Routine Use of Swallowing Outcome Measures Following Head and Neck Cancer in a Multidisciplinary Clinic Setting

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Abstract

Introduction Chemoradiotherapy treatment for head and neck cancer (HNC) can have a major impact on swallowing function and health-related quality of life. The use of outcome measures in early detection of patients with swallowing problems provides the opportunity for targeting speech and language therapy (SLT) interventions to aid adaption and promote better clinical outcomes.

Objective The purpose of the present study was to assess relationships between four outcomes measures over time, in a cohort of HNC patients, treated by (chemo-) radiotherapy.

Methods Data were collected at 3 months and 12 months, on 49 consecutive patients with primary squamous cell cancer of the oropharynx, nasopharynx or hypopharynx stage T1–4, N0–2b, M0 disease.

Results Out of 49 eligible patients, 45 completed assessment at 3 months and 20 at 12 months. The 3-month outcomes gave a strong indication of performance at 1 year. There were several strong correlations found between measures. The strongest was between the 3-month Performance Status Scale for Head and Neck Cancer (PSSHN) and the 12-month PSSHN ($rs = 0.761$, $n = 17$), the 12-month PSSHN and the 12-month Functional Oral Intake Scale (FOIS) ($rs = 0.823$, $n = 20$), and the 12-month University of Washington Head and Neck Quality of Life (UWQoL) swallow and the 12-month Water Swallow Test (WST) capacity ($rs = 0.759$, $n = 17$).

Conclusion The UW-QoL swallow item and WST are easy to incorporate into routine care and should be used as part of a standard assessment of swallow outcome. These measures can serve to help screen patients for dysfunction and focus allocation of resources for those who would benefit from more comprehensive assessment and intervention by SLT.

Keywords
- quality of life
- outcomes
- cancer
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- swallowing
- head and neck cancer

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Introduction

Treatment for head and neck cancer (HNC) can have a major impact on the swallowing function, and it is frequently identified by patients as a priority after treatment.[1–4] Non-surgical approaches are favored for certain subsites of HNC due to the functional morbidity associated with surgery combined with radiotherapy. However, the use of radiotherapy and chemoradiotherapy can result in very significant deficits and poor health related quality of life (HRQoL), with the potential for late treatment effects.

Early detection of patients with swallowing problems allows the opportunity for Speech and Language Therapy (SLT) interventions which can aid adaption and promote better outcomes. Patient Reported Outcome Measures (PROMS) are a standard means of identifying the perspective of the patient and can help to screen patients for dysfunctional symptoms that may delay or inhibit rehabilitation.[5] Clinical assessment of swallowing should always be performed at all stages of the treatment pathway,[6] as the subjective deficits do not necessarily match the objective findings.[7,8] In order for PROMS and objective measures to be routinely used in clinical care, they need to be straightforward and have minimum patient-clinical completion burden.

Several PROMs have been used to evaluate the perception of the ability to swallow, and the wider impact on everyday life and socioemotional function and 'quality of life'.[9–13] No one questionnaire is a gold standard, and each has its strengths and weaknesses. Assessing a patient using a battery of questionnaires can be time consuming to complete and involve duplication of concepts and swallowing-related issues. The University of Washington Head and Neck Quality of Life (UW-QoLv4)[14] is a commonly used HNC specific PROM. It can be used for screening, to assist in the identification of those who report poor swallow function who could benefit from additional intervention and support,[15] and can be included into routine practice.[16] Strong correlations have been found in previous studies with the M D Anderson Dysphagia Inventory (MDADI), the Sydney Swallow Questionnaire (SSQ) and the Swallowing Quality of Life Questionnaire (SWAL-QOL).[7,16] The Patients Concerns Inventory (PCI) is a prompt list that has been developed to identify the concerns that patients would like to discuss during their consultation.[17] It helps focus the consultation onto patient needs and can be used as part of an enhanced consultation package in combination with the UWQoL and promotes multidisciplinary care. There is a randomized control trial evaluation currently taking place, looking at the regular use of the UW-QoL and PCI in clinic consultations during the first year, when the primary outcomes are a clinically meaningful and significant difference in overall QoL, emotional dysfunction, and distress.

