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Title: Gender differences in health-related quality of life following total laryngectomy

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Abstract

Background: The impact of a total laryngectomy on an individual's life has primarily been measured from a male viewpoint reflecting the demographics of a diagnosis of laryngeal cancer. A small number of studies have looked specifically at females but very few are comparison studies. Consequently, there is little consistent research regarding any potential gender differences.

Aims: to investigate whether there are gender differences in perceptions of health related quality of life (QOL) and functional abilities following total laryngectomy.

Participants and Method: A total of 43 participants (22 males, 21 females), who had undergone a total laryngectomy procedure at least one year previously, took part in the study. They completed The European Organisation for Research and Treatment of Cancer Core Questionnaire Version 3.0 (EORTC QLQ-C30) in conjunction with the disease-specific Head & Neck Cancer Module (QLQ-H&N35).

Outcomes and results: There were no significant differences between males and females on demographic and disease-related variables, except for the following: significantly more females lived alone and changed their employment status following surgery. Males had a significantly higher global health status/QOL than females ($p<.05$) and significantly higher levels of physical ($p=.01$), emotional ($p<.01$), cognitive ($p<.05$) and social functioning ($p<.05$). After adjusting for differences in living arrangements and change in employment status, differences in emotional and social functioning remained significant. There was a general trend for females to have higher symptom/impairment levels and to report more treatment-related problems but the majority of these differences were not significant.

Conclusions and implications: Following total laryngectomy, females appear to be worse affected in aspects of QOL than males. Emotional and social functioning are particularly vulnerable. The findings imply that rehabilitation programmes after total laryngectomy need to evaluate QOL and address these specific areas in order to improve patient-reported long-term outcomes.

What this paper adds*What is already known about the subject:*

There are gender differences in how males and females adjust to diseases processes in general. Laryngectomy typically has been male dominated; however, the proportion of female laryngectomees is rising. Studies looking at quality of life post total laryngectomy have not consistently investigated whether there are gender differences.

What this study adds:

Our results indicate that there are gender differences in aspects of health related quality of life, with women being more vulnerable in emotional and social functioning. This study suggests that rehabilitation programmes that consider and aim to improve emotional and social functioning post total laryngectomy may be particularly beneficial for women.

Introduction

Treatment for carcinoma of the larynx ranges from curative radiotherapy to multi-modal treatments including total ablation of the larynx. In recent years, organ preservation protocols with concomitant chemo - radiotherapy regimes are being used even for advanced stage disease (Genden et al 2007). However, in some instances total laryngectomy is still undertaken for malignancies that do not respond to pre-operative chemotherapy, in cases where there is disease recurrence following radiotherapy, or where other surgical procedures do not allow clear surgical margins for elimination of the disease. There are morbidities associated with all treatment modalities primarily affecting voice and swallowing: components that can impact quality of life (Woodard et al 2007). In the case of total laryngectomy, respiration is also affected due to the redirection of the trachea resulting in the elimination of an upper respiratory tract. Post-operative recovery therefore includes

physical, psychological and social adjustments: Armstrong et al (2001) found in their longitudinal study that there were long term and persistent difficulties with speech and swallowing after total laryngectomy, as well as with social / emotional adjustment.

Measures of quality of life (QOL) following head and neck cancer tend to be health related, i.e. primarily focus on the impact of disease on the patient's life and tend to incorporate physical, emotional and social domains (Bullinger et al., 1993). Vileseca et al (2006) found that long-term QOL does not seem to decrease after total laryngectomy when it is measured with general health instruments and compared with the normal population. However impairment on physical aspects of QOL is found when disease-specific questionnaires are included. In the head and neck cancer literature, measurement of quality of life tends to reflect functional outcomes and is dependent on the timing of completion of the QOL surveys. There is evidence that patient-reported QOL changes over time (Jones et al 1992; Murphy et al 2007), and that for total laryngectomy, although there are early post operative issues reported for voice, in the long term patients report that their general health is the same or better compared with the year prior to the diagnosis of cancer (Deleyiannis et al., 1999). More recent studies indicate that social support is a more important determinant of quality of life and psychological adjustment than the physical sequelae of total laryngectomy (Ramirez et al 2003). Other studies suggest that although in the long term voice is no longer such a major issue, due to the advances in surgical voice restoration (Singer & Haymaker 1998), QOL is reported to be lower (De Santo et al 1995; Palmer & Graham 2004). One

longitudinal QOL study (de Graeff et al 2000), found that treatment generally resulted in short-term physical and psychological deterioration most of which resolved within a year.

