-dose vial 0.25 mL into the affected ear canal twice daily (approximately every 12 hours) for 7 days. Use this dosing for patients aged 6 months of age and older.
- Warm the solution by holding the vial in the hand for 1 to 2 minutes. This is to avoid dizziness, which may result from the instillation of a cold solution into the ear canal.
- The patient should lie with the affected ear upward, and then instill the medication.
- Pump the tragus 4 times by pushing inward to facilitate penetration of the medication into the middle ear.
- Maintain this position for 1 minute. Repeat, if necessary, for the opposite ear *[see Instructions for Use].*

3 DOSAGE FORMS AND STRENGTHS

Otic Solution: Each single-dose vial of OTOVEL (ciprofloxacin 0.3 % and fluocinolone acetonide 0.025 %) delivers 0.25 mL of solution equivalent to ciprofloxacin 0.75 mg and fluocinolone acetonide 0.0625 mg.

4 CONTRAINDICATIONS

OTOVEL is contraindicated in:

- Patients with known hypersensitivity to fluocinolone acetonide or other corticosteroids, ciprofloxacin or other quinolones, or to any other components of OTOVEL.
- Viral infections of the external ear canal, including varicella and herpes simplex infections and fungal otic infections.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

OTOVEL should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria and itching. Serious acute hypersensitivity reactions may require immediate emergency treatment.

5.2 Potential for Microbial Overgrowth with Prolonged Use

Prolonged use of OTOVEL may result in overgrowth of non-susceptible bacteria and fungi. If the infection is not improved after one week of treatment, cultures should be obtained to guide further treatment. If such infections occur, discontinue use and institute alternative therapy.

5.3 Continued or Recurrent Otorrhea

If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within 6 months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor.

6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling: Hypersensitivity Reactions [*see Warnings and Precautions (5.1)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, 224 patients with AOMT were treated with OTOVEL for a median duration of 7 days. All the patients received at least one dose of OTOVEL. There were 220 patients who received at least one dose of ciprofloxacin (CIPRO) and 213 patients received at least one dose of fluocinolone acetonide (FLUO). The most common adverse reactions that occurred in 1 or more patients are as follows:

Table 1: Selected Adverse Reactions that Occurred in 1 or more Patients in the OTOVEL Group

	Number (%) of Patients		
Adverse Reactions[1]	**OTOVEL N=224**	**CIPRO N=220**	**FLUO N=213**
Otorrhea	12 (5.4%)	9 (4.1%)	12 (5.6%)
Excessive granulation tissue	3 (1.3%)	0 (0.0%)	2 (0.9%)
Ear infection	2 (0.9%)	3 (1.4%)	1 (0.5%)
Ear pruritus	2 (0.9%)	1 (0.5%)	1 (0.5%)
Tympanic membrane disorder	2 (0.9%)	0 (0.0%)	0 (0.0%)
Auricular swelling	1 (0.4%)	1 (0.5%)	0 (0.0%)
Balance disorder	1 (0.4%)	0 (0.0%)	0 (0.0%)

[1] Selected adverse reactions that occurred in ≥ 1 patient in the OTOVEL group derived from all reported adverse events that could be related to the study drug or the drug class.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of ciprofloxacin and fluocinolone acetonide otic solution, 0.3% / 0.025% outside the US. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Immune system disorders: allergic reaction.
- Infections and infestations: candidiasis.
- Nervous system disorders: dysgeusia, paresthesia (tingling in ears), dizziness, headache.
- Ear and labyrinth disorders: ear discomfort, hypoacusis, tinnitus, ear congestion.
- Vascular disorders: flushing.
- Skin and subcutaneous tissue disorders: skin exfoliation.
- Injury, poisoning and procedural complications: device occlusion (tympanostomy tube obstruction).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

OTOVEL is negligibly absorbed following otic administration and maternal use is not expected to result in fetal exposure to ciprofloxacin and fluocinolone acetonide (12.3)].

8.2 Lactation

Risk Summary

OTOVEL is negligibly absorbed by the mother following otic administration and breastfeeding is not expected to result in exposure of the infant to ciprofloxacin and fluocinolone acetonide.

8.4 Pediatric Use

OTOVEL has been studied in patients as young as 6 months in adequate and well-controlled clinical trials. No major differences in safety and effectiveness have been observed between adult and pediatric patients.

8.5 Geriatric Use

Clinical studies of OTOVEL did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

10 OVERDOSAGE

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Table 2. Significant problems in patients treated with or without laryngectomy

Without laryngectomy (n = 14)			Laryngectomy (n = 21)		
Problem domain	**n**	**%**	**Problem domain**	**n**	**%**
Speech	6	42.9	Speech	16	76.2
Activity	6	42.9	Activity	15	71.4
Saliva	6	42.9	Appearance	10	47.6
Recreation	5	35.7	Taste	9	42.9
Mood	4	28.6	Pain	9	42.9
Swallowing	4	28.6	Recreation	9	42.9
Pain	3	21.4	Mood	8	38.1
Appearance	3	21.4	Anxiety	7	33.3
Anxiety	3	21.4	Swallowing	7	33.3
Chewing	3	21.4	Shoulder	5	23.8
Taste	3	21.4	Chewing	5	23.8
Shoulder	1	7.1	Saliva	3	14.3

ference of >10 points between groups, with lower scores observed for the laryngectomy group. No statistically or clinically significant differences in the global score or QOL assessments were observed during the 7 days before the interview.

