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How much of a problem is too much saliva for patients following head and neck cancer

Mr Damian Broderick, P.G.Dip Med Ed, P.G.Dip Conc Sed, FFD (OSOM), FRCS. Liverpool Head and Neck Centre, Aintree University Hospital, Lower Lane, Liverpool, UK. broderd@tcd.ie

Derek Lowe MSc C.Stat. Medical Statistician, Astraglobe Ltd, UK. astraglobeltd@btconnect.com

Professor Anastasios Kanatas, MFDSRCS, FRCS (OMFS), MD, PGC,FHEA. Consultant Surgeon / Honorary Professor, Leeds Teaching Hospitals and St James Institute of Oncology and Leeds Dental Institute.

Professor Simon N Rogers FDS, RCS, FRCS, MD. Evidence-Based Practice Research Centre (EPRC), Faculty of Health and Social Care, Edge Hill University, St Helens Road, Ormskirk, and Consultant Regional Maxillofacial Unit, Aintree University Hospital, Lower Lane, Liverpool, UK. simonn.rogers@aintree.nhs.uk

Address for correspondence: Mr Damian Broderick, Liverpool Head and Neck Centre, Aintree University Hospital, Lower Lane, Liverpool, UK. broderd@tcd.ie

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Abstract

The aim of this paper is to report the clinical characteristic of those patients reporting 'I have too much saliva' following treatment for head and neck cancer. As a new addition to the saliva question of the UW-QOL, another aim is to make recommendations on how this new option should be scored and handled.

Patients treated with curative intent were recruited between April 2017 and October 2019. Assessment was at the first baseline clinic a median (IQR) of 194 (125-249) days after diagnosis and 103 (71-162) days after the end of treatment. Patients completed the modified UW-QOLv4, Patient Concerns Inventory (PCI), Distress thermometer, EQ-5D-5L.

In 288 patients, saliva was of normal consistency for 28% (80), less than normal but enough for 20% (57), too little for 32% (91), too much for 16% (45), and there was no saliva at all for 5% (15). Of patients with too much saliva, two-thirds (69%, 31/45) had tumours located in the oral cavity and 45% (18/40) had the highest rates of free-flap use during surgery. Salivation response was associated strongly with the other measures of HRQOL and the PCI. Of those with too much saliva their results were similar to or worse than those with too little saliva or with no saliva at all.

In conclusion, having too much saliva is relatively less frequently reported but is an important HRQOL consideration. Its scoring in the UW-QOL should be at a level similar to too little saliva.

Introduction

There are a wide range of issues that affect head and neck cancer patients (HNC) (S N Rogers *et al.*, 2016) and it is accepted that in routine practice, no one questionnaire has the ability to cover all aspects (Vartanian, Rogers and Kowalski, 2017). The problems patients experience with saliva can have profound detrimental consequences on health-related quality of life (HRQOL) (Høxbroe Michaelsen *et al.*, 2017). The focus in the various patient reported outcome questionnaires has been reduced saliva and this has led to the development of xerostomia specific questionnaires. The issue of too much saliva as an outcome has been relatively over looked.

Too much saliva is a recognised problem for patients following for treatment for HNC (Bomeli *et al.*, 2008). This can have a negative impact on the patient's quality of life and often results in patients seeking treatment to resolve this issue. Treatment approaches exist, and therefore it is important to recognise it and offer clear management strategies. More frequently reported following major radical surgery and reconstruction are oral competency, poor lip function, poor tongue and swallowing function. This is seen with our without preceding RT. Even in the presence of normal saliva volume and consistency, RT can cause fibrosis and poor function which can lead to poor control of saliva impacting further on patients overall QOL. There exists only a few questionnaires that specifically ask about the issue of too much saliva for example Groningen radiotherapy-induced xerostomia (GRIX) questionnaire (Beetz *et al.*, 2010), Drooling Severity and Frequency Scale (Li *et al.*, 2015), Liverpool Oral Rehabilitation Questionnaire (LORQ)(Pace-Balzan, 2008).

The three commonest questionnaires used to report HRQOL following HCN are the EORTC, FACT and University of Washington head and neck Cancer quality of life questionnaire (UW-QOL). (Kanatas and Rogers, 2008). These focus on reduced saliva. The UW-QOL was first published in 1993 (Hassan et al 1993) and in 2002 version 4 was published (Rogers *et al.*, 2002). The UW-QOL saliva domain has four hierarchical response options ranging from a total lack of saliva to having saliva of normal consistency. One of the limitations when using the saliva domain is that some patients reported difficulty in answering it because they had too much saliva and this can result in slightly greater missing data rates with this domain compared to other domains and sometimes a free-text reference to having too much (Millsopp *et al.*, 2003).

