PSYCHOMETRIC EVALUATION OF THE SWALLOWING OUTCOMES AFTER LARYNGECTOMY (SOAL) PATIENT-REPORTED OUTCOME MEASURE

Abstract

Objectives: To evaluate the psychometric properties of the Swallowing Outcomes After Laryngectomy (SOAL) patient-reported outcome measure in a large group of people with laryngectomy.

Design: cross-sectional psychometric study.

Participants: Laryngectomy patients (minimum 3-months post-treatment) attending routine hospital follow-up.

Main outcome measure: psychometric evaluation of SOAL.

Results: One hundred and ten people participated. Thirteen percent had a laryngectomy, 63% had laryngectomy with radiotherapy, and 24% had laryngectomy with chemoradiation therapy. The SOAL showed good quality of data (minimal missing data and floor effects); good internal consistency (α=.91); and adequate test-retest reliability (intra-class correlation coefficient =.73). In terms of validity, it differentiated people by treatment group ($F(2,85)=8.02$, $p=0.001$) and diet texture group ($t(102)=-7.33$, $p<0.001$).

Conclusions: The SOAL demonstrates good validity and has potential for use in research. Further study is required to determine its clinical application.

INTRODUCTION

Measures of patient-reported functional outcomes have an established place in clinical research, but have more recently also been explored for their use in routine clinical practice. [1,2] In the field of head and neck cancer, patient reported outcome measures can be useful tools in prompting discussions between clinician and patient about rehabilitation priorities and clinical interventions so that the greatest concerns for patients are given due attention during their follow-up visits. [3,4] Such tools must demonstrate good reliability and validity if they are to be widely used in clinical practice and/or research. [5,6]

There have been a number of tools developed, focusing on dysphagia-related symptoms and dysphagia-related quality of life [7-10]. All of these questionnaires were developed for a more general head and neck population and all assume the presence of a larynx. They highlight aspects of swallow that are not always relevant in the absence of a larynx and may not always capture swallowing changes post total laryngectomy. Currently, there are no validated tools specifically addressing swallowing outcomes after total laryngectomy.

The Swallowing Outcomes After Laryngectomy (SOAL) was developed as the first laryngectomy specific measure to report *swallowing* problems experienced by this subset of patients with head and neck cancer who have their larynx surgically removed. [11] In addition to the loss of laryngeal voicing, laryngectomees also have altered swallowing and respiratory anatomy and physiology. [12] A questionnaire that takes account of these unique changes was devised in consultation with a patient focus group and expert clinicians.

The SOAL is a 17-item scale listing problems people may experience with their swallowing after laryngectomy. Full details of the questionnaire development and preliminary validation in a small sample of patients are described in an earlier paper.[11] Notably, only 19 of the 58 patients in the preliminary validation had undergone a total laryngectomy with the remaining patients representing the dysphagic and non-dysphagic groups. The SOAL was shown to have good discrimination for known groups testing. Dysphagic, non-dysphagic (non-complaining volunteers) and laryngectomy groups demonstrated significantly different scores ($p<0.001$). The non-complaining group showed very low scores (least impaired) and the dysphagic group showed much higher scores (most impaired). The laryngectomy group demonstrated a range of scores, which correlated well with the type of diet recorded: patients with the lowest SOAL scores were eating a normal diet whilst those having a very soft/liquid diet and supplements had higher scores. A relationship between the SOAL and an instrumental measure of swallowing was also demonstrated by a positive and significant correlation ($r=0.5$; $p=0.03$) between SOAL and a modified barium swallow checklist score.[11]

The findings from our earlier work was based on a small sample of laryngectomees. The current study therefore aims to evaluate further the psychometric properties of the SOAL in a larger sample. In particular,

we have evaluated the quality of the data collected on the measure, its reliability (internal consistency and test-retest), and construct validity in a generic sample of laryngectomy patients under hospital follow-up.

METHODS

Participants & procedures

We carried out a cross-sectional, questionnaire based, psychometric study. Ethical approval was obtained from an NHS multicentre Research Ethics Committee. Recruitment took place over an 18-month period in four NHS hospitals. Patients over 18 years of age who had undergone a total laryngectomy, were a minimum of 3 months post their last oncological treatment, and who had no known head and neck recurrent disease were eligible to take part. Individuals with extended laryngectomy (eg flap reconstruction) were also included. Ability to understand English was necessary for participation. Patients were excluded if they had: a partial laryngectomy, which did not include a complete separation of the trachea and oesophagus and creation of a stoma; other known conditions which affected swallowing (eg neurological disease); or if they were unable to provide informed consent.

