Research Article

Cross-cultural adaptation, reliability, validity and responsiveness of Urdu version of neck outcome score (NOOS)

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ABSTRACT

Background: Neck pain and associated disability significantly impact individuals' daily lives and well-being. Effective assessment and management of neck-related conditions require the use of standardized Outcome Measures. The Neck Outcome Score (NOOS) is a well-recognized tool designed to evaluate neck pain, in Urdu-speaking individuals is needed.

Objective: to cross-culturally adapt the NOOS into Urdu and evaluate its reliability, validity, and responsiveness.

Methods: Translation and cross-cultural adaptation of the Urdu version of NOOS were brought about and administered to n=200 patients and n=70 healthy participants. All participants were asked to fill out NOOS-U, Neck Disability Index-U, Visual Analog Scale pain, and VAS disability. For test-retest reliability, n=46 patients filled NOOS-U twice after 48 hours. Toward the end of 3 weeks, Patients were asked to fill out NOOS-U, Short Form-36, NDI-U, VAS scales, and the Global Rating of Change. NOOS-U was evaluated for Reliability, Validity, and Responsiveness

Results: NOOS-U exhibited good Test-Retest Reliability (ICC2,1=0.86-0.99) and Internal Consistency (Cronbach alpha=0.93). Construct validity results had satisfactory correlations of NOOS-U with NDI-U, SF-36, VAS pain, and VAS disability ($p<0.001$). In the analysis for discriminant validity, a notable difference in the total scores of NOOS-U between the patients and healthy participants was observed ($p<0.001$). Furthermore, the responsiveness of NOOS-U was statistically significant ($p<0.001$) among the improved and not improved group.

Conclusions: This study demonstrated that NOOS-U is a valid, reliable and responsive instrument for the assessment of nonspecific neck pain among patients who can understand Urdu.

Keywords: Neck pain; reliability; responsiveness; translation; validity.

Designation & Affiliation

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INTRODUCTION

Non-specific neck pain is defined as pain perceived in the cervical region whose origin and pathophysiological mechanism are unknown [1]. It has a high prevalence all around the world [2, 3]. In Pakistan, a 54% occurrence of neck pain was found over a 6-month period, with 37% of people reporting persistent symptoms [4]. It prevails in various vocational groups in Pakistan, ranging from 26.5% to 72% [5-7]. According to a study conducted in 2017, there is a high prevalence of non-specific neck pain especially in widowed or separated people with low income and low educational levels who perform their work in sitting or leaning postures throughout the day [8].

The cervical region being the most intricate articular system of the human body, has a complex arrangement of bones, muscles, nerves, discs, tendons, and ligaments that make it an important structure anatomically and physiologically where pain mostly presents along decreased muscle flexibility, strength, and decreased range of motion leading to functional limitations and disabilities at worst [8]. Other signs and symptoms include stiffness, headache, radiating pain, and numbness to name some.

Pain itself is subjective and therefore only the patient can truly rate and describe its characteristics including onset, intensity, location, duration, etc. Pain assessment is a multi-dimensional process crucial to tailor the treatment protocol [9]. Clinicians may use different self-report pain measures along with clinical tests, labs, and imaging to get firsthand information on the patient's condition. Many valid and reliable tools are widely used in practice. These include Visual Analog Scale-Pain [10], Visual Analog Scale-Disability [10], Neck Disability Index [11], Northwick Park Questionnaire [12], Neck OutcOme Score [13] etc.

The NOOS scale assesses the patients comprehensively with its 34 questions under 5 domains including mobility and stiffness, symptoms, sleep disturbance, everyday life and pain, participation in everyday life and Quality of Life (QoL). It incorporates a range of activities and situations a person may come across that exacerbate a person's neck pain in daily living [13].

Muslims may experience neck pain during prayers which were seemingly not addressed in scales like the Northwick pain scale and NDI. We can find questions regarding QoL in NOOS, particularly in its participation domain which is not observed in NDI. Such a wide array of questions like those in NOOS is always a better alternative than simpler tools with little expanse like NDI and much better than a single question tool such as numeric pain rating scale (NPRS), which leaves the examiner with very little understanding of the patient's condition [13, 14].