There are several clinician-rated scales that capture information about oral intake and complement the PROMs. These include the Performance Status Scale for Head and Neck Cancer (PSS-HN) Normalcy of Diet scale[18] and the Functional Oral Intake Scale (FOIS).[19]

Previous studies have found correlations between the PSS-HN and the MDADI,[20] the MD Anderson Symptom Inventory – Head and Neck (MDASI-HN)[12] and the FOIS,[21] suggesting strong relationships between patient reported swallow function, symptom severity and oral intake.

Taste changes and dry mouth are commonly reported symptoms following (chemo-) radiotherapy and are reported by patients as important issues following treatment.[1,2,21] They are strong drivers of oral intake and have been found to be significantly correlated with the FOIS in long-term HNC survivors.[21]

The UW-QoL taste and saliva domains are widely used in this group[1,2,22] and the UW-QoL saliva domain has also been shown to be suitable as a screening tool for dry mouth.[23]

Recent studies have found that PROMs are poorly aligned with Fiberoptic Endoscopic Evaluation of Swallowing (FEES),[7,8] suggesting PROMs may not detect clinically significant dysphagia. Objective assessments, such as FEES, are not always accessible, and cannot be easily incorporated into a routine clinical assessment. The Water Swallow Test (WST) has been shown as a means of quickly assessing swallowing performance and has been shown to be a useful indicator of outcome.[24,25] It can identify patients with oropharyngeal dysphagia postsurgery[26] and aspiration post (chemo-) radiotherapy,[25] who may require intervention and instrumental assessments. It is widely used as a clinical swallowing assessment tool in combination with objective assessment such as videofluoroscopy, trismus measures, and PROMS including the MDADI and PSS-HN.[22,27–32] It has been found to be a pretreatment predictor of function at12 months and has been shown to detect significant changes in function in patients under long-term follow up.[33,34] Studies that have looked at correlations between WST and PROMS have found some correlations with both the MDADI and PSS-HN.[8]

As summarized in the previous section, there is a large number of outcome measures available to clinicians for use with the HNC population. The consideration is to which combination of assessments to use routinely in a busy multidisciplinary team (MDT) clinical setting. They need to be simple and quick to use to present a realistic means to help focus resources, by having sufficient sensitivity to detect changes in function following treatment, and to identify those patients who might benefit from additional support and clinical intervention. Several studies have found strong correlations between different PROMS to guide their use in the clinical setting. However, to date, there have been no prospective studies looking at direct correlation over time between the FOIS, PSS-HN, UW-QoL and WST. These measures have the potential to be widely integrated into the clinical practice. The objective of the present study was to compare four post-treatment outcome measures of swallowing function, over time, in a cohort of HNC patients treated by (chemo-)radiotherapy.

Ethical Considerations

The measures used were part of the regular care in the follow-up of our HNC patients. Data for the present study

were collected as part of the routine clinical practice. The present study was granted local audit approval but did not require formal IRAS ethics approval.

Method

This was a prospective cohort study. Subjects were consecutively assessed at 3 months and 12 months as part of normal care in an outpatient hospital setting during attendance at a HNC MDT clinic. Subjects had unknown primary or primary squamous cell cancer of the oropharynx, nasopharynx or hypopharynx stage T1-4, N0- 3, M0 disease.[35] Treatment was with (chemo-)radiotherapy, including induction, with curative intent. Treatment schedules included (1) chemoradiotherapy (cisplatin 40 mg/m2 in 6 cycles) combined with 60/30 Gy (2.1 Gy per fraction) over a 6-week period, (2) chemoradiotherapy (cisplatin 40 mg/m2 in 6 cycles) combined with 65/30 Gy over a 6-week period (3) Cetuximab

Table 1 Outcome measures

UW-QoL swallow	
100	I can swallow as well as ever
70	I cannot swallow certain foods
30	I can only swallow liquid food
0	I cannot swallow because it “goes down the wrong way” and chokes me
UW-QoL saliva	
100	My saliva is of normal consistency
70	I have less saliva than normal, but it is enough
30	I have too little saliva
0	I have no saliva
UW-QoL taste	
100	I can taste food normally
70	I can taste most foods normally
30	I can taste some food
0	I cannot taste any foods
PSS-HN Normalcy of Diet	
100	Full diet (no restrictions)
90	Peanuts
80	All meat
70	Carrots, celery
60	Dry bread and crackers
50	Soft, chewable foods (e.g., macaroni, canned/soft fruits, cooked vegetables, fish, hamburger, small pieces of meat)
40	Soft foods requiring no chewing (e.g., mashed potatoes, apple sauce, pudding)
30	Pureed foods (in blender)
20	Warm liquids
10	Cold liquids
0	Non-oral feeding (tube fed)
FOIS- Functional Oral Intake Scale	
1	Nil By Mouth (NBM)
1	Tube dependent with minimal attempts of food/liquid
2	Tube dependent with consistent oral intake of food or liquid
3	Total oral diet of a single consistency
4	Total oral diet with multiple consistencies, but requiring special preparation or compensations
5	Total oral diet with multiple consistencies without special preparation, but with specific food limitations
6	Total oral diet with no restrictions

