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Translation and validation of the Parotidectomy Outcome Inventory 8 (POI-8) to Spanish

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ABSTRACT

Introduction: There are > 400 million of native Spanish speakers around the world, being the second most spoken language in regard to the number of native speakers. For this reason, a valid questionnaire to access the quality of our patients after parotidectomy is necessary.
Material and methods: Validation and cross-cultural adaptation of the POI-8 questionnaire to the Spanish language. Internal consistency of Sp-POI 8 measured with Cronbach α.
Results: 35 patients met the inclusion criteria during the mentioned period. Mean age was 59 ± 15,37 (Min: 18/Max: 87). 20 patients (57,1%) were male and 15 (42,9%) were female. Internal consistency with Cronbach α was 0.868. The intraclass correlation coefficient was 0.830 [CI] (95%: 0,791–925). Hypoesthesia was the most severely weighted problem (0,91) and xerostomia was the second (0,89). However, the high score was for fear of revision surgery (1,26).
Conclusion: The Spanish Language is the second most spoken language with regard to the number of native speakers and the Sp-POI 8 translation represents a valid option for the Spanish-speaking medical community, from which a large number of patients can benefit.

1. Introduction

Surgical techniques for extirpation of tumors of the parotid gland has significantly evolved in the last century. It was mainly a very limited surgery in the nineteenth century (enucleation) evolving through a more extensive surgery justified by a lower recurrence rate. In recent years we came back to less aggressive techniques without a negative impact in its recurrence rate.

Besides the wide diffusion of the technique, superficial parotidectomy is not a harmless procedure. The most common long-term related complications correspond to temporal or permanent facial nerve dysfunction, great auricular nerve hypoesthesia and Frey's syndrome [1,2,3]. These complications can be objectively assessed and numerous previous published papers have analyzed them [4,5]. Besides the amount of works studying these complications, few studied the quality of life (QOL) after surgery, and, as Wolber *et al.* [6] highlighted, the objective rate of complications does not reflect the QOL after surgery.

Standardized QOL questionnaires for post-parotidectomy patients with a benign disease are rare, and only one questionnaire has been published. We attribute it to the difficulty in the analysis of subjective data. In 2009 Baumann et al. published the German-language validated Parotidectomy Outcome Inventory Test (POI-8) designed to measure the health-related QOL in post-parotidectomy patients with benign tumors [7]. Its reliable application and comparability to other validated QOL surveys was demonstrated by Ciuman et al. in a retrospective study [8]. Recently, a non-validated English version of the POI-8 was presented by Wolber et al. Due to the lack of well-designed QOL questionnaires for post-parotidectomy patients, and the good development of the POI-8 test, it has gained wide acceptance and diffusion among head and neck surgeons.

Spanish language speakers are > 400 million around the world, being the second most spoken language with regard to the number of native speakers. The aim of this study was to document the reliability, validity and cross-cultural adaptation of the POI-8 to the Spanish Language.

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2. Material and method

This study was approved by the Research and Ethics Committee of the blinded Hospital, register code 2017/CCH027. Clinical and demographic variables were obtained from medical records. The study was performed in accordance with the ethical standards laid down in the Declaration of Helsinki.

Parotidectomy Outcome Inventory 8 (POI-8) is a questionnaire designed for measuring health-related QOL in post-parotidectomy patients with benign tumors. It includes eight related symptoms (Pain, Hypoesthesia, Appearance of the scar, Facial palsy, Substance loss, Frey's syndrome, Xerostomia and Fear of revision surgery). Each item can be rated in a 6 levels Likert style scale according to its subjective severity.

We followed the recommendations of the World Health Organization for the translation and adaptation of instruments and the crosscultural adaptation of healthrelated quality of life measures proposed by Guillemin et al. [9], the following way: Stage I: first translation was carried out by two independent Otolaryngologists - Head & Neck Surgeons, Spanish-German native speakers. No consensus was needed since the two translations were perfectly similar. Stage II: After translation the survey was sent to a panel of six experts in Parotid Gland Surgery throughout Spain. Stage III: After general consensus was reached the definitive version was sent to a third bilingual German-Spanish speaker Otorhinolaryngology - Head & Neck Surgeon for back-translation. Afterward, Stage IV: the comprehensibility of the translated questionnaire was evaluated in a group of patients to check the reliability of the questionnaire. Stage V: The definitive version of the questionnaire obtained was finally reviewed again by a panel of experts and a general consensus was obtained (Image 1).

To assess the reliability of the Spanish translation of this questionnaire, those patients treated for benign tumors of the parotid with a suprafacial parotidectomy between July 15th of 2016 and July 15th of 2017 at our department, older than 18 years old, were prospectively included. Exclusion criteria was malignant histology, the need of a total parotidectomy, extracapsular dissection, revision surgery, preoperative facial nerve dysfunction, refusal to participate and patients who did not have sufficient cognitive skills to complete the questionnaires. To assess cognitive skills previous interview and review of pre-existent medical records of cognitive impairment was performed. Participants were invited to fill the questionnaire in the clinic 6 months after surgery. A second measurement was made to those patients included after 1 month to prevent memory bias, and result was compared between both tests.

