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FACTORS AFFECTING SWALLOWING OUTCOMES AFTER TOTAL LARYNGECTOMY: PARTICIPANT SELF-REPORT USING THE SOAL (SWALLOWING OUTCOMES AFTER LARYNGECTOMY) QUESTIONNAIRE

INTRODUCTION

Swallowing function for individuals without a larynx (laryngectomees) is different due to the anatomical separation of the airway from the digestive system during total laryngectomy surgery. Bolus transit is altered because of changes in swallowing pressures caused by the reconstruction of a pharyngo-oesophageal segment and the alteration of pharyngeal musculature following removal of the larynx.[1–3] Reported symptoms in the literature reflect difficulty with bolus propulsion through the neo-pharynx.[4] However, it is less clear whether the difference in swallowing physiology brought about by these changes is perceived as a swallowing problem for this group of patients.[5,6] Prevalence of swallowing problems or dysphagia post total laryngectomy range from 10% - 90%.[7,8] Lack of standardised measurement tools and differences in how dysphagia is defined contribute to this wide variation. In order to better understand dysphagia in this group of patients we explored the relationship between factors likely to contribute to swallowing dysfunction after laryngectomy with patient self-reports of dysphagia.

Multiple factors may contribute to poor swallowing in patients after total laryngectomy: The presence of flap reconstruction, whether microvascular free flap (jejunum), pedicled rotational flap (pectoralis major), anterior lateral thigh flap, or gastric transposition (gastric pull-up) can affect swallow physiology and subsequent function in a variety of different

ways.[7,9] A systematic review of the literature found that voice and swallowing outcomes were worse in total laryngectomy with flap repair compared to those with primary closure, with a concomitant lowering of quality of life.[10]

Additional treatments, including radiation (RT) either prior to or following total laryngectomy have an adverse effect on swallowing function.[11] Salvage total laryngectomy following chemo-radiation (CRT) has a higher rate of post-surgical complications such as fistula formation and stenosis or stricture.[12–14] Both situations may then have a concomitant effect on swallowing, either in the short or longer term although there are few studies addressing this directly. Silverman and colleagues in their review of outcomes following salvage total laryngectomy reported that complications were more pronounced after CRT than RT alone, with dysphagia as one of the more common complications at 18.6% (range 2.9 – 30.2%). [15]

Age and gender may play a role in swallowing related quality of life after total laryngectomy: older patients tend to report better quality of life, particularly in relation to swallowing and communication.[16–18] Length of time post total laryngectomy may also influence health related quality of life, with quality of life rated as poorer immediately post-surgery and generally worse than the normative population.[19–21] However, many of the studies are retrospective, and make use of health related quality of life measures that assume presence of a larynx. There is a clear need for laryngectomy-specific measures to be used in these studies.

Thus, the literature provides isolated studies that illustrate the different factors that can affect swallowing outcomes following total laryngectomy, but to our knowledge there has not been a study that has specifically explored multiple known factors with patients' self-reported dysphagia. With the development of the psychometrically robust, self-reported Swallowing

Outcomes after Laryngectomy (SOAL) questionnaire,[5,22,23] it is now possible to more closely examine the factors which may influence perceived swallowing outcomes.

The first aim of this study was to identify whether patient demographics, surgical variables, use of additional treatment and time since surgery had a significant impact on perceived swallowing outcomes. We then looked at the relative importance of significant variables on self-reported swallowing outcomes.

METHODS AND MATERIALS

Participants and procedures

We undertook a cross-sectional questionnaire-based survey of laryngectomee patients from eight hospitals in South East England, United Kingdom. Ethics approval was obtained from a multi-centre National Health Service Research Ethics Committee. Data from part of this study and full information on the design and recruitment of the overall study have been previously reported.[22] Participants were recruited from the participating hospitals through an 18-month period and had to meet the following eligibility criteria: be > 18 years old, have undergone a total laryngectomy (including extended laryngectomy, e.g. flap reconstruction), be > 3 months post their last oncological treatment, and have no known head and neck recurrent disease. Participants 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, had other known conditions that affected swallowing (e.g., neurological disease), did not understand English, or if they were unable to provide informed consent. Participants were recruited and data was collected by Speech and Language Therapists in the recruiting sites, who had undergone training on all aims and processes of the study in order to ensure consistency in

data collection across hospital sites. Potential participants were provided with the study participant information sheet and consent form as well as verbal explanation of the study, and had the option to take these away and return by post or complete while waiting for their visit.

