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REVIEW ARTICLE

Questionnaire based gastroesophageal reflux disease (GERD) assessment scales

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Abstract Questionnaire based assessment scales for gastroesophageal reflux disease (GERD) have been utilized for assessment of the patient's symptomatology, assessment of symptom severity and frequency, assessment of health-related quality of life and for assessment of response to treatment. A multitude of unidimensional and multidimensional questionnaires exist for making symptom assessment and monitoring quality of life in GERD. Many of the scales meet some of the parameters of an ideal evaluative GERD specific assessment instrument. Yet, there are certain shortcomings and challenges which are faced in development of GERD questionnaires. This review discusses the features of an ideal symptom assessment instrument, examines the strengths and weaknesses of currently available questionnaires.

Keywords Diagnosis · Gastroesophageal reflux disease · Health-related quality of life · Treatment assessment

The prevalence of gastroesophageal reflux disease (GERD) ranges from 10% to 30% in the population of Western countries [1]. There is paucity of data regarding the magnitude of the problem in India. A recent study has shown the prevalence of GERD to be 16.2% among the employees of a large tertiary hospital in North India [2].

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GERD as a disease entity has varied presentations. The symptoms may not correlate with the endoscopic picture. The patients may present as any of the following:

1. typical heartburn and reflux symptoms with endoscopic evidence of mucosal injury
2. symptoms of heartburn and reflux but a normal upper gastrointestinal endoscopy (UGIE)
3. no esophageal reflux symptoms but evidence of mucosal injury on UGIE or
4. atypical symptoms such as dyspepsia, cough, asthma, etc.

So aptly the 2006 consensus meeting held at Montreal defined GERD as "a condition that develops when the reflux of stomach contents causes troublesome symptoms and/or complications" [3].

Because of these diverse clinical manifestations, diagnosis of GERD is not easy or straightforward. Traditional diagnostic modalities such as barium swallow and endoscopy have a sensitivity of 10% to 50% [4] and 30% to 50% [5, 6] respectively. 24-h esophageal pH monitoring is also normal in 6%–15% of patients with abnormal symptom index and not commonly available [7]. So an objective gold standard diagnostic test is lacking. In the Indian setting, a study evaluating the diagnostic algorithm of GERD found that a combination of omeprazole challenge test, endoscopy and histology will identify all cases of GERD [8]. This study concluded that 24-h esophageal pH testing, despite being the gold standard, has no utility in routine clinical settings and hence its availability should be limited to tertiary care settings. The patients were recruited on the basis of symptom score evaluation (heartburn and/or regurgitation) highlighting the importance of symptom-based questionnaires in the diagnosis of this disease.

Structured questionnaires for diagnosis of GERD have been formulated based on the patients' history. As GERD is a chronic disease, assessment of quality of life is another important aspect of the disease evaluation. Questionnaire-based evaluation has played an important role in clinical trials of GERD. This has been so because symptom improvement and improvement of health-related quality of life (HRQOL) are the main goals of treatment of GERD.

The aim of this review is to discuss the features of an ideal symptom assessment instrument, and to examine the strengths and weaknesses of currently available questionnaires. The utility of questionnaires in GERD has been found in the following settings:

1. assessment of the patient's symptoms
2. assessment of symptom severity and frequency
3. assessment of HRQOL
4. assessment of response to treatment

For achieving these objectives the questionnaires should be:

1. sensitive to diagnose the disease
2. easily scored
3. easily understandable
4. easily translatable to local languages
5. able to evaluate the disease as completely as possible, covering all types of typical and atypical symptoms
6. able to assess changes with therapy over shorter as well as longer duration
7. self reported/self administered
8. economical
9. psychometrically validated in clinical trials

The questionnaires may be classified into - a) symptom assessing questionnaires (Table 1), b) health-related quality of life assessing questionnaires (Table 2), and c) hybrid questionnaires which assess symptom response as well as quality of life (Table 3). The symptom assessing questionnaires are either specific to GERD or wide covering other allied GI diseases.

Symptom assessment scales in GERD

Symptom scales used for diagnosis of GERD

Greatorex and Thorpe [9] developed the esophageal symptom questionnaire to assist the diagnosis of GERD. It contained six items namely heartburn, regurgitation, dysphagia, bleeding, dyspepsia and vomiting, which were scored on a 4-point adjectival scale; the questionnaire was completed by the patient in the presence of the examining doctor. They found that the questionnaire was valid, but reliability and responsiveness were not assessed.

