

RAPID COMMUNICATION

Selective sphincteroplasty of the papilla in cases at risk due to atypical anatomy

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lithotripsy or rescue sphincterotomy.

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Abstract

AIM: To analyze the indications, efficacy and safety of sphincteroplasty in our centre.

METHODS: A retrospective study of sphincteroplasty in 53 cases of papilla at high risk was performed in 2004-2006. The procedure consisted of duodenoscopy with Olympus TJF 145 Videoduodenoscope, approach to the biliary tract using a catheter with a guidewire, and dilatation of the papilla with a dilatation balloon catheter using a syringe with a manometer for control of the filling pressure.

RESULTS: The indications included intradiverticular papilla in 26 patients (49%), stenosis of a previous sphincterotomy in 19 patients (35.8%), small size of the papilla in 4 patients (7.5%), Billroth II gastrectomy in 3 patients (5.6%), and coagulopathy in one patient (1.9%). The efficacy was 97.8%, with all the calculi extracted from the common bile duct in 84.4% of the patients, even though 21 of the patients (39.6%) had calculi with a diameter equal to or greater than 10 mm. Seven patients (13.2%) presented complications: haemorrhage in 1 patient (1.9%) and mild pancreatitis in 6 patients (11.3%). The mean hospital stay in case of complications was of 3 ± 0.63 d.

CONCLUSION: Sphincteroplasty is highly effective, with a complication rate similar to that of sphincterotomy, furthermore, the complications are of low clinical importance. The use of the 10 mm balloon makes it possible to extract calculi with a diameter of over 15 mm and to extract more than 3 calculi without increasing the rate of complications and reduces the need to resort to

INTRODUCTION

The prevalence of cholelithiasis is 10%-15% in adult population. Calculi are detectable in the biliary tract in 17% of patients with symptomatic cholelithiasis^[1]. The introduction of laparoscopic cholecystectomy has led to an increase in the demand for endoscopic treatment of choledocholithiasis.

Currently, the standard treatment for calculi located in the biliary tree is endoscopic retrograde cholangio-pancreatography (ERCP) with sphincterotomy. This procedure is not exempt from risks and the incidence of complications is of 6%-10%, with a mortality of 1%^[2]. The early complications occurring after ERCP include acute pancreatitis, haemorrhage and perforation. Sphincterotomy also causes a permanent loss of function of the sphincter of Oddi, thus exposing the biliary tree to reflux of the duodenal contents. This leads to bacterial colonisation and chronic inflammation of the biliary tree, which, hypothetically, could increase the incidence of primary choledocholithiasis and tumours of biliary origin. Although this is not a significant problem in elderly patients, it is the cause for concern in younger individuals. For this reason, Staritz, in 1983, proposed the hydrostatic dilation of the papilla as an alternative that would enable the removal of calculi without the risks of sphincterotomy^[3].

At that time, it was hypothesised that the dilation of the papilla could become the treatment of choice in younger individuals as it transiently increases the diameter of the papillary orifice, allowing the extraction of calculi while preserving the architecture and function

of the sphincter. However, Disario^[4] showed that a high frequency of complications could lead to hydrostatic dilation of papilla falling into disuse as the treatment of choice in choledocholithiasis. Currently, it is considered as an alternative to sphincterotomy in certain cases at a high potential risk, principally of haemorrhage or perforation.

The objective of the present study was to analyse the indications, efficacy and safety of hydrostatic dilation of the papilla and to compare them with the same variables for conventional sphincterotomy in our centre.

MATERIALS AND METHODS

A retrospective study of 461 consecutive ERCPs was performed in our centre between February 2004 and March 2006. Sphincterotomy was performed in 231 (50%) and hydrostatic dilation of the papilla in 53 patients (11.5%). This study was to focus on these latter cases.

