

# Prevention Strategy for Ulcer Recurrence in Patients with Type II Diabetes Mellitus: A Quasi-Experimental Study

## Abstract

**Background:** Many strategies exist to prevent diabetic ulcer recurrence, yet an effective method does not currently exist. This study evaluates the effectiveness of a prevention strategy to reduce ulcer recurrence in patients with Diabetes Mellitus (DM). **Materials and Methods:** A quasi-experimental, two group study was undertaken with 60 participants with type 2 DM. Two trained nurses participated in this study as study assistants. Participants were divided into two groups: the intervention group received preventive treatment, including examination and assessment, foot care, and an educational program; the control group received standard care using the five pillars of DM management in Indonesia. **Results:** An equal number of men (n = 30) and women (n = 30) participated in this study. Neuropathy was noted in 76.70% and 56.70% of patients in the intervention and control groups, respectively. Furthermore, 63.30% of patients in the control group and 56.70% in the intervention group had foot deformities. The recurrence rate was lower in the intervention group (13.30%) than in the control group (33.30%). Moreover, 83.30% in the control group and 76.70% in the intervention group did not smoke. The duration of DM in both groups was >9 years (50% in the intervention and 43.30% in the control group). There were no significant differences between the two groups, with mean (SD) in age ( $t_{29} = -0.87, p = 0.389$ ), ankle-brachial index ( $t_{29} = -1.05, p = 0.144$ ), and HbA1C ( $t_{26} = -0.35, p = 0.733$ ). **Conclusions:** Prevention strategies combining examination and assessment, foot care, and educational programs can reduce ulcer recurrence in diabetic patients.

**Keywords:** Diabetic, foot ulcer, prevention, recurrence

## Introduction

In Indonesia, two studies report incidence rates of diabetic ulcer recurrence as 43% and 54.3%,<sup>[1,2]</sup> which is high compared to the global diabetic foot ulcer recurrence rate of between 4.3% and 44.4%.<sup>[3]</sup> Therefore, preventive measures to reduce ulcer recurrence in patients with Diabetes Mellitus (DM) should be established as early as possible.<sup>[4]</sup> Another study investigated the prevention of ulcer recurrence in patients with DM, including the use of a self-assessment tool, infrared temperature measurement, self-management, use of therapeutic/appropriate footwear, integrated foot care, pressure offloading, and patient education.<sup>[5-8]</sup> Other strategies for preventing ulcers in patients with DM include identifying the foot at risk, examining and inspecting the foot, and treating the foot at risk of ulcer.<sup>[7]</sup> An educational program was provided to patients with DM to prevent ulcers, including glycemic control

education and advice on diet, exercise, and medication.<sup>[8]</sup> A prevention strategy involving integrated foot care, including professional foot care, patient education, use of therapeutic footwear, and prevention of ulcer recurrence, was also applied.<sup>[9]</sup> Another study found that thermography can detect the risk for foot ulcers in patients with DM.<sup>[10-12]</sup> Many original articles and systematic reviews described strategies to prevent ulcer recurrence. Unfortunately, an effective method for avoiding ulcer recurrence has not yet been found.

Many hospitals in Indonesia have diabetic foot clinics; however, there has not been an optimal review of ulcer prevention in at-risk feet using integrated foot care strategies, such as therapeutic footwear. Almost all polyclinics still use conventional, standard strategies to prevent ulcers and recurrence using the five-pillar method based on PERKINI (Perhimpunan Endokrinologi Indonesia) from 2011.<sup>[11]</sup> PERKINI is an

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abbreviation of the Indonesian Society of Endocrinology, which stipulates the management of DM through five pillars: diet, physical exercise, medication, glucose monitoring, and education. Although the five-pillar PERKINI program is implemented nationally, the incidence of ulcer recurrence in Indonesia is still high. Nurses play a vital role in helping to prevent ulcer recurrence in diabetic patients and are actively involved in the early detection of diabetes. Nurses carry out physical examinations and assessments and provide foot care and educational programs to help prevent diabetic foot ulcers; therefore, strategies to prevent ulcer recurrence need to include nursing care. This study used a three-part combination strategy to prevent ulcer recurrence in patients with DM: (1) physical examination and assessment of the foot<sup>[9,13]</sup> using a thermograph to detect skin temperature<sup>[14]</sup>; (2) foot care; and (3) patient education. We set out to answer the following research question: How effective are strategies for preventing ulcer recurrence that include physical examination, foot care, and education programs in patients with DM? Therefore, this study aims to evaluate the effectiveness of prevention strategies in reducing the incidence of ulcer recurrence in patients with DM.

