

ORIGINAL RESEARCH

Interaction of functional and participation issues on quality of life after total laryngectomy

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Abstract

Objective: Total laryngectomy (TL) leads to lifelong physical changes which can lead to functional and participation issues. To assess the relationship between self-reported quality of life and functional and participation issues, a large international online questionnaire was used.

Method: A questionnaire was sent out to 8119 recipients of whom 1705 (21%) responded. The questionnaire consisted of 26 questions regarding demographic information, product use of the respondents, experienced overall health and independence, and functional and participation issues. Respondents were grouped based on sex, age, time since TL, educational level, and country of residence. Questions were grouped in one measure of reported quality of life (r-QoL) and seven issue themes ("esthetic issues," "experienced limitations in daily activities," "avoiding social activities," "communication issues," "experienced vulnerability due to environmental factors," "pulmonary issues," and "sleep issues") to assess the underlying relations.

Results: This study showed that more functional and participation issues and a lower r-QoL are reported in the group of younger respondents (<60 years), women, and respondents who have had the TL procedure less than 2 years ago. The issue themes "experienced limitations in daily activities" and "avoiding social activities" are related to r-QoL. Most participants report "pulmonary issues," and these issues have a strong correlation with most other themes.

Conclusion: The ability to participate in meaningful and social activities is a major factor in r-QoL. Due to the frequency and strong correlations of pulmonary issues with other issue themes, pulmonary issues might be an underlying cause of many other issues.

Level of evidence: 3b

KEYWORDS

participation, quality of life, rehabilitation, self-reported issues, total laryngectomy

Klaske E. van Sluis and Maartje Leemans share first authorship.

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1 | INTRODUCTION

A total laryngectomy (TL) leads to lifelong changes in physical, psychological, and social functioning, severely impacting the patients' normal daily functioning and quality of life (QoL). First of all, due to the removal of the larynx, one of the immediate consequences is that the patient loses his ability of laryngeal speech. The fact that patients now breathe through a tracheostoma instead of their nose or mouth can lead to pulmonary problems, such as coughing, dyspnea, excessive mucus production, forced expectoration, and stoma cleaning.¹⁻⁶ A total laryngectomy can also lead to other functional problems such as difficulties in swallowing, olfaction, sleeping difficulties, fatigue, and pain in throat and neck.^{4,6,7}

The functional consequences of the TL procedure also impact the patient's self-image, which can lead to psychological problems such as anxiety and depression,^{4,5,8,9} and reduced sexuality.^{7,10-12} Last, due to the visible scarring and difficulties with communication it can lead to worsened social interactions and participation.^{4,5,7,13}

To help total laryngectomized patients rehabilitate their lost functions, in particular their pulmonary condition and speech, multiple medical devices have been developed in the last few decades. The most important medical devices include the voice prosthesis, and the heat and moisture exchanger (HME) with various fixation methods. It has been proven that HMEs reduce pulmonary issues, such as coughing and mucus production, and improve other related functional issues such as voice and sleeping.¹⁴⁻¹⁸ To restore speech and voice, tracheoesophageal speech generated with the help of a voice prosthesis has become the "gold standard" in the many parts of the world.¹⁹

To ensure an optimal rehabilitation and QoL for each patient, an understanding of possible consequences of the TL procedure and the correlation of self-reported participation and functional issues can provide a unique insight. Atos Medical AB (Malmö, Sweden), with help of ReD Associates (Copenhagen, Denmark), a strategy consultancy company, recently send out a questionnaire to Atos Medical clients from different countries to investigate the hidden needs and complaints of total laryngectomized patients. We were able to use the obtained responses for our analysis. Thus, with the aforementioned physical and social consequences of the TL procedure in mind, we developed the following research question:

What relation exists between demographic characteristics and reported-quality of life (r-QoL) ratings of total laryngectomized individuals and their self-reported participation and functional issues?

2 | MATERIALS AND METHODS

2.1 | Questionnaire

An online questionnaire was developed by Atos Medical AB (Malmö, Sweden) and ReD Associates (Copenhagen, Denmark) with input from the Netherlands Cancer Institute. The scope of the questionnaire was

to assess the impact of TL on daily life and examine the use of medical devices, experienced functional and participation issues, and possible hidden needs regarding medical devices for the rehabilitation after TL. A pilot version of the questionnaire was sent via email by Atos Medical AB to a cohort of 250 TL clients in the United States of America, with a response rate of 12%. Based on the pilot, adjustments were made. The final version of the online questionnaire consisted of 26 main questions regarding demographic information (not obligatory) and product use of the respondents, experienced overall health and independence, and experienced functional and participation issues. The final questionnaire was sent out via email by Atos Medical AB to 8119 clients in nine countries; the United Kingdom, United States, Germany, France, Sweden, the Netherlands, Brazil, Italy, and Spain. All approached Atos Medical clients were treated with TL and older than 18 years. One reminder-email was sent out and the questionnaire was available online for 3 weeks. The data were collected by ReD Associates, and made available to the Netherlands Cancer Institute.

