Research article

Thai version of the Questionnaire for Diabetes-Related Foot Disease (Thai Q-DFD): validity and reliability

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ABSTRACT

Aims: To reduce diabetic foot complications, an annual screening of diabetes-related foot disease (DRFD) should be promoted. The screening tool as the Thai translated Questionnaire for Diabetes-related Foot Disease, Thai Q-DFD, has been established. The study was designed to assess the validity and reliability of the Thai Q-DFD before practical use in the community.
Methods: One hundred and thirty-nine persons with diabetes volunteered in a concurrent validity testing for agreement in diagnosis between the Thai Q-DFD and the standard clinical examinations. The test-retest reliability (a stability of a tool over time between three days apart) was assessed in 50 volunteers. The agreement in either validity or reliability test was evaluated using kappa coefficient.
Results: The screening diagnosis as DRFD by the Thai Q-DFD substantially agreed with that by the standard clinical examinations (kappa = 0.71). The Thai Q-DFD also showed high sensitivity (0.92) and specificity (0.78). Additionally, the Thai Q-DFD presented good test-retest reliability for DRFD diagnosis (kappa = 0.74).
Conclusions: The Thai Q-DFD is comparable to the original English version in terms of concurrent validity and test-retest reliability. Therefore, it can be used for a screening of DRFD in Thai people.

1. Introduction

Diabetes Mellitus (DM) is a metabolic disease with a hyperglycemic condition caused by either defect in insulin secretion or insulin action [1]. High levels of blood sugar over long periods of time result in blood vessel damage. So, persons with DM is strongly associated with both microvascular and macrovascular complications [2]. Diabetes-related foot diseases (DRFD) are pathological complications resulting from vascular complications in DM [3]. The previous studies found that dominant pathological complications of DRFD are peripheral arterial disease (PAD), diabetic peripheral neuropathy (DPN), foot deformity, and a history of foot ulceration or amputation [4, 5, 6, 7]. Patients with a history of foot ulceration have higher mortality rates than those without foot ulceration [8]. Thus, DRFD (or foot complications) is a significant problem in people with DM. The study related to a diabetes cost model of a hospital in Thailand found that the cost was increased up to 88.33 % in the case of diabetic foot condition [9]. Also, it demonstrated that prevention or screening of complications in DM was more cost-effective than a cure [9]. From those reasons, the study suggested that diabetic management in Thailand should take initiative in promoting and enhancing

an annual screening of diabetes complications in all persons with DM. A proactive prevention has proven to be more beneficial instead of applying a cure after complications have already occurred [10].

Previous studies showed that less than half of diabetic patients in Thailand received annual foot examinations and there were limited data available on diabetes related foot disease [11, 12, 13]. Moreover, only a few researches showed the prevalence of DRFD in the community of Thailand [13]. This is important information for the future planning/policy of the health care services involving Thai people with DM, especially in the rural areas. Therefore, the health policy should rather focus more on health promotion and disease prevention than treatment [14]. Similarly, to reduce diabetic foot complications and lower extremity amputations, an annual screening for DRFD in all patients should be promoted. Thus, a tool for DRFD screening, which has a good psychometric property and is easy to use for a mass of DM population in Thai communities will prove very helpful. American Diabetes Association in 2016 recommended that an annual comprehensive foot evaluation should be performed to identify risk factors of ulcers and amputations. The foot assessment should include the skin and foot deformity inspection, neurological and vascular examinations [15].

Although the clinical examination is the gold standard for DRFD screening, it is costly and time consuming and not widely accessible in rural populations [10]. Therefore, a valid and reliable clinical screening tool, that is easy and reduces time to administer, will be valuable and cost effective in identifying those persons with DRFD in rural areas of Thailand. In addition, it will be useful not only for clinical screening purposes, but also for epidemiological surveys. Many questionnaires concerning DRFD have been developed, such as Michigan Neuropathy Screening Instrument (MNSI) [16], Diabetic Neuropathy Symptom Score (DNS) [17], and Edinburgh Claudication Questionnaire (ECQ) [18]. Then again, most of them evaluate only one component of DRFD as DPN or PAD. After an extensive search, the Questionnaire for Diabetes-Related Foot Disease (Q-DFD) is the only survey that addresses all the components of DRFD within one tool [3]. The Q-DFD demonstrated an agreement with either clinical assessment and medical record for an overall diagnosis of DRFD, where any of DPN, PAD, ulcer, amputation or foot deformity was identified (kappa 0.65, sensitivity 89.0%, specificity 77.8%) [3]. Moreover, inter and intra-rater reliability and test-retest reliability of the Q-DFD was moderate to high for all survey domains [3].

