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Quality of Life Scores Compared To Objective Measures of Swallowing Function After Oropharyngeal Chemoradiation

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Running title: QOL deglutition oropharyngeal chemoradiation

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Conflict of Interest: None

ABSTRACT

Objectives:

To compare objective measures of swallowing function with patient reports of swallowing-related Quality of Life one year after treatment of oropharyngeal cancer with chemoradiation therapy.

Study Design:

Patients seen for follow-up at least one year after treatment of oropharyngeal carcinoma with chemoradiation therapy were sequentially approached and asked to participate in the study.

Methods:

Maximum pharyngeal constriction, hyoid elevation, upper esophageal sphincter (UES) opening size and bolus pharyngeal transit time were measured from modified barium swallowing studies in a group of 31 patients at least one year after chemoradiation therapy for the treatment of oropharyngeal carcinoma. Measures were made for a liquid 1cc, 3cc and 20cc bolus. Objective measure results were compared to scores from the MD Anderson Dysphagia Inventory and The University of Washington Swallowing Quality of Life Questionnaire results from the same patients.

Results:

No strong correlation was identified between any of the objective measures of swallowing physiology and quality of life scores.

Conclusion:

Patient perception of the impact of swallowing function on quality of life does not correlate well with actual physiologic functioning.

KEY WORDS Oropharyngeal Carcinoma, deglutition, quality of life, MDADI, UW-QOL, dysphagia, chemoradiation

LEVEL OF EVIDENCE 4

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INTRODUCTION

The assessment of quality of life and functional outcomes in patients after treatment of head and neck cancer has become more important as multiple treatment modalities are now available. In particular, for oropharyngeal carcinoma, there has been a shift in treatment preference away from the traditional surgical excision of the tumor followed by radiation therapy to treatment with primary chemoradiation therapy. Both modalities have similar cure rates so treatment decisions are likely to be determined by which modality can offer the patient the best functional outcome.[1] The rationale behind chemoradiation therapy as primary treatment, rather than surgery followed by radiation, is that "organ sparing" treatment rather than removal of cancerous tissues by surgery, should improve functional outcomes. However, dysphagia is a frequent side effect of chemoradiation therapy. Swallowing problems are likely caused by radiation-induced edema and muscular fibrosis. Some patients experience permanent lymphedema resulting in long-term swelling of supraglottic structures. Clinical factors that increase the risk for permanent dysphagia after chemoradiation therapy include increasing patient age, increasing size of the tumor, and radiation portal size and dose to the pharyngeal constrictors.[2,3,4]

Despite a large body of literature that documents significant dysphagia in patients after treatment with chemoradiation therapy, [5-9] little is known about the specific physiologic changes that occur in swallowing function after this type of treatment. A prior systematic objective evaluation of swallowing functional changes in this patient population is lacking. Rather, research has focused on a variety of surrogate measures such as quality of life scores,[4] patient reported diet,[10] weight loss[11] and gastrostomy tube requirements.[12,13] Previous studies include subjective assessments made from modified barium swallowing studies.[11,14] However, these measures do not objectively evaluate the pathophysiology of patient swallowing function. Furthermore, no direct comparison between quality of life measures and objective measures of swallowing function has been done.

Quality of life measures typically comprise many facets of both emotional and physical functioning but ultimately rely on an individual's perception of their functional state. In measuring quality of life, it is difficult to measure only those elements that may be affected by a particular illness or treatment. Although there is no question that swallowing difficulties likely have a negative impact on quality of life, patient attitudes can potentially significantly impact quality of life scores as well, irrespective of functional abilities.[12] Treating physicians are tasked with addressing both the emotional and physical needs of individual patients, however. As such, this study proposes to evaluate if and how specific functional outcomes are reflected in quality of life scores by comparing individual quality of life scores for a group of oropharyngeal cancer patients to the objective measures of swallowing function from their swallowing studies.

METHODS

Subject Selection:

This study was approved by the Minneapolis VA Medical Center IRB. Videofluoroscopic swallowing studies were performed on 31 male patients at least one year after the completion of chemoradiation therapy for the treatment of oropharyngeal carcinoma. When patients were seen in the clinic for routine follow-up examinations, they were asked if they would be willing to participate in the study. Patients were recruited without consideration of swallowing complaints. All subjects were free of recurrence.