2.2 | Statistical analysis

The responses of the questionnaire were analyzed anonymously by the Netherlands Cancer Institute using the statistical package R (version 3.5.1.). Respondents from the pilot study ($n = 29$) were excluded from the analysis, resulting in a cohort of $n = 1705$. As primary outcome measure the relation between the reported quality of life (r-QoL) ratings and the reported participation and functional issues was tested. As secondary outcome measure the relations between demographics and participation and functional issues were tested. A linear model was selected with the "step" function (setting direction "both") in R using the Bayesian information criterion.²⁰ The relative importance of the themes was determined with the "calc.relimp" function (setting type "first").²¹

2.3 | Grouping of respondents

For the analysis of the primary and secondary outcomes, the respondents were grouped. The grouping was based on:

- Sex: male vs female
- Age: <60 years of age vs 60+ years of age. In the questionnaire, the respondents were asked to indicate their age through a choice between five decade age brackets. The age brackets were simplified in our analyses to just two age groups, roughly representing the "pre-retirement" age group and "post-retirement" age group.
- Time since TL: <2 years since TL vs 2+ years since TL. This grouping was based on clinical experts consensus that the most initial rehabilitation issues of the TL procedure are resolved within 2 years.
- Educational level: respondents without tertiary education (defined as an educational degree after High School) vs respondents with tertiary education.

- Country of residence: country specific analyses were only performed for countries with a response rate of >5%. The countries Sweden, Brazil, and Spain were therefore excluded in this specific analysis.

2.4 | Grouping of questions

Because this questionnaire was not based on validated QoL scales or validated questionnaires, we performed a clustering of semantically related questions into general issue themes. Because some questions could belong to multiple themes, the semantic clustering of questions was based on the experience of the clinical experts (K. E. v S. and M. W. M. vd B.), discussed in multiple consensus meetings.

The self-reported ratings of overall health and independence (both rating scales from 0 to 10) were combined to one sum measure: the reported r-QoL rating (scale from 0 to 20). In this article, the term r-QoL is used to refer to this combined measure of the following two specific scale questions:

“How would you rate your overall health from 0 to 10? 0 means worst imaginable health state, 10 means best imaginable health state”

“On a scale from 0 to 10, how independent do you feel in completing the activities you want? 0 means the least imaginable independence in completing the activities you want, 10 means the most imaginable independence in completing the activities you want”

The internal correlation between these two scale questions is $R^2 = .366$ (percentage of variance explained).

Clustering of related self-reported participation and functional issues questions was performed into the following general issue themes (see Supporting Information Appendix A for an overview of the grouped questionnaire per theme):

- Esthetic issues (5 yes-no questions)
- Experienced limitations in daily activities (9 yes-no questions)
- Avoiding social activities (2 yes-no questions)
- Communication issues (4 yes-no questions)
- Experienced vulnerability due to environmental factors (7 yes-no questions)
- Pulmonary issues (14 yes-no questions)
- Sleep issues (3 yes-no questions)

2.5 | Average number of reported experienced issues per theme

The average number of reported issues per patient per theme (as a percentage of the maximum number of questions of that theme), and the influence of the grouping of respondents on the number of

reported experienced issues is presented. This approach was chosen to make the themes mutually comparable on the basis of seriousness, since the average weight per issue is not linear and the number and content of issue questions per theme were different.

