

Critical Review:
In individuals with unilateral vocal fold immobility, is vocal fold medialization an effective intervention method for dysphagia?

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This critical review examines evidence of the efficacy of vocal fold medialization as a treatment method for dysphagia in individuals with unilateral vocal fold immobility (UVFI). A literature search of the subject resulted in six retrospective case studies and one single subject study. The articles were evaluated based on level of evidence, study design, methods, data collection, analysis, and interpretation. Overall, results were inconclusive as to whether vocal fold medialization is an effective method of improving dysphagia symptoms for patients with UVFI. Clinical implications of these findings and recommendations for future research are discussed.

Introduction

Unilateral vocal fold immobility (UVFI) occurs when one vocal fold is unable to move towards the midline of the pharynx. It results in reduced glottic closure which may cause dysphonia, or voicing difficulty, difficulty breathing, and dysphagia, or difficulty with swallowing (Cates et al., 2016). It is estimated that 55-69% of those that have UVFI will develop symptomatic dysphagia that may affect their health, their quality of life, and their relationships with others (Zhou et al., 2019).

Vocal fold medialization has long been used to treat dysphonia in individuals with reduced glottic closure, such as those with UVFI (Zuniga, Ebersole & Jamal, 2018). The specific focus of this intervention is to reduce glottal opening by moving the affected vocal fold towards the midline and stabilizing it in this position in order to improve glottal closure for the purpose of speech. There are two main processes used in vocal fold medialization intervention: thyroplasty, in which an implant is placed within the larynx to move the vocal fold to the midline, and injection laryngoplasty, in which a substance is injected into the immobile vocal fold to provide bulk, thereby shifting the vocal fold to midline.

Because vocal fold medialization aims to reduce glottal space, it may also play a role in the treatment of dysphagia. Dysphagia can occur when material falls below the level of glottic closure into the trachea and can cause aspiration pneumonia if not treated (Zhou et al., 2019). This symptom of dysphagia occurs when full glottal closure is not achieved; therefore, reducing the glottal opening using vocal fold medialization for an individual with UVFI may also provide positive outcomes for symptoms of dysphagia. However, research regarding the efficacy of vocal fold medialization as a treatment for dysphagia is limited.

In the diagnosis of dysphagia, visual assessment using videofluoroscopy or fiberoptic endoscopic evaluation studies (FEES) are considered direct, objective assessments of swallowing. Indirect assessments include observed changes to diet, palpation of swallows, and patient-reported outcome measurements, such as the Eating Assessment Tool – 10 (EAT-10), a symptom-specific self-reported assessment of dysphagia (Belafsky et al., 2008). Both subjective and objective measures of dysphagia play a role in research regarding the efficacy of dysphagia treatments. In this critical review, both subjective and objective measures are used to record dysphagia symptoms experienced by individuals and to determine treatment efficacy.

Objectives

The primary objective of this paper is to critically evaluate existing literature regarding the efficacy of the treatment of dysphagia using vocal fold medialization in individuals with UVFI. The secondary objective is to determine the implications of this evidence for clinical practice and future research.

Methods

Search Strategy

The following online databases were used to locate relevant articles: Western Library's search engine Omni, Google Scholar, PubMed, and SCOPUS. The following search terms were employed: (vocal cord) OR (vocal fold) AND (paralysis) OR (immobility) OR (glottal-)AND (medialization) OR (laryngoplasty) OR (thyroplasty) OR (inject-) AND (dysphagia) OR (swallow-).

Selection Criteria

Studies selected for this critical review were required to be peer-reviewed and published in English. In addition, studies were required to focus specifically on the impact of vocal fold medialization on dysphagia for UVFI. All data regarding dysphonia were not considered for the purpose of this critical review. Patient-reported outcomes and visual evaluation of swallowing results were accepted, and all etiologies of vocal fold immobility were accepted. Studies involving medialization by either injection laryngoplasty or thyroplasty were accepted.

Data Collection

The literature search generated seven articles that met the inclusion criteria. Papers selected for this review included six retrospective case series and one single-subject repeated measures study.