Currently, an original English version of the Q-DFD has been translated into Thai with some items being modified to accommodate cultural differences. However, reliability and validity of the Q-DFD Thai version (Thai Q-DFD) have not been evaluated. This study, therefore, aimed to examine test-retest reliability and concurrent validity of the Thai Q-DFD.

2. Material and methods

The research was a cross-sectional study to prove a test-retest reliability and concurrent validity of the Thai Q-DFD which was conducted following the guidelines proposed by the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) [19]. The research methodology was approved by the Research Ethics Committee of the Strategic Wisdom and Research Institute (Certificate Number SWUEC/E/G-002/2563) and the Faculty of Physical Therapy (Certificate Number PTPT2020-002), Srinakharinwirot University, Thailand.

2.1. Participants

The participants in this study were selected using convenience sampling from the Ban Nong Khla Health Promoting Hospital, Wang Wiset District, Trang Province, Thailand. They had to pass the inclusion as follows: 1) age 45 years or over, 2) be diagnosed with type 1 or type 2 diabetes mellitus, 3) permanent residents in rural areas of Thailand, and 4) able to understand and speak Thai to complete the survey. The participants bearing communication disorder, hearing loss, neurological diseases, such as Parkinsonism, stroke, or cognitive impairment were excluded. Cognitive impairment was determined by a score <5 from a dementia screening test (DST) for Thai elderlies [20]. All participants were informed about the research procedure and signed the consent form before participation.

The sample size for the test-retest reliability was calculated using the formula for reliability study with binary outcome measures [21] by setting the expected value of kappa 0.90, the probability of positive rating 0.50, the desired width of confidence interval 0.20, and the Z score at 95% confidence (1.96). The calculated sample size was 45 participants. Assuming 10% of participant might refuse to repeat the Thai Q-DFD. Hence, with 10% dropout reserve, a total of 50 participants were recruited.

The sample size for the concurrent validity study was calculated using the formula for sensitivity/specificity study with binary test outcome [22]. The calculation was based on the sensitivity of ankle-brachial index 0.90 [23], the degree of error allowance 0.05, and the Z score at 95% confidence. Thus, the estimated sample size for the concurrent validity study was 139 participants.

2.2. Procedure

2.2.1. Test-retest reliability

The fifty participants who passed the inclusion and exclusion criteria attended the test-retest reliability evaluation. Each participant completed the Thai Q-DFD on two occasions independently. Those participants who were unable to read were interviewed by the village health volunteers using the same context as written in the Thai Q-DFD, also during two occasions. The second occasion was conducted 3 days after the first occasion during the same time of day. No intervention was given during the 3 days interval. This time period was chosen to prevent memory effects and changes in DRFD symptoms. Prior to the study, the village health volunteers were trained how to conduct an interview by using the Thai Q-DFD.

2.2.2. Concurrent validity

The 139 participants, who volunteered and passed the inclusion and exclusion criteria, were recruited for a concurrent validity test. Concurrent validity was to prove the agreement between the results of DRFD diagnosis by the Thai Q-DFD and those by the clinical examinations. The participants completed the Thai Q-DFD by themselves, except for those who were unable to read. Those participants were interviewed using the same context as written in the Thai Q-DFD by the village health volunteers. After completion of the Thai Q-DFD, they received clinical examination by the healthcare professionals who had at least five years' experience in diabetic foot assessment. The healthcare professionals who performed the clinical examination were blind to the Thai Q-DFD screening outcomes.

2.3. Outcome measures

The outcome measures of the concurrent validity study were the DRFD screening results from the Thai Q-DFD and those from the clinical examination. The clinical examination included the assessment of peripheral sensory neuropathy with a vibration sense test using a 128-Hz tuning fork, and a pressure sense test using 10-gram monofilament; the assessment of PAD with manual palpation of pedal pulses and determination of Ankle Brachial Index (ABI); and the assessment of foot deformity, foot ulcers/amputation by observation and history taking. Components of the clinical examination were based on current literature and the best practice recommendations for clinical evaluation in the diabetic foot condition [15, 24]. The screening result as a "DRFD" was defined by showing at least one of these complications: peripheral arterial disease (PAD), diabetic peripheral neuropathy (DPN), foot deformity, and a history of foot ulceration or amputation.

