

Reliability and Validity of the Adapted Nepali Version of the AO Spine Patient Reported Outcome Spine Trauma

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ABSTRACT

Background: The AO Spine Patient Reported Outcome Spine Trauma has been validated in English and Dutch language, however, there is an absence of a translated and validated version in Nepali language. The purpose of this study was to translate the AO Spine Patient Reported Outcome Spine Trauma into Nepali and adapt cross-culturally as outlined by established guidelines, as well as test its psychometric properties among Nepali speaking spine trauma patients.

Methods: Patients were recruited from two Nepali centers as a cross-sectional multicenter validation study. The English version of AO Spine Patient Reported Outcome Spine Trauma was translated and cross-culturally adapted into Nepali language following international guidelines. Next to AO Spine Patient Reported Outcome Spine Trauma also the EQ-5D-3L was filled out by the patients for concurrent validity. Descriptive statistics were used to analyze the patient characteristics. Assessment of measurement properties included content validity (floor and ceiling effects), internal consistency (Cronbach's α and item total-correlation coefficients) and test-retest reliability by the Bland-Altman plot and Intraclass Correlation Coefficients. Spearman correlation tests were performed within the items and in correlation to EQ-5D-3L.

Results: Sixty two spine trauma patients completed the instrument with a mean time of 6.8 minutes. The translated version showed good content validity with no floor and ceiling effects. The internal consistency was excellent with a Cronbach's α of 0.95. The Spearman correlations within the AO Spine Patient Reported Outcome Spine Trauma items were 0.07 – 0.65 and the test-retest analysis showed excellent results with an Intraclass Correlation Coefficients value of 0.95 (CI 0.93 – 0.97). Inverse correlation was observed between Nepali AO Spine PROST with EQ-5D-3L components.

Conclusions: The Nepali version of AO Spine Patient Reported Outcome Spine Trauma demonstrated excellent validity and reliability results for measuring patient-reported outcomes of spine trauma patients.

Keywords: AO spine PROST; Nepali; translation; validation.

INTRODUCTION

The annual incidence of spinal injury ranges from 12.1 to 57.8 cases per million.¹ Neurological deficit leading to disability from spinal trauma is a huge drain on the health care resources of the state and society.² Resource constrained regions face greater challenges in managing patients with spine trauma with the potential of poor outcomes.

The absence of a disease-specific outcome measure for spine trauma patients makes it difficult to assess the optimal treatment options. Moreover, usage of tools that were developed for other patient population

such as degenerative spine conditions and polytrauma results in comparing treatment options in an unreliable fashion.³ Realizing this lacunae, the AO Spine Knowledge Forum Trauma developed such instrument for spine trauma patients: the AO Spine PROST (Patient Reported Outcome Spine Trauma).⁴ Recently, the AO Spine PROST has been validated for the Dutch and English languages, and showed very satisfactory results.^{5,6}

The AO Spine PROST was developed using a systematic approach and methodology based on the results of four different preparatory studies.⁴ The AO Spine PROST appeared to be a simple and reliable tool with the potential to be globally applicable as a disease-specific

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outcome instrument for spinal trauma patients. The instrument is believed to contribute to the efficacy of treatment protocols, quality of spine care, treatment strategies and devise possible new policies in managing spine trauma patients. The aim of the current study was to translate and cross-culturally adapt the AO Spine PROST into Nepali language and test its psychometric properties among spine trauma patients.

METHODS

The original AO Spine PROST questionnaire⁴ was provided by AO Spine Knowledge Forum Trauma and permission for translation and validation into Nepali was availed. Subsequently, the Nepali version was tested for its psychometric properties on spinal trauma patients. Ethics approval was obtained from the Institutional Review Board of the participating centers.

Translation and cross-cultural adaptation of the AO Spine PROST was undertaken according to established guidelines and consisting of multiple stages.⁷ The first stage (forward translation) involved translation of the original questionnaire from English to Nepali language by two translators whose mother tongue was Nepali but with English educational background. One of the two translators was a physiotherapist and was aware of the concepts being examined in the questionnaire. The other was a naïve translator without any medical knowledge. In the second stage, the two Nepali translations were synthesized into a common Nepali version. Stage 3 consisted of the back translation into English, and was performed by two non-medical native English speakers residing and working in Nepal as missionaries for more than ten years. Neither of them were aware of the purpose of the translation and worked independently. The back translations were forwarded to the original developer of the instrument to check for inconsistencies (stage 4). In stage 5, a discussion meeting was performed including an expert committee comprising of a statistician, two research professionals, two orthopedic surgeons and the translators. After reviewing all the translations, a pre-final version was developed (stage 6).

