

# Initial linguistic and psychometric validation of the Arabic version of Nepean Dyspepsia Index

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## ABSTRACT

**Objectives:** To report the initial evaluation of the linguistic and psychometric validation of the Nepean Dyspepsia Index (NDI), as part of the ongoing research of quality of life among dyspeptic patients.

**Methods:** The Arabic version of the NDI was administered to 158 subjects (54 with non-ulcer dyspeptic [NUD]), 50 with gastro-esophageal reflux disease (GERD) and 54 with no history of gastroenteritis disease), with a mean age of 46.6 and SD 10.7. All subjects answered the Arabic versions of the General Health Questionnaire (GHQ), the Self-Report Questionnaire (SRQ), and the Short Form-12 Quality of Life (QOL) scale. We administered the final translation of the NDI by consensus. The study was conducted in King Fahad Hospital of the University, Al-Khobar, Saudi Arabia, between December 2002 and January 2004.

**Results:** The NDI has shown adequate internal consistency. Cronbach Alpha coefficient ranged between 0.88 to 0.93, and Split-half correlation reliability ranged between 0.82 and 0.94. Correlations between NDI subscales and total

scores were high and significant. Adequate Face and content validity was demonstrated by consultation with gastroenterologists and clinical psychologists. Convergent validity was shown in the moderate and significant correlation of the NDI subscales and global index with the indices of the SF-12. Divergent validity was shown in that subscales of the NDI revealed low correlation with scales which measure other dimensions; thus, both QOL subscales and symptom checklist have discriminated patients from non-patients groups ( $p > 0.01$ ). The factorial structure of the NDI was also examined, and it revealed 4 factors, which is similarly the same with other studies.

**Conclusion:** The initial validation of the Arabic version of the NDI has shown that this scale has adequate psychometric and linguistic property and can represent a good addition to health outcome measures in dyspepsia research. Further validation studies are recommended.

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During the last 2 decades, there has been a rapidly increasing interest in the study of Quality of Life (QOL) in the medical literature. This has been accompanied by the development of several numbers of instruments and measures of QOL. Many of these QOL measures are now accepted and established as an important measure of health care outcome and treatment evaluation. The study of QOL, and more specifically Health-Related Quality of Life (HRQOL)

represents an essential part in all studies examining such issues as health care outcome, treatment evaluation and clinical trials, as well as health-care cost.<sup>1,2</sup> The concept of QOL is a global and multidimensional one. All attempts to define it incorporate the role of psychological, social, physical and spiritual well being. Extensive research on developing QOL measures resulted mainly into 3 types of measures.<sup>3,4</sup> First, the global or general QOL measures include

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such aspects as personal income, location of residence, leisure time and activities, interpersonal relationships, meaningful work, or spiritual fulfillments, among other "non-medical" aspects of life. The second type includes General HRQOL measures, which involve large numbers of items that might not necessarily be related to specific illness.<sup>3</sup> Example of this kind of measure is the Short Form-36 (SF-36),<sup>5,6</sup> and the World Health Organization-Quality of Life (WHO-QOL).<sup>7</sup> The third type include the Disease Specific HRQOL: examples of such scales are the Nepean Dyspepsia Index (NID),<sup>8</sup> the Gastrointestinal Symptom Rating Scale,<sup>9</sup> and The Quality Of Life in Reflux and Dyspepsia (QOLRAD).<sup>10</sup> The objective of "HRQOL" measure is to assess the impact of the disease on physical, psychological, and social well-being. Several types of mental and physical disorders, particularly chronic diseases, have been studied with reference to HRQOL, and there are several researches and reviews of the literature in this subject.<sup>11-17</sup> In relation to gastrointestinal disease, there has also been a growing interest in developing psychometrically valid and reliable disease specific instruments.<sup>8</sup> In this connection, Talley et al<sup>8</sup> emphasized the importance of QOL studies as an outcome measure in studies of disease that has no obvious biological or clinical markers, such as functional dyspepsia. They also drew attention to the rarity of suitable disease-specific QOL measure of dyspepsia.<sup>18</sup> However, none of the disease-specific QOL instruments has been developed or adapted for use in Arabic culture or language. There is also extreme lack in studies that investigate HRQOL among Arabic speakers and Arab culture. The main reason behind this situation could be the novelty of the subject matter and, largely, because of the absence of suitable measurement instrument. The present study is an attempt to adapt one of the newly developed disease-specific QOL measures of dyspepsia, which has been developed in the western culture, and to examine its psychometric and linguistic validity. So, the main objective of the present study is to record the initial evaluation of the linguistic and psychometric validation of the NDI, as part of the ongoing research of QOL among dyspeptic patients. There are many other measure that were developed specifically to assess QOL in gastrointestinal disease. To our knowledge none of them has been Arabised or tested in the Arabic culture. This study was conducted in accordance with the guidelines of the Medical Ethical Committee of King Faisal University and according to Helsinki declaration.

