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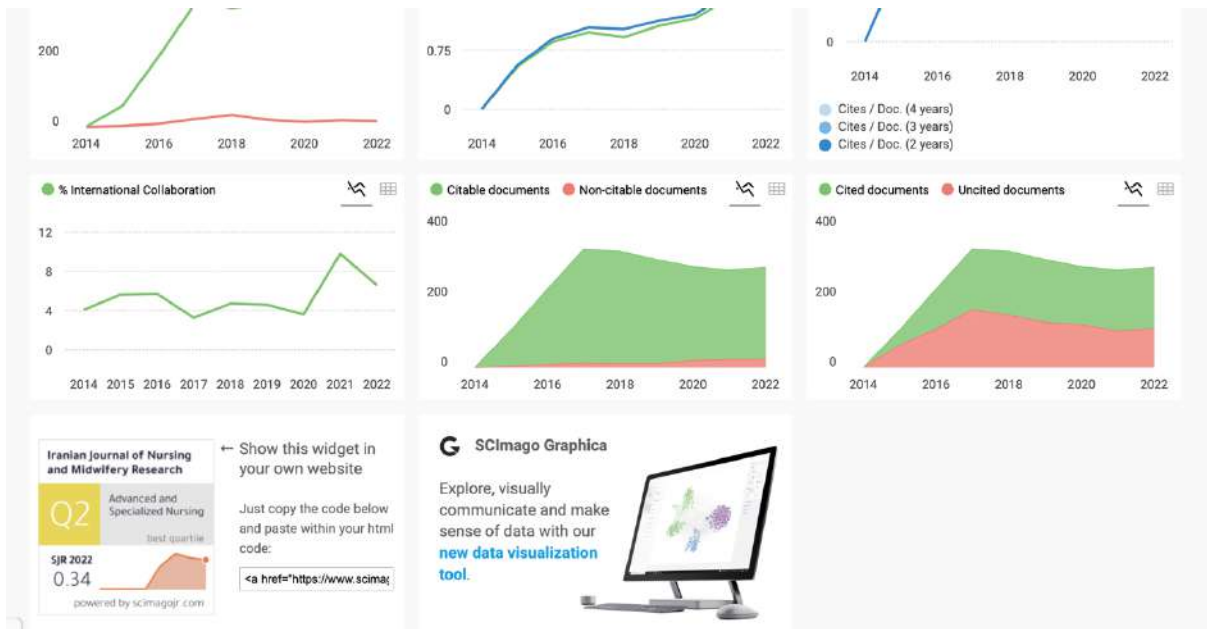
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Risk Factors of Recurrent Diabetic Foot Ulcers Based on the Delphi Method

Abstract

Background: The risk factors for recurrence are poorly understood. The purpose of study is to investigate the risk factors that contribute to the recurrence of diabetic foot ulcers. **Materials and Methods:** This is a cross-sectional study, and the two-phase Delphi method was used. A category was developed to investigate the risk factors of recurrent diabetic foot ulcers by experts. The recurrent items with risk factors were analyzed. Furthermore, the risk factor variables were clinically tested for inter-rater reliability agreement. Fourteen experts and two patients were included from February 15 to September 28, 2020, Indonesia. **Results:** There were 13 risk factors for recurrent diabetic foot ulcers. The mean authority coefficient was 0.71. The positive coefficients were 100% and 78%, respectively. The Kendall coordination coefficient was statistically significant ($p < 0.01$), and inter-rater reliability agreement was perfect (1.00). **Conclusions:** This study found some risk variables related with recurrent diabetic foot ulcers, which might serve as guidance to prevent future recurrences.

