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# Prophylactic pancreatic stents to prevent ERCP-induced pancreatitis: When do you use them?

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## INTRODUCTION

Endoscopic placement of polyethylene stents is a well-established therapy for treating a variety of benign and malignant biliary tract diseases. Application of similar techniques in the pancreas is emerging. Pancreatic duct stents have been placed to bridge dominant strictures, bypass obstructing pancreatic duct stones, drain pseudocysts, seal duct disruptions, treat symptomatic minor (ie, pancreas divisum) and/or major (ie, sphincter of Oddi dysfunction) sphincter stenosis, prevent procedure-induced pancreatitis, serve as a guide for sphincterotomy, and facilitate bile duct cannulation ( [table 1](#)).

This topic review will focus on the indications and efficacy of placing a pancreatic stent to prevent post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis. An overview of pancreatic stenting and its complications is provided separately. (See "[Pancreatic stenting at endoscopic retrograde cholangiopancreatography \(ERCP\): Indications, techniques, and complications](#)".)

## RISK FACTORS FOR POST-ERCP PANCREATITIS

Pancreatitis is the most common complication of diagnostic and therapeutic ERCP occurring in 1 to 15 percent of patients [1-3]. (See "[Overview of endoscopic retrograde](#)

## [cholangiopancreatography \(ERCP\) in adults".\)](#)

The pancreas is subjected to many types of potential injury during ERCP and endoscopic sphincterotomy: mechanical, chemical, hydrostatic, enzymatic, microbiological, allergic, and thermal [4]. These mechanisms of injury may act independently or in concert to induce postprocedure pancreatitis. Several patient- and procedure-related risk factors for post-ERCP pancreatitis have been found, which are described separately. (See "[Post-endoscopic retrograde cholangiopancreatography \(ERCP\) pancreatitis](#)".)

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## PROPHYLACTIC STENTING

**Rationale** — Recognition of risk factors associated with post-ERCP pancreatitis provided the rationale for evaluating a number of measures for preventing post-ERCP pancreatitis. A possible approach is to use prophylactic pancreatic stents.

Studies evaluating the use of prophylactic stents have included different indications for stenting, interventions, and outcome measures, and several have only been reported in preliminary form. As a result, the findings are not always directly comparable. Several randomized prospective trials evaluating stenting reached varying conclusions [5-11]. Some of the inconsistency may be due to variable rates of pancreatitis in the control groups, the degree of risk in the various patient populations, the power of the studies, and the endoscopic techniques used. Not surprisingly, the use of pancreatic stents is variable among expert biliary endoscopists [12]; our approach is similar to that proposed by other authorities [13]. (See '[Summary and recommendations](#)' below.)

Meta-analyses suggest that the use of stents decreases the rate of post-ERCP pancreatitis [14-17]. In a meta-analysis of 15 randomized trials (12 published articles and three abstracts) that included 2510 patients, the stent group had a significantly lower incidence of post-ERCP pancreatitis (4 versus 10.4 percent) [16]. Subgroup analysis also showed a reduction in mild and severe post-ERCP pancreatitis in the stented group.

Individual trials that found stenting significantly decreased the risk of post-ERCP pancreatitis included the following types of patients [5,7-9]:

- Patients treated with prophylactic pancreatic duct stents in the settings of pancreatic sphincter hypertension undergoing biliary sphincterotomy [7]
- Patients undergoing endoscopic ampullectomy [8]

- Patients with one or several risk factors for post-ERCP pancreatitis [5]
- Consecutive patients with zero or more risk factors for post-ERCP pancreatitis [9]

The European Society of Gastrointestinal Endoscopy (ESGE) guideline on prophylaxis of post-ERCP pancreatitis recommended placement of a 5 Fr prophylactic pancreatic stent in high-risk cases [18].