Much of the QOL literature on the impact of a total laryngectomy arises from a predominantly male subject population. This has reflected the demographics associated with a diagnosis of laryngeal cancer. Since there has been a higher incidence of laryngeal cancer in males, typical care of the laryngectomee tends to have been defined by this (Brown and Doyle 1999). The male to female ratio of laryngeal cancer in the UK is approximately 4.5:1 and although the incidence of laryngeal cancer in males is decreasing, this is not the case in the female population (Office for National Statistics, 2008). With proportionally more women being diagnosed with laryngeal cancer new concerns are emerging: issues that may not have been previously considered for laryngectomised males may impact rehabilitation for females. There is evidence that when men and women are affected by the same health problems, they may experience them differently (Gijsbers, Van Wijck, Van Vliet & Kolk 1996)

Gardner (1966), as one of the first to study the adjustment issues of laryngectomised women found reports of both positive and negative experiences. Many women reacted unfavourably to the change the presence of a stoma made to their appearance. As well, there were a broad range of attitudes that affected confidence about learning to use a laryngeal voice for communication. Particular concerns for female laryngectomees were the

reduced intelligibility, and being mistaken for a man on the telephone. This study, although old, still has merit, as some of these concerns continue to be reported to clinical practitioners working with this population (Vilaseca et al 2006).

Women report pre and post-operative fear and anxiety and are less likely than men to obtain appropriate information about surgery and its consequences (Graham & Palmer, 2002; Salva & Kallail, 1989). de Graeff et al. (2000), in their longitudinal study of QOL of patients with head and neck cancer, 43% of whom were laryngectomees, reported significant gender differences: women were found to report worse global health status/QOL, physical, emotional and social functioning. A later study supported these findings for female laryngectomees and concluded that women have unique concerns regarding physical condition, informational needs and emotional support (Palmer & Graham 2004).

The studies above begin to inform whether there are important differences between males and females on how they respond to total laryngectomy. However, although two of these studies specifically aimed at comparing males and females (Palmer & Graham, 2004; Salva & Kallail, 1989), others comprised of males and females together (Vilaseca et al., 2006) or females only (Gardner 1966).

This study aimed to address the following questions: Are there any significant differences in health-related QOL following total laryngectomy between males

and females? Do any demographic variables differ significantly for males and females and if so, do they impact QOL?

Methods

A cross-sectional postal survey was conducted. Laryngectomy clubs across England and Scotland were contacted and an advertisement was placed in national newsletters calling for volunteers for the study. Eligibility criteria comprised:

- Total laryngectomy
- At least 50 years of age
- At least one year post-surgery/ other medical treatment, including radiotherapy
- Disease free
- English speaking
- Functional hearing and vision (self reported by subjects)

Materials: The European Organisation for Research and Treatment of Cancer Core Questionnaire Version 3.0 (EORTC QLQ-C30) in conjunction with the disease-specific Head & Neck Cancer Module (QLQ-H&N35) were used. The EORTC core module is a patient-based, self-administered modular instrument designed to assess the health-related QOL of a broad range of cancer patients (Aaronson et al, 1993). Reliability, validity and cross-cultural applicability have been confirmed (Aaronson et al 1991; Sherman et al 2000). It is widely used in research in this area (Bjordal et al 1999; 2000, Hammerlid et al 1997; Jones et al, 1992) and studies have confirmed its accessibility and

ease of use. Pusic et al (2007) in a systematic review of patient – reported outcome measures in head and neck surgery found that the EORTC QLQ-C30 was one of only three measures that fulfilled guidelines for instrument development and evaluation as outlined by the Medical Outcomes Trust.

The core questionnaire consists of five multi item functional scales including physical (5 items), role (2 items), cognitive (2 items), emotional (4 items), and social (2 items). There is also a global health status/QOL scale (2 items). There are three symptom scales: fatigue (3 items), pain (2 items), nausea/vomiting (2 items); and six single additional symptom items of dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties.