2.3.1. Thai version of the Questionnaire for Diabetes Related Foot Disease (Thai Q-DFD)

The study has received a permission from the first author of the original Q-DFD for translation and cross-cultural adaptation to Thai version. The process of the translation and cross-cultural adaptation demonstrated that the Thai Q-DFD was equivalent to the original English version in either semantic, idiomatic, conceptual, or experimental aspects. Also, the Thai Q-DFD was straightforward enough to understand for individuals with diabetes living in rural areas of Thailand, of which whom were mostly at primary education level. Each question in the Thai Q-DFD is a nominal scale which requires dichotomous "yes/no" responses based on self-report, and it was not designed to have a total score. The items are grouped into five domains that are screening of DPN, PAD, foot deformity or skin issue, foot ulceration, and lower extremity amputations [3]. The Thai Q-DFD aims to detect the presence or absence of self-reported signs and symptoms for DPN (questions 3a through 3e), PAD (questions 5a through 5c, questions 7a) and/or the history of clinical diagnosis of sensory DPN (questions 8a through 8c) or PAD (questions 8d

through 8f, questions 9), foot ulcers (questions 10a), amputation (questions 11a), and foot deformity/skin issue (questions 12a through 12e). The sensory DPN and/or PAD are recognized based on symptomology, one or more of the nominated symptoms must have been presented for at least a month, and remained constant over that time period. The symptoms used for sensory neuropathy diagnosis are tingling, burning, numbness, pins and needles and tightness, while that for PAD diagnosis are claudication and rest pain. The last in each domain of DPN (questions 4) and PAD (questions 6, 7b) is an open-ended question permitting participants to elaborate on a relief for their symptoms and how it is effective. The interpreted diagnostic results, as having DRFD, was defined by presenting the response with at least one of DPN, PAD, ulcer, amputation, or deformity from the Thai Q-DFD completion similar to the original QDFD [3].

2.3.2. Vibration sense assessment

Vibration testing was conducted using a 128-Hz tuning fork applied to the bony prominence at the dorsum of the first interphalangeal joint of the great toe when the toe was extended. The participant was asked to report the perception of both the start and the cessation of vibration from the tuning fork. The testing was conducted twice on each great toe. During the test, the tester also felt the starting and cessation of the vibration from the tuning fork that the tester was holding. Then, the tester measured the time difference between the patient reporting the cessation of vibration until the tester felt that the vibration disappeared. The time difference $\geq$10 s was considered as abnormal sensation of the patient [25].

2.3.3. Pressure sense assessment

Pressure sensation of the foot was tested with 10 g Semmes–Weinstein monofilament which shows to be valid and reliable for testing. The examiner applied the monofilament on the appropriately selected locations (plantar surface of the 1st, 3rd, 5th metatarsal heads, and distal hallux) of the participants for 1–2 s while their eyes were closed [25, 26]. The examiners avoided areas of callus when testing and used the required force. Then, participants were asked to answer "yes" or "no" to indicate whether they felt pressure from the monofilament and also to report the correct sites [27]. An absent sensation at any one of the four tested sites found was indicated that pressure or protective sensation of the tested foot was lost [28].

2.3.4. Ankle-brachial index measure

The ankle-brachial index (ABI) is a sensitive and specific test for determining PAD. The ABI was performed by measuring systolic blood pressure in the upper (brachial artery) and lower (dorsalis pedis and posterior tibialis arteries) extremities. The systolic blood pressures of the brachial artery, dorsalis pedis and posterior tibial arteries were measured bilaterally after a 5 min rest in the supine position using a sphygmomanometer and an 8 MHz Doppler to detect pulses. The lower edge of the cuff was 2 cm above the superior aspect of the medial malleolus [29]. The sequences of systolic blood pressure measurement were started from the right arm, followed by the right ankle, left ankle and left arm. The systolic blood pressure at the first blood flow sound is heard from the Doppler as the cuff of an aneroid sphygmomanometer deflating was recorded. ABI was calculated for each lower limb using arm highest systolic pressure as denominator, and ankle highest pressure as numerator. An ABI of less than 0.90 was a predictive of PAD [2, 30].

