



Validation of the Amharic version of the Pelvic Organ Prolapse Symptom Score (POP-SS)

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Received: 27 August 2018 / Accepted: 9 November 2018 / Published online: 21 November 2018
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Abstract

Introduction and hypothesis We aimed to translate and culturally adapt the Pelvic Organ Prolapse Symptom Score (POP-SS) into Amharic and evaluate its psychometric properties.

Methods We followed an intercultural adaptation procedure to translate and adapt the POP-SS. One hundred and eighty-six women with POP symptoms completed the Amharic POP-SS and Prolapse Quality of Life (P-QoL) questionnaires. All women were examined using a simplified Pelvic Organ Prolapse Quantification (SPOP-Q) system and were divided into four groups based on the POP-Q scores as stage 1, 2, 3, and 4. Internal consistency and test–retest reliability were determined using Cronbach’s alpha and the intraclass correlation coefficient (ICC), respectively. Criterion validity was assessed against the SPOP-Q stage and the P-QoL scale. Furthermore, we tested construct validity using exploratory factor analysis.

Results The POP-SS score was successfully translated and achieved good content validity. It had high internal consistency (Cronbach’s alpha = 0.86) and test–retest reliability (ICC = 0.81; $p < 0.001$). There was a statistically significant difference among four groups of stages in POP-SS score, and women with stage 3 had the highest median score (Kruskal–Wallis test; $p < 0.05$). The POP-SS score was also significantly correlated with the P-QoL score (Spearman’s correlation coefficient = 0.28, $p < 0.001$). The exploratory factor analysis identified two factors, namely, physical symptoms and evacuation symptoms.

Conclusions The POP-SS scale was successfully translated to Amharic and appears reliable and valid for women with symptoms of POP. However, further studies are needed to evaluate its responsiveness.

Keywords Pelvic organ prolapse · Reliability · Validity · Amharic validation · Ethiopian

Abbreviations

ICC	Intraclass correlation coefficient
CVI	Content validity index
QoL	Quality of life
POP	Pelvic organ prolapse

P-QoL	Prolapse Quality of Life
POP-SS	Pelvic Organ Prolapse Symptom Score
SPOP-Q	Simplified Pelvic Organ Prolapse Quantification

The study was conducted in Gondar, Ethiopia.

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Introduction

Pelvic Organ Prolapse (POP), descent of one or more pelvic organs into or out of the vaginal canal [1], is a common morbidity among adult women [2]. The reported prevalence varies depending on definitions applied and the population investigated. In Ethiopia, a population-based study reported a 55% prevalence of POP based on anatomic findings [3].

Women with POP exhibit multiple and overlapping symptoms [4] that affect the quality of life (QoL) [5, 6]. Due to the serious implications, symptom scores with known psychometric properties are recommended as outcome measures in the management of POP [7]. However, prior to using this instrument in a language other than that for which it was designed, translation, cross-cultural adaptation, and validation for the

language of the target population is necessary [8]. This enables comparison of outcome measures and thereby increases the accuracy of measurements [9].

The Pelvic Organ Prolapse Symptom Score (POP-SS), originally written in English, is a validated symptom index that assesses the presence and extent of common prolapse symptoms [10, 11]. It has been translated to and validated in Turkish [12] and has been used as an outcome measure to evaluate the effectiveness of POP interventions in a number of randomized controlled trials [10, 13, 14].

According to the 2007 Ethiopian census, ~86 languages (e.g., Amharic, Oromo, Somali, Tigrinya, Sidamo, Wolaytta, Gurage, Afar, and others) are spoken in Ethiopia [15]. Amharic is the official working language, with 21.6 million native and 4 million second-language speakers. It is spoken as the first language in the region where the study was conducted [15, 16]. In Ethiopia, POP accounted for ~40% of major gynecological operations [17]. Although the problem is extensive, the focus on evaluating POP symptoms and subsequent usage in decision making during management and follow-up is limited. One problem is the lack of a validated, condition-specific measurement questionnaire. Therefore, we aimed to translate the POP-SS into the Amharic language and evaluate its measurement properties (reliability and validity) among women with POP symptoms.

Materials and methods

This study comprised two phases. Phase one involved cultural adaptation of the POP-SS; phase two evaluated its psychometric properties of reliability (internal consistency and test–retest reliability) and validity (cross-cultural validity, structural validity, and criterion validity). Figure 1 illustrates the steps in the study.

