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## Research Article

### ASSESSMENT ON PATIENTS HEALTH RELATED QUALITY OF LIFE ASSOCIATED WITH GERD

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GERD, RESQ7, HRQOL.

#### ABSTRACT

**Background:** Gastroesophageal reflux disease (GERD) has become a major health problem globally. It is a chronic, painful disease which has substantial effects on the everyday lives of affected individuals. GERD often needs long-term treatment and it can affect quality of life by disturbing the quality of eating and drinking, physical activities and rest. Therefore, improved quality of life has become another target of GERD management. The reflux symptom questionnaire 7 day recall (RESQ 7) are PRO (patient related outcome) instruments that were developed and validated for measuring the intensity and frequency of GERD symptoms in patients with a partial response to PPI's. **AIM:** To assess the Patients Health Related Quality of Life Associated with GERD in our Indian community **Methods:** By using randomized open label cohort study, 150 GERD Patients between 20-80 Years Males and females, out patients were assessed to health related quality of life. GERD Patients were invited to complete the GERD Questionnaire (RESQ 7) and the results were evaluated by using the likert scale. **Results:** A Total of 150 patients diagnosed with GERD, in that 117(78.10%) were Males and 33 (21.09%) were Females. In 150 Cases, 115 Patients (76.82%) were diagnosed as grade A GERD, 27 patients (17.88%) were grade B, 6 Patients (3.97%) were grade C and 2 Patients (1.32%) were diagnosed as grade D GERD. **Conclusion:** Our study reveals 118 are adhere to the given therapy, with improved outcomes out of 150 patients. Patients, who have with improved outcomes, overcame sleeping problems (90), and professional difficulties (81). Our study assessed males (117) are more susceptible for GERD than females (33). And 36- 45 year age group patients are more. We noticed that Endoscopic GRADE -A patients (115) are more.

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#### INTRODUCTION

Gastroesophageal reflux disease (GERD) has become a major health problem globally<sup>(1-4)</sup>. Patients with GERD usually suffer from various symptoms, including heart burn, acid regurgitation, epigastralgia, non-cardiac chest pain, chronic cough, asthma and hoarseness. Nighttime acid regurgitation symptoms may interfere with sleep. Therefore, patients with GERD may experience losses on their health-related quality of life (HRQOL) compared with the healthy population<sup>(5-8)</sup>. GERD is a chronic, painful disease which has substantial effects on the everyday lives of affected individuals. The negative effects of GERD are dependent on the frequency and severity of symptoms rather than the presence of esophagitis.<sup>(9-11)</sup> GERD is a chronic disease that often needs long-term treatment and it can affect quality of life by disturbing the quality of eating and drinking, physical activities and rest.<sup>(12-15)</sup> Anxiety and depression in GERD patients are significantly

higher compared to healthy subjects group. It demonstrates that GERD can affect mental and emotional aspects of an individual that eventually lower the quality of life. The socio-economic burden caused by GERD is also quite severe, which may need a special attention.<sup>(16-24)</sup> The effect of GERD on the quality of life of patients who have experience the disease does not correlate with the lesion on mucosa as seen on endoscopy; therefore, improved quality of life has become another target of GERD management.<sup>(16,17)</sup> Many questionnaires have been developed to evaluate GERD, either the general questionnaires to evaluate quality of life or questionnaires that have been specifically developed for GERD. The GERD-QOL questionnaire has been tested for its validity and reliability for Asian populations and it is considered to be a relatively good and specific instrument to evaluate the quality of life of GERD patients.<sup>(16)</sup> The questionnaire evaluates the quality of life of Asian population before and after receiving proton pump inhibitor (PPI) treatment.

