

# Endoscopic Pancreatic Stent Drainage in Chronic Pancreatitis and a Dominant Stricture: Long-Term Results

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**Background and Study Aims:** Endoscopic pancreatic stent drainage has been reported to relieve pain due to chronic pancreatitis in patients with ductal outflow obstruction. However, data regarding the long-term results, as presented here, have hitherto been lacking.

**Patients and Methods:** Over a nine-year period, 93 patients (65 males, mean age 49 years) with narcotic-dependent pain due to chronic pancreatitis and with a dominant pancreatic duct stricture visualized by endoscopic retrograde cholangiopancreatography (ERCP), were treated by stent drainage. The duration of pain prior to treatment averaged 5.6 years. The stents were exchanged according to symptoms, and removed if the stricture was judged to be adequately dilated after stenting.

**Results:** Sixty-nine patients (74 %) reported complete (n = 46) or partial (n = 23) pain relief at six months. In

this group of "early responders", 60 patients experienced sustained improvement during a mean follow-up of 4.9 years (nine had recurrent pain after a mean of 1.2 years). Stents were removed in 49 patients after a mean of 15.7 months; during a mean follow-up of 3.8 years, 36 patients remained pain-free, and 13 had a relapse of pain (11 were retreated by endoscopic drainage and subsequently became pain-free). Complications seen included mild pancreatitis (n = 4) and abscess formation secondary to stent clogging (n = 2). Most patients experienced a regression of the ductal dilation after stenting.

**Conclusion:** In selected patients, early responders to pancreatic stent drainage are likely to benefit over the long term. Stent removal after stricture dilation may be associated with continued pain relief.

## Introduction

Chronic pancreatitis is a progressive disease for which there is no curative treatment short of transplantation. Therapeutic efforts have therefore centered around palliative relief of the severe pain associated with the condition. Ductal obstruction leading to increased ductal and pancreatic tissue pressures has been suggested as being a major factor in the pathogenesis of pain in chronic pancreatitis (1-6). This has led to the development of surgical procedures to decompress the pancreatic duct in selected patients. Surgical decompression has been shown to provide pain relief in 70-90% of patients (7-9). However, surgery may be associated with significant morbidity and mortality, especially when the patient is suffering from multiple comorbid diseases in chronic alcohol abuse (10). In appropriately selected patients, endoscopic stent drainage provides an alternative, less invasive way of achieving pancreatic duct decompression.

Preliminary results with endoscopic stent drainage for pancreatic duct strictures have shown that there is effective relief of pain in chronic pancreatitis in patients with ductal outflow obstruction, but data on the long-term outcome have been scanty (11-14). We therefore carried out a retrospective study to evaluate the short-term and long-term results of endoscopic stent drainage for the relief of pain in patients with chronic pancreatitis and a dominant stricture on pancreatography.

## Patients and Methods

### Patients

Hospital records spanning a nine-year period (April 1985 to July 1994) were retrospectively reviewed. Ninety-three patients with a diagnosis of chronic pancreatitis by endoscopic retrograde cholangiopancreatography (ERCP) met the following criteria for inclusion in this study: a) a history of narcotic-dependent pain of sufficient severity to necessitate repeated visits to the emergency room and hospitalizations; b) a dominant pancreatic duct stricture on ERCP; and c) treatment by endoscopic pancreatic stent placement. Patients

who underwent concurrent treatment of pancreatic pseudocysts were excluded. There were 65 males and 28 females, with a mean age of 49 years. The mean duration of pain prior to endoscopic treatment was 5.6 years (range 0.3-23.4 years). The etiologies of the chronic pancreatitis were chronic alcohol abuse in 61 patients (66%), familial or trauma in three (3%), and idiopathic in 29 (31%). All patients were being treated with pancreatic enzyme extracts prior to entering the study; eight patients had steatorrhea documented by stool studies, and 16 patients had diabetes mellitus, attributed to chronic pancreatitis.

