Translation, Pilot Psychometric Validation, and Comparative Performance of the Arabic Version of the Anti-Clot Treatment Scale (ACTS)

Sireen Abdul Rahim Shilbayeh1, Sahar Abd El Rahman Ismail2

1Department of Pharmaceutical Practice, College of Pharmacy, Princess Nourah Bint Abdulrahman University (PNU), Riyadh, Saudi Arabia, 2Department of Computer Science, College of Computer and Information Sciences, Princess Nourah Bint Abdulrahman University, Riyadh, Saudi Arabia

Background: Anticoagulation management is a complex process that is managed through careful monitoring, and patient satisfaction has a significant impact. Given the lack of a valid and reliable tool in Arabic to examine patient satisfaction, the present study aimed to translate and examine some of the psychometric properties of the Anti-Clot Treatment Scale (ACTS) among Saudi patients. Materials and Methods: This was a cross-sectional, methodological study conducted among patients receiving warfarin. The questionnaire was subjected to translation by using a multistep method. The final Arabic translated version of the ACTS underwent face and content validity assessments by independent experts to ensure its conceptual equivalence to the original English version. Subsequently, pilot testing of convergent, discriminant, and criterion validities were examined. Results: Overall, 136 patients participated in the study. All patients were asked to complete the generic Treatment Satisfaction Questionnaire for Medication (TSQM) alongside the ACTS tool. Convergent validity analyses revealed statistically significant positive correlations (p < 0.01) between the ACTS subscales and the four TSQM subdomains, as reflected by the Spearman correlation coefficient (r). Interestingly, the strongest correlations were observed between ACTS Burdens and the TSQM convenience domain (r = 0.61) and between ACTS Benefits and the TSQM effectiveness satisfaction score (r = 0.58). Similarly, discriminant validity was evidenced by moderate to high significant loading of all 12 items on each of their corresponding ACTS subscales. Conclusion: These findings of adequate validity support the use of the ACTS in Saudi patients receiving anticoagulant medications to measure their specific satisfaction levels with this type of therapy. However, future research addressing the clinical impact of ACTS scores in the Saudi population is needed.

Keywords: Patient-reported outcomes, satisfaction, translation, validation, warfarin

INTRODUCTION

Over the last two decades, research on health-related outcomes has emphasized that patient-based evaluations are an additional, or even preferred, method of assessment compared with physicians outcome ratings or disease-specific physiological outcomes.1

Patient-reported outcomes (PROs) are deemed to be meaningful and important, particularly in conditions where symptoms and other complaints from patients

Address for correspondence: Prof. Sireen Abdul Rahim Shilbayeh, Department of Pharmaceutical Practice, College of Pharmacy, Princess Nourah Bint Abdulrahman University (PNU), P.O. Box 84428, Riyadh 11671, Saudi Arabia. E-mail: ssabdulrahim@pnu.edu.sa

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

How to cite this article: Shilbayeh SA, Ismail SA. Translation, pilot psychometric validation, and comparative performance of the Arabic version of the Anti-Clot Treatment Scale (ACTS). J Pharm Bioall Sci 2021;13:61-8.
are the primary endpoints for evaluating improvements in a disease status upon management with various therapeutic approaches.[2-4]

PROs are usually classified as generic, disease-specific, or treatment-specific outcomes. Generic measures offer a comprehensive assessment of health, including mental, emotional, social, and physical health.[5] Disease- and treatment-specific measures focus on aspects of the disease (or condition) and therapy that are relevant to patients and clinicians.[6] The advantage of generic measures compared with specific measures is that the former category allows comparisons across conditions or treatments. However, generic measures are generally less effective than other scales at reflecting the clinical consequences of treatment because the former type does not address the concerns of individual patients.[7]

In the context of evaluating the success of drug treatment, among the most interesting and influential outcomes are the PROs of adherence, compliance, quality of life, and satisfaction.[2-4]

Treatment satisfaction is defined as the patient’s rating of or report on relevant elements of the process and consequences of his/her treatment experience based on specific standards; these elements often focus on users’ concerns.[7] Compared with other PROs, satisfaction has additional unique strengths and is increasingly suggested as an outcome measure in clinical trials of drug treatments for multiple reasons.[5-8,9] For example, adherence describes drug intake in a way that can be objectively measured by physicians (by asking questions about missing doses, forgetting doses, or skipping doses, or using more “objective” measures such electronic systems or pill counts), while satisfaction may be directed toward the benefits of drug intake, which are reflected by patients’ subjective evaluation of salient aspects of a treatment experience.

