Adaptação e validação da versão Portuguesa do *Tonsil Adenoid Health Status Instrument* (TAHSI)

Artigo Original

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Resumo

Objetivo: Validação e adaptação transcultural do instrumento *Tonsil and Adenoid Health Status Instrument* para a língua portuguesa.

Métodos: Foi realizado um estudo prospetivo para avaliar e comparar 51 pacientes consecutivos submetidos à operação de amigdalectomia ou adenoamigdalectomia (pré-operatório e 6 meses pós-operatório) e um grupo de controlo. Seguiramse as orientações para o processo de adaptação transcultural, para traduzir a versão original em inglês para uma versão em português europeu. Avaliaram-se as propriedades psicométricas da versão em português europeu do TAHSI (EP-TAHSI), sua viabilidade, reprodutibilidade, consistência interna, confiabilidade, validade discriminatória e capacidade de resposta à mudança.

Resultados: O teste de Mann-Whitney mostrou diferença estatisticamente significativa para a pontuação média entre os pacientes e o grupo controlo, com validade clínica. O valor do coeficiente de Cronbach para o EP-TAHSI para 50 casos foi de 0,946, com boa consistência interna. O teste de Wilcoxon revelou uma franca melhoria 6 meses após a cirurgia. O teste de Spearman e as correlações de Pearson foram utilizadas para avaliar os *scores* médios do EP-TAHSI, com significância estatística.

Conclusões: O EP-TAHSI é um instrumento válido para avaliar o efeito subjetivo da amigdalectomia e adenoidectomia na saúde e na qualidade de vida e, portanto, é recomendado para uso na pesquisa e na prática diária da amigdalectomia e adenoidectomia. Apresenta valor no follow-up pós-cirúrgico e para questões legais que possam surgir no mesmo contexto.

Palavras-chave: Amigdalectomia; Questionário; Validação; Adaptação; Pediatria; Português; Qualidade de vida

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Introdution

Tonsillectomy and adenoidectomy are two of the most common surgical procedures performed all over the world. The commonest surgical indications in children are chronic tonsillitis or obstructive sleep apnea. 1 Objective evaluation of the results of adenoidectomy or tonsillectomy and patient reported outcome measurements (PROMs) needs a careful study with objective tools, in order to know its effect on child health, his family, and the longterm effect on the patient himself. In line with that, several PROMs have been developed as trials to study this effect.2 Stewart et al. have developed the Tonsil and Adenoid Health Status Instrument (TAHSI) in 2001 in the United States of America, and it is considered a validated disease specific, health-related research tool.3-6

European-Portuguese version was made to be fulfilled by the parents of children. It is a European-Portuguese questionnaire includes 15 questions (Table 1) divided into 6 categories: airway and breathing (questions 1, 7, 11, 13), inflammations (questions 2, 8, 9), healthcare usage (questions 3, 4, 5, 6), eating and swallowing (questions 12, 14), cost of the services (question 10) and behavior (question 15). Each question is scored on a scale that measures the severity of each symptom using five increasing points starting from: 0 (not a problem), 1 (mild problem), 2 (moderate problem), 3 (fairly bad problem), and 4 (severe problem).

The aim of our study was to validate and adapt cross-culturally the TAHSI into the European-Portuguese language, and evaluate its effect on the patient's quality of life.

Material and Methods

Place, duration, and design of the study: This prospective single-centre validation tool study was performed at the Department of Otolaryngology of a tertiary center between April 2020, and February 2021.

Ethics: The institutional review board approval has been obtained prior to the study. Formal consent was signed by the parents of the children for contribution in this research.

Population: The study included 2 groups. The first group was composed of 51 patients with indication for tonsillectomy or adenoidectomy, while the other group was composed of 49 children who did not complain of any tonsils or throat problems, but they were admitted for other diseases - orthopedic pathology without any compromise of the upper airway. The sample size was calculated to make a confidence level up to 90%.

