KORESPONDENSI JOURNAL OF MEDICINE AND LIFE

1. Submitted to the journal "Journal of Medicine and Life" (8-Mar-2023)
2. First revision (23-Mar-2023)
3. Second revision (16 Jun 2023)
4. Paper accepted for publication (24-July-2023)
5. Manuscript published (3 January 2024)

1. Submitted to the journal "Journal of Medicine and Life" (8-Mar-2023)

08-Mar-2023

Dear Dr. Haryanto:

Your manuscript entitled "A new diabetic foot risk recurrence assessment tool: INDIFURUTO" has been successfully submitted online and is presently being given full consideration for publication in the Journal of Medicine and Life.

Your manuscript ID is JML-2023-0058. Please mention the above manuscript ID in all future correspondence.

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Thank you for submitting your manuscript to the Journal of Medicine and Life.

Sincerely,
Journal of Medicine and Life Editorial Office

2. First Revision (23 Maret 2023)

Decision Letter (JML-2023-0058)

From: dafinm@ssnn.ro

To: haryanto@stikmuhptk.ac.id

CC:

Subject: Journal of Medicine and Life - Decision on Manuscript ID JML-2023-0058

Body: 23-Mar-2023

Dear Dr. Haryanto:

Manuscript ID JML-2023-0058 entitled "A new diabetic foot risk recurrence assessment tool: INDIFURUTO" which you submitted to the Journal of Medicine and Life, has been reviewed. The comments of the reviewer(s) are included at the bottom of this letter.

The reviewer(s) have recommended publication, but also suggest some revisions to your manuscript. Therefore, I invite you to respond to the reviewer(s)' comments and revise your manuscript.

To revise your manuscript, log into https://mc04.manuscriptcentral.com/jml and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

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When submitting your revised manuscript, you will be able to respond to the comments made by the reviewer(s) in the space provided. You can use this space to document any changes you make to the original manuscript. In order to expedite the processing of the revised manuscript, please be as specific as possible in your response to the reviewer(s).

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Because we are trying to facilitate timely publication of manuscripts submitted to the Journal of Medicine and Life, your revised manuscript should be submitted by 23-May-2023. If it is not possible for you to submit your revision by this date, we may have to consider your paper as a new submission.

Once again, thank you for submitting your manuscript to the Journal of Medicine and Life and I look forward to receiving your revision.

Sincerely,
Prof. Dafin Muresanu
Editor-in-Chief, Journal of Medicine and Life
dafinm@ssnn.ro

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Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
none

Reviewer: 2

Comments to the Author
1. Why did you start the original article with statistical data? First, explain about the diabetic foot complication and what factors can cause its ulcer?
2. In the material and method section, it is said that type 2 diabetes mellitus (DM) patients were selected, so not all types of diabetes are included, so it should be mentioned in the title of the article.
3. Do you have a specific reference for selecting patients who are native Indonesian, older than 35 years, and without mental illness?
4. The number of patients should be mentioned in the material and method section.
5. Attach the picture of the questionnaire that you have given to the patients to fill out to the article.
6. Present the prognostic recurrence factors of diabetic foot ulcer in a table.

Date Sent: 23-Mar-2023

3. Second revision (16 June 2023)

Decision Letter (JML-2023-0058.R1)

From: dafinm@ssnn.ro
To: haryanto@stikmuhptk.ac.id
CC:
Subject: Journal of Medicine and Life - Decision on Manuscript ID JML-2023-0058.R1
Body: 16-Jun-2023

Dear Dr. Haryanto:

Manuscript ID JML-2023-0058.R1 entitled "A new diabetic foot risk recurrence assessment tool: INDIFURUTO in type 2 diabetes mellitus" which you submitted to the Journal of Medicine and Life, has been reviewed. The comments of the reviewer(s) are included at the bottom of this letter and in the attached file.

The reviewer(s) have recommended publication, but also suggest some revisions to your manuscript. Therefore, I invite you to respond to the reviewer(s)' comments and revise your manuscript.

To revise your manuscript, log into https://mc04.manuscriptcentral.com/jml and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

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Once the revised manuscript is prepared, you can upload it and submit it through your Author Center.

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Because we are trying to facilitate timely publication of manuscripts submitted to the Journal of Medicine and Life, your revised manuscript should be submitted by 16-Aug-2023. If it is not possible for you to submit your revision by this date, we may have to consider your paper as a new submission.

Once again, thank you for submitting your manuscript to the Journal of Medicine and Life and I look forward to receiving your revision.

Sincerely,
Prof. Dafin Muresanu
Editor-in-Chief, Journal of Medicine and Life
dafinm@ssnn.ro

Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
Dear Authors:

The topic is interesting however we note some critical issues should revise:

the author should explaine firstly what is INDIFUROTU particularly the development process

line 23
does INDIFURUTO also able to prevent infection and amputation?

method
since INDIFURUTO a recurrence instrument, why authors didnt include patient with 1st ulcer then follow up prospectively

please explain correctly ABI and Monofilamanet procedure, tipe of data, and interpretation and support by citations

why did author evaluate foot care, what is the relevance with study aim?

line 43-50
do not repeat ABPI and monofilament test explanation

ethical clearance has not declar

authors should present INDIFUROTU data regarding particapant score including three risk level

indifuroto rules should explain in method not in result section

Date Sent: 16-Jun-2023
File 1: JML-2023-0058.R1-Proof-hi.pdf

4. Paper accepted for publication (24-July-2023)

Dear Dr. Haryanto:

It is a pleasure to accept your manuscript entitled "A new diabetic foot risk recurrence assessment tool: INDIFURUTO in type 2 diabetes mellitus" in its current form for publication in the Journal of Medicine and Life. The comments of the reviewer(s) who reviewed your manuscript are included at the foot of this letter.

Thank you for your fine contribution. On behalf of the Editors of the Journal of Medicine and Life, we look forward to your continued contributions to the Journal.

Sincerely,
Prof. Dafin Muresanu
Editor-in-Chief, Journal of Medicine and Life
dafinm@ssnn.ro

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The Journal of Medicine and Life is committed to providing authors with a seamless and efficient publishing experience. To ensure the timely and accurate publication of each article a one-time payment of 600 euro upon acceptance of the article is necessary.

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Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
Dear Authors

Our previous suggestion has been revised properly.
We recommend to improve grammatical

Thansk

Date Sent: 24-Jul-2023

A new diabetic foot risk recurrence assessment tool: INDIFURUTO

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INTRODUCTION

According to data from the International Diabetes Federation (IDF), in 2019 in Indonesia, about 463 million people were living with diabetes, and expected increase to 578 million by 2030 and 700 million by 2045. For this reason, Indonesia's diabetes population is among the ten largest worldwide [1].