Fluoroscopic Swallowing Studies/ Data Collection:

Modified barium swallowing studies were performed for each patient. Objective measures of swallow timing and structural displacements, considered to be crucial to a functional swallow, were made from each study. Although objective measures are not universally routinely employed in the

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analysis of modified barium swallowing studies, this type of analysis improves the interpretation of swallowing studies by enabling the identification of subtle changes in swallowing function that are usually missed in a quick review of the study in the fluoro suite. Timing and displacement measures are relatively easy to make and are reliable.[15,16] They have also been shown to be clinically significant in that they correlate to the risk of developing aspiration pneumonia.[17] Normative data for both young and older subjects is available. Furthermore, objective measures can be used to document change after an intervention such as swallowing therapy.[18]

The radiographic studies were performed by a Speech Language Pathologist at the Minneapolis VA Medical Center in accordance with the routine radiographic protocols approved by the institution. Equipment used included a properly collimated radiographic/fluoroscopic unit. Recordings were made for liquid swallows of two 1cc, two 3cc, and one 20 cc bolus. Subjects were presented with each measured bolus and asked to hold it briefly in the oral cavity before a command to swallow. The swallow studies were recorded at 30 frames/sec. Fluoroscopy studies were recorded onto a Kay Elemetrics swallowing station and saved in an .avi format. Completed recordings were analyzed without information about the identity of the subject. Viewing the studies in Quicktime allowed frame-by-frame advance and reverse in order to determine the exact study frame from which to measure timing of bolus transit and maximal structural displacement. Timing information in 1/100 of a second increments was available for each frame, allowing detailed timing measurements. The software programs used for spatial analysis of fluoroscopic images was J-IMAGE (http://rsb.info.nih.gov/nih-image) and Universal Desktop Ruler. Spatial measurements were made after calibration of the digitized image to the size of a 1.8-cm-diameter radiopaque disc taped to the chin of the study subject. All measures were obtained from lateral views and included bolus pharyngeal transit time, airway closure relative to arrival of the bolus at the UES, maximal hyoid displacement, upper esophageal sphincter opening size, and pharyngeal

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area at maximum constriction. A detailed technical description of these measures and their acquisition has been previously reported and will be summarized here.[15,16]

Timing Measures:

Bolus pharyngeal transit time is defined as the time between when the bolus head passes the posterior nasal spine and when the upper esophageal sphincter closes behind the tail of the bolus.

Displacement Measures:

Maximum hyoid elevation was defined by measuring the shortest distance between the hyoid position at bolus "hold" and at its point of maximal anterior and superior excursion during the swallow. Bolus "hold" is the position of the hyoid prior to the swallow with the bolus held in the oral cavity **(Figure 1)**. Maximum upper esophageal sphincter opening size was defined as the maximum anterior–posterior opening of the narrowest portion of the aerodigestive tract between C4 and C6 during bolus passage **(Figure 2)**. Pharyngeal area is defined posteriorly by the posterior pharyngeal wall from the mid-portion of the tubercle of the atlas down to the level corresponding to the top of the upper esophageal sphincter. The inferior border of the pharynx extends forward from this point over the arytenoid cartilages and anteriorly to outline the epiglottis, vallecula, and posterior tongue to the point where the soft palate makes contact with the tongue base. The boundary of the pharynx then extends over the pharyngeal surface of the soft palate to its point of insertion into the posterior nasal spine. The superior border of the pharynx is defined by a straight line between the posterior nasal spine and the mid-point of the tubercle of the atlas **(Figure 3a)**. Pharyngeal area at maximal constriction during the swallow was defined by the outline of the same structures during maximal constriction **(Figure 3b)**.

At the time of study enrollment, each subject was asked to complete the MD Anderson Dysphagia Inventory and the University of Washington Quality of Life Questionnaire (version 3). The MDADI and the UW-QOL are limited to head and neck-related functional domains and are quick and simple for patients to complete and correlate well with other quality of life measures.[19,20]

Questionnaires were scored without knowledge of the patient identity. Scoring of the MDADI involves analysis of a global score from a single question about how swallowing problems have affected the patient's overall daily routine. The physical sub-score combines patient responses to eight questions regarding swallowing difficulty. This sub score was calculated for each patient to determine if patient perception of their physical swallowing functioning correlates with the objective measures made from their swallowing study. Each question on the MDADI has five possible responses that are then given a numeric score from one to five. The final score ranges from 0 (very poor functioning) to 100 (perfect functioning).[19]