Additionally, a literature review strongly supported a positive association between satisfaction and adherence.[8] Therefore, measurement of patient satisfaction is a good signal for adherence because satisfied patients have an increased likelihood of complying with treatment and achieving favorable clinical outcomes. Hence, satisfaction is increasingly used to evaluate drug treatments, particularly those that require long-term adherence (persistence) to achieve their intended clinical outcomes.[9] In particular, this use of satisfaction data could be helpful in chronic conditions where compliance and persistence cannot be ideally estimated in short-term clinical trials because their patient follow-up measures are not sensitive enough to accurately predict long-term patient adherence.[9]

However, in terms of estimation, satisfaction is a complex phenomenon with multiple aspects and depends on both positive and negative patient perceptions and attitudes toward treatment; these diverse variables contribute to adherence.[10] For example, the convenience, effectiveness, ease of use, and adequacy of a treatment are positive satisfaction parameters that increase patients’ intention to persist.[10] Negative aspects that increase the burden of treatment, such as side effects or a high frequency or an inconvenient route of administration are associated with reduced satisfaction and reduced compliance.[11]

Therefore, satisfaction measurement tools often include multiple domains with subelements reflecting benefits and burdens of treatment.[12]

A review of the literature on satisfaction tools revealed that there was great diversity in the measurement methods used for satisfaction; different studies used different questionnaires even for the same condition, and many of them were incompletely or not at all validated.[5-8,13] It was also noted that “excellent” and “poor” satisfaction were usually not well defined.[9]

The Anti-Clot Treatment Scale (ACTS) is a patient-reported instrument that has been robustly validated as a measure of treatment satisfaction, specifically for anticoagulants.[14] This scale includes 17 items across two subscales: Burdens (13 questions) and Benefits (4 questions). The ACTS is available in a diversity of languages but not in Arabic.[14] While the Treatment Satisfaction Questionnaire for Medication (TSQM 1.4) is a generic patient-satisfaction measure developed for various patients and medications,[15] The TSQM includes four essential domains of satisfaction with medications: effectiveness (items 1–3), side effects (items 4–8), convenience (items 9–11), and global satisfaction (items 12–14). The scores for the domains range from 0 (extremely dissatisfied) to 100 (extremely satisfied). The TSQM has been widely employed in different clinical settings[16-18] as a multilingually validated questionnaire, and the Arabic translation has been previously validated in Saudi anticoagulant clinics (ACCs).[19]

Previous national surveys in Saudi Arabia revealed that patients’ nonadherence scores were high[19-24] but consistent with those of other populations internationally.[25,26] Endeavors to formally measure the outcomes of anticoagulants on patient satisfaction have been inadequate and have often used unvalidated tools.[21,22]

Accordingly, well-structured research within the context of anticoagulant treatment satisfaction is still required to evaluate the reasons for poor adherence and actions to enhance it in our individual patient culture.
Therefore, the present study aimed to translate and comparatively validate the ACTS among patients who were being treated with oral anticoagulants in Saudi ACCs. The secondary objective was to evaluate the burdens and benefits of oral anticoagulants according to sociodemographic criteria, thus providing a solid verification to improve the management of individual patients.

**MATERIALS AND METHODS**

**Study design**

This was a cross-sectional, methodological study aimed at translation and pilot validation of the ACTS among patients who were being treated with warfarin in Riyadh, Saudi Arabia.

**Sample size and participants**

We purposely sampled patients regularly visiting ACCs at the three main medical centers (King Khalid Medical City, Security Forces Hospital, and Prince Sultan Military Medical City) in Riyadh in the period between September 30, 2017 and December 30, 2017.

A review of the literature revealed that no consensus exists to define the sample size of studies aimed at assessing PRO psychometric properties (e.g. arbitrarily determined sample size or subject to an item ratio greater than or equal to 2).27

In the present study, we included a total of 136 patients who satisfied the following criteria: (a) patients who were age >18 years, (b) patients who spoke Arabic, and (c) patients receiving warfarin for a minimum of 3 months for any indication. The exclusion criteria were as follows: (a) patients who were <18 or ≥ 75 years; (b) naïve patients (i.e. warfarin had been prescribed but not received yet); (c) patients previously diagnosed with mental disorders; and (d) patients with visual, auditory, or oral communication deficiencies.