The aim of this paper is to report the inclusion of ‘I have too much saliva’ into the saliva domain of the UW-QOL, to investigate how much of a problem having too much saliva is to patients, and to make recommendations on how this new option should be scored and handled.

Method

The UW-QOLv 4 questionnaire consists of 12 single question domains, these having between 3 and 5 response options that are scaled evenly from 0 (worst) to 100 (best) according to the hierarchy of response (Rogers *et al.*, 2002). The UW-QOL V4 saliva domain has four possible responses scored as (100) 'My saliva is of normal consistency', (70) 'I have less saliva than normal, but it is enough', (30) 'I have too little saliva' and (0) ' I have no saliva. In regard to overall QOL, patients are asked to consider not only physical & mental health, but also many other factors, such as family, friends, spirituality or personal leisure activities that were important to their enjoyment of life. The whole questionnaire focuses on the past 7 days, and there is also a question asking which domains (to a maximum of three) have been most important. Subsequent analysis has led to the development of subscale composite scores (Rogers *et al.*, 2010) and domain algorithms to screen for significant problems/dysfunction (Rogers and Lowe, 2009). Previously, a significant problem or dysfunction with salivation was indicated either by someone having no saliva at all or by someone having too little saliva and stating that salivation had been important to them in the past week. Question domains for intimacy and fears of recurrence have also been developed using a similar system of possible hierarchical responses as the UWQOLv4 (Low *et al.*, 2009),(Simon N. Rogers *et al.*, 2016)

The baseline data we report come from a pragmatic cluster-controlled trial, with consultants (clusters) randomised to ‘using’ or ‘not using’ an intervention incorporating the PCI prompt list at all their trial clinics. The PCI consists of 56 clinical items (Rogers and Lowe, 2009) which patients select from before their appointment, to help guide the outpatient consultation through the symptoms and problems that they may experience following their treatment for HNC. The methods of the PCI trial have been described previously (Rogers *et al.*, 2018). Eligible patients were treated curatively for primary or secondary HNC, and all sites, stage of disease and treatments were included. Palliation and recurrence were exclusion criteria as were cognitive impairment, psychoses or dementia.

Unit researchers collected baseline clinical/demographic data either via a baseline clinic questionnaire with demographic questions chosen as far as possible to match those included in the head and neck 5000 project (Ness, 2015) or by extraction from baseline clinical records. Baseline data included cancer site, disease severity, treatment details, gender, age and comorbidity. Trial HRQOL outcome baseline data included the UW-QOLv4 (Rogers *et al.*, 2002), Distress thermometer (Hegel MT, Collins ED, Kearing S, Gillock KL, Moore CP, 2008) and the EQ-5D-5L (EuroQol 2015), and the categorisations used in this paper for these measures are consistent with decisions pertaining to the trial.

Fishers exact test (categorical data) or the Kruskal-Wallis test (numerical data) was used to compare patients with different responses to the saliva domain question in regard to case-mix and HRQOL outcome baseline data. There was a particular focus on describing the characteristics and responses of those with too much saliva. Interpretation was required to suggest an appropriate scoring for this option on the 0-100 saliva scale, given that patient saliva scores are important in the calculation of the physical function composite scale. The algorithm to indicate significant problems or dysfunction with salivation was also reviewed.

The PCI trial has ethical approval from North West - Liverpool Central Research Ethics Committee REC reference: IRAS **16/NW/0465**, Project ID: **189554**. It also has approval from the Health Research Authority (HRA). The Research and Development Department at Aintree University Hospital NHS Trust (AUH) is coordinating the trial and AUH is the sponsor for the trial. This trial is funded by the RfPB on behalf of the NIHR (PB-PG-0215-36047).

Results

Trial patients with baseline data were first discussed at MDT meetings between January 2017 and December 2018, with baseline trial clinics between April 2017 and October 2019. A total of 288 patients attended trial baseline clinics a median (IQR) of 194 (125-249) days after diagnosis and 103 (71-162) days after the end of treatment.