In the final stage (7), the pre-final Nepali version of AO Spine PROST was tested for the level of comprehensibility and cognitive equivalence of the translation through cognitive debriefing among 10 spinal trauma patients.

Since none of the patients had any difficulty, no changes were made to the questionnaire, making it the final Nepali version for further validation.

Adult patients (>18 years) sustaining spine injuries within one year after trauma with American Spinal Injury Association (ASIA) Impairment grade C, D and E were included. Pediatric patients (<18 years), non-traumatic spine fracture, patients with cognitive problems were excluded. These inclusion and exclusion criteria were in line with the patients included in the original validation studies of the English and Dutch language versions of the AO Spine PROST.^{5,6} Patients were recruited from a tertiary referral trauma center and a spine injury rehabilitation center in Province 3 of Nepal. After obtaining an informed consent from the included participants, they were administered the Nepali AO Spine PROST and EQ-5D-3L in the outpatient clinic of both centers. After an interval of two weeks, the patients were re-administered both the instruments for the purpose of test-retest reliability.

The instrument administered to the participants consisted of multiple parts: AO Spine PROST, EQ-5D-3L and additional evaluation and demographic questions. The final Nepali version of AO Spine PROST consists of 19 items (Figure 1A, 1B, 1C, 1D, 1E). Each item has a 0-100 numeric rating scale supported by smileys at either end, with 0 indicating no function at all and 100 the pre-injury level of function. Inquiry pertaining to difficulty in filling the questionnaire, comprehensibility of any item, and any inconsistencies was also made. To test the concurrent validity, the Nepali version of the EQ-5D-3L was administered to the patients. This strategy was chosen because of the absence of spine trauma specific outcome instrument, and the EQ-5D-3L had been translated and validated into Nepali by EuroQol Research Foundation.⁸ It consists of 5 descriptive items with three levels of perceived problems (Level 1: indicating no problems, Level 2: indicating some problems, Level 3: indicating extreme problems) and the EQ Visual Analogue Scale (EQ VAS).⁹ The patients included in the study were asked to fill out their demographic profile. Hospital admission records and discharge summaries were utilized for retrieval of injury related data such as level and type of fracture and type of treatment provided, as well as neurological status.

AOSpine PROST (Patient Reported Outcome for Spine Trauma)

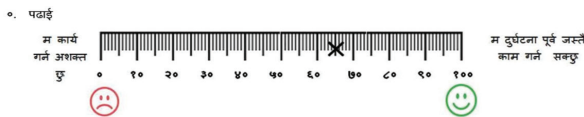
विरामिको नाम:.....
 मिति(म/म/सा):...../...../.....
 विरामि पहिचान संख्या:.....
 (स्वास्थ्य कर्मीले भर्नु पर्ने)

तपाइको अहिलेको र दुर्घटना पूर्वको अवस्था तुलना गरिएको

यस प्रश्नावलीमा १९ वटा प्रश्नहरू छन् जसले तपाइको दुर्घटना पश्चात भएको मेरुदण्ड को घोटले गर्दा भएको जीवन अवस्था देखाउँछ। कृपया ध्यान दिएर प्रश्नहरू र स्केल मापनका विवरण पढ्नुहोला। कृपया सबै प्रश्नहरूको जवाफ मापन स्केलमा (X) चिन्ह लगाएर दिनुहोला। यसले तपाइको दुर्घटना पूर्व र दुर्घटना पश्चात गर्ने कार्यको अवस्था दर्शाउँछ।

यो स्केलमा ० देखि १०० सम्म श्रेणीगत छ। यो महसुस गर्नु महत्वपूर्ण छ कि ० ले तपाइको कार्यअशक्तताको स्तर संकेत गर्दछ। तपाइको दुर्घटना पूर्व अवस्था जति राम्रो अथवा कमजोर भएपनि १०० ले तपाइको दुर्घटना पूर्वको स्तर संकेत गर्दछ।

