Biliary Stenting in the Management of Large or Multiple Common Bile Duct Stones


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Endoscopic biliary stenting with a plastic stent is often performed to prevent impaction of common bile duct (CBD) stones. The therapeutic effect of a plastic stent placement in terms of reduction in stone size and number is however controversial. In this retrospective, single-center study, the authors evaluated the effect of biliary stenting as a therapy for CBD stones. They included 40 patients with large (>20 mm) and/or multiple (>3) stones, and placed a single 7F double-pigtail plastic stent without stone extraction at the initial ERCP. Twenty-two included patients had multiple CBD stones, and 20 patients had large stones. Stone extraction was not attempted because these patients were judged to be an ‘increased risk’ (either because of advanced age, or because of the use of anticoagulant and/or antiplatelet agents). No oral dissolution agent like Ursodeoxycholic acid (UDCA) was co-prescribed. Approximately 2 months later sphincterotomy was performed and stone removal was attempted. The number and size of CBD stones before and after stent placement, stone clearance, complications, and 180-day mortality were evaluated. The authors also defined the parameter of stone index as the summation of stone diameter(cm) X the number of stones. This scale was designed to express changes in both the number and the size of CBD stones. As stones fragment, the stone number can actually increase and the stone index provides a convenient method of measuring the reduction in stone burden after stenting.

The duration of stent placement averaged 65 days (range: 50-82 days). The median number (interquartile range) of stones per patient fell after stent placement (4.0 [3.0] before vs. 2.0 [1.0] after; p < 0.0001). Characteristically, larger stones became smaller and small stones disappeared. The median stone index decreased from 4.6 [3.0] to 2.0 [1.5] (p<0.0001). Stone clearance at the second ERCP was achieved in 37 out of 40 patients (93%). Complications included cholangitis (13%) and pancreatitis (5%) after the second ERCP. No 180-day mortality occurred.

The authors concluded that stent placement for 2 months was associated with large and/or multiple CBD stones becoming smaller and/or disappearing without any complications. They suggest that stenting followed by a wait period may assist in difficult CBD stone removal.

Commentary

This is not the first study that has proposed the use of therapeutic stenting for bile duct stones. Three earlier studies have found that indwelling endoprosthesis may be associated with a decrease in stone size and/or stone fragmentation.

Chan et al reported 46 patients with large CBD stones, who were managed by endoscopic stenting over a 6-year period. Of the 28 patients who underwent a second ERCP after a median period of 63 days (range: 17-1002 days), the largest diameter of the stones was found to have reduced from a mean of 24.9 mm to 20.1 mm.

Jain et al prospectively managed 20 patients with ‘difficult to extract’ bile duct stones, by placing a 7F double-pigtail stent in the bile duct for 6 months. After repeat ERCP at 6 months, 35% patients had no stones, 20% patients had small stone fragments that were easily extracted, and 30% patients continued to have large stones.

Similarly, Katsinelos et al reported that in 11 of 25 (44%) patients there was reduced size or fragmentation of stones after a period of biliary stenting, allowing their endoscopic removal.

What could be the explanation for the reduction in stone index with stenting? The authors postulate that friction between the plastic stent and stones, influx of duodenal contents, or both, may be responsible for their observations.

So what message can we take from the current and the previous studies? Should it be ‘stent and forget’ for CBD stones from now? Definitely not! Several limitations of the current and previous studies need to be considered. All but one of these studies were retrospective, and included self
Complications of Single-balloon Enteroscopy: A Prospective Evaluation of 166 Procedures