Table 1 Scales for symptom assessment in gastroesophageal reflux disease (GERD)

GERD specific
GERD specific esophageal symptom questionnaire [9]
GERD specific questionnaire by Mold et al. [10]
GERD specific questionnaire by Räihä et al. [11]
GERD questionnaire [12]
Infant gastroesophageal reflux questionnaire (I-GERQ) [13]
Gastroesophageal reflux questionnaire (GERQ) [14]
GERD Activity Index (GRACI) [15]
GERD specific questionnaire by Carlsson et al. [16]
GERD specific questionnaire by Manterola et al. [17]
GERD score [18]
GERD Symptom Assessment Scale (GSAS) [19]
GERD screener [20]
Questionnaire used by Vigneri et al. [21]
Reflux disease diagnostic questionnaire (RDQ) [22]
Chinese GERD Questionnaire (Chinese GERDQ) [23]
Scores for assessment of other diseases along with GERD
Standardized esophageal symptom questionnaire [24]
Questionnaire by Andersen et al. [25]
Gastrointestinal Symptoms Rating Scale (GSRS) [26]
Questionnaire by Ruth et al. [27]
Ulcer esophagitis subjective symptoms scale (UESS) [28]
Digestive health status instrument (DHSI) [29]
Modified bowel disease questionnaire (BDQ) [30]

Table 2 Scales for quality of life assessment in gastroesophageal reflux disease (GERD)

GERD specific
Gastroesophageal reflux disease health-related quality of life (GERD-HRQL) [31]
Heartburn - specific quality of life instrument (HBQOL) [32]
GERD specific QoL questionnaire by Jasani et al. [33]
QOL questionnaire in gastroesophageal reflux (Reflux-Qual) [34]
Reflux-qual short-form (RQS) [35]
Work Productivity and Activity Impairment Questionnaire for GERD (WPAI-GERD) [36]
QoL questionnaire for patients undergoing antireflux surgery (QOLARS) [37]
GERD-QOL [38]
GI specific
Gastrointestinal quality of life index (GIQLI) [39]
Quality of life in reflux and dyspepsia (QOLRAD) [40]
Patient assessment of upper gastrointestinal disorders (PAGI-QOL) [41]
Generic
Psychological general well-being index (PGWB) [42]
EuroQoL-5 dimensions (EQ-5D) [43]
36-Item short-form general health survey (SF-36) [44]

Table 3 Hybrid scales assessing both symptoms and quality of life in gastroesophageal reflux disease (GERD)

Questionnaires by Colwell et al. [45] and Mathias et al. [46]
HRQoL batteries [47]
Domestic/International Gastroenterology Surveillance Study (DIGEST) [48]
Reflux questionnaire (ReQuest) [49]
Nocturnal GERD symptom severity and impact questionnaire (N-GSSIQ) [50]

Johnsson et al. [12] used four structured and descriptive questions in their self reported GERD questionnaire. The description of symptoms rather than using the term heartburn may have been a factor in improving the predictive value of this questionnaire, but a positive response to all four questions was required to achieve a high positive predictive value, thus limiting its usefulness. Moreover, this questionnaire was specific for erosive GERD and/or patients with pathological pH values. This questionnaire was not validated.

Ornstein et al. [13] devised a 138-item questionnaire to diagnose GERD in infants and to identify potentially provocative caretaking practices. In a validation study, it was shown that the questionnaire has high positive and negative predictive values for diagnosing GERD.

Reidel et al. [24] assessed all patients referred over a one-year period for clinical esophageal manometry (not clear) by means of a self-reported questionnaire. Symptoms assessed were chest pain, dysphagia for solids and liquids, heartburn, regurgitation. They found esophageal symptoms to be poor predictors of manometric findings. However the questionnaire was not validated.

Carlsson et al. [16] used word pictures of symptoms to design a self-assessment questionnaire that was intended to identify responders to PPI therapy. They found that the sensitivity of a scale increased whenever descriptions or word pictures were used instead of single terms. Prospective validation of this questionnaire in a primary care population did not find the questionnaire superior to the physician's provisional diagnosis for discriminating omeprazole responders.