तल उदाहरण देखाइएको छ।



विरामिले पूर्ण रूपमा भर्नु पर्ने

प्रश्नावली यहाँबाट शुरू हुन्छ।

प्रायः सबै प्रश्नहरूमा विभिन्न अवस्था अथवा उदाहरणहरू कोस्टमिज देखाइएको छ।

कृपया तपाईंले अवस्था अथवा उदाहरणमा आफु सबभन्दा बढी अपांगता भएको आधारित भएर उत्तर दिनुहोला।

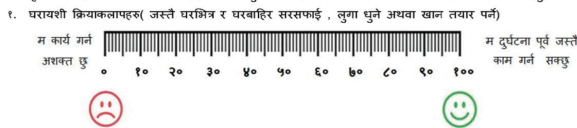


Figure 1A. Translated and validated Nepali PROST

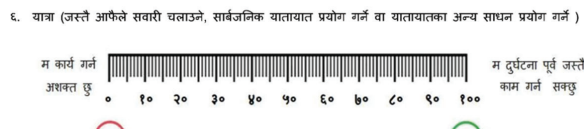
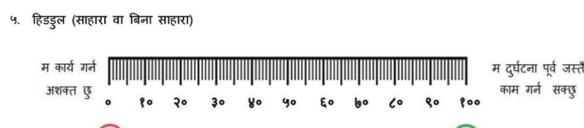
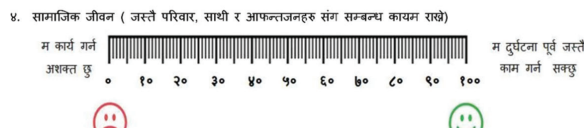
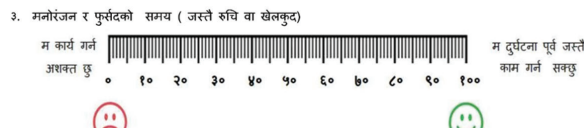
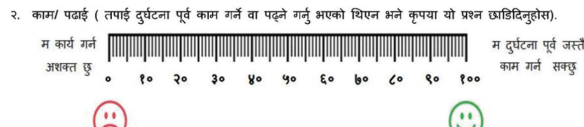
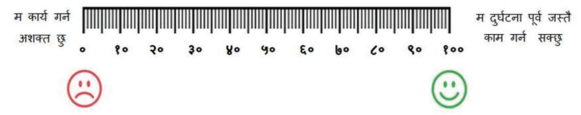
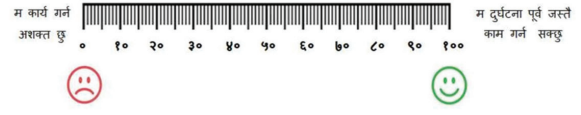


Figure 1B. Translated and validated Nepali PROST (continued)

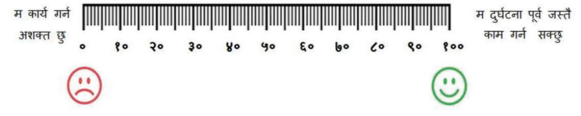
७. शारीरिक अवस्था परिवर्तन गर्ने (जस्तै पल्टिने, बस्ने वा उभिने)



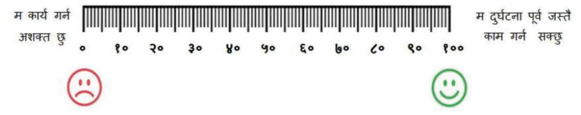
८. शारीरिक अवस्था कायम राख्ने (जस्तै आवश्यकता अनुसार लाग्ने समय सम्म पल्टिने, बस्ने वा उभिने)



९. उचाल्ने र बोक्ने (जस्तै सामानको झोला उचाल्ने वा बच्चा बोक्ने)



१०. व्यक्तिगत हेरचाह (जस्तै नुहाउने, शौचालय प्रयोग गर्ने वा लुगा लगाउने र फुकाल्ने)



११. पिशाब फेर्ने (तपाईं पिशाब गर्न सक्नुहुन्छ, तपाईं पिशाब रोक्न सक्नुहुन्छ)

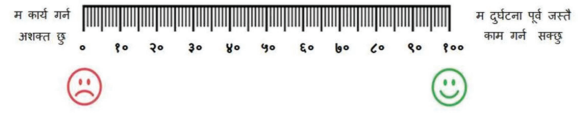
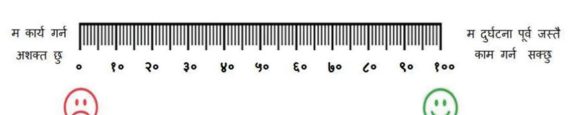
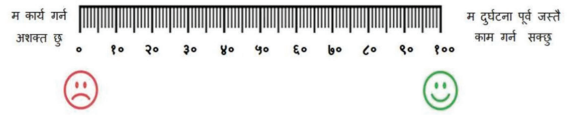