In all cases, ERCP and dilation of the papilla procedure consisted of signing of the informed consent form for anaesthesia and ERCP, antibiotic prophylaxis with amoxicillin-clavulanic acid (ciprofloxacin in cases of allergy) at the time of starting the endoscopy, monitoring and deep sedation with propofol supervised by an anaesthetist, Olympus TJF 145 Videoduodenoscope, approach to the biliary tract using a catheter ("XL cannula", Microvasive Rapid Exchange, taper tip) with a 0.035/260 cm Jagwire Stiff Shaft guide wire.

A cholangiography was performed after introduction of the catheter into the biliary tract. If pathological material observed justified therapeutic action, the catheter was withdrawn, leaving the guide wire in place. Dilatation of the papilla was performed with a Hurricane Rx Microvasive biliary dilation balloon catheter (180 cm long with a balloon length of 4 cm and diameter of 6 or 10 mm) using a syringe with the "Breeze TM RX inflation device" manometer (Boston Scientific) for control of the filling pressure. The dilation balloon catheter was advanced over the guide wire and until the mid-portion of the balloon was situated in the region of the biliary sphincter. After positioning, a diluted contrast (50% contrast plus 50% saline) was introduced under endoscopic and fluoroscopic control to maintain the correct position until a pressure of 11 atmospheres was reached in the case of the 6 mm balloon and 8 atmospheres in the 10 mm balloon. The pressure was maintained until the notch in the balloon was gradually observed to disappear, after which the balloon was maintained inflated for a further 60 s.

Extraction of the possible calculi was then attempted using a balloon catheter (Extractor RX retrieval balloon, Boston Scientific). A dormier basket (Boston Scientific) was occasionally used and a mechanical lithotripsy basket was also available in case it was required.

Finally, removal of all the calculi and pathological biliary material from the common bile duct was confirmed by an occlusion cholangiography.

The patient remained in the day hospital after the procedure. Depending on the clinical course and the blood amylase level, the patient was either discharged 4-8 h after the procedure or was admitted.

Table 1 Indication of hydrostatic balloon dilation

Indication	n	%
Intradiverticular papilla	26	49
Stenosis of previous sphincterotomy	19	35.8
Papilla of small size	4	7.5
Billroth II gastrectomy	3	5.6
Coagulopathy	1	1.9

The size of the calculi was calculated by the ratio between the diameters of the calculus and the tip of the endoscope, both measured on the X-ray image and corrected according to the true diameter of the endoscope^[5].

The complications were evaluated in accordance with the consensus document published by Cotton *et al*^[6] in 1991.

Statistical analysis

The qualitative variables were described by absolute numbers and percentages. Quantitative data are expressed as mean \pm SD. Comparison of the qualitative variables was performed using the odds ratio (OR) and the 95% confidence interval (CI).

RESULTS

A total of 461 ERCPs were performed in February 2004-March 2006. Endoscopic sphincterotomy was performed in 231 patients (50%) and hydrostatic dilation in 53 patients (11.5%).

Our study focused on these 53 patients, 22 males (41.5%) and 31 females (58.5%). The mean age was 73 ± 12.9 years. The most common indication for endoscopic balloon dilation (Table 1) was intradiverticular papilla. In only one case the indication was a septic shock with a secondary coagulopathy (platelets: 39 000, international normalized ratio: 2.1) but a coagulopathy was detected in two further cases: a cirrhotic patient in the group of intradiverticular papilla and a patient on acenocoumarol anticoagulation in the stenosis group.

Of the patients treated with dilatation, 24 (45.3%) did not undergo a cholecystectomy, and 29 (54.7%) were previously cholecystectomized. Of the non-cholecystectomised patients, one underwent laparoscopic cholecystectomy with hydrostatic dilation (Endolap).

In 42 cases (79.2%), calculi were detected on cholangiography. In 44 cases (83%), biliary sludge or calculi were obtained after the dilatation and clearance using a balloon catheter and lavage. The cholangiography gave a false positive result in one case and false negative results in three cases.

