KORESPONDENSI IRANIAN NURSING AND MIDWIFERY JOURNAL

1. Submitted to the journal “Iranian Nursing and Midwifery Journal” (23-Oct-2021)
2. First revision (2-Nov-2021)
3. Second revision (22 Feb 2022)
4. Third revision (17 March 2022)
5. Fourth revision (27 June 2022)
6. Fifth revision (24 August 2022)
7. Sixth revision (14 May 2023)
8. Seventh revision (10 July 2023)
9. Paper accepted for publication (10-August-2023)
10. Manuscript published (January-Pebruary 2024)

1. Submitted to the journal “Iranian Nursing and Midwifery Journal” (23-Oct-2021)

Iranian Journal of Nursing and Midwifery Research <editor@ijnmrjournal.net> Sab, 23 Okt 2021, 21.46

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Iranian Journal of Nursing and Midwifery Research has received your manuscript entitled "Risk Factors of Recurrent Diabetic Foot Ulcers Based on the Delphi Method" for consideration for publication. The reference number for this manuscript is "ijnmr_391_21". Kindly quote this in future correspondences related to this manuscript.

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2. First Revision (2 Nov 2023)

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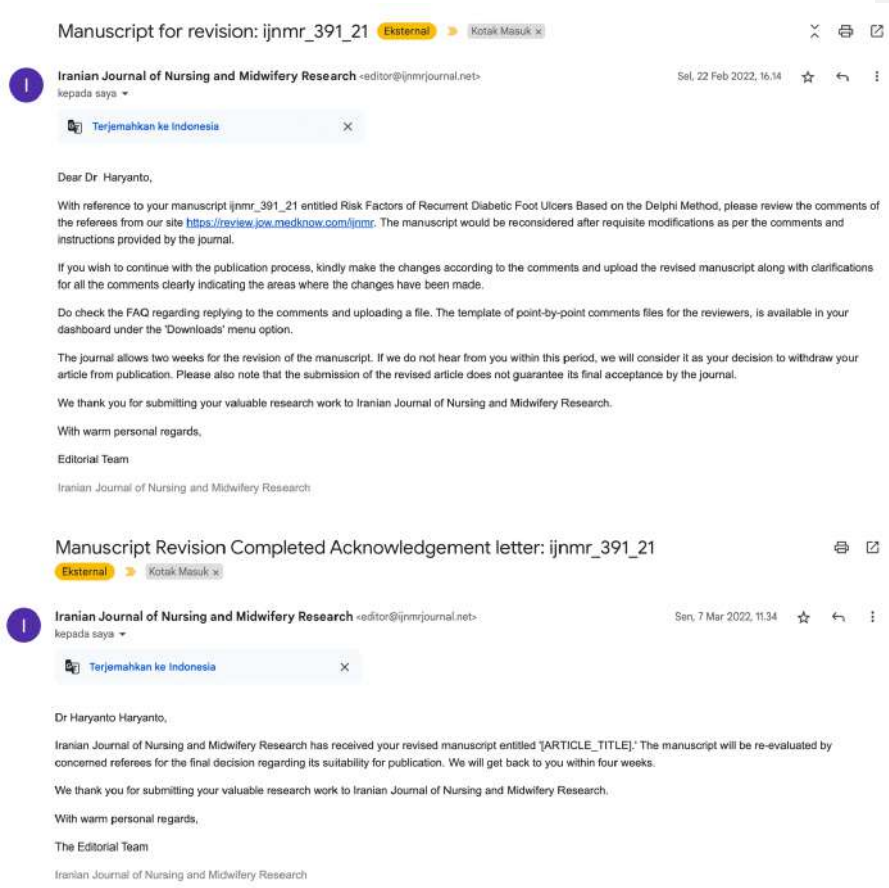
3. Second Revision (22 February 2022)



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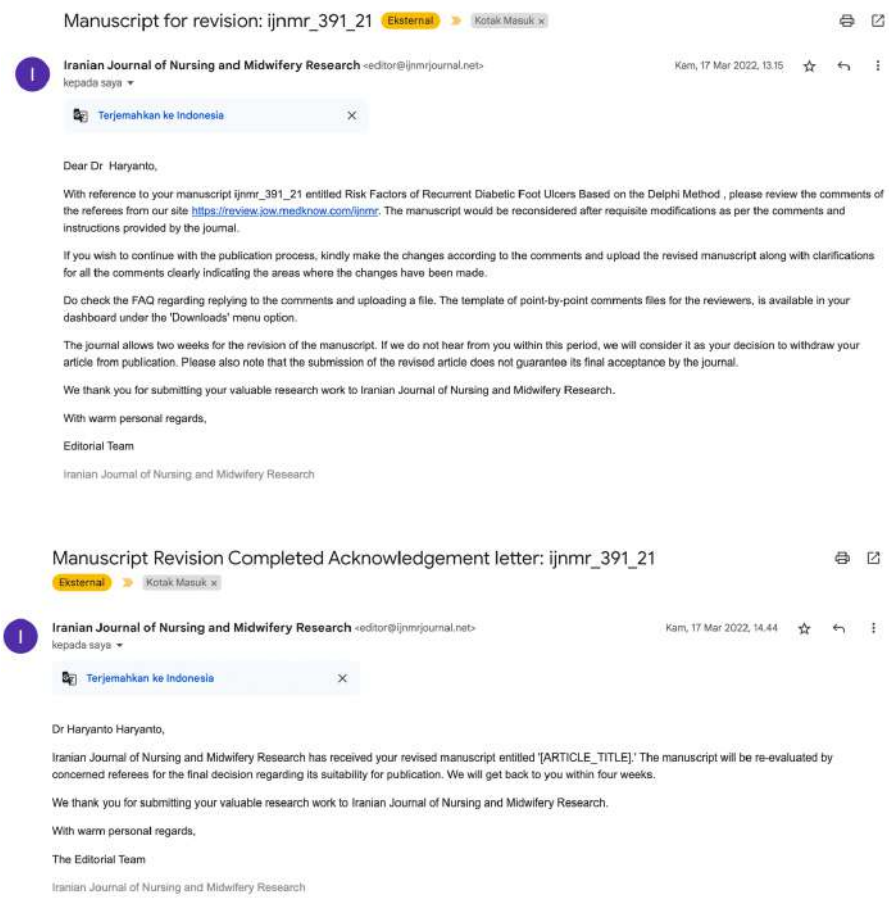
4. Third revision (17 March 2022)