Saliva was of normal consistency for 28% (80) of patients, less than normal but enough for 20% (57), too little for 32% (91), too much for 16% (45), and there was no saliva at all for 5% (15). Salivation response was most notably associated with tumour location, tumour stage and treatment (Table 1). Two-thirds (69%, 31/45) of patients with too much saliva had tumours located in the oral cavity, compared to 51% (41/80) of those with saliva of normal consistency and 38%, (62/163) of those deficient in saliva to a lesser or greater degree. One-quarter (26%, 21/80) of those with normal consistency had advanced stage 3-4 disease, in contrast to most other patients, range 60-75% among the four other groups (60% for those with too much saliva). Three-quarters (76%, 61/80) of those with normal consistency were treated only by surgery, compared to 47% (21/45) with too much saliva and 21% (34/163) of those deficient in saliva to a lesser or greater degree. Those with too much saliva had higher observed rates of free-flap use during surgery, and higher levels of comorbidity, than patients in the other four groups.

Salivation response was associated strongly with most other measures of HRQOL (Table 2). Patients with saliva of normal consistency and those with 'less saliva than normal but enough' consistently reported better HRQOL than other patients. In terms of the key outcome measures of the trial, 51% (23/45) of those with too much saliva reported overall QOL that was less than good, 60% (27/45) had distress thermometer values of 4 or above, and the median (IQR) UWQOL social-emotional composite score was 62 (37-73). These results were similar to or worse than those with too little saliva or with no saliva at all and this was a consistent observation across all the HRQOL measures. If for pragmatic reasons having too little or too much saliva were scored the same (i.e. as 30), then the median (IQR) full physical function composite score was 69 (54-86). If having too much saliva was treated in the same way as having too little saliva in triggering an algorithm to identify a significant problem/dysfunction, i.e. that the issue was important to the patient, then 34% (99) were affected. This compares to 27% (77) if the trigger only applied to those with too little saliva.

For the 140 patients in the trial group that completed an electronic PCI prompt sheet immediately prior to their outpatient consultation, the main items they selected for discussion are shown in Table 3, and these are stratified by how patients responded about salivation. Patients with too much saliva most commonly selected 'chewing/eating' (55%), 'fatigue/tiredness' (45%), 'salivation' (41%), 'fears of cancer coming back' (36%), 'swallowing' (36%), 'pain in head and neck' (32%), 'shoulder' (32%), 'sore mouth' (32%)

and ‘speech/voice /being understood’ (32%). Most of those lacking saliva to a lesser or greater degree selected ‘dry mouth’ (76%, 59/77), and other common items they selected included ‘salivation’, ‘swallowing’, ‘chewing/eating’, ‘taste’, ‘dental health/teeth’, ‘sore mouth’, ‘energy’, ‘fatigue/tiredness’, ‘pain the in head and neck’, and ‘fears of the cancer coming back’. Patients with normal consistency selected fewer items with ‘fears of the cancer coming back’ (29%), and ‘dental health/teeth’ (24%) the most prevalent.

Discussion

The study represents a large sample of HNC patients participating in a multicentre trial. The addition of more focused questioning on the concept of “I have too much saliva” has allowed for greater precision in collecting data regarding the impact of saliva on QOL. However, it is important to note that no objective data on saliva flow is available to support these perceptions. Longer, longitudinal data may give more data as to how patients see this impacting on their lives.

Sixteen percent of the participants reported too much saliva as a problem. Tumour location had a significant association with this, 69% of such patients having tumours in the oral cavity. Further subsite analysis is not available, as it maybe that it is the control of saliva in the oral cavity that of an issue than actual increased flow of saliva. This is also reinforced by a clear association with free flap reconstruction, again which may alter the oral anatomy. Increased saliva flow is also associated with increased co morbidities, the implication of which is not as clear.

Historically, the UWQOL has had an evenly spaced scoring system for its domains: 0 25 50 75 100 for five response options, 0 30 70 100 for four options, or 0 50 100 for three, these being based on hierarchy in severity of response. This has merit in being simple and pragmatic. The new 'too much saliva' response option must find a place in the hierarchy of response based on severity and impact on the patient, and needs to be allocated a score. We tend now not to report domain scores per se and rely more on whether the UWQOL responses indicate significant problems or dysfunction in regard to each domain. However, the saliva domain score is important for computing the UWQOL physical function composite score, which is the mean of the six component domain scores that make up the subscale.