Keywords: *Diabetic foot, recurrence, risk factors*

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Introduction

According to the International Diabetes Federation, the prevalence of diabetes patients in Indonesia would rise from 7.3 million in 2011 to 19.5 million by 2021. This report ranks Indonesia as the second in Western Pacific, indicating a steady increase in diabetes patients.[1] Furthermore, diabetic foot ulcers are commonly observed among diabetes patients, with varying prevalence in different countries.[2] In Indonesia, this disease is known to be predominant in 7.3–9.1% of individuals.[3,4] A complication that often occurs in diabetes patients is amputation. According to a study, 80% of amputations are caused by diabetic foot ulcer.[5] Meanwhile, the incidence of amputation in Indonesia is around 37.5%.[6]

This disease has the risk of recurring or developing a new ulcer and also serious implications for Quality Of Life (QOL); hence, its prevention is necessary. Furthermore, recurrence can occur at the same location or a new site. Clarifying the risk factors associated with this disease is essential to inhibit a new development. These risk factors for the onset of diabetic foot ulcers have been clarified;[7] however, the determinants for its recurrence are yet to be elucidated. Thus, it is very important to be known and understood, which can ultimately prevent complication. In addition, the development of risk factors including patients is still little. Therefore, this study aims at investigating the risk factors associated with recurrence.

Materials and Methods

The study was conducted from February 15 to September 28, 2020. The Delphi method was used in this study.[8] The sample size for experts in this study was 14. The size of the panel members varies from 10 to 1000 (usually between 10 and 100) in published research depending on complexity of the problem, homogeneity (or heterogeneity) of the panel, and availability of the resources.[9] Meanwhile, the sample size for patients was two people; the alpha and power were 0.05 and 80%, respectively. According to the literature, a sample size of Cohen's kappa test of at least 2 is allowed for inter-rater agreement.[10] Furthermore, the inclusion criteria are experts and patients as participants. Experts with more than

10 years' experience in a hospital or clinic, a bachelor's or higher degree, and wound training or certificate were included. Subsequently, the patients with diabetic foot ulcers had to be ≥21 years of age, should have recurrence (the same or another location), and should have received a diagnosis of type 2 Diabetes Mellitus (DM) according to the American Diabetes Association 2013 guidelines. This diagnosis consists of glycated hemoglobin ≥6·5% and fasting blood glucose ≥126 mg/dl (7·0 mmol/l) or 2-hour plasma glucose ≥200 mg/dl (11·1 mmol/l) during an oral glucose tolerance test.[11] Patients who did not fulfill these criteria were not permitted to participate in the study. Also, informed consent was obtained from the participants and their family members. In the first phase, the questionnaire-based literature review and reference were developed using the google form application to obtain information from experts about recurrence risk factors. These questionnaires were sent by e-mail and contained the following: 1) instructions of the research background, time returned, contact information, and acknowledgment and 2) the suggestion from experts about "risk factors associated with the recurrence of diabetic foot ulcers". Moreover, this phase took place between February 15 and March 25, 2020. Based on input from experts, the questionnaires in the second phase were also developed through the google form application. These experts were obtained using previously identified variables to collect risk factors associated with recurrence. Furthermore, this instrument was structured similar to phase 1, where the risk factors' evaluation form on diabetic foot ulcer recurrence was the only difference, with a score ranging from 1 to 4 (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree). All questionnaires were sent via e-mail and between August 31 and September 28, 2020. Subsequently, two patients were used as raters to investigate the reliability agreement in a clinical setting. The questionnaires from the variable risk factors of recurrence in the second phase yielded a mean authority coefficient of 0.71. These variables included the following: 1) feet check, 2) knowledge, 3) diet pattern, 4) activity pattern, 5) foot care, 6) DM duration, 7) blood sugar value, 8) neuropathy status, 9) monofilament test check, 10) ankle-brachial pressure index examination, 11) ultrasonography assessment, 12) skin temperature, and 13) previous amputation. The questionnaire scoring included the following: 1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree. Moreover, data analysis was conducted with the IBM SPSS software (version 26.0., IBM Corp., Armonk, NY, USA). Each item was described using descriptive statistics, such as mean and standard deviation, while the Delphi method's reliability and validity were examined using expert opinion consensus and calculation of the positive predicative value. The authority coefficients (Cr) were determined by two factors, namely, the familiarity with the field (Cs) and criteria (Ca). Consequently, Cs used a value between 0.0 and 0.9[12] to determine the five degrees of familiarity, namely, very,