Figure 1C. Translated and validated Nepali PROST (continued)

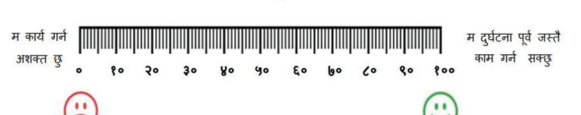
१२. दिशाको चाल (तपाईं दिशाको चाल थाहा पाउनुहुन्छ, तपाईं दिशाको चाल रोक्न सक्नुहुन्छ)



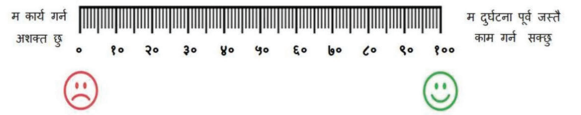
१३. यौन क्रियाकलाप



१४. भावनात्मक क्रियाकलाप (जस्तै उदास, चिन्तित वा ब्याकुल भावना)



१५. ऊर्जा स्तर (जस्तै थकान वा अनुत्साह)



१६. निन्द्रा (जस्तै कति घण्टा र गुणस्तर)

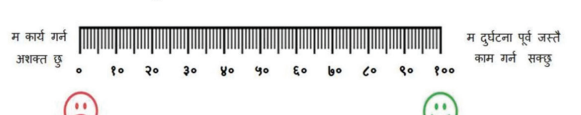


Figure 1D. Translated and validated Nepali PROST (continued)

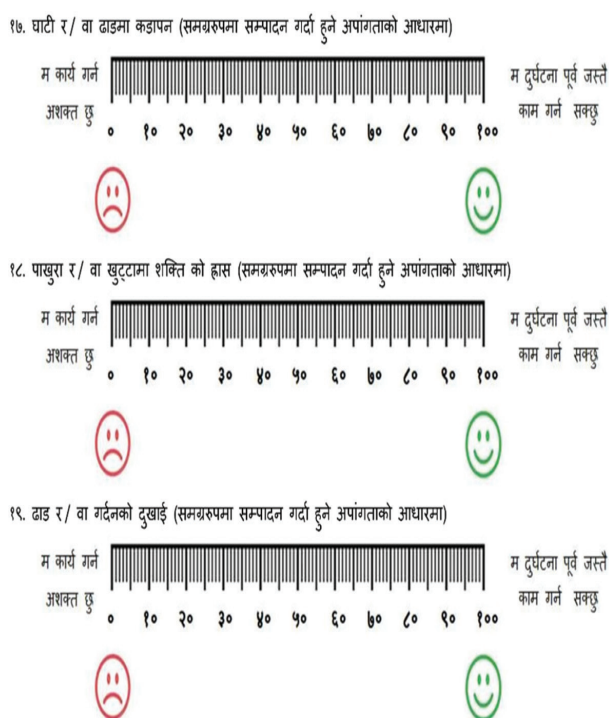


Figure 1E. Translated and validated Nepali PROST (continued)

Demographic characteristics of the included patients were analyzed by descriptive statistics. The content validity was assessed during the pretest stage of the questionnaire development. Also, floor and ceiling effects were observed if more than 15% of the participants achieved the minimum or maximum possible scores respectively.

The enrolled patients were asked to indicate whether there were any issues with comprehension of any of the items, if any relevant items were missing and repetition of an item. Cronbach's α was performed to determine the internal consistency of the instrument. Cronbach's α between 0.70 - 0.95 has been considered to be a measure of good internal consistency.¹⁰

Concurrent validity explored the Spearman correlation coefficient between AO Spine PROST and EQ-5D-3L. A value of 0.70 depicts good concurrent validity.¹⁰ Test-retest reliability was analyzed by Bland-Altman plot and Intraclass Correlation Coefficients (ICC) and scores of 0.60 - 0.70 and >0.75 indicating good and excellent results, respectively.¹¹

RESULTS

The prefinal version was tested on 10 spine trauma patients for comprehensibility and cognitive equivalence of the translation. Since none of the patients reported any difficulty in comprehension, vocabulary and item content, no changes were made to the questionnaire.

