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Advancements in Early Detection of Diabetic Foot Ulcers: A Systematic Review

Avances en la detección temprana de las úlceras del pie diabético: Una revisión sistemática

Sri Wahyuni Awaluddin[1a,c*], Nursalam Nursalam[2b], Yulis Setiya Dewi[3b], Hamka Hamka[4d]

SUMMARY

Introduction: *Diabetic foot ulcers are a major complication of diabetes that can lead to amputation and reduced quality of life. Early detection is very important, but is often constrained by conventional clinical method. This systematic review aimed to map and synthesize the latest evidence on advancements in diabetic foot ulcers early detection..*
Methods: *This systematic review followed PRISMA guidelines with literature searches in PubMed (128), ScienceDirect (12), Scopus (19), and the Cochrane Library (5) using the PICO approach. The studies analyzed included randomized controlled trials (RCTs), cohort studies, and case-control studies. To ensure the most up-to-date data, only studies published in the last 7 years (2018–2024) and available in English or with official translations are considered. The Joanna Briggs Institute (JBI) Critical Appraisal Checklist was used to assess the study's quality.*
Results: *Of the 128 articles identified, 14 met the inclusion criteria. The latest findings in early detection of diabetic foot ulcers are that innovative technologies such as "Foot Selfie", D-Foot, smart socks, and telehealth applications through patient self-monitoring. Machine Learning and high-accuracy models such as CNNs, YOLOv2-DFU, and SNNs were used in medical imaging for high-accuracy wound classification. Biomarkers and Genetic Analysis, such as IL-18, PTX-3, PCT, PA, and TyG Index, showed potential in predicting the risk and severity of DFU.*
Conclusion: *Digital technology, medical imaging, and biomarkers contribute significantly to the early detection of DFU, reduce the risk of amputation, and improve the management of diabetic patients.*

Keywords: *Diabetic foot ulcer, early detection, artificial intelligence, wearable sensor technology, digital health innovation.*

RESUMEN

Introducción: *Las úlceras del pie diabético son una complicación importante de la diabetes que puede provocar amputación y reducir la calidad de vida. La detección temprana es esencial, pero los métodos clínicos convencionales la limitan. Esta revisión*

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ORCID: 0009-0005-0976-4976[1]
ORCID: 0000-0002-9052-6983[2]
ORCID: 0000-0003-4407-0433[3]
ORCID: 0009-0004-2350-0101[4]

[a] Doctoral Program Student, Faculty of Nursing, Universitas Airlangga Surabaya, East Java, Indonesia.
[b] Faculty of Nursing, Universitas Airlangga Surabaya, East Java, Indonesia.
[c] Poltekkes Kemenkes Makassar, South Sulawesi, Indonesia.
[d] STIKES Tanawali Takalar, South Sulawesi, Indonesia.

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*Corresponding Author: Sri Wahyuni Awaluddin
E-mail: sri.wahyuni.awaluddin-2023@fkp.unair.ac.id

sistemática tuvo como objetivo mapear y sintetizar la evidencia más reciente sobre los avances en la detención temprana de las úlceras del pie diabético.
Métodos: *Esta revisión exploratoria siguió las directrices PRISMA y se realizó mediante búsquedas bibliográficas en PubMed (128), ScienceDirect (12), Scopus (19) y la Biblioteca Cochrane (5), con el enfoque PICO. Los estudios analizados incluyeron ensayos controlados aleatorizados (ECA), cohortes y estudios de casos y controles. Para garantizar la información más actualizada, solo se incluyeron estudios publicados en los últimos 7 años (2018-2024) y disponibles en inglés o con traducciones oficiales. Se utilizó la Lista de Verificación de Evaluación Crítica del Instituto Joanna Briggs (JBI) para evaluar la calidad del estudio.*
Resultados: *De los 128 artículos identificados, 14 cumplieron los criterios de inclusión. Los hallazgos más recientes en la detección temprana de úlceras del pie diabético indican que tecnologías innovadoras como "Foot Selfie", D-Foot, calcetines inteligentes y aplicaciones de telesalud mejoran la detección temprana de dichas úlceras mediante el autocontrol del paciente. El aprendizaje automático y técnicas de alta precisión, como CNN, YOLOV2-DFU y SNN, se utilizan en imágenes médicas para clasificar con precisión las heridas. Los biomarcadores y el análisis genético, como IL-18, PTX-3, PCT, PA y el índice TyG, muestran potencial para predecir el riesgo y la gravedad de las úlceras del pie diabético.*
Conclusión: *La tecnología digital, las imágenes médicas y los biomarcadores contribuyen significativamente a la detección temprana de UPD, reducen el riesgo de amputación y mejoran el tratamiento de los pacientes diabéticos.*

