Measuring health-related quality of life (HRQoL) in functional dyspepsia: is it really important?

“Measure what is measurable, and make measurable what is not so”
Galileo Galilei (1564-1642)

Concern for measuring health outcomes in real life and from the patients’ perspective has been included for years in the management of many and various diseases, regardless of the presence or absence of a known organic basis and/or objective markers associated with their course or response to treatments. This approach partly results from patient participation in decisions involving their health, and also from the health definition put forward by the World Health Organization (WHO) as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Patient-reported outcomes (PROs) emerge in this setting as variables including symptoms, self-perception of health status, degree of satisfaction with treatments, or health-related quality of life (HRQoL), defined as the impact of disease on health status as perceived by patients themselves, and its negative influence on physical, psychological, and social aspects (1-3). This approach is particularly relevant in the field of neurogastroenterology, where many disorders are pathogenetically characterized by complex, still poorly understood interactions between brain and gut, and their relationship with several pathophysiological abnormalities, psychosocial factors, etc., all of it comprised within a biopsychosocial model of disease development conditioning a vast clinical heterogeneity. This scenario makes it difficult to develop objective parameters useful for the identification of homogeneous patient groups, and to assess disease progression and treatment response, hence PROs are the sole measurements that ultimately support our clinical decision making.

As early as in 1995 Talley et al. demonstrated the impact of functional dyspepsia (FD) on HRQoL (4), a fact corroborated in subsequent studies (5). The article published in the present issue of the Revista Española de Enfermedades Digestivas by Orive et al. (6) assesses, in patients with dyspepsia on drug therapy with or without psychological intervention, the psychometric characteristics of the only two specific HRQoL questionnaires that have been translated into Spanish and culturally adapted to our setting, the Glasgow Dyspepsia Severity Score (GDSS) (7) and the Questionnaire of Dyspepsia-Related Health Scale (QoL-PEI) (8). Despite their being validated years ago, and the fact that their conceptual background and relevance were argued for in an excellent review (9), the dearth of studies assessing their usefulness is striking, and their real-world implementation remains unknown outside the scope of therapy assessment studies. The use of these tools may be limited by time constraints, challenging reading of scale-based results, high external factor influence, and reduced availability as compared to generic questionnaires (2,10). Furthermore, clinical practice guidelines, the development of which is extraordinarily complex, include no explicit recommendations yet regarding their use.

A relevant fact emerges from the definition recently included in the Rome IV criteria for the diagnosis of FD (11). Albeit the Rome III classification already considered symptom severity (12), the newer classification overcomes this approach and, for the first time, incorporates the impact symptoms have on daily living into its diagnostic criteria. This is a key aspect justifying the measurement of HRQoL. Therefore, we are witnessing a new stage in the management of this condition, a stage where we must stop and review these tools in order to define their role in our clinical practice.

As is discussed in the paper by Orive et al., both the GDSS and QoL-PEI reveal in this study aspects that warrant revision (first, suboptimal inner consistency; second, need to improve the items in the patient-reported satisfaction dimension). The primary limitations of this study include its relying on inpatients and absence of Helicobacter pylori infection assessment, factors that may modify HRQoL measurement. These facts are related to the disparity seen in the available data regarding the prevalence of dyspepsia: 7-35% for uninvestigated dyspepsia (depending on definition, geographic distribution and study period) and 11-29% for FD. Uninvestigated dyspepsia with predominant epigastric pain has a prevalence of 7-34%, which goes up to 23-45% when including all types of discomfort in the upper abdomen (13-15). While most studies differentiate uninvestigated dyspepsia from FD, a high proportion of patients without alarm symptoms will exhibit no changes during gastroscopy or other studies, hence both conditions might be considered to be comparable (13). In addition, their actual prevalence might be underestimated as up to one half of patients never seek medical help (15). In this respect, the newer Rome classification reviews such aspects and establishes a minimum frequency for symptoms in its diagnostic criteria (11), which will contribute to unify data on prevalence.

The formulation of the dimensions considered for HRQoL, and the items included in the questionnaires, is highly complex, as is the selection of the most appropriate tool for each individual case. They must have adequate validity, reliability or ability to provide consistent repeat measurements under similar conditions (including inner consistency, assessed with Crohnbach's alpha coefficient), sensitivity to change or responsiveness, and generalizability, such that it should not be used outside the context for which it was initially conceived (1,16). Many controversial aspects exist that should be analyzed in detail before establishing a recommendation on their generalized use. First, the selection of a generic versus a specific questionnaire. The former (e.g., SF-36) allows comparisons with the general population, and the index-based
(e.g., Euro-QoL) variety may be used for economic studies by measuring quality-adjusted life years (QALY). However, this type is inadequate to detect changes and has too many items when it comes to assessing a specific disease, hence their combination with specific questionnaires has been recommended (1,2). Specifically for FD, the use of questionnaires also assessing other aspects is arguably an added benefit given a high overlap with other functional gastrointestinal disorders, including gastroesophageal reflux disease and irritable bowel syndrome (13). In fact, tools have been developed to assess HRQoL jointly with these conditions (Quality of Life in Reflux and Dyspepsia [QOLRAD], Functional Digestive Disorders Quality of Life questionnaire [FDDQL] and Digestive Health Status Instrument [DHSII]) (9), and to evaluate the impact of psychological comorbidities on HRQoL on FD (the latter occurring in at least 1/3 of patients with FD) (17), as well as the impact of other highly prevalent disorders such as fibromyalgia. HRQoL may be influenced by all the above common associations, hence both generic and specific questionnaires may be ineffective to assess treatment response even when FD-related symptoms improve. Anyway, we should bear in mind that administering more than one questionnaire would make their use even more difficult in clinical practice.

In view of the newer Rome criteria, another aspect supporting the measurement of HRQoL in clinical practice would be the need to update the so-called “modifiers” using the “multidimensional clinical profile” in order to plan individualized therapy according to each patient's clinical profile, bearing in mind the status of selected clinical, psychological and pathophysiological factors that may to a greater or lesser extent modify the clinical picture as well as patient self-perceived severity (18). This approach is very interesting as it may allow the design of tailored therapies based on symptoms and their impact on HRQoL, aiming at the mechanisms potentially involved in each specific case, i.e., addressing the biopsychosocial model.

In summary, the article published by Orive et al. in this issue of the Revista Española de Enfermedades Digestivas helps to increase the scarce evidence available on the two HRQoL questionnaires currently translated and adapted to our context, and to identify areas in need of improvement. Developing further studies in this respect is highly relevant since the clinical management of FD cannot be approached without measuring HRQoL, and many aspects still require clarification before such measuring is widespread. The newer Rome IV criteria will no doubt help facilitate further research in this field.

REFERENCES

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