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The complication rate after double-balloon enteroscopy (DBE) is 1%. The main concern after diagnostic DBE is acute pancreatitis. Until now, no case of pancreatitis has been reported after single-balloon enteroscopy (SBE). In this study from Erasmus University Medical Center, Rotterdam, Netherlands, the authors sought to prospectively evaluate the complication rate and frequency of post-

procedure hyperamylasemia after SBE. Consecutive patients undergoing peroral (“proximal”) or combined approach SBE were included. A total of 166 SBE procedures were performed in 105 patients (53 male; mean age: 51 years; range: 9 – 87 years). The indications for SBE were: anemia (n = 55), Crohn’s disease (n = 31), suspicion of inflammatory bowel disease (n = 5), Peutz-Jeghers syndrome (n = 1), and others (n = 13). The mean total procedure time was 70 minutes (range: 30 – 120 minutes). Therapeutic interventions were performed during 21 (13%) procedures. Serum amylase and C-reactive protein (CRP) were assessed immediately before and 2 – 3 hours after SBE. Acute pancreatitis was defined as typical pancreatic abdominal pain persisting for several hours, in association with hyperamylasemia (serum amylase above the normal upper limit).

One perforation (1 of 21 therapeutic interventions, 4.8%) occurred after dilation of a benign stricture. While 13 patients (16%) had post-SBE hyperamylasemia, none had complaints suggesting acute pancreatitis. Factors such as gender, indication, procedure duration, number of passes, route of SBE, endoscopic findings, and/or treatment showed no significant correlation with occurrence of hyperamylasemia. The authors conclude that SBE appears to be a safe diagnostic endoscopic procedure. The incidence of hyperamylasemia and pancreatitis after peroral SBE seems comparable to that reported after DBE.

Commentary

The major complication reported after diagnostic DBE is acute pancreatitis, occurring in 0.3% of cases. It has been suggested that the inflation of two balloons in the duodenum results in an increase of intraluminal pressure, leading to reflux of duodenal fluids into the pancreatic duct, direct obstruction of the pancreatic duct by the insufflated balloon(s), or repeated ‘push- and-pull’ with stretching of the small intestine, can lead to pancreatitis. So far no cases of acute pancreatitis have been reported after SBE. It is possible that the lower incidence of acute pancreatitis after SBE might be because of the lower intra-duodenal pressure with this technique, which uses only one balloon.

In the three published SBE series so far, the overall risk of perforation has been 0% to 2.3% of procedures. This may be a higher complication rate compared with the perforation rate reported after diagnostic DBE (0.3%). Perforations after SBE were caused by advancing the overtube, either with the tip of the scope being angulated or over an anastomotic stricture. These preliminary data might suggest that the hook-shaped tip of the SBE enteroscope is more dangerous than the ballooned tip of the DBE enteroscope. However, the perforation in the current study was related to the dilation of a post-radiation stricture and not to the enteroscopy technique.

The present study, and the above mentioned data suggest that the perforation rate may be slightly higher with
SBE, while the incidence of acute pancreatitis may be higher with DBE. The overall incidence of hyperamylasemia may be similar, and is mostly asymptomatic and without any clinical consequence. However, we must remember that neither this, nor any previous study was a randomized head-to-head comparison of SBE and DBE techniques. Nevertheless, there is now sufficient published data to conclude that SBE is safe for diagnostic evaluation and endoscopic therapy of the small bowel. The observed incidence of hyperamylasemia and acute pancreatitis in the present study suggests that with SBE, the frequency of injury to the pancreas and small bowel seems to be similar to or even lower than that associated with the DBE technique.

References

Effect of the BioEnterics Intragastric Balloon on Weight, Insulin Resistance, and Liver Steatosis in Obese Patients


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In this prospective, single-center study from Italy, the investigators evaluated the effectiveness of BioEnterics intragastric balloon (BIB) insertion on weight control and amelioration of components of the metabolic syndrome. The authors recruited 130 obese patients with a mean (SD) weight of 118 (24) kg, and mean (SD) body mass index (BMI) of 43 (8) kg/m$^2$. The mean (SD) age of patients was 38.6 (12) years, and the majority were female (64%). Patients with active peptic ulcer, previous gastric surgery, large (>5 cm) hiatus hernia, eating disorders, and ongoing alcohol use were excluded.

