

# Measurement of Health-related Quality of Life in Patients with Functional Dyspepsia

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## ABSTRAK

Hampir 80% pasien dispepsia yang berobat ke rumah sakit merupakan dispepsia fungsional. Dispepsia fungsional walaupun tidak meningkatkan mortalitas, namun dapat menjadi beban bagi komunitas dan negara, karena menimbulkan gangguan terhadap fisik, mental dan sosial pasien, sehingga berpengaruh terhadap kualitas hidup pasien. Kualitas hidup terkait kesehatan merupakan konstruksi multidimensi yang terdiri dari setidaknya tiga domain yaitu fungsi fisik, psikologis dan sosial yang ketiganya dipengaruhi oleh penyakit dan pengobatan yang diberikan. Penilaian kualitas hidup terkait kesehatan merupakan hal yang penting pada pasien dispepsia fungsional untuk dapat mengidentifikasi dampak dari penyakit dan pengobatan yang diberikan kepada pasien. Instrumen generik dan spesifik penyakit dapat digunakan untuk menilai kualitas hidup terkait kesehatan pada pasien dispepsia fungsional. Masing-masing instrumen memiliki kelebihan dan keterbatasan. Pemilihan instrumen untuk menilai kualitas hidup terkait kesehatan ditentukan berdasarkan populasi penelitian, pertanyaan penelitian, entitas penyakit, dan preferensi dari peneliti. Tujuan dari penulisan artikel ini adalah untuk menjelaskan mengenai konsep kualitas hidup terkait kesehatan dan penilaian kualitas hidup terkait kesehatan pada pasien dispepsia fungsional.

**Kata kunci:** kualitas hidup terkait kesehatan, dispepsia fungsional.

## ABSTRACT

In up to 80% of dyspepsia patients who consult a physician in the hospital, dyspepsia is considered to be functional dyspepsia. Although not associated with increased mortality, functional dyspepsia is a burden at both the community and national levels because it can cause physical, mental, and social distress that can affect a patient's quality of life. Health-related quality of life (HRQOL) is a multidimensional construct comprising at least three broad domains—physical, psychological, and social functioning—which can all be affected by a disease and its treatment. It is important to assess HRQOL in patients with functional dyspepsia to identify the effects of the disease and its treatment on patients. Both disease-specific and generic instruments can be used to assess HRQOL in patients with functional dyspepsia. Each instrument has its own advantages and limitations. The selection of instrument to assess HRQOL is determined by the study population, research questions, disease entities, and researcher preferences. The purpose of this article is to explain the concept of HRQOL and the use of HRQOL assessment in patients with functional dyspepsia.

**Keywords:** health-related quality of life, functional dyspepsia.

## INTRODUCTION

Symptoms of dyspepsia are common in the community and clinical practice.<sup>1</sup> In up to 80% of dyspepsia patients who consult a physician in the hospital, the condition is classified as functional dyspepsia.<sup>1,2</sup> Functional dyspepsia is defined as the presence of symptoms thought to originate in the gastroduodenal region in the absence of any organic, systemic, or metabolic disease that is likely to explain the symptoms. The Rome criteria subdivide functional dyspepsia into postprandial distress syndrome and epigastric pain syndrome).<sup>3</sup> The pathophysiology of functional dyspepsia is complex and is not fully understood, although it is known that abnormal gut motility, visceral hypersensitivity, genetic influence, infection, and psychosocial factors play a role.<sup>4</sup>

Functional dyspepsia is a burden at both the community and national levels. It carries significant direct and indirect costs and decreases work productivity.<sup>5,6</sup> Although functional dyspepsia is not associated with increased mortality,<sup>7</sup> it can lead to physical, mental, and social distress, which can affect the quality of life.<sup>8-14</sup>

Health-related quality of life (HRQOL) is increasingly being assessed as a patient-reported outcome in clinical research.<sup>15,16</sup> It is important to assess HRQOL in patients with functional dyspepsia to identify the effects of the disease and its treatment in patients.<sup>17,18</sup> Both disease-specific and generic instruments can be used to assess HRQOL in patients with functional dyspepsia.<sup>19</sup> However, as a new concept, HRQOL is not well understood by many clinicians in Indonesia, and its use in research and clinical practice is lacking. The purpose of this article is to explain the concept of HRQOL and the use of HRQOL assessment in patients with functional dyspepsia.