The NOOS questionnaire has been previously translated and validated into three languages: Turkish [15), Arabic [16] and Chinese [17]. As Urdu is one of the major languages spoken by millions of people in Pakistan, India, and other regions. However, a validated and culturally adapted Urdu version of the NOOS is not yet available for clinical and research use. The absence of a standardized Urdu version limits healthcare professionals from accurately assessing neck-related conditions in Urdu-speaking populations. The study aimed to cross-culturally adapt the NOOS into Urdu and evaluate its reliability, validity, and responsiveness.

METHODOLOGY

The study was conducted for the duration of 1 year, June 2022 to June 2023 after the approval from the ethics review committee of Margalla Institute of Health Sciences (MIHS) (ERC #. DN/149/22). The study was approved by the Declaration of Helsinki. The tool has been translated after obtaining permission through the concerned authorization via email.

The translation process followed the established guidelines of Beaton et al [18]. There were five steps in the process as follows;

Step 1 was the *Forward Translation* of the original document of Neck Outcome Score (NOOS)was independently forward translated conceptually by two translators fluent in both Urdu and English languages named T1 and T2. One translator was an Assistant Professor (M-Phil) from the linguistic department of a university and the other translator was a senior physiotherapy lecturer having master's degree in Musculoskeletal Physical Therapy. After translation, both translators provided the written reports.

Step 2 was the *Synthesis of* the combined version developed after evaluation and consensus on identifying and resolving the discrepancies to create a preliminary initial translation (PI-TL) of the instrument in Urdu.

Step 3 was *Back Translation* by the two self-employed professional translators having master's degree in linguistic without any medical background then back-translated the unified PI-TL version into the English language (BT1 and BT2), to accurately reflect the original meaning in Urdu. One translator was an Assistant Professor (M-Phil) from the Urdu department of a university and the other translator was a senior physiotherapy lecturer having master's degree in Musculoskeletal Physical Therapy. After translation both translators provided the written reports. Both translators were unaware of the explored concepts.

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Step 4 was the *Expert Review*, In which an expert committee reviewed all reports from steps 1-3 and evaluated for clarity of the instructions, items, and response format. Based on the initial steps and suggestions made by the expert committee, the translated tool was rendered in the pre-final instrument. The committee included methodologists, health professionals both Physical therapists and Dentists, language professionals, translators, and researchers. The expert committee ensured equivalence between the English and Urdu versions of the questionnaire.

Step 5 was the *Cognitive Debriefing* of the tool. The pre-final form of Neck Outcome Score-Urdu (NOOS-U) was administered to a sample of n=40 patients for face validity. All patients were subjected to a structured interview after completion of the NOOS-U. All subjects answered the questionnaire and were encouraged to point out any difficulties and necessary modifications are made based on patient feedback. Findings of the adaptation process were evaluated by the researchers and a final approved NOOS-U questionnaire was subjected to further psychometric testing.

Sample Size: a total of n=200 patients and 70 healthy participants were recruited in the study in accordance with international guidelines for psychometric testing [19].

Instruments: The *NOOS-U* was administered in the study which comprises 34 questions as discussed above. The standardized Likert scale options are given as answers with a minimum score of 0 to a maximum score of 4. The scores calculations were done as; Subscale Score= (100-Mean Score of the Subscale) ×100)/4. Thus, a higher score indicates better functioning, while a lowers indicates poor [25]. It takes on average 10-15 minutes to complete the questionnaire. Subjective pain and disability were measured by *VAS pain and VAS disability* respectively. Both have been proven to be valid and reliable tools time and again by numerous research [10]. Both these tools have a scale of 0 to 10 on a 100-mm horizontal line denoting no pain/restriction at all at "0" to the worst pain/restriction imaginable at a score of "10". The quality of life was assessed using a well-researched self-reported measure called *Short Form-36* Health Survey. This measure consists of 36 questions that cover 8 domains of health [20]. Available in multiple languages, SF-36 has proven to be a valid, reliable, and responsive measure [21]. *Neck Disability Index (NDI-U)* was also used which is a valid and reliable (ICC=0.99) tool widely used in clinical settings. It consists of 10 items, each scored from 0 (no disability) to 5 (complete disability) which adds up to a total score of 50 [22]. The *Global Rating of Change (GROC) scale* is a 15-point scale used to evaluate a patient's self-perception of pain deterioration or improvement over time. Patients were requested to rate the general condition of their neck from 7 ("a very much worse") to +7 ("very much better") since the start of treatment. The scale is easy to administer, has good reproducibility, requires minimal skills, and is also sensitive(sensitivity=0.83-0.93) to change [23].