The Digestive Health Status Instrument (DHSI) was designed as a self reported questionnaire incorporating 34 items to assess functional gastrointestinal diseases related to bowel dysfunction/irritable bowel syndrome, reflux, dysmotility and pain in primary care settings [29]. Psychometric analyses were performed and multiple types of reliability, validity and responsiveness were demonstrated in study populations including community, primary care and gastroenterology subjects [51].

Symptom scales used for epidemiological studies of GERD

Mold et al. used a self reported GERD specific questionnaire with 15 items assessing GERD symptoms and pulmonary symptoms [10]. They found that 14% of elderly population had at least weekly heartburn and 24% of elderly population with alkaline reflux had pulmonary symptoms in contrast to none with acid reflux.

Räihä et al. used a self reported GERD specific questionnaire designed in Finnish language to study the prevalence of GERD in elderly population [11]. The response rate and the completeness of the filling of forms were found to be high (~ 90%). They found that 54% of males and 66% of females among the elderly population had symptoms of GERD at least once a month. However both these questionnaires were not validated.

Locke et al. developed a GERD specific self reported GERD questionnaire (GERQ) originally in English language [14]. They compared the symptoms assessed by this questionnaire with endoscopy findings and found that heartburn frequency was associated with esophagitis, the duration of acid regurgitation was associated with Barrett's esophagus and strictures were associated with dysphagia severity and duration. However the questionnaire overall was only able to modestly predict endoscopic findings. The same questionnaire was later on translated into Spanish language and adapted to the Spanish population with good reproducibility and concurrent validity [52].

Manterola et al. developed an observer reported questionnaire in Spanish language to study the prevalence of GERD in the general population [17]. Validation of this tool has been done in a further study and its usefulness was established [53]. However it's performance and reliability if translated into English language was not further investigated.

GERD screener is an interview based questionnaire assessing three subscales namely heartburn, regurgitation and medication use and the construct, convergent and predictive validity of this instrument were demonstrated [20]. This instrument was practical, short and easily administered and was intended to be used as a case finding tool in primary care settings and managed care organizations.

Investigators from the All India Institute of Medical Sciences, New Delhi used a truncated scale (evaluated heartburn and regurgitation as a symptom score) originally developed by Vigneri et al. [21] (evaluated heartburn, pain and regurgitation as a symptom score) and found that a symptom score ≥4 had a high diagnostic accuracy for GERD [8]. This questionnaire was interview based. This validated score was then used to determine the prevalence of GERD among the employees of the same tertiary hospital [2]. This questionnaire was also used to diagnose GERD and then assess response to therapy in a randomized controlled trial [54]. The same scale was used in another population based cross-sectional study which intended to investigate the prevalence and risk factors of GERD in a high altitude area [55].

Ho et al. modified the "Bowel Disease Questionnaire (BDQ)" originally designed by Talley et al. [56] according to their local conditions and translated the English version into Chinese and Malay languages [30]. This questionnaire was interview based and used to assess various functional GI disorders. Prevalence of various GI symptoms with particular mention of reflux-type symptoms was assessed in a multiracial Asian population in Singapore. Feasibility, reproducibility and validity of the modified BDQ questionnaire were also demonstrated.

Andersen et al. developed a self reported questionnaire in Danish language to detect benign esophageal diseases in epidemiological studies [25]. Ruth et al. developed a self reported questionnaire related to various esophageal diseases in Swedish language to assess the prevalence and severity of symptoms suggestive of esophageal diseases in a general population [27]. Both these questionnaires were neither translated and assessed in English language nor further validated.

Symptoms scales to assess response to treatment

GERD score is a symptom questionnaire developed to measure the outcome after the medical and surgical treatment of GERD [18]. This is a six item questionnaire administered by an external observer rather than being self reported. It is used to assess the severity (on a 4-point scale) and frequency (on a 5-point scale) of six GERD symptoms namely heartburn, regurgitation, epigastric or chest pain, epigastric fullness, dysphagia, cough by applying the scale to patients before and 6 months after treatment. This tool was validated psychometrically and shown to be reproducible, valid with significant correlation between the baseline GERD score and lower esophageal sphincter pressure, 24-hr esophageal pH, and 8 subscales of the 36-item Short-Form General Health Survey (SF-36) and responsive to change. However this scale has certain limitations. It has not been validated for the assessment of short-term response of treatment of less than 6 months duration and the reproducibility over longer periods of time more than 6 months has not been assessed. It doesn't include atypical symptoms, is available only in English language and has to be administered by an external observer.

