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Original article

Hiatal hernia repair and gastroesophageal reflux disease in gastric banding patients: analysis of a national database

Ali Ardestani, M.D., M.Sc.[a], Ali Tavakkoli, M.D., F.R.C.S., F.A.C.S.[b,*]

[a]*Postdoctoral Research Fellow, Department of Surgery, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts*
[b]*Assistant Professor of Surgery, Department of Surgery, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts*

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Abstract

Background: Hiatal hernia (HH) is a risk factor for complications after laparoscopic adjustable gastric banding (LAGB), with recommendation to repair these at the time of LAGB placement. We reviewed the characteristics and outcomes of bariatric patients undergoing HH repair during LAGB. The aim of this study was to determine the prevalence of HH repair in LAGB patients and its potential effect on outcomes.

Methods: Using the Bariatric Outcomes Longitudinal Database, we identified patients who had hiatal hernia repair at the time of their LAGB (HHR group) and compared them to other LAGB patients without a HH repair (NonHHR group).

Results: Of 41,611 patients who underwent LAGB during 2007–2010, 8120 (19.5%) had HH repair (HHR), adding only 4 minutes to the operating time, without an increase in blood transfusion, length of stay, or band-related complications. Preoperatively, the HHR cohort had a higher incidence of gastroesophageal reflux disease (GERD) compared with nonHHR (49% versus 40%, respectively; $P < .001$) with a higher GERD score (1.13 versus .88, respectively; $P < .001$). Of those with GERD, similar percentage of patients in the HHR and nonHHR groups experienced improvement 1-year after surgery (53% versus 52%, respectively, $P = .4$), with similar GERD scores at this time point.

Conclusion: HH are repaired in one fifth of LAGB patients, with a surprisingly minimal increase in operative times and no change in length of stay, morbidity, or mortality. In patients with GERD, HH repair had minimal effect on postoperative improvements in reflux symptoms. These findings suggest that many of the repairs may involve small hernias with unclear clinical effect. (Surg Obes Relat Dis 2014;▮:00–00.)

Keywords: Gastric banding; Hiatal hernia; Gastroesophageal reflux disease

Since the approval of first laparoscopic adjustable gastric band (LAGB) by the Food and Drug Administration in 2001, this form of bariatric surgery has gained increasing popularity in the United States. LAGB was the second most common bariatric procedure, accounting for about 40% of bariatric procedures in the Unites States in 2007, and although the popularity of the procedure has declined in the past couple of years, it remains a choice as the least risky bariatric intervention [1].

Hiatal hernia (HH) and gastroesophageal reflux disease (GERD) are obesity-related co-morbidities and are associated with increased body mass index (BMI) in obese patients [2]. HH is also a known risk factor for complications after LAGB, such as pouch dilation and slippage [3]; HHs (especially large ones) were therefore regarded initially as a contraindication for LAGB. Follow-up studies, however, verified the tolerability and benefits of simultaneous crural repair and LAGB in patients with HH [4,5]. Further studies have advocated for routine evaluation and repair of

*Correspondence: Ali Tavakkoli, M.D., Department of Surgery, Brigham and Women's Hospital, Harvard Medical School, 75 Francis Street, Boston, MA, 02115.

E-mail: atavakkoli@partners.org

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detected hernias [6–8]. A recent report from a large patient cohort (n = 8677) has verified the tolerability and efficacy of HH repair at the time of primary LAGB in contrast to when these operations are done at the time of a revision [9]. Although, in a smaller study, Bueter et al. reported that preoperative diagnosis of hiatal hernias that were not repaired at the time of LAGB placement had no effect on outcomes or long-term complications, general recommendations are to repair these hernias at the time of LAGB placement [10].

The goals of this study were to evaluate the experience with HH repair (HHR) in LAGB patients on a national scale, to highlight the characteristics of patients with HH, and to assess the effect of LAGB on these patients. We anticipated that HHR would add significantly to the surgical times and lead to improvements in GERD scores.