Questionnaires

Pelvic Organ Prolapse Symptom Score The POP-SS questionnaire has seven items that focus on symptoms caused or aggravated by prolapse [10]. Each question requires participants to rate the frequency of a POP symptom experienced in the 4 weeks prior to evaluation. Symptoms were:

- (1) Feeling of something coming down from the vagina
- (2) Pain or discomfort in the vagina that worsened when standing
- (3) Dragging sensation in the lower abdomen
- (4) Feeling of heaviness or dragging sensation in the lower back
- (5) Need to strain to empty the bladder
- (6) Sensation of incomplete bladder emptying

- (7) Sensation of incomplete bowel emptying

Symptom responses were rated on a 5-point Likert scale (0 = never, 1 = somewhat, 2 = sometimes, 3 = most of the time, and 4 = always). The total score ranged from 0 to 28, and was calculated by summing response scores for individual symptoms [10].

Prolapse Quality of Life The Prolapse Quality of Life (P-QoL) scale is a condition-specific instrument for measuring health-related (HR) QoL in women with POP. It has been validated in English-speaking patients [18] and translated into several languages, including Amharic. The detailed translation and validation of the Amharic version is currently pending publication [19]. The questionnaire consists of 20 items representing nine QoL domains of general health, prolapse impact, role physical and social limitations, personal relationships, emotional problems, sleep/energy disturbances, and severity measures. Total score for each domain ranged from 0 to 100. A high total score indicates greater impairment, while a low total score indicates good QoL [18].

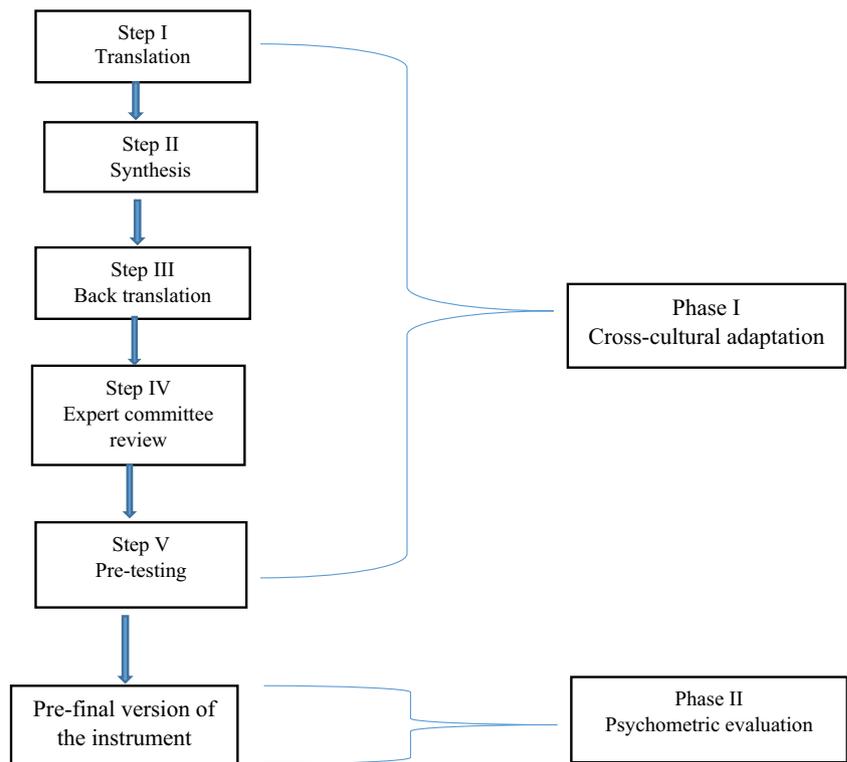
Phase 1

Translation and cultural adaptation of POP-SS After receiving authorization from the author of the POP-SS, the standardized method for translation and adaptation was followed [20, 21]. The translation was carried out independently by two native Amharic speakers fluent in English, and a single harmonized version was produced. This version was back-translated into English by two independent native English speakers fluent in Amharic and blinded and naïve to the English version. The original and back-translated versions were checked for discrepancies by the authors and then referred back to the questionnaire developer. After inclusion of comments from the author, a panel of experts with medical, public health, allied health science, and sociology backgrounds reviewed the final forward- and back-translations against the original version. Any issues raised were addressed, and a preliminary version of the instrument was created and circulated among review members. The subsequent version was pretested among ten women admitted to a gynecology ward with stages 3/4 on the Pelvic Organ Prolapse Quantification (POP-Q) system and 41–60 years old. After amendment of minor discrepancies, the final version was adopted for use in the psychometric evaluation. The final Amharic version is available from the first author upon request.

