Original Investigation

Translation and Validation of the Turkish Parotidectomy Outcome Inventory-8

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Abstract

Objective: Salivary gland tumors are common tumors of the head and neck region, and most are located in the parotid gland and the majority are benign. Parotidectomy, which is applied in the treatment of these tumors, is a very specific procedure in terms of both surgical technique and complications. Many quality of life (QoL) questionnaires have been used to evaluate the patient after parotid surgery; however, none are specific to parotidectomy. The Parotidectomy Outcome Inventory-8 (POI-8) was developed and validated in German to measure QoL after parotidectomy in patients with benign tumors. In this study, our aim was to translate POI-8 into Turkish and study its validity and reliability.

Methods: Fifty patients had parotidectomy due to benign pathologies and they were included in the study. All participants were administered the Turkish version of the University of Washington QoL questionnaire (UW-QoL), which had previously been validated in Turkish, and the Turkish version of the POI-8, which was prepared with expert committee evaluation. Validity assessment, internal consistency analysis, intra-rater and inter-rater reliability assessment were performed for POI-8.

Results: In the Turkish version of POI-8, a high level of intra-rater and inter-rater reliability was detected. A high-level, negative correlation was observed between POI-8 and UW-QoL. A strong internal consistency was detected with a high Cronbach's alpha coefficient.

Conclusion: POI-8, which we translated into Turkish and validated, can be used safely by head and neck surgeons to measure QoL after parotidectomy with its high reliability values.

Keywords: Parotidectomy, parotid neoplasms, quality of life questionnaires, surveys and questionnaires, validation study

Introduction

Parotid tumors are well-known tumors of the head and neck region and most of them are benign. Pleomorphic adenoma and Warthin's tumors are the most common. However, unlike malignant masses, their true incidence is difficult to determine because there are no clear national registries for benign masses. Although most parotid masses are benign,

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accurate diagnosis prior to parotid surgery is critical for surgical planning and selecting the most appropriate treatment modality for the patient (1).

In the 1940s, intracapsular dissection was performed for benign tumors. However, superficial parotidectomy, which removes the tumor along with the surrounding salivary gland tissue and exposes the facial nerve, was suggested to be safer and have a lower recurrence rate. Over time, superficial parotidectomy for benign tumors became more common (2). Complications that may occur after surgery for benign parotid tumors include palsy of the facial nerve, loss of sensation around the auricle, Frey's syndrome, salivary fistula, sialocele, hematoma and hemorrhage (3).

Health-related quality of life (QoL) represents a patient's subjective assessment of how a disease, and its treatment influence their physical, psychological, social and functional well-being. Unlike purely clinical parameters, QoL captures the multidimensional impact of illness on daily life and overall life satisfaction. Recently, it has become an essential endpoint in clinical research, complementing traditional outcomes such as disease-free and overall survival. This concept holds particular relevance for patients with head and neck cancer, as communication, social interaction and self-expression are intimately linked to the structural and functional integrity of the head and neck region. Consequently, in modern head and neck oncology, functional and rehabilitative outcomes have gained increasing prominence, often guiding surgical planning and reconstructive strategies. Evaluating QoL in this patient population provides critical insight into the broader consequences of treatment and supports a more holistic approach to patient care (4-6). Various QoL questionnaires, such as the European Organization for Research and Treatment of Cancer questionnaire and University of Washington QoL questionnaire (UW-QoL) have been used to assess patient status after salivary gland surgery (5,7-9). However, the primary shortcoming of these questionnaires is that most of them are not oriented towards parotid surgery and may be impractical to administer. Baumann et al. (10) originally developed the Parotidectomy Outcome Inventory-8 (POI-8), validated in German to measure the QoL after parotidectomy for benign disease.

In this prospective study, we aimed to translate POI-8 into Turkish and examine its validity and reliability. This will provide a reliable QoL questionnaire that can be used by otolaryngologists for Turkish-speaking patients undergoing parotidectomy for benign pathologies.