Materials and methods

We reviewed the patient records in the Bariatric Outcomes Longitudinal Database (BOLD). BOLD has been developed to prospectively collect patient information (including demographic characteristics, co-morbidities, surgery outcomes, and follow-up) in patients undergoing bariatric surgery in American Society for Metabolic and Bariatric Surgery Centers of Excellence. The primary goal of BOLD is to monitor quality improvement in these centers; the database, however, provides a valuable source of information for research on various topics in bariatric and metabolic surgery. A range of measures have been taken to ensure quality and accuracy of the data [11,12]. All patients have consented to the secondary use of their data for research purposes. BOLD is available to researchers in the form of a de-identified national data repository.

After obtaining approvals from our Internal Review Board and BOLD's Data Dissemination Committee, a copy of the BOLD database was acquired that contained information on patients who had undergone bariatric surgery from 2007 to 2010. Patient follow-ups from the database are reported at 1 month, 3 months, 6 months, and every 6 months afterward. Also, the 3 most common major adverse events are reported. The major adverse events were entered in the database by trained personnel to reflect surgeon's notes based on following definitions: slippage, slippage of the gastric band (adjustable or nonadjustable) previously used to restrict pouch opening; erosion, erosion of the gastric band previously used to restrict the pouch opening; esophageal dilation.

For the purpose of the present study, we included patients who had undergone LAGB, were 18 years or older, and had a BMI of ≥ 35 kg/m^2. We excluded patients who had LAGB with hand-assisted or robotic-assisted approaches. We also excluded patients who had concurrent procedures other than HHR such as cholecystectomy, endoscopy, liver biopsy, lysis of adhesions, and umbilical or ventral hernia repair. We categorized patients who had HHR as the HHR group and patients without any concurrent procedures as the nonHHR group.

In the BOLD database, all co-morbidities including GERD are reported in a Likert scale with 6 levels; these levels for GERD are as follows: 0, no history of GERD; 1, intermittent or variable symptoms (no medication); 2, intermittent medication; 3, H_2 blockers or low-dose proton pump inhibitors (PPI); 4, high-dose PPIs, and 5, meet criteria for antireflux surgery or have had prior surgery for GERD. We considered a negative change in the scale as an improvement, no change as stable, and positive change in the scale as worsening of GERD. American Society of Anesthesiologists (ASA) scores were recorded and categorized in 2 classes: severe, which reflected an ASA score ≥ 3, and mild (ASA score < 3).

Primary and case-matched data analyses

Because of baseline differences between the 2 groups (NonHHR and HHR), data analysis was performed in 2 stages, primary and case matched. Primary data analysis was carried out on all cases to determine preoperative distribution of patient characteristics and co-morbidities and comparison of outcomes in the BOLD database. A thorough case-match analysis was also performed to validate the findings in the primary data set. We used the coarsened exact matching procedure to reduce the potential selection bias caused by nonrandom assignment of patients in these 2 groups [13]. Using coarsened exact matching, the 2 groups were matched based on 38 preoperative patient characteristics to reduce the imbalance in covariates between the groups (Table 2). In exact matching, first all the patients are arranged into strata, each of which has identical values for all the coarsened preoperative covariates, and then discarding all patients within any stratum who do not have at least 1 observation for each unique value of the grouping variable. One-to-one exact matching was used to eliminate the requirement of adding weights in a parametric model to carry out comparisons and control for variations across the groups. Patients who could not be matched were discarded from the case-matched analysis.

Data are presented as mean and standard deviation unless stated otherwise. Metropolitan Life Insurance tables were used to calculate percentage of excess weight loss (%EWL). To minimize the effect of outliers, the nonparametric Wilcoxon rank-sum test was used to compare continuous variables. X2 test was used to compare categorical variables. Multiple regression analysis was performed to control for potential confounders that affect %EWL after LAGB.

Results

Of the 41,611 patients who met our inclusion criteria, 8120 (19.5%) had a concurrent HHR. There was a