




Accuracy of High-Resolution Manometry in Hiatal Hernia Diagnosis in Primary and Revision Bariatric Surgery

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Abstract

Purpose There is a complex association between obesity, hiatal hernia (HH), and reflux. There is a deficiency of literature on the accuracy of preoperative high-resolution manometry (HRM) in detecting HH before both primary and revision bariatric surgery.

Materials and Methods A retrospective analysis of a prospective database of all HRM performed before bariatric surgery from 2014 to 2019. An electronic medical records review was conducted. Sensitivity, specificity, and global diagnostic test accuracy were calculated.

Results Sixty-seven patients with HRM (mean age of 44.0 ± 11.3 years, body mass index 40.8 ± 6.9 kg/m²) were eligible. Intraoperative diagnosis of HH was made in 37 patients (55.2% prevalence). The HRM sensitivity was 48.7% (95% confidence interval (CI) 31.9–65.6%), specificity 90.0% (95% CI 73.5–97.9%), and accuracy was 67.2% (95% CI 54.6–78.2%). Comparing primary (28) and revision (39) surgery, the sensitivity (37.5% vs 57.1%), specificity (75.0% vs 100%), and diagnostic accuracy (54.3% vs 76.3%) were comparable, with overlapping 95% CI. Endoscopy performed in 30 patients had a sensitivity of 25.5% (95% CI 6.8–49.9%), specificity of 100% (95% CI 75.3–100%), and accuracy of 57.8% (95% CI 38.5–75.5%) and was comparable to HRM.

Conclusion High-resolution manometry for the detection of HH before bariatric surgery has a high specificity and maintains a high accuracy in both primary and revision bariatric surgery.

Keywords Hiatal hernia · Manometry · Bariatric surgery · Obesity · Accuracy

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Introduction

Obesity is a global health issue driven by over-nutrition and a sedentary lifestyle [1]. In Australia, almost two-thirds of adults and a quarter of children were overweight or obese in 2014–15 [2]. Over two decades, one in ten more adults are now obese. Australia has the highest prevalence of overweight and obesity among countries in the Asia Pacific region [3]. The morbidity and cost associated with obesity is well recognized [4, 5]. Despite the difficulties faced in the provision of bariatric surgical services, it remains an effective means of sustained weight loss that is associated with reduced overall mortality [6, 7].

There is a worldwide growth of bariatric surgery, reflecting increasing demand [8, 9]. In parallel, revision bariatric procedures after inadequate weight loss, weight regain, and reflux symptoms are increasingly common [10]. Laparoscopic sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass

(RYGB) are two bariatric procedures, commonly used in both primary and revision surgery, particularly after failed laparoscopic adjustable gastric banding (LAGB). These procedures involve dissection of the angle of His and provide an opportunity to assess the esophageal hiatus.

There is a complex interplay between hiatal hernia (HH), obesity, gastro-esophageal reflux disease (GERD), and bariatric surgery [11–14]. Only a few studies compare the accuracy of endoscopy, barium swallow, and high-resolution manometry (HRM) for preoperative HH detection against intraoperative findings as the reference standard [15, 16]. A recent systematic review, although not specifically for obese patients, suggested HRM is the golden standard for preoperative HH diagnosis [17]. Only four of the seven included studies were related to bariatric surgery and none of these assessed HRM. There is a paucity of literature assessing the accuracy of HRM in HH diagnosis of revision bariatric surgery.

Materials and Methods

A retrospective analysis was performed on a prospective database of patients undergoing high-resolution manometry assessment before bariatric surgery (Fig. 1). Consecutive patients were included from 2014 to 2019, of a single surgeon, from a single Centre of Excellence in Metabolic and Bariatric Surgery. Further electronic medical record review was conducted to ensure the comprehensiveness of data collection. Data points of interest included patient demographics—age, sex, body mass index (BMI), preoperative pharmacotherapy for reflux, previous diagnosis of GERD, endoscopy results (HH presence and size), HRM results (HH presence and size), intraoperative findings, and type of bariatric surgery. Inclusion criteria were consecutive adult patients undergoing primary or revision bariatric surgery with preoperative HRM assessment. Assessment for revision surgery patients was conducted after removal of LAGB and within 6 months of revision surgery intraoperative findings. Exclusion criteria included patients aged <18 years of age and patients who did not proceed to a bariatric procedure ($n=3$) (Fig. 1). Ethics approval was granted by the University of New South Wales Human Research Advisory Panel (HC 200316).