combined with 65 /30 Gy over a 6-week period or (4) radiotherapy 60/30 Gy over a 6-week period. Induction was with 3 cycles of TPF; Cisplatin, Docataxel and 5 FU. Percutaneous Endoscopic Gastrostomy (PEG) tube was used as the method of supplementary feeding. Tubes were placed prophylactically, and subjects were encouraged to maximize oral intake throughout the treatment, as per current practice in our unit.

UW-QoL v4

The UWQoL questionnaire has 12 domains. The current study used the swallow, saliva, and taste domains (►**Table 1**).

PSS-HN Normalcy of Diet

The diet texture restrictions of the patients were rated using the PSS-HN Normalcy of Diet scale (►**Table 1**).

FOIS

The degree of oral intake and supplementary feeding via tube was recorded using the FOIS. (►**Table 1**)

100 mL Water Swallow Test

The WST involved patients being instructed to swallow 100 mL of water 'as quickly as is comfortably possible'[24] The number of swallows taken was counted simultaneously by the researcher, by feeling the thyroid cartilage for laryngeal elevation. Time for swallowing was measured from when the water first touched a patient's lips to when the larynx came to rest. Three swallowing performance parameters were calculated (1) swallow volume (millilitres per swallow = mL swallowed divided by number of swallows taken) (2) swallow capacity (milliliters per second = mL swallowed divided by time taken) (3) swallow speed (time per swallow = time taken divided by number of swallows). Patients who choked during swallowing were asked to stop immediately, regardless of whether they had finished drinking the water.

Analysis

The data were analyzed using IBM SPSS Statistics for Windows, Version 23 (IBM Corp., Armonk, NY, USA) using a range of statistics appropriate to the data type. The Spearman Correlation coefficient (r_s) was used to explore the relationships between variables. Where data were missing, cases were excluded from the data analysis.

Table 2 Demographics

	***n* = 49**	
Age (years old):		
Minimum / Maximum	44	80
Range	36	
Mean / standard deviation	59.9	8.69
	No. of patients	%
Gender:		
Male	41	84
Female	8	16
Site:		
oropharynx	40	82
hypopharynx	5	10
nasopharynx	2	4
Cancer of unknown primary	2	4
T-stage:		
T1	9	18
T2	27	55
T3	4	8
T4	7	14
Tx	2	4
Nodal Stage:		
N0	6	12
N1	9	18
N2	8	16
N2a	4	8
N2b	20	41
N2c	1	2
N3	1	2
Treatment:		
Cisplatin 60 Gy /30	4	8
Cisplatin 65 Gy /30	30	61
Cetuximab 65 Gy /30	9	18
Radiotherapy only	6	12
Induction	4	8

Results

Sample

►**Table 2** summarizes the disease, treatment patient characteristics for the study sample. The cohort consisted of 49 patients, comprising 41 males and 8 females. The age range was between 44 and 80 years old and the mean age was 59.9 years old. The most common site of disease was the oropharynx and T stage was predominantly T1/T2. The majority of patients were treated with chemoradiotherapy.

Data were collected on a total of 45 patients at 3 months post-treatment, although this had decreased to a total of 20 patients at 12 months post-treatment. Details of data completion are shown in ►**Table 3**.

At 3 months, 75% of the patients reported impairment in swallowing, scoring < 100 on the UW-QoL swallow item, which reduced to 25% at 12 months. This was reflected in changes in the use of the PEG tube with 21 patients using the tube at 3 months ($n = 45$); this number dropped to 1 at 12 months ($n = 20$).

Correlations analysis found several relationships between measures. Cohen[36] suggested guidelines for grouping the strength of relationship between outcomes, which can be used to interpret the coefficients.