## Materials and Methods

This study employed a quasi-experimental, non-equivalent control group design to evaluate the effectiveness of a strategy for preventing ulcer recurrence in patients with DM. The study was conducted at the Kitamura Wound Clinic in Pontianak City and in-home settings in Indonesia, from August 2020 to August 2021. Based on the calculated sample size, a total of 60 participants (two groups of 30 people) were recruited. The sample size formula suggested for comparing two groups (considering  $\alpha = 0.05$ ,  $\beta = 0.95$ ,  $p1 = 0.12$ , and  $p2 = 0.54$ <sup>[21]</sup>) was calculated using G Power software analysis.<sup>[15]</sup> Both groups were recruited through convenience sampling. The inclusion criteria were recovery from ulcers for >2 weeks, absence of kidney and heart disease complications, ability to perform daily activities, and ability to cooperate. Exclusion criteria were foot infection, active foot ulcer, Charcot neuro-osteoarthropathy, chronic limb-threatening ischemia, current use of foot temperature monitoring, and severe illness or complications.

The intervention and control groups consisted of patients who had been treated at the clinic and recovered from their wounds. Individuals were identified by searching medical records, followed by the researcher contacting the person via telephone. After screening to confirm eligibility, willing participants provided written informed consent before enrolment. The 60 patients willing to participate in the study were divided into intervention and control groups. In the intervention group, patients were invited to come to the clinic if they could; patients unable to come to the clinic were visited by the researcher and received the interventions at home. In the control group, the researcher

visited the patients' houses. The intervention group received the study treatment, and in the control group, follow-up care was performed according to the standard of care provided by the healthcare provider using leaflets about the care of patients with DM using the five pillars, including ulcer prevention.

Two study assistants were trained according to the study protocol on DM foot examination, including the use of tools for foot examination, such as the thermograph, monofilament test, vascular Doppler ultrasonography, conventional foot plantar scan, diabetic foot and nail care, demographic data collection, diabetic wound assessment, and patient education. In the intervention group, patients underwent examination and evaluation of the foot, including deformity, foot care, and education. Patient education included regular blood sugar control, diet management, exercise, regular foot inspection, medication, and footwear, following the results of pressure measurements on the plantar foot. Data were collected during the 1 to 1.50 h intervention procedure. Data for the intervention group were collected once a month through examination and inspection. Foot care and education were provided at the beginning of the assessment. The patient was then followed up two times a month for up to 6 months.<sup>[13]</sup> During the study period, patients received tips on diabetic foot care, diet, exercise, and skin care with a moisturizing cream (CeraVe cream, recommended by a dermatologist) applied to the entire foot once a day, except on the soles of the feet and between the toes, medication, use of footwear according to the distribution of plantar imprint, callus removal, and stress management. Abnormal early signs in the feet, such as callus, dryness, fissures, and nail changes, and signs of ulcer, such as warmth, swelling, abnormal skin color (blue or black as an ischemic symptom), and interdigital fungal infection (tinea pedis) were identified.

During the study period, for the control group, primary DM education was conducted, including DM management, medication, diet, exercise, and a foot care booklet. The patients received follow-up care at the healthcare center. In the control group, monitoring was conducted once a month for 6 months by visiting patients at home and/or by calling and assessing foot conditions on patient-provided photographs. The treatment was discontinued in patients with ulcers, and the patients were advised to visit the wound clinic immediately.

