

Outcome of Endoscopic Band Ligation in Cases with Gerd Refractory to Once Daily Medical Therapy of Dexlansoprazole

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Abstract: ***Background:** The conventional surgeries for the treatment of gastroesophageal reflux disease (GERD) results in high cost, post-operative complications and also add to our socioeconomic burden. The aim in our study was to study the effectiveness of endoscopic band ligation on symptom relief and quality of life in patients with GERD refractory to once daily medical therapy of Dexlansoprazole, to evaluate the endoscopic response and also to study any adverse effects. **Method:** Banding was done for the patients having symptoms of GERD despite treatment by dexlansoprazole. They were evaluated before and after treatment using oodscopy, 24 hr pH monitoring and GERD HRQoL questionnaires. **Result:** In our study, 13 cases were selected out of which maximum number of cases was within the age group of 21 to 30 yrs On pre op and post op ph monitoring De Meester score shows marked reduction in the score. On comparative study of pre op GERD HRQoL and post of GERD HRQoL, it shows marked reduction in its value. Out of 13, 5 patients shows normal study in post op endoscopy. Most common finding in post op endoscopy was partially reduced hiatus hernia which was seen in 6 patients and least common finding is post banding fibrosis and concentric ring at esophagogastric region. **Conclusion:** Endoscopic band ligation proved to be a good treatment choice for GERD Refractory to PPI. Endoscopic band ligation is a safer endoscopic approach and has lower rates of complications and higher rates of resolving of symptoms.*

Keywords: GERD, HRQoL, Banding, DeMeester score, oodscopy, 24hr pH monitoring, Dexlansoprazole

1. Introduction

The most widespread definition of refractory GERD is the clinical condition that present. GERD can be further classified into symptoms without erosions on endoscopic examination with pathological acid reflux in 24-h ambulatory pH (non erosive disease or NERD) or GERD symptoms with erosions (ERD) (1). The gastro esophageal junction hinders the flow of the gastric contents into the esophagus and provides a barrier against gastro esophageal reflux. It provides a high-pressure zone created by the smooth muscle of the lower esophageal sphincter (LES), the skeletal muscle of the crural diaphragm together with the clasp and sling fibers of the gastric cardia (2). Patients with GERD who exhibit partial or no-response to the twice daily dose of PPI are considered refractory to PPI after exclusion of patient noncompliance (3). The underlying mechanisms of refractoriness to the therapeutic effects of PPI include timing adherence as they should be taken 30min before a meal for better acid control (4), poor compliance, functional heartburn according to the Rome IV criteria (5), non or weak-acid reflux due to esophageal distension or hypersensitivity to the reflux ate (6), bile acid reflux (7), nocturnal acid breakthrough (8), patients with rapid metabolism of PPIs, resistance to PPI due to mutations in the proton pump gene (9). While most GERD patients do well with lifestyle modification and PPI therapy, approximately 30–40% of patients may need a surgical intervention, including anti-reflux surgery (ARS), sphincter augmentation, and bariatric surgery in obese patients [10]. The benefits of surgery for GERD have been demonstrated in several randomized controlled trials (RCTs) [11–13]. Careful patient

selection for surgery based on symptoms, response to medical therapy, barium esophagography, endoscopy, manometry, and impedance pH monitoring optimizes the likelihood of achieving effective and durable postoperative symptom control. The tremendous development of drugs which control the gastric PH and the therapeutic surgical interventions face many challenges as the high cost, the complications and the unsatisfactory outcome which had led to a significant socioeconomic burden (10). Being one of the most common diseases encountered by the gastroenterologists, GERD can be further classified as the presence of symptoms without erosions on endoscopic examination (nonerosive disease or NERD) or GERD symptoms with erosions present (ERD). (11, 12, 13)

Epidemiologically stating, the typical symptoms of heartburn and regurgitation are the bases on which estimates of the prevalence of GERD can be made. In the current scenario, western populations are having a much higher incidences of GERD than the developing nations. A systematic review found the prevalence of GERD to be 10 – 20% of the Western world with a lower prevalence in Asia (14). Clinically troublesome heartburn is seen in about 6 % of the population (15). Regurgitation was reported in 16 % in the systematic review noted above.