Table 3 Data completion

	Completed	Completed	Drop-out	Drop-out
	n	%	*n*	%
At 3 months:				
3-month UW swallow	45	91.8%	4	8.2%
3-month UWtaste	45	91.8%	4	8.2%
3-month PSSHN (normalcy of diet)	45	91.8%	4	8.2%
3-month FOIS	45	91.8%	4	8.2%
3-month WST	33	67.3%	16	32.7%
At 12 Months:				
12-month UWQoL swallow	20	40.8%	29	59.2%
12-month UWQoL taste	20	40.8%	29	59.2%
12-month PSS-HN (normalcy of diet)	20	40.8%	29	59.2%
12-month FOIS	20	40.8%	29	59.2%
12-month WST	17	34.7%	32	65.3%

Abbreviations: FOIS, Functional Oral Intake Scale; PSS-HN, Performance Status Scale for Head and Neck Cancer; UWQoL, University of Washington Head and Neck Quality of Life; WST, Water Swallow Test.

PSS-HN and FOIS (►Table 4)

This analysis showed that the 3-month PSS-HN was significantly correlated with both the 12-month PSS-HN ($r_s = 0.761$, $n = 17$) and the 12-month FOIS ($r_s = 0.657$, $n = 17$). The 3-month FOIS was significantly correlated with the 3-month PSS-HN ($r_s = 0.579$, $n = 45$, ►**Fig. 1**). Finally, the 12-month PSS-HN was significantly correlated with the 12-month FOIS ($r_s = 0.823$, $n = 20$, ►**Fig. 2**).

UW-QoL Taste and UW-QoL Saliva Domain with PSS-HN and FOIS (►Table 4)

This analysis showed that the 12-month UW-QoL taste score was significantly correlated with both the 3-month PSS-HN ($r_s = 0.651$, $n = 17$) and the 3-month FOIS ($r_s = 0.519$, $n = 17$). The 12-month UW-QoL taste was also significantly correlated with the 12-month PSS-HN ($r_s = 0.588$, $n = 20$) and with the 12-month FOIS ($r_s = 0.496$, $n = 20$).

The UW-QoL saliva scores were not significantly correlated with 3-month or 12-month PSS-HN and FOIS. However, the 3-month saliva score was significantly correlated with the 12-month saliva score ($r_s = 0.633$, $n = 17$). Eight patients reported a slight improvement in saliva scores at 12 months, with the remainder reporting no change.

WST and UW-QoL Swallowing Domain (►Table 4)

Correlations analyses were used to identify any relationships between the WST clinical swallowing measures and the UW-QoL swallowing domain, at 3 months and 12 months post-treatment. The strongest relationship was found at 12 months post-treatment between the three WST measures and UW-QoL swallowing, as follows: 12-month UW-QoL swallow with 12-month WST Capacity ($r_s = 0.759$, $n = 17$), 12-month UW-QoL swallow with 12-month WST Volume ($r_s = 0.591$, $n = 17$) and 12-month UW-QoL swallow with 12-month WST Speed ($r_s = 0.588$, $n = 17$). The correlations analysis suggested a relationship between the WST and UW-QoL reported swallowing outcomes at 12 months post-treatment, so this was explored further using Multivariate General Linear Model analysis using UW-QoL swallow as the predictor variable and the 3 clinical WST swallowing measures as dependent variables. The 3-month model was, as expected, nonsignificant. The 12-month data produced a better model.

However, a Stepwise model retained only one variable, and that was WST Capacity ($R^2 = 0.40$; $F = 10.203$; $p < 0.01$). The authors here add a caveat that the sample size is obviously too small for any robust predictive analysis, so these results should be treated with caution.

Discussion

We found several strong relationships between our PSS-HN, FOIS, UW-QoL and WST data in the 12 months following treatment. To the best of our knowledge, this is the only study that has compared the four measures, in a prospective, longitudinal study, across more than one time point.

