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Residue influences QoL independently of penetration and aspiration in H&N cancer survivors

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Abstract

Introduction—Dysphagia is one of the most significant side effects of the treatment of head and neck cancer. Residue and aspiration are two indicators of a dysphagia, but aspiration is historically the only indicator of interest since it may impact health outcomes. Clinicians have anecdotally used residue as another marker of swallowing dysfunction but it is understudied. This project investigated the impact of aspiration vs. residue on function and QoL in these patients

Methods—168 head and neck cancer survivors with moderate to severe dysphagia were enrolled in a randomized clinical trial comparing two swallow therapy interventions. Data at time of entry were used for the current study. A modified barium swallow (MBS) study was done to compute Penetration-Aspiration Scale (PAS) scores, %oral residue (%OR), and %pharyngeal residue (%PR) with three bolus consistencies (5ml thin, nectar and pudding). The Performance Status Scale (PSS) and the Head Neck Cancer Inventory (HNCI) questionnaires were administered. Data were analyzed to determine associations between aspiration and residue estimates with function and quality of life scores.

Results—Worsening aspiration and residue estimates were all correlated with decreased scores on the PSS functional scales ($r=-0.190$ to -0.324 , $p=0.031$). However, only increasing residue estimates were significantly related to decreased patient perceived QoL on the HNCI ($r=-.178$ to $-.194$, $p<.046$). This effect was more pronounced with oral vs pharyngeal residue.

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Conclusions—In this group of head and neck cancer survivors, penetration/aspiration and residue show independent effects. PAS affects functional status only, but residue affects **both** functional status and QoL. This study supports that residue should be considered a primary measurement of swallowing function and be a target for identification, treatment and evaluation of swallowing.

Keywords

Quality of Life; Radiation Therapy; swallowing/dysphagia

Introduction

Despite recent improvements in the treatment options for head and neck cancer (HNC), clinicians still struggle with the balance between optimizing control of the cancer while preserving organ function and maintaining quality of life (QoL).

Swallowing function is a major concern in patients with HNC, and dysphagia as an acute toxicity and late/persistent side effect is present in an estimated 30 to 100% of cancer survivors¹. Dysphagia has been described as the most important problem affecting QoL in many studies^{2–4}.

The modified barium swallow(MBS) is a validated instrumental examination of swallowing function which provides dynamic information about bolus preparation and timing, laryngeal penetration and aspiration, oral and pharyngeal residue and sensory response during deglutition. Of these measures, aspiration has been considered the most concerning aspect of dysphagia because it is thought that aspiration will lead to pneumonia. However, patients with HNC treated with chemoradiation (CRT) often do not aspirate, or aspirate but don't develop pneumonia. Although residue may lead to aspiration and then to pneumonia^{5–7}, the relationship has been shown to be more complicated. Additional considerations such as the presence of dementia, ability to self-feed, ability to provide oral care and ambulatory status are also critical for pneumonia development. While aspiration is required for a patient to develop aspiration pneumonia, other aspects like oral hygiene and the number of co-morbidities have been shown to be more important to the development of pneumonia^{8,9}. Finally, while aspiration is often the primary focus of instrumental swallow exams, many HNC patients are not able to eat and drink normally despite the fact that they do not aspirate. In these cases, the dysphagia reflects difficulty masticating solid food and then propelling and clearing the bolus through the pharynx, leaving post-deglutitive residue. This suggests that dysphagia is influenced by factors other than just aspiration, and that these factors can have a significant impact on both function and QoL outcomes.

This study was designed to delineate the relative impact of aspiration versus residue on the functional status and swallowing-related quality of life of HNC survivors.

Methods

This current study is a secondary analysis of a larger multi-center randomized clinical trial evaluating the efficacy of electrical stimulation and behavioral swallowing therapy in HNC

survivors¹⁰ with moderate to severe dysphagia as assessed by modified barium swallow (MBS) evaluation.