Inclusion criteria: The inclusion criteria for the first group were recurrent attacks of acute bacterial tonsillitis (according to Paradise criteria 7), obstructive sleep apnea, and a previous episode of a peritonsillar abscess.

Exclusion criteria: Cases with tonsillar tumors, emergent cases with peritonsillar abscess, and single adenoidectomy. The presence of cardiac pathology, immune compromise or diabetes, resulted in an exclusion of the present study in the selection of cases.

Translation: The English to European-Portuguese translation was performed by 2 translators with a medical background. The 2 versions were combined into 1 edition (Tab. 1) which was reviewed by 3 ENT specialists with a forward and backward mechanism of translation. We asked 20 different people to answer it, in order to check its accessibility and ease of response.

Intervention: The questionnaire was filled in the pre-operative visit (to ensure reliability), and six months after the operation (to evaluate responsiveness). No personal data was collected; any unreached patient was excluded from the research - although, we had no excluded patients. The tonsillectomy or adenotonsillectomy operations were done under general anesthesia by cold technique or bipolar radiofrequency. In the other group, the questionnaires were filled by the parents during the admission of their children to the hospital and repeated 6 months after.

Table 1 The questionnaire in european-portuguese language

| | Não é um problema | Um problema leve | Um problema moderado | Um problema bastante sério | Um problema grave |
|--|----------------------|------------------------|----------------------------|-------------------------------------|-------------------------|
| 1. Ressonar alto enquanto dorme | 0 | 1 | 2 | 3 | 4 |
| 2. Infeções bacterianas / estreptocócicas | 0 | 1 | 2 | 3 | 4 |
| 3. Muitas idas ao consultório médico | 0 | 1 | 2 | 3 | 4 |
| 4. Tomar antibióticos por mais de 3 semanas seguidas | 0 | 1 | 2 | 3 | 4 |
| 5. Tomar antibióticos repetidamente por menos de 2 semanas de cada vez | 0 | 1 | 2 | 3 | 4 |
| 6. Muitas chamadas para o consultório médico | 0 | 1 | 2 | 3 | 4 |
| 7. Respiração irregular ou pausas respiratórias, também conhecidas como apneias durante o sono | 0 | 1 | 2 | 3 | 4 |
| 8. Infeções repetidas a curto prazo (ou agudas) da amígdala que duram menos de 2 semanas | 0 | 1 | 2 | 3 | 4 |
| 9. Infeção constante ou crónica das amígdalas que dura mais de 2 semanas | 0 | 1 | 2 | 3 | 4 |
| 10. O custo dos cuidados médicos e prescrições / medicamentos | 0 | 1 | 2 | 3 | 4 |
| 11. Respirar pela boca durante o dia | 0 | 1 | 2 | 3 | 4 |
| 12. O seu filho não está a crescer ou a ganhar peso como esperado | 0 | 1 | 2 | 3 | 4 |
| 13. Respiração ruidosa durante o dia | 0 | 1 | 2 | 3 | 4 |
| 14. Problemas de falta de apetite ou maus hábitos alimentares | 0 | 1 | 2 | 3 | 4 |
| 15. Problemas comportamentais em casa ou na escola, más notas ou maus relatórios escolares | 0 | 1 | 2 | 3 | 4 |

Psychometric proprieties: We checked the psychometric values of the tool to check the possibility of being used by different people for academic purposes.

Statistical analysis: Collected data was organized, tabulated, and statistically analyzed using SPSS version 26 (Statistical Package for Social Studies) created by IBM, Illinois, Chicago, USA. For numerical values, the range mean, and standard deviations were calculated. The differences between the two mean values were used using the Mann-Whitney U test. Differences in mean values before and after the intervention were done by Wilcoxon signed ranks test. The correlation between items was performed using Spearman's correlation test and between total score and score of domains of the TAHSI were done using Pearson's correlation coefficient. To confirm that the domains remained stable in the translation, factor analysis was performed by the Varimax's orthogonal rotation with Kaiser Normalization and the Maximum Likelihood method. A factor analysis tries to capture the correlation (relationship) between the variables (items). The objective is to identify latent factors or dimensions that reflect what the variables have in common.

