Validation of the Arabic version of the Short Form Leeds' Dyspepsia Index (SF-LDQ) amongst patients with type II diabetes

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ABSTRACT

Since an unambiguous clinical definition of dyspepsia does not currently exist, the diagnosis is made on the basis of symptoms. For this purpose, a tool which is valid, reliable and convenient to use is needed that can accurately assess both frequency and severity of dyspepsia. Short-Form Leeds Dyspepsia Questionnaire meets all of these requirements and thus, has to be validated in native languages before it can be used to diagnose dyspepsia. We conducted a cross-sectional study at King Abdullah Bin Abdulaziz University Hospital (KAAUH) in Riyadh, Saudi Arabia. Adult patients with type II diabetes were recruited in the study after giving informed consent. A total of 245 patients were recruited in the study; 95 (38.8%) were males, while 149 (61.1%) were females. We found that 27.3% (n = 67) of the participants had dyspepsia according to the SF-LDQ Arabic version compared to 24.1% (n = 59) by physician's diagnosis. The Area Under the Curve was 0.86 (95% CI: 0.81–0.9). At a cut-off value of 7/32, the tool has a sensitivity of 69.49% and a specificity of 83.24%. In conclusion, The Short-Form Leeds Dyspepsia Questionnaire was found to be valid for assessment of frequency and severity of dyspepsia among Arab diabetes Type 2 patients.

What we already know

- Dyspepsia is a common symptom amongst patients with Type II Diabetes Mellitus
- Since there is no clinically established definition of dyspepsia, the diagnosis is made on the basis clinical history and examination
- The Short Form - Leeds Dyspepsia Questionnaire (SF-LDQ) is a validated instrument that assesses both frequency and severity. Therefore, it provides an accurate measure of clinical diagnosis

What this article adds

- Validates the Short Form - Leeds Dyspepsia Questionnaire (SF-LDQ) in the Arabic language

- Determines the prevalence of dyspepsia, on the basis of severity and frequency, amongst the Arab population with Type II Diabetes Mellitus
- Establishes the diagnostic accuracy of the tool, determining both its sensitivity and specificity

1. Introduction

Although dyspepsia is a commonly used term in clinical practice, there is a significant amount of ambiguity regarding its definition.¹ One of the commonly accepted definitions of dyspepsia is, presence of pain, discomfort or nausea relating to upper gastrointestinal tract, which does not result from physical strain, nor resolves within 5 min of rest, and is either continuous or intermittent.² Dyspepsia is considered to be a global

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health issue, with a gross prevalence of 25%.³ In patients with Type II diabetes, gastrointestinal symptoms, ranging from mild dyspepsia to gastroparesis, are fairly common.⁴ Gulcelik et al. conducted a study, in which 60.3% of the diabetic patients exhibited symptoms of dyspepsia.⁵ Another study published by Osipenko et al., in 2013 found that the prevalence of dyspepsia amongst Type II diabetics was 71%.⁶

According to a systematic review of 21 peer reviewed articles published in 2016, the prevalence of type II diabetes mellitus in Saudi Arabia was 32.8%. The predicted prevalence of this disease was estimated to rise to 35.37% in 2020 and 45.36% in 2030.⁷

Due to the absence of a clinically established definition of dyspepsia, the diagnosis is made on the basis clinical history and examination sometimes aided by validated tools.⁸ Uni-dimensional questionnaires measure either the frequency or severity of dyspepsia; it has been determined that frequency is more closely associated with a clinical diagnosis of dyspepsia, while severity is a better indicator of response to therapy.⁹ The Short Form - Leeds Dyspepsia Questionnaire (SF-LDQ) is a validated instrument, which was designed in 2007, that assesses both frequency and severity, therefore, providing an accurate measure of clinical diagnosis and responsiveness to change.¹⁰ The tool has been validated in numerous languages before, such as English, Italian and Kinyarwanda; this study aimed to use this instrument to measure frequency and severity of dyspepsia amongst type II diabetic patients and validate the tool in the Arabic language.^{10,11,12}

2. Materials and methods

2.1. SF-LDQ and translation

SF-LDQ is a shortened version of the Leeds Dyspepsia Questionnaire (LDQ), a validated 8-item questionnaire assessing frequency and severity. This 4-item tool assesses, over the last two months, the frequency on the basis of symptoms of upper gastrointestinal tract, such as indigestion, heartburn, regurgitation and nausea, while severity is assessed by scoring the questionnaire from 0-32.¹³ The responses are scored from 0 (not at all) to 4 (once a day or more), the overall score is then calculated by summing the scores of frequency and severity of all symptoms. There is an additional question inquiring about the symptom which the patient finds the most inconvenient.¹³ SF-LDQ was translated into Arabic, independently, by two bilingual native speakers. It was then back translated into English and reviewed by two family physicians (native Arabs) for clarity and content validity.