**Methods.** The sample is composed of 2 main groups: 1) controls - healthy subjects aged  $\geq 18$

were randomly selected from people who were accompanying patients in different outpatient clinics. Subjects under medical treatment or care for gastrointestinal complaints or other medical illnesses were excluded. 2) Patients - 2 subgroups of patient were included in this study. Patients with documented evidence of either NUD or GERD, and aged  $>18$  years were chosen for this study. The diagnoses for all patients were established by 2 gastroenterologists. Dyspepsia was defined as pain or discomfort centered in the upper abdomen over the 3 past months.<sup>9</sup> Since this study aims at adapting and validating a western developed instrument of disease-specific QOL, we adopted exclusion criteria for the patient, similar to those adopted in the original studies.<sup>8,18</sup> Thus, patients with symptoms of gastrointestinal bleeding or abnormal physical or laboratory findings from prior outpatient visits were excluded from study. In addition, inability to understand or speak Arabic language, cognitive impairment affecting understanding of the questionnaire, previous gastric surgery, regular use of non steroidal anti-inflammatory drug intake, history of malignancy or significant systemic disease, were also used as exclusion criteria.

**1) The Nepean Dyspepsia Index.** This was the main tool used in this study and both its linguistic and psychometric properties were examined. The conceptual basis of the NDI was developed by the Sydney Research Team.<sup>8</sup> The initial process of item development included consultation with patients, gastroenterology and psychology staff, and have been pre-tested in 4 European countries. The face and content validity of the NDI was established by reviewers of the international panel expert of gastroenterologists.<sup>8</sup> The revised NDI was composed of 42 items disease-specific QOL instrument with documented validity and reliability, and has been translated into several languages, including, Australian English, French, Dutch, Italian, German, and American English.<sup>8,18</sup> The Arabic version of the NDI-QOL scale consisted of the original questions, measuring health-related QOL structured around 17 key areas of life. The questionnaire examines the impact of illness on QOL by referring to the 2 dimensions of interferences. This includes interference with the subject's ability to perform or engage in specific functions, and interference with their enjoyment of the same area of life. These were measured by 5-point Likert scales from 0 (not at all or not applicable), 1 (a little), 2 (moderately), 3 (quite a lot) to 4 (extremely). The QOL items in the original scale were sub-grouped, on the basis of factor analysis, into 5 subscales. These included interference with daily activities (9 question items), knowledge/control

(six items), tension (3 items), work/study (4 items) and eating/drinking (3 items). The first part of the NDI, which deals with dyspepsia symptoms and their severity was also included in the Arabic translated version of the scale. This part of the scale measured the frequency, severity and bothersomeness of 15 upper gastrointestinal symptoms, applying a scale of 0 (not at all) to 4 (daily) for frequency, 0 (not at all) to 5 (very severe) for intensity, and 0 (not at all) to 4 (extremely bothersome) for bothersomeness. Scores were added over the 3 groups of symptoms.<sup>8</sup>

**2) The Short Form-12.** This is a shorter version of the medical outcome study SF-36 health survey SF-36.<sup>6</sup> The SF-12 includes 12 questions from the SF-36, which reproduce its Physical Component Summary (PCS) and Mental Component Summary scores.<sup>20</sup> Scoring of individual items is identical to the SF-36.<sup>21</sup> This scale has been translated into Arabic and its initial validity and reliability was reported in a study of QOL with diabetes (Unpublished Thesis).<sup>22</sup>

**3) The GHQ-30 and the SRQ-20.** These 2 scales are the most widely used scales of general mental health and psychopathology.<sup>28</sup> The GHQ is a self-report questionnaire designed to detect psychiatric morbidity in general practice and medical outpatient settings. The scale has been shown to have good reliability and validity.<sup>28</sup> It has been widely used in