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## Pathophysiology

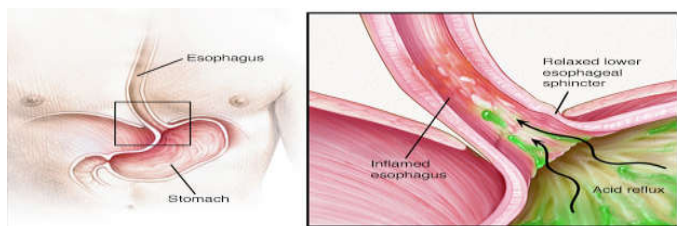


Figure 1

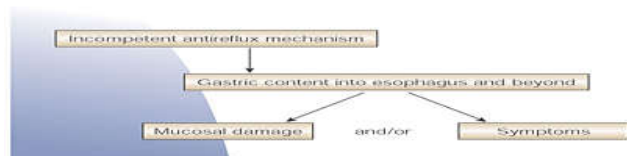


Figure 2

A dysfunctional LES allows reflux of large amounts of gastric juice. Delayed gastric emptying can increase the volume and pressure in the reservoir until the valve mechanism is defeated, leading to GERD

**Risk factors:**-Smoking, Obesity, Hiatal hernia, High Serum calcium levels, Delayed gastric emptying time, Hyperparathyroidism.<sup>(41)</sup>

## HRQoL

Health-related quality of life (HRQoL) is by definition subjective and multi-dimensional. Key and core domains reflecting HRQoL are represented by physical, mental and social functioning.<sup>(25-31)</sup> The best and most relevant way of accessing HRQoL is to ask the patient. This is usually done by using standardized and scientifically well documented questionnaires. The questionnaires can be divided into 2 types 1) Generic 2) Condition Disease specific.<sup>(32-34)</sup>

Benefits and shortcomings of generic as compared with disease- or treatment-specific questionnaires<sup>(35)</sup>

	Generic questionnaires	Disease/treatment specific questionnaires
Comprehensiveness and scope	Comprehensive and wide in scope	Deliberately narrow in scope
Applicability	General applicability over populations; low in precision	Targeted to a specific patient group, condition or treatment; high in precision
Generalizability	Can be generalized over populations and used for comparisons, norms or reference values available	Focuses on its target and cannot be used for comparisons between conditions; norms or reference values not applicable
Familiarity	Well known with a widespread use over many years	Unfamiliar, used to a limited extent
Relevancy	Too general for a specific patient population; low in patient and clinician credibility	Highly relevant to its target population; credible to patient and clinician
Responsiveness	Less responsive to treatment induced changes	Highly responsive in detecting small, clinically relevant changes
Practical, logistical and motivational considerations	Lengthy, time-consuming, less acceptable	Short, acceptable

Although erosive gastro-oesophageal reflux disease (GERD) is a highly prevalent condition, there is no specific, valid, reliable and sensitive questionnaire that allows evaluating treatment-induced changes in health-related quality of life (HRQoL).

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## Objectives of HRQoL

- To assess the overall treatment efficacy, including subjective morbidity.
- To help determine whether the goals of treatment have been met
- To educate patients and clinicians about the full spectrum of treatment outcomes.
- To facilitate medical decision making
- To provide the defining issue if treatments are otherwise equivalent.
- To compare outcomes across treatments and population.<sup>(37)</sup>

**RESQ7:** The Reflux Disease Questionnaire is a measure for assessment of treatment response for 7 Days. The questionnaires generally use short recall periods or ask patient to describe their current or recent state, asking patient to think back over can reduce the accuracy of recall.

The reflux symptom questionnaire 7 day recall (RESQ 7) are PRO (patient related outcome) instruments that were developed and validated for measuring the intensity and frequency of GERD symptoms in patients with a partial response to PPI's<sup>(38-40)</sup>

The RESQ-7 is a 13-item reliable and valid questionnaire measuring gastroesophageal reflux disease symptoms: Heartburn (5 items), Regurgitation (4 items), Cough, difficulty swallowing, hoarseness (3 items), Burping (1 item). The RESQ-7 has shown high inter-item correlation ( $\alpha = 0.77-0.87$  for intensity and  $0.72-0.82$  for frequency). Test-retest reliability was good or excellent ( $0.70-0.78$  for intensity and  $0.65-0.75$  for frequency).

- Developed for paper administration
- Takes approx 2-4 minutes to complete
- Recall period is last seven days
- Each item is rated on a 6-point Likert scale
- Developed for adult patients with a partial response to PPI treatment.

