1	Original Research Article
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3	Laparoscopic fundoplication for gastro-esophageal reflux disease and
4	hiatus hernia: A short term outcome of first 8 cases.
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6	Abstract
7	Background
8	Acute gastro-esophageal reflux disease is a common ailment in kashmiri population. Most of
9	these patients are managed by gastroenterologist, physicians and surgeons in daily outpatient
10	basis. Majority of them settle by medical management with the help of proton pump inhibiters,
11 12	prokinetics and antacids. , laparoscopic Nissen's fundoplication (LNF) is currently the procedure of choice for the surgical management of GERD.
13	Aims and objectives
14	The aim of this study was to know the feasibility of laparoscopic fundoplication for hiatus hernia
15	and acute gastro-esophageal disease in terms operative time, post operative pain, length of
16 17	nospital stay, conversion rate and recurrence of symptoms.
18	Material and methods
19	The present prospective observational study was conducted in the Post-Graduate Department of
20	General Surgery and minimal access surgery Government Medical College Srinagar from June
21	2013 to June 20117. The patients that were included in the study had symptomatic gastro-
22	esophageal reflux (documented by endoscopy) with either persistent symptoms despite adequate
23	and prolonged medical treatment, C1 documented hiatus hernia and patients, who wanted to
24 25	void long-term medical deatment. The duration of remux symptoms ranged from 9 months to 30 years (median 6 years). Patients who were excluded from the study were those unfit for
26	anesthesia. Informed consent was taken before surgery in the language, the patients understood.
27	Results

- This study includes 8 patients, with median age of 40 years (range 20-70 years). In the study
- 29 group, 5 were males and 3 were females. The mean operative time was 90 minutes (range 60 t0
- 30 120 minutes). There were no major intra operative and post operative complications. The post
- 31 operative pain was minimal as compared to open surgery. The median hospital stay was 3.5 days
- (range 3 -6 days). Two patients developed symptoms of bloating, early satiety, nausea and
   diarrhea. However these symptoms improved within weeks with a good response to appropriate
- medication. The median time until normal physical activity resumed was 2 weeks (range 3 days
- to 4 weeks). Median follow-up was 6 months (range 1-12 months). The overall short-term results
- 36 in appropriately selected patients were excellent. The recurrence of symptoms was not observed
- in any patient within follow up of 6 months.

#### 39 Conclusion

- 40 We conclude from our early series of 8 cases, that patients having long standing GERD not
- responding to medical management who are at a threat to develop barrettes esophagus should be
- 42 given the benefit of laparoscopic fundoplication. However proper evaluation, patient's selection
- 43 is mandatory. The choice of fundoplication should be dictated by the surgeon's preference and
- 44 experience. Currently, the main indication for laparoscopic fundoplication is represented by PPI-
- 45 refractory GERD, provided that objective evidence of reflux as the cause of ongoing symptoms

- 46 has been obtained by impedance-pH monitoring.
- 47 Keywords; laparoscopy, hiatus hernia, riflux, fundoplication
- 48

## 49 Introduction

Gastroesophageal reflux disease (GERD) is currently defined as a condition that develops when 50 the reflux of gastric contents into the esophagus leads to troublesome symptoms and/or 51 complications[1,4]. The management of GERD is multi-disciplinary, often involving general 52 practitioners, gastroenterologists, surgeons and specialist nurses, all of whom should have an 53 awareness of the pros and cons of each management option. Barrett's esophagus is a condition in 54 55 which the stratified squamous esophageal epithelium is replaced by endoscopically detectable columnar metaplasia [5,6]. It occurs in 2% of the general adult population and represents the 56 57 most dreaded complication of GERD because it predisposes to esophageal adenocarcinoma, the fastest growing cause of cancer mortality. There is still debate about the working definition of 58 Barrett's esophagus [5,6]. According to the American Gastroenterological Association, Barrett's 59 esophagus is a change in the distal esophageal epithelium of any length that can be recognized as 60 columnar type mucosa at endoscopy and is confirmed to have intestinal metaplasia by biopsy of 61 62 the tubular esophagus [5]. According to the British Society of Gastroenterology, only 1 cm or more of endoscopically visible columnar epithelium above the gastro-esophageal junction 63 64 dictates biopsy sampling, whereas the detection of intestinal metaplasia is not a prerequisite for the definition of Barrett's esophagus but only for the necessity of endoscopic surveillance [6]. 65 Although multiple variants of anti-reflux operations are described, laparoscopic Nissen's 66 fundoplication (LNF) is currently the procedure of choice for the surgical management of GERD 67 This is reiterated in the **RCSE**[Please elaborate at the first instance] guidance, which 68 recommends fundoplication for the surgical management of GERD.Since fundoplication was 69 reported by Nissen in 1956[7,8], it has become the most common surgical procedure for gastro-70 71 esophageal reflux disease, achieving long-term relief of reflux symptoms in 90% of patients [9-72 11], with low morbidity rates (12-13%) and negligible mortality [12], to reduce the incidence of 73 post-fundoplication sequelae. The fundoplication offers the potential of reduced postoperative 74 pain and hence a shorter stay in hospital and reduced convalescent times compared with the open