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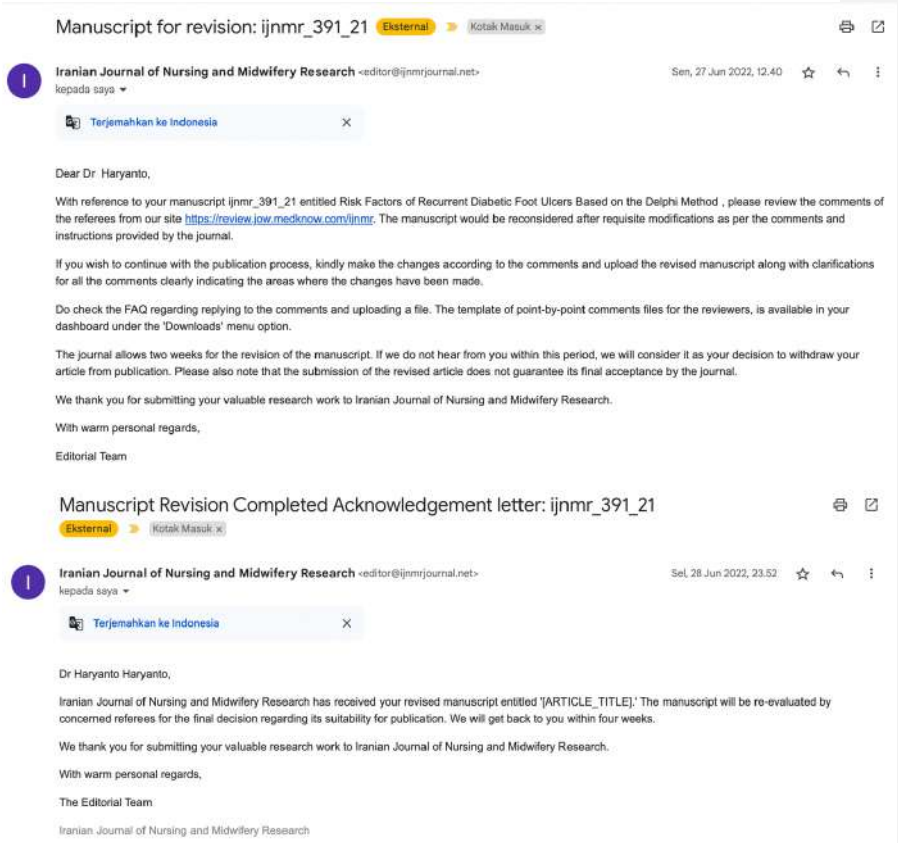
5. Fourth Revision 27 June 2022



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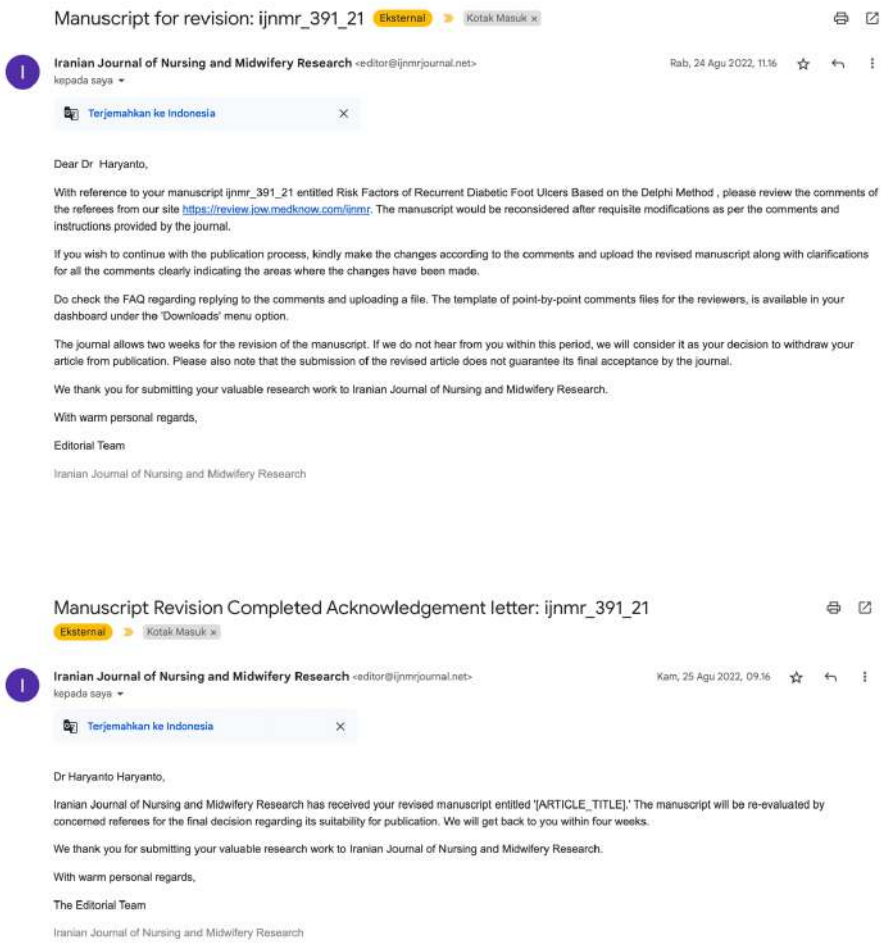
6. Fifth revision (24 August 2022)



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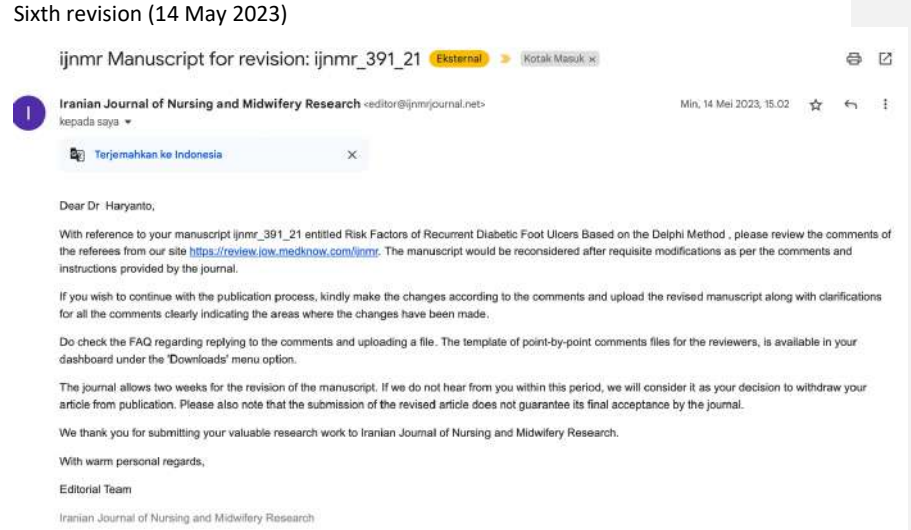
7. Sixth revision (14 May 2023)



