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Effects of diabetes-related foot ulcer depth on healing days, cost, and quality of life: A prospective observational study

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1 | INTRODUCTION

Diabetes-related foot ulcer is defined as a foot ulcer in a person with current or previously diagnosed diabetes mellitus, and usually accompanied by peripheral neuropathy and/or peripheral artery disease in the lower extremity.¹ This has become a global issue due to the increase in the number of patients with diabetes, as these ulcers can affect not only the physical prognosis, such as amputations and life prognosis, but also the quality of life (QOL) of patients and the socioeconomic outlook.^{2,3}

It goes without saying that it is extremely important to prevent these diabetes-related foot ulcers due to the serious effects associated with these ulcers. Moreover, it is also understood that when these do occur, treatment needs to be started before the condition can worsen. Therefore, the purpose of our current study was to examine the relationship between the depth of the diabetes-related foot ulcers, and the healing days, cost, and QOL. In this study, the depth of the depth, maceration, inflammation/infection, size, tissue type of the wound bed, type of wound edge, and tunneling/undermining (DMIST) measurements, which is utilized as a monitoring tool for the healing process of diabetes-related foot ulcers, was used as an indicator of severity.⁴ As is commonly known in the DESIGN-R tool for pressure ulcers, depth is an independent factor that affects healing, with depth information regarded as important from various perspectives, since chronic wounds have different healing processes depending on the depth.⁵ The findings of this study will help to provide basic data regarding the importance of early consultations in diabetes-related foot ulcers.

2 | MATERIALS AND METHODS

The study was conducted as a secondary analysis of a prospective observational study entitled: "Evaluating the cost-effectiveness of diabetic foot ulcer management by wound care specialists in

Makoto Oe and Suriadi Jais contributed equally to this work.

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Indonesia."⁶ Patients with diabetes-related foot ulcers who visited two national hospitals and one wound clinic in Indonesia between April 2022 and June 2023 were examined for the depth of ulcers, healing days, cost, and QOL, with these patient followed until the ulcer healed. The depth of the ulcer was assessed by the DMIST depth scoring determined on the day of the first visit. The depth score is defined based on the depth that is reached as follows: Depth 0 is intact, Depth 1 is the superficial layer/epidermis, Depth 2 is the subcutaneous/dermis to fatty tissue, Depth 3 is the tendons, Depth 4 is the fascia tissue and/or muscle, and Depth 5 is the bones. As for healing days, the number of days was counted from the first visit to the healing date. In terms of costs, the costs for services, equipment, dressings, and drugs were examined as direct costs while transportation costs for the patient's visits to the hospital were viewed as indirect costs. As of July 31, 2023, 1 USD was converted to 15,099.9 Indonesian rupiahs (IDR).⁷ QOL was investigated using the Indonesian version of the EQ-5D 5 L on the day of the first visit, with the utility values then calculated.⁸ The characteristics of the participants collected included, data on age, sex, duration of diabetes, HbA1c, and ankle-brachial index.

Continuous variables were expressed as the mean and standard deviation. Continuous variables were tested by a one-way analysis of variance and the Tukey HSD method as post hoc testing in relation to the DMIST depth. Categorical data were validated by a chi-square test performed in relation to the DMIST depth. SPSS version 22 was used for statistical analysis, with a significance level of p = 0.05. All tests were two-sided.

The study was conducted in compliance with the Declaration of Helsinki. The protocol for this study was approved by Institut Teknologi dan Kesehatan Muhamamdiyah Kalimantan Barat Ethics Committee in Pontianak, Indonesia (290/II.I.AU/KET.ETIK/II/2022). All participants gave written informed consent.

Key points

- The relationship between the depth of the diabetesrelated foot ulcers, and the healing days, cost, and QOL was examined.
- Depth 4 and 5 ulcers, namely beyond the tendons, exhibited significantly longer healing days and higher costs than Depth 2 and 3 ulcers. As for QOL, there were no significant differences in utility values between the depth categories.
- Results on healing time and cost reiterate the importance of early consultation, especially before the depth becomes deeper than the tendon.