**Measurement instrument**

**Translation process**

Initially, the researchers communicated with Mapi Research Trust (Lyon, France—Internet: https://eprovide.mapi-trust.org) to obtain permission for the use of the ACTS and translation to the Arabic language according to the User Agreement terms. The main researchers, who are native speakers of the target language (Arabic) and fluent in the source language (English), have undertaken the forward translation process. Additionally, an independent translator who is a professional in the translation of medical terminology, a native speaker of the Arabic language, and fluent in the English language, and resides in Saudi Arabia was assigned to perform additional forward translation. Afterwards, the researchers conducted a series of meetings with the independent translator to compare both forward translated versions to resolve divergent interpretations of the original version items, and to finalize the reconciliation of both forward translations into a single forward translation. Another Arabic language expert in writing skills performed a peer review and proofread the final translated version to highlight and correct any typographic, grammatical, or other errors. No backward translation or cognitive debriefing (involving patients) was performed before the initiation of the study. Instead, four Arabic professors of pharmacy at Princess Nourah University (PNU) judged the face and content validity of the final Arabic version of this questionnaire. Regarding cognitive debriefing, the questionnaire was administered to selected patients who completed the study questionnaires in the ACC waiting area in the presence of the research team during their routine appointments. Patients were encouraged to contact any member of the research team if they had inquiries concerning the questionnaires. For illiterate patients, the researcher sequentially read the questions and answer choices aloud.

**Ethics approval**

The Institutional Review Board at PNU approved this study (17–0074). Before starting the study, the study aims were clarified to the participants, and their informed consent was obtained. In addition, the participants were assured that their personal information would remain completely confidential.

**Study procedures**

In this study, during the ACC test visit, both the ACTS and the TSQM were administered at their usual clinic visits. The patients were asked to complete the TSQM alongside the ACTS to provide a benchmark for assessing the convergent validity of the ACTS score via hypothesized correlations between the ACTS and the TSQM subscales. Subscale scores were calculated in accordance with the developers’ guidelines.

The final satisfaction estimation in this study was grounded on patients’ responses to the anticoagulation-specific ACTS, and supportive analysis was provided by the generic TSQM 1.4 for validation purposes.

**Data analysis**

All data were coded and analyzed using the Statistical Package for Social Sciences (SPSS) (version 25.0; IBM SPSS Statistics for Windows. Armonk, NY: IBM Corp.). For the purpose of descriptive evaluation of demographic and clinical data, continuous variables are expressed as the mean (standard deviation, SD), their normality having been confirmed by the
Kolmogorov–Smirnov test, while categorical variables are presented as proportions.

Among the data collected, the following properties of the ACTS were selected to be examined for the purpose of pilot psychometric validation of the scale:

The **convergent validity** of the ACTS domains (Burdens and Benefits) was assessed by their correlations with scores on the TSQM and its four subdomains (effectiveness, side effects, convenience, and global satisfaction) using Spearman rank-order correlation coefficients.

The **discriminant validity** of ACTS items was tested by calculating Pearson’s $r$ or Spearman’s rho for the correlation of each item with its own subscale and each of the other subscales. Burden items are expected to have moderate correlations (0.30–0.70) with the total Benefits score and strong correlations (0.7 and above) with the total Burdens score.

**Criterion validity analysis** was conducted to test the possible impact of demographic and clinical characteristics on the patients’ responses to ACTS Burdens and Benefits. These associations were first examined using one-way analysis of variance with Tukey’s post hoc test for categorical variables or Pearson’s correlation for continuous variables. All variables that were significant at the 95% level in the univariate analysis were further examined in the multivariate linear regression model.

**RESULTS**

**Demographic characteristics**

A total of 136 patients participated in the study. The mean age was 50.68 years (SD, 14.6; range: 19–97). Overall, the participants were primarily female ($n = 97; 71.3\%$). At the time of enrollment, the patients had been receiving warfarin for an average of 3.6 years (SD = 3.2). The most common warfarin indication was atrial fibrillation ($n = 31; 22.8\%$) followed by prosthetic heart valve replacement ($n = 29; 21.3\%$).