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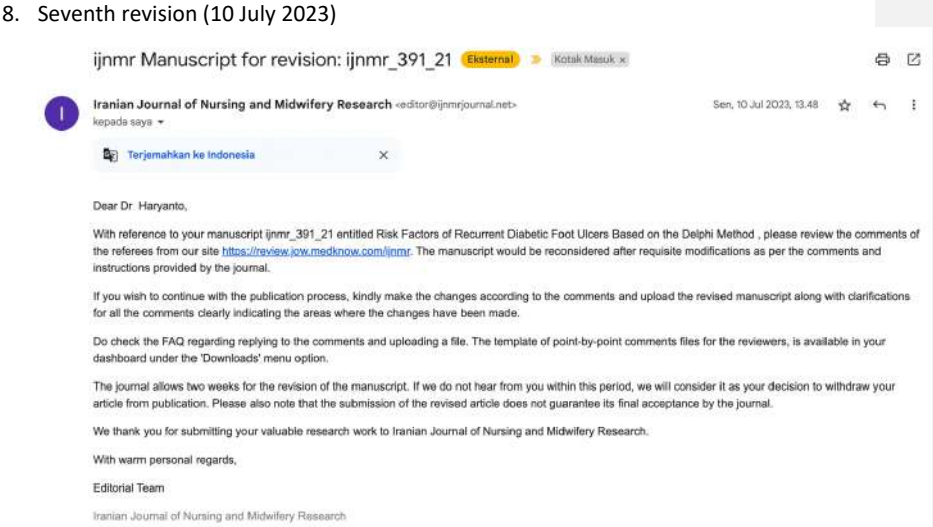
8. Seventh revision (10 July 2023)



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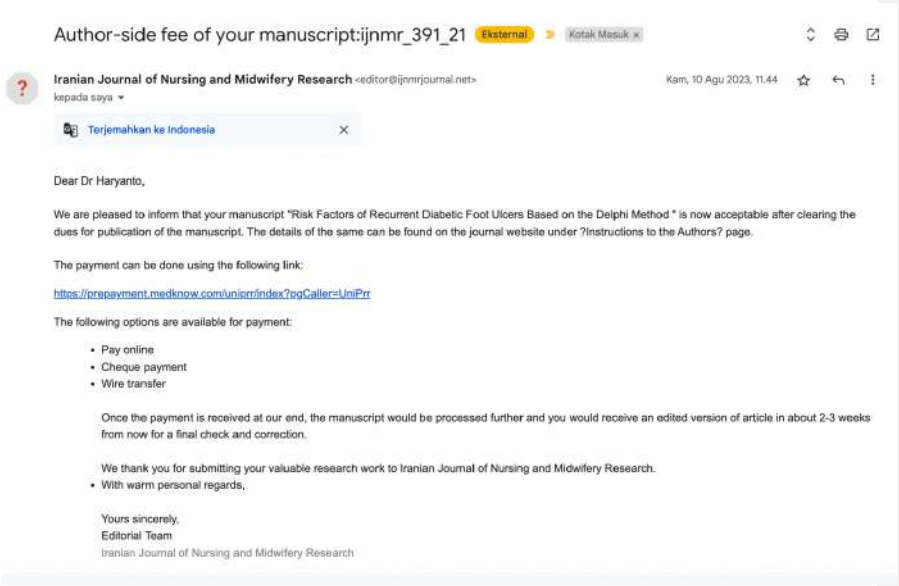
9. Paper accepted for publication (10-August-2023)



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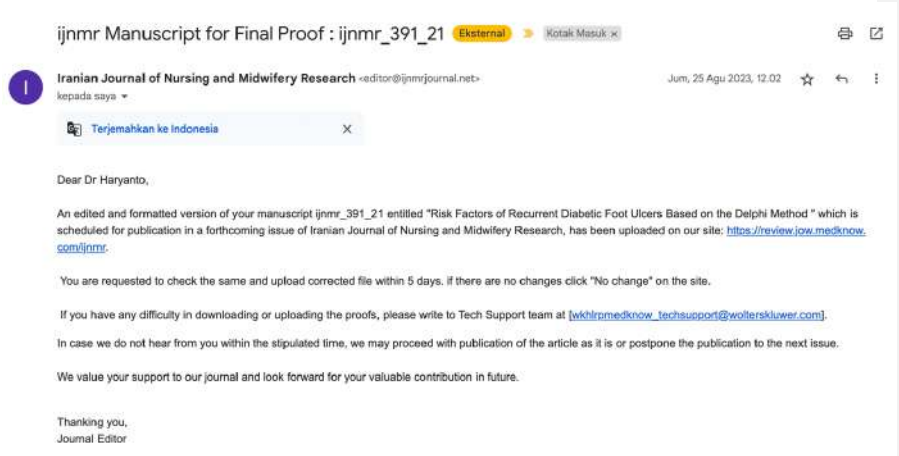

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We value your support to our journal and look forward for your valuable contribution in future.

Thanking you,
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Lampiran Revisi dan Koreksi

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After greeting

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With best regards

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Commented [p1]: The name of the study is incorrect, please correct it. A quasi-experimental or interventional study should be provided

Commented [p2]: Mention type of study

Deleted: cross-sectional,

Commented [p3]: Please describe how determine sample size

Commented [p4]: Mention place of study

Commented [p5]: Name the country and year of study

Commented [p6]: Determine the sample size and mention the criteria for entering and leaving the samples Criteria

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

Abstract

Background: Risk factors of recurrence have not been much elucidated. Therefore, this study aims at investigating the risk factors involved in the recurrence of diabetic foot ulcers. **Materials and methods:** This study was divided into two phases, firstly is, the development of a category used to investigate the risk factors of recurrent diabetic foot ulcers by experts. Secondly phase is, the development of the recurrent items risk factors using the Delphi method. Finally, all the risk factor variables were clinically tested for inter-rater reliability agreement. **Results:** There were thirteen list risk factors for recurrent diabetic foot ulcers. Mean authority coefficient was 0.71. Positive coefficients were 100% and 78% respectively. Kendall coordination coefficient was statistically significant (χ^2 test, $P < 0.01$), and inter-rater reliability agreement was perfect (1.00). **Conclusions:** This study demonstrated that there were several risk factors associated with recurrent diabetic foot ulcers. Therefore, these variables could serve as guidelines to prevent recurrence in the future.