Whether pancreatic stenting is preferred among the preventive strategies for patients who are at high risk for post-ERCP pancreatitis is uncertain, while efficacy, complication risk, and the availability of technical expertise are important considerations [19]. In a network meta-analysis of 29 trials including 7862 patients at high risk for post-ERCP pancreatitis, several strategies (ie, rectal nonsteroidal antiinflammatory drugs [NSAIDs], combination of rectal NSAIDs with hydration with [lactated ringer's solution](#), and pancreatic stenting) resulted in lower risk of post-ERCP pancreatitis compared with placebo. Among the strategies, pancreatic stenting was most effective for reducing the risk of post-ERCP pancreatitis (surface under the cumulative ranking probability 0.81, 95% CI 0.83-0.80) [20]. (See "[Post-endoscopic retrograde cholangiopancreatography \(ERCP\) pancreatitis](#)", section on '[Preventive strategies](#)' and '[Complications of pancreatic stents](#)' below.)

A cost-effectiveness analysis indicated that pancreatic stent placement in high-risk patients yielded the highest number of life years gained compared with no placement or placement in all patients [21]. These data need to be considered in the context of other experience (including results from uncontrolled studies), which will be reviewed below. Together, these form the basis for our recommendations. (See '[Summary and recommendations](#)' below.)

**After excessive manipulations of the papilla** — There are limited data evaluating stenting in patients who underwent excessive manipulation of the papilla. In a randomized study, 76 high-risk patients (because of difficult cannulation, or because they were undergoing manometry or endoscopic sphincterotomy) were treated with a 5 Fr 2 cm pancreatic stent, a nasopancreatic drain, or no drainage [5]. The two stented groups had a significantly lower rate of post-ERCP pancreatitis (5 versus 28 percent).

In a randomized trial of patients with difficult cannulation, placement of a 3 Fr pancreatic stent (4, 6, or 8 cm) was associated with a lower rate of post-ERCP pancreatitis than no stent placement (12 versus 29 percent) [22]. On multivariable analysis, pancreatic stent placement was the only factor associated with preventing post-ERCP pancreatitis (odds ratio [OR] 0.13, 95% CI 0.03-0.63).

**Sphincter of Oddi dysfunction or a small bile duct** — A controlled trial included 98 patients with sphincter of Oddi dysfunction and/or a small diameter common bile duct who were randomly assigned to receive a main pancreatic duct stent (2 or 2.5 cm; 5 or 7 Fr) following the sphincterotomy or no stent [6]. The incidence of postprocedure pancreatitis (14 versus 18 percent) and the degree of amylase and lipase elevation (860 versus 1380 international unit/L and 5978 versus 8121 international unit/L, respectively) were reduced in the stented group, although the results were not statistically significant.

Another study suggested that placing a pancreatic duct stent prior to combined pancreatic and biliary sphincterotomy (for therapy of sphincter of Oddi dysfunction) had a lower post-ERCP pancreatitis rate than biliary sphincterotomy alone (11 versus 28 percent) [23].

It is possible that the risk of pancreatitis in patients with sphincter of Oddi dysfunction undergoing biliary sphincterotomy is related to underlying pancreatic sphincter hypertension. This hypothesis was supported in a prospective, randomized, controlled trial of 80 patients with manometrically proven pancreatic sphincter hypertension. Stenting of the pancreatic sphincter of Oddi segment (5 or 7 Fr) after biliary sphincterotomy significantly reduced the risk of pancreatitis (7 versus 26 percent with no stenting) ( [table 2](#)) [7].

These results strongly suggest that this high-risk subset of patients (pancreatic sphincter hypertension undergoing biliary sphincterotomy alone) should be considered candidates for pancreatic stenting. However, the rate of pancreatitis in the control group was probably increased due to a number of patient- and procedure-related risk factors.

Another, retrospective study suggested that prophylactic stenting benefits those who were suspected of having sphincter of Oddi dysfunction but had normal manometry [24]. The study included 430 such patients, 115 of whom had a prophylactic stent placed at the discretion of the endoscopist. The rate of post-ERCP pancreatitis was only 0.9 percent in the stent group compared with 9.8 percent in the nonstent group.