Palabras clave*: Úlcera del pie diabético, detección temprana, inteligencia artificial, tecnología de sensores portátiles, innovación en salud digital.*

INTRODUCTION

Diabetes mellitus represents a major global public health challenge, affecting an estimated 589 million individuals worldwide. This staggering number is projected to reach approximately 853 million by 2050, underscoring the urgent need for effective prevention and management strategies (1). Among the various complications associated with diabetes, diabetic foot ulcers (DFU) are particularly severe and costly, accounting for the majority of diabetes-related hospitalizations and amputations (2). The World Health Organization has noted that DFU not only increases morbidity and mortality but also imposes a significant psychological and socioeconomic burden on patients, their families, and the healthcare system. In Western countries, approximately 2 % of the diabetic population experiences foot ulceration every year, resulting in substantial healthcare costs primarily because of hospital admissions and surgical procedures, including amputations (3). The direct medical costs per DFU episode vary widely across countries, ranging from approximately $3 300 in Singapore to over $27,000 in the USA, reflecting differences in healthcare systems and treatment modalities (4-6). In contrast, developing countries face significant challenges with DFU management due to limited healthcare infrastructure, lower access to advanced therapies, and often delayed presentation of cases. Cost analyses from countries such as India, Nigeria, and Brazil highlight lower absolute but relatively burdensome costs, with episodes costing $300 to $2 000 on average. Moreover, socio-economic factors, limited awareness, and disparities in healthcare access exacerbate disease severity and outcomes in these regions (4,7,8). The incidence of global DFU continues to increase, particularly in low- and middle-income countries where early detection and preventive care are limited, exacerbating the existing health disparities (6). The severity of this issue is further highlighted by the fact that diabetic foot ulcers are often preventable. Yet, they remain a leading cause of hospitalization and amputation, resulting in substantial economic and human costs (9,10). Indonesia exemplifies the growing challenge of DFU in developing countries. With over 10 million adults diagnosed with type 2 diabetes mellitus (T2DM), Indonesia ranks sixth globally in diabetes prevalence (11).

DFU develops as a result of complex interactions between neuropathy, peripheral vascular disease, and wound healing disorders. This multifaceted interplay significantly increases the risk of infection, gangrene, and amputation once ulceration occurs (10,12). The lifetime risk of developing a foot ulcer among individuals with diabetes is estimated at 19 %-34 %, indicating a substantial and long-term threat to their health (10). Furthermore, in people with diabetes, 85 % of lower limb amputations are preceded by ulcerative lesions, underscoring the critical importance of early detection and treatment of DFUs (13). Approximately 15 % of people with diabetes may develop a DFU over time, emphasizing the need for regular monitoring and preventive measures to mitigate the risk of this debilitating condition (14). Barriers such as late diagnosis, limited specialized wound care facilities, and insufficient health literacy remain critical challenges in mitigating the burden of DFUs in Indonesia (15-17).

Early detection and intervention are critical to reduce complications and healthcare costs because they allow for timely intervention, which can prevent the progression of the wound and reduce the risk of amputation (18-20). Consequently, understanding current methods and emerging technologies for DFU detection is vital to enhance evidence-based clinical practice and improve patient outcomes (21). Up-to-date knowledge of advances in early detection of DFU is essential, as foot ulcers remain one of the most debilitating complications of diabetes, frequently resulting in osteomyelitis, amputation, impaired mobility, decreased quality of life, and increased mortality (9,10).

Conventional methods for detecting diabetic foot ulcers (DFU), such as physical examination and manual risk assessment, often rely on subjective clinical evaluations and are limited by the variability in how different observers interpret the results. This traditional approach may fail to identify subtle physiological or structural abnormalities that can occur before ulcer formation (22,23). As a result, many patients seek treatment only after significant tissue damage has occurred, which can lead to less favorable outcomes. To address this issue, new technologies have been developed that integrate digital health, wearable sensors, artificial intelligence, computer vision, and biomarker analysis to improve early DFU screening and monitoring (18,22,24). Infrared thermal imaging, for example, can detect small changes in temperature in the foot, which can indicate inflammation or infection before it becomes clinically apparent (22,25). Plantar pressure analysis can identify areas with high pressure on the legs, which can increase the risk of ulceration (23).

By promoting accessible, innovative, and sustainable healthcare solutions, this approach can significantly improve the quality of life for individuals affected by diabetes. The convergence of digital health, wearable sensors, artificial intelligence, telehealth, and biomarker analysis has the potential to revolutionize diabetic foot management by enabling early detection, timely intervention, and personalized treatment. This convergence is not only a technological advancement but also a strategic move towards achieving the SDGs, specifically SDG 3 (Good Health and Well-being) and SDG 9 (Industry, Innovation, and Infrastructure). This systematic review aims to map and synthesize the latest evidence on advancements in early DFU detection, focusing on innovations in digital health, wearable sensor technology, artificial intelligence, computer vision, telehealth monitoring, and biomarker analysis.