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Commented [a8]: Sample size - year - place - be mentioned

Keywords: *Diabetic foot, recurrence*, *risk factors*

Introduction

According to the International Diabetes Federation, the prevalence of diabetes patients in Indonesia would rise from 10.3 million in 2017 to 10.7 million by 2045.[1] This report ranks Indonesia as the 6th globally, indicating a steady increase in diabetes patients. 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 7.3-24% of individuals.[3] According to a study, these individuals have a 10-20 times risk of amputation compared to non-diabetics,[4] with an incidence of 25% in Indonesia.[5]

This disease has the risk of recurring or developing a new ulcer and also serious implications for 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,[6] 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 patient is still little. Therefore, this study aims at investigating the risk factors associated with recurrence.

Materials and Methods

Study was conducted February 15th- September 28th, 2020. The Delphi method was used in this study, with the inclusion of 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, had recurrence (the same or another location), and received a diagnosis of type 2 DM according to the American Diabetes Association 2013 guidelines. This diagnosis consists of glycated haemoglobin ≥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.[7] 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 email and contained: 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 similarly to phase one, where the risk factors' evaluation form on diabetic foot ulcer recurrence was the only difference, with a score ranging from 1-4 (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree). All questionnaires were sent via email 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: 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: 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 0.0-0.9[8] to determine the five degrees of familiarity, namely very, more, generally, less, and not familiar.[9] 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] The Kendall's concordance coefficient was also used to reflect the coordination level of experts' opinion with a value between 0 and 1, where a higher denomination indicates a better coordination. Furthermore, Cohen's Kappa was used to analyse 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 age of experts and total working time was 39.4±1.4 and 10.9±1.6 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 11.2±1.7 and 39.2±1.5 years, respectively. Also, one expert had a surgeon's medical doctorate, three had a doctorate, while 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 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 expert's opinion and their experience. Moreover, recurrence patients were 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.

Reliability

First, positive coefficients indicated that experts were interested and optimistic about the study, with a high positive response rate of 60% or above.[10] Second, the literature demonstrated that these individuals could be considered of high authority if a coefficient > 0.7 was obtained. Third, the variable coefficient mean had a high concentration of expert suggestions. These retained literature suggestion items should have a score >3.5. (11) Finally, the coordination coefficient in the second phase was consistent, hence choosing appropriate experts was the key to a successful Delphi method. [11]

Recurrent diabetic foot ulcers risk factors

Our study demonstrated that there some recurrent diabetic foot ulcers 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 factor of recurrent diabetic foot ulcer. Thus, similarly with previous study.[6],[12] A previous study reported that the duration of diabetes increased with the risk of diabetic foot ulcer recurrence.[6] Education about pre-ulcerative signs and foot care play an important role in the prevention of diabetic foot ulcers.[13] Screening such as monofilament test ABPI and ultrasound are important to early detection peripheral arterial ischemia in diabetic foot ulcer.[13] Checking skin temperature, which is a feasible procedure, aids the prevention of recurrence.[14] 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.[15]

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 professional (clinicians, nurses and others). However, the current study has limitation. Participant in inter-rater reliability agreement test was relatively small. Thus, generalizability may be limited.

Implication for clinical settings

The recurrence of diabetic foot ulcers was related to several risk factors, which could be prevented by involving the patients and their families. Consequently, the patient's quality of life is improved.

Conclusion

This study demonstrated that there are several risk factors associated with recurrent diabetic foot ulcers. Therefore, these variables could serve as guidelines to prevent recurrence in the future that will improve quality of nursing of diabetic foot ulcer patients.

Commented [a9]: Conclusion Revision in three separate paragraphs Dedicate the first paragraph to a summary of the findings and apply the second paragraph to the results and suggest the third paragraph for further research in this field.

References

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1. Federation International Diabetes. IDF Diabetes Atlas. Ninth. 2019.
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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

DM; diabetes mellitus, Cr; authority coefficients'; familiarity with the field, Ca; criteria

Table 2. Coefficients and significance of variables

Variables	M±SD	CV
Check feet every day	7.0±4.0	0.57
Check using monofilament test	8.0±3.0	0.38
Check ankle-brachial pressure index	8.0±3.0	0.38
Check ultrasonography	7.0±4.0	0.57
Knowledge wound healing	8.0±3.0	0.38
Diet pattern	7.0±4.0	0.57

Activity pattern	6.5±4.5	0.69
Footcare	7.5±3.5	0.47
Duration of DM	9.0±2.0	0.22
Blood sugar	9.0±2.0	0.22
Skin temperature	6.5±4.5	0.69
Amputation previous	7.5±3.5	0.47
Neuropathy status	9.0±2.0	0.22
Mean	7.8±3.1	0.41

M, mean, SD, standard deviation, CV, coefficient of variation

Dear author(s),

After greeting

Please correct the following item:

With best regards

Editorial team

First page

Kindly note that the first page in your manuscript is not based on IJNMR template. Please refer to: https://nm.mui.ac.ir/fa/ijnmr/format for further information. Send first page with the following format: Word 97- Document

Article

Your article cannot be reviewed as original article. If you like, modify your article and submit that as a short communications article.

Reviewers' comments

These risk factors are specified in other articles. Many studies have reported risk factors in any way. The present topic did not require the use of the Delphi technique, as the result is clear. The writing is very poor.

The article is repetitive and it doesn't contain anything new for journal readers. Please see below a list of some articles that might be related to your manuscript under review and use them as necessary:

- Risk factors for diabetic foot ulcer recurrence: A prospective 2-year follow-up study in Egypt
- Risk factors for the recurrence of diabetic foot ulcers among diabetic patients: a meta-analysis
- Risk Factors for Recurrent Diabetic Foot Ulcers
- Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup
- Incidence and Risk Factors of Diabetic Foot Ulcer: A Population-Based Diabetic Foot Cohort (ADFC Study)—Two-Year Follow-Up Study
- Risk of diabetic foot ulcer and its associated factors among Bangladeshi subjects: a multicentric cross-sectional study
- Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup
- The Complexity of Diabetic Foot Management: From Common Care to Best Practice. The Italian Expert Opinion by Delphi Survey

In all sections of the article

1. Please strengthen the different sections of the article (especially the introduction, discussion and application of the results) concerning the journal scope (nursing or midwifery).
2. Please integrate the separate paragraphs together all through the article.

Abstract

1. Arrange abstract sections as the following order

Background, Materials and Methods, Results, Conclusions, Keywords
2. Abstract should not exceed 150 words

Materials and Methods

1. Materials and Methods does not need separate sections (please combine Separate sections)
2. Please add the year of the study at the beginning of the materials and methods.

