

Validation of the Romanian Translated ABC-V (Assessment of Burden in Chronic – Venous Disease) Questionnaire

D. Casian, E. Gutsu, V. Culiuc

Department of General Surgery, State University of Medicine and Pharmacy “Nicolae Testemitanu”, Chisinau, Republic of Moldova

Rezumat

Validarea chestionarului ABC-V (Assessment of Burden in Chronic – Venous disease) tradus în limba română

Obiectivul studiului a fost evaluarea psihometrică a versiunii traduse în limba română a chestionarului ABC-V (Assessment of Burden in Chronic – Venous Disease) la pacienții cu boala varicoasă necomplicată a extremităților inferioare. Toate componentele chestionarului au fost traduse din versiunea engleză în limba română și ulterior invers, apoi discutate, adaptate și pre-testate. Evaluarea versiunii finale a chestionarului tradus a demonstrat rezultate acceptabile: întrebări ratate în 3% din chestionare, lipsa efectului “de plafon” (ceiling-effect) și un floor-efect redus, o bună fiabilitate split-half ($r_s = 0,61$, $p < 0,01$) și corelație semnificativă între scorurile de testare și re-testare ($r_s = 0,86$, $p < 0,01$). Scorurile medii ABC-V nu au fost influențate semnificativ de vârsta și genul pacienților. Rezultatele studiului susțin aplicarea chestionarului ABC-V pentru evaluarea severității patologiei venoase cronice precum și pentru analiza cantitativă a satisfacției pacienților și ameliorării sănătății după tratamentul bolii varicoase la populația vorbitoare de limbă română.

Cuvinte cheie: boala varicoasă, chestionarul ABC-V, calitatea vieții

Abstract

The objective of this study was a psychometric evaluation of the Romanian translated version of ABC-V (Assessment of Burden in Chronic – Venous Disease) questionnaire in patients with uncomplicated varicose disease of lower limbs. All components of the questionnaire were translated from the English version into the Romanian language and after that backwards, discussed, adopted and pre-tested. Evaluation of the final version of the translated questionnaire demonstrated acceptable results: missed questions in 3% of forms, no ceiling effect and low floor effect, good split-half reliability ($r_s = 0.61$, $p < 0.01$) and significant correlation between test and re-test scores ($r_s = 0.86$, $p < 0.01$). There was no significant influence of age and sex upon average ABC-V scores. Study results support the application of ABC-V questionnaire for assessing the severity of chronic venous disease as well as for quantitative evaluation of patient satisfaction and health status improvement after varicose vein treatment in the Romanian-speaking population.

Key words: varicose vein, ABC-V questionnaire, quality of life

Corresponding author:

Casian Dumitru, MD
29 – 32 Vasile Lupu Street
Chisinau, 2008, Republic of Moldova
+373 – 79155903
E-mail: dcasian@mail.ru

Introduction

Varicose veins are common among the adult population of many countries. The prevalence of primary chronic venous disease is approximately 20%, and about 5% of patients have venous edema, skin changes or venous ulcerations. Active venous ulcers are present in up to 0.5%, and between

0.6% and 1.4% have healed ulcers (1). Quality of life in patients with varicose veins has been shown to be globally impaired (2). Analysis of the impact that chronic venous disease may have on patients' daily activities and the evaluation of the results of surgical treatment with scientifically rigorous measures of quality of life, have become important issues in modern phlebology. Although various quality of life scales offer some evaluation of the patients' distress and disability they are not optimal for direct assessment of the burden generated by varicose veins disease. The ABC-V (Assessment of Burden in Chronic – Venous Disease) questionnaire was developed and validated with this purpose by Guex (3). Three versions of the questionnaire are currently available – in English, Spanish and French language.

To implement the ABC-V questionnaire in the Republic of Moldova we adapted it into Romanian language with subsequent psychometric evaluation of the translated version in patients with varicose veins.

