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Comparison of endoscopic papillary balloon dilatation and endoscopic sphincterotomy for bile duct stones

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Abstract

Endoscopic treatment for bile duct stones is low-invasive and currently considered as the first choice of the treatment. For the treatment of bile duct stones, papillary treatment is necessary, and the treatments used at the time are broadly classified into two types; endoscopic papillary balloon dilatation where bile duct closing part is dilated with a balloon and endoscopic sphincterotomy (EST) where bile duct closing part is incised. Both procedures have advantages and disadvantages. Golden standard is EST, however, there are patients with difficulty for EST, thus we must select the procedure based on understanding of the characteristics of the procedure, and patient backgrounds.

Key words: Bile duct stones; Endoscopic papillary balloon dilatation; Endoscopic sphincterotomy; Endoscopic retrograde cholangiopancreatography; Post endoscopic retrograde cholangiopancreatography pancreatitis

Core tip: For the treatment of the bile duct stones, it is necessary to perform papillary treatment, and the treatment used at the time are broadly classified into two groups such as endoscopic papillary balloon dilatation and endoscopic sphincterotomy (EST). Golden standard is EST, however, there are patients with difficulty for EST, thus we must select the procedure based on understanding of the characteristics of the procedure, and patient backgrounds.

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INTRODUCTION

Currently, the treatment for the bile duct stones are widely conducted with endoscopic treatment as the first choice[1]. Advantages of endoscopic treatment when compared with the surgery lie in that it can cope with promptly even at the emergent time and it is possible to perform the treatment low-invasively with less human power in a short period of time. Percutaneous transhepatic approach exists, too, but I have long time for treatment and am not performed very much because a maneuver is complicated. The papillary treatment conducted at the time includes endoscopic papillary balloon dilatation (EPBD) and endoscopic sphincterotomy (EST). Although EST is the golden standard procedure, there are patients who are indicated for EPBD. This report describes treatment success rate, procedural accidents, long term prognosis, and indication of EPBD and EST for the bile duct stones.

HISTORY OF EPBD AND EST

EPBD is the procedure reported by Staritz *et al*[2] in 1982. Then during 1990's Mac Mathuna *et al*[3] and Komatsu *et al*[4] have reported. However, it has scarcely been used in Western countries because of problems of postoperative pancreatitis, whereas EST has been used for 40 years or longer after reported by Kawai *et al*[5] and Classen *et al*[6] in 1974, and currently it has become established as the first choice of endoscopic treatment method for bile duct stones all over the world.

INDICATION OF EPBD AND EST

Based on advantages and disadvantages of EPBD and EST, their respective good indication and points to notice are described. Basically, EST is the first choice, however, patients with liver cirrhosis, blood disease, or patients undergoing anticoagulant therapy or dialysis who have bleeding tendency or patients who are treated with Billroth-Ⅱ method or gastric bypass with Roux en Y Reconstruction and have anatomical difficulty in undergoing EST are good indications of EPBD[7,8]. On the other hand, in patients who underwent pancreatography which is considered as high risk factor of post-EPBD pancreatitis, indication must be carefully examined[9]. In using the mechanical crushing tool for a number of stones or giant stones, it becomes necessary to repeatedly insert the basket balloon catheter into the bile duct for lithotomy. In EPBD, the bile duct opening is not so dilated, thus due to papillary edema, it becomes difficult to insert the treatment tool in the early stage, leading to high frequency of the erroneous insertion into the pancreatic duct. It is considered that incidence of post-EPBD pancreatitis is high in the younger people, however we hesitate to eliminate the papillary function by conducting EST, considering long term prognosis. There is a report of the study including only 5 patients which describes that bile duct stones in the children were safely and effectively treated with EPBD[10]. If the treatment can be done more safely by device of safer procedure, indication for EPBD may spread.

ACTUAL PROCEDURE OF EPBD AND EST

The difference between EPBD and EST lies in dilation method of the bile duct closing part of the duodenal papilla, one dilates by dilatating with the balloon and the other dilates by incising with a sphincterotome. In EPBD, once the guidewire can be inserted into the bile duct, the balloon catheter is selected by conforming bile duct diameter through this guidewire, and inserted for dilatation, thus easy by far when compared with EST in terms of the procedure. In EPBD, the bile duct opening of the papilla is not cut and dilated as in EST, thus function of sphincter of Oddi is conserved to some degree. However, on the other hand, insertion of a stone harvesting and crushing tool is more difficult than EST because bile duct opening is small. Furthermore stones around 10 mm in size which can be removed in EST without any treatment cannot be removed in EPBD if they are not crushed with the mechanical lithotripsy tool. In EST, incision is conducted by adjusting the position of the scope with the blade of sphincterotome in the direction of 11-12 o'clock. The procedure must be conducted always paying attention to insertion angle, depth, direction of blade, and incising speed of a sphincterotome into the papilla because risk of perforation and bleeding is high differently from balloon dilatation, thus difficulty level of the procedure is high.

TREATMENT RESULTS OF EPBD AND EST

The results of comparison test on EPBD and EST reported up to the present are described (Table 1)[11-24]. High complete stone removal rate of 90% or greater is obtained by both methods in a number of reports, and based on these results, it can be determined that final treatment success rate is almost the same. On the other hand, as to procedural accidents, there are reports describing that pancreatitis[18-20,24] was observed in EPBD, whereas bleeding[19-21] in EST, and each frequency is high. In particular, in multi-center study conducted in United States, death case due to post-EPBD pancreatitis was observed, which led to that EPBD has been scarcely conducted in Western countries[20]. As the risk factor of post-EPBD pancreatitis, young people, past history of pancreatitis, no dilated bile duct (9 mm or less), use of the mechanical lithotripsy tool, and pancreatography are reported up to the present[9,25-28]. As the measure

Table 1 Short term treatment results of endoscopic papillary balloon dilatation and endoscopic sphincterotomy

Ref.	Sample size (EPBD/EST)	Indication	Complete stone removal	Early procedural accident (whole)	Pancreatitis	Mild	Moderate	Severe	Cholecystitis	Cholangitis	Bleeding	Perforation	Basket impaction
Minami *et al*[11]	20/20	No limit	100% /100%	10% /10%	10%/10%	-	-	-	-	-	-	-	-
Bergman *et al*[12]	101/101	No limit	89%/91%	17% /24%	6.9%/6.9%	-	-	-	-	-	0%/4.0%	2.0%/1.0%	-
Ochi *et al*[13]	55/55	Diameter < 15 mm, number < 10	98.1%/92.7%	2.0%/5.6%	0%/3.7%	0%/0%	0%/3.7%	0%/0%	-	-	-	0%/1.9%	-
Yasuda *et al*[14]	35/35	No limit	100%/100%	5.7% /8.6%	5.7%/5.7%	5.7%/5.7%	0%/0%	0%/0%	-	-	0%/2.9%	-	-
Arnold *et al*[15]	30/30	Diameter < 20 mm, number < 5	77%/100%[1]	30.0%/16.7%	20%/10%	13.3%/10%	0%/0%	6.7%/0%	-	10%/0%	0%/6.7%	-	-
Natsui *et al*[16]	70/70	No limit	92.9%/98.6%	10.0%/11.4%	5.7%/4.3%	5.7%/4.3%	-	-	-	2.9%/4.3%	0%/2.9%	-	1.4%/0%
Vlavianos *et al*[17]	103/99	No limit	87.4%/86.9%	6.8%/3.0%	4.9%/1.0%	1.9%/0%	1.9%/1.0%	1.0%/0%	-	1.9%/1.0%	-	-	-
Fujita *et al*[18]	138/144	Diameter < 14 mm	99.3%/100%	14.5%/11.8%	10.9%/2.8%[1]	8.7%/2.1%	2.2%/0.7%	9%/0%	2.2%/4.2%	1.4%/4.2%	0%/1.4%	-	0.7%/0.7%
Baron *et al*[19]	552/554	Meta-analysis	94%/96%	10.4%/10.3%	7.4%/4.3%[1]	-	-	-	2.7%/3.6%	-	0%/2.0%[1]	0.4%/0.4%	-
Disario *et al*[20]	117/120	Diameter < 10 mm, number < 4	97.4%/92.5%	17.9%/3.3%[1]	10.3%/0.8%[1]	-	-	5.1%/0%	0%/0.8%	0.9%/0.8%	10.5%/27.0%[1]	0%/0.8%	-
Lin *et al*[21]	51/ 53	Diameter < 20 mm	94.1% /100%	-	-	-	-	-	-	-	2.0%26.4%[1]	0%/0.8%	-
Takezawa *et al*[22]	46/45	No limit	100%/100%	0%/0%	-	-	-	-	-	-	-	-	-
Tanaka *et al*[23]	16/16	No limit	100%/100%	18.8%/25.0%	18.8%/18.8%	-	-	-	-	0%/12.5%	-	-	-
Watanabe *et al*[24]	90/90	No limit	86.6%/95.6%	14.4%/3.3%[1]	10.0%/2.2%[1]	8.9%/0%	1.1%/2.2%	-	-	3.3%/0%	1.1%/0%		1.1%/0%

[1]$P < 0.05$. EPBD: Endoscopic papillary balloon dilatation; EST: Endoscopic sphincterotomy.

to prevent onset of post-EPBD pancreatitis, intraoperative intravenous drip of isosorbide dinitrate with relaxant effect for the sphincter of Oddi[29,30], postoperative papillary epinephrine spray to prevent papillary edema[31], indwelling of pancreatic duct stent[32] or endoscopic nasobiliary drainage[33] are attempted and their respective usefulness is reported.