Sixty two patients with traumatic spine injury were enrolled and included in the study. All patients were adults above 18 years with the majority being male (77.4%). The mean age was 37.4 years (SD \pm 11.9). 53.2% sustained fall injuries with lumbar spine being the most common level of injury. 74.2% patients received surgical treatment. Demographic characteristics of the patients are outlined in Table 1.

The mean time taken to complete the AO Spine PROST questionnaire was 6.8 minutes. None of the patients reported any difficulty with the individual items, indicating that all items were understandable and the translation was found to be acceptable. No floor and ceiling effects were observed.

The Standard Cronbach's α for translated AO Spine PROST was excellent with 0.95 (confidence interval 0.93-0.97). The item- total correlation was also significant with a range of 0.60 to 0.87 (Table 2). "Social life" and "Back and /or neck pain" had smallest correlation measuring 0.62 and 0.60, respectively. The Cronbach's α did not change significantly when an item was removed.

Table 3 shows Nepali AO Spine PROST and EQ-5D-3L Spearman correlations. Moderate negative correlation was seen between walking component of Nepali AO Spine PROST and mobility of EQ-5D-3L ($r = -0.60$) and highest negative correlation between social life component of Nepali AO Spine PROST and usual activities of EQ-5D-3L ($r = -0.07$). Majority of the EQ-5D-3L and Nepali AO Spine PROST had negative correlation with minimum correlation being 0.07 and maximum 0.65. Table 4 shows the Spearman correlation coefficient across the translated AO Spine PROST items.

The Bland-Altman plot for the test-retest reliability at an interval of two weeks shows agreement before and after measurements and identifies the possible outlier. Each item on the graph reveals the mean value of the two assessments in X - axis and the difference between the 2 assessments in Y - axis (Figure 2A, 2B, 2C). The ICC was found to be excellent (0.95; CI 0.93 - 0.97).

