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Wolters Kluwer

Endoscopic balloon dilation for removal of bile duct stones

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INTRODUCTION

Endoscopic balloon dilation of the biliary sphincter can be a valuable adjunct to the therapeutic arsenal of the biliary endoscopist for removal of bile duct stones during endoscopic retrograde cholangiopancreatography (ERCP) in highly selected patients.

This topic will review endoscopic balloon dilation of the biliary sphincter. ERCP with endoscopic sphincterotomy is discussed separately. (See "[Overview of endoscopic retrograde cholangiopancreatography \(ERCP\) in adults](#)" and "[Endoscopic biliary sphincterotomy](#)".)

RATIONALE

Endoscopic balloon dilation (EBD) permits effective stone removal with a success rate similar to that of endoscopic sphincterotomy (EST), the standard treatment for bile duct stones. In patients with small stones (≤ 10 mm), EBD successfully removes stones in virtually all cases without the need for an additional sphincterotomy or mechanical lithotripsy. In patients with more complicated stones (eg, stone diameter > 10 mm or number > 3) ([table 1](#)), the success rates of EBD and EST are comparable, but lithotripsy is required in approximately 50 percent of patients, and an additional sphincterotomy or repeat ERCP in 15 to 30 percent of patients [1].

EBD has a number of potential advantages compared with standard sphincterotomy.

- After EBD, the function of the biliary sphincter is preserved, whereas it is permanently lost after EST [2]. This has the potential benefit of preventing the chronic reflux of gastroduodenal contents into the biliary system observed after EST. However, although patients who have undergone EST may have bacterial colonization and chronic inflammation of the biliary epithelium, its clinical significance is uncertain since long-term follow-up studies after EST have not shown a high rate of serious complications [3,4].
- Compared with EST, EBD reduces the risk of bleeding after the ERCP and is therefore especially suited for the treatment of patients with hemostatic disorders [1,5,6].

Despite these advantages, some reports have found a high rate of pancreatitis following EBD compared with EST, although the data have been conflicting [1,7-9]. As a result, most endoscopists are reluctant to perform EBD for stone removal.

Because of the above considerations, the main indications for stone removal using EBD are for patients who are at risk of bleeding after sphincterotomy, and patients in whom the local anatomy makes a sphincterotomy impossible or dangerous (eg, patients with a periampullary diverticulum or Billroth II gastrectomy) [10-13]. (See "[Endoscopic retrograde cholangiopancreatography \(ERCP\) after Billroth II reconstruction](#)".)

Another indication for EBD is to widen the sphincterotomy opening after EST to allow for removal of large bile duct stones [14-16]. For this purpose, large diameter EBD balloons (eg, 15 to 20 mm diameter) are used [14]. (See '[Endoscopic papillary large balloon dilation](#)' below.)

TECHNIQUE

After a diagnostic cholangiogram has confirmed the presence of bile duct stones and deep cannulation of the bile duct has been obtained, a 0.035 inch guidewire should be advanced through the diagnostic cannula and positioned high in the biliary tree [17]. A balloon catheter is then passed over the guidewire and positioned in the biliary orifice with the middle portion of the balloon located at the site of the biliary sphincter. A variety of balloon catheters are commercially available that differ in the maximum inflated balloon diameter, the length of the balloon, and/or maximum tolerated balloon pressure ("burst pressure"). The length of the balloon and its maximum inflated diameter are important issues that will be discussed below. The burst pressure may be important for dilation of tight biliary strictures, but the amount of radial force exerted by inflation of the balloon is less important in dilating the relatively flexible and non-stenosed biliary sphincter.

Maximum inflated diameter — Although initial studies used balloons that dilated the biliary sphincter to 10 mm or larger, we typically use an 8 mm dilation balloon, and this approach is supported by subsequent studies [1]. EBD of the biliary sphincter to a diameter of 8 mm preserves sphincter function, in contrast to sphincter dilation to 10 mm or larger [2].

