

Italian translation, cross-cultural adaptation and validation of the Mayo Clinic Vestibular Schwannoma Quality of Life (VSQOL) Index

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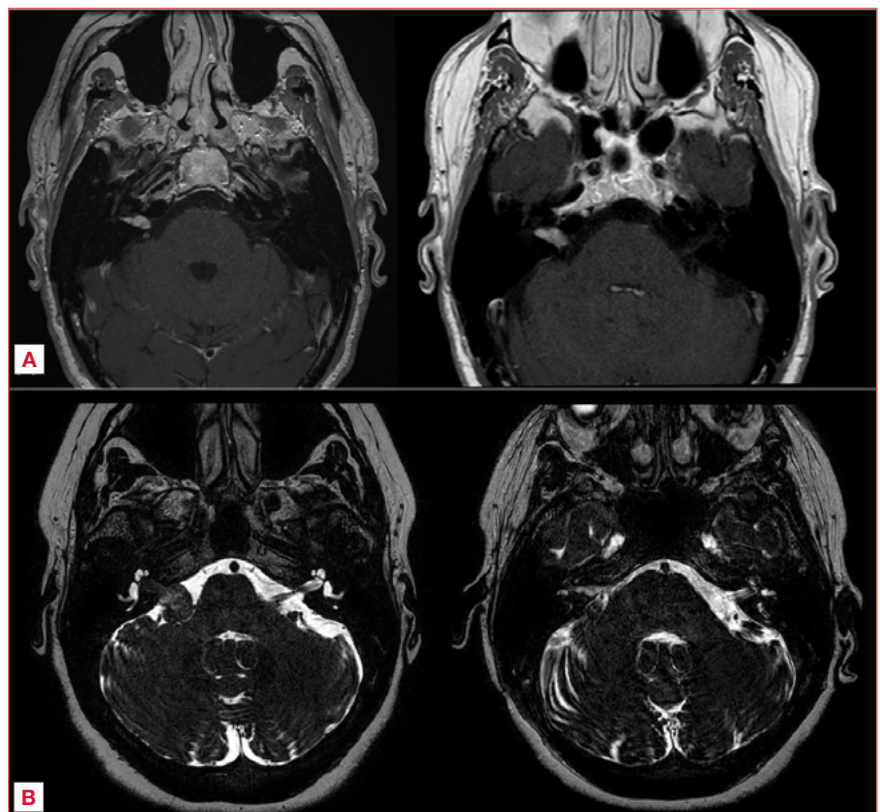
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Cover figure. A) Contrast enhanced T1-MRI sequence at diagnosis and after 24 months of wait-and-scan of a right vestibular schwannoma; B) T2-MRI sequence of pre- and post-surgical excision of a right vestibular schwannoma.

Summary

Background. The Mayo Clinic Vestibular Schwannoma Quality of Life (VSQOL) Index is a disease-specific instrument for assessing health-related quality of life (HRQoL) in patients with sporadic vestibular schwannoma (VS). To date, there is no validated Italian version of this questionnaire.

Objectives. This study aimed to translate, culturally adapt, and validate the VSQOL Index Version 2 in Italian (Italian VSQOL Index) while assessing its psychometric properties.

Methods. The VSQOL Index Version 2 was translated and culturally adapted according to the Functional Assessment of Chronic Illness Therapy (FACIT) methodology. A cohort of 39 Italian-speaking VS patients completed the Italian VSQOL Index alongside the Penn Acoustic Neuroma Quality of Life (PANQOL) Scale, the 36-Item Short Form Health Survey (SF-36), and the 21-Item Depression, Anxiety, and Stress Scale (DASS-21). Internal consistency (Cronbach's α), test-retest reliability (intraclass correlation coefficient, ICC), and construct validity were analysed.

Results. The Italian VSQOL Index demonstrated excellent internal consistency, with Cronbach's α ranging from 0.89 to 0.95 across its domains, and high test-retest reliability, indicated by an ICC ranging from 0.78 to 0.92 among the domains. Significant correlations with PANQOL, SF-36, and DASS-21 scores confirmed convergent validity. Patients received the questionnaire positively, with no major comprehension issues reported during cognitive debriefing.

Conclusions. The Italian VSQOL Index is a valid and reliable instrument for assessing HRQoL in Italian-speaking VS patients. Its application in clinical practice and research will enhance the evaluation of disease impact and treatment outcomes within this population.

Keywords: vestibular schwannoma, quality of life, acoustic neuroma, lateral skull base, questionnaire

Introduction

Vestibular schwannoma (VS) is the most prevalent tumour in the cerebellopontine angle, accounting for approximately 90% of cases and representing about 8% of all intracranial neoplasms. The incidence of its sporadic variant ranges between 3 and 5.2 per 100,000 person-years, with a median age of 60 years at diagnosis^{1,2}. Despite extensive research, no consensus has been reached on the optimal treatment approach. Current management options include microsurgery, radiosurgery, and active observation, with the choice largely dependent on factors such as tumour size, patient comorbidities, and patient preferences³.