Chest pain (often misinterpreted, in actual being a heartburn) may be a symptom of GERD, even the presenting symptom (11, 16). There have been various methods and interventions which were used in the past for the treatment of GERD. They have resulted in failures, added to the high cost treatments and also caused various adverse effects. So there was a need to develop a minimal invasive, relatively

cheaper technique to counter problems associated with conventional methods. Therefore our present study focused on the outcome of Endoscopic Band ligation in the cases of GERD refractory to once daily therapy of Dexlansoprazole.

2. Methodology

Our study was a time bound, prospective study conducted at MGM Medical College and Hospital, Aurangabad after obtaining permission from institutional ethics committee. Patients suffering from GERD symptoms either attending the Surgery OPD / IPD or referred from other Departments

into the Department of General Surgery were taken for the study. This study was done for period of 2 years from October 2019 to October 2021. Patients who were included in the study underwent oodscopy. They were asked to fill up GERD HRQoL questionnaires and severity was assessed using it. They also underwent 24 hr pH monitoring for severity assessment. Then banding was done for those patients. The patients were asked to follow up 1 and half months after banding for check scopy, pH monitoring was done on 3 months follow up, and they were asked to fill up GERD HRQoL questionnaires again to compare with previous reports and questionnaires.

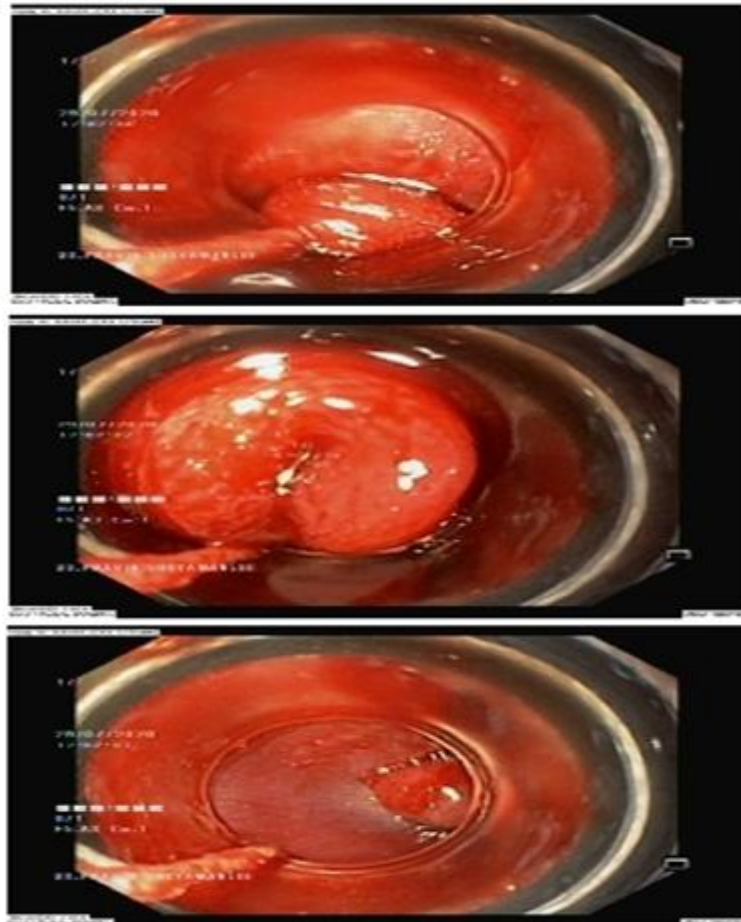


Figure 1: Showing procedure of Endoscopic Banding



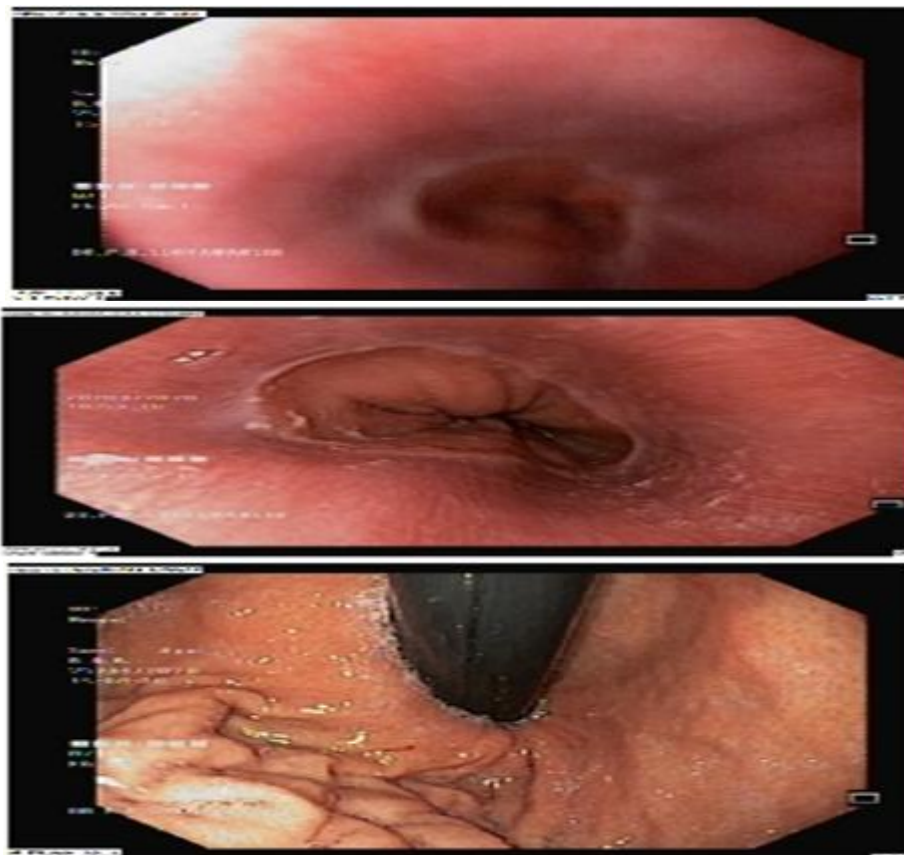


Figure 2: Showing post banding fibrosis and reduced hiatus hernia.

GERD-Health Related Quality of Life Questionnaire (GERD-HRQL)

Scale:

