Quality of life in patients with gastroesophageal reflux disease in an Iranian population

Iradj Maleki, Abbas Masoudzadeh, Alireza Khalilian, Elnaz Dahevelopment
1Inflammatory Diseases of Upper Gastrointestinal Tract Research Center, Mazandaran University of Medical Sciences, Sari, Iran
2Department of psychiatry, Faculty of Medicine, Mazandaran University of Medical Sciences, Sari, Iran
3Department of Community Medicine, Faculty of Medicine, Mazandaran University of Medical Sciences, Sari, Iran

ABSTRACT

Aim: The study was designed to evaluate quality of life (QOL) for Iranian patients with gastroesophageal reflux disease (GERD).

Background: GERD is a common and chronic world-wide disease. Impact of GERD on QOL has been studied in many countries, but it has not been studied in Iranian population.

Patients and methods: Fifty five patients suffering from GERD and fifty five age and sex matched controls were enrolled. Patient inclusion criteria were based on clinical and endoscopic findings. All other major diseases having an impact on QOL had been excluded. All the subjects were asked to fill the validated translation of SF-36 and GHQ-28 questionnaires. Results of the SF-36 questionnaire was analyzed directly and after correction for the results obtained from the GHQ-28 tool.

Results: GERD patients had lower QOL scores than controls. Correction of the results based the findings of GHQ-28 questionnaire did not change the results.

Conclusion: QOL in GERD patients is impaired and should be considered in clinical practice and implementing research studies upon GERD patients.

Keywords: Gastroesophageal Reflux Disease, Quality of Life, Iran, SF-36, Mental health.

Introduction

Gastroesophageal reflux disease (GERD) is a common disease all across the world (1-3). Many studies have demonstrated a considerably high prevalence of this disease in Iran (4, 5). GERD and its gastrointestinal and extra-intestinal symptoms can affect the quality of life (QOL) of patients (1, 6, 7). The impact of GERD on QOL of patients has been demonstrated in many studies, but there have been few studies performed in Iran (8,9). We decided to study the QOL of GERD patients on an Iranian sample.

Patients and Methods

Patients and controls have been enrolled from a private clinic and a public university hospital in Sari, a central city of Mazandaran province at Caspian Sea, during a six month period from March to September 2010. The patients have been selected in the age group of 20 to 70 years old.
Cases had the typical symptoms of reflux disease (heartburn and/or acid regurgitation) with a frequency of at least twice a week, as is required for the definition of the GERD. They did not have epigastric pain, post-prandial bloating and other symptoms of dyspepsia syndrome. All patients had a compatible endoscopy (either reflux esophagitis or normal). Patients having other chronic diseases, which could affect QOL adversely, have been excluded from the study. These diseases included major cardiovascular, chronic kidney disease, obstructive pulmonary disease, cirrhosis, rheumatologic diseases and any history of malignant diseases. Controls were selected from the relatives of patients and from other clinics in the hospital, without having the inclusion (and exclusion) criteria for the cases.

After enrollment, all patients and controls have filled validated translation of SF-36 questionnaire. This questionnaire is a general and non-disease specific tool, which has been used for the evaluation of HR-QOL in Iran and other countries. The validity of this translated version of the questionnaire has been shown previously in Iranian population (10). The 36 items in this tool evaluate eight bodily and mental aspects of the QOL (physical functioning [PF], role physical [RP], bodily pain [BP], general health [GH], vitality [VT], social functioning [SF], role emotional [RE], mental health [MH]). These items are lastly summarized in two major categories, namely physical component summary [PCS] and mental component summary [MCS]. Data from the questionnaire have been compared with the normalized rates using the SF-36 calculator at the original website of the questionnaire (www.sf-36.org). The higher score with this questionnaire indicates of better health related QOL.