Although VS is histologically benign, it frequently results in neurological and functional issues due to either disease progression or treatment, leading to a diminished health-related quality of life (HRQoL) for affected individuals. The majority of studies comparing management strategies have primarily focused on a narrow range of technical outcomes, such as tumour control and postoperative facial and auditory functions. However, additional critical factors, including pain, postural and gait instability, psychosocial well-being, and satisfaction with treatment decisions, significantly influence patient outcomes and experiences. Symptoms arising from either disease progression or treatment may impair HRQoL in ways that may not be fully reflected by objective measures like hearing thresholds, facial paralysis, or tumour size.

In recent decades, there has been an increasing emphasis on QoL outcomes in managing VS. A longstanding challenge in assessing HRQoL in these patients has been the absence of disease-specific measuring tools. Earlier tools, such as the generic 36-item Short Form Survey (SF-36)⁴, were highly susceptible to confounding factors like comorbidities and lacked the sensitivity to capture subtle, disease-specific changes in a patient's clinical status. The introduction of the Penn Acoustic Neuroma Quality of Life (PANQOL) Scale⁵ in 2010 addressed these limitations, demonstrating superior sensitivity compared to the SF-36 in evaluating VS management strategies. In 2023, Apa et al. translated and validated the PANQOL Scale⁶ into Italian, providing a valuable tool for assessing the HRQoL of Italian-speaking patients with sporadic VS. However, important domains –

including physical pain and its emotional burden, cognitive difficulties, the effect of auditory and balance issues on feelings of safety, satisfaction or regret regarding treatment decisions, and the socioeconomic impact of the pathology – remained underrepresented. To address these gaps, Carlson et al. developed the Mayo Clinic Vestibular Schwannoma Quality of Life (VSQOL) Index⁷ in 2022.

The present study aimed to translate the VSQOL Index into Italian and to assess its structural validity and internal consistency, thereby establishing it as a reliable tool for evaluating HRQoL in Italian-speaking patients with sporadic VS. Validating this tool in Italian is critical to ensure its cultural and linguistic applicability, and to provide clinicians and researchers with a comprehensive, disease-specific resource that can support clinical decision-making and facilitate multicentre and cross-cultural research involving this population.

Mayo Clinic Vestibular Schwannoma Quality of Life (VSQOL) Index

The Mayo Clinic VSQOL Index, published by Carlson and colleagues in 2022, represents the most recently developed disease-specific QoL instrument for sporadic VS⁷. It consists of 40 items grouped into 8 domains: Hearing Problems; Dizziness and Imbalance; Pain, Discomfort, and Tinnitus; Problems with Face or Eyes; Impact on Physical, Emotional, and Social Well-Being; Difficulty with Thinking and Memory; Satisfaction or Regret, and Impact on Employment. The first 7 domains consist of items with 5 possible responses, and a domain score is calculated as the average of responses to the items. The domain scores range from 0 to 100, with higher scores denoting a better QoL. A global QoL score is calculated as the average of the first 6 QoL-related domain scores. The last domain contains 3 items assessing the impact of the diagnosis of sporadic VS and its management on employment.

Materials and methods

Study design

The present study encompassed 2 phases. In the first phase, the VSQOL Index was translated into Italian and culturally

adapted by a multidisciplinary group comprising neurosurgeons, otolaryngologists, and a professional translator. Collaboration with the original authors of the questionnaire was crucial during this process, as they reviewed the back-translation and made adjustments to the original version of the instrument as part of a decentralised translation approach ⁸. The second phase was conducted in the outpatient clinics of the Department of Otolaryngology-Head and Neck Surgery and the Department of Neurosurgery, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy, between March and September 2024. During this phase, the Italian version of the VSQOL Index was administered alongside other generic and disease-specific QoL instruments (PANQOL, SF-36, and DASS-21) to a sample of 39 VS patients. Five of these patients participated in interviews to qualitatively assess the questionnaire's acceptability. The Italian version of the VSQOL Index was then re-administered to the remaining 34 patients after 2 to 5 weeks to assess test-retest reliability.

Translation process and cultural adaptation of the VSQOL Index

With the approval of the original authors at Mayo Clinic, the VSQOL Index was translated into Italian following the Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology ⁸.

FORWARD TRANSLATION

The original English version of the VSQOL Index was independently translated into Italian by 2 bilingual native Italian speakers: one translator was a professional linguist with no clinical or medical expertise, and the other was a physician who had lived in the United States for 3 years.

A third bilingual translator reconciled the forward translations. The reconciliation process involved selecting the most appropriate phrasing from each version, resolving discrepancies, and ensuring the translation maintained conceptual and linguistic equivalence with the original English version. Particular attention was given to clarity, accuracy, and comprehensiveness.

