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Cross-Cultural Adaptation and Validation of the Greek SPOT-25 Quality of Life Questionnaire in Patients with Otosclerosis

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ABSTRACT

Objective: *To translate, adapt and validate in Greek the stapesplasty outcome test (SPOT)-25 quality of life questionnaire for patients with otosclerosis.*

Materials and methods: *SPOT-25 was translated to Greek and completed by otosclerosis patients on the day of diagnosis, the day before surgery and three months postoperatively. Fifty controls without any otological history, symptom or finding also completed the questionnaire. Pure-tone average was obtained both preoperatively and three months postoperatively.*

Results: *Test-retest evaluation on 56 patients was accepted. The Greek-SPOT-25 had an excellent internal consistency. All its items and subscales were significantly correlated between test and retest evaluation. Controls had significant lower SPOT-25 scores, and the postoperative scores were significantly lower than preoperative ones. Pure-tone average of four frequencies (PTA4) was significantly correlated to preoperative SPOT-25 total and subscales scores (P<0.001) before surgery and significantly correlated only with the "hearing function" subscale (p<0.05) postoperatively.*

Keywords: Greek-SPOT-25 proved a valid instrument, with satisfactory internal consistency, reliability, validity, and responsiveness.

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INTRODUCTION

Otosclerosis is a primary disease of the otic capsule. It is characterized by alternating phases of absorption of compact bony tissue and replacement with spongy bone, which has higher density, cellularity and vascularity. The most common site of location is the oval window that causes the stapedial ankylosis. The main symptoms of the disease include progressive conductive hearing loss and tinnitus, while sensorineural hearing loss may also occur in 10% of patients (1, 2). Hearing disability caused by otosclerosis compromises physical, cognitive, behavioral, social and psychological functions as well as patients' health related quality of life (HRQOL) (3-6).

Stapes surgery (both stapedotomy and stapedectomy) is a well-established treatment option for patients with otosclerosis, while the efficiency of stapes surgery is traditionally measured by the improvement of audiological performance (3-6). The 1995 and 2012 American Academy of Otolaryngology–Head and Neck Surgery guidelines on minimal reporting standards for evaluating outcomes in conductive hearing loss recommend the use of pure-tone audiometric thresholds and/or speech discrimination scores (7, 8). Audiometric tests are able to assess only surgical success but not also the HRQOL of otosclerosis patients. On the other hand, most studies which evaluated HRQOL after stapes surgery have not used otosclerosis specific but generic and hearing-specific questionnaires (3-6).

Stapesplasty outcome test-25 (SPOT-25) is the first validated otosclerosis disease specific HRQOL questionnaire (3-6). It was developed in German (4) and has already been validated in Danish (5), while it is under validation for the Dutch language (6). The questionnaire consists of 25 items, which can be divided into four subscales: "hearing function" (items 1–10), "tinnitus" (items 11–13), "mental condition" (items 14–19), "social restrictions" (items 20–24), while the 25th item focuses on the general evaluation of the otosclerosis impact on HRQOL. Each question needs to be rated on a six-point ordinal scale from 0 (no impact) to 5 (most severe impact), depending on the level of inconvenience or frequency of symptoms (4-6).

The aim of this study was to translate, adapt and validate the Greek version of the SPOT-25 questionnaire. ❑

MATERIAL AND METHODS

Translation of SPOT-25 questionnaire

Validation of the Greek questionnaire included translation of SPOT-25 questionnaire (Appendix) from German into Greek by two independent native Greek translators and retranslation back from Greek into German by two native German translators (5, 6).

Ethical considerations

The study was approved by the Review Board and Ethics Committee. All participants' data were handled according to the principles of the Helsinki Declaration and Health Insurance Portability and Accountability acts (HIPAA).

Study participants and setting

A prospective instrument validation study was conducted on adult patients undergoing primary stapes surgery in our hospital. Otosclerosis was suspected in case of bone conduction hearing loss combined with type A tympanogram and missing stapes reflexes, an intact non-irritated eardrum, and no history of chronic ear disease. Only patients with intraoperative confirmation of stapes footplate fixation were included in the study. Patients undergoing revision surgery as well as those who were unable to read and understand Greek were excluded from the study.

