Original Article

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Translation and validation of the Tonsillectomy Outcome Inventory 14 into Danish

Hannah Inez Houborg & Tejs Ehlers Klug

Department of Otorhinolaryngology, Head and Neck Surgery, Aarhus University Hospital, Denmark

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ABSTRACT

INTRODUCTION. No Danish validated patient-reported outcome measure (PROM) exises for assessing throat-related quality of life in patients with recurrent acute tonsillitis (RT) and chronic tonsillitis (CT). We aimed to translate and linguistically validate the Tonsillectomy Outcome Inventory 14 (TOI-14) into Danish and describe scores in RT and CT patients before and after tonsillectomy as well as in healthy controls.

METHODS. We followed the guideline for PROM translation and cultural adaption set out by the Quality of Life Special Interest Group - Translation and Cultural Adaptation group formed by ISPOR. We included RT and CT patients undergoing elective tonsillectomy, who answered the questionnaire pre- and post-operatively (six-month follow-up) as well as healthy controls who answered the questionnaire once.

RESULTS. A Danish version of the TOI-14 was developed according to the guideline. A total of 49 RT patients, 34 CT patients and 67 controls were included in the final analysis. Preoperatively, RT and CT patients had markedly higher TOI-14 scores than controls (mean total scores: RT: 45.6; CT: 21.7; controls: 8.9, both p < 0.001). Post-operatively, scores fell to levels similar to those of controls (RT: 10.2, p = 0.51; CT: 4.7, p = 0.05).

CONCLUSION. We translated, culturally adapted and linguistically validated the Danish version of the TOI-14, finding scores in RT patients, CT patients and controls similar to those recorded by previous studies in German, English and Finnish.

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Recurrent acute tonsillitis (RT) and chronic tonsillitis (CT) are among the most prevalent throat-related diseases in teenagers and adults. Both diagnoses are associated with a significant disease burden and affect patients' wellbeing for long periods. The only treatment for these conditions is tonsillectomy; one of the most frequently performed surgical procedures in Denmark and world-wide [1].

Tonsillectomy aims to minimise tonsillitis-related symptoms and accompanying problems. Many outcome measures have been used to assess the disease burden: the number of acute tonsillitis episodes, doctor visits, antibiotic treatments and days of sick leave. More recently, quality of life (QOL) has gained increasing recognition in the evaluation of surgical interventions. Patient-reported outcome measures (PROMs) are paramount in measuring QOL as they include patients' subjective assessment. Hence, it is important to develop

reliable QOL measurement tools. In otorhinolaryngology, the most commonly used PROM is the generic Glasgow Benefit Inventory [2], but a more customised tool is needed for assessing the benefits of tonsillectomy in patients suffering from tonsillar disease. Here, the Tonsillectomy Outcome Inventory 14 (TOI-14) [3], originally developed in German for adults suffering from CT and/or RT, is becoming one of the leading PROMs in this field.

Currently, there is no validated Danish PROM for assessing throat-related QOL (TR-QOL). Our aim was to translate and linguistically validate the TOI-14 into Danish. In addition, we aimed to describe the TOI-14 scores in RT and CT patients before and after tonsillectomy as well as in healthy controls to support the validity of the TOI-14 and to provide comparative data for future studies.

METHODS

The Tonsillectomy Outcome Inventory 14

The TOI-14 is used pre- and post-operatively to detect changes in TR-QOL. It consists of 14 questions covering four subscales: throat discomfort (questions 1-4), general health (questions 5-6), resources (questions 7-10) and social psychological restrictions (questions 11-14). The questionnaire uses a six-point Likert scale with 0 representing "no problem" and 5 representing "couldn't be worse" [4]. The points are summed, divided by the number of questions, multiplied by five and multiplied by 100, giving scores in the 0-100 range [5]. Higher scores reflect poorer QOL.

