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A New Nitinol Stent Produced Locally Versus Surgery in Palliation of Distal Malignant Biliary Obstruction Rodrigo Castano, Edilberto NuñEz, Mario H. Ruiz, Fabian Juliao,

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Background: This study pretend to compare the efficacy to palliate patients with malignant distal common bile duct obstruction between surgery and the uncovered nitinol metal stent produced locally in Medellín-Colombia. Methods: In this two years retrospective study, 60 patients (median age, 67 years, range, 43-78 years) with inoperable malignant distal common bile duct strictures receive either surgery (n = 30) or an uncovered 30 FR self-expandable nitinol stent (n = 30). The patients were clinically evaluated, and biochemical tests were analyzed if necessary until their death or interventions for biliary or gastric outlet obstruction. Cumulative biliary patency, hospital stay and patient survival were compared between the two groups. Kaplan-Meier analyses were used to compare patient survival and biliary patency rates. Results: The two groups were comparable in terms of age, gender, and diagnosis. Technical success was achieved in 29 surgical (97%) and 28 (93%) stented patients, with functional biliary decompression obtained in 26 (87%) patients in both groups. In stented patients, there was a lower procedure-related mortality (3% vs 14%, p = 0.01), major complication rate (11% vs 29%, p = 0.02), and median total hospital stay (16 vs 22 days, p = 0.01). Recurrent jaundice occurred in 8 stented patients (27%) and 2 surgical patients (7%). Late gastric outlet obstruction occurred in 17% of stented patients and 7% of the surgical group. Despite the early benefits of stenting there was no significant difference in overall survival between the two groups (median survival: surgical 22 weeks; stented 24 weeks; p = 0.65). Conclusions: Endoscopic stenting and surgery are effective palliative treatments with the former having fewer early treatmentrelated complications and the latter fewer late complications. The patients who are definitely unsuitable for curative resection are better managed by positioning a stent. The use of metal stents should be preferred in those less serious patients who may supposedly survive longer.

M1295

Combined Partial Endoscopic Biliary Sphincterotomy and Endoscopic Balloon Sphincteroplasty in the Management of Difficult Bile Duct Stones

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Background: Endoscopic biliary sphincterotomy (EBS) is currently the standard procedure for removal of bile duct stones. Endoscopic balloon dilation (EBD) can be a valuable adjunct to sphincterotomy when difficult extraction is anticipated (e.g., large stones, small native papilla, non-dilated distal duct, etc). EBD dilates the intraduodenal and intrapancreatic portion of the distal bile duct, which may theoretically facilitate stone extraction in these cases. However, EBD alone is associated with an increased risk of pancreatitis. A combined approach of performing a partial EBS (pEBS) followed by EBD has been used to minimize this risk. Aim: To report our experience with this combined method for removing bile duct stones. Methods: We retrospectively identified all patients who underwent combined pEBS and EBD between January 2005 and September 2006. Patient demographics, clinical information, size and number of bile duct stones, and procedural variables (balloon size, need for additional extraction modalities (e.g., lithotripsy)), successful rate of stone extraction, need for repeat procedure(s), and complications were reviewed. Results: Combined pEBS and EBD was performed in 13 patients (M: F 8:5; mean age: 68.6 years, 27-91 years). Mean stone diameter was 11.6 mm (5-18). Stone number ranged from 1-10; 6 patients had one, 6 had 3-5, and one had 10 stones. Three patients had BII gastrectomy, 4 had large periampullary diverticulae, and 3 had a small papilla limiting the achievable sphincterotomy length. One patient had Glanzmann thrombasthenia, and 2 were referred after failed stone extraction elsewhere. All patients underwent pEBS with an average size of 6.2 mm (3-10 mm); pEBS was defined as an EBS length of 25-50% of the distance between the papillary orifice and the duodenal wall. CRE balloon diameter was influenced by stone size and individual anatomy, and ranged from 8-18 mm. Endoscopic removal of all stones was achieved in all 13 patients (100%); 9 (70%) required only one session, 3 (23%) required two sessions, and one (7%) required 3 sessions. Removal was accomplished by retrieval balloon only in 6 patients (46%), a balloon plus a basket in 6 (39%), and mechanical lithotripsy in 2 (19%). There were no immediate or short-term complications, including perforation or pancreatitis. Conclusion: EBD after partial EBS appears to be a safe and effective option when difficult stone extraction is anticipated. The incidence of EBD-induced pancreatitis appears low following a partial EBS, suggesting a partial EBS may have a protective effect. Larger trials comparing this approach to other techniques for managing challenging stone cases are warranted.

