



## OPEN Clinical validation of defining characteristics of the NANDA-I nursing diagnosis “ineffective peripheral tissue perfusion” (00204) in patients with diabetic foot ulcers

Sara Beigzadeh<sup>1</sup>, Fateme Eshghi<sup>2</sup> & Mitra Zandi<sup>3</sup>✉

The study aimed to clinically validate the defining characteristics (DCs) of the NANDA-I nursing diagnosis Ineffective Peripheral Tissue Perfusion (00204) in patients with diabetic foot ulcers. We conducted a cross-sectional diagnostic validation study at Rasoul Akram Hospital in Tehran during 2024–2025, involving 146 adult outpatients with type 2 diabetes and diabetic foot ulcers. Two trained, independent nurse raters evaluated eleven DCs measures through structured interviews and physical examinations. Impaired peripheral tissue perfusion was identified using colour or duplex Doppler ultrasound, which served as the reference standard. According to Fehring’s classification, DCs with a frequency exceeding 0.80 were designated as major, those between 0.50 and 0.80 as minor, and those below 0.50 as irrelevant. The overall clinical diagnostic validity (CDV) score was determined as the average of individual validation scores for each DC. Sensitivity, specificity, positive and negative predictive values, and likelihood ratios were calculated for each diagnostic criterion. Statistical analyses were conducted using SPSS version 21, and inter-rater reliability was evaluated with Cohen’s kappa coefficient. Among 146 participants, 104 (71.2%) were diagnosed with ineffective peripheral tissue perfusion using colour Doppler as the reference standard. Altered skin characteristics (97.3% and 93.8%) and delayed peripheral wound healing (91.8% for both raters) were the most commonly observed DCs. Sensitivity ranged from 67.3% to 75.8% for the first researcher and from 68.9% to 73.1% for the second, while specificity varied considerably across DCs. Overall inter-rater agreement was excellent, with a mean Cohen’s  $\kappa$  of 0.85. The highest diagnostic accuracy was noted for delayed colour return after limb elevation (positive likelihood ratio > 10). The overall clinical diagnostic validity score was 0.79. This study provides evidence confirming the clinical validity of specific DCs for diagnosing ineffective peripheral tissue perfusion within nursing practice. Several DCs exhibited high sensitivity and exceptional inter-rater reliability, demonstrating their reliability in clinical settings. The most diagnostically valuable indicator was delayed colour return following limb elevation, although variations in specificity indicate that certain signs should be interpreted with caution.

**Keywords** Nursing Diagnosis, Peripheral Perfusion, Diabetic Foot Ulcer, NANDA-I, Diagnostic Validation

According to the World Health Organization (WHO) in 2022, 14% of adults aged 18 years and older worldwide were living with diabetes<sup>1</sup>, and national estimates indicate a rising prevalence of type 2 diabetes in Iran (10.8% in 2024)<sup>2</sup>.

Patients with diabetes are prone to various health complications, among which diabetic foot ulcers are among the most serious and disabling. The development of diabetic foot ulcers is influenced by neurological, vascular, and biomechanical factors. The WHO defines diabetic foot syndrome as a foot ulcer (including the ankle)

<sup>1</sup>Student Research Committee, MSc in Medical-Surgical Nursing, Department of Nursing, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran. <sup>2</sup>Department of Nursing, School of Nursing and Midwifery, Shiraz University of Medical Science, Shiraz, Iran. <sup>3</sup>Department of Medical Surgical Nursing, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran. ✉email: mitra.zandi@yahoo.com

associated with neuropathy, ischemia, and infection<sup>2</sup>. Approximately 50% to 60% of ulcers become infected<sup>3</sup>. The prevalence of diabetic foot ulcers among hospitalized patients ranges from 4 to 10%.

Diabetic foot ulcers are the leading cause of nontraumatic amputations. It has been estimated that up to 34% of patients with type 2 diabetes may develop a diabetic foot ulcer at some point in their lives. Early prevention and treatment of risk factors, as well as ongoing education for patients and/or caregivers, are essential for preventing and managing diabetic foot complications<sup>4</sup>. Many patients with diabetic foot ulcers suffer from peripheral vascular disease, most commonly due to atherosclerosis, which significantly interferes with tissue perfusion and wound healing. Peripheral arterial disease may remain asymptomatic or be underdiagnosed in patients with diabetes, leading to delayed recognition of impaired peripheral perfusion. Therefore, accurate and timely nursing diagnosis is a fundamental component of high-quality nursing care, enabling individualised, patient-centred interventions. Nurses, due to their continuous presence at the bedside, require diagnostic tools that are practical, accessible, and clinically applicable<sup>5,6</sup>.

Providing high-quality nursing care based on clinical reasoning and critical thinking requires the use of standardized nursing languages, such as the NANDA-International Classification of Nursing Diagnoses. According to the NANDA-I 2024–2026 edition, the nursing diagnosis Ineffective Peripheral Tissue Perfusion is defined as reduced blood flow to peripheral tissues that may compromise their function. This diagnosis was introduced in 2008 and is classified within the Cardiovascular/Pulmonary Responses domain (Class 4) and currently includes 21 defining characteristics (DCs)<sup>7</sup>. DCs are observable clinical indicators that help nurses identify patients' responses to health problems and select appropriate nursing interventions<sup>8</sup>.

