



CODEN [USA]: IAJPBB

ISSN: 2349-7750

**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**<http://doi.org/10.5281/zenodo.2529741>Available online at: <http://www.iajps.com>

Research Article

**EFFECT OF LIFESTYLE MODIFICATIONS ON PATIENTS
QUALITY OF LIFE WITH GASTROESOPHAGEAL REFLUX
DISEASE TAKING TREATMENT WITH PROTON PUMP
INHIBITORS AND A PROKINETIC AGENT**¹Dr. Muhammad Mohsan Ali, ²Dr. Fasiha Mushtaq, ³Dr. Unaiza Anwar¹Services Hospital, Lahore, ²Fatima Jinnah Medical University, Lahore, ³Multan Medical and Dental College, Multan**Abstract:**

Objective: The study to know whether Life style modifications has an beneficial impact on health and quality of life in patients of gastroesophageal reflux disease taking treatment with pantoprazole and itopride.

Study Design: An open-label observational study.

Place and Duration: In the Gastroenterology Department of Services Hospital, Lahore for one year duration from June 2017 to June 2018.

Methods: Patients with GERD were given pantoprazole and for 8 weeks itopride. Health-related quality of life (HRQOL) was evaluated using a 8-item short form health questionnaire (SF-8) and GERD-specific quality-of-life questionnaires at the beginning of the study and one to two months after treatment. The scores of mental and physical components (MCS, PCS) and specific GERD scores were recorded.

Results: Of the 187 patients checked, 41.08% were recommended for a modified lifestyle at the beginning of giving pantoprazole / itopride (Group A). In 33.3% suggesting that they should continue with lifestyle as recommended previously in Group B and in Group C 26.09% not recommended with any modification. For Group A, the PCS change at 8 weeks was 5.7 ± 8.1 and significantly higher than Group C (4.1 ± 7.5) and B (4.2 ± 7.6) ($P < 0.002$). The MCS changes and GERDS were also significantly higher in Group A than in other groups. Changes in the current quality of life were higher significantly in A Group than in the other groups, regardless of the characteristics of the initial pt.

Conclusion: Lifestyle change may be clinically useful in improving life quality in some of the patients with GERD treated with PPI.

Key words: Quality of life, gastroesophageal reflux, proton pump inhibitor.

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Please cite this article in press Muhammad Mohsan Ali et al., *Effect of Lifestyle Modifications On Patients Quality Of Life With Gastroesophageal Reflux Disease Taking Treatment With Proton Pump Inhibitors And A Prokinetic Agent.*, Indo Am. J. P. Sci, 2019; 06(01).

INTRODUCTION:

Quality of life measures (QOL) have become a vital part of health outcomes assessment. Taking a chronic disease such as GERD, which is common in a population with limited resources and where recovery is generally not possible, measuring quality of life provides a meaningful way to determine the effect of medical care. GERD is one of the most common, but not the most common, encountered by physicians in urban and especially rural populations. It is estimated that it takes place in 10-20% of Western societies and 2.6-6.8 in populations of Asia and its general frequency has increased in recent years. Lifestyle recommendations are generally well accepted, and patients with GERD are expected to improve quality of life (QOL) and symptoms, but there is little available data from clinical randomized trials to support this observation. Recently, we have conducted an observation study to evaluate the basal features and HRQOLs of GERD patients and the effect of antisecretory therapy given for short time with proton pump inhibitor (PPI) pantoprazole and the effect of propanopump inhibitor (PPI) with pantoprazole. This result shows the post-hoc analysis results investigating whether lifestyle modification has an effect on improving HRQOL in GERD patients treated with pantoprazole / itopride.