M1296

Minor EST with EPLBD Is a Safe Treatment Modality for Removal of Difficult Bile Duct Stones in Patients with Periampullary Diverticuli

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Background/Aims: Periampullary diverticuli (PAD), which are frequently noticed during endoscopic retrograde cholangiopancreatography (ERCP) examination in patients with pancreaticobiliary diseases, have been reported to be associated with difficult bile duct canulation and an increased incidence of endoscopic sphincterotomy (EST). The aim of this study is to investigate the safety of combined minor EST and endoscopic papillary large balloon dilatation (EPLBD) for the removal of difficult CBD stones in patients with periampullary diverticuli group by comparing the success rate of stone removal and complications with patients who have normal ampullas. Patients and Methods: Between May 2005 and Sep. 2006, 69 patients underwent minor EST with EPLBD for the removal of CBD stones. Thirty two patients(mean age 71.8 years; 12 men, 20 women) had periampullary diverticului and thirty seven patients(mean age 66.9 years; 17 men, 20 women) had normal ampulla. Results: The mean number of CBD stones was 2.5 in PAD and 3.2 in normal. The mean diameter of stones was 17.5 mm and 18.2 mm, respectively. The success rate of complete stone removal for first endosocopic session was 93.8% (30/32) in the PAD group and 89.2% (33/37) in the normal ampullary group (p > 0.05). The complication rate was 3.1% (1/32; delayed bleeding) in the PAD group and 10.8% (4/37; all were mild pancreatitis) in the normal ampullary group (p > 0.05). The overall success rate of stone removal was 100% in both group. Conclusion: Minor EST with EPLBD in PAD is a safe treatment modality for removal of large CBD stones.

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Endoscopic Large Balloon Sphincteroplasty for Removal of Large Bile Duct Stones in Patients with High Risk of Major Endoscopic Sphincterotomy Related Complications

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Background: Stone removal after endoscopic sphincterotomy (ES) is the standard treatment modality for the extrahepatic bile duct (EHD) stones. But for the large EHD stone (size more than 15 mm), major ES (M-ES) almost need to remove the stone and endoscopic mechanical lithotripsy (EML) usually need to crush the large stone. And it may result in longer procedure time, increased complication rates, and repeat procedure to remove all stones. The patients with periampullary diverticulum (PD) or previous ES stated major papilla may have a higher risk of complications such as perforation or bleeding after M-ES. Aims: The aims of this study were to evaluate the clinical usefulness and safety of endoscopic large ballon sphincteroplasty (ELBS) for removal of large EHD stone in patients with high risk of M-ES related complications. Methods: In 38 patients (14 men, 24 women; mean age 70.8 ± 12.4 years) with large EHD stone and PD or previous ES stated papilla were enrolled. ELBS was carried out one step inflation of a 15, 18 or 20 mm diameter balloon. In patients with PD, small endoscopic sphincterotomy was carried out before balloon dilatation. In patients with previous ES stated papilla, balloon dilatation was carried out without ES. The duration of balloon dilation time was 60 seconds. Bile duct stone removal was tried with conventional retrieval basket or balloon catheter. Results:1) All patients underwent ELBS. PD was present in 23 patients (Type I;6, II;10, III;7). 20 patients had a previous ES stated papilla. 5 patients had PD and previous ES stated papilla. 2) The mean diameter of maximal EHD stone was 18.9 ± 5.3 mm (range, 15.0-38.2 mm). The mean number of stones was 1.8 ± 2.4 (range, 1-15). 3) In 37 patients (97.4%), EHD stones were complete removed without EML. EML was carried out in one patient with distal CBD stricture. In 36 (94.7%) patients, the EHD stones were removed only one session of procedure. Two patients (5.3%) needed two sessions of procedure to complete removal of EHD stones. One patient had EHD and IHD stones and one patient had occurred minor bleeding after ELBS. 4) After the procedure, serum amylase or lipase level were elevated in 5 patients (13.2%). However, no episode of true pancreatitis happened. Minor bleeding occurred in 1 patient (2.6%) and was easily controlled epinephrine spray and balloon compression. No procedure related cholangitis, perforation or mortality was observed. Conclusions: ELBS is safe and effective for the retrieval of large EHD stones and may avoid EML in most cas ELBS may be considered an alternative to conventional M-ES in patients with high risk of M-ES related complications.