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# Accuracy and Cost-effectiveness of the Diabetic Foot Screen Proforma in Detection of Diabetic Peripheral Neuropathy in Myanmar

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**Abstract**

Objective. Proper foot assessment is important for early detection and treatment of diabetic peripheral neuropathy (DPN), the main cause of diabetic foot ulcers (DFUs). This study aimed to determine the accuracy and cost-effectiveness of the locally developed Diabetic Foot Screen (DFS) proforma in detecting DPN among diabetic patients at 10 selected clinics in Yangon, Myanmar.

Methodology. The study included 625 type 2 diabetics from 10 primary care clinics who participated in the diagnostic accuracy and cost-effectiveness analysis. They were assessed with DFS proforma and biothesiometry by two examiners independently. The cost-effectiveness analysis was conducted based on available data in the local primary care setting.

Results. The overall accuracy of the DFS proforma assessment was 74.76% (95% CI: 70.46%- 79.06%). The optimal cut-off DFS score was ≥1.5 (sensitivity 62%; specificity 76%) in detecting DPN. Compared to biothesiometry, the cost-effectiveness of DFS proforma assessment in DPN detection was 41.79 USD per DPN case detected.

Conclusion. This study supported the use of DFS proforma for DPN detection in primary care clinics. It also provided new information on the estimated costs per patient with DPN detected in Myanmar.

*Key words: foot screening, diabetic peripheral neuropathy, biothesiometry, cost-effectiveness, Myanmar primary care*

## INTRODUCTION

The global prevalence of diabetes mellitus (DM) has been increasing exponentially, from 422 million people in 2014 to 463 million people in 2019.[1,2] In Myanmar, the estimated prevalence of DM was 6.6% of the total population in 2016[3] and its prevalence among adults aged 25- 64 years in Yangon region was 18% in 2014.[4] The escalating rise of global and local DM prevalence rates reflects the increasing number of people who are susceptible to diabetic complications annually.

Among individuals with diabetes, the lifetime risk of developing non-traumatic foot ulcers is approximately 15%.[5] Foot ulcers secondary to diabetes are commonly associated with increased morbidity and mortality and are a financial burden to healthcare systems.[6] Among several causes for diabetic foot ulcers (DFUs), peripheral neuropathy is the most important.[6]

Diabetic peripheral neuropathy (DPN) can affect up to 50% of diabetic patients.[7] The prevalence of DPN is around 33.7% in Myanmar.[8] Despite its high prevalence, DPN often remains undiagnosed by healthcare professionals,[2] especially at primary care clinics in Myanmar. The early detection of DPN is recommended for all diabetic patients.[9]

Diabetic foot examination is essential for the primary prevention of neuropathy-related foot complications, and the secondary prevention of neuropathic foot ulcers and amputations. As the comprehensive foot exam requires a detailed investigation of the lower limb by a specialist, it is not feasible in resource-limited primary care clinics in Myanmar.[10] In clinical practice, only a few primary care physicians provide regular foot screening for DM patients, using a 10-gram monofilament to test for DPN. Hence, the Diabetic Foot Screen (DFS) proforma was developed by the Myanmar Ministry of Health and Sports, in collaboration with the World Diabetes Foundation (WDF), as a clinical tool to screen for risk factors for foot ulceration among DM patients. Its initial implementation was at the launch of the Myanmar Diabetic Foot Care Program in 2016.[11]

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The DFS proforma includes focused history taking, foot examination, and three bedside tests: 10-gram monofilament test, ankle reflex, and vibration perception test (VPT) by a 128-Hz tuning fork. It contains a scoring system for each item except for background data, history taking and checking of foot pulses. Although the DFS proforma has already been used in out-patient clinics of a few government hospitals, it has not yet been widely introduced to Myanmar primary care physicians.

As the three bedside tests of the DFS proforma can be done with relatively low expense, it can be useful as a screening tool to detect DPN in primary care. However, its accuracy and cost-effectiveness in the diagnosis of DPN are not known, and need to be studied especially in a primary care setting.