### ERCP Results

The ERCP findings were based on written reports and archival radiographs. Measurements on ERCP films were made relative to the diameter of the duodenum. All patients had ductal changes on ERCP that were consistent with the diagnosis of chronic pancreatitis. The location of the dominant stricture was in the pancreatic head in 80%, the genu in 11%, and the body in 9%. Upstream ductal dilation measured over 5 mm in 82%. Pancreas divisum was diagnosed in 25% of patients, all of whom had the dorsal duct opacified via the minor papilla. Among the patients with pancreas divisum, the etiology of chronic pancreatitis was alcoholic in 11, familial in 1, and idiopathic in 11 patients.

Thirty-four patients (36%) had a dominant stricture in the head of the pancreas associated with intraductal calculi. Prior to stent placement, all of the patients in this subgroup had undergone stone fragmentation by extracorporeal shock wave lithotripsy (ESWL) using an electromagnetic lithotripter (Siemens Lithostar Plus, Nuremberg, Germany). A dominant stricture was diagnosed after stone fragmentation had been judged to be complete and repeat ERCP demonstrated a persistent stricture.

### Technique

The pancreatic stents used (Wilson-Cook, Inc., Winston-Salem, NC, USA) were made of Teflon and had multiple side holes at intervals of approximately 1 cm along the entire length for drainage of side branches (Figure 1). At the proximal (ductal) end, the tip was tapered to allow snug passage over a 0.035-inch guide wire, and was slightly curved to provide anchorage (modified single pigtail). The distal (duodenal) end had a single side flap to prevent proximal migration. The stents were 5, 7, and 10 Fr in diameter; the largest-diameter stent that could traverse the stricture was deployed. The length of the stent was tailored to the anatomical location of the stricture.

ERCP was carried out using a standard protocol under intravenous sedation. Parenteral antibiotics were not routinely given before ERCP. The pancreatic duct was selectively cannulated and injected with contrast medium (Telebrix N, 45 g in 250 ml, Byk Gulden, Constance, Germany), supplemented with gentamycin (400 mg). A pancreatic sphincterotomy measuring 0.5-1.0 cm was made using an Erlangen-type

sphincterotome. Cholangiography was performed if the patient had biochemical cholestasis; biliary sphincterotomy was not routinely performed either before or after pancreatic sphincterotomy. The pancreatic duct stricture was negotiated with a 0.032-inch angulated hydrophilic polymer-coated guide wire (Terumo Corporation, Tokyo, Japan), and the wire was advanced to the tail-end of the pancreas (Figure 2 a). A 7-Fr dilating catheter was advanced over the guide wire to dilate the stricture. Contrast medium was injected through the catheter to define the ductal anatomy proximal to the stenosis. The hydrophilic guide wire was exchanged for a conventional 0.032-inch or 0.035-inch Teflon-coated stainless-steel guide wire. The dilating catheter was removed, and the stent was inserted over the guide wire using a pusher tube to advance it (Figure 2 b). Drainage was achieved with only one stent.

Stent placement in patients with pancreas divisum was carried out via the minor papilla (Figure 3). A sphincterotomy of the minor papilla was made with the needle knife (Wilson-Cook, Inc.) after insertion of the pancreatic stent, using the stent as a guide rail for the incision. The technique of stent placement was otherwise identical to that described above.

### Follow-Up

Patients were initially followed up at monthly intervals, and later with progressively longer intervals of 3-12 months on an outpatient basis. Pain relief was termed "partial" if there was a significant reduction in the severity and frequency of the pain, and "complete" if pain was absent or minimal, did not require analgesics, and did not necessitate emergency room visits. Routine stent exchanges were not performed; stents were exchanged only if patients developed relapsing pain. Stents were removed and not replaced if the stricture could be easily passed with a 7-Fr dilating catheter (universal catheter, Wilson-Cook, Inc.) and there was prompt drainage of the contrast after ductal filling. The period until a stent required replacement or was removed was defined as the "stent survival time". Stent patency was not evaluated in this study. Relapse of pain after removal of the stent constituted an indication for reinsertion of a stent.