Translation and validation

Several guidelines on PROM translation have been developed [6-8]. This study followed the principles set out by the Quality of Life Special Interest Group - Translation and Cultural Adaptation Group formed by ISPOR [9]. Our Results section mirrors their recommended ten-step guideline for PROM translation and cultural adaption.

Study participants

Patients aged \geq 15 years undergoing elective tonsillectomy due to RT or CT at Randers Regional Hospital and Aleris-Hamlet Private Hospital in Aalborg and Aarhus from February to June 2021 were included.

RT was defined as \geq 5 episodes of tonsillitis in one year or \geq 3 episodes of tonsillitis per year in two consecutive years. CT was defined as constant or intermittent throat symptoms for at least three months related to tonsillar inflammation with or without tonsillar debris.

Exclusion criteria were: partial tonsillectomy (i.e. tonsillotomy), previous tonsillectomy, diseases that may affect TR-QOL (sleep apnoea; history of benign or malignant tumour in the oral cavity, the pharynx or the larynx; previous radiation therapy on the head or neck) and inability to answer questionnaires in Danish.

Patients completed the TOI-14 preoperatively on the day of surgery and six months after surgery. The questionnaires were delivered electronically via e-mail through REDCap.

Fifth-year medical students from Aarhus University were asked to participate as healthy controls in May 2022. The exclusion criteria were the same as for patients. Controls answered the TOI-14 once.

Tonsillectomy

Patients underwent elective extracapsular removal of both palatine tonsils under general anaesthesia using cold knife dissection. Haemostasis was achieved by compression and bipolar coagulation.

Statistical methods

Comparisons were made using Student's t-test for continuous data and Fisher's exact test for categorical data.

Statistical significance was defined as p < 0.05.

Registration

The study was registered as a research project at the Central Denmark Region (-16-02-723-20). According to Section 14 of the Danish National Committee on Health Research Ethics Law, questionnaire studies do not require ethical approval.

Trial registration: Central Denmark Region -16-02-723-20.

RESULTS

1. Preparation

Permission to use the questionnaire was given by the TOI-14 developer group. A conceptual approach was chosen. The concepts of the questionnaire were clarified by the project manager (HH) and the key in-country consultant (TK). It was decided to validate the questionnaire for adults (aged \geq 15 years) with special attention to younger adults (15-25 years) who have the highest prevalence of RT and CT [1]. The questionnaire should be used before and after elective tonsillectomy to quantify changes in TR-QOL.

2. Forward translation

Two forward translators were chosen, both native Danish speakers living in Denmark and fluent in German. Both translators have experience in translating PROMs. One translator has a medical background. The translators were informed of the concepts of the questionnaire and the target group and were asked to do a conceptual translation.

3. Reconciliation

This step was performed by the project manager, the key in-country consultant and a forward translator. The forward translations were compared and the panel agreed on a common version. The following elements were noteworthy deviations from the original version (**Figure 1**):

		Intet problem	Meget lille problem	Lille problem	Middelstort problem	Stort problem	Det kan ikke blive værre
1)	Tør hals	0	0	0	0	0	0
2)	Sejt sekret (slim) i halsen	0	0	0	0	0	0
3)	Halssmerter	0	0	0	0	0	0
4)	Synkebesvær	0	0	0	0	0	0
5)	Sygdomsfølelse	0	0	0	0	0	0
6)	Nedsat kropsliv arbejdsevne (arbejde/daglige gøremål)	0	0	0	0	0	0
7)	Hyppighed af lægebesøg	0	0	0	0	0	0
8)	Omkostninger ved lægebesøg (transport, mistet arbejde osv.)	0	0	0	0	0	0
9)	Hyppighed af antibiotikum (f.eks. penicillin)	0	0	0	0	0	0
10)	Omkostninger ved medicin	0	0	0	0	0	0
11)	Passe arbejde/skole på grund af halsbetændelser/halsgener	0	0	0	0	0	0
12)	Nedsat deltagelse i begivenheder eller aktiviteter på grund af halsgener	0	0	0	0	0	0
13)	Færre sammenkomster med venner/familie på grund af halsgener	0	0	0	0	0	0
14)	Tristhed på grund af hyppige halsbetændelser/halsgener	0	0	0	0	0	0

1) In item 2, we added "slim" (= mucus) after "sekret" (= secrete) as a lay Dane might not understand the original wording.