**Convergent validity**

Table 1 displays the results for convergent validity, as expressed by Spearman’s rho coefficients between the ACTS subscales and the scores of the total TSQM and its four subdomains. As expected, all correlations between the ACTS Burdens scale and TSQM subdomains, except for the domain of side effects, were positive, moderate (0.3–0.7), and statistically significant ($p < 0.01$). Similar correlations were noted between the ACTS Benefits score and all TSQM subdomains. These correlations imply that high scores on the specific ACTS (greater satisfaction with warfarin) were associated with a high degree of general treatment satisfaction as measured by the TSQM. Interestingly, the strongest correlations were observed between ACTS Burdens and the TSQM convenience domain ($r = 0.61$) and between ACTS Benefits and the TSQM effectiveness satisfaction score ($r = 0.58$).

**Discriminant validity**

As shown in Table 2, discriminant validity was evidenced by moderate to high significant item loading on each of the ACTS subscales. All 12 items that were intended to measure burdens significantly loaded onto the Burdens scale; however, the three Benefits items loaded weakly onto the Burdens scale. These loadings suggest that the three items are distinct from the Burdens scale and associated with the Benefits scale.

**Criterion validity**

Overall, there were no significant differences in patients’ mean scores on the ACTS Burdens or Benefits scales with respect to different demographic criteria, including age groups, sex, level of education, duration of warfarin use, and concurrent illnesses (Table 3: Table 1: Convergent validity of the ACTS Burdens and Benefits scales—correlations with the TSQM (total and sub-scales), $n = 42$)

| Domain          | ACTS Burdens | ACTS Benefits | TSQEFF | TSQSIDE | TSQCON | TSQGLO | TSQM Total |
|-----------------|--------------|---------------|--------|---------|--------|--------|------------|
| ACTS Burdens    | 1.000        |               |        |         |        |        |            |
| ACTS Benefits   | 0.402**      | 1.000         |        |         |        |        |            |
| TSQEFF          | 0.473**      | 0.581**       | 1.000  |         |        |        |            |
| TSQSIDE         | 0.240        | 0.380*        | 0.201  | 1.000   |        |        |            |
| TSQCON          | 0.605**      | 0.328*        | 0.530**| 0.215   | 1.000  |        |            |
| TSQGLO          | 0.420**      | 0.557**       | 0.619**| 0.330*  | 0.578**| 1.000  |            |
| TSQM Total      | 0.620**      | 0.486**       | 0.794**| 0.320*  | 0.848**| 0.843**| 1.000      |

ACTS = Anti-Clot Treatment Scale, TSQEFF = TSQM Effectiveness, TSQSIDE = TSQM Side effects, TSQCON = TSQM Convenience, TSQGLO = TSQM Global Satisfaction

*Correlation is significant at $p < 0.05$

**Correlation is significant at $p < 0.01$
**DISCUSSION**

Previous studies have increasingly suggested satisfaction as a PRO outcome measure[^2-5,8,9] and highlighted its potential to reflect an assortment of individual perceptions regarding barriers to adherence with anticoagulation therapy, along with their associated lifestyle factors, according to psychosocial factors, attitudes, and cultural habits.[^29] Given that instruments designed specifically to assess treatment satisfaction in patients receiving oral anticoagulation have been developed in languages other than Arabic and are mostly validated in patient populations and clinical settings outside the Arab cultural world,[^6,13,14,29,30] research is needed to adapt these instruments for use in Arabic-speaking patients. Accordingly, this study was conducted with the primary aim of translating, partially validating, and reporting some of the psychometric properties of a treatment-specific satisfaction assessment tool, the ACTS, in patients undergoing warfarin therapy.