The extraction was complete, with total clearance of the biliary tract in 37 of the 44 patients (84%). Although 21 patients (39.6%) presented calculi with a diameter equal to or greater than 10 mm (Table 2), the calculi were over 15 mm in diameter in 10 cases (19%). In one of the cases, the dilatation was not sufficient to achieve extraction of the calculi and a rescue sphincterotomy was performed.

Partial extraction was achieved in 7 patients (16%).

Table 2 Classification of patients according to the presence, size and number of calculi

Biliary material	n	%
Normal common bile duct	8	15.1
Biliary sludge / microcalculi / calculi ≤ 10 mm	24	45.3
Calculi > 10 mm and ≤ 15 mm	11	20.7
Calculi > 15 mm	10	18.9
Total number of calculi > 10 mm	21	39.6
Total number of cases with 3 or more calculi	14	26.4
Number of cases with calculi > 10 mm or with 3 or more calculi	25	47.2

In 6 cases, despite the extraction of calculi and biliary sludge, one or more residual calculi were observed on occlusion cholangiography, proceeding to the insertion of a 7 cm 10 Fr polyethylene stent. The remaining case was a patient with a Billroth II gastrectomy and 19 calculi in the common bile duct, 7 of which had a diameter greater than 12 mm. After the extraction of multiple calculi, an occlusion cholangiography was performed, showing the identified images as air bubbles. The patient was readmitted 11 d later for cholangitis and, in view of the technical difficulty experienced in the previous exploration, it was decided to treat the patient surgically. Choledochoduodenostomy was performed and residual choledocholithiasis was found.

A polyethylene stent was inserted in another 5 cases. In 4 cases, despite evidence of complete clearance of the common bile duct after the extraction manoeuvres, it was decided to ensure biliary drainage by the insertion of a stent because their tendency to recur, stenosis of the previous sphincterotomy with multiple episodes of cholangitis or choledocholithiasis. In the remaining case, the patient presented residual choledocholithiasis with a biliary fistula after laparoscopic cholecystectomy. The papilla was intradiverticular and balloon dilation was therefore performed, with extraction of the calculi and insertion of a plastic stent.

Overall, 43 of 44 patients (97.8%) with bile duct stones had successful bile duct clearance or drainage (endoprosthesis).

Acute pancreatitis was the most common complication, being mild in 5 cases and moderate in 1 case. In our series, no relationship was found between post-dilatation pancreatitis and the size or number of the calculi (Table 3). The incidence of reactive pancreatitis was 11.3% in balloon dilation and 5.2% in sphincterotomy, with an OR of 2.33 (95% CI: 0.83-7.54).

Late haemorrhage occurred in one (1.9%) of our patients. This was a patient on acenocoumarol anticoagulation who presented with late haemorrhage five days after the dilatation with melaena and a fall in the haemoglobin (2 g/dL). Early upper GI endoscopy did not detect a potentially haemorrhagic lesion and blood residues. The other two patients with coagulopathy did not present any complication. None of the other complications was serious.

During the same period of time, complications were detected in 21 (9.2%) of the cases treated with sphincterotomy: acute pancreatitis in 12 cases (5.2%),

haemorrhage in 5 cases (2.2%), cholangitis in 3 cases (1.3%), and perforation in 1 case (0.4%). Although they were not homogeneous populations, as the high-risk patients were preferentially treated with hydrostatic balloon dilation, we compared the incidence of different complications in the two groups and found no statistically significant differences. However, in view of the frequency of events and the size of the sample, we recognised that our series had an insufficient statistical power.

DISCUSSION

Currently, the standard treatment of choledocholithiasis is endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy. However, this technique is not exempt from risks such as haemorrhage, perforation and pancreatitis in an early phase and complications derived from the loss of function of the sphincter of Oddi in a late phase. The incidence of early complications after sphincterotomy is 6%-10%^[2,6], with a mortality of 1% (Table 4). The incidence of complications in our series was similar to that found in the literature.