Methods

This study was initiated after obtaining permission from the Necmettin Erbakan University Decision of the Ethics Committee for research other than drug and medical device investigation (approval no: 2023/4259, date: 17 March 2023).

In our study, we aimed to translate the POI-8 questionnaire into Turkish and study its validity and reliability in the Turkish population. Therefore, Ingo Baumann was first contacted via e-mail for copyright permissions, and his approval was obtained to design and conduct this study.

Patient Selection and Study Design

Patients over the age of 18 who underwent superficial parotidectomy for benign disease in our clinic between June 2023 and June 2024 were included in the study. Detailed information was provided to the participants before the study. Those who wanted to participate were evaluated according to the study's inclusion and exclusion criteria, and appropriate volunteers were included after signing a voluntary consent form. Patients' age, sex, tumor localization, pathology results, POI-8 and UW-QoL results were recorded.

Volunteer patients of both sexes, aged over 18 years, who underwent surgery for a benign parotid mass in our clinic between the specified dates were included. Since malignant cases were not included in Baumann's original study describing POI-8, they were excluded. In addition, patients diagnosed with facial paralysis in the preoperative period, those who underwent total parotidectomy or revision parotid surgery, and those with a history of previous facial surgery were also excluded.

Surgical Technique

All patients were operated on by the same surgeon under general anesthesia with a facial nerve monitor using a superficial parotidectomy method. In this surgery, we preferred the modified Blair incision and started the parotidectomy, exposed the main trunk of the seventh nerve, and the peripheral branches were revealed with antegrade follow-up. The tumor was then removed along with the surrounding salivary gland tissue. We did not choose any flap to replace the parotid tissue removed during closure. We tried to preserve the great auricular nerve (GAN) as much as possible, but it was sacrificed in many patients. Therefore, a grouping between the patients could not be made in this respect.

Stages of Study

Expert Committee Evaluation

Firstly, the POI-8 questionnaire was translated from its original language, i.e., from German into Turkish, by professional translators whose native language is Turkish (forward translation). Then, a team of otolaryngologists with at least five years of parotid surgery experience and an adequate command of German reviewed the Turkish questionnaire, comparing it with the original in terms of meaning. The Turkish questionnaire was double-checked by a linguist. In the next stage, the Turkish version of the questionnaire was back-translated from Turkish into

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German by a different person (who had a good command of Turkish) who had never read the test before (backward translation). The same team of otolaryngologists evaluated this translation, reviewing in terms of semantic integrity. Thus, the final version of the questionnaire was created. The questionnaire was pilot tested on a small sample of 24 Turkish patients to evaluate its clarity, readability and question interpretation. No significant issues were identified, so the final version was approved as-is. Turkish version of the POI-8 is given in Table 1.

Validity and Reliability Assessment

In addition to POI-8, all patients were evaluated using the UW-QoL, which was previously validated in Turkish (11-13). This assessment was carried out by a team of otolaryngologists. Validity was tested by performing correlation analyses between the results of both questionnaires.

Internal Consistency Analysis

A single otolaryngologist administered the Turkish adaptation of the POI-8 questionnaire to all participating patients. To evaluate the internal reliability of the test, Cronbach's alpha coefficient was calculated. A value of Cronbach's alpha ≥ 0.70 was regarded as indicating strong internal consistency. Furthermore, Spearman's correlation tests were performed to examine the relationships between each item. Correlation coefficients were categorized as follows: 0.81 and above indicated excellent; 0.61 to 0.80 indicated very good; 0.41 to 0.60 indicated good; and 0.21 to 0.40 indicated acceptable correlation. Correlations of 0.20 or lower were considered inadequate.

Intra-rater Reliability Assessment

To test intra-rater reliability, an otolaryngologist was asked to administer the POI-8 questionnaire to the same patients at two different times. To avoid time-related bias, an interval of more than 60 minutes was left between two measurements performed on the same day. All patients were subjected to this assessment. The POI-8 scores obtained as a result of

both assessments were tested with intraclass coefficient correlation (ICC) analysis. An ICC value of 0.7 and above was defined as acceptable reliability.