With regard to dilatation pressure and time of the balloon, it has been considered that dilatation at low pressure and short time gives less burden on the papilla and develops less postoperative papillary edema, thus is good for prevention of pancreatitis[34], however, there appeared a report that longer dilatation time leads to less incidence of pancreatitis[35,36], which we need to study hereafter.

PAPILLARY FUNCTION OF POST-EPBD AND POST-EST

Sato *et al*[37] reported after conducting EPBD that significant decrease in bile duct inner pressure, papillary basic pressure, and papillary contraction pressure were observed at 1 wk after EPBD, whereas they were recovered to around the value before EPBD at 1 mo after. Minami *et al*[11] examined inner pressure and measured papillary function before treatment and at 1 mo after in randomized controlled trial (RCT) comparing EST with EPBD, and reported that a significant decrease was observed in EST, whereas recovery was found without any significant difference in EPBD. Kawabe *et al*[38] histologically studied the papillary finding of patients who underwent surgery after EPBD

Table 2 Comparison of long term prognosis between endoscopic papillary balloon dilatation and endoscopic sphincterotomy

Ref.	Sample size (EPBD/EST)	Follow-up period	Total	Stone recurrence	Cholangitis	Cholecystitis	Liver abscess	Biliary cancer
Bergman *et al*[12]	101/101	6 mo	18%/23%	7.9%/6.9%	-	1.3%/9.9%	0%/1.0%	-
Ochi *et al*[13]	51/54	Median 23 mo	3.9%/14.8%	3.9%/5.6%	3.9%/3.7%	3.3%/18.5%	-	-
Yasuda *et al*[14]	235/126	Median 37.4/36.3 mo	-	10%/14%	0%/3.2%	2.0%/8.8%	-	-
Natsui *et al*[16]	68/69	Median 30 mo	5.9%/8.7%	4.4%/4.3%	-	3.6%/7.9%	-	-
Vlavianos *et al*[17]	103 /99	12 mo	11.7%/15.2%	1.9%/3.0%	1.9%/1.0%	1.9%/2.0%	-	-
Lin *et al*[21]	51/53	Median 16 mo	-	5.9%/7.5%	-	-	-	-
Yasuda *et al*[51]	138 /144	Median 6.7 yr	10.1%/25.0%[1]	7.8%/17.4%[1]	0%/2.8%	5.5%/8.3%	0%/1.4%	0%/0.7%

[1]$P < 0.05$. EPBD: Endoscopic papillary balloon dilatation; EST: Endoscopic sphincterotomy.

(2-63 wk after EPBD), and reported that breakage of the sphincter was found only in 1 patient at 3 wk after EPBD, and EPBD does not affect the papillary function. According to the above reports, it seems certain that in EPBD the papillary function is recovered in the comparatively early stage in most of patients. On the other hand, as to the report on the papilla and bile duct inner pressure after conducting EST, there are many reports of short term follow up whereas long term follow up is less. Ponce *et al*[39] reported that papillary basic pressure disappeared immediately after EST, and bile duct inner pressure is also decreased, however, papillary basic pressure partly remains in some patients, which is considered to be related to incision length. Geenen *et al*[40] conducted papillary inner pressure examination at 1 and 2 years after EST and reported that although bile duct inner pressure and papillary basic pressure disappeared even at 2 years after, height of papillary contracting wave was recovered at 2 years after, showing no significant difference when compared with before EST. According to report of Bergman *et al*[41] on the study at 15-17 years after conducting EST, papillary basic pressure disappeared and papillary contracting wave disappeared in 75% of patients. Study by Sugiyama *et al*[42] revealed that incision length by EST is contracted during the course and becomes the length of about 70% at 5 years after, and improvement of papillary function to some degree is expected in the long term. Although papillary basic pressure disappears in a large number of patients after EST, in part of patients with short incision length, it is presumed that remaining or recovery of papillary contracting wave is expected.

LONG TERM PROGNOSIS OF EPBD AND EST

As for long term prognosis after EPBD, Tsujino *et al*[43] conducted the investigation including 837 patients with mean follow-up period of 4.4 years and reported that stone recurrence was found in 8.8%, and cholecystitis was in 3.4%, whereas, as to long term prognosis after EST, it is reported that stone recurrence was found in 8.0%-12.3% and cholecystitis in 4.0%-6.7% during mean follow-up period of 6.2-15 years[44-50]. These are reports by a single procedure. There are some comparative control studies on EPBD and EST (Table 2)[12-14,16,17,21]. Bergman *et al*[12] compared late complications until 6 mo after in RCT, and reported that cholecystitis occurred in 1.3% after EPBD, whereas 9.9% after EST, showing significant low rate in EPBD group. Ochi *et al*[13] also reported that cholecystitis occurred in 3.3% after EPBD and 18.5% after EST during mean follow-up period of 23 mo, and if limited to patients with cholecyst conserved, its frequency was 4.5%, and 29.4%, respectively, showing significant difference[13]. Yasuda *et al*[14] conducted retrospective study on late complications in EST and EPBD, and reported that stone recurrence/cholangitis occurred in 10.0% for EPBD, and 17.2% for EST and cholecystitis occurred in 2.0% for EPBD, and 8.8% for EST during median follow-up period of about 3 years (12-67 mo), showing incidence was high in EST with significant difference. Furthermore, Yasuda *et al*[51] reported the results of long term follow-up in patients of RCT[18] studying the short term results of EPBD and EST[51]. According to this, accumulated recurrence rate of stone recurrence/cholangitis was significantly higher after EST during median follow-up period of 6.7 years. These results suggest that whether papillary function can be conserved or not after treatment of the bile duct stones affects long term prognosis, particularly stone recurrence. In considering long term prognosis, a possibility is concerned that inflammation of the bile duct mucosa developed by back-flow of duodenal juice into the bile duct for a long time causes onset of cancer, particularly in patients who underwent EST. However, such a concern is denied by two population-based studies, and actually incidence of biliary cancer is as low as 0%-0.6% in the follow-up of mean 8-14 years after EST. Even in the follow-up of mean 4.4-9.3 years after EPBD, its incidence is

as low as 0%-0.2%, thus the relation between both papillary treatments and onset of biliary cancer may be negative[52,53].

CONCLUSION

For the treatment of bile duct stones, it is necessary to conduct papillary treatment, and the treatment used at the time is broadly classified into two types; EPBD and EST. Golden standard is EST, however, since there are patients difficult in conducting EST, it is necessary to select the procedure based on understanding of the characteristics of the procedure and patients background.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Safety of direct endoscopic necrosectomy in patients with gastric varices

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Abstract

AIM: To determine the feasibility and safety of transgastric direct endoscopic necrosectomy (DEN) in patients with walled-off necrosis (WON) and gastric varices.

METHODS: A single center retrospective study of consecutive DEN for WON was performed from 2012 to 2015. All DEN cases with gastric fundal varices noted on endoscopy, computed tomography (CT) or magnetic resonance imaging (MRI) during the admission for DEN were collected for analysis. In all cases, external urethral sphincter (EUS) with doppler was used to exclude the presence of intervening gastric varices or other vascular structures prior to 19 gauge fine-needle aspiration (FNA) needle access into the cavity. The tract was serially dilated to 20 mm and was entered with an endoscope for DEN. Pigtail stents were placed to facilitate drainage of the cavity. Procedure details were recorded. Comprehensive chart review was performed to evaluate for complications and WON recurrence.

RESULTS: Fifteen patients who underwent DEN for WON had gastric varices at the time of their procedure. All patients had an INR < 1.5 and platelets > 50. Of these patients, 11 had splenic vein thrombosis and 2 had portal vein thrombosis. Two patients had isolated gastric varices, type 1 and the remaining 13 had > 5 mm gastric submucosal varices on imaging by CT, MRI or EUS. No procedures were terminated without completing the DEN for any reason. One patient had self-limited intraprocedural bleeding related to balloon dilation of the tract. Two patients experienced delayed bleeding at 2 and 5 d post-op respectively. One required no therapy or intervention and the other received 1

unit transfusion and had an EGD which revealed no active bleeding. Resolution rate of WON was 100% (after up to 2 additional DEN in one patient) and no patients required interventional radiology or surgical interventions.

CONCLUSION: In patients with WON and gastric varices, DEN using EUS and doppler guidance may be performed safely. Successful resolution of WON does not appear to be compromised by the presence of gastric varices, with similar rates of resolution and only minor bleeding events. Experienced centers should not consider gastric varices a contraindication to DEN.

