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Development and validation of a brief diabetic foot risk screening scale for diabetic patients

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ABSTRACT

Objective: To develop a concise screening tool for diabetic foot risk assessment in patients with diabetes, and rigorously evaluate its reliability and validity.
Methods: 390 adults diagnosed with diabetes were selected for a study in Changsha, China. The study was conducted in two phases. In the first phase, initial items were developed by amalgamating existing diabetic foot risk screening tools and group discussions. Additionally, diabetic foot experts established content validity during this phase. In the second phase, the validity and reliability of the developed items were evaluated through various methods such as item analysis, exploratory factor analysis, confirmatory factor analysis, Cronbach's alpha coefficient, retest reliability, inter-rater reliability, ROC curve and AUC.
Results: The Brief Diabetic Foot Risk Screening Scale consists of 6 dimensions and 19 items. An exploratory factor analysis was conducted on the scale, revealing six principal factors that accounted for 74.139 % of the total variance. The I-CVI was greater than 0.8, indicating good content validity, while the S-CVI was 0.737. Confirmatory factor analysis showed that the model fit well. The scale's Cronbach's α coefficient was 0.770, indicating good internal consistency, and its test-retest reliability was 0.958. The AUC suggests that the Brief Diabetic Foot Risk Screening Scale is an effective measure for identifying diabetic foot.
Conclusion: The Scale is a reliable and valid tool for assessing foot risk.

What is already known

- Foot complications are a prevalent issue among people with diabetes, leading to high morbidity, mortality, and resource use.
- Preventing ulcers is crucial in managing diabetic foot disease.
- Current screening tools are difficult for primary medical institutions to use due to complex equipment and numerous items, resulting in slow screenings and delayed results.

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What this paper adds

- The present study has developed a screening tool for diabetic foot risk that is in line with the latest guidelines. The tool features simple items, fast screening procedures, and prompt evaluation outcomes that are suitable for primary healthcare facilities.
- The screening items now incorporates self-care behavior for diabetic patients, whether they have foot ulcers or not.
- The Scale underwent a validation process to assess its reliability and validity using sound data analysis methodologies.

1. Introduction

Foot complications are a common issue for people with diabetes (Author, 2017), which can lead to high morbidity, mortality, and resource utilization (Lazzarini et al., 2018a; Jupiter et al., 2016). Diabetic foot ulcers (DFU) have associated one-, three-, and five-year survival rates of 86.9 %, 66.9 %, and 50.9 %, respectively (Chen et al., 2023). The burden of diabetic foot disease is ranked among the top 10 of all medical conditions (Lazzarini et al., 2018b), and up to 34 % of all people with diabetes are estimated to develop a foot ulcer at some point in their lives (Armstrong et al., 2017a). Prevention of ulcers is crucial in managing diabetic foot disease.

Foot ulcerations can be prevented with early risk identification and prevention (Lim et al., 2017). Studies have shown that timely screening can prevent up to 50 % of diabetic patients from developing foot ulcers or amputations (Lee et al., 2022; Bus and van Netten, 2016). Therefore, it is essential to conduct regular and timely foot risk screening for diabetic patients. Primary healthcare providers, such as general practitioners and nurses in community health service centers and township health centers, play a crucial role in facilitating this process (Patel et al., 2022). Despite the importance of foot risk screening, its clinical implementation remains suboptimal, particularly in low- and middle-income countries like China (Zhangrong, 2019). Lack of time and limited screening tools are identified as critical factors affecting primary healthcare workers' foot-screening behavior (Zhao et al., 2023). Therefore, a simple and rapid screening tool is required to help primary care facilities carry out efficient screening. Currently, there are a few risk assessment tools available for diabetic foot, such as Gavin's score, Boyko's prediction tool, IWGDF risk stratification system, Simplified 60 S Diabetic Foot Screening Tool, and SIGN risk system. However, the existing scales exhibit deficiencies in detection methods, quantification of screening indicators, test duration, and calculation approaches, thereby resulting in a lack of a comprehensive gold standard for diabetic foot risk assessment.