All patients were hospitalized, and the procedures were done with propofol sedation. A preliminary upper endoscopy was first performed to exclude pathologic lesions. Thereafter, the balloon was passed into the gastric fundus and inflated with a saline solution infusion (500 mL) mixed with methylene blue (10 mL). The time taken for for BIB placement ranged from 10-20 minutes. Intravenous hydration, antemetics, antispasmodics, and acid suppression therapy was given to all. In the 48 hours after BIB insertion, 60% of patients reported nausea, vomiting, and mild abdominal pain, which were successfully managed by medical therapy in the majority of cases. During the 6 months after the procedure, patients were maintained on balanced solid food diet of 1000 to 1200 kcal per day.

Of the 130 patients, 10 (8%) required early balloon removal. Blowout of the balloon occurred in one patient after 3 months, and required removal. Overall, the mean (SD) weight and BMI decreased by 13.2 (8.2) kg and 5.1 (3.2) kg/m$^2$, respectively, compared with baseline. The mean fasting glucose and insulin levels, Homeostasis Model Assessment index (HOMA), triglyceride levels, and alanine aminotransferase (ALT) levels were significantly reduced. In the 91 responders (defined by a BMI decrease of > 3.5 kg/m$^2$), the mean (SD) weight and BMI decreased by 16.4 (6.3) kg and 6.4 (2.3) kg/m$^2$, respectively, and severe liver steatosis decreased from 52% to 4% ($p<0.0001$). After a median follow-up of 22 months after BIB removal, 50% of responders maintained or continued to lose weight.

The authors concluded that BIB treatment is effective in inducing weight loss, improving liver steatosis, and restoring some components of the metabolic syndrome.

Commentary

The authors predefined therapeutic response as a BMI decrease of > 3.5 kg/m$^2$. Of the 120 patients who had the BIB in place for the entire 6-month period, 91 (76%) achieved a therapeutic response. The absolute percentages of participants achieving 5% and 10% weight loss thresholds were 23% and 57%, respectively. Weight loss was accompanied by improvements in serum values of glucose, insulin, triglycerides, ALT, and the HOMA index. No substantial improvement in the above-mentioned metabolic parameters was found in the non-responders. All patients were followed with medical, dietary, and exercise supervision for a median of 22 months (range 14-26 months) after BIB removal. Of note, among the responders, all but 3 patients were compliant with diet and exercise. At the end of follow up, 50% patients had regained some weight, 39% patients maintained their weight,
and the remaining 11% patients continued to lose weight.

Several limitations of the current study deserve mention. No sham-treated patients were included as comparative controls. The severity of liver steatosis was estimated qualitatively by sonography, and not by histology. Furthermore, the median follow up after balloon removal was less than 2 years.

Three models of intragastric balloon are commercially available: The BioEnterics intragastric balloon (BIB), and two air-filled models—Heliosphere Bag and Endogast.

The greatest experience has been with the BioEnterics balloon, and numerous studies have reported on its efficacy. The mean weight loss achieved after BIB placement, among 4,371 patients compiled from 22 studies, was 17.8 kg. In a large, yet to be published study from Madrid, Spain, 714 outpatients with a BMI > 40 kg/m² affected by sleep apnea or chronic obstructive pulmonary disease, were included. At 6 months, the mean BMI loss was 6.5 kg/m², similar to the present study. More than 100 patients underwent a second consecutive balloon placement, and at 1 year the weight loss was incremental.

Clinical evaluation of the BIB candidate by the endoscopist himself is essential for optimal results. The patient must be on liquid diet for 2-3 days prior to balloon placement. The patients are told that it is likely that they will experience nausea, vomiting, abdominal pain and cramping for the first few days following balloon placement. This usually lasts 1-5 days but may extend up to 2 weeks. Early endoscopic BIB removal (mainly for digestive intolerance) has been required in 4.2% patients. It is also important to inform the BIB candidate that 20%–40% of patients will fail to achieve a significant weight loss with this treatment. The need to comply with a simultaneous diet and exercise regimen should also be stressed.