Inter-rater Reliability Assessment

To test inter-rater reliability, two otolaryngologists were asked to administer the POI-8 questionnaire to the same patients at different times. To avoid time-related bias, an interval of more than 60 minutes was left between two measurements performed on the same day. All patients were subjected to this assessment. The POI-8 scores obtained as a result of the evaluations of the patients by both otolaryngologists were tested with ICC analysis. An ICC value of 0.7 and above was defined as acceptable reliability.

Statistical Analysis

All statistical analyses were done using the SPSS software. The Kolmogorov-Smirnov test was preferred to study whether numerical variables were normally distributed. For comparisons between independent groups, the Student's t-test and the Mann-Whitney U test were used. To compare categorical variables between independent groups, either the chi-square test or the Fisher's exact test was used. In all analyses, $p<0.05$ was accepted as statistical significance level.

Results

There were 50 patients in our study. The median age of patients was 57 years and most of the patients were male (33/50). The most common pathological diagnoses were found to be Warthin's tumor and pleomorphic adenoma. The total POI-8 median score was 4.

Comparison between male and female patients showed no statistical differences in terms of age, POI-8 total scores, pathological diagnoses and tumor localizations ($p>0.05$). The median of the 8th question from the POI-8 subgroups was found to be higher in female patients (5 vs. 3 points, $p<0.001$). Detailed analysis results are shown in Table 2.

Table 1. Turkish version of the Parotidectomy Outcome Inventory-8

Bireysel semptomların ciddiyetini değerlendirebilmek için, lütfen her bir soru için ilgili numarayı işaretleyin	Sorun değil	Çok küçük sorun	Küçük sorun	Orta derece sorun	Yüksek derece sorun	Daha kötüye gidemez
1. Ameliyat bölgesinde ve/veya yüzde ağrı	0	1	2	3	4	5
2. Ameliyat bölgesinde ve/veya boyunda duyusal bozukluklar	0	1	2	3	4	5
3. Yara izinin belirginliği	0	1	2	3	4	5
4. Yüz felci nedeniyle değişen görünüm	0	1	2	3	4	5
5. Parotis bezinin çıkarılmasına bağlı olarak değişen görünüm (doku kaybı)	0	1	2	3	4	5
6. Ameliyat bölgesinde terleme (özellikle yemek yerken)	0	1	2	3	4	5
7. Ameliyatın bir sonucu olarak ağız kuruluğu	0	1	2	3	4	5
8. Tekrar ameliyat olmak zorunda kalma olasılığından korkuyorum	0	1	2	3	4	5

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Table 2. Comparison of study data by sex

Parameters	All patients (n=50)	Male (n=33)	Female (n=17)	p
Age	57 (25-81)	57 (29-81)	55 (25-74)	0.412
POI-8 questions				
- Question-1	0 (0-3)	0 (0-3)	0 (0-3)	0.097
- Question-2	1 (0-4)	0 (0-4)	1 (0-4)	0.501
- Question-3	0 (0-4)	0 (0-4)	0 (0-4)	0.621
- Question-4	0 (0-4)	0 (0-4)	0 (0-0)	0.029
- Question-5	0 (0-4)	0 (0-4)	0 (0-1)	0.209
- Question-6	0 (0-5)	0 (0-5)	0 (0-2)	0.684
- Question-7	0 (0-4)	0 (0-4)	0 (0-4)	0.713
- Question-8	0 (0-5)	0 (0-5)	3 (0-5)	<0.001
Total POI-8 score	4 (0-22)	3 (0-22)	5 (0-20)	0.090
UW-QoL score	96.54 (75.75-100.00)	97.91 (81.34-100.00)	90.34 (75.75-100.00)	0.014
Pathologic diagnosis				0.094
- Pleomorphic adenoma	20 (40.0)	12 (36.4)	8 (47.1)	
- Warthin's tumor	22 (44.0)	18 (54.5)	4 (23.5)	
- Non-specific	7 (14.0)	3 (9.1)	4 (23.5)	
- Oncocytic cystadenoma	1 (2.0)	0 (0.0)	1 (5.9)	
Tumor localization				0.765
- Right	25 (50.0)	17 (51.5)	8 (47.1)	
- Left	25 (50.0)	16 (48.5)	9 (52.9)	