Gavin's score (Gavin et al., 1993) is the most commonly used tool for diabetic foot risk assessment in China, as it is simple and time-efficient. However, it was developed in 1993 and its criteria differ from current guidelines and research findings, especially regarding renal failure and history of diabetic foot. Moreover, the evaluation method is relatively abstract (Spiliopoulos et al., 2021; Chinese Diabetes Society, 2019). Boyko's prediction tool (Boyko et al., 2006), developed in 2006, uses clinical information to predict the development of diabetic foot ulcers and identify high-risk patients within a five-year timeframe. However, its complex calculation methods and high screening requirements make it unsuitable for primary healthcare settings (Monteiro-Soares et al., 2011). Furthermore, the tool only presents the area under the receiver operating characteristic curve (AUC) and cutoff values, without offering comprehensive diagnostic accuracy measures or access to raw data (Monteiro-Soares and Dinis-Ribeiro, 2010). The 2019 IWGDF risk stratification system (Schaper et al., 2020) has proposed different follow-up frequencies for different risk levels, but its predictive capability for foot ulcer development is yet to be validated (Diabetic Foot Problems: Prevention and Management, 2023). The validation of the biothesiometer and ankle-brachial artery pressure index (ABI) for the assessment of peripheral arterial disease (PAD) remains to be demonstrated as well (Hinchliffe et al., 2020). The Simplified 60-Second Diabetic Foot Screening Tool (Woodbury et al., 2015) is a convenient and time-saving method that can identify diabetic foot risk factors rapidly, making it suitable for use in primary medical institutions and outpatient screening. However, it does not align with the latest IWGDF guidelines in certain factors such as toenail growth and tool-related blisters. Moreover, crucial risk factors like a history of end-stage diabetic nephropathy and diabetic retinopathy are omitted from the medical history, increasing the likelihood of misdiagnosis during rapid screening processes and delaying treatment for patients. The SIGN stratification system primarily identifies the risk of foot ulcers in low-risk feet, neglecting potential high-risk diabetic foot patients within the population, which lacks specificity (Diabetic Foot Problems: Prevention and Management, 2023). All in all, the current scales are outdated and inconsistent with the latest guidelines. Furthermore, they require complex screening equipment and include numerous items that make it difficult for primary medical institutions to conduct rapid screenings and obtain immediate results.

This study utilizes the most recent evidence to create a simple and convenient screening tool for diabetic foot risk. The intended audience of this design is primary medical staff working in primary care facilities lacking access to sophisticated equipment. The tool effectively addresses issues such as low efficiency, high professional requirements, and complex item content in existing screening tools. Moreover, it can be used in regions or countries where access to professional screening equipment is limited.

2. Materials and methods

This research is an instrument development and cross-sectional validation study to develop a diabetic foot risk screening scale for diabetes.

2.1. Instrument development

The initial items of the instrument were selected from an item pool that was developed based on two sources: 1) literature about screening and prevention of complications associated with diabetic foot, and 2) Delphi results obtained from a panel of 25 experts in the field of diabetic foot.

2.1.1. Literature

We conducted a comprehensive search for articles published between January 2010 and June 2022 in five international databases (MEDLINE, Embase, Web of Science, Cochrane Library, and Up To Date) as well as three Chinese databases (CKIN, CBM, and Wanfang Medical Network). Using keywords related to diabetic foot ulcers, screening methods, risk ranking, identification, and prevention. After reviewing 34,568 articles and excluding duplicates and irrelevant titles/abstracts, we included a total of 228 relevant articles after full-text assessment (80 in Chinese and 148 in English). By conducting a comparative analysis of the literature findings, the research team meticulously deliberated and determined the initial items for diabetic foot risk screening.

2.1.2. Delphi method

Two rounds of Delphi surveys were conducted via email to create a comprehensive and accurate questionnaire. In the first round, experts evaluated the dimensions covering the theme, item distribution within each dimension, and made sure that the language used was concise and precise. Based on statistical findings and expert opinions, a second questionnaire was prepared, which included some statistical outcomes from the initial consultation for reference. After every survey, extensive discussions were held to review the results of each item. Consensus was achieved if 80 % of the panelists agreed or strongly agreed, or disagreed or strongly disagreed. Only items that achieved consensus were accepted. Items without consensus were assessed to determine whether their wording or language played a vital role or if there was simply a lack of agreement. During the second round, panelists revised their stances on items where consensus had not been reached, after comparing viewpoints and discussing the issues in more detail.