Despite their widespread use, concerns have been raised regarding the empirical support of several nursing diagnoses and their DCs. Some nurses report discrepancies between the DCs listed in the NANDA-I taxonomy and those observed in real clinical settings. One major reason is that many nursing diagnoses have not been sufficiently validated through robust empirical methods across diverse patient populations<sup>9</sup>. Therefore, systematic validation of nursing diagnoses is essential to ensure their clinical accuracy, reliability, and applicability in practice<sup>10</sup>.

Few practical approaches have been proposed for empirically validating nursing diagnoses. In this regard, Fehring (1987) proposed two validation models<sup>11</sup>. NANDA-I emphasizes that generating evidence for the validity of a nursing diagnosis is a continuous and cumulative process involving several interrelated stages. While content validation concentrates on expert consensus regarding the relevance of DCs, clinical validation evaluates the performance of these characteristics in actual patients, primarily through physical examinations and patient interviews. Consequently, clinical validation provides stronger evidence of diagnostic accuracy in practical applications<sup>7,12</sup>.

In the previous content validation, of the twelve DCs examined, eight were evidenced, excluding intermittent claudication, paresthesia, decreased peripheral pulses, and delayed peripheral wound healing<sup>13</sup>. In this regard, a cross-sectional study by Vitória Costa Gontijo et al. assessed the accuracy of DCs in the nursing diagnosis of ineffective peripheral tissue perfusion in patients with diabetic foot. 12 DCs were examined in 132 patients with diabetic foot syndrome through interviews and physical examinations. Finally, the sensitivity and accuracy of each feature were examined, with the two characteristics of “Colour does not return to limb after 1 minute elevation” and “edema” demonstrating the highest sensitivity<sup>13</sup>. Another study conducted a content analysis of the nursing diagnosis of ineffective peripheral tissue perfusion in patients with diabetic foot. The methodological study took a qualitative approach to verify the adequacy of etiological factors, clinical indicators, and conceptual and operational definitions. “Colour does not return to limb after 1 minute elevation,” and “cold foot” had a content validity index (CVI) of < 0.9 with respect to the relevance and precision of the operational definitions<sup>14</sup>.

Nevertheless, a review of the existing literature indicates that no studies have used Fehring's clinical validation model to systematically evaluate the DCs of ineffective peripheral tissue perfusion in patients with diabetic foot ulcers. Furthermore, only one prior study has investigated this diagnosis in a comparable patient population; to date, no clinical validation studies of this nature have been conducted in Iran. Given the high prevalence of diabetes and diabetic foot complications in Iran<sup>2,15</sup>, it is essential to generate population-specific empirical evidence. Educating nursing professionals on the application of clinically validated DCs may facilitate the prompt identification of impaired peripheral perfusion, support timely clinical decisions, and enhance patient outcomes. Significantly, this study advances current knowledge by utilizing Fehring's clinical validation model to assess the actual diagnostic performance of DCs in real-world clinical settings, rather than relying solely on expert opinion or isolated indicators of accuracy.

Therefore, this study aimed to clinically validate and assess the diagnostic accuracy of selected DCs of the nursing diagnosis Ineffective Peripheral Tissue Perfusion (00204) in patients with diabetic foot ulcers.

## Methods

### Study design

This cross-sectional observational study used the clinical validation method proposed by Fehring (1987), as outlined in the STROBE guideline. This study used a modified clinical diagnostic validity (CDV) model that obtains clinical information directly from patients. The chosen approach depends on the nature of the nursing diagnosis being assessed<sup>11</sup>. The modified CDV model can be used for both examination and observation, and it can obtain clinical information directly from patients. To assess effective peripheral tissue perfusion, both nurse observation and patient information are required. The latter includes demographic characteristics and symptoms that cannot be obtained by clinical examination. Thus, the modified model was selected for validation in the present study. In this model, information was obtained from the patient in addition to observation by two evaluators<sup>11</sup>.

## Participants

The study population comprised patients diagnosed with type 2 diabetes mellitus and diabetic foot ulcers, who were referred to the Infectious Disease Clinic at Rasoul Akram Hospital, affiliated with Iran University of Medical Sciences, from December 2024 to January 2025. Purposive sampling was employed to select outpatients with diabetic foot ulcers requiring a single daily dressing change, representing clinically relevant cases routinely managed within the outpatient dressing clinic.

The inclusion criteria encompassed patients aged over 18 years with a confirmed diagnosis of type 2 diabetes mellitus, presenting with diabetic foot ulcers that require only once-daily dressing changes. Participants were required to demonstrate willingness to participate, be alert and oriented to time, place, and person, and be able to communicate verbally.

The exclusion criteria included patients presenting with grade 4 or 5 ulcers, gangrene, or a history of previous lower-limb amputation. Furthermore, patients experiencing numbness or paralysis due to other conditions (e.g., stroke-related plegia), as well as those diagnosed with mental illnesses, were also excluded.

## Reference standard assessment

Peripheral tissue perfusion in the lower extremities was assessed in all participants utilizing colour Doppler ultrasound or duplex Doppler ultrasound. The Doppler findings served solely as the reference standard to ascertain the presence or absence of inadequate peripheral tissue perfusion and were not employed as an eligibility criterion. This approach allowed for the inclusion of both patients with and without impaired perfusion, thereby facilitating the calculation of sensitivity, specificity, and predictive values for each DC.