The University of Washington Quality of Life composite score is the mean of 10 individual "domain" scores from 10 questions. Each question is rated by the patient as 0 (severe, difficult to control problem), 25 (severe but controllable problem), 50 (moderate problem), 75 (mild problem), and 100 (no problem). The best possible score is 100 and the worst score is 0.[20]

Data Analysis:

To assess association between life quality and individual measures of swallowing function, Spearman correlation coefficients were calculated for the MDADI global score and each swallowing function variable. Pearson correlation coefficients were calculated for the MDADI, the MDADI physical domain, and the UW-QOL and each swallowing function variable.

RESULTS

Thirty-one patients were enrolled in the study. The age range of study subjects was from 51 to 78 years old. Four patients were stage III and the remainder stage IV. Tumor location was in the tongue base in 10 patients, in the tonsil in 13 patients, on the epiglottis in 3 patients, in the lateral pharynx in 2 patients and 3 patients had radiation to Waldeyer's ring for an unknown primary. Maximum radiation dose ranged from 40 to 70 Gray. Twenty patients reported that they ate a regular oral diet with minimal restriction. Eight patients reported modifying their diet ranging from soft diet to thickened liquids only.

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Two patients were entirely PEG dependent. One patient had a PEG but took some liquids by mouth. Aspiration was noted on six studies. Two of those patients who aspirated reported eating a regular diet and two reported eating a modified diet with soft foods and thickened liquids and two were PEG dependent.

One and 3cc timing data was could be measured from 30 studies because one study only recorded the 20cc swallow. 20cc data was not recorded for 4 studies due to concern for aspiration seen on the smaller bolus sizes and discontinuation of the study with the result that 20cc timing data was available for 27 studies. Complete timing data including all bolus size categories was thus available for 26 studies. One of those studies did not have a calibration marker placed so no displacement measures could be made and thus complete timing and displacement data was available for 25 studies.

Two patients failed to complete the MDADI (presumably because they didn't see the second page) so data for the MDADI score and sub-score analysis was available for 29 patients. One of those subjects also had incomplete swallowing measurement data so complete swallow measurement data and complete QOL data was available for 24 patients. Mean, standard deviation, and median score for the MDADI were 61.38, 17.16, and 63.16 respectively. Mean, standard deviation, and median score for the UW-QOL were 66.69, 14.55, and 68.2. These scores are consistent with previously reported scores measured one year after treatment.[4,12] The Pearson Correlation Coefficient calculated comparing the responses on the MDADI to the UW-QOL in this study showed fairly good correlation (r=0.726).

The analysis of how each swallowing measure for each patient correlated to the patient's QOL scores showed no correlation of QOL scores and any individual measure of swallowing function. **(Table 1-3)** A graph example of the data for the 20cc bolus transit timing is shown in **Figure 4.**

DISCUSSION

This is the first study that evaluates the correlation between QOL Scores and objective measures of swallowing function made from modified barium swallowing studies in patients after treatment of oropharyngeal cancer. Recognizing that overall or global QOL scores may be influenced by emotional reactions to the diagnosis and treatment of head and neck cancer, this study further evaluated the correlation of the physical sub-score from the MDADI QOL instrument to determine if patients are able to accurately assess their physiologic functioning. The results of the study show a remarkable lack of correlation with the degree of pathophysiology, as defined by objective swallowing measures, and patient perception of their degree of pathophysiology. This lack of patient ability to judge their own physiologic functioning is further confirmed by the finding that 2/3 of the patients who aspirated on their modified barium swallowing study ate an oral diet, half of them with no modifications.