The Delphi method employs convenient sampling, wherein professionals with extensive knowledge in fields such as endocrinology, orthopedics, dermatology, burns, vascular surgery, diabetic foot diagnosis and treatment, nursing and management, public health, or related fields are included. The inclusion criteria require individuals with at least ten years of experience in a relevant field, holding the title of deputy senior or above, and willing to voluntarily participate in the study. For our research, we sent email invitations to 25 professionals who met the study selection criteria and possess clinical and scientific expertise in diabetes. These professionals were asked to rate their agreement or disagreement with each statement on a 5-point Likert scale ranging from ’1′ (extremely disagree) to ’5′ (extremely agree).

2.2. Validation tests

2.2.1. Participants

The present study employed a cluster random sampling method to allocate codes to 78 community hospitals in Changsha. From July to October 2022, three community health centers were randomly selected, and diabetic patients visiting these centers were included in the sample. The inclusion criteria consisted of being diagnosed according to the diagnostic criteria recommended by ADA in 2020 (Diabetic foot problems: prevention and management, 2020); being aged ≥18; having an ulcer that had healed for more than 28 days (Armstrong et al., 2020), or not having a foot ulcer. Patients with existing foot ulcers or those whose ulcers have not healed within 28 days, as well as those with severe hearing or visual impairment, cognitive dysfunction or mental disorders, movement disorders, or other serious physical diseases were excluded from the study. Finally, patients with incomplete medical records were also excluded.

2.2.2. Content validity test

Seven experts, including three nursing professors, two endocrinologists, and one nurse, assessed the content validity of the initial items using a Content Validity Index (CVI). The Item-level CVIs (I-CVI) for individual items and Scale-level CVI (S-CVI/Ave) for the overall scale were calculated separately. Items with an I-CVI rating above 0.8 were selected while those rated below 0.8 were either revised or removed based on expert opinions.

2.3. Data collection

After conducting an investigation, the researchers and an international diabetic podiatrist underwent systematic training and a unified assessment of screening methods using an assessment form. Only those who passed the assessment were allowed to participate in the study, ensuring consistency and scientific accuracy of the results. Revised sentence: Subsequently, 30 eligible patients were recruited for the preliminary test and feedback was provided based on their actual screening experience. The researcher then synthesized the results. In this study, 320 questionnaires were distributed, with items in the recycling scale that had missing values exceeding 5 % being excluded from analysis. For retest reliability evaluation, a sample of 30 participants who met the inclusion criteria was selected; for inter-test reliability evaluation, a sample of 60 participants was chosen

2.4. Statistical analysis

The collected data underwent statistical analysis using IBM SPSS version 26 software for questionnaire validation, with a significance level set at $\alpha = 0.05$ and all P values calculated as two-tailed probabilities. Continuous variables were described using mean and standard deviation (SD), while categorical variables were presented as numbers and percentages. Exploratory factor analysis (EFA) was conducted to reveal the underlying structure of a large set of variables, assessing data suitability through Kaiser Meyer Olkin's (KMO) measure of sampling adequacy and Bartlett's test of sphericity. Factors were extracted using the principal component method with Varimax rotation and Kaiser's eigenvalue >1 criteria. Internal consistency, inter-rater reliability, and test-retest reliability were assessed using Cronbach's alpha coefficient and Pearson correlation coefficient, respectively to evaluate tool stability. Criterion validity was assessed using the simplified 60-s diabetic foot risk screening tool, lower limb vascular color Doppler ultrasound results, and neuro electromyography. Confirmatory factor analysis (CFA) utilizing structural equation modeling (SEM) confirmed the model's factor structure. The sensitivity and specificity of the Brief Diabetic Foot Risk Screening Scale were determined by mapping a Receiver Operating Characteristic (ROC) curve and calculating the area under the curve (AUC), effectively measuring its accuracy in identifying diabetic foot conditions. Youden's index was used to identify the best cut-off value, with higher values indicating better diagnostic performance.

3. Results

3.1. Instrument development-deliphi

A total of 25 experts, ranging in age from 32 to 66 with an average age of 46 (SD = 8.79), participated in this consultation survey. They have been working in the field of diabetic podiatry for an average of (24.48±10.79) years, with a range of experience spanning from 10 to 41 years, and hold titles primarily at the deputy high level or above. Their areas of expertise are concentrated on diabetes and diabetic foot care, as indicated in Table 1.

