The Nepean Dyspepsia Index: Translation and Validation in Indonesian Language

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ABSTRACT

Background: Dyspepsia is an important health problem from economic and quality of life point of view. However, to date, there has not been specific instrument of quality of life to evaluate patients with dyspepsia specially design in Indonesian language. The Nepean Dyspepsia Index (NDI) is a reliable and valid instrument regarding quality of life in patients with dyspepsia and had been validated in Australia, Germany, Italy and Netherlands.

Objective: To report translation of NDI in Indonesian language and validation in Indonesian patients with dyspepsia and also evaluate the possibility of its use in subjects who speak Indonesian language.

Methods: NDI was translated into Indonesian language. The amount of 49 subjects with a clinical diagnosis of dyspepsia according to the inclusion and exclusion criteria were recruited. Collection of data included demographic data, physical and laboratory examination. All subjects were asked to complete translation of NDI. Reliability analysis was evaluated by α -Cronbach's and test-retest. Since dyspepsia has no gold standard, validity was evaluated using factor analysis.

Result: Reliability of the questionnaire was good, α -Cronbach's and interclass correlation coefficient were found to be > 0.70 respectively and Kaiser-Meyer-Olkin value was found to be > 0.64, suggesting that all items were appropriate to measure.

Conclusion: translated NDI in Indonesian language can be used in dyspepsia, patients who understand Indonesian language.

Keywords: dyspepsia, disease-related quality of life, the Nepean Dyspepsia Index, reliability, validity

INTRODUCTION

To date, dyspepsia has becoming center of attention in clinical research, far more beyond other gastrointestinal disease¹ and already health problem in Indonesia.² This caused by high cost medical expense³⁻⁵ and decreased quality of life.⁶⁻⁸

Quality of life described attitude and individual behavior related to recent or previous health status. Evaluation of quality of life using generic instrument or more specific with quality of life from patient's point of view to observe impact/output of disease. O Quality of life mainly used to evaluate disease with no specific clinical or biological marker. In this situation, control of symptoms, comfort and function of patient becoming treatment target. In general, quality of life instrument in questionnaires form related to severity of symptoms and quality of life improvements as result of effective treatment. In Instrument of quality of life

related to specific disease like dyspepsia like Severity of Dyspepsia Assessment (SODA),¹¹ Quality of Life in Reflux and Dyspepsia (QOLRAD),¹² Digestive Health Status Instrument (DHSI),¹³ Nepean Dyspepsia Index (NDI),¹⁴ Quality of Life in Peptic Disease Questionnaire (QPD),¹⁵ and Gastroesophageal Reflux Disease Health Related Quality of Life Scale (GERD-HRQL).¹⁶

In principal, a questionnaire would fail to be implemented if it could not be understand by respondent. Thus, translation of questionnaires into language that well recognized by respondent is necessary.¹⁷

Before health related quality of life instrument was used in clinical studies, it must be validated to evaluate reliability and validity.¹⁷ Objective of this study was to translate to Indonesian language as one of disease-related quality of life instrument for patients with

dyspepsia or Indonesian language translated NDI for patients who speak Indonesian language.

METHODS

Subjects

This study had been approved by ethical commission Margono Soekarjo hospital in Purwokerto and conducted in Department of Internal Medicine, Faculty of Medicine, University of Jenderal Soedirman from January 2 until December 31, 2005 in patients with symptoms of dyspepsia. Subjects of study was patient with symptoms who speak Indonesian language.