Results

Retrospective case series

A retrospective case study series is the description of a group of similar cases in which the same disease is treated or the same treatment is used for all cases (Hess, 2004). The term “retrospective” is used to denote that data collected for the purpose of the study was originally recorded for reasons other than research, such as patient medical charts. Given the non-experimental design and lack of control group, the level of evidence for this design is weak. This study design results in level four evidence according to the Oxford Levels of Evidence (2011).

Cates et al. (2016) studied the dysphagia symptoms of 44 patients with unilateral vocal fold paralysis prior to and after vocal fold medialization by either thyroplasty or injection laryngoplasty in order to determine the effect of medialization on dysphagia symptoms. Patients with confirmed UVFI self-reported about their swallowing impairment using the EAT-10. In addition to assessment prior to and following medialization, follow-up of swallowing symptoms also occurred within a year following the procedures.

Appropriate statistical analysis revealed that in comparison with preoperative EAT-10 scores, statistically significant improvements in mean EAT-10 scores were recorded at the first post-operative follow-up. At the second post-operative follow-up, the mean improvement remained significant for patients treated with injection laryngoplasty, but not significant for those treated with thyroplasty. The authors also note that though improvements were found and remained stable post-operatively, symptoms of dysphagia were

not entirely resolved through either vocal fold medialization procedure.

The methods of data collection and analysis are adequate and well-documented, but patient selection, though well-outlined in the study, did not identify if patients had dysphagia symptoms prior to the onset of UVFI; this calls into question the validity of the study. Overall, Cates et al. provide suggestive evidence that vocal fold medialization may improve swallowing symptoms in patients with UVFI.

Zuniga, Ebersole, & Jamal (2018) investigated the effect of injection laryngoplasty on self-reported and visually assessed swallowing outcomes. Self-reports of dysphagia symptoms using the EAT-10 assessed symptoms of 21 patients with new-onset UVFI following head and neck and thoracic surgery who were treated with injection laryngoplasty. Swallowing assessments using FEES were also employed at the time of UVFI diagnosis, and Functional Oral Intake scores (FOIS) were assigned to mark dysphagia symptoms based on FEES findings. Both subjective and objective assessments occurred immediately prior to and following injection and at one-month post-injection.

Patients were chosen based on clear and adequate criteria and the authors confirmed that all patients had abnormal swallow function that was associated with the diagnosis of UVFI. Appropriate statistical analysis demonstrated that FOIS and EAT-10 scores were significantly improved following injection. After injection, all patients with restricted diets were able to return immediately to regular diets, and one patient deemed *nil per os* was able to tolerate a restricted diet.

This study provides both subjective and objective measures of swallowing symptoms and notes observed dietary changes for patients involved. The inclusion of both indirect and direct measures and proof that dysphagia was associated with UVFI provides credible evidence to support medialization for dysphagia treatment; however, the small sample size, lack of control group, and possible selection bias in terms of the etiology of UVFI provide some limitations to this study.

Overall, this study provides suggestive evidence that vocal fold medialization is an effective method to reduce dysphagia symptoms in individuals with UVFI.

Anderson & Mirza (2001) studied the efficacy of injection thyroplasty in decreasing the risk of aspiration resulting from acute UVFI in patients with confirmed dysphagia based on FEES assessment. 11 patients were examined using FEES for aspiration and penetration (the presence of food at or below the level of the vocal

folds) prior to and following injection. All patients showed significant improvement in dysphagia symptoms of aspiration and penetration following the post-injection study and successfully returned to full oral diet accompanied with compensatory swallowing strategies. Two of the 11 participants later required treatment for recurrent aspiration, suggesting improvements may be short-term.

This study accepts that injection medialization of the vocal folds may lead to temporary relief of dysphagia symptoms in patients but should not be used as a long-term solution. No later follow-up measures were conducted, and measurement of swallowing symptoms were limited to aspiration and penetration as viewed by FEES. While aspiration is one symptom of dysphagia, this outcome measure does not provide a wholly accurate picture of the effects of vocal fold medialization on all dysphagia symptoms.

This study provides compelling evidence that injection medialization is a viable solution for patients during recovery after injury or weakness and can be used to avoid short-term enteral access. However, it provides only suggestive evidence for vocal fold medialization as a treatment method for dysphagia beyond aspiration.