The experts' positive coefficients were 89.29 % and 88 % in the two rounds of the study, respectively, with an expert authority degree of 0.89. In the first round, the importance weight of item content was 0.53, while operability weighted 0.45. In the second round, the values were adjusted to assign an importance weight of 0.58 to item content and a weight of 0.47 to operability. The Kendall's W statistic showed that the variation in expert opinion ranged from a minimum value of 0.000 to a maximum value of 0.178 in the first round, while it ranged from a minimum value of 0.00 to a maximum value of 0.125 during the compilation in Round Two.

During the initial consultation, the screening scale contained 6 primary-level items and 15 secondary-level items. The mean importance scores ranged from 4.440 to 5.000, with coefficients of variation ranging from 0.000 to 0.142, and full mark rates between 60 and 100 %. To pass the screening criteria for primary-level items, an average score of $\geq$4.878, a coefficient of variation of $\leq$0.077, and a full score rate of $\geq$89.562 % were required. In the second round of consultation, the scale was revised to consist of 6 first-level items and 18 s-level items. The mean importance scores ranged from 4.591 to 5.000 with a coefficient of variation ranging from 0.000 to 0.117 and a full score rate ranging from 59.091 % to 100 %. All six dimensions passed the screening criteria for level-1 items, which were a mean of $\geq$4.909, a coefficient of variation of $\leq$0.060, and a full score rate of $\geq$90.909 %. During the Delphi process, a consensus of 72 % was achieved to specify both the quantity and duration of smoking in the "smoking history" section, as well as including a dual referral remark. There was 89 % agreement to changing "arterial pulse" to "dorsalis pedis pulse". To account for the peripheral vascular reflux of patients, it was proposed to add "Raise the lower limbs 45°, drooping 3 min later, and observe the changes of skin color at the

Table 1
Characteristics of the experts.

Items	N (%)/mean ± standard deviation	
Gender		
Male	10	40 %
Female	15	60 %
Ages(years)	46.96±8.78	
Education		
Senior College	1	3.8 %
College/University	10	38 %
Master degree	5	19.2
Doctor degree	9	36 %
Professional title		
Middle title	4	16 %
Vice-senior Title	9	36 %
Senior Title	12	48 %
Work area		
Endocrine	10	40 %
Dermatology	2	8.0 %
Vascular surgery	2	8.0 %
Diabetes specialist care	3	12.0 %
Diabetic foot wound care	7	28.0 %
Medical statistics	1	4 %

extremities" (83 % agreement). The description of foot skin temperature was revised from a binary "cold or not" classification to a more nuanced categorization of "normal, reduced, or inconsistent" (with 90 % agreement). Ultimately, a brief diabetic foot risk screening scale was developed with six primary indicators and nineteen secondary indicators.

3.1.1. Project analysis

The purpose of item analysis is to assess the appropriateness and reliability of each item in the prediction questionnaire, which can be achieved through various methods such as discreteness degree, correlation coefficient, factor analysis, and discrimination analysis (Dai et al., 2015). Referring to the extant literature (Li and Liu, 2012), this study excluded three or more items that failed to meet the index in item analysis. C8, E13, F17, F18, and F19 did not satisfy the deletion criteria of project analysis and thus should be retained. Following item analysis, a 19-item rapid screening scale for diabetic foot risk was developed; details of the item analysis are presented in Table 2.

3.2. Validation tests

Among the 390 patients diagnosed with diabetes, the mean age was 56.96 years (SD = 12.879). The majority of them were male (n = 212, 54.35 %), and most were married (n = 307, 85.47 %). Junior school education or below was common among this population (n = 219, 62.39 %), and they lived with their families (n = 342, 87.69 %). Retirees made up the largest occupational group (n = 105, 26.92 %) followed by farmers (n = 78, 20 %).

3.2.1. Reliability testing

To establish the scale's reliability, we conducted tests for retest reliability and internal consistency. For test-retest reliability, a sample of 30 adult diabetic patients was selected as research subjects for retesting every two weeks. Correlation coefficients were calculated to determine their level of consistency. Cronbach's α method was used to assess score reliability and internal consistency. The raters included one diabetes specialist and two diabetic podiatrists. Results indicate that the overall Cronbach's α of the scale is 0.770, with each dimension ranging from 0.714 to 0.845 in Cronbach's α value. The scale demonstrated an overall retest reliability of 0.958, with each dimension exhibiting a retest reliability between 0.670 and 0.758; score reliability was calculated at 0.858.