First, a multistep translation process was conducted to translate the questionnaire from English to Arabic, according to guidelines recommended by the US Food and Drug Administration to ensure the quality of the translated instruments. Additionally, these standards were advocated by the ACTS User Agreement terms.[^31]

*Table 2: Convergent/discriminant validity of the ACTS items, n = 136*

| Item | Burdens scale | Benefits scale |
|------|---------------|----------------|
| Item 1 | 0.535** | -0.008 |
| Item 2 | 0.584** | 0.007 |
| Item 3 | 0.457** | -0.910 |
| Item 4 | 0.642** | 0.339** |
| Item 5 | 0.571** | 0.047 |
| Item 6 | 0.685** | 0.117 |
| Item 7 | 0.759** | 0.133 |
| Item 8 | 0.644** | 0.247** |
| Item 9 | 0.640** | 0.435 |
| Item 10 | 0.725** | 0.192* |
| Item 11 | 0.710** | 0.356** |
| Item 12 | 0.707** | 0.380** |
| Item 14 | 0.141 | 0.753** |
| Item 15 | 0.238** | 0.855** |
| Item 16 | 0.195* | 0.862** |

Values refer to correlations of items to their own scale (corrected-item total correlations) and other scales with Spearman’s rho.

*Correlation is significant at p < 0.05 (2-tailed)

**Correlation is significant at p < 0.01 (2-tailed)

*Table 3: Criterion validity analysis: characteristics of study participants and relative levels of treatment satisfaction*

| Variable | Treatment satisfaction | p-value |
|----------|------------------------|---------|
| Age group | Burden | Benefit | Mean ± SD | |
| 19–37 | 46.2 ± 10.9 | 42.3 ± 8.8 | 0.59 |
| 38–55 | 43.5 ± 8.2 | 12.0 ± 2.6 | 0.58 |
| 56–73 | 43.2 ± 11.6 | 11.5 ± 2.4 | 0.016 |
| ≥74 | 42.3 ± 8.8 | 11.1 ± 1.8 | |
| Sex | Burden | Benefit | |
| Female | 44.4 ± 9.2 | 11.9 ± 2.4 | 0.32 |
| Male | 42.5 ± 11.3 | 11.6 ± 2.6 | 0.49 |
| Education | Burden | Benefit | |
| No formal education | 43 ± 11.0 | 11.5 ± 2.2 | 0.43 |
| Primary/secondary | 44.6 ± 7.3 | 11.2 ± 1.9 | 0.12 |
| High school | 45.5 ± 10.9 | 12.6 ± 2.8 | 0.016 |
| Diploma/university | 41.6 ± 10.2 | 11.8 ± 2.5 | 0.98 |
| Current warfarin therapy | Burden | Benefit | |
| New to warfarin therapy | 44.1 ± 9.87 | 11.8 ± 2.2 | 0.024 |
| Continuing warfarin therapy | | 11.8 ± 2.5 | |
| Concurrent illnesses | Burden | Benefit | |
| DM | 42.7 ± 10.3 | 11.5 ± 2.6 | 0.38 |
| Yes | 44.4 ± 9.7 | 11.9 ± 2.3 | |
| No | 45.7 ± 9.04 | 12.2 ± 2.4 | 0.016 |
| HTN | 41.6 ± 10.4 | 11.4 ± 2.5 | 0.08 |
| Yes | 45.7 ± 9.04 | 12.2 ± 2.4 | |
| No | 11.5 ± 2.6 | 11.97 ± 2.3 | 0.29 |

*p-value consistently greater than 0.05). However, the mean Burdens satisfaction score was found to be significantly lower among hypertensive patients than among their counterparts in this sample (p = 0.016).
Subsequently, the translated Arabic version underwent face and content validity assessments to ensure its conceptual equivalence to the original English version. This phase is quite significant to confirm that all items convey to patients precisely what they intend to convey. Then, the final ACTS version was administered to this study population to obtain selected validity parameters.

Given that closer proximity of the mean score to the scale midpoint indicates better targeting, the overall sample of patients receiving warfarin in this study reported reasonable mean Burdens (M = 44) and Benefits (M = 11.9) satisfaction scores compared with each subscale reference range (12–60 and 3–15, respectively). Interestingly, upon comparing our findings to a large-scale, seven-country open-label trial addressing patients’ satisfaction with their anticoagulant therapy, we found lower scores in the Burdens domain but higher scores in the Benefits domain among current warfarin users than among patients receiving the standard anticoagulant therapy (enoxaparin/VKA). In addition, the Burdens scores in this study were lower than those reported by rivaroxaban users; however, their Benefits scores were equal. Previous observational studies have highlighted the possibility of variability in individual perceptions and experiences regarding warfarin therapy according to psychosocial factors, attitudes, and cultural practices, and their conclusions are often controversial.