Eligible subjects were HNC survivors that were currently cancer free, over 21 years old, and had completed definitive radiation at least three months prior to enrollment. Additional therapies could include chemotherapy and/or surgical resection limited to less than 50% of any part of oral, pharyngeal or laryngeal cavities without violation of the floor of mouth musculature. All subjects suffered from moderate to severe dysphagia as defined by a Penetration-Aspiration Score(PAS)¹¹ 4 on MBS. This score signifies deep penetration of swallowed material contacting the vocal folds. Key exclusion criteria included history of dysphagia unrelated to head and neck cancer, prior use of electrical stimulation therapy, neurologic disease, presence of pacemaker/defibrillator, and inability to follow the study protocol.

A baseline MBS was performed to assess PAS, percent oral residue (%OR)¹² and percent pharyngeal residue (%PR)¹² for five bolus consistencies. Two questionnaires were administered to determine functional status and QoL; the Performance Status Scale (PSS)¹³ and the Head Neck Cancer Inventory (HNCI)¹⁴ respectively.

The MBS study was performed following a strict protocol for which each participating speech language pathologist was trained prior to participating in the study protocol. The MBS consisted of 17 swallows of the following consistencies and volumes: thin liquid (5ml, 10ml, 30ml, 3oz cup) thick liquid (5ml), pudding (5ml), banana, and cracker. Each consistency and volume was repeated twice in the lateral orientation. A single bolus of 5ml thick liquid was presented in the AP orientation. If the patient aspirated on 2 consecutive boluses of thin liquid of the same volume, the clinician did not administer any of the larger volumes of thin liquid. Similarly, if the patient could not swallow the first bolus of pudding, banana, or cracker, expectorated the bolus, or >50% of the bolus remained in the pharynx/larynx, or there was severe aspiration, then the second trial of that bolus was not given.

To ensure internal consistency of the measurements, a single central laboratory blindly analyzed all MBS videos from each clinical trial site according to a standard protocol¹⁵. Each bolus was judged on PAS, %OR and %PR. The Penetration and Aspiration Scale¹¹ is an 8-point, ordinal scale that describes penetration and aspiration events in order of increasing severity. Scores are determined primarily by the depth to which material passes into the airway and by whether or not material entering the airway is expelled. A PAS score of 1 indicates neither penetration nor aspiration. A score of 2 through 5 indicates progressively deeper penetration. And a score of 6 through 8 indicates aspiration with a sequential degradation of the patient's ability to sense and expel the aspirated material. A higher PAS score indicates a worse swallow

Various estimates and ratings of oral and pharyngeal residue have been used extensively to characterize oropharyngeal swallow function¹⁶ in healthy subjects^{17,18} and persons with various medical conditions,^{19–22} including head and neck cancer.^{23–25} For this study, oral residue (%OR) and pharyngeal residue (%PR) were judged as the approximate percent of the bolus remaining in the oral and pharyngeal cavity respectively after the first swallow of a

bolus. This was estimated from 0 – 100%, at intervals of 5%. Estimates of oral and pharyngeal residues from videofluorographic (modified barium swallow) studies have been demonstrated to be significantly correlated with objective measures of residue from scintigraphic studies, supporting the validity of estimates of oral and pharyngeal residue made by trained observers.¹² The posterior boundary of the oral cavity was the circumvallate papillae, signifying the termination of the oral tongue and the beginning of the tongue base²⁶ (Figure 1). Residue anterior to the circumvallate papillae was included in the estimation of percent %OR, while residue posterior to this point was included in the estimate of %PR. Residue was estimated in the lateral view with a higher value indicating a greater percentage of residue remaining after the first swallow of a bolus (Figure 2).

At entry each patient completed demographic information and the chart was reviewed for details regarding cancer treatment and chemo radiation protocol. The clinician completed the Performance Status Scale for Head and Neck Cancer Patients (PSS)¹³. The PSS is a standard scale which measures **functional status** in three domains: normalcy of diet, ability to eat in public, and understandability of speech. As an example of the scoring for normalcy of diet, a score of 0 indicates the patient takes nothing by mouth and is tube fed, a score of 50 indicates the patient can eat soft foods such as macaroni and soft canned fruits, and a score of 100 indicates the patient has a full unrestricted diet. The PSS is completed by the clinician in cooperation with the patient and objectively documents the subject's current function in these three domains. For this scale a higher number indicates a higher functional status in the given domain. A composite PSS score, the average of the scores of each domain, was also calculated for each subject.