Endoscopic HH was diagnosed if the esophagogastric junction was ≥ 2 cm above the diaphragmatic pinch, using hash marks on an endoscope (spaced 5 cm apart). Intraoperative laparoscopic inspection of the hiatus for dimpling anterior to the esophagus, migration of the esophageal fat pad, and the phreno-esophageal ligament and left crus were routinely exposed. If present, the right crus was also exposed and primary repair performed. In revision cases, greater dissection was undertaken to dissect the previous LAGB pseudocapsule and determine the presence or absence of a hiatal defect. The technique of HH repair was standardized. Following the reduction

of abdominal contents from the thoracic cavity, the left and right crura were dissected and HH sac resected. A 2-0 continuous posterior crural repair combined with a non-circumferential (270°) esophageal to crura suture with the recreation of the phreno-esophageal ligament was performed. The single operating surgeon performed the endoscopic assessment and HRM analysis and was thus aware of preoperative investigation results.

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0. (IBM Corp. Released 2017. Armonk, NY: IBM Corp). Continuous variables were assessed for normality of distribution using the Shapiro-Wilk test and presented as mean \pm standard deviation (range) and categorical data as number (percentage). Comparative analysis was performed using the *t*-test and Chi-squared test where appropriate. Intraoperative findings were the reference (“gold standard”) of HH presence or absence. A *p* value of <0.05 was considered statistically significant. Sensitivity, specificity, predictive values, and accuracy were calculated and presented as percentages (95% confidence intervals (CI)). Positive and negative likelihood ratios and 95% CI were presented. Accuracy was calculated as (sensitivity \times prevalence) + (specificity \times [1 – prevalence]) [18, 19]. This study conforms to the Standards for Reporting of Diagnostic Accuracy Studies (STARD) 2015 guidelines [20].

Results

The total number of patients included in the study was 67 patients (Fig. 1). There were 28 primary and 39 revision surgery patients. All revision surgery patients had previous LAGB and removal. The mean preoperative BMI was 40.8 ± 6.9 kg/m². The prevalence of preoperative pharmacotherapy for reflux was 35.8%. Intraoperative diagnosis confirmed 37 patients had HH, resulting in a cohort prevalence of 55.2%. Operations performed were LSG in 53 patients (79.1%), RYGB in 13 patients (19.4%), and LAGB in one case (1.5%). Patients with HH tended to be older (47 years vs 40.3 years, $p=0.02$). There were no significant differences in patient sex ($p=0.78$), preoperative BMI ($p=0.2$), or preoperative pharmacotherapy for reflux ($p=0.33$) (Table 1). There was also no significant association with positive intraoperative HH finding and the type of operation performed ($p=0.53$) and whether patients were undergoing primary or revision bariatric surgery ($p=0.07$).

High-resolution manometry detected HH in 21 patients (31.3%). Of these patients, 18 (true positive) had HH confirmed on intraoperative findings and three (false positive) did not have HH. Of the 46 patients with negative HRM diagnosis, 19 (false negative) had intraoperative findings of HH. The remaining 27 (true negative) patients had both negative HRM and intraoperative findings (Table 2) (Fig. 1). The HRM