research and clinical settings, including screening for several psychiatric disorders.<sup>24,25</sup> Bowling<sup>26</sup> included the GHQ and the SRQ among the scales which are used to measure QOL. The 30-item version was used in this study because its Arabic translated version has shown adequate clinical and psychometric validity.<sup>27</sup> The standard scoring method recommended by Goldberg was used in this study.<sup>28,29</sup> The Arabic version of the Self-Reporting Questionnaire (SRQ-20) was also used.<sup>23,27</sup> The original version of the scale was developed by the WHO and has been translated into several languages. It has well established psychometric and clinical validity.<sup>23,30,36</sup> It consists of 20 questions, designed to identify individuals with possible, non psychotic (mainly anxiety and depression) mental health problems in primary care settings. Goulash et al,<sup>27</sup> translated both the GHQ-30 and the SRQ into Arabic and carried out a large-scale validity study on a sample of 217 patients from primary health centers in Al-Ain, UAE.<sup>27</sup> Their results demonstrated very reasonable sensitivity and specificity estimates of the scales against psychiatric classifications and acceptable homogeneity.

**Statistical analysis.** The standard procedure of translation and back-translation was adopted. The final translation was fixed by consensus of all authors. Internal consistency reliability was assessed through

**Table 1** - Factors extracted by the principal component analysis (varimax rotation).

Factors	1	2	3	4
Ability to engage in leisure	0.81			
Ability to work/study	0.8			
Enjoyment of work/ study	0.79			
Gen. Emotional well-being	0.78			
Enjoyment of usual daily activities	0.77	0.43		
Enjoyment of leisure activities	0.77	0.42		
Ability to perform usual activities	0.76	0.34		
Enjoyment of time with friends	0.76			
Overall health	0.66	0.35	0.34	
Interfere with daily activity	0.65	0.36	0.35	
Difficulty in concentration/Thinking	0.58	0.45		
Irritable/ tense/ frustrated	0.58			0.42
Upset of not knowing causes		0.83		
Upset of not able to control/cure	0.32	0.8		
Worried about seriousness (danger)		0.72	0.45	
Worried about always having problem		0.68	0.44	
Diet change			0.83	
Enjoyment of eating/drink.			0.81	
Ability to eat or drink	0.32		0.75	0.30
Feeling empty of emotion/ helpless				0.85
Ability to sleep				0.84
Quality of sleep	0.31		0.32	0.79
Depressed/ sad	0.30			0.69
Anxious/nervous/worried	0.36			0.66
Felt tired. Weak-low energy	0.33			0.55

**Table 2 -** Comparison between numbers of factors revealed by factor analysis of the NDI in 3 studies.

Studies	T/M	INT	E/D	K/C	W/S
Present study	6	12	3	4	0
Australian	2*	13	3	7	0
USA	9	6	3	4	3

\*sleep disturbance items only, T/M - Tension and Mood, INT - Interferences, E/D - Eating and drinking, K/C - Knowledge and Control, W/S - Work and Study, NDI - Nepean Dyspepsia Index

**Table 4 -** The internal consistency of the sub-domain identified by factor analysis.

Scale	No. of items	Cronbach Alpha	Split-half
Symptom severity	15	0.88	0.82
Interference	12	0.93	0.94
Knowledge/Control	4	0.89	0.84
Eat/Drink	3	0.88	0.87
Tension/Mood	6	0.90	0.91
Total quality of life	25*	0.92	0.90

**Table 3 -** Correlation coefficient between the NDI subscale scores and the SF-12, the GHQ, and the SRQ indices.

Scale	SYM	INT	K/C	E/D	T/M	NDI-QOL	GHQ	SRQ	SF-12-M	SF-12-P
SYM	1.00	0.42 <sup>†</sup>	0.53 <sup>‡</sup>	0.48 <sup>‡</sup>	0.82 <sup>‡</sup>	0.55 <sup>‡</sup>	0.17	0.11	-0.17	-0.23
INT	0.42*	1.00	0.39*	0.19	0.47 <sup>†</sup>	0.94 <sup>‡</sup>	0.09	0.12	0.29*	-0.27*
K/C	0.53 <sup>†</sup>	0.40*	1.00	0.57 <sup>‡</sup>	0.65 <sup>‡</sup>	0.56 <sup>‡</sup>	0.15	0.22	-0.31*	-0.16
E/D	0.48 <sup>†</sup>	0.19	0.42*	1.00	0.37*	0.53 <sup>‡</sup>	0.19	0.17	0.18	-0.17
T/M	0.82 <sup>†</sup>	0.47 <sup>†</sup>	0.65 <sup>‡</sup>	0.37*	1.00	0.68 <sup>‡</sup>	0.49 <sup>‡</sup>	0.45 <sup>†</sup>	-0.77 <sup>‡</sup>	-0.18
NDI-QOL	0.55 <sup>†</sup>	0.94 <sup>‡</sup>	0.64 <sup>†</sup>	0.53 <sup>‡</sup>	0.68 <sup>‡</sup>	1.00	0.42 <sup>†</sup>	0.37*	-0.46 <sup>†</sup>	-0.33*
GHQ <sup>2</sup>	0.17	0.13	0.15	0.19	0.49 <sup>‡</sup>	0.42 <sup>†</sup>	1.00	0.64 <sup>‡</sup>	-0.41 <sup>†</sup>	-0.23
SRQ	0.11	0.12	0.22	0.17	0.45 <sup>†</sup>	0.37*	0.64 <sup>‡</sup>	1.00	-0.34*	-0.19
SF-12-M	-0.10	-0.29*	-0.31*	-0.18	-0.77 <sup>‡</sup>	-0.46 <sup>†</sup>	-0.41 <sup>†</sup>	-0.34*	1.00	0.44 <sup>†</sup>
SF-12-P	-0.15	-0.27*	-0.16	-0.17	-0.18	-0.33*	-0.23	-0.19	0.44 <sup>†</sup>	1.00