Phase 2: psychometric evaluation

Study participant Between December 2017 and March 2018, women aged ≥ 18 years with POP symptoms were recruited consecutively from the Gynecology Outpatient Clinic at the

Fig. 1 Study steps



University of Gondar Hospital. Symptoms of POP were assessed using two questions [3, 22]: Do you have a feeling of bulging/pressure or something coming down through the vagina? Do you have a visible mass protruding from the vagina? If the participant had experienced one or both of these problems in the past 1 year, they were considered to have symptoms of POP and were defined as symptomatic. Women who had a psychiatric problem, could not speak or understand Amharic, had undergone previous POP surgery, had a known or suspected pregnancy, were postpartum (first 6 weeks following childbirth), or had an ultrasound-reported pelvic mass (uterine, ovarian, colorectal, bladder) were excluded. To ensure the statistical robustness of the analyses, a subject-to-item ratio recommendation (i.e., 5–10:1 for the number of subjects and the number of items in the questionnaire) by the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) was utilized to determine the number of participants [23].

Study procedures We used a two-stage strategy in which women were first asked to complete a paper form of the translated Amharic questionnaire (POP-SS and P-QoL) at the outpatient visit. If a woman could not read or write, a relative or accompanying person, if available, helped her complete the questionnaire. If not, the research assistant, who was unfamiliar with the concepts of urogynecology and questionnaires, provided nondirective assistance. After completing the questionnaires, all women were examined in the dorsolithotomy

position and prolapse stage was classified using the simplified POP-Q (SPOP-Q) system [24]. One research team member (TG) blinded to the questionnaire score performed the pelvic examination. To measure the test–retest reliability, 70 women were asked to participate by completing a second questionnaire 2 weeks later in the same clinic. Stability was evaluated using the Patients’ Global Impression of Change (PGIC) scale [25]. Participation in the study was voluntary, and verbal and/or informed written consent was obtained prior to inclusion. Ethical approval was obtained from the Institutional Review Committee at the University of Gondar.

Statistical analysis

Data were analyzed using STATA 14.0 software (StataCorp, College Station, TX, USA). Statistical significance was set at 0.05 for all analyses. Outcome variables were not normally distributed and were therefore analyzed using nonparametric tests.

Floor and ceiling effects We computed floor and ceiling effects by the percentage frequency of the lowest and highest score achieved. If >15% of participants achieved this score, floor and ceiling effects were considered to be present [23].

Reliability We assessed reliability using agreement and consistency indices. Cronbach’s alpha was computed to assess the internal consistency of items in the POP-SS questionnaire, and

values of ≥ 0.70 were considered adequate [23]. We further analyzed each item's reliability by assessing its item-total correlation and the overall reliability when a specific item was deleted. Item-total correlations of ≥ 0.5 and interitem correlations ≥ 0.3 were considered adequate [26].

Test–retest reliability was computed using the interclass correlation coefficients (ICC). Single rating, absolute agreement, and a two-way mixed-effects model were used. We hypothesized that POP-SS scores of the two tests would be in agreement and that ICC values ≥ 0.7 were acceptable [23].

Content validity We evaluated whether the questionnaire could be understood by experts and patients and whether all important and relevant items had been included by the expert panel. Expert agreement on relevance was calculated using the Content Validity Index (CVI), and agreement $\geq 80\%$ was considered acceptable [27].

Construct validity We evaluated construct validity using two approaches: First, we completed the explanatory factor analysis using principal component analysis (PCA). The Kaiser–Meyer–Olkin (KMO) statistic and Bartlett's test of sphericity were used to determine the appropriateness of running the factor analysis. KMO values varied from 0 to 1; values > 0.5 are acceptable [28]. Bartlett's test requires a significant result ($p < 0.05$). We used the Scree plot representing eigenvalues associated with each factor to identify the number of meaningful factors. Factors with eigenvalues > 1 were assumed to be meaningful and were retained for rotation. We applied the varimax orthogonal rotation procedure to estimate factor correlations. Communalities ≥ 0.4 and factor loadings > 0.4 were considered sufficient. Items with factor loadings ≥ 0.4 on more than one factor were considered to be cross-loading [28]. Second, we evaluated known-groups validity. Median difference of POP-SS values among four groups (as defined by POP-Q 1, 2, 3, and 4) were compared using the Kruskal–Wallis test.