**Precut sphincterotomy** — As noted above, the frequency of post-ERCP pancreatitis appears to be higher in patients undergoing precut sphincterotomy compared with those undergoing standard biliary sphincterotomy. One group evaluated the efficacy of placing a pancreatic duct stent prior to precut sphincterotomy and leaving it in place following the precut [25]. During a 32-month interval of 1122 patients undergoing sphincterotomy, 151 (13.5 percent) required precut sphincterotomy. In 93 patients, selective cannulation of the pancreatic duct was achieved and a 5 Fr or 7 Fr diameter, 2 or 2.5 cm length stent was placed in the pancreatic duct. Using the pancreatic duct stent as a guide, a needle-knife sphincterotomy

was performed. Following completion of the sphincterotomy, these 93 patients were randomly assigned to having the stent left in place for 7 to 10 days (stent group) or immediate removal (stent removed group). The remaining 58 patients who did not undergo pancreatic duct stent placement (no stent group), had a needle-knife sphincterotomy performed in a similar fashion.

Pancreatitis occurred significantly more often in the stent removed group compared with the stent group (21 versus 4 percent). Patients who did not have a pancreatic stent placed had a postprocedure pancreatitis rate of 14 percent. These data suggest that placing and maintaining a pancreatic duct stent following needle-knife precut sphincterotomy reduces the frequency of postprocedure pancreatitis.

**Pancreatic sphincterotomy** — Endoscopic pancreatic sphincterotomy has not been widely practiced because of a lack of well-defined criteria for its use. In most studies in which it has been used, pancreatic sphincterotomy was performed as an adjunctive therapy to allow access to the pancreatic duct for other maneuvers (eg, stone removal, stent placement, and tissue sampling). There are limited data regarding the use of pancreatic sphincterotomy alone to treat disorders of the pancreas or sphincter [26].

The role of stenting when a pancreatic sphincterotomy is required can be understood in the context of the two standard methods to cut the pancreatic sphincter (minor or major) [27]. One method involves placement of a standard pull-type sphincterotome in the pancreatic duct oriented along the axis of the pancreatic duct. An incision of 5 to 10 mm is usually made. A second method uses a needle-knife to perform the sphincterotomy over a previously placed pancreatic stent. In the former technique, a pancreatic stent is usually placed after the sphincterotomy, particularly when the pancreatic duct is normal (eg, in the setting of sphincter of Oddi dysfunction or pancreas divisum).

Accumulating data suggest that placement of a pancreatic stent in this setting can reduce the incidence of postpancreatic sphincterotomy pancreatitis. This approach was supported in a retrospective study in which the frequency of postpancreatic sphincterotomy pancreatitis was determined in 164 patients treated with overnight nasopancreatic catheter drainage (60 percent), pancreatic stenting (30 percent), or no drainage (10 percent) [26]. The type of pancreatic drainage used varied according to the indication for the sphincterotomy. Patients undergoing pancreatic sphincterotomy as the primary therapy (without other treatments) more commonly had a nasopancreatic catheter placed (94 versus 6 percent for stent). In contrast, when the sphincterotomy was done as an adjunct for further interventions, the method of drainage was more commonly a pancreatic stent (71 versus 29 percent for a

nasopancreatic catheter).

Post-ERCP pancreatitis occurred in three patients (2 percent) and was graded mild in two and moderate in one. Pancreatitis occurred significantly less often in patients treated by a nasopancreatic catheter or a pancreatic stent compared with those not undergoing a drainage procedure (2 and 0 versus 13 percent, respectively) ( [table 3](#)).

