Critical Review: Impact of Trans Oral Robotic Surgery (TORS) on acute swallowing-related outcomes in adults with oropharyngeal cancer.

Julia Caggianiello
M.Cl.Sc SLP Candidate
University of Western Ontario: School of Communication Sciences and Disorders

This critical review examined the evidence for best-practice standards for assessing acute swallowing-related outcomes in adults with dysphagia following Transoral Robotic Surgery (TORS) without adjuvant therapy. A literature search yielded six studies that met inclusion criteria. Study designs included one systematic review, four cohort reviews, and one case- series study. Overall, the evidence gathered for this review suggests that TORS is a reliable and less invasive treatment for adults with oropharyngeal cancer; however, due to the lack of objective swallowing measurements, and heterogeneity in this population, further evaluations are needed to provide practical clinical recommendations for best practice. Study limitations and recommendations for future research were discussed.

Introduction

In the past three decades, the prevalence of oropharyngeal squamous cell carcinoma (OPSCC) continues to rise (You, Henry, & Zeitouni, 2019). OPSCC refers to cancer of the base and posterior one third of the tongue, soft palate, tonsil, and posterior and lateral pharyngeal walls (Schiff, 2019). Historically, traditional open therapy was used to treat oropharyngeal cancers, with the current standard treatment being chemoradiotherapy (CRT). Although effective, this treatment has extensive short- and long-term side effects including cosmetic deformity, dysphagia, and a decline in quality of life (Sethia et al., 2017). Dysphagia, or difficulty swallowing, is highly prevalent with 20-30% of OPSCC patients requiring a permanent percutaneous gastrostomy tube (You et al., 2019). Fortunately, these patients are often younger, healthier, have a higher socioeconomic status, and little to no history of smoking. To support better functional outcomes and long-term survival, findings of a newer technique would be of interest.

A newer surgical technique, Transoral Robotic Surgery (TORS), has been used to treat and diagnose oropharyngeal carcinomas (Owen et al., 2016). This procedure was designed to reduce the intensity of overall treatment (Lazarus et al., 2019) and preserve quality of life (Sethia et al., 2017). Moreover, TORS provides information on staging, decision making, and tailoring therapy treatment (Dias, Walder, & Leonhardt, 2017). In addition to TORS, it is common for patients to receive postoperative radiotherapy or chemoradiotherapy (Sethia et al., 2017). Very few studies have examined swallow safety, efficiency, and protocols following TORS procedures without adjuvant therapy. In addition, the effect of TORS on swallowing has not been sufficiently researched to determine if it improves clinical outcomes and patient quality of life.

The purpose of this review was to examine acute swallowing measures such as tube dependence, swallow function, and quality of life with TORS alone. It is important for Speech-Language Pathologists to understand implications of TORS and be a part of the decision-making process on speech and swallowing outcomes, and to provide different assessment and treatment options regarding prognosis.

Objectives

The first objective of this study was to evaluate the factors influencing outcome of dysphagia after TORS procedures in comparison to chemoradiotherapy and adjuvant chemoradiotherapy or radiotherapy. The second objective is to provide recommendations for clinical best practice and future research for the assessment of dysphagia in this high-risk population.

Methods

Search Strategy

Online databases (Google Scholar, Western Libraries, Wiley Online Library, American Cancer Society, JAMA Network, Science Direct) were searched using the following terms: (instrumental swallow* assessment) AND (swallow safety) AND (speech) AND (transoral robotic surgery) AND (without adjuvant therapy).

Selection Criteria

Studies selected for inclusion were required to implement TORS as well as report outcomes and investigate safety and efficiency of this procedure following a standardized instrumental swallow assessment.

Data Collection

Papers included in this review search yielded one systematic review, four cohort reviews, and one case-series study.

Results

Systematic Review:

A systematic review is a study designed to provide a summary of the available literature in response to a particular research question (Clarke, 2011).