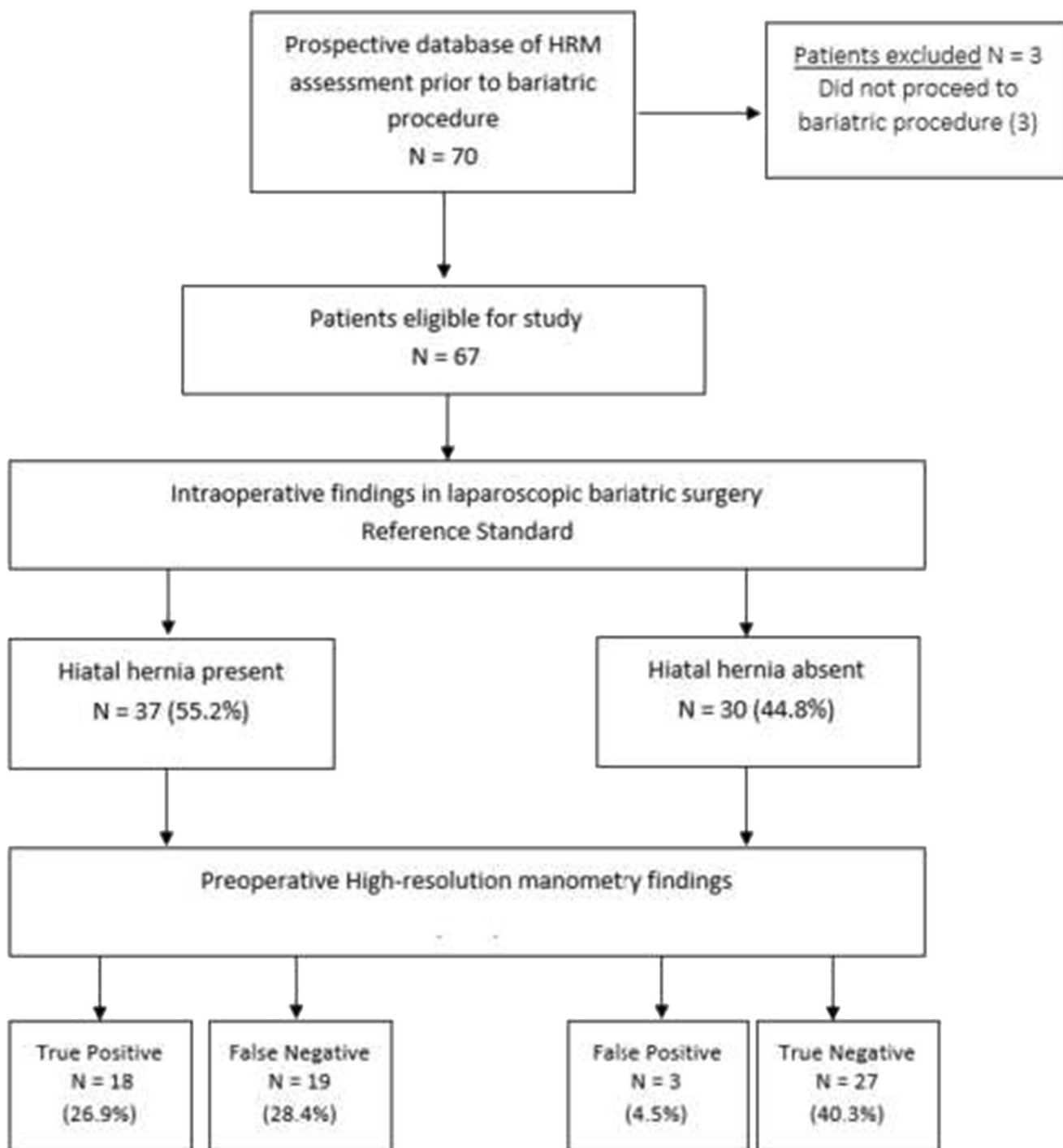


Fig. 1 High-resolution manometry (HRM) patient flow diagram

sensitivity was 48.7% (95% CI 31.9–65.6%), and specificity 90.0% (95% CI 73.5–97.9%). The positive likelihood ratio was 4.9 (95% CI 1.6–15.0) and the negative likelihood ratio was 0.6 (95% CI 0.4–0.8). The positive predictive value of HRM was 85.7% (95% CI 66.1–94.9%) and negative predictive value 58.7% (95% CI 50.4–66.5%). The accuracy of HRM for preoperative detection of HH was 67.2% (95% CI 54.6–78.2%) in this study cohort (Table 3).