As the major psychiatric diseases could affect health-related quality of life (HR-QOL) as well, all patients and controls have been asked to fill a 28 item questionnaire, GHQ-28. All questions had a four scale answer. The scores ranged zero to 3 and one could have a score of zero to 84, the lower end indicating of better psychiatric health. This questionnaire and its Persian translation have showed reliable in identification of major psychiatric diseases. In the second phase, the results for the study have been adjusted for the score of GHQ-28. Cases and controls have been then categorized according to their score from this tool; the cutoff point being score 23.

Data were entered in MS Excel 2007 and then analyzed using SPSS version 16. The student t-test was used for numerical and chi square for the nominal and categorical variables. P values less than 0.05 has been accepted as significant.

Results

One hundred and ten people were enrolled in the study (55 cases and 55 age and sex matched controls). The demographic data of the groups are summarized in table 1.

| Table 1. Demographic specification of cases and controls |
|-----------------------------------------------|
| Sex | Cases (n=55) | Controls (n=55) | P-value |
| Male | 17 | 17 | N.S. |
| Female | 38 | 38 | N.S. |
| Age | | | |
| 20-35 yrs | 18 | 21 | N.S. |
| 36-50 yrs | 23 | 21 | N.S. |
| 51-70 yrs | 14 | 13 | N.S. |
| Marital status | | | |
| Single | 6 | 11 | N.S. |
| Married | 47 | 40 | N.S. |
| Widow | 2 | 4 | N.S. |
| Education | | | |
| Illiterate | 8 | 14 | N.S. |
| Undergraduate | 28 | 19 | N.S. |
| Postgraduate | 19 | 21 | N.S. |
| Income | | | |
| Low | 29 | 31 | N.S. |
| Medium & high | 26 | 24 | N.S. |
Scores of GERD patients were lower in all eight domains of SF-36 compared to the controls. When data was gathered in two major categories of PCS and MSC, again GERD patients showed lower scores (Table 2).

To exclude the effect of background psychiatric disorder in GERD patients, the resultant scores of the SF-36 have been further corrected for the scores obtained from the GHQ-28. All people having a score less than 23 have been excluded from the secondary calculation of SF-36 normalized scores. This excluded 4 cases and 4 controls. After this correction the SF-36 scores were again lower in GERD patients (Table 3).

### Table 2. Results of SF-36 normalized scores in cases and controls

| Item                          | Cases (n=55) | Controls (n=55) | p-value |
|-------------------------------|--------------|-----------------|---------|
| Physical functioning [PF]     | 51.92 ± 5.61 | 55.25 ± 2.37    | < 0.001 |
| Role physical [RP]            | 48.76 ± 7.34 | 54.51 ± 2.83    | < 0.001 |
| Bodily pain [BP]              | 50.69 ± 11.74| 61.07 ± 3.71    | < 0.001 |
| General health [GH]           | 46.36 ± 10.76| 61.25 ± 4.36    | < 0.001 |
| Vitality [VT]                 | 53.28 ± 7.25 | 59.98 ± 5.38    | < 0.001 |
| Social functioning [SF]       | 48.08 ± 9.46 | 55.51 ± 3.30    | < 0.001 |
| Role emotional [RE]           | 47.37 ± 10.33| 51.71 ± 4.55    | < 0.001 |
| Mental health [MH]            | 45.93 ± 8.96 | 53.92 ± 5.33    | < 0.001 |
| Physical component summary [PCS]| 52.0 ± 7.85 | 58.99 ± 3.46    | < 0.001 |
| Mental component summary [MCS]| 44.86 ± 9.64 | 53.78 ± 4.87    | < 0.001 |