For very small stones (eg, <5 mm), dilation of the sphincter to a diameter of 6 mm probably suffices. However, since spontaneous passage usually occurs with such small stones, only a few patients fall into this category. Furthermore, most 6 mm dilation balloons are only available with a relatively short balloon length and are difficult to maintain in position during balloon dilation since the balloon has the tendency to move either into the bile duct or out into the duodenum. Thus, we prefer dilation balloon catheters with a minimum balloon length of 3 cm.

Despite earlier reports of successful dilation with balloons ≥ 12 mm [18-20], in our opinion, dilating the biliary sphincter to ≥ 10 mm may be beyond the scope of minimizing the trauma applied to the sphincter of Oddi. As a result, for extraction of larger stones, we prefer to dilate the biliary sphincter to 8 mm and to crush the stones by mechanical lithotripsy instead of dilating the sphincter to a larger diameter.

Sphincter dilation — Once the dilation balloon is correctly positioned in the biliary orifice, sphincter dilation is a simple procedure compared with endoscopic sphincterotomy for which many maneuvers (all important for the safety and efficacy of the procedure) require significant expertise [21,22]. During dilation of the sphincter, the balloon is gradually filled with diluted contrast under endoscopic and fluoroscopic guidance to maintain the correct position of the dilation balloon and to observe the gradual disappearance of the waist in the balloon, indicating the progress of dilation of the biliary sphincter ([image 1](#)). Once the waist in the balloon has disappeared, we prefer to maintain the inflated dilation balloon in position for 45 to 60 seconds before deflation and removal.

Other dilation procedures have been suggested, including manometry-guided control [2,23] and multiple dilation cycles [9]. Manometry is not imperative since the non-stenosed and relatively flexible biliary sphincter easily permits dilation well before the burst pressure of the balloon is reached, in contrast to dilation of tight biliary strictures in patients with sclerosing cholangitis or postcholecystectomy stenoses.

Cannulation of the bile duct — In most patients, cannulation of the bile duct is easily permitted after balloon dilation of the biliary sphincter. This is similar to the straightforward cannulation sometimes encountered in patients with recent spontaneous stone passage through the papilla. However, repeated cannulation of the bile duct may occasionally prove difficult after EBD, especially in patients in whom the initial deep cannulation of the bile duct,

prior to the balloon dilation, was difficult. In our series, this problem was encountered in only 2 of 101 patients (2 percent) who underwent EBD for removal of bile duct stones [1]. This occasional difficulty with repeated entrance to the bile duct after EBD can be overcome by exchanging catheters and wire baskets over a guidewire left in situ after the removal of the balloon.

Stone extraction — Extraction of bile duct stones after EBD should be performed according to standard guidelines using wire baskets [21]. When the basket reaches the biliary sphincter, some resistance is usually encountered that can be overcome by using the up/down knob on the endoscope and by inserting the endoscope slightly further into the duodenum. Extraction of stones up to 10 mm in diameter is typically safe and successful using this technique while applying traction force in the axis of the bile duct. (See "[Endoscopic management of bile duct stones](#)".)

For larger stones, the amount of space created by dilation of the biliary sphincter is usually insufficient for controlled stone extraction; thus, mechanical lithotripsy should be available. To prevent impaction of the wire basket, we prefer to start with the lithotripter crushing basket to capture these larger stones (eg, >10 mm diameter). In most cases, this permits effective mechanical lithotripsy when the maneuvers described above fail, without having to release the stone from the basket [21].

When stone removal is unsuccessful after EBD, an additional sphincterotomy can be performed as an "escape procedure." Further attempts can be made to remove the remaining stones through the further enlarged biliary orifice.

Residual stones are less likely to pass spontaneously after EBD compared with endoscopic sphincterotomy. Thus, an occlusion cholangiogram should always be obtained to check for residual stones after stone extraction has been completed.

SUCCESS RATE

Success rates of stone extraction following endoscopic balloon dilation (EBD) range from 85 to 100 percent in various reports [1,2,8,9,24,25]. A systematic review concluded that EBD was slightly less successful than endoscopic sphincterotomy (EST) [26]. However, comparison of results with known success rates of EST is hampered by several problems concerning the definition of success and selection of patients.