Closer inspection of mean scores at the level of ACTS items revealed that patients reported the lowest satisfaction on item 7, which measures the inconvenience of the occasional aspects of ant clot treatment (e.g. the need for blood tests, going to or contacting the clinic/doctor, and making arrangements for treatment while traveling). This outcome was similar to what was found in the questionnaire’s original validation study; however, patients were on different types and regimens of anticoagulants. These findings warrant further investigation in a head-to-head anticoagulant comparison study in Saudi patients.

In our analysis, which is presented in Table 1, the results within convergent validity revealed a significant positive correlation (r values ranging from 0.33 to 0.61, p < 0.01) between the ACTS subscales and total scores as well as most subdomain scores of the general treatment satisfaction tool (TSQM Arabic version), which was previously validated in the patient population of Saudi ACCs. These results were in contrast to those obtained in the original validation study in which the degrees of association between both the ACTS subscale scores and the TSQM domains were shown to be less than expected (r = 0.27–0.35). Conversely, the nonsignificant correlation between the ACTS Burdens subscale and the TSQM side-effects domain in the current appraisal was consistent with the original validation study. These domino effects can be explained by the fact that the TSQM side effects items do not clearly specify the decisive anticoagulation-specific side effects of bleeding and bruising, which are assessed in the ACTS Burdens items. Additional study endorsed significant positive associations between the ACTS (Spanish version) and the Self-Assessment of Treatment Question (SAT-Q) and EuroQol (EQ-5D) questionnaires, both proposed to evaluate the level of general, not specific, patient satisfaction with treatment.

Furthermore, the discriminant validity analyses in this study were in agreement with those of the original version in verifying the categorizing of the ACTS items into two subscales (Burdens and Benefits) and validating their correlation with the corresponding subdomains.

Additionally, the criterion validity analysis that was conducted in this population excluded the possible impact of demographic and clinical characteristics on the patients’ responses to the ACTS Burdens and Benefits. Accordingly, these results provided strong evidence that the ACTS scales are not correlated with other measures of different constructs.

This study is the first to assess the psychometric properties of the Arabic version of the ACTS among Arabic patients receiving warfarin.

Overall, the results of initial validity testing indicated that the Arabic version of the ACTS has good validity and that the questionnaire can be used to sufficiently assess our patients’ satisfaction with their anticoagulation treatments in terms of burdens and benefits. However, the present study had some limitations. In the current report, the clinical outcomes concerning anticoagulant therapy, mostly the international normalized ratio (INR) was not considered, which limits the assessment of concurrent validity. Future studies using the INR and other clinical endpoints to assess the concurrent validity of the ACTS in Saudi patients are required. Therefore, future studies focusing on the evaluation of the clinical parameters associated with ACTS scores are warranted to provide a complete picture regarding routine usage of this scale to measure satisfaction in anticoagulated patients visiting ACCs. Nevertheless, the study provided adequate evidence for some of the important psychometric properties such as face, content, convergent, discriminant, and criterion validities in Saudi patients. Future analyses encompassing other validity and reliability measures should be considered.
CONCLUSION

These findings of adequate validity provide initial support for the use of the ACTS in Saudi patients receiving anticoagulant medications to measure their specific satisfaction level with this type of therapy. Future research to establish the clinical impact of the ACTS scores and to screen for factors associated with nonadherence with anticoagulant therapy in the Saudi population is needed.

Acknowledgement

The authors thank Alnada Abdalla Ibrahim (Assistant Professor at the Pharmaceutical Practice Department of PNU) who participated in the adaptation of the study tools to the Arabic language and participated in the literature review of similar studies.

Statement of ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Institutional Review Boards (IRBs) of PNU (17–0074) and KKMC (17/0321) and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Author contributions

SS performed the literature review, conceived and designed the protocol, supported the enrolment of the patients, supervised the data collection, drafted the manuscript and substantively revised it to meet the journal requirements. Both SS and SI supervised the adaptation of the ACTS scale to the Arabic language and performed the statistical analyses for psychometric validation. Both authors have reviewed and approved the final version of manuscript for submission.