The finding that QOL scores did not correlate with actual physical functioning is surprising when one considers the results of a study of 132 patients after treatment for head and neck cancer wherein Pauloski, et al, found that patients who complained of dysphagia had lower swallowing efficiency, longer pharyngeal transit times, more oral and pharyngeal residue and a higher incidence of aspiration. Patients with dysphagia complaints were also more likely to have modified their diet than those patients without dysphagia complaints.[21] On the other hand, there are many other reports more consistent results of this study, in particular, if the incidence of silent aspiration is considered. Langerman, et. al., found the incidence of aspiration after head and neck chemoradiation therapy to be 69%, with 75% of those who aspirated to be unaware of the problem.[22] Other studies have also documented a high incidence of silent aspiration, even as far as five years out from diagnosis.[11] In a well-designed study of IMRT and swallowing function, Feng, *et. al.,* prospectively evaluated 73 patients with oropharyngeal cancer treated with chemoradiation using IMRT to avoid exposure of the pharyngeal constrictors. This study demonstrated excellent oncologic results (>90% survival at one year) and 94% of patients were eating a normal diet at one year after treatment. Interestingly, despite a preponderance of dietary

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normalcy, 26% of patients demonstrated aspiration on a videofluorscopic study of swallowing and 60% of those that aspirated did so silently or with an ineffective cough response.[23] These results, and the results of this study, support the hypothesis that patient perception of function after chemoradiation therapy may not be consistent with the findings of more objective means of evaluation.

Despite the evidence from this study and others indicating that patients are not able to judge their functional ability, QOL instruments have been capable of discerning differences in outcomes related to function, depending on treatment approach, when groups of patients are compared to one another. [24] The MDADI has been previously used to evaluate post treatment differences in oropharyngeal and laryngeal cancer patients.[12,24] In oropharyngeal cancer patients, differences in the emotional and functional sub-scales, based on treatment modality, could be identified, but no difference in the physical sub-scale was reported. Furthermore, this study found that baseline depression was a risk factor for poorer quality of life scores post-treatment, further confirming the influence of base line emotional state, irrespective of functional state, on post-treatment scores.[13] The study of the MDADI in laryngeal cancer patients was able to demonstrate that MDADI sub-scores were different depending on the treatment group and that patients treated with chemoradiation therapy were more likely to report difficulty with chewing and swallowing compared to those treated with surgery and chemoradiation therapy.[24]

This study is limited by the fact that the patient population included only male patients. The exclusion of females from the study was not an intentional element of the study design but is reflective of the patient population seen at a VA medical center in the age range at risk for the development of head and neck cancer. Although there is no reason to believe that women might report QOL scores more closely tied to their actual swallowing function than males, the results of this study should not be generalized to female patients without further studies confirming similar results in females.

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Furthermore, it should be kept in mind that dysphagia symptom scoring scales, rather than quality of life instruments, may more accurately reflect swallowing function objectively measured from modified barium swallowing studies. Further research into this question would be helpful.

The findings of this study indicate that, although QOL instruments may be able to help make judgments about outcomes in large patient populations, they may not an appropriate mechanism for the evaluation of swallowing pathophysiology in individual patients and are likely not sufficient to determine if a given patient is eating safely. Previous studies evaluating the correlation of QOL scores with aspiration identified on a swallowing study have both refuted and supported this conclusion. Campbell, et. al., compared the results of UWQOL (version 4) and the finding of aspiration on a modified swallowing study in patients with multiple types of head and neck cancer. A statistically significant correlation between the scores from the subdomains of chewing and swallowing and the finding of aspiration on the swallow study was demonstrated. The same study also identified an association between weight loss and poor oropharyngeal swallowing efficiency (this is an estimate of the amount of the bolus swallowed divided by bolus transit times) with aspiration.[11] On the other hand, similar to the results of this study, Gillespie, et al, found no correlation with the penetration/aspiration scores from swallowing studies and the MDADI scores in a group of oropharyngeal cancer patients.[14]

CONCLUSION

In this homogeneous study population of male oropharyngeal cancer patients, no correlation was found between disease specific quality of life measures and objective measures of swallowing function made from modified bariums swallowing studies. The results from QOL instruments, even when isolated to physical sub-scores, may not accurately reflect swallowing ability in a given patient.

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	Pharyngeal Area	Hyoid Elevation	UES Opening Size	Bolus Transit Time
MDADI*	-0.35	0.11	0.29	-0.32
UW-QOL*	-0.24	0.28	0.14	-0.12
MDADI global**	0.07	0.005	0.14	-0.08
MDADI physical*	-0.384	0.044	0.137	0.172

Table 1: Correlation Coefficients for **1cc** bolus. *Pearson's correlation coefficients. **Spearman's correlation coefficients.