MATERIALS AND METHODS:

This open-label observational study was held in the Gastroenterology Department of Services Hospital Lahore for one year duration from June 2017 to June 2018. 250 total patients were included in the study. Patients included in the study were newly diagnosed GERD patients who had recurrent GERD after previous anti-inflammatory treatment. Patients were treated with 40-80 mg / day pantoprazole and 150 mg / day itopride for 8 weeks. The methodology and purpose of this analysis was explained to all subjects before the start of treatment. A self-administered questionnaire using a Quality of Life Questionnaire on quality of life and 8-item Short Form Health Questionnaire (SF-8) and gastroesophageal reflux disease (specific QERD for GERD) evaluated 4 weeks with pantoprazole / itoprid and 8 weeks after

treatment. A generic SF-8 questionnaire from the shortest 36-item Health Questionnaire (SF-36) was gathered and developed according to eight points to estimate Health-related Quality of Life (HRM). The scores for physical (PCS) summaries and mental components (MCS) were recorded according to the SF-8 guidelines. 50 points are the average of eight areas in our general area and 2 summary points; a better HRQOL is indicated by higher scores. Although it is known that hunger and sleep are affected in patients with GERD, SF-8 does not address these conditions, so we developed a new quality of life questionnaire for GERD consisting of five questions. "Difficulty in everyday life etc," dissatisfaction with the amount of food etc, "satisfaction with staying away from the most loved foods i," dissatisfaction with sleep discomfort evaluated using a five-point scale (5, not at all, 4, mild, 3, moderate, 2, very quiet, 1, extremely). The score of the above was used for three areas: "daily life" "" "food" and "sleep." The average score of these three areas was defined as a specific GERD (summary score) score. A higher score indicates a better quality of life. The quality of life was self-administered when each patient was required to fill out the questionnaire in the clinic. The average time to complete the scale was 5 minutes and QOLS was scored by adding points to each item in order to take a total score for the instrument. In mean \pm s.d, Numerical data were presented. Chi-square tests were used to compare the patients' characteristics between the groups. To compare the HRQOL scores, Paired t-tests were used between the baseline and the 8th week after treatment, and to compare the difference in HRQOL and baseline score between the 8 groups Student's t-tests were used. The Bonferroni setting is used for multiple comparisons. $P < 0.05$ values (two hundred) were taken significant statistically.

RESULTS:

The patients characteristics in 250 patients included in this study were found to be suitable for analysis (not completed the quality of life questionnaire at 63, 4 and 8 weeks excluded). The characteristics of the patients in the study subjects are given in Table 1.

Table 1: Summary of baseline patient characteristics

	Group A (n=76)	Group B (n=63)	Group C (n=48)
Sex ^{a,b}			
Male	42.0	37.7	41.1
Female	58.0	62.3	58.9
Age ^{a,b,c}			
<60years	38.5	25.8	33.2
>60years	61.5	74.2	66.8
Severity of typical symptoms (heartburn/regurgitation) ^{a,b,c}			
Severe	15.6	12.3	11.7
Moderate	51.6	48.6	44.5
Mild	28.3	33.2	35.9
None	4.2	5.4	7.2
Initial dose of Pantoprazole/Itopride ^{a,b,c}			
40mg/150mg	63.2	54.0	57.0
80mg/150mg	36.8	46.0	43.0

aP<0.05(Group A vs Group B). *bP*<0.05(Group B vs Group C).
cP<0.05(Group A vs Group C).

40.8% of the analyzed patients were recommended for the modified lifestyle at the beginning of the application of pantoprazole / itopride (Group A). In group B 33% recommended to continue the previously recommended lifestyle and 26.09% were not advised for lifestyle change (Group C). There

were significant statistically variations between the groups in terms of gender, age, the initial typical symptoms severity, and initial pantoprazole / itopride dose. The mean scores of MCS, PCS and GERDS at baseline and after 2 months are given in Table 2.

Table 2: Summary of HRQOL scores

	Group A	Group B	Group C
Physical component summary			
Baseline	44.2±7.6	44.6±7.5	45.0 ±7.6
Week 8	49.9±6.0a	48.9±6.6a	49.1±6.5a
Mental component summary			
Baseline	46.0±7.9	47.0±7.8	46.9±7.5
Week 8	50.7±5.9a	50.3±6.2a	50.3±6.1a
GERD-specific summary			
Baseline	3.45±0.91	3.56 ±0.87	3.60 ±0.87
Week 8	4.46±0.63a	4.38±0.66a	4.45±0.64a

HRQOL, health-related quality of life; GERD, gastroesophageal reflux disorder. Mean± s.d. *aP* < 0.01 baseline vs. week 8.