A study reported that people with a healed diabetic foot ulcer (DFU) are at increased risk of developing a new foot ulcer, with a recurrence incidence of 33.1% per year [2]. In addition, a systematic study reported that the recurrence rate is high globally [3]. Several risk factors can lead to a recurrence of DFU [4]. Therefore, preventing the risk of recurrence is crucial.

On the other hand, the recurrence of DFU can influence the quality of life, increasing financial burden and may lead to amputation or even mortality [5,6]. Previous studies have shown the rate of lower extremity amputation in diabetic patients in Indonesia was 36.3%-39.5% [7,8]. These data were higher than the Netherlands and England, which are 15.5% and 16%, respectively [9,10] In addition, a previous systematic and meta-analysis study reported low quality of life for people with DFU [11]. In other study reported, DFU has an impact on the social and economic conditions due to long wound healing and high treatment costs [12]. Therefore, assessment of risk recurrence of DFU is needed to prevent amputation and improving quality of life.

An accurate assessment of the risk of recurrence of diabetic foot is essential to guide daily clinical practice. Currently, there are many classification systems for DFU development[13]. However, of all these studies, there is not a single specific to the study of recurrence of diabetic foot. To date, the assessment of risk of recurrence of diabetic foot in Indonesia are still unknown as, to our knowledge, no study has explored them. Therefore, we aimed to evaluate diabetic foot ulcer recurrence using a new diabetic foot risk recurrent

assessment tool, INDIFURUTO (Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool). The results of this study could assist nurses to predict recurrence and could preventive infection and amputation.

MATERIALS AND METHODS

Research Design

Prospective cohort study. We followed the Standard for Reporting of Diagnostic Accuracy (STARD) initiative [14].

Participants

Diabetic patients in multisite in West Kalimantan, Indonesia, were the study's target population. Purposive sampling was used as the sampling method. Between July to September 2022, all the subjects in this study were patients who had attended the Community Health Centre for type 2 diabetes mellitus (DM) treatment during the observation period (three months follow up). The researcher administered a questionnaire to participants after they had completed an informed consent form. Inclusion criteria included: native Indonesian, older than 35 years, and without mental illness.

Collecting Data

For new model assessment data included amputation history, smoking, ankle brachial pressure index (ABPI) value, and monofilament test consisting of one item (1=yes, no=2) using the 10g (5.07 Semmes-Weinstein) monofilament, skin foot temperature consists of two things (difference of both of right and left foot).

For foot care, we used some variables according to the expert panel and IWGDF guidelines[15]. Foot care consists of three domains, namely 1) checking the foot consists of five items, including checking the foot every day, touching and feeling its temperature,

observing bulla, changing color and shape, studying fingers (dry and fungal), and observing nails. 2) physical activity consists of three items: foot exercise minimizes ten motions, foot exercise twice a day, and walking minimizes 1000 steps. 3) knowledge consists of four items: foot exercise, walking, foot care, and preventing DFU. To answer, we used a Likert scale of 1-5.

Demographic data were obtained using a minimum data sheet of compounding factors. The questions were related to sex, age, occupation, education, DM duration, co-morbid, and glycaemic status (haemoglobin A1c [HbA1c] value). For new model assessment data included amputation history, smoking, ankle brachial pressure index (ABPI) value, foot care (five items), physical activity (three items), knowledge (four items), monofilament test consists of one item (1=yes, no=2) using the 10g (5.07 Semmes-Weinstein) monofilament, and skin foot temperature consists of two items (difference of both of right and left foot).

Data Analysis

We considered that creating three risk groups would be clinically relevant: low, medium, and high risk. The required cut-off was defined using a visual assessment of the ROC curve and the sensitivity and specificity coordinate. Prognostic accuracy measures were calculated: sensitivity, specificity values, AUC, and respective 95% confidence interval (CI). Data were analyzed using IBM SPSS Statistic for Windows version 26.0 (IBM Corp., Armonk, NY. USA).

RESULTS

Participant characteristics

A total of 33 participants were assessed in this study. The respondent characteristics according to their sex, age, education, employment status, DM duration, co-morbid, blood

sugar value, and HbA1c are shown in **Table 1**. Table 1 shows that most patients were female (75.8%), mean of age was 59.2±9.5, had a background of junior high school (33.3%), were housekeeping (57.6%), mean of DM duration was 4.8±4.8 years, co-morbid was hypertension (78.8%), mean of serum glucose level was 188,5±91,5 g/dl, and mean of HbA1c was 5,0±4,6%.

DFU of recurrence Prediction

INDIFURUTO rule = if there was amputation history (yes=1, no=2), If there was smoking history (yes=1, no=2), if serum glucose level (abnormal=1, normal=2), if ABPI (abnormal=1, normal=2), if monofilament test (yes=1, no=2), if there was difference skin temperature (yes=1, no=2). Using these values, we propose that subjects with less than 22 points should be classified as high risk, between 23 and 45 as medium risk, and over 46 as low risk.

This rule showed an AUC of 97.4% [95% confidence interval (CI) 0.91–1.00]. for DFU of recurrence prediction. The cut-off point (Yauden Index) is a score < 45 with sensitivity and specificity values of 100% and 90%, respectively. (**Figure 1**).

DISCUSSION

To the best of our knowledge, this is the first study to evaluate DFU recurrence using a new diabetic foot risk assessment tool in Indonesia. Our study showed that a new model has high validity because sensitivity and specificity values were more than 80%, respectively[16]. For relevant clinically, the new classification, INDIFUROTO, included three categories: high risk, moderate risk, and low risk. Similarly, a previous study created three risk groups, including low, medium, and high risk [17]. Therefore, INDIFUROTO can be used to detect diabetic foot ulcer recurrence.

A previous study, diabetic foot risk assessment (DIAFORA) was equally or more accurate for lower extremity amputation prediction in diabetic foot ulcer patients [17]. Contrast of our study, The INDIFUROTO could be used to predict diabetic foot recurrence.

In our study, The INDIFUROTO has higher sensitivity and specificity because we used skin foot temperature measure in this classification. Similarly, to previous study, Infrared thermography revealed local temperature differences in high-risk diabetic feet[18]. In addition,

another study reported that reliability of thermal imaging system for temperature assessment showed very good agreement [19]. According to a previous study that thermal imaging could be used for early prediction of the healing of the ulcers. In addition, temperature self-assessment, might increase the effectiveness of this method to predict the development of foot ulcers in people with diabetes[20]. Therefore, this model has validity in detecting DFU recurrence.