The morbidity due to endoscopic balloon dilation of the papilla varies between 17% and 21% in randomised, controlled studies and between 7% and 19% in the non-controlled studies. The morbidity is due principally to pancreatitis which, in some cases, can be severe (3% to 6.8%) and even lead to death^[4,7]. A meta-analysis^[8] of randomized, controlled studies comparing sphincterotomy with hydrostatic dilation of the papilla was published recently, and included a total of 1106 patients, which showed that papillary dilation is a theoretically attractive option in young patients as it preserves sphincter function, although the high rate of reactive pancreatitis limits its use in selected cases. Paradoxically, the risk of pancreatitis is higher in young patients who would theoretically benefit most from the preservation of sphincter function.

The results of the meta-analysis showed no haemorrhage after papillary dilation, thus favouring this procedure in patients with a coagulopathy and in those who require re-initiation of anticoagulation within a period of 72 h. Platelet or whole blood transfusions could prevent early haemorrhage but do not protect against late bleeding, which is responsible for 50% of the cases of haemorrhage^[9,10].

Currently, hydrostatic balloon dilation is considered an alternative in patients with coagulation disorders and in cases of atypical anatomy, such as an intradiverticular papilla, a Billroth II gastrectomy or Roux-en-Y anastomosis and in stenosis of the papilla due to scarring of a previous sphincterotomy.

Cirrhotic patients represent another higher-risk population which could benefit from dilatation. Sphincterotomy in these patients has a mortality of 6.4%-25% in different series, whilst dilatation did not cause any complications in one series of 9 cirrhotic patients, of whom 6 presented a coagulopathy^[11-13]. Three patients in our series presented a coagulopathy: one patient on acenocoumarol anticoagulation who developed melaena 5 d after the procedure, one with hepatic cirrhosis and the other with cholangitis, septic shock and a consumption

Table 3 Analysis of the patients with post-dilatation pancreatitis and possible risk factors

Case	Diameter largest calculus	Total number of calculi	Diameter balloon (mm)	Indication	Hospital stay (d)
1	20 mm	19	10	Billroth II	4
2	Microcalculi	Several	10	Intradiverticular	3
3	14.5 mm	3	10	Intradiverticular	3
4	Microcalculi	Several	10	Stenosis	3
5	10.5 mm	Several	10	Intradiverticular	2
6	0	0	10	Intradiverticular	3

Table 4 Complications of sphincterotomy in the literature^[2,61]

Complication	Percentage (%)	Surgery (%)	Death
Pancreatitis	1-7	6.3	10-10.9 (0.2% of the total)
Haemorrhage	2.5	22	13 (0.6% of the total)
Perforation	1.3	27	16 (0.2% of the total)
Sepsis	1.7		

coagulopathy, who presented no complications.

Stenosis of the papilla after sphincterotomy is not a rare event, with a prevalence ranging 3.4%-13%^[14,15]. In these cases, sphincterotomy appeared to be associated with a higher rate of perforation and pancreatitis^[6], and papillary balloon dilation was thus proposed as an alternative. Stenosis of the papilla due to scarring from a previous sphincterotomy was the indication for dilatation in 21 of the cases in our series. Complications arose in two of these cases (9.5%): one presenting mild pancreatitis and the other a late haemorrhage (the patient mentioned above was on treatment with acenocumarol).

The majority of authors consider that sphincterotomy is associated with a higher morbidity and mortality in patients with a Billroth II gastrectomy. However, controversy exists on this matter^[5,16]. In a randomised study, hydrostatic dilation was not found to be associated with a higher morbidity in patients with a Billroth II gastrectomy than in patients with a normal anatomy of the papilla and was also not associated with an increase in the need for mechanical lithotripsy. In our series, dilatation had no complications in 3 patients with a Billroth II gastrectomy.

Balloon dilation is highly effective, with extraction of the calculi and complete clearance of the biliary tract achieved in 80%-100% of cases, comparable to the success rate after sphincterotomy (96%). Some authors have proposed a rescue sphincterotomy when it is not possible to extract all the calculi after dilatation^[17].