2.2. Patients

All adult patients with type II diabetes coming to the Diabetes Clinic at King Abdullah Bin AbdulAziz University Hospital (KAAUH) in Riyadh, Saudi Arabia were approached to participate in the study. Those who gave their consent were included in the study.

2.3. SF-LDQ evaluation

After consent, patients were asked some questions on their demographic and clinical history and the Arabic version of SF-LDQ was self-administered before they went into the physician's office. The physician took detailed medical history and assessed all patients for symptoms of dyspepsia, blinded to their interview outside, so that the diagnosis could be confirmed clinically. This physician's assessment was taken as a "quasi gold standard" for comparing the performance of the SF-LDQ Arabic version. Routine laboratory parameters were also recorded; the most recent report of HbA1c was used to determine control of diabetes over the last 3 months. Data was analyzed using SPSS version 24. SF-LDQ scores were calculated by summing the individual frequency and severity scores for each symptom to produce a total summed score. The range of the total score was 0–32. A Receiver Operating Characteristics (ROC) curve was then plotted against the physician's diagnosis

to determine the point of greatest specificity and sensitivity. A two-tailed *P-VALUE* < 0.05 was considered significant.

3. Results

Among the 245 participants, 61% were females (Table 1) and most had studied till bachelor's level (32.7%). Majority of the participants (76.7%) were married and 88.6% were Saudis. Median age of the participants was 55 (47–61) years. Mean age of male participants was 54.7 (12.1) years, with minimum and maximum age being 20 and 81 years, respectively. While, the mean age of female participants was 54 (13.6) years, with minimum and maximum age being 18 and 77 years, respectively. There was no significant difference in the duration or control of diabetes (HbA1C) when the genders were compared (*P-VALUE* > 0.05) (Supplementary Table 1). Similarly, no relationship was observed between dyspepsia frequency (both on SF-LDQ and physician's assessment) and diabetes control (*P-VALUE* > 0.05) (Supplementary Table 2).

3.1. Dyspepsia frequency

Cutoff scores for frequency and severity of dyspepsia were based on those outlined by an SF-LDQ validation study conducted by Fraser et al.¹³ On the basis of the cutoff for summed frequency score of dyspepsia (4/16), 25.3% (n = 62) of the 245 participants were categorized as having dyspepsia. On the basis of the cutoff for summed severity score of dyspepsia (2/16), 30.2% (n = 74) participants were categorized as having dyspepsia. On the basis of the cutoff for summed total score of both frequency and severity (7/32), 27.3% (n = 67) participants were classified as having dyspepsia on SF-LDQ Arabic version, whereas 72.7% (n = 178) were classified as having no dyspepsia. According to the physician's diagnosis, 24.1% (n = 59) participants from this population had dyspepsia on clinical examination, whereas 75.5% (n = 185) did not have dyspepsia.

3.2. Concurrent validity OF SF-LDQ (Arabic version)

Concurrent validity was determined by comparing the physician's clinical diagnosis with the scores of SF-LDQ; this was seen in 244 participants who had both physician's diagnosis and SF-LDQ scores. It was seen that there was no significant difference between the frequency of dyspepsia on SF-LDQ (27.3%) and physician's diagnosis (24.1%) (*P-VALUE* > 0.05: Table 2). When assessed by both methods 15% of the participants (n = 37) had dyspepsia and 63.5% (n = 155) had no dyspepsia.

Table 1
Baseline characteristics of participants.

Demographics	Categories	Frequency	Percentage
Gender	Male	95	38.8
	Female	149	61.1
Highest level of education	None at all	9	3.7
	Primary school	18	7.3
	Secondary school	14	5.7
	High school	31	12.7
	Bachelors	80	32.7
Marital status	Single	27	11
	Married	188	76.7
	Separated	1	0.4
	Divorced	5	2
	Widowed	18	7.3
Nationality	Saudi	217	88.6
	Non-saudi	24	9.8
	Mean (SD)	Min-Max	Median (IQR)
Age	52.2 (13.2)	18–81	55 (47–61)

Table 2

Concurrent validity between SF-LDQ Arabic version & physician's diagnosis.

SF-LDQ Summed total dyspepsia score ^b	Physician's diagnosis		Total	P-Value
	Dyspepsia	No dyspepsia		
Dyspepsia	37(15.2)	22(9)	59(24.2)	0.332 ^a
No dyspepsia	30(12.3)	155(63.5)	185(75.8)	

^a McNemar test applied.^b Cut-off score: 7/32.

3.3. Diagnostic accuracy

A Receiver Operating Characteristics (ROC) curve was then plotted against the physician's diagnosis to determine the appropriate specificity and sensitivity (Fig. 1). Similar to the recommendation by Fraser et al. the cutoff point with the most sensitivity and specificity was 7/32 in our data also.¹³ At this cut-off the sensitivity of SF-LDQ was found to be 69.49%, while the specificity was 83.24% with the best correct classification rate of 79.9% and AUC of 0.86 (95% CI: 0.81–0.9) (Supplementary Table 3).