The authors concluded that a drainage catheter or stent is required after pancreatic sphincterotomy to reduce the incidence of pancreatitis. They suggested that nasopancreatic drainage is the method of choice since it has a similar complication rate as stenting, avoids the need for a repeat procedure to remove the stent, and presumably avoids the other complications associated with stenting because of the extremely short period (usually less than 24 hours) of drainage (see '[Complications of pancreatic stents](#)' below). However, pancreatic stents without an internal flange have a high spontaneous migration rate out of the duct and are much more commonly used in clinical practice than nasopancreatic drains.

**Balloon sphincter dilation** — A possible benefit to prophylactic pancreatic stent placement was suggested in a study of 40 patients with bile duct stones [28]. The study compared patients who had a stent placed prior to balloon dilation of the sphincter of Oddi to historic controls who did not have a stent placed [28]. The postprocedure serum amylase level was significantly less in the group who received a stent. A nonstatistically significant trend toward a lower rate of pancreatitis was also observed. The nonrandomized study design, small sample size, and unclear clinical benefit limit the conclusions that can be derived from this report. Furthermore, the modest treatment benefit (if any) and the need for a follow-up procedure to remove the stent raises questions about the cost-effectiveness of stenting in this setting. (See "[Endoscopic balloon dilation for removal of bile duct stones](#)".)

**Snare excision of the duodenal ampulla** — A reduced risk of pancreatitis with pancreatic stent insertion was found in a controlled trial of patients undergoing snare excisions of the duodenal ampulla [8]. (See "[Ampullary adenomas: Management](#)".)

**Routine prophylactic pancreatic duct stenting** — A randomized controlled multicenter study from Japan evaluated the efficacy of a pancreatic stent without an internal flange in 201 consecutive patients undergoing ERCP [9]. Many of the patients in this study would not have been considered high risk.

Ninety-eight patients received a 5F straight polyethylene stent, 3 cm in length, unflanged on the pancreatic ductal side and with two flanges on the duodenal side (S group), and 103 patients did not receive a stent. Stent dislodgement was confirmed by daily abdominal x-rays

with stent removal if dislodgement did not occur by day 4. All patients in the study were given antibiotics and gabexate mesylate after the ERCP.

The diagnosis and grading of the severity of pancreatitis were based on standardized criteria. Patient demographics, procedure indication, difficulty of cannulation, grade of ERCP skill of the endoscopist, procedure time, and procedures performed were similar for the two groups. Pancreatic stents were successfully placed in 96 percent and the rate of stent dislodgement by day 3 was 95.7 percent.

The overall frequency of pancreatitis was 8.5 percent (17 of 201). It occurred significantly less often in the stent group compared with the nonstent group (3.2 versus 13.6 percent). The mean increase in serum amylase level in pancreatitis patients, the overall serum amylase levels, and the frequency of abdominal pain were significantly higher in the nonstent group. There were no episodes of severe post-ERCP pancreatitis in either group. There were no major complications related to stenting and pancreatitis did not occur in the four patients who failed stent placement. This study shows that placement of unflanged stents leads to a high stent migration rate, thus avoiding a second procedure to remove the stents, and provides protection against post-ERCP pancreatitis.

**Facilitating bile duct cannulation** — Placement of a pancreatic stent may have a role in facilitating difficult bile duct cannulation. A 99 percent success rate using this approach was described in a series of 39 patients [29]. Two patients (5 percent) developed post-ERCP pancreatitis, both mild.

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## WHICH PANCREATIC STENT TO USE

The most effective diameter and length stent to prevent post-ERCP pancreatitis warrants further study. Published studies have generally not been powered to detect a difference in post-ERCP pancreatitis rates for different stent diameters and lengths. While some studies have suggested that stent diameters do not impact post-ERCP pancreatitis rates, a systematic review and network meta-analysis reported that the 5 Fr stent was superior to the 3 Fr stent in high-risk patients [30-32]. In a published study powered to detect a difference in pancreatitis rates based on stent length, 240 consecutive patients undergoing ERCP to remove bile duct stones or for biliary drainage for obstructive jaundice were randomized to undergo prophylactic insertion of an unflanged 5 Fr 3 or 5 cm pancreatic stent [33]. In the per-protocol analysis, the pancreatitis rate was significantly lower with the shorter stent (2 versus 8.8 percent), although they were not significantly different in the intention to treat

analysis. The shorter stent migrated in a significantly shorter interval (two versus four days).