3 | RESULTS

This study evaluated 89 patients with diabetes-related foot ulcers. There were no participants classified as Depth 1, while there were 23 in Depth 2, 30 in Depth 3, 27 in Depth 4, and 9 in Depth 5. There were no significant differences in participant characteristics found between the depth categories (Table 1).

Regarding healing days, Depth 2 ulcers had a significantly shorter healing time as compared to the Depth 4 and 5 ulcers. Depth 3 ulcers had a significantly shorter healing time versus the Depth 4 ulcers (Table 2). In terms of costs, Depth 2 ulcers had a significantly lower total cost versus the Depth 4 and 5 ulcers. Depth 3 ulcers had a significantly lower total cost than Depth 4 ulcers. In contrast, as for QOL, there were no significant differences found in the utility values between the depth categories.

	DMIST depth ^a				
	2 n = 23	3 n = 30	4 n = 27	5 n = 9	р
Age (y)	59.5 ± 9.1	55.6±6.8	53.7 ± 15.9	58.2 ± 6.5	0.27 ^b
Sex					0.38 ^c
Male	10 (43.5)	16 (53.3)	10 (37.0)	6 (66.7)	
Female	13 (56.5)	14 (46.7)	17 (63.0)	3 (33.3)	
Duration of diabetes (y)	6.6 ± 5.4	5.8 ± 4.0	8.4 ± 6.9	7.0 ± 7.7	0.39 ^b
HbA1c (%)	8.9 ± 2.0	8.3 ± 1.5	8.9 ± 1.5	10.0 ± 2.3	0.10 ^b
Ankle-brachial index	0.97 ± 0.12	1.01 ± 0.14	1.00 ± 0.15	1.04 ± 0.07	0.67 ^b

TABLE 1 Characteristics of participants.

Note: mean \pm standard deviation or n (%).

^aDMIST Depth 2: subcutaneous/dermis to fatty tissue, 3: tendons, 4: fascia tissue and/or muscle, 5: bones.

^bOne-way analysis of variance.

^cChi-square test.

	DMIST Depth ^b					
	2 n = 23	3 n = 30	4 n = 27	5 n = 9	p	
Healing time (days)	$29.5 \pm 19.0^{1,2)}$	$45.8 \pm 21.2^{3)}$	$83.3 \pm 58.9^{1,3)}$	$70.6 \pm 39.4^{2)}$	<0.001	
Direct costs (IDR Rp)						
Service	$710,000 \pm 427,232^{4)}$	905,000 ± 489,079 ⁵⁾	$1,949,607 \pm 1,615,830^{4,5)}$	1,677,778 ± 631,522	<0.001	
Equipment	462,609 ± 365,541 ⁶⁾	661,000 ± 507,559 ⁷⁾	1,487,222 ± 1369734 ^{6,7)}	1,355,556 ± 943,479	<0.001	
Dressing	$354,348 \pm 243,400^{8)}$	480,000 ± 332,745 ⁹⁾	1,047,037 ± 1,266,134 ^{8,9)}	925,556 ± 696,946	0.006	
Drug	$309,956 \pm 198,293^{10,11)}$	$371,973 \pm 248,771^{12}$	$676,222 \pm 504,345^{10,12)}$	685,778 ± 352,573 ¹¹⁾	<0.001	
Sum	$1,836,913 \pm 1,043,540^{13)}$	$2,417,973 \pm 1,367,496^{14}$	5,160,089 ± 3,958,353 ^{13,14)}	4,644,667 ± 2,124,213	<0.001	
Indirect costs (IDR Rp)						
Transport	$123,043 \pm 66,311^{15)}$	235,333 ± 285,301	$513,340 \pm 731,446^{15)}$	28,222 ± 124,753	0.02	
Total cost (IDR Rp)	$1,959,957 \pm 1,092,046^{16,17)}$	$2,653,306 \pm 1,550,521^{18}$	5,673,429 ± 4,575,457 ^{16,18)}	$4,926,889 \pm 2,196,522^{17}$	<0.001	
Quality of life	0.6828 ± 0.08121	0.6416 ± 0.07592	0.6532 ± 0.10513	0.6586±0.10283	0.42	

TABLE 2 Relationship between depth of diabetes-related foot ulcer and healing time, cost, and quality of life.^a

Note: mean ± standard deviation, one-way analysis of variance.