BACK TRANSLATION

The reconciled forward translation was then translated backward into English by another translator, a native English speaker who was blind to the original version of the instrument.

The original authors of the instrument at Mayo Clinic reviewed the back-translated and the Italian versions of the questionnaire to identify potential discrepancies and assess equivalence with the source material. This stage also provided an opportunity to recognise concepts that posed

translation challenges and refine the original items through a “decentring” process, ensuring cultural and conceptual alignment across both language versions ⁸. Through this review process, and based on linguistic discrepancies observed across different languages, the original authors developed a second version (Version 2) of the VSQOL Index. Our Italian translation was based on this revised version.

COMMITTEE REVIEW

The original, forward, reconciled, and back-translated versions of the VSQOL Index, along with the original authors' comments, were consolidated into a consensus version by an expert committee, comprising neurosurgeons, otolaryngologists, and a professional translator. They evaluated the semantic, idiomatic, experiential, and conceptual equivalence of the translations, finalising the Italian version of the instrument, which is provided in Appendix 1, and preparing it for field testing.

Other questionnaires

PENN ACOUSTIC NEUROMA QUALITY OF LIFE (PANQOL) SCALE

The PANQOL Scale ⁵, developed by Shaffer and colleagues in 2010, is the first disease-specific HRQoL instrument for patients with sporadic VS. It consists of 26 questions that assess 7 dimensions, including VS-specific domains: Hearing, Balance, Face, Anxiety, Energy, Pain, and General Health. The PANQOL Scale scores range from 0 to 100, with higher scores suggesting better QoL. The present study uses the Italian-validated translation of the PANQOL Scale, provided by Apa et al. in 2023 ⁶.

36-ITEM SHORT FORM HEALTH SURVEY (SF-36)

The SF-36 ⁹ is a generic instrument for evaluating HRQoL. It consists of 36 multiple-choice questions grouped into 8 scales: Physical Functioning (PF), Social Functioning (SF), Physical Role limitations (PR), Emotional Role limitations (ER), Mental Health (MH), Vitality (VT), Bodily Pain (BP), and General Health (GH). The SF-36 scores range from 0 to 100, and higher scores indicate a status of better health. The present study uses the Italian-validated version of the SF-36, produced by Apolone and Mosconi in 1998 ¹⁰.

21-ITEM DEPRESSION ANXIETY AND STRESS SCALE (DASS-21)

The DASS-21 ¹¹ is a short form of the 42-item self-report measure of depression, anxiety, and stress ¹². It consists of 7 questions for each of the 3 domains: Depression (De), Anxiety (An), and Stress (St). The items are scored on a 4-point scale ranging from 0 to 3. A scale score is calculated by doubling the sum of the item scores, with higher scores indicat-

ing greater psychological impairment. The present study uses the Italian-validated translation of the DASS-21¹³.

Eligibility criteria

Participants were recruited from the Otolaryngology-Head and Neck Surgery and the Neurosurgery Units of the IRC-CS University Hospital of Bologna.

Eligible participants were Italian-speaking adults aged 18 years or older diagnosed with sporadic VS who were able to understand and write Italian. Patients were required to be either under conservative management with active surveillance, with a diagnosis at least 6 months before the recruitment to ensure a stable HRQoL, or to have undergone microsurgical resection between December 2020 and November 2022. Exclusion criteria were: type II neurofibromatosis, previous surgical or radiation treatment in the head and neck region, pre-existing psychiatric conditions, neurological conditions responsible for chronic headache or postural instability, pre-existing facial paresis, and physical, psychological, or practical limitations that could interfere with completing the questionnaire.

In total, 45 patients were approached, of whom 6 (13%) declined to participate in the study, leaving a final sample of 39, including 13 (33%) who were managed with active surveillance and 26 (67%) who were treated with microsurgical resection. The sample size was determined to be sufficient to ensure adequate statistical power for the validation process.

Data collection

The questionnaires were administered during the outpatient visits for either active surveillance or postoperative care at the Department of Otolaryngology-Head and Neck Surgery and the Department of Neurosurgery of IRCCS Azienda Ospedaliero-Universitaria at Bologna, between March and September 2024.

The study form required approximately 20 minutes to complete and was organised into 3 distinct sections: the first section addressed informative consent for the use of personal and clinical data; the second contained the Italian VSQOL Index; and the third included additional HRQoL measures, namely the PANQOL Scale, SF-36, and DASS-21.

Before the main quantitative analysis involving the full sample, a pilot phase was conducted with a sample of 5 patients who had undergone surgery for VS. The aim was to evaluate the items in the Italian VSQOL Index for clarity and relevance, after the administration of the 3-section form, using semi-structured interviews. Participants were prompted with the following inquiries: (1) Were there any questions or statements that were difficult to understand?