Parotidectomy was generally performed utilizing a Blair modified incision or a facelift incision according to the patient preference. Always when we perform a Facelift incision, we perform a SMAS flap to

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Cuestionario sobre calidad de vida post-parotidectomía.

NHC:

Para poder juzgar la intensidad de sus síntomas marque el número que corresponda en cada fila.	No es problema	Es un problema mínimo	Es un problema leve	Es un problema moderado	Es un problema grave	El problema no puede ser peor
Siento dolor en la zona de la operación o en la cara.	0	1	2	3	4	5
Noto alterada la sensibilidad en la zona de la operación o en la cara.	0	1	2	3	4	5
Me preocupa el aspecto de la cicatriz	0	1	2	3	4	5
Mi cara ha cambiado a consecuencia de la parálisis facial.	0	1	2	3	4	5
Mi cara ha cambiado a consecuencia de la pérdida de volumen por la extirpación de la glándula.	0	1	2	3	4	5
Siento sudoración en el área de la intervención (especialmente al comer).	0	1	2	3	4	5
Noto sequedad de la boca tras la intervención.	0	1	2	3	4	5
Tengo miedo ante la posibilidad de necesitar una reintervención	0	1	2	3	4	5

Image 1. Spanish translation of POI-8.

fill the post-operative defect. Monopolar electrocautery was used for raising of the skin flap and dissection of the anterior border of sternocleidomastoid and posterior belly of digastric muscles, and for incision of parotid tissue where this had been performed far from branches of the facial nerve, and then we created a tunnel in the pre-tragal zone and dissected the gland looking for the tragal pointer. Parotid tissue was then divided with the Harmonic Focus Scalpel (Ethicon Endo-Surgery, Cincinnati, OH, USA). In all cases of Suprafacial lateral parotidectomy the main trunk of the facial nerve was identified at the outset of the operation. The extent of parotid resection depended mainly on the size and location of the parotid tumor. In general, the aim was to remove tumors with a surrounding normal parotid tissue wherever this was feasible. Patients were classified according to volume of excised parotid tissue > 30 cc *vs.* < 30 cc. Facial nerve monitorization and facial nerve stimulation, before and after tumor resection was performed in all cases. A vacuum suction (Jost-Redon) drain was routinely placed. The type and extent of parotid gland resection was defined according to the parotidectomy classification of the ESGS. The posterior branch of the major auricular nerve was preserved when was possible.

Statistical analysis was conducted with SPSS for Macintosh Version 21.0 (IBM Corp, Armonk, NY). Internal consistency was measured with Cronbach α and temporal stability by using the intraclass correlation coefficient ($p < 0.05$). The Kolmogorov-Smirnov was used to assess the normal distribution. To analyze potential differences between groups with continuous variables, we performed the Wilcoxon test for nonparametric data and student's *t*-test for parametric data. Differences between groups with categorical variables were computed by Chi-square test and Fisher's exact test. A p value < 0.05 was considered significant.

In the psychometric evaluation of the instruments, *Reliability* refers to consistency or dependability after repeated measurements. *Consistency*, to evaluate which each question of the scale relates to the rest, using the Cronbach α method to measure it, and taking a value over 0.80 to suggest a strong construct validity, which gets better the closer it is to 1. And finally, *Temporal Stability* known as test-retest reliability; it refers to the concordance between the scores of repeated measurements from the same participant. It can be assessed by the intraclass correlation coefficient, considering 0.80 as a high correlation value.

Table 1
Demographic data of included patients.

Variable	N	%
Age	59 ± 15,37 (Min: 18/Max: 87)	
Sex		
Men	20	57,1
Women	15	42,9
Histology		
Pleomorfic Adenoma	14	40
Warthin Tumor	18	51,4
Oncocytoma	2	5,7
Lithiasis	1	3,3
Levels included		
I	6	17,15
II	15	42,85
I + II	14	40
Type of incision		
Modified Blair	21	60
Facelift	14	40
Muscle flap		
SMAS Flap	13	37,2
SCM Flap	2	5,7
No	20	57,1
Facial Nerve Palsy		
All Branches	0	0
Marginal mandibular Branch	1	2,85
Facial Nerve Paresis		
All Branches	0	0
Marginal mandibular Branch	3	8,6

3. Results

35 patients met the inclusion criteria during this period. Mean age was 59 ± 15,37 (range 18–87). 20 (57,1%) were male and 15 (42,9%) were female. According to histology, the most common type was Warthin tumor diagnosed in 18 (51,4%) patients and the most common level dissected was level II in 15 (42,85%) of cases. Any patient was lost during the follow up. (Table 1).