more, generally, less, and not familiar.[13] The terms practical experience (0.5, 0.4, and 0.3), theoretical analysis (0.3, 0.2, and 0.1), domestic and foreign references (0.1, 0.1, and 0.1), and subjective judgement (0.1, 0.1, and 0.1) were used to divide Ca into more, medium, and less. In addition, the degree of expert authority was expressed by Cr:Cr = (Ca + Cs)/2, while coordination was altered based on the variable and coordination coefficients.[8] We used two indicators to evaluate the degree of coordination among expert opinions: the Coefficient of Variation (CV) and the coordination coefficient (Kendall's W). To calculate Kendall's coefficient, a value between 0 and 1 was used, where a higher denomination indicates better coordination. Furthermore, Cohen's Kappa was used to analyze the patient's inter-rater reliability agreement. The level of significance was set at $p < 0.05$.

Ethical considerations

This study was approved by the Ethics Review Committee of STIK Muhammadiyah Pontianak, West Kalimantan Province (Ethical Approval Number: 62/II.I.AU/KET. ETIK/II/2020, and Date: February 2nd, 2020). Also, participation was voluntary, anonymous, and confidential. All participants received the consent document through the google form application and were requested to respond with a fill and return, indicating their readiness to participate in the study.

Results

In this study, the mean(SD) age of experts and the total working time were 39.40 (1.40) and 10.90 (1.60) years, respectively, with five having worked for >10 years. Furthermore, among these experts, one had a Ph.D. in medical surgery, three had a doctorate, two had a masters, and three possessed a bachelor's degree. Five of these individuals were from the wound clinic in West Kalimantan, two from the Middle Java's wound clinic, and one each from the wound clinics in Jakarta, Aceh, West Sulawesi, and East Kalimantan. The mean working time and age of the second Delphi experts were 11.20 (1.70) and 39.20 (1.50) years, respectively. Also, one expert had a surgeon's medical doctorate, three had a doctorate, and two and five had a master's and bachelor's degree. The positive coefficient was 100% (14 experts) in the first phase and 78% in the second. Table 1 shows that the mean authority coefficient in the second phase was 0.71, while Table 2 illustrates that the mean variable coefficient was 0.41. Subsequently, the coordination coefficient in the second phase was 0.177 (X^2 = 25.359, df = 13, p = 0.02) with a perfect inter-rater reliability agreement of 1.00.

Discussion

This is the first study that aims to investigate the risk factors associated with recurrence using experts' opinion and their experience. Moreover, recurrence patients were

Table 1: Coefficient expert of authority of variables

Variables	Ca*	Cs**	Cr***
Check feet every day	0.58	0.87	0.72
Check using monofilament test	0.57	0.85	0.71
Check ankle-brachial pressure index	0.60	0.85	0.72
Check using ultrasonography	0.55	0.85	0.70
Amputation previous	0.62	0.82	0.72
Knowledge wound healing	0.62	0.85	0.73
Diet pattern	0.61	0.81	0.71
Activity pattern	0.61	0.77	0.69
Footcare	0.64	0.75	0.69
Duration of DM****	0.63	0.79	0.71
Blood sugar	0.62	0.83	0.73
Neuropathy status	0.62	0.75	0.69
Skin temperature	0.61	0.84	0.73
Mean	0.61	0.82	0.71

*Criteria, **Familiarity with the field, ***Authority coefficients, ****Diabetes mellitus