\*p<0.05, <sup>†</sup>p<0.01, <sup>‡</sup>p<0.001, negative sign - SF-12 high scores indicate better QOL, SYM - Symptom severity, T/M - Tension and Mood, INT - Interferences, E/D - Eating and drinking, K/C - Knowledge and Control, GHQ - General Health Questionnaire, SF - Short Form-12, SRQ - Self-Report Questionnaire, QOL - Quality of Life scale, NDI - Nepean Dyspepsia Index, M - mental, P - physical

Cronbach Alpha coefficient and Split-half correlation reliability. Validity was assessed through face, concurrent, and discriminant validity of the scale. The factorial structure of the NDI was also examined.

**Results.** After establishing the process of forwards and back translation of the NDI, adequate face and content validity was demonstrated by consultation with 2 gastroenterologists and clinical psychologists. The main criteria of assessing the scale included comprehensiveness and comprehensibility of the scale (suitability of words and their clarity), and the relevance of items to functional dyspepsia and HRQOL. The factorial structure of the NDI was examined using principal components analysis with varimax rotation. The analysis has identified 4 factors similar to those revealed on the original version of

the scale, with eigenvalues value >1. The 4 factors together accounted for 74.5% of the total variance as shown in **Table 1**. The first factor accounted 27.8 of the total variance and included items that related to the question of interference with several functions and activities. This factor was named interference. The second factor accounted for 19.3 of the total variance and it was named knowledge and control as it contained all items related to being upset of lacking in knowledge and control about the disease. The third factor, which was named as food and drink explained 16.7% of the variance, and the fourth factor explained 9.8% of the total variance. This fourth factor included items related to tensions, anxiety frustration and sleep disturbances. Therefore, it was named Tension/Mood. The result of factor analysis is comparable to the previous factorial analysis on the same scale,<sup>8,18</sup>

thereby giving further support to the construct validity of the scale. However, there are some variation in the number of items loading in Factors 1 (interferences, and 2 (knowledge/control), and 4 (tension/mood), as shown in the following **Table 2**. Inspection of **Table 2** indicates that there are several similarities between the 3 mentioned studied in the types of factor, and the number of item loading in each factor. These findings add further support to the assumption that the underlying structure of the NDI measure similar construct related to QOL. However, our findings is much more closer to the study of the USA sample in identifying the factors related to mental health, (Tension and sleep) and knowledge and control, while it identified similar loading of number of items to the study of the Australian samples regarding the second factor (interference). Concurrent validity was also examined through convergent and divergent validity of the NDI, using Spearman rank correlation coefficient. The results of this analysis are shown in **Table 3**, which presents 2 indices: 1) Convergent validity was shown in moderate to high and significant correlation between the tension/mood subscale and the global index of the NDI; the Mental health index of the SF-12; the GQ-30; and the SRQ-20, indicating good convergent validity. 2) Divergent validity was shown in the low correlation between the other indices of the NDI and the GHQ-30 the SRQ-20, and the physical health component of the SF-12, suggesting that the NDI measure a relatively distinct construct, and supporting the divergent validity of the scale.<sup>31,32</sup> Additionally, both the QOL subscales and symptom's checklist of the NDI have discriminated patients from non patients groups ( $p>0.01$ ). The internal consistency reliability was assessed through Cronbach  $\alpha$ .<sup>31</sup> **Table 4** shows that internal consistency ranged between 0.88 for eat and drink to 0.93 for the interference subdomain. Split half reliability revealed similar results with reliability coefficients ranging from 0.84 for the knowledge/control sub-domain to 0.94 for the interference subdomains. These finding strongly support the internal consistency and reliability of the NDI.

