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The GerdQ Cannot Identify a Treatment Benefit for GERD when the Asymptomatic Patient Score is Six and a Score of Zero Requires Symptoms

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Abstract **Original Research Article**

The aim of this article is to raise awareness of the limitations if using the Gastroesophageal Reflux Disease Questionnaire (GerdQ) to evaluate a treatment benefit for patients with gastroesophageal reflux disease (GERD) or gastroesophageal reflux (GER) symptoms. The GerdQ is currently a widely used questionnaire estimated to be referred to in over 100 publications per year. A hypothetical example comparing a patient group before and after a treatment shows when using the GerdQ, a score of 6 can represent both a symptomatic and asymptomatic state. It is shown that the patient group with scores < 8 can have significant GER symptoms despite a cut-off score of ≥ 8 being recommended to diagnose GERD. It is also shown a score of zero does not represent an asymptomatic state or an achievable endpoint to determine a treatment benefit. Evaluation of a treatment benefit using scores from the 2 main symptoms, heartburn and regurgitation, that make up 2 of the 6 question GerdQ can be relied upon. Evaluation of a treatment benefit using the sum of all 6 question scores that make up the GerdQ may potentially be unreliable as an asymptomatic patient must have a score of 6 and symptoms are required for a score of zero.

Keywords: Gastroesophageal reflux disease, GERD, GerdQ.

1. INTRODUCTION

The GerdQ was developed in 2009 and reported to be a patient centred self-assessment questionnaire to assist health professionals in the diagnosis and management of gastroesophageal reflux disease (GERD) [1]. The GerdQ consists of 6 questions to score the frequency (not severity) of symptoms during the previous week [1].

A Likert scale of 0-3 is used for 4 questions (Q) such that having zero days of symptoms per week gives a score of 0, symptoms 1 day a week a score of 1, symptoms 2-3 days a week a score of 2 and symptoms 4-7 days a week a score of 3 giving a maximum score of 4x3 = 12 [1]. These 4 questions are the positive predictors of GERD and are summarised as questions Q1: heartburn symptoms, Q2: regurgitation symptoms, Q5: difficulty getting a good night's sleep due to heartburn and/or regurgitation and Q6: how often over the counter medication was taken for your heartburn and/or regurgitation [1].

A reversed Likert scale of 3-0 is used for 2 questions such that having zero days of symptoms per week gives a score of 3, symptoms 1 day a week a score of 2, symptoms 2-3 days a week a score of 1 and symptoms 4-7 days a week a score of zero adding to a maximum score of 6 [1]. These 2 questions are the negative predictors of GERD summarised as questions Q3: how often pain occurred in the centre of the upper stomach and Q4: nausea [1]. The combined Likert and reverse Likert scoring can result in a GerdQ score from zero to a maximum of 12 + 6 = 18. Scores above a recommended cut-off score of ≥ 8 indicate a diagnosis of GERD [1].

From the 2020 Seoul consensus on the diagnosis and management of gastroesophageal reflux disease, Statement 8 noted that the GerdQ and Reflux Disease Questionnaire (RDQ) were the most frequently used questionaries with multilingual versions [2]. It was stated that the GerdQ and the RDQ were both modestly accurate for GERD's symptom-based diagnosis but had limitations as a stand-alone diagnostic tool [2].

In 2022 it was reported the GerdQ could not accurately quantify reflux symptoms to show a treatment benefit because the asymptomatic patient score was 6 and that this was not a suitable endpoint for assessment [3]. To date, a revised consensus on the suitability of the GerdQ questionnaire to assess treatment benefits for GERD patients was not found to have been undertaken.

An artificial intelligence (AI) search using a readily available major world-wide AI provider for the question: How many published articles have used the GerdQ in the past year, reported an approximate number between 150-200 and that the GerdQ was the gold standard for large scale clinical surveys. This is not surprising as an overwhelming number of articles, possibly in the thousands and in high profile journals, refer to the GerdQ.

This report demonstrates, using a further example, why the use of the aggregated 6 question GerdQ score to assess treatment benefits should be discontinued [3].

2 RESULTS

2.1 Example: GERD below the cut-off score and a post treatment benefit obscured

To conduct a clinical trial using the GerdQ in this example, Table 1, scores from the Patient group (A-D) with GERD symptoms are taken, then a treatment is applied and scores after the treatment are re-taken, using the comparison to assess the treatment benefit.

Scores above a cut-off score of ≥ 8 have been recommended to indicate a diagnosis of GER /GERD [1]. For example, 2 points for Q2, regurgitation symptoms 2 /3 days per week, 3 points for Q3 (no pain in the centre of the upper stomach) and 3 points for Q4 (no nausea symptoms per over the past week) give a score of 2+3+3 = 8, identifying GER symptoms.

The problem arises for the patient group (A-D) in Table 1 because patients with a score of < 8 can also have GER symptoms showing the cut-off score of ≥ 8 cannot identify all patients with GERD.