On PPIs Off PPIs If off, for how long? Days / months

0 = No symptom

1 = Symptoms noticeable but not bothersome

2 = Symptoms noticeable and bothersome but not every day

3 = Symptoms bothersome every day

4 = Symptoms affect daily activity

5 = Symptoms are incapacitating to do daily activities

Please check the box to the right of each question which best describes your experience over the past 2 weeks

1. How bad is the heartburn? 0 1 2 3 4 5

2. Heartburn when lying down? 0 1 2 3 4 5

3. Heartburn when standing up? 0 1 2 3 4 5

4. Heartburn after meals? 0 1 2 3 4 5

5. Does heartburn change your diet? 0 1 2 3 4 5

6. Does heartburn wake you from sleep? 0 1 2 3 4 5

7. Do you have difficulty swallowing? 0 1 2 3 4 5

8. Do you have pain with swallowing? 0 1 2 3 4 5

9. If you take medication, does this affect your daily life? 0 1 2 3 4 5

10. How bad is the regurgitation? 0 1 2 3 4 5

11. Regurgitation when lying down? 0 1 2 3 4 5

12. Regurgitation when standing up? 0 1 2 3 4 5

13. Regurgitation after meals? 0 1 2 3 4 5

14. Does regurgitation change your diet? 0 1 2 3 4 5

15. Does regurgitation wake you from sleep? 0 1 2 3 4 5

16. How satisfied are you with your present condition? Satisfied Neutral Dissatisfied

Administered by _____ Monitored by _____
Date (mm/dd/yy) Date (mm/dd/yy)

GERD-HRQL Questionnaire –Instructions

The GERD-HRQL questionnaire was developed and validated to measure changes of typical GERD symptoms such as heartburn and regurgitation in response to surgical or medical treatment. ⁽¹⁰⁾ When comparing GERD-HRQL scores post-TIF to scores pre-TIF, it is important to take medication use into consideration. It is recommended to request patients take this questionnaire twice at screening (once off PPIs and the other time on PPIs) for fair comparison at follow-ups post-TIF

Total Score: Calculated by summing the individual scores to questions 1-15.