Definition of dyspepsia according to Rome II criteria was chronic abdominal pain or discomfort centered in upper abdomen. Discomfort was negative subjective feeling, not too painful and may be accompanied by several symptoms like early satiety, fullness, nausea or distended upper abdominal.¹⁸ Abdominal pain or discomfort at epigastrium would differentiate dyspepsia and gastroesophageal disease which characterized by symptoms like heartburn and acid regurgitation.¹⁹

Patients included in this study were patients with uninvestigated dyspepsia, aged 18 years or more, consume proton pump inhibitor or H, antagonist

Table 1. Translated NDI in Indonesian language

| Tension (ketegangan) | | 1 = tídak | 2 = ringan | 3 = sedang | 4 = berat | 5 = şangat berat |
|--------------------------|--|-------------------------------|-------------------------|---------------|-------------------------|---------------------|
| 1. | Apakah mengalami gangguan emosi akibat keluhan lambung dalam 2 minggu terakhir? | 7670 | | | | |
| 2. | Apakah anda sensitif, tegang atau frustasi akibat keluhan lambung dalam 2 minggu terakhir? | | | | | |
| Pem | abatasan aktifitas seharl-harl | | | | | |
| 3. | Apakah kemampuan untuk kegiatan yang menyenangkan (rekreasi, jalan-jalan, hobi, olah raga dan sebagainya) terganggu akibat keluhan lambung dalam 2 minggu terakhir? | | | \mathcal{O} | | |
| 4. | Apakah kenikmatan dalam kegiatan yang menyenangkan (rekreasi, jalan-jalan, hobi, olah raga dan sebagainya) terganggu akibat keluhan lambung dalam 2 minggu terakhir? | 7.8 X | 5 |)))) | | |
| Mak | an/minum | | | | | |
| 5. | Apakah kemampuan untuk makan dan minum terganggu akibat keluhan lambung dalam 2 minggu terakhir? | 10 | | | | |
| 6. | Apakah kenikmatan dalam makan dan minum terganggu akibat keluhan lambung dalam 2 minggu terakhir? | | | | | |
| Pengetahuan/pengendalian | | 1 = hampir tidak pernah | 2= kadang- kadang | 3 = sering | 4 = sangat sering | 5 = selalu |
| 7. | Apakah anda berfikir bahwa anda akan selalu mengalami keluhan lambung dalam 2 minggu terakhir? | | | | | |
| 8. | Apakah anda berfikir bahwa keluhan lambung anda disebabkan karena sakil sangat serius (kanker atau jantung) dalam 2 minggu terakhir? | _ | | | | |
| Ker | a/studi | . 1 = tidak | 2 = ringan | 3 = sedang | 4 = berat | 5 = sangat berat |
| 9. | Apakah kemampuan anda dalam bekerja atau studi terganggu oleh keluhan lambung dalam 2 minggu terakhir? | | | | | |
| 10. | Apakah kesenangan anda dalam bekerja atau studi terganggu oleh keluhan lambung dalam 2 minggu terakhir? | | | | | |

receptor without symptom improvement and signed the informed consent. Exclusion criteria were patients with alarm symptoms (family history of upper gastro-intestinal cancer, progressive dyspepsia, odinophagia, iron deficiency anemia with unknown etiology, persistent vomit, abdominal mass or lymphadenopathy and icterus,²⁰ symptoms of gastroesophageal reflux, regular consumption of NSAID, antibiotics treatment in the last weeks, history of surgery of upper gastrointestinal and or pregnancy.

The Nepean Dyspepsia Index

NDI was developed by Sydney research team with 42 questions and 17 aspects. Those questions included Upper gastrointestinal symptoms in the last 2 weeks. The questionnaires then were translated from Australian English into French, Dutch, Italian, German, Spanish and American English. Validity test was good in every country. 14,21,22 Later, questionnaires were developed becoming easier, shorter and more sensitive to clinical changes and patients could fill it by themselves. Simple version of NDI consists of 10 questions with 5 domains (tension, interference with daily activity, eating/drinking, knowledge/control, work/study). Simpler NDI had been validated in many countries. 21,22

Study Proposal

This study consisted of 3 phases. First phase patients were interviewed according to NDI translation and repeated in second phase 5 days after and phase 3 on 14 days after. In every phase, patients were interviewed by doctors according to NDI questionnaire, anamnesis and complete physical examination. Therapy was given according to previous treatment.