The subject was asked to complete the **Quality of Life** instrument: Head and Neck Cancer Inventory (HNCI). The HNCI is a patient-administered survey that yields a measure of health related QoL in four areas: speech, eating, aesthetics, and social engagement. An example of a question in the eating domain is, "Have you been bothered by a change in your eating habits?" which would be scored between 1 (extremely) to 5 (not at all). For this scale a higher number indicates a better QoL in the given domain²⁷.

Separate Pearson correlations were computed to determine associations among (1) the worst PAS score on each bolus type and (2) the worst oral and pharyngeal residue percentages on each bolus type - with measures of QoL (HNCI) and functional (PSS) scores. Partial correlations were performed to determine the associations seen between %OR and %PR with QoL (HNCI) and functional (PSS) scores after adjusting for PAS score to determine the independence of these associations. All events of pneumonia that occurred over the course of the study were noted. A p-value of 0.05 or lower was taken as significant.

This was a multi-institutional study led by Boston University Medical Center (BUMC). All patients gave written informed consent and this study was approved by each participating site's institutional review board. This current project used the findings from the MBS studies and the completed questionnaires from the entry visit only. Thus, this project used baseline data and did not evaluate for the possible effect of swallowing therapy on the variables of interest.

Results

A total of 168 HNC survivors completed entry questionnaires and a qualifying MBS. The median age of the subjects was 62 years (33–87) and there was a six fold male predominance. The age and gender distribution of this sample is consistent with published epidemiologic data.²⁸ The median interval since completion of definitive radiation was 24.5 months, with a range of 3 to 267 months. The study group sites of disease, feeding status and cancer stages are detailed in Table 1. All patients were ambulatory and independent feeders.

In the parent study protocol, five consistencies were analyzed by MBS. For safety concerns, nearly half of the trials of banana and cracker were not administered by the participating speech language pathologist. Thus, only subjects who had at least one trial of 5 mL thin liquid, 5 mL nectar-thick liquid, and 5 mL pudding boluses were analyzed, bringing the number of subjects in this analysis from 168 to 138.

The worst PAS from the 2 trials of each of these 3 consistencies was used for analysis. All subjects had data for the clinician administered PSS functional scale. The HNCI was completed by all subjects, but some domains were not entirely answered (for instance only 124 of the 138 subjects completed the HNCI score on Aesthetics).

Table 2 shows Pearson correlations for PAS, oral residue and pharyngeal residue with QoL scores (HNCI scores on speech, eating, aesthetics and social engagement) and functional scores (PSS scores on normalcy of diet, eating in public and understandability of speech and overall function as an average of the 3 individual scores). Significance was determined at a $p < 0.05$ value. Significant p -values are indicated by grey shading. Values that remain significant after adjusting for PAS through a partial correlation analysis are indicated by darker grey shading and an asterisk (*).

Worsening function as measured by a lower PSS score was significantly correlated with worsening PAS, %OR and %PR (this is an inverse correlation so a lower PSS score correlates with a higher PAS, %OR and %PR). Looking at each swallowing measure individually, increasing PAS scores for thin, nectar and pudding were inversely correlated with total PSS scores and individually with some diet and eating in public scores. This means that worsening penetration-aspiration (a higher PAS score) was correlated with worsening function (a lower PSS) especially with regard to normalcy of diet and eating in public.

Increasing %OR and %PR were also moderately correlated with worsening PSS functional scores over all consistencies. %PR showed significant and stronger correlations over more domains of the PSS functional scale than did %OR. These correlations held even when controlling for the other two effects indicating that these measures are independent of the other effects (PAS is independent of both %OR and %PR; %OR is independent of both PAS and %PR; %PR is independent of both PAS and %OR).