Criterion validity We assessed criterion validity, which describes how well the questionnaire correlates with an existing gold standard, by comparing POP-SS scores with the Amharic P-QoL score and objective vaginal examination findings using POP-Q stage. Spearman's correlation coefficient (SCC) and Kruskal–Wallis test were used for statistical analysis, respectively.

Results

Participant characteristics

This study recruited 221 women. Of these, 21 were recruited to the translation process and 200 to the validation process. Of

the 200 invited to take part in the validation procedure, 193 consented to participate. However, seven were excluded due to withdrawal before physical examination ($n = 5$) or were missing after completion of the interview ($n = 2$). Thus, a total of 186 women were included in the final analysis, giving a response rate of 93%. Most women were from rural areas (80.1%) and lacked formal education (96.2%). Mean \pm standard deviation (SD) age was 48.7 ± 12.4 years. There were 31 women in POP stage 1, 16 in stage 2, and 139 in stages 3 and 4. Characteristics of the study participants are presented in Table 1.

Reliability and item analysis

Internal consistency of the POP-SS questionnaire was 0.86 [95% confidence interval (CI) 0.82–0.89; $p < 0.001$]. As seen in Table 2, the magnitude of change in Cronbach's alpha was almost uniform across items, and in no instances did removal of an item from the scale result in an increase in the value of Cronbach's alpha.

The percentage distributions of responses were as follows: an answer of zero (0) was given most frequently to question A7, and an answer of four (4) was given most frequently to questions A3 and A4. Floor and ceiling effects for each scale item are shown in Table 2. A total of 70 women participated in the retest. Of these, ten reported a change in POP severity and were removed from the analysis. Test–retest reliability revealed a strong significant correlation between the paired test–retest POP-SS total scores (ICC = 0.81; $p < 0.001$) (Table 3).

Content validity

No questions were added to the original questionnaire after review by the panel of experts. CVI mean for the whole questionnaire was 0.9. Only one item achieved an index < 0.8 . Most items were well understood by the women who evaluated readability and comprehensibility. However, they suggested a few changes when drafting a final version of the instrument. There were no missing items.

Construct validity: factor analysis

The KMO measure of sampling adequacy was very good (0.81), and Bartlett's test of sphericity was significant (chi-square = 655.56; $p < 0.001$). The PCA extracted two factors based on an extraction criterion of a minimum eigenvalue of 1.0. Both factors accounted for 71.5% of the common variance (41.3% for Factor 1 and 30.3% for Factor 2). Communalities were also fairly high, ranging from 0.63 to 0.81. To interpret factor loads more accurately and clarify the structure, the two factors were orthogonally rotated using a varimax approach. Accordingly, both factors had high

Table 1 Characteristics of study participants ($n = 186$)

	POP-Q stage				Entire group
	1	2	3	4	
Number (%)	31 (16.7)	16 (8.6)	113 (60.8)	26 (13.9)	186 (100)
Age in years					
Mean \pm SD	45.3 (14.7)	39.6 (15.6)	50.4 (10.9)	50.9 (10.5)	48.7 (12.4)
Median (range)	45.0 (20–70)	37.5 (20–70)	50.0 (25–70)	52.5 (26–70)	50.0 (20–70)
Parity					
Mean \pm SD	5.5 (2.9)	5.8 (4.1)	6.9 (2.6)	5.7 (2.3)	6.4 (2.8)
Median (range)	5.0 (1–12)	6.5 (0–12)	7.0 (0–12)	6.0 (1–10)	6.0 (0–12)
Residence					
Rural	18 (9.7)	13 (7.0)	95 (51.1)	23 (12.4)	149 (80.1)
Urban	13 (7.0)	3 (1.6)	18 (9.7)	3 (1.6)	37 (19.9)
Educational status ^a					
Illiterate	28 (15.0)	15 (8.1)	113 (60.7)	23 (12.3)	179 (96.2)
Literate	3 (1.6)	1 (0.5)	0 (0.0)	3 (1.6)	7 (3.8)

SD standard deviation, POP-Q Pelvic Organ Prolapse Quantification system

^a Literate participants attended formal education at primary, secondary, preparatory or/and university/college level; illiterate participants did not attend formal education and include those who could and could not read and write

loading and were considered strong (each included at least three items with loading value between 0.73 and 0.90). Four items (A1, A2, A3, and A4) were entered with item loadings ranging from 0.73 to 0.90 in Factor 1, which was designated physical symptoms. Three items (A5, A6, and A7) were entered for factor 2, which was designated evacuation symptoms. The internal consistency reliability of each factor (convergent validity) was determined using Cronbach's alpha coefficients and found to be acceptable (factor 1 0.87; factor 2 0.77). Factor loading of items is shown in Table 4.