2.4. Data analysis

The questions in the Thai Q-DFD are nominal scale and was not designed to have a summative score. So, the test-retest reliability was estimated on each question of DRFD, each domain of DRFD (DPN, PAD, ulcer, amputation, deformity), and on the interpreted diagnostic results as DRFD (defined as presenting with at least one of DPN, PAD, ulcer, amputation, or deformity) by Cohen's kappa statistic [31, 32, 33]. The

concurrent validity was estimated on the final interpreted diagnostic results from the Thai Q-DFD with those from the standard clinical examination by kappa coefficient, sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratios (positive likelihood ratio [LR+] and negative likelihood ratio [LR-]) [31, 32].

Based on a suggestion of Landis and Koch [34], a kappa value of 0–0.20 was considered as slight agreement, 0.21–0.40 was fair agreement, 0.41–0.60 was moderate agreement, while a kappa value of 0.61–0.80 was considered as substantial agreement, and a kappa value of 0.81–1.00 was considered as an almost perfect agreement.

3. Results

3.1. Test-retest reliability

The test-retest reliability of Thai Q-DFD was assessed on each question related DRFD, on each domain of DRFD (DPN, PAD, ulcer, amputation, deformity), and on the interpreted diagnostic results as DRFD (defined as presenting with at least one of DPN, PAD, ulcer, amputation, or deformity). The participants for the test-retest reliability consisted of 50 diabetic patients from Ban Nong Khla Health Promoting Hospital, Wang Wiset District, Trang Province, Thailand. Thirty-five participants (70%) were women, and the rest fifteen persons (30%) were men. Their ages were 47–83 years (64.56 $\pm$ 9.42 years). Most participants (82%) possessed primary educational levels. The average BMI was 25.81 $\pm$ 5.58 kg/m^2. The average duration of diabetes was 9.32 $\pm$ 7.12 years. All participants had no cognitive impairments evaluated by DST. Details of the participants' characteristics are presented in Table 1.

Table 2 presents results of the test-retest reliability as kappa values for individual questions in the Thai Q-DFD. The kappa values of the test-retest reliability for all questions ranged from 0.15 (slight agreement) to 1.00 (almost perfect agreement).

Kappa values for each domain of DRFD (DPN, PAD, ulcer, amputation, deformity), and on the interpreted diagnosis as DRFD of the Thai Q-DFD are presented in Table 3. The results showed that test-retest reliability of the domains of DRFD ranged from moderate (kappa = 0.56, p = 0.0001) to almost perfect (kappa = 0.83, p = 0.0001). The deformity domain showed the almost perfect agreement (kappa = 0.83, p = 0.0001). The PAD (kappa = 0.79, p = 0.0001) and ulcer (kappa = 0.79, p = 0.0001) domains demonstrated substantial agreement. The DPN domain had a moderate agreement (kappa = 0.56, p = 0.0001). However, no analysis was made for amputation domain, as no individual reported this domain. Meanwhile, the test-retest reliability on the interpreted diagnosis as DRFD (defined as presenting with at least one of DPN, PAD, ulcer, amputation, or deformity) by the Thai Q-DFD was substantial agreement (kappa = 0.74, p = 0.0001).

3.2. Concurrent validity

Concurrent validity of the Thai Q-DFD was evaluated by the correlation of the screening outcomes from the Thai Q-DFD and that from the clinical examinations. The participants completed the Thai Q-DFD, and then received the clinical examinations in the same day. The participants consisted of 139 diabetic patients from Ban Nong Khla Health Promoting Hospital, Wang Wiset District, Trang Province, Thailand. They were aged 45–87 years (63.42 $\pm$ 10.06 years). Ninety-five participants were women (68.3%), while the rest, forty-four participants, were men. Most of them (82%) were educated at primary level. The averaged BMI was 25.85 $\pm$ 5.69 kg/m^2, and the duration of diabetes was 9.70 $\pm$ 7.01 years. All participants had no cognitive impairments as seen by the score of DST. For more details, see Table 4.

As a concurrent validity of Thai Q-DFD correlated to the clinical examinations, a substantial agreement on the interpreted diagnosis as DRFD was obtained by kappa analysis (kappa 0.719, p < 0.001). In addition, the concurrent validities on diagnosis of foot complication for individual domains of the Thai Q-DFD compared to individual

Table 1. Characteristics of participants (n = 50) in the test-retest reliability studies of Thai Version of The Questionnaire for Diabetes-Related Foot Disease (Thai Q-DFD).