- Greatest possible score (worst symptoms) = 75
- Lowest possible score (no symptoms) = 0

Heartburn Score: Calculated by summing the individual scores to questions 1-6.

- Worst heartburn symptoms = 30
- No heartburn symptoms = 0
- Scores of ≤ 12 with each individual question not exceeding 2 indicate heartburn elimination.2

Regurgitation Score: Calculated by summing the individual scores to questions 10-15.

- Worst regurgitation symptoms = 30
- No regurgitation symptoms = 0
- Scores of ≤ 12 with each individual question not exceeding 2 indicate regurgitation elimination. (11)

3. Observation and Results

In our cross sectional clinical observation study, 13 cases were selected, out of which maximum number of cases was within the age group of 21 to 30 yrs. Minimum age in our study is 18 yrs and maximum age in our study is 63 yrs. Mean age of sample is 37 yrs.

Table 1: Showing age group distribution of study population

Age group	No. of cases
11 to 20	3
21 to 30	4
31 to 40	1
41 to 50	2
51 to 60	2
61 to 70	1
71 to 80	0
>80	0
TOTAL	13

Sex distribution of study population:

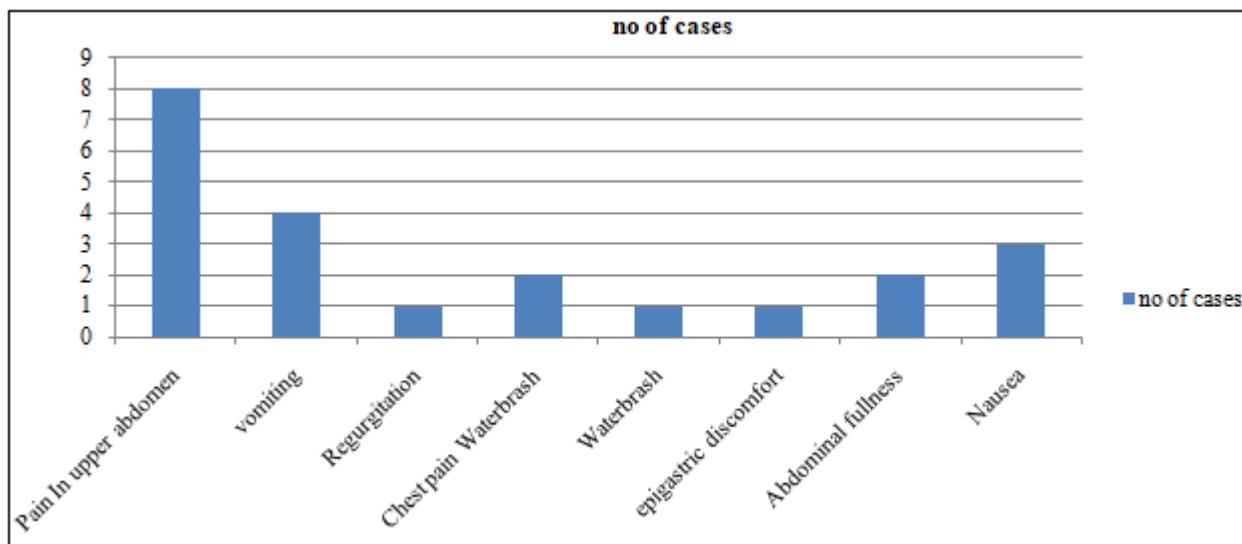
There are 5 males and 8 females. There was a significant preponderance of female patients.