2) In item 6, we added "arbejde/daglige gøremål" (= work/daily activity) after "arbejdsevne" (= physical capacity) as a lay Dane might interpret this term as related only to professional work rather than general physical capacity.

3) In item 8, we added the examples "transport, mistet arbejde osv." (= transportation, lost workdays etc.) to clarify which extra costs the item refers to as healthcare is free of charge in Denmark.

4) In item 9, we added the example "f.eks. penicillin" (= e.g., penicillin) as a lay Dane might not know what antibiotics means.

5) In items 11-14, we decided not to use first person pronouns as in the original version. The change from a short sentence structure (items 1-10) to first person sentences (items 11-14) was deemed inconsistent and unnecessary.

6) In item 11, "berufliche Probleme" (= professional problems) was translated to "problemer med arbejde/skole" (= problems with work/school) as we found that the intention was to quantify problems attending paid work as well as school. We wanted to eliminate the risk of misunderstanding the item as only referring to paid labour since a young lay Dane may be either a student or an employee.

7) In item 12 and 14, we decided to add "/halsgener" (= throat problems) after "halsbetændelse" (= throat infection) to include the impact from throat problems in a wider sense than just the impact from verified throat infections, which is how a lay Dane might interpret the literal translation.

8) In question 12, we translated "öffentlichen Veranstaltungen" (= public events) to "begivenheder eller aktiviteter" (= events or activities) as a lay Dane might interpret the literal translation as referring to formal events only.

4. Back translation

Three back translators were chosen, all native German speakers living in Denmark and fluent in Danish. All were unacquainted with the original version. The translators were instructed to do a conceptual back translation.

5. Back translation review

The project manager and the key in-country consultant performed a review of the back translations. All were deemed acceptable as deviations from the original version could be explained by the choices made in step 3.

6. Harmonisation

This step was deemed irrelevant as we only translated the questionnaire into one language.

7. Cognitive debriefing

The key in-country consultant interviewed eight patients from the target group (four RT and four CT patients, age range: 15-33 years, equal gender distribution) to assess the comprehensibility of the translation. Patients were asked to point out items that were difficult to understand and, if so, suggest a different phrasing, and to judge the relevance of each item. All patients found all items relevant and easy to understand and had no suggestions for linguistic improvements.

8. Review of cognitive debriefing results and finalisation

The project manager and the key in-country consultant reviewed the results from step seven and found that no changes were required for the final version.

9. Proofreading

Proofreading was performed by the key in-country consultant.

10. Final report

The final report was written by the project manager and the key in-country consultant and is reported in this document. The final version is presented in Figure 1.

Study participants

A total of 46 RT patients, 35 CT patients and 67 healthy controls matched the inclusion criteria and were invited to participate. Two patients declined participation. Among the included 45 RT and 34 CT patients, one RT patient was excluded due to a misunderstanding regarding the time frame. Three RT patients were lost to follow-up. Hence, 41 RT patients (91%), 34 CT patients (100%) and 67 controls (100%) were included in the final analysis.

Controls (mean age 26.7 years) were older than RT patients (23.0 years, p = 0.001, Student's t-test) and younger than CT patients (31.6 years, p = 0.006) (**Table 1**). RT and CT patients had a higher prevalence of smokers/previous smokers (41% and 32%, respectively) than controls (4%) (both p < 0.001, Fisher's exact test). RT and CT patients had suffered from tonsillar symptoms for long periods of time (median 48 and 54 months, respectively). RT patients had endured a considerable mean number of tonsillitis episodes during the previous 12, 24 and 36 months (6.3, 10.8, and 14.1, respectively).