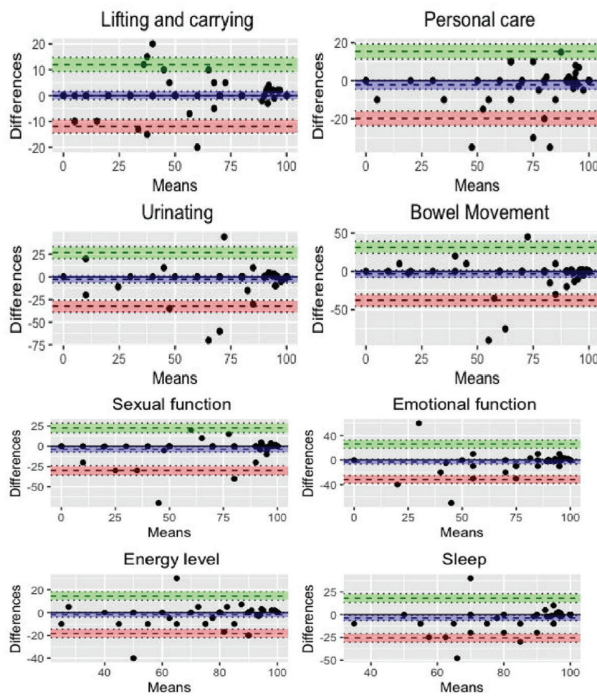


Figure 2A. Bland-Altman plot for test-retest reliability

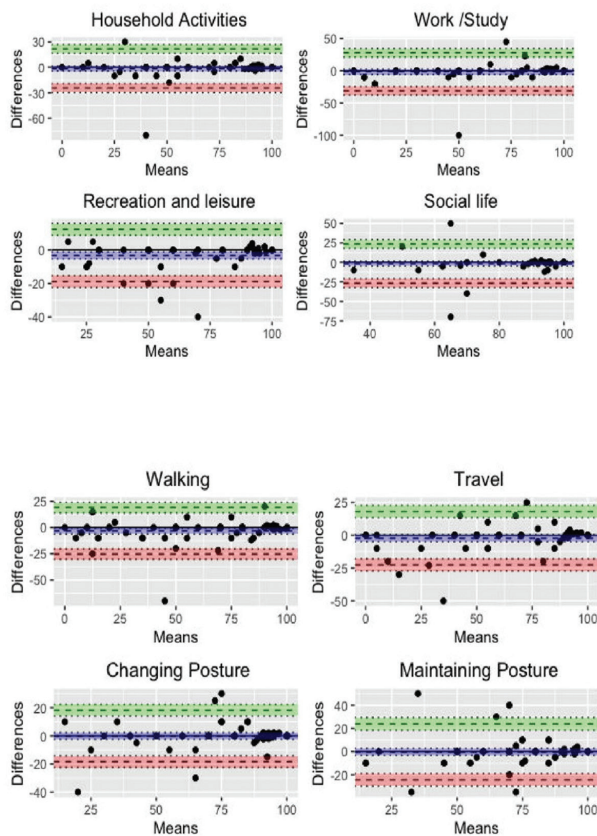


Figure 2B. Bland-Altman plot for test-retest reliability (continued)

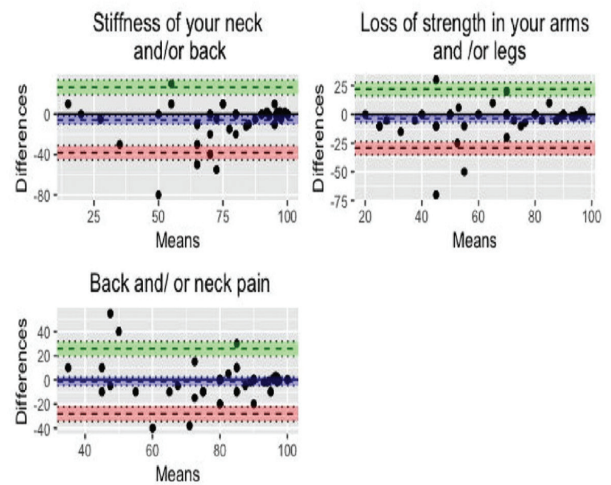


Figure 2C. Bland-Altman plot for test-retest reliability (continued)

Table 1. Patient Characteristics and Demographics

Variable	Number	Percentage
Gender		
Male	48	77.4
Female	14	22.6
Smoking		
No	54	87.1
Yes	8	12.9
Occupation		
Service	9	14.5
Business	10	16.1
Agriculture	15	24.2
Student	6	9.7
Abroad	2	3.2
Unemployed	20	32.3
Mode of Injury		
Fall injury	33	53.2
Road Traffic Injuries	24	38.7
Other injury	5	8.1
Time after Trauma (months, range)	7.5 (1–12)	
Level of Injury		
Cervical	17	27.4
Thoracic	20	32.3
Lumbar	25	40.3
AO Classification		
AO Type C (translational injury)	5	8.1

AO Type B3 (hyperextension type)	4	6.5	AO Type A3 (incomplete burst fracture)	6	9.7
AO Type B2 (posterior ligamentous injury with anterior bony and disc injury)	21	33.9	ASIA score		
AO Type B1 (three column transosseous bony injury)	13	20.9	C	23	37.1
AO Type A4 (complete burst fracture with involvement of both end plates and retropulsion)	13	20.9	D	28	45.2
			E	11	17.7
			Treatment		
			Conservative	16	25.8
			Surgery	46	74.2

Table 2. Item total correlation and Cronbach's α between Nepali AO Spine PROST items.

AO Spine PROST item	Item total correlation	Cronbach's alpha if item deleted	Intraclass correlation coefficient (ICC)
Household activities	0.79	0.95	0.95 (0.93-0.97)
Work/study	0.62	0.94	
Recreation and leisure	0.74	0.95	
Social life	0.62	0.94	
Walking	0.84	0.95	
Travel	0.86	0.95	
Changing posture	0.79	0.95	
Maintaining posture	0.68	0.95	
Lifting and carrying	0.85	0.94	
Personal care	0.81	0.95	
Urinating	0.80	0.95	
Bowel movement	0.75	0.95	
Sexual function	0.78	0.95	
Emotional function	0.60	0.95	
Energy level	0.73	0.95	
Sleep	0.62	0.95	
Stiffness of your neck and / or back	0.74	0.95	
Loss of strength in your arms and legs	0.87	0.94	
Back and/ or neck pain	0.64	0.95	

Table 3. Spearman Rank Correlation between Nepali AO Spine PROST and EQ-5D-3L.