Gastroesophageal Activity Index (GRACI) is a GERD specific symptom scale developed by using multiple logistic regression analysis techniques to correlate clinical data with a physician's assessment of GERD activity [15]. The scale has a combination of interview based (12 items) and patient reported items (5 items noted in a diary daily for 1 week). The questionnaire is available in English language and is administered at baseline and subsequently at 3-month intervals. The validity and reliability of the scale were demonstrated. It was developed as a major outcome variable in clinical trials. However it needs to be tested in further clinical trials as its responsiveness has not been proven conclusively.

GERD Symptom Assessment Scale (GSAS) is a GERD specific self assessed scale available in English language and developed to be administered before and after treatment [19]. It has 15 items including various symptoms such as bloating, nausea, early satiety, etc. which usually are not included in other assessment tools. However it does not include all the atypical symptoms and nocturnal symptoms. It has been validated and shown to have acceptable reliability, content and construct validity and sensitive to changes in severity of symptoms and to changes over time.

The Reflux Disease Questionnaire (RDQ) was originally developed to facilitate the diagnosis of GERD in primary care settings [22]. It is a self administered GERD specific questionnaire which assessed the frequency and severity of three parameters namely regurgitation, heartburn and dyspepsia. The validity, reliability and responsiveness of this scale have been demonstrated. In contrast to the original RDQ, a German version was created to assess treatment response for a period of 1 week [57]. Latter on in a study of 439 Scandinavian patients randomized to either esomeprazole or placebo, RDQ has been shown to be useful to evaluate treatment response [58]. The assessed time period is over the last 4 weeks at baseline and the last 1 week period in patients being assessed for post-treatment benefit. This questionnaire was also shown to effectively differentiate various levels of patient-assessed symptom severity in comparision to physician-assessed severity of symptoms. The results were found to be consistent when the questionnaire was translated to Swedish and Norwegian languages.

Madan et al. utilized the questionnaire developed to diagnose GERD in North Indian patients to assess response to therapy in a randomized controlled trial and found that a combination of pantoprazole and mosapride was more effective than pantoprazole alone in providing symptomatic relief to patients with erosive GERD [54].

The Chinese GERD Questionnaire (Chinese GERDQ) [23] is a GERD specific, self reported instrument whose main framework is derived from the GERQ questionnaire [14]. Few additional questions based on the usual encountered clinical problems in their respective clinical settings were added to the original questionnaire and translated into Chinese language. The final questionnaire is usable in epidemiological studies and interventional studies of GERD. Content validity, construct validity, discriminant validity, reproducibility, test-retest reliability and internal consistency of the scale were demonstrated. However the questionnaire is available to be used only in Chinese language.

The Ulcer Esophagitis Subjective Symptoms Scale is a self assessed and validated questionnaire with visual analogue scale for assessment of concerned dimensions in patients of peptic ulcer disease and esophagitis at baseline and after 4 weeks of treatment [28]. Thus this scale is not specific to GERD. It is available only in Swedish language.

The Gastrointestinal Symptom Rating Scale (GSRS) was originally developed as a interview based tool to measure the outcomes for irritable bowel syndrome and peptic ulcer disease [59]. Later on it was modified to a self reported tool and extended for the assessment of GERD also [26]. Thus this scale is not GERD specific. It has 15 items combined into 5 symptom clusters namely reflux, abdominal pain, indigestion, diarrhea, constipation and scored on a 7-point Likert scale defined by verbal descriptors. It was made available for usage in many languages including English. Psychometric evaluation indicated that the 5 scales of the GSRS have good internal consistency, reasonable test-retest reliability, acceptable construct validity and it was proven to be responsive to treatment in clinical trials [60]. However the instrument was not found to be very sensitive for GERD [61].

Quality of life assessment scales in GERD

HRQOL scales specific for GERD

The Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) questionnaire is a self assessed, GERD specific scale devised in English language and is mainly used before and after anti-reflux surgery [31]. It has 10 items scored on 6-point Likert scales addressing domains like severity of heartburn, conditions of heartburn, dysphagia, odynophagia, effect of medication and flatulence. But no extra-esophageal symptoms were included. This scale has been subjected to only limited psychometric evaluation. There was no significant correlation between the GERD-HRQL scores and the eight domains of the SF-36 scale [62].