## DEFINITION OF HEALTH-RELATED QUALITY OF LIFE

The World Health Organization defines quality of life as an “individual’s perception of their position in life in the context of the culture and value systems in which they live and in

relation to their goals, expectations, standards and concerns”.<sup>20</sup> HRQOL is a multidimensional construct comprising at least three broad domain physical, psychological, and social functioning which can all be affected by disease and treatment.<sup>21</sup> The term HRQOL is used to differentiate this measure from other more general aspects of life that are not considered to be health related such as income, freedom, and quality of the environment.<sup>22</sup>

## WHY MEASURE HEALTH-RELATED QUALITY OF LIFE?

Physicians often rely on objective findings when managing patients.<sup>17</sup> However, patients may be less interested in the value of traditional biomarkers than physicians.<sup>23</sup> Moreover, traditional biomarkers often fail to correlate with functional capacity and well-being.<sup>22</sup> Assessment of HRQOL may counter this problem, and help physicians to understand that patients often value outcomes in a different way than their physician.<sup>23</sup>

HRQOL assessment can guide physicians when making a clinical decision in situations in which there may be multiple effective strategies from which to choose. HRQOL can offer an added value when choosing a treatment when there may be only a small difference in survival between treatments. Physicians can also use HRQOL to help them decide on a treatment strategy for patients with asymptomatic or mildly symptomatic disease.<sup>18</sup>

Measuring HRQOL is important for understanding the effects of chronic disease, especially for those diseases with major effects on morbidity but not mortality.<sup>22,23</sup> Determining disease burden by using traditional measures such as the prevalence of a disease, direct and indirect costs, and effects on productivity is insufficient for understanding the true burden of any disease.<sup>23</sup> Identifying the adverse effects of a disease on HRQOL is important for society and health providers to appreciate fully the true burden. HRQOL data can also help national health policy makers when developing a healthcare budget.<sup>23,24</sup>

## HOW TO CHOOSE A HEALTH-RELATED QUALITY OF LIFE INSTRUMENT

The best and most relevant way to assess HRQOL is to ask patients by using a validated questionnaire.<sup>17</sup> HRQOL instruments include a range of questions that correspond to the number of domains assessed. A domain is an area of behavior or experience and questions may relate to mobility, self-care, depression, anxiety, and well-being.<sup>22</sup> The selection of the specific HRQOL instrument to be used is determined by the study population, research questions, disease entities, and researcher preferences.<sup>18</sup> Each instrument has its own advantages and limitations. Most current research uses a combination of generic and specific instruments. This combination can overcome the limitations of the use of only one type of instrument and help to obtain good sensitivity and generalizability.<sup>18,25</sup> Nevertheless, the combined use HRQOL instruments may also increase the time required for the patient to complete the questionnaires, and modified questionnaires have been developed.<sup>18</sup>

## GENERIC INSTRUMENTS

The generic questionnaire allows physicians and researchers to evaluate comprehensively the effects of different illnesses and symptoms on quality of life. Generic instruments can be used to compare HRQOL in patients with that in other groups with or without illness.<sup>17</sup> However, a major limitation of generic instruments is that they may not include unique and important indicators for some special groups and may therefore be less sensitive to changes in specific symptoms.<sup>18,25</sup> Generic instruments are more reliable for identifying the general effects on wide range of daily activities, mental health and functioning.<sup>17,26</sup>

The Short Form 36 Health Survey (SF-36) is the most commonly used generic questionnaire in gastroenterology research.<sup>18,19</sup> The SF-36 was originally developed to assess the health status of participants in the Medical Outcomes Study. This instrument is designed for use in clinical practice and research, health policy evaluation, and surveys in the general population.<sup>19,27</sup> The SF-36 is commonly used to define and measure differences in HRQOL between patients with

gastrointestinal disease and control populations.<sup>27</sup> The SF-36 includes one scale for each of eight measured health domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. The scores for these eight domains are aggregated into a physical component summary (PCS) and mental component summary (MCS). The PCS correlates with the scale of physical functioning, role-physical, and bodily pain, and the MCS correlates with mental health, role-emotional, and social functioning. Three scales of vitality, general health, and social functioning correlate with both component summaries.<sup>28</sup> All health domains are scored using norm-based scores ranging 0 to 100, with higher scores indicating better health. The SF-36 questionnaire can be self-administered by the patient, in a direct interview, or by telephone. The time required to complete the questionnaire is 5–10 minutes for most people and about 15 minutes in older people.<sup>28,29</sup>