The definition of successful stone removal after EBD varies among studies. Some studies report the rate of successful stone removal after EBD only, considering the procedure to have failed if a

sphincterotomy with additional stone extraction is required. On the other hand, others argue that only the presence or absence of bile duct stones at the end of the endoscopic retrograde cholangiopancreatography (ERCP) should determine the qualification "success" or "failure," and that the relative contributions of EBD and additional EST are secondary outcomes.

Some endoscopists are reluctant to perform a sphincterotomy in patients in whom stone removal was unsuccessful after EBD, and reschedule such patients for a separate procedure [8]. In these settings, the success rate of EBD may be overestimated since multiple endoscopic procedures were required.

Another problem in comparing the success rate of stone removal after EBD and EST concerns the criteria by which patients are selected for these procedures. Most studies on EBD have restricted the maximum stone diameter and sometimes also the maximum number of stones for inclusion in the study. It is inappropriate to compare the success rate of EBD in such a selected group of patients with that reported in most series on EST in which an "all-comers" policy is usually followed.

Randomized trials are imperative to compare the results and complications of EBD and EST, and several trials have been completed [1,2,7,25,27-31]. In addition, two systematic reviews [26,31] have summarized the available studies.

The following conclusions can be drawn from these studies:

- For removal of stones of all sizes, EBD is slightly less effective than EST (RR 0.90, 95% CI 0.84-0.97). For patients with smaller and fewer bile duct stones, the overall success rates are comparable.
- Mechanical lithotripsy is more often required after EBD than after EST (RR 1.34, 95% CI 1.08 to 1.66), probably because EBD does not enlarge the papillary orifice to the same extent as EST. However, in patients with relatively "easy" bile duct stones (diameter ≤ 10 mm and number ≤ 3), mechanical lithotripsy after EBD is required in only 5 percent of cases [1].

In patients with smaller and fewer bile duct stones, EBD therefore almost always facilitates successful stone removal. In patients with larger or multiple stones, the bile duct can be cleared successfully in most patients after EBD, but lithotripsy is required in about 50 percent of patients and an additional sphincterotomy or repeat ERCP in 15 to 30 percent.

EARLY COMPLICATIONS

The risk of bleeding appears to be decreased in endoscopic balloon dilation (EBD) compared with endoscopic sphincterotomy (EST). Bleeding has been reported in 2 to 5 percent of patients undergoing EST for bile duct stones [22] and was observed in 2 percent of the EST patients in the aforementioned eight randomized trials. By contrast, no significant bleeding has been observed following EBD in a total of over 1000 reported patients [1,2,7-10,24,25,32].

Furthermore, two of these series included patients with cirrhosis and known hemostatic disorders [6,8], who have a six- to eightfold higher risk for bleeding post-EST [6,22]. This very low frequency of bleeding suggests that EBD is especially suited for patients with an increased risk of bleeding.

EBD has not evolved into widespread use because of concern related to complications, especially pancreatitis, which occurs more often after EBD than after EST (RR 1.96, 95% CI 1.34 to 2.89) [31].

There are several theoretical reasons why EBD is associated with an increased risk for pancreatitis:

- Balloon dilation produces circumferential trauma to the biliary sphincter and therefore partially in the direction of the pancreatic duct. This in contrast to EST where, ideally, the incision of the biliary sphincter is directed away from the pancreas.
- During balloon dilation of the biliary sphincter, the ampullary sphincter is also dilated. This sphincter, which is shared by common bile duct and main pancreatic duct at their most distal part, has a variable length and may measure several millimeters in patients with a long common channel ([figure 1](#)). Studies in pigs have demonstrated that transmural inflammation and intramucosal bleeding of the biliary sphincter (and possibly the ampullary sphincter) occurs immediately after EBD [33]. This may result in a relative outflow obstruction of the pancreatic duct causing an increase in the rate of hyperamylasemia and/or pancreatitis. This may be especially relevant in patients in whom prior cannulation of the bile duct was difficult, with multiple unintentional cannulations of the pancreas.
- Hyperamylasemia and/or pancreatitis may occur more frequently after EBD because stone removal takes more time and involves more manipulation of the papillary complex.

LATE COMPLICATIONS

Most studies on endoscopic balloon dilation (EBD) have reported only short-term follow-up. In two reports with one-year follow-up [8,9], no hepatobiliary problems were identified except for

residual stones in 2 percent of patients in one report [8].