**Discussion.** The objective of this study was to report our initial findings on the validation of the Arabic version of the NDI as a disease-specific measure of QOL. It should be noted that, although the research in the HRQOL and in the development of its measurements tools is rapidly growing in the western literature, this observation does not apply to the Arabic community or to some research studies that carried out in the Arab community. In particular, there is an extreme rarity of research in the development and

validation of these kinds of research instrument, which is now considered as a corner stone of health outcome research. In the present study, which is the first to validate an Arabic version of a disease-specific QOL instrument for gastroenterology, we were successfully able to provide data to support the psychometric and linguistic adequateness of the Arabic NDI as a disease specific QOL for dyspepsia. Our results consistently supported the content and construct validity of this scale. In this study, construct validity was examined through factor analysis and concurrent validity (Convergent and divergent validity). Validity of a psychometric measure is generally defined as the extent to which an instrument measures the construct it purports to measure, and construct validity is defined as the extent to which empirical data support hypotheses concerning the construct the instrument is purported to measure.<sup>32</sup> One of the most important finding in this aspect is the results of factor analysis which showed several agreement to the findings of the original validation studies carried in the western society.<sup>8,18</sup> In addition to the support given to the factorial and construct validity of this scale, our results also suggest that translating the items of the NDI into Arabic did not significantly affect the content and components of the scale. In other words, this similarity gives further support to the content validity, which was established through consensus of the gastroenterologists and clinical psychologists. Concerning the convergent and divergent validity, correlation analysis depicted in **Table 3**, suggest that the NDI may comprise a relatively distinct measure of QOL. The moderate and high correlation between the (tension and sleep) subscale, and the global index of the NDI with the mental health component of the SF-12, and the other screening scales of mental health, explain the degree of agreements between these sales. The direction, pattern and magnitude of correlations are consistent with our expectations. Since SF-12 is scored in a reversed direction and since it is considered as a generic measure of HRQOL and the NDI is disease-specific one, we predicted that they will have moderate negative correlations. Moreover, both the severity and the global indices of the NDI differentiated well between the patient and the control groups. These findings is consistent with the findings of the original studies,<sup>8,18</sup> providing further evidence to support the convergent, divergent and discriminant validity and indicating that the NDI measures a disease-specific QOL. The performance of the NDI Arabic version was found to be similar to that reported for the original study, regarding the reliability of the scale.<sup>8</sup> We found excellent internal

reliability of 0.88 for the severity index and 0.90 for the total QOL index, indicating the suitability of the total scale scores for individual analysis. The subscales which were based on factor analysis also showed internal consistency reliability that exceeded 0.88, making them acceptable for group comparisons.<sup>31</sup> This result is comparable to the other studies which reported reliability coefficients over 0.90 for the subscales of the original NDI.<sup>8,18</sup> By supporting the reliability of the Arabic NDI our study suggests that random error of the NDI is minimized, and that the scores which it measures reflect a consistent measure of the constructs of QOL.<sup>31,32</sup>

Finally, one of the limitations of this study is that test-retest reliability and responsiveness was not examined. Responsive is one of the most important psychometric requirements in measures of health care and treatment evaluation, and adequate reliability and validity do not guarantee responsiveness.<sup>33</sup> As maintained by some authors, responsiveness (sensitivity to change) might be one of the most important characteristics of scales used to evaluate the effects of treatment.<sup>33</sup> Concerning test-retest assessment, it was practically difficult to apply it in our present study. Some authors stressed that as dyspepsia is a disease with natural remissions, and relapse, a long interval between baseline and retesting could confound the results of assessment.<sup>34</sup> For this reason Tally et al,<sup>18</sup> used 48 hours gaps, and Wayne et al,<sup>35</sup> used only 3 hours. However, some authors agreed that test-retest reliability may be less useful than internal consistency reliability in HRQL instrument development.<sup>35</sup>

In conclusion, the initial validation of the Arabic version of the NDI has shown that this scale has adequate psychometric and linguistic property and can represent a good addition to health outcome measures in dyspepsia research. The results of this study suggest that, in general, the psychometric properties of the NDI are within acceptable limits and comparable to that of other HRQL measures. This scale could be used as a reliable and valid measure of quality of life and how it is affected by dyspepsia. The translation, and examination of the psychometric property of the NDI as a disease-specific QOL will certainly add to the improvement of this kind of measures of health status and health care and treatment evaluation. It is recommended that further validation studies should be conducted targeting other important psychometric properties.

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