In contrast to the patterns observed for PSS functional scores, worsening QoL as measured by the HNCI was significantly correlated with worsening %OR and %PR but not with

worsening PAS. Looking at each swallowing measure individually, %OR, more so than %PR, was significantly correlated with worsening HNCI QoL scores, predominately for speech and eating. PAS did not show any significant correlation with worsening QoL. The one exception to this observation was that the PAS score for 5ml pudding showed a low positive correlation with the HNCI on Social Engagement. This was a positive but weak correlation at a Pearson r value of 0.195 meaning that an increasing PAS for 5ml pudding was correlated with a higher score on Social Engagement. This is a non-intuitive result and likely represents a Type 1 error.

Although increasing PAS, oral and pharyngeal residue were all correlated with worsening functional scores, only oral and pharyngeal residue were significantly correlated with the QoL scores. These associations remained significant when controlling for PAS, suggesting that correlations of oral and pharyngeal residue with the functional and QoL domains were independent of PAS scores.

Discussion

HNC survivors often complain of the distressing symptom of “food sticking,” which typically reflects post-deglutitive residue. This study found that oral and pharyngeal residue impacted functional outcomes as much as PAS scores, and impacted quality of life more than PAS scores, thus highlighting the importance of residue as a primary problem for treated HNC patients. Although aspiration was frequently observed in this cohort, pneumonia was a rare event in these post-radiated HNC patients with chronic dysphagia; in fact, only 3 patients from the entire group developed pneumonia over the 3 month therapy period. Rather, functional restrictions and disrupted quality of life more frequently impacted their lives.

A patient’s functional status reflects an individual’s ability to perform basic self-care tasks required to maintain health and well being²⁹; in this study, function referred mainly to activities related to eating. A patient’s functional status is measured in relation to what is considered normal. It is objective in that the subject or an observer can complete the rating to the same accuracy. Functional status is distinct from QoL. Individuals with the same functional status can have dramatically different ratings for QoL.

A patient’s QoL is determined by their attitude towards their functional status. The QoL can vary dramatically and is determined by their perceived “gap” between the functional status they currently have and the functional or performance status they desire. Only the subject can complete the QoL assessment³⁰. Individuals with a high functional status may report a low QoL if they are not satisfied with their functional level or their functional level is not meeting their personal expectations. Thus patients with the same functional or performance level can have a very different QoL depending on their personal outlook and expectations regarding their disease process. Health-related QoL is distinct but related to functional status.^{31–33}

In this study we used the PSS to measure functional status and the HNCI to measure patient perceived QoL. Worsening penetration/aspiration (PAS), oral residue and pharyngeal residue

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were all significantly correlated with a worsening functional status as measured by the PSS. Yet, only worsening oral and pharyngeal residue significantly correlated with a worsening QoL. To determine if these observations were independent of each other, partial correlations were performed confirming that oral and pharyngeal residue were independently correlated with QoL, regardless of their penetration/aspiration status. These results corroborate findings from a previous study documenting that patients are more bothered by issues affecting their well-being (food sticking, having to spit food out, etc.) rather than health outcomes (the potential for pneumonia).³⁴

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A noteworthy observation of this study was that oral and pharyngeal residue significantly impacted patient perceived QoL as measured by the HNCI in the Speech and Eating domains whereas PAS had no significant negative correlation with these QoL measures. This emphasizes that residue, an important component of swallowing function, had an independent effect on a patients' diet, willingness to eat in public, and ability to participate in social gatherings. In both research and clinical domains, residue should be identified as a primary problem, targeted for intervention and earmarked as an outcome measure of our diagnostic and therapeutic interventions.

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Unlike many other fields of medicine where the primary goal of treatment is to improve or restore function, the goal of curative-intent for oncologic procedures has traditionally been measured by the eradication of tumor burden and disease free survival. Recently we have focused more on the balance between elimination of disease, preserving organ function, and guarding the quality of remaining life. This study highlights that when considering eating and swallowing, function is distinct from quality of life. These are separate and important domains to consider when choosing treatment and rehabilitative modalities.