The QLQ-H&N35 is a supplement 35-item questionnaire that assesses symptoms and side-effects of treatment encountered specifically by patients with head and neck cancer.

There are seven multi item (2-5) symptom scales: pain, swallowing, senses, speech, social eating, social contact and sexuality. In addition, there are 11 single symptom items regarding problems with: teeth, opening mouth, dry mouth, sticky saliva, coughing, feeling ill, painkillers, nutritional supplements, feeding tube, weight loss and weight gain.

All the scales and single items are scored on a four-point Likert scale except the QOL scale which is a seven-point scale. All raw scores are linearly transformed to a scale of 0-100. Functional scales and global health

status/QOL scales are reverse scored so that higher scores indicate better levels of functioning or higher QOL. In contrast, higher scores on the symptom scales and individual items represent greater impairment. The scores are calculated according to the EORTC QLQ-C30 scoring manual (Fayers et al 2001).

Data analysis: Descriptive statistics were used to summarise participant characteristics and scores on the EORTC QLQ-C30 and H&N35 questionnaires. Chi-square tests and independent samples t-tests were used as appropriate to explore differences between men and women on demographic and quality of life variables. ANCOVA was used to control for potential demographic differences when exploring quality of life differences between men and women.

Results

Fifty questionnaires were distributed and 44 (88%) were returned. Of these, 21 responses were from females and 23 were from males. Data from one male participant could not be used as he did not fulfil the inclusion criteria. Table one details participant characteristics. On average, male participants were slightly older [mean = 69.6yrs] than females [mean = 65.6yrs], but this difference was not significant. The majority of both samples were between one and 10 years post operative [18 (81.8%) for males, 15 (71.4%) for females] and less than five years post treatment or still having speech and language therapy [15 (68%) for males, 13 (62%) for females]. A larger proportion of males communicated through surgical voice restoration (68% as

opposed to 48%), but this difference was not significant. All patients had undergone a course of radiotherapy and had neck dissection at initial surgical procedure.

Significant differences between males and females were observed in two demographic variables: living arrangements and changes in employment post surgery. Most men lived with their spouse (86.4%) and only 3 (13.6%) lived alone, whereas 12 (57.1%) of women lived alone ($X^2 = 8.95$, $p < .05$). Only two males (9%) experienced a change in employment post surgery as opposed to eight (38%) of females ($X^2 = 5.06$, $p < .05$).

[table 1 here]

EORTC QLQ-C30 Global health status/QOL and functional scale scores are presented in table two and figure one. Males had a higher global health status/QOL [mean (SD) = 76.5 (17.2)] than females [65.7 (20.6)] and this difference was significant ($t(41) = 1.87$, $p < .05$). On the functional scales, mean scores ranged 70.5 - 90.1 for males and 50.8 - 78.6 for females. Significant differences were found on the physical ($t(41) = 2.36$, $p = .01$), emotional ($t(41) = 3.92$, $p < .01$), cognitive ($t(31) = 2.09$, $p < .05$) and the social functioning ($t(41) = 2.27$, $p < .05$) scales.

[table 2 and figure 1 here]

As significantly more women were living alone and had experienced a change in their employment status, ANCOVA was used with these two variables as co-variates to explore their effect on the observed QOL differences between males and females. Preliminary checks were conducted to ensure that there was no violation of the assumptions of normality, linearity, homogeneity of variances, homogeneity of regression slopes and reliable measurement of covariates. After adjusting for living arrangements and employment status change, there were significant differences between males and females in emotional functioning ($F(1, 39) = 11.0, p < .01$) and social functioning ($F(1, 39) = 5.28, p < .05$). There were no significant differences between males and females in global health status/QOL, cognitive and physical functioning.

Table three presents scores on the symptom items of the EORTC QLQ-C30. There was a trend for females to have higher symptom / impairment levels [mean scores ranged 4.8 – 39.7 as opposed to 6.1 – 24.2 for males]. However, significant gender differences were found for only two of the variables: insomnia ($t(41) = -2.05, p = .05$) and financial difficulties ($t(35), p < .05$).