Key words: Necrosectomy; Pancreatic necrosis; Endoscopy; Necrotizing pancreatitis; Gastric varices; Varices; Walled off necrosis; Walled-off necrosis; Gastrointestinal hemorrhage; Endoscopic ultrasound

Core tip: In this retrospective cohort, 15 out of 90 patients (16.7%) presenting for endoscopic necrosectomy had gastric varices. When performed with best practice technique, direct endoscopic necrosectomy may be safely performed in patients with gastric varices. The best practice technique, from Thompson *et al*. Pancreatology, 2015 includes: (1) EUS evaluation with doppler to confirm absence of intervening vessels; (2) injection of contrast to distend collection and create wall tension for access; (3) stiff guidewire looped in cavity to mark access site for duration of the case; (4) entry into the cavity with stiff balloon catheter dilated to 4-8 mm, then 20 mm; (5) exchange for a large-channel endoscope for lavage and debridement of necrosis; (6) placement of pigtail catheters for ongoing drainage of the cavity; and (7) avoid proton pump inhibitor to encourage ongoing digestion of necrotic material.

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INTRODUCTION

Pancreatic walled-off necrosis (WON) may result from acute necrotizing pancreatitis. Direct endoscopic necrosectomy (DEN) has emerged as the treatment of choice supported by high resolution and low complication rates for WON[1-4]. In the patient with WON resulting from acute necrotizing pancreatitis, the presence of gastric varices must be carefully considered, as they may contribute to significant complications including intraprocedural and postprocedural hemorrhage. The prevalence of gastric varices in patients presenting for DEN is unknown, however bleeding is the most common serious adverse event associated with the procedure[1-3]. Gastric varices may be present in this patient population for at least two reasons, (1) local inflammation from necrotizing pancreatitis may result in splenic vein thrombosis and/or portal vein thrombosis leading to gastric variceal formation; or (2) a patient with alcoholic pancreatitis may have concomitant alcoholic cirrhosis leading to portal hypertension and development of gastric varices. Portal vein, splenic vein and mesenteric venous thrombosis is reported to occur in up to 53% of patients with severe acute necrotizing pancreatitis[5,6]. It is therefore possible that the presence and associated procedural risk of gastric varices is underappreciated in this patient population.

Computed tomography (CT) is often used to evaluate the complications of acute pancreatitis and is also used in the pre-procedural evaluation for DEN. CT has been reported to be extremely sensitive at detection of submucosal gastric varices at up to 100%, with good interobserver variability (κ = 0.90) for both variceal diameter and location[7]. While endoscopic evaluation outperforms external urethral sphincter (EUS) in detection of esophageal varices, data supports the opposite for detection of gastric varices, where EUS clearly outperforms the eye of the endoscopist[8].

Non-endoscopic therapies for WON include open and minimally invasive surgical drainage, as well as percutaneous interventional radiology drainage. One randomized control trial comparing endoscopic to surgical necrosectomy found that composite clinical endpoints and inflammatory markers were improved with DEN over surgical drainage[3]. Complications of surgical drainage may include intra-abdominal hemorrhage, which has been reported in 16%-44% of patients in surgical case series[9-11]. Percutaneous catheter drainage, with the poorest clinical success rates among the interventional treatment modalities, has reported bleeding complications ranging from 2%-4%[12,13].

As performance of DEN gains increasing popularity among gastroenterologists managing patients with symptomatic WON, it is important to determine relative and absolute contraindications to the procedure. The aim of this study is to determine the feasibility and safety of transgastric DEN in patients with WON and gastric varices, as this data is previously lacking.

MATERIALS AND METHODS

Population and outcomes

A single center retrospective study of consecutive DEN for WON was performed from 2012 to 2015. Patients were considered for DEN if they met radiographic criteria of a walled-off fluid collection along with presence of symptoms secondary to the collection, including; sepsis, abdominal pain, early satiety, intolerance of full oral diet, nausea and vomiting. All DEN cases with gastric

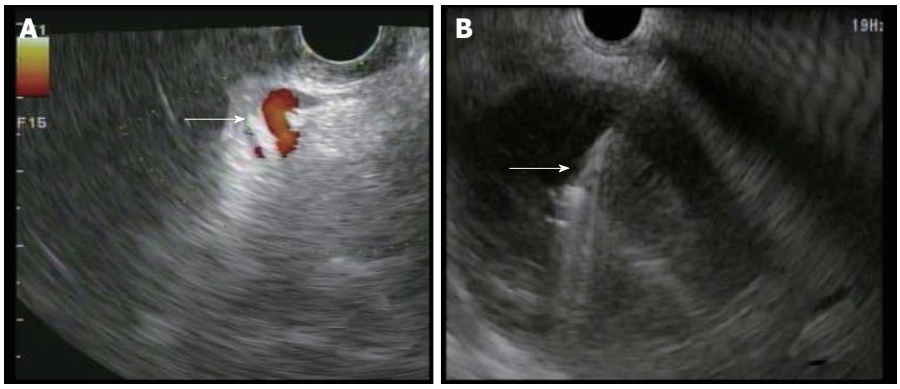

Figure 1 Endoscopic ultrasound of walled off necrosis. A: Doppler used to visualize any interventing vessels (arrow) including varices; B: FNA needle (arrow) seen entering necrotic cyst under EUS guidance. EUS: External urethral sphincter; FNA: Fine-needle aspiration.

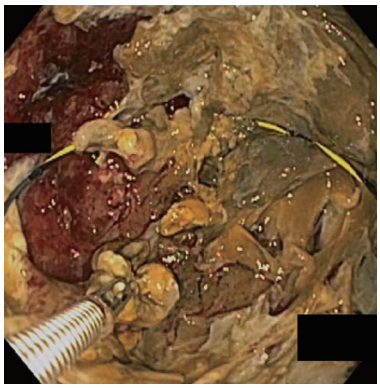

Figure 2 Endoscopic necrosectomy performed with debridement of the cyst cavity. Wire is seen coiled within the cyst to maintain access through the procedure.

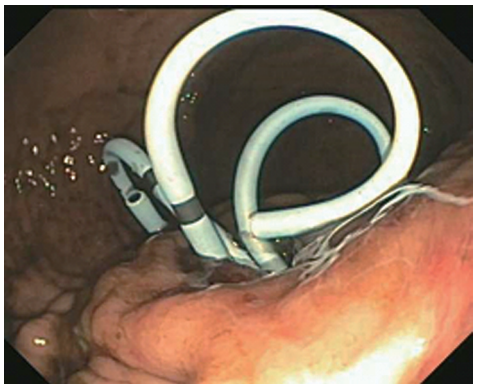

Figure 3 Pigtail stents left in place at the end of endoscopic necrosectomy to encourage ongoing drainage.

varices noted on endoscopy, CT or magnetic resonance imaging (MRI) during the admission for DEN were collected for analysis. Procedure characteristics including patient demographics, procedure characteristics, acute and delayed adverse events and clinical success were recorded. Clinical success was defined as complete resolution of the primary WON symptom leading to DEN, along with absence of any abdominal pain, early satiety, nausea, vomiting, markers of systemic inflammatory response (fever or hypothermia, leukocytosis or severe leukopenia, tachypnea, tachycardia) and bacteremia.

Direct endoscopic necrosectomy

In all cases, patients received general anesthesia and were intubated with endotracheal tube for mechanical ventilation and to provide airway protection. A linear EUS scope with color doppler (GIF-UC240P, Olympus, Tokyo, Japan) was used to exclude the presence of intervening gastric varices or other vascular structures prior to 19 gauge fine-needle aspiration (FNA) needle (Cook, Winston-Salem, NC) access into the cavity (Figure 1). Necrotic fluid was aspirated and sent for culture and gram stain. The cavity was injected with contrast for fluoroscopic visualization and to expand the cavity to compensate for the fluid previously removed. A stiff wire was advanced and coiled into the cavity and the needle was removed. The tract was serially dilated starting with a 4-mm Hurricane balloon (Boston Scientific, Natick, MA) continuing up to 20 mm with a radially expanding through-the-scope balloon (Boston Scientific). The echoendoscope was then exchanged for a larger channel therapeutic endoscope (GIF XTQ-160 or GIF 2T-160, Olympus) that was used to perform the remaining maneuvers for DEN. This larger channel scope was used to suction out all fluid from the cavity, and then immediate attention was turned to physical debridement of the necrotic material along the cavity walls using various tools including endoscopic retrieval net, forceps and snares until all loose debris was removed (Figure 2). Next 1 to 2L of warmed bacitracin-laden saline solution (25000 UI/L) was used to lavage the cavity. Finally, two to three, 10 French double-pigtail stents (Cook) were placed at the end of the procedure to facilitate ongoing drainage of the cavity (Figure 3). All patients were given two to four weeks of systemic oral antibiotic prophylaxis. Stents, by protocol, were removed at 6-8 wk after placement if they did not spontaneously migrate in that period of time. Follow up procedures for delayed bleeding, repeat DEN or stent retrieval were performed as indicated. Repeat DEN was performed only if patient-reported symptoms of an ongoing fluid collection were present, at which time