## METHODOLOGY

### Subjects, materials and methods

This study was aimed to determine the diagnostic accuracy and cost-effectiveness of the DFS proforma in the detection of DPN among diabetic patients at primary care clinics in Yangon, Myanmar. The first part of the study was the cross-sectional study for diagnostic accuracy of the DFS proforma (which was a one-time assessment without repetition) and the second part was the cost-effectiveness analysis.

### Study subjects

For the diagnostic accuracy study, 10 private primary care clinics of the members of the General Practitioners' Society located in Yangon were first selected. Participants were then selected by purposive sampling. Previously diagnosed diabetic patients, 18 years and above, who came to the selected clinics at least once during the data collection period, were included. Diabetic patients who were previously diagnosed with any kind of neuropathy other than diabetic peripheral neuropathy and those with peripheral vascular disease and unhealed foot ulcers were excluded. The sample size calculated using the formula for ROC analysis [$n = ((Z_{\alpha/2}))^2 V((AUC)\hat{\ }))/(d^2)$] was 184, while sample size calculated by using the formula for the cross-sectional diagnostic study was 620 [$n = p(1-p)/d^2*(Z_{\alpha/2})^2$]. This study was approved by the Research Ethics Board of the University of the Philippines Manila (UPMREB 2020-254-01) in May 2020 and by the Institutional Review Board of the University of Public Health (UPHIRB 2020/Research/13), Myanmar, in July 2020.

### Data collection procedure

All eligible participants from the ten clinics were continuously recruited through their respective doctors from July 12, 2020, to January 17, 2021. Detailed information about the study was provided to the participants in the Burmese language and written informed consent was taken.

Before data collection, the primary investigator (PI) and his research assistant (RA) received training from a footcare specialist for biothesiometry and the DFS proforma assessment using the standardized procedures, respectively. The results of biothesiometry reported by the PI were compared with the results reported by the footcare specialist to test the inter-rater reliability.

All participants were assessed with the DFS proforma by the RA and with a biothesiometry test by the PI independently. The results of one examiner were blinded to the other while they were assessing the patients. The DFS proforma assessment was done according to the standard procedures in the guideline of the Myanmar Diabetic Foot Care Program.[11]

Biothesiometry assessment was used as the reference-standard test in this study because there were several limitations to referring the patients to hospitals for nerve conduction studies during the time of coronavirus 2019 (COVID-19) pandemic. The vibration perception threshold (VPT) of each patient was assessed with Vibrasens - a portable digital biothesiometer (Mediko Foot Care, India) according to the standard procedure for biothesiometry.

The cost-effectiveness analysis of the DFS proforma assessment in DPN detection was done based on the available data from the selected clinics. The primary care physicians were asked to collect the cost-related data for the DFS proforma test and the mean of 10 different costs was taken as the estimated cost for the DFS proforma test per patient.

In the cost-effectiveness analysis, only the direct costs related to the DFS proforma test and biothesiometry were considered. Cost estimations were done for local primary care settings from the patients' perspective. Indirect costs due to transportation and loss of productivity were not included because of the lack of a standardized way to measure such costs in the local context.

### Data processing and analysis

Background characteristics of the patients were analyzed as mean and standard deviation (SD) for quantitative variables and numbers with percentages for qualitative variables. The sensitivity, specificity and likelihood ratios of the DFS proforma assessment with different cut-off scores in detecting DPN were obtained from the receiver operating characteristics (ROC) curve analysis by using Stata 15.0. From ROC analysis and Youden's index, the receiver operator cut-off score of the DFS proforma, with the optimal sensitivity and specificity, was determined.

The cost-effectiveness analysis included 2 hypothetical groups of 1000 diabetic patients: the DFS group, assessed with the DFS proforma and the biothesiometry group. Theanalysis was done by comparing the cost and the number of DPN cases detected in the DFS group, with the cost of biothesiometry and the number of DPN cases detected in the biothesiometry group. The effect of false positive and false negative test results was considered in analyzing the cost-effectiveness. Sensitivity analysis was done by using the different costs of the DFS proforma test and biothesiometry and the estimated number of DPN cases detected for the DFS group and biothesiometry group. All cost estimations were done in local currency, Myanmar kyat (MMK), which were converted to the equivalent US dollar (USD) at the time of data analysis.