METHOD

This systematic review is registered in the Open Science Framework (OSF) with code (osf.io/x2bh3). This article is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure transparency and systematics in the reporting of review results (Figure 1).

The research approach uses the Population, Intervention, Comparison, Outcome (PICO) strategy to formulate a comprehensive research question and search strategy. The PICO questions used in this review were: How effective is the latest early detection method (I) in identifying diabetic foot ulcers (P) compared to conventional methods (C), based on diagnostic accuracy and clinical benefit (O)?

A comprehensive literature search was conducted on February 14, 2025, in the following databases: PubMed, ScienceDirect, Scopus, and the Cochrane Library. The search targeted articles published between January 2018 and February 2024, available in English or with official translation using keywords based on Medical Subject Headings (MeSH) and combined using Boolean operators. Examples of search strategies in PubMed are as follows: ((“Diabetic Foot Ulcers”) OR (“DFU”) OR (“Foot Ulcer in Diabetes”)) AND ((“Early Detection”) OR

("Screening") OR ("Diagnosis") OR ("Predictive Markers")) AND (("Randomized Controlled Trial") OR ("Cohort Study") OR ("Case-Control Study")).

Studies were included if they involved adults with type 1 or type 2 diabetes at risk of, or diagnosed with, DFU, and assessed early detection methods using digital technologies, AI, imaging, or biomarkers. Excluded were reviews, meta-analyses, case reports, expert opinion, animal studies, and treatment-only trials.

The data selection and screening process was carried out manually by two independent reviewers (SWA and N) using the established inclusion and exclusion criteria. Articles identified in the initial search are evaluated based on their titles and abstracts to determine their relevance. Studies that meet the initial criteria are then checked for full text to ensure suitability with the objectives of this systematic review. If there is a difference of opinion regarding the study selection, the final decision is made through discussion or by involving a third reviewer (YSD or H) as a mediator. This process aims to ensure transparency and accuracy in the selection of articles for further analysis. From the initial search results, 128 articles were identified; after removing duplicates and adjusting inclusion and exclusion criteria, 14 articles were further evaluated (Figure 1).

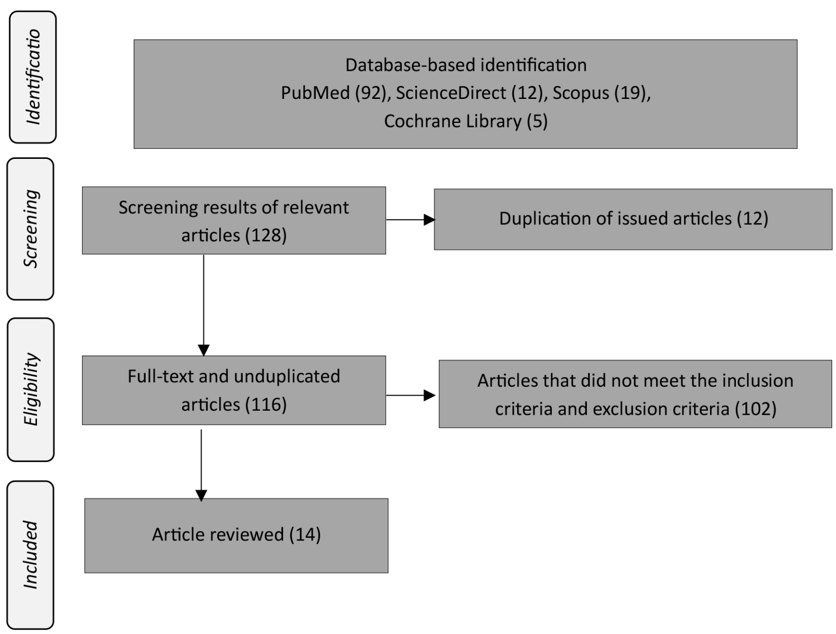

Figure 1. Flowchart of Study Selection.

The methodological quality of the included articles was assessed using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for randomized controlled trials and observational studies. The data extracted from the article included: title, author, year of publication, objectives, methodology, participant characteristics, type of intervention, and key outcomes. Two independent reviewers (SWA and N) performed data extraction and evaluation of article quality. Any differences in assessment are resolved through discussion or, if necessary, by involving a third reviewer (Table 1).