On the other hand, some authors^[18] performed dilatation of the papilla with large diameter balloons (12-20 mm in diameter) in patients with retained calculi after sphincterotomy, whether due to their large size or to narrowing of the distal common bile duct, but they could not extract the calculi (11% of cases). However, the efficacy of mechanical lithotripsy was 80%-98%.

The most frequent complication of papillary dilation is pancreatitis, with an incidence ranging 4%-35%, depending on the series. During dilatation, trauma is applied circumferentially to the sphincter and, therefore, partially in the direction of the pancreatic duct, causing transmural inflammation and intramucosal haemorrhage of the

sphincter. The traction exerted on the calculi in the attempts to extract them^[17] also gives rise to additional trauma to the sphincter.

Hydrostatic dilatation of the papilla with an 8 mm balloon enables extraction of calculi in almost all cases with a diameter of less than 10 mm^[19]. However, mechanical lithotripsy is required in 50% of cases when there are more than 3 calculi or when the calculi have a diameter greater than 10 mm. Mechanical lithotripsy makes the procedure more laborious, and its manipulation can increase the incidence of pancreatitis^[20]. Furthermore, additional sphincterotomy or repetition of ERCP is required in 15% to 30% of the patients^[9]. For this reason, some authors^[8] do not favour balloon dilation in patients with calculi of these characteristics.

Vlavianos^[21] used a 10 mm balloon and lithotripsy was only required in 6.8% of cases, despite the total clearance of calculi with a diameter greater than 10 mm was achieved in the biliary tract of 70.7% of cases.

In the present study, although 39.6% of the patients presented calculi with a diameter greater than 10 mm, and more than 3 calculi were extracted in 26.4% of cases, mechanical lithotripsy was not required in any case and rescue sphincterotomy was only required in one case in order to extract the calculus (Table 2). The incidence of pancreatitis was not related either to the number of calculi or to their size. We do not know whether these results are due to the use of the 10 mm hydrostatic balloon, as the previously mentioned data come from studies in which an 8 mm or smaller diameter balloon was used^[22].

A recent study in Japan^[23] showed that the effect of balloon dilation is associated with the temporary insertion of a stent into the pancreatic duct. A tendency to reduce the rate of pancreatitis was observed, though this did not reach statistical significance due to the low incidence of pancreatitis in the control group (6%).

Another advantage of dilatation derives from its capacity of preserving sphincter function. The loss of function of the sphincter of Oddi after sphincterotomy is permanent and exposes the biliary tree to reflux of the duodenal contents, producing bacterial colonisation and chronic inflammation of the biliary tree. This may be a cause for concern in younger patients as it can increase the incidence of primary choledocholithiasis caused by deconjugation of the bilirubin by bacterial enzymes, and the number of tumours of biliary origin. Acamada^[24] detected primary cancer of the biliary tree detected in 7.4% of patients undergoing transduodenal surgical destruction of the muscle fibres of the sphincter of Oddi after a mean follow-up of 18 (10-22) years. In the majority of these

cases, bacterial contamination of the biliary tract was also observed. However, studies on series of sphincterotomy with long-term follow-up have not detected serious complications despite the permanent abolition of the function of the sphincter of Oddi^[25]. The incidence of late complications after sphincterotomy was 24% in one study with a mean follow-up of 15 years^[26].

Dilatation of the papilla preserves the function of the biliary sphincter in the majority of cases, thus preventing chronic reflux of the duodenal contents into the biliary system. Studies have shown that the pressure in the common bile duct, the basal pressure of the sphincter of Oddi, the peak pressure and the contractile frequency are significantly reduced one week after dilatation of the papilla^[19,27,28]. Two studies of the histology of the papilla after dilatation, one performed in pigs^[29] and the other in humans^[30], demonstrated no disruption of the smooth muscle or distortion of the architecture, although inflammation and mild or moderate fibrosis was observed in the majority of cases.