^a(1-18) indicate that there was a significant difference in the Tukey HSD method. (1) p < 0.001, (2) p = 0.04, (3) p = 0.002, (4) p < 0.001, (5) p = 0.001, (6) p = 0.001, (7) p = 0.004, (8) p = 0.01, (9) p = 0.03, (10) p = 0.002, (11) p = 0.03, (12) p = 0.008, (13) p < 0.001, (14) p < 0.001, (15) p = 0.01, (16) p < 0.001, (17) p = 0.04, (18) p = 0.001, (19) p = 0.001, (10) p = 0.002, (11) p = 0.03, (12) p = 0.008, (13) p < 0.001, (14) p < 0.001, (15) p = 0.01, (16) p < 0.001, (17) p = 0.04, (18) p = 0.001.

^bDMIST Depth 2: subcutaneous/dermis to fatty tissue, 3: tendons, 4: fascia tissue and/or muscle, 5: bones.

4 | DISCUSSION

This is the first study to compare the healing days, costs, and QOL according to the depth of the diabetes-related foot ulcer, although there has only been a small amount of data reported without any associated statistical analysis.⁹ As a result, our current findings showed that deep ulcers, especially beyond the tendons, had a significantly longer healing time and higher cost as compared to shallow ulcers.

It was not surprising that it takes time for a necrotic tendon to be removed and for the granulation to cover up, which is associated with a concomitant increase in treatment costs. Reports on the monthly cost according to the Wagner classification, and reports without statistical analysis that verified the cost for the presence or absence of infection or decreased blood flow have also shown that the cost tends to increase as the disease becomes more severe.^{10,11} However, one of the important findings of our current study is that our results suggest that the depth beyond the tendon can be used as a guide. This finding indicates the importance of patients seeking medical attention before the disease progresses beyond the tendon, and for the need of healthcare professionals to educate patients and/or families about this issue. Furthermore, developing techniques to rapidly heal ulcers deeper than the tendon may be a solution to this potentially increasing medical burden.

In contrast, there was no significant difference found between the ulcer depth and the QOL. It has been reported that patients with healed diabetes-related foot ulcers have a higher quality of life than patients who still have diabetes-related foot ulcers.^{12,13} In addition, these results may suggest the importance of early healing and the prevention of ulcers, regardless of the depth of the ulcer.

As this study was conducted in Indonesia, it is necessary to pay attention to the extrapolation due to differences in prices of commodities and insurance systems. Furthermore, since this is a secondary analysis, the available data was limited. As the original study revealed,⁶ treatment varied among facilities, which may have affected costs. Since this was a secondary analysis, no sample size calculation was performed. Although the one-way analysis of variance showed a statistically significant difference, if the effect size is 0.25, the post hoc analysis showed a power of 0.47, which is not high. In addition, there are some issues that have yet to be verified, such as the actual situation associated with the Depth 1 ulcers and the effects of infection. However, it is believed that these limitations do not threaten the novelty of varying treatment days and costs depending on the depth.

In conclusion, our current results showed that deep diabetesrelated foot ulcers, especially beyond the tendons, had significantly longer healing days and higher costs as compared to the shallow diabetes-related foot ulcers. This reiterates the importance of early consultation and suggests the need to consider depth when calculating the treatment cost of diabetes-related foot ulcers.

AUTHOR CONTRIBUTIONS

Makoto Oe: Conceptualization; formal analysis; writing-original draft; writing-review and editing. Suriadi Jais: Investigation; supervision; writing-review and editing. Nurmila Sari: Investigation; writing-review and editing. Hiromi Sanada: Supervision; writing-

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review and editing. Agung Sasongko: Supervision; writing-review and editing. Haryanto Haryanto: Investigation; supervision; writingreview and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study. Data sharing is not applicable to this article as no new data were created in this study.

TRANSPARENCY STATEMENT

The lead author Suriadi Jais affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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