## RESULTS

### Diagnostic accuracy study

The diagnostic accuracy study consisted of 625 diabetic patients from 10 selected primary care clinics located in seven townships of Yangon, Myanmar. The baseline characteristics of the participants are summarized in Table 1.

The majority of the participants were female (71.4%), with a mean age of 57.8 years. The average height, weight and body mass index (BMI) of the participants were 156.9 cm, 65.4 kg, and 26.5 kg/m$^2$, respectively. All had type 2 diabetes with a mean diabetes duration of 6.2 years. Majority of the participants were non-smokers (77.9%); 81.6% did not drink alcoholic beverages. Only 231 participants had hemoglobin A1c (HbA1c) results tested within the previous 6 months. Their mean HbA1c value was 7.9% (63 mmol/mol).

### Results of the DFS proforma assessment

All participants received both the DFS proforma assessment (Figure 1) and biothesiometry during their respective visits at 10 selected clinics. The flow of participants throughout the study is described in Figure 2.

**Table 1.** Baseline characteristics of the study participants

| Characteristics | | |
|---|---|---|
| Female gender | Frequency (%) | 446 (71.4%) |
| Age (years) | Mean (SD) | 57.8 (10.09) |
| BMI (kg/m$^2$) | Mean (SD) | 26.5 (4.69) |
| Duration of diabetes (years) | Mean (SD) | 6.2 (5.97) |
| Smoking status | Frequency (%) | |
| Non-smoker | | 487 (77.9%) |
| Current smoker | | 57 (9.1%) |
| Ex-smoker | | 81 (13.0%) |
| Alcohol drinking status | Frequency (%) | |
| Non-drinker | | 510 (81.6%) |
| Current | | 54 (8.6%) |
| Ex-drinker | | 61 (9.8%) |
| HbA1c results (%)* | Mean (SD) | 7.9 (2.01)* |

*Only 231 participants had HbA1c results; SD: standard deviation

The DFS proforma assessment found that 48.3% (302/625) of patients had neuropathic symptoms (tingling, numbness, or altered sensation). The majority did not have intermittent claudication (95.7%), rest pain (99%), or previous foot ulcers (96.8%). The foot examination revealed that: 89.6% (560/625) of participants did not have any sign of infection on either foot; 31.7% (198/625) had callus and/or dry skin; and 58 patients had foot deformities. None of the participants had a foot ulcer at the time of examination.

The results of the monofilament test were scored as 'all present' (score-0), '>2 points absent' (score-0.5), or 'all absent' (score-1) for each foot. We found 511 patients (81.8%) had protective sensation in all 10 points tested on each foot; 34 had a loss of protective sensation (LOPS) in >2 points on one foot, and 59 had LOPS in >2 points on both feet.

Ankle reflex was present in all but two of the study participants (623, 99.7%). The results of the 128-Hz tuning fork test were scored as 'present' (score-0), 'reduced' (score-0.5), or 'absent' (score-1) for each foot. Vibration perception was present on both feet in 435 patients (69.6%); reduced on both feet in 19 patients (3%), and absent on both feet in 61 patients (9.8%). The remaining 17.6% had reduced and/or absent vibration perception on one or both feet.

The overall result of the DFS proforma assessment was described as the DFS score, the sum of the scores from the foot examination and the three bedside tests. A DFS score of less than 1.5 was found in 64.8% (405/625) of the participants, while the rest scored between 1.5 to 8.

### Results of the biothesiometry

During biothesiometry training, the inter-rater reliability was checked as follows: the footcare specialist and PI independently assessed 10 DM patients. The overall agreement on VPT values between the two assessors was 80%. Due to constraints in getting appointments with the same foot-care specialist for the inter-rater reliability test, it involved only 10 patients. However, the PI strictly followed the specialist's guidance and the standard procedure for biothesiometry during data collection.

In the diagnostic accuracy study, 185 patients (29.6%) with the average VPT value of >25 V on one or both feet were diagnosed with DPN (DPN-positive). On the other hand, 440 patients (70.4%) with the average VPT ≤25 V were not diagnosed with DPN (DPN-negative).