Dawe, Patterson & O'Hara (2015) published a systematic review evaluating the literature on comparing swallowing outcomes between contemporary surgical and non-surgical treatment options for OPSCC. The researchers screened and examined online databases. Articles were considered if they were published after 1990, were written in English, conducted trans-oral techniques or (C)RT, and were not a case report or included fewer than 10 patients. Due to the heterogeneity of the studies, meta-analysis was not feasible. The initial literature search was narrowed down to thirty-seven relevant papers. Of those 37, 15 articles reported swallowing outcomes for TORS and transoral laser microsurgery (TLM), and one compared treatment. Each article was assessed systematically and reported within the International Classification of Functioning, Disability and Health (ICF) framework domains.

Comparing TORS/ TLM with (C)RT, this study revealed that dysphagia severity in the TORS groups significantly returned to baseline by 12 months, but only improved slightly in RT group. The MD Anderson Dysphagia Inventory (MDADI) is a patient -reported questionnaire that quantifies swallowing related outcomes. Comparing treatment modalities using the MDADI, pre-treatment swallowing exercises can improve swallowing outcomes for patients undergoing (C)RT. Further research is needed to examine pre-treatment swallowing exercises on patients undergoing TORS. Overall, TORS may improve swallowing outcomes, but the impact on swallowing outcomes differ and is difficult to compare between studies.

In addition, there is a lack of instrumental swallowing assessments in the TORS and the OPSCC literature. Moreover, there is a weak relationship between patient reported swallowing measures and instrumental swallow tests, such as videofluoroscopic swallow study (VFSS). Determining the optimal assessment tool is a key consideration moving forward. The authors recognize the 'gold standard measure of swallow', VFSS, is expensive, time-consuming, and involves radiation, therefore videofluoroscopic evaluations should be administered with caution.

Limitations of this study include the heterogenous disease stages, no objective standardized swallowing outcomes measures, selection bias, and high study dropout rates. Further, the authors did not define the duration of time and control of the collection of the MDADI scores. A potential reporting bias in this review include the use of clinician-rated tools. This study provides suggestive evidence regarding how TORS compares to dysphagia severity in OPSCC populations but does not provide practical clinical recommendations for best practice. In addition, there is lack of evidence demonstrating the direct comparison between CRT and TORS, suggesting that TORS may decrease post-treatment swallowing morbidity, but future research is necessary. Nonetheless, the study welcomes further controlled trials examining standardized swallowing outcome measures, allowing adequate and informed decision making on different treatment modalities.

Prospective Cohort Reviews:

A prospective cohort review is a study designed to obtain information before dysphagia develops and is followed longitudinally. This design investigates risk factors and outcomes associated with development of dysphagia. These studies have a high chance of loss to follow-up and selection bias.

Albergotti et al. (2018) conducted a prospective cohort study to describe short-term dysphagia over the first month post- TORS for OPSCC (n=51; median age of 58). Speech- language pathologist completed a clinical swallowing evaluation on postoperative day 0 or 1 for appropriateness for oral diet, including compensatory strategies and dietary modifications as needed. As well, the EAT-10 (Belasfky et al., 2008) was used to measure swallowing dysfunction on post-operative day 1, 7 and 30 using diagnostic criteria.

Appropriate statistical analysis revealed a significantly average increase in swallowing dysfunction in the first week postoperatively, followed by a decrease in swallowing dysfunction 30 days postoperatively, with the greatest decrease being in "painful swallowing". With 10% of patients returning to normal swallowing function by start of adjuvant therapy, the authors suggested that patients normal swallowing should not be anticipated. Out of the 51 patients, 45 patients were put on an oral diet day zero or day one postoperative, with two patients following an oral diet on day 3, and 4, respectively. Out of the 47 patients, 27 required compensatory strategies or change in liquid consistency. Overall, higher EAT-10 scores and postoperative feeding tube were demonstrated for self-reported preoperative dysphagia.

Although preoperative instrumental assessment was not routine, 19 patients underwent modified barium swallow study (MBSS), with mild posterior spillage being prevalent for eight patients. Among those with a feeding tube, 1-month postoperative MBSS or fiberoptic endoscopic evaluation of swallowing (FEES) revealed no increase in laryngeal penetration or aspiration. In addition, the authors found preoperative MBSS abnormalities to not be predictive of postoperative outcomes such as EAT-10 score or placement of feeding tube.