In the Amsterdam trial, the rate of complications was similar for patients who underwent EBD or endoscopic sphincterotomy (EST) (18 versus 23 percent) [1]. The majority of complications were due to symptomatic recurrent bile duct stones. Acute cholecystitis was observed more often after EST than after EBD (10 versus 1 percent) [1]. This latter finding may be explained by preservation of sphincter function after EBD, preventing reflux of duodenal contents and bacteria. The origin of these "recurrent" bile duct stones is difficult to ascertain. Stone formation *de novo* in the bile duct seems unlikely given the relatively short period of follow-up. It is more likely that these stones passed from gallbladders *in situ* or were left behind at the initial endoscopic retrograde cholangiopancreatography.

One of the largest series with relatively long-term follow-up included 1000 patients who had undergone EBD for common bile duct stones; 837 were followed for a mean of 4.4 years [34]. Biliary complications occurred in 104 patients (12 percent), mainly in those in whom the gallbladder was left *in situ* and who were known to have residual gallstones. The most common complications in such patients were recurrence of common bile duct stones and cholecystitis. Three patients developed cholangitis. No long-term follow-up is available for any of the randomized studies, making it difficult to relate these results to the rate of late complications after EST.

Sphincter preservation — While the early complications after endoscopic sphincterotomy have been extensively studied, less is known about the long-term effects of endoscopic balloon dilation of the biliary sphincter. We found that biliary sphincter function was absent up to 17 years after endoscopic sphincterotomy [3]. Permanent loss of the physiologic barrier between duodenum and biliary tract was associated with bacterial colonization of the biliary tract.

The presence of bacteria in the biliary system (which is sterile under physiological conditions), reflux of gastroduodenal contents, and biochemical changes in bile composition after EST may cause late complications [3]. These complications may include recurrence of bile duct stones due to deconjugation of bilirubin by bacterial enzymes, inflammatory changes of the hepatobiliary system, and, in theory, malignant degeneration.

In a retrospective study of 100 patients, 15 to 17 years after EST for bile duct stones, late complications, primarily recurrent bile duct stones, occurred in as many as 24 percent of patients [4]. However, the related mortality was low (1 percent) and only one patient required surgical treatment; the remaining patients were effectively managed endoscopically or conservatively. More serious complications such as malignancy were not observed. However, the low incidence of hepatobiliary malignancies in the general population suggests that the

power of retrospective studies may be too small to detect an increased risk for this complication after EST.

Although long-term data are not yet available, EBD may reduce the risk of some long-term complications related to EST since sphincter function appears to be preserved following EBD. In one report, for example, sphincter manometry revealed that sphincter function was intact after EBD while it was absent after EST [2]. Similar findings were noted in a study in pigs in which the architecture of the biliary sphincter remained intact after EBD without signs of sphincter fibrosis [33].

TIME REQUIRED FOR ENDOSCOPIC STONE REMOVAL

In the Amsterdam trial, the median duration of endoscopic retrograde cholangiopancreatography (ERCP) was slightly longer for endoscopic balloon dilation (EBD) compared with endoscopic sphincterotomy (EST) (50 versus 35 minutes) [1]. Multivariate analysis identified four parameters associated with the duration of ERCP: stone diameter, stone number, EBD or EST, and prior Billroth-II gastrectomy. In the EBD group, the median duration of ERCP markedly increased for stone diameters over 9 mm; in the EST group this increase was observed only when stone diameters exceeded 15 mm. Thus, the difference in time required for ERCP between EBD and EST was most pronounced for patients with stone diameters between 10 and 15 mm. In these patients, EBD usually required additional lithotripsy, whereas EST usually permitted stone extraction without lithotripsy. For patients with stones <10 mm in diameter, stone removal after EBD required about five minutes more than EST.