	Mobility	Self Care	Usual Activities	Pain/discomfort	Anxiety / Depression
Household activities	-0.40	-0.47	-0.44	-0.33	-0.21
Work/study	-0.41	-0.33	-0.38	-0.24	-0.08
Recreation and leisure	-0.37	-0.39	-0.31	-0.25	-0.28
Social life	-0.09	-0.12	-0.07	-0.19	-0.20
Walking	-0.64	-0.49	-0.45	-0.43	-0.25
Travel	-0.50	-0.46	-0.35	-0.34	-0.21
Changing posture	-0.45	-0.45	-0.42	-0.38	-0.31
Maintaining posture	-0.50	-0.39	-0.42	-0.26	-0.07
Lifting and carrying	-0.45	-0.41	-0.35	-0.37	-0.19
Personal care	-0.42	-0.65	-0.58	-0.47	-0.40
Urinating	-0.37	-0.55	-0.42	-0.40	-0.44
Bowel movement	-0.38	-0.48	-0.37	-0.38	-0.36
Sexual function	-0.31	-0.34	-0.27	-0.33	-0.23
Emotional function	-0.29	-0.36	-0.35	-0.36	-0.44
Energy level	-0.38	-0.38	-0.41	-0.50	-0.38
Sleep	-0.26	-0.35	-0.34	-0.34	-0.41
Stiffness of your neck and /or back	-0.35	-0.52	-0.44	-0.40	-0.32
Loss of strength in your arms and legs	-0.54	-0.48	-0.40	-0.37	-0.21
Back and/ or neck pain	-0.34	-0.35	-0.31	-0.48	-0.30

Table 4. Spearman correlation between the Nepali PROST items.

	q1	q2	q3	q4	q5	q6	q7	q8	q9	q10	q11	q12	q13	q14	q15	q16	q17	q18
q2	0.63																	
q3	0.55	0.52																
q4	-0.17	-0.09	-0.24															
q5	0.49	0.36	0.42	0.08														
q6	0.52	0.38	0.47	0.06	0.72													
q7	0.47	0.31	0.35	0.10	0.74	0.64												
q8	0.60	0.37	0.32	-0.06	0.68	0.57	0.81											
q9	0.66	0.6	0.54	0.13	0.59	0.69	0.61	0.71										
q10	0.42	0.18	0.31	0.13	0.57	0.51	0.48	0.36	0.66									
q11	0.54	0.31	0.56	-0.14	0.56	0.55	0.45	0.39	0.53	0.71								
q12	0.58	0.41	0.60	-0.18	0.57	0.48	0.37	0.43	0.56	0.53	0.88							
q13	0.55	0.36	0.55	-0.19	0.50	0.52	0.39	0.34	0.54	0.5	0.76	0.75						
q14	0.20	0.15	0.15	0.31	0.44	0.46	0.52	0.27	0.34	0.61	0.31	0.24	0.36					
q15	0.46	0.43	0.37	0.08	0.51	0.53	0.53	0.26	0.51	0.54	0.51	0.49	0.60	0.59				
q16	0.31	0.33	0.27	0.20	0.38	0.28	0.41	0.30	0.51	0.47	0.47	0.52	0.44	0.56	0.47			
q17	0.40	0.32	0.31	-0.37	0.24	0.15	0.35	0.33	0.28	0.39	0.45	0.51	0.43	0.20	0.40	0.24		
q18	0.49	0.40	0.38	-0.22	0.75	0.66	0.57	0.45	0.61	0.50	0.45	0.44	0.45	0.38	0.49	0.29	0.36	
q19	0.56	0.29	0.15	-0.14	0.54	0.44	0.47	0.48	0.59	0.42	0.39	0.40	0.40	0.48	0.59	0.48	0.39	0.54

DISCUSSION

This study describes the translation and cross-cultural adaptation of AO Spine PROST into Nepali following established guidelines⁷. Outcome instruments should not only be linguistically translated well but also properly adapted culturally.¹² The AO Spine PROST was initially developed in the Dutch language with good validation results.¹ A recent translation into the English version showed similar results.⁶