The Heartburn-specific Quality of Life instrument is a self assessed, patient diary based, GERD specific scale, available in English language and was developed to detect changes in HRQOL before and after GERD therapy in clinical trials [32]. The questionnaire contains 15 items assessing 6 dimensions namely diet, mental health, pain, role physical, sleep and social activity. In a randomized controlled trial comparing ranitidine vs. placebo its responsiveness, reliability and validity were demonstrated [63]. However this scale has not been used widely in clinical trials.

Jasani et al. devised a GERD-specific self-assessed HRQOL questionnaire consisting of 20 items [33]. But this scale was not subjected to psychometric evaluation.

Raymond et al. developed a GERD-specific HRQOL questionnaire (Reflux-Qual) consisting of 37 items assessing 7 dimensions including daily life, discomfort, well-being, physical functioning, anxiety, sleep, food by using 5-point Likert scales [34]. The validity, reliability and responsiveness of this scale were demonstrated. However the validation has been performed only for the original French version of this scale, though it is available in various languages.

The Reflux-Qual Short-Form measures the HRQOL in patients with GERD by assessing 5 domains including daily life, well-being, psychological impact, sleep and eating using 8 items by means of 5-point Likert scales [35]. It was devised for use in daily practice. Psychometric evaluation demonstrated good internal consistency, construct validity, reliability, discriminant validity and responsiveness. There was a good concurrent validity regarding the correlation between the SF-12 scores and the RQS score. However similar to the Reflux-Qual questionnaire, validation of this scale has also been performed only for the French version, though the scale has been translated and made available in various other languages.

Work Productivity and Activity Impairment Questionnaire for GERD (WPAI-GERD) is a self-assessed tool designed to assess absence from work, reduction in productivity and activities as measured in hours per day and in percent reduction respectively in patients of GERD specifically [36]. The discriminant and convergent validity of the instrument have been demonstrated.

The QOL questionnaire for patients undergoing Antireflux Surgery (QOLARS) was developed to assess HRQOL in GERD patients who underwent laparoscopic fundoplication [37]. The questionnaire consists of 45 items when administered preoperatively and 50 items when administered postoperatively and is devised in English language. The QOLARS questionnaire is a combination of the European Organization of Research and Treatment of Cancer quality of life questionnaire (EORTC-QLQ-C30) [64], the Visick score [65] and a modified GERD-HRQL [31]. All these scales have been validated. However the responsiveness of the QOLARS scale has not been reported clearly.

Chan et al. developed the GERD-specific self-administered GERD-QOL questionnaire in Chinese language for multidimensional assessment of quality of life impairment because of GERD before and after treatment [38]. It is a pure HRQOL instrument with no symptom-specific questions. The final questionnaire had 16 items grouped into four subscales including daily activity, treatment effect, diet and psychological well-being assessed by a 5-point Likert scale. Psychometric validation was performed and internal consistency, test-retest reliability, construct validity, discriminant validity, responsiveness were demonstrated. The questionnaire was

translated into English and linguistic validation was done. However the English version of the GERD-QOL questionnaire needs to validated further in English population and other ethnic groups to confirm its robustness for multiethnic studies.

HRQOL scales specific for various GI diseases

The Gastrointestinal Quality of Life Index (GIQLI) was developed to measure HRQOL in various GI diseases and not specific for GERD [39]. It is a system specific questionnaire assessing how frequently a symptom has interfered with the patients' HRQOL during the past 2 weeks. It consists of 36 items assessing 5 domains namely core symptoms, physical, emotional, social and disease-specific items and scoring is done on a 5-point Likert scale. The GIQLI scale has been validated in a variety of research settings. In the patients of GERD, it was shown to be responsive after antireflux surgery. It is available and validated in various languages including English. The inability to discriminate between different GI diseases and that more than half the items in the questionnaire are related to the symptom frequency rather than HRQOL are the main limitations of this scale.

The Quality of Life in Reflux and Dyspepsia (QOLRAD) scale is a self-assessed questionnaire developed to evaluate patients with GERD and dyspepsia [40]. It consists of 25 items assessing the domains of emotional stress, sleep disturbance, food and drink problems, physical and social functioning and vitality. The degree of distress and frequency of the patients' feelings during the last week are assessed by a 7-point Likert scale. Psychometric evaluation has been performed and the validity, reliability and responsiveness of this scale have been demonstrated. The QOLRAD scale showed a high concurrent validity when compared to the respective domains of the SF-36 or GSRS scales [40, 66]. It was validated and made available in various languages including English. Presence of more than one HRQOL domain in some of the subscales of this instrument may pose problems in clinical studies.