Follow-up data from hospital records were complemented by telephone interviews with the family doctor and, whenever possible, with the patient. The duration of follow-up for the study population is illustrated in Figure 4. Statistical analysis in this study was carried out using the chi-squared test, with the significance level set to  $p < 0.05$ .

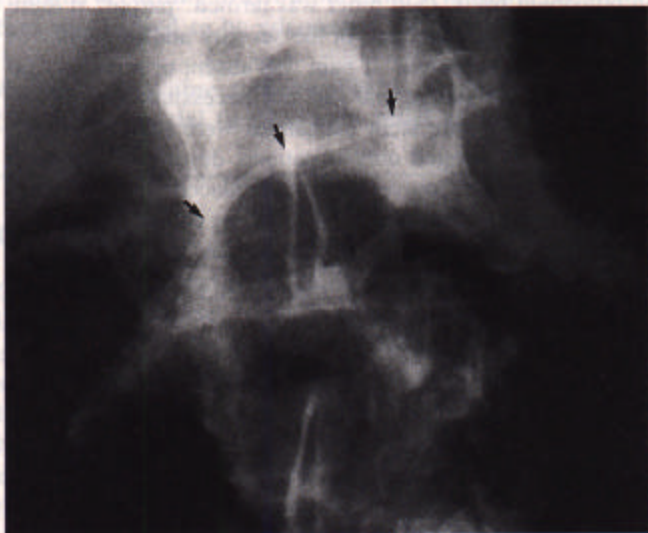
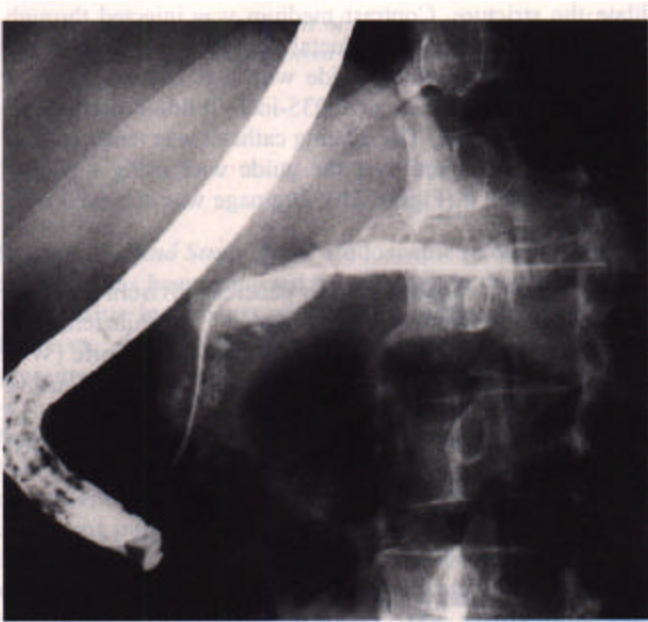
## Results

### Short-Term Response

The results were analyzed at six months after stent insertion to determine the short-term results of stent therapy. Sixty-nine patients (74%) reported that they had experienced



**Figure 1:** Standard 7-Fr Teflon pancreatic stent (Wilson-Cook Medical, Inc). Note the multiple side holes for drainage of side branches.



**Figure 2:** Endoscopic retrograde pancreatography, showing pancreatic stent placement. a Tight dominant stricture of the main pancreatic duct in the head portion, with upstream dilation. A guide wire has been inserted through the stricture to the tail end of the pancreas. b A 7-Fr pancreatic stent (arrows) draining the pancreatic duct.



**Figure 3:** Endoscopic retrograde pancreatography, showing pancreatic stent placement in a patient with pancreas divisum. a A dominant stricture (arrows) in the head of the pancreas, with upstream dilation. b Guide wire placement through the stricture. c Drainage with a 7-Fr stent.