For Group A, the variation between PCS at baseline and at 8 weeks was 5.7 ± 8.1 , which was significantly greater. In addition, the MCS changes and GERDS

were significantly higher in A Group than in other groups. The stratified analysis results are summarized in Table 3, based on the initial characteristics of

patients.

Table 3: Changes in HRQOL scores from baseline at week 8 according to patient characteristics

Group	PCS			MCS			RES		
	A	B	C	A	B	C	A	B	C
Male	6.1a,b 0.80	4.2 0.83	3.9	4.5a,b	3.4	3.5	1.04a,b		
Female	5.5a,b 0.83	4.3 0.85	4.1	4.8a,b	3.3	3.4	1.00a,b		
<i>Age</i>									
<60 years	6.2a,b 0.95	4.7	4.9	5.5a	4.1	4.7	1.08a,b	0.88	
>60 years	5.4a,b 0.80	4.1 0.79	3.6	4.2a,b	3.1	2.8	0.97a,b		
<i>Baseline severity of typical symptom (heartburn or regurgitation)</i>									
Severe	9.7a,b 1.37	7.4 1.36	7.0	8.3a,b	6.8	5.8	1.60a,b		
Moderate	5.6a,b 0.93	4.8 0.94	4.4	4.8a,b	3.8	3.7	1.08a,b		
Mild	3.9a,b 0.64	2.9	3.2	2.8a	1.8b	2.7	0.66a	0.55c	
<i>Initial dose of pantoprazole/itopride</i>									
40mg/150mg	5.7a,b 0.84	4.3 0.87	4.4	4.8a,b	3.4	3.6	1.01a,b		
80mg/150mg	5.8a,b 0.80	4.3 0.80	3.6	4.5a,b	3.3	3.3	1.02a,b		

HRQOL, health-related quality of life; MCS, mental component summary; PCS, physical component summary; GERDS, gastroesophageal reflux disorder specific summary.

aP < 0.05 (Group A vs. Group B). bP < 0.05 (Group A vs. Group C). cP < 0.05 (Group B vs. Group C).

At the 8th week, HRQOL changes scores from the beginning were higher significantly in A Group than in the other groups, gender, and age, regardless of the initial intensity of typical symptoms or the initial dose of pantoprazole / itoprid.

Details of recommended lifestyle changes:

Fatty foods, sweets, carbonated drinks, spicy food, coffee, hearty meals, alcohol, meals before bedtime, weight loss, belly tightening clothes, quit smoking and avoid lifting your head.

DISCUSSION:

Among the different modifications in lifestyle available to patients with GERD, it is considered to be one of the most important dietary recommendations because after meals most of the reflux symptoms occur. It has been reported that chocolate, spicy foods and fatty foods reduce the pressure of the lower esophageal sphincter, which

may cause gastroesophageal reflux. In addition, it increases the likelihood of temporarily loosening gastric discomfort with low esophageal sphincter (TLESR) after heavy meals, which increases the risk of reflux. Many doctors believe that diet modification decreases the symptoms severity linked with GERD; In this analysis, for all areas HRQOL scores of GERD HRQOL and specific SF-8 questionnaires improved significantly after 2 months of pantoprazole / itoprid treatment. HRQOL scores from the beginning of the 8th week were significantly higher in patients recommended for lifestyle change at the beginning of treatment compared to patients who continued treatment. Lifestyle and non-existent as previously reported. Although the present analysis suggests the benefits of lifestyle modification in HRQOL of patients with GERD, there are some limitations. Patients were not randomly assigned to treatment groups according to lifestyle changes because this analysis was not a primary endpoint of

the study, but a post hoc evaluation. A statistically significant difference was observed between the initial severity of the typical symptoms and the initial pantoprazole / itoprid dose, and a stratified analysis was performed according to the patient's initial characteristics. Changes in HRQOL scores from the beginning of the study were significantly higher in patients who proposed a lifestyle change regardless of the patient's baseline characteristics. These findings support the positive effect of lifestyle change on HRQOL.

CONCLUSION:

As a result, according to this post hoc analysis, lifestyle modification appears to be clinically useful for improving HRQOL.

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