The Patient Assessment of upper Gastrointestinal disorders (PAGI-QOL) has been designed to measure the HRQOL in patients of upper GI disorders [41]. The questionnaire can be either self-administered or interview administered and used to assess the patients' HRQOL in the last 2 weeks. It consists of 30 items assessing 5 domains including daily activities, clothing, diet and food habits, relationship, and psychological well-being and distress with the scoring done on a 6-point Likert scale. Only the initial validation studies are available. It has ability to differentiate various GI disorders is yet to be demonstrated. It was translated and made available in many languages including English but validated in only few of them. Further validation studies in a broader population are needed for this instrument.

Generic HRQOL scales

The Psychological General Well-Being (PGWB) Index is a generic QOL instrument originally developed in healthy populations to measure subjective psychological well-being and distress [42]. It is a self-assessed questionnaire consisting of 22 items covering 6 dimensions of HRQOL including anxiety, depressed mood, positive well-being, self-control, general health and vitality, all these scored on a 6-point Likert scale. It assesses the HRQOL over the last 4 weeks. It has been shown to have excellent reliability and validity in studies of GERD and upper gastrointestinal diseases [42, 67]. It is useful for comparison when the construct validity and responsiveness of a new scale are tested. It is available, validated and being used in many languages and countries. That this scale doesn't cover all the essential core domains of a HRQOL measure and instead focuses only on psychological or emotional domains and inability to distinguish between the underlying diseases are its limitations.

The EuroQOL-5 Dimensions (EQ-5D) is a self-administered questionnaire available worldwide and in many languages [43]. It was developed as a generic measure of health status and is useful in describing and evaluating HRQOL. However its main role is in generating cross-national comparisons for economic evaluations, thus it is useful for calculating quality-adjusted life years (QALYs) for pharmaco-economic studies. It is not considered to be a sensitive tool in disease-based outcome research. Adequate validation is not available for this scale.

Thirty-six-Item Short-Form General Health Survey (SF-36) is a self-reported, generic HRQOL survey widely used in primary care settings and in various chronic diseases including GERD [44]. It consists of 8 domains covering physical function, role limitations - physical, bodily pain, vitality, general health perceptions, social functioning, role limitations - emotional, and mental health assessed by means of 36 items in the questionnaire. It has been demonstrated in various studies to have excellent reliability, content validity, construct validity and responsiveness [68]. It is available and validated in various languages including English. The standard SF-36 has a recall period of the last 4 weeks. A different version with a recall period of 1 week has also been developed to assess more rapid treatment effects. SF-36 is used to compare between subgroups of patients and across the general population. It has also been used as a gold standard in various studies done for validation of other HRQOL questionnaires. As the scale is generic and multipurpose, it is recommended that it be used with a more specific questionnaire while assessing the HRQOL in a

particular disease [69]. However such an approach requires more manpower as well as is time consuming. Though more practicable versions like SF-12 and SF-20 have been developed, they have been used only in few studies as in the case of the former or not used at all as in the case of the SF-20 scale. Also the reliability and validity of the SF-12 are slightly lower compared to that of the SF-36, but sufficient for large sample studies [70].

Hybrid scales assessing both symptoms and quality of life

Colwell et al. [45] and Mathias et al. [46] developed an assessment tool for patients of erosive GERD, which measures quality of life as well as symptom frequency and distress, sleep problems, work disability and treatment satisfaction. It was shown to have acceptable reliability and validity. Another version of the same questionnaire is the HRQOL batteries developed to measure HRQOL in patients with symptomatic non-erosive GERD patients [47]. The HRQOL batteries questionnaire contains demographic items, two domains derived from the SF-12 namely physical component summary and mental component summary, six other domains assessing the frequency and bothersomeness of general GERD symptoms, symptoms related to eating, social restrictions, problems with sleep, work disability and treatment satisfaction. Psychometric evaluation has been done and the internal consistency, construct validity and responsiveness have been demonstrated. The correlations between the changes in HRQOL and change in heartburn symptoms were found to be low to moderate. Both these questionnaires are available in English.