Participants were recruited by speech and language therapy clinicians, during follow-up clinics. All clinicians who contributed to data collection in the study were members of a Head and Neck Special Interest Group. This forum afforded the opportunity for a group training session to ensure a level of consistency in the data collected across the hospital sites. Clinicians were fully apprised of the inclusion/exclusion criteria, and the demographic and treatment data to be obtained from the medical notes. Written information following the training session was sent to all clinicians for reference at any stage in the study. A system was put in place for queries during recruitment to be directed to the chief investigator so that any relevant information could be cascaded to all sites.

Recruitment occurred face to face during routine follow-up clinics. The protracted period of recruitment allowed clinicians to ascertain when laryngectomy patients were scheduled for their clinic visit and to plan ahead thereby maximising recruitment in this minority population. Following a brief explanation about the study, a patient information leaflet and a consent form were given to the patient usually whilst still in the waiting room. Patients were given the option of taking the information away and returning the questionnaire by post, or consenting and completing the questionnaire while they waited. Patients who agreed to participate had the choice of completing the questionnaire on their own or having the clinician go through the questionnaire with them. This allowed for inclusion of those patients who had difficulty reading or simply preferred an interview style to self-completion of the questionnaire. Clinicians were instructed to read the questions verbatim to minimise any differences that could occur between participants who chose to complete the questionnaire independently and those who required the clinician to read out the questions.

Clinicians were advised to clearly explain the response format at the outset and only to provide clarification when requested. It was also explained to the patient that any discussion about their swallowing could be expanded upon after completion of the questionnaire. Based on our preliminary paper, completion of the SOAL requires 5- 15 minutes [11]. Patients returned their questionnaires on the same day. In cases where time prohibited questionnaire return on the same day or if patients chose to take the questionnaire away, a stamped addressed envelope was provided for the patient to return the questionnaire by post. Demographic details and treatment information was obtained by the clinician from the medical notes. Test-retest reliability data were collected from one hospital site with a 2-week test-retest interval time. Participants invited to complete a repeat questionnaire were chosen on the basis that they were known to be clinically stable. This decision was based on no recent hospital admissions and no reports of new symptoms noted in the medical notes over the previous 2 months.

The Swallowing Outcome After Laryngectomy Questionnaire

A copy of the questionnaire is attached (Appendix 1). It consists of 17-items presented on a single page. It has a 3-point response scale (0 = No, 1 = A little, 2 = A lot). Whilst this is potentially a limited range, the format derived from patient descriptors that emerged during the initial focus groups was retained in the final questionnaire. Scores range from 0-34 with higher scores reflecting greater self reported problems. The direction of this scoring system is consistent with other symptom burden questionnaires such as the Sydney Swallow Questionnaire [8,9], where higher scores reflect greater symptom burden or poorer swallow function.

Psychometric evaluation and data analysis

All completed questionnaires were returned to a central site. Responses were transferred to an electronic template and populated into an excel spreadsheet. Data input was done by two speech and language therapists to improve accuracy. Additionally, a third clinician performed random checks on 10% of the data entries to observe for any errors. Data analysis was performed using SPSS v19.

Standard psychometric methods [13,14] were used to evaluate the quality of the data, internal consistency, test-retest reliability and construct validity (known groups), using a previously developed framework [15,16.] The criteria adopted for this study and summarised below is based on the framework outlined by Lamping et.al. (2002) [15]

Quality of data, internal consistency and test-retest reliability

Quality of data is evaluated by the completeness of the data and the distribution of scores: missing data should be <10%; floor effects should be <80%, and ceiling effects should be <80% (ie, frequency of

endorsement / percentage of people choosing the bottom and top end of the response scale); and skewness values should range between 1 and -1 (meaning data is normally distributed) for 75% of questionnaire items (some skewness is expected post-laryngectomy). Internal consistency reflects the homogeneity of the scale, i.e. all items measuring the same underlying construct: criteria were Cronbach's alpha >.70 and item total correlations ≥.30. Test-retest reliability is about the stability of the measure when administered twice across time, when no change is expected: total score intra-class correlation coefficient (ICC) >.75.

Construct validity

Factor structure: within-scale analyses should show that a single entity is measured and that items can be combined to give an overall score. As well as internal consistency and high item-total correlations, evidence from principal component factor analysis was sought to demonstrate that a single construct is being measured: in unrotated Principal Components Analysis (PCA) items should load >.30 on the first component. Additionally, factor analysis (Principal Axis Factoring, PAF) was undertaken to explore whether there was an underlying factor model (whether items grouped into subdomains). A sound factor model should be conceptually clear and meet the following criteria: [17,18] Items should load ≥0.40 and should not cross-load (i.e., load on ≥2 factors with values ≥0.4 and with a difference of <0.2 between them) and there should be at least 3 items per factor.