Strengths of this research include minimal loss to follow-up, and team-based approach with a speech-language pathology evaluation. Limitations of this study include the lack of patients with complicated postoperative courses, lack of baseline data, and lack of functional swallowing assessment. The article addresses the shortcomings without prospective functional swallowing assessment data. This study provides suggestive evidence of improved acute- swallowing related outcomes and compensatory strategies needed post- TORS.

Sethia et al. (2018) conducted a prospective study that evaluated the functional, clinical and quality of life outcomes of TORS without adjuvant therapy for oropharyngeal cancer. Patients were selected based on tumour site of origin description; inclusion/exclusion criteria were well described (n=111). The participants were administered the Head and Neck Cancer Inventory (HNCI), deemed a highly reliable and valid instrument (Funk et al., 2003). This test measured speech, eating, aesthetics, and social disruption, and an overall QOL score at 3 weeks and 3, 6, and 12 months. Speech-Language Pathologists evaluated swallow preoperatively, and throughout treatment.

There were significant associations between lower overall QOL scores and chemoradiation therapy (CRT) compared to TORS alone and adjuvant RT. There were statistically significant higher scores for eating and functional/ attitudinal domains for TORS alone at 3 months and 6 months post-surgery. There were less reports of hoarseness, odynophagia, oral thrush, and no reports of xerostomia with TORS alone. Further, TORS-alone patients did not need a percutaneous endoscopic gastrotomy (PEG) or tracheostomy. The authors concluded that important consideration should be placed on determining an appropriate dose of adjuvant therapy and assessment of short- term effects on human health.

The main strength of this research being the first study to compare QOL outcomes of TORS alone and TORS with adjuvant therapy in OPSCC. The authors found that these findings are consistent with previous studies examining patients QOL outcomes who underwent TORS alone. A limitation was that an instrumental assessment was not used. This study provides suggestive data post- TORS on patient's improvement in QOL in multiple domains.

Lazarus et al. (2019) completed a prospective cohort study to explore how TORS alone impacts swallow function and QOL in 10 patients (median age: 61) with people with oropharyngeal cancer. Patient inclusion/ exclusion criteria and study methodology were clearly described. Measurements were completed at baseline and one-month post-surgery. All patients underwent a MBSS evaluation that was conducted by two speech-language pathologists with a clearly described protocol. A gold-standard scale, Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) (Hutcheson et al., 2017) was used to provide a global score of swallow safety and efficiency. Tongue Range of Motion (ROM) composite score, Performance Status Scale (PSS) Normalcy of Diet Subscale, and MD Anderson Dysphagia Inventory (MDADI) were used to observe tongue range of motion, diet type, and patient-rated swallowing QOL.

Appropriate statistical analysis revealed that at 1-month post-surgery, 8/10 patients score remained the same as baseline. The remainder, who underwent radical oropharyngectomy had a score of 1 due to reduced base of tongue motion. All patients presented with a regular diet pre-surgery and 1-month post-surgery, and a regular diet with no restrictions on the PSS Normalcy of Diet Subscale scale. The authors concluded that this indicated normal understandability of speech, normal diet, and tongue range of motion. There was no significant difference between DIGEST scores pre-surgery to post-surgery. There was no significant difference in PSS Eating in Public scores pre-surgery and 1-month post-surgery.

The authors concluded that both subjective and objective outcomes should be measured when deciding treatment plans. In comparison to Owen and colleagues (2018), diet and QOL was preserved. No patient required a tracheostomy and PEG tubes, and only half of the patients needed adjuvant radiotherapy. Speech and swallow function remained unimpaired in patients that did not undergo adjuvant chemoradiotherapy. The authors noted patient-centred care and shared-decision making is precedent regarding treatment.

Strengths of this research include being the first study to examine swallow functioning regarding safety and efficiency pre-TORS and post-TORS, the use of reliable and validated measurement tools, and the use of

a MBSS procedure. Further, the authors attempted to improve interjudge and intrajudge reliability by consulting with a radiologist and 2 speech-language pathologists. A limitation to this research includes the small number of patients. This study provides suggestive evidence of improved swallowing outcomes and quality of life post-TORS without adjuvant therapy.