PRIOR BILLROTH-II GASTRECTOMY

Endoscopic sphincterotomy (EST) can be difficult and is associated with increased risk for adverse events in patients who have undergone a Billroth-II gastrectomy. Several reports have described the use of EBD in this setting [11,23,35,36]. In a randomized trial, complete stone removal was achieved in 14 of 16 EBD patients (88 percent) versus 15 of 18 EST patients (83 percent) [11]. Mechanical lithotripsy was required in three and four patients, respectively, and only one EBD patient required an EST for stone removal after unsuccessful EBD. The median time required for stone removal was 30 minutes in both groups. Complications occurred in seven EST patients (39 percent, including three patients with bleeding) and in three EBD patients (19 percent, including one patient with pancreatitis). These data and other reports suggest that EBD in patients who have undergone Billroth-II gastrectomy appears to be successful and safe and may be superior to EST.

ENDOSCOPIC PAPILLARY LARGE BALLOON DILATION

Endoscopic papillary large balloon dilation (EPLBD) with a large-diameter (12 to 20 mm) dilation balloon is an adjunctive technique to enlarge the papillary orifice after endoscopic sphincterotomy (EST) to facilitate the removal of large or difficult stones.

The concept is to combine the advantages of EST with those of EBD. Theoretically, the risk of perforation or bleeding is reduced by performing a less than maximal EST, while the risk of pancreatitis from balloon dilation is reduced by first separating the biliary and pancreatic orifices with EST [18].

In a randomized comparative study between EPLBD and EST, 200 consecutive patients with bile duct stones were treated with EST plus EPLBD (12 to 20 mm balloon diameter) or EST alone [19]. Outcomes were similar in terms of overall successful stone removal (97 versus 98 percent), large (15 mm) stone removal (94 versus 97 percent), and the use of mechanical lithotripsy (8 versus 9 percent). Complications were similar between the two groups (5 versus 7 percent). There was no difference in the rate of postprocedure pancreatitis.

Data have suggested that a shorter balloon dilation time lowered the risk of post-ERCP pancreatitis for patients undergoing EST combined with balloon dilation. In a trial including nearly 2000 patients with common bile duct stones, balloon dilation for 30 seconds reduced the rate of post-ERCP pancreatitis compared with dilation for 300 seconds (7 versus 15 percent; odds ratio 0.40, 95% CI 0.25-0.66), while the rates of successful stone extraction were not significantly different between groups [37].

SOCIETY GUIDELINE LINKS

Links to society and government-sponsored guidelines from selected countries and regions around the world are provided separately. (See "[Society guideline links: Biliary infection and obstruction](#)".)

SUMMARY AND RECOMMENDATIONS

- **General principles** – Endoscopic balloon dilation (EBD) of the biliary sphincter can be a valuable adjunct to the therapeutic arsenal of the biliary endoscopist for removal of bile duct stones during endoscopic retrograde cholangiopancreatography (ERCP) in selected

patients. EBD permits effective stone removal with a success rate similar to that of endoscopic sphincterotomy (EST). (See '[Rationale](#)' above.)

In our opinion, EST should remain the standard procedure for removal of uncomplicated bile duct stones. This is not because the results of EBD are disappointing, but because many of the arguments that led to interest in EBD (mainly concern related to complications from EST) have been put into better perspective. Prospective studies have shown that EST for bile duct stones is much safer than was once believed. The most common serious complication of endoscopic stone removal is pancreatitis, the one complication for which EBD may carry an increased risk. (See "[Post-endoscopic retrograde cholangiopancreatography \(ERCP\) pancreatitis](#)".)

Concern related to long-term complications after EST was another consideration that spurred interest in EBD since EBD preserves the biliary sphincter. EST results in a permanent loss of sphincter function, leading to chronic duodenobiliary reflux with bacterial colonization and low-grade inflammation of the biliary system. However, the clinical consequences of these events remain unclear since long-term follow-up studies have not revealed any severe late complications. (See '[Late complications](#)' above.)

- **Indications** – EBD is a technique that should be reserved for selected patients:
 - We consider EBD to be a reasonable option in young patients (<40 years of age) with small stones who do not have additional risk factors for pancreatitis. Risk factors for post-ERCP pancreatitis include younger age, female sex, suspected type I or II sphincter of Oddi dysfunction, prior ERCP-induced pancreatitis, difficult cannulation, precut (access) sphincterotomy, pancreatic duct injection, and a small common bile duct diameter (<5 mm), particularly in the setting of sphincter of Oddi dysfunction. (See "[Post-endoscopic retrograde cholangiopancreatography \(ERCP\) pancreatitis](#)", section on '[Risk factors](#)'.)