TABLE 1 Characteristics of patients with recurrent acute tonsillitis, chronic tonsillitis, and controls.

	RT patients	CT patients	Controls	p value, patients vs controls		
	(Nrt = 41)	(Nct = 34)	(Nco = 67)	RT patients	CT patients	
Age, mean (95% CI), yrs	23.0 (20.3-25.6)	31.6 (26.8-36.5)	26.7 (26.0-27.4)	0.001ª	0.006ª	
Females, n (%)	28 (68)	26 (76)	42 (63)	0.679 ^b	0.185 ^b	
Tobacco, n (%)				< 0.001 ^b	< 0.001 ^b	
Smoker	14 (34)	4 (12)	0			
Previous smoker	3 (7)	7 (21)	3 (4)			
Never smoker	23 (56)	23 (68)	63 (94)			
Did not wish to answer	1(2)	0	1(1)			
Duration of symptoms, median (range), mos.	48 (9-480)	54 (12-780)	-	-	-	
Tonsillitis episodes, mean (95% Cl), n			-	-	-	
Previous 12 mos.	6.3 (5.4-7.2)	0.6 (0.2-1.0)				
Previous 24 mos.	10.8 (9.4-12.2)	1.5 (0.7-2.3)				
Previous 36 mos.	14.1 (12.1-16.2)	2.2 (0.9-3.5)				

CI = confidence interval; CT = chronic tonsillitis; RT = recurrent acute tonsillitis.

a) Student's t-test.

b) Fisher's exact test

Tonsillectomy Outcome Inventory 14 scores

Preoperatively, RT patients had significantly higher mean scores than controls in all items, total scores and all subscores (**Table 2**). Post-operatively, no statistically significant differences were recorded between the mean scores in RT patients and controls, except for items 1 and 2, where RT patients had somewhat higher scores.

 TABLE 2 Single item and total scores of the Tonsillectomy Outcome Inventory 14 in

 patients with recurrent acute tonsillitis and chronic tonsillitis before and after tonsillectomy

 as well as in controls. The values are mean scores (95% confidence interval).

