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Quality of life in tongue cancer treated patients before and after speech therapy: a randomized clinical trial



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Abstract

Introduction: Tongue cancer is one of the most common subtypes of head and neck cancer. The aggressive effects of treatment cause aesthetic, psychosocial and functional deficits, especially dysphagia, which affects patient quality of life. Rehabilitation, which is essential for functional maximum recovery, helps patients deal with new and altered structures and has a positive impact on quality of life.

Objective: To verify the impact of speech therapy on swallowing quality of life in tongue cancer patients after treatment.

Methods: This parallel randomized clinical trial was conducted at a public hospital in Porto Alegre, RS, Brazil. Before and after the intervention, a quality of life questionnaire (the Deglutition Handicap Index) was employed, dysphagia severity was assessed with fiberoptic endoscopic evaluation of swallowing, and the Functional Oral Intake Scale carried out. The experimental group underwent four-week sessions of speech therapy over one month, while the control group received the institution's usual follow-up.

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Results: Thirty individuals treated for tongue cancer were divided into a study and a control group. Deglutition Handicap Index scores decreased significantly (approximately 40 points) ($p < 0.001$) after the intervention in the study group. There was a significant correlation between improved quality of life, reduced dysphagia severity and increased in Functional Oral Intake Scale scores ($p < 0.001$).

Conclusion: After speech therapy, quality of life scores related to deglutition and dysphagia severity improved in patients treated for tongue cancer.

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Introduction

The incidence of oral cavity cancer is high in Brazil, ranking fifth among the most common tumors in men.¹ Epidemiological studies conducted in several Brazilian cities indicate that the tongue is one of the main sites affected by these tumors, with a 30%–40% prevalence, and is responsible for high morbidity and mortality rates.^{2–4}

The tongue is the protagonist in the deglutition process. In the oral phase, it provides perception of the bolus' volume, consistency, and flavor, positioning it and serving as the main source of pressure for propelling it towards the pharynx and esophagus. The effectiveness of this phase is fundamental for the subsequent phases to occur dynamically, and the integrity of complex neurophysiological control is necessary for its functionality.^{5,6}

In tongue cancer, the effects of extensive surgical treatments, with or without reconstruction, radiotherapy and chemotherapy, have a serious aesthetic and psychosocial impact and lead to functional deficits, mainly dysphagia.^{7–10} Dysphagia is defined as any alteration on deglutition that affects the safe and efficient transport of food and liquids from the mouth to the stomach.¹¹ Although aggressive combinations of treatment modalities lead to better survival rates, their effects on patient Quality of Life (QOL) are devastating.⁹

Concern has been expressed in the literature about the description and evaluation of swallowing QOL in tongue cancer patients.^{9,12,13} However, studies on speech therapy intervention in these patients are still uncommon, predominantly case studies or interventions performed by multidisciplinary teams.^{6,14–16} Thus, the present study aimed to verify the impact of speech therapy on swallowing QOL in tongue cancer patients after treatment.

Methods

This parallel randomized clinical trial was conducted at a public reference hospital in Porto Alegre, RS, Brazil. The sample included adults and older adults who were surgically treated for tongue cancer, regardless of gender or adjuvant chemotherapy and/or radiation therapy, between January 2016 and January 2018.

Participants were selected by a query. Participant eligibility was verified through telephone contact regarding the following criteria: (1) having been surgically treated for

tongue cancer, (2) complaints of deglutition difficulties, (3) no previous speech therapy, and (4) no understanding and/or communication deficits.

Eligible individuals who agreed to participate were randomly allocated to the Study Group (SG) or the Control Group (CG). Randomization was performed by an independent researcher in WinPEPI version 11.43 with the Random command.

Data collection

At the first visit, both groups were assessed by one of the researchers, who had had no prior contact with the patients. Data was collected on sociodemographic and disease history, the QOL questionnaire (Dysphagia Handicap Index – DHI) was applied and the Fiberoptic Endoscopic Evaluation of Swallowing (FEES) was performed. After four weeks of followup, the patients in both groups were reassessed for QOL and for swallowing.

The DHI, developed by Silbergleit et al.¹⁷ and translated to Portuguese and culturally validated by Souza in 2014,¹⁸ was used to assess the patients' QOL. Its purpose is to identify the success or failure of swallowing therapy in the functional, emotional, and physical spheres, as well as to verify the patients' self-reported swallowing difficulty.

Speech therapy intervention

After the evaluation stage, the each patient in the SG received 30 min of speech therapy, once a week, over one month, and were instructed to perform care and exercises at home. The intervention protocol was performed by the same researcher in all patients. A different researcher applied the QOL questionnaires.