Construct validity: known groups

There were statistically significant differences in POP-SS scores among the four groups (Kruskal–Wallis, chi-squared 62.98; $p < 0.05$). The highest median POP-SS was found in

stage 3, followed by stage 4 and then stage 1 (Table 5). Although there was a statistically significant difference among groups, its clinical difference was moderate (partial Eta squared value 0.37).

Criterion validity

POP-SS were significantly higher in stages 3/4 compared with stage 2 or 1 (Mann–Whitney U test; $p < 0.001$). Spearman's rank correlation analysis confirmed that POP-SS was significantly correlated with the total P-QoL score (SCC 0.28, $p < 0.001$). As seen in Table 6, POP-SS scores also had a statistically significant correlation with P-QoL domain scores ($p < 0.05$); the highest level of relationship was with prolapse impact (SCC = 0.58) and the lowest level with general health perception and sleep/energy (SCC = 0.14).

Table 2 Internal consistency, item-total correlations, and alpha if item deleted from the Amharic Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire

POP-SS items	Corrected item-total correlation	Cronbach's alpha if item deleted	Ceiling (n)	Floor (n)
A1	0.62	0.84	14	10
A2	0.73	0.82	16	7
A3	0.68	0.83	19	17
A4	0.65	0.83	19	20
A5	0.62	0.84	8	47
A6	0.64	0.83	4	27
A7	0.46	0.86	3	73
Overall Cronbach's alpha (A1 to A7) = 0.86				

Bold indicates most frequently given answers (ceiling 4 always; floor 0 never)

Table 3 Test–retest reliability of the Amharic Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire ($n = 60$)

Variables	ICC	95% CI	<i>P</i> value*
POP-SS	0.81	0.54–0.91	< 0.001
A1	0.61	0.35–0.76	< 0.001
A2	0.70	0.46–0.82	< 0.001
A3	0.77	0.57–0.87	< 0.001
A4	0.83	0.70–0.91	< 0.001
A5	0.79	0.63–0.88	< 0.001
A6	0.74	0.55–0.85	< 0.001
A7	0.81	0.68–0.88	< 0.001

ICC intraclass correlation, CI confidence interval

*Single rating, absolute agreement, and two-way mixed-effects model

Discussion

To our knowledge, this is the first validation of the Amharic version of the POP-SS questionnaire. The questionnaire demonstrated excellent reliability (ICC = 0.81 and Cronbach's alpha = 0.86) and provided strong evidence for the construct validity (Kruskal–Wallis test, chi-square 62.98; $p < 0.05$). When compared with a criterion gold standard (P-QoL and POP-Q stage), the translated POP-SS showed a significant correlation (SCC 0.28, $p < 0.001$ and Mann–Whitney *U* test; $p < 0.001$, respectively). Finally, factor analysis revealed two factors with acceptable factor loadings and adequate item

Table 4 Exploratory factor analysis with factor loadings for the Amharic Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire

POP-SS items	Item loading	Eigenvalue	Variance (%)
Factor 1		3.83	41.27
A1	0.86		
A2	0.90		
A3	0.89		
A4	0.73		
A5	0.47		
A6	0.52		
A7	0.31		
Factor 2		1.15	30.29
A1	0.38		
A2	0.46		
A3	0.42		
A4	0.48		
A5	0.84		
A6	0.76		
A7	0.87		
			71.56

Items with high loading to factors are indicated in bold

Factor 1 physical symptoms, Factor 2 evacuation symptoms

Table 5 Pelvic Organ Prolapse Symptom Score (POP-SS) totals according to prolapse stage

Stage	Number	Median	Minimum	Maximum	<i>P</i> value
Stage 1	31	7.00	2.00	17.00	< 0.05*
Stage 2	16	12.00	3.00	19.00	
Stage 3	113	17.00	1.00	26.00	
Stage 4	26	18.00	8.00	22.00	

*Calculated using the Kruskal–Wallis test

discrimination values. Our findings are consistent with reports from hospital-based studies conducted elsewhere [10–12].