Methods

The ABC-V questionnaire includes 36 items concerning six aspects: pain (questions 1 – 4); daily life (questions 5 – 14); family and personal relationships (questions 15 – 18); work (questions 19 – 22); psychological impact (questions 23 – 32); and treatment by general practitioner (questions 33 – 36). In order to better measure the impact of chronic venous disease, the questionnaire was complemented with three Visual Analog Scales (VAS): “psychological VAS”, “physical VAS” and “living with the varicose veins VAS”. Answers to the 36 questions are simple and valued from 0 to 2 points: 0 points – for answer “No, not in my case”; 1 point – for answer “Yes, in my case but it is not hard to live with” and 2 points – for answer “Yes, in my case and it is very hard to live with”. Dealing with scores out of 10 rather than six is generally more common. It also may be easier to consider a score with a maximum of 10. Therefore, the total of each of the six aspects is reduced to a maximum of 10 by virtue of a simple rule of three: this same common maximum of 10 for each dimension helps for understanding of the result and comparisons. Moreover, each of the three VAS has a value from 0 to 10; therefore, the minimum total score or the ABC-V is 0 (no venous burden), and the maximum (corresponding to the worst venous burden) is $6 \times 10 + 3 \times 10 = 90$ (3).

In the process of adaptation three specialists in phlebology, native speakers in Romanian, independently translated all components of ABC-V questionnaire from the English version into the Romanian language. During the translation process, priority was given to the simplest and clearest words or phrases rather than the correct medical terms. Members of the group performed a debriefing of the three drafts of translated versions and reached a consensus. According to the recommendation for translation of health status questionnaires, the backward translation from Romanian to English was also performed (4). The translated documents were compared with the original version of ABC-V and several corrections were made in the Romanian ABC-V to attain the notional equivalence of the questionnaires. The resulting versions of Romanian ABC-V questionnaire were pre-tested by face-to-face interview with four consecutive patients with varicose veins demonstrating no problem in practical application. The final version of the translated questionnaire is provided in the *Appendix*.

Psychometric evaluation of Romanian ABC-V was performed on a sample of 50 patients, referred to the Clinic of General Surgery (Municipal Hospital no. 1, Chisinau) for surgical treatment of varicose veins of lower limbs. Only patients with uncomplicated venous disease (C2 or C3 of CEAP), primary etiology (Ep, Pr of CEAP) and unilateral varicose veins were enrolled in the study. Nobody refused to participate. The questionnaire was filled-in by patients during pre-treatment consultation in the clinic and the completed form was directly returned to the investigator. The investigator ran through the form and if any blank items were detected the patient was asked to answer the missed question. Re-evaluation using Romanian ABC-V was performed in all patients on the day of admission to the department for surgical treatment, aiming to check the test-retest reliability. Average time between first and second evaluation was 16 days (range 10 – 25 days) and no interventional treatments were administered in this interval.

The tests used for psychometric evaluation of completed Romanian ABC-V questionnaires are shown in *Table 1*.

Results

70% of the included patients with varicose veins were females and the age range was 24 – 55 years (mean 42 ± 7.9 SD). Generally, the Romanian language version of ABC-V

Table 1. Psychometric tests used for evaluation of Romanian version of ABC-V questionnaires

Psychometric property	Definition	Test
Feasibility	Completeness of data and score distribution	Response rates, proportion of missing/non-unique data, floor/ceiling effects
Internal consistency	Correlations between different items on the same test	Split-half reliability
Test-retest reliability	Stability of measuring instrument	Correlation of summary scores of first and second test
Discriminant validity	Scale is not correlated with other measures of different constructs	Correlations between ABC-V scores and age and gender