Measures

Demographic, treatment and surgical variables were drawn from the medical notes, including age, gender, time post-treatment, surgical repair and additional treatment. The Swallowing Outcomes After Laryngectomy (SOAL) questionnaire was used to capture perceived swallowing outcomes. The SOAL is a psychometrically robust laryngectomy specific self-reported outcome measure.[22] It consists of 17 items and is scored from 0-34. Patients were asked to rate statements about their swallowing ability based on their perceived difficulty: no (0); a little (1) a lot (2). Higher scores therefore reflect greater swallowing burden or functional difficulties.

Data analyses

Descriptive statistics were used to summarise participant characteristics, disease and treatment related variables. The impact of these variables on swallowing outcomes was explored with a Pearson's Product correlation coefficient for age, independent samples t-tests (gender, time post-onset ≤ or > 5 years), and between-groups ANOVAs (type of treatment, surgical repair). Bonferroni corrections were applied for multiple comparisons. The relative contribution of those variables that had a significant impact on self-reported

swallowing outcome was explored with a linear multiple regression analysis. As well as standardised (β) and unstandardized (B) coefficients, the standard error, significance values, the 95% confidence intervals for B, squared semi-partial correlations (sri^2) for variables that made a significant contribution to the model are reported in the results. sri^2 provides a measure of the unique variance accounted for by each significant variable in the model and measures the total amount of variance explained by unique variance and shared variance.

RESULTS

Two hundred and sixty-eight people with total laryngectomy were included in the study. The majority (85%) were male. Age ranged from 38 to 95 years old [mean (SD) = 66.7 (10.2). The majority were within five years of their diagnosis (67.2%), had a primary closure (81.6%) and had additional radiotherapy (64.9%). Two hundred and twenty one had complete data on all treatment related variables. Of these, 11 had missing data on the SOAL: 10 had one item missing and one had two items missing. SOAL scores for these 11 participants were imputed from the average of the rest of the SOAL items. This participant sample of 221 was used for data analyses. Their characteristics were similar to the overall sample: 86% male, mean (SD) age = 66.8 (10.3), 70.6% within five years of onset, 81.9% with primary closure and 64.7% with additional radiotherapy. Participant characteristics and treatment related variables are provided in table 1.

[table 1 about here]

Table 2 shows participant and treatment variables and the associated effect on participant scores on SOAL. In terms of participant variables, age was negatively correlated with SOAL scores (r= -.19, p=.004), i.e. older people tended to have better swallowing outcomes. However, the effect size was small (r^2=0.04) There was no effect of gender (p= .85).

In terms of treatment related variables, participants who were less than five years from completing their treatment reported significantly worse swallowing outcomes (p= .001), with a small to medium effect size (d= 0.47). Type of surgical repair had a significant impact on perceived swallowing outcome (p< .001), with a large effect size (η_p^2= .15): pairwise comparisons revealed that those who had a free jejunum flap had a significantly worse outcome than those who had a primary closure (p< .001), a pectoralis major flap (p= .006), or those who had a stomach pull-up (p= .001). The differences between the other three groups (primary, pectoralis major, stomach pull-up) were not significant. In terms of additional treatments, there were no significant differences on swallowing outcomes between those who had radiotherapy prior to or following total laryngectomy (p=.19) and those who had chemo-radiation prior to or following total laryngectomy (p=.36). These categories were therefore collapsed to radiotherapy and chemo-radiation and compared to those who had no additional treatment. Additional treatment had a significant impact on perceived swallowing outcome (p< .001), with a large effect size (η_p^2= .14). In pairwise comparisons, those who had chemo-radiation had worse outcomes than those who had no additional treatment (p< .001) and those who had radiotherapy without chemotherapy (p< .001). There was no significant difference between those who had no additional treatment and those who had radiotherapy (p= .23).