Patients undergoing primary and revision bariatric surgery underwent subgroup analysis. Twenty-eight (41.8%) patients underwent primary bariatric surgery and 39 (58.2%) underwent revision bariatric surgery. Comparing primary and revision surgery, the sensitivity (37.5% vs 57.1%), specificity (75.0% vs 100%), and diagnostic accuracy (54.3% vs 76.3%) were comparable, and in favor of revision bariatric surgery patients (Table 4).

Table 1 Patient demographics

	Total cohort	Patient with HH	Patients without HH	<i>p</i> value
Patients	67 (100)	37 (55.2)	30 (44.8)	
Age (years)	44.0 ± 11.3	47.0 ± 10.4	40.3 ± 11.5	0.02
Sex (female)	48 (71.6)	26 (54.2)	22 (45.8)	0.78
BMI (kg/m ²)	40.8 ± 6.9	39.8 ± 5.4	42.1 ± 8.3	0.2
Preoperative reflux pharmacotherapy	24 (35.8)	15 (40.5)	9 (30)	0.33
Gastric banding	1 (1.5)	1 (2.7)	0 (0)	0.53
Sleeve gastrectomy	53 (79.1)	30 (81.1)	23 (76.7)	
Gastric bypass	13 (19.4)	6 (16.2)	7 (23.3)	
Primary surgery	28 (41.8)	16 (43.2)	12 (40.0)	0.07
Revision surgery	39 (58.2)	21 (56.8)	18 (60.0)	

HH hiatal hernia, BMI body mass index

Endoscopy also performed preoperatively in 30 patients. Endoscopy detected HH in four patients (13.3%). All four of these patients had HH confirmed on intraoperative findings (true positive). There were no false positives. Of the 26 patients with negative HH on endoscopy, 13 (false negative) had intraoperative findings of HH. The remaining 13 (true negative) patients had both negative endoscopy and intraoperative findings (Table 2). The endoscopic sensitivity was 25.5% (95% CI 6.8–49.9%), and specificity 100% (95% CI 75.3–100%). The negative likelihood ratio was 0.8 (95% CI 0.6–1.0). The positive predictive value of endoscopy was 100% and the negative predictive value 51.5% (95% CI 44.9–58.0%). The accuracy of endoscopy for preoperative HH diagnosis was 57.8% (95% CI 38.5–75.5%) in this study cohort (Table 3). Endoscopy was performed in 28 primary surgeries and two revision surgeries, and comparisons between these groups were not appropriate.

There were no adverse events noted from performing preoperative HRM, endoscopy, or intraoperative hiatal assessment.

Discussion

Hiatal hernias are common among Western patients undergoing preoperative workup before bariatric surgery. There is a

multifaceted relationship between truncal obesity, GERD, and HH that remains incompletely understood [13, 14]. There is also a concern that LSG, as a treatment for obesity, can also exacerbate existing and cause the development of de novo GERD in patients [12]. However, meticulous intraoperative inspection of the esophageal hiatus also appears to improve patient-evaluated GERD quality of life scores in the medium term [21].

Accurate preoperative esophageal hiatus assessment for HH is important to increase the clinical suspicion for small hernias that might otherwise be overlooked intraoperatively. Barium swallow x-ray and endoscopy have been the preoperative investigations traditionally used. When the utility of conventional manometry in detecting HH was assessed, there was poor sensitivity (20%), despite good specificity (99%) [22]. High-resolution manometry allows for better identification of anatomical landmarks compared to conventional manometry with more closely spaced pressure sensors. Detection of HH in HRM is illustrated by complete separation ≥2 cm if the lower esophageal sphincter and crural diaphragm pressure zones [23].