(2) Were there any questions or statements that seemed irrelevant? (3) Do you have any additional comments regarding the questionnaire?

Based on the pilot phase feedback, the Italian VSQOL Index was confirmed. Subsequently, the questionnaires in the 3-section form were administered to the remaining 34 participants. The retesting employed the same methodology but with a streamlined form containing only the first 2 sections. It occurred within a period of 2 to 5 weeks after the initial administration, a timeframe chosen to minimise the risk of recall bias while ensuring participants' clinical stability.

Demographic and clinical characteristics were gathered following the first administration of the questionnaires. The features collected included: age at administration, gender, age at diagnosis and treatment, type and date of treatment, tumour size prior to the surgical treatment or at the most recent radiological exam, and assessment of auditory and facial functions.

Data analysis and psychometric properties

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (Armonk, NY: IBM Corp). Demographic and clinical features of the participants were reported using descriptive statistics. Continuous variables were expressed as means with standard deviations, while categorical variables were reported with frequencies and percentages. Statistical significance was defined as a *p* value < 0.05. The statistical analysis focused on evaluating the internal consistency, validity, and reliability of the Italian VSQOL Index questionnaire, as detailed below.

INTERNAL CONSISTENCY

Internal consistency of the Italian VSQOL Index domains was evaluated using Cronbach's α coefficient. Values between 0.70 and 0.95 were considered indicative of acceptable internal consistency¹⁴.

CONVERGENT VALIDITY

The convergent validity was assessed by examining the correlation between the domains of the Italian VSQOL Index and other measures such as the physical and mental components of the SF-36, the Depression, Anxiety, and Stress scales of the DASS-21, and the domains of the PANQOL-IT. Correlations were analysed using Pearson's correlation coefficients (*r*) or Spearman rank correlation coefficients (ρ), with values between 0.2 and 0.35 considered poor, values between 0.35 and 0.5 considered moderate, and values greater than 0.5 considered strong¹⁵.

TEST-RETEST RELIABILITY

Test-retest reliability was assessed by determining the reproducibility of responses from the 34 sporadic VS patients who

were asked to complete the Italian VSQOL Index twice, within a 2 to 5-week interval. Reproducibility was determined using the Intraclass Correlation Coefficient (ICC), which was considered acceptable with a value higher than 0.70¹⁶.

STATISTICAL POWER

The sample size of 39 patients provides adequate statistical power for the analyses performed. The estimate of the internal consistency, using Cronbach's α coefficient, is deemed reliable for samples of more than 30, although the confidence intervals may remain relatively wide. For the correlation analysis, using Pearson (r) or Spearman rank (ρ) correlation coefficients, the study has > 0.80 power to detect medium-to-large associations (r or $\rho \geq 0.50$) at a significance level of 0.05. This aligns with effect sizes typically expected in validity studies; however, smaller effect sizes would require larger samples.

Results

Patient demographics

The study included 39 Italian-speaking adults diagnosed with sporadic VS, of whom 26 (67%) underwent microsurgical excision of the lesion, while 13 (33%) were managed conservatively with periodic radiological exams. Of those included, 34 participants completed the questionnaire twice within a 2 to 5-week interval. Demographic and clinical characteristics of the participants in the 2 phases of the current study are presented in Table I.

Item analysis

A summary of responses to the Italian VSQOL Index items for the 39 participants included in the study was presented in Table II of the Supplemental Material. The mean scores ranged from 62 ($SD \pm 26$) in the Hearing Problems domain to 81 ($SD \pm 21$) in the Difficulty with Thinking and Memory domain.

Questionnaire scores

The scores of the Italian VSQOL Index domains across both phases of the study are reported in Table II. Additionally, Table III summarises the scores from the PANQOL, DASS-21, and SF-36 obtained during phase I of the study.

Qualitative exploration of acceptability

The qualitative exploration was unanimous among all 5 participants interviewed during the pilot phase, as they found the Italian version of the VSQOL Index was easy to understand and envisioned no challenges in responding to its

items. They proposed no modifications or improvements, confirming the acceptability of the measure.

Psychometric properties, validity, and reliability

INTERNAL CONSISTENCY

Internal consistency of the first 7 domains of the Italian VSQOL Index was assessed using Cronbach's α (α). The domain *Impact on Employment* was not included in this analysis, as its 3 items are not intended to be combined into a domain score.

The Cronbach's α for the first 7 domains ranged from 0.89 (*Hearing Problems*) to 0.95 (*Problems with Face or Eyes; Satisfaction or Regret*). These values exceed the acceptability threshold set at 0.7, indicating a good internal consistency and therefore a high degree of homogeneity across items (Tab. IV).

CONVERGENT VALIDITY

Convergent validity of Italian VSQOL Index domains was measured using Pearson's correlation coefficients (r) with the physical and mental components of the SF-36, the *Depression, Anxiety, and Stress* scales of the DASS-21, and the domains of the PANQOL-IT.