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	Pharyngeal Area	Hyoid Elevation	UES Opening Size	Bolus Transit Time
MDADI*	-0.14	0.25	-0.07	-0.21
UW-QOL*	-0.03	0.36	-0.18	-0.05
MDADI global**	0.25	0.15	-0.21	-0.02
MDADI physical*	-0.05	0.318	-0.164	0.256

Table 2: Correlation Coefficients for **3cc** bolus. *Pearson's correlation coefficients. **Spearman's correlation coefficients.

Figure 1

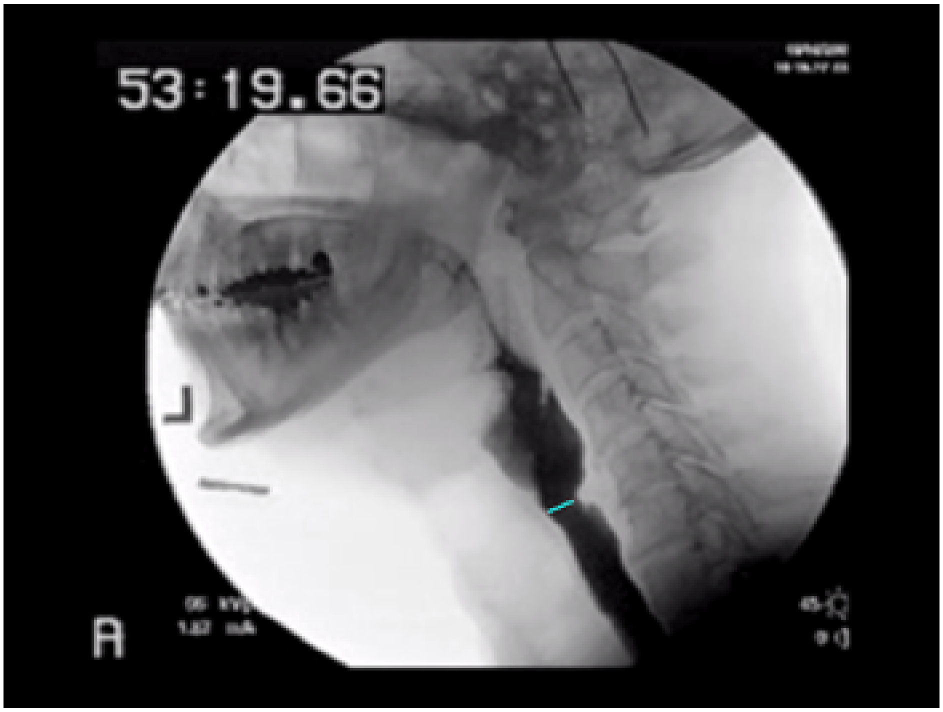

Figure 2

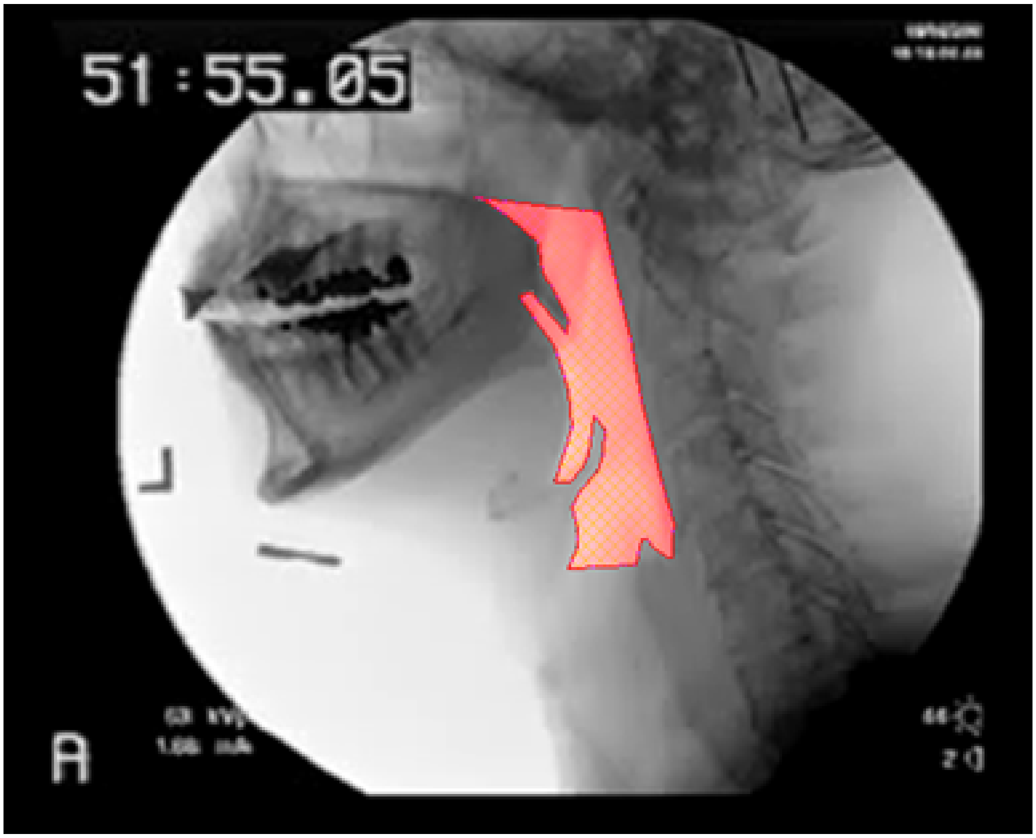

Figure 3a

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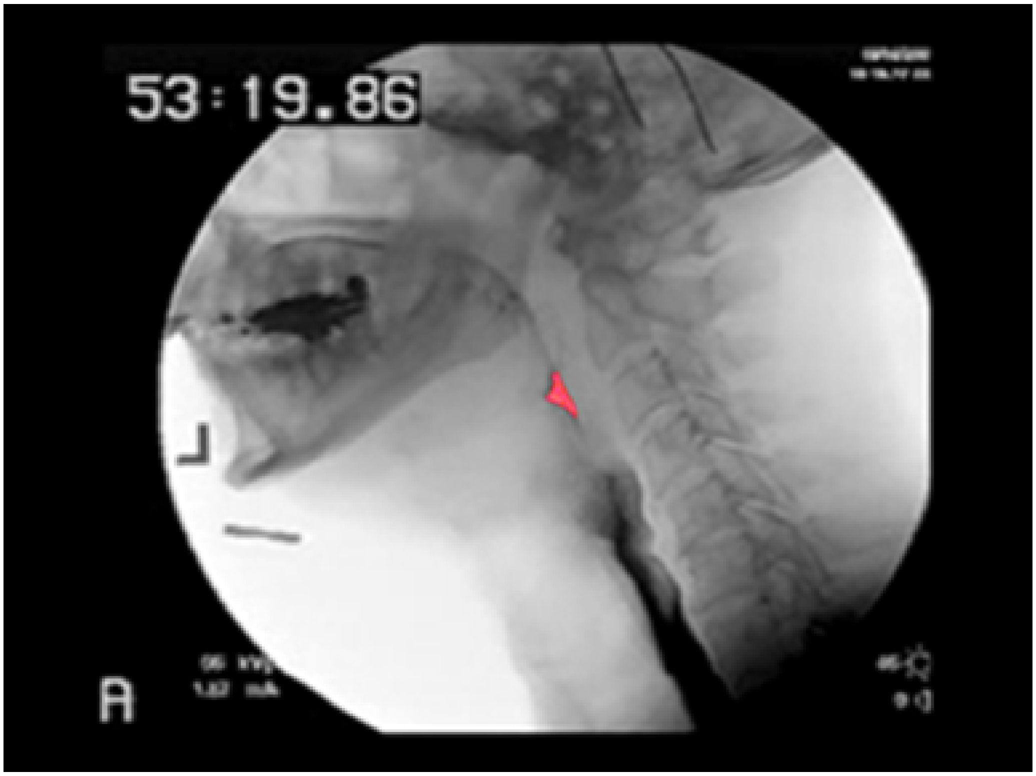