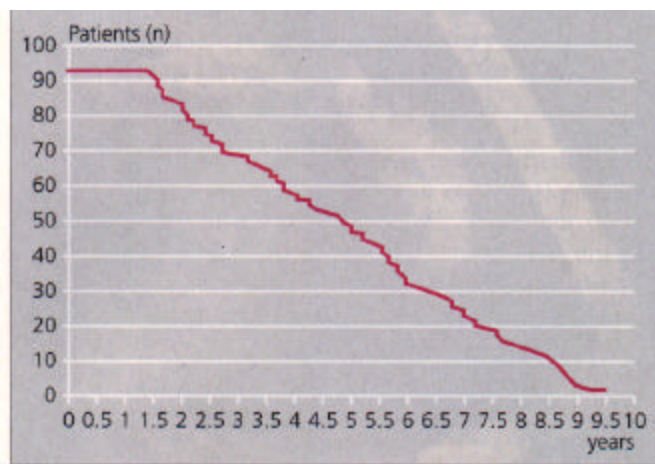


Figure 4: The duration of follow-up in years for the study population (n = 93).

partial pain relief (n = 23) or complete pain relief (n = 46) after stent insertion. None of these patients reported emergency room visits or hospitalizations for pain. This subgroup, labeled "early responders", constituted the denominator for long-term follow-up. Analysis of the 24 patients who did not respond to stent therapy showed that 12 (50%) had undergone ESWL treatment for intraductal calculi, and three (12.5%) had absent upstream ductal dilation on ERCP.

#### Long-Term Response

Of the 69 early responders, 60 patients (87%) experienced sustained improvement during a mean follow-up of 4.9 years (range 1.3-9.5 years). This subgroup was labeled the "longterm responders". Seventy-two percent discontinued analgesic intake altogether, 80% required no further emergency room visits or hospitalizations other than for stent exchanges, and 75% had a weight gain of at least 5% of their pretreatment weight and improvement of their general well-being.

Alcohol abuse, either prior to or after endoscopic treatment, was not found to have a significant bearing on the response to endoscopic treatment (Table 1). The presence of pancreas divisum was also not found to influence response. The patients who did not respond to treatment were found to have a history of symptomatic chronic pancreatitis that was nearly twice as long as that of the patients who responded (7.0 vs. 4.1 years, respectively). There was no difference in the occurrence rate of diabetes mellitus before or after treatment in the "responder" and "nonresponder" groups.

Nine patients among the early responders experienced a relapse of pain. In eight patients, the stents were found to be functional (stent clogging or migration was ruled out by ERCP), and in one patient stent clogging resulted in abscess formation. The mean duration until pain relapse was 1.2 years (range 2.7-36.3 months).

**Table 1:** Analysis of various study parameters among long-term "responders" (n = 60) and "non responders" (n = 33); information about alcohol abuse was only available for 36 (responders) and 23 (nonresponders) patients

	Responder	Nonresponder p	
Alcoholic etiology of chronic pancreatitis	36	23	> 0.05
Discontinued alcohol abuse after treatment	21	23	> 0.05
Pancreas divisum	14	9	> 0.05
Associated bile duct strictures	5	6	> 0.05
Diabetes mellitus			
Before treatment	11	5	> 0.05
After treatment	22	13	> 0.05