75 approach.

76

## 77 Aims and objectives

- 78 The aim of this study was to know the feasibility of laparoscopic fundoplication for hiatus hernia
- and acute gastroesophageal disease in terms of operative time, post operative pain, length of
- 80 hospital stay, conversion rate and recurrence of symptoms.
- 81

# 82 Material and methods

- 83 The present prospective observational study was conducted in the Post-Graduate Department of
- 84 General Surgery and minimal access surgery, Government Medical College Srinagar from June
- 2013 to June 2017. A total of 8 patients were included in the study. [These are results, move to
- 86 results portion] The approval from the ethics committee and a signed informed consent were
- obtained from the patients. The median age was 40 years (20-70), 5 were male, and the median
- 88 weight of the adult patients was 70 kg (60-105). [These are results too] The patients that were
- 89 included in the study were symptomatic gastro-esophageal reflux (documented by endoscopy)
- 90 with either persistent symptoms despite adequate and prolonged medical treatment, CT
- 91 documented and patients, who wanted to avoid long-term medical treatment. The duration of
- 92 reflux symptoms ranged from 9 months to 30 years (median 6 years). [Results again, should be
- 93 under results section] Patients who were excluded from the study were those unfit for anesthesia.
- 94 The following data was collected prospectively: age, sex, operative time, intra-operative and post
- 95 operative complications, postoperative pain, hospital stay, conversion to open and recurrence of 96 symptoms. All the patients enrolled for the study were evaluated by detailed history, thorough
- symptoms. All the patients enrolled for the study were evaluated by detailed history, thorough
- general physical examination, and focused systemic examination. Informed consent was taken
  before surgery in the language, the patients understood. The patient was kept fasting overnight.
- 99 All patients received a prophylactic dose of injection ceftriaxone 1 g one hour before surgery.

#### 100 Operative procedure

- 101 Position of patient
- 102 After induction of general anesthesia and introduction of a bladder catheter, the patient was
- 103 placed in lithotomy, position, the table tilted  $30^{0}$  head up, and the surgeon standing between the
- 104 patient's legs with the first assistant to the patient's left and the second assistant to the patient's
- right. We preferred camera man to stand on the left side of surgeon. We use only one monitor on
- the side of the right shoulder of the patient. All procedures were completed by using 30 degree
- 107 telescope

#### 108 Port position

- 109 After placing an orogastric tube to deflate the stomach, Pneumo-peritoneum up to 15 mmHg was
- achieved by a direct trocar technique. Five ports were used (Fig. 1). A 10 mm optical port for
- the laparoscope was introduced just to the left of the midline, midway from the xiphistemum to
- the umbilicus. Additional ports were placed under vision; 5 mm ports was placed in the mid-
- clavicular line just below the right costal margin for a fan shaped retractor used for liver
- retraction, two working ports were made on either side of the optical port, 10 mm working port
- in the mid-clavicular line 5 cm away from the optical port on the left side of the abdomen, while
- as 5 mm working port was placed on the right side of abdomen, 5 cm away from the optical port
- in the mid-clavicular line and additional 5mm port was made in the anterior axillary line for
- 118 retraction of the stomach by the left assistant
- 119 Surgical procedure