Participants with Doppler-positive findings were classified as having impaired perfusion, indicating a “diagnosis present,” whereas those with Doppler-negative results were classified as not having impaired perfusion, indicating a “diagnosis absent.” To preserve blinding, the nurse evaluators conducting the DC assessments were blinded to the Doppler results.

## Test methods

Two clinical nursing experts, each pursuing a Master’s degree in nursing and possessing valid wound-care certification, with routine clinical experience in diabetic foot assessment, evaluated the patients in accordance with all designated DCs. They reviewed medical records and selected participants based on the inclusion criteria. Both evaluators completed standardized training to ensure consistent assessment of all DCs before patient evaluation. Each rater individually examined the patients, recorded their findings, and finally provided their results to the statistician. Prior Doppler examinations were used solely as the reference standard for participant classification. Colour Doppler ultrasound has been shown to be highly accurate (> 90%) in diagnosing ineffective tissue perfusion (the gold standard)<sup>16,17</sup>. In this study, the eleven-item index test served as the DC of ineffective peripheral tissue perfusion nursing diagnosis (Supplementary material 1). Due to the unavailability of tools to examine some of the DCs, six of the seventeen DCs listed in the NANDA 2021–2023 were not studied<sup>18</sup>. Additionally, because the research commenced before the publication of NANDA 2024–2026, the DCs incorporated into the new NANDA were not reviewed. Data were collected through a structured interview based on the intended nursing diagnosis and a clinical examination, provided the inclusion criteria were met. The Wagner classification tool was used to categorize patients’ foot ulcers. This tool is simple and widely used to evaluate diabetic foot lesions, scoring ulcers on a scale of 0 to 5. This classification is as follows: Grade 0: No open lesions, though the skin may be intact with deformities or signs of a “foot at risk”. Grade 1: A superficial, partial- or full-thickness ulcer on the outer layers of skin. Grade 2: A deeper ulcer that extends to the ligament, tendon, joint capsule, bone, or deep fascia without abscesses or osteomyelitis. Grade 3: A deep ulcer complicated by an abscess, osteomyelitis (bone infection), or joint sepsis. Grade 4: Localized necrosis (gangrene) in the toes or forefoot. Grade 5: Necrosis of the entire foot<sup>19</sup>. The following were investigated in the interviews with the patients: demographic information; symptoms that could not be obtained by examination and observation; pain level; limb sensation level (ability to feel touch and strong stimuli); ability to move limbs easily; burning sensation; tingling; limb numbness; and other symptoms the patient experienced. All information was recorded. The following were examined in clinical examination: colour does not return to the limb after 1 min of elevation, altered skin characteristics, altered motor function, absence of peripheral pulses, pale skin colour with leg elevation, edema, paresthesia, decreased peripheral pulses, delayed peripheral wound healing, and capillary refill time greater than three seconds. The principal investigator and her assistant (a second person for reliability assessment) recorded and evaluated all information obtained in a patient-specific checklist.

To assess the validity of the scientific content, it was first presented to ten experts (two infectious disease specialists, two orthopedic specialists, two vascular surgeons, two endocrinologists, and two clinical nurse experts), and their opinions were sought. After the experts approved the content, clarity, understandability, and relevance to the topic, the tool was used to examine the nursing diagnosis of “ineffective peripheral tissue perfusion.” Also, previous studies have shown that the defining characteristics of the nursing diagnosis of ineffective peripheral tissue perfusion have high validity<sup>13,14</sup>. Because two researchers participated, Cohen’s kappa was used to assess the instrument’s reliability, with a significance level of < 0.05. Cohen’s kappa is a statistical measure used to assess agreement between two raters. The value of kappa ranges from – 1 to + 1. The closer this score is to + 1, the greater the agreement between the two raters<sup>20</sup>.

Supplementary Material 1 shows how to evaluate the 11 DCs of nursing diagnosis of ineffective peripheral tissue perfusion, as examined in this study. These characteristics are based on the 2021–2024 NANDA-I.

## Statistical methods

The collected data were coded, defined, and analyzed using SPSS version 21. The recent version of NANDA (2024–2026) eliminated the assignment of DCs to two major and minor categories<sup>21</sup>. However, researchers recommend

using the Fehring method (1987–1994) to validate nursing diagnoses when the number of DCs exceeds seven, and using major and minor classifications<sup>22</sup>. DCs with a frequency greater than 0.8 were considered major, those with a frequency between 0.5 and 0.8 were considered minor, and those with a frequency less than 0.5 were considered irrelevant. These major and minor classifications are descriptive and do not imply diagnostic validity, in accordance with the tentative weighted cutoffs in the Fehring DCV model. The discriminative ability of each DC was independently evaluated using sensitivity, specificity, positive and negative predictive values, and likelihood ratios<sup>11</sup>. The total validation score was calculated by summing the individual ratio scores and dividing the sum by the total number of nursing diagnosis DCs tested. Scores below 0.5 were excluded. A total score above 0.6 is considered valid. True positive and negative rates were identified using sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios.

### Ethical considerations

The Ethics Committee of Shahid Beheshti University of Medical Sciences approved this study as a master's thesis (Ethics Code: IR.SBMU.PHARMACY.REC.1403.176). All patient information was received and kept confidential. Prior to the study, patients had already undergone colour Doppler ultrasound of their lower extremities as ordered by their physician, and no cost was incurred.