In the first speech therapy session, the SG received guidance on deglutition management, including utensils use, rhythm and posture while eating, and adaptations in the consistency, volume, and temperature of the food. They were also taught exercises and speech therapy techniques to be repeated in five sets, three times a day. The techniques were aimed at improving swallowing and were selected in view of the participants' post-surgical anatomy, based on both clinical practice and the literature. Orofacial and laryngeal muscle stretching and mobility exercises, airway protection maneuvers and tactile/thermal/gustatory sensory stimula-

Table 1 Sample characterization (n = 30).

Variables	Study group (n = 15)	Control group (n = 15)	p
Age (years) — average ± SD	60.3 ± 6.7	59.4 ± 10.1	0.767
Gender — n (%)			0.330
Male	14 (93.3)	11 (73.3)	
Female	1 (6.7)	4 (26.7)	
Smoking — n (%)			0.301
Never	4 (26.7)	6 (40.0)	
Formerly	10 (66.7)	6 (40.0)	
Currently	1 (6.7)	3 (20.0)	
Alcohol use — n (%)			0.909
Never	3 (20.0)	4 (26.7)	
Formerly	11 (73.3)	10 (66.7)	
Currently	1 (6.7)	1 (6.7)	
Education — n (%)			0.641
Basic ed. incomplete	9 (60.0)	10 (66.7)	
Basic ed. complete	3 (20.0)	1 (6.7)	
High school incomplete	1 (6.7)	2 (13.3)	
High school complete	0 (0.0)	1 (6.7)	
Higher ed. incomplete	1 (6.7)	0 (0.0)	
Higher ed. incomplete	1 (6.7)	1 (6.7)	
Ethnicity — n (%)			0.475
Caucasian	14 (93.3)	12 (80.0)	
Afro-Brazilian	1 (6.7)	2 (13.3)	
Mixed	0 (0.0)	1 (6.7)	

Statistical analysis with Student's *t*-test, Pearson's Chi-Square test and Fisher's Exact test.

tion techniques were used. The guidelines and exercises were provided in writing to the participants at the first session, with subsequent sessions consisting of review and reorientation.

The CG received the institution's usual health monitoring followup, which does not include speech therapy. For ethical reasons, all patients received speech therapy after the end of the study.

Data analysis

The QOL questionnaires were scored according to developer recommendations. The DHI includes 25 items with three answer options: (0) never, (2) sometimes and (4) always. Total scores vary from 0 to 100 points. The higher the score, the worse the individual's QOL in relation to deglutition. It also includes an item in which patients self-evaluate their swallowing difficulty on a scale from 0 to 7: (0) or (1) being normal, (2) or (3) mildly altered, (4) or (5) moderately altered and (6) or (7) seriously altered.¹⁸

To classify oral intake, the Functional Oral Intake Scale (FOIS), which varies from 1 (no oral intake) to 7 (totally oral diet with no restrictions), was used before and after follow-up.¹⁹

The FEES data were evaluated by three speech therapists with expertise in the area who were not otherwise involved in the study and were blinded regarding group and time. They determined dysphagia severity according to the classification system of Macedo Filho et al.,²⁰ for analysis through FEES.

Statistical analysis

Sample size calculation was based on Zhen et al.,⁶ and performed in WinPEPI version 11.43. Considering a significance level of 5%, a power of 80% and an effect size of one standard deviation in QOL scores, a minimum of 15 patients were necessary per group.

Quantitative variables were described as mean and standard deviation or median and interquartile range. Categorical variables were described as absolute and relative frequencies. Student's *t*-test was used to compare means between groups, and Pearson's Chi-Square or Fisher's Exact tests were used to compare proportions. To assess the impact of speech therapy on QOL and dysphagia scores by study group, a Generalized Estimation Equations model with least significant difference adjustment was applied. To assess the association between dysphagia severity and FOIS scores with QOL scores, Spearman's correlation coefficient was applied. The significance level was set at 5% ($p < 0.05$) and the analyses were performed in SPSS version 21.0.

Since the analyses were carried out on an intention-to-treat basis, patients who for some reason did not complete the study remained in the original allocation groups for the analysis.

Ethical aspects

The study was conducted according to ethical standards and was approved by the Research Ethics Commit-

Table 2 Disease data and oncology treatment (n = 30).