Figure 3b

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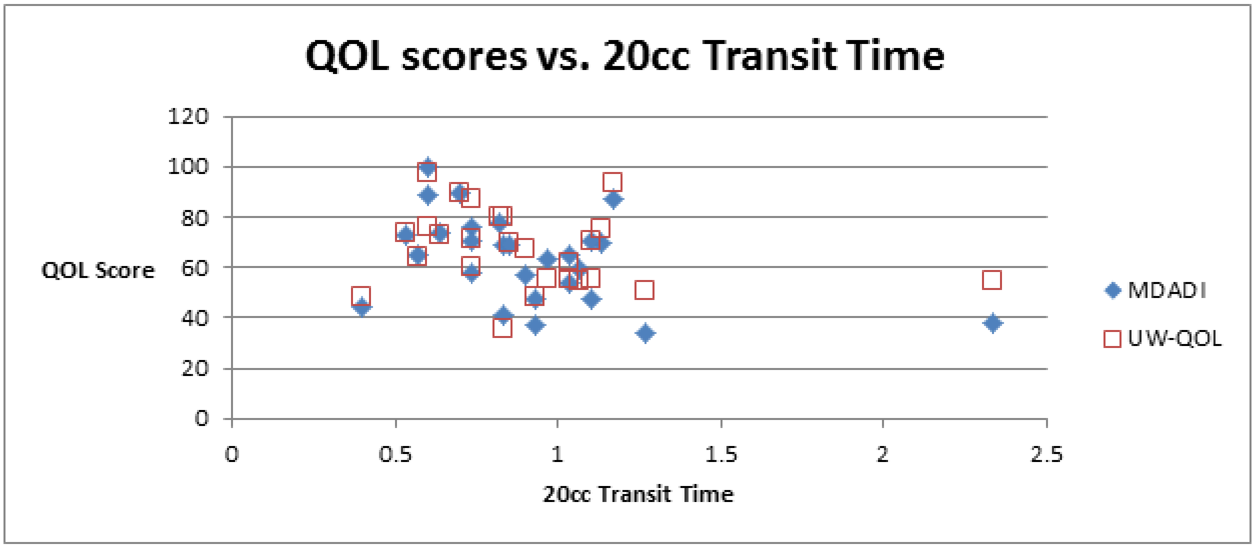

Figure 4

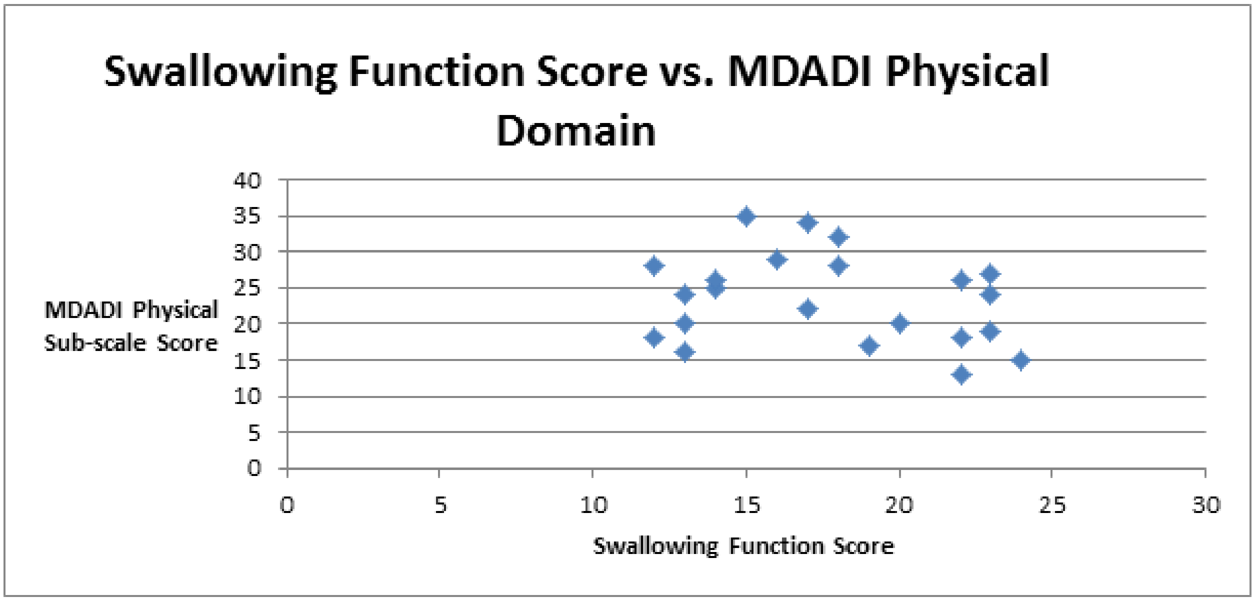
Swallowing Function Score vs. MDADI Physical Domain
MDADI Physical Sub-scale Score
40
35
30
25
20
15
10
5
0
0
5
10
15
20
25
30
Swallowing Function Score