Results

Translation and fulfillment time: The European-Portuguese version of the Tonsil and Adenoid Health Status Instrument (EP-TAHSI) has been developed after cross-cultural adaptation and translation of the original English study tool. The parents of the children filled the questionnaire without any trouble, in a short time $(4.5 \pm 1.8 \text{ min})$.

Demographic results: The first group included the patients who underwent tonsillectomy or adenotonsillectomy - 51 patients, while the control group included 49 children. The final number of participants was 100 children. (Table 2)

Internal consistency and reliability: The internal consistency was tested by Cronbach's correlation coefficient. α was 0.946 for the total score. Item-to-item correlation was done using Spearman's correlation test (Table 3) while the subscale score to total score correlation was done Pearson's correlation coefficient. (Table 4). The reliability coefficient was adequate at y = 0.9.

Validity: The comparison between the first group (control group) and the second group (intervention group, before the operation) was performed, using the Mann-Whitney U test. It showed a significant difference between the

Table 2 Comparision of age and sex between the studied groups

| Variables | Control group (49 child) | Intervention group (51 child) | | |
|--------------|--------------------------|-------------------------------|--|--|
| Age in years | 6.00±2.96 | 6.06±3 | | |
| Males | 27 | 25 | | |
| Females | 22 | 26 | | |

Item by item correlation matrix of tonsil and adenoids health status instrument (TAHSI). Tested by cronbach's correlation coefficient

| | Item 2 | Item 3 | Item 4 | Item 5 | Item 6 | Item 7 | Item 8 | Item 9 | Item 10 | Item 11 | Item 12 | Item 13 | Item 14 | Item 15 |
|---------|--------|--------|--------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|---------|
| 1.Sno | .442** | .540** | .452** | .519** | .438** | .752** | .506** | .486** | .537** | .681** | .222* | .465** | .292** | .249* |
| 2.Strep | | .841** | .754** | .642** | .683** | .505** | .777** | .775** | .701** | .509** | .378** | .367** | .390** | .204* |
| 3.Trip | | | .843** | .775** | .830** | .570** | .908** | .909** | .820** | .561** | .453** | .400** | .480** | 0.188 |
| 4.>3w | | | | .836** | .792** | .578** | .853** | .856** | .674** | .539** | .484** | .510** | .422** | .234* |
| 5.<2w | | | | | .716** | .594** | .747** | .751** | .625** | .506** | .401** | .432** | .473** | .202* |
| 6.Call | | | | | | .484** | .813** | .811** | .781** | .519** | .492** | .440** | .470** | 0.111 |
| 7.Apn | | | | | | | .578** | .561** | .600** | .709** | .408** | .570** | .403** | .308** |
| 8.Acu | | | | | | | | .950** | .806** | .582** | .485** | .454** | .435** | .225* |
| 9.Chr | | | | | | | | | .783** | .521** | .502** | .456** | .440** | .257** |
| 10.Cost | | | | | | | | | | .576** | .425** | .457** | .443** | 0.107 |
| 11.Mou | | | | | | | | | | | .408** | .514** | .372** | .205* |
| 12.Grow | | | | | | | | | | | | .286** | .591** | 0.097 |
| 13.Nois | | | | | | | | | | | | | .231* | 0.182 |
| 14.Eat | | | | | | | | | | | | | | 0.124 |
| 15.Beha | | | | | | | | | | | | | | |

^{**} Significant correlation at the 0.01 level (bilateral).

^{*} Significant correlation at the 0.05 level (bilateral).