Two of the assistants stand on the patient's right side; The camera man and the assistant who 120 retracts the liver. The assistant on the right side of the surgeon pulls the stomach down to expose 121 the gastro-esophageal junction. The first step is to incise the lesser omentum and pars flaccida 122 123 and proceed up towards the right side of gastro-esophageal junction. The phreno-esophageal membrane is incised and the dissection is carried across the esophagus. The lesser omentum is 124 incised to expose the right crus of diaphragm. A plane is created between the right crus and 125 Para-esophageal tissue and deepened. The Para-esophageal fat is dissected from the esophagus 126 taking care not to damage the hepatic branches of vagus nerve, next to that dissection of 127 esophagus hiatus is done. The dissection of the hiatus is done to mobilize the lower esophagus 128 and making it free from all the structures. The dissection is also carried to the left of the 129 esophagus interiorly till the left crus is reached. A cleavage is developed between the esophageal 130 Wall and the left crus. Again the left Para-esophageal fat is dissected off the esophagus to expose 131 the whole of left crus. Next step is to complete the dissection of esophagus within the the 132 esophageal hiatus and to further extend the peri-esophageal dissection in the mediastinum in 133 order to mobilise enough length of it, thereby avoiding the upward retraction of gastro-134 esophageal junction and fundoplication. At least 3-4 cm tension free abdominal esophagus must 135 be present within the abdomen at the end of dissection. During the upper dissection of the 136 hiatus, a great care is taken not to damage the anterior vagus nerve. The mobilization of upper 137 part of the fundus of the stomach is the next step; this is achieved by dividing the gastro 138 139 esophageal adhesions and short gastric vessels until the upper part of fundus is liberated. The dissection and division of these vessels is greatly facilitated by using harmonic scalpel. After the 140 dissection is completed, the reconstruction beginning by approximately the two pillars in order to 141 narrow the esophageal hiatus. The narrowing of the esophageal hiatus should be calibrated to a 142 size that allows the supple passage of a 10 mm scope along side of esophagus. The fundus is 143 passed behind the esophagus to initiate the fundoplication. The fundoplication is performed by 144 stitching the both sides of gastric fundus together in front of esophagus. To assess the tightness 145 of gastric wrap, a 5 mm grasper forcep is passed between fundal gastric wrap along side of 146 gastro-esophagus. Anchoring the fundoplication to the esophagus using an additional suture 147 completes the procedure. We also fixed the wrap with the right crus of diaphragm to avoid the 148 prolapse of fundal wrap. The drain was placed and secured in all cases. The ports were closed 149 and dressing applied. (Figure 1-14). 150

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- 152 153
- Figure 1 Port position in Laparoscopic Fundoplication
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156 157 Fig. 3 Longitudinal section of CECT abdomen showing hiatus hernia





Figure 2 Post operative picture





Fig 4 Release of gastro hepatic ligament byHarmonic. This exposes the lesser sac distally

and proximally from the hepatic branches of

the vagal nerves which are left intact.



Fig. 5 the right crus is incised and the dissection is extended anteriorly, posteriorly on to the V- shaped commisure of the right crus. The mediastinum is opened widely which helps in localizing the left piller and esophagus



- 178 Fig 6 A ribbon guaze is passed in the window
- 179 behind the esophagus and placed around the
- 180 abdominal part of esophagus. This maneuver
- 181 allows the traction onto the esophagus and
- 182 gastroesophageal junction which helps in
- 183 opening dissection planes.



- 184
- Fig 8 The greater omentum is dissected fromthe stomach along the greater curvature. The
- 187 short gastric vessels are divided individually
- using the harmonic scalpel. It is important to
- 189 mobilize the fundus completely away from
- 190 the diaghragm i.e until reaching the base of
- 191 the piller posteriorly to avoid undue torsion on
- 192 the gastro-esophageal junction when
- 193 constructing the fundoplication.