In conclusion, our results indicate that balloon dilation of the papilla is highly effective, the complication rate is comparable to that of sphincterotomy, and the clinical importance of the complications is low. The use of a 10 mm balloon enables extraction of multiple calculi with a size greater than 15 mm with no increase in the complication rate and reduces the need for lithotripsy or sphincterotomy.

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COMMENTS

Background

Endoscopic sphincterotomy was introduced in 1973 as a nonsurgical procedure enabling removal of bile duct stones and has become the treatment of choice for their extraction. This is a most dangerous technique performed by endoscopists with an early complication rate of 6%-10% and a mortality of 1%. Sphincterotomy also causes a permanent loss of function of the sphincter, thus exposing the biliary tree to bacterial colonisation and chronic inflammation. In 1983, Staritz proposed the endoscopic balloon dilation as a safe and effective alternative to sphincterotomy with the hope of avoiding these short and long-term complications by preserving the function of the sphincter. However, the high frequency of complications can lead to papillary dilation, thus falling into disuse as the treatment of choice in choledocholithiasis. A meta-analysis of randomized, controlled studies comparing sphincterotomy with balloon dilation of the papilla concluded that in young patients, the dilation is a theoretically attractive option as it preserves sphincter function, although the high rate of reactive pancreatitis would limit its use in selected cases. Currently, it is considered an alternative to sphincterotomy in certain cases at a high potential risk, principally of haemorrhage or perforation.

Research frontiers

Nowadays, the safety and efficacy of larger endoscopic balloons for great size

lithiasis extraction are under investigation. Some authors have adapted the balloon diameter to the distal choledochal diameter or to the lithiasis size. A very interesting investigation field is the study of drugs and procedures with the capacity of reducing the incidence of acute pancreatitis after hydrostatic dilatation of the papilla. Another interesting field of research is the study of the incidence of late complications and stone recurrence after endoscopic balloon dilation.

Innovations and breakthroughs

The use of a 10 mm balloon enables extraction of multiple calculi with a size greater than 15 mm with no increase in the complication rate and reduces the need for lithotripsy or sphincterotomy.

Applications

Papillary dilation is the treatment of choice in patients with coagulopathy and a local anatomy that makes dangerous a sphincterotomy (Billroth II gastrectomy, periampullary diverticula) independently of the size and the number of calculi.

Terminology

Patients with papilla at high risk: patients in whom the local anatomy makes a sphincterotomy impossible or dangerous (e.g., patients with periampullary diverticula or undergoing Billroth II gastrectomy). Occlusion cholangiography: occlusion cholangiography is done after the balloon catheter is inflated and withdrawn from the papilla (to avoid contrast leak). Endolap: single-stage treatment with laparoscopic cholecystectomy and intraoperative ERCP.

Peer review

In the current paper, the authors report their experience with endoscopic balloon dilation of the sphincter of Oddi for the treatment of bile duct stones versus endoscopic sphincterotomy. Their results indicate that balloon dilation of the papilla is highly effective, and the complication rate is comparable to that of sphincterotomy. The paper is of interest.