Our study results suggest that having 'less saliva than normal but enough' seems to impact less on patients than 'having too much', while across the various HRQOL measures recorded those with too much saliva had similar results to those with too little saliva or with no saliva at all. If these are reasonable measures to make such judgements then this suggests a suitable score for the 'too much saliva' option at the lower end of the 0-100 scale, and it is difficult from these data to be more precise. For pragmatic reasons of making the scale as simple as possible moving forwards we recommend giving equal weight to having too little and having too much, i.e. a score of 30. However, the two should remain as separate options as viewed on the UWQOL questionnaire and should not to be merged into a single response option - their wording should be – 'I have too little saliva' and 'I have too much saliva'.

A significant problem or dysfunction with salivation has previously been indicated either by someone having no saliva at all or by someone having too little saliva and stating that salivation had been one of at most three issues important to them in the past week. In keeping with the above scoring we now recommend that having too much saliva and this being important should also be added as an indicator of dysfunction. In this patient population, this raised the rate of dysfunction by 7% from 27% to 34%. Further research in collecting more detailed concurrent salivation data on salivation issues alongside the UWQOL would help assess the validity of this recommendation. The EORTC HN43 has overlooked this are in its most recent questionnaire.

Strategies exist for the management of too much saliva in the HNC patient. It is important to identify this subset. It is an area that requires further research to develop a robust treatment algorithm.

Conclusion

Having too much saliva for post treatment HNC patients can have a detrimental impact on thei HRQOL with further research needed as to how best to manage this. Historically under

reported and not always considered by clinicians it is clear that its scoring in the UW-QOL should be at a level similar to havingtoo little saliva.

Conflict of interest statement

We have no conflicts of interest.

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Table 1. UWQOL salivation and case-mix

		I have no saliva	I have too little saliva	I have less saliva than normal, but it is enough	My saliva is of normal consistency	I have too much saliva	P value*
	All patients	15	91	57	80	45	
Gender	Female	33% (5)	26% (24)	35% (20)	29% (23)	40% (18)	0.50
Age (diagnosis)	Median (IQR)	63 (50-68)	61 (54-66)	59 (55-67)	64 (56-73)	63 (58-73)	0.06 KW
Tumour site	Oral cavity	27% (4)	35% (32)	46% (26)	51% (41)	69% (31)	<0.001
	Oropharynx	60% (9)	43% (39)	44% (25)	10% (8)	22% (10)	
	Larynx	-	14% (13)	5% (3)	29% (23)	4% (2)	
	Other	13% (2)	8% (7)	5% (3)	10% (8)	4% (2)	
Overall stage	Advanced 3-4	67% (10)	75% (68)	67% (38)	26% (21)	60% (27)	<0.001
Treatment	Surgery only	13% (2)	19% (17)	26% (15)	76% (61)	47% (21)	<0.001
	RT or RT/CT only	40% (6)	32% (29)	19% (11)	9% (7)	11% (5)	
	Surgery & RT or RT/CT	47% (7)	49% (45)	54% (31)	15% (12)	42% (19)	
Free-flap	Yes	44% (4/9)	27% (17/62)	30% (14/46)	19% (14/73)	45% (18/40)	0.05
Comorbidity	WHO 1-4	27% (4)	41% (37)	30% (17)	35% (28)	51% (23)	0.19
	ACE27 Mod/Severe	7% (1)	19% (17)	18% (10)	16% (13)	33% (15)	0.13
Consultation time	Median (IQR)	10 (7-12)	11 (8-16), n=90	10 (7-14)	9 (7-12), n=78	11 (9-15), n=44	0.009 KW

*Fishers exact test apart from KW (Kruskal-Wallis test)