The composite Italian VSQOL Index and its individual domains showed significant ($p < 0.05$) positive correlations ($r > 0.4$) with the PANQOL and SF-36 scores that measure similar QoL dimensions, supporting the construct validity of the Italian VSQOL Index. For instance, the *Hearing and Problems* domain of the Italian VSQOL Index exhibited a strong positive ($r = 0.85$) correlation with the *Hearing* domain of the PANQOL. Likewise, a strong positive correlation ($r = 0.92$) was observed between the *Dizziness and Imbalance* domain of the Italian VSQOL Index and the *Balance* domain of the PANQOL.

Additionally, significant negative correlations were observed between the scores of the *Impact on Physical, Emotional, and Social Well-Being* and *Satisfaction or Regret* domains of the Italian VSQOL Index and the *Depression, Anxiety, and Stress* scales of the DASS-21, as shown in Table V.

TEST-RETEST RELIABILITY

Test-retest reliability was assessed in the 34 participants who completed the questionnaire twice, with an average latency between the 2 repeated administrations of 32 days (range, 14-40).

The ICC for the domains of the Italian VSQOL Index ranged from 0.78 (*Pain, Discomfort, and Tinnitus*) to 0.92 (*Hearing Problems*). All ICC values exceeded the acceptability threshold of 0.7, demonstrating high stability of the responses over time (Tab. VI).

Table I. Demographic and clinical characteristics of the participants in the 2 phases of the study.

	Phase I			Phase II		
	Total group	Surgical excision	Wait and scan	Total group	Surgical excision	Wait and scan
Number	39	26 (67%)	13 (33%)	34	21 (62%)	13 (38%)
Gender						
Female	15 (38%)	11 (42%)	4 (31%)	14 (41%)	10 (48%)	4 (31%)
Male	24 (62%)	15 (58%)	9 (69%)	20 (59%)	11 (52%)	9 (69%)
Age						
Age at diagnosis	50 ($\pm$ 12)	52 ($\pm$ 12)	49 ($\pm$ 12)	49 ($\pm$ 12)	50 ($\pm$ 12)	49 ($\pm$ 12)
Age at treatment	NA	54 ($\pm$ 12)	NA	NA	53 ($\pm$ 12)	NA
Age at survey	56 ($\pm$ 12)	55 ($\pm$ 12)	59 ($\pm$ 12)	55 ($\pm$ 13)	54 ($\pm$ 13)	59 ($\pm$ 12)
Tumour size						
Koos I	5 (13%)	1 (4%)	4 (31%)	5 (15%)	1 (5%)	4 (31%)
Koos II	14 (36%)	10 (38%)	4 (31%)	12 (35%)	8 (38%)	4 (31%)
Koos III	13 (33%)	10 (38%)	3 (23%)	11 (32%)	8 (38%)	3 (23%)
Koos IV	7 (18%)	5 (19%)	2 (15%)	6 (18%)	4 (19%)	2 (15%)
Hearing function						
AAO-HNS A	5 (13%)	0 (0%)	5 (38%)	5 (15%)	0 (0%)	5 (38%)
AAO-HNS B	6 (15%)	1 (4%)	5 (38%)	6 (18%)	1 (5%)	5 (38%)
AAO-HNS C	1 (3%)	0 (0%)	1 (8%)	1 (3%)	0 (0%)	1 (8%)
AAO-HNS D	27 (69%)	25 (96%)	2 (15%)	22 (64%)	20 (95%)	2 (15%)
Facial function						
HB I	18 (46%)	5 (19%)	13 (100%)	18 (53%)	5 (24%)	13 (100%)
HB II	1 (3%)	1 (4%)	0 (0%)	1 (3%)	1 (5%)	0 (0%)
HB III	7 (18%)	7 (27%)	0 (0%)	5 (15%)	5 (24%)	0 (0%)
HB IV	6 (15%)	6 (23%)	0 (0%)	4 (11%)	4 (18%)	0 (0%)
HB V	5 (13%)	5 (19%)	0 (0%)	5 (15%)	5 (24%)	0 (0%)
HB VI	2 (5%)	2 (8%)	0 (0%)	1 (3%)	1 (5%)	0 (0%)

Values are presented as mean ($\pm$ SD) for continuous variables and frequency (percentage) for categorical variables. The facial nerve function was classified according to the House-Brackmann (HB) Scale, the auditory function according to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Classification, and the tumoural radiological size with the Koos classification. For the surgical group, tumour size reflects the pre-treatment measurement, while for the wait-and-scan group, it refers to the size recorded during the most recent radiological follow-up. NA: not applicable.

Table II. Summary of the first 7 VSQOL Index domain scores for 39 participants of Phase I and 34 participants of Phase II. Values are presented as mean ($\pm$ SD).