- 194
  195 Fig 10 Narrowing of esophageal hiatus is access
- 196 -ed by passing grasper forcep alongside of

Fig 7 Vagus nerve on the posterior aspect of esophagus Continuously keeping in mind the presence of both vagus nerves limits the possibility of harming them



Fig 9 The pillars are approximated from the right of the esophagus with interrupted nonabsorbable sutures. In order to narrow the opening of esophageal hiatus.



Fig 11 The fundoplication is performed by stitching both sides of gastric fundus together infront of esophagus

197 esophagus.

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199 200

- Fig 12 To acess the tightness of gastric wrap Grasper forcep is passed between fundal 201
- 202 gastric wrap and esophagus

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- Fig 14 Removing the ribbon gauze. The 205
- Floppy aspect of the fundoplication is again 206
- Checked by passing grasper alongside of 207
- esophagus 208
- 209



- To avoid forceful vomiting the first hours postoperatively as this may cause early disruption of 211
- the sutures and intra-thoracic migration of the fundoplication an anti-emetics was administered. 212
- A naso-gastric tube was routinely kept in place for 24 h after the surgery. Oral fluid intake was 213
- started on the 1st postoperative day and soft solids on the 2nd day. Patients left hospital as soon 214
- as they are well enough, continuing with a soft diet for the next 4 weeks. All patients were again 215
- seen at the outpatient clinic at 1 week, 6 weeks and 6 month after the procedure. Further follow-216
- 217 up was arranged on individual basis.



Fig 13 complete fundoplication



Fig 15 Drain placed and secured

## 218 Results

- 219 This study includes 8 patients, with median age of 40 years (range 20-70 years). In the study
- group 5 were males and 3 were females. The mean operative time was 90 minutes (range 60 t0
- 120 minutes). There was no major intra operative and post operative complications (such as
- bleeding, perforation of esophagus, injury to diaphragm, phrenic nerves and conversion to
- 223 open). The post operative pain was minimal as compared to open surgery. The median hospital
- stay was 3.5 days (range 3 -6 days). Two patients developed symptoms of bloating, early satiety,
   nausea and diarrhea. However these symptoms improved within weeks with a good response to
- nausea and diarrhea. However these symptoms improved within weeks with a good response to
   appropriate medication. The median time until normal physical activity was resumed was 2
- 227 weeks (range 3 days to 4 weeks). Median follow-up was 6 months (range 1-12 months). All
- patients were currently free of reflux symptoms. Postoperative gastroscopy was performed in all
- 229 patients, revealing a satisfactory fundoplication on direct inspection and the absence of
- 230 oesophagitis in all patients. The overall short-term results in appropriately selected patients were
- excellent. The recurrence of symptoms was not observed in any patient within follow up of 6
- months.
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Table 1 shows variables and there results.

Variable	Results	
Age (years)	40 (20-70)	
Sex	Male=5, Female=3	
Median weight(kgs)	70 (60-105 )	
Mean Operative time(minutes)	90 (60-120)	
Post operative pain	Minimal	
Intra and postoperative complication		
Bleeding	0	
Esophageal perforation	0	
Diaghragmatic injury	0	
Vagal nerve injury	0	
Conversion to open	0	
Post operative fever	1	
Port site infection	1	
Mean hospital stay (Days)	3.5(3-6)	
Recurrence of symptoms	0	
Mean Follow up	6 (1-12 months)	

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239 Discussion

- 240 Acute gastro-esophageal reflux disease is a common ailment in kashmiri population. Most of
- these patients are managed by gastroenterologist, physicians and surgeons in daily outpatient
- basis. Majority of them settle by medical management with the help of proton pump inhibiters,

prokinetics and antacids [1,2,3]. There is an association of gall stones with esophageal reflux