**Table 2.** Direct cost and estimated number of patients with DPN detected per group

| Name of the groups | The direct cost of the test per group in USD (min.- max.) | Estimated number of patients with DPN detected (n; 95% CI) |
|---|---|---|
| DFS group | 3080 (1337.1 - 6685.4) | 184 (160 - 208) |
| Biothesiometry group | 7760 (6016.8 - 11365.2) | 296 (268 - 324) |

n: point estimate; 95%CI: 95% confidence interval; min.-max.: minimum – maximum

**Results of the ROC analysis**

The area under the curve (AUC) was defined as the measure of overall diagnostic accuracy, which reflected the probability of correctly diagnosing a DM patient with DPN by using the DFS proforma. From the ROC analysis (Figure 3), the overall accuracy (AUC) of the DFS proforma assessment in detecting DPN was 74.76% with a 95% confidence interval (CI) of 70.46% - 79.06%. The DFS score of ≥1.5 was determined as the receiver operator cut-off score, with the optimal sensitivity of 62.2% (95% CI: 55.17%- 69.15%), and specificity of 76.1% (95% CI:

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**Diabetic Foot Screen** **Date of examination.........................**

Patient name...............................................Male ☐ Female ☐ Date of Birth...................

Type1 ☐ Type 2 ☐ Year at onset.......... Treatment - Diet ☐ OHA ☐ Insulin ☐

| Ask the patient | Yes | No | Look at both feet | Lf | | Rt | |
|---|---|---|---|---|---|---|---|
| Neuropathic symptoms | ☐ | ☐ | Infection | + | - | + | - |
| Intermittent claudication | ☐ | ☐ | Callus/dry skin | + | - | + | - |
| Rest pain | ☐ | ☐ | Deformity | + | - | + | - |
| Previous ulcer or amputation | ☐ | ☐ | Ulcer | + | - | + | - |
| | | | **If YES score 1** | | | | |

**Monofilament test**

| | Left | Right |
|---|---|---|
| **All present** | **0** | **0** |
| **>2 abscent** | **0.5** | **0.5** |
| **All abscent** | **1** | **1** |

| Check foot pulses | Left | | Right | |
|---|---|---|---|---|
| | Yes | No | Yes | No |
| Dorsalis pedis | ☐ | ☐ | ☐ | ☐ |
| Posterior Tibial | ☐ | ☐ | ☐ | ☐ |
| **If No refer for BAI** | | | | |

| Ankle reflex (please tick) | Left | Right | Vibration | Left | Right |
|---|---|---|---|---|---|
| Present | 0 | 0 | Present | 0 | 0 |
| Reinforced | 0.5 | 0.5 | Reduce | 0.5 | 0.5 |
| Absent | 1 | 1 | Abscent | 1 | 1 |

| score | Risk Category | √ | | Follow up |
|---|---|---|---|---|
| 0- 1.5 | 0 | | No LOPS or peripheral artery disease | Annually |
| ≥ 2 | 1 | | Peripheral neuropathy | 6 months |
| ≥ 2 + PVD (or) PVD alone | 2 | | Peripheral neuropathy with peripheral artery disease and/or a foot deformity | 3-6 months |
| amputation | 3 | | Peripheral neuropathy and a history of foot ulcer or lower-extremity amputation | 1-3 months |