Known groups validity: We evaluated known group differences by testing two hypotheses: SOAL scores will be better for people who have undergone simple laryngectomy than for those who also had radiotherapy or chemo-radiation therapy. This was analysed with an independent groups ANOVA followed by pairwise comparison with Tukey correction. Additionally, SOAL scores will be better for those having a normal diet than those on a modified diet or no oral intake. An independent samples t-test was used to compare the normal diet group vs the combined modified diet and no oral diet groups.

RESULTS

Participants

Questionnaire responses were obtained from 110 participants across the 4 hospital sites. Three patients who were eligible and approached for participation declined. We did not systematically collect information on which patients required assistance to complete the questionnaire. The majority of patients returned the questionnaire on the same day. Of the small number that took the questionnaire away, only one patient failed to return it via the post following a telephone reminder. This provided a response rate of 96.5%. Table one presents the participant characteristics.

[Table 1 about here]

20 patients were invited to participate in the test-retest reliability subsample; 19 (95%) returned both questionnaires. As total SOAL scores were used in the analysis, incomplete questionnaires had to be omitted. 4 patients were therefore excluded due to missing data. 15 patients (11 males and 4 females) who ranged in age from 57 to 71 with a mean (SD) = 65.2 (4.04) were included in the test-retest analysis.

Psychometric properties

Quality of data, internal consistency and test-retest reliability (see table two)
In terms of quality of data, three items showed floor effects, meaning that few patients reported these difficulties (problems swallowing thin and thick liquids and liquids sticking in throat). No items showed ceiling effects. Five item distributions (29%) were positively skewed (problems swallowing thin and thick liquids; liquids sticking in the throat; problems eating soft food; problems eating due to dry mouth). There were no floor or ceiling effects and no skewness in the overall SOAL scores. Although no items failed the criterion for missing data, for five of 110 participants (4.5%) we could not calculate an overall SOAL score, because of missing data.

The SOAL showed high internal consistency (Cronbach's alpha = 0.91). Item-total correlations ranged from 0.38 to 0.77. Test-retest reliability was acceptable (*ICC* = .73).

[table 2 about here]

Validity
Factor structure: On PCA, all items loaded with values > 0.44 on the first component, confirming that a single construct was being measured. In PAF factor analysis three factors had Eigen values >1 (50.6% of variance explained) but the scree plot indicated a two-factor structure (46% of variance explained). Inspecting the factors did not reveal a conceptually clear and statistically robust subdomain structure.

Known groups validity (see table 3)*:* Results confirmed our hypothesis of different SOAL scores for different treatment groups. Mean (SD) SOAL scores were significantly different ($F(2,85)=8.02$, $p=0.001$) with those with a simple laryngectomy having the best scores [7.4 (7.7)] followed by those with additional radiotherapy [10.2 (6.2)] and those with additional chemoradiation therapy [16.6 (8.8)]. The effect size was large ($\eta_p^2 = 0.16$) suggesting a large difference between the groups. Pairwise comparisons with Tukey correction showed there was no significant difference between the simple laryngectomy group and the laryngectomy with additional radiotherapy group ($p=0.44$). However, those treated with laryngectomy and additional

chemoradiation therapy had significantly worse SOAL scores than those with simple laryngectomy (p=0.002) and those with laryngectomy and radiotherapy (p=0.002). Additionally those on a normal textured diet had significantly better SOAL scores [mean (SD) = 8.5 (6.0)] than those on modified/no oral intake [mean (SD) = 18.3 (6.5)] ($t(102)=-7.33$, $p<0.001$).The effect size was large ($d=-1.55$) suggesting a substantial difference between the two groups.

[table 3 about here]

Discussion

In this study of 110 laryngectomy patients, we examined further the psychometric properties of the SOAL that was initially tested in a smaller sample of patients). [11] The SOAL showed good quality of data (minimal missing data and floor effects); good internal consistency and acceptable test-retest reliability. It differentiated patients by treatment group and diet group demonstrating good Known groups validity. No items on the questionnaire failed the criterion for missing data which suggests that respondents understood and were able to complete all questions. This was consistent with our findings in the preliminary validation when face validity was established during the development phase of SOAL.

