EDITORIAL

Pancreatic stents in chronic pancreatitis: do they function as a tube, a wick, or a placebo?

One of the most challenging aspects in the management of chronic pancreatitis is the treatment of pain, which can be infrequently achieved by conservative measurements. The origin of pain seems to be multifactorial, with combinations of mechanisms like pancreatic ductal hypertension, increased interstitial fluid pressure, ischemia, and inflammatory damage of pancreatic nerves.[1] Additional pain associated complications of chronic pancreatitis, e.g., pseudocysts or biliary obstruction, have to be considered. Because of these variations of the etiology of pain, it is difficult to determine the leading factor in the individual case, and there is a lack of parameters predicting success of different therapeutic options. A dilatation of the main pancreatic duct of more than 7 mm is considered to be an indicator for increased ductal and parenchymal pressure causative for pain. For this selected group of patients, surgical drainage procedures are frequently recommended instead of more difficult and aggressive resection techniques. However, recently introduced, more organ-preserving resective operations or their combination with pancreaticojejunostomy offer an effective alternative; however, they have not yet reached an international position as a standard operation for chronic pancreatitis.[2]

Endoscopic measurements also aim at ductal decompression in patients with chronic pancreatitis, and they have been increasingly used as minimally invasive procedures. Because all of these strategies are palliative, they should only be considered in symptomatic patients. The application of a variety of techniques depends on the causes of ductal obstruction, such as stones, strictures, or their combinations. Endoscopic sphincterotomy (EST) and extracorporeal shock wave lithotripsy (ESWL) are usually required for ductal clearance of stones, which should always be attempted. Associated strictures of the main pancreatic duct or strictures without stones are frequently more difficult to manage than biliary stenoses by means of bougienage, balloon dilation, and subsequent placement of pancreatic stents. The best candidates seem to be patients with one dominant stricture in the pancreatic head with upstream ductal dilatation.

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The efficacy of these endoscopic procedures for the treatment of chronic pancreatitis is difficult to determine for many reasons. Most series were retrospectively performed in single centers, with a limited number of patients and a lack of control groups. Intention-to-treat analysis, data completeness, and the number of patients lost to follow-up were infrequently reported.[3,4] Because of a retrospective design and a frequent lack of a study protocol, the selection criteria for patients, the type of endoscopic techniques, and the postprocedural strategies vary considerably. There are no prospective data on long-term follow-up and only a few retrospective analyses for mean periods of more than 4 years.[3,5] Although the endoscopic methods have been performed for more than 20 years, these limitations may explain that a recent report on the results of evidence-based assessment of ERCP for the treatment of pancreatitis only considered 3 studies on drainage of pancreatic pseudocysts but none on ductal decompression in patients with chronic pancreatitis.[6] In spite of its limited evidence, endotherapy is frequently performed as a first-line procedure in selected patients with chronic pancreatitis. A variety of uncontrolled studies indicate that ductal clearance from stones and/or stent placement of strictures is technically successful in more than 90% of cases.[3,7] Major complications are rare, and there seems to be no stent-related mortality. Stent-induced ductal changes may develop, but they are obviously clinically irrelevant, particularly in advanced chronic pancreatitis. They usually resolve after stent removal.[7-9] Pain relief or pain reduction can be achieved in approximately two thirds of patients during follow-up periods of up to 3 or even more years. A large, retrospective, multicenter study demonstrated that one fourth of patients ultimately underwent surgery because of the failure of endoscopic treatment during a mean follow-up of 5 years.[3] Endoscopic procedures do not preclude subsequent

There is a need for formal prospective trials on stent placement in chronic pancreatitis to evaluate the efficacy and the impact of ductal anatomy, stent type, stent-placement duration, and the need for keeping stents patent.

surgery, and stent placement showed no adverse effects on the outcome of pancreaticojejunostomy.[10]