3.2.2. Content validity

The concept of content validity refers to the appropriateness and representativeness of scale contents or topics, specifically focusing on the extent to which test items accurately reflect the measured content (Haiqi et al., 2007). In this particular study, individual items demonstrated a content validity index (I-CVI) ranging from 0.857 to 1.000, while S-CVI/UA was found to be 0.737 and S-CVI/Ave was determined as 0.905.

3.2.3. Construct validity

The KMO and Bartlett sphericality tests were conducted on 19 items in the evaluation table, resulting in a statistically significant KMO value of 0.642 ($\chi 2 = 518.577$, $P < 0.01$). This indicates that there were common factors among each item, making them suitable for factor analysis. Only factors with characteristic roots greater than 1 were considered during the factor analysis process to screen common factors. Items with a commonality less than 0.2 or a loading less than 0.4 on only one factor, or a loading greater than 0.4 on two or more factors, were excluded (n = 28). A total of six common factors were extracted in this study, accounting for a cumulative

Table 2
Results of Project Analysis.

Items	Discreteness Degree Method	Correlation Coefficient Method	Factor Analysis	Distinction Analysis Method	Not Conform	Results
A1	√	√	√	√	0	Retain
A2	√	√	√	√	0	Retain
A3	√	√	√	√	0	Retain
A4	√	√	√	√	0	Retain
B5	√	√	√	√	0	Retain
B6	√	√	√	√	0	Retain
C7	√	√	√	√	0	Retain
C8	×	√	√	√	1	Retain
D9	√	√	√	√	0	Retain
D10	√	√	√	√	0	Retain
D11	√	√	√	√	0	Retain
D12	√	√	√	√	0	Retain
E13	×	√	√	√	1	Retain
E14	√	√	√	√	0	Retain
F15	√	√	√	√	0	Retain
F16	√	√	√	√	0	Retain
F17	√	×	√	√	1	Retain
F18	√	×	√	√	1	Retain
F19	√	×	√	√	1	Retain

Note: √ is the qualifying item, × is the unqualified item.

variance contribution rate of 74.139 %. The common degree of the 19 items ranged from 0.443 to 0.956, and all items had factor loadings >0.4 without any double-loading items, indicating good structural validity of the evaluation table (Table 3).

The color Doppler ultrasound results of lower limb vessels were used to calibrate peripheral artery disease in this study, and a statistically significant Pearson's correlation coefficient of 0.609 ($P < 0.01$) was obtained. Electromyogram (EMG) was used as the criterion for the "peripheral neuropathy" dimension, resulting in a statistically significant Pearson's correlation coefficient of 0.816 ($P < 0.01$). The simplified version of the 60-second diabetic foot risk screening tool was analyzed about the total score of the scale, yielding a statistically significant Pearson's correlation coefficient of 0.492 ($P < 0.01$). The six-factor model was confirmed by CFA (Fig. 1).

However, the smoking index, foot warm behaviors, and test water temperature had suboptimal factor loadings on their corresponding dimensions. Overall, the goodness-of-fit ranged from acceptable to good for the model (RMSEA = 0.036, GFI = 0.936, AGFI = 0.912, CFI = 0.909).

3.2.4. ROC

The ROC curve was used to determine the sensitivity and specificity of the Brief Diabetic Foot Risk Screening Scale and Simplified 60-Second Diabetic Foot Screening Tool (see Fig. 2). The positive criteria included the history of diabetic amputation, foot ulcer, active ulcer, foot deformity, pre-ulcerative lesion, loss of protective sensation (LOPS), and peripheral arterial disease (PAD) ≥1. The AUC was 0.804; $p < 0.001$ (95 %CI 0.754–0.855). The Youden's index indicated that a cut-off of ≤10 yielded the best sensitivity/specificity trade-off: sensitivity at 78.3 % and specificity at 69.0 %.