In this study, the researchers used several procedures for data collection, including vascular Doppler ultrasonography to examine the Ankle-Brachial Index (ABI) and the monofilament test to examine neuropathic status.<sup>[16]</sup> If the sensation of a 10-g monofilament was diminished, the patient was diagnosed as having sensory neuropathy. Also included were the traditional plantar pressure devices to determine the pressure distribution in the plantar area<sup>[17]</sup> and a callus removal device. The patients were clinically

examined for structural and functional foot deformities such as claw/hammer toe, hallux rigidus, hallux valgus, bony prominence, pes cavus, pes planus, and metatarsal head.<sup>[18]</sup> Other procedures included thermography to detect skin temperature,<sup>[19]</sup> blood pressure examination, demographic data assessment, and the use of a wound classification tool. The Texas University wound classification system was used to assess the presence and absence of ulcers in the two groups.<sup>[20]</sup>

Data analysis included descriptive analysis performed to determine the characteristics of the patients with and without ulcers and the characteristic differences between patients in the two groups using a *t*-test ( $p < 0.05$ ). The Statistical Package for the Social Sciences v. 22 (SPSS Inc., Chicago, IL, USA) for Windows was used in this study.

### Ethical consideration

The Ethics Committee Board of the Institute of Nursing of Muhammadiyah Pontianak approved this study (no. 96//KEP/II).I/AU/D/2020—February 23, 2020). Patients were informed of the study objectives and provided written consent before data collection. They could refuse to participate in the study at any time without any consequences.

### Results

The number of female and male respondents in both groups was equal (13 males, 17 females) [Table 1]. Non-smoking status was 83.30% and 76.70% in the control and intervention groups, respectively. Neuropathy was noted in 76.70% and 56.70% of patients in the intervention and control groups, respectively. Furthermore, 63.30% of patients in the control group and 56.70% in the intervention group had foot deformities. This study found that the incidence of ulcer recurrence was 33.30% in the control group and 13.30% in the intervention group [Table 1]. The majority of participants have had DM for more than 9 years (50% in the intervention group and 43.30% in the control group). There were no significant differences between the two groups with regard to the mean (SD) of participants' age, ABI, and HbA1C: 62 (10.46) and 59.67 (11.48) years; 1.17 (0.24) and 1.09 (0.19); and 9.27 (2.13%) and 9.03 (2.73%), in the intervention group and control group, respectively [Table 2].

### Discussion

This study aimed to evaluate the effectiveness of a prevention strategy for reducing ulcer recurrence in patients with DM. The ulcer recurrence rate in the control group was higher than that in the intervention group. The ulcer recurrence rate was still high in the intervention group compared to the global ulcer recurrence rate of 4.30%.<sup>[3]</sup> However, compared with the incidence of ulcer recurrence in the first year after healing, predicted to be approximately 40%,<sup>[21]</sup> it was lower in both the intervention

**Table 1: Percentage distribution of participants' characteristics in the two groups**

Characteristics	Intervention <i>n</i> (%)	Control <i>n</i> (%)
Gender ( <i>n</i> )		
Male	13 (43.30)	13 (43.30)
Female	17 (56.70)	17 (56.70)
Smoking		
Yes	7 (23.30)	5 (16.70)
No	23 (76.70)	25 (83.30)
Neuropathy		
Yes	23 (76.70)	17 (56.70)
No	7 (23.30)	13 (43.30)
Foot deformity		
Yes	13 (56.70)	19 (63.30)
No	17 (43.30)	11 (36.70)
Ulcer recurrence		
Yes	4 (13.30)	10 (33.30)
No	26 (86.70)	20 (66.70)
Duration of Diabetes Mellitus (DM) (years)		
1-3	5 (16.70)	7 (23.30)
3-6	6 (20)	5 (16.70)
6-9	4 (13.30)	5 (16.70)
>9	15 (50)	13 (43.30)
History of ulcer (times)		
1	15 (50)	16 (53.30)
2	6 (20)	4 (13.30)
3	7 (23.30)	7 (23.30)
4	2 (6.70)	3 (10)
Length of ulcer recurrence in (months) from the previous ulcer		
<6	18 (60)	23 (76)
6-12	9 (30)	3 (10)
12-18	1 (3.30)	2 (6.70)
18-24	1 (3.30)	2 (6.70)
24-30	0 (0)	0 (0)
>30	1 (3.30)	0 (0)

and control groups in this study. Our study found that neuropathic conditions in the intervention group were greater than those in the control group, a major risk factor for ulcers in diabetic patients.<sup>[22]</sup> These outcomes show that a combination of prevention strategies is likely to be effective.