Participants: The individuals between the ages of 18 and 65 years, irrespective of their gender and suffering from non-specific neck pain, were part of the research study. Moreover, the participants of the study required sufficient literacy skills to read Urdu language. The participants without any history of neck pain and/or pathologies or injuries were recruited in the healthy group of the study. Patients with a history of neck fracture or surgery in the last 3 months, neurological deficits, tumors, rheumatological diseases, or infections. Furthermore, diagnosed psychiatric disorders patients were also excluded from the study.

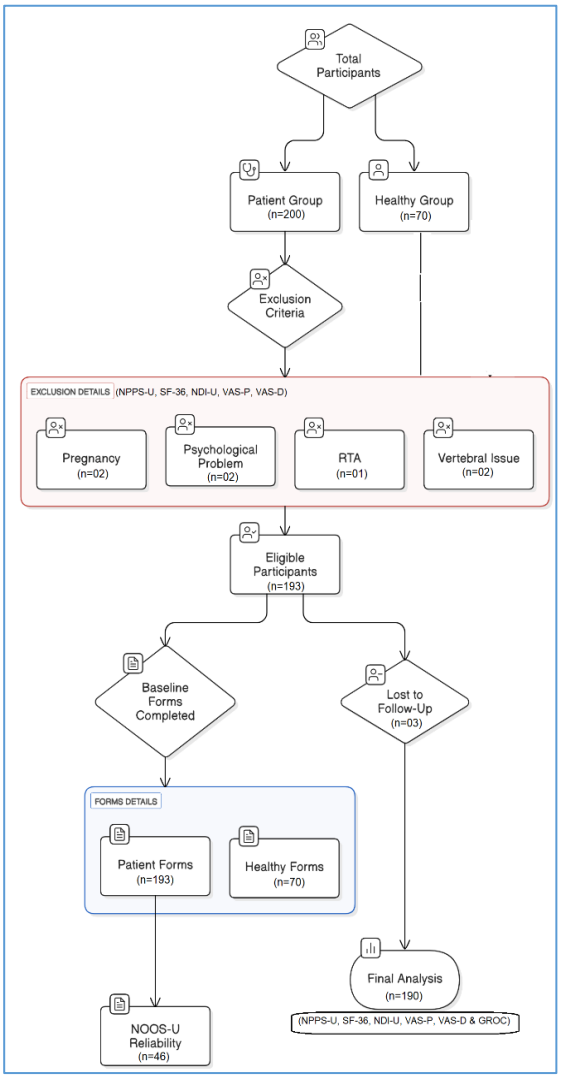

Figure 1: Study flow chart

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Data collection procedure: Self-structured questionnaire was used for demographic data and disease-related questions. Patients and healthy participants were required to fill NOOS-U, SF-36, NDI-U, VAS pain, and VAS disability. From the patient's group, n=46 randomly nominated people were asked to fill out NOOS-U after a 48-hrs interval. After 3 weeks during which the patients received standard physiotherapy and/or allopathic (comprising mainly of electrotherapy, cervical stretching, hot pack, and NSAIDs) treatment, NOOS-U, SF-36, NDI-U, VAS pain, VAS disability and the GROC scale were again administered as post-treatment assessment. All patients and healthy participants provided written informed consent.

