### **ADVANCES IN ENDOSCOPY**

Current Developments in Diagnostic and Therapeutic Endoscopy

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### Prophylactic Pancreatic Duct Stents

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#### **G&H** Could you briefly describe the prophylactic pancreatic duct stent placement procedure?

**GE** In a patient selected for a prophylactic pancreatic duct stent, a wire is placed into the pancreatic duct and the stent of choice is inserted over the wire. There are several different stent choices. In these patients, physicians often select a stent that will spontaneously dislodge to avoid performing a second procedure for the removal of the stent. A radiograph is obtained 2 weeks after stent placement to ensure that the stent has passed, as occasionally the stent does not and it should not remain in the pancreatic duct indefinitely. However, there are several experts in the United States who prefer to insert pancreatic stents that do not spontaneously dislodge and must be endoscopically removed 1 or 2 days after the stent placement. Thus, the type of stent placed determines the required follow-up procedure.

### **G&H** Which indications have demonstrated a benefit in the use of prophylactic pancreatic stents?

**GE** The goal of placing a prophylactic pancreatic stent is the prevention of pancreatitis as a complication of a procedure. There are several indications that have been supported either by expert consensus or study outcomes for the use of pancreatic stents in the prevention of pancreatitis. Patients with sphincter of Oddi dysfunction who are undergoing sphincterotomy (biliary, pancreatic, or both) have been studied in a randomized fashion, and these procedures have been shown to be an indication for pancreatic stent placement. This original indication for prophylactic pancreatic stent placement was confirmed

in a meta-analysis of several studies that showed a 3-fold lower odds of developing pancreatitis compared with the no stent groups. The analysis of the number needed to treat showed that 1 in every 10 patients would be expected to benefit from pancreatic duct stent placement. In addition, a recent retrospective study suggested that patients who have suspected sphincter of Oddi dysfunction with intact papillas but normal manometry should also have stent placement. A randomized trial of patients undergoing ampullectomy was stopped early due to the clear benefit of stent placement for that indication. Nearly all experts also include pancreatic sphincterotomy, whether at the major orifice or the minor orifice, as a clear indication for prophylactic pancreatic duct stent placement.

# **G&H** Which indications have been suggested as possibilities for pancreatic stents but have not been definitively supported by research findings or expert consensus?

**GE** There are several other potential indications that have not been studied in randomized fashions. One indication is in cases requiring multiple or complete pancreatic injections, as multiple injections of contrast into the pancreatic duct, particularly if filled to the tail of the pancreas, increases the risk of pancreatitis. Sphincter balloon dilation is another possible indication, as inflation of a balloon in order to stretch an intact sphincter also increases the risk of pancreatitis. Many experts believe that precut sphincterotomy, in which a needleknife is used to gain access to the bile duct, should be considered as another possible indication for the use of prophylactic pancreatic duct stents. Other possible indications include trauma to the papilla and history of prior endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis or idiopathic pancreatitis.

It should be noted that although studies have not definitively proven that a pancreatic duct stent lowers the incidence of postprocedure pancreatitis in these indications, some research has been conducted leading to this conclusion. Contrast injection to the tail has been shown to increase the risk of pancreatitis when compared to a small amount of contrast introduced into the pancreatic duct, and a prior history of ERCP-induced pancreatitis is one of the strongest risks known. More research, however, is needed to categorize these indications as clear cut.

### **G&H** How are patients selected for the placement of these stents?

GE Patients who are young have a higher risk of post-ERCP pancreatitis; thus, in a younger patient, a physician may be more prone to place a prophylactic pancreatic stent, particularly if the patient presents with an indication that is considered possible, but not definitive. Another mitigating factor is female sex, as several studies have shown that women have a higher risk of post-ERCP pancreatitis than men. The presence of wire pancreatic cannulation instead of contrast is another consideration that should be taken into account; cannulation with wire is less worrisome than with contrast. Two controlled trials have now shown that initial wire cannulation instead of contrast injection may lower the risk of post-ERCP pancreatitis. Any prior history of post-ERCP pancreatitis is a clear risk factor. In the end, however, patient selection comes down to the judgment of the physician.