^{1.} Sno - item 1, snoring loudly; 2. Strep-item 2, streptococcal/bacterial throat infections; 3. Trip-item 3, physician trips; 4.>3w-item 4, taking antibiotics for more than 3 weeks straight; 5.-2w - item 5, taking antibiotics over and over for less than 2 weeks; 6. Call-item 6, many phone calls to doctor; 7. Apn-item 7, apnoea; 8. Acu-item 8, repeated acute infections of the tonsils; 9. Chr-item 9, constant chronic infections of the tonsils; 10. Cost-item 10, cost of medical care and prescriptions; 11. Mou-item 5, mouth breathing; 12. Grow - nor growing or gaining weight; 13. Nois - item 13, noisy breathing; 14. Eat-item 6, poor appetite or poor eating habits 15. Beha-behavior problems.

Table 4 Correlation of domains of tonsil and adenoids health status instrument. Tested by Pearson's correlation coefficient (*significant if <1).

| | Airway and breathing | Infection | Healthcare utilization | Eating and swallowing | Cost of care | Behavior | Total score |
|------------------------|-------------------------|-----------|---------------------------|-----------------------|--------------|----------|----------------|
| Airway and breathing | (0.872) | .578** | .655** | .371** | .627** | .293** | .850** |
| Infection | | (0.938) | .928** | .507** | .810** | .202* | .843** |
| Healthcare utilization | | | (0.942) | .511** | .814** | 0.175 | .894** |
| Eating and swallowing | | | | (0.744) | .487** | 0.118 | .572** |
| Cost of care | | | | | | 0.107 | .773** |
| Behavior | | | | | | | .356** |
| Total score | | | | | | | (0.946) |

^{**} Significant correlation at the 0.01 level (bilateral).
* Significant correlation at the 0.05 level (bilateral).

Table 5 Comparisons of tonsil and adenoids health status instrument among cases and control. Tested by Mann-Whitney u test

| Subscales EP-TAHSI | Control group (n=49) | Intervention group (n=51) | Z-score | p-value |
|---|-------------------------|------------------------------|---------|---------|
| Airway and breathing Range Average ± SD | 0-2 0.495 ±0.509 | 0-4 2.25 ±1.00 | -7.323 | 0,000 |
| Infection Range Average ± SD | 0-2 0.088 ±0.310 | 0-4 1.78 ±1.261 | -7.328 | 0,000 |
| Healthcare utilization Range Average ± SD | 0-2 0.041 ±0.193 | 0-4 1.544 ±1.168 | -7.934 | 0,000 |
| Eating and swallowing Range Average ± SD | 0-3 0.316 ±0.592 | 0-4 1.353 ±1.254 | -4.538 | 0,000 |
| Cost of care Range Average ± SD | 0-1 0.061 ±0.242 | 0-4 1.412 ±1.220 | -6.616 | 0,000 |
| Behavior Range Average ± SD | 0-2 0.388 ±0.786 | 0-4 1.00 ±1.442 | -2.361 | 0,018 |
| Total score Range Average ± SD | 0-18 3.490 ±3.150 | 4-58 25.628 ±12.955 | -8.395 | 0,000 |

EP - European Portuguese; SD (Standard Deviation); P (p value); Z (Standard Score). (* significant at p value ≤ 0.05).

Table 6Comparisons of tonsil and adenoids health status instrument (TAHSI) among cases before and after the intervention-tested by Wilcoxon Signed Ranks Test