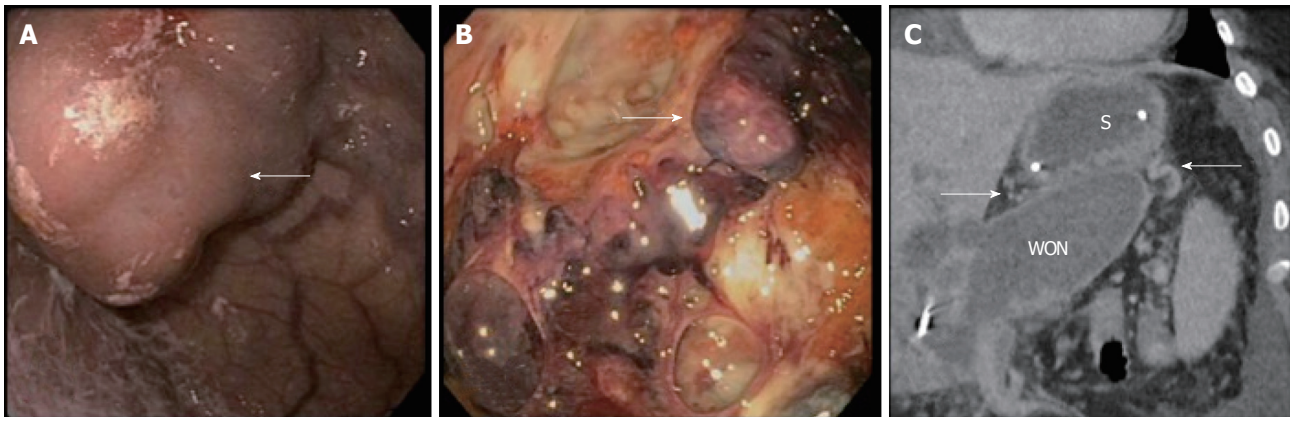

Figure 4 Varices identified through various methods. A: Large gastric varix (arrow) seen endoscopically; B: Peri-gastric varix (arrow) seen within the cyst cavity during endoscopic necrosectomy; C: Computed tomography scan showing gastric varices (arrows) in close proximity to the stomach (S) and walled off necrosis (WON).

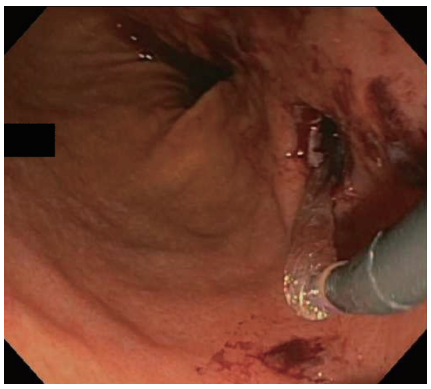

Figure 5 Status-post balloon dilation of the necrosectomy tract, shown with self-limited bleeding.

repeat imaging was used to confirm continued presence of a fluid collection prior to repeating the procedure. Procedure details were recorded retrospectively and comprehensive chart review was performed to evaluate for delayed complications and any recurrence of symptomatic WON occurring after the interval episode of pancreatitis.

RESULTS

Patient characteristics

Out of 90 patients undergoing DEN for WON between 2012 and 2015, a total of 15 patients (16.7%) were determined to have gastric varices at the time of their procedure (Table 1). Mean age was 47.1 years (range 27-62) and six patients (40%) were female. Etiology of pancreatitis leading to WON was alcohol in six patients (40%), gallstone disease in 5 patients (33%) and other/unspecified in four patients (27%). All patients had an INR less than 1.5 (mean 1.16) and platelets greater than 50000/μL (mean 237000/μL). Of these patients, 11 (73%) had splenic vein thrombosis, 2 (13%) had portal vein thrombosis, and two had no notable thrombosis on imaging. Large endoscopically visualized isolated gastric varices, type 1 were present in two patients (13%) and the remaining 13 (87%) had 5 mm or greater gastric submucosal varices identified on imaging by CT, MRI or EUS (Figure 4). No procedures were terminated early without fully completing the DEN.

Adverse events

One patient had self-limited intraprocedural bleeding noted upon balloon dilation of the necrosectomy tract (Figure 5). Two patients experienced delayed bleeding at two and five days post-procedure, respectively. One, diagnosed incidentally on the basis of blood seen on CT within the cyst required no therapy or intervention. The other, diagnosed on the basis of hemoglobin and hematocrit drop, received one unit transfusion of packed red blood cells and underwent EGD, which revealed no active bleeding. Some clot material was seen at the entrance to the necrosectomy cavity, suggesting that the source of resolved hemorrhage was within the cavity or emanating from the wall of the endoscopic necrosectomy tract.

Clinical resolution

Clinical success and resolution rate of WON in this patient cohort was 100% after up to two additional DEN procedures. One patient required two additional DEN procedures and four patients required one additional DEN for complete resolution of symptoms. No patients required interventional radiology or surgical interventions for complications of the procedure, or for management of the pancreatic necrosis. No patients required adjunctive endoscopic therapies including nasocystic irrigation or pancreatic duct stenting. A total of five patients underwent follow-up imaging after clinical resolution of WON with thrombosis and varices noted to have dissipated in two out of five patients (40%) over a range of 19-36 mo.

DISCUSSION

Gastric varices are common in patients referred for management of WON. Over 16% of our cohort

Table 1 Patient characteristics

Patient	Age	Sex	Etiology of pancreatitis	Presence of PVT/SVT	Platelet count (normal range 150-450)	INR (normal range 0.9-1.1)	Gastric varices type	Intraprocedural bleeding?	Postprocedural bleeding?	Any variceal bleeding reported?	Repeat therapy required?	Resolution of varices?[1]
1	37	F	Gallstone	SVT	185	1.0	IGV-1	-	-	-	DEN × 2	Unknown
2	44	F	Alcohol	SVT	235	1.3	SMV	-	-	-	DEN × 1	No (24 mo)
3	45	M	Alcohol	-	131	1.1	SMV	-	-	-	-	Unknown
4	39	M	Alcohol	PVT	256	1.4	SMV	-	-	-	DEN × 1	No (14 mo)
5	42	M	Gallstone	SVT	130	1.0	IGV-1	-	-	-	-	Unknown
6	60	F	Unknown	SVT	167	1.2	SMV	Minimal	-	-	-	Yes (36 mo)
7	27	M	Alcohol	SVT	248	1.0	SMV	-	-	-	-	No (32 mo)
8	82	F	Unknown	SVT	145	1.1	SMV	-	-	-	-	Yes (19 mo)
9	41	F	Gallstone	SVT	224	1.0	SMV	-	-	-	DEN × 1	Unknown
10	58	M	Unknown	SVT	252	1.2	SMV	-	Self-limited (seen in cyst on CT 5d later), no transfusion, no EGD	-	-	Unknown
11	62	F	Unknown	SVT	199	1.3	SMV	-	-	-	-	Unknown
12	42	M	Gallstone	SVT	151	1.2	SMV	-	-	-	-	Unknown
13	50	M	Gallstone	SVT	604	1.2	SMV	-	-	-	DEN × 1	Unknown
14	43	M	Alcohol	-	356	1.0	SMV	-	-	-	-	Unknown
15	35	M	Alcohol	PVT	276	1.4	SMV	-	Self-limited, 1u pRBC given. EGD: Clots on pigtail catheters no active bleeding	-	-	Unknown

[1]Time interval between procedure and last noted presence of varices. PVT: Portal vein thrombosis; SVT: Splenic vein thrombosis; IGV: Isolated gastric varices; SMV: Submucosal varices; DEN: Direct endoscopic necrosectomy; Male; F: Female.

undergoing DEN had gastric varices[1,3,10]. The outcomes in this cohort with gastric varices included similarly high clinical resolution rates and similarly low adverse event rates in line with previously reported DEN cohorts. This study suggests that patients with WON and known or suspected gastric varices may safely undergo DEN guided by EUS with doppler. In our cohort, successful resolution of WON using DEN does not appear to be compromised by the presence of gastric varices. A previously reported cohort of 60 patients undergoing DEN at our institution showed a clinical success rate of nearly 90%, with 3.3% major complication rate[1]. In this cohort of patients undergoing DEN with gastric varices, only minor bleeding events were seen, which did not meet criteria to be listed as a major complication. Importantly, no bleeding events involved puncture or trauma to a gastric varix, likely given the use of EUS doppler guidance when choosing the location of the necrosectomy tract. Furthermore, DEN may be the preferred treatment modality for WON in a population with gastric varices given the ability of EUS to detect submucosal varices, which are not seen when "blindly" accessing the cavity *via* a surgical or percutaneous route.

Limitations

The retrospective nature of this cohort study is a limitation and the fact that the study was performed in a multidisciplinary center of excellence could limit generalizability. We advocate performing this procedure at a center with DEN-trained endoscopists, and with capable surgical and/or interventional radiology services to manage any procedural complications or therapeutic failures should the need arise. Our single center experience with DEN is relatively robust in numbers, however larger numbers of pooled data would be helpful in making statistically powered clinical observations.