VSQOL index domain	Phase I			Phase II		
	Total group	Surgery	Wait and scan	Total group	Surgery	Wait and scan
Hearing problems	62 ($\pm$ 26)	55 ($\pm$ 25)	75 ($\pm$ 24)	68 ($\pm$ 21)	61 ($\pm$ 18)	80 ($\pm$ 21)
Dizziness and imbalance	77 ($\pm$ 22)	71 ($\pm$ 22)	89 ($\pm$ 17)	79 ($\pm$ 21)	74 ($\pm$ 18)	88 ($\pm$ 24)
Pain, discomfort, and tinnitus	79 ($\pm$ 20)	77 ($\pm$ 22)	85 ($\pm$ 15)	83 ($\pm$ 17)	80 ($\pm$ 17)	87 ($\pm$ 15)
Problems with face or eyes	68 ($\pm$ 31)	54 ($\pm$ 29)	97 ($\pm$ 8)	77 ($\pm$ 29)	63 ($\pm$ 29)	99 ($\pm$ 2)
Impact on physical, emotional, and social well-being	77 ($\pm$ 18)	71 ($\pm$ 19)	90 ($\pm$ 10)	80 ($\pm$ 18)	73 ($\pm$ 18)	90 ($\pm$ 12)
Difficulty with thinking and memory	81 ($\pm$ 21)	81 ($\pm$ 21)	81 ($\pm$ 24)	85 ($\pm$ 17)	84 ($\pm$ 17)	87 ($\pm$ 16)
Global QoL score	74 ($\pm$ 18)	68 ($\pm$ 18)	86 ($\pm$ 13)	77 ($\pm$ 19)	73 ($\pm$ 13)	83 ($\pm$ 25)
Satisfaction or regret	73 ($\pm$ 21)	75 ($\pm$ 22)	70 ($\pm$ 18)	69 ($\pm$ 23)	65 ($\pm$ 26)	74 ($\pm$ 17)

Table III. Summary of PANQOL Scale, SF-36, and DASS-21 scores for the 39 participants included in the study. Values are presented as mean ($\pm$ SD) or median (IQR).

PANQOL domains	Total group	Surgery	Wait and scan
Balance	80 ($\pm$ 21)	75 ($\pm$ 21)	90 ($\pm$ 20)
Hearing	60 ($\pm$ 26)	53 ($\pm$ 25)	76 ($\pm$ 20)
Anxiety	85 ($\pm$ 20)	81 ($\pm$ 22)	92 ($\pm$ 13)
Energy	77 ($\pm$ 20)	71 ($\pm$ 21)	89 ($\pm$ 13)
Pain	77 ($\pm$ 26)	76 ($\pm$ 26)	79 ($\pm$ 29)
Face	63 ($\pm$ 33)	48 ($\pm$ 28)	93 ($\pm$ 14)
General	59 ($\pm$ 16)	55 ($\pm$ 16)	66 ($\pm$ 13)
Total score	73 ($\pm$ 16)	67 ($\pm$ 13)	84 ($\pm$ 14)
SF-36 domains			
Physical Functioning (PF)	84 ($\pm$ 19)	81 ($\pm$ 18)	90 ($\pm$ 20)
Social Functioning (SF)	73 ($\pm$ 24)	67 ($\pm$ 25)	86 ($\pm$ 17)
Physical Role limitations (PR)	66 ($\pm$ 44)	55 ($\pm$ 46)	88 ($\pm$ 30)
Emotional Role limitations (ER)	69 ($\pm$ 41)	59 ($\pm$ 46)	90 ($\pm$ 21)
Mental Health (MH)	68 ($\pm$ 17)	64 ($\pm$ 18)	75 ($\pm$ 14)
Vitality (VT)	56 ($\pm$ 18)	50 ($\pm$ 14)	65 ($\pm$ 20)
Bodily Pain (BP)	79 ($\pm$ 26)	73 ($\pm$ 28)	92 ($\pm$ 16)
General Health (GH)	59 ($\pm$ 23)	56 ($\pm$ 20)	67 ($\pm$ 26)
DASS-21 domains			
Depression	4 (0-11)	8 (2-14)	0 (0-4)
Anxiety	6 (2-10)	6 (2-12)	2 (0-6)
Stress	8 (3-14)	11 (4-16)	4 (2-10)

Discussion

Key findings

The present study aimed to translate and culturally adapt the VSQOL Index Version 2 into Italian, producing an Italian version of the questionnaire with good internal consistency, validity, and reliability. For this purpose, permission from the original authors⁷ was granted and the questionnaire was translated according to the FACIT methodology⁸. The psychometric properties of the Italian VSQOL Index were evaluated in a sample of 39 patients with VS who were either managed with active surveillance or had undergone microsurgical resection.