Internal consistency of Sp-POI 8 measured with Cronbach α was 0.868. Internal consistency was still over 0.857 after removing every item of the test, and the consistency was higher in questions one, three and eight. (Table 2).

Consistency was measured within a subgroup analysis according to sex. The Cronbach α values for male and female were 0.835 and 0.911, respectively. After removing every item of the test, minimum values were 0.833 and 0.873, respectively (Table 2).

The intraclass correlation coefficient was 0.830 (confidence interval [CI] 95%: 0791–0.925). In women, it was 0.908 (CI 95%: 0.815–0.964), and 0.817 in man (CI 95%: 0.782–0.923); there were no differences by sex. These results demonstrate this test as having a high correlation. (Table 2). Finally, the average result according to every question can be seen on Table 3.

Performing an overview of POI-8 questionnaire considering subjective evaluation of the post-parotidectomy complications (Pain, Hypoesthesia, Appearance of the scar, Facial palsy, Substance loss, Frey's syndrome Xerostomia, Fear of revision surgery) after six months. Hypoesthesia was the most severely weighted problem (0,91) and xerostomia was the second (0,89). However, the high score was for fear of revision surgery (1,26).

Table 2
Consistency and interclass correlation coefficient of the Spanish version of the Parotidectomy Outcome Inventory 8 (POI-8) measured with Cronbach α.

	Total	Male	Female
Cronbach α	0.868	0.831	0.911
POI-8 = 1	0.871	0.838	0.906
POI-8 = 2	0.814	0.898	0.876
POI-8 = 3	0.929	0.835	0.909
POI-8 = 4	0.815	0.897	0.876
POI-8 = 5	0.821	0.835	0.873
POI-8 = 6	0.814	0.846	0.874
POI-8 = 7	0.813	0.898	0.839
POI-8 = 8	0.888	0.835	0.909
Interclass correlation coefficient	0.830 (CI 95% = 0.791–0.925)	0.817 (CI 95% = 0.782–0.923)	0.908 (CI 95% = 0.815–0.964)

Table 3
Average rate of response of the Spanish version of the Parotidectomy Outcome Inventory 8 (POI-8).

	Average	SD	Min/Max
POI-8 = 1	0.40	0.65	0/2
POI-8 = 2	0.91	0.87	0/3
POI-8 = 3	0.37	0.38	0/1
POI-8 = 4	0.17	0.53	0/3
POI-8 = 5	0.51	0.63	0/4
POI-8 = 6	0.20	0.61	0/3
POI-8 = 7	0.89	0.67	0/3
POI-8 = 8	1.26	0.61	0/3

4. Results per item

4.1. Pain

6 months after surgery, 9/35 (25,71%) of the patients consider pain as a problem. However, pain was weighted as a not relevant problem on average (0.41) after six months. We don't found any relation between the volume of the excised tissue, SMAS flap, SCM flap, type of incision, sex, GAN status (preserved *vs.* not preserved).

4.2. Hypoesthesia

After 6 months, 30/35 (85,7%) of the patients named sensation loss as a problem with a mean POI-8 score of 0.91. Also, hypoesthesia was the most severely weighted problem at 6 months of follow-up, compared to other post-parotidectomy complications included in the POI-8. Hypoesthesia equally affected patient´ independent of the status of the Greater Auricular Nerve (GAN preserved *versus* GAN sacrificed (p = 0.238)).

4.3. Appearance of the scar

In our cohort of patient, the scar was considering a marginal cosmetic issue for the patients during the entire follow-up (0.37). 13/35 (37,14%) of patients mention the appearance of the scar as a problem after 6 months. Extent of surgery (measured by volume of the excised parotid tissue), SMAS flap, SCM flap and sex did not influence significantly the subjective rating of the scar (p = 0.345). However, there was a significant difference between those patients in the group of facelift incision compared with those in the group of modified Blair incision (p = 0.048).

4.4. Facial palsy

Facial palsy was not considering a problem in 32/35 (91.4%) of the patients after six months. The mean POI-8 score (0,17). Patients with an objectively assessed facial nerve dysfunction showed a slightly higher but not significantly POI-8 scores after 6 months (p = 0.124). Moreover, 1 patient in the group of facial paresis did not consider this as a problem.

4.5. Substance loss

After 6 months, 24/35 (68,57%) of the patients, consider the changed appearance due to substance loss did not represent any problem, being the mean POI-8 score 0.51. Patients with a higher volume of excised parotid tissue during surgery weighted substance loss at 6 months after surgery more severely than patients with lower surgery extent (p = 0.03), for volume of excised parotid tissue. SCM flap, SMAS flap or sex did not significantly influence the subjective impairment due to substance loss (p = 0,645). After six months, 4/35 (11,42%) of all patients affirmed dissatisfaction with the postoperative cosmetic result.