Anis & Memon (2018) assessed patient-reported swallowing outcomes based on EAT-10 score differences prior to and following injection medialization laryngoplasty. 17 patients who reported dysphagia with diagnosis of UVFI completed EAT-10 assessments prior to treatment and at each follow-up visit.

Appropriate statistical analysis showed that 76% of participants reported significant improvement in EAT-10 scores following treatment, and, for several patients with idiopathic UVFI, improvement persisted past follow-up visitation. However, the limitations of this study require the results to be considered with caution: follow-up timelines were not specified, and only subjective measures of outcomes were recorded. No visual confirmation of UVFI or dysphagia were required for inclusion in this study, and none were reported. Therefore, the validity of this study can be called into question.

Overall, the evidence provided by this study for the effect of vocal fold medialization as a treatment of dysphagia for individuals with UVFI is suggestive.

Hendricker, deSilva & Forrest (2010) examined the management of dysphagia using Gore-Tex medialization laryngoplasty in patients. Their retrospective examination of the charts of 113 patients

treated for UVFI showed that of that group, only 47 required swallowing evaluations prior to treatment. 20 required gastrostomy tubes for feeding prior to treatment; following injection laryngoplasty, 11 of these patients were able to return to oral feeding.

This paper judged changes in swallowing solely on the use of gastrostomy tubes prior to or after treatment. In addition, they describe a highly heterogeneous population requiring gastrostomy tubes. The authors note it is possible some patients did not require gastrostomy tubes due to their UVFI, and also that the discontinuation of gastrostomy tubes may not have been related to the injection laryngoplasty procedure for some patients. No other post-treatment measures were recorded, and no statistical analysis was conducted to examine the significance of the findings. In addition, all patients were given speech and swallowing therapy prior to and following treatment, which may have played a role in the discontinuation of g-tube use.

The lack of validity and reliability of this test makes the evidence equivocal for the effect of vocal fold medialization to improve dysphagia in individuals with UVFI.

Tateya et al. (2010) assessed eight patients with UVFI and dysphagia symptoms prior to and within seven months following thyroplasty treatment. UVFI was confirmed visually using FEES, but dysphagia symptoms were not visually assessed. The clinical classification of Fujishima for swallowing function, a subjective measure grading the diet level (e.g. normal diet, *nil per os*, chewable food only, etc.) of individuals, was conducted prior to and following treatment at the last follow-up visit.

Appropriate statistical analysis found that in six participants, swallowing function significantly improved based on dietary changes. In patients that did not show improvement, vocal fold visualization revealed that the fixed vocal fold position may decrease the impact of vocal fold medialization procedures.

While the data presented in this case study is analyzed well and though significant improvement was found in most cases, the improvement was measured based solely on dietary changes made by individuals using a scale for which no evaluations of its quality as an assessment tool have been found. In addition, the data did not examine any patients with idiopathic or iatrogenic etiologies; the limitations of the sample population narrow the scope of this study.

A strength of this study is that it examines the limitations to vocal fold medialization for the

improvement of dysphagia by further examining patients who did not benefit from medialization for dysphagia. Overall, the evidence provided by the study is suggestive of improved dysphagia symptoms in populations with UVFI.

Single-subject study

Single-subject study designs use repeated measures to compare variables measured before, during, and after intervention for one individual. A single-subject study design can be effective in determining causal relationships between intervention and individual change and allows individual patterns of change to be identified. A weakness of the design is that results are rarely generalizable and study results are difficult to replicate (Rogers & Graham, 2008). This study design results in level two evidence according to the Oxford Levels of Evidence (2011).

Kammer et al. (2019) used high-resolution manometry (measure of changes in pharyngeal pressure) and the penetration/aspiration scale based on FEES assessment to measure changes in glottal closure and swallowing outcomes following injection laryngoplasty. 17 adults with confirmed UVFI and dysphagia with penetration or aspiration, documented by FEES, were included in the study. Data from the penetration/aspiration scale and high-resolution manometry were collected one week prior to and after injection, and one month after injection. Only objective data was collected and analyzed in this study.

Appropriate statistical analysis demonstrated no significant changes in penetration/aspiration scores at any point in time for any consistency. Changes in pressure in the velopharynx were not significant at any point in time, but significant increases in the rise rate of the mesopharynx were noted. No significant changes were noted in the pressure of the upper esophageal sphincter or in the timing of the swallow duration. In conclusion, this study found that changes to glottal closure via vocal fold medialization were not sufficient to make positive changes to swallowing symptoms.