All research was performed in accordance with relevant guidelines and regulations, and in compliance with the Declaration of Helsinki<sup>23,24</sup>. Written informed consent was obtained from all study participants, and a verbal explanation of the research process was provided. Also, to ensure participant confidentiality, all personal identifiers were irreversibly coded before analysis, and access was limited to de-identified demographic and clinical variables.

## Results

### Participant flow

All 146 patients assessed for eligibility met the inclusion criteria and were enrolled in the study; no participants were excluded during the assessment period. A flow diagram illustrating participant enrollment, assessment, and inclusion is provided (Fig. 1).

### Participant characteristics

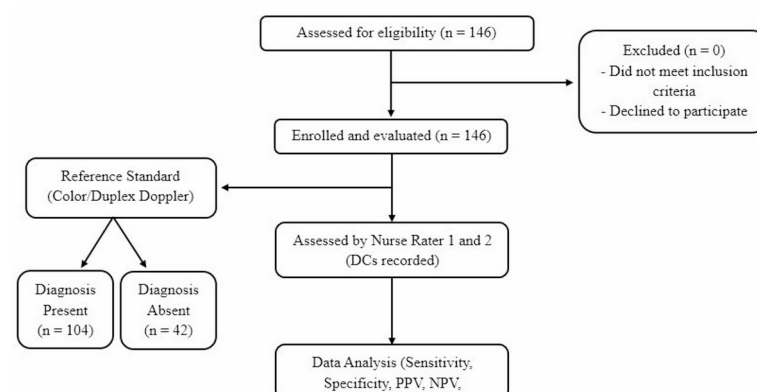
A total of 146 participants were incorporated into the study. No missing or indeterminate data were encountered. Table 1 shows the demographic characteristics of the participants. According to Table 1, most of the participants were male (52.7%), married (56.2%), had lower to moderate levels of education (89.7%), were housewives (41.1%), and were city dwellers (74%). Additionally, the majority of participants reported having had diabetes for less than ten years (63.3%) and having had diabetic ulcers for more than thirty days (52.5%).

### Prevalence of ineffective peripheral tissue perfusion nursing diagnosis

Using Doppler as the benchmark, 104 of the 146 participants were found to have impaired peripheral tissue perfusion, corresponding to a prevalence of 71.2%.

### Validation and frequency of defining characteristics (DCs)

Table 2 delineates the observed frequency of each DC as independently assessed by two nurse raters. Of these, altered skin characteristics were the most prevalently observed DC (97.3% and 93.8%, respectively), followed by delayed peripheral wound healing (91.8% for both raters), and altered motor function (84.9% and 87.7%, respectively). The underlying 2×2 contingency tables for all DCs are provided in Supplementary material 2. In accordance with Fehring's frequency thresholds applied herein, five DCs were classified as major and six as minor. The overall clinical diagnostic validity (CDV) score—derived as the mean of individual DC validation scores—was 0.79 for the eleven examined DCs.



**Fig. 1.** Flow diagram of participant enrollment, assessment, and diagnostic classification.

| Variable                       | Category          | Frequency<br>N (%) |
|--------------------------------|-------------------|--------------------|
| Gender                         | Female            | 69 (47.3%)         |
|                                | Male              | 77 (52.7%)         |
| Marital status                 | Married           | 82 (56.2%)         |
|                                | Single            | 64 (43.8%)         |
| Age                            | 30–50 years       | 27 (18.5%)         |
|                                | 51–80 years       | 114 (78.1%)        |
|                                | 81–90 years       | 5 (3.4%)           |
| Education                      | Undergraduate     | 59 (40.4%)         |
|                                | Diploma           | 72 (49.3%)         |
|                                | Bachelor's Degree | 15 (10.3%)         |
| Occupation                     | Housekeeper       | 60 (41.1%)         |
|                                | Office employee   | 13 (8.9%)          |
|                                | Laborer           | 9 (6.2%)           |
|                                | Retired           | 23 (15.8%)         |
|                                | Self-employed     | 28 (19.2%)         |
|                                | Other             | 13 (8.9%)          |
| Income                         | Sufficient        | 25 (17.1%)         |
|                                | Median            | 85 (58.2%)         |
|                                | Insufficient      | 36 (24.7%)         |
| A familial history of diabetes | Yes               | 92 (63%)           |
|                                | No                | 54 (37%)           |
| Residence                      | Urban             | 108 (74%)          |
|                                | Rural             | 31 (21.2%)         |
|                                | Other             | 7 (4.8%)           |
| Comorbidities                  | Yes               | 70 (47.9%)         |
|                                | No                | 76 (52.1%)         |

Table 1. Demographic characteristics.