Ethical considerations

1. Add the Ethical considerations after the Materials & Methods (add ethics committee code and date)

Discussion

1. Please mention limitations of the study clearly at the end of discussion.

References

1. When you need to mention an old reference, use references preferably up to 5-10 years old.
2. The references in the article should be written according to the format of the journal ((References should be numeric))
3. References should not exceed 15 references

Tables and figures

1. Move the tables and the figure to the end of references
2. If you have downloaded figures, send it copyright

3. All figures in the article must have a title and number

4. The number of the tables should not exceed 2 numbers.

please notice that if the number of the words exceeds the regular number should not exceed 1000 words), you should pay extra US $ 50 for each 600 words(each diagram or figure equals 300 extra words)

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For further information.

Reply to the reviewers' comments

Reviewer Number	Original comments of the reviewer	Reply by the author(s)	Changes done on page number and line number
MS2	It would have been better if this article had talked more about the risk factors associated with recurrent diabetic foot ulcers. To be able to use its results as a guideline to prevent future recurrence of the disease, which improves the quality of care for diabetic foot ulcers. But in this article, the focus was on the Delphi members and the Delphi method, and very little attention was paid to the recurrence results	Thank you for your kind reminders for improving our manuscript. We revised and added more about the recurrence in the results and discussion	The results: Page 6-7, line 146-164 Discussion: Page 7-9, line 167-217
toghyani	In the introduction, please also talk about the technique used; why did you use the Delphi technique? What are the benefits of using this technique? And...	Thank you for your kind reminders. We revised and added as your request in introduction	Page 2-3, line 51-72
asus	The type of study should be given	Thank you for your kind reminders. Thank you for your kind reminders. We added Delphi technique in abstract	Page 1, line 7
toghyani	Unknown field code changed	Thank you for your nice reminders. We revised	Page 2, line 43

toghyani	Unknown field code changed	Thank you for your nice reminders. We revised	Page 2, line 47
asus	Sample size - year - place - be mentioned	Thank you for your kind reminders. We added as your suggestion.	Page 1, line 7-13
MS2	You can use the ‹Delphi Method› as another keyword.	Thank you for your nice reminder. We added Delphi method as keyword	Page 1, line 27
toghyani	Unknown field code changed	Thank you for your nice reminders. We revised	Page 2 line 43
toghyani	Unknown field code changed	Thank you for your nice reminders. We revised	Page 2 line 47
MS2	The introduction is short, at least one more paragraph should be added.	Thank you for your nice reminders. We added as your suggestion. We added new paragraph about prevalence, impact of recurrence, Delphi method (what, why and advantage)	Page 2-3, line 51-72
MS2	Please write the “Materials and Methods” in separate paragraphs	Thank you for your kind reminders. We revised and separated between materials and methods	Materials: Page 3, line 75-91 Methods: Page 4, line 92-136
toghyani	Check speliing and grammar	Thank you for your kind reminder. We revised	Page 3, line 89
MS2	The role of patients in this section is not clearly stated.	Thank you for your kind reminder. As we mentioned in materials and methods section. To test inter-rater agreement, we used diabetic patients. Therefore, in the result was added.	Page 6, line 154-156
MS2	It is suggested that in addition to Delphi method and data of this technique, data related to recurrence factors should also be mentioned.	Thank you for your suggestion to improve our manuscript. We revised and added Delphi method and data of this technique. Also, data related to recurrence	Page 6, line 167-187

MS2	The discussion is written in line with the data on diabetes recurrence.	Thank you for your nice reminders. We revised and added more data on diabetes recurrence in discussion section	Page 7, line 175-217
MS2	Delete this title	Thank you for your nice reminder. We deleted this title	Deleted
MS2	only this!!!! These data should be statistically presented in the results section.	Thank you for your kind reminders. We revised and presented data statistically. We presented these results because had high score statistically.	Page 6, line 158-160
MS2	This section should be given in the discussion section with more details and comparison of each result with similar and contradictory articles.	Thank you for your nice reminders. We revised discussion section with more detail and comparison of each similar and contradictory article	Page 8-9, line 185-219
toghyani	Check speliing and grammar	Thank you for your nice reminders. We checked	
MS2	What was the reason for this limitation? What is your suggestion for this limitation?	Thank you for your kind reminder. We revised and added several limitations. Then, we added our suggestion for the limitation in future	Page 9, line 219-225
MS2	In this article, it is better to talk more about family, patient, quality of life, and causes of diabetes recurrence.	Thank you for your kind reminders. We revised and added role of health providers, medical and nurses to prevent recurrence. Also, role of patient and their family to reduce and prevent recurrence with increasing knowledge about wound healing and skin temperature on foot, and control blood sugar regularly.	Page 9, line 228-233

asus	Conclusion Revision in three separate paragraphs Dedicate the first paragraph to a summary of the findings and apply the second paragraph to the results and suggest the third paragraph for further research in this field.	Thank you for your nice reminder. We revised conclusion in three separate paragraphs. First paragraph one, we added the summary of finding. Second paragraph, we added the result of finding. Finally, third paragraph we added suggestion in future	Page 10, line 236-245
asus	Bring a new reference 2022	Thank you very much for your nice reminders. We revised using some new references	Page 11, line 262-338
toghyani	Unknow field code changed	Thank you very much for your nice reminders. We revised	Page 11, line 262
MS2	In the results section, refer to the data from this table.	Thank you for your kind reminder. We revised and added these data in result section	Page 6, line 158-159
toghyani	Table 1	Thank you very much for your nice reminders. We revised	Page 15, line 378
toghyani	Table 2	Thank you very much for your nice reminders. We revised	Page 16, line 399

Dear author(s)

After greeting

Please revise the manuscript according to reviewers' comments as the followings using the track change system. If you do not agree with the reviewer's comment, please mention that in the comment box. Do not remove the comments and track changes in the comment file and upload it as the comment file in the system. Then, accept the track changes and remove omments and upload it as the final revised article file

You should use the track change system in your comment file when you answer the reviews comments

This cross-sectional, one-group, pre-post-teaching study was carried out on 60 first year nursing students from a professional teaching institute in Maharashtra A non-probability convenience sampling technique was used for this study. Before initiating the study, students were explained about the study's procedures and objectives, and then consent was taken from all the participants. Those who were not willing to participate were exempted.

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Commented [p13]: Please describe how determine sample size

Commented [p14]: Mention place of study

Commented [p15]: Name the country and year of study

Commented [p16]: Determine the sample size and mention the criteria for entering and leaving the samples
Criteria

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With best regards

Editorial team

Editorial team's comments:

In all sections of the article

3. Arrange article sections as the following order

Introduction, Materials and Methods, Ethical considerations, Results, Discussion, Conclusion, References, Tables

4. Remove italics and bolded from the word and sentences
5. Remove dent from the begging of paragraph
6. Please integrate the separate paragraphs together all through the article.
7. Please write what the abbreviation stands for, if appeared in the text for the first time.