Demographic data	Mean ± SD or N (%)	Range
Age (years)	64.56 ± 9.42	47–83
Gender		
Male	15 (30)	-
Female	35 (70)	-
Education		
None	3 (6)	-
Primary education	41 (82)	-
Secondary education	6 (12)	-
BMI (kg/m^2)	25.81 ± 5.58	15.07–47.05
Duration of diabetes (years)	9.32 ± 7.12	1–28
DST/8 (score)	5.76 ± 0.96	5–8

BMI = Body mass index, DST = Dementia screening test.

components of the clinical examinations were analyzed. The results showed that concurrent validities of individual domains of Thai Q-DFD ranged from fair to almost perfect agreement. The domains related to amputation (kappa = 1.00, p < 0.001) and deformity (kappa = 0.915, p < 0.001) diagnosis showed almost perfect agreement with the clinical examinations. The domain relevant to ulcer (kappa = 0.763, p < 0.001), and DPN (kappa = 0.464, p < 0.001) diagnosis presented substantial and moderate agreement with the clinical examinations in respective. Meanwhile, the domain involved in PAD (kappa = 0.249, p < 0.001) demonstrated fair agreement. Moreover, the diagnostic psychometric

properties of the Thai Q-DFD were found as follows; sensitivity (92.5%), specificity (78.3%), positive predictive value (89.6%), negative predictive value (83.7%), positive likelihood ratio (4.26), and negative likelihood ratio (0.09). Table 5 shows calculation of sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio of the Thai Q-DFD.

4. Discussion

Test-retest reliability defined as the stability of a tool over time through repeated testing at two different time points [35]. Our study had a time interval that was long enough to discard the memory effects of the last answer and to reduce the effect of symptomatic changes in DRFD resulting from blood glucose, physical activities, and drug treatment [36, 37, 38, 39, 40, 41]. The Thai Q-DFD showed substantial test-retest agreement for any DRFD diagnosis with a Cohen's kappa of 0.74 (p = 0.0001), indicating that it is a stable instrument over time through repeated testing [34, 35]. In addition, the test-retest reliability of the Thai Q-DFD was comparable to the other language versions of the Q-DFD, for example the Spanish version (Cohen's kappa = 0.63) [42]. In addition, the test-retest reliability of Thai Q-DFD is higher than that of the original Q-DFD study [3]. Since the participants of this study completed the Thai Q-DFD by themselves. So, they may have more time to consider, read and answer the questions than by telephone interviews in a reliability test of the original Q-DFD [3, 41, 43]. This confirms that the Thai Q-DFD is reliable to use by self-responding.

In addition, a test-retest reliability of each domain related DRFD in the Thai Q-DFD was also evaluated. Each domain showed moderate to almost perfect levels of agreement in the test-retest reliability (kappa =

Table 2. Test-retest reliability results for each question related DRFD (nominal scale) in the Thai Q-DFD.