Table 2: Showing sex distribution of study population

Sex	No. of cases
Male	5
Female	8

Presenting Complaint

Presenting complaints in our study is pain in upper abdomen, vomiting, regurgitation, chest pain, waterbrash, epigastric discomfort, abdominal fullness and nausea. most common presenting complaints is pain in upper abdomen and vomiting.8 patients have pain in upper abdomen and 4 patients having vomiting. Least common complaint is regurgitation and epigastric discomfort.1 patient have epigastric discomfort and 1 patient have regurgitation.

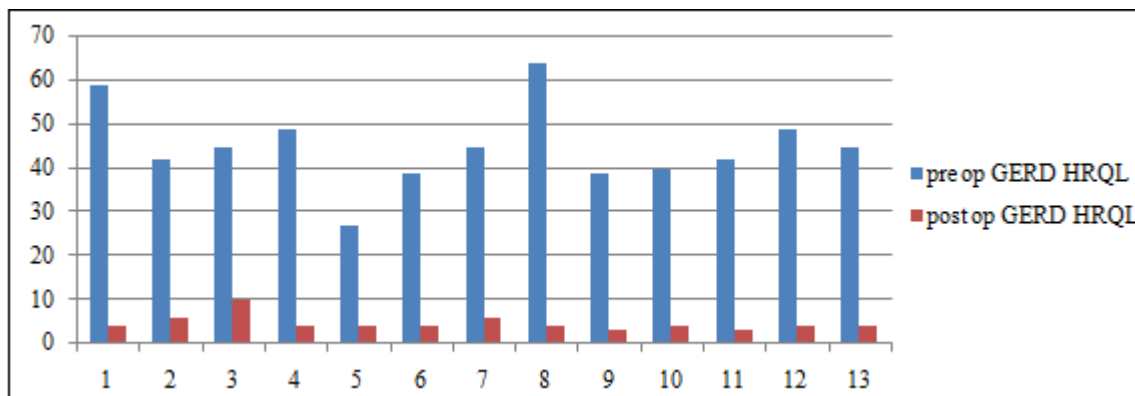


Graph 3: Graph showing presenting complaint in study population

Pre OP and Post OP GERD HRQL

HRQL focuses on impact of health on persons ability to live a fulfilling life. It represent broad concept of physical, psychological with social functioning and well being. On

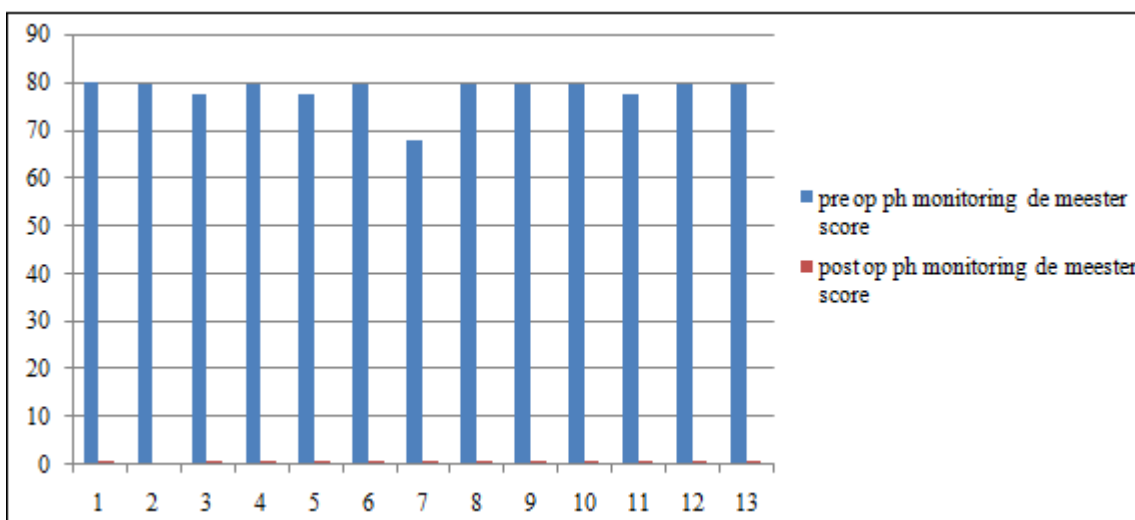
comparative study of pre op GERD HRQL and post of GERD HRQL shows markedly reduction in its value. The value of paired t test for the given sample is 3.5187.