TABLE 1 Demographic characteristics of respondents

Characteristic		No. (%)
Countries	United Kingdom	159 (9)
	United States	786 (46)
	Germany	98 (6)
	France	342 (20)
	The Netherlands	184 (11)
	Italy	79 (5)
	Sweden	43 (3)
	Brazil	10 (<1)
	Spain	4 (<1)
Sex ^a	Male	1361 (80)
	Female	263 (15)
Age (y) ^a	<60	296 (17)
	60+	1328 (78)
Time since TL (y)	<2	336 (20)
	2-5	568 (33)
	5-10	392 (23)
	>10	294 (17)
	No answer	115 (7)
Employment status ^a	Retired	1124 (66)
	Full-time	183 (11)
	Part-time	108 (6)
	Occasionally	0 (0)
	Unpaid work	62 (4)
	Seeking work	33 (2)
	Not seeking work	114 (7)
	No answer	0 (0)
Education	No High School	113 (7)
	High School	508 (30)
	Occupational	411 (24)
	University	617 (36)
	No answer	56 (3)
Level of tertiary education (defined as an educational degree after High School)	Total	1028 (62)
	United Kingdom	105 (67)
	United States	519 (68)
	Germany	50 (54)
	France	215 (67)
	The Netherlands	76 (43)
	Italy	32 (43)

Note: Total number of respondents $n = 1705$. Respondents of which we obtained the complete demographic information $n = 1624$ (including sex, age, and employment status).

Abbreviation: TL, total laryngectomy.

^aA small number of respondents ($n = 81$) did not consent to provide this (personal) demographical information.

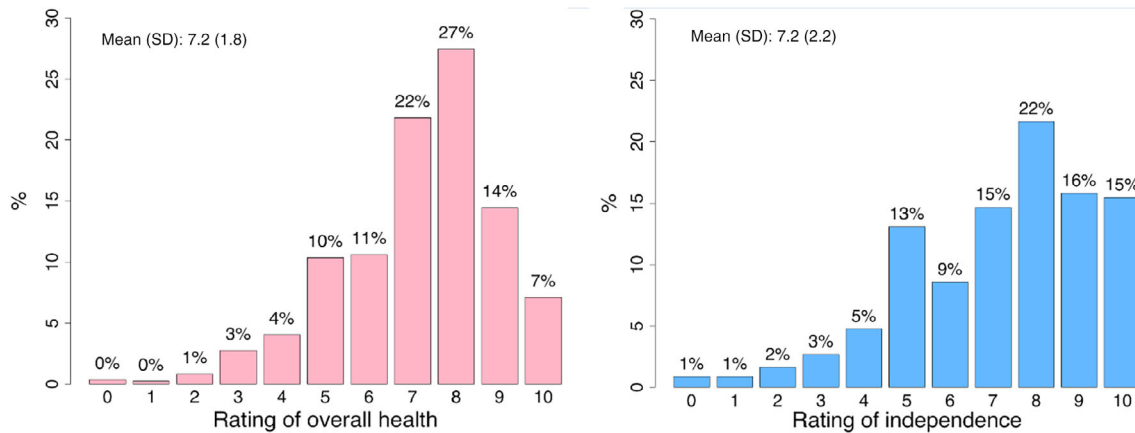


FIGURE 1 Distribution of the self-reported rating of overall health and independence (the score of 0 is the worst imaginable situation, the score of 10 is the best imaginable situation). Due to rounding off, the sum does not add to 100%

3 | RESULTS

3.1 | Respondents

The demographic characteristics of the respondents are shown in Table 1. In total, 1705 clients completed the questionnaire (response rate of 21%), of which the majority were from United States, France, The Netherlands, United Kingdom, Germany, and Italy. A minority of the respondents were from Sweden, Brazil, and Spain. Of 1624 respondents, we obtained the complete demographic information, including the more personal information, such as sex, age, and employment status ($n = 81$ respondents did not give consent to provide this information). Type of voice rehabilitation was not in the scope of this questionnaire. Most respondents are male (male-to-female ratio 5:1) with a median age in the 60-69 bracket, and have had their TL procedure in the last 5 years (median 5 years ago). The distribution of age between countries is very comparable. The education level of the respondents, however, varies between countries, with 68% of respondents having tertiary education in the United States, vs only 43% of respondents in the Netherlands and Italy.

3.2 | r-QoL rating

Figure 1 shows the distribution of the two separate rating scales (scale 0-10) of which this combined r-QoL rating consists; a score of 7 (out of 10) or higher was given by more than 50% of the respondents for their overall health and independence. Age and time since TL procedure have a significant influence (a negative relation $p = .004$, and a positive relation $p < .001$, respectively) on the overall health rating and time since laryngectomy has a significant influence on the independence rating (negative relation $p \leq .001$).

Since the overall health and independence ratings have a high internal correlation and were combined to one sum measure, from now on they will be represented as one outcome measure r-QoL. The average combined r-QoL rating is 14.4 (scale 0-20). It appears

that respondents under 60 years of age and who have had their TL procedure less than 2 years ago at the time of the questionnaire rate their r-QoL much lower. Sex, educational level, and country of residence did not have a significant influence ($p > .05$) on the r-QoL rating.