	RT patients (N _{rt} = 41)		CT patients			p valueª, patients vs controls			
			(N _{ct} = 34)		Controls	RT patients		CT patients	
	pre-op	post-op	pre-op	post-op	$(N_{co} = 67)$	pre-op	post-op	pre-op	post-op
Single items									
Item 1	2.1 (1.7-2.6)	1.0 (0.7-1.4)	2.0 (1.6-2.4)	0.5 (0.1-0.8)	0.5 (0.3-0.7)	< 0.001	0.006	< 0.001	0.791
Item 2	2.6 (2.2-3.0)	1.3 (0.9-1.7)	2.0 (1.5-2.5)	0.9 (0.4-1.4)	0.8 (0.5-1.0)	< 0.001	0.017	< 0.001	0.619
Item 3	3.3 (3.0-3.6)	1.0 (0.7-1.4)	2.0 (1.5-2.5)	0.4 (0.1-0.6)	1.0 (0.8-1.2)	< 0.001	0.904	< 0.001	0.001
Item 4	2.9 (2.5-3.3)	0.5 (0.3-0.8)	1.5 (1.0-2.1)	0.4 (0.1-0.7)	0.5 (0.3-0.7)	< 0.001	0.953	< 0.001	0.663
Item 5	2.9 (2.6-3.2)	1.0 (0.7-1.4)	1.4 (1.0-1.9)	0.3 (0.0-0.6)	0.9 (0.6-1.1)	< 0.001	0.493	0.015	0.003
Item 6	2.0 (1.5-2.4)	0.2 (0.0-0.4)	0.4 (0.2-0.7)	0.2 (0.0-0.4)	0.4 (0.2-0.6)	< 0.001	0.265	0.759	0.180
Item 7	2.0 (1.5-2.4)	0.2 (0.0-0.4)	0.6 (0.3-1.0)	0.1 (0.0-0.1)	0.3 (0.1-0.5)	< 0.001	0.474	0.092	0.060
Item 8	1.1 (0.7-1.5)	0.2 (0.0-0.4)	0.3 (0.1-0.5)	0.0 (0.0-0.1)	0.1 (0.0-0.3)	< 0.001	0.688	0.267	0.265
Item 9	2.0 (1.5-2.5)	0.2 (0.0-0.4)	0.3 (0.1-0.5)	0.1 (0.0-0.2)	0.1 (0.0-0.2)	< 0.001	0.382	0.078	0.843
Item 10	1.4 (1.0-1.8)	0.2 (0.0-0.4)	0.5 (0.2-0.8)	0.1 (0.0-0.3)	0.1 (0.0-0.2)	< 0.001	0.272	0.007	0.889
Item 11	2.3 (1.9-2.7)	0.4 (0.1-0.7)	0.8 (0.4-1.2)	0.1 (0.0-0.3)	0.4 (0.2-0.7)	< 0.001	0.749	0.075	0.067
Item 12	2.5 (2.1-3.0)	0.3 (0.1-0.5)	0.8 (0.4-1.1)	0.1 (0.0-0.2)	0.4 (0.3-0.6)	< 0.001	0.313	0.074	0.013
Item 13	2.2 (1.7-2.6)	0.2 (0.0-0.4)	0.7 (0.3-1.0)	0.0 (0.0-0.1)	0.4 (0.2-0.6)	< 0.001	0.128	0.174	0.006
Item 14	2.6 (2.1-3.0)	0.3 (0.1-0.6)	1.8 (1.3-2.4)	0.1 (0.0-0.3)	0.2 (0.0-0.3)	< 0.001	0.287	< 0.001	0.776
Total ^b	45.6 (40.6-50.5)	10.2 (7.5-13.0)	21.7 (17.0-26.4)	4.7 (2.0-7.5)	8.9 (6.3-11.6)	< 0.001	0.514	< 0.001	0.050
Subscales									
Throat discomfort	54.6 (49.6-59.7)	19.5 (15.0-24.0)	37.6 (30.5-44.8)	10.7 (5.6-15.8)	14.0 (10.4-17.7)	< 0.001	0.064	< 0.001	0.297
General health	48.5 (42.0-55.1)	12.4 (7.7-17.2)	18.8 (13.0-24.6)	4.7 (0.8-8.6)	12.7 (8.7-16.6)	< 0.001	0.937	0.078	0.011
Resources	32.6 (25.4-39.7)	4.1 (1.3-7.0)	8.5 (4.1-13.0)	1.5 (-0.2-3.2)	3.4 (1.2-5.7)	< 0.001	0.695	0.024	0.249
Social psychological restrictions	48.0 (41.0-55.1)	6.0 (2.7-9.3)	20.4 (14.2-26.7)	2.1 (-0.1-4.2)	7.5 (4.1-10.8)	< 0.001	0.551	< 0.001	0.030

CT = chronic tonsillitis; op = operatively; RT = recurrent acute tonsillitis.

b) See the Methods section for details of the calculation of the values.

Preoperatively, CT patients had significantly higher mean scores than controls in seven items (1-5, 10, and 14) (Table 2), whereas no statistically significant differences were recorded in the remaining items. The mean total scores and subscores were significantly higher in CT patients than in controls, except for the general health subscores. Post-operatively, CT patients had significantly lower scores than controls in four items (3, 5, 12, and 13), whereas no statistically significant difference was registered in the remaining items. CT patients' total scores, general health and social psychological restrictions subscores were significantly lower than those of controls, whereas no significant difference was recorded in the remaining subscores.