[table 3 here]

Scores on the symptom items of the EORTC QLQ-H&N35 questionnaire are detailed in table four. Females rated themselves as having higher symptoms / impairment than males on 13 out of 18 of these items. Independent t-tests indicated significant differences between males and females on 3 items: less

sexuality ($t(38) = -3.14, p < .01$), painkillers ($t(39) = -2.40, p < .05$) and weight loss ($t(20) = -2.17, p < .05$).

[table 4 here]

Discussion

This study explored whether there were any differences between male and female laryngectomees in perceptions of global health status/QOL and physical, role, emotional, cognitive and social aspects of QOL as well as symptoms and side-effects of treatment. In terms of symptoms and side-effects of treatment, females tended to report more problems than males but very few differences were significant. This is in line with the findings of other studies. When looking at specific problems, rather than broader QOL, Vilaseca et al (2006) found there were no differences between men and women, except for the area of swallowing, with women being more adversely affected. Graham and Palmer (2002) also found that the responses of men and women were more similar than dissimilar.

In terms of QOL, we found significant differences between males and females in their global health status/QOL and perceptions of functioning (except for role). However, females were more likely to live alone and to have experienced a change in their employment status after laryngectomy. After adjustment for these demographic differences, females continued to experience significantly worse emotional and social functioning.

Other studies suggest that functional limitations caused by laryngectomy do not necessarily mean a worse overall QOL (Deleyiannis et al 1999; Vilaseca et al 2006). Patients may learn to cope effectively with disease and treatment and make adjustments with time and thus the importance of QOL domains may change accordingly (Deleyiannis et al 1999). In general, quality of life in head and neck patients declines immediately following medical treatment, and returns to pre-diagnosis levels by the end of the first year (Murphy et al 2007).

In this study, although there was a significant difference between male and female laryngectomees in global health status/QOL, this effect disappeared when adjusted for differences in living arrangements and change in employment status. This finding needs to be interpreted with caution. If indeed these demographic differences between males and females occurred by chance or because of the small-moderate sample size, then ANCOVA was an appropriate technique to be used in analysing our results and this finding is valid. If, however, female laryngectomees change their employment status and live by themselves because of their laryngectomy, then these variables should not be assumed to be equal between the two groups and female laryngectomees may indeed experience worse global health status/QOL. Longitudinal, larger scale studies in this area are needed to unravel these effects.

The finding that females have significant lower emotional functioning in the present study is in line with the general medical literature which indicates that women are more likely to experience depression / emotional problems, particularly when there are other concurrent health problems (Aro et al 2001;

Grigoriadis and Robinson, 2007). Emotional problems interfere with patient response to rehabilitation. In the head and neck cancer literature, emotional distress has been reported as the most consistent factor in determining QOL over time (Morton et al., 2003); and Palmer and Graham (2004) found that women have unique concerns regarding their emotional support systems during rehabilitation. Salva & Kallail (1989), whilst investigating the counselling needs of male and female laryngectomees, found that women reported more fear and anxiety than men post-surgery and that the needs of female laryngectomees had been overlooked.

Social functioning is an important factor to consider as it is significantly associated with social support (Karnell et al., 2007). Social support is also significantly associated with depression and social support seeking behaviour is the most prevalent strategy for coping in patients with head and neck cancer (Karnell et al., 2007; List et al., 2002). Social support and depression also mediate the effect of functional limitations on disability (Phillips and Stuifbergen, 2008). Looking at psychosocial adjustment post treatment for laryngeal cancer, Ramirez et al (2003) found that adjustment was good in the area of social activities: 90% of their sample maintained the same interest in leisure activities as before the surgery. In their sample, 99% (61/62) were males. When female laryngectomees are included in studies, as in this present study, the picture emerging is different: women experienced severely affected social functioning (lowest mean of all QOL subscales) and their social functioning was significantly worse than men.

In summary, emotional and social aspects of QOL are worse in females than males in the long term after total laryngectomy. Emotional distress, social support and social functioning are complex concepts that are affected by multiple variables. This study was a small cross-sectional survey that cannot begin to unravel these complex effects. Large scale longitudinal studies are essential in this population, to help understand why women cope worse emotionally, engage in less social activities and are less likely to work after total laryngectomy.