Another limitation to this study population includes the issue that patients should not be subjected to repeat imaging, including the inherent radiation exposure associated with CT, in the absence of symptoms. Because of this, our patients who were asymptomatic on follow up from their initial DEN did not undergo routine repeat

imaging, which limited our ability to comment with confidence on variceal resolution rate as well as radiographic resolution rate of the fluid collections. Instead, resolution of symptoms was used to define clinical success.

Future studies

In our study, 40% of patients who had follow up imaging after DEN had resolution of thrombosis and gastric varices. What role DEN may play in affecting recanalization rates of splanchnic venous thrombosis resulting in portal hypertension and gastric varices is unknown, and is an interesting question. Theoretically, this highly clinically effective procedure, with previously mentioned reductions in inflammatory markers as compared to other treatment modalities, may result in timely reduction of inflammation resulting in reabsorption of thrombosis and vessel recanalization. It is also possible that earlier DEN may reduce thrombotic sequelae of acute pancreatitis. This question should be studied in a larger patient population undergoing DEN.

In conclusion, use of EUS guidance appears to allow the endoscopist to safely avoid intervening gastric varices and bleeding complications, a necessity which both surgical and percutaneous interventional radiology techniques lack. As such, reduction in bleeding complications may be considered one advantage to an endoscopic approach to necrosectomy over other techniques. Experienced centers should not consider gastric varices a contraindication to DEN.

COMMENTS

Background

Increasingly minimally invasive techniques, including both percutaneous and endoscopic, have replaced surgery in the management of infected and symptomatic pancreatic necrosis. Pancreatitis may be associated with portal and splenic thrombosis leading to gastric varices, and is an important consideration in the bleeding risk when performing drainage procedures.

Research frontiers

The role of endoscopic management of pancreatic fluid collections has increased significantly over the past 10 years. The American Society for Gastrointestinal Endoscopy has recently published the first guideline statement regarding the flexible endoscopic management of inflammatory pancreatic fluid collections, available on the web at: http://www.asge.org/uploadedFiles/Publications_(public)/Practice_guidelines/Inflammatory_pancreatic_fluid_collections.pdf.

Innovations and breakthroughs

This is the first report suggesting a reasonably high prevalence of gastric varices (16.7%) in patients presenting to a tertiary care facility for endoscopic management of walled off pancreatic necrosis. This may have implications regarding the safety and best approach to resolution of these fluid collections in this patient population.

Applications

This study suggests a need for increased awareness of the relevance of gastric varices in the patient with pancreatic necrosis. The presence of varices should be considered when determining the best approach to managing these patients. Endoscopic ultrasound-guided access, with protocol driven debridement appears to be safe and feasible in this patient population.

Terminology

Walled-off necrosis (WON) is an inflammatory collection of debris and fluid that may form and persist after an episode of acute necrotizing pancreatitis. This collection may become infected, leading to sepsis and bacteremia, or may cause symptoms including abdominal pain, early satiety, anorexia, nausea and/or vomiting; direct endoscopic necrosectomy (DEN) is a per-oral procedure using flexible endoscopes to enter WON and provide debridement of non-viable and infected tissue to aid in resolution of the fluid collection and its associated symptoms.

Peer-review

The purpose of this paper is to determine the feasibility and safety of transgastric DEN in patients with WON and gastric varices. The results are feasible, safe and effective.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Place of upper endoscopy before and after bariatric surgery: A multicenter experience with 3219 patients

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Data sharing statement: The original anonymous dataset is available on request from the corresponding author at surg_latif@hotmail.com.

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Abstract

AIM: To study the preoperative and postoperative role of upper esophagogastroduodenoscopy (EGD) in morbidly obese patients.

METHODS: This is a multicenter retrospective study by reviewing the database of patients who underwent bariatric surgery (laparoscopic sleeve gastrectomy, laparoscopic Roux en Y gastric bypass, or laparoscopic minigastric bypass) in the period between 2001 June and 2015 August (Jahra Hospital-Kuwait, Hafr Elbatin Hospital and King Saud Medical City-KSA, and Mansoura

University Hospital - Egypt). Patients with age 18-65 years, body mass index (BMI) > 40, or > 35 with comorbidities after failure of many dietetic regimen and acceptable levels of surgical risk were included in the study after having an informed signed consent. We retrospectively reviewed the medical charts of all morbidly obese patients. The patients' preoperative data included clinical history including upper digestive symptoms and preoperative full workup including EGD. Only patients whose charts revealed weather they were symptomatic or not were studied. We categorized patients accordingly into two groups; with (group A) or without (group B) upper digestive symptoms. The endoscopic findings were categorized into 4 groups based on predetermined criteria. The medical record of patients who developed stricture, leak or bleeding after bariatric surgery was reviewed. Logestic regression analysis was used to identify preoperative predictors that might be associated with abnormal endoscopic findings.

RESULTS: Three thousand, two hundred and nineteen patients in the study period underwent bariatric surgery (75% LSG, 10% LRYDB, and 15% MGB). Mean BMI was 43 ± 13, mean age 37 ± 9 years, 79% were female. Twenty eight percent had presented with upper digestive symptoms (group A). EGD was considered normal in 2414 (75%) patients (9% group A *vs* 66% group B, $P = 0.001$). The abnormal endoscopic findings were found high in those patients with upper digestive symptoms. Abnormal findings (one or more) were found in 805 (25%) patients (19% group A *vs* 6% group B, $P = 0.001$). Seven patients had critical events during conscious sedation due to severe hypoxemia (< 60%). Rate of stricture in our study was 2.6%. Success rate of endoscopic dilation was 100%. One point nine percent patients with gastric leak were identified with 75% success rate of endoscopic therapy. Three point seven percent patients developed acute upper bleeding. Seventy-eight point two percent patients were treated by conservative therapy and EGD was performed in 21.8% with 100% success and 0% complications.

CONCLUSION: Our results support the performance of EGD only in patients with upper gastrointestinal symptoms. Endoscopy also offers safe effective tool for anastomotic complications after bariatric surgery.

Key words: Morbid obesity; Obesity surgery; Endoscopy; Complications; Dilation; Stenting

Core tip: It is still a major controversial point to do routine screening endoscopy for obese patients before surgery. Many authors suggest doing upper esophagogastroduodenoscopy (EGD) for all patients before bariatric procedures because of the lack of correlation between patient symptoms and EGD findings. On the contrary, many other investigators advocate selective approach for asymptomatic patients because of the relatively weak clinical relevance of the majority of the lesions discovered on routine EGD along with the cost and invasiveness of the EGD. The upper endoscopy is commonly indicated in the postoperative bariatric patient to evaluate post-bariatric symptoms, to detect and manage complications, as well as evaluation of failure of weight loss. Post-bariatric complications prompting upper endoscopy include bleeding, anastomotic or staple line leaks or fistulae, sleeve stricture in laparoscopic sleeve gastrectomy or stomal stenosis in laparoscopic Roux en Y gastric bypass, or laparoscopic minigastric bypass. We aimed in this retrospective study to answer if it is still necessary to do pre-bariatric screening endoscopy and to evaluate the efficacy and safety of the endoscopic therapy for management of post-bariatric complications.

Abd Ellatif ME, Alfalah H, Asker WA, El Nakeeb AE, Magdy A, Thabet W, Gheith MA, Abdallah E, Shahin R, Shoma A, Dawoud IE, Abbas A, Salama AF, Ali Gamal M. Place of upper endoscopy before and after bariatric surgery: A multicenter experience with 3219 patients. *World J Gastrointest Endosc* 2016; 8(10): 409-417 Available from: URL: http://www.wjgnet.com/1948-5190/full/v8/i10/409.htm DOI: http://dx.doi.org/10.4253/wjge.v8.i10.409

INTRODUCTION

Obesity represents a serious health problem in nearly the whole world[1-5]. Obesity surgery is the most effective treatment due to the sustainable and significant weight loss results in addition to the resolution of the comorbidities in up to 80%[6-8]. Upper digestive diseases are 2-3 times more common in obese then normal weight individuals, including erosive esophagitis, gastroesophageal reflux, hiatal hernia, Barrett's esophagus and *Helicobacter pylori* (*H. pylori*) infection[9].

It is still a major controversial point to do routine screening endoscopy for those patients before surgery[10]. There is evidence that some pathologic esophagogastroduodenoscopy (EGD) findings change the chosen procedure such as a large hiatal hernia or Barrett's esophagus. Many authors suggest doing EGD for all patients before bariatric procedures because of the lack of correlation between patient symptoms and EGD findings[11-15]. On the contrary, many other investigators advocate selective approach for asymptomatic patients because of the relatively weak clinical relevance of the majority of the lesions discovered on routine EGD along with the cost and invasiveness of the EGD[16,17]. One of the outmost important points is the risk of conscious sedation at the time of EGD due to hypertension and obstructive sleep apnea[18].