Financial support and sponsorship

This research was funded by the Deanship of Scientific Research at Princess Nourah bint Abdulrahman University through the Fast-track Research Funding Program.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Wright JG. Outcomes research: what to measure. World J Surg 1999;23:1224-6.
2. Calvert M, Kyte D, Mercieca-Bebber R, Slade A, Chan AW, King MT, et al.: the SPIRIT-PRO Group. Guidelines for inclusion of patient-reported outcomes in clinical trial protocols: the SPIRIT-PRO extension. JAMA 2018;319:483-94.
3. Lavallee DC, Austin E, Franklin PD. How can health systems advance patient-reported outcome measurement? Jt Comm J Qual Patient Saf 2018;44:439-40.
4. US Department of Health and Human Services FDA Center for Drug Evaluation and Research, US Department of Health and Human Services FDA Center for Biologics Evaluation and Research, US Department of Health and Human Services FDA Center for Devices and Radiological Health. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. Health Qual Life Outcomes 2006;4:79.
5. Katusiime B, Corlett S, Reeve J, Kriska J. Measuring medicine-related experiences from the patient perspective: a systematic review. Patient Relat Outcome Meas 2016;7:157-71.
6. Bombardier C, Meli CA, Paul J, Green R, Hawker G, Wright J, et al. Comparison of a generic and a disease-specific measure of pain and physical function after knee replacement surgery. Med Care 1995;33:AS131-44.
7. Weaver M, Patrick DL, Markson LE, Martin D, Frederic I, Berger M. Issues in the measurement of satisfaction with treatment. Am J Manag Care 1997;3:579-94.
8. Barbosa CD, Balp MM, Kulich K, Germain N, Rofail D. A literature review to explore the link between treatment satisfaction and adherence, compliance, and persistence. Patient Prefer Adherence 2012;6:39-48.
9. Revicki DA. Patient assessment of treatment satisfaction: methods and practical issues. Gut 2004;53:iv40-4.
10. Patrick DL, Burke LB, Gwaltney CJ, Leidy NK, Martin ML, Molsen E, et al. Content validity—establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO good research practices task force report: part 2—assessing respondent understanding. Value Health 2011;14:978-88.
11. Utens CM, Joore MA, van dW, Dirksen CD. Towards integration of research evidence on patient preferences in coverage decisions and clinical practice guidelines: a proposal for a taxonomy of preference-related terms. Value Health 2014;17:A583-4.
12. Kimman ML, Rotteveel AH, Wijserbeek M, Mostard R, Tak NC, van Jaarsveld X, et al. Development and pretesting of a questionnaire to assess patient experiences and satisfaction with medications (pesam questionnaire). Patient 2017;10:629-42.
13. Wild D, Murray M, Shakespeare A, Raneay M, von Maltzahn R. Patient-reported treatment satisfaction measures for long-term anticoagulant therapy. Expert Rev Pharmacoecon Outcomes Res 2008;8:291-9.
14. Cano SJ, Lamping DL, Bamber L, Smith S. The anti-clot treatment scale (ACTS) in clinical trials: cross-cultural validation in venous thromboembolism patients. Health Qual Life Outcomes 2012;10:120.
15. Atkinson MJ, Kumar R, Cappelleri JC, Hass SL. Hierarchical construct validity of the treatment satisfaction questionnaire for medication (TSQM version II) among outpatient pharmacy consumers. Value Health 2005;8:S9-S24.
16. Aljumah K, Ahmad Hassali A, AlQhatani S. Examining the relationship between adherence and satisfaction with antidepressant treatment. Neuropsychiatr Dis Treat 2014;10:1433-8.
17. Alkatheri AA, Albekairy AM, Jarab A, Bustami R, Khalidi N, Alshaya A, et al. Medication adherence and treatment satisfaction among renal transplant recipients. Ann Transplant 2016;21:270-8.
18. Zyoud SH, Al-Jahi SW, Sweileh WM, Morisky DE. Relationship of treatment satisfaction to medication adherence: findings from a cross-sectional survey among hypertensive patients in Palestine. Health Qual Life Outcomes 2013;11:191.