| Defining Characteristics                                   | Presence or Absence of Ineffective Peripheral Tissue Perfusion |                                       |                                      |                                      |                |
|------------------------------------------------------------|----------------------------------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|----------------|
|                                                            | Researcher 1: Present<br><i>n</i> (%)                          | Researcher 2: Present<br><i>n</i> (%) | Researcher 1: Absent<br><i>n</i> (%) | Researcher 2: Absent<br><i>n</i> (%) | Classification |
| Color does not return to the limb after 1 min of elevation | 103 (70.5)                                                     | 104 (71.2)                            | 43 (29.5)                            | 42 (28.8)                            | Minor*         |
| Altered skin characteristics                               | 142 (97.3)                                                     | 137 (93.8)                            | 4 (2.7)                              | 9 (6.2)                              | Major*         |
| Altered motor function                                     | 124 (84.9)                                                     | 128 (87.7)                            | 22 (15.1)                            | 18 (12.3)                            | Major*         |
| Absence of peripheral pulses                               | 108 (74.0)                                                     | 107 (73.3)                            | 38 (26.0)                            | 39 (26.7)                            | Minor          |
| Skin pallor with limb elevation                            | 122 (83.6)                                                     | 120 (82.2)                            | 24 (16.4)                            | 26 (17.8)                            | Major*         |
| Extremity pain                                             | 91 (62.3)                                                      | 90 (61.6)                             | 55 (37.7)                            | 56 (38.4)                            | Minor          |
| Extremity edema                                            | 109 (74.7)                                                     | 107 (73.3)                            | 37 (25.3)                            | 39 (26.7)                            | Minor          |
| Extremity paresthesia                                      | 101 (69.2)                                                     | 98 (67.1)                             | 45 (30.8)                            | 48 (32.9)                            | Minor          |
| Decreased peripheral pulse                                 | 126 (86.3)                                                     | 117 (80.1)                            | 20 (13.7)                            | 29 (19.9)                            | Major*         |
| Delayed peripheral wound healing                           | 134 (91.8)                                                     | 134 (91.8)                            | 12 (8.2)                             | 12 (8.2)                             | Major*         |
| Capillary refill time > 3 s                                | 111 (76.0)                                                     | 108 (74.0)                            | 35 (24.0)                            | 38 (26.0)                            | Minor*         |

Table 2. Distribution of defining characteristics according to independent raters' assessments.

Sensitivity and specificity of DCs

Sensitivity and specificity for each DC (by rater) are presented in Table 3. Sensitivity estimates were generally moderate and consistent across raters: Researcher 1 sensitivities ranged from 67.3% to 75.8%, with the lowest for extremity paresthesia (67.32%) and the highest for altered motor function (75.80%). Researcher 2 sensitivities ranged from 68.9% to 73.1%. Specificity estimates exhibited greater variability between DCs and raters: Researcher 1 specificities ranged from 8.33% to 72.02%, with the lowest for delayed peripheral wound healing and the highest for extremity edema. Researcher 2 specificities ranged from 8.33% to 44.44%.

Inter-rater agreement for the defining characteristics was generally high, with a mean Cohen's  $\kappa$  of 0.85. Most DCs showed substantial to nearly perfect agreement. However, notable variability was observed among specific



| Defining Characteristics                                   | Sensitivity  |              | Specificity  |              | Cohen's Kappa |
|------------------------------------------------------------|--------------|--------------|--------------|--------------|---------------|
|                                                            | Researcher 1 | Researcher 2 | Researcher 1 | Researcher 2 |               |
| Color does not return to the limb after 1 min of elevation | 72.81        | 73.07        | 32.55        | 33.33        | 0.851         |
| Altered skin characteristics                               | 71.12        | 72.26        | 25.00        | 44.44        | 0.440         |
| Altered motor function                                     | 75.80        | 72.65        | 54.54        | 38.88        | 0.711         |
| Absence of peripheral pulses                               | 68.51        | 71.02        | 21.05        | 28.20        | 0.771         |
| Skin pallor with limb elevation                            | 71.31        | 69.16        | 29.16        | 23.19        | 0.759         |
| Extremity pain                                             | 68.13        | 68.88        | 23.63        | 25.00        | 0.985         |
| Extremity edema                                            | 70.64        | 71.02        | 72.02        | 28.02        | 0.858         |
| Extremity paresthesia                                      | 67.32        | 69.38        | 20.00        | 25.00        | 0.953         |
| Decreased peripheral pulse                                 | 70.63        | 72.64        | 25.00        | 34.48        | 0.586         |
| Delayed peripheral wound healing                           | 69.40        | 69.40        | 8.33         | 8.33         | 1.000         |
| Capillary refill time > 3 s                                | 70.27        | 69.44        | 25.71        | 23.68        | 0.799         |

**Table 3.** Sensitivity, specificity, and Cohen's kappa coefficient based on assessments by independent raters. Note: Sensitivity and specificity are reported as percentages. Cohen's kappa coefficient indicates inter-rater agreement between the two researchers.

| Defining Characteristics                                   | LR+          | LR+          | LR–          | LR–          | PPV (%)      | PPV (%)      | NPV (%)      | NPV (%)      |
|------------------------------------------------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
|                                                            | Researcher 1 | Researcher 2 | Researcher 1 | Researcher 2 | Researcher 1 | Researcher 2 | Researcher 1 | Researcher 2 |
| Color does not return to the limb after 1 min of elevation | 10.8         | 10.1         | 0.84         | 0.81         | 72.11        | 73.07        | 33.33        | 33.33        |
| Altered skin characteristics                               | 0.95         | 1.30         | 1.16         | 0.62         | 97.11        | 95.19        | 2.38         | 9.52         |
| Altered motor function                                     | 1.67         | 1.19         | 0.44         | 0.70         | 90.38        | 89.42        | 28.57        | 16.66        |
| Absence of peripheral pulses                               | 0.87         | 0.99         | 1.50         | 1.03         | 71.15        | 73.07        | 19.06        | 26.19        |
| Skin pallor with limb elevation                            | 1.01         | 0.86         | 0.98         | 1.60         | 83.65        | 79.80        | 16.66        | 11.90        |
| Extremity pain                                             | 0.89         | 0.92         | 1.35         | 1.24         | 59.61        | 59.61        | 30.95        | 33.33        |
| Extremity edema                                            | 2.52         | 0.99         | 0.41         | 1.03         | 74.03        | 73.07        | 23.80        | 26.19        |
| Extremity paresthesia                                      | 0.84         | 0.93         | 1.63         | 1.22         | 65.38        | 65.38        | 21.42        | 28.57        |
| Decreased peripheral pulse                                 | 0.94         | 11.10        | 1.17         | 0.79         | 85.57        | 81.73        | 11.90        | 23.80        |
| Delayed peripheral wound healing                           | 0.76         | 0.76         | 3.67         | 3.67         | 89.42        | 89.42        | 2.38         | 8.33         |
| Capillary refill time > 3 s                                | 0.95         | 0.91         | 1.16         | 1.29         | 75.00        | 72.11        | 21.42        | 21.42        |