This study ensured that voice and swallowing therapy was not given to patients during the duration of the study in order to ensure validity of the results. It also provides evidence of high intra-rater reliability in speech language pathologists that rated the penetration/aspiration scores in each FEES evaluation.

Yet, this study also has many limitations. Interrater reliability was not recorded for this study and, unlike other studies, selection criteria excluded patients with a history of laryngeal surgery or radiation to the larynx. Since iatrogenic and noniatrogenic trauma and radiation

are common etiologies of UVFI, this excludes a significant portion of the population with UVFI (Zhou et al., 2019). Lastly, the lack of control group and the lack of follow-up from potential participants, suspected by the authors to be those who showed improvement, causes this study's evidence that vocal fold medialization does not improve dysphagia to be suggestive.

Discussion

Dysphagia is a serious health concern for patients with UVFI (Zhou et al., 2019). Vocal fold medialization has been used to treat dysphonia in this population, but the evidence of its impact on dysphagia has not been widely studied. The purpose of this paper was to critically review articles that examined the impact of vocal fold medialization as a treatment for dysphagia in patients with UVFI. The results of the seven articles included in this review provide inconclusive evidence that vocal fold medialization is an effective treatment for dysphagia in this population.

Retrospective studies of the topic provided detailed findings suggesting that vocal fold medialization may provide at least short-term improvements in dysphagia symptoms in individuals with UVFI. These studies relied on a mixture of subjective, objective, or mixed measurements of dysphagia to determine changes. However, these studies varied in terms of protocol regarding measurement of dysphagia and determining what was included in the definition of dysphagia. In addition, retrospective studies were unable to provide clear data as to when post-procedure measurements were collected; therefore, measurements of changes may be impacted by the temporal component of data collection.

Retrospective case studies included provided small sample sizes that included various etiologies. Some studies, such as Zuniga et al.'s (2018) retrospective study, focused on specific etiologies; therefore, results cannot be generalized to the entire population of individuals with UVFI. Lastly, as noted by Cates et al. (2016), selection criteria in retrospective studies requires that patients that did not return for follow-up assessments be excluded from analysis. This requires some caution in the interpretation of results as only patients who elected to undergo surgery and return for follow-up assessments can be included, which may not provide an adequate picture of the presence and change in dysphagia symptoms in individuals with UVFI.

Kammer et al.'s (2019) single-subject study approach found that vocal fold medialization was not an effective method for improving dysphagia in individuals with

UVFI. This study also maintains that patients lost to follow-up may have shown improvement and may not have deemed re-assessment as necessary. Therefore, results must be interpreted with caution. Kammer et al. were the only study to analyze purely objective changes in patient dysphagia without considering subjective changes in diet and self-reported changes to the swallow. While this may provide the most accurate picture of the individuals swallow, it does not allow for the changes the patient has observed outside of assessment to be considered.

Overall, evidence is mixed as to whether vocal fold medialization is an effective method of improving dysphagia symptoms for patients with UVFI. Further research must be conducted to determine functional changes in swallowing following vocal fold medialization and the improvement of patient quality of life as an outcome measurement. It is recommended that future research should include randomized controlled designs that directly compare vocal fold medialization to traditional methods of relieving dysphagia symptoms in individuals with UVFI; however, it is acknowledged that this type of study may be challenging due to ethical considerations.

Clinical Implications

Traditional methods of relieving dysphagia, including exercise and compensatory strategies, require patients to have adequate cognitive function and motivation for improvement. Those with UVFI sometimes develop this diagnosis due to iatrogenic and non-iatrogenic trauma or as a side effect to radiation therapy. These individuals may benefit from a temporary relief that requires no additional effort as fatigue is often involved in recovery from these etiologies. Therefore, UVFI may be considered a possible method of treatment for these individuals.

Results of this review do not provide compelling evidence to recommend vocal fold medialization as a primary treatment option for dysphagia in patients with UVFI. However, in the absence of other treatment options due to time, cognitive function, or patient choice, vocal fold medialization may be effective in improving symptoms of dysphagia in patients with UVFI.

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