## COMPLICATIONS OF PANCREATIC STENTS

Although the results of the above studies strongly suggest that pancreatic stenting reduces the incidence of post-ERCP pancreatitis in certain subgroups of patients, the endoscopist should be aware that pancreatic stenting has a clear downside. A variety of complications directly related to the pancreatic stent can occur, including stent occlusion (occasionally associated with pancreatitis or pain), migration into or out of the duct (the former may require surgery for stent removal), duodenal erosions, infection, ductal perforation, and morphologic changes of the pancreatic duct and parenchyma [34,35].

The morphologic changes are concerning particularly when they occur in a previously normal pancreas. In seven published series, new morphologic pancreatic ductal changes were seen in 54 percent of 297 patients stented [34,36-41]. The risk may be reduced by using small (3 to 4 Fr), unflanged stents [42].

It should be appreciated that the risk of pancreatitis after failing to place a pancreatic stent may be greater than no attempt at all [43]. (See "[Pancreatic stenting at endoscopic retrograde cholangiopancreatography \(ERCP\): Indications, techniques, and complications](#)".)

In a secondary analysis of a randomized controlled trial [44] evaluating the efficacy of rectal [indomethacin](#), the incidence of post-ERCP pancreatitis among patients in the placebo group who experienced a failed stent attempt was significantly higher in patients who underwent successful stenting and in those without a stent attempt (38, 16, and 12 percent, respectively). A failed stent attempt was found to be independently associated with post-ERCP pancreatitis and was attenuated by rectal administration of indomethacin. In an observational study including 14 patients with post-ERCP pancreatitis, repeat ERCP with initial pancreatic stent placement or replacement (if the first stent had migrated prematurely) was associated with improvement in pain, biochemical tests (eg, lipase), and resolution of systemic inflammatory response syndrome [45].

Another downside of placing a prophylactic pancreatic stent is the need in many cases for a second endoscopy to remove the stent. As a result, some authorities advocate placement of a nasopancreatic tube since it can easily be removed at the bedside within 24 hours of the procedure [26] (see '[Prophylactic stenting](#)' above). However, it is possible that small caliber stents may be effective while (because of their tendency to spontaneously dislodge) avoiding the need for a second endoscopy [42,46]. This issue was addressed in a study that compared



the spontaneous dislodgement rates of small diameter (3 Fr and 4 Fr), long length (8 to 12 cm), and no intraductal flange pancreatic stents [46]. Eighty-six percent of 3 Fr stents spontaneously passed within 30 days (compared with 73, 67, and 65 percent of 4 Fr, 5 Fr, and 6 Fr stents, respectively).

In the Japanese study described above, stent passage was recognized in 96 percent of patients after an average of two days when using a "spontaneous dislodgement stent" [9]. The stent was 5F, straight, polyethylene, 3 cm in length, unflanged on the pancreatic side and with two flanges on the duodenal side (GPDS-5-2; Cook Endoscopy Inc, Winston-Salem, NC).

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## 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: Acute pancreatitis](#)" and "[Society guideline links: Endoscopic retrograde cholangiopancreatography \(ERCP\)](#)".)

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## SUMMARY AND RECOMMENDATIONS

Considering the above discussion, available evidence, and clinical experience, we suggest the approaches outlined below with regard to prophylactic pancreatic stent placement to prevent post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis. These recommendations are based upon the assumption that a highly skilled endoscopist with experience in pancreatic stenting is available. In other settings, the benefit of stenting may be outweighed by the risk of excessive and potentially unsuccessful pancreatic duct manipulation.