Diabetic Foot awareness campaign

**Figure 1.** The Diabetic Foot Screen Proforma.

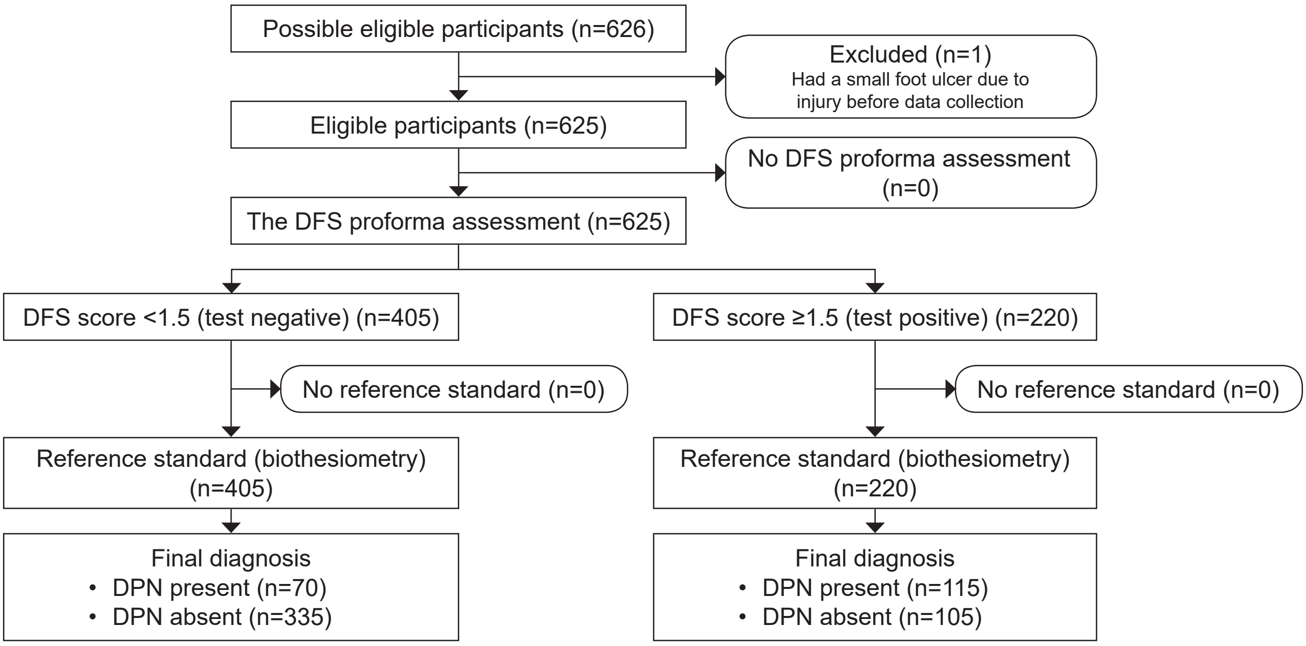


**Figure 2.** Diagram showing the flow of participants throughout the diagnostic study.

72.15%- 80.12%). The Youden's index (*J*) of the cut-off score ≥1.5 was 0.383. For the cut-off score ≥1.5, the positive predictive value was 52.3% (95% CI: 45.67%- 58.87%), negative predictive value was 82.7% (95% CI: 79.03%- 86.39%), likelihood ratio for a positive test was 2.6 (95% CI: 2.13- 3.19), and likelihood ratio for a negative test was 0.5 (95% CI: 0.41- 0.60).

### Cost-effectiveness analysis

The results of the cost-effectiveness analysis included the following: the direct costs of the DFS proforma and biothesiometry assessments, the number of patients with DPN (DPN cases) detected by the DFS proforma test, the number of DPN cases detected by biothesiometry, and the cost-effectiveness of the DFS proforma assessment compared to biothesiometry in the detection of DPN.