All patients with suspected otosclerosis were asked to complete the Greek SPOT-25 during their first visit to the outpatient clinic, while air-conduction thresholds were calculated as pure-tone average of four frequencies (0.5, 1, 2, and 3 kHz) (PTA4), according to the 1995 guidelines of the Committee on Hearing and Equilibrium (7). Furthermore, the SPOT-25 questionnaire was also completed in the evening prior to surgery, while three months postoperatively pure-tone audiogram and SPOT-25 scores were obtained for those in whom stapes footplate fixation was confirmed.

Fifty (50) consecutive adult individuals from our outpatient clinic with no history of hearing problems or prior ear surgery and no findings on ear examination were asked to complete the Greek version of SPOT-25 in order to recruit our

control group. Persons unable to read and understand Greek were excluded.

A minimum sample size of 50 participants, similar to that of the original German SPOT-25 validation study (4), was considered sufficient for our purpose. ❑

RESULTS

Otosclerosis group consisted of 56 patients (female/male ratio 41/15) with a mean age of 52.62 (±11.27) years stapes surgery, and the control group comprised 50 patients (female to male ratio 28/22), with a mean age of 35.94 (±11.68) years. All participants have fully completed the questionnaires. Table 1 shows the mean SPOT-25 scores of all groups.

The mean SPOT-25 score was 64.96 (±15.83) in the initial test and 66.75 (±15.89) in the retest evaluation, while the mean time between test-retest evaluations was one month. Cronbach's alpha was 0.908 and 0.901 at the initial and retest examinations, respectively, with both values indica-

TABLE 1. Means (±SD) of SPOT-25 total and subscales scores for the otosclerosis (preoperative test–retest and postoperative) and control groups

	Otosclerosis group: preoperative (test study)		Otosclerosis group: preoperative (re-test study)		Otosclerosis group: postoperative		Control group	
	mean	SD	mean	SD	mean	SD	mean	SD
Total score	65.45	15.83	66.75	15.89	29.04	5.18	18.12	10.76
Hearing function	28.76	6.29	29.54	6.32	15.46	3.88	7.88	5.68
Tinnitus	7.64	2.49	7.84	2.61	2.32	2.67	2.22	1.02
Mental condition	15.50	5.02	15.89	5.11	4.84	1.88	5.40	3.00
Social restrictions	10.43	4.26	10.79	4.34	4.54	1.06	2.12	2.35
General	3.11	0.71	2.70	0.89	1.87	0.63	0.50	0.99

SD: standard deviation

TABLE 2. Test–retest reliability for SPOT-25 questionnaires completed during the initial clinic visit (test) and prior to surgery (retest); validity by comparing SPOT-25 (test) scores of otosclerosis to control group and correlation of SPOT-25 (test) scores to pure-tone air-conduction thresholds average over the frequencies 0.50-3 kHz (PTA4); significant postoperative reductions in SPOT-25 total score and scores for subscales, suggesting adequate responsiveness; and a significant correlation with postoperative PTA4 only for the "hearing function" subscale

	Test-retest reliability	Validity: otosclerosis *vs.* control group	Validity in relation to PTA4	Responsiveness in SPOT-25 scores following surgery	Postoperative correlations of SPOT-25 to PTA4
	Pearson's correlation between test and retest SPOT-25 scores	Mann-Whitney U	Spearman's coefficient Rho between SPOT-25 scores and PTA4	Paired t-test P	Spearman's coefficient Rho between SPOT-25 scores and PTA4
SPOT-25 total score	0.999**	13.5**	0.562**	<0.001**	-0.110
Hearing function	0.992**	0**	0.518**	<0.001**	-0.442*
Tinnitus	0.989**	87**	0.264*	<0.001**	-0.560
Mental condition	0.993**	78**	0.503**	<0.001**	0.640
Social restrictions	0.992**	109.5**	0.625**	<0.001**	-0.038
General	0.957**	137.5**	0.627**	<0.001**	-0.114

* P<0.05 (2-tailed)

** P<0.01 (2-tailed)

ting a good internal consistency. All correlations between test and retest evaluation were significant (P<0.01) for the total score and subscale scores (Table 2).

The Greek SPOT-25 showed sufficient validity. The mean total score in otosclerosis (test score) and control groups was 65.45 (±15.83) and 18.12 (±10.76), respectively; this difference was significant (U=13.5, P<0.001). The mean preoperative PTA4 was 53.46 (±7.36); Spearman's test showed that PTA4 was significantly correlated (P<0.001) to SPOT-25 total and subscale scores (Table 2).