DISCUSSION

We translated and linguistically validated the TOI-14 questionnaire into Danish. We included RT and CT patients before and after tonsillectomy as well as healthy controls to support the validity of the TOI-14.

RT patients had significantly higher preoperative item scores, subscores and total scores than controls. Postoperatively, the majority of scores had improved to levels similar to those of the controls. These findings suggest that TOI-14 is well suited for evaluating the TR-QOL in RT patients.

Preoperatively, the mean scores of CT patients were significantly higher in seven items and trended to be higher in five items than among controls. The mean total scores and two subscores were significantly higher in CT patients than in controls. These findings suggest that some TOI-14 items are less important for measuring the CT patients' TR-QOL, but the total score is a useful tool for measuring CT patients' TR-QOL.

Post-operatively, CT patients had lower scores than controls in four items, the total score and two subscores. The reason for these low post-operative scores remains unclear, but may be related to relief from long-lasting symptoms.

a) Student's t-test.

Analyses of the effects of tonsillectomy (difference in patients' pre- and post-operative TOI-14 scores) and predictive parameters for improvement will be presented elsewhere (yet unpublished).

Previous studies

The TOI-14 has been used in German studies [3, 10] and it is translated to English [11] and Finnish [5].

Four studies have examined the TOI-14 scores of RT and/or CT patients (**Table 3**). The preoperative total scores and subscores (when presented) were similar to our findings in all studies [3, 5, 10, 11]. Laajala et al. [5] found post-operative scores comparable to ours, whereas Plath et al. [10] found disappointing results after tonsillectomy, which may be related to some questionable methodologic choices (discussed elsewhere [12]).

TABLE 3 Tonsillectomy Outcome Inventory 14 (TOI-14) scores from previous studies including recurrent acute tonsillitis (RT) patients, chronic tonsillitis (CT) patients, and controls.

	RT patients and 0	CT patients		Controls				
	Skevas et al., 2012 [3]	Roplekar et al., 2016 [11]	Laajala et al., 2020 [5]		Plath et al., 2021 [10]	Skevas et al., 2012 [3]	Laajala et al., 2020 [5]	Plath et al., 2021 [10]
	RT patients	RT patients	RT patients	CT patients	RT patients	healthy persons	healthy persons	healthy persons
Participants, n	108	150	16	26	108	67	42	1,000
					58ª			
					42 ^b			
Mean scores								
Preoperative TOI-14:								
Total ^d	47.4	45.6	42.9	27.0	52.3°	8.7	5.0	11.8°
Throat discomfort	55.1	-	-	-	-	14.7	2.9	-
General health	61.6	-	-	-	-	13.3	2.0	-
Resources	49.1	-	-	-	-	6.7	0.1	-
Social psychological restrictions	32.0		-	-	-	2.5	0.0	
Post-operative TOI-14:								
Total ^d	-	-	9.0ª	5.9ª	53 ^{a, o}	-	-	-
					52.5 ^{b, c}			
a) 6 ma follow up								

a) 6-mo. follow-up. b) 12-mo. follow-up.

c) Unknown whether mean or median

d) See the Methods section for details on the calculation of the values

Three studies [3, 5, 10] collected the TOI-14 scores of healthy controls (Table 3), all finding total scores and subscores similar to ours.

Limitations

It is inevitable to have small differences when translating and adapting a questionnaire, but as the Danish and German language and culture share many similarities, the encountered problems were manageable. This is supported by the similarity in scores between the present and previous studies in German. Our controls may not represent a normative population as the cohort was recruited from a selected group, but they were well matched to the patients in terms of age and gender, and lack of tonsillar diseases.

CONCLUSION

We translated, culturally adapted and linguistically validated the Danish version of the TOI-14, finding scores similar to those recorded by previous studies in German, English and Finnish.

Correspondence Hannah Inez Houborg. E-mail: 201610187@post.au.dk

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