UW-QoL: University of Washington quality of life questionnaire, POI-8: Parotidectomy Outcome Inventory-8

Table 3. Intra-rater and inter-rater reliability analysis results

	ICC	95% confidence interval		p-value
		Lower limit	Upper limit	
Intra-rater	0.984	0.972	0.991	<0.001
Inter-rater	0.985	0.973	0.991	<0.001

ICC: Intraclass coefficient correlation

POI-8 demonstrated high reliability, with ICC values of 0.984 for intra-rater and 0.985 for inter-rater assessments (p<0.001) (Table 3). The validity analysis between POI-8 and UW-QoL revealed a high, statistically significant, negative correlation (rho=-0.661, p<0.001) (Figure 1).

Internal consistency analysis of the POI-8 questionnaire showed a high level of Cronbach's alpha coefficient (0.706). It was determined that there were comparisons with low correlation coefficients, especially in the eighth question (there were values of 0.200 and below). Detailed findings regarding the internal consistency results are given in Table 4.

Exploratory factor analysis (EFA) initially suggested a three-factor structure with eigenvalues greater than one, explaining 70.6% of the total variance. However, due to overlap between certain items, the analysis was repeated after the removal of item 5. The revised analysis indicated a two-factor structure. The Kaiser-Meyer-Olkin (KMO) measure of sampling
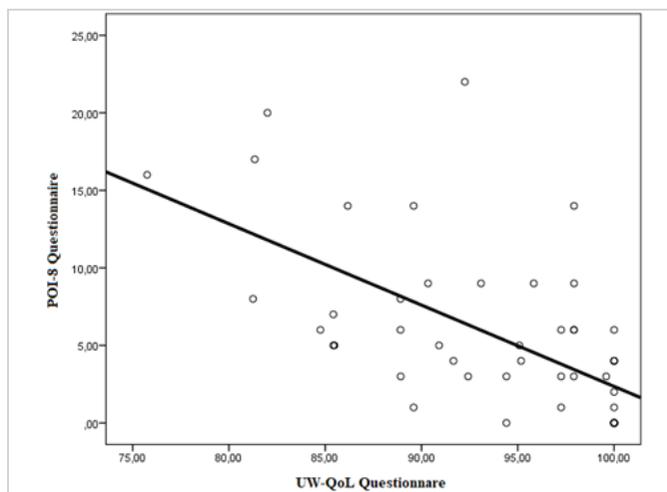

Figure 1. Correlation analysis results between Parotidectomy Outcome Inventory-8 and University of Washington quality of life questionnaires (rho=-0.661, p<0.001)
UW-QoL: University of Washington quality of life questionnaire, POI-8: Parotidectomy Outcome Inventory-8

adequacy was 0.706, and Bartlett's test of sphericity was significant (χ^2=65.378, p<0.001), supporting the suitability of the data for factor analysis. The two-factor model explained 55.2% of the total variance. Item 1 demonstrated a relatively low factor loading (<0.40) and was therefore excluded, and

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Table 4. Internal consistency analysis results of the Parotidectomy Outcome Inventory-8 (Cronbach's alpha coefficient =0.706)