Data analysis: All statistical analyses were conducted using the Statistical Package for the Social Sciences version 26 software. The reliability of NOOS-U was established by test-retest reliability and internal consistency. To conduct test-retest reliability, n=46 randomly selected people completed the NOOS-U twice with a 48 hrs interval. A good reliable tool should have an ICC value of ≥ 0.80 [24]. Internal consistency was measured by the value of Cronbach's Alpha. A value of +0.80 or greater is good internal consistency [25]. Content validity observes the completeness of item responses, and the distribution of scores and assesses magnitudes of floor and ceiling effects. Floor and ceiling effects were to be considered if more than 15% of the respondents reached the lowest or highest possible score, respectively. Discriminant validity was gauged by calculating the differences in the total score of NOOS-U between the patient (n=190) and healthy group (n=70) using an independent t-test. To test construct validity, analysis was performed through correlation among NOOS- U and SF-36, NDI-U, VAS pain, and VAS disability [25]. The global rating of change (GROC) scale dichotomized the patients into improved and not improved groups. Responsiveness was analyzed by comparing the change scores between improved and not improved groups, through Pearson's correlation.

RESULTS

Translation and cross-cultural adaptation was done under the guidelines of Beaton et al[18]. There were no additional problems found throughout the translation, review, or pilot-testing processes. The results of the pilot testing phase revealed no differences in terminology or meaning in the translated version of the NOOS-U. Participants did not ask for help understanding the questionnaire or any of its items. As a result, no changes were made to this version. Hence, the final version of NOOS-U was administered to the sample for Psychometric Testing. The table 1 displays demographics and clinical characteristics of both groups.

Table 1: Demographic characteristics of patient (n=193) and healthy (n=70) group

Variables		Patient Group M±SD/n(%)	Healthy Participants M±SD/n(%)
Age (Years)		34.85±11.75	26.44±8.27
Gender	Female	104(53.9)	47(67.1)
	Male	89(46.1)	23(32.9)
BMI		25.03±5.03	23.71±5.28
Duration Of Neck Pain In Months		11.24±14.82	NA
Work Status	Employed	127(65.8)	45(64.3)
	Un-Employed	66(34.2)	25(35.7)
Education	Matric	17(8.8)	1(1.4)
	Intermediate	21(10.9)	4(5.7)
	Undergraduate	45(23.3)	31(44.3)
	Graduate	110(57.0)	34(48.6)
VAS		-	-
Pain	-	5.12±1.33	NA
Disability		5.02±1.28	NA
Noos-U		-	-
Mobility		58.93±16.85	100±0.00
Symptoms	-	50.87±15.33	95.79±7.25
Sleep		64.54±22.59	100±0.00
Activity		59.04±13.54	100±0.00
Participation		65.54±19.08	100±0.00
SF-36		-	-
Physical Functioning		59.17±16.32	95.71±6.32
Role Physical		55.18±37.75	95.7±15.33
Bodily Pain		40.23±13.41	79.13±12.54
General Health	-	69.24±17.04	82.33±11.86
Vitality		54.66±16.12	72.07±13.77
Social Functioning		64.77±18.72	89.28±14.94
Role Emotional		38.17±35.99	84.29±29.88
Mental Health		67.19±14.78	79.31±12.69

BMI-Body Mass Index; M-Mean; SD-Standard Deviation; SF- Short Form; VAS-Visual Analogue Scale

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For content validity, all the participants completed the questionnaires with no missing items. Furthermore, No floor or ceiling effect was observed for any domain or the total score of NOOS-U. For construct validity, the domains of NOOS-U had a weak to moderate correlation ($p<0.05$) with VAS pain and VAS disability as observed in Table 3. All the domains of NOOS-U had moderate correlations with NDI-U whereas NOOS-U and SF-36 had a weak to moderate correlation among related domains.

Regarding the Internal consistency and test-retest reliability of the NOOS-U, most domains, including mobility, sleep, and participation, showed excellent (ICC>0.95) reliability. The symptoms and activity were slightly lower but still good reliability. Cronbach's Alpha values were exceptionally high (≥0.93), indicating strong coherence of items within each domain. Furthermore, minimal changes in mean scores between measurements suggest no significant practice effect or measurement drift. (table 2)

For Discriminant validity, a significant difference in the total score of NOOS-U was found between patients and healthy participants with a $p<0.001$ as the healthy group had better scores falling towards the higher limits while the patient group had scores closer to the lower limits.

A total of n=190 patients were evaluated for responsiveness. The results exhibited a significant difference ($p<0.05$) in NOOS-U change scores between the two groups, with the improved group having a higher change score than the stable (not improved) group. (table 4).