The present study has some limitations, such as the small sample size. In the future, the study will need a larger sample size and multisite. A strength of this study is that it is the first to evaluate DFU recurrence using a new diabetic foot risk recurrent assessment tool in Indonesia.

In conclusion, this study showed that a new model had a high prediction. Therefore, this model better stratifies people at high risk of foot ulceration. In addition, using this model can help monitor to improve the prevention of foot ulcer recurrence in people with diabetes.

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Table 1. Participants characteristic

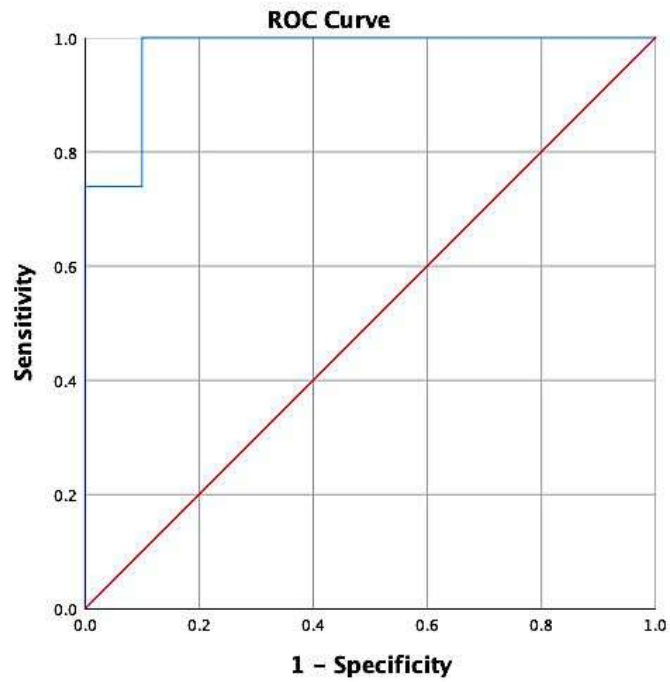| Characteristics	Participants (N=33)
Sex, Numbers (%)	
Women	25 (75.8)
Men	8 (24.2)
Age (years), (Mean±SD)	59,2±9.5
Occupation, Numbers. (%)	
Private	6 (18.2)
Housekeeping	19 (57.6)
Employee	7 (21.2)
Retired	1 (3.0)
Education, Number. (%)	
No	2 (6.1)
Elementary school	7 (21.2)
Junior high school	11 (33.3)
Senior high school	7 (21.2)
University	6 (18.2)
Duration of DM (years), (Mean±SD)	4.8±4.8
Co-morbid, Numbers. (%)	
No	1 (3.0)
Gastritis	2 (6.1)
Hypercholesterol	2 (6.1)
Hypertension	26 (78.8)
Heart disease	1 (3.0)
Dizziness	1 (3.0)
Serum glucose level (g/dl), (Mean±SD)	188.5±91.5
HbA1c (%), (Mean±SD) (N=32)	5.0±4.6

Figure 1. Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool (INDIFURUTO) area under the receiver operating characteristic curve for recurrence prediction. INDIFURUTO classification presents an area under the receiver operating characteristic curve of 97.4% [95% confidence interval (CI) 0.91–1.00]. The cut-off point (Yauden Index) is a score < 45 with sensitivity and specificity values of 100%

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A new diabetic foot risk recurrence assessment tool: INDIFURUTO in type 2 diabetes mellitus

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4 **INTRODUCTION**
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6   Diabetes is a group of metabolic diseases characterized by hyperglycaemia caused by
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8 insulin secretion, insulin action, or both. Diabetes' chronic hyperglycaemia is linked to long-
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10 term damage, dysfunction, and failure of various organs, particularly the eyes, kidneys,
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12 nerves, heart, and blood vessels [1]. According to data from the International Diabetes
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14 Federation (IDF), in 2019 in Indonesia, about 463 million people were living with diabetes,
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16 and expected increase to 578 million by 2030 and 700 million by 2045. For this reason,
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18 Indonesia's diabetes population is among the ten largest worldwide [2].
19
20   Diabetic foot ulcers (DFU) is one of the most common complications of diabetes. DFU
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22 is a severe chronic diabetes consequence characterized by deep tissue lesions coupled with
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24 neurological diseases and peripheral vascular disease in the lower extremities [3]. There
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26 are many factors to contribute ulcers such as distal sensorimotor peripheral neuropathy,
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28 autonomic neuropathy, PAD, deformity, age, sex, and duration of diabetes, ethnicity,
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30 repetitive minor trauma, past foot ulceration or amputation, and other microvascular
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32 complications [4].   A study reported that people with a healed DFU are at increased risk of
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34 developing a new foot ulcer, with a recurrence incidence of 33.1% per year [5]. In addition,
35
36 a systematic study reported that the recurrence rate is high globally [6]. Several risk factors
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38 can lead to a recurrence of DFU [7]. Therefore, preventing the risk of recurrence is crucial.
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40 On the other hand, the recurrence of DFU can influence the quality of life, increasing
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42 financial burden and may lead to amputation or even mortality [8,9]. Previous studies have
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44 shown the rate of lower extremity amputation in diabetic patients in Indonesia was 36.3%-
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46 39.5% [10,11]. These data were higher than the Netherlands and England, which are 15.5%
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48 and 16%, respectively [12,13] In addition, a previous systematic and meta-analysis study
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50 reported low quality of life for people with DFU [14]. In other study reported, DFU has an
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52 impact on the social and economic conditions due to long wound healing and high treatment

costs [15]. Therefore, assessment of risk recurrence of DFU is needed to prevent amputation and improving quality of life.

An accurate assessment of the risk of recurrence of diabetic foot is essential to guide daily clinical practice. Currently, there are many classification systems for DFU development[16]. However, of all these studies, there is not a single specific to the study of recurrence of diabetic foot. To date, the assessment of risk of recurrence of diabetic foot in Indonesia are still unknown as, to our knowledge, no study has explored them. Therefore, we aimed to evaluate diabetic foot ulcer recurrence using a new diabetic foot risk recurrent assessment tool, INDIFURUTO (Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool) in type 2 diabetes mellitus. The results of this study could assist nurses to predict recurrence and could preventive infection and amputation.

MATERIALS AND METHODS

Research Design

Prospective cohort study. We followed the Standard for Reporting of Diagnostic Accuracy (STARD) initiative [17].