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There were several limitations in this study that deserve mention. First, there was some missingness of data that forced us to limit our analysis to the patients that had completed swallows for thin, nectar and pudding consistencies (elimination of 30 subjects from analysis). This missingness was not random and primarily occurred because the patient had aspirated on prior bolus or left substantial residue on prior boluses, causing the examiner to skip more 'difficult' bolus consistencies. Ad hoc analysis of all the data showed that the subjects with missing PAS and residue scores had lower (worse) total PSS scores compared to other subjects (Table 3). Although this suggests that the missing PAS and residue scores would have been even worse than the scores on 'easier' bolus types, there was not sufficient confidence in this observation to impute the missing values and thus the decision was made to not use those data points.

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There was also missingness for the banana and saltine consistencies for the same reason as just described, which prompted us to only use patients that were able to complete at least one swallow in the remaining three consistencies. Thus it is important to qualify that these results apply to patients that are able to participate in the testing procedure for thin, nectar and pudding consistencies and may bias against individuals with more severe swallowing dysfunction.

Second, the correlation values were overall low to moderate although still significant. Third, this study evaluated multiple measures which can predispose the results to type 1 error. Finally there was a large variation in the time since definitive treatment (earliest at 3 months and the latest at 22 years) of the enrolled subjects. We have shown in a separate analysis that at baseline evaluation, those patients with longer times post-RT had worse swallowing function³⁵. It is possible that patients in the early years post-RT react differently to their dysphagia than patients who have survived for many years post-RT.

Conclusions

We can make the following conclusions regarding this group of head and neck cancer survivors with dysphagia:

1. Penetration and aspiration rated with PAS and estimates of oral and pharyngeal residue are all measures of swallowing function but PAS and residue had an independent influence on a patient's functional status as measured by the PSS and perceived Quality of Life as measured by the HNCL.
 - a. Increasing PAS scores were significantly correlated with a worsening functional status but not with a worsening QoL.
 - b. Increasing oral and pharyngeal residue were significantly correlated with both a worsening functional status and a worsening QoL.
 - c. Pharyngeal residue had a more pronounced effect on the functional status than oral residue, and this effect was independent of PAS score.
2. Pharyngeal and oral residue demonstrated independent correlations with functional and QoL domains which may indicate that residue in different areas of the upper digestive tract reflect different deficits in the swallowing mechanism.
3. This study strongly supports the premise that residue should be considered a primary measurement of swallowing function and be a target for identification, evaluation, and treatment of swallowing outcomes.

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Figure 1.

Lateral radiographic view taken per the study MBS protocol. The black line indicates the boundary between the oral cavity and pharynx. Residue anterior to this line was included in the estimation or percent oral residue, while residue posterior to this point was included in the estimate of pharyngeal residue.

Figure 2.
MBS view showing oral and pharyngeal residue. This was rated as an oral residue of 5% and a pharyngeal residue of 25%.

Table 1

Patient Characteristics

Patient Characteristic	
Sex	
Male	144
Female	24
Age years (SD)	61.9 (9.6)
Months since completion of RT [mean(SD)]	53.7 (60.9)
TNM Stage	
I	7 (5%)
II	14 (9.9%)
III	26 (18.4%)
IV	94 (66.7%)
Site	
oral	14 (8.3%)
nasopharynx	17 (10.2%)
oropharynx	78 (46.7%)
hypopharynx	23 (13.8%)
larynx	22 (13.2%)
other	18 (10.8%)
Feeding Status	
Full Diet	15 (8.9%)
Mild Limitation	27 (16.1%)
Soft	69 (41.1%)
Pureed	9 (5.4%)
Liquid	17 (10.1%)
NPO	31 (18.5%)

Table 2

Pearson Correlations, restricted to patients who were able to complete at least one thin liquid, one nectar, and one pudding trial