Table 2: Coefficients and significance of variables

Variables	Mean (SD)*	CV**
Check feet every day	7.00 (4.00)	0.57
Check using monofilament test	8.00 (3.00)	0.38
Check ankle-brachial pressure index	8.00 (3.00)	0.38
Check ultrasonography	7.00 (4.00)	0.57
Knowledge wound healing	8.00 (3.00)	0.38
Diet pattern	7.00 (4.00)	0.57
Activity pattern	6.50 (4.50)	0.69
Footcare	7.50 (3.50)	0.47
Duration of Diabetes Mellitus (DM)	9.00 (2.00)	0.22
Blood sugar	9.00 (2.00)	0.22
Skin temperature	6.50 (4.50)	0.69
Amputation previous	7.50 (3.50)	0.47
Neuropathy status	9.00 (2.00)	0.22
Mean	7.80 (3.10)	0.41

*Standard deviation, **Coefficient of variation

used as participants, with different variables between the first and second phases, as indicated by the experts based on their experiences. The variables were also consistent with the patient's opinions. Experts with a bachelor's or higher degree and >10 years working experience in a hospital or clinic were questioned. These individuals were familiar with the study content and had in-depth knowledge of diabetic foot ulcers. The representation of experts was acceptable, and the participants included diabetes patients.

In reliability, the present study demonstrated positive coefficients indicating that experts were interested and optimistic about the study, with a high positive response. The literature indicated that a response rate of 60% or above was high positive response.[12] Interestingly, our study demonstrated that the authority coefficient was high. In line of the literature, if a coefficient is >0.7, the result of the inquiry was scientific and representative.[14] Furthermore, the coefficient of variance was <3 and the mean values were ≥4 and ≤15, respectively, thus indicating that better coordination and a high index could be maintained.[15] Finally, the coordination coefficient in the second phase was consistent with good coordination. As a result, selecting qualified experts from various specialties and geographical distributions was critical to the success of the Delphi approach.[9]

Our study demonstrated that there were some recurrent diabetic foot ulcer risk factors including neuropathy status, blood sugar, previous amputation, monofilament test, Ankle Brachial-Pressure Index (ABPI), foot care, duration of diabetes, activity and dietary pattern, wound healing knowledge, skin temperature, and assessment using ultrasonography.

Neuropathy status, blood sugar, and previous amputation were risk factors of recurrent diabetic foot ulcer, thus similar with previous studies.[7,16] A previous study reported that the duration of diabetes increased with the risk of diabetic foot ulcer recurrence.[7] Education about pre-ulcerative signs and foot care play an important role in the prevention of diabetic foot ulcers.[17] Screening such as monofilament test ABPI and ultrasound are important to early detection peripheral arterial ischemia in diabetic foot ulcer.[17] Checking the skin temperature, which is a feasible procedure, aids the prevention of recurrence.[18] The last variables are activity and dietary pattern. The American Diabetes Association recommended physical activity and management of food on diabetes to prevent complication, particularly diabetic foot ulcer.[19]

Generally, all variables were consistent with previous studies. Hence, they can be used to investigate risk factors associated with the recurrence of diabetic foot ulcers by health care professionals (clinicians, nurses, and others). The recurrence of diabetic foot ulcers was related to several risk factors that could be prevented by involving the patients and their families. Consequently, the patient's QOL is improved.

The limitation of the current study was that the number of participants in the inter-rater reliability agreement test was relatively small. Thus, generalizability may be limited. Future research is needed to evaluate these risk factors to recurrent diabetic foot ulcer patients with larger samples in clinical setting.

Conclusion

This study demonstrated that there are several risk factors associated with recurrent diabetic foot ulcers including neuropathy status, blood sugar, previous amputation, monofilament test, ABPI, foot care, duration of diabetes, activity and dietary pattern, wound healing knowledge, skin temperature, and assessment using ultrasonography. These

variables could serve as guidelines to prevent recurrence in the future that will improve quality of nursing of diabetic foot ulcer patients.

Conflicts of interest

Nothing to declare.

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