Participants

Diabetic patients in multisite in West Kalimantan, Indonesia, were the study's target population. Purposive sampling was used as the sampling method. Between July to September 2022, all the subjects in this study were patients who had attended the Community Health Centre for type 2 diabetes mellitus (DM) treatment during the observation period (three months follow up). Thus, 33 patients were included in the study. The researcher administered a questionnaire to participants after they had completed an informed consent form. Inclusion criteria included: native Indonesian, older than 35 years, and without mental illness.[18,19]

Collecting Data

For new model assessment data included amputation history, smoking, ankle brachial pressure index (ABPI) value, and monofilament test consisting of one item (1=yes, no=2) using the 10g (5.07 Semmes-Weinstein) monofilament, skin foot temperature consists of two things (difference of both of right and left foot).

For foot care, we used some variables according to the expert panel and IWGDF guidelines[20]. Foot care consists of three domains, namely 1) checking the foot consists of five items, including checking the foot every day, touching and feeling its temperature, observing bulla, changing color and shape, studying fingers (dry and fungal), and observing nails. 2) physical activity consists of three items: foot exercise minimizes ten motions, foot exercise twice a day, and walking minimizes 1000 steps. 3) knowledge consists of four items: foot exercise, walking, foot care, and preventing DFU. To answer, we used a Likert scale of 1-5.

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We considered that creating three risk groups would be clinically relevant: low, medium, and high risk. The required cut-off was defined using a visual assessment of the ROC curve and the sensitivity and specificity coordinate. Prognostic accuracy measures

were calculated: sensitivity, specificity values, AUC, and respective 95% confidence interval (CI). Data were analyzed using IBM SPSS Statistic for Windows version 26.0 (IBM Corp., Armonk, NY. USA).

RESULTS

Participant characteristics

The respondent characteristics according to their sex, age, education, employment status, DM duration, co-morbid, blood sugar value, and HbA1c are shown in **Table 1**. Table 1 shows that most patients were female (75.8%), mean of age was 59.2$\pm$9.5, had a background of junior high school (33.3%), were housekeeping (57.6%), mean of DM duration was 4.8$\pm$4.8 years, co-morbid was hypertension (78.8%), mean of serum glucose level was 188,5$\pm$91,5 g/dl, and mean of HbA1c was 5,0$\pm$4,6%.

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This rule showed an AUC of 97.4% [95% confidence interval (CI) 0.91–1.00]. for DFU of recurrence prediction. The cut-off point (Yauden Index) is a score < 45 with sensitivity and specificity values of 100% and 90%, respectively. (**Figure 1**).

DISCUSSION

To the best of our knowledge, this is the first study to evaluate DFU recurrence using a new diabetic foot risk assessment tool in Indonesia. Our study showed that a new model has high validity because sensitivity and specificity values were more than 80%,

respectively[21]. For relevant clinically, the new classification, INDIFUROTO, included three categories: high risk, moderate risk, and low risk. Similarly, a previous study created three risk groups, including low, medium, and high risk [22]. Therefore, INDIFUROTO can be used to detect diabetic foot ulcer recurrence.

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The present study has some limitations, such as the small sample size. In the future, the study will need a larger sample size and multisite. A strength of this study is that it is the first to evaluate DFU recurrence using a new diabetic foot risk recurrent assessment tool in Indonesia.

In conclusion, this study showed that a new model had a high prediction. Therefore, this model better stratifies people at high risk of foot ulceration. In addition, using this model can help monitor to improve the prevention of foot ulcer recurrence in people with diabetes.

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Table 1. Participants characteristic

Characteristics	Participants (N=33)
Sex, Numbers (%)	
Women	25 (75.8)
Men	8 (24.2)
Age (years), (Mean±SD)	59,2±9.5
Occupation, Numbers. (%)	
Private	6 (18.2)
Housekeeping	19 (57.6)
Employee	7 (21.2)
Retired	1 (3.0)
Education, Number. (%)	
No	2 (6.1)
Elementary school	7 (21.2)
Junior high school	11 (33.3)
Senior high school	7 (21.2)
University	6 (18.2)
Duration of DM (years), (Mean±SD)	4.8±4.8
Co-morbid, Numbers. (%)	
No	1 (3.0)
Gastritis	2 (6.1)
Hypercholesterol	2 (6.1)
Hypertension	26 (78.8)
Heart disease	1 (3.0)
Dizziness	1 (3.0)
Serum glucose level (g/dl), (Mean±SD)	188.5±91.5
HbA1c (%), (Mean±SD) (N=32)	5.0±4.6

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Table 2. The prognostic recurrence factors of diabetic foot ulcers

Factors
Amputation history
Smoking history
Serum glucose level
ABPI
Monofilament test
Skin foot temperature

ABPI (Ankle Brachial Pressure Index)

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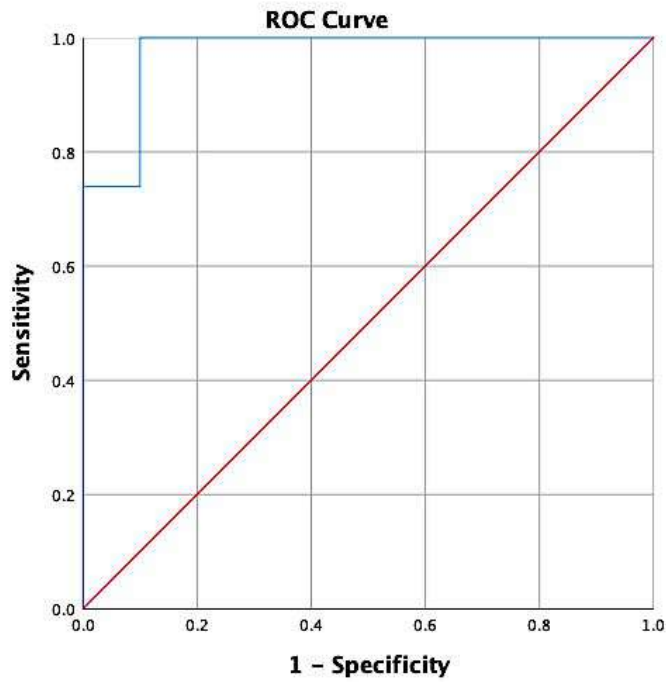**Figure 1**. Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool (INDIFURUTO) area under the receiver operating characteristic curve for recurrence prediction. INDIFURUTO classification presents an area under the receiver operating characteristic curve of 97.4% [95% confidence interval (CI) 0.91– 1.00]. The cut-off point (Yauden Index) is a score < 45 with sensitivity and specificity values of 100%

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Instrument to Early Detection Risk Recurrent Of Diabetic Foot Ulcers
(Version 1)