244 disease and duodenum diverticulum (saint's triad). Gastro-esophageal reflux disease and gall

stone presentation share the common clinical scenario of symptoms. It is difficult to differentiate 245 the one entity from the other clinically. Unfortunately, there are only few places in our state, 246 where these patients would be evaluated in the true scientific spirit and helped on scientific 247 logical ground. Under this perspective most of these patients stay on a continued medical 248 249 management of PPIs even though they could be helped by surgical management called Nissen's fundoplication. To detect acute gastro-esophageal disease, we need impedance PH monitoring, 250 esophageal manometry and establish imaging diagnosis of hiatus hernia, we require endoscopy 251 and CECT scan. The patients that were sent to us were highly suspicious of having acute gastro-252 esophageal disease on clinical scoring systems and having a resistance to treatment by PPIs for 253 duration of more than two years. The patients having acute gastro-esophageal disease were with 254 the persistent symptoms of retrosternal burning pain, regurgitation of gastric aspirate, hoarseness 255 of voice and irritative cough [13, 14]. The patients with hiatus hernia were Nissen's 256 257 fundoplication were performed were diagnosed on clinical, radiological (barium meal study), 258 Endoscopy and CECT scan. Stein and De-Meester [15] have stated that the established principles of anti-reflux surgery should not be jettisoned in order to perform a procedure laparoscopically. 259 They state that the 'construction of a loose  $360^{\circ}$  fundoplication' should be the goal. Dallemagne 260 et al [16] demonstrated the feasibility of this in their initial series of 12 patients. Geagea [17] and 261 262 Falk et al [18] all reported good initial results in preliminary series of 10 and 16 patients, respectively. Five patients of our study group presented with a documented hiatus hernia on 263 endoscopy and CT scan. Four of them had sliding hiatus hernia and one had Para-esophageal 264 type. However the rest three patients were taken for surgery for acute gastro-esophageal disease 265 on their clinical presentation only, due to paucity of esophageal manometry and PH monitoring. 266 We could not document their reflux before taking them for surgery. Nevertheless, after a 267 threadbare discussion with the treating gastroenterologist, a unanimous consensus was generated 268 that Nissen's fundoplication will help these patients. It is agreed that the two entities may coexist 269 270 together, however it is also known that they are not related to each other. A small hiatus hernia 271 may have severe symptoms of gastro-esophageal disease and converse is also true. All these patients were councilled in the preoperative setting about the nature of surgery, advantages, 272 disadvantages approach of surgery, conversion possibility and long term outcome. The risk of 273 barrettes esophagus in three of our patients who were resistant to medical management was 274 275 explained to them. A formal consent was obtained from the patients. 276 In our study, median age was 40 years (range 20-70 years) and there are 5 male patients and 3 female patients and median weight was 70 kg (range 60-105 kg). There was a noticeable lack of 277 data on the demographic group in the study conducted previously. Mean operative time was 90 278 minutes (range 70-120), the operating time decreased with experience. The operating time was 279 comparable to the study conducted by David I Watson, with mean Operative time of 81 minutes 280 (range 45-154) minutes. Two patients developed symptoms of bloating, early satiety, nausea and 281 diarrhea. These symptoms improved within weeks and responded to appropriate medication. 282 The mean hospital stay was 3.5 days (range 3-6 days) and mean follow was 6 months (range 283 1month-1 year) this was comparable to study conducted by David I Watson with mean hospital 284 stay of 3 days (rang 3 -8 days) and follow up 5 months rang (1 month 1 year). 285

- In our study the results demonstrated excellent symptomatic out come with shorter operative
- time , hospital stay, early discharge and early return to normal physical activity and also cost
- effective, as well as beneficial to patients by reducing the morbidity of surgery [19], with no
- reduction in efficacy. One of our patients in this series developed postoperative fever which
- responded to usual analgesics prescribed. One more patient developed port site infection which
- settled within first 10 days of surgery performed. We didn't have any conversions to open
- technique and we followed them for around 1 year.

## 293 Conclusion

- 294 We conclude from our early series of 8 cases, that patients having long standing GERD not
- responding to medical management who are at a threat to develop barrettes esophagus should be
- 296 given the benefit of laparoscopic fundoplication. Patients having CT documented hiatus hernia
- are also indications for laparoscopic fundoplication. Laparoscopy gives them all the benefits of
- 298 minimal access surgical procedure and avoids a big laparotomy on them. However proper
- evaluation, patient's selection is mandatory. The choice of fundoplication should be dictated by
- 300 the surgeon's preference and experience. Currently, the main indication for laparoscopic
- 301 fundoplication is represented by PPI-refractory GERD, provided that objective evidence of
- reflux as the cause of ongoing symptoms has been obtained by impedance-pH monitoring.

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