		HNCI score on Speech	HNCI score on Eating	HNCI score on Aesthetics	HNCI score on Social Engagement [#]	PSS score on Normalecy of Diet	PSS score on Eating in Public	PSS score on Understandability of Speech	PSS Total (average of 3 domain scores)
PAS	5 mL thin liquid	Pearson r	-.063	-.053	.019	-.259 [^]	-.069	-.089	-.190 [^]
		p-value	.464	.542	.832	.002	.422	.298	.026
		N	135	133	133	138	138	138	138
	5mL nectar	Pearson r	-.073	-.118	-.090	-.328 [^]	-.240 [^]	-.167	-.342 [^]
		p-value	.398	.175	.302	.000	.005	.051	.000
		N	135	133	133	138	138	138	138
Oral Residue	5mL pudding	Pearson r	.117	.080	.195 [^]	-.151	-.154	-.083	-.183 [^]
		p-value	.178	.361	.024	.077	.071	.336	.031
		N	135	133	133	138	138	138	138
	5 mL thin liquid	Pearson r	-.240 [*]	-.243 ^{*/^}	-.070	-.329 ^{*/^}	-.058	-.151	-.237 ^{*/^}
		p-value	.005	.005	.427	.000	.500	.078	.005
		N	134	132	132	137	137	137	137
Pharyngeal Residue	5mL nectar	Pearson r	-.147	-.173	-.014	-.307 ^{*/^}	-.086	-.088	-.222 ^{*/^}
		p-value	.088	.047	.875	.000	.317	.305	.009
		N	135	133	133	138	138	138	138
	5mL pudding	Pearson r	-.178 [*]	-.182 ^{*/^}	-.174 [*]	-.232 ^{*/^}	-.208 ^{*/^}	.020	-.218 ^{*/^}
		p-value	.039	.036	.046	.006	.014	.820	.010
		N	135	133	133	138	138	138	138
Pharyngeal Residue	5 mL thin liquid	Pearson r	-.162	-.130	-.041	-.236 ^{*/^}	-.209 ^{*/^}	-.185 ^{*/^}	-.287 ^{*/^}
		p-value	.060	.137	.639	.005	.014	.030	.001
		N	135	133	133	138	138	138	138
	5mL nectar	Pearson r	-.182 [*]	-.143	-.011	-.314 ^{*/^}	-.210	-.184	-.324 ^{*/^}
		p-value	.035	.101	.898	.000	.013	.031	.000
		N	135	133	133	138	138	138	138

		HNCI score on Speech	HNCI score on Eating	HNCI score on Aesthetics	HNCI score on Social Engagement [#]	PSS score on Normalcy of Diet	PSS score on Eating in Public	PSS score on Understandability of Speech	PSS Total (average of 3 domain scores)
5mL pudding	Pearson r	-.039	-.194 ^{*,^}	.038	-.057	-.245 ^{*,^}	-.185 ^{*,^}	-.118	-.256 ^{*,^}
	p-value	.650	.025	.675	.513	.004	.030	.170	.002
	N	135	133	123	133	138	138	138	138

Grey shading indicated p < 0.05

* remained significant when partial correlation adjusted for effect of PAS, also indicated with darker grey shading

[^] remained significant when partial correlation adjusted for oral and/or pharyngeal residue

[#] referred to as Social Disruption in the original reference

Table 3

Missing values are associated with lowest PSS scores

PSS score on Normalcy of Diet section		PSS Total score (average of 3 domain scores)					
		Mean	SEM	Valid N	Mean	SEM	Valid N
thin liquid	Neither	65	7	13	75	6	13
	Penetration	56	4	39	68	3	39
	Aspiration	39	3	103	60	2	103
	missing	19	6	14	46	5	14
nectar	Neither	56	6	24	71	4	24
	Penetration	58	3	61	71	2	61
	Aspiration	32	3	71	54	2	71
	missing	16	7	13	43	5	13
pudding	Neither	51	3	117	67	2	117
	Penetration	38	5	14	54	3	14
	Aspiration	34	8	19	55	5	19
	missing	12	5	19	40	3	19
bannana	Neither	55	3	100	68	2	100
	Penetration	43	11	8	64	7	8
	Aspiration	33	9	11	53	7	11
	missing	23	4	50	51	3	50
saline	Neither	57	3	81	70	2	81
	Penetration	50	19	4	69	16	4
	Aspiration						
	missing	30	3	84	53	2	84

Neither indicates a PAS = 0; Penetration indicates a PAS of 2–5; Aspiration indicates a PAS of 6–8; Missing indicates no value recorded for the indicated bolus