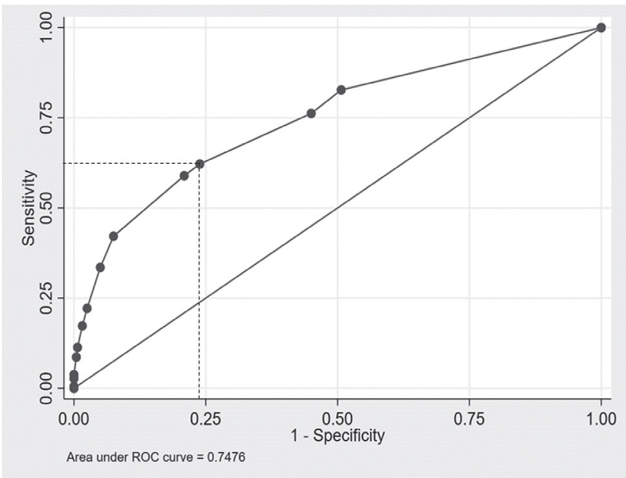


**Figure 3.** ROC curve of the DFS proforma assessment with different cut-off DFS scores.

### Direct costs of the DFS proforma and biothesiometry assessments

In Myanmar private GP clinics, the consultation fees and service fees are fees charged to individual patients for each clinic visit. Doctors do not usually charge additional fees for simple bedside tests (such as monofilament test, ankle reflex test, and 128-Hz tuning fork test) which can be done as part of a physical examination. Among the 10 clinics, the mean consultation and service fee was USD 3.08 per patient. The DFS proforma assessment could be done during the consultation, and the investment costs of the required instruments (monofilament, 128-Hz tuning fork and reflex hammer) per patient were negligible (<USD 0.05). Therefore, the direct cost for each patient was taken as the mean of consultation fees and service fees totaling USD 3.08.

Similarly, the direct cost of biothesiometry for each patient was calculated by adding the average of consultation and service fees (mentioned above) with an extra charge for each biothesiometry assessment. The additional extra charge (MMK 7000 or USD 4.68) covered the cost of the biothesiometer device. The direct cost of biothesiometry was approximately USD 7.76 per patient.

### Estimation of the number of patients with DPN

Based on the results of the diagnostic study, the proportion of diabetic patients with DPN detected by the DFS proforma test was calculated for a group of 1000 DM patients as follows:

Proportion of DM patients with DFS score ≥1.5 x positive predictive value x 1000 patients = 0.352 x 0.523 (PPV) x 1000 = 184 patients

From the above calculation, the number of patients with DPN detected by the DFS proforma assessment was 184 out of 1000 DM patients ($N_{DFS}$).

Similarly, the proportion of diabetic patients with DPN detected by biothesiometry was determined in the diagnostic study as 29.6%. Hence, the number of patients with DPN detected by the biothesiometry assessment was 296 out of 1000 DM patients ($N_{Bio}$).

### Results of sensitivity analysis on the cost of tests and number of DPN cases detected

By doing the sensitivity analysis, the minimum and maximum direct costs of the DFS proforma test and biothesiometry were found for each hypothetical cohort of 1000 diabetic patients (the DFS group and the biothesiometry group). The 95% confidence interval for the number of DPN cases detected in each group was also determined. The results of the sensitivity analysis are summarized in Table 2.

### Cost-effectiveness of the DFS proforma

Compared to biothesiometry, the cost-effectiveness (CE) of the DFS proforma test in DPN detection was determined by dividing the difference in the direct costs of the DFS proforma test and biothesiometry test with the difference in the number of DPN cases detected in the DFS group and the biothesiometry group. The calculation was done as follows:

$$\text{Cost-effectiveness ratio (DFS vs Bio)} = \frac{C_{Bio} - C_{DFS}}{N_{Bio} - N_{DFS}}$$

Where, $C_{Bio}$ = direct cost of biothesiometry (7760 USD), $C_{DFS}$ = direct cost of the DFS proforma test (3080 USD), $N_{Bio}$ = 296 patients, $N_{DFS}$ = 184 patients, CE ratio (DFS vs Bio) = 4680/112 = 41.79 USD per DPN case detected.

Thus, the cost-effectiveness of the DFS proforma assessment in DPN detection was USD 41.79 per DPN case detected.

## DISCUSSION

This study is the first of its kind to determine the accuracy of the DFS proforma in detecting DPN among diabetic patients in Yangon, Myanmar. The background characteristics of participants showed that the results could apply to a similar population of patients with Type 2 DM consulting in primary care clinics in Yangon.

The mean BMI of participants (26.5 kg/m$^2$) was higher than the average BMI of the adult population in Myanmar (22.3 kg/m$^2$).[4] Comparing the smoking and drinking status of participants were to that of the general adult population, the proportions of smokers (9.1%) and drinkers (18.4%) among participants were lower than that of smokers (26.1%) and drinkers (31.2%) among Myanmar adults.[4]

Only 37% of patients had HbA1c rechecked within six months which could partly be due to stay-at-home regulations and fear of visiting healthcare centers during the COVID-19 pandemic.

According to International Diabetes Federation, more than two-thirds of physicians can miss signs and symptoms of DPN.[2] An Indonesian study found that most physicians rely on history taking alone to screen for DPN.[12] In this study, only 120 out of 302 patients (39.7%) with neuropathic symptoms were diagnosed with DPN. It is clear DPN should not be diagnosed with history taking alone.