Conclusions and clinical implications

Following total laryngectomy, females appear to be more adversely affected in aspects of QOL than males. Emotional and social functioning are particularly vulnerable.

Rehabilitation programmes that consider and aim to improve emotional and social functioning post total laryngectomy are essential and may be particularly beneficial for women. Providing adequate information about the long-term consequences of total laryngectomy in a timely manner -not just before the surgery- may help reduce such worries. Counselling and other treatments for depression need to be available to patients. Efforts to promote social integration and maximise social support, particularly for those who rate theirs as low, may improve outcomes for this population. Such efforts may include, for example, more targeted support and advice to friends and relatives of the laryngectomee; facilitation to pursue activities of choice; and more active promotion of peer support groups.

Finally, quality of life is multi-factorial and is affected by the complex combination of characteristics that make each individual unique (Brown & Doyle, 1999). With this in mind, it becomes increasingly apparent that there is a need to consider each individual patient's perspective, opinions and needs in all types and stages of treatment.

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Table 1: Participant characteristics

Characteristic		Males (n=22) n (%)	Females (n=21) n (%)
Age	Mean	69.6	65.6
	Range	52-81	49-84
Living arrangements*	Alone	3 (13.6)	12 (57.1)
	Spouse	19 (86.4)	9 (42.9)
Years post operative	1<3	2 (9.1)	5 (23.8)
	3 – 5	9 (40.9)	5 (23.8)
	>5 – 10	7 (31.8)	5 (23.8)
	>10	4 (18.2)	6 (28.6)
	Range	1.02 – 15.09	1.04 – 56.03
Years post medical treatment	Ongoing (SLT)	2 (9)	5 (24)
	< 3	6 (27)	5 (24)
	3 – 5	7 (32)	3 (14)
	>5	7 (32)	8 (38)
Employment	Before surgery: no	13 (59)	9 (43)
	yes	9 (41)	12 (57)
	After surgery: no	15 (68)	17 (81)
	yes	7 (32)	4 (19)
	Change*: no	20 (91)	13 (62)
	yes	2 (9)	8 (38)
Communication method	Non verbal	3 (14)	1 (5)
	Surgical voice restoration	15 (68)	10 (48)
	Oesophageal Speech	2 (9)	7 (33)
	Electrolarynx	2 (9)	3 (14)

*p<.05

Table 2: Global Health Status/QOL and Functional Scale scores of EORTC QLQ-C30

Type	Males (n=22)		Females (n=21)	
Functional Scales	Mean	SD	Mean	SD
Global Health Status/ QoL*	76.5	17.2	65.7	20.6
Physical**	84.9	18.3	71.4	18.9
Role	81.1	22.6	71.4	32.9
Emotional**	87.9	16.0	65.1	21.8
Cognitive*	90.1	12.2	78.6	22.4
Social*	70.5	24.1	50.8	32.3

*p<.05

**p≤.01

Table 3: Symptom Items of EORTC QLQ-C30

Type	Males (n=22)		Females (n=21)	
Symptom Items	Mean	SD	Mean	SD
Fatigue	20.2	17.0	31.2	24.0
Nausea / vomiting	6.8	19.0	11.1	24.3
Pain	12.1	18.7	17.5	26.6
Dyspnoea	24.2	31.2	39.7	32.6
Insomnia*	18.2	24.6	34.9	28.8
Appetite loss	15.1	22.4	17.5	27.1
Constipation	16.7	26.7	19.0	34.3
Diarrhoea	6.1	13.1	4.8	11.9
Financial difficulties*	10.6	15.9	23.8	23.9