POI-8 questions	Question-1	Question-2	Question-3	Question-4	Question-5	Question-6	Question-7	Question-8
Question-1	1.000							
Question-2	0.188	1.000						
Question-3	0.333	0.313	1.000					
Question-4	0.226	0.110	0.374	1.000				
Question-5	0.259	-0.049	0.609	0.593	1.000			
Question-6	0.222	-0.061	0.418	0.319	0.690	1.000		
Question-7	0.340	0.445	0.566	0.245	0.297	0.242	1.000	
Question-8	0.186	0.179	0.146	-0.162	0.102	0.119	0.288	1.000

POI-8: Parotidectomy Outcome Inventory-8

the analysis was repeated. In the final EFA model, a two-factor structure was retained, with KMO=0.655 and Bartlett's test remaining significant (χ^2=56.950, p<0.001). The total variance explained increased to 60.2%. Items 3, 4, and 6 loaded onto factor 1, while items 2, 7, and 8 loaded onto factor 2.

Subsequently, confirmatory factor analysis was performed using analysis of moment structures (version 22.0) to evaluate the two-factor structure. During this process, item 8 was excluded due to a low standardized factor loading (<0.40). The final model consisted of two factors including a total of five items. Model fit indices indicated an acceptable level of fit (χ^2/df=4.526, Tucker-Lewis index =0.969, goodness of fit index =0.965, root mean square error of approximation =0.052, standardized root mean square residual =0.068). Standardized factor loadings ranged from 0.42 to 0.93, and all items loaded significantly onto their respective factors (p<0.05). These findings suggest that the Turkish version of the scale demonstrates a two-factor structure with acceptable psychometric properties.

Discussion

QoL surveys provide subjective data to measure how a disease or treatment affects a patient. This information is obtained by answering questions about life satisfaction, which only the patients themselves can assess. Therefore, it is essential that every QoL survey be conducted in the patient's own language. To the best of our knowledge, this study is the first study designed and published to investigate the translation and validity of POI-8 from German into Turkish. POI-8 has been translated into English, Spanish and Danish and used in studies so far. However, only validation was done in Spanish and Danish. Chiesa-Estomba et al. (14) reported that they obtained an internal consistency over 0.8. Therefore, they argue that this form can be applied reliably in Spanish-speaking patients (14). Hilton et al. (15) translated POI-8 into Danish. The authors reported a weighted kappa coefficient value of 0.74, a Cronbach's alpha coefficient value of 0.78 and an ICC value of >0.50 and stated that this form

had moderate to good reliability, which is sufficient to use POI-8 after parotidectomy surgery (15).

The inventors of POI-8, Baumann et al. (10), designed this form as a 20-question alpha and 8-question beta version. In their study, the authors determined the Cronbach's alpha value to be 0.84 and this was a good result in terms of internal consistency. In our study, when we tested the POI-8 for reliability, we found high levels of both intra-rater (ICC: 0.984) and inter-rater (ICC: 0.985) reliability. The internal consistency analysis revealed a high level of Cronbach's alpha coefficient (0.706). Additionally, we determined that there were comparisons with low correlation coefficients in the eighth question. With values of 0.200 or below, we speculated that this might be related to the relatively small patients sample size and low correlation coefficients.

We observe that POI-8 has attracted more attention from head and neck surgeons over the years and is increasingly used in the evaluation of both early and long-term complications and health-related QoL after parotidectomy. The early period generally refers to the first year after parotidectomy surgery, while the long-term refers to the first year and beyond. In their study, Ciuman et al. (7) evaluated symptom-specific QoL with POI-8 and argued that parotidectomy has little effect on general QoL and general health status. In another study in which POI-8 was used, esthesia was the most bothersome issue six months after superficial parotidectomy, followed by concern of re-surgery and dissatisfaction with pain and scarring. Although the effects of esthesia and pain decreased during follow-up, the same symptoms were reported to still affect symptom-specific QoL after two years. Complaints related to Frey's syndrome were found to worsen (9). A study examining the QoL of patients who underwent parotidectomy with a 13-year follow-up reported that hypoesthesia and concern of re-surgery were the most significant long-term disorders, while palsy of the facial nerve was considered a minor issue. However, hypoesthesia has been shown to improve significantly over time without reducing QoL in patients with long-term follow-up (16). In our study, we also found that the most disturbing situation

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for patients was hypoesthesia or dysesthesia in the operation area. We attribute this to the fact that our study was conducted in the early postoperative period of six months, as stated in similar studies in literature. We believe that patients' complaints may change with long-term follow-up.