What are the complications associated with BIB placement? Besides the immediate symptoms of nausea, abdominal pain and fullness, gastric perforation, gastric necrosis, asymptomatic fungal and bacterial colonization of the intragastric balloon, gastro-duodenal ulceration, and esophagitis may occur. Spontaneous BIB deflation has been reported in 3% –23% cases. Most deflated balloons are spontaneously eliminated, but both small and large bowel obstructions have occurred.

In conclusion BIB treatment is a promising modality for properly selected obese patients. However, although the BIB has been available since 1991, data are still lacking about the success of weight maintenance e”2 years after BIB removal and about predictive factors for short- and long-term success.

References


copy performed within 12 hours. Seventeen of these patients bled after their first EVL session. A case-control study was performed comparing these 17 patients with 84 of the 584 controls who underwent first endoscopic variceal ligation without bleeding complication.

Bleeding occurred a mean (SD) of 13.5 (7.3) days with a range of 2-29 days, following the ligation. For hemostasis, Cyanoacrylate glue injections were performed in 10 patients (43%), five patients (24%) required esophageal balloon tamponade, and two patients (14%) had an emergency transjugular intrahepatic portosystemic shunt placement. Eleven (52%) patients died following the bleeding complication. Using multivariate analysis, previous upper variceal bleeding [OR 12.07, 95%CI: 2.3–63.43], peptic esophagitis [OR 8.9, 95%CI: 1.65–47.8], high platelet ratio index (APRI) score [OR 1.54, 95%CI: 1.11–2.16] and low prothrombin index [OR 0.54, 95% CI: 0.31–0.94] were independent predictive factors of bleeding.

The authors conclude that bleeding related to post-bandung ulcer is a rare, but severe complication. The proposed predictive factors should be looked for and minimized before variceal ligation.

**Commentary**

After strangulation, variceal thrombosis occurs inducing detachment of the applied rubber band. The shallow ulcers that form heal within 2–3 weeks, allowing the development of fibrosis in the submucosa. Limited histological data suggests that vascular thrombosis does not occur immediately after ligation, but may be delayed for a few days. Before thrombosis occurs, there is necrosis of the mucosa, necrosis of the vessel walls, and persistence of patent deeper varices. Hence there remains a potential for bleeding if early slippage of bands occur. The mean time to healing of post-EVL ulcers has been reported to be 2-3 weeks.2,3

The most important observation of this study was that although post-EVL ulcer bleeding was infrequent (2.4%), its outcome was very poor, with 11 of the 21 patients (52%) dying within a few days. The cause of death was sepsis in 5, hepatic insufficiency in 3, and uncontrolled bleeding in 3 patients.

On multivariate analysis, four independent factors (previous upper variceal bleeding, the presence of peptic esophagitis, a high APRI score and a low prothrombin index) were found to predict this life-threatening complication. Poor liver condition (Child Pugh C class, high MELD score) has been previously identified as a predictive factor of re-bleeding in cirrhotic patients.4,5 Peptic esophagitis was also found to predict bleeding after EVL. It is possible that the mucosal damage induced by acid exposure of the lower esophagus might promote early slippage of the rubber bands, or induces bleeding from the post-banding ulcer. The use of PPI to induce healing of post-EVL ulcers is controversial, and higher rates of infectious complications like spontaneous bacterial peritonitis, and pneumonia have been reported in some studies. The authors used a single dose of PPI for a minimum of 3 days in all patients, but this was clearly not sufficient to prevent bleeding in this study. The authors speculate whether using higher doses of PPI might have better prevented the bleeding complications.

What might be learned from this very important study? Firstly, patients with advanced liver disease and poor coagulation should be anticipated to have a higher incidence of post-EVL ulcer bleeding. Secondly, mucosal changes of peptic esophagitis, often ignored in the presence of varices, should be carefully sought. Lastly, a liberal antibiotic policy among bleeding patients might be beneficial.

**References**