A significant reduction in SPOT-25 total score after surgery was noted: 29.04 (±5.18) postoperatively *vs* 65.45 (±15.83) preoperatively; P<0.001. Furthermore, significant differences in scores of all SPOT-25 subscales were seen. The mean postoperative PTA4 was 30.43 (±5.52), while a significant correlation was noticed only with the "hearing function" subscale (Spearman's rho: -0.442, p=0.016) (Table 2). ❑

DISCUSSION

QOL is increasingly recognized as an important health outcome measure in clinical medicine, since it reflects the World Health Organization's definition of health as "the state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (11). Thus, lately, apart from the other outcome measures, validated translations of questionnaires are being widely used, which helps to compare populations of different countries and cultures and to establish protocols for global health. Otosclerosis impairs patients' HRQOL, while most studies which evaluated HRQOL after stapes surgery have used generic and hearing-specific questionnaires. Until now, SPOT-25 represents the only disease specific-HRQOL questionnaire for otosclerosis (3-6), and therefore we believe that its cross-cultural adaptation and validation will be useful for research as well as for Greek patients with otosclerosis.

Internal consistency measures how well the scores for individual items on the instrument correlate with each other (12). The internal consistency of the Greek SPOT-25 was explored with Cronbach's alpha test, while the minimum acceptable value to represent and evaluate internal consistency is 0.7 (9, 10). In our study, Cronbach's alpha was 0.907 and 0.901 at the initial and retest examination, respectively, both values suggesting an excellent internal consistency. Similar results were reported for the German and Danish versions of the questionnaire (4, 5).

Test-retest reliability reflects the stability of calculated scores with repeated testing and can be evaluated by correlating initial test and subsequent retest scores (12). The German SPOT-25 also demonstrated acceptable test-retest reliability (4), while the Danish version showed a high degree of correlation in "hearing function", "tinnitus", and total scores, whereas the degree of correlation was moderate in "mental condition", "social restrictions", and "general HRQOL" subscales (5). In our study, correlations of test-retest evaluation were significant for total SPOT-25 scores as well as for scores assigned to all subscales and items.

The validity of the measures is the capacity of the questionnaire to reflect differences between known groups (12). The Greek SPOT-25 validity was assessed by comparing SPOT-25 scores between otosclerosis and control groups as well as by exploring potential correlations between survey results and PTA4. In our study, total SPOT-25 and subscale scores were significant higher in the otosclerosis group as well as in the German and Danish version studies (4, 5). Furthermore, the Greek SPOT-25 total and subscale preoperative scores were significantly correlated to preoperative PTA4; it should be noticed that the "tinnitus" subscale score was correlated in the 0.05 level, while the rest of subscales in the 0.01 level.

Responsiveness refers to the ability of an instrument to detect clinical change. If a treatment results in an important difference in the QOL, the instrument should be able to detect it even if it is a small one (13). Responsiveness of SPOT-25 can be evaluated by comparing scores before and after stapes surgery. Lailach *et al* reported significantly better ratings of total and subscale score postoperatively for the German SPOT-25 (3, 4), while for the Danish SPOT-25 postoperative results were not reported (5). In our study, postoperative total and subscale scores were significantly lower than the preoperative ones, confirming responsiveness of the Greek translated instrument and suggesting a significant improvement of HRQOL after surgery. Lailach *et al* also reported a significant correlation of postoperative audiometric data with postoperative "hearing function" subscale, while "tinnitus", "social restriction", and

"mental condition" subscales were not significantly correlated (3). In our study, postoperative PTA4 was also significantly correlated only with the postoperative "hearing function" subscale, suggesting that audiometric data may not be an adequate tool to assess HRQOL-related aspects of otosclerosis. ❑

CONCLUSION

Our study demonstrates that the Greek SPOT-25 questionnaire is a valid and easy to use instrument for assessing QOL of patients with otosclerosis. It has satisfactory internal consistency, reliability, validity, and responsiveness. Greek SPOT-25 showed a good consistency within subscores by discriminating individuals with otosclerosis patients from normal hearing. It is a valid and easy to use instrument and it may be as well a very useful complement tool to the audiometric data in everyday otolaryngology practice as well as in research. ❑

Conflicts of interest: none declared.

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Availability of data and material: Data that support the findings of this study are available on request from the corresponding author; they are no publicity available due to privacy or ethical restrictions.

Ethics Committee Approval: Ethics committee approval was received for this study, University of Thessaly, Larissa, Greece.

Informed consent: Written and oral consent was obtained by all participants to the present study prior to participation.

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