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LAPAROSCOPIC NISSEN FUNDOPLICATION- IS OESOPHAGEAL BOUGIE NECESSARY?

Surgery

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ABSTRACT

Aim: To evaluate incidence of post operative dysphagia and Quality of Life (QOL) after laparoscopic Nissen fundoplication (LNF) without bougie, based on Gastroesophageal reflux disease-Health related Quality of Life Questionnaire (GERD-HRQL).

Study Design: A pilot study to analyze postoperative dysphagia in patients who underwent LNF/Laparoscopic assisted fundoplication (LAF) without esophageal bougie from January 2014 through June 2017. Patients without follow up of at least 6 weeks were excluded.

Methods: Patients who underwent LNF/LAF without use of bougie were analysed using GERD-HRQL questionnaire proposed by Velanovich(2) et al for heartburn, regurgitation & dysphagia. GERD-HRQL was administered pre & post operatively and the scores noted.

Results: Out of 16 patients, 14 patients underwent LNF, 2 had LAF. One was lost to follow up. Median preoperative GERD-HRQL overall score was 34 & post operative score: 4. Post operative Dysphagia (grade 2) which persisted for more than 6 weeks occurred in 2/15 (13.3%). Median heartburn scores were 14 and 2, pre & post procedure. Median regurgitation scores were 15 and zero. 8/15(60%) had postoperative gas bloat and 5/15(38%) patients continued to take proton pump inhibitors. Satisfaction towards the procedure was assessed, 10/15(66.6%) were satisfied with procedure, 4/15(26.6%) were neutral and one patient (6%) was not satisfied with the procedure.

Conclusion: The incidence of postoperative dysphagia after LNF/LAF without esophageal bougie is comparable to that with bougie in literature and hence its routine use with attendant risk of perforation may not be warranted.

KEYWORDS

Laparoscopic Nissen Fundoplication, esophageal bougie, dysphagia, perforation, quality of life.

INTRODUCTION:

Laparoscopic Nissen fundoplication (LNF) has become the preferred procedure of choice for gastroesophageal reflux disease, with a reported success rate of 90% in various studies[1]. Traditionally, LNF is done with use of intra operative esophageal bougie while creating a fundoplication[2]. Esophageal bougie use is associated with esophageal and gastric perforation in 0.8% [4]. LNF despite being minimally invasive in nature is associated with similar postoperative complications & adverse effects to that of an open approach. Gas bloat, recurrent reflux and post operative dysphagia are the most commonly identified sequelae. Persistent dysphagia has been reported in 11-31% after fundoplication in literature. Post operative dysphagia may result in dangerous food impactions and aspiration pneumonia. In this study, we evaluate the postoperative Dysphagia and Quality of life with reference to regurgitation, heartburn & dysphagia using GERD-HRQL questionnaire by Velonovich et al [2] in patients who had LNF/LAF without use of oesophageal bougie.

Hypothesis: Laparoscopic fundoplication/laparoscopic assisted fundoplication has equivalent results when constructed without use of esophageal bougie.

STUDY DESIGN AND MATERIALS:

A pilot study to analyze the postoperative dysphagia and quality of life using GERD-HRQL questionnaire in patients undergoing LNF/LAF without esophageal bougie from January 2014 to June 2017.All patients undergoing Laparoscopic Nissen Fundoplication/Lap assisted fundoplication during the study period, without the use of esophageal bougie were included and those without follow up of 6 weeks were excluded from analysis.

Patients were analyzed using GERD-HRQL questionnaire proposed by Velonovich et al (Fig.1) for Heart burn, Regurgitation and Dysphagia. GERD-HRQL[2] questionnaire was administered preoperatively & post operatively at 6 weeks and scores were noted.

Incidence and severity of dysphagia was assessed by standard scoring system (Table-1). Dysphagia persisting for less than 6 weeks was considered transient and for more than 6 weeks as significant.

TABLE 1: Dysphagia scoring

Grade **0** - None
Grade **1** - some solids, no liquids
Grade **2** - many solids, no liquids
Grade **3** - most solids, no liquids
Grade **4** - all solids, some liquids
Grade **5** - all solids, all liquids

Scale:
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	

FIGURE 1: GERD-HRQL questionnaire Velanovich V et al. The development of the GERD-HRQL symptom severity instrument. Dis Esophagus 2007; 20:130-4)

RESULTS

16 patients were included in this study for evaluation during the study period. 14 patients underwent LNF and 2 underwent LAF (due to technical difficulties).One patient was lost to follow up.15 out of 16 were considered for evalu-ation of results. GERD-HRQL questionnaire [2] was applied preoperatively and after six weeks of fundoplication to assess the quality of life. Median Pre-operative and postoperative scores were calculated. Median preoperative GERD-HRQL Score was 34 and postoperative score was 4. Median preopera-tive heartburn score was

16 and postoperative score was zero. Median pre-operative regurgitation score was 15 and postoperative score was zero. Post-operative dysphagia was assessed using standard scoring system (Table 1). Dysphagia which persisted for more than 6 weeks after surgery was considered as significant. Postoperative dysphagia occurred in two out 15 (13.3%) patients. Both patients had grade 2 dysphagia, which did not require any interventions. 9 out of 15 (60%) patients had postoperative gas bloat. Postoperatively, 5 out of 15 (33.3%) patients continued to take proton pump inhibitors. Satisfaction towards the procedure was assessed, 10/15(66.6%) were satisfied with procedure, 4/15(%) were neutral and one patient (6%) was not satisfied with the procedure (Table.3).