Establishing the preoperative gold standard for HH detection has been problematic given the application of different reference standards of HH diagnosis. Intraoperative findings have been accepted as the reference standard of HH diagnosis by consensus. A recent meta-analysis examined the performance of barium swallow x-ray, endoscopy, and HRM in preoperative HH detection, against intraoperative findings as the reference [17]. Current literature suggests HRM demonstrates better diagnostic performance when compared with endoscopy and barium swallow. However, there are only three trials that have examined HRM, none of which was in a bariatric population. Indeed, with limited published literature on the issue, the pooled diagnostic sensitivity and specificity for all three investigations had largely overlapping confidence intervals. A recent Italian series of 41 patients published after this meta-analysis, compared HRM, endoscopy, and barium swallow x-ray against intraoperative reference in a prospective design [16]. Though the sensitivity of HRM was superior

Table 2 Intraoperative vs preoperative findings of Hiatal hernia

HRM	Intraoperative hiatal hernia		
	Positive	Negative	
Positive	18	3	21
Negative	19	27	46
	37	30	67
Endoscopy	Positive	Negative	
	Positive	4	0
Negative	13	13	26
	17	13	30

HRM high-resolution manometry

Table 3 Accuracy for preoperative hiatal hernia diagnosis

	High-resolution manometry (<i>n</i> =67) value (95% confidence interval)	Endoscopy (<i>n</i> =30) value (95% confidence interval)
Sensitivity (TP / TP + FN)	48.7% (31.9–65.6%)	23.5% (6.8–49.9%)
Specificity (TN / FP + TN)	90.0% (73.5–97.9%)	100% (75.3–100%)
Positive likelihood ratio (sensitivity / 1 – specificity)	4.9 (1.6–15.0)	
Negative likelihood ratio (1–sensitivity / specificity)	0.6 (0.4–0.8)	0.8 (0.6–1.0)
Positive predictive value (TP / TP + FP)	85.7% (66.1–94.9%)	100%
Negative predictive value (TN / TN + FN)	58.7% (50.4–66.5%)	51.5% (44.9–58.0%)
Accuracy (sensitivity × prevalence) + (specificity × [1 – prevalence])	67.2% (54.6–78.2%)	57.8% (38.5–75.5%)

TP true positive, *TN* true negative, *FP* false positive, *FN* false negative

(90.9%), the specificity (63.3%) was lower than both endoscopy (66.7%) and barium swallow (86.7%).

Our series represents the largest series to date examining the accuracy of HRM to detect HH, before bariatric surgery. In our experience, though the sensitivity of HRM (48.7%) was lower than the 95% CI range of the meta-analysis, the two CIs overlapped and specificity (90.0%) was comparable [17]. This likely reflects regional variability between studies and the higher disease prevalence of HH (55.2%) within this cohort. The diagnostic accuracy was 67.2%, which is a global measure of diagnostic accuracy, affected by disease prevalence. For the same sensitivity and specificity, the diagnostic accuracy of an investigation decreases as the disease prevalence increases [24].

The variability of HRM accuracy is likely due to heterogeneity among patient populations, given the objectivity of HRM assessment. Patients are routinely offered HRM assessment before revision LSG in our center, particularly if there is any suspicion of esophageal motility disorder. The primary bariatric surgery patients that underwent HRM were all asymptomatic and had their investigations as part of another esophageal motility study. These patients serve as an

opportunistic control group but may introduce a potential selection bias given the lower prevalence of HH within the primary surgery patients.

Endoscopy, though not part of routine preoperative workup in our center, was performed in 30 asymptomatic patients (44.8%), as part of another interventional clinical trial. This provided an opportunistic comparison between the accuracy of endoscopy and HRM in our series. Although HRM was more sensitive than endoscopy (48.7% vs 23.5%) in our experience, specificity was reduced (90.0% vs 100%). The overall diagnostic accuracy of HRM was higher than endoscopy (67.2% vs 57.8%), which is broadly consistent with current literature [15, 16]. Interestingly the specificity of endoscopy was higher than HRM in our series, but this compensated a low sensitivity of our experience. The lack of false positive endoscopy HH detection in this cohort likely reflects the subjectivity of the assessment and limited sample size, though a recent Asian series of 434 preoperative endoscopies in bariatric surgery patients, where the prevalence rate was lower at 8.6%, were able to achieve a sensitivity of 75.7%, specificity of 91.4%, and an accuracy of 90.1% [25]. This variability reflects the subjectivity of endoscopy, movement of the