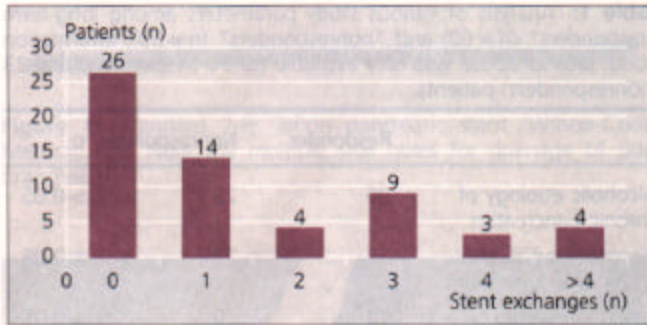
Stents were removed in 49 of the long-term responders after a mean duration of 15.7 months. The mean follow-up after stent removal was 3.8 years (range 0.3-7.4). Thirteen patients (27%) experienced a relapse of pain after a mean of 2.1 years (range 4 days-6.4 years). Stents were replaced in 11 patients, all of whom became, and have remained, free of pain over a mean follow-up period of 2.3 years. The remaining two patients underwent ESWL treatment for pancreatic duct stones (de novo in one, recurrent in the other), one of whom experienced an improvement of pain after ESWL, while the other failed to improve and opted for resective pancreatic surgery.

#### Stent Exchanges

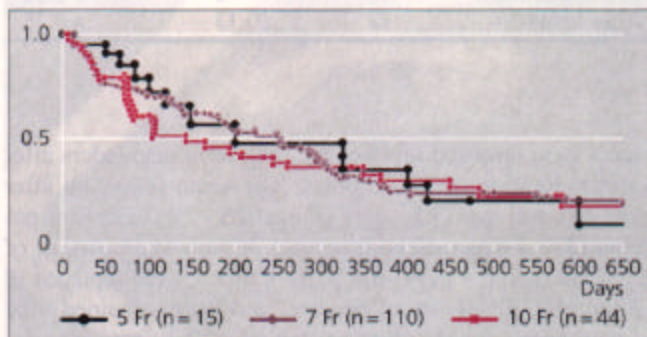
In total, 215 pancreatic stents were placed in the 93 patients entered into this study. An analysis of the number of stent exchanges required in the 60 patients who had long-term responses to stent drainage revealed that 43% had only one stent placed; of the remaining patients, 41% had one stent exchange, and only four patients required more than four stent exchanges (Figure 5). The "stent survival time" in the long-term responders is shown in Figure 6 in Kaplan-Meier plots for 5, 7, and 10 Fr stents. The mean survival time for all stents was 181 days (range 34-1584). The "survival curves" for stents of different calibers were found to be similar.

Complications of stent placement included post-ERCP pancreatitis in four patients, and abscess formation secondary to stent clogging in two patients. Post-ERCP pancreatitis was mild in all patients, and was treated conservatively, with an uneventful hospital course. The two patients who developed abscesses required prompt surgical debridement. Stent migration and clogging were not judged to constitute complications if this resulted in an uneventful stent exchange.

Complete pancreatograms before and after stenting were reviewed in 58 patients who responded to endoscopic stent drainage. Fifty-one patients were found to have a mean



**Figure 5:** Numbers of stent exchanges in long-term responders (n = 60).



**Figure 6:** Kaplan-Meier plot of pancreatic "stent survival time" in long-term responders to endoscopic stent drainage (n = 60).