patients undergoing warfarin therapy in Saudi Arabia. Value Health Reg Issues 2018;16:14-21.
20. Al-Omair S, Musallam N, Al-Deghaither N, Al-Sadoun N, Bayoumy N. Compliance with and awareness about long-term oral anticoagulant therapy among Saudi patients in a university hospital, Riyadh, Saudi Arabia. J Appl Hematol 2016;7:10-6.
21. Balkhi B, Al-Rasheedi M, Elbur AI, Alghamadi A. Association between satisfaction with and adherence to warfarin therapy on the control of international normalized ratio: a hospital-based study in Saudi Arabia. Saudi Pharm J 2018;26:145-9.
22. Elbur AI, Albarraq A, Magrabi M, Alharthi S. Knowledge of, satisfaction with and adherence to oral anticoagulant drugs among patients in King Faisal Hospital: taif, Kingdom Saudi Arabia. Int J Pharm Sci Rev Res 2015;31:274-80.
23. Mayet AY. Patient adherence to warfarin therapy and its impact on anticoagulation control. Saudi Pharm J 2016;24:29-34.
24. Shilbayeh SAR, Almutairi WA, Alyahya SA, Alshammari NH, Shaheen E, Adam A. Validation of knowledge and adherence assessment tools among patients on warfarin therapy in a Saudi hospital anticoagulant clinic. Int J Clin Pharm 2018;40:56-66.
25. Davis NJ, Billett HH, Cohen HW, Arnsten JH. Impact of adherence, knowledge, and quality of life on anticoagulation control. Ann Pharmacother 2005;39:632-6.
26. Wang Y, Kong MC, Ko Y. Comparison of three medication adherence measures in patients taking warfarin. J Thromb Thrombolysis 2013;36:416-21.
27. Anthoine E, Moret L, Regnault A, Sébille V, Hardouin JB. Sample size used to validate a scale: a review of publications on newly-developed patient reported outcomes measures. Health Qual Life Outcomes 2014;12:176.
28. Kneeland PP, Fang MC. Current issues in patient adherence and persistence: focus on anticoagulants for the treatment and prevention of thromboembolism. Patient Prefer Adherence 2010;4:51-60.
29. Apenteng PN, Murray ET, Holder R, Hobbs FD, Fitzmaurice DA; UK GARFIELD Investigators and GARFIELD Steering Committee. An international longitudinal registry of patients with atrial fibrillation at risk of stroke (GARFIELD): the UK protocol. BMC Cardiovasc Disord 2013;13:31.
30. Prins MH, Bamber B, Cano SJ, Wang MY, Erkens P, Bauersachs R, et al. Patient-reported treatment satisfaction with oral rivaroxaban versus standard therapy in the treatment of pulmonary embolism: results from the EINSTEIN PE trial. Thromb Res 2015;135:281-8.
31. Bottomley A, Jones D, Claassens L. Patient-reported outcomes: assessment and current perspectives of the guidelines of the food and drug administration and the reflection paper of the European medicines agency. Eur J Cancer 2009;45:347-53.
32. Breugelmans R. Dangers in using translated medical questionnaires: the importance of conceptual equivalence across languages and cultures in patient-reported outcome measures. Chest 2009;136:1175-7.
33. McDowell I. Measuring health: a guide to rating scales and questionnaires. New York; Oxford: Oxford University Press; 2006.
34. Das AK, Ahmed A, Corrado OJ, West RM. Quality of life of elderly people on warfarin for atrial fibrillation. Age Ageing 2009;38:751-4.
35. Gage BF, Cardinalli AB, Owens DK. The effect of stroke and stroke prophylaxis with aspirin or warfarin on quality of life. Arch Intern Med 1996;156:1829-36.
36. Suarez C, Pose A, Montero-Perez-Barquero M, Roquer J, Gallego J, Rafols C, et al.; en representación del Grupo de Trabajo Comité Cientifico Estudio ALADIN. [Validation of satisfaction questionnaire ACTS in outpatients with atrial fibrillation treated with oral anticoagulants in spain. ALADIN study]. Med Clin (Barc) 2016;147:192-8.
37. Thuppal S, Markwell S, Crabtree T, Hazelrigg S. Comparison between the EQ-5D-3L and the SF-6D quality of life (QOL) questionnaires in patients with chronic obstructive pulmonary disease (COPD) undergoing lung volume reduction surgery (LVRS). Qual Life Res 2019;28:1885-92.