3.3 | Average number of reported experienced issues per theme

Figure 2 shows the average percentage of reported issues per patient per theme (as a percentage of the number of questions in that theme), and the influence of the grouping of respondents on the number of reported issues. The figures do not represent the percentage of respondents that experiences these issues, but the percentage of specific issues within the theme that an average respondent will have experienced or encountered. Because the results are averaged over a large group of respondents, it gives a sensitive comparison method. See Supporting Information Appendix A for an overview of the grouped questionnaire questions per theme and their response rate. Educational level and country of residence did not have a significant influence ($p > .05$) on the experienced issues per theme and were therefore excluded from the presentation of the results. Sex, age, and time since TL procedure do all have an influence on the number of experienced issues of almost all themes. In general, younger respondents (<60 years), especially women, who have had the TL procedure less than 2 years ago, are uniquely disadvantaged in terms of reported participation and functional issues.

3.4 | Correlations between r-QoL rating and themes

The correlations between different themes, representing overarching issues, and the r-QoL can be found in Table 2 and Figure 3. To illustrate, as seen in Table 2 ~29% of the variance (R^2) in the r-QoL ratings

can be explained by the reported issues in the themes “experienced limitations in daily activities” (71% of the 29%) and “avoiding social activities” (29% of the 29%).

However, the theme “pulmonary issues” seems to play an important role and has a significant correlation to most other themes: ~41% of the variance (R^2) can be explained by the reported issues in the themes “experienced limitations in daily activities” (22% of the 41%), “avoiding social activities” (10% of the 41%), “communication issues” (16% of the 41%), “experienced vulnerability

due to environmental factors” (20% of the 41%), and “sleep issues” (32% of the 41%).

The significance of the pulmonary issues can be illustrated by the fact that of the specific included questions within this “pulmonary issues” theme, for example 89% of the respondents report they have to clean out mucus from their stoma or HME several times a day (see Supporting Information Appendix A, 7.5.), and 47% of the respondents experience frequent coughing during the day (see Supporting Information Appendix A, 7.1.).