4. Discussion

The objective of this study was to create a simple and convenient tool to evaluate the risk of diabetic foot among patients with diabetes. Based on the latest research, an item framework for risk screening was developed by incorporating the contents of the 2019 IWGDF and 2020 American Diabetes Association guidelines (Schaper et al., 2020; Diabetic foot problems: prevention and management, 2020). The result was the development of the Brief Diabetic Foot Risk Screening Scale consisting of six dimensions and nineteen items. The analysis confirmed the reliability and validity of the scale.

The 2019 IWGDF and 2020 American Diabetes Association guidelines stipulate that comprehensive foot screening protocols should encompass the evaluation of loss of protective sensation (LOPS), peripheral arterial disease (PAD), as well as the presence of foot ulcers, excessive callus formation, or pre-ulcerative lesions such as blisters, fissures, and hemorrhages (Schaper et al., 2020; Diabetic foot problems: prevention and management, 2020). The absence of symptoms in individuals with diabetes does not necessarily mean they do not have foot disease; they may have asymptomatic neuropathy, PAD, pre-ulcerative signs, or even an ulcer. Recurrent episodes may also occur in patients with a history of diabetic foot complications (Bus et al., 2023). Therefore, our study included all diabetes patients except those currently presenting with diabetic foot ulcers. Therefore, the 6 dimensions encompassed in our scale include a history of diabetic foot conditions, changes in skin and toenails, foot deformities, peripheral vascular disease, diabetic peripheral neuropathy, and an assessment of self-care behaviors related to diabetic foot care. The results of a study examining the patterns of non-traumatic lower limb amputation in diabetic patients with end-stage renal disease revealed a significantly elevated risk of amputation associated with the presence of end-stage renal disease (Harding et al., 2019), thus warranting its inclusion in the patient's medical history. Research indicates that the presence of nail ingrowth and dry skin are significant indicators of a patient's susceptibility to developing diabetic foot ulcers (Schaper et al., 2020; Diabetic foot problems: prevention and management, 2020; Naemi et al., 2020). Skin and toenails, as an important indicator for diabetic foot screening, were also included in our study. While

Table 3
Results of Exploratory Factor Analysis.

Items	Common factor 1	Common factor 2	Common factor 3	Common factor 4	Common factor 5	Common factor 6	Common degrees
A1	**0.451**						0.638
A2	**0.588**						0.443
A3	**0.654**						0.571
A4	**0.625**						0.447
B5		**0.750**					0.928
B6		**0.728**					0.937
C7			**0.956**				0.956
C8			**0.934**				0.891
D9				**0.864**			0.835
D10				**0.927**			0.918
D11				**0.794**			0.848
D12				**0.895**			0.939
E13					**0.682**		0.762
E14					**0.738**		0.684
F15						**0.622**	0.618
F16						**0.522**	0.445
F17						**0.740**	0.554
F18						**0.410**	0.600
F19						**0.482**	0.684

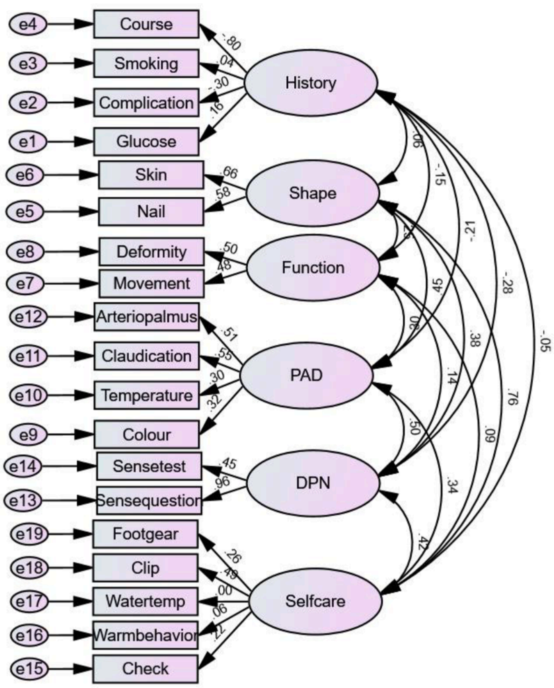

Fig. 1. Confirmatory factor analysis for Brief Diabetic Foot Risk Screening Scale.

there is no direct research on the impact of walking barefoot, in socks without shoes, or in thin-soled standard slippers on foot ulceration risk, several large prospective studies have demonstrated that individuals with diabetes who are at risk exhibit increased levels of mechanical plantar pressure when engaging in these activities (Fernando et al., 2014, 2013). These elevated pressures are a significant and independent risk factor for the development of foot ulcers, necessitating their avoidance (Armstrong et al., 2017b). For that reason, we have innovatively incorporated foot health behavior into diabetic foot screening.