Discussion

QOL assessment has become important in decision making for patients with head and neck cancer. The impact of a disease and its treatment is correlated with survival, ability to return to work, and social functioning.[18] Many instruments with a general or specific focus have been designed to evaluate QOL in patients with head and neck cancer. Although generic QOL instruments can be used in a wide range of patients with different types of tumors, they lack responsiveness for specific ailments of each disease. The UW-QOL for head and neck cancer is a widely used instrument with high reliability that has been validated in the Spanish language, which enables its use in populations of developing countries in Latin America.[16]

Due to its location in the body and its close relationship with feeding, communication, and interpersonal relationships, head and neck cancer imposes an important burden on QOL. Moreover, its related treatments (chemotherapy, radiotherapy, and surgery) adversely affect functions such as swallowing, speech, breathing, and mastication, which can lead to even poorer QOL.

Since the 1990s, organ preservation protocols for patients with advanced tumors have been considered to offer outcomes similar to those of laryngectomy followed by radiotherapy, with the enormous advantage of larynx preservation and the consequent gain in QOL, as demonstrated in randomized, controlled trials and meta-analyses.[19,20] The introduction of these protocols relegated laryngectomy to a secondary method in the treatment of advanced tumors due to the negative impact of a definitive tracheostomy with the loss of vocal ability and the related consequences of this procedure on appearance.[21] However, for transglottic tumors with massive cartilage invasion, laryngectomy has recently been demonstrated to offer advantages in terms of disease-free and overall survival compared with chemoradiotherapy, producing a renaissance of indications for and the use of total laryngectomy.[22] Nonetheless, patients and physicians are aware of the negative effects of total laryngectomy on QOL, which impedes its wide use.

QOL assessments have been made in patients who underwent laryngectomy or organ preservation protocols and have shown similar or better results with organ preservation in the most recent studies.[5,6] However, the perception of laryngectomy as a disastrous event has not been proven by data. List et al[23] and Eadie and Bowker[24] suggested that the ability to cope with impairments produced by laryngectomy shortens early differences compared with organ preservation in QOL scores.

In periodic assessments, Deleyiannis et al[25] found that QOL scores return to values similar to the presurgical stage after 2 years postlaryngectomy, whereas Hammerlid et al[26] found that a 1-year period is sufficient to compensate for the acute effects of treatment on QOL score. Therefore, although functional limitations persist over time, the overall QOL scores reach those that are similar to those of other diseases with an intact larynx.[27]

In our study, we found that the UW-QOL instrument could define the specific ailments that decrease QOL in patients with head and neck cancer who had undergone (or had not undergone) laryngectomy. For patients who have undergone laryngectomy, the importance of appearance due to the scar, neck deformity produced by the surgery, and the presence of a definitive tracheostomy in the neck were ranked as important domains that affect QOL.

The taste factor also ranked high due to the loss of smell and the difficulty in rehabilitating this sense after surgery. In contrast, patients in the organ preservation group revealed that saliva and swallowing were important factors in QOL. The recreation factor ranked high in both groups and represents a new finding. No data exist that shed

light on the meaning of this finding for patients with head and neck cancer, although it may be a proxy for depression or life enjoyment.

The most important finding of this study was that QOL global scores were similar in both groups, even though individual domains such as activity and speech ranked lower in the laryngectomy group. These results are similar to those reported in other studies. In 42 patients, Hanna et al could not find global differences in QOL between patients who underwent laryngectomy or organ preservation protocols, as measured with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, Head and Neck Module.[28]

Table 3. Comparison of UW-QOL scale between patients treated with or without laryngectomy

	Without laryngectomy (n = 14) mean ± SD (median)	Laryngectomy (n = 21) mean ± SD (median)	*p* Value*
Global	69.8 ± 18.7 (74.7)	61.4 ± 18.4 (66.3)	0.13
Previous QOL	71.4 ± 32.3 (75)	66.3 ± 37.4 (75)	0.71
QOL last 7 days	60.0 ± 27.2 (50)	67.4 ± 26.8 (60)	0.35
Social subscale	75.1 ± 21.1 (74.6)	65.9 ± 18.9 (70)	0.27
Physical subscale	65.6 ± 21.1 (65.4)	57.0 ± 20.1 (62.5)	0.29
Speech	57.1 ± 31.9 (70)	26.8 ± 28.1 (30)	<0.01
Activity	73.2 ± 26.8 (75)	52.4 ± 26.1(50)	0.03
Appearance	78.6 ± 19.2 (75)	65.5 ± 23.0 (75)	0.09
Saliva	59.3 ± 38.3 (70)	80.5 ± 25.6 (100)	0.10
Taste	70.0 ± 35.9 (70)	52.9 ± 38.2 (70)	0.17
Shoulder	88.6 ± 27.7 (100)	73.3 ± 37.7 (100)	0.18
Anxiety	76.4 ± 33.7 (100)	65.2 ± 31.9 (70)	0.23
Swallowing	62.3 ± 24.9 (70)	51.5 ± 31.2 (70)	0.36
Chewing	61.5 ± 41.6 (50)	66.6 ± 42.8 (100)	0.66
Recreation	67.8 ± 28.5 (75)	65.5 ± 24.3 (75)	0.71
Mood	67.8 ± 31.7 (75)	64.3 ± 33.1 (75)	0.76
Pain	76.8 ± 22.9 (75)	75 ± 28.5 (100)	0.98

**Kruskal-Wallis test*
Key: UW-QOL = University of Washington quality of Life questionnaire, SD = standard deviation, QOL = quality of life.