[table 2 about here]

The extent to which the significant variables predicted SOAL scores was explored further in a linear multiple regression analysis. Two dummy variables were created for additional treatment (no additional treatment vs. radiation, no additional treatment vs. chemo-radiation) and three dummy variables were created for surgical repair (primary closure vs.

free jejunum, primary closure vs. pectoralis major and primary closure vs. stomach pull up). These variables together with age (a continuous variable) and time since surgery (a binary variable) were entered simultaneously. Key assumptions for regression analysis were met and inspection of a scatterplot revealed that no cases had a standardised residual of >3 or < -3.

[table 3 about here]

Table 3 shows the standardised (β) and unstandardized (B) coefficients, the standard error, significance values, the 95% confidence intervals for B and squared semi-partial correlations (sri^2) for variables that made a significant contribution to the model. As can be seen in table 3, once the other variables were taken into account, age and time post-surgery did not add significantly to the model. Only two of the variables added significantly to the prediction of SOAL scores: no additional treatment vs. chemo-radiation and primary closure vs. free jejunum, explaining 8% and 7% of variance respectively. The variables in combination contributed another 11% in shared variability. Altogether the model was significant with 26% (23% adjusted) of the variability of SOAL scores predicted by the variables entered into the regression, with more than half of the variability explained by the unique contribution of two variables.

DISCUSSION

We explored factors affecting patient perceived swallowing outcomes after total laryngectomy via a cross sectional survey using the SOAL questionnaire. The sample with complete data used in our analyses was similar to the overall sample and generally well represented in terms of the typical age and gender demographics for laryngeal cancer in England.[24] In univariate analyses, individuals who were older, earlier post onset, had chemo-

radiation and a free jejunum flap reported more difficulty swallowing. However, when all the variables were considered together in regression analysis, having a free jejunum flap repair and requiring chemo-radiation were the only two variables that added significantly to the regression model of self-reported swallowing outcomes.

In line with previous findings, age was negatively associated with greater self-reported swallowing problems.[16] Whilst this could be related to the potential impact of swallowing problems on social life in younger people such as eating out, [25] the overall effect of age was small in our study. We also found that participants who were less than 5 years from completing their treatment reported poorer swallowing. A Scottish survey of 179 people with laryngectomy found no differences in swallow function based on the time since treatment, which ranged from 0-27 years.[26] However, in that study there was a trend for those who were over 15 years since treatment to have better swallowing outcomes, which was also the case in our data. Moreover, the Scottish study used the MD Anderson Dysphagia Inventory (MDADI) which measures dysphagia related quality of life.[27] Unlike SOAL, the MDADI does not measure symptom burden, and is not specific to laryngectomy patients. The SOAL questionnaire may therefore be more sensitive to identifying specific symptoms experienced by people with laryngectomy across time post-surgery. Still, the effect size in our study was small to medium; and time post onset, as well as age, did not add significantly to the regression model.

In our study, type of surgical repair and additional treatment were the most important variables affecting perceived swallowing function. Decisions regarding flap reconstruction may be influenced by extent and location of disease, with disease clearance as the primary consideration in line with oncological principles. However, when considering the type of flap

repair to use in extended laryngectomy, consideration should also be given to the functional impact of the different repair options. The results of our study are consistent with the literature in that swallowing outcomes are generally worse in the presence of flap repair.[10,28] Yet we found no clear guidelines that one type of flap is superior to another and offers consistently better functional outcomes. It is noteworthy that a survey of otolaryngologists and plastic surgeons in the United States highlighted that the type of flap selected by surgeons may be motivated by a number of different factors, aside from functional outcomes.[29] This may include their own training, skill, experience, institutional practice, as well as factors such as flap failure rates and donor site morbidity. Furthermore, the primary specialty of the surgeon undertaking the reconstruction may also influence decision-making: otolaryngologists tended to focus more on voice and swallow outcomes whereas plastic surgeons placed high emphasis on cosmesis.[29] The data reported in our study reflect practices in the south of England where choice of flap repair following total laryngectomy may be different to other geographic regions. At the time of data collection, anterior lateral thigh flaps were not a common choice of free flap repair as reflected in the absence of such flaps in our data.