A. Health Problem

Patient Initial:	Date of Assessment	Result	Reference Value
Duration of DM			
Location of wound previous			
Previous amputation			
Active/Previous Smoking			
Random Blood Sugar		mg/dl	80-144 mg/dl (Ref: WHO)
BMI (Body Massa Index)			Less (<18) Normal (18,5-22,9) Overweight with risk (23-29,9) Obesity I (25-29,9) Obesity II ($\geq$ 30) (Ref: Health Department)
Ankle Brachial Pressure Index Right Ankle: Brachial: Left: Ankle: Brachial		Right: mmHg Left: mmHg	

BMI= weight (kg) ÷ height^2 (meters)

1. Foot Care

   Foot Check

   How often do you check your foot for:

   (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always)

No	Questions	Answer				
		1	2	3	4	5
1a	Daily foor check?					
1b	Touch and feel the temperature?					
1c	Observe the feet for thickening, blistering, discoloration and shape?					
1d	Checking for dry scaly and fungal toes?					
1e	Observing the nails on the toes are not too long and pressing into the skin or irregular?					

2. Physical activity

   How often do you the activity:

   (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always)

No	Questions	Answer				
		1	2	3	4	5
2a	Do foot exercises with at least 10 movements?					
2b	Do foot exercises twice in one day?					
2c	Walk at least 1000 steps every day?					

3. Knowledge
   How knowledgeable are you about knowledge:
   (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always)

No	Questions	Answer				
		1	2	3	4	5
3a	Foot exercise?					
3b	Walking?					
3c	Diabetic foot wound care?					
3d	Prevention of diabetic foot wounds?					

4. Monofilament test
   Do monofilaments test using 10g monofilament equipment

No	Questions		
4a	Is loss of sensation < 8 point?		No=2
			Yes=1

5. Foot skin temperature
   Check the temperature on both feet using infrared thermography (flir-one)

No	Questions	°C	Difference ≥2,2°C	
5a	Right foot temperature			No=2
5b	Left foot temperature			Yes= 1

How to determine the risk score:
History of amputation (Yes=1, No=2)
Smoking history (Yes=1, No=2)
Blood sugar result (Abnormal=1, Normal=2)
ABPI result (Abnormal=1, Normal=2)
Monofilament test result (Yes=1, No=2)
Temperature difference result (Yes=1, No=2)

A new diabetic foot risk recurrence assessment tool: INDIFURUTO in type 2 diabetes mellitus

SCHOLARONE™
Manuscripts

INTRODUCTION

Diabetes is a group of metabolic diseases characterized by hyperglycaemia caused by insulin secretion, insulin action, or both. Diabetes' chronic hyperglycaemia is linked to long-term damage, dysfunction, and failure of various organs, particularly the eyes, kidneys, nerves, heart, and blood vessels [1]. According to data from the International Diabetes Federation (IDF), in 2019 in Indonesia, about 463 million people were living with diabetes, and expected increase to 578 million by 2030 and 700 million by 2045. For this reason, Indonesia's diabetes population is among the ten largest worldwide [2].

Diabetic foot ulcers (DFU) is one of the most common complications of diabetes. DFU is a severe chronic diabetes consequence characterized by deep tissue lesions coupled with neurological diseases and peripheral vascular disease in the lower extremities [3]. There are many factors to contribute ulcers such as distal sensorimotor peripheral neuropathy, autonomic neuropathy, PAD, deformity, age, sex, and duration of diabetes, ethnicity, repetitive minor trauma, past foot ulceration or amputation, and other microvascular complications [4]. A study reported that people with a healed DFU are at increased risk of developing a new foot ulcer, with a recurrence incidence of 33.1% per year [5]. In addition, a systematic study reported that the recurrence rate is high globally [6]. Several risk factors can lead to a recurrence of DFU [7]. Therefore, preventing the risk of recurrence is crucial. On the other hand, the recurrence of DFU can influence the quality of life, increasing financial burden and may lead to amputation or even mortality [8,9]. Previous studies have shown the rate of lower extremity amputation in diabetic patients in Indonesia was 36.3%-39.5% [10,11]. These data were higher than the Netherlands and England, which are 15.5% and 16%, respectively [12,13] In addition, a previous systematic and meta-analysis study reported low quality of life for people with DFU [14]. In other study reported, DFU has an impact on the social and economic conditions due to long wound healing and high treatment

costs [15]. Therefore, assessment of risk recurrence of DFU is needed to prevent amputation and improving quality of life.

An accurate assessment of the risk of recurrence of diabetic foot is essential to guide daily clinical practice. Currently, there are many classification systems for DFU development[16]. However, of all these studies, there is not a single specific to the study of recurrence of diabetic foot. To date, the assessment of risk of recurrence of diabetic foot in Indonesia are still unknown as, to our knowledge, no study has explored them. Therefore, we aimed to evaluate diabetic foot ulcer recurrence using a new diabetic foot risk recurrent assessment tool, INDIFURUTO (Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool) in type 2 diabetes mellitus. The results of this study could assist nurses to predict recurrence and could preventive infection and amputation.

MATERIALS AND METHODS

Research Design

Prospective cohort study. We followed the Standard for Reporting of Diagnostic Accuracy (STARD) initiative [17].

Participants

Diabetic patients in multisite in West Kalimantan, Indonesia, were the study's target population. Purposive sampling was used as the sampling method. Between July to September 2022, all the subjects in this study were patients who had attended the Community Health Centre for type 2 diabetes mellitus (DM) treatment during the observation period (three months follow up). Thus, 33 patients were included in the study. The researcher administered a questionnaire to participants after they had completed an informed consent form. Inclusion criteria included: native Indonesian, older than 35 years, and without mental illness.[18,19]

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For new model assessment data included amputation history, smoking, ankle brachial pressure index (ABPI) value, and monofilament test consisting of one item (1=yes, no=2) using the 10g (5.07 Semmes-Weinstein) monofilament, skin foot temperature consists of two things (difference of both of right and left foot).