Item	Cohen's Kappa	P-value	Strength of agreement
(3a) Have you ever had foot burning sensation during last month?	0.61	<0.001	Substantial
(3b) Have you ever had the symptom of foot tingling sensation (the feeling like insects climbing) during last month?	0.64	<0.001	Substantial
(3c) Have you ever had foot numbness during last month?	0.64	<0.001	Substantial
(3d) Have you ever had the symptom of pins and needles sensation during last month?	0.50	<0.001	Moderate
(3e) Have you ever had feeling tightness or tight feeling at your foot during last month?	0.46	<0.01	Moderate
(5a) Have you ever had the symptom of calf pain while walking during last month?	0.87	<0.001	Almost perfect
(5b) Have you ever had the symptom of back thigh pain while walking during last month?	0.79	<0.001	Substantial
(5c) Have you ever had buttock pain or pain in the area around buttock during last month?	0.60	<0.001	Moderate
(7a) Have you ever have foot pain/calf pain while sleeping?	0.73	<0.001	Substantial
(8a) Have you ever been diagnosed by a doctor or a healthcare professional that you've partially lost foot sensation or totally lost foot sensation caused by diabetes?	0.54	<0.001	Moderate
(8b) Have you ever been diagnosed by doctor or healthcare professional that nerves at your foot were damaged caused by diabetes?	0.63	<0.001	Substantial
(8c) Have you ever been diagnosed by a doctor or healthcare professional that you've got neuropathy or peripheral neuropathy caused by diabetes?	0.46	<0.001	Moderate
(8d) Have you ever been diagnosed by a doctor or healthcare professional that you have legs or foot artery stenosis caused by diabetes?	0.66	<0.001	Substantial
(8e) Have you ever been diagnosed by a doctor or healthcare professional that you have legs or foot with poor blood circulation caused by diabetes?	0.48	<0.001	Moderate
(8f) Have you ever been diagnosed by a doctor or healthcare professional that you have peripheral artery disease caused by diabetes?	0.47	<0.001	Moderate
(9) Have you ever been given the surgical treatment to improve the blood circulation at leg or foot; this is not including the surgical for varicose vein?	no respondent reported	-	-
(10a) Have you ever had chronic wound at foot (the area below ankle)?	0.79	<0.001	Substantial
(11a) Have you ever had any toe amputation, foot amputation or leg amputation caused by diabetes?	no respondent reported	-	-
(12a) Have you ever had toes deformity or toes abnormality?	0.70	<0.001	Substantial
(12b) Does your big toe is misshaped?	0.85	<0.001	Almost Perfect
(12c) Do you have lump or blister on your foot? Does it hurt when your skin rubbed against the interior of your shoes?	0.29	<0.05	Fair
(12d) Do you have corns on your foot?	1.00	<0.001	Almost Perfect
(12e) Do you have thickened skin on your foot?	0.15	0.241	Slight

Table 3. Test-retest reliability for each domain of DRFD and on the interpreted diagnosis as DRFD (defined as presenting at least one of DPN, PAD, ulcer, amputation, or deformity domain) of the Thai Q-DFD.

Domain	Cohen's Kappa	P-value	Strength of agreement
Interpreted diagnosis as DRFD	0.74	<0.001	Substantial
DPN domain	0.56	<0.001	Moderate
PAD domain	0.79	<0.001	Substantial
Ulcer domain	0.79	<0.001	Substantial
Amputation domain	no respondent reported	-	-
Deformity domain	0.83	<0.001	Almost Perfect

DRFD = Diabetes-related foot diseases, DPN = Diabetic peripheral neuropathy, PAD = Peripheral artery disease.

0.56–0.83, p = 0.0001). DPN domain showed the lowest test-retest reliability with a kappa score of 0.56. This may be because the responses to DPN domain are subjective symptoms based on participants' feeling over a minimum of one-month period. Also, there are various feeling for identifying neuropathic symptoms, such as burning, tingling, numbness, pins and needles, and tightness [3]. Therefore, these may affect the self-report consistency of the DPN domain more than other domains. Meanwhile, the subjective response to the PAD domain is more explicit than sensory neuropathy. Thus, PAD domain showed higher test-retest reliability than DPN domain. On the other hand, ulcer and foot deformity domains are objective observation which are obvious and consistent to response. Therefore, these two domains showed almost perfect test-retest reliability. In addition, the participants of this study did not have a history of amputation. So, there was no response to the amputation domain and was non-applicable for the test-retest calculation. Nevertheless, it will not affect the stability of the answer to the repeated testing because the amputation is a clear question that is easy to respond to.

Table 4. Characteristics of participants in the concurrent validity studies (n = 139).

Demographic data	Mean ± SD or N (%)	Range
Age (years)	63.42 ± 10.06	45–87
Gender		
Male	44 (31.7)	-
Female	95 (68.3)	-
Education		
None	6 (4.3)	-
Primary education	114 (82)	-
Secondary education	18 (13)	-
Undergraduate	1 (0.7)	-
BMI (kg/m^2)	25.85 ± 5.69	10.20–47.05
Duration of diabetes (years)	9.70 ± 7.01	1–31
DST/8 (score)	5.83 ± 0.94	5–8

BMI = Body mass index, DST = Dementia screening test.

Table 5. Sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio of Thai Q-DFD.