Figure 5

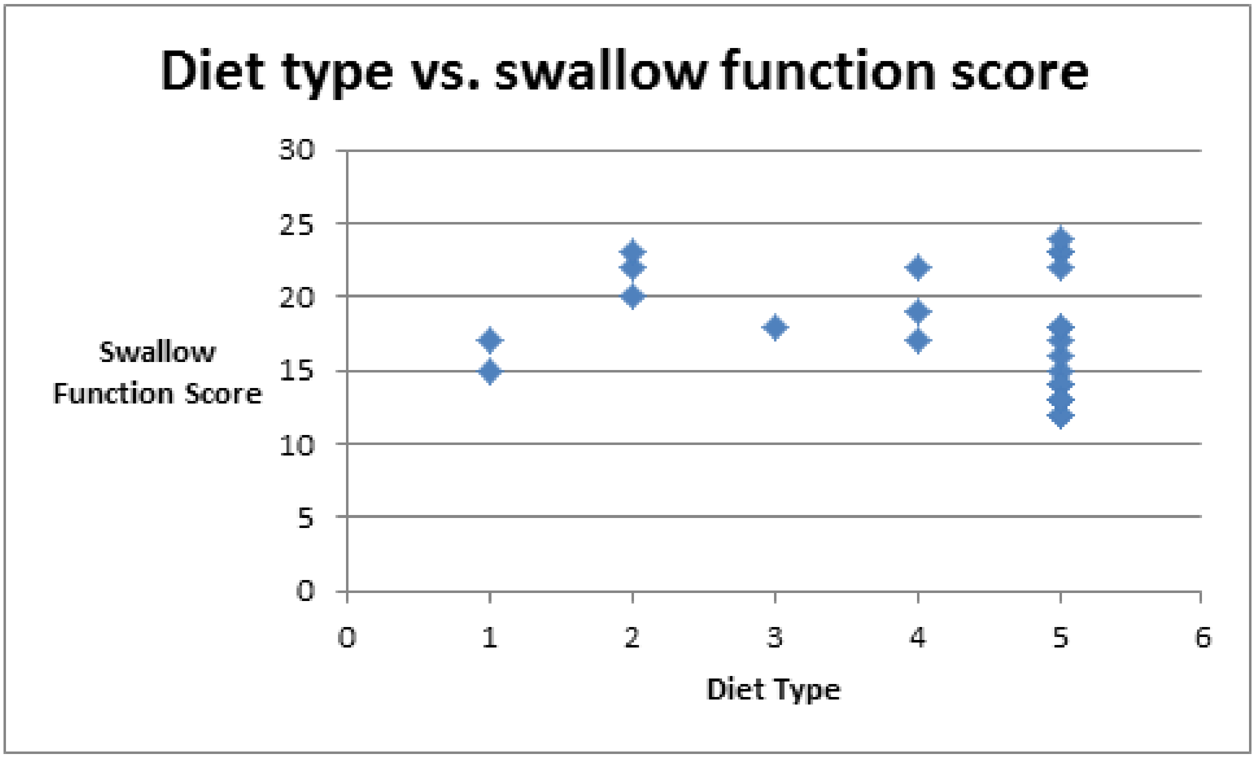

Figure 6

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	Pharyngeal Area	Hyoid Elevation	UES Opening Size	Bolus Transit Time
MDADI*	-0.135	0.39	0.18	-0.40
UW-QOL*	0.32	0.39	-0.24	-0.24
MDADI global**	0.25	0.125	-0.01	-0.24
MDADI physical*	-0.231	0.415	0.253	-0.224

Table 3: Correlation Coefficients for **20cc** bolus. *Pearson's correlation coefficients. **Spearman's correlation coefficients.

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FIGURE LEGENDS

Figure 1: The distance of hyoid elevation is made by overlying the “hold” frame of the study with the frame in which there is maximal hyoid elevation, correcting for head tilt by lining up the cervical spine, and measuring the distance.

Figure 2: The distance of maximal UES opening is measured at the narrowest part of the UES between C2 and C6 when maximally distended during the swallow.

Figure 3a: The outline of the pharynx at a “hold” position with the bolus in the oral cavity is used to calculate the area.

Figure 3b: The outline of the pharynx at maximal constriction.

Figure 4: Comparison of MDADI scores, UW-QOL and 20cc transit times.