**Table 4.** Positive likelihood ratio, negative likelihood ratio, positive predictive value, and negative predictive value based on assessments by independent raters' assessments. **Abbreviations:** LR+ = Positive Likelihood Ratio; LR– = Negative Likelihood Ratio; PPV = Positive Predictive Value; NPV = Negative Predictive Value.

characteristics: "altered skin characteristics" had moderate agreement ( $\kappa=0.440$ ), and "decreased peripheral pulse" also showed moderate agreement ( $\kappa=0.586$ ). In contrast, "delayed peripheral wound healing" achieved perfect agreement ( $\kappa=1.000$ ). This suggests that while overall reliability is strong, certain DCs may require more standardized assessment procedures to reduce subjectivity.

### Predictive values and likelihood ratios

The data presented in Table 4 delineate the positive predictive values (PPV), negative predictive values (NPV), and likelihood ratios for each DC and rater. Notably, PPVs were high for several DCs—particularly altered skin characteristics (97.11% and 95.19%) and delayed peripheral wound healing (89.4% for both raters)—reflecting the high prevalence of these conditions in the sample. Conversely, NPVs were generally low to moderate; the highest observed NPV was for the criterion "colour does not return to the limb after 1 minute of elevation" (33.3% for both raters). Several DCs, including altered skin characteristics and delayed wound healing, exhibited very low NPVs, thereby illustrating the influence of disease prevalence on these predictive values.

Positive likelihood ratios (LR+) exhibited considerable variability. The highest LR+ values were observed for the characteristic "color does not return to the limb after one minute of elevation" (10.8 and 10.1, respectively), suggesting it may help confirm the condition in this sample. Conversely, several DCs yielded LR+ values  $\leq 1.0$  (or LR– values  $> 1.0$ ), reflecting limited discriminative capacity for diagnosing or excluding the condition; therefore, these parameters should be interpreted with caution. As predictive values depend on disease prevalence, the clinical utility of PPV and NPV may vary across populations with different incidence rates.

## Discussion

The present study evaluated the clinical validity of eleven DCs associated with the NANDA-I nursing diagnosis “Ineffective Peripheral Tissue Perfusion” in patients suffering from diabetic foot ulcers. The diagnosis showed a high prevalence of 71.2%, underscoring the frequent occurrence of peripheral perfusion impairment in this population. Among the DCs, altered skin characteristics, delayed peripheral wound healing, and altered motor function were the most commonly observed features. Sensitivity was highest for altered motor function in Researcher 1 and for the absence of colour return to the limb after elevation in Researcher 2, suggesting they may serve as early indicators of perfusion deficits. Extremity edema demonstrated relatively higher specificity, indicating that its presence may support the diagnosis, while other DCs provided complementary diagnostic information.

Inter-rater reliability was generally strong, with an overall Cohen’s  $\kappa$  of 0.85. However, variability across specific defining characteristics was noted. “Altered skin characteristics” ( $\kappa = 0.440$ ) and “decreased peripheral pulse” ( $\kappa = 0.586$ ) showed moderate agreement, highlighting the potential subjectivity in assessing these features. Conversely, “delayed peripheral wound healing” demonstrated perfect agreement ( $\kappa = 1.000$ ). These findings suggest the need for standardized training and assessment protocols for DCs that require interpretive judgment, which could enhance consistency in clinical practice. Nevertheless, the concordance between altered skin characteristics and diminished peripheral pulses was lower, underscoring the potential subjectivity inherent in visually evaluating skin changes and palpating pulses. These findings underscore the importance of a hierarchical approach to bedside evaluation, whereby DCs indicative of motor and vascular alterations may serve as primary indicators, while supplementary features enhance overall diagnostic precision. Collectively, the findings provide empirical support for prioritising high-performing DCs in the clinical assessment of peripheral tissue perfusion in patients with diabetic foot ulcers.