Uncomplicated stones in such patients can be removed easily without lithotripsy while preserving sphincter function. However, there are no published data to support this approach.

- We usually perform EBD without sphincterotomy in settings where EST is associated with increased risk of adverse events or is technically more difficult, such as in patients with risk factors for post-sphincterotomy bleeding, those who have undergone a Billroth-II gastrectomy, and those with a periampullary diverticulum. (See "[Post-endoscopic retrograde cholangiopancreatography \(ERCP\) bleeding](#)" and "[Endoscopic retrograde cholangiopancreatography \(ERCP\) after Billroth II reconstruction](#)".)

However, most patients have uncomplicated bile duct stones without increased risk for adverse events. Thus, EST remains the cornerstone of the endoscopic management of bile duct stones. (See "Endoscopic management of bile duct stones".)

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Topic 631 Version 19.0

GRAPHICS

Factors associated with difficult bile duct stone extraction during ERCP

Stone characteristics
▪ Large size (>1 cm)
▪ Multiple stones (>3 stones)
▪ Location: Proximal to biliary stricture, impacted in bile duct, or intrahepatic
Anatomic factors*
▪ Surgically altered anatomy (eg, Roux-en-Y anatomy)
▪ Tortuous bile duct

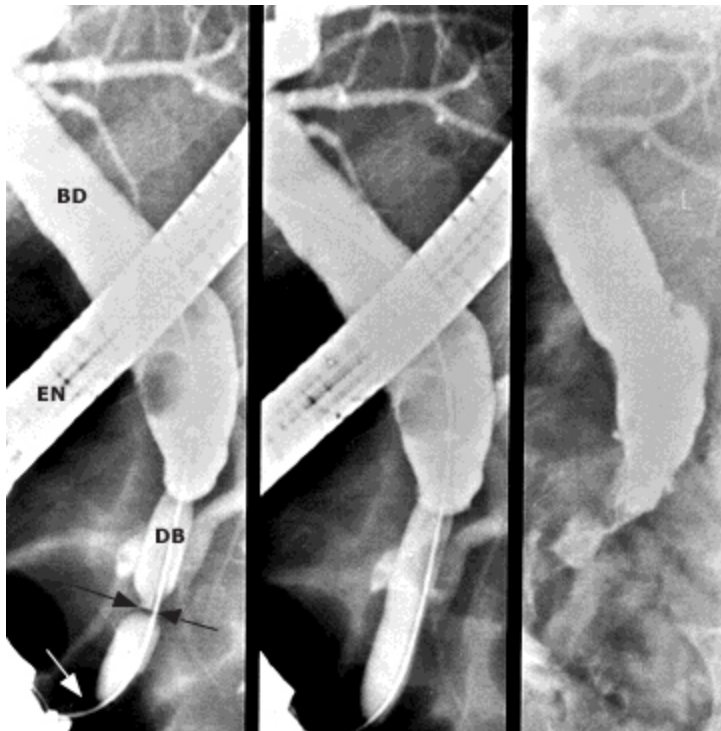
Refer to UpToDate content on endoscopic management of bile duct stones for more detail.

ERCP: endoscopic retrograde cholangiopancreatography.

* Anatomic factors associated with difficult stone extraction may be the result of one or more technical difficulties (ie, reaching the ampulla endoscopically, difficulty cannulating the biliary tree, and/or performing sphincterotomy). Refer to UpToDate content on ERCP in patients with altered anatomy.

Graphic 138304 Version 1.0

Endoscopic removal of bile duct stones after endoscopic balloon dilation of the biliary sphincter



Left: EN = endoscope positioned in descending duodenum; BD = bile duct filled with contrast, two bile duct stones visible; DB = dilation balloon placed in bile duct opening after passage over a guidewire (white arrow) and inflated with dilute contrast - biliary sphincter is seen as a "waist" in the balloon (black arrows). Middle: biliary sphincter adequately dilated if "waist" in balloon has completely disappeared. Right: after removal of bile duct stones.