Our results show, for the first time, that the PSS-HN and FOIS have significant correlations across two time points. We showed that in 3-month PSS-HN scores relating to 12-month PSS-HN scores, there was also a relationship between the two measures. This is similar to other studies which have reported 3-month PSS-HN scores which remained low at 12 months,[20,33] and to other PROMS studies which have shown pre-treatment PSS-HN can predict function at 12 months, and have also shown very little change in MDADI and UW-QoL between 3 and 12 months.[2,33] Improvements in PSS-HN scores between 3 and 12 months have been reported in the literature; however, this was in a specific group of patients given parotid sparing intensity modulated radiotherapy (IMRT), which differs from the cohort in the present study.[22] Clinicians need to select which measure to use, based on which information they want. The PSS-HN provides

Table 4 Correlations

			3m PSSHN	3m FOIS	3m UWQoL Saliva	3m UWQoL taste	12m PSSHN	12m FOIS	12m UWQoL saliva	12m UWQoL taste
Spearman rho	3-month PSS-HN	Correlation Coefficient	1.000	.579**	.090	.285	.761**	.657**	.194	.651**
		n	45	45	44	45	17	17	17	17
	3-month FOIS	Correlation Coefficient	.579**	1.000	.146	.310*	.416	.464	.331	.519*
		n	45	45	44	45	17	17	17	17
	3-month UWQoL Saliva	Correlation Coefficient	.090	.146	1.000	.226	.159	.026	.633**	.340
		n	44	44	44	44	17	17	17	17
	3-month UWQoL taste	Correlation Coefficient	.285	.310*	.226	1.000	.123	.013	-.191	.401
		n	45	45	44	45	17	17	17	17
	12-month PSS-HN	Correlation	.761**	.416	.159	.123	1.000	.823**	.375	.588**
		n	17	17	17	17	20	20	20	20
	12-month FOIS	Correlation	.657**	.464	.026	.013	.823**	1.000	.325	.496*
		n	17	17	17	17	20	20	20	20
	12-month UWQoL saliva	Correlation	.194	.331	.633**	-.191	.375	.325	1.000	.423
		n	17	17	17	17	20	20	20	20
	12-month UWQoL taste	Correlation	.651**	.519*	.340	.401	.588**	.496*	.423	1.000
		n	17	17	17	17	20	20	20	20

Abbreviations: FOIS, Functional Oral Intake Scale; PSS-HN, Performance Status Scale for Head and Neck Cancer; UWQoL, University of Washington Head and Neck Quality of Life.
**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

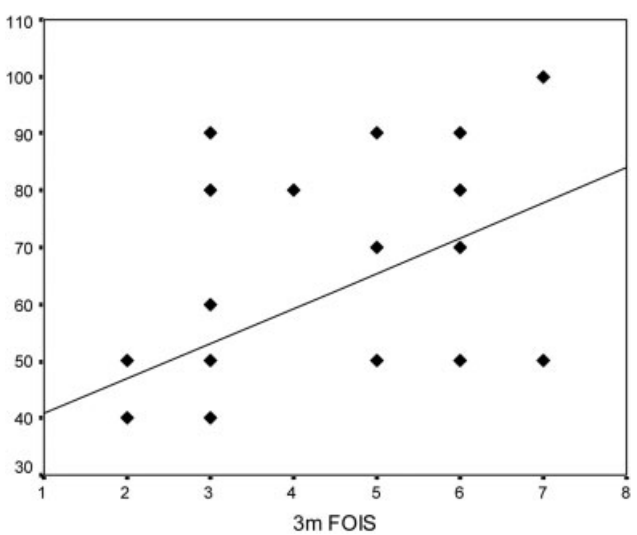

Fig. 1 Correlation between 3 month Functional Oral Intake Scale and 3 month Performance Status Scale for Head and Neck Cancer.

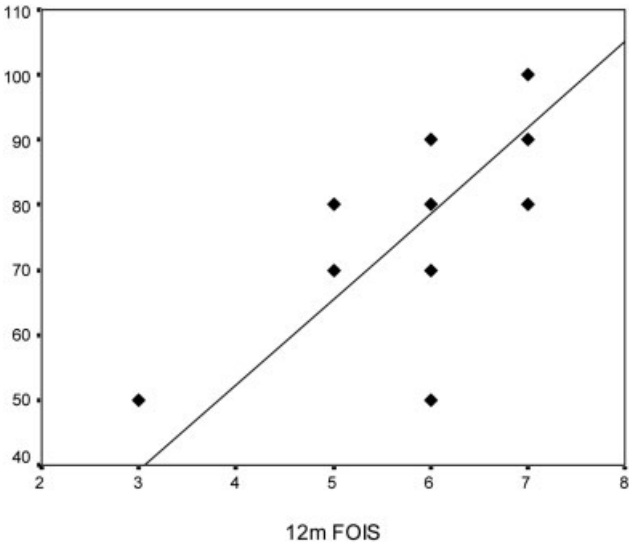

Fig. 2 Correlation between 12 month Functional Oral Intake Scale and 12 month Performance Status Scale for Head and Neck Cancer.

information about diet texture, whereas the FOIS records the degree of oral intake and supplementary feeding via tube. We suggest that the use of either provides valuable information and can give an idea of expected changes in function over time.

