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Screening Diabetic Foot Ulcer using Artificial Intelligence Modelling based on Digital Image Analysis : A Systematic Review

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 February 2025 and was last updated on 4 February 2025.

INTRODUCTION

Review question / Objective In this literature review, the authors summarized the conducted research and drew several conclusions about the potential directions of future research. Specifically, this literature study aims to: (I) identify the predictive models used in the development of AI-based digital image analysis in DFU cases, and (II) determine the features and segmentation used in the construction of DFU screening algorithm models.

Rationale Previous research shows that artificial intelligence has been used to diagnose and predict diabetes mellitus and its complications. This has transformed the field with the introduction of AI-based solutions due to the ease of collecting massive data and the power of computational processing (8,12). The use of AI in cases of diabetic foot ulceration is expected to improve early diagnosis, data augmentation, data analysis, risk prediction, and the development of personalized wound care (12,13). Additionally, by using this method, clinicians can better utilize predictive models to determine which high-risk diabetes patients should be monitored more closely and treated more intensively (13,24).

Condition being studied Diabetes Mellitus is a metabolic disorder characterized by high blood glucose levels (hyperglycemia) (9,10). The International Diabetes Federation (IDF) atlas reports that the prevalence of diabetes among those aged 20–79 in 2021 is estimated to be 10.5% (536.6 million people) and is projected to increase to 12.2% (783.2 million) by 2045 (11,12). Diabetic foot ulcers (DFUs) are a common chronic complication and the leading cause of amputation in patients with diabetes (13,14). DFUs have a significant impact on an individual's quality of life and impose a substantial burden on the public

healthcare system (15–17). One way to prevent complications from diabetic foot ulcers is through proper wound care (18,19). Effective DFU management requires a multidisciplinary team (doctors, nurses, and other healthcare professionals) who play a crucial role in early detection, education, and effective treatment, including referrals to specialized DFU clinics. (15,20,21).

Artificial Intelligence (AI) is a manifestation of human-made machines as a branch of computer science and is used to analyze complex medical data (6,22). Artificial intelligence applications are also used in the alignment of diabetic foot ulcer images as an initial step in the wound care process (1,23). Convolutional neural networks (CNNs) are a relevant model for use in medical imaging. This convolutional architecture can scan image pixels, detect simple features, and then combine these features into more complex forms (12). Furthermore, the combination of these filters can produce a wound classification. The use of wound classification using artificial intelligence can provide better results and cost-effectiveness compared to conventional methods (5).

METHODS

Search strategy A literature analysis was conducted by searching for articles tht discuss the screening of diabetic foot ulcers using artificial intelligence. Articles were obtained from Science Direct, PubMed, Proquest and CINAHL databases. The keywords used with Boolean search were "Artificial Intelligence" AND "Diabetic Foot Ulcer Prediction" to obtain articles relevant to the research objectives.

Participant or population Diabetes patient with diabetic foot ulcer.

Intervention Diabetic foot ulcer screening or assessment using digital image analysis with artificial intelligence.

Comparator Diabetic foot ulcer screening or assessment with conventional methods or using questionnaire.

Study designs to be included The selected articles were randomized controlled trials, comparisons, correlations, original articles, and development of AI algorithm models.

Eligibility criteria The inclusion criteria for the selected articles were: (i) Articles published in 2019–2024, (ii) Articles written in Indonesian or English, (iii) Randomized controlled trials, comparisons, correlations, original articles, and development of AI algorithm models, (iv) the article should explain the construction of an AI model using digital image analysis about DFU. The results of the literature search were then systematically analyzed to obtain empirical evidence related to DFU screening using image-based artificial intelligence. The exclusion criterion for this literature review were : (i) articles that were duplicates and review articles (such as systematic review, commentaries, narrative analysis, protocols, editorials, etc), (ii) sourced from encyclopedias, videos or books, (iii) not open acces as full text (iv) does not explain the development of AI algorithms and does not use digital image analysis.

Information sources Articles were obtained from Science Direct, PubMed, Proquest and CINAHL databases.

Main outcome(s) Applications of diabetic foot ulcer screening of the proposed AI model algorithm, accuracy, sensitivity and specitivity.

Additional outcome(s) None.

Data management The authors extracted data using two stages. The first stage is that the author independently searches and filters related to titles and abstracts from the three databases. All articles were identified by both authors (ADP and HKS). Excluded studies are studies that do not meet the criteria. The assessment of potentially relevant articles for review and this is done by all authors. Disagreements were documented and then the selection process was documented in the form of a PRISMA 2020 flowchart.

Quality assessment / Risk of bias analysis Given the lack of prospective studies and the high risk of publication bias in this area, the quality of the study was assessed using the Methodological Index for NonRandomized Study (MINORS) criteria. The evaluation of non-randomized and non-comparative studies was conducted by including 8 questions that were assessed with a score of 0 – 2 (0 = "not reported"; 1 = "reported but inadequate"; 2 = "reported and adequate"). Then the scores are summed up and a score of 0 – 16 is obtained with the highest score indicating the highest quality. The quality of the research analyzed using MINORS (Table 3) showed that 8 articles showed non-comparative studies with a score of 12 or less, as many as 4 articles reflecting the quality of the medium methodology which means that some weaknesses were found but still could be used. Meanwhile, the other 4 articles

received a score of more than 12 which indicates high methodological quality and low risk of bias. In total, the non-comparative study had a score of 11.2, which means that the quality of the methodology was moderate.

Strategy of data synthesis Data from the included studies were extracted and analyzed independently by the first authors (ADP) using Nvivo. Content identification and analysis are carried out by the researcher by systematically encoding information relevant to the research question. Coding is organized into categories of introduction, data sources and digital imaging features as well as artificial intelligence (AI) models and algorithms. All encoding results are organized in spreedsheet format using Microsoft Excel to facilitate comprehensive analysis of the reviewed studies.

Subgroup analysis Subgroup analysis was carried out in the following categories: (i) introduction: author, year of publication and research objectives, (ii) data sources and digital imaging features: type of imaging used, number of data or respondents and method of data retrieval or data source, (iii) AI methodology: type of AI used and results of prediction algorithm for digital image analysis.

Sensitivity analysis None Sensitivity analysis conducted for this study.

Language restriction English.

Country(ies) involved Indonesia.

Other relevant information The citation style that used in this protocol is Vancouver Style.

Keywords Diabetic Foot Ulcer, Screening, Machine Learning, Artificial Intelligence.

Dissemination plans Public Publications.

Contributions of each author

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