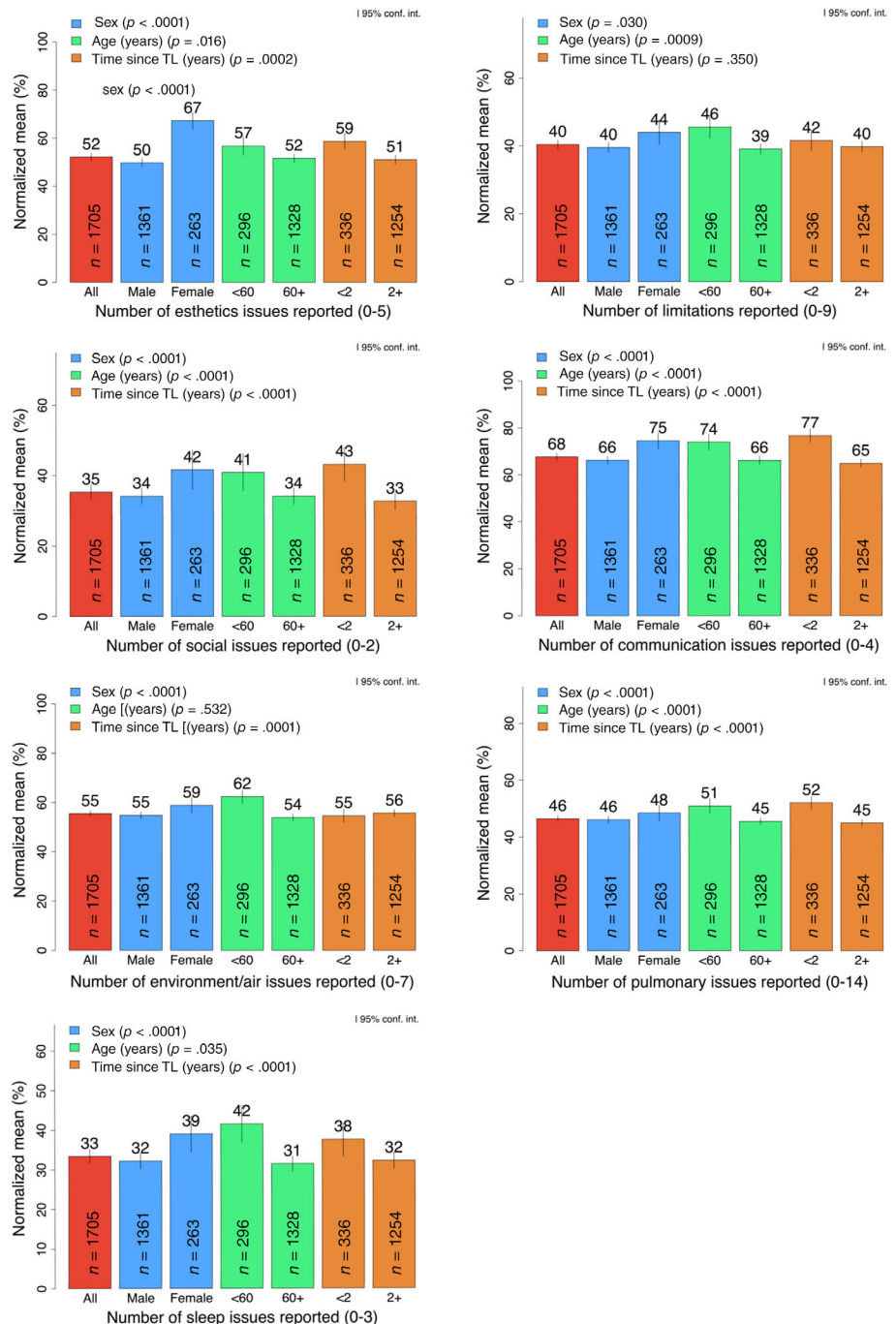


FIGURE 2 The influence of the grouping of respondents on the average percentage of reported issues per respondent per theme. The specific grouping of respondents does not add up to the total number of respondents: missing data in the “time since TL” ($n = 115$ respondents gave “no answer”), “sex” and “age” ($n = 81$ respondents did not give consent to provide this personal information). r-QoL, reported quality of life; TL, total laryngectomy

TABLE 2 Correlations between themes and r-QoL

Theme	Influence on variance (%) % of theme variance (R^2) explained by other themes	Relative importance, sum 100%							
		r-QoL	Esthetic issues	Experienced limitations daily activities	Avoiding social activities	Communication issues	Experienced vulnerability due to environ. factors	Pulmonary issues	Sleep issues
r-QoL	29	X		71	29				
Esthetic issues	4		X		40	60			
Exp. limitations in activities	39	41		X	20			25	14
Avoiding social activities	25		7	46	X	26		21	
Communication issues	20		10		37	X		53	
Exp. vulnerability environ.	18		6				X	60	34
Pulmonary issues	41			22	10	16	20	X	32
Sleep issues	25				15			85	X

Note: Due to the type of analysis, the correlations are not symmetrical. Abbreviation: r-QoL, reported quality of life.

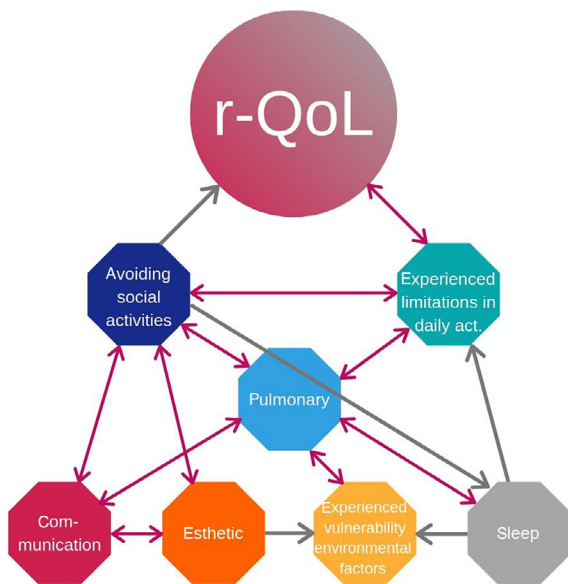


FIGURE 3 Correlations between themes and r-QoL. The single arrows indicate a one-way correlation (e.g. “esthetics issues” only has an influence on the variance of the “experienced vulnerability due to environmental factors,” but not vice versa), the double arrows indicate an asymmetrical interdependent correlation. r-QoL, reported quality of life