Statistical Analysis

After collection of data, we conducted data cleaning, coding, tabulating and data entry into computer. Data analysis includes descriptive analysis and validation. In descriptive analysis, categorical scale variables were described in frequency distribution and proportion (n and %), while continuous data was described in mean value and standard deviation.

Validation of translated-NDI used reliability and validity test. Reliability test conducted based on internal consistency and reproducibility. Internal consistency was calculated using alpha Cronbach and was considered valid is alpha value more than 0.70. Reproducibility was evaluated by using test-retest (intra-class correlation). Minimal standard of intra-class correlation coefficient was 0.70.¹⁷ To implement an instrument without gold standard such dyspepsia, validity was valued by factor analysis methods. An instrument is considered valid if Kaiser-Meyer-Olkin value was even or higher than 0.64.²³

RESULTS

Subject Characteristics

In first stage of study, 467 patients, second were 153 and third were 49 patients. Of 49 patients (table 1), male were 21 (42.9%), and female were 28 (57.1%). Age was ranging from 20-82 years, with mean 47.55 \pm 15.52 years. College educated was 4 patients (8.2%) and the rest had lower educational level (92.8%). Twenty six (53.1%) patients were unemployed.

Alpha-Cronbach was ranging between 0.96 and 0.99 and ICC between 0.77 and 0.80. All those values were above minimal standard which was 0.77. Thus, internal consistency and reproducibility of NDI translation is acceptable.

Validity Test

Validity test of NDI translation using factor analysis Kayser-Meyer-Olkin value was 0.84 which was above minimal standard of 0.64. Thus, translated NDI is valid.

Table 2. Subject characteristics

| Characteristic | (n = 49) |
|--------------------|----------|
| Male, n (%) | 21(42.9) |
| Age (year) | |
| Interval | 20-82 |
| Mean | 44.55 |
| Standard deviation | 15.52 |
| Education | |
| ≤ Callege (%) | 92.8 |

Reliability test of NDI translation

Realibility test of NDI is show in table 3

Table 3. Reliability test of NDI between step first and second

| Characteristic | α-Cronbach | CC | Р |
|----------------------------------|------------|------|------|
| Tension/anxiety | 0.99 | 0.77 | 0.00 |
| Interference with daily activity | 0.96 | 0.77 | 0.00 |
| Eating/drinking | 0.96 | 0.79 | 0.00 |
| Knowledge/control | 0.87 | 0.77 | 0.00 |
| Work/study | 0.99 | 0.80 | 0.00 |

DISCUSSION

There have been reports that using standard instrument is an important thing in developing clinical research. Some questionnaires can evaluate many problems in primary healthcare and observe the impact of disease to patient's quality of life. ¹¹⁻¹⁶

NDI evaluate symptoms and quality of life in patients with dyspepsia. Subscale of quality of life related to symptoms may directly evaluate severity of symptoms. Quality of life in patients with dyspepsia are influenced by several important factors such as anxiety, interference with daily activity, eating/

drinking, lack of control and knowledge including fear of serious illnesses and work-related activity.²¹

All aspect in Indonesian language NDI indicated very good internal consistency and test-retest ≥ 0.70 . As validity test using factor analysis, Kayser-Meyer-Olkin grade was 0.84 which was above minimal standard of 0.64. This means this test was very valid.

Translation of NDI (Australian English) into French, Dutch, Italian, German, Spanish, and American English had been proven to have good validity test in each country. 14,21,22

CONCLUSION

Based on the result reability and validity analysis, translation of NDI into Indonesian language can be used for Indonesian patients with dyspepsia who speak Indonesian language for clinical study in the future.