To develop a user-friendly tool for simple screening without requiring specialized equipment, we explored available methods. When evaluating LOPS caused by diabetic peripheral neuropathy, the 10-gram monofilament (which detects loss of protective sensation) and a tuning fork (128 Hz, which detects loss of vibratory sensation) should be used. The 10-gram monofilament test should be performed at three different sites on both feet. If a 10-gram monofilament is unavailable, the Ipswich Touch Test may be employed as an alternative (Rayman et al., 2011). A meta-analysis has shown comparable outcomes for the Ipswich Touch Test. This test can be utilized in clinical settings and for self-monitoring purposes (Zhao et al., 2021). If monofilament testing does not indicate LOPS, a screening for limited vibratory sensation using a tuning fork may be conducted, as it may also serve as an indicator of foot ulceration risk (Armstrong et al., 2017a). In our study, we utilized the 10-g monofilament along with a tuning fork or the Ipswich Touch Test to assess potential changes in foot nerve function among patients. Our screening protocol for PAD involves assessing pulsations in the dorsal or posterior tibial arteries, intermittent claudication symptoms, and skin temperature of both feet.

Revised and added items were identified based on expert opinions, with four items being revised. No items were excluded from the original item pool based on selection criteria. Smoking was considered a risk factor for ulceration due to its potential to cause tissue hypoxia, which can lead to vascular and neuropathic disorders in diabetic patients' lower extremities. Smoking is a risk factor for diabetic foot due to its ability to cause tissue hypoxia, leading to vascular and neuropathic disorders in the lower extremities. Studies consistently show that both the duration and quantity of smoking are positively associated with the development of diabetic foot (Coffey et al., 2019). After extensive deliberation by the research group, it was determined to retain this item despite not meeting the screening criteria, following significant modifications. The same principle was applied to other measurements, such as arterial pulse, range of motion in the index finger, and skin temperature in the foot.

Then we assessed the reliability of a brief diabetic risk screening scale in China. The scale structure was confirmed as one factor and internal consistency was high (Cronbach's $a = 0.941$). Exploratory factor analysis identified six factors that explained 74.139 % of total variance across 19 items. Furthermore, all factor loadings in the unforced factor solution exceeded 0.40, indicating satisfactory correlations between the items and their corresponding factors. In the subsequent confirmatory factor analysis, we divided the scale items into 6 factors and obtained similar results as before, thus confirming construct validity. These findings suggest that the scale is well-suited for use among Chinese populations and may be broadly applicable throughout Asia.