Recent evidence suggests that nursing diagnoses and the complexity of nursing care extend beyond mere descriptive documentation<sup>25,26</sup>; they also predict significant clinical outcomes. For example, a comprehensive retrospective study involving over 42,000 hospitalized adult and pediatric patients demonstrated that specific nursing diagnoses were variably associated with transfers to the ICU, indicating that diagnostic profiles offer critical insights into clinical deterioration beyond simple diagnosis counts. Such profiles can be employed to stratify risk and facilitate proactive clinical monitoring<sup>27</sup>. Furthermore, research conducted in pediatric settings has shown that higher nursing care complexity—measured by more nursing diagnoses—is associated with a higher likelihood of intra-hospital transfers and ICU admissions, underscoring the importance of nursing diagnostic data in predicting adverse events<sup>28</sup>. These findings are consistent with the literature, indicating that nursing diagnoses can be correlated with outcomes such as length of stay, mortality, and organizational metrics. This underscores the potential significance of thorough diagnostic validation in enhancing patient outcomes, quality of care, and decision-making within health systems<sup>29</sup>. Our research advances this broader understanding by empirically validating DCs for the nursing diagnosis of ineffective peripheral tissue perfusion in patients with diabetic foot ulcers. By pinpointing DCs with stronger diagnostic signals, our findings provide practical evidence that may enhance bedside assessment accuracy, inform clinical decision-making, and ultimately improve patient outcomes.

Studies have shown that motor dysfunction is common in patients with diabetic foot syndrome and is associated with peripheral neuropathy, atrophy, and decreased muscle strength<sup>30</sup>. Although a very high NPV was anticipated, the DC “colour does not return to the limb after 1 minute of elevation” had the highest NPV in our sample, which may reflect the relative frequency of this sign in this cohort rather than a universal diagnostic property. Because predictive values depend on the condition’s prevalence, these observations should be interpreted in the context of our study population rather than generalised to other settings. This DC was observed more frequently among men and among those with a family history of diabetes, which could have influenced its diagnostic profile. Studies have demonstrated that diabetes leads to peripheral vascular ischaemia and pallor of the lower extremities<sup>31</sup>. Studies have shown that approximately 70% of patients with diabetes exhibit pathological skin changes<sup>32</sup>. The main mechanism behind the skin changes observed in people with diabetes appears to be the formation of nonenzymatic glycation end products and changes in the physical and chemical properties of connective tissue and other proteins in the body<sup>33</sup>. Additionally, peripheral arterial disease is more prevalent and severe in people with diabetes and results in pallor of the extremities<sup>34</sup>. Doctors or nurses are recommended to compare the skin on the feet with that on the arms and hands, and to record any changes in temperature, colour, firmness, and skin turgor<sup>35</sup>.

The feature of “altered skin characteristics” in the DC was identified as the most frequently observed and exhibited a high positive predictive value within our cohort. This suggests that it may serve as a significant clinical marker for peripheral perfusion issues rather than a definitive diagnostic criterion. This particular feature was more commonly observed among men, individuals possessing diplomas, married persons, and those with a family history of diabetes. Research has indicated that one consequence of diabetes includes foot tissue lesions, commonly referred to as diabetic foot syndrome. The primary factor in the development of foot tissue lesions in diabetic patients is microvascular dysfunction<sup>36</sup>. Based on studies, microvascular lesions in various organs, including the feet, appear in the early stages of diabetes<sup>37</sup>. This criterion is common among patients with diabetes and is typically associated with impaired peripheral tissue perfusion and damaged blood vessels<sup>38,39</sup>. Altered blood circulation and nerve function may contribute to changes in skin colour and appearance, including pallor, cyanosis, cracking, fissuring, and dryness of the lower extremities<sup>40</sup>.

Delayed peripheral wound healing is among the more prevalent DCs, and given its pathophysiological association with chronic inflammation and local hypoxia, it may indicate ongoing perfusion impairment rather than serving as an early marker. Studies indicate that, at the molecular level, diabetic foot ulcers are characterized by a chronic inflammatory state. Additionally, increased local hypoxic conditions and impaired cellular responses to hypoxia are pathogenic factors that contribute to delayed wound healing<sup>41</sup>.

Altered motor function performed relatively well in our diagnostic evaluation and may be considered a potentially useful indicator associated with neuropathic and vascular contributors to foot dysfunction, with two raters showing good agreement on this sign. Studies show that peripheral neuropathy is a common diabetes-related complication. It is believed that the loss of muscle strength in patients with diabetes is primarily due to skeletal muscle atrophy, closely linked to motor unit denervation and incomplete innervation, leading to motor unit loss. Emerging evidence suggests that motor nerve dysfunction is present in the early stages of diabetic sensorimotor polyneuropathy, which is associated with more widespread muscle disorders<sup>30</sup>.

Extremity edema demonstrated higher specificity in our sample, indicating that its presence may increase the likelihood of impaired perfusion (useful for ‘ruling in’ rather than ‘ruling out’), while other DCs contributed complementary information. According to the results of a similar study, the DC of “edema” has high accuracy for assessing the nursing diagnosis of ineffective peripheral tissue perfusion<sup>13</sup>. Studies have shown that people with diabetes typically have thicker skin on their feet. However, if diabetic neuropathy and ulcers develop, the skin becomes thinner. These findings suggest that arteriovenous shunting increases in individuals with diabetes. Additionally, increased subepidermal edema is observed in individuals with diabetes<sup>42</sup>. Lower extremity edema is often an early sign of significant fluid retention. This condition can lead to cardiac overload, heart failure, and other health issues, and is a common clinical finding in people with diabetes<sup>43</sup>. In particular, people with type 2 diabetes have a higher prevalence of peripheral edema than healthy individuals<sup>44</sup>.