Table 4 High-resolution manometry findings in primary vs revision bariatric surgery

High-resolution manometry	Primary bariatric surgery (<i>n</i> =28) value (95% confidence interval)	Revision bariatric surgery (<i>n</i> =39) value (95% confidence interval)
Sensitivity (TP / TP + FN)	37.5% (15.2–64.6%)	57.1% (34.0–78.2%)
Specificity (TN / FP + TN)	75.0% (42.8–94.5%)	100% (81.5–100%)
Positive likelihood ratio (sensitivity / 1 – specificity)	1.5 (0.5–4.8)	
Negative likelihood ratio (1–sensitivity / specificity)	0.8 (0.5–1.4)	0.4 (0.3–0.7)
Positive predictive value (TP / TP + FP)	64.9% (36.6–85.6%)	100%
Negative predictive value (TN / TN + FN)	49.3% (37.1–61.6%)	65.4% (53.6–75.6%)
Accuracy (sensitivity × prevalence) + (specificity × [1 – prevalence])	54.3% (34.5–73.1%)	76.3% (60.0–88.4%)

diaphragmatic crura during assessment, and non-physiological context of an inflated stomach.

Furthermore, our study is the first to compare the accuracy of HH detection with HRM in both primary and revision bariatric surgeries. Although revision bariatric surgery can be performed with comparable perioperative outcomes in experienced hands, adhesions complicate surgical dissection, making preoperative HH detection even more important [10, 26]. Patients undergoing revision bariatric surgery to LSG after LAGB removal are routinely assessed with HRM in our center. This subgroup analysis was conducted due to concerns that previous surgery could result in alterations to the native angle of His or be associated with adhesions that would potentially reduce the diagnostic accuracy of HRM. However, this concern was not reflected in the findings from the study cohort. High-resolution manometry had a comparable and even favorable sensitivity, specificity, and diagnostic accuracy in revision bariatric surgery patients. However, we recognize the diagnostic test accuracy of primary (54.3%, 95% CI 34.5–73.1%) and revision (76.3%, 95% CI 60.0–88.4%) bariatric surgery had mostly overlapping confidence intervals.

Preoperative HH detection has potential advantages in reducing the amount of intraoperative dissection required for hiatal assessment and improving the validity of the patient consent process. Although accurate preoperative assessment could negate dissection of a dense pseudocapsule and right crural exposure in revision surgery, the low sensitivity of HRM assessment (48.7%) does not support this. Preoperative HH detection helps inform patient consent and operative decision making. If HH was diagnosed preoperatively in patients with significant GERD symptoms, LSG and HH repair remained a valid operative option. In patients with significant GERD symptoms, without a correctable anatomical defect, RYGB or other bypass procedure was favored. Additionally, it is recognized that HRM assessment provides valuable motility assessment, well beyond the identification of HH. Although HRM findings of esophageal dysmotility would guide the type of revision surgery offered, detailed motility description and analysis were not within the scope of this study.

Our study is limited by its retrospective nature. As preoperative endoscopy was not protocol, the comparison between HRM and endoscopy in our series is subject to potential selection bias. Revision bariatric surgery is also a term that covers an array of primary and revision procedures. The primary operation was LAGB and revision procedure was a combination of LSG and RYGB in our series. Although a different primary bariatric operation could affect the accuracy of HRM assessment for HH, it was not in the scope of this study. The inherent subjectivity of intraoperative findings as the reference standard by consensus is an ongoing concern. Perhaps additional intraoperative esophageal hiatus measurements and blinding the surgeon to preoperative investigation results may improve the objectivity of assessment and reduce the risk of bias with the reference standard.

Conclusions

High-resolution manometry for the detection of HH before bariatric surgery has a high specificity and maintains a high accuracy in both primary and revision bariatric surgery. Accuracy of HRM was superior to endoscopy in preoperative HH detection.

Declarations

Ethical Approval Statement Ethics approval was granted by the University of New South Wales Human Research Advisory Panel (HC 200316). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Informed Consent Statement Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare no competing interests.

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