Variables	Study group (n = 15)	Control group (n = 15)	p
T staging — n (%)			0.128
II	2 (13.3)	5 (33.3)	
III	9 (60.0)	4 (26.7)	
IV	4 (26.7)	6 (40.0)	
Injury site — n (%)			0.272
Tongue	10 (66.7)	6 (40.0)	
Tongue and jaw	5 (33.3)	9 (60.0)	
Reconstruction — n (%)	5 (33.3)	6 (40.0)	1.000
Neck dissection — n (%)			0.390
Unilateral	10 (66.7)	13 (86.7)	
Bilateral	5 (33.3)	2 (13.3)	
Radiotherapy — n (%)	15 (100)	11 (73.3)	0.100
Chemotherapy — n (%)	3 (20.0)	3 (20.0)	1.000

Statistical analysis with Pearson's Chi-Square test and Fisher's Exact tests.

Table 3 Participant quality of life, dysphagia severity and Functional Oral Intake Scale scores before and after the follow-up.

Variables	Study group Average ± SE	Control group Average ± SE	Effect (p-value)		
			Time	Group	Time × group
DHI scores			<0.001	0.003	<0.001
Before	61.6 ± 5.9 ^a	51.9 ± 4.3 ^a			
After	21.6 ± 3.8 ^a	61.8 ± 4.8 ^b			
Difference (95% CI)	−40 (−47.7 to −32.4)	9.9 (1.8 a 18.1)			
Self-reported DHI			<0.001	0.051	<0.001
Before	5.4 ± 0.4 ^a	4.7 ± 0.5 ^a			
After	2.5 ± 0.3 ^a	5.1 ± 0.3 ^b			
Difference (95% CI)	−2.9 (−3.4 to −2.4)	0.5 (−0.2 to 1.1)			
Dysphagia severity			<0.001	0.185	<0.001
Before	3.2 ± 0.2 ^a	3.0 ± 0.2 ^a			
After	2.3 ± 0.2 ^a	3.1 ± 0.2 ^b			
Difference (95% CI)	−0.9 (−1.2 to −0.6)	0.1 (−0.2 to 0.3)			
FOIS scores			<0.001	0.064	<0.001
Before	3.3 ± 0.4 ^a	4.0 ± 0.4 ^a			
After	6.4 ± 0.1 ^b	4.1 ± 0.3 ^a			
Difference (95% CI)	3.1 (2.3–3.8)	0.1 (−0.3 to 0.6)			

DHI, Dysphagia Handicap Index; FOIS, Functional Oral Intake Scale.

Statistical analysis with a generalized estimation equations model and least significant difference test.

^{a,b}Repeated letters did not differ at 5% significance in the least significant difference test — comparison between groups.

tee of the responsible institution (n° 20180572 and 96487218.3.0000.5327), as well as the International Clinical Trials Registry Platform (n° NCT04126226). All participants were informed about the study design and provided written informed consent prior to participation.

Results

The total sample consisted of 30 men and women. Table 1, which shows the sample's characteristics, demonstrates that there were no significant differences in sociodemographic data between the groups. The median time between surgery and inclusion in the study was 7 months (25–75:3–17 per-centiles).

The research protocol could not be completed for two participants, one from the CG (death) and one from the SG (tumor recurrence). Both remained in their original groups and were analyzed on an intention-to-treat basis.

Table 2 shows the participants' disease and oncology treatment data.

Table 3 presents the DHI, FOIS and dysphagia severity results before and after the follow-up.

Table 4 shows the association between variations in swallowing QOL with dysphagia severity and FOIS scores. There was a statistically significant inverse association with FOIS scores, i.e., lower DHI scores were associated with higher FOIS scores. There was a direct association between dysphagia severity and DHI scores, i.e., lower DHI scores were associated with less severe dysphagia.

Table 4 Associations between variations in quality of life, dysphagia severity and Functional Oral Intake Scale scores.

Variables	DHI Spearman's correlation coefficient	<i>p</i>
FOIS	–0.727	<0.001
Dysphagia severity	0.762	<0.001

DHI, Dysphagia Handicap Index; FOIS, Functional Oral Intake Scale.

Statistical analysis with Spearman's correlation coefficient.

Discussion

Despite the ease of detection, 85% of head and neck tumors are only identified in advanced stages, when more aggressive treatments are needed and healing is less likely.^{7,10,21} A 2019 epidemiological study by INCA found that 78.9% of tongue cancers are detected in stages III and IV, demonstrating the challenging nature of this diagnosis.^{1,7} In our study, 76.3% of the patients were diagnosed with advanced disease processes, undergoing extensive surgical treatments associated with neck dissection.