| Subscales EP-TAHSI | Pre-operative | Post-operative | Z-score | p-value |
|--|------------------------|----------------------|---------|---------|
| Airway and breathing Range Average ± SD | 0-4 2.250 ±1.001 | 0-1 0.245 ±0.221 | 7.323 | 0,001 |
| Infection Range Average ± SD | 0-4 1.778 ±1.261 | 0-1 0.007 ±0.047 | 7.328 | 0,001 |
| Healthcare utilization Range Average ± SD | 0-4 1.544 ±1.168 | 0-1 0.059 ±0.204 | 7.934 | 0,001 |
| Eating and swallowing Range Average ± SD | 0-4 1.353 ±1.254 | 0-1 0.226 ±0.336 | 4.538 | 0,001 |
| Cost of care Range Average ± SD | 0-4 1.412 ±1.221 | 0-0 0.000 ±0.000 | 6.616 | 0,001 |
| Behavior Range Average ± SD | 0-4 1.000 ±1.442 | 0-2 0.177 ± 0.478 | 2.361 | 0,001 |
| Total score Range Average ± SD | 4-58 26.628 ±12.956 | 0-5 1.863 ±1.429 | 8.395 | 0,001 |

 $EP-European \ Portuguese; SD \ (Standard \ Deviation); P \ (p \ value); Z \ (Standard \ Score). \ (* \ significant \ at \ p \ value \ \le 0.05).$

Table 7 Rotated factor matrix

| | Factor | | | | | | | | |
|---------|--------|------|------|------|--|--|--|--|--|
| | 1 | 2 | 3 | 4 | | | | | |
| Q9 - 1 | .873 | .261 | .291 | .110 | | | | | |
| Q8 - 1 | .847 | .379 | .222 | .071 | | | | | |
| Q3 - 1 | .839 | .332 | .204 | .170 | | | | | |
| Q2 - 1 | .768 | .324 | .119 | .112 | | | | | |
| Q6 - 1 | .764 | .170 | .366 | .197 | | | | | |
| Q4 - 1 | .711 | .332 | .238 | .404 | | | | | |
| Q5 - 1 | .669 | .307 | .203 | .631 | | | | | |
| Q10 - 1 | .624 | .481 | .296 | 005 | | | | | |
| Q7 - 1 | .235 | .845 | .199 | .152 | | | | | |
| Q1 - 1 | .222 | .774 | .082 | .079 | | | | | |
| Q11 - 1 | .285 | .731 | .233 | .005 | | | | | |
| Q13 - 1 | .271 | .543 | .286 | .117 | | | | | |
| Q15 - 1 | .190 | .291 | .062 | .169 | | | | | |
| Q12 - 1 | .295 | .235 | .923 | .071 | | | | | |
| Q14 - 1 | .298 | .305 | .473 | .114 | | | | | |

Extraction Method: Maximum Likelihood. Rotation Method: Varimax with Kaiser Normalization a. Rotation converged in 7 iterations.

2 groups: the total score in the first group was $3.490 \pm 3.150 (0-18)$; in the second group was $25.628 \pm 12.955 (4-58)$. (P-value <0.001) (Table 5).

Responsiveness: The differences in the mean values before and after the intervention was done by Wilcoxon signed ranks test. Before the intervention, the total score was 25.628 \pm 12.955 (4-58), while after the operation, the score obtained was 1.863 \pm 1.429 (0-5). It was found a significant difference between both groups (P-value<0.001) (Table 6).

Factorial analysis: The anti-image correlation matrix reveals a strong correlation for each item (r>0.8) that validated their integration in analysis. The KMO statistic equal to 0,915 and significative Bartlett's test of sphericity (p-value < 0,001) validate the factorial solution. All items have communalities higher than 0.4 (only item 15 has commonalities below 0.3 reveal little in common with the other items and the extracted factors). Four factors were extracted from the data: healthcare utilization and infections (items 9, 8, 3, 2, 6, 4 and 5; factor loadings: 0.87, 0.85, 0.84, 0.77, 0.76, 0.71 and 0.67, respectively); airway and breathing (items 7,1,11 and 13; factor loadings: 0.85, 0.77, 0.73, and 0.54, respectively); eating and swallowing (items 12 and 14; factor loadings: 0.92 and 0.47, respectively). The three factors explain a total variance of 68%: the healthcare utilization and infections factor explain 34,47%; airway and breathing 21,78%; eating and swallowing 11,80%. Cost of care (item 10 with factor loading equal to 0.62 saturates in healthcare utilization and infections factor) and behavior (item 15 with factor loading equal to 0.29 saturates in airway and breathing factor) did not meet criteria to load onto any of the three principal factors and were included as separate subscales. (Table 7)

Discussion

Goals proposed: The main goal of this study was to adapt and validate the European-Portuguese version of the TAHSI with an analysis of the advantages of the psychological

dimension. This can only be archived if the tool matches the original version.