4.6. Frey's syndrome

Frey's syndrome was subjectively reported as a minor issue after six months of follow-up with a mean POI-8 score of 0.20. For 33/35 (94,28%) of the patients the Frey's syndrome did not pose any problem according to the POI-8 questionnaire. Dissection of the SMAS or SCM flap showed no influence on the subjective perception of the Frey's syndrome (p = 0.435).

4.7. Xerostomia

Interestingly, Xerostomia was the second most weighted problems after superficial parotidectomy in our cohort, being the average of POI-8 score for xerostomia 0.89. After 6 months, 21/35 (60%) of the patients described xerostomia as unproblematic.

4.8. Fear of revision surgery

Fear of revision surgery was the major issues after parotidectomy in our cohort, being the average of POI-8 score 1.26. Patients who experienced early complications like seroma or salivary fistula showed higher POI-8 scores (p = 0.01).

5. Discussion

To the best of our knowledge, this is the first study designed to perform a translation, validation and cross-cultural adaptation of the POI-8 from German to Spanish. As we previously mention, the POI-8 is the sole specific quality of life questionnaire developed for surgery of benign tumors of the parotid gland.

Across the indexed literature, other questionnaires are used to assess the QOL of these patients. However, the validity of those results can be limited or not always objective. The 36-item Short Form health survey (SF-36), which is also frequently used for evaluation of the global QOL, is not a specific questionnaire develop for post-operative patients [9,10]. Moreover, other surveys like the QLQ-C30 or QLQ H&N35 used frequently were specifically developed for head and neck cancer patients [7,8,11,12]. Consequently, using those surveys, various study groups repeatedly observed only marginal impact of surgery on general and disease-specific QOL in patients with a benign parotid tumor [11,12].

Reviewing the literature, we were not able to found any previous validated translation of the POI-8 test from German to English or other language. However, in a recent paper published by Wolber *et al.* [6] from Germany, they include a non-validated English version of the POI-8. After reading this paper, our group consider this can be an interesting instrument to measure the QOL of our patients.

In this way, the aim of our study was to validate a Spanish Language Version of the Parotidectomy Outcome Inventory 8 (POI-8) for measuring health-related QOL in post-parotidectomy patients with benign tumors. The psychometric evaluation of the translated test demonstrated a high internal consistency over 0.8, a high specific sex related consistency also higher than 0.8 and a good intraclass correlation coefficient (0.964) were obtained. Our results suggest its reliable application in Spanish-Speaking patients about the subjective perspective on complications as hypoesthesia, pain, cosmetic impairment (facial palsy, appearance of the scar and substance loss), Frey's syndrome, xerostomia and fear of revision surgery after superficial parotidectomy.

The good performance and results obtained in this analysis allow us to use this questionnaire. Our results are similar to the previous published data by Wolber *et al.* [6], in their study hypoesthesia (1,68) and Fear to revision surgery (1,43) were the most common issues. However, in their study the appearance of the scar was the third more important issue for the patient while in our group was xerostomia, this can be related to psychological different between both population or differences in the surgical technique used. In this way, more studies about the

quality of life of patients after parotidectomy for benign tumors using the POI-8 questionnaire are necessary to make comparisons in the future.

The consistency of each item was good comparing the subjective results in the test and surgical objective results. Due to the low rate of facial palsy, the use of the facelift approach when the patient wants this incision, the use of the SMAS flap or ECM flap to fill the defect and improve the contour of the lateral side of the face, the preservation of the posterior branch of the major auricular nerve in the majority of our patients. And the use of Botulinum Toxin in those patients how lost quality of life due to Frey syndrome.

The translation of this test was done in Spain. Even though Latin American Spanish is almost the same as mainland Spain Spanish, there are slight differences between them. However, two of the main authors and reviewers of this translated version of POI-8 are from Latin America and the Caribbean, so we have tried to use words and expressions used in these countries.

Finally, there are a major clinical limitation in our study due to the short follow-up period (6 months). Common issues in parotid gland surgery remains or not a problem after several months. Subjective perception of hypoesthesia, scar and cosmetic results or substance loss can improve during the follow up. However, subjective perception of xerostomia and Frey's syndrome can be worse after 6 months. In this way, prospective studies, with a longer follow up are necessary to assess the severity of subjective disturbance of each item and evaluate the decrease during the follow-up using the Spanish version of the POI-8.

6. Conclusion

Nowadays, quality of life in the treatment of benign pathology represent an important objective. Post-Operative QOL questionnaire give us a subjective perception of patients feeling after surgery. Spanish Language is the second most spoken language regarding the number of native speakers and POI-8 translation represent a valid option for Spanish-Speaking medical community, with which a large number of patients can benefit.

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