## Likert scale

- It is the most widely used approach to scaling responses in survey research. After the questionnaire is completed, each item may be analyzed separately or in some cases item responses may be summed to create a score for a group of items. Hence, Likert scales are often called summative scales.
- There are different types of likert scales like 5 point, 6 point, 7 point. In our study we have applied 6 point

likert scale based on the parameter used. Each item is rated on a 6-point Likert scale.

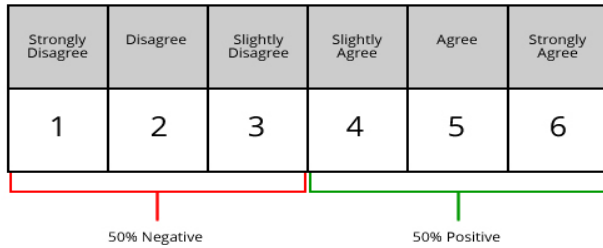


Figure 3

**METERIALS & METHODS**

By using randomized open prospective cohort study, 150 GERD Patients between 15-90 Years Males and females, out patients were assessed to health related quality of life. GERD Patients were invited to complete the GERD Questionnaire (RESQ 7) and the results were evaluated by using the Llikert scale.

**Inclusion criteria**

- Age between 15-90 years males and females.
- Patients with GERD & NERD
- OUT Patient.

**Exclusion criteria**

- Pregnant Women
- Lactating Mothers
- Patients with disorders other than GERD
- Patients with carcinoma conditions
- In Patients.

**Study Design**

Our study was Prospective, open cohort study in tertiary care hospital at Hyderabad. Number of subjects taken are 150. Data from patients diagnosed with GERD will collect by using RESQ-7. The characteristics of these individuals shall be analyzed. During the period from November 2017 to January 2018 conducted our study by giving patient counseling and fallow up.

A prospective cohort study is a longitudinal cohort study that follows over time a group of similar individuals (cohorts) who differ with respect to certain factors under study, to determine how these factors affect rates of a certain outcome. The prospective study is important for research on the etiology of diseases and disorders. The distinguishing feature of a prospective cohort study is that at the time that the investigators begin enrolling subjects and collecting baseline exposure information, none of the subjects have developed any of the outcomes of interest. After baseline information is collected, subjects in a prospective cohort study are then followed "longitudinally," i.e. over a period of time, to determine if and when they become diseased and whether their exposure status changes outcomes. In this way, investigators can eventually use the data to answer many questions about the associations between "risk factors" and disease outcomes.

**RESULTS**

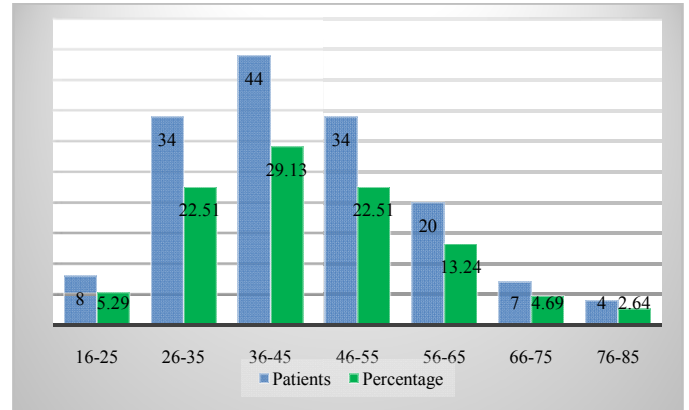
**Based on gender:** - In our study from the collected 150 patients data we assessed based on gender the male patients are more

susceptible to the disease than females. From the data the male patients for GERD found to be 117. The female patients were 33.

**Table 1**

Gender wise distribution		
Gender	Number	Percentage
Males	117	78.10%
Females	33	21.09%

**Based on Age:** - - In our study from the collected 150 patients data we assessed them by age wise distribution.



Graph 1

Based on age in between 16-25 age group the patients suffering from GERD are 8, in between 26-35 age group are 33 patients, in between 36-45 age group are 44 patients, in between 46-55 age group are 34 patients, in between 56-65 age group are 20 patients, in between 66-75 are 7 patients, and in between 76-85 age group are 4 patients.