In our study, free jejunum contributed to worse swallowing outcomes than other flaps, including pedicled. It is difficult to interpret this without more detailed information on surgical procedures, which were not reported with sufficient detail in the medical records in our study. In their review, Mahalingam and colleagues found that outcomes tended to be poorer with pedicled flaps than free flaps.[10] Although this may appear discrepant to our study, the review used enteral feeding and time to commencement of oral intake as outcomes, whereas our study used a tool specifically validated for laryngectomy to investigate self-reported long-term outcomes. [5,22] Overall, two reviews in the literature report a clear lack of

high quality evidence of functional outcomes after total laryngectomy.[4,10] They concluded that there were methodological limitations in many studies, including the use of non-validated measures, insufficient information on treatment, and populations that were heterogeneous.

Regardless, post-operative complications rates tend to be higher in salvage laryngectomy and range from stricture formation to percutaneous fistula formation,[4, 30] all of which would impact swallowing function. Our data showed no significant differences in SOAL scores between the group of patients who received radiotherapy as first line treatment prior to total laryngectomy, compared to the group who received radiotherapy after. Radiotherapy given either before or after total laryngectomy did not alter patients' self-reports of their swallowing. However, this was not the case for chemo-radiation. In terms of additional treatment, it was the fifth of our sample that had chemo-radiation who reported the worst swallowing outcomes, whereas the two thirds of the sample who had had radiotherapy did not differ to those who had surgery alone. In contrast, the findings from the DeCasso [11] and Robertson[26] studies both concluded that radiotherapy had a significant negative effect on swallow function post total laryngectomy. There are several factors that could contribute to the apparent discrepancy with our results. Although the Robertson study used a questionnaire for self-reported swallowing function, this questionnaire was validated assuming the presence of a larynx and looked more broadly at quality of life. The DeCasso study looked at swallowing function in terms of food consistencies managed by their patient cohort and was based on a judgement made by clinicians. This type of reporting, which focuses on type of oral intake and reliance on enteral feeding as the main outcome measures, is common throughout much of the literature. [15, 30] There is a dearth of literature addressing

the burden of swallowing as defined by laryngectomees themselves, using tools validated on a laryngectomy population.[23]

In terms of clinical implications, our findings highlight the complexity of the decision-making regarding treatment and the importance of providing the client with evidence based information on functional outcomes. The challenge for the multidisciplinary team is adherence to the oncological principle of providing treatment to optimise disease cure while minimising complications and maximising functional outcomes. In terms of client management, discussions necessarily involve consideration of client priorities regarding morbidity vs. mortality and the factors that affect each. For example, it is reported that in general in head and neck cancer the addition of chemotherapy increases survival rate by 6-8%.[31] Our findings suggest that there may be a trade off in functional outcomes with the addition of chemotherapy, particularly in regards to swallowing. With that in mind, multidisciplinary team discussions should carefully consider the impact of functional outcomes with additional chemo-radiation vs. radiation alone. In addition, patient coping strategies and psychological wellbeing may also contribute to quality of life and should be taken into account. [16,21]

A limitation of our study was that there was incomplete information in the medical notes on any additional interventions such as dilatations, flap revisions and closure technique (vertical, T, horizontal). As a result we could not use this data in our analysis. However, this study is the first of its kind to use a validated self-reported questionnaire developed for the target population. It provides a reliable measure of swallowing outcomes along with identifying the burden associated with function for patients. Another strength of the study is its sample size which is one of the largest reported in the literature.