REFERENCES

- Malagelada JR. Review article: the continuing dilemma of dyspepsia. Aliment Pharmacol Ther 2001;15(Suppl 1):6-9.
- Jones RH. Clinical economics review: gastrointestinal disease in primary care. Aliment Pharmacol Ther 1996;10:233-9.
- Hession PT, Malagelada J. Review article: the initial management of uninvestigated dyspepsia in younger patientsthe value of symptom-guided strategies should be reconsidered. Aliment Pharmacol Ther 2000;14:379-88.
- AgreÂus L. Socio-economic factors, health care consumption and rating of abdominal symptom severity. Fam Pract 1993;10:152-63.
- Jones R, Lydeard S. Dyspepsia in the community: a follow-up study. Br J Clin Pract 1992;46:95-7.
- Talley NJ, Weaver AL, Zinsmeister AR. Impact of functional dyspepsia on quality of life. Dig Dis Sci 1995;40:584-9.
- DimenaÈs E, Glise H, Hallerback B, Hernqvist H, Svedlund J, Wiklund I. Well-being and gastrointestinal symptoms among patients referred to endoscopy owing to suspected duodenal ulcer. Scand J Gastroenterol 1995;30:1046-52.
- Wiklund I, Glisc H, Jerndal P, Carlsson J, Talley NJ. Does endoscopy have a positive impact on quality of life in dyspepsia?. Gastrointest Endosc 1998;47:449-54.
- Irvine EJ. Quality of life issues in patients with inflammatory bowel disease. Am J Gastroenterol 1997;92(suppl):18-24S.
- Guyatt GH, Feeny DH, Patrick DL. Measuring healthrelated quality of life. Ann Intern Med 1993;118:622-9.
- Kuykendall DH, Rabeneck L, Campbell CJM, et al. Dyspepsia. How should we measure it? J Clin Epidemiol 1998;51:99-106.
- Wiklund IK, Junghard O, Grace E, et al. Quality of life in reflux, and dyspepsia patients. Psychometric documentation of a new disease-specific questionnaire (QOLRAD). Eur J Surg 1998;583(suppl):41-9.
- Shaw M, Talley NJ, Adlis S, et al. Development of a digestive health status instrument: Tests of scaling assumptions, structure and reliability in a primary care population. Aliment Pharmacol Ther 1998;12:1067-78.
- Talley NJ, Haque M, Wyeth JW, et al. Development of a new dyspepsia impact scale: The Nepean Dyspepsia Index (NDI). Aliment Pharmacol Ther 1998;12:1067-78.
- Bamfi F, Olivieri A, Arpinelli F, et al. Measuring quality of life in dyspeptic patients. Development and validation of a new specific health status questionnaire. Am J Gastroenterol 1999;94:730-8.

- Velanovich V, Vallance SR, Gusz JR, et al. Quality of life scale for gastroesophageal reflux disease. J Am Coll Surg 1996;183:217-24.
- Fitzpatrick R, Davey C, Buxton MJ, Jones DR. Evaluating patient-based outcome measures for use in clinical trials. Health Technol Assessment 1998;2:1-74.
- Drossman DA, Corrazziari E, Talley NJ, et al. Rome II: The functional gastrointestinal disorders. 2^{nt} ed. McLean: Degnon 2000.
- Bytzer P, Talley NJ. Dyspepsia. Ann Intern Med 2001;134:815-22.
- Talley NJ. Vakil NB, Moayyedi P. American gastroenterological association technical review on the evaluation of dyspepsia. Gastroenterology 2005;129:1756-80
- Talley NJ, Verlinden M, Jones M. Validity of a new quality of life scale for functional dyspepsia: A United States multicenter trial of the Nepean Dyspepsia Index. Am J Gastroenterol 1999;94:2390-7.
- Talley NJ, Verlinden M, Jones M. Quality of life in functional dyspepsia: Responsiveness of the Nepcan Dyspepsia Index and development of a new 10-item short form. Aliment Pharmacol Ther 2001;15:207-16.
- Ware JE, Snow KK, Kosisnski M, Gandek B. SF-36 Health Survey. Manual and Interpretation Guide. 2nd ed. Lincoln, RI: Quality Metric Inc 2002.

PERPUSTAKAAN PUSAT UNEVSEOPTA AMAGATOSTA