Table 1

Critical appraisal

Article	Criteria of JBI											
	1	2	3	4	5	6	7	8	9	10	Total	Quality
Swerdlow et al., 2023	Y	Y	U	Y	Y	Y	X	Y	Y	N/A	7/9	High
Al-Farra et al., 2024	Y	Y	U	Y	X	X	Y	Y	N/A	N/A	5/8	Medium
Zügner et al., 2022	Y	Y	Y	X	Y	Y	Y	U	N/A	N/A	6/8	High
Guo et al., 2024	Y	Y	U	Y	Y	Y	X	N/A	N/A	N/A	5/7	Medium
Ardelean et al., 2023	Y	Y	X	Y	Y	U	Y	N/A	N/A	N/A	5/7	Medium
Arteaga-Marrero et al., 2023	Y	Y	X	Y	X	Y	Y	N/A	N/A	N/A	5/7	Medium
Soler Climent et al., 2024	Y	Y	Y	U	Y	Y	Y	N/A	N/A	N/A	6/7	High
Billings et al., 2024	Y	Y	U	Y	Y	X	Y	N/A	N/A	N/A	5/7	Medium
Suganthi & Robin, 2024	Y	Y	U	Y	U	Y	Y	N/A	N/A	N/A	5/7	Medium
Toofanee et al., 2023	Y	Y	U	Y	U	Y	Y	N/A	N/A	N/A	5/7	Medium
Sendilraj et al., 2024	Y	Y	Y	Y	U	Y	Y	N/A	N/A	N/A	6/7	High
Qalhati et al., 2018	Y	X	X	Y	Y	X	Y	N/A	N/A	N/A	4/7	Low
Saminathan et al., 2020	Y	Y	U	Y	U	Y	Y	N/A	N/A	N/A	5/7	Medium
Ming et al., 2024	Y	Y	Y	X	X	Y	Y	Y	Y	U	7/10	Medium

Y = yes; U = Unclear; X = No, N/A (Not Applicable)

RESULT

The results of this study were obtained through a systematic review that followed the PRISMA guidelines by searching the literature on PubMed (128), ScienceDirect (12), Scopus (19), and the Cochrane Library (5) using the PICO approach. A total of 128 articles were identified; 14 met the inclusion criteria for further analysis (Table 2).

Technological Innovations

Technological innovations are continuously being developed to improve the monitoring and management of diabetic foot ulcers (DFU). Swerdlow introduced "Foot Selfie", a smartphone-based system that allows patients to monitor the condition of their feet through photos independently (26). Meanwhile, Zügner evaluated the D-Foot tool for DFU risk factor screening, which focuses on early identification of high-risk patients (28). Another innovation is the smart compression sock developed by Billings, equipped with temperature, pressure, and blood oxygen sensors for continuous monitoring (33). Ming also developed a telehealth application integrated with sensor insoles to monitor foot temperature and DFU risk, enabling timely interventions based on data collected in real-time (39).

Table 2

Characteristics of included studies

Title, Author, Year	Method	Intervention	Finding
Initial Clinical Experience with a Simple, Home System for Early Detection and Monitoring of Diabetic Foot Ulcers: The Foot Selfie (Swerdlow et al., 2023)(26)	A smartphone-based system, "Foot Selfie," enables patients to take unassisted photos of the plantar surface of their feet and transmit them to a remote server. This method allows for early detection and remote monitoring of diabetic foot ulcers (DFUs). The pilot study involved patients imaging their feet daily for six months, with results reviewed weekly. Diagnostic-quality image capture system, enabling remote clinical management decisions.	Participants used a smartphone-based "Foot Selfie" system to photograph their feet daily for remote monitoring. Technical support includes app installation and live demonstrations to ensure participant understanding. The study involved a weekly review of the transmitted images to monitor for pre-ulcerative signs. Participants are contacted if they don't upload images during the week to address potential issues. -	The study developed a smartphone-based "Foot Selfie" system for remote monitoring of diabetic foot ulcers. Patients transmit diagnostic-quality images of their feet with minimal training. Participants upload images on average 76% of eligible study days. The system allows doctors to review serial images and make clinical decisions remotely. Healing of seven wounds and reversal of 20 pre-ulcerative lesions were observed during the study. Patients find this system useful and preferable to previous methods of foot screening. This study demonstrates the potential of inexpensive home-based foot screening and monitoring for diabetic foot ulcers.
Potential Biomarkers for the Early Diagnosis and Severity Prediction of Diabetic Foot Ulcer (Al-Farra et al., 2024)(27)	The study calculates the PEDIS (perfusion, extent, depth, infection, and sensation) scores to assess the severity of diabetic foot ulcers (DFU). ELISA, a common laboratory technique for quantifying biomarkers, is used to measure serum levels of IL-18 and PTX-3.		The study found that IL-18 and PTX-3 levels were higher in patients with DFU than in those with T2DM or healthy controls. The cut-off value of IL-18 to predict the severity of DFU is ≥ 124.0 pg/mL, while PTX-3 > 8.67 ng/mL. Significant differences were observed in fasting blood glucose levels, HbA1c, urea, and creatinine between the groups studied. The results showed that PTX-3 was a promising biomarker for predicting DFU, whereas IL-18 predicted severity.
Experiences of using a digital tool, the D-foot, in the screening of risk factors for diabetic foot ulcers (Zügner et al., 2023) (28)	The study uses the think-aloud method, a common approach to usability testing, in which the principal investigator records spontaneous comments from users, including patients and Certified Prosthetists and Orthotists (CPOs), during use of the D-Foot device.	Clinical examinations are conducted by Certified Prosthetists and Orthotists (CPOs) using D-Foot software.	This study evaluated the user experience with the D-Foot tool for screening for risk factors associated with diabetic foot ulcers. CPO finds the D-Foot system usable, with above-average usability scores.
Integrating bioinformatics and multiple machine learning to identify mitophagy-related targets for the diagnosis and treatment of diabetic foot ulcers: evidence from transcriptome analysis and drug docking (Guo et al., 2024)(29)	The study used several methods to identify mitophage hub (MRG)-related genes associated with diabetic foot ulcers (DFUs). Specifically, it uses three machine learning algorithms: support vector engine recursive feature elimination (SVM-RFE), least absolute shrinkage and selection operator (LASSO), and random forest (RF) for the identification of differentially expressed mitophage-associated genes (DMGs).	Treatment of diabetic foot ulcers (DFU) includes debridements, wound dressings, anti-infection medications, and strict glycemic control. Activator mitophagy is proposed as a new therapeutic approach for DFU. The study uses machine learning to aid in the diagnosis of DFU. - - -	The study identified 702 differently expressed genes associated with diabetic foot ulcers (DFUs) and highlighted their relationship with mitochondria and energy metabolism. Key mitochondrial-related genes identified include HK2, RPS3, and LDHA, which were confirmed by multiple machine learning algorithms.