Failure of clinical response to pancreatic stent placement implies that ductal hypertension was not the dominant cause of pain in the individual case, and a surgical resection procedure should be considered. However, the majority of patients will improve and can be further treated by means of endoscopy or they are potential candidates for surgical drainage. The endoscopic approach is competitive because of the low morbidity rate and promising long-term results but frequently requires reinterventions for stent exchanges or recurrences after stent removal. Unfortunately, it is difficult to conclude from previous series which technique and therapeutic strategy has the potential to overcome these drawbacks. Pancreatic stents should be as short as possible to reduce the risk from ductal changes but long enough to bridge the most proximal stricture. The diameter of the stent is usually tailored to the size of the obstructed duct, with the aim of achieving resolution of strictures. This goal was obtained in only every fifth patient during a median follow-up of approximately 2 years after extraction of temporary stents according to collected data of retrospective series.[11] However, every second patient showed a persistent symptom improvement, which indicated that luminal patency is still sufficient or that factors other than ductal hypertension had induced pancreatic pain. The interpretation of results of studies on the optimal period of stent placement and protocol for stent exchanges is difficult. A common strategy includes a scheduled clinical follow-up every 3 or 6 months, with routine stent exchange, for a total period of up to 1 year, or stent extraction with replacement only in case of difficult passage of a 6F catheter or incomplete drainage.[5,12,13] Additional ERCP is performed in case of recurrence of symptoms with stent exchange or with stent replacement. However, comparable clinical results were reported when stents were exchanged only if patients developed relapsing pain.[7] Of 69 early responders of pancreatic-stent placement, 60 patients (87%) had sustained improvement during a mean follow-up of close to 5 years. The analysis in these patients revealed that 43% had only one stent placed, and 41% had one stent exchange. Abscess formation secondary to stent clogging occurred in two cases. In a recent trial, stents were also only exchanged on demand in 100 patients over a median period of approximately 2 years.[14] There was no case with evidence of infectious complications. The stents were removed and not replaced in patients with pain control during the stent placement period and at least one of several well-defined objective parameters, suggesting sufficient spontaneous ductal drainage. Only about one third of the patients required repeat stent placement during a study period of more than 2 years after stent extraction; 4 patients underwent elective surgery. These results imply that a clinical response does not necessarily require stent patency in view of reports that nearly all pancreatic stents are occluded within 8 weeks after placement.[15,16] In spite of a potential risk of pancreatic sepsis or abscess formation, stent occlusion itself is insufficient to cause clinical infection.[17]

Although not convincingly shown in clinical trials, a longer patency of pancreatic stents seems to be desirable. Farnbacher et al[18] recently studied the composition of clogging material and showed that albumin and lithostathine seem to play an important role in this context. In his accompanying editorial, Devière[19] recommended that the ideal stent would be hydrophilic, ultrasmooth, and soft, with a large diameter. In addition, he emphasized the advantage of stents with no side holes to minimize surface irregularities. Surprisingly, stents with multiple side holes were successfully used in several previous trials, so that the clinical impact remains undetermined.[7,12,13]

In this issue of *Gastrointestinal Endoscopy,* Farnbacher et al[16] experimentally measured stent occlusion of 100 pancreatic endoprostheses removed in 47 patients. The study period was within the study period of their previous trial on clogging material in pancreatic stents.[18] They did not report on criteria for the selection of stents for the two different trials. The indications for stent placement were strictures in 30 cases, strictures plus stones in 50, and only stones in 20 cases. Success rates for stone removal, e.g., by means of ESWL, were not mentioned. Long-term stent placement for stones without associated strictures does not seem to be a widely used procedure. In addition, the presumable larger amount of lithostathine in patients with pancreatic-duct stones may cause earlier stent clogging.[18,19] The number and location of ductal stenoses, as well as the type and clinical relevance of concomitant pseudocysts in 39% of cases were not reported. This broad spectrum of patient characteristics may explain large variations of the diameter and the length of pancreatic stents. They were mainly removed for a scheduled exchange after a median period of 92 days, with a range from 2 to 334 days. Recurrence of pain caused stent extraction in only 7% of cases. After endoscopic removal, occlusion rates were then studied in an elegant experimental setting. The median reduction of water flow in comparison with native endoprostheses was measured. The results at 10-cm water pressure seemed to be most relevant, because no visible washout of clogging material was recorded at this level. Major stent occlusion was defined as flow reduction by more than 75%. The results indicated that 97 of 100 endoprostheses were at least partially occluded. These high occlusion rates, after a relatively short period of stent placement, were also observed in previous experimental trials and clinical series, which differed, however, in the definition of occlusion.[9,15] Farnbacher et al[16] performed a univariate analysis of a large number of risks factors for stent clogging. The statistical power was too low for an appropriate comparison of patency curves.[16] However, the multifactorial analysis revealed a stent diameter of more than 8.5F, a stent length of more than 8 cm, female gender, and the presence of regular oral enzyme supplementation as independent risk factors for major stent occlusion. Interpretation of these interesting

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