Ulcer recurrence is common in patients with DM. This study showed that most patients in both groups had ulcer recurrence within 6 months after healing, indicating that the ulcer recurrence rate may still be high after 1 year. This remains a concern for practitioners because it has been predicted that the ulcer recurrence rate in patients with DM after 3 years is 60% after healing and 65% at 5 years after healing.<sup>[21]</sup> Additionally, patients with DM recovering from ulcers want to prevent recurrence as much as possible; therefore, it is necessary for providers to identify other

**Table 2: Comparing clinical characteristics of the two intervention and control groups**

Variables	Mean (SD)*		95% confidence interval		df	t-test	p
	Intervention	Control	Lower	Upper			
Age (years)	62 (10.46)	59.67 (11.48)	-7.80	3.13	29	-0.87	0.389
ABI** (number)	1.17 (0.24)	1.09 (0.19)	-0.19	0.02	29	-1.05	0.144
HbA1C (%)	9.27 (2.13)	9.03 (2.73)	-1.69	1.20	26	-0.35	0.733

\* Standard deviation, \*\*Ankle-Brachial index

factors that may contribute to ulcer recurrence. Factors that cause ulcer recurrence include minor ulcers, longer duration of foot ulcers, location of previous foot ulcers, smoking, neuroischemia, irregular blood sugar control, bone infections, and elevated C-Reactive Protein (CRP) levels.<sup>[23-25]</sup> This study identified the risk factors following examination and assessment, except for the CRP because the increase in CRP can be associated with the presence of osteomyelitis and inflammation<sup>[26]</sup> and can be detected by a thermograph.<sup>[19]</sup> Prevention strategies for ulcer recurrence in patients with DM involve multiple interventions.<sup>[21]</sup> Previous studies reported that an integrated foot care program was the most effective preventive strategy for patients with DM.<sup>[27]</sup> The frequency of foot care actions also varies from once to six times a month.

Our study does not use the term “integrated foot care” because it is still not a common requirement to offer, for example, therapeutic footwear, in Indonesia. In this study, appropriate footwear and custom footwear were recommended to those in the intervention group. Another study reported that there were no significant differences in patients who received integrated foot care intervention compared to standard care to reduce ulcer recurrence in the two groups.<sup>[9,10,27]</sup> Therefore, foot care needs to be combined with other strategies. In conducting examinations and assessments of the foot area in this study, one of the strategies was to use a thermograph, which is an excellent tool for detecting an increase in the foot skin temperature. An increase in foot temperature warns the patient to be more alert to reduce their risk of ulcers.<sup>[28]</sup> Another preventive measure in foot care is the removal of callus and the use of skin moisturizers on the feet to prevent and reduce the risk of ulcers.<sup>[29,30]</sup> This study reveals that education provided to patients with DM to prevent ulcers may reduce recurrence rates. Furthermore, education for patients with DM is essential because it can help them understand their condition and be aware of self-care management to prevent complications, such as ulcers.<sup>[30]</sup>

Preventing ulcer recurrence in patients with DM should be an issue for national governments. Prevention efforts, specifically in developing countries, such as Indonesia, are essential. Archipelagic countries require adequate support facilities and infrastructure and trained professional health workers to prevent ulcer recurrence and further complications in patients with DM. The limitation of this study is that the sample was small, so future studies will

need to increase the proportion of the incidence of recurrent ulcers and the number of participants while using the same sample composition and methodology.

## Conclusion

A prevention strategy for ulcer recurrence conducted by nurses in a home care setting can significantly improve the quality of service by reducing the incidence rate. This study has brought new expectations for areas with limited resources to provide the best care to patients with DM and reduce the incidence of foot ulcers. In implementing the prevention program, a trained DM team is needed to provide knowledge and skills training to prevent ulcers and recurrence in patients with DM. For all patients with DM who have recovered from ulcers, it is essential for them to take preventive measures by implementing the strategies in the community setting. Nurses were responsible for detecting any changes in skin and foot condition, foot care, and education program. This study postulated evidence to support interventional strategies to prevent ulcer recurrence in patients with DM showing that the prevention of recurrent foot ulcers through integrated care is effective.

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## Conflicts of interest

Nothing to declare.

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