The mean and SD for the change score NDI-U were 5.80±4.95, for the change score VAS pain were 2.72±1.35, for the change score VAS disability were 3.87±1.63, and for the change score Bodily pain was 23.42±17.62. (table 5)

Table 2: Test-retest reliability of all domains of NOOS-U

NOOS-U	1st Measurement M±SD	2nd Measurement M±SD	Cronbach's α	ICC Value	CI (95%)
Mobility	58.93±16.85	60.02±17.34	0.98	0.97	0.95-0.98
Symptoms	50.87±15.33	50.11±17.49	0.96	0.93	0.88-0.94
Sleep	64.54±22.59	64.40±22.36	0.99	0.99	0.99-0.99
Activity	59.04±13.54	59.99±15.40	0.93	0.86	0.76-0.92
Participation	65.54±19.08	66.41±19.41	0.99	0.99	0.98-0.99

CI-Confidence Interval; ICC-Intraclass correlation; NOOS-Neck OutcOme Score; M-Mean; SD-Standard Deviation

Table 3: Correlation between NOOS-U, Vas Pain, Vas Disability, NDI-U, bodily pain (SF-36), physical functioning (SF-36)

	NOOS-U				
	Mobility (r)	Symptoms (r)	Sleep (r)	Activity (r)	Participation (r)
VAS pain	-0.59***	-0.4**	-0.39**	-0.49***	-0.34**
VAS disability	-0.4**	-0.33**	-0.29*	-0.59***	-0.43***
NDI-U	-0.58***	-0.46***	-0.59***	-0.57***	-0.65***
Bodily Pain (SF-36)	0.56***	0.37***	0.37**	0.53***	0.37**
Physical functioning (SF-36)	0.54***	0.33**	0.47***	0.67***	0.49***

*Significance level: p<0.001***, p<0.01** & p<0.05**

Table 4: Responsiveness between improved and not improved group

NOOS-U Domains	Improved Group (Mean ± SD)	Not Improved Group (Mean ± SD)	Mean Difference	p-value
Mobility	19.22 ± 11.24	10.95 ± 11.24	8.27	0.001**
Symptoms	17.22 ± 14.97	4.67 ± 18.66	12.55	0.001**
Sleep	14.88 ± 15.19	7.92 ± 10.75	6.96	0.00***
Activity	18.24 ± 13.66	6.25 ± 13.00	11.99	0.001**
Participation	13.36 ± 13.99	4.33 ± 19.22	9.03	0.00***

*Significance level: p<0.001***, p<0.01** & p<0.05**

Table 5: Change scores correlations between NOOS-U, SF-36, NDI-U, VAS pain, and VAS disability

	NOOS-U				
	Mobility (r)	Symptoms (r)	Sleep (r)	Activity (r)	Participation (r)
Bodily pain (SF-36)	0.36**	0.25**	0.22**	0.43***	0.16
Physical functioning (SF-36)	0.25**	0.15*	0.15*	0.25**	0.25**
VAS pain	0.45***	0.37***	0.31**	0.43***	0.28**
VAS disability	0.26**	0.33**	0.16*	0.32**	0.18*
NDI-U	0.47***	0.52***	0.54***	0.49***	0.58***

*Significance level: p<0.001***, p<0.01** & p<0.05**

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DISCUSSION

The main objective of the study was to translate and cross-culturally validate the original version of NOOS into Urdu language, followed by its psychometric testing. To the best of our knowledge, this study was the fourth to translate and validate NOOS after Chinese, Turkish, and Arabic ever since its development in 2015. No changes were made during the adaptation and translation process of the questionnaire. This study included n=193 patients and 70 healthy participants where the female population outnumbered the male population, making it a female-dominant study. In the original study, the Turkish and the Chinese study were female-dominant as well. The Arabic study however was a male-dominant study [15-17, 26].

The mean age of the participants in our study was 34.85±11.75 years in the patient group (table 1). In the Turkish study, the mean age was 35.88 ± 13.79 years, the original study had 47.8 ± 13.7 years, the Arabic study had 42.19 ± 2.91 years, and the Chinese version had a mean age of 48.9 years. The difference in mean age especially with the Chinese version is that they only included patients who needed cervical disc surgery, for which the average age is 35 to 55 years [27].