Continued in pag. S199…

…continuation Table 2. Characteristics of included studies.

Title, Author, Year	Method	Intervention	Finding
Pentraxin-3 and Other Inflammatory Markers for an Infected Diabetic Foot Ulcer Diagnosis: A Prospective Study (Ardelean et al., 2023) (30)	Data collection involves standard laboratory blood tests, including WBC, ESR, HbA1c, and fibrinogen, taken from patient file charts. Overall, the study aims to assess pentraxin-3 as a biomarker for infected diabetic foot ulcers (iDFU) and employs a range of statistical methods to analyze the collected data.	-	Pentraxin-3 was identified as a significant predictor of death in infected diabetic foot ulcers (iDFU) with $p = 0.047$. Other markers such as procalcitonin (PCT) show the highest AUROC of 0.91 to identify iDFU. The study concluded that the duration of diabetes does not affect the prognosis of iDFU.
State-of-the-Art Features for Early-Stage Detection of Diabetic Foot Ulcers Based on Thermograms (Arteaga-Marrero et al., 2023)(31)	The research employed a variety of feature-selection methods, including classical techniques such as random forests and Lasso, as well as two novel deep learning (DL) approaches, namely concrete dropouts and variational dropouts. The extracted features are used as inputs to the support vector machine classifier to differentiate between diabetic and healthy subjects, demonstrating the effectiveness of the methodology used.		The study successfully differentiated between healthy and pathological subjects using plantar temperature measurements. The study emphasizes the need for standard thermograms to improve feature selection. These findings contribute to the early identification of diabetic foot ulcers, reducing the risk of amputation.
Identification of phase angle and Triglyceride-Glucose index as biomarkers for prediction and management of diabetic foot disease (Soler et al., 2024)(32)	The study used a comparative case-control methodology conducted at the Elche General Hospital, involving 70 participants, with 33 suffering from diabetes and 37 without. The analysis aimed to assess the association between Phase Angle (PA) and Triglyceride-Glucose index (TyG) and the risk of diabetic foot ulcers, highlighting their potential as easily measurable biomarkers.		The study identified Phase Angle (PA) and Triglyceride-Glucose (TyG) indices as strong predictors of diabetic foot risk. The PA and TyG indices can serve as valuable biomarkers for assessing diabetic foot risk.
Smart Compression Sock for Early Detection of Diabetic Foot Ulcers (Billings et al, 2024)(33)	The study used smart compression socks that integrate temperature, plantar pressure, and blood oxygen sensors to monitor physiological changes in the foot and are specifically designed to prevent diabetic foot ulcers. Data collection is facilitated by a smartphone app that connects to the sensor via Bluetooth, with the data transferred to a personal OneDrive account for analysis.	The study tested smart compression socks designed to prevent diabetic foot ulcers, with integrated sensors to monitor temperature, pressure, and blood oxygen levels. Participants were instructed to wear smart socks for at least 1.5 hours during the test. Smartphone apps are used to collect and monitor data during the intervention.	The study evaluated smart compression socks designed to prevent diabetic foot ulcers, equipped with integrated sensors for temperature, pressure, and blood oxygen saturation. The results show the potential effectiveness of smart socks in preventing diabetic foot ulcers and warrant further clinical trials.
SoleScan: Innovating Diabetic Foot Ulcer Identification and Evaluation (Suganthi and Robin et al., 2024)(34)	This study employs a systematic approach to identify and localize diabetic foot ulcers (DFUs) using machine learning. The study introduces a 16-layer Convolutional Neural Network (CNN) model specifically designed to classify images of diabetic feet into different pathological regions.	A promising intervention to improve diagnostic accuracy in diabetic foot ulcer studies. The innovative "SoleScan" system aims to improve early detection and personalized treatment strategies for diabetic foot ulcers.	The study introduces "SoleScan," a new approach to improving the management of diabetic foot ulcers using machine learning and computer vision. The findings suggest ongoing research is needed to explore new therapies and address health care gaps in diabetes care.