### Table 3. Results of SF-36 normalized scores in cases and controls after exclusion of suspicious cases of psychiatric illness

| Item                          | Cases (n=55) | Controls (n=55) | p-value |
|-------------------------------|--------------|-----------------|---------|
| Physical functioning [PF]     | 52.42 ± 5.40 | 55.32 ± 2.09    | < 0.001 |
| Role physical [RP]            | 49.23 ± 7.30 | 54.66 ± 2.70    | < 0.001 |
| Bodily pain [BP]              | 52.23 ± 10.46| 60.90 ± 3.84    | < 0.001 |
| General health [GH]           | 47.35 ± 9.78 | 61.35 ± 4.39    | < 0.001 |
| Vitality [VT]                 | 53.74 ± 7.27 | 60.11 ± 5.39    | < 0.001 |
| Social functioning [SF]       | 48.89 ± 9.32 | 55.62 ± 3.13    | < 0.001 |
| Role emotional [RE]           | 44.29 ± 10.00| 51.92 ± 4.16    | < 0.001 |
| Mental health [MH]            | 46.99 ± 8.21 | 54.06 ± 5.50    | < 0.001 |
| Physical component summary [PCS]| 52.71 ± 7.34 | 58.99 ± 3.46    | < 0.001 |
| Mental component summary [MCS]| 45.75 ± 9.33 | 54.00 ± 4.89    | < 0.001 |

### Discussion

GERD is a chronic and recurrent disease and its management and treatment is challenging for every gastroenterologist. Esophageal and extra-intestinal manifestations, diurnal and nocturnal symptoms and differentiation GERD from other functional disorders like functional heartburn makes management of this disease individualized for each patient.

Despite its diversity, the impact of GERD on QOL of patients has been shown worldwide. Many studies from western countries have confirmed this effect (11,12). In Asian countries, such as Japan, QoL studies have also been published (13). Some studies in Iran have pointed indirectly investigated this (8,14). We have shown
the impact of GERD on HR-QOL in these patients.

As it was demonstrated in this study, all aspects and domains of the QOL was impaired in comparison to the controls. In a recent systematic review including the results of nineteen studies, many aspects of QOL scales were impaired, but the impact of GERD on mental status domains was not clear. Further studies with a focus on vague aspects of burden of GERD on GERD patients are recommended.

As the background psychiatric disease could be a real confounder for the effect of GERD on QOL, we have tried to exclude this issue. GERD is sometimes included in the category of motility and functional disorders of the GI tract, like irritable bowel syndrome (IBS). As an association of IBS and other functional disorders of the GI tract have shown previously, there has been always a concern about the probable association of GERD disease and psychiatric disorders. If so, the background major psychiatric disorder could affect the QOL directly. Considering this hypothesis we have asked the patients and controls to fill out the GHQ-028 questionnaire to identify these disorders and have also corrected the SF-36 scores based on the finding from GHQ-28 scores. We showed that the impaired QOL in GERD patients was apart from any major psychiatric disease.

As the prevalence of GERD in Iran and local countries is likely to increase, other studies in the field of QOL and GERD are recommended using general and disease specific tools. Any study in management and treatment of GERD patients should include QOL as one of its endpoints. Authors recommend the evaluation of other disease-specific questionnaires in the field of reflux disease, that can show the impact of GERD on HR-QOL concisely. SF-36 is a well-known general QOL questionnaire, that can be used in all diseases and the results can be compared between diverse diseases, but it is not specific to diseases and many of aspects of disturbances in QOL in patients including GERD patients can be overlooked; so use of disease specific GERD-QOL questionnaires (like QOLRAD-Heartburn) in Iranian population is recommended.

In the enrolment of cases in this study we have recruited patients with known GERD and newly diagnosed cases. As the treatment can improve the symptoms and hence the QOL, we recommend to differentiate new and old onset patients in the enrolment phase in further studies, this could be a limitation in this study.

Acknowledgment

This study was supported by a grant for the thesis of Dr. Elnaz Daheshpour from Mazandaran University of Medical Sciences.

References

1. Gerson LB, Ullah N, Hastie T, Triadafilopoulos G, Goldstein M. Patient-derived health state utilities for gastroesophageal reflux disease. Am J Gastroenterol 2005;100:524-33.