The SF-36 instrument has been tested for reliability and validity. The median internal consistency alpha coefficient obtained from several studies is >0.8 for all scales except for social functioning, which has an alpha coefficient of 0.76. The test-retest correlation over 2 weeks is >0.8 for the physical functioning, vitality, and general health scales. The lowest coefficient of 0.6 is for the social functioning scale.<sup>29</sup> The content validity of the SF-36 has been compared with other widely used generic health surveys. Systematic comparisons show that the SF-36 includes eight of the most frequently assessed health concepts. Some concepts not covered in the SF-36 including cognitive functioning, sleep, health distress, social support, family and marital functioning, sexual functioning, and physical and psychophysiologic symptoms. Evaluation of 32 general concepts and 19 specific symptoms with eight scales and two summaries of the SF-36 show that the SF-36 scales correlate ( $r \geq 0.4$ ) with most general health concepts and with the frequency and severity of specific symptoms and problems.<sup>28</sup> The results of the analysis of the seven dimensions of the SF-36 evaluating functioning and well-being were strongly associated with patient reports of overall

general health. Kruskal-Wallis tests indicated clear linear trends for decreasing SF-36 scores (i.e., reporting more health related problems) on all seven dimensions with worsening self-rated general health.<sup>30</sup> The SF-36 has been translated and validated for use in Indonesia.<sup>31</sup>

## DISEASE-SPECIFIC INSTRUMENTS

A disease-specific instrument is designed to detect changes in HRQOL that may not be detected using a generic instrument but may be important manifestations of disease. Specific instruments tend to be more sensitive than generic instruments.<sup>26</sup> However, an overly sensitive disease-specific instrument has the disadvantage of possibly detecting clinically unimportant changes in the placebo group.<sup>25</sup> Another limitation is that, because of its narrow focus, a specific instrument may be unable to detect unexpected major changes in the HRQOL and cannot be used widely for different diseases.<sup>26</sup> Instruments may be specific to a disease (such as heart failure or asthma), a patient population (such as the frail elderly) to certain functions (such as sleep or sexual function), or specific problems (such as pain).<sup>22</sup> The Irritable Bowel Syndrome Quality of Life instrument and Nepean Dyspepsia Index (NDI) are examples of specific questionnaires commonly used in functional gastrointestinal disorders in Asia.<sup>19</sup>

The NDI was developed by a team of researchers in Sydney, Australia. The questionnaire originally comprised 42 questions that assessed quality of life in 17 major aspects and a list of symptom frequency, intensity, and disturbance of 15 upper gastrointestinal symptoms within the past 2 weeks. The assessment of this questionnaire uses a five-level Likert scale. The questionnaire has been translated from Australian English into French, Dutch, Italian, German, Spanish, and American English.<sup>32</sup> The NDI was simplified from 42 questions to 25 questions for five subscales (domains): effects on general tension/sleep (nine items), interference with daily activities (six items), effects on eating/drinking (three items), knowledge/control of dyspepsia (four items), and the effects of dyspepsia on work/study (three items). Validity testing noted good face validity and internal consistency

results; Cronbach's  $\alpha$  for all subscales was  $>0.85$ . Good reliability of the questionnaire has also been reported, with an intraclass correlation of all subscales of  $>0.84$ .<sup>33</sup>

The NDI questionnaire was further simplified into 10 questions with each subscale comprising two questions. The NDI evaluates the symptoms and HRQOL in patients with functional dyspepsia. The quality of life subscale associated with symptoms can be used to assess directly the severity of disease symptoms. The questionnaire is responsive and has sufficient internal consistency ( $>0.7$ ) for all scales as well as a strong and meaningful correlation with the complete questionnaire.<sup>34</sup> A short-form NDI has been translated and its validity tested for use in Indonesia.<sup>35</sup>

## CONCLUSION

It is important to assess HRQOL in patients with functional dyspepsia to identify the effects of the disease and its treatment in patients. Both disease-specific and generic instruments can be used to assess HRQOL in patients with functional dyspepsia. Understanding the advantages and limitations of both generic and disease-specific instruments is critical when choosing to assess HRQOL in patients with functional dyspepsia.

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