Reproduced with permission from: Bergman JJ, et al. Lancet 1997; 349:1124. Photo courtesy of Jacques Bergman and Kees Huibregtse.

Graphic 81600 Version 4.0

Sphincter of Oddi in relation to the ampulla of Vater

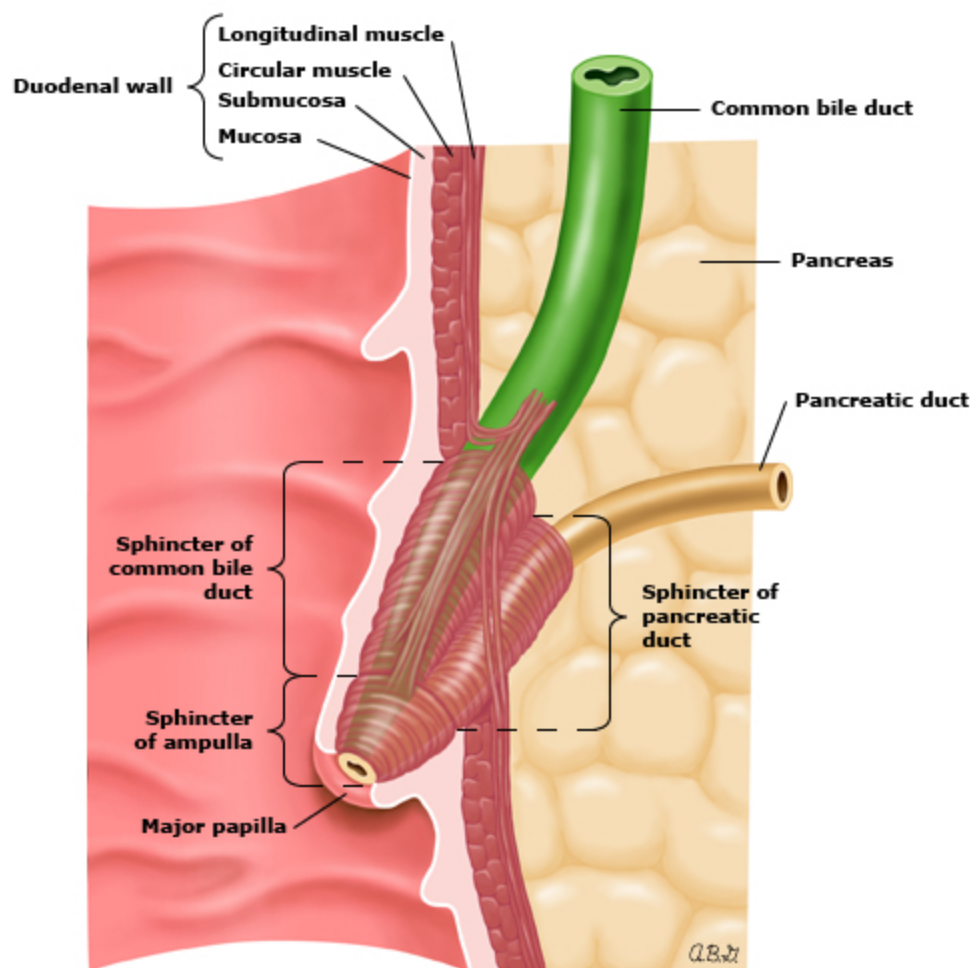


Diagram of the anatomy of the sphincter of Oddi and ampulla of Vater. The muscle fibers of the sphincter of Oddi surround the intraduodenal segment of the common bile duct and the ampulla of Vater. A circular aggregate of muscle fibers, known as the sphincter choledochus (or sphincter of Boyden), keeps resistance to bile flow high and thereby permits filling of the gallbladder during fasting and prevents retrograde reflux of duodenal contents into the biliary tree. A separate structure, called the sphincter pancreaticus, encircles the distal pancreatic duct. The muscle fibers of the sphincter pancreaticus are interlocked with those of the sphincter choledochus in a figure-of-eight pattern.

Graphic 78786 Version 4.0

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