4. Discussion

Currently, there is no established “gold standard” to diagnose dyspepsia.^{9,14} In this study, the physician's clinical diagnosis was used as a “quasi gold standard” to determine concurrent validity. There have been a number of studies in which the clinical diagnosis was used as a reference for comparison in the absence of any “gold standard”.^{15–17} Other studies have used scores of quality of life questionnaires,^{18,19} written accounts of self-assessment by patients²⁰ and severity of dyspepsia assessment as alternatives.²¹ In our study, using clinician's diagnosis for concurrent validity led to 69.49% sensitivity and 83.24% specificity of SF-LDQ. This indicates that the Arabic validated version of SF-LDQ can be used to screen for dyspepsia in the Arabic speaking population.

Dyspepsia is seen frequently in diabetics, probably related to the autonomic neuropathy, gastroparesis and a presumed relationship with *H. pylori* bacteria. A study conducted in India reported an *H. pylori* prevalence of 77% among diabetics compared to 58% in controls (P -VALUE < 0.05).²² However, other studies fail to show any association of

H. pylori with diabetes mellitus.^{23–26} Due to the high prevalence of this condition in diabetics, we chose to validate the Arabic version of SF-LDQ in the native diabetic Arab population.

A number of tools have been developed to assess dyspepsia but majority are either too lengthy to be used in an outpatient setting or lack assessment of severity of symptoms.^{18,20,21} A systematic review of symptom based questionnaires for dyspepsia and GERD identified 26 questionnaires amongst which only 11 assessed both frequency and severity of symptoms and Leeds Dyspepsia Questionnaire was one of them.⁸ Its Short form (SF-LDQ) was developed in 2007¹³ and has since been translated in numerous languages.^{11,12,27,28}

Saudi Arabia has a high diabetes prevalence which is projected to increase.⁷ This will lead to a huge segment of the population suffering from its associated conditions like dyspepsia requiring chronic management. For the assessment of dyspepsia, only one validated tool exists in Arabic language, the ‘Nepean Dyspepsia Index’ consisting of 42 items falling short of a quick screener in the outpatient setting.²⁹ Hence, the current validated version of SF-LDQ, will serve as a screening tool allowing for early diagnosis and better assessment of response to therapy in the Arab population.

In the original study by Fraser et al. the recommended summed total cutoff score for diagnosis of dyspepsia was also 7/32; with a sensitivity of 77.3% and specificity of 73.2%.¹³ Another similar study, using the Italian version of SF-LDQ, found sensitivity of 80.4% and a specificity of 82.5% for dyspepsia.¹¹ However, these studies also measured discriminant validity along with test-retest reliability which should be the next step forward.

In conclusion, the Arabic version of SF-LDQ has proven to be a valid and feasible tool to accurately measure the frequency and severity of dyspepsia in the outpatient setting. We recommend testing the instrument for test re-test reliability and validation among other patient populations than diabetes mellitus type 2.

5. Conclusion

Based on the results of our study, we conclude that SF-LDQ is both a sensitive and specific tool which can be used to determine the frequency and severity of dyspepsia. Arabic version of SF- will prove to be of immense value in conducting a quick clinical screen along with contributing to the determinants of dyspepsia in this population. We recommend further research and the validation of this Arabic version in other patient populations and age groups so that it can benefit further.

6. Limitations

Our study did not measure parameters such as discriminant validity, test-retest reliability and responsiveness to change since it was not feasible to follow up these patients. Measurement of these parameters would have added to the validation of the SF-LDQ questionnaire in the Arabic language and provided a more accurate assessment of the psychometric properties of the tool. We used a quasi-gold standard of physician diagnosis as a reference but we believe that dyspepsia is a symptom which can be present in the absence of any documented pathology (functional dyspepsia). Hence, it is not possible to select a perfect “gold standard” for comparison of the results. The original author I has also used physician diagnosis for validation of the tool.¹³

Ethical statement

Institutional Review Board of Princess Nourah Bint Abdulrahman University, IRB Registration Number with KACST, KSA: H-01-R-059, RB Log Number: 18-0001, Category of Approval: EXEMPT.

Study was EXEMPT from IRB Review as it posed no more than minimal risk to participants. Informed consent was taken from participants before being included in the study.

The paper reflects the authors' own research and analysis in a

Fig. 1. Receiver Operating Characteristic (ROC) curve for the summed total score of the SF-LDQ Arabic version. AUC = 0.86 (95% CI:0.81–0.90).

truthful and complete manner. All authors have been personally and actively involved in substantial work leading to the paper, and will take responsibility for its content.

Declaration of competing interest

The authors declare that they have no conflict of interest pertaining to this study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cegh.2021.100790>.

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