The edema DC may serve as a valuable indicator for identifying individuals with compromised peripheral tissue perfusion, owing to its high specificity and positive likelihood ratio. Meanwhile, DCs such as altered skin characteristics, absence of peripheral pulses, and altered motor function appear to provide complementary sensitivity for assessment<sup>13,14</sup>. Overall, DCs indicating peripheral vascular damage may have greater diagnostic significance; however, their efficacy is context-dependent and should supplement, rather than supplant, comprehensive clinical judgement<sup>31</sup>. The main difference between our study and others is that two researchers conducted the DC assessments here, whereas prior studies often relied on a single evaluator.

Two DCs — altered skin characteristics and decreased peripheral pulse — exhibited lower kappa values (<0.7), which may reflect the inherent challenges in consistently evaluating these signs. Variability could arise from the subjective nature of visually assessing skin changes and the difficulty of gauging pulse strength by palpation, both of which are prone to inter-rater variability. In the 2024–2026 edition of NANDA-I, the defining characteristic “altered skin characteristics” was removed and replaced with more specific indicators. Although this study was based on the 2021–2023 edition, all newly added indicators were assessed, and the presence of any was considered positive; however, they were not analyzed separately. Concerning ‘decreased peripheral pulse,’ enhanced guidance on assessment protocols or the optional use of adjunctive tools (e.g., Doppler) might improve consistency, although further investigation is warranted. These findings suggest that some DCs may inherently require interpretive judgment, underscoring the importance of meticulous clinical training and standardized assessment methodologies to improve reliability and inform future NANDA revisions.

## Limitations

One of the primary limitations of this study was the lack of tools to examine six of the DCs; this issue was addressed by excluding those DCs. Notably, the feature “altered skin characteristics” was removed from the NANDA-I 2024–2026 classification, and other features describing this change were added. Nonetheless, this study continued to address those items to evaluate altered skin characteristics. Since the study commenced before the publication of NANDA 2024–2026, these DCs were not analyzed separately. In certain instances, dressings could not be removed due to medical orders related to the wound treatment process; consequently, these samples were excluded. Another limitation concerns the study’s observational design, which inherently limits causal inference. Furthermore, the study population consisted solely of patients with type 2 diabetes who were outpatients requiring once-daily dressing changes, recruited through purposive sampling. Furthermore, certain diagnostic categories relied on subjective judgement or patient self-report, which may be conceptually linked to diabetic neuropathy rather than isolated perfusion impairment. This potential confounding factor, together with comorbidities or local infections, could influence the observed diagnostic accuracy. Excluding patients with more severe diabetic foot conditions further limits the generalisability of the findings. Finally, it is crucial to interpret terminology carefully, as the prevalence of the nursing diagnosis does not necessarily reflect confirmed perfusion impairment in all cases.

## Conclusion

This study presents empirical evidence affirming the clinical validity of selected defining characteristics of the NANDA-I nursing diagnosis, Ineffective Peripheral Tissue Perfusion, in patients afflicted with diabetic foot ulcers. Among the eleven DCs examined, altered motor function, persistent colour change on limb elevation, and extremity oedema exhibited the most robust diagnostic performance. These characteristics should be prioritized during bedside assessments to enhance early detection of impaired peripheral perfusion. Although most DCs demonstrated acceptable reliability and diagnostic accuracy, certain features—such as altered skin characteristics and decreased peripheral pulses—may necessitate standardized assessment protocols to improve consistency. Overall, the findings endorse the application of these high-performing DCs in clinical practice, while underscoring the need for additional studies involving broader populations and all NANDA-I DCs to establish their generalizability.

## Implications

Nurses should prioritize the high-performing DCs identified herein—such as altered motor function, colour response upon elevation, and extremity oedema—during focused bedside assessments. Objective diagnostic tests (e.g., Doppler ultrasound) should be employed to confirm suspected perfusion impairments. Implementing



standardized assessment protocols and specialized training may enhance reliability, particularly for DCs that rely on subjective judgment, such as assessing skin changes and pulse intensity. These findings underscore areas within the NANDA taxonomy that could benefit from refinement of operational definitions and major/minor classifications. Future research should encompass all 21 DCs, involve multiple blinded raters, utilize multicenter study designs, and pursue prospective data collection to improve generalizability and facilitate the establishment of temporal relationships.

## Data availability

The dataset of this study is available upon reasonable request from the corresponding author.

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## Author contributions

Sara Beigzadeh: Data Curation, Writing - Original Draft, Review & Editing. Mitra Zandi: Project administration, Conceptualization, Writing - Review & Editing. Fateme Eshghi: Statistical analysis, Methodology, Supervision, Writing - Review & Editing.

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## Declarations

## Competing interests

The authors declare no competing interests.

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There are no materials from other sources.

## Ethical Considerations

The Ethics Committee of Shahid Beheshti University of Medical Sciences approved this study as a master's thesis (Ethics Code: IR.SBMU.PHARMACY.REC.1403.176). All patient information was received and kept confidential. Prior to the study, patients had already undergone colour Doppler ultrasound of their lower extremities as ordered by their physician, and no cost was incurred. All research was performed in accordance with relevant guidelines and regulations, and in compliance with the Declaration of Helsinki. Written informed consent was obtained from all study participants, and a verbal explanation of the research process was provided. Also, to ensure participant confidentiality, all personal identifiers were irreversibly coded before analysis, and access was limited to de-identified demographic and clinical variables.

## Additional information

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**Correspondence** and requests for materials should be addressed to M.Z.

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