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Table 1. Participants characteristic

Characteristics	Participants (N=33)
Sex, Numbers (%)	
Women	25 (75.8)
Men	8 (24.2)
Age (years), (Mean±SD)	59,2±9.5
Occupation, Numbers. (%)	
Private	6 (18.2)
Housekeeping	19 (57.6)
Employee	7 (21.2)
Retired	1 (3.0)
Education, Number. (%)	
No	2 (6.1)
Elementary school	7 (21.2)
Junior high school	11 (33.3)
Senior high school	7 (21.2)
University	6 (18.2)
Duration of DM (years), (Mean±SD)	4.8±4.8
Co-morbid, Numbers. (%)	
No	1 (3.0)
Gastritis	2 (6.1)
Hypercholesterol	2 (6.1)
Hypertension	26 (78.8)
Heart disease	1 (3.0)
Dizziness	1 (3.0)
Serum glucose level (g/dl), (Mean±SD)	188.5±91.5
HbA1c (%), (Mean±SD) (N=32)	5.0±4.6

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Table 2. The prognostic recurrence factors of diabetic foot ulcers

Factors
Amputation history
Smoking history
Serum glucose level
ABPI
Monofilament test
Skin foot temperature

ABPI (Ankle Brachial Pressure Index)

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Figure 1. Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool (INDIFURUTO) area under the receiver operating characteristic curve for recurrence prediction. INDIFURUTO classification presents an area under the receiver operating characteristic curve of 97.4% [95% confidence interval (CI) 0.91–1.00]. The cut-off point (Yauden Index) is a score < 45 with sensitivity and specificity values of 100%

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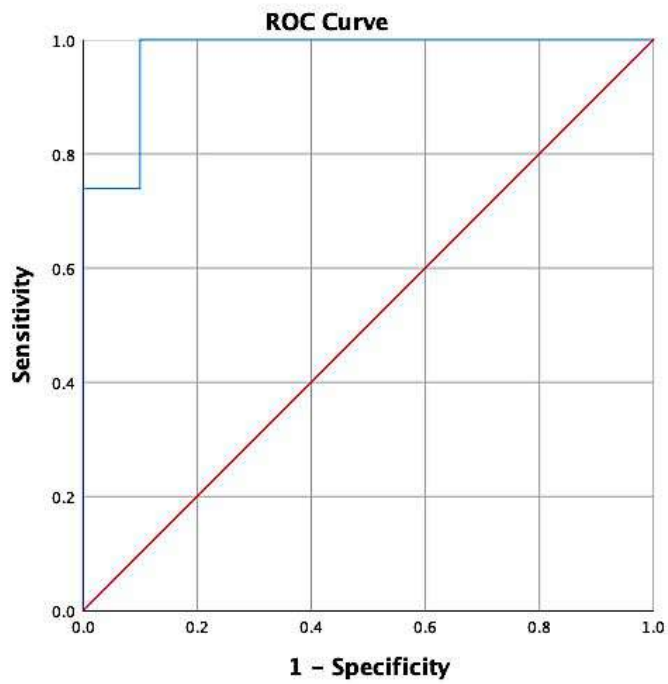43
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Instrument to Early Detection Risk Recurrent Of Diabetic Foot Ulcers
(Version 1)

A. Health Problem

Patient Initial:	Date of Assessment	Result	Reference Value
Duration of DM			
Location of wound previous			
Previous amputation			
Active/Previous Smoking			
Random Blood Sugar		mg/dl	80-144 mg/dl (Ref: WHO)
BMI (Body Massa Index)			Less (<18) Normal (18,5-22,9) Overweight with risk (23-29,9) Obesity I (25-29,9) Obesity II (≥ 30) (Ref: Health Department)
Ankle Brachial Pressure Index Right Ankle: Brachial: Left: Ankle: Brachial		Right: mmHg Left: mmHg	

BMI= weight (kg) ÷ height^2 (meters)

1. Foot Care
   Foot Check
   How often do you check your foot for:
   (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always)

No	Questions	Answer				
		1	2	3	4	5
1a	Daily foor check?					
1b	Touch and feel the temperature?					
1c	Observe the feet for thickening, blistering, discoloration and shape?					
1d	Checking for dry scaly and fungal toes?					
1e	Observing the nails on the toes are not too long and pressing into the skin or irregular?					

2. Physical activity
   How often do you the activity:
   (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always)

No	Questions	Answer				
		1	2	3	4	5
2a	Do foot exercises with at least 10 movements?					
2b	Do foot exercises twice in one day?					
2c	Walk at least 1000 steps every day?					

3. Knowledge

How knowledgeable are you about knowledge:

(1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always)

No	Questions	Answer				
		1	2	3	4	5
3a	Foot exercise?					
3b	Walking?					
3c	Diabetic foot wound care?					
3d	Prevention of diabetic foot wounds?					

4. Monofilament test

Do monofilaments test using 10g monofilament equipment

No	Questions		
4a	Is loss of sensation < 8 point?		No=2
			Yes=1

5. Foot skin temperature

Check the temperature on both feet using infrared thermography (flir-one)

No	Questions	°C	Difference ≥2,2°C	
5a	Right foot temperature			No=2
5b	Left foot temperature			Yes= 1

How to determine the risk score:

History of amputation (Yes=1, No=2)

Smoking history (Yes=1, No=2)

Blood sugar result (Abnormal=1, Normal=2)

ABPI result (Abnormal=1, Normal=2)

Monofilament test result (Yes=1, No=2)

Temperature difference result (Yes=1, No=2)

A new diabetic foot risk recurrence assessment tool: INDIFURUTO in type 2 diabetes mellitus

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Ankle Brachial Pressure Index Right Ankle: Brachial: Left: Ankle: Brachial		Right: mmHg Left: mmHg	

BMI= weight (kg) ÷ height^2 (meters)

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History of amputation (Yes=1, No=2)

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Blood sugar result (Abnormal=1, Normal=2)

ABPI result (Abnormal=1, Normal=2)

Monofilament test result (Yes=1, No=2)

Temperature difference result (Yes=1, No=2)

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INTRODUCTION
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6   Diabetes is a group of metabolic diseases characterized by hyperglycaemia caused by
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8   insulin secretion, insulin action, or both. Diabetes' chronic hyperglycaemia is linked to long-
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10 term damage, dysfunction, and failure of various organs, particularly the eyes, kidneys,
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12 nerves, heart, and blood vessels [1]. According to data from the International Diabetes
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14 Federation (IDF), in 2019 in Indonesia, about 463 million people were living with diabetes,
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16 and expected increase to 578 million by 2030 and 700 million by 2045. For this reason,
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19 Indonesia's diabetes population is among the ten largest worldwide [2].
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21   Diabetic foot ulcers (DFU) is one of the most common complications of diabetes. DFU
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23 is a severe chronic diabetes consequence characterized by deep tissue lesions coupled with
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25 neurological diseases and peripheral vascular disease in the lower extremities [3]. There
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27 are many factors to contribute ulcers such as distal sensorimotor peripheral neuropathy,
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29 autonomic neuropathy, PAD, deformity, age, sex, and duration of diabetes, ethnicity,
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31 repetitive minor trauma, past foot ulceration or amputation, and other microvascular
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33 complications [4].   A study reported that people with a healed DFU are at increased risk of
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36 developing a new foot ulcer, with a recurrence incidence of 33.1% per year [5]. In addition,
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38 a systematic study reported that the recurrence rate is high globally [6]. Several risk factors
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40 can lead to a recurrence of DFU [7]. Therefore, preventing the risk of recurrence is crucial.
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42 On the other hand, the recurrence of DFU can influence the quality of life, increasing
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44 financial burden and may lead to amputation or even mortality [8,9]. Previous studies have
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46 shown the rate of lower extremity amputation in diabetic patients in Indonesia was 36.3%-
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49 39.5% [10,11]. These data were higher than the Netherlands and England, which are 15.5%
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51 and 16%, respectively [12,13] In addition, a previous systematic and meta-analysis study
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53 reported low quality of life for people with DFU [14]. In other study reported, DFU has an
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55 impact on the social and economic conditions due to long wound healing and high treatment
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costs [15].   Therefore, assessment of risk recurrence of DFU is needed to prevent amputation and improving quality of life.