The annual incidence of spinal injuries worldwide range between 236 and 1009 per million per year.¹³ Although the annual incidence of spinal injuries from Nepal has not been reported, Dhakal et al., have analyzed the neurological outcome following surgery on 30 cervical spine injury and 91 thoracic and lumbar spine injury patients over a period of two years.^{2,14} Another study from eastern Nepal depicts the clinico-epidemiological profile of 149 cervical spine injuries patients over three years.⁸ Studies from Nepal depict an increasing trend with serious challenges in managing spinal trauma patients.^{2,14,15} In spite of advances in medical and surgical care, there is an absence of a patient-reported outcome instrument specific to spinal injuries. The application of generic health-related quality of life measures or instruments designed for degenerative or deformity specific instruments in traumatic spinal injuries will result in discrepancies in quality of care and research activities.¹⁶

Similar to the English version of AO Spine PROST, the translated and adapted Nepali version also showed good content validity.⁶ None of the patients involved in the study reported any difficulty in comprehending the questions. With Cronbach's α and ICC of 0.95, the Nepali version showed excellent internal consistency and reliability. Sexual function is a very intimate affair in the Nepali society and not every individual is open to express it. However, even when this item was deleted or not answered by the patient, there was no reduction in the internal consistency and reliability of the instrument.

Unlike the English version, wherein AO Spine PROST was compared to SF-36, the translated Nepali version was compared to EQ-5D-3L. This was considered as the EQ-5D-3L has also been validated in Nepali and utilized in the translation and validation of Nepali version of the Neck Disability Index and Numerical Rating Scale for Neck Pain⁸. Tsang et al., have also demonstrated the EQ-5D-3L to having a good correlation with SF-36¹⁷. Multiple clinical studies have utilized EQ-5D-3L as an

outcome assessment instrument in traumatic and non-traumatic spinal conditions.¹⁷⁻²⁰ Also, compared to SF-36 (8 domains and 36 items), the EQ-5D-3L includes only 5 descriptive items and an EQ VAS which makes the administration of the instrument less burdensome for patients.⁹ A zero score in each AO Spine PROST item depicts no function at all (worse outcome) while the lowest level (level 1) in each EQ-5D-3L item indicates no problem. This would mean that a spine trauma patient returning back to normal activities post injury without any major issues would provide a score near 100 in the AO Spine PROST items while Level 1 (no problem at all) in the EQ-5D-3L.

This moderate inverse correlation was seen with walking component of AO Spine PROST and mobility component of EQ-5D-3L, while higher correlation was observed with social life component and usual activities. The possible explanation for patients scoring higher on social life component (AO Spine PROST) and usual activities (EQ-5D3L) than walking and mobility component could be that patients consider social interactions within the community more important. In Nepalese society, the sick, injured and differently abled are supported by the society and community by frequent visits and assistances. The community and society takes precedence over the individual's disability. The limited social interactions could also be a result of their compromised neurological function (ASIA C and D). Because there was exclusion of patients with complete motor deficit (ASIA A and B), the correlation between the walking component of AO Spine PROST and mobility component of EQ-5D-3L could be greater due to the profound neurological deficit status restricting mobility to a wheel chair. Further validation studies in ASIA A and B patients could explore any possible discrepancies. However good social support system and social interaction have led to improved patient outcomes in spine trauma patients.²¹ This is especially true in countries where spine trauma patients have limited access to prompt medical and surgical care, rehabilitation services, and socio-economic support system.

The Nepali version of the AO Spine PROST shows good test-retest reliability as depicted by the Bland-Altman plot and ICC between the two measurements. The interval between the two measurements was two weeks. A two weeks' time interval was chosen to minimize recall bias and significant change in the clinical outcome of the patients would not be expected to occur.

ASIA A and B patients were excluded in the current study in line with the original AO Spine PROST being validated among ASIA C, D and E patients.^{5,6} The authors of the

original instrument advocated to focus on patients sustaining injuries to their spinal column and excluded completely paralyzed and polytrauma patients, in order to identify specific problems related to spine trauma.^{5,6} To the best of our knowledge, the authors of the original instrument aim to further validate the AO Spine PROST among ASIA A and B patients, which is also our purpose in future studies with the Nepali version. Unlike the original study which used SF-36, we have utilized EQ-5D-3L which could lead to discrepancies in the validation process. The authors of this study plan to perform a pilot study comparing SF-36 to EQ-5D-3L while validating this instrument in ASIA A and B patients.

CONCLUSIONS

The Nepali version of AO Spine PROST can be recommended as a valid and reliable patient-reported outcome measure in the evaluation, clinical care, rehabilitation and research work in spine trauma patients.

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CONFLICT OF INTERESTS

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