The three items that demonstrated floor effects (problems swallowing thin and thick liquids, liquids sticking in the throat) were predictable as most laryngectomees are able to swallow liquids relatively well. It is therefore unsurprising that more than 80% of our sample of follow-up patients reported no problems with swallowing liquids. Problems eating soft foods and problems eating due to dry mouth also demonstrated positive skewness. This too might be expected given that the target radiation fields in treating laryngeal cancer will most often spare the parotids and sublingual glands even when the submandibular glands are resected as part of a neck dissection. This may minimise the problems with dry mouth which many other head and neck patients (most notably oropharyngeal and nasopharyngeal cancers) often experience. Several other studies have also reported that swallowing of solid foods present the greatest challenge and burden to this group of patients. [19-22.] In this study, we excluded patients with recurrent disease and other known neurological conditions which may perhaps be the group more likely to have problems with swallowing liquids. When used in clinical practice with a full range of laryngectomy patients (healthy and those with further/comorbid disease), it is possible that scores on these three items of the SOAL may be worse. It is also possible that late effects of radiotherapy may result in increased fibrotic tissue and stenosis that in turn may impede swallowing many years post treatment. [23] These floor effects could therefore shift and until further work is done maintaining these items is important.

In addition to demonstrating good internal consistency, principal component analysis indicated that all scale items loaded onto the first component. This confirmed that the same underlying construct is being measured and that item scores may be combined to give a single score. Furthermore, factor analysis did not support a

robust subdomain culture. We also confirmed our hypothesis that individuals with a simple laryngectomy would have better scores than those with laryngectomy and radiotherapy, and laryngectomy and chemoradiation. Likewise, as hypothesized patients on a normal textured diet reported better scores than those on a modified diet. We may therefore speculate that the best SOAL scores will be obtained for those patients with a simple laryngectomy who are reporting a normal diet. Further work will be necessary before score boundaries that represent normal post laryngectomy swallow function or mild, moderate, severe swallowing problems can be determined.

Each item of the SOAL scale includes a rating for 'bother' [yes/no] as well as ratings for severity ['no' to 'a lot']. The 'bother ' rating was included, as it was evident from the patient focus groups that patients sometimes experience a symptom but learn to adjust to it and are no longer bothered by it. Other symptoms may be more bothersome, and they may be more inclined to want help with reducing or minimising these symptoms. We did not focus on the 'bother' ratings in the current analyses, and the role of perceived bother and patient adjustment will need further investigation. It will be useful to explore the potential contribution of bother in clinical decision-making, and choosing when to provide intervention.

The high response rate in this study (96.5 %) is reflective of the data collection strategy used. Despite the lengthy time taken to collect data, this method was chosen in favour of postal surveys that have a poorer response rate. [24] Further to this, clinicians were required to gather information about treatment modality, surgical and disease variables from the patient's medical notes during the clinic visit.

Study limitations and directions for future work

This study was designed so that data could be collected during routine clinical practice and with minimal disruption to patients and SLT clinicians. In limiting the response burden for patients and the number of measures collected by clinicians, we omitted to include convergent validity (comparing the SOAL with other similar validated dysphagia measures) and discriminant validity (comparing the SOAL with different constructs). We also have a small sample for the test – retest study, and a modest but acceptable sample size for the factor analysis. However, it has been demonstrated that reliable results can be obtained with smaller samples. [25] Furthermore, as suggested in the COSMIN checklist [26], it will also be necessary to establish the measure's sensitivity and responsiveness to change. A future study with greater resources will be helpful in more fully addressing these issues.

Despite every effort to ensure a full complement of data, 17 patients were excluded from the known groups analyses due to incomplete data collection. This was mainly due to incomplete entries in the medical notes and / or failure to obtain the medical notes during the patients' clinic visits.

We did not systematically collect information on how many patients returned their questionnaires by post primarily because we had set out to ask all patients to complete the questionnaire in the waiting room. As it is possible for responses to be affected by different conditions, it will be useful to plan for this contingency in future work.

Another possible limitation within this study is the absence of data on comorbidities of the patients. We excluded those patients with neurological conditions associated with possible dysphagia. It may be helpful in future studies to systematically collect all information that may impact swallowing function. Other descriptive variables such as social history (alcohol, smoking, marital status) and education level could also be useful.

Finally work is already underway by our own group to examine the swallowing outcomes following total laryngectomy as measured by the SOAL in relation to the effect of treatment and surgical variables.