The upper endoscopy is commonly indicated in the postoperative bariatric patient to evaluate post-bariatric symptoms, to detect and manage complications, as well as evaluation of failure of weight loss. Post-bariatric

complications prompting upper endoscopy include bleeding, anastomotic or staple line leaks or fistulae, sleeve stricture in laparoscopic sleeve gastrectomy (LSG) or stomal stenosis in laparoscopic Roux en Y gastric bypass (LRYGB), or laparoscopic minigastric bypass (MGB). We aimed in this retrospective study to answer if it is still necessary to do pre-bariatric screening endoscopy and to evaluate the efficacy and safety of the endoscopic therapy for management of post-bariatric complications.

MATERIALS AND METHODS

Patients studied

This is a multicenter retrospective study by reviewing the database of 3219 patients who underwent bariatric surgery (LSG, LRYGB, or MGB) in the period between 2001 June and 2015 August (Jahra Hospital-Kuwait, Hafr Elbatin Hospital and King Saud Medical City-KSA, and Mansoura University Hospital - Egypt). The study was reviewed and approved by Mansoura Institutional Review Board. Local ethical committee approval for data base management was obtained at each hospital. Patients with age 18-65 years, body mass index (BMI) > 40, or > 35 with comorbidities after failure of many dietetic regimen and acceptable levels of surgical risk were included in the study after having an informed signed consent. Those patients who underwent routine EGD pre-bariatric and patients' charts revealed whether these patients were actually symptomatic before surgery. We excluded patients with prohibitive surgical risk, indications of lack of compliance with perioperative regimen, uncontrolled alcohol or drug abuse, uncontrolled depression or other mental disorders, and lack of family support or significant discord within the family about the planned surgery.

Preoperative data

All patients underwent detailed clinical history including upper gastrointestinal tract (GIT) symptoms, physical examination, and diagnostic work up including routine upper endoscopy. Only patients whose charts revealed weather they were symptomatic or not were studied. Upper digestive symptoms recorded included heartburn, reflux, acid regurgitation, nausea, vomiting and abdominal pain. We categorized patients accordingly into two groups; with (group A) or without (group B) upper digestive symptoms. The endoscopic findings were categorized into 4 groups based on predetermined criteria suggested by Sharaf *et al*[11]: (1) group 0: With normal EGD study; (2) group 1: If there were abnormal findings that neither changed the surgical approach nor postponed it; (3) group 2: Abnormal EGD findings that changed or postponed the surgical approach; (4) group 3: The abnormal findings that were absolute contra-indications to surgery. In case if there was more than one endoscopic finding, we considered the most significant lesion was the diagnosis (Table 1).

Table 1 Classification system for endoscopic findings

Group 0: No findings
Normal study
Group 1: Abnormal findings that do not change surgical approach/ postpone surgery
Mild esophagitis, gastritis, and/or duodenitis
Esophageal webs
Group 2: Findings that change the surgical approach/postpone surgery
Mass lesions (mucosal/submucosal)
Ulcers (any location)
Severe erosive esophagitis, gastritis, and/or duodenitis
Barrett's esophagus
Bezoar
Hiatal hernia (any size)
Peptic stricture
Zenker's diverticula
Esophageal diverticula
Arteriovenous malformations
Group 3: Absolute contraindications to surgery
Upper GI cancer
Varices

GI: Gastrointestinal.

Preoperative endoscopy was done routinely for all patients. Endoscopy was done by our experienced gastroenterology doctors using local throat anesthesia spray. Conscious sedation was done in some cases (if requested by the patient) with nasal oxygen supply and careful monitoring in presence of an anesthetist. Propofol was the standard sedation used which was extended to midazolam if needed. Esophagitis was graded according to the Savary-Miller classification[19]. Tissue biopsies for *H. pylori* were taken from the corpus and the antrum of patients following the American College of Gastroenterology guideline[20] and additional biopsies were taken if other abnormalities were seen. If *H. Pylori* was detected, eradication therapy was given for 1 wk (amoxicillin 750 mg *bid*, clarithromycin 500 mg *bid*, and omeprazole 40 mg once daily); the success of HP eradication was not assessed.

Postoperative data

The medical record of patients who developed stricture after bariatric surgery were reviewed for imaging results, time from surgery until symptoms onset, site of stricture, way of treatment, types gastrointestinal anastomosis in case of LRYGB or MGB (end or linear stapler or hand sewn). If endoscopic management was used; number of dilation sessions, diameter of the balloon used for dilation and duration till patient tolerate soft diet. Sleeves narrowing or stomas less than 10 mm in diameter, or if the scope failed to pass through were considered significant strictures and were treated with balloon dilations.

Data from patients who developed leak included: Methods used to detect and manage leaks, interval between surgery and leak, interval between detection and closure and type of stents used. Acute leaks were defined as those occurring within 7 d of the primary procedure, early leak from 1 to 6 wk of the

Table 2 Patient characteristics

Variable	Summary = 3219
Age	37 ± 9 yr
Female:male	79%:21%
BMI	43 ± 13
Haemoglobin	13 ± 4 g/dL
Upper GI symptoms: 902 (28%)[1]	
Heartburn	19.2%
Acid regurgitation	17.6%
Abdominal pain	7.3%
Nausea with or without vomiting	5.7%
Comorbedities: 1159 (36%)[2]	
Obstructive sleep apnea	4.9%
Hypertension	57.8%
Arthritis	56.9%
Diabetes mellitus	40.5%
Hypothyroidism	36.6%
Asthma/COPD	15.1%
Coronary artery disease	9.9%
Type of endoscopy	
Conscious sedation	354 (11%)
Local anesthesia spray	2865 (89%)
Type of bariatric procedure	
Vertical sleeve gastrectomy	2415 (75%)
Roux-en-Y gastricbypass	322 (10%)
Laparoscopic minigastric bypass	482 (15%)

[1]Some patients have more than one symptoms; [2]Some patients have more than one comorbidity. GI: Gastrointestinal.

Table 3 Endoscopic findings during routine upper gastrointestinal endoscopy and their prevalence

EGD findings	Group A (n = 902)	Group B (n = 2317)	P value
Esophagus			
Normal = 65%	19%	46%	0.001
Abnormal = 35%	25%	10%	0.001
Hiatal hernia	21.9%	7.9%	
Esophagitis	19%	6%	
Barrett's esophagus	1.1%	0.1%	
Stomach			
Normal = 77%	24%	53%	0.001
Abnormal = 23%	17%	6%	0.001
Spotty gastropathy	4%	1.3%	
Erythematous gastropathy	7%	2.5%%	
Erosive gastropathy	8%	1.2%%	
Atrophic gastropathy	1%	0.48%	
Multiple polyps	0.1%	0.02%	
Ulcer	2.4%	0.5%	
Duodenum			
Normal = 87%	23%	64%	0.001
Abnormal = 13%	9%	4%	0.001
Erythematous bulbopathy	6%	2.2%	
Erosive bulbopathy	2.6%	1%	
Ulcer	1.4%	0.8%	
+ve biopsy for *H. pylori*, 407 (14.6%)	10.7%	3.9%	0.001

EGD: Esophagogastroduoudenoscopy; *H. pylori*: *Helicobacter pylori*.

primary procedure, late leak after 6 wk of the primary procedure. Post-bariatric hemorrhage was defined as patients who presented with hematemesis and/or melena with significant hemodynamic changes including one or more of increase in heart rate > 20 beat/min, decrease in systolic blood pressure > 20 mmHg, significant drop in hemoglobin > 2 g/dL or endoscopic signs of active or recent bleeding.

Statistical analysis

Continuous variables were compared using a Student *t* test or a nonparametric test, as appropriate. Categorical variables were compared using the χ^2 or Fisher's exact test. A two-tailed $P < 0.05$ was considered statistically significant. All data are expressed as mean (SD). Statistical analysis was performed using a commercially available software package (SPSS version 11.5 for Windows; SPSS Inc, Chicago, IL). Logestic regression analysis was used to identify preoperative predictors that might be associated with abnormal endoscopic findings.

The primary outcome of this study was to compare prevalence of clinically significant lesions found on upper endoscopy before bariatric surgery in patients who have (group A) or do not have (group B) upper digestive symptoms. Secondary outcome was to evaluate the safety and efficacy of upper endoscopy to diagnose and treat post-bariatric surgery complications such as bleeding, leakage and stenosis.

RESULTS

During the study period, 3219 patients underwent bariatric surgery [2415 (75%) LSG, 322 (10%) LRYDB, and 482 (15%) MGB]. Mean BMI was 43 ± 13, mean age 37 ± 9 years, 79% were female and 36% had co-morbid diseases (Table 2). Nine hundred and two (28%) had presented with upper digestive symptoms, with the most common symptoms being heartburn (19.2%), acid regurgitation (17.6%), abdominal pain (7.3%), and nausea with or without vomiting (5.7%).

EGD was considered normal in 2414 (75%) patients [9% (group A) *vs* 66% (group B), P = 0.001]. Abnormal findings (one or more) were found in 805 (25%) patients [19% (group A) *vs* 6% (group B), P = 0.001]. Small hiatal hernia was the most common findings (29.7%) followed by gastritis (23%), esophagitis (15%) and Barrett's esophagus (1.2%). Benign polyps and ulcers were detected in (0.12%) and 2.9%, respectively (Table 3). The prevalence of endoscopic findings using Sharaf *et al*[11] classification system was as follows: Group 0 (65%), group 1 (18.2%) [9.2% (group A) *vs* 8.9% (group B), P = 0.43], group 2 (6.8%) [5.2% (group A) *vs* 1.6% (group B), P = 0.001], and group 3 (0.0%). In no patients were upper GIT cancers or esophageal varies identified. Thirteen percent underwent EGD in supine position instead of standard left lateral position due to their body weight.