Appendix. Romanian translation of ABC-V questionnaire

Întrebarea	Nu, nu în cazul meu	Da, în cazul meu, dar cu aceasta nu e greu de trăit	Da, în cazul meu, și cu aceasta este foarte greu de trăit									
1. Senzațiile de durere depind de perioada anului	0	1	2									
2. Senzațiile de durere se accentuează spre sfârșitul zilei	0	1	2									
3. Senzațiile de durere se accentuează în urma șezutului îndelungat sau aflării în picioare un timp îndelungat	0	1	2									
4. Senzațiile de durere îmi limitează posibilitățile	0	1	2									
5. Din cauza problemelor cu venele nu-mi ajung puteri pentru unele activități	0	1	2									
6. Mi-i frică să mă apuc de careva activități din cauza problemelor venoase	0	1	2									
7. Îmi este greu să adorm din cauza că găsesc cu dificultate o poziție confortabilă pentru picioare	0	1	2									
8. Mă trezesc noaptea din cauza "circeilor" la nivelul membrelor inferioare	0	1	2									
9. Din cauza problemelor venoase îmi vine greu să merg mult timp	0	1	2									
10. Din cauza patologiei venoase îmi este greu să urc scările	0	1	2									
11. Din cauza patologiei venoase îmi este greu să efectuez un lucru greu (acasă)	0	1	2									
12. Din cauza patologiei venoase îmi este greu să merg după cumpărături	0	1	2									
13. Din cauza patologiei venoase îmi vine greu să duc greutatea	0	1	2									
14. Eu îmi limitez odihna activă din cauza problemelor cu picioarele	0	1	2									
15. Eu discut mai puțin cu alte persoane din cauza problemelor cu picioarele	0	1	2									
16. Viața mea familială a suferit din cauza bolii venoase	0	1	2									
17. Relațiile mele cu partenerul au suferit din cauza patologiei venoase	0	1	2									
18. Activitatea mea sexuală s-a modificat din cauza bolii venoase	0	1	2									
19. Boala mea venoasă, semnifică că eu lucrez mai puțin productiv	0	1	2									
20. Activitatea mea profesională a suferit din cauza patologiei venoase	0	1	2									
21. Câștigul meu financiar s-a micșorat din cauza patologiei venoase	0	1	2									
22. Eu am început să cheltui mai mulți bani din cauza bolii venoase	0	1	2									
23. Mă simt neprotejat/ă atunci când mă gândesc la patologia mea venoasă	0	1	2									
24. Mă simt trist/ă, atunci când mă gândesc la boala mea venoasă	0	1	2									
25. Simt, că nimeni nu mă crede, atunci când eu povestesc cuiva despre patologia mea venoasă	0	1	2									
26. Simt, că nimeni nu înțelege problema mea, atunci când eu povestesc cuiva despre boala mea venoasă	0	1	2									
27. Eu simt o nedreptate, când mă gândesc la patologia mea venoasă	0	1	2									
28. Simptomele patologiei venoase mă sperie	0	1	2									
29. Simptomele bolii venoase mă îngrijorează	0	1	2									
30. Mă simt cu handicap fizic, atunci când mă gândesc la patologia mea venoasă	0	1	2									
31. Simt, că corpul meu mă conduce, atunci când mă gândesc la boala mea venoasă	0	1	2									
32. Îmi este greu să mă concentrez, atunci când mă gândesc la patologia mea venoasă	0	1	2									
33. Atunci când mă gândesc la boala mea venoasă, îmi spun însumi, că stabilirea diagnosticului va ocupa mult timp	0	1	2									
34. Atunci când mă gândesc la boala mea venoasă, consider, că în realitate tratamentul nu ajută	0	1	2									
35. Când mă gândesc la boala mea venoasă, consider, că medicii nu mă i-au în calcul (nu mă cred) în mod serios	0	1	2									
36. Când mă gândesc la boala mea venoasă, consider, că medicii nu sunt în stare să mă ajute în mod real	0	1	2									
37. Suferințele psihice, pe care le suport din cauza patologiei venoase: Sunt absolut tolerabile (pot fi răbdate/suportate)	0	1	2	3	4	5	6	7	8	9	10	Sunt absolut insuportabile
38. Suferințele fizice, pe care le simt din cauza patologiei venoase: Sunt absolut suportabile	0	1	2	3	4	5	6	7	8	9	10	Sunt absolut insuportabile
39. A trăi cu patologie venoasă: Este absolut suportabil	0	1	2	3	4	5	6	7	8	9	10	Este absolut insuportabil

Evaluarea rezultatelor:

Nr. întrebării	Compartimentul apreciat	Metoda de calcul a punctajului
De la 1 până la 4	Senzațiile algice (de durere)	Suma obținută de puncte este înmulțită cu 10 și împărțită la 8
De la 5 până la 14	Activitatea cotidiană	Suma obținută de puncte este înmulțită cu 10 și împărțită la 20
De la 15 până la 18	Relațiile familiare și personale	Suma obținută de puncte este înmulțită cu 10 și împărțită la 8
De la 19 până la 22	Activitatea profesională	Suma obținută de puncte este înmulțită cu 10 și împărțită la 8
De la 23 până la 32	Dereglările fiziologice	Suma obținută de puncte este înmulțită cu 10 și împărțită la 20
De la 33 până la 36	Corelațiile cu medicul	Suma obținută de puncte este înmulțită cu 10 și împărțită la 8
De la 37 până la 39	Sumăm punctele conform scării VAS pentru fiecare din cele trei întrebări	

showed good acceptability. Usually, questionnaires took less than 15 minutes to complete. During the initial check of questionnaires by the investigator, missed questions were determined in 3% of forms. There were no incomplete forms or non-unique answers during the final test and retest evaluation. Score distribution analysis showed no ceiling effect and no low floor effect: 2% - for "treatment by general practitioner", 4% - for "pain" and "work" aspects and 8% - for family and personal relationships.

Using Spearman's rank correlation coefficient we found a good split-half reliability of the Romanian ABC-V questionnaire. Correlation of scores for even and odd items, excluding VAS, was statistically significant ($r_s = 0.61$, $p < 0.01$). Average ABC-V test score was 26.7 ± 4.9 SD and average re-test score was 26.2 ± 4.7 SD. The Spearman's coefficient demonstrates a statistically significant correlation between test and re-test scores ($r_s = 0.86$, $p < 0.01$).

Non-parametric testing (Mann-Whitney U test) for differences between the average ABC-V scores in males and females was not significant ($U = 244$, $p > 0.05$). Average score in patients with age younger than 40 years does not differ significantly from older patients ($U = 198$, $p > 0.05$). These calculations reflect good discriminant validity of the questionnaire.

Discussion

Many different treatment modalities for varicose veins have been introduced during the last decade (endovenous laser and radiofrequency ablation, foam-sclerotherapy, steam ablation) and had to be validated in prospective studies. Results of these studies are based mostly on surrogate end-points: occlusion/recanalization rates, recurrence rate, hemodynamic improvement. Unfortunately, the efficacy of the above mentioned criteria does not necessarily correspond with the main therapeutic goal of the treatment – patient satisfaction by surgery and improvement of quality of life (5). The optimal outcome measure following treatment of superficial venous reflux is contentious, and there is a wide range of investigations available, from surrogate end-points to clinical and functional improvements, with numerous quality-of-life questionnaires available, each with their own advantages and disadvantages (6,7).

The ABC-V questionnaire is a specific tool, which represents a different approach to the assessment of disease severity and treatment outcome. Direct measurement of the burden caused by varicose veins may be closer to patients' concerns, comparing with other disease-specific quality of life questionnaires (Aberdeen Varicose Vein, VEINES-QOL/Sym, CIVIQ-2), especially in patients with low clinical classes. Our limited experience with the Romanian version of ABC-V demonstrates the good feasibility, reliability, consistency and validity of the questionnaire. Extremely good response rate and completeness of data can be partially interpreted by means of an interview during evaluation with immediate check for

missed items. The average scores of the test and re-test were slightly higher in the present study than in the trial performed by the author of the questionnaire (3). This fact is difficult to explain. Perhaps younger patients are more concerned by the impact of varicose veins upon their life. At the same time, the ABC-V score is higher in subjects aged 50 and over according to Guex et al (3). There was no possibility to evaluate differences between the known groups because only C2 and C3 patients were included in the study. Acceptable preliminary results of the validation of Romanian ABC-V allow us to extend practical and scientific application of the questionnaire upon postoperative follow-up in patients with all C classes of CEAP.

Conclusions

Based on the current results we can conclude that the psychometric properties of the Romanian version of ABC-V questionnaire are satisfactory and do not differ significantly from the original English version. The questionnaire is an essential tool for assessing severity of chronic venous disease as well as for quantitative evaluation of patient satisfaction and health status improvement after varicose vein treatment.

Acknowledgement

We would like to thank Jean-Jérôme GUEX, M.D., FACPh, (Nice, France) for his kind permission to translate and use the ABC-V questionnaire.

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