An accurate assessment of the risk of recurrence of diabetic foot is essential to guide daily clinical practice.   Currently, there are many classification systems for DFU development[16]. However, of all these studies, there is not a single specific to the study of recurrence of diabetic foot. To date, the assessment of risk of recurrence of diabetic foot in Indonesia are still unknown as, to our knowledge, no study has explored them. Therefore, we aimed to evaluate diabetic foot ulcer recurrence using a new diabetic foot risk recurrent assessment tool, INDIFURUTO (Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool) in type 2 diabetes mellitus. According to our previous studied (unpublished), INDIFURUTO was developed based on experts panel used Delphi method, which the risk factors variable had 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). Therefore, the results of this study could assist nurses to predict recurrence so that could improve quality of life of diabetic mellitus patients.

MATERIALS AND METHODS

Research Design

Prospective cohort study. We followed the Standard for Reporting of Diagnostic Accuracy (STARD) initiative [17].

Participants

Diabetic patients in multisite in West Kalimantan, Indonesia, were the study's target population. Purposive sampling was used as the sampling method. Between July to September 2022, all the subjects in this study were patients who had attended the Community Health Centre for type 2 diabetes mellitus (DM) treatment during the observation

period (three months follow up) who had ulcer previous or the first ulcer has healed. Thus, 33 patients were included in the study. The researcher administered a questionnaire to participants after they had completed an informed consent form. Inclusion criteria included: native Indonesian, older than 35 years, and without mental illness.[18,19]

Collecting Data

In table 1, for new model assessment data included amputation history, smoking, ankle brachial pressure index (ABPI) value. The ABPI was carried out two stages including *brachial pressure*: 1) place cuff around the upper arm, 2) apply the gel over the area of the brachial artery (can be palpated first), 3) ensure that a clear audible signal is detected, 4) inflate the cuff to supra-systolic values, i.e. about 30 mmHg above the pressure when the signal disappears completely, 5) slowly deflate the cuff at a rate of 2–3mmHg per second until an audible signal re-appears, the cuff pressure at that moment equals the systolic pressure in the artery. *Ankle pressure*: 1) place the calf cuff approximately 2 cm above the malleolus, with the tubes pointing upwards, 2) apply the gel in the areas of the dorsalis pedis and posterior tibial arteries, 3) place the doppler probe with an angle of 40-60° pointing upstream in the area of each artery, 4) slowly move the prove to select the area with the best signal. To calculate ABPI for each limb by dividing the lower value of the dorsalis pedis or posterior tibial pressures of the foot by the highest of the left or right brachial pressures [20]. In this study, we considered abnormal=1, if ABPI above 1.3 or below 0.9, and normal=2, if ABPI between 0,8-1.00 [21].

Monofilament test consisting of one item. Monofilament testing was performed using a Semmes-Weinstein 5.07/10-g monofilament at 8 points in each foot, including the plantar aspect of the first, third, and fifth digits; the plantar aspect of the medial, central, and lateral aspect of the midfoot; the posterior of the plantar foot; and the point between the first and second toes on the dorsal surface of the foot. The test results were considered weak if the

patients could not describe the localization although they could feel the monofilament [22]. In this study, value 2 (no), if the result was considered negative if the patient could not feel the monofilament at any 1 point (lest than 8 point). Value 1 (yes), if the patient could feel the monofilament at any 1 point.

Skin foot temperature consists of two things (difference of both of right and left foot). This study used FILR ONE PRO mobile phone external probe infrared thermal imager (produced by FLIR, USA), the size is 68 mm × 34 mm × 14 mm, and the weight is 36.5g. The device has one optical camera and one infrared camera. The mobile device was connected by USB interface combined with the matching software FLIR One to shoot. The shooting modes included visible light images, normal thermal images, and dynamic enhancement thermal images (MSX). It was capable of taking still images, videos, and time-lapse shots. Its visible light resolution is up to 1440×1080 dpi, thermal resolution is 160×120 dpi, and the temperature range is -20°C to 400°C with resolution of 0.1°C. The mobile device supported simultaneous display of up to 3 movable temperature measurement points and 6 movable temperature measurement areas on the screen. The measuring of procedure of skin foot temperature was based on the study by Kanazawa[23].

For foot care, we used some variables according to the expert panel and IWGDF guidelines[24]. Foot care consists of three domains, namely 1) checking the foot consists of five items, including checking the foot every day, touching and feeling its temperature, observing bulla, changing color and shape, studying fingers (dry and fungal), and observing nails. 2) physical activity consists of three items: foot exercise minimizes ten motions, foot exercise twice a day, and walking minimizes 1000 steps. 3) knowledge consists of four items: foot exercise, walking, foot care, and preventing DFU. To answer, we used a Likert scale of 1-5.

Demographic data were obtained using a minimum data sheet of compounding factors. The questions were related to sex, age, occupation, education, DM duration, co-

morbid, and glycaemic status (haemoglobin A1c [HbA1c] value). <mark>INDIFURUTO rules = if there was amputation history (yes=1, no=2), If there was smoking history (yes=1, no=2), if serum glucose level (abnormal=1, normal=2), if ABPI (abnormal=1, normal=2), if monofilament test (yes=1, no=2), if there was difference skin temperature (yes=1, no=2).</mark>

<mark>Ethical Consideration</mark>

<mark>The institutional review board approved this study of STIK Muhammadiyah Pontianak (number: 275/VII/2022). The Declaration of Helsinki principle was followed in this study.</mark>

Data Analysis

We considered that creating three risk groups would be clinically relevant: low, medium, and high risk. The required cut-off was defined using a visual assessment of the ROC curve and the sensitivity and specificity coordinate. Prognostic accuracy measures were calculated: sensitivity, specificity values, AUC, and respective 95% confidence interval (CI). Data were analyzed using IBM SPSS Statistic for Windows version 26.0 (IBM Corp., Armonk, NY. USA).