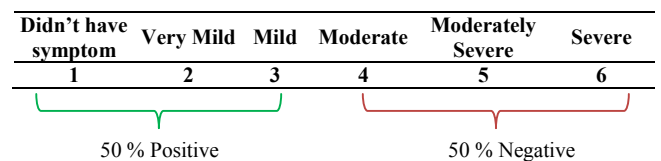
**Based on endoscopic GRADE:** - Based on diagnostic test the severity of GERD was graded as A, B, C, and D.

**Table 2**

GERD Grade wise Distribution		
Endoscopic Grade	Diagnosed Patients	Percentage
A	115	76.82%
B	27	17.88%
C	6	3.97%
D	2	1.32%
Total	150	100%

Based on the GRADE of GERD, most of the patients were found to be GRDE-A even though the patients have the symptoms from long past history, the symptoms have become severe or more frequent. From this we understand that even frequent or more intense symptoms most of the time resembles the initial stage of GERD (GR-A) compared to other GRADES.

**Based on patient reported out comes:** - Applied Method of likert scale in this study:-



In our study we have taken the initial 3 points as 50 % positive and remaining 3 points as 50 % negative. Higher the positive % value on follow up more will be desired result (i.e the patient

condition is improving with positive % compared to negative %)

**Table 3**

Based on Patient treatment outcomes	
IMPROVED	NOT IMPROVED
118	32

During 7 days follow up in the 150 patients 118 patients have started to experience the improvement in their health (as most of them GR-A patients) and only 32 patients have no improvement in their health condition (as most of them are GR-B,C,D patients).

Male patients belong to 20 to 45 age groups were responded well and adhere to the therapy. 89 Male patients were come out with improved health. And they have reported on follow up.

**Table 4**

Males (Age wise)	Improved	Not Improved
16-25	5	0
26-35	22	7
36-45	27	9
46-55	19	4
56-65	10	1
66-75	4	3
76-85	2	1

Female patients belong to 36 to 55 age groups were responded well and adhere to the therapy. 29 female patients were come out with improved health. And they have reported on follow up. And the incidence of GERD in males rather than females was high. Our study confirmed the prevalence of GERD is more in males.

**Table 5**

Females (Age wise)	Improved	Not Improved
16-25	3	0
26-35	5	1
36-45	8	2
46-55	8	2
56-65	5	2
66-75	0	0
76-85	0	0

We consider the treatment of GERD patients during the study period, more patients were received by proton pump inhibitors than H2 -R Antagonists.

Drug	No. patients	Sex	
		Males	Females
PPI's	138	108	30
[Pantoprazole	75	51	24
Esmoprazole	42	30	12
Rabeprazole]	21	15	6
H-2 RA [Ranitidine]	12	8	4

## DISCUSSION

In this study male patients with GERD found to be 117 and the female patients were 33. We came to know that males were more susceptible than females. We found 26-35 age groups are 34 patients, in between 36-45 age groups are 44 patients, in between 46-55 age groups are 34 patients. The percentage of Grade of GERD, we considered 150 subjects as 100%. Among them 76.2% of patients suffer from GR-A GERD, 17.88% of patients suffer from GR-B GERD, 3.97% of patients have GR-C, and 1.32 % of patients have GR-D GERD. During 7 days follow up in the 150 patients 118 patients have started to

experience the improvement in their health (as most of them GR-A patients) and only 32 patients have no improvement in their health condition (as most of them are GR-B,C,D patients). Most of the patients (138) were prescribed proton pump inhibitors than H2 antagonists (12). Patients experienced sleeping disturbances (123) and professional difficulties (86) were identified and they over coming these difficulties on treatment, on follow up 90 patients of sleeping disturbances and 81 patients have professional difficulties are reduced by the therapy and life style modifications.

## CONCLUSION

We assessed the patients with GERD by HRQOL RESQ-7 for 7 days in institute of Asian gastroenterology, after patient counseling and follow up, we collected data and applied Likert 6-points scale. Our study assessed males (117) are more susceptible than females (33). And 36- 45 year age group patients are more. We noticed that Endoscopic GRADE -A patients (115) are more. Our study reveals 118 are adhere to the given therapy, with improved outcomes out of 150 patients. Patients, who have with improved outcomes, overcame sleeping problems (90), and professional difficulties (81). Our study confirms that Resq-7 has given valid and reliable measurement for patient outcomes report.

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