Before the abbreviations, the first letter of each word should be written in capital letters
For example: Iranian Journal of Nursing and Midwifery Research (IJNMR)

8. Please mention mean (SD) Before reporting their values
9. In cases when p=0.000 replace it with p<0.001 all through the article.
10. Please integrate the separate paragraphs together all through the article.
11. Except p-values, round numbers after point up to two digits all through the article and tables consistently. If the second digit after point is zero, add 0 , for example, 5.20.

Abstract

3. Arrange abstract sections as the following order

   Background, Materials and Methods, Results, Conclusions, Keywords
4. Abstract should not exceed 250 words
5. Results of statistical tests (if significant for T, F .....)and df and relevant p values should be mentioned the result of the abstract and the article: for examples:

($F_{1,67}$=1089, p<0.001).

(t_{54}=2.39,p=0.01)

(χ^2=15.79, df=1, p<0.001)

6. Check your key words in mesh

Introduction

Mention the introduction in 2 or 3 paragraphs

Materials and Methods

1. Please add the year of the study at the beginning of the materials and methods.
3. sections)
4. Please mention how the sample size was calculated? (Provide power, Sig,...). The formula is not needed to be written. Write the exact values and all components of the formula. For example: sample size was calculated according to power analysis with z1=..., z2=..., r=... ()
5. Please write the type of the study at the beginning of the methods.
6. Please provide complete name and the manufacturer details of the SPSS

Ethical considerations

2. Add the Ethical considerations after the Materials & Methods (add ethics committee code and date)

Discussion

2. Please combine the limitation section with the end of the discussion. (research limitation does not need a separate section)

References

4. When you need to mention an old reference,use references preferably up to 5-10 years old.

Tables

1. Please Cite the number of tables in the article sequentially(first cite the number of 1 and then 2,3,4...)
2. Avoid using mean +- SD but use mean(SD) in a unique column
3. Avoid mentioning percentage in a separate column. Please report that in a unique column in parenthesis.N(%)
4. Please put the statistics in the head of columns in all tables. For example: Mean (SD) or N(%).
5. Please expand the abbreviations under the table.
6. First report the statistical test results (such as F) and then df and then p-values.
7. Please integrate mean and standard deviation's columns together, for example: mean (sd) all through tables.

Figure.

1. if you have downloaded this figure, send it copyright

Reviewers' comments: as the followings

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Thanks the authors for their attempts to preparing the article; there is some problem about the article that should be considered before publication:

1. **It is better to use newer references, preferably in the last 5 years.**
2. **In the introduction, please also talk about the technique used; why did you use the Delphi technique? What are the benefits of using this technique? And...**

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

Commented [M217]: It would have been better if this article had talked more about the risk factors associated with recurrent diabetic foot ulcers. To be able to use its results as a guideline to prevent future recurrence of the disease, which improves the quality of care for diabetic foot ulcers. But in this article, the focus was on the Delphi members and the Delphi method, and very little attention was paid to the recurrence results.

Abstract

Background: Risk factors of recurrence have not been much elucidated. Therefore, this study aims at investigating the risk factors involved in the recurrence of diabetic foot ulcers. **Materials and methods:** This study was divided into two phases, firstly is, the development of a category used to investigate the risk factors of recurrent diabetic foot ulcers by experts. Secondly phase is, the development of the recurrent items risk factors using the Delphi method. Finally, all the risk factor variables were clinically tested for inter-rater reliability agreement. **Results:** There were thirteen list risk factors for recurrent diabetic foot ulcers. Mean authority coefficient was 0.71. Positive coefficients were 100% and 78% respectively. Kendall coordination coefficient was statistically significant (χ^2 test, $P < 0.01$), and inter-rater reliability agreement was perfect (1.00). **Conclusions:** This study demonstrated that there were several risk factors associated with recurrent diabetic foot ulcers. Therefore, these variables could serve as guidelines to prevent recurrence in the future.

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Commented [a19]: Sample size - year - place - be mentioned

Keywords: *Diabetic foot, recurrence, risk factors*

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You can use the ‘Delphi Method’ as another keyword.

Introduction

According to the International Diabetes Federation, the prevalence of diabetes patients in Indonesia would rise from 10.3 million in 2017 to 10.7 million by 2045.[1] This report ranks Indonesia as the 6th globally, indicating a steady increase in diabetes patients. 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 7.3-24% of individuals.[3] According to a study, these individuals have a 10-20 times risk of amputation compared to non-diabetics,[4] with an incidence of 25% in Indonesia.[5]

This disease has the risk of recurring or developing a new ulcer and also serious implications for 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

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disease is essential to inhibit a new development. These risk factors for the onset of diabetic foot ulcers have been clarified,[6] 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 patient is still little. Therefore, this study aims at investigating the risk factors associated with recurrence.

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Materials and Methods

Commented [M222]: Please write the " **Materials and Methods"** in separate paragraphs

Study was conducted February 15th- September 28th, 2020. The Delphi method was used in this study, with the inclusion of 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, had recurrence (the same or another location), and received a diagnosis of type 2 DM according to the American Diabetes Association 2013 guidelines. This diagnosis consists of glycated haemoglobin ≥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.[7] 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 email and contained: 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

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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 similarly to phase one, where the risk factors' evaluation form on diabetic foot ulcer recurrence was the only difference, with a score ranging from 1-4 (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree). All questionnaires were sent via email 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: 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: 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 0.0-0.9[8] to determine the five degrees of familiarity, namely very, more, generally, less, and not familiar.[9] 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] The Kendall's concordance coefficient was also used to reflect the coordination level of experts' opinion with a value between 0 and 1, where a higher denomination indicates a better coordination. Furthermore, Cohen's Kappa was used to analyse the patient's inter-rater reliability agreement. The level of significance was set at $p < 0.05$.

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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

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In this study, the mean age of experts and total working time was 39.4±1.4 and 10.9±1.6 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 11.2±1.7 and 39.2±1.5 years, respectively. Also, one expert had a surgeon's medical

doctorate, three had a doctorate, while 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 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.