The Italian VSQOL Index domain scores in both phases of the study were aligned with those reported in the original validation study⁷. The statistical analysis revealed an excellent internal consistency, with a Cronbach's α coefficient ranging from 0.89 in the *Hearing Problems* domain to 0.95 in the *Problems with Face or Eyes* and the *Satisfaction or*

Table IV. Internal consistency (α) of Italian VSQOL Index domains for the 39 participants included in the study.

Italian VSQOL index domains	Cronbach's alpha (α)
Hearing problems	0.89
Dizziness and imbalance	0.91
Pain, discomfort, and tinnitus	0.87
Problems with face or eyes	0.95
Impact on physical, emotional, and social well-being	0.92
Difficulty with thinking and memory	0.92
Global QoL	0.95
Satisfaction or regret	0.96

Regret domains. These results were consistent with the original VSQOL Index, where Cronbach's α ranged from 0.83 in the *Hearing Problems* domain to 0.91 in the *Impact on Physical, Emotional, and Social Well-Being* domain.

Table V. Correlations of Italian VSQOL Index scores with other general and disease-specific instruments for the 39 participants included in the study.

Pearson correlation coefficient (r)	VSQOL index							
	Hearing	Dizziness	Pain/tinnitus	Face/eyes	Well-being	Cognition	Global QoL	Satisfaction
PANQOL scale								
Hearing	0.85	0.75	0.48	0.59	0.67	0.41	0.81	-0.08*
Balance	0.68	0.92	0.64	0.57	0.65	0.61	0.83	0.11*
Pain	0.42	0.48	0.79	0.31*	0.51	0.62	0.64	0.16*
Face	0.42	0.64	0.38	0.97	0.68	0.38	0.77	-0.10*
Anxiety	0.30*	0.40	0.58	0.33	0.67	0.47	0.56	0.33
Energy	0.48	0.67	0.67	0.66	0.82	0.61	0.82	0.18*
General	0.39	0.56	0.57	0.59	0.75	0.36	0.68	0.21*
Total score	0.66	0.82	0.75	0.77	0.86	0.64	0.95	0.09*
SF-36								
Physical Functioning (PF)	0.20*	0.59	0.53	0.42	0.45	0.46	0.55	0.18*
Social Functioning (SF)	0.42	0.57	0.42	0.58	0.82	0.32	0.66	0.20*
Physical Role limitations (PR)	0.10*	0.40	0.35	0.53	0.58	0.25*	0.47	0.05*
Emotional Role limitations (ER)	0.18*	0.40	0.47	0.44	0.64	0.30*	0.51	0.09*
Mental Health (MH)	0.18*	0.28*	0.28	0.43	0.58	0.26*	0.47	0.21*
Vitality (VT)	0.22*	0.30*	0.16	0.42	0.40	0.28*	0.43	0.09*
Bodily Pain (BP)	0.09*	0.38	0.44	0.27*	0.35	0.19*	0.36	-0.04*
General Health (GH)	0.24*	0.51	0.45	0.46	0.47	0.43	0.54	0.32*
DASS-21								
Depression	-0.25*	-0.51	-0.41	-0.56	-0.71	-0.38	-0.61	-0.24*
Anxiety	-0.25*	-0.57	-0.65	-0.38	-0.59	-0.52	-0.60	-0.15*
Stress	-0.16*	-0.49	-0.42	-0.35	-0.65	-0.33	-0.52	-0.35

Removing item 4 from the *Hearing Problems* domain and item 8 from the *Dizziness and Imbalance* domain slightly improved the internal consistency of their respective domains, as shown in Table 3 of the Supplemental Material. Construct validity of the Italian VSQOL Index was demonstrated through significant positive and negative correlations with domains of both generic and disease-specific HRQoL instruments measuring similar constructs. These correlations were evaluated using the Italian versions of a disease-specific instrument, the PANQOL Scale ^{5,6}, and the generic measures, namely the SF-36 ^{9,10} and the DASS-21 ^{11,13}.

The Italian VSQOL Index domains showed positive strong correlations, with a Pearson's *r* coefficient greater than 0.5, with corresponding domains of the PANQOL and SF-36 that

assess similar QoL dimensions. As expected, positive correlations were found between: the *Hearing Problems* domain of the VSQOL and the *Hearing* domain of the PANQOL; the *Dizziness and Imbalance* domain (Italian VSQOL) and the *Balance* domain (PANQOL); the *Problems with Face or Eyes* domain (Italian VSQOL) and the *Face* domain (PANQOL); the *Pain, Discomfort, and Tinnitus* domain (Italian VSQOL) and the *Pain* domain (PANQOL); the global scores of the Italian VSQOL and PANQOL; the *Impact on Physical, Emotional, and Social Well-being* domain (Italian VSQOL) and the *Physical Functioning, Social Functioning, Physical Role Limitations, and Emotional Role Limitations* domains of the SF-36; and *Pain, Discomfort, and Tinnitus* (Italian VSQOL) with the *Bodily Pain* of SF-36.