The same results were obtained by other authors.[25,29-31] The consistency of these findings confirms that after an initial period of adaptation (as long as 2 years), patients who undergo laryngectomy reach QOL scores that are similar to those of patients treated with chemoradiotherapy and weakens the notion that laryngectomy is a disastrous event in a patient's life. This lack of difference also may be explained by the high frequency of definitive tracheostomy in the organ preservation group, which reduces the potential advantages offered by organ preservation treatments in the voice and breath domains.

In other studies, the rate of tracheostomy was approximately 30%, whereas in our study, nearly three-fourths of patients had a tracheostomy. It is impossible to discard any of these hypotheses due to the design of this study.

Most studies on QOL in laryngectomy or organ preservation protocols were performed in developed countries with specific socioeconomic and cultural characteristics. Until now, little information was available on outcomes in patients in developing countries. A study by Vilaseca et al in 49 laryngectomized patients found mean scores on the UW-QOL that ranged from 72 for taste to 89 for chewing.[32] In our study patients, domain scores varied from 26 for speech to 80 for saliva.

Most of our scores were comparatively lower than those reported elsewhere, which indicates that the relative importance of domains is different in our population and that these differences should be considered when treatments are offered. In the Scotland Laryngectomy Audit, Robertson et al found a global score of 72.9 with high importance for speech, swallowing, activity, mood, and appearance.[27] In our study, taste, pain, and recreation were important domains. They are not currently reported in other studies and could represent a different weight for items in the QOL questionnaire as rated by Latin American patients.

Some weaknesses of this study should be noted. The first is related to the small sample size, which can explain clinically meaningful but not statistically significant differences in some domain scores. The second limitation is related to the design of this study. It was not a randomized trial, and treatment decisions were made by surgeons; thus, comparisons can introduce bias. Third, although a clear treatment protocol has been established, not all patients received the same treatments, doses, and procedures. All of these factors can affect the measurement of QOL.

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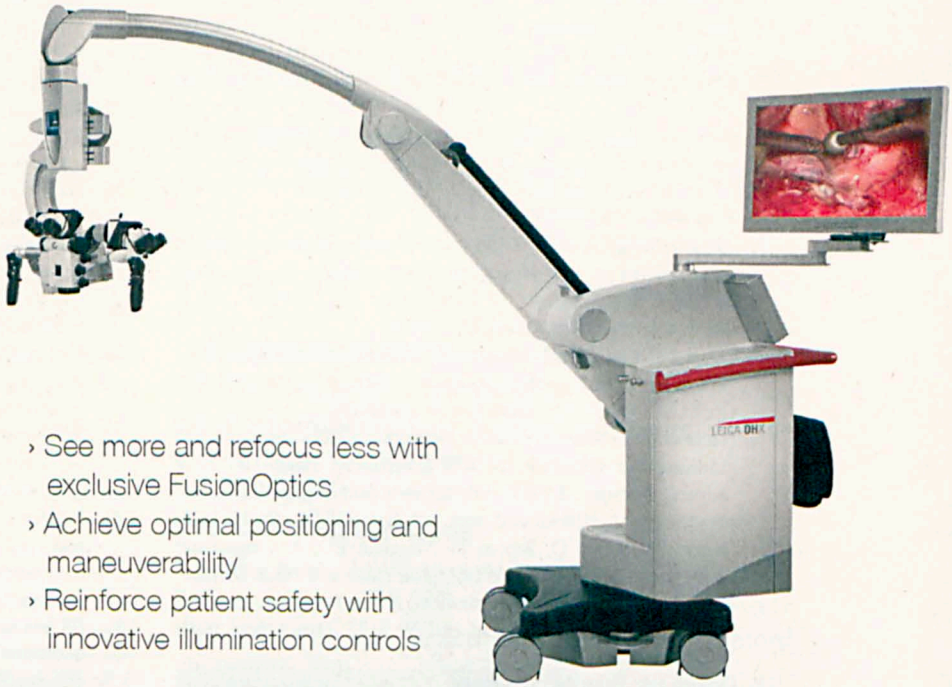

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In conclusion, in a cohort of Latin American patients with laryngeal cancer, global QOL assessments were similar when comparing laryngectomy with organ preservation protocols. Important differences in specific domains should be identified to better explain the consequences of treatment. The relevance of domains and the scores of the UW-QOL instrument differ from those reported in developed countries; thus, local evaluations of QOL should be integrated in decision making.

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