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Discussion

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

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Reliability

First, positive coefficients indicated that experts were interested and optimistic about the study, with a high positive response rate of 60% or above.[10] Second, the literature demonstrated that these individuals could be considered of high authority if a coefficient > 0.7 was obtained. Third, the variable coefficient mean had a high concentration of expert suggestions. These retained literature suggestion items should have a score >3.5. (11) Finally, the coordination coefficient in the second phase was consistent, hence choosing appropriate experts was the key to a successful Delphi method.[11]

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Recurrent diabetic foot ulcers risk factors

Our study demonstrated that there some recurrent diabetic foot ulcers 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 factor of recurrent diabetic foot ulcer. Thus, similarly with previous study.[6],[12] A previous study reported that the duration of diabetes increased with the risk of diabetic foot ulcer recurrence.[6] Education about pre-ulcerative signs and foot care play an important role in the prevention of diabetic foot ulcers.[13] Screening such as monofilament test ABPI and ultrasound are important to early detection peripheral arterial ischemia in diabetic foot ulcer.[13] Checking skin temperature, which is a feasible procedure, aids the prevention of recurrence.[14] 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.[15]

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 professional (clinicians, nurses and others). However, the current study has limitation. Participant in inter-rater reliability agreement test was relatively small. Thus, generalizability may be limited.

Implication for clinical settings

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The recurrence of diabetic foot ulcers was related to several risk factors, which could be prevented by involving the patients and their families. Consequently, the patient's quality of life is improved.

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Conclusion

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This study demonstrated that there are several risk factors associated with recurrent diabetic foot ulcers. Therefore, these variables could serve as guidelines to prevent recurrence in the future that will improve quality of nursing of diabetic foot ulcer patients.

References

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1. Federation International Diabetes. IDF Diabetes Atlas. Ninth. 2019.
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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

DM; diabetes mellitus, Cr; authority coefficients'; familiarity with the field, Ca; criteria

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Table 2. Coefficients and significance of variables

Variables	M±SD	CV
Check feet every day	7.0±4.0	0.57
Check using monofilament test	8.0±3.0	0.38
Check ankle-brachial pressure index	8.0±3.0	0.38
Check ultrasonography	7.0±4.0	0.57
Knowledge wound healing	8.0±3.0	0.38
Diet pattern	7.0±4.0	0.57
Activity pattern	6.5±4.5	0.69
Footcare	7.5±3.5	0.47
Duration of DM	9.0±2.0	0.22
Blood sugar	9.0±2.0	0.22
Skin temperature	6.5±4.5	0.69
Amputation previous	7.5±3.5	0.47
Neuropathy status	9.0±2.0	0.22
Mean	7.8±3.1	0.41

M, mean, SD, standard deviation, CV, coefficient of variation

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Reviewers' comments

These risk factors are specified in other articles. Many studies have reported risk factors in any way. The present topic did not require the use of the Delphi technique, as the result is clear. The writing is very poor.

The article is repetitive and it doesn't contain anything new for journal readers. Please see below a list of some articles that might be related to your manuscript under review and use them as necessary:

- Risk factors for diabetic foot ulcer recurrence: A prospective 2-year follow-up study in Egypt
- Risk factors for the recurrence of diabetic foot ulcers among diabetic patients: a meta-analysis
- Risk Factors for Recurrent Diabetic Foot Ulcers
- Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup
- Incidence and Risk Factors of Diabetic Foot Ulcer: A Population-Based Diabetic Foot Cohort (ADFC Study)—Two-Year Follow-Up Study
- Risk of diabetic foot ulcer and its associated factors among Bangladeshi subjects: a multicentric cross-sectional study
- Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup
- The Complexity of Diabetic Foot Management: From Common Care to Best Practice. The Italian Expert Opinion by Delphi Survey

In all sections of the article

12. Please strengthen the different sections of the article (especially the introduction, discussion and application of the results) concerning the journal scope (nursing or midwifery).
13. Please integrate the separate paragraphs together all through the article.

Abstract

7. Arrange abstract sections as the following order

Background, Materials and Methods, Results, Conclusions, Keywords
8. Abstract should not exceed 150 words

Materials and Methods

7. Materials and Methods does not need separate sections (please combine Separate sections)
8. Please add the year of the study at the beginning of the materials and methods.

Ethical considerations

3. Add the Ethical considerations after the Materials & Methods (add ethics committee code and date)

Discussion

3. Please mention limitations of the study clearly at the end of discussion.

References

5. When you need to mention an old reference, use references preferably up to 5-10 years old.
6. The references in the article should be written according to the format of the journal ((References should be numeric))
7. References should not exceed 15 references

Tables and figures

5. Move the tables and the figure to the end of references
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Risk Factors of Recurrent Diabetic Foot Ulcers Based on the Delphi Method

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Abstract

Background: Risk factors of recurrence have not been much elucidated. Therefore, this study aims at investigating the risk factors involved in the recurrence of diabetic foot ulcers. **Materials and methods:** This study was cross-sectional used Delphi method, with two phases, firstly is, the development of a category used to investigate the risk factors of recurrent diabetic foot ulcers by experts. Secondly phase is, the development of the recurrent items risk factors. Finally, all the risk factor variables were clinically tested for inter-rater reliability agreement. Study was conducted February 15th- September 28th, 2020, in Indonesia, used 14 experts. **Results:** There were thirteen list risk factors for recurrent diabetic foot ulcers. Mean authority coefficient was 0.71. Positive coefficients were 100% and 78% respectively. Kendall coordination coefficient was statistically significant (χ^2 test, $P < 0.01$), and inter-rater

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reliability agreement was perfect (1.00). **Conclusions:** This study demonstrated that there were several risk factors associated with recurrent diabetic foot ulcers. Therefore, these variables could serve as guidelines to prevent recurrence in the future.

Keywords: *Diabetic foot, recurrence*, *risk factors*

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 2nd 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 7.3-24% of individuals.[3] According to a study, these individuals have a 10-20 times risk of amputation compared to non-diabetics,[4] with an incidence of 25% in Indonesia.[5]

This disease has the risk of recurring or developing a new ulcer and also serious implications for 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,[6] 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 patient is still little. Therefore, this study aims at investigating the risk factors associated with recurrence.

Materials and Methods

Study was conducted February 15th- September 28th, 2020. The Delphi method was used in this study, with the inclusion of 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, had recurrence (the same or another location), and received a diagnosis of type 2 DM according to the American Diabetes Association 2013 guidelines. This diagnosis consists of glycated haemoglobin ≥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.[7] 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 email and contained: 1)

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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 similarly to phase one, where the risk factors’ evaluation form on diabetic foot ulcer recurrence was the only difference, with a score ranging from 1-4 (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree). All questionnaires were sent via email 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: 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: 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 0.0-0.9[8] to determine the five degrees of

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Results

In this study, the mean age of experts and total working time was 39.4±1.4 and 10.9±1.6 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

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Discussion

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

Reliability

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Implication for clinical settings

The recurrence of diabetic foot ulcers was related to several risk factors, which could be prevented by involving the patients and their families. Consequently, the patient's quality of life is improved.