- We suggest pancreatic stents be placed in patients undergoing ERCP in the following settings (**Grade 2B**):
  - Those undergoing pancreatic endotherapy
  - Suspected or documented sphincter of Oddi dysfunction
  - Prior post-ERCP pancreatitis
  - Difficult cannulation
  - Precut sphincterotomy starting at the papillary orifice

- Pancreatic sphincterotomy (major or minor)
  - Aggressive instrumentation of the pancreatic duct (such as brush cytology)
  - Balloon dilation of an intact sphincter
  - Endoscopic ampullectomy
- In patients considered high risk for post-ERCP pancreatitis, it is reasonable to attempt filling of the pancreatic duct in patients in whom it was not filled during attempts at biliary cannulation. If the pancreatic duct fills easily, and the anatomy is favorable, placement of a stent is reasonable. In other patients, the benefit of aggressive attempts at pancreatic duct filling or stenting may be outweighed by associated trauma.
  - Prophylactic pancreatic duct stenting is generally not recommended in low-risk patients, in patients undergoing needle-knife precut or fistulotomy starting above the papillary orifice in the absence of other risk factors, or if the pancreatic duct is not injected with contrast and there is limited guidewire manipulation in an otherwise low-risk patient.
  - In patients with suspected sphincter of Oddi dysfunction, we suggest **not** performing empiric pancreatic duct stenting as a primary therapy or as a trial to predict response from pancreatic sphincterotomy, primarily because of stent-related complications (**Grade 2C**). Such patients should undergo sphincter of Oddi manometry and definitive therapy (sphincter ablation) when indicated.
  - In patients undergoing prophylactic pancreatic duct stenting, we suggest a stent be left in place for at least 24 hours and preferably less than 14 days (particularly if the pancreatic duct has normal morphology), depending upon stent size.
  - The most effective diameter and length stent to prevent post-ERCP pancreatitis warrants further study.

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Topic 2661 Version 20.0

## GRAPHICS

### Settings in which pancreatic stents are being used

|  |
|--|
| Pancreatic ductal strictures                 |
| Benign                                       |
| Malignant                                    |
| Unextractable pancreatic ductal stones       |
| Pancreatic pseudocysts and duct disruptions  |
| Transpapillary                               |
| Transmural (duodenal/gastric)                |
| Papillary stenosis                           |
| Minor (pancreas divisum)                     |
| Major  |
| Prevention of procedure-induced pancreatitis |
| Facilitating bile duct cannulation           |
| Guide for sphincterotomy                     |
| Biliary                                      |
| Pancreatic                                   |

Graphic 51003 Version 2.0

## Pancreatic stenting after biliary sphincterotomy for sphincter of Oddi dysfunction in patients with pancreatic sphincter hypertension

| Therapy           | Pancreatitis, percent |      |          |        |
|-------------------|-----------------------|------|----------|--------|
|                   | Total                 | Mild | Moderate | Severe |
| Stent (n = 41)    | 2                     | 0    | 2        | 0      |
| No stent (n = 39) | 26*                   | 13   | 13       | 0      |

\* p = 0.003 (N.B. incidence of pancreatitis was 7 percent in the stent group when including two patients who developed pancreatitis after stent removal).

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Data from: Tarnasky PR, et al. *Gastroenterology* 1998; 15:1518.

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Graphic 81201 Version 2.0



## Incidence of pancreatitis according to the type of pancreatic drainage

|                                |                  |
|--------------------------------|------------------|
| <b>Nasopancreatic drainage</b> | 0 of 98 (0%)     |
| <b>Pancreatic stenting</b>     | 1 of 50 (2%)     |
| <b>Any drainage</b>            | 1 of 148 (0.7%)* |
| <b>No drainage</b>             | 2 of 16 (12.5%)* |

\*  $p < 0.003$  for pancreatic duct drainage versus no drainage.

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Data from: Elton E, et al. *Gastrointest Endosc* 1998; 47:240.

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Graphic 78326 Version 3.0

## Contributor Disclosures

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