Owen et al. (2016) investigated clinical characteristics of patients who underwent TORS, and pre-treatment swallowing measures in relation to post-operative swallowing outcomes. This prospective study included 51 patients with primary or recurrent cancers or a diagnostic tongue base mucosectomy. Age was divided into two groups, respective of swallowing function deterioration at age 65 and older. Patients underwent an instrumental swallow assessment when clinically specified pre and post-operatively up to six weeks. Additionally, patients were counselled regarding feeding needs and prognosis, with a plan for nasogastric tube placement for all patients to assist with expectation and patient comfort. Outcome measures included a Performance Status Scale (PSS), the Water Swallow Test (WST), and tube feeding duration.

Appropriate statistical analysis revealed that 14 patients who did not receive a pre-treatment swallowing assessment were more likely to undergo tongue base mucosectomy. Factors influencing tube feed duration include advanced age, laryngeal tumour site and burden (specifically T2 disease), and comorbidities such as COPD. There was a moderate significant negative correlation between pre-treatment swallowing function and feeding tube days. At 6 weeks, 39 patients did not require a feeding tube. The findings that this study demonstrated slightly longer tube duration compared to other studies suggested that the patients included had poorer pre-treatment status. This study concluded that with pre-operative swallowing measures, routine instrumental assessments may be avoided in addition to assisting patients needing additional nutritional and swallowing support. Overall, in terms of clinical practice, caution should be taken when implementing pre-swallowing counselling due to limited evidence and lack of comparison to other studies.

Strengths of this study include being the first study to specifically examine tongue base mucosectomy and swallowing outcomes. However, the study included a small and heterogeneous patient population as well as potential bias due to loss of data at follow-up. This study provides suggestive evidence of factors influencing acute dysphagia as well as length of feeding tube post-TORS, and the benefit of counselling in the early stage of treatment.

Case Series Study:

A case series study is a study designed to examine patients given a similar treatment with no comparison group.

Hutcheson et al. (2019) conducted a case series study to investigate the use of MBS studies to identify pharyngeal dysphagia before and after TORS at 3 to 6 months, and to identify swallow symptom trajectories over the course of treatment. A total of 257 patients (median age: 59.54) met well-specified inclusion criteria of having a low-volume disease at the primary site and neck. The participants were divided into two groups based on the treatment trajectory: 75 undergoing primary TORS and 182 receiving primary radiotherapy. Outcome measures included an instrumental examination before treatment, postoperatively, and 3 to 6 months post-operatively with a reported standard protocol and validated graded tool. The Speech-Language Pathologist conducting the DIGEST review was blinded to MBSS procedure. At the time of MBSS performance, patients completed the MDADI and the MD Anderson Symptom Inventory–Head and Neck Module (MDASI-HN).

Appropriate statistical analysis revealed a large difference in the N-stage tumour classification, radiotherapy dose, bilateral radiotherapy fields, and neck dissection between groups. The results of acute dysphagia outcomes post-TORS revealed the DIGEST grade scores to be significantly worse after TORS, suggesting that dysphagia severity and surgery correlates with a large effect size. Out of the 75, 17 patients had moderate to severe acute dysphagia post-TORS before adjuvant therapy. A no to mild pharyngeal dysphagia score increased to moderate to severe dysphagia in 14 patients. In the acute post-surgical period, the authors found clinically significant pharyngeal dysfunction in addition to impaired velopharyngeal seal and unilateral pharyngeal weakness. The authors concluded that 22.7% of patients developed moderate to severe dysphagia score, which was significantly associated with primary tumour volume post-TORS, and not significantly associated with age, N classification, tumour site, and baseline DIGEST grade. At 3 to 6 months, 38 patients returned for postoperative MBS study; findings suggest that dysphagia grades improved by 3 to 6 months but remained worse than baseline. Further, the authors concluded that a large effect on poorer swallowing function at 3 to 6 months compared to baseline was indicative of adjuvant therapy.

MDASI-HN swallowing symptom severity items revealed significantly worse scores post-TORS for patients who underwent adjuvant therapy compared to

primary radiotherapy or treatment naïve. In addition, the primary TORS group presented had worse baseline dysphagia. However, DIGEST and MDASI scores by 3 to 6 months in all groups did not significantly differ. This study suggests important implications on preoperative counselling due to the increased swallowing burden during the acute stage post-operative.