Table VI. Test-retest reliability (ICC) for Italian VSQOL Index scores in the 34 participants in the study who completed the questionnaire twice, compared with the original VSQOL Index validation study.

VSQOL index domain	ICC in the current study	ICC from Carlson et al. ⁷
Hearing problems	0.92	0.89
Dizziness and imbalance	0.91	0.95
Pain, discomfort, and tinnitus	0.78	0.90
Problems with face or eyes	0.90	0.93
Impact on physical, emotional, and social well-being	0.86	0.93
Difficulty with thinking and memory	0.87	0.89
Global QoL	0.91	0.96
Satisfaction or regret	0.80	0.86

Furthermore, as hypothesised, significant negative correlations were observed between the scores of the *Impact on Physical, Emotional, and Social Well-Being* and *Satisfaction or Regret* domains of the Italian VSQOL Index and the *Depression, Anxiety, and Stress* scales of the DASS-21.

Test-retest reliability was evaluated by administering the questionnaire a second time 2 to 5 weeks later. The results revealed strong stability, with ICC of 0.91 values ranging from 0.78 in the *Pain, Discomfort, and Tinnitus* domain to 0.92 in the *Hearing Problems* domain. These findings were comparable to those of the original version of the questionnaire, where ICC values ranged from 0.86 in the *Satisfaction or Regret* domain to 0.96 in the *Global QoL* domain.

Strengths and limitations

A key strength of this study is the rigorous methodology employed in the translation and cultural adaptation of the VSQOL Index. Unlike simpler translation methods, this study followed a comprehensive and systematic procedure, beyond the basic double back-translation technique. It incorporated multiple steps, including forward translation by independent bilingual experts, reconciliation, back-translation by a native English speaker, and thorough review by an expert committee. This iterative process, combined with direct collaboration with the original authors of the VSQOL Index, ensured linguistic, conceptual, and cultural equivalence between the English and Italian versions. This procedure was meticulously monitored, documented, and reported following the FACIT methodology ⁸, ensuring transparency and traceability throughout every stage.

From a cross-cultural perspective, some idiomatic expressions required careful adaptation. For instance, smoke detectors are not common devices in Italian households; therefore, as shown in Supplemental Table 1, we agreed with the original authors to render “smoke alarm” as a generic “alarm”.

The same item of the questionnaire posed an additional challenge for translating the phrase “direction of oncoming traffic”, which, according to the FACIT decentred process of translation, the original authors revised to “direction of traffic”. Although semantic equivalence was achieved, further multicentre studies are needed to confirm generalisability.

While the study was conducted at a single Italian institution, efforts were made to enhance the representativeness of the sample. Participants were recruited from both neurosurgery and otolaryngology clinics, encompassing individuals with varying disease severity and treatment histories. Furthermore, because patients travelled from different regions of Italy to receive care, the findings may be broadly applicable to the general Italian-speaking population affected by VS. The main limitation of the present study is its relatively low sample size. While sufficient for the initial validation of the instrument with adequate statistical power, it may restrict the generalizability of the findings. Additionally, the participants may represent a selection of healthier patients, who were more inclined to participate, potentially leading to an underestimation of the true burden of the pathology. These issues should be addressed in future research involving larger and multicentre cohorts. Longitudinal studies evaluating the responsiveness of the questionnaire to clinical changes over time would further enhance its utility in both research and clinical settings.

Clinical implications

The availability of a validated Italian version of the VSQOL Index Version 2 enables healthcare providers to better understand the impact of VS on patients’ daily lives and the outcomes of its treatment. This tool can aid in informing therapeutic decisions and improving patient care. Furthermore, it offers a valuable resource for conducting research within the Italian population and facilitates cross-cultural comparisons in QoL studies.

Conclusions

The present study successfully developed and validated an Italian version of the VSQOL Index Version 2, demonstrating its reliability and validity as a tool for assessing the HRQoL in Italian-speaking patients with sporadic VS. It can therefore be applied in daily clinical practice to assist in tailoring treatment plans and support scientific research in this field.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

AE: conceptualization, methodology, formal analysis, writing original draft, review & editing; CeB: conceptualization, methodology, formal analysis, supervision, review & editing; AR: methodology, formal analysis, visualization, writing original draft, review & editing; FF: supervision, review & editing; CaB: supervision, review & editing; CS: supervision, review & editing; AC: supervision, review & editing; Ga.M: conceptualization, supervision, review & editing; LP: conceptualization, supervision, review & editing; GiM: conceptualization, methodology, formal analysis, supervision, review & editing.

Ethical considerations

This study was approved by the CE-AVEC (No. 436/2023/Oss/AOUBo, 14th February 2024).

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki. Written informed consent was obtained from each participant/patient for study participation and data publication.

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