Continued in pag. S200…

...continuation Table 2. Characteristics of included studies.

Title, Author, Year	Method	Intervention	Finding
	The YoloV2-DFU model was developed to accurately detect and localize dFU by integrating features from the YoloV2 and ShuffleNet architectures, thereby improving its performance in identifying abnormal regions in images.	-	
DFU-Helper: An Innovative Framework for Longitudinal Diabetic Foot Ulcer Diseases Evaluation Using Deep Learning (Toofanee et al., 2023)(35)	The study introduced a new framework, DFU-helper, that uses a Siamese Neural Network (SNN) to assess diabetic foot ulcers (DFUs) over time. This method leverages SNNs' learning capabilities to provide an accurate and objective evaluation of DFU development.	DFU-Helper, a tool that utilizes a Siamese Neural Network for the assessment of diabetic foot ulcers.	This study introduces DFU-helper, a framework that uses Siamese Neural Networks to assess diabetic foot ulcers over time. DFU-helper provides visual and numerical representations of disease progression across five conditions: absent, infectious, ischemia, both, and healthy.
DFUCare: deep learning platform for diabetic foot ulcer detection, analysis, and monitoring (Sendilraj et al., 2024)(36)	The DFUcare platform integrates computer vision and deep learning algorithms, leveraging the pre-trained YoloV5s algorithm for wound localization and deep learning models for infection and ischemia classification.	DFUcare is a non-invasive platform for analyzing diabetic foot ulcers using deep learning algorithms and mobile phone images. The platform classifies infections and ischemia, helping with timely intervention.	The study developed DFUcare, a non-invasive platform for monitoring diabetic foot ulcers (DFU) using deep learning algorithms. The platform shows strong performance with an error rate of less than 10% in clinical trials. DFUcare offers a cost-effective, convenient solution for early detection of infection and ischemia in DFU.
Design and Development of Graphical User Interface (GUI) with MATLAB for Early Detection of Diabetic Foot Ulcers using Infrared Imaging (Qalhati et al., 2018)(37)	The research discusses the use of Otsu Hybrid Segmentation, which combines three methods: k-means clustering, Otsu thresholding, and the watershed method. This method is specifically used to detect leg ulcers. The Otsu method is widely used for threshold selection in real-world images, particularly for symmetry and shape size, which are essential for effective image segmentation.	The proposed system uses infrared imaging to monitor and early detect diabetic foot ulcers, employing a computer-aided detection (CAD) system implemented in MATLAB for image analysis.	Research shows that infrared thermal imaging is effective for the early detection of diabetic foot ulcers. A computer-aided detection system was developed using MATLAB to analyze and extract the region of interest. The Otsu hybrid segmentation technique is used to process and segment images of foot ulcers. The system provides risk assessments categorized as low or high risk based on image analysis.
Computer-aided detection of diabetic foot ulcer using asymmetry analysis of texture and temperature features (Saminathan et al., 2020)(38)	This study uses an asymmetric analysis method to detect diabetic foot ulcers by comparing temperature and texture features between the ipsilateral and contralateral foot regions. Thermal and color images of plantar feet were obtained from subjects, including non-diabetic and diabetic individuals, to form a control group and a DM group. The feature extraction process involves computing the Gray Level Co-Matrix (GLCM) to derive texture features from thermal images.	Thermal Drawing	The study developed a computer-aided diagnostic system for the early detection of diabetic foot ulcers using texture and temperature features. Asymmetry analysis was performed on features extracted from the ipsilateral and contralateral foot regions. The SVM classifier achieves an accuracy of 95.61%, sensitivity of 96.5%, and specificity of 92.41%. The methodology can serve as the basis for early identification of diabetic foot complications.

Continued in pag. S201...

...continuation Table 2. Characteristics of included studies.