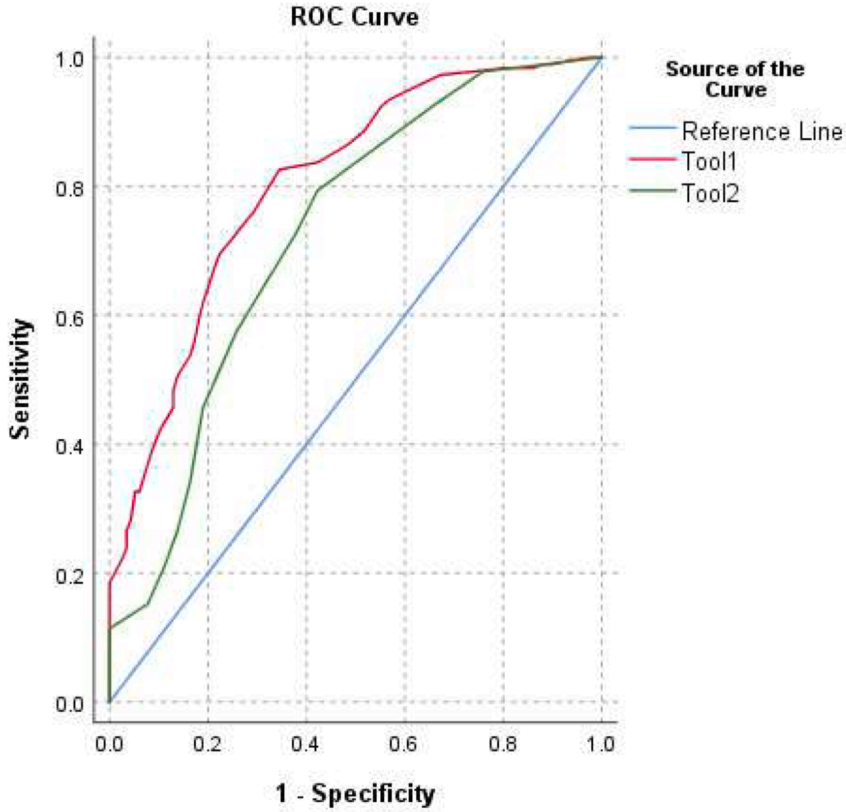

Fig. 2. Tool 1: The Brief Diabetic Foot Risk Screening Scale. Tool 2: Simplified 60-Second Diabetic Foot Screening Tool.

The CFA model showed that while the overall fit was acceptable, the factor loadings for self-care behaviors were suboptimal. Categorizing the various risk factors associated with DFU remains a challenge, given their complexity. However, it has been observed that ill-fitting or inadequate footwear and other foot self-care behaviors can contribute to the development of diabetic foot complications. Therefore, the IWGDF guidelines recommend evaluating these behaviors (Bus et al., 2023). Relevant interventions can potentially enhance these modifiable risk factors upon identification (Coffey et al., 2019; Waaijman et al., 2014). Despite its limited alignment with the model, we decided to retain self-care behavior. Further studies are needed to improve the construct of the tool.

4.1. Strengths and limitations

This study's strength lies in its broad range of subjects, including both diabetic patients with foot ulcers and those without complications. Furthermore, a novel dimension of self-care behavior related to diabetic foot care was incorporated to enhance the evidential basis beyond traditional medical history, skin and toenail assessments. The assessment content is straightforward, the scoring method is uncomplicated, and it boasts excellent user-friendliness which is suitable for community medical staff with weak professional knowledge and limited screening equipment. The physical examination can be easily performed and mastered using simple equipment, enabling swift screening of diabetic foot risk making it highly suitable for large-scale screenings (Xie and Xu, 2020; Luo et al., 2021; Gao et al., 2018).

This study has several limitations. Firstly, the recruitment of diabetic patients was exclusively conducted at three community health centers, which may limit the generalizability and authority of the findings to other regions in China. A future national multi-center survey is needed for a more representative sample. Secondly, the initial items of the scale are solely based on existing literature and their objectivity and comprehensiveness can be validated through expert consultation and a larger sample size. Furthermore, despite computing the Youden index, risk classification still remains broad in scope. Future investigations should use this scale to assess individuals with diabetes and those presenting with diabetic foot conditions to derive a more precise risk classification system for tailored management recommendations based on varying levels of risk.

5. Conclusions

In this study, the Delphi-prepared Brief Diabetic Foot Risk Screening Scale comprises 6 dimensions and 19 items, exhibiting high reliability and validity as an assessment tool for medical practitioners in clinical settings. With a concise screening process and simple tools, it is particularly suitable for primary healthcare institutions with limited resources.

Ethics approval

The study was approved by the ethics committee of Xiangya School of Nursing, Central South University, approval no. E202117. It complied with all ethical criteria on research involving human beings and was respectful of the fundamental principles enshrined in the World Medical Association's Declaration of Helsinki, its updates and current legislation (informed consent and right to information, protection of personal data and guarantees of confidentiality).

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Disclaimers

The views expressed in the submitted article are authors' own and not an official position of the institution and funder.

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CRediT authorship contribution statement

Wenjing Luo: Writing – original draft, Methodology, Data curation, Conceptualization. **Qiuhong Zhou:** Writing – review & editing, Supervision. **Jingcan Xu:** Writing – review & editing, Methodology, Conceptualization. **Zheyu Tan:** Methodology, Data curation, Conceptualization. **Xinyi Li:** Methodology, Data curation. **Ying Ye:** Investigation. **Honglin Wang:** Writing – review & editing, Supervision. **Shuyi Peng:** Investigation.

Declaration of competing interest

We declare that we have no financial and personal relationships with other people or organizations that can inappropriately influence our work, there is no professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled.

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