4 | DISCUSSION

This study presents a large sample of total laryngectomized respondents from multiple countries, examining both a large range of participation and functional issues and r-QoL. The study data is unique and relevant, nevertheless the study lacks validated measures as well as respondents' information regarding, for example, marital status and type of voice rehabilitation. To reduce this limitation of the use on a non-validated questionnaire, the method of semantic clustering of questions was used,

comparable to validated QoL questionnaires (e.g. EORTC-C30).²²⁻²⁴ Clustering of both questions in r-QoL seems feasible since it is known that independence is an attribute of the concept QoL.^{23,24}

The demographic characteristics of the respondents (the distribution of age, sex, educational level, and time since laryngectomy) were comparable to other studies and correspond to the characterization of “the average total laryngectomized person” as a middle-aged man (around 65 years old, male-to-female ratio of ~6:1).^{13,25-29}

Outcomes of the rating scales regarding overall health and independence both had an average rating of 7.2 (on a scale 0-10). These two ratings are both notably high, since a TL procedure is usually associated with a lower QoL rating and depressive symptoms.^{13,30} However, retrospective study set-ups like this questionnaire tend to have a larger inclusion of nonproblematic patients than prospective studies, and thus, more positive results (e.g. a more positive r-QoL rating).³⁰ However, the distribution of the independence rating is disconcerting: for example, 25% of respondents rate their independence a score of 5 or lower, which can be interpreted as being unable to participate in many daily activities.

Our study shows that respondents who were <2 years since TL, and respondents <60 years old in general report a lower r-QoL rating. For almost all the issue themes, sex, age, and time since laryngectomy have a significant influence on (the number of) experienced participation and functional issues. Therefore, younger respondents (<60 years), especially women, and those who have had the TL procedure less than 2 years ago, seem to be uniquely disadvantaged in terms of r-QoL ratings and reported participation and functional issues.

The influence of age, sex, and time since TL procedure have also been underlined by other studies. Age as an influencing factor on r-QoL is supported by multiple studies reporting that indeed younger total laryngectomized patients experience a higher psychological distress, impacting their coping, since younger patients may have a better preoperative baseline functional status and activity level.^{4,31,32}

Time since laryngectomy as an influencing factor on reported issues has been supported by multiple papers: on average the reported problems decrease over time.^{5,33} The fact that after the first 2 years after the TL procedure the r-QoL improves, shows that rehabilitation and coping can be effective, but take several years. Earlier studies have shown that gender differences are present in reported issues after TL. Women are inclined to experience more post-operative complaints, and issues with social interaction due to stigmatization.^{4,31,34}

The “pulmonary issues” seem to have a strong correlation to most other themes. Therefore these pulmonary issues might be partially responsible for other reported issues.⁵ Although reported less frequently, the issues from the two themes “avoiding social activities” and “experienced limitations in daily activities” are the main influencers of the variance in r-QoL. Thus, the ability to fulfill meaningful activities seems to have a greater impact on r-QoL than the purely physical consequences of TL in general. The inclusion of the independence rating in the r-QoL rating could have introduced a bias in the correlation analysis. The concept QoL includes development and improvement of life (adapting to changed health condition and finding new meaning), independence, achievement of goals and aspirations, and autonomy.²²⁻²⁴

The study design has its limitations. The response rate was 21%; the questionnaire was sent via email and was shortly available online. Non-response bias might be present and can cause a bias in how well the data represents the actual total laryngectomized population. Additionally, the respondents of this questionnaire were all clients of Atos Medical AB. The selection bias concerns patients most likely using voice prostheses and/or HMEs, education level and internet use overall and across countries, financial status, and insurance or reimbursement systems between countries.³ It is likely that Atos Medical clients with a higher age or lower educational level were less well reached with this online questionnaire in certain countries. This could explain the differences in education level between countries as well as the relatively high education level in this questionnaire.

5 | CONCLUSION

Younger respondents (<60 years), especially women, and those who have had the TL procedure less than 2 years ago, seem to be uniquely disadvantaged in terms of r-QoL ratings and reported participation and functional issues. The experienced limitations in daily activities and avoiding social activities are associated with decrements in the respondents' r-QoL rating. The r-QoL rating is mainly influenced by the ability to do meaningful activities, and less by purely physical consequences of TL. Most issue themes are interdependently correlated. The theme “pulmonary issues” seems to have a strong correlation with most other themes and is key in most other reported issues. Therefore, pulmonary issues might be an underlying cause of many other issues, including experienced limitations in daily activities and avoiding social activities. To improve clinical practice, it is recommended to adequately prepare and monitor patients regarding their participation in social activities, meaningful activities, and pulmonary issues to enhance their QoL.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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