Graph 4: Graph for comparing Preop and post op GERD HRQL

Pre OP and Post OP ph Monitoring De Meester score

On pre op and post op ph monitoring De Meester score shows marked reduction in the score. The comparative study shows reduction to about 1 %. The value of paired t test for the given sample is 3.609.



Graph 5: Graph showing pre op and post op ph monitoring De Meester score

Pre OP Endoscopic Finding

Pre OP endoscopic finding is lax esophageal hiatus, small hiatus hernia, class A reflux esophagitis and antral gastritis. Among which most common pre op endoscopic finding is small hiatus hernia which was seen in all patient and 2nd most common pre op endoscopic finding is lax esophageal hiatus which was seen in 9 patient, least common pre op endoscopic finding is antral gastritis and class A reflux esophagitis seen in 3 patient.

Table 6: Table showing pre op endoscopic finding

Pre OP Endoscopic Finding	No. of Cases
lax esophageal hiatus	9
small hiatus hernia	13
class A reflux esophagitis	3
antral gastritis	3

Post OP Endoscopic Finding

Post OP endoscopic findings are partially reduced hiatus hernia, improved laxity of spincter, post band fibrosis, concentric ring at esophagogastric region and normal study.

Out of 13, 5 patients shows normal study in post op endoscopy, most common finding in post op endoscopy was partially reduced hiatus hernia which was seen in 6 patients

and least common finding is post banding fibrosis and concentric ring at esophagogastric region

Table 7: Table showing Post op endoscopic finding

Post OP Endoscopy Finding	No. of Cases
Normal study	5
partially reduced hiatus hernia	6
Improved laxity of sphincter	5
post banding fibrosis	1
concentric ring at esophagogastric region	1

4. Discussion

Nowadays patients not responding to medications are in increasing trend, who were treated empirically with PPIs for symptoms of GERD are being seen. The term refractory GERD includes a group of patients that may differ in symptom severity and frequency, PPI dosing regimen (twice or once daily), and response to therapy (partial to absent). It could be seen as a patient-driven phenomenon as there is lack of established evidence regarding the definition of refractory GERD in terms of degree of therapeutic response, symptom burden, and dose of PPI at which failure occurs (17). Also, there has a significant impact on QOL by refractory GERD. Persistent reflux symptoms on PPI

therapy are associated with reduced mental and physical health-related QOL founded in a recent systematic review of 9 studies (18). Therefore, any patient who seeks consultation for bothersome symptoms that are attributable to GERD and that persist despite treatment with a PPI merits evaluation and management. To differentiate those with persistent reflux as the cause of the ongoing symptoms, from those with non-GERD etiologies are most important goal of the diagnostic evaluation in these patients. There are few studies in which refractory GERD patients with documented ongoing reflux have been treated with either surgery or medication. Impact of health on person's ability to live a fulfilling life is focused by HRQL. It represent broad concept of physical, psychological with social functioning and well being. In our study, On compative study of pre op GERD HRQL and post of GERD HRQL shows markedly reduction in its value.

A desirable alternative should be effective, less unfriendly impacts and with less adverse effects than other procedures so that the aim of the recent work is to evaluate the efficacy and safety of the endoscopic rubber band ligation in the GERD management as another simple, safe, competitive and less time consuming intervention with greater financial benefit. Through this study, we aim to compare the effects of endoscopic techniques (gastric banding in this study) with that of oral dexlansoprazole therapy (PPI) and apply the results in future management of this disease.

5. Conclusion

Endoscopic band ligation proved to be a good treatment choice for GERD Refractory to PPI. It is a safer endoscopic approach and has lower rates of complications and higher rates of resolving of symptom. Endoscopic intervention using EBL to treat refractory GERD with no major side effects as bleeding, perforation or stenosis when compared to the other procedures. This procedure not only can control reflux symptoms, but also relieve reflux related extra-esophageal symptoms. In case of Endoscopic band ligation postoperative results are stable and satisfactory and therefore this treatment modality can be considered for refractory GERD.

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