RESULTS

Participant characteristics

The respondent characteristics according to their sex, age, education, employment status, DM duration, co-morbid, blood sugar value, and HbA1c are shown in **Table 2**. Table 2 shows that most patients were female (75.8%), mean of age was 59.2 ± 9.5, had a background of junior high school (33.3%), were housekeeping (57.6%), mean of DM duration was 4.8 ± 4.8 years, co-morbid was hypertension (78.8%), mean of serum glucose level was $188,5 \pm 91,5$ g/dl, and mean of HbA1c was $5,0 \pm 4,6\%$.

DFU of recurrence Prediction

Based on the INDIFURUTO rules, we proposed that subjects with less than equal to 22 points should be classified as high risk, between 23 and 45 as medium risk, and more than equal to 46 as low risk. **(Table 3)**

This rule showed an AUC of 97.4% [95% confidence interval (CI) 0.91–1.00]. for DFU of recurrence prediction. The cut-off point (Yauden Index) is a score < 45 with sensitivity and specificity values of 100% and 90%, respectively. (**Figure 1**).

DISCUSSION

To the best of our knowledge, this is the first study to evaluate DFU recurrence using a new diabetic foot risk assessment tool in Indonesia. Our study showed that a new model has high validity because sensitivity and specificity values were more than 80%, respectively[25]. For relevant clinically, the new classification, INDIFUROTO, included three categories: high risk, moderate risk, and low risk. Similarly, a previous study created three risk groups, including low, medium, and high risk [26]. Therefore, INDIFUROTO can be used to detect diabetic foot ulcer recurrence.

A previous study, diabetic foot risk assessment (DIAFORA) was equally or more accurate for lower extremity amputation prediction in diabetic foot ulcer patients [26]. Contrast of our study, The INDIFUROTO could be used to predict diabetic foot recurrence. In our study, The INDIFUROTO has higher sensitivity and specificity because we used skin foot temperature measure in this classification. Similarly, to previous study, Infrared thermography revealed local temperature differences in high-risk diabetic feet[27].

In addition, another study reported that reliability of thermal imaging system for temperature assessment showed very good agreement [28]. According to a previous study that thermal imaging could be used for early prediction of the healing of the ulcers. In addition, temperature self-assessment, might increase the effectiveness of this method to

predict the development of foot ulcers in people with diabetes[29]. Therefore, this model has validity in detecting DFU recurrence.

The present study has some limitations, such as the small sample size. In the future, the study will need a larger sample size and multisite. A strength of this study is that it is the first to evaluate DFU recurrence using a new diabetic foot risk recurrent assessment tool in Indonesia.

In conclusion, this study showed that a new model had a high prediction. Therefore, this model better stratifies people at high risk of foot ulceration. In addition, using this model can help monitor to improve the prevention of foot ulcer recurrence in people with diabetes.

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2   Table 1. The prognostic recurrence factors of diabetic foot ulcers
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5   **Factors**
6   Amputation history
7   Smoking history
8   Serum glucose level
9   ABPI
10   Monofilament test
11   Skin foot temperature
12   ABPI (Ankle Brachial Pressure Index)
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Table 2. Participants characteristic

Characteristics	Participants (N=33)
Sex, Numbers (%)	
Women	25 (75.8)
Men	8 (24.2)
Age (years), (Mean±SD)	59,2±9.5
Occupation, Numbers. (%)	
Private	6 (18.2)
Housekeeping	19 (57.6)
Employee	7 (21.2)
Retired	1 (3.0)
Education, Number. (%)	
No	2 (6.1)
Elementary school	7 (21.2)
Junior high school	11 (33.3)
Senior high school	7 (21.2)
University	6 (18.2)
Duration of DM (years), (Mean±SD)	4.8±4.8
Co-morbid, Numbers. (%)	
No	1 (3.0)
Gastritis	2 (6.1)
Hypercholesterol	2 (6.1)
Hypertension	26 (78.8)
Heart disease	1 (3.0)
Dizziness	1 (3.0)
Serum glucose level (g/dl), (Mean±SD)	188.5±91.5
HbA1c (%), (Mean±SD) (N=32)	5.0±4.6

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Table 3. Categories of risk of recurrence of diabetic foot ulcers

Categories	Participants (N=33)
High risk	0
Medium risk	24
Low risk	9

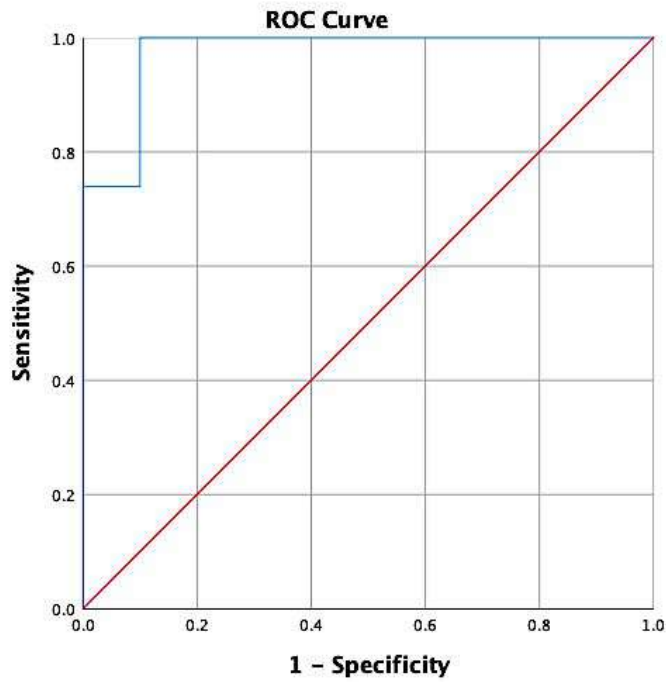High risk ($\leq$ 22), medium risk (23-45), low risk ($\geq$ 46)

Figure 1. Indonesia Diabetic Foot Ulcer Recurrence Assessment Tool (INDIFURUTO) area under the receiver operating characteristic curve for recurrence prediction. INDIFURUTO classification presents an area under the receiver operating characteristic curve of 97.4% [95% confidence interval (CI) 0.91–1.00]. The cut-off point (Yauden Index) is a score < 45 with sensitivity and specificity values of 100%

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