REFERENCES

- 1 **Rhodes M**, Sussman L, Cohen L, Lewis MP. Randomised trial of laparoscopic exploration of common bile duct versus postoperative endoscopic retrograde cholangiography for common bile duct stones. *Lancet* 1998; **351**: 159-161
- 2 **Freeman ML**, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ, Moore JP, Fennerty MB, Ryan ME, Shaw MJ, Lande JD, Pheley AM. Complications of endoscopic biliary sphincterotomy. *N Engl J Med* 1996; **335**: 909-918
- 3 **Staritz M**, Ewe K, Meyer zum Büschenfelde KH. Endoscopic papillary dilation (EPD) for the treatment of common bile duct stones and papillary stenosis. *Endoscopy* 1983; **15** Suppl 1: 197-198
- 4 **Disario JA**, Freeman ML, Bjorkman DJ, Macmathuna P, Petersen BT, Jaffe PE, Morales TG, Hixson LJ, Sherman S, Lehman GA, Jamal MM, Al-Kawas FH, Khandelwal M, Moore JP, Derfus GA, Jamidar PA, Ramirez FC, Ryan ME, Woods KL, Carr-Locke DL, Alder SC. Endoscopic balloon dilation compared with sphincterotomy for extraction of bile duct stones. *Gastroenterology* 2004; **127**: 1291-1299
- 5 **Bergman JJ**, van Berkel AM, Bruno MJ, Fockens P, Rauws EA, Tijssen JG, Tytgat GN, Huibregtse K. A randomized trial of endoscopic balloon dilation and endoscopic sphincterotomy for removal of bile duct stones in patients with a prior Billroth II gastrectomy. *Gastrointest Endosc* 2001; **53**: 19-26
- 6 **Cotton PB**, Lehman G, Vennes J, Geenen JE, Russell RC, Meyers WC, Liguory C, Nickl N. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 1991; **37**: 383-393
- 7 **García-Cano J**. Fatal pancreatitis after endoscopic balloon dilation for extraction of common bile duct stones in an 80-year-old woman. *Endoscopy* 2006; **38**: 431
- 8 **Baron TH**, Harewood GC. Endoscopic balloon dilation of the biliary sphincter compared to endoscopic biliary sphincterotomy for removal of common bile duct stones during ERCP: a metaanalysis of randomized, controlled trials. *Am J Gastroenterol* 2004; **99**: 1455-1460