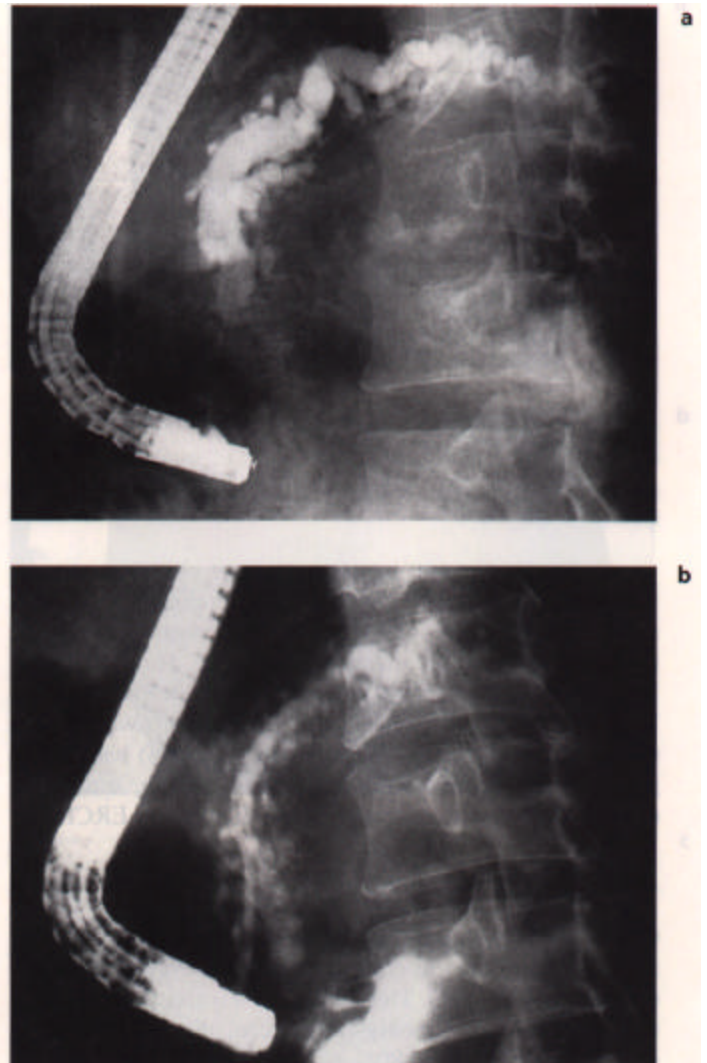
reduction of duct diameter of 1.6 mm after stenting (Figure 7), six had no change in duct diameter, and one showed an increase in duct diameter. None of the patients developed new strictures.

*Surgical Treatment*

Twenty-four patients underwent surgical procedures, including 22 patients who had failed to respond to endoscopic treatment and two patients who developed abscesses as a complication of stent clogging (Table 2). Most patients in whom endoscopic treatment failed underwent pancreatic resective procedures. Pain relief after surgery was reported in 15 patients during a mean follow-up of 3.3 years (range 1.1 -7.6 years).

**Discussion**

The study focused on the results of endoscopic pancreatic stent drainage in patients with chronic pancreatitis and a dominant stricture on pancreatography. Stent drainage was found to provide early pain relief in approximately 75 % of patients. This validates prior studies that have reported pain relief following pancreatic stent drainage (11-14). However, our response rate was substantially lower than the 94% rate reported by Cremer et al. (14) in their study of 74 patients with severe chronic pancreatitis and a distal pancreatic duct stricture. An explanation for the higher response rate in their



**Figure 7:** Endoscopic retrograde pancreatography, (a) before and (b) one year after 7-Fr stent drainage. a High-grade prepapillary pancreatic duct stricture, with marked upstream dilation. b After stent removal, the stricture could be easily traversed with a 7-Fr catheter. Note the reduction in the caliber of the pancreatic duct.

**Table 2:** Surgical procedures in 24 patients in whom endoscopic stent drainage failed (n = 22), or who experienced complications from it (n = 2).

Surgical procedure	n	Pain relief
Whipple	6	4
Duodenum-preserving resection of pancreatic head	8	4
Resection of pancreatic body	1	0
Resection of pancreatic tail	2	1
Pancreaticojejunostomy (Puestow)	5	4
Abscess drainage'	2	2
<b>Total</b>	<b>24</b>	<b>15</b>

Complication of endoscopic stent drainage.

study is not evident from the available data. The failure of stent decompression to relieve pain in some patients selected for endoscopic treatment is consistent with the multifactorial etiology of pain in chronic pancreatitis (15).