TABLE 2. Median scores of QOL, heartburn and regurgitation.

PARAMETERS	MEDIAN PREOPERATIVE SCORE	MEDIAN POSTOPERATIV E SCORE
GERD-HRQL SCORE	34	4
HEARTBURN	16	0
REGURGITATION	15	0

TABLE 3. Satisfaction towards Laparoscopic Nissen fundoplication.

SATISFIED	NEUTRAL	DISSATISFIED
10	4	1

DISCUSSION

Laparoscopic nissen fundoplication has become the standard surgical procedure of choice for gastroesophageal reflux disease[1]. Dr Rudolph Nissen described the first fundoplication in 1950's for severe reflux esophagitis with 360 degree fundal wrap. Traditionally, Nissen fundoplication, a 360 degree fundal wrap is done with the intraoperative bougie. Evidence for use of esophageal bougie comes from a retrospective study by Demeester et al[3].Increasing the diameter of bougie from 36 Fr to 60 Fr decreased the chances of postoperative dysphagia[3]. Major limitation of that study was that three different modifications of the same procedure were employed during the study period. Both trans thoracic and trans abdominal approach were used Incidence of temporary swallowing discomfort (<3 months) was statistically significant between 36 Fr and 60 Fr bougie group, 83% in 36 Fr and 39% in 60 Fr groups ($p<0.001$). Whereas induced persistent dysphagia didn't show statistically significant difference (24% to 21%, p=NS)[3].

The 2010 Guidelines for Surgical Treatment of Gastroesophageal Reflux disease by the Society of American Gastrointestinal and Endoscopic Surgeons give a Grade B recommendation for the placement of an esophageal dilator that is largely based on the outcomes of the study by Patterson et al. in 2000[6]. In our study, incidence of postoperative dysphagia is 13.3% which is comparable to that in literature with or without bougie use.

A retrospective study by Lowham et al showed 0.8 % chances of esophago-gastric injuries during 1620 laparoscopic fore gut surgeries, either by bougie or nasogastric tube placement. Commonest site of injury is anterior gastroesophageal junction 38% followed by posterior distal esophagus 23 % [4]. In our series, we didn't encounter any foregut injuries.

In a double blinded, prospective randomized clinical trial by Patterson et al, overall long term dysphagia (persisting >1 year) was 17 v/s 31% ($p=0.047$) in bougie versus boogie omitted groups[6]. Preoperative dysphagia, sex, dysphagia frequency, esophagitis, dysmotility and stricture did not predict postoperative dysphagia. The use of a bougie during the creation of a fundoplication decreases the long-term incidence of dysphagia as per their study. The bougie omitted group was also more likely to have dysphagia classified as severe, frequent or severe and frequent[6]. Major limitation of this study is that significant proportion of patients with preoperative dysphagia underwent fundoplication with 56Fr bougie.

Somasekhar et al conducted a retrospective cohort comparative study of 82 patients operated by a single surgeon, 40 patients with 56 Fr bougie and 42 patients without bougie. Mean dysphagia score at 12 weeks, 24 weeks and 1 year were 1 versus 0 ($p=0.3$), 0 versus 0 and 0 versus 0 for bougie and no bougie group respectively. Progression of dysphagia after 1 year, cox regression analysis did not show any significant difference between the two groups ($P = 0.375$)[7].

A prospective cohort study of 28 patients by Ng et al evaluated quality of life after fundoplication with bougie and without bougie and found no difference (5.291 (2.63–7.0) vs. 6.272 (3.57–7.0), $P = 0.069$)[8].A retrospective cohort comparative study by Zacharoulis et al also showed no difference in incidence of postoperative dysphagia at median follow up of 60 months (53% vs. 46% (OR, 1.16; 95% CI 0.82–1.64; $P = 0.41$) and 0.2% risk of esophageal injury attributed to use of 56 Fr bougie[9].

In our study, quality of life was satisfactory in 66.6%, neutral in 26.6% and not satisfactory in 6.6% patients, with persistent dysphagia not different from that reported in literature.

CONCLUSIONS

- The incidence of post operative dysphagia after LNF/LAF without esophageal bougie is comparable to that reported in literature with bougie.
- Hence, the routine use of esophageal bougie with attendant risk of perforation may not be warranted.

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