The study findings demonstrated that NOOS-U had good reliability, internal consistency, and responsiveness. The values for internal consistency for all domains of NOOS-U were greater than 0.90 proving good internal consistency. This observation is analogous to the previously reported results of NOOS-Tr (≥0.80) and NOOS-C (0.89). NOOS-Ar had a value > 0.89 with the lowest value in subscale 'sleep' IC=0.89 and the highest in the subscale of participation i.e., IC=0.96. The original study had the Cronbach alpha value of 0.85-0.92 with the exception of subscale symptoms (0.77) [15-17]. The test-retest reliability results represented strong consistency with previous studies. The ICC values for NOOS-U, NOOS-TR, NOOS-Original, and NOOS-AR showed high reliability across all domains, with NOOS-AR demonstrating the highest values (≥0.98) in mobility, symptoms, sleep, activity, and participation. NOOS-U also showed excellent reliability, particularly in mobility (0.97), sleep (0.99). and participation (0.99).

Regarding the construct validity, the domains of NOOS-U had a weak to moderate correlation ($p<0.001$) with VAS pain and VAS disability. All the domains of NOOS-U had moderate correlations with NDI-U ($r=0.45-0.65$, $p<0.001$), well backed up by the findings of NOOS-TR that also had moderate correlations with the related subscales of NDI [15]. The original study displayed a moderate correlation between NOOS and NDI as well (r=0.25-0.54). The Chinese version of NOOS and NDI-C had shown a strong correlation (r=-0.872, P=0.001) [17]. NOOS-U and SF-36 had a weak to moderate correlation among related, consistent with the results of the original study and NOOS-TR, both of which had displayed moderate correlations with SF-36 [13,15]. There were no floor or ceiling effects in any domains or the total scores of NOOS-U demonstrating excellent content validity, as observed in other versions [15-17,26].

The change scores of NOOS-U had demonstrated a moderate correlation with the change scores of NDI-U. The change scores of NOOS-U had a weak to moderate correlation with the change scores of SF-36 and change scores of the VAS pain scale, however, there was a weak correlation with the change scores of VAS disability. Thus, NOOS-U has shown significant results in terms of change scores ($p<0.001$). None of the other studies had analysed for change scores. The change scores of NOOS-U were statistically significant ($p<0.001$) among the improved and not improved groups, thus indicating that NOOS-U can detect differences between different stages of outcomes. This is uniform with the findings of NOOS-C ($p<0.001$) and the difference in the improved and not improved groups of the NOOS-Original study [17,26].

The strength of the study is that all the analysis has been carried out following the international guidelines, including sample size determination. This study is the first to translate NOOS into Urdu language and test for its psychometric properties, enabling the Urdu-speaking population to use NOOS-U in clinical and research settings around the globe. However, the study solely focused on non-specific neck pain and it remains ambiguous whether these outcomes can be generalized to patients with neck pain originating due to other aetiologies.

CONCLUSION

This study demonstrates that NOOS-U is a valid, reliable and a responsive tool for the assessment of non-specific neck pain among patients who can understand Urdu language.

DECLARATIONS & STATEMENTS

Author's Contribution

MNF and SN: substantial contributions to the conception and design of the study.
AI, HN, and KSA: acquisition of data for the study.
AI, HN and KSA: interpretation of data for the study.
SN, AI, HN, KSA: analysis of the data for the study.
AI: drafted the work.
AI and SN: revised it critically for important intellectual content.
MNF, SN, AI, HN, KSA: final approval of the version to be published and agreement to be accountable for all aspects.

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of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors contributed to the article and approved the submitted version.

Ethical Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Research Ethical committee of Margalla Institute of Health Sciences (ERC Ref no. DN/149/22)

Consent Statement

Written informed consent was obtained from all participants of the study.

Data Availability Statement

Due to privacy the data presented in this study are available upon request from the corresponding author, as they are not publicly accessible.

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Conflicts of Interest

The authors declare no conflict of interest.

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No funding was involved in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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