In cases involving soft and bone tissues, swallowing difficulties become even more evident. In our study, the mandibular tissue of a significant number of participants (46.6%) was compromised, leading to more complex surgical procedures and worse functional results.²² When patients undergo radiotherapy, with or without chemotherapy, the consequences for deglutition can be even more overwhelming due to fibrosis, mucositis, dysgeusia, dry mouth and trismus.^{13,22,23} In our study, the vast majority of individuals received adjuvant radiotherapy treatment (86.6%), while only 20% of the individuals required chemotherapy treatment. These aggressive combined treatment modalities result in significantly better survival results.⁹ However, they have significant aesthetic, psychological, and social effects and lead to functional deficits, especially dysphagia, which lowers QOL.^{10,24}

It is well-documented in the literature that tongue cancer treatments have a negative impact on patient QOL, and a number of authors have investigated treatment-related deglutition disorders.^{9,12,13} However, a limited number of studies have proposed interventions for dysphagia in this population, including deglutition training programs developed by interdisciplinary teams and applied by nurses (rather than speech therapists), although the most relevant outcomes are associated with emotional aspects of QOL.^{6,14} Among studies that have performed speech therapy interventions, case studies and case series predominate.^{15,16} Despite the methodological differences between the studies, all of them obtained positive results for dysphagia, which demonstrates the importance of rehabilitation for recovering functionality and QOL in this population. We could find no randomized clinical trial involving a speech therapy intervention in individuals with tongue cancer in the compiled literature.

A quasi experiment by Zhen et al. evaluated the effectiveness of an interdisciplinary swallowing therapy protocol and its impact on QOL in tongue cancer patients who had been surgically treated. The protocol consisted of 30 min of

therapy, six days a week for two weeks. The authors used the MD Andersen Dysphagia Inventory, which assesses the impact of dysphagia on QOL, and found that swallowing therapy had a positive effect on QOL, with higher patient scores in the global, functional, emotional and physical domains.⁶ In our DHI results, there was a significant decrease – approximately 40 points ($p < 0.001$) – between the pre- (61.6 ± 5.9) and post-intervention (21.6 ± 3.8) scores in the SG, demonstrating that the intervention had a positive impact on swallowing QOL. These results also showed that the DHI was able to assess the effectiveness of swallowing therapy. On the other hand, the QOL scores for the CG were worse at the end of the follow up (mean increase of 9.9 points), which indicates that QOL indices tend to worsen when there is no rehabilitation, even if dysphagia severity and oral intake levels remain similar (Table 3). Zhen et al. also found that patients who underwent the intervention had more confidence in their ability to swallow and fewer problems with food preparation and eating in public places.⁶ Our study included analysis of the DHI self-assessment, in which patients self-reported the degree of swallowing difficulty before and after the intervention. These results were encouraging, since the SG reported a mean improvement of approximately 3 points (Table 3), i.e., moderate difficulty became slight difficulty.

Studies on the correlation between QOL and deglutition assessments have demonstrated a link between patient complaints and alterations in clinical and objective measures.²⁵ We also found such an association, since improved QOL, represented by lower DHI scores, was correlated with reduced dysphagia severity and increased FOIS scores ($p < 0.001$). In the SG, there was a mean reduction of approximately one degree in FEES level (i.e. dysphagia severity) by the end of the intervention, while there was a mean increase of three levels in FOIS scores (Table 3). This resulted in cases where the alternative feeding route was withdrawn and the safety oral route was reestablished, as well as cases where ingested consistencies number was increased. Another study involving an interdisciplinary intervention in individuals treated for tongue cancer found improvement in dysphagia severity. After 30 min of therapy a day for 10 days, the authors evaluated outcomes of dysphagia and depression in 58 patients. After the follow-up, there was improvement in dysphagia and depression severity, showing the importance of early intervention in the postoperative period.¹⁴

The conflict between therapeutic results and QOL is receiving more intense scrutiny. Although healing is the focus of cancer treatment, functional aspects and QOL are often neglected.^{6,8} With the increasing number of cancer survivors, diagnosis and treatment have also improved, and rehabilitation has now become even more important in an effort to achieve maximum functional recovery and autonomy.²⁶ Patient QOL and expectations, especially regarding their position as agents during treatment, has received increasing focus, influencing the codes of conduct of medical and multi-professional teams. It is fundamental to consider patient desires, beliefs and expectations when selecting the course of treatment, since this is an individualized process that impacts each individual differently.⁸ In our study, speech therapy proved indispensable, contributing to better swallowing QOL in tongue cancer patients after oncological treatment.

Conclusions

According to self-reported improvement in dysphagia severity and post-intervention QOL scores, speech therapy had a positive impact on swallowing QOL patients who had been treated for tongue cancer. There was also a significant correlation between QOL improvement, reduced dysphagia severity and higher FOIS scores, which led to better swallowing function.

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Conflicts of interest

The authors declare no conflicts of interest.

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