Hypoesthesia is one of the most disturbing issues that patients experience after parotidectomy surgery. Preserving the GAN (especially the posterior branch) has been shown to be beneficial in reducing this complication. However, there are also publications reporting that this only reduces early-stage esthesia, does not provide significant positive effects in the long-term, and does not significantly affect health-related QoL (17-19).

The POI-8 questionnaire aims to measure patient satisfaction only in the postoperative period. However, symptoms experienced by patients preoperatively (such as visual disturbance due to the size of the mass) can also affect postoperative satisfaction. Therefore, measuring postoperative QoL independently of preoperative symptoms can be considered a shortcoming of this questionnaire. Another shortcoming of the POI-8 questionnaire is that it is designed for patients undergoing parotidectomy for benign diseases. Patients with malignant lesions will experience all the troubles experienced by patients with benign lesions, as well as additional troubles. Malignant diseases may present different symptoms and have a completely different clinical course. Surgical treatment may require more extensive surgery and additional procedures such as neck dissection along with parotidectomy. This may lead to changes in postoperative symptoms and a decrease in QoL. We believe that malignant patients will score higher on the eighth question, which specifically addresses the fear of reoperation after surgery. Therefore, additional questionnaires are needed to evaluate the QoL of patients with malignant diseases. Alternative questions that could impact postoperative QoL, such as changes in surgical site skin, pre- and post-symptom differences, bleeding and discharge, could be added to the survey. Furthermore, questions about the surgical site and neck could be asked separately (especially for malignant lesions). While increasing the number of questions could increase the survey's value, it would also make it more difficult to administer.

Study Limitations

In this study, the number of patients was limited to emphasize language validation, construct validity, intra-rater and inter-rater reliability. For this reason, factor analysis could not yield meaningful results for all survey questions. Therefore, it is necessary to evaluate the results of factor analysis using studies with larger patient numbers.

Conclusion

The POI-8 questionnaire, which was translated into Turkish and validated for the first time in this study, can be used safely to measure QoL after parotidectomy surgery for benign disease in Turkish-speaking patients with its high reliability and consistency values.

Ethics

Ethics Committee Approval: This study was initiated after obtaining permission from the Necmettin Erbakan University Decision of the Ethics Committee for research other than drug and medical device investigation (approval no: 2023/4259, date: 17 March 2023).

Informed Consent: Those who wanted to participate were evaluated according to the study's inclusion and exclusion criteria, and appropriate volunteers were included after signing a voluntary consent form.

Footnotes

Authorship Contributions

Surgical and Medical Practices: H.Y., Concept: H.Y., A.Y., M.A.E., Design: H.Y., M.A.A., M.C.K., Data Collection and/or Processing: M.C.K., B.D., E.B., M.G., Analysis or Interpretation: A.Y., M.A.A., M.C.K., Literature Search: A.Y., M.A.E., B.D., M.G., Writing: H.Y., M.G.

Conflict of Interest: The authors declare that they have no conflict of interest.

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Main Points

- The Parotidectomy Outcome Inventory-8 (POI-8) is a German questionnaire developed in 2009 to assess quality of life after parotidectomy.
- The most important point that distinguishes POI-8 from other quality of life questionnaires is that it is specific to parotidectomy surgery.
- POI-8 has been previously translated into Spanish and Danish and validated.
- In our study, POI-8 was translated into Turkish and validated, and made available to Turkish-speaking head and neck surgeons.
- High levels of intra-rater and inter-rater reliability and high and negative correlations between University of Washington quality of life were observed in the Turkish version of POI-8.

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