Thai Q-DFD	Standard Clinical Examination		Total
	DRFD	No DRFD	
Positive	86 (a)	10 (b)	96
Negative	7 (c)	36 (d)	43
Total	93	46	139

Note: Sensitivity: a/(a + c) = 86/(86 + 7) = 0.925 × 100 = 92.5%.
Specificity: d/(b + d) = 36/(10 + 36) = 0.783 × 100 = 78.3%.
Positive predictive value: a/(a + b) = 86/(86 + 10) = 0.896 × 100 = 89.6%.
Negative predictive value: d/(c + d) = 36/(7 + 36) = 0.837 × 100 = 83.7%.
Positive likelihood ratio: sensitivity/1 - specificity = 0.925/(1–0.783) = 4.26.
Negative likelihood ratio: 1 - sensitivity/specificity = (1–0.925)/0.783 = 0.09.

The test-retest reliability for each domain of the Thai Q-DFD is in similar range to either the original version or Spanish version of the Q-DFD. The original version of the Q-DFD reported that the domain of DPN, PAD, ulcer, deformity, and amputation achieving a kappa score of 0.71, 0.52, 1.0, 0.42 and 1.0 respectively [3]. In addition, the Spanish version of the Q-DFD reported that the individual domains achieved moderate to almost perfect agreement with DPN (kappa = 0.69), PAD (kappa = 0.53), ulcer (kappa = 1.0), and deformity (kappa = 0.75) [42]. However, the kappa value of PAD domain and the foot deformity domain of the Thai Q-DFD was higher than the original study and the Spanish version [3, 42]. This may be due to the participants of this study completing the Thai Q-DFD by themselves, or in a face-to-face interview for participants who cannot read [44]. So, the participants may have more time to read the details and consider the characteristics of the feet [41, 43]. Meanwhile, the previous studies required to complete the survey via telephone interviews may have had limited time for answering questions and to consider the characteristics of the feet [41, 43]. Therefore, this study has a higher value of kappa in a deformity domain than previous studies [3, 42].

In addition, the kappa values of the Thai Q-DFD for DPN domain and ulcer domain are lower than previous studies [3, 42]. If analyzed closer, the test-retest reliability score for each question of DPN domain in the Thai Q-DFD, from the item 3d and 3e regarding "the pins and needles sensation" and "feeling tightness at foot", showed moderate agreement (kappa <0.60). These results may have occurred from the questions being difficult to understand [43]. Further studies may need to add a description of "the pins and needles sensation" and "feeling tightness at foot" to make the respondents understand the questions easier. In addition, ulcer domain has specific definitions about diabetic ulcer which differs from conventional wounds. It is possible that the participants may be unsure for self-response about diabetic ulcer. This question would be easier to understand by the respondent with an addition of a picture displaying a diabetic ulcer for a better definition of their condition. However, the kappa values of DPN and the ulcer domains of this study are still acceptable [34]. Therefore, the Thai Q-DFD can aid primary screening of DRFD in mass populations living in rural areas of Thailand to help compensate for the shortage of health care staff.

This study is the first study that conducted the test-retest reliability for each item of the Q-DFD. The kappa coefficients of the test-retest study for each item of the Thai Q-DFD were moderate to almost perfect agreement which reflected stability over repeated measures. However, the items related "lump/blister on foot" and "thickened skin on foot" had slight to fair agreement. These results may be due to the participants not clearly understanding the question and required more explanation. Therefore, further studies may need to add descriptions about "the lump/blister on foot" and "thickened skin on foot" to help the respondents understand the questions easier. These two items are significant as history has shown that "lump/blister" and/or "thickened skin" on foot in persons with DM will increase risk of foot infection and ulceration [45].

As the concurrent validity test, the kappa statistic agreement of DRFD diagnosed by the Thai Q-DFD and by the standard clinical examinations was 0.719 (p = 0.0001) which indicated a substantial

correlation. So, the Thai Q-DFD can be recommended to use as a primary screening tool for annual checkup or self-assessment of DRFD in persons with diabetes. The concurrent validity of the Thai version of the Q-DFD was in accordance with the original version (kappa = 0.65) and Spanish version (kappa = 0.77) [3, 42]. Additionally, as a concurrent validity of individual domains of Thai Q-DFD, all domains presented moderate to almost perfect detectability for each component of diabetic foot risk separately when compared to the standard clinical examinations (kappa = 0.464–1.00, p < 0.001), except the PAD component. The PAD domain showed fair concurrent validity with a kappa coefficient of 0.249 (p < 0.001). This might be due to the PAD are subjective self-report of symptoms which is not obvious as the objective observable-report alike ulcer, amputation, and foot deformity. The concurrent validities for DPN, ulcer, and amputation domains of the Thai Q-DFD are according to those of the Spanish version [42], while the foot deformity domain of the Thai Q-DFD showed higher concurrent validity than the original study and the Spanish version [3, 42]. However, the kappa values of the Thai Q-DFD for PAD domain are lower than previous studies [3, 42]. Thus, the PAD domain of Thai Q-DFD should be further reconsidered and revised to improve its validity.