Findings of endoscopy had clinical consequences in 219 (6.8%) patients as showed in (Table 4): Patients with hiatus hernia required crural repair and reduction of the hernia, gastric ulcers, doudenal ulcer operation postponed and medications prescribed till full healing was checked by follow up endoscopy. *H. pylori* was assessed at histopathological examination in 493 (15.3%) patients, and was positive in 407

Table 4 Lesions identified on upper endoscopy and impact on bariatric surgery, *n* = 219 (6.8%)

Lesion	Group A	Group B	Result
Hiatal hernia	25%	10%	Crural repair/reduction of hernia
Gastritis	17%	6%	Medical treatment, postpone surgery
Esophagitis	19%	6%	Medical treatment, postpone surgery
Gastric ulcer	2.4%	0.5%	Await biopsy results, medical treatment, repeat endoscopy
Barrett's esophagus	1.1%	0.1%	Await biopsy results, medical treatment, repeat endoscopy
Duodenal ulcer	1.4%	0.8%	Await *Helicobacter pylori* results, medical treatment

Table 5 Univariate analysis of clinical predictors of abnormal upper endoscopy

Variables	Total population	Normal EGD (65%)	Abnormal EGD (35%)	*P* value
Age (yr)	37 ± 9	31 ± 9	43 ± 10	0.26
BMI	43 ± 13	43 ± 11	47 ± 16	0.09
Gender (F:M)	79%:21%	64%:36%	69%:31%	0.17
GIT symptoms	13.80%	72%	28%	0.001
Haemoglobin (g/dL)	13 ± 4	13 ± 3.4	11 ± 3.2	0.07
Comorbidities	36%	52%	48%	0.18

F: Female; M: Male; EGD: Esophagogastroduodenoscopy; BMI: Body mass index; GIT: Gatrointestinal tract.

[14.6% (10.7% in group A *vs* 3.9% in group B, P = 0.001)] of them. Polyps removed from stomach came histopathologically to be hyperplastic polyps. Conscious sedation was used in 354 (11%) on patient request. Those patients were observed for a minimum of 12 h after the endoscopy. Seven (1.97%) patients had critical events during conscious sedation due to severe hypoxemia (< 60%). They received oxygen insufflation *via* ambu bag, endo-tracheal intubation was necessary in no one. No other critical events, such as aspiration or severe hypotension, occurred. Six hundred and twelve (19%) of our patients, EGD showed presence of esophagitis with GERD symptoms. Of those patients, 307 (9.7%) underwent LSG whose GERD symptoms improved in 217 (70.7%) and worsen in 90 (29.3%). Total number who developed *de novo* GERD was 197 (8.2%) during the 1st year which declined significantly to 48 (2%) after 3 years of their follow up.

Multivariate logestic regression analysis was used to identify clinical predictors that might be associated with abnormal EGD. Univariate analysis demonstrated that 6 independent variables were associated with abnormal endoscopic findings: Age, gender, preoperative BMI, co-morbidities, anaemia and GIT symptoms. The upper digestive symptoms were predictive for presence of abnormal endoscopic finding ($P \leqslant 0.001$). No significant differences were observed in age, gender, preoperative BMI, co-morbidities or anaemia. Univariate (Table 5) and multivariate regression analysis (Table 6) established that presence of GIT symptoms was the only clinical variable associated with abnormal endoscopic findings (OR = 2.649; 95%CI: 1.904-3.684) with $P \leqslant 0.05$.

Fifty-four (2.2%) patients after sleeve had stricture at the site of incisura (47/54) or at the gastro-esophageal junction (7/54). Stomal stenosis developed in 16 (4.7%) patients after LRYGB and 15 (3.2%) after MGB. They have been diagnosed by contrast study and confirmed and treated by EGD. The Endoscopic dilation was done *via* through the scope balloon dilation. The mean time from surgery to initial endoscopic dilation was 59 ± 9 d. The mean number of dilations was 1.7, and the median balloon size was 15 mm. The mean time from the first dilation to toleration of a soft diet was 31 ± 7 d. Success rate for endoscopic intervention was 100% with no complications. None of our patients required operative revision to correct the symptomatic stenosis. One hundred and ninety (3.7%) patients had postoperative GIT bleeding in form of drop of hemoglobin or overt melena and hypotension. Seventy-eight point two percent patients were just treated conservatively. Twenty-one point eight percent patients required endoscopic management in form of adrenaline injection, no one required surgical treatment.

Sixty-one (1.9%) patients had leak; 49 (2.02%) after sleeve (all of them had leakage from gastro-esophageal junction), 5 (1.55%) after LRYGB and 7 (1.45%) after MGB. Twenty-six patients had acute leak; leak site suture was successful in 19/26 patients and gastrostomy tube was placed in 7 patients. All of them were treated by laparoscopic reoperation, thorough washout and drainage. Fourteen cases with early leak were managed successfully with endoscopic wallstent and percutaneous drainage. The other 21 patients had late leak; 11 patients were managed by endoscopic wallstent and percutaneous drainage. One of those patients, gastrograffin study on the 5th day showed leakage which was unsuccessfully treated by one more stent at the same day. His problem has been finished by gastrectomy and oesophagojejunostomy. Ten patients without signs of uncontrolled sepsis were treated non-operatively. Four of these patients required only maintenance of the operatively placed suction tube. Percutaneous drainage was done in 43 patients. Endoscopic clips in 14 patients for chronic leak. A total of 74 stents were placed in our patients (some patients required more than one stent). Success rate was 75%. Forty-three of these were polyester based (Polyflex) and 31 were nitinol based (Alveolus). Migration occurred in 27% stent placements.

One hundred and nineteen (3.7%) patients developed post-operative hemorrhage out of total 3219. Seventy-nine patients had one episode of bleeding, 29 had two episodes and 11 had three episodes, for a total 170 episodes of bleeding. Hematemesis was the predominant manifestation. Table 7 shows the clinical and endoscopic findings of these bleeding episodes. All

Table 6 Multivariate regression analysis of clinical predictors of abnormal esophagogastroduodenoscopy

Variables	OR	95%CI	*P* value
Age	1.414	0.772-2.59	0.26
BMI	1.092	0.923-1.723	0.38
Gender	0.225	0.028-1.826	0.162
GIT symptoms	2.649	1.904-3.684	0.001
Comorbidities	0.68	0.335-1.381	0.286
Anaemia	0.945	1.241-2.093	0.274

OR: Odds ratio; GIT: Gastrointestinal tract symptoms; BMI: Body mass index.

of these endoscopic procedures have been performed in operative rooms with the patients intubated.

DISCUSSION

The role of routine EGD before bariatric surgery still remains unclear. So far, this study is the largest series trying to find answer for this question. Many authors suggest doing EGD for all patients before bariatric procedures because of the lack of correlation between patient symptoms and EGD findings[11-15]. On the contrary, many other investigators advocate selective approach for asymptomatic patients because of the relatively weak clinical relevance of the majority of the lesions discovered on routine EGD along with the cost and invasiveness of the EGD[16,17].

Only patients whose medical charts revealed if upper gastrointestinal (GI) symptoms recorded were enrolled in the study. Prevalence of upper GI symptoms in morbidly obese patients ranges from 10% to 87%[21-24]. Upper GI symptoms were present in 28% of our patients. We have found, opposite to others[25,26], strong correlations between patients symptoms and endoscopic findings. EGD was considered normal in 75% patients (9% group A *vs* 66% group B, $P = 0.001$). Abnormal findings (one or more) were found in 25% patients (19% group A *vs* 6% group B, $P = 0.001$). Küper *et al*[14] found that 80% of the patients with pathological findings are asymptomatic.

Our study showed that no EGD findings were absolute contraindications to surgery or changed the decision plans and findings of endoscopy had clinical consequences in 6.8% (5.2% group A *vs* 1.6%, $P = 0.001$) patients as showed in Table 4: Patients with hiatus hernia required crural repair and reduction of the hernia, gastric ulcers, duodenal ulcer operation postponed and medications prescribed until full healing was checked by follow-up endoscopy. The majority of preoperative EGD findings were benign or mild and of little clinical consequence and the abnormal EGD findings were found to be high in those patients who had upper GIT symptoms. In 93.2% of patients, the EGD findings were either entirely negative or had no effect on the preoperative management or choice of surgery. We found in this study that it might not be wise to expose those morbidly obese patients to routine invasive uncomfortable procedure which carries potential risk although it is minimal. We do not screen the general population for those minor EGD findings; so why should we do it on people planned for bariatric surgery?