Title, Author, Year	Method	Interventi	Finding
Telemedical Monitoring of Plantar Temperature in Diabetic Patients at Risk of Foot Ulcers: The Randomized Smart Prevent Diabetic Feet Trial (Ming et al., 2024)(39)	Study Design: An open-label, prospective, randomized clinical trial for diabetic patients at risk of diabetic foot ulcers (DFU) due to peripheral neuropathy. Recruitment: 283 patients from the University Hospital of Magdeburg were randomized into the control and intervention groups. Randomization: Performed by statisticians using RITA software to minimize bias.	Intervention: The intervention group used a telehealth app with a sensor sole to monitor foot temperature and a mobile phone app to report abnormalities. Control: The control group received standard care without telehealth intervention.	Recruitment and Randomization: 283 of the 351 diabetic patients at risk of foot ulcers were randomized 1:1 to the control and intervention groups. Observation Days: More than 80,000 observation days in both groups, showing comprehensive data. Compliance: A 70% compliance rate for telehealth applications, indicating good acceptance. Quality of Life: Both groups experienced improved quality of life, with a slightly greater improvement in the intervention group after 24 months.

Machine Learning and Computer Vision

These studies demonstrate significant advances in applying image processing and deep learning methods to detect and classify diabetic foot ulcers (DFU). Arteaga-Marrero successfully applied Convolutional Neural Networks (CNNs) and YOLOV2-DFU for DFU image detection and classification, which allows for more accurate visual diagnosis (31). Toofanee used the Siamese Neural Network (SNN) in DFU-Helper to evaluate the progression of DFU wounds, aiding in the monitoring of disease progression (35). Sendilraj developed DFUcare, a deep learning-based platform specifically designed to detect and classify DFUs, which has the potential for large-scale screening (36). Qalhati utilized Otsu hybrid segmentation in infrared image processing to detect DFU, demonstrating a non-invasive approach (37). Saminathan used the Support Vector Machine (SVM) to analyze the temperature asymmetry and texture of the foot, which is an effective image processing method for the early detection of DFU (38).

Biomarkers and Genetic Analysis

Recent research has focused on identifying biomarkers and using machine learning to predict the risk and severity of diabetic foot ulcers (DFUs). Guo et al. (2024) used machine learning, including SVM-RFE, LASSO, and RF, to identify mitophage-associated genes in DFU, which could pave the way for targeted genetic therapies (29). Al-Farra examined the roles of interleukin-18 (IL-18) and pentraxin-3 (PTX-3) as predictors of DFU severity, which may aid in stratifying patient risk (27). Ardelean et al. (2023) focused on pentraxin-3 and procalcitonin (PCT) as biomarkers of infection in DFU, which are important for early diagnosis and appropriate management (30). Meanwhile, Soler Climent examined phase angle (PA) and the triglyceride-glucose (TyG) index as predictors of DFU risk, which can help identify high-risk patients before ulcers develop (32).

DISCUSSION

The development of health technology has revolutionized the approach to early detection and treatment of diabetic foot ulcers (DFU). The latest innovations in digital health, wearables, and artificial intelligence (AI) have introduced new strategies for identifying foot complications before they become severe. DFU is particularly crucial because it is a leading cause of non-traumatic lower limb amputation, which is associated with high morbidity and mortality rates among diabetic patients globally (33,39). The integration of digital health systems improves early screening, improves patient monitoring, and supports self-care behaviors, especially among populations with limited access to regular clinical services (36). By leveraging these technologies, healthcare providers can more effectively identify and manage DFU, ultimately reducing the risk of amputation and improving patient outcomes.

Digital and mobile-based systems can effectively monitor foot conditions. The "Foot Selfie" system utilises mobile phones to enable patients to photograph their feet, which are then transmitted to healthcare professionals for review, thereby facilitating ongoing evaluation and prompt detection of irregularities. The D-Foot tool has established a standardized method for assessing DFU risk factors, enabling healthcare professionals to conduct consistent, evidence-based screenings in both clinical and community settings. The D-Foot tool enables healthcare professionals to conduct standardized, evidence-based screening for risk factors for diabetic foot ulcer in both clinical and community settings. These applications highlight the potential of digital technologies to enable patients to take a more active role in preventing complications (28). The Technology Acceptance Model (TAM) posits that perceived usefulness and ease of use are crucial determinants of technology adoption in healthcare settings (40,41). For digital health interventions to be effective, patients must be highly engaged and literate, and healthcare professionals must receive comprehensive training to interpret data and provide timely, accurate feedback.