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Conclusion

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This study demonstrated that there are several risk factors associated with recurrent diabetic foot ulcers 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.

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

Future research is needed to evaluate these risk factors to recurrent diabetic foot ulcers patients with larger sample in clinical setting.

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Please add Acknowledgments(add the approved project number in acknowledgments) , Financial support and sponsorship, Conflict of interest, before references

References

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Table 1: Coefficient expert of authority of variables

Variables	Ca	Cs	Cr
Check feet every day	0.58	0.87	0.72

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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

DM; diabetes mellitus, Cr; authority coefficients'; familiarity with the field, Ca; criteria

Table 2. Coefficients and significance of variables

Variables	M±SD	CV
Check feet every day	7.0±4.0	0.57
Check using monofilament test	8.0±3.0	0.38
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Skin temperature	6.5±4.5	0.69
Amputation previous	7.5±3.5	0.47
Neuropathy status	9.0±2.0	0.22
Mean	7.8±3.1	0.41

M, mean, SD, standard deviation, CV, coefficient of variation

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These risk factors are specified in other articles. Many studies have reported risk factors in any way. The present topic did not require the use of the Delphi technique, as the result is clear. The writing is very poor. ¶
The article is repetitive and it doesn't contain anything new for journal readers. Please see below a list of some articles that might be related to your manuscript under review and use them as necessary:¶
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Risk Factors for Recurrent Diabetic Foot Ulcers¶
Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup¶
Incidence and Risk Factors of Diabetic Foot Ulcer: A Population-Based Diabetic Foot Cohort (ADFC Study)—Two-Year Follow-Up Study¶
Risk of diabetic foot ulcer and its associated factors among Bangladeshi subjects: a multicentric cross-sectional study¶
Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup¶
The Complexity of Diabetic Foot Management: From Common Care to Best Practice. The Italian Expert Opinion by Delphi Survey¶
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Ethical considerations¶
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Risk Factors of Recurrent Diabetic Foot Ulcers Based on the Delphi Method

Abstract

Background: Risk factors of recurrence have not been much elucidated. Therefore, this study aims at investigating the risk factors involved in the recurrence of diabetic foot ulcers. **Materials and methods:** This study used Delphi method, with two phases, firstly is, the development of a category used to investigate the risk factors of recurrent diabetic foot ulcers by experts. Secondly phase is, the development of the recurrent items risk factors. Finally, all the risk factor variables were clinically tested for inter-rater reliability agreement. Study was conducted February 15th- September 28th, 2020, in Indonesia, using 14 experts. **Results:** There were thirteen list risk factors for recurrent diabetic foot ulcers. Mean authority coefficient was 0.71. Positive coefficients were 100% and 78% respectively. Kendall coordination coefficient was statistically significant (χ^2 test, $P < 0.01$), and inter-rater reliability agreement was perfect (1.00). **Conclusions:** This study demonstrated that there were several risk factors associated with recurrent diabetic foot ulcers. Therefore, these variables could serve as guidelines to prevent recurrence in the future.

Keywords: *Diabetic foot, recurrence*, *risk factors*

Introduction

According to the International Diabetes Federation, the prevalence of diabetes patients in Indonesia would rise from 10.3 million in 2017 to 10.7 million by 2045.[1] This report ranks Indonesia as the 6th globally, indicating a steady increase in diabetes patients.

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 7.3-24% of individuals.[3] According to a study, these individuals have a 10-20 times risk of amputation compared to non-diabetics,[4] with an incidence of 25% in Indonesia.[5]

This disease has the risk of recurring or developing a new ulcer and also serious implications for 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,[6] 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 patient is still little. Therefore, this study aims at investigating the risk factors associated with recurrence.

Materials and Methods

Study was conducted February 15th- September 28th, 2020. The Delphi method was used in this study, with the inclusion of 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, had recurrence (the same or another location), and received a diagnosis of type 2 DM according to the American Diabetes Association 2013 guidelines. This diagnosis consists of glycated haemoglobin ≥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.[7]

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 email and contained: 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 similarly to phase one, where the risk factors’ evaluation form on diabetic foot ulcer recurrence was the only difference, with a score ranging from 1-4 (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree). All questionnaires were sent via email 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: 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: 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 0.0-0.9[8] to determine the five degrees of familiarity, namely very, more, generally, less, and not familiar.[9] 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] The Kendall's concordance coefficient was also used to reflect the coordination level of experts' opinion with a value between 0 and 1, where a higher denomination indicates a better coordination. Furthermore, Cohen's Kappa was used to analyse 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 age of experts and total working time was 39.4±1.4 and 10.9±1.6 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 11.2±1.7 and 39.2±1.5 years, respectively. Also, one expert had a surgeon's medical doctorate, three had a doctorate, while 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 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 expert's opinion and their experience. Moreover, recurrence patients were 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.

Reliability

First, positive coefficients indicated that experts were interested and optimistic about the study, with a high positive response rate of 60% or above.[10] Second, the literature demonstrated that these individuals could be considered of high authority if a coefficient > 0.7 was obtained. Third, the variable coefficient mean had a high concentration of expert suggestions. These retained literature suggestion items should have a score >3.5. (11) Finally, the coordination coefficient in the second phase was consistent, hence choosing appropriate experts was the key to a successful Delphi method. [11]

Recurrent diabetic foot ulcers risk factors

Our study demonstrated that there some recurrent diabetic foot ulcers 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 factor of recurrent diabetic foot ulcer. Thus, similarly with previous study.[6],[12] A previous study reported that the duration of diabetes increased with the risk of diabetic foot ulcer recurrence.[6] Education about pre-ulcerative signs and foot care play an important role in the prevention of diabetic foot ulcers.[13] Screening such as monofilament test ABPI and ultrasound are important to early detection peripheral arterial ischemia in diabetic foot ulcer.[13] Checking skin temperature, which is a feasible procedure, aids the prevention of recurrence.[14] 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.[15]

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 professional (clinicians, nurses and others). However, the current study has limitation. Participant in inter-rater reliability agreement test was relatively small. Thus, generalizability may be limited.

Implication for clinical settings

The recurrence of diabetic foot ulcers was related to several risk factors, which could be prevented by involving the patients and their families. Consequently, the patient's quality of life is improved.

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, ankle brachial-pressure index (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.

Future research is needed to evaluate these risk factors to recurrent diabetic foot ulcers patients with larger sample in clinical setting.

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