In this example Patient A has GERD symptoms with a score of 3 points for Q1 and 3 points for Q2 to give a total score also of 3+3+0+0+0+0 = 6, indicating significant GERD symptoms, Table 1. After treatment, Patient A became asymptomatic with a score of zero for each of the positive predictors, Q1, Q2, Q5, Q6 and score of 3 for each of the negative predictors Q3, Q4 showing no symptoms to give a total score of 0+0+3+3+0+0 = 6, Table 1. Patient A had the same score before and after the successful treatment showing numerically the GerdQ could not identify the treatment benefit. Similar examples are shown for Patients B-D all with significant GERD symptoms before treatment and no symptoms after the treatment, with the treatment benefit being for GERD obscured, Table 1.

Table 1: In this example using the GerdQ, the patient group (A-D) all had GERD symptoms below the cut of score of ≥ 8 before the treatment and no GERD symptoms after the treatment with the benefit obscured

Questions with scores for frequency over the past week based on a Likert scale 0-3 for the positive predictors (Q1, Q2, Q5, Q6), and a reverse Likert scale 3-0 for the negative predictors (Q3, Q4).	**GERD patients A-D with symptoms prior to administering the treatment**				**GERD patients A-D after administering the treatment and now all asymptomatic with the endpoint score of 6**
	A	**B**	**C**	**D**	
Q1: Likert scale 0-3 for heartburn with a score of 0 indicating no symptoms per week	3	3	3	0	0 (asymptomatic)
Q2: Likert scale 0-3 for regurgitation with a score of 0 indicating no symptoms per week	3	2	0	3	0 (asymptomatic)
Q3: Reverse Likert 3-0 for pain in centre of upper stomach with a score of 3 indicating no symptoms per week	0	0	0	1	3 (asymptomatic)
Q4: Reverse Likert 3-0 for nausea with a score of 3 indicating no symptoms per week	0	0	0	1	3 (asymptomatic)
Q5: Likert scale 0-3 for difficulty getting a good night's sleep due to heartburn and /or regurgitation with a score of 0 indicating no symptoms per week	0	0	0	1	0 (asymptomatic)
Q6: Likert scale 0-3 for use of over-the-counter medications for heartburn and /or regurgitation with a score of 0 indicating no symptoms per week	0	1	3	0	0 (asymptomatic)
Total score	6	6	6	6	6 (asymptomatic)

2.2 Obtaining a score of zero

To obtain a score of zero using the GerdQ, scores for both the negative predictors Q3, requiring pain in the centre of the upper stomach and Q4 nausea, must occur 4-7 days per week and would represent a severely ill patient but without GERD symptoms [1]. Scores of zero do not indicate an asymptomatic state and any initial score reducing to zero due to a treatment, do not indicate

that an asymptomatic state or an ideal treatment benefit has been achieved. Questionaries usually show scores reducing or ideally reaching zero after a successful treatment. For the GerdQ, the score of zero represents the maximum score for the negative predictors of GERD and shows the presence of non-GERD symptoms rather than GERD symptoms [1]. The GerdQ requires the presence of the negative predictors to obtain a score of zero and so is not an achievable treatment endpoint.

In addition, a GerdQ score of 12 can represent the most symptomatic patient with positive predictors Q1+Q2+Q5+Q6 = 12 (GERD symptoms 4-7 days per week) and negative predictors Q3+Q4 = 0 (non-GERD symptoms 4-7 days per week). Also, a score of 18 can represent fewer overall symptoms than the score of 12 above, with positive predictors Q1+Q2+Q5+Q6 = 12 (GERD symptoms 4-7 days per week) and negative predictors Q3+Q4 = 6 (zero days of symptoms per week).

2.3 Studies using the GerdQ

Many articles use more than one questionnaire or additional independent assessment methods such that results are not based solely on the GerdQ score. Scores for Q1 (heartburn) and Q2 (regurgitation), the primary symptoms of reflux disease can be used to determine treatment benefits [4]. If results have relied solely on an aggregated 6 question GerdQ scores, they may be potentially unreliable and should not be included in systematic reviews or meta-analysis without qualification.

3 DISCUSSIONS

From the example given, the GerdQ may not numerically distinguish between the pre-treatment and post treatment patient groups despite a successful treatment benefit for GERD having occurred. It has been shown a score of 6, representing the asymptomatic patient, is not a suitable endpoint to assess a treatment benefit, Table 1.

Reporting separate scores for both regurgitation and heartburn, the primary symptoms of GER /GERD are the most informative and scoring for symptom severity daily (which also result in the frequency being given) using a scale of 0-3 would be a more accurate symptom assessment.

For case reports, it can be more practical to use an individualised scoring system, for example a single score for both regurgitation and heartburn if symptoms usually occur together [5,6]. Simple scoring systems are more practical if multiple scores per day are being recorded, for example before and after meals, after treatments, during the night and in the morning and allow for a more precise daily assessment of treatment benefits [5,6].

4 CONCLUSIONS

It has been shown using an example that the GerdQ scores may not necessarily distinguish between patients with or without GERD symptoms, scores could obscure a treatment benefit, a cut-off score of ≥ 8 may not necessarily identify all patients with GERD and a score of zero is not an achievable endpoint to measure a treatment benefit. It is suggested daily severity scores for heartburn and regurgitation, the primary symptoms of GER, should be reported separately or possibly combined for individualised scoring as for case reports.

Conflict of interest

No conflicts of interest to declare, no funding was received for this work.

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