Strengths of this study include being the first study to compare MBS study and patient-reported swallowing outcomes, the therapists were blinded, a relatively large sample cohort, and validated clinical swallowing variables. Limitations of this study include loss of data at follow-up, and selection bias within and between groups. This study provides a highly suggestive evidence of swallowing outcomes in the acute post-TORS period and pre-operative counselling. The authors welcome future physiological changes associated with dysphagia post-TORS.

Discussion

The purpose of this paper was to review the literature on practice standards for assessing acute-dysphagia outcomes in patients with oropharyngeal squamous cell carcinoma, focusing on how transoral robotic surgery compares to adjuvant therapy and traditional techniques. The one systematic review study revealed suggestive evidence supporting how TORS compares to dysphagia severity as a treatment option for OPSCC. The utility of the literature review is somewhat low because the authors do not make any formal conclusions or provide professional suggestions for best practices other than highlighting many different assessment methods. Owen et al. (2016) produced a prospective study that supported the importance of pre-treatment counselling on feeding needs and prognosis in the early stage of treatment as patients with poorer pre-treatment status demonstrated slightly longer tube duration. Hutcheson et al. (2019) were the only researchers found to directly compare the use of VFSS and MDADI in evaluating dysphagia swallowing outcomes among adults with OPSCC and provided highly suggestive conclusions. Primarily, Hutcheson et al. (2019) found that primary tumour volume was significantly associated with moderate to severe dysphagia and poorer swallowing function was suggestive of adjuvant therapy. In addition, patients who received primary TORS presented with worse baseline dysphagia as well as significantly worse swallowing outcome in the acute post-operative stage. Overall, these articles demonstrated pre-treatment swallowing counselling may improve swallowing outcomes and patients' perceptions.

Lazurus et al. (2019) completed a prospective cohort study that provided suggestive evidence regarding both subjective and objective outcomes being used when implementing treatment plans pre-TORS and post-TORS. For patients who underwent TORS alone, this study found no significant difference on speech and swallow function 30-days postoperatively. Sethia et al. (2018) were the only researchers found to directly compare QOL outcomes of TORS alone and TORS with adjuvant therapy; however, it failed to include an instrumental assessment providing suggestive evidence on patients QOL improvement post-TORS alone. Their study concluded that TORS alone patients did not require a gastrotomy tube, although appropriate dose of adjuvant therapy should be considered for patients in need of additional radiotherapy. Albergotti et al. (2018) produced a prospective study to describe short-term dysphagia post- TORS for OPSCC. The authors found that approximately over 50% of patients required compensatory strategies or change in liquid consistency and among those with a feeding tube, instrumental assessments revealed no increase in laryngeal penetration of aspiration 30 days post-TORS.

Overall, this literature was limited by the minimal research available, heterogenous samples, and the lack of consistent objective standardized swallowing outcome measures between studies. The findings suggest that TORS alone is a valuable surgical method for treating patients with OPSCC who are at high risk for dysphagia. The use of varied study methodology and inclusion of heterogenous population makes it challenging to draw definitive conclusions to the implementation of certain assessment protocols across different stages of OPSCC. In addition, it suggests that compliance with dysphagia management is multifactorial and requires shared-decision making and patient-centred care. Clinical indications for best-practice standards for assessing acute swallowing-related outcomes and implementing decision-making process remain to be investigated.

Clinical Implications

Through critical appraisal of the literature, due to the overall suggestive nature of these studies, it is premature to conclude that acute-swallowing related outcomes with TORS alone is superior to other traditional or adjuvant therapy. More studies comparing both objective and subjective outcomes are needed to shed light on best-practice standards. Further, future research should develop clinical recommendations and implications pre and post-TORS treatment and suggested timelines for instrumental evaluation use. Based on the information provided in this literature review, an evaluation of pre-treatment swallowing

counselling regarding feeding needs and prognosis may be implemented for patients with OPSCC with caution due to limited strength of evidence. In working with a multidisciplinary team to problem-solve and provide practical recommendations, patient quality of life and acute-swallowing outcomes will likely benefit.

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