## **G&H** What have studies reported regarding the efficacies of the various types of pancreatic stents?

**GE** Pancreatic duct stents can vary in material, diameter, length, the presence of internal flanges, and other features. The issue of the most effective stent remains a controversial one in the literature, and there are several ongoing randomized trials attempting to answer this question. As mentioned previously, the main goal of placing a prophylactic pancreatic stent is the prevention of pancreatitis. As pancreatitis is relatively uncommon, a very large number of patients would be needed to compare this outcome with two different stent types. Thus, I am not sure that a study will ever be conducted that shows superiority for preventing pancreatitis.

A simpler point of stent comparison is to determine which stents are most effective at passing spontaneously. It is easier to obtain good data on this aspect of stents, as it occurs frequently, unlike pancreatitis. There have been studies in the literature examining this issue, including a retrospective study suggesting that a smaller 3F stent may be better and safer for the patient and may spontaneously

pass more effectively, even though a preliminary report of a randomized controlled trial showed that a larger 5F stent performed just as well. More research is needed to definitively determine the type of stent that is best for spontaneous passage, to decrease the need for a second procedure.

One of the other key issues when comparing types of stents involves the safety of the stent in the pancreatic duct. Prophylactic pancreatic duct stents have been known to traumatize and damage the pancreatic duct, which is the reason that the stents are not supposed to remain long in the duct. It would be beneficial to know which of the various stent types and sizes, if any, cause less trauma to the pancreatic duct, which is a different and separate issue from which stents are better at preventing postprocedure pancreatitis. Unfortunately, these data are also difficult to obtain. There are some old animal data showing that pancreatic stents are quite traumatic to the duct and cause scarring and inflammation, especially if the pancreatic duct stent remains in a normal duct for a long period of time. However, as damage to the pancreatic duct is fairly uncommon and patients are not re-examined unless they return with recurrent problems, the actual frequency and extent of the damage to the pancreatic duct is uncertain.

## **G&H** Could you discuss the complications and risks associated with placement of prophylactic pancreatic stents?

**GE** Spontaneous internal migration can occur in the pancreatic duct, which can cause serious problems for the patient, including repeat procedures and even surgical intervention. Stents that spontaneously dislodge are designed to migrate out of the duct. On rare occasions, the stents can become stuck in the small bowel, particularly in patients who have multiple adhesions. I treated one such patient with familial adenomatous polyposis and an abdominal desmoid, in whom a 3F stent got stuck in the midjejunum. It was eventually removed by enteroscopy. These complications, however, are rare.

A significant complication associated with prophylactic pancreatic duct stents is that they can be technically intricate to place; it may be difficult to access the pancreatic duct after ampullary therapy or in a curlicue ductal anatomy, to pass the wire deeply into the duct. There is a small case series in the literature that suggests that merely attempting to enter the pancreatic duct for stent placement requires a fair amount of manipulation, and if the physician fails, the risk to the patient is even greater than no attempt at all.

Despite this difficulty, in my opinion, even physicians in fairly low-volume-ERCP community centers

should acquire the ability to place pancreatic duct stents, as even a "simple" gallstone case can be difficult to cannulate, requiring several injections into the pancreas, causing trauma to the orifice or necessitating the patient to undergo precut sphincterotomy. I think that any physician who performs ERCPs should have pancreatic stent placement in his or her treatment armamentarium; pancreatic duct stent placement should not be considered merely the work of tertiary care centers.

### **G&H** What has cost-effectiveness analysis shown regarding the use of prophylactic pancreatic stents?

**GE** Inserting prophylactic pancreatic stents does add a fair amount of cost. After all, stent placement often requires the use of an additional wire; the pancreatic stent itself adds costs; and to remove the stent, either a follow-up radiograph is needed to ensure that the stent has spontaneously dislodged or a second procedure must be performed for endoscopic removal.

Nevertheless, there has been a cost-effectiveness analysis reported in the literature examining the costs versus the benefits of prophylactic pancreatic stents, and for high-risk patients, placement of prophylactic pancreatic stents are cost-effective.

#### **G&H** What do you foresee as the next steps for future research?

**GE** More research is certainly needed regarding the best type of stent, in terms of the different issues mentioned above: which stent best prevents pancreatitis, which stent causes the least damage to the pancreatic duct, and which stent spontaneously passes the best and avoids the need for a second procedure. We also need more studies of the various high-risk indications to help us decide which patients will benefit from stent placement.

#### **Suggested Reading**

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