Table 2. UWQOL salivation and case mix

		I have no saliva	I have too little saliva	I have less saliva than normal, but it is enough	My saliva is of normal consistency	I have too much saliva	P value *
	All patients	15	91	57	80	45	
Physical function	Appearance	13% (2)	14% (13)	7% (4)	3% (2)	16% (7)	0.03
subscale	Swallowing	27% (4)	20% (18)	7% (4)	4% (3)	29% (13)	<0.001
dysfunction	Chewing	40% (6)	15% (14)	4% (2)	3% (2)	31% (14)	<0.001
	Speech	13% (2)	11% (10)	2% (1)	1% (1)	20% (9)	<0.001
	Taste	53% (8)	26% (24)	16% (9)	6% (5)	24% (11)	<0.001
Composite score**	Median (IQR)	53 (35-73)	65 (54-77)	73 (65-85)	90 (83-95)	62 (37-73)	<0.001KW
Social-emotional	Pain	47% (7)	29% (26)	28% (16)	13% (10)	53% (24)	<0.001
subscale	Activity	20% (3)	11% (10)	12% (7)	8% (6)	18% (8)	0.34
dysfunction	Recreation	13% (2)	10% (9)	2% (1)	5% (4)	16% (7)	0.05
	Shoulder	7% (1)	10% (9)	14% (8)	6% (5)	29% (13)	0.009
	Mood	27% (4)	25% (23)	4% (2)	4% (3)	29% (13)	<0.001
	Anxiety	27% (4)	29% (26)	7% (4)	4% (3)	27% (12)	<0.001
Composite score	Median (IQR)	61 (46-70)	70 (54-83)	76 (66-91)	88 (78-96)	58 (48-75)	<0.001KW
Intimacy	Dysfunction	33% (5)	9% (8)	0% (0)	0% (0)	4% (2)	<0.001
Fear of recurrence	Dysfunction	27% (4)	33% (30)	30% (17)	11% (9)	33% (15)	0.005
Overall QOL	Less than good	33% (5)	40% (36)	26% (15)	13% (10)	51% (23)	<0.001
Distress thermometer	≥4	67% (10)	53% (48)	37% (21)	29% (23)	60% (27)	<0.001
EQ-5D-5L							
Mobility	Mod/Sev/Un	47% (7)	23% (21)	11% (6)	14% (11)	44% (20)	<0.001
Self-care	Mod/Sev/Un	33% (5)	13% (12)	2% (1)	6% (5)	20% (9)	0.001
Usual activities	Mod/Sev/Un	53% (8)	25% (23)	18% (10)	13% (10)	44% (20)	<0.001
Pain Discomfort	Mod/Sev/Ext	47% (7)	38% (35)	21% (12)	14% (11)	51% (23)	<0.001
Anxiety Depression	Mod/Sev/Ext	40% (6)	25% (23)	5% (3)	4% (3)	29% (13)	<0.001
EQ- 5D TTO values	Median (IQR)	0.57 (0.19-0.74)	0.75 (0.58-0.84)	0.80 (0.70-0.88)	0.84 (0.74-1.00)	0.65 (0.50-0.84)	<0.001KW
EQ- 5D VAS	Median (IQR)	60 (45-75)	71 (50-82)	80 (70-87)	81 (71-90)	63 (50-82)	<0.001KW

*Fishers exact test apart from KW (Kruskal-Wallis test)
**computed without saliva score
Mod/Sev/Ext: Moderate/Severe/Unable
Mod/Sev/Ext: Moderate/Severe/Extreme

TTO: EQ-5D-5L TTO crosswalk values
VAS: The EQ-5D self-reported questionnaire includes a visual analog scale (VAS), which records the respondent's self-rated health status on a graduated (0–100) scale, with higher scores for higher HRQoL.

Table 3. UWQOL salivation and the PCI items that patients most want to discuss in their consultations

I have no saliva N=4	I have too little saliva N=52	I have less saliva than normal, but it is enough N=21	My saliva is of normal consistency N=41	I have too much saliva N=22
Dry mouth (100%)	Dry mouth (83%)	Dry mouth (52%)	Fear of cancer coming back (29%)	Chewing/Eating (55%)
Energy levels, Fatigue/tiredness, Salivation (all 75%)	Salivation (58%)	Fear of cancer coming back (38%)	Dental health/teeth (24%)	Fatigue/tiredness (45%)
	Dental health/teeth (48%)	Dental health/teeth, Sore mouth (both 33%)	Hearing, Shoulder (both 15%)	Salivation (41%)
Chewing/Eating, Dental health/teeth, Swallowing, Taste (all 50%)	Chewing/Eating, Swallowing (both 44%)	Energy levels (29%)		Fear of cancer coming back, Swallowing (both 36%)
15 other items all 25%	Mucus, Taste (both 38%)	Chewing/Eating, Pain in head and neck, Swallowing, Taste (all 24%)		Pain in head and neck, Shoulder, Sore mouth, Speech/Voice/being understood (all 32%)
	Fear of cancer coming back, Fatigue/tiredness (both 37%)			Dry mouth, Mucus, Taste, Weight (all 27%)
	Pain in head and neck, Shoulder, Sore mouth (all 29%)			Appetite, Coughing, Mouth opening (all 23%)
	Appetite, Mouth opening (both 27%)			
	Cancer treatment, Weight (both 25%)			
	Hearing (23%)			
	Appearance (21%)			

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