This study also showed that the monofilament test had low sensitivity (44.3%) and high specificity (92.7%) in detecting DPN. A systematic review on the accuracy of the monofilament test recommended using it with the 128-Hz tuning fork test, ankle reflex test, and pinprick test.[13] Based on our results, the monofilament test should be used together with other neurological tests for DPN screening in daily practice.

We also found that nearly all participants (99.7%) had a normal ankle reflex. In a study by Jayaprakash et al., the accuracy of the ankle reflex test was 62.3%.[14] Therefore, the ankle reflex test should also not be used alone to diagnose DPN. One study reported that the DPN detection rates of the 128-Hz tuning fork test (32.6%) and 10-gram monofilament test (31.4%) were similar while both rates were higher than that of the ankle reflex test (23.1%).[15] In our study, the 128-Hz tuning fork test showed a relatively higher sensitivity (59.5%) and lower specificity (81.8%) than the monofilament test. So, the 10-gram monofilament, ankle reflex and 128-Hz tuning fork tests should be used together for better DPN detection.

The Michigan Neuropathy Screening Instrument (MNSI) cut-off of 2 had 65% sensitivity and 83% specificity whereas the DFS cut-off score of 1.5 had 59% sensitivity and 79% specificity. The accuracy of the DFS proforma with a cut-off score ≥1.5 (72%) is comparable to that of the MNSI with cut-off ≥2 (76%).[16]

This study also determined the cost-effectiveness of the DFS proforma in the detection of DPN. We estimated the proportion of patients with DPN among DM patients in the primary care setting but our findings do not apply to diabetic patients who are not treatment compliant or who are consulting in public hospitals because the prevalence of DPN may be higher in those patient groups.

Primary care physicians play an important role in the early detection and treatment of DPN since they care for the majority of DM patients in the community. One clinical review mentioned that the prevention of DFUs should begin with DPN screening in primary care settings. While screening, doctors can simultaneously provide patient education to reduce the risks for DFUs.[6]

As the reported costs were estimated from March to April 2021, the costs are liable to change later, responding to inflation. This study reported that there would be an additional cost of nearly USD 42 (MMK 62,824) for one patient with DPN detected if the biothesiometry test is used, instead of the DFS proforma test. DFS proforma assessment was less costly but less accurate than the biothesiometry test in diagnosing DPN among diabetic patients. Despite this, the DFS proforma test can be easily done by any healthcare professional trained to fill up and calculate the scores of the proforma and how to do three bedside tests (monofilament test, tuning fork test, and ankle reflex test). In addition to requiring electricity, biothesiometry entails advanced hands-on training by a foot care specialist or an experienced operator of biothesiometer devices which are not widely available in Myanmar. Thus, the DFS proforma test may be more feasible and applicable for DPN detection in the resource-limited primary care setting.

Although there is no cost-effectiveness threshold for diagnostic tests to detect diabetic complications in Myanmar, the direct cost of the DFS proforma test per DPN case detected is less than 3% of the local gross domestic product (GDP) per capita (USD 1407).[17] The assessment is cost-effective and affordable for most DM patients consulting at Myanmar primary care clinics.

### Limitations of the study

The main limitation of the diagnostic study is the use of biothesiometry as an alternative reference standard test. Due to the use of purposive sampling, the generalizability of the results is relatively limited. However, the results would still apply to patients of similar background characteristics in the primary healthcare setting. In the cost-effectiveness analysis, the indirect costs for the two diagnostic tests were not included because of the lack of a standardized way to measure such costs in Myanmar.

## CONCLUSION

In conclusion, the results of this study supported the use of the DFS proforma as a screening tool for DPN and provided valuable information for primary care physicians and health authorities about the estimated costs of using the DFS proforma compared to biothesiometry. The use of the DFS proforma should be promoted among physicians in the resource-limited primary care setting of Myanmar.

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**Statement of Authorship**
All authors certified fulfillment of ICMJE authorship criteria.

**Author Disclosure**
The authors declared no conflict of interest.

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