Before psychometric instrument can be applied in a new language, linguistic translation, cultural adaptation, and evaluation of psychometric properties are necessary. This helps to reduce flawed research conclusions and allows comparison between international studies [11, 21]. In translating the original POP-SS, we adopted the process of scale translation described by Beaton et al. [20] and others [21]. Emphasis was given to maintaining the original context and meaning of the words rather than a direct word-for-word translation. We found the questionnaire to be content valid after excellent expert panel agreement on the relevance of items, review by multilingual expert translators and pretest on symptomatic women. There were no missing items which partly suggests good acceptability of the Amharic version in the region in which the study was conducted. Moreover, the format of the POP-SS was the same as the original scale, i.e., seven questions that use a 5-point Likert scale, thus ensuring technical equivalence.

In this study, the Amharic version of POP-SS demonstrated excellent internal consistency (0.86). This finding was higher than the result of the original study (0.72–0.83) [10] and the Turkish validation study (0.71) [12]. The 2-week test–retest reliability analysis also demonstrated good correlation between paired test–retest scores (ICC for agreement 0.81;

Table 6 Correlation between Pelvic Organ Prolapse Symptom Score (POP-SS) and Prolapse Quality of Life (P-QoL) scores (criterion validity)

P-QoL domains	SCC	<i>P</i> value*
General health perceptions (GHP)	0.14	0.03
Prolapse impact (PI)	0.58	0.04
Role limitation (RL)	0.15	0.04
Physical limitation (PL)	0.24	0.001
Social limitation (SL)	0.23	0.002
Personal relationship (PR)	0.24	0.001
Emotions (E)	0.17	0.02
Sleep/energy (SE)	0.14	0.05
Severity measures (SM)	0.31	0.001

*Calculated using Spearman's rank correlation (SCC) analysis

$p < 0.001$). The result is comparable with the Turkish version (0.98) [12] and considerably higher than the traditional threshold of 0.7 [29], indicating stability of the scale over time.

The correlation between the POP-SS score with the Amharic P-QoL score and POP-Q stage were calculated for criterion validity. The Amharic version was significantly correlated with P-QoL score (SCC 0.28, $p < 0.001$), with the highest P-QoL score having the highest POP-SS value. Moreover, values of POP-SS changed according to the prolapse stage, with the highest stage having the highest POP-SS value. Both results confirm the Amharic POP-SS criterion validity, indicating that women with the highest POP-SS value were associated with poor QoL, especially women with a higher stage of POP. A strong correlation was reported between P-QoL and POP-Q stage [18, 30–32].

In terms of construct validity, the factor structure that emerged was reasonably clear and interpretable, and was consistent with the factor structure reported in the previous study, which showed a two-factor structure of the POP-SS [12]. Our study showed that items found in each factor were strongly related to the underlying construct. For both items, the correlation between items and construct was >0.73 . The presence of discriminant validity in each factor provides further evidence of the conceptual clarity of items grouped within the two factors. The two strong extracted factors were similar to those reported in the Turkish study and were designated physical and evacuation symptoms [12]. Factor analysis was not performed for the original version of the POP-SS.

Strengths of this study are the adoption of a multistep translation method, as supported by existing evidence—rather than the simple translation/back-translation process [20, 21]—and a relatively large sample size [12], which enabled us to conduct a robust factor analysis. Some caveats, however, must be considered when interpreting results. First, our study was conducted in a single urban hospital; therefore, results may not be generalizable to populations in rural and remote areas. Specifically, rates of illiteracy may impact validity. Further validation studies in more general contexts are therefore recommended. Second, responsiveness to change was not evaluated. Since the ability to detect a change in prolapse symptoms due to an intervention is an important scale property, we recommend inclusion of this in future studies. Third, sensitivity of the topic being studied carries the risk of providing socially desirable answers instead of true responses.

In conclusion, the Amharic version of the POP-SS achieved good semantic, conceptual, idiomatic, and content equivalence. The translated Amharic version of the POP-SS was a consistent, valid, and reliable instrument to assess common prolapse symptoms. This questionnaire can be easily administered and completed by patients and used in research and clinical environments. Further studies are needed to evaluate the responsiveness of POP-SS.

Acknowledgments The authors acknowledge all study participants. We thank Professor Suzanne Hagen, the original developer of the tool, for allowing us to translate the instrument into our language. We also would like to express our heartfelt thanks to the research assistants and the expert panel who provided input to this study.

Funding This work was supported by a grant, R.No: O/VP/RCS/05/216/2017, from the University of Gondar. The University was not involved in the design, conduct, analysis, or interpretation of the study or review or approval of the manuscript.

Compliance with ethical standards

Conflicts of interest None.

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