*p≤.05

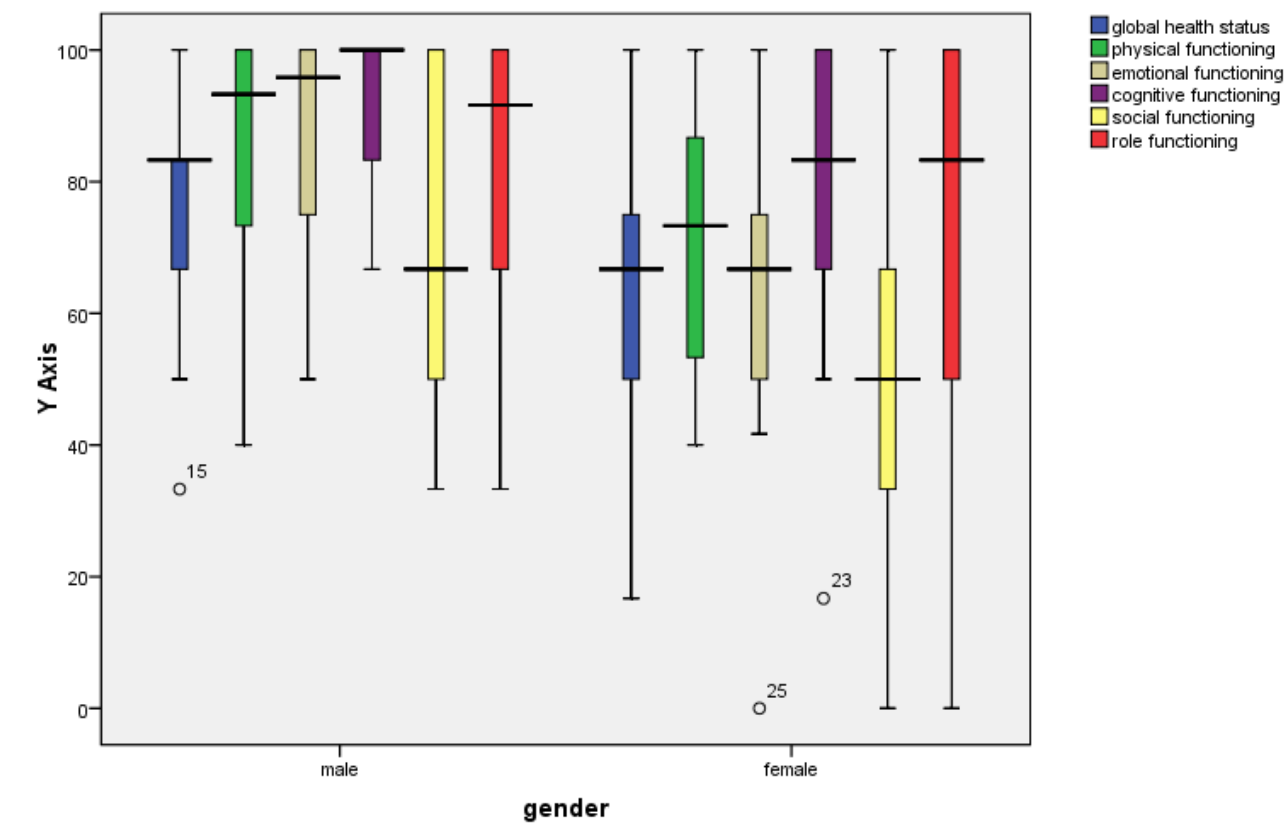
Table 4: Symptom Items for EORTC QLQ-H&N35

Type	Males(n=22)		Females(n=21)	
Symptom Items	Mean	SD	Mean	SD
Pain	9.1	11.8	8.7	13.3
Swallowing	15.9	20.09	15.5	22.8
Senses problems	61.4	31.4	56.3	31.8
Speech problems	34.4	27.2	40.2	28.8
Social eating trouble	20.5	25.6	28.2	31.7
Social contact trouble	21.2	24.3	35.9	30.2
Less sexuality**	48.5	42.1	83.3	29.8
Teeth	18.2	36.7	7.9	17.9
Opening mouth	15.2	28.6	15.9	24.9
Dry mouth	15.2	24.6	30.1	34.8
Sticky saliva	18.2	24.6	28.6	36.9
Coughing	39.4	22.2	50.8	37.5
Felt ill	6.1	13.1	9.5	21.5
Painkillers*	22.7	42.9	57.1	50.7
Nutritional	18.2	39.5	20.6	40.1
supplements	4.6	21.3	0.0	0.0
Feeding tube	0.0	0.0	19.1	40.2
Weight loss*	22.7	42.9	28.6	46.3
Weight gain				

*p<.05

**p<.01

Figure 1: Graphic representation of global health status/QOL and functional scale scores of EORTC QLQ-C30



Y axis: EORTC QLQ-C30 scale scores