Our cross-sectional data has provided important evidence of the patients' perception of their swallowing difficulties. We achieved this using the SOAL, a laryngectomy specific validated tool. This tool can be used in much needed longitudinal studies to monitor swallowing outcomes post total laryngectomy in order to better understand what impacts in the long-term on both function and quality of life and inform clinical practice.

In conclusion, this study has shown that the SOAL is a sensitive measure, revealing a wide range of self-reported swallowing outcomes after laryngectomy. Our study suggested that the type of surgical closure performed and the type of additional treatment given influenced the swallowing outcome reported by patients. Free jejunal flaps and chemo-radiation resulted in the poorest swallowing outcome. It remains a challenge to define which type of surgical closure optimises swallowing. Consistency of practice and more detailed reporting on surgical detail will facilitate improved understanding of the precise relationship. Changes in perceived swallowing function, using a standardised and validated questionnaire following total laryngectomy, need to be routinely evaluated to inform clinical decision-making and intervention.

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Table 1: Participant characteristics and treatment related variables (n=221)

Variable	Mean (SD) Or Number of participants (%)
Age	
Mean (SD)	66.8 (10.3)
Range	38-95
Gender	
Male	190 (86.0%)
Female	31 (14.0%)
Time post onset	
≤ 5 years	156 (70.6%)
> 5 years	65 (29.4%)
Surgical Repair	
Primary closure	181 (81.9%)
Free jejunum flap	12 (5.4%)
Pectoralis major flap	23 (10.4%)
Stomach pull-up	5 (2.3%)
Additional treatment	
None (total laryngectomy only)	35 (15.8%)
Radiotherapy	143 (64.7%)
Chemo-radiation	43 (19.5%)
SOAL scale score	
Mean (SD)	10.09 (7.38)
Range	0-34

SOAL: Swallowing Outcome After Laryngectomy

Table 2: Impact of participant and treatment variables on swallowing outcome (n=221)

Variable (number of participants)	SOAL score, mean (SD)	Statistical comparison
Age	N/A	r= -.19, p= .004 r^2=0.04
Gender		
Male (190)	10.05 (7.40)	t(219)= .19, p= .85
Female (31)	10.32 (7.39)	d= 0.04
Time post onset		
≤ 5 years (156)	11.04 (7.82)	t(164.34)= 3.44, p=.001
> 5 years (65)	7.81 (5.63)	d= 0.47
Surgical repair		
Primary closure (181)	9.12 (6.67)	F(3, 217)= 12.86, p< .001,
Free jejunum flap (12)	20.92 (9.62)	η_p^2= .15
Pectoralis major flap (23)	12.83 (7.05)	
Stomach pull-up (5)	6.60 (3.58)	
Additional treatment		
None (35)	6.89 (5.92)	F(2, 218)= 18.18, p< .001,
Radiotherapy (143)	9.25 (6.32)	η_p^2= .14
Chemo-radiation (43)	15.49 (9.03)	

Table 3: Multiple linear regression analysis of concurrent predictors of SOAL scores (n=221)

Predictors	B	SE	β	p value (BS)	95% CI for B (BS)	sri^2
Age	-.06	.04	-.08	.19	-.15 - .03	
Time post-surgery	-1.18	1.02	-.07	.25	-3.19 - .83	
No additional treatment vs. radiation	2.13	1.23	.14	.09	-.30 - 4.56	
No additional treatment vs. chemoradiation	6.64	1.53	.36	<.001	3.63 - 9.65	.07
Primary closure vs. free jejunum	9.43	1.98	.29	<.001	5.53 - 13.34	.08
Primary closure vs. pectoralis major	2.46	1.47	.10	.10	-.43 - 5.35	
Primary closure vs. stomach pull up	-2.52	2.94	-.05	.39	-8.3 - 3.27	
Total model F(7, 213)=10.48, p<.001; R square=.26 (adjusted)=.23						
Unique variability=.15; shared variability=.11						