Taste is a common side effect reported by patients following treatment and can affect their diet choices.[1,21] Our results showed that 12-month UW-QoL taste was significantly correlated with both the 3-month PSS-HN and the 3-month FOIS. The 12-month UW-QoL taste was also significantly correlated with the 12-month PSS-HN and the 12-month FOIS. These results are similar to long-term studies that have found correlations with the MDASI-HN and FOIS,[21] and suggests that perceived impairment of taste is an important measure. We recommend the use of the UW-QoL taste domain as a valuable tool to guide intervention. It can enhance the discussion between the clinician and patient about expected change, and tailor rehabilitation to optimize oral intake post-treatment.

In addition, our data suggest, for the first time, a relationship between WST and the UW-QoL swallow domain. The WST was found to have some predictive power in terms of PROMs, with WST capacity being the best potential predictor of UW-QoL swallow score. This is similar to other studies that showed that WST capacity is sensitive to change[24] and found that it had a moderate relationship with the MDADI.[8] Our results were insufficient to propose the UW-QoL swallow as a stand-alone screening tool in this setting. However, this suggests that assessment of the perception of the patients of their swallow function may have the potential to help to highlight patients who may require intervention.

Dry mouth is frequently reported as an issue post-treatment.[1,2] A relationship was found between 3-month and 12-month UW-QoL saliva scores, with some variability across the cohort. This may be explained by the size and heterogeneous nature of the sample in relation to site and treatment schedule, and further studies with a larger cohort would be valuable.

Limitations of the Study

The data have many limitations. Data collection was performed prospectively, thus limiting recall bias; however, the relatively small sample restricted the scope for the statistical analyses. A multivariate analysis was attempted using UW-QoL swallowing as the dependent variable, but the sample size was an issue for the robustness of this test. As part of the current study, data were collected without additional funding, as part of routine clinical follow-up appointments. This was dependent on availability of staff, and patient attendance. These factors, in addition to disease-specific and all-cause mortality, account for the missing data.

The target for data collection was 40 patients with no a priori statistic power calculation. This resulted in a small sample size, restricted range of responses, and/or poor distribution of responses to some questions. As a consequence, the results should be interpreted with caution.

The current study used the WST as a clinical assessment tool, as it was quick and easy to use in a routine clinical setting. Further research incorporating the instrumental assessment of swallowing would be valuable.

The sample in the present study was heterogeneous in terms of tumor size, location and treatment schedule. While the sample was very relevant in terms of the context of this study, it would be valuable to collect more data to support PROMs that can be applied to specific patient groups.

Conclusion

Several measures were found to have clinical significance, and 3-month outcomes gave an indication of performance at 1 year. This supports the use of relatively simple assessments as a realistic way to collect outcome data in a clinic setting. The UW-QoL swallow item and the WST are easy to incorporate into routine care for all HNC patients and should be used as standard post-treatment outcome measures of the swallowing function, as part of the routine clinical assessment. Clinicians can select additional questionnaires, which assess taste and diet, to enhance the clinical interaction and tailor rehabilitation. Patients assessed as having poor swallow performance on the WST can be referred for further instrumental assessments such as FEES and video fluoroscopy to help inform and guide the appropriate intervention. Both the UW-QoL swallow question and the WST can be performed in the out-patient consultation setting, and the ease of assessment means that they can be performed by different members of the head and neck team, and not limited to SLT. These measures can serve to help screen patients for dysfunction and focus allocation of resources for those who would benefit from more comprehensive assessment and intervention by SLT. Further research is needed to help underpin the robustness of basing routine screening on the UW-QoL swallow question and the WST and to establish their role in repeated longitudinal assessment to monitor the impact of intervention strategies.

Note
Preliminary data presented as poster at BAHNO 2017.

Conflict of Interests
The authors have no conflict of interests to declare.

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