The Domestic/International Gastroenterology Surveillance Study (DIGEST) questionnaire was designed to determine the 3 months prevalence of upper GI symptoms and the impact of these symptoms on HRQOL [48]. The questions in this instrument pertain to several gastrointestinal symptoms, socio-demographic data and quality of life for upper gastrointestinal diseases. The internal consistency and test-retest reliability have been demonstrated, but the responsiveness was not assessed. The main limitation of this scale is its length due to which it was not found to be conducive for routine use in clinical trials [71].

ReQuest™ (Reflux Questionnaire) is a scale designed as a diary to be used by patients to quantify their total GERD symptoms daily [49]. The frequency and intensity of seven dimensions namely acid complaints, upper abdominal/stomach complaints, lower abdominal/digestive complaints, nausea, sleep disturbances, other complaints and general well-being are assessed. A total of 67 symptom descriptions are incorporated in these seven dimensions. This questionnaire is self-administered and is available in 30 different languages. Two subscales of the ReQuest have been designed namely the ReQuest™-GI and ReQuest™-WSO, which measure symptoms traditionally associated with reflux and with general well-being, respectively, and permit these to be quantified and tracked independently. The ReQuest™/LA-classification is developed by integrating the ReQuest™-GI subscale with the modified Los Angeles scale used to grade esophagitis seen at endoscopy [72]. This tool allows both the symptoms and endoscopy appearances to be assessed in a single scale and thus complete remission of symptom relief as well as endoscopic healing can be identified. Such integrated indices help in standardization of clinical assessments and simplify comparison of results of different clinical trials. As minor degrees of reflux are common among healthy individuals, a 'GERD symptom threshold' has been calculated in a large population using ReQuest™ [73]. Recognizing this will help in targeting a more realistic end point in clinical trials rather than the difficult 'complete absence' of symptoms. For day-to-day clinical practice, a simplified version of the ReQuest™ has been devised and is referred to as ReQuest in Practice™ [74]. Psychometric evaluation and validation of ReQuest and its 2 subscales in both patients with erosive esophagitis [75] and nonerosive reflux disease [76] have demonstrated a high internal consistency, test-retest reliability, and responsiveness.

Spiegel et al. developed and validated an instrument in English to assess the severity and impact of nocturnal symptoms of GERD [50]. The Nocturnal Gastroesophageal reflux disease symptom severity and impact questionnaire (N-GSSIQ) included 20 items and three subscales namely, nocturnal GERD symptoms, morning impact of nocturnal GERD, and concern about nocturnal GERD. The internal consistency, reliability and validity were demonstrated. The briefness of the questionnaire is an added advantage and it can be used either alone or in combination with other instruments for a more comprehensive assessment of patient-reported outcomes.

Conclusions

A multitude of unidimensional and multidimensional questionnaires exist for making symptom assessment and monitoring quality of life in GERD. Many of the scales meet some of the parameters of an ideal evaluative GERD specific assessment instrument. Yet, there are certain shortcomings and challenges that are faced in development of GERD questionnaires. Primarily the development of the ideal assessment instrument is impeded by some of the inherent clinical features of GERD. There is no clear consensus regarding which symptoms constitute a diagnosis

or how to define response to the treatment in managing patients with GERD. Furthermore, although many GERD patients may manifest with typical symptoms, such as heartburn and acid regurgitation, others may predominantly complain of atypical symptoms, such as epigastric pain or pressure, nausea/vomiting, hoarseness, chest pain, and wheezing. The symptoms most often used for the diagnosis of GERD i.e. heartburn and regurgitation are highly specific (89% and 95%, respectively), but have low sensitivity (38% and 6%, respectively) leading to a trade-off while making a diagnostic assessment [5].

The period of time that outcome measures are looked for is referred to as the time frame. This is prone to recall bias. One month is the maximum time frame which ensures a good balance between education of recall bias and having appropriate information on outcome measures [77].

In summary, amongst the available assessment scales there is no perfect evaluative scale. In the last decade there has been significant progress in developing proper tools that provide better assessment of symptom change but the sensitivity to show daily alterations is not high. GERD studies should utilize questionnaires based on unidimensional or multidimensional outcome measures that assess both symptom frequency and severity and have proven validity, reliability and responsiveness.

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