Table 7 Clinical and endoscopic characteristics of bleeding episodes

	1st episode *n* = 119	2nd episode *n* = 40	3rd episode *n* = 11
Presentation			
Hematemesis	93	33	5
Melena	39	19	9
Hypotension	17	3	-
Management			
EGD	28	7	-
Observation	91	33	11
Blood transfusion	43	19	3
Prominent findings on EGD			
Active blood oozing	17/28	7/3	
Bleeding vessel	28/6	7/4	
Adherent clot	28/4	-	
Other findings (visible vessel, red streaks, *etc.*)	28/4	-	
Endoscopic therapy			
Epinephrine injection	10	5	
Heater probe	9	4	
Clip	7	3	

EGD: Esophagogastroduodenoscopy

EGD was indicated if LSG is planned because of the idea that LSG increases prevalence of GERD. Some showed an increase in prevalence[27-29] and on opposite, some found reduced prevalence of GERD after sleeve[30-32]. LSG may promote GERD by reducing LES pressure, reduced gastric compliance and distensibility and increased gastric pressure[33]. Factors that thought to reduce GERD after LSG include; accelerated gastric emptying, weight loss, reduced acid production and fundal resection which is considered the source of relaxation waves to the lower esophageal sphincter[32]. Scott *et al*[34] found that overall GERD symptoms are not more common in patients who have had LSG *vs* LRYGB. Six hundred and twelve (19%) of our patients, EGD showed presence of esophagitis with GERD symptoms. Of those patients, 307 (9.7%) underwent LSG whose GERD symptoms improved in 217 (70.7%) and worsen in 90 (29.3%). Total number who developed *de novo* GERD was 197 (8.2%) during the 1st year which declined significantly to 48 (2%) after 3 years of their follow up. These data in addition to others[30-32] confirm that presence of GERD could not be considered as a contraindication for LSG.

In gastric bypass surgery, the EGD was routinely done because the rest of the stomach will be out of reach of endoscopy, for our countries risk of gastric cancer is low and there is no regular screening program for gastric cancer in the normal population; so why would we screen bariatric patients for gastric cancer? Moreover, only the gastric remnant is excluded in gastric bypass, but access to esophagus and possibility

of controlling esophageal abnormalities still remains. We have 1% Barrett's esophagus without dysplasia. Barrett's esophagus can be diagnosed, followed up and even treated after all types of bariatric surgery because for all types the access to the esophagus still remains.

Incidence of gastrointestinal stomal anastomotic stenosis occurs in 5.1%-6.8% of patients following laparoscopic R-Y gastric bypass and most commonly presents within the first year after surgery[35]. The incidence of this anastomotic stenosis has been found to be technique dependent. The circular stapled anastomoses have been reported to have higher rate anastomotic strictures more than the linear stapled anastomoses[36]. Hand sewn technique yield the lowest rate of anastomotic stricture[35]. Endoscopic balloon dilation is the mainstay of treatment of these anastomotic strictures. In our study, rate of success endoscopic dilation of stomal stricture was 100% with no complications. We found stenosis rate after LSG is 1.6% comparable to the previously reported in other studies[37,38]. We have found, as have others[37] that the incisura angularis is the place with the greatest potential place for stricture development. The possible reason for this organic stricture could be if stapling has been accidentally performed too close to the insisura creating too tight sleeve in spite of the bougie is in place. Functional stenosis occurs if the gastric tube got twisted due to asymmetrical traction. Symmetrical lateral traction while stapling is of the utmost importance.

Leaks after LSG are reported to occur in 1.4%-5.3% of cases[38-41] and 1%-5% after LRYGP[42,43]. In a previous study over 1395 patients who had LSG, we found that neither the distance of the first stapler from the pylorus nor the caliber of the bougie was related to postoperative leak, the same finding we noticed also regarding reinforcement of the suture line[44]. Management options are varied and dependent on the timing and clinical presentation of the leak. Immediate re-operation is the preferred course of action for the unstable patient, usually with washout, irrigation of the abdominal cavity, wide drainage, and an attempt at suturing of the leak if the tissue condition allows it[9]. Sound surgical judgment is imperative in deciding whether the tissues are amenable to suturing or whether further intervention will only impose further damage. Endoscopic stent treatment could have a major impact on managing anastomotic complications after bariatric surgery. Standard treatments are time-consuming and can result in substantial morbidity, including patient discomfort and decreased quality of life. It is our impression that stents will shorten hospital stays and reduce complications of specialized feeding. Care will likely be improved as stent manufacturers customize stents for use in bariatric surgery. Our data suggest that the use of covered stents after bariatric surgery can be safe and effective in the treatment of acute leaks, chronic fistulas, and strictures. These stents effectively seal any leak while allowing secretions and food to pass, without compromising healing. We believe the use of endoscopically placed stents will become the preferred treatment for bariatric patients with staple line complications.

Upper GI hemorrhage occurs in approximately 1%-4% patients after LRYGP[45]. This hemorrhage usually arises from staple line. We have 3.7% incidence of upper GI hemorrhage. All patients were successfully controlled with observation or endoscopic management, no patient required re-operation for control of bleeding, thus avoiding exposure of these morbidly obese patients for another major surgery with its potential morbidity. Conservative treatment with fluid and blood transfusion is usually effective. Patients who will not respond to conservative therapy will require either endoscopic or surgical management. Some recommend against endoscopy for fear of perforation at the immature anastomotic sites[46]. The availability of standard hemostatic endoscopic measures, such as epinephrine injection, heater probe, and endoscopic clips, either alone or in combinations, made the success of endoscopic management available in all our patients. The majority of our patients manifested with hematemesis, which may place these patients at a high risk of aspiration. All our patients were managed in the operative room with pre-endoscopy intubation to avoid possibility of aspiration. We have reported, as others have, that endoscopy could be used in controlling postoperative bleeding with good experienced hands and enough precautions[47-49]. Despite the relatively big number of patients we enrolled in this study, this study is not without limitations. While it is a review of prospectively collected data, it is still retrospective in nature. Additionally, there was no randomization in allocating the patients into either group. We recommend another study to be conducted on a prospective randomized way.

In conclusion, the upper digestive symptoms were predictive for presence of abnormal endoscopic finding. These endoscopic findings were found to be benign and mild. No findings were absolute contraindications to surgery or changed the decision plans. Our results support the performance of EGD only in patients with upper gastrointestinal symptoms. Endoscopy also offer safe effective tool for anastomotic complications after bariatric surgery. Endoscopic dilation of stricture is safe and effective with high success rate. Endoscopic therapy for gastric leak using covered stent is also a good option and should be considered an appropriate intervention. Most post-bariatric bleeding occurs within the first 4 h after the operation and is most commonly arising from the staple line. With experienced hands, EDG is a safe and successful tool in controlling significant post-operative hemorrhage which is best done in operative room with intubation to avoid aspiration.

COMMENTS

Background

Obesity surgery is the most effective treatment due to the sustainable and

significant weight loss results in addition to the resolution of the comorbidities in up to 80%. It is still a major controversial point to do routine screening endoscopy for those patients before surgery. Many authors suggest doing esophagogastroduodenoscopy (EGD) for all patients before bariatric procedures because of the lack of correlation between patient symptoms and EGD findings. Upper endoscopy in those patients is not without risk, one of the outmost important points is the risk of conscious sedation at the time of EGD due to hypertension and obstructive sleep apnea.

Research frontiers

The authors supposed that the upper digestive symptoms were predictive for presence of abnormal endoscopic finding and they provide support to their hypothesis with this paper.

Innovations and breakthroughs

Upper endoscopy was routinely done as a routine preoperative preparation of every obese patient before bariatric operation.

Applications

The upper digestive symptoms were predictive for presence of abnormal endoscopic finding. These endoscopic findings were found to be benign and mild. No findings were absolute contraindications to surgery or changed the decision plans. The results support the performance of EGD only in patients with upper gastrointestinal symptoms. Endoscopy also offer safe effective tool for anastomotic complications after bariatric surgery. Endoscopic dilation of stricture is safe and effective with high success rate. Endoscopic therapy for gastric leak using covered stent is also a good option and should be considered an appropriate intervention. Most post-bariatric bleeding occurs within the first 4 h after the operation and is most commonly arising from the staple line. With experienced hands, EGD is a safe and successful tool in controlling significant post-operative hemorrhage which is best done in operative room with intubation to avoid aspiration.

Terminology

Upper digestive symptoms recorded included heartburn, reflux, acid regurgitation, nausea, vomiting and abdominal pain. Esophagogastroduodenoscopy is a test to examine the lining of the esophagus, stomach and upper part of the duodenum. Laparoscopic sleeve gastrectomy is a safe and effective surgery that can help obese people lose weight. Patients may undergo sleeve gastrectomy as a single surgery or the first stage before a gastric bypass. Laparoscopic R in Y gastric bypass surgery makes the stomach smaller and causes food to bypass part of the small intestine. Mini gastric bypass surgery is a short and relatively simple procedure that has been shown by the available research to have low risk and result in good short and long-term weight loss.

Peer-review

The article is aimed to study the preoperative and postoperative role of upper endoscopy in morbidly obese patients. The clinical application of the study is very important.

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