- 9 **Bergman JJ**, Rauws EA, Fockens P, van Berkel AM, Bossuyt PM, Tijssen JG, Tytgat GN, Huibregtse K. Randomised trial of endoscopic balloon dilation versus endoscopic sphincterotomy for removal of bile duct stones. *Lancet* 1997; **349**: 1124-1129
- 10 **Nelson DB**, Freeman ML. Major hemorrhage from endoscopic sphincterotomy: risk factor analysis. *J Clin Gastroenterol* 1994; **19**: 283-287
- 11 **Sugiyama M**, Atomi Y, Kuroda A, Muto T. Treatment of choledocholithiasis in patients with liver cirrhosis. Surgical treatment or endoscopic sphincterotomy? *Ann Surg* 1993; **218**: 68-73
- 12 **Moreira VF**, Arribas R, Sanroman AL, Meroño E, Larena C, Garcia M, Torres G. Choledocholithiasis in cirrhotic patients: is endoscopic sphincterotomy the safest choice? *Am J Gastroenterol* 1991; **86**: 1006-1010
- 13 **Kawabe T**, Komatsu Y, Tada M, Toda N, Ohashi M, Shiratori Y, Omata M. Endoscopic papillary balloon dilation in cirrhotic patients: removal of common bile duct stones without sphincterotomy. *Endoscopy* 1996; **28**: 694-698
- 14 **Fujita N**, Maguchi H, Komatsu Y, Yasuda I, Hasebe O, Igarashi Y, Murakami A, Mukai H, Fujii T, Yamao K, Maeshiro K. Endoscopic sphincterotomy and endoscopic papillary balloon dilatation for bile duct stones: A prospective randomized controlled multicenter trial. *Gastrointest Endosc* 2003; **57**: 151-155
- 15 **Hawes RH**, Cotton PB, Vallon AG. Follow-up 6 to 11 years after duodenoscopic sphincterotomy for stones in patients with prior cholecystectomy. *Gastroenterology* 1990; **98**: 1008-1012
- 16 **Prat F**, Fritsch J, Choury AD, Meduri B, Pelletier G, Buffet C. Endoscopic sphincterotomy: a useful therapeutic tool for biliary endoscopy in Billroth II gastrectomy patients. *Endoscopy* 1997; **29**: 79-81
- 17 **Bergman JJ**, van Berkel AM, Bruno MJ, Fockens P, Rauws EA, Tijssen JG, Tytgat GN, Huibregtse K. Is endoscopic balloon dilation for removal of bile duct stones associated with an increased risk for pancreatitis or a higher rate of hyperamylasemia? *Endoscopy* 2001; **33**: 416-420
- 18 **Ersoz G**, Tekesin O, Ozutemiz AO, Gunsar F. Biliary sphincterotomy plus dilation with a large balloon for bile duct stones that are difficult to extract. *Gastrointest Endosc* 2003; **57**: 156-159
- 19 **Espinell J**, Muñoz F, Vivas S, Domínguez A, Linares P, Jorquera F, Herrera A, Olcoz JL. Dilatation of the papilla of Vater in the treatment of choledocholithiasis in selected patients. *Gastroenterol Hepatol* 2004; **27**: 6-10
- 20 **Yasuda I**, Tomita E, Moriwaki H, Kato T, Wakahara T, Sugihara J, Nagura K, Nishigaki Y, Sugiyama A, Enya M. Endoscopic papillary balloon dilatation for common bile duct stones: efficacy of combination with extracorporeal shockwave lithotripsy for large stones. *Eur J Gastroenterol Hepatol* 1998; **10**: 1045-1050
- 21 **Vlavianos P**, Chopra K, Mandalia S, Anderson M, Thompson J, Westaby D. Endoscopic balloon dilatation versus endoscopic sphincterotomy for the removal of bile duct stones: a prospective randomised trial. *Gut* 2003; **52**: 1165-1169
- 22 **Mathuna PM**, White P, Clarke E, Merriman R, Lennon JR, Crowe J. Endoscopic balloon sphincteroplasty (papillary dilation) for bile duct stones: efficacy, safety, and follow-up in 100 patients. *Gastrointest Endosc* 1995; **42**: 468-474
- 23 **Aizawa T**, Ueno N. Stent placement in the pancreatic duct prevents pancreatitis after endoscopic sphincter dilation for removal of bile duct stones. *Gastrointest Endosc* 2001; **54**: 209-213
- 24 **Hakamada K**, Sasaki M, Endoh M, Itoh T, Morita T, Konn M. Late development of bile duct cancer after sphincteroplasty: a ten- to twenty-two-year follow-up study. *Surgery* 1997; **121**: 488-492
- 25 **Bergman JJ**, van Berkel AM, Groen AK, Schoeman MN, Offerhaus J, Tytgat GN, Huibregtse K. Biliary manometry, bacterial characteristics, bile composition, and histologic changes fifteen to seventeen years after endoscopic sphincterotomy. *Gastrointest Endosc* 1997; **45**: 400-405
- 26 **Bergman JJ**, van der Mey S, Rauws EA, Tijssen JG, Gouma DJ, Tytgat GN, Huibregtse K. Long-term follow-up after endoscopic sphincterotomy for bile duct stones in patients younger than 60 years of age. *Gastrointest Endosc* 1996; **44**: 643-649
- 27 **Yasuda I**, Tomita E, Enya M, Kato T, Moriwaki H. Can endoscopic papillary balloon dilation really preserve sphincter of Oddi function? *Gut* 2001; **49**: 686-691
- 28 **Sato H**, Kodama T, Takaaki J, Tatsumi Y, Maeda T, Fujita S, Fukui Y, Ogasawara H, Mitsufuji S. Endoscopic papillary balloon dilatation may preserve sphincter of Oddi function after common bile duct stone management: evaluation from the viewpoint of endoscopic manometry. *Gut* 1997; **41**: 541-544
- 29 **Mac Mathuna P**, Siegenberg D, Gibbons D, Gorin D, O'Brien M, Afdhal NA, Chuttani R. The acute and long-term effect of balloon sphincteroplasty on papillary structure in pigs. *Gastrointest Endosc* 1996; **44**: 650-655
- 30 **Kawabe T**, Komatsu Y, Isayama H, Takemura T, Toda N, Tada M, Imai Y, Shiratori Y, Omata M. Histological analysis of the papilla after endoscopic papillary balloon dilation. *Hepatogastroenterology* 2003; **50**: 919-923

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