The Thai Q-DFD presented 92.5 % sensitivity, 78.3% specificity, 89.6% positive predictive value, 83.7% negative predictive value, 4.26 positive likelihood ratio, and 0.09 negative likelihood ratio. The high sensitivity of the Thai Q-DFD represents that it is an ideal screening test for DRFD in diabetic patients [41]. Furthermore, the Thai Q-DFD presented a high positive likelihood ratio and a low negative likelihood ratio. This shows that the Thai Q-DFD performs well in excluding those without DRFD, as well as to correctly detect DRFD in diabetic patients [41]. Although the clinical examination is the gold standard for DRFD screening, it is costly and time consuming, and not widely accessible in rural populations [10]. So, the Thai Q-DFD is also suitable for exploring prevalence of DRFD in communities in Thailand; which is important information for future planning/policies of health care services involving people with DM in Thailand, especially in the rural areas. The diagnostic psychometric properties' finding of the Thai Q-DFD was comparable with the original Q-DFD reported by a previous study, the sensitivity (92.5% versus 89%), specificity (78.3% versus 77.8%), positive likelihood ratio (4.26 versus 4.10), and negative likelihood ratio (0.09 versus 0.19) [3]. Therefore, the Thai Q-DFD has good sensitivity and specificity that can be used for DRFD screening similar to the original Q-DFD.

When comparing Thai Q-DFD to the Spanish version of the Q-DFD, the sensitivity of the Thai Q-DFD is higher than the Spanish version (92.5% versus 80.4%), but the specificity is lower (78.3% versus 91.5%) [42]. The small difference in sensitivity and specificity between the Thai Q-DFD and the Spanish version may be caused by the different method for the assessment of DPN. The present study assessed peripheral sensory neuropathy using a 128-Hz tuning fork, and 10-gram monofilament based on the best practice recommendations for clinical examination of the diabetic foot condition [24]. Meanwhile, the study of the Spanish version used only a pinprick test to assess peripheral sensory neuropathy [42], which may not be sensitive enough [46]. A small-fiber neuropathy has been associated with neuropathic pain and the fibers are believed to be damaged earliest during the diabetes condition [47]. However, the clinical diagnosis of DPN using the pinprick test has a lower sensitivity than the tuning fork and the monofilament test in four areas of the foot [48]. Moreover, the combinations of more than one test was suggested for the more sensitive detection of DPN (>87%) [49, 50].

4.1. Limitation and further study

This study had some limitations. The psychometric properties in terms of test-retest reliability and concurrent validity testing were performed in the diabetic patients who lived in the rural community. Future studies should cover the diabetic patients who live in the city due to the difference in lifestyles, health habits, health care service, education level, and income between rural and urban populations.

5. Conclusion

The Thai Q-DFD has effective psychometric properties for screening of diabetes-related foot disease in Thai people with diabetes. The concurrent validity for DRFD diagnosis by the Thai Q-DFD when compared to the clinical examination was also substantial agreement (kappa 0.719). The diagnostic psychometric properties of the Thai Q-DFD were good to excellent, including sensitivity (92.5%), specificity (78.3%), positive predictive value (89.6%), negative predictive value (83.7%), positive likelihood ratio (4.26), and negative likelihood ratio (0.09). The test-retest reliability of the DRFD diagnosis by the Thai Q-DFD was substantial agreement (kappa = 0.74) and that of the individual domains in the Thai Q-DFD ranged from moderate (kappa = 0.56) to almost perfect (kappa = 0.83), as follows. The deformity domain showed almost perfect agreement (kappa = 0.83). The PAD (kappa = 0.79) and ulcer (kappa = 0.79) domains demonstrated substantial agreement. The DPN domain had a moderate agreement (kappa = 0.56). Therefore, the Thai Q-DFD can be applied for primary screening of DRFD in the rural population either by self-respondent in patients who can read or via interviews by village health volunteers for whom cannot read depending on education and awareness of the patients.

Declarations

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