Conclusions:

This study has tested the psychometric properties of the SOAL scale in a representative sample of patients following total laryngectomy and provided strong evidence on its internal consistency and validity. The SOAL can be used as a research tool to capture information about swallowing function in the laryngectomy population particularly those under long-term follow-up care. It is easily administered to patients whilst waiting for routine check-ups in oncology clinics. It has the potential to signpost clinicians to specific areas of concern regarding a patient's swallow function, an aspect all too commonly missed in this group of patients for whom voice restoration is generally the main focus. As is common with new measures, further research can confirm its psychometric properties and determine its appropriateness as a clinical outcome measure.

Acknowledgement

This study received no specific funding but was made possible by the collaborative efforts of several speech and language therapists affiliated with the Head & Neck Special Interest Group (South of England). The authors would like to thank all the clinicians at the participating hospitals who contributed to this project. A special thanks to Sarah Pilsworth, Lauren Murphy and Carlene Perris for their substantial contribution to the data collection process.

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Table 1: Participant characteristics

Variable	Number of participants = N (%)	
	Main sample N = 110	Test / retest N = 15
Gender		
Male	94 (86%)	11 (73.3%)
Female	16 (14%)	4 (23.5%)
Age		
Mean (SD)	66 (9.1)	65.2 (4.04)
Range	38-90	57-71
T-stage		
T3	22 (20%)	2 (13.3%)
T4	43 (39.1%)	12 (80%)
Salvage	40 (36.7%)	1 (6.6%)
Unknown	5 (4.5%)	
Flap reconstruction		
Primary Closure	80 (72.7%)	12 (80%)
Radial forearm free flap	2 (1.8%)	
Pectoralis Major	8 (.2%)	1 (6.6%)
Free Jejunum / Gastric pull-up	10 (9%)	1 (6.6%)
Unknown	11 (10%)	1 (6.6%)
Resection		
Larynx alone	66 (60%)	13 (86.7%)
Pharynx	25 (22.7%)	1 (6.6%)
Tongue Base	4 (3.7%)	
Other	5 (4.5%)	1 (6.6%)
Closure technique		
Horizontal	37 (33.6%)	6 (40%)
T-Closure	8 (7.3%)	3 (20%)
Vertical	6 (5.5%)	0
Unknown	50 (45.5%)	4 (26.7%)
Not applicable	9 (8.2%)	2 (13.3%)
Layers of closure		
Two	31 (28.2%)	2 (13.3%)
Three	26 (23.6%)	4 (26.7%)
Unknown	53 (48.2%)	9 (60%)
Myotomy		
Yes	71 (64.5%)	8 (53.3%)
No/Not applicable	14 (12.7%)	2 (13.3%)
Unknown	25 (22.7%)	5 (33.3%)

Table 1 continued: Participant characteristics

Variable	Number of participants = N (%)	
	Main sample N = 110	Test / retest N = 15
Additional reported interventions		
Dilatation	20 (18.2%)	1 (6.6%)
Botox	10 (9.1%)	0
Time post surgery (in months)		
Mean [SD]	61 [65.2]	66 [46.8]
Median [IQR]	39 [12-84]	60 [22-103]
Range	3-252	12-156
Diet		
Normal	77 (70%)	12 (80%)
Modified	31 (28%)	3 (20%)
No oral intake	1 (1%)	
Missing data	2 (2%)	
Treatment group		
Laryngectomy only	12 (11%)	4 (26.7%)
Laryngectomy and radiotherapy	59 (54%)	6 (40%)
Laryngectomy and chemo-radiation	22 (20%)	5 (33.3%)
Missing data	17 (15%)	

Table 2: Mean(SD) and selected psychometric properties of the Swallowing Outcomes After Laryngectomy (SOAL) measure

	Results
Mean (SD)[a]	11.3 (7.6)
Sample score range (possible range)	0 – 34 (0 – 34)
Missing data[b] (> 10%)	0 items
Ceiling effects[b] (>80%)	0 items
Floor effects[b] (>80%)	3 items (17%)
Skewness[b] (> ±1)	5 items (29%)
Cronbach's alpha[a]	0.91
Item-total correlations[a]	0.38 - 0.77
Test-retest reliability[c]	
Intra-class correlation coefficient	0.73

NOTE: aN=105; bN=110; cN=15

Table 3: Known groups validity of SOAL

Group	**N**	***Mean***	**SD**	**df**	**t-statistic**	**p**
Diet						
Normal diet	74	8.6	6.0	102	-7.33	<0.001
Modified or no oral diet	30	18.3	6.5			
Treatment					**F-ratio**	
Laryngectomy	12	7.4	7.7	2, 85	8.02	0.001
Laryngectomy + radiotherapy	56	10.2	6.2			
Laryngectomy + chemoradiation	20	16.6	8.8			