2. Locke GR 3rd, Talley NJ, Fett SL, Zinsmeister AR, Melton LJ 3rd. Prevalence and clinical spectrum of gastroesophageal reflux: a population-based study in Olmsted County, Minnesota. Gastroenterology 1997; 112:1448-56.

3. Shaheen N, Provenzale D. The epidemiology of gastroesophageal reflux disease. Am J Med Sci 2003;326:264-73.

4. Delavari A, Moradi G, Birjandi F, Elahi E, Saberisfrooz M. The prevalence of gastroesophageal reflux disease (GERD) in the Islamic Republic of Iran: A systematic review. MEJDD 2012;4:5-15.

5. Pourhoseingholi A, Pourhoseingholi MA, Mohghimi-Dehkordi B, Barzegar F, Safaee A, Vahedi M, et al. Epidemiological features of gastroesophageal reflux disease in Iran based on general population. Gastroenterol Hepatol from Bed to Bench 2012;5:54-59.

6. Eloubeidi MA, Provenzale D. Health-related quality of life and severity of symptoms in patients with Barrett's esophagus and gastroesophageal reflux
disease patients without Barrett's esophagus. Am J Gastroenterol 2000; 95:1881-87.

7. Wiklund I, Carlsson J, Vikal N. Gastroesophageal reflux symptoms and well-being in a random sample of the general population of a Swedish community. Am J Gastroenterol 2006;101:18-28.

8. Nasseri-Moghaddam S, Razjouyan H, Alimohamadi SM, Mamarahadi M, Ghotbi MH, Mostajabi P, et al. Prospective Acid Reflux Study of Iran (PARSI): methodology and study design. BMC Gastroenterol 2007;7:42.

9. Tofangchiha S, Razjouyan H, Nasseri-Moghaddam S. Quality of life in reflux and dyspepsia (QOLRAD) questionnaire in Iranian patients with GERD: A validation study. MEJDD 2010;2:84-90.

10. Montazeri A, Goshtasebi A, Vahdaninia M, Gandek B. The Short Form Health Survey (SF-36): translation and validation study of the Iranian version. Qual Life Res 2005;14:875-82.

11. Becher A, El-Serag H. Systematic review: the association between symptomatic response to proton pump inhibitors and health-related quality of life in patients with gastro-oesophageal reflux disease. Aliment Pharmacol Ther. 2011;34:618-27.

12. Tack J, Becher A, Mulligan C, Johnson DA. Systematic review: the burden of disruptive gastro-oesophageal reflux disease on health-related quality of life. Aliment Pharmacol Ther 2012; 35:1257-66.

13. Fujiwara Y, Arakawa T. Epidemiology and clinical characteristics of GERD in the Japanese population. J Gastroenterol 2009;44:518-34.

14. Nasseri-Moghaddam S, Mofid A, Ghotbi MH, Razjouyan H, Nouraie M, Ramard AR, et al. Epidemiological study of gastro-oesophageal reflux disease: reflux in spouse as a risk factor. Aliment Pharmacol Ther 2008; 28:144-53.

15. Pourhoseingholi A, Vahedi M, Pourhoseingholi MA, Ashtari S, Moghimi-Dehkordi B, Safae A, et al. Irritable bowel syndrome, gastro-oesophageal reflux disease and dyspepsia: Overlap analysis using loglinear models. Arab J Gastroenterol 2012; 13:20-23.

16. Flook NW, Wiklund I. Accounting for the effect of GERD symptoms on patients' health-related quality of life: supporting optimal disease management by primary care physicians. Int J Clin Pract 2007; 61:2071-78.

17. Kulich KR, Wiklund I, Junghard O. Factor structure of the Quality of Life in Reflux and Dyspepsia (QOLRAD) questionnaire evaluated in patients with heartburn predominant reflux disease. Qual Life Res 2003;12:699-708.