Wearable devices have also emerged as important innovations for continuous foot monitoring. For instance, smart compression socks and sensor-embedded insoles can measure plantar pressure, temperature, and oxygen saturation in real time, transmitting data to clinicians through mobile applications (29,42). Changes in these physiological parameters often indicate early-stage tissue damage or ulcer formation. This approach is consistent with the pathophysiological understanding of DFU, which attributes ulcer development to repetitive pressure, neuropathy, and ischemia that compromise skin integrity (43). Thus, wearable devices offer a proactive means of identifying warning signs before ulcer onset. The continuous monitoring provided by these devices enables early intervention and may reduce the risk of complications. This proactive approach is crucial for managing DFU because it allows clinicians to implement preventive measures and improve patient outcomes. Several hurdles, such as their cost, patient compliance, and long-term outcome reliability, must be addressed before these devices can be widely implemented in resource-constrained regions.

Interest in artificial intelligence and computer vision systems is growing due to their ability to automate the identification and classification of DFUs. Convolutional Neural Networks (CNNs) and YOLO-based algorithms have achieved high diagnostic accuracy in distinguishing among various ulcer types and predicting healing outcomes (31,44). The DFU-Helper system uses Siamese neural networks to track changes in ulcer size and severity over time, enabling clinicians to assess treatment progress objectively (30). These applications are based on supervised learning theory, in which algorithms are trained to identify visual and clinical features from large annotated datasets (27). The reliability of AI models heavily relies on the quality and diversity of the training data used. Algorithms may not generalize effectively across diverse ethnicities or clinical settings when datasets are biased or insufficient. The development of diverse datasets that represent multiple patient populations is crucial for improving accuracy and ensuring fair clinical use.

Parallel to digital and AI-based approaches, biomarker and genetic research have significantly contributed to understanding the biological mechanisms underlying DFU. Studies have identified several inflammatory biomarkers—such as Interleukin-18 (IL-18), Pentraxin-3 (PTX-3), and Procalcitonin (PCT)—that correlate with infection severity and wound chronicity (16-18). Elevated IL-18 levels reflect excessive inflammatory responses that delay tissue repair, whereas elevated PTX-3 levels indicate immune activation and endothelial dysfunction. Mitochondrial dysfunction plays a key role in DFU development, as impaired mitophagy reduces cellular energy production and slows healing (45). This process is a complex interplay of various cellular mechanisms that ultimately lead to the development of DFU. Integrating biomarker analysis with digital screening could enable the early identification of high-risk patients and the design of personalized therapeutic interventions. However, the high cost and limited laboratory infrastructure remain barriers to the incorporation of such advanced diagnostics into routine diabetic care in many developing regions.

Taken together, these findings highlight that the convergence of digital health, wearable technology, artificial intelligence (AI), and biomolecular innovation has created a multidimensional framework for the early detection of DFU. Each approach has unique strengths: digital tools improve accessibility and patient engagement, wearable sensors enable real-time physiological monitoring, AI systems enhance diagnostic precision, and biomarkers provide molecular-level insight into disease progression (28). To achieve optimal outcomes, these components should be integrated into a comprehensive, multidisciplinary model of diabetic foot care. This integrative approach aligns with Leininger's transcultural nursing theory, which emphasizes the importance of considering cultural values, beliefs, and practices in the design and application of healthcare interventions (46). Culturally adapted education, ethical data management, and interprofessional collaboration are crucial to ensure that diverse patient populations effectively implement and accept technological innovations. A team of healthcare professionals from diverse fields must collaborate to integrate these components and implement technological advancements in a culturally aware context. Moreover, culturally adapted education and training programs must be developed to equip healthcare professionals with the skills to implement and manage technological advancements across diverse patient populations successfully.

Further studies must confirm the effectiveness of advanced technologies for early identification and prevention of DFU in real-world settings. These advancements also require the development of standardized procedures to guarantee equitable access. The global burden of diabetic foot complications can be significantly reduced by integrating technological advancements with comprehensive, culturally aware care methods, ultimately enhancing the quality of life and preventing unnecessary amputations among patients with diabetes. This integration would involve healthcare professionals working closely with patients and their families to understand their specific needs and provide tailored care. By doing so, it is possible to create a more effective and sustainable approach to managing diabetic foot complications.

CONCLUSION

Advances in monitoring technology, medical imaging, and biomarkers have led to innovations in DFU early detection and complication prevention. Digital technologies enable patients' continuous self-monitoring and the detection of psychological changes in real time, while still relying on patient adherence and health professional oversight. On the other hand, medical imaging and computer-based image analysis show strong potential for automated DFU detection and classification, but face limitations relation to dataset diversity, validation, and clinical adoption. Further validation is required to ensure the accuracy of results in various clinical conditions.

The integration of technological innovations, medical imaging, and biomarkers has the potential to enhance early detection of DFU, reduce the risk of amputation, and improve the quality of life for patients with diabetes. For future studies, collaboration between researchers, medical personnel, and technology developers is needed to ensure the effectiveness and accessibility of these solutions in clinical practice.

Conflict of Interest

We declare no conflict of interest

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