Translation and evaluation of the statistical power of EP-TAHSI: The adequate translation was established by following the principles of forward and backward translation - this allowed the assembly of a version of an easy and reliable answer.8 This can be also reinforced by the short time of fulfillment of all items, which demonstrates the feasibility of this version. Reproducibility is given by the degree of stability of the information when the measurement is repeated under similar conditions. Our reliability coefficient was very high indicating a homogenous reproducible Portuguese version.9

The strength of any research tool is directly linked to internal consistency. It measures whether several items that propose to give the identical general construct produce similar scores. In our study item to item relations were strong as Cronbach's parametric statistic was 0.946, making our European-Portuguese version a reliable one.⁹

Validity refers to the degree to which a study or questionnaire accurately reflects the precise concept that the researcher is attempting to give. Item to item correlations, correlations within each item, subscales, and total score, had a positive relation with the initial TAHSI - confirming the validity of our research tool. Discriminatory validity is that the degree to which a test or measure diverges from another measure whose underlying construct is conceptually unrelated thereto the power of the questionnaire to differentiate between interventional and control groups. The high statistically significant results regarding comparing the whole score and subscale scores between both groups indicated that our research tool is valid. Responsiveness is the ability of the questionnaire to detect changes of status over time.9 Our tool proved to be responsive, this can be confirmed by comparing the overall score and subscale scores before and after the procedure, which showed respectively higher and lower scores. Also, these results were statistically significant. The psychometric merits of our version coincide with the initial English study tool and Arabic version with the identical 6 domains.^{2,10} They also coincide with other versions just like the Spanish version which used only 5 domains 11

Limitations: The varied limitations which can be stated about our study can be the actual fact of the assessment of patient's status and their course after surgery being based only on self-administrated questionnaires and not by objective methods like image studies, sleep studies, or maybe nasal and oral air-flow measures. However, we don't consider that this limitation would translate into a unique result and we consider that it doesn't take strength from the validation archived.

Usefulness of the tool: We also consider that the score can be used in the follow-up of patients who underwent tonsillectomy and can help the physician into legal issues that can arise after surgery.

Conclusion

The Portuguese version of the Tonsil and Adenoid Health Status Instrument is well accessible and reliable with strong internal consistency, responsiveness, and validity. It's a good method to detect changes on health and quality of life. We advocate its use, within the Portuguese context, when an adenoidectomy or tonsillectomy is taken into account, and can be used in the follow-up of patients who underwent surgery and being a great tool for the physician into legal issues that can arise after surgery.

Conflito de Interesses

Os autores declaram que não têm qualquer conflito de interesse relativo a este artigo.

Confidencialidade dos dados

Os autores declaram que seguiram os protocolos do seu trabalho na publicação dos dados de pacientes.

Proteção de pessoas e animais

Os autores declaram que os procedimentos seguidos estão de acordo com os regulamentos estabelecidos pelos diretores da Comissão para Investigação Clínica e Ética e de acordo com a Declaração de Helsínguia da Associação Médica Mundial

Política de privacidade, consentimento informado e Autorização do Comité de Ética

All procedures performed in the current study, including human participants were ethically approved: in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki and its later declaration amendments or comparable ethical standards. Ethical committee approval was obtained with the reference: 2020.176 (137-DEFI/139-CE). Formal consent was signed by the parents of the children for contributing to this research.

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Disponibilidade dos Dados científicos

Não existem conjuntos de dados disponíveis publicamente relacionados com este trabalho.

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