There are few data on the long-term results of endoscopic stent drainage in the literature. Cremer et al. (14) provide a mean follow-up of 37 months in their study, but do not specify any data on pain relief. Their data are also difficult to interpret, since a sizable portion of patients underwent surgery or placement of self-expandable stents after endoscopic drainage. We found that 87% of the patients who responded to stent drainage experienced sustained improvement during a mean follow-up of 4.9 years. Approximately two-thirds of the patients discontinued analgesic intake altogether, 80% required no further hospitalizations other than for stent exchanges, and 75% reported weight gain and an improvement in their general well-being.

We removed a stent electively if follow-up pancreatography demonstrated resolution of the stricture, or the stricture could be easily passed with a 6-Fr catheter, or both. Stents were removed after a mean duration of 15.7 months in 49 of the long-term responders. The mean follow-up after removal was 3.8 years. It would therefore appear that stents can achieve sufficient dilation of the stricture to allow subsequent removal in the majority of patients. However, the duration of stent placement is variable, and some strictures may require an extended period of in situ stent dilation. In selected cases, we placed 10-Fr stents to maximize the dilation effect, but it remains unclear whether 10-Fr stents dilate strictures more effectively than 7-Fr stents.

Post-ERCP pancreatitis occurred in four patients, and was the most common complication in this study. In all cases, the pancreatitis was mild, and subsided with conservative management. Other authors have also reported pancreatitis following stent insertion (11-13). It is unclear whether stent placement increases the risk of pancreatitis above that associated with pancreatography and pancreatic sphincterotomy. McCarthy et al. (16) found that stent insertion alone did not increase the incidence of post-ERCP pancreatitis.

As has been observed with biliary stents, pancreatic stents may occlude over time. The exact mechanism is not well understood, but it is probably triggered by bacterial colonization, as seen with biliary stents (17). The stent patency rates reported in the literature have been found to be extremely variable. Huijbregste et al. (11) reported no complete pancreatic stent occlusions during a follow-up of 2-3 years; Cremer et al. (14) found the mean stent patency to be 12 months; Geenen et al. (18) reported frequent clogging at 46 months. A study using the 10-cm water-column test to evaluate pancreatic stent occlusion rates showed that essentially all pancreatic stents occlude by nine weeks (19). The discrepancies in the results can best be explained by different schedules for stent exchange or removal, and by different definitions of occlusion. In spite of occlusion, stents may still function as a "wick" around which pancreatic juice can

drain. We left pancreatic stents in situ until pain or pancreatitis recurred, which was after a mean of 181 days. This approach, involving waiting for symptomatic clogging, did have the drawback of abscess formations in two patients in our study.

Pancreatic stents have been reported to induce ductal changes such as dilation and pseudocyst formation, and this has raised concern about potential adverse effects of stent therapy (20,22). However, apart from morphological alterations, which improved or normalized after stent removal in the majority of patients, adverse sequelae have not been documented. Gulliver et al. (22) did not find any correlation between morphologic changes associated with stenting and clinical outcome. It is noteworthy that the majority of patients in whom stent-induced changes were observed had normal pancreatic anatomy prior to stent placement. There are still insufficient data to determine whether stent therapy accelerates the progression of ductal changes in patients with chronic pancreatitis. The retrospective nature of this study does not allow any reliable conclusions here. However, based on the available data from this study, long-term stent drainage does result in a reduction of ductal diameter, and appears to result only rarely in the progression of chronic pancreatitis changes.

Of the patients who failed to respond to endoscopic stent drainage, 22 underwent surgical procedures for chronic pancreatitis. Most of the patients underwent pancreatic resective procedures (Table 2). Pain relief after surgery (mean followup of 3.3 years) was reported in 13 of 22 patients (59%). This high response rate argues in favor of surgical treatment in patients who fail endoscopic stent drainage. The optimal type of surgery (decompressive versus resective versus combined) for the patient population of this study remains to be determined (23).

In conclusion, this study validates the efficacy of pancreatic stent drainage in the subset of patients with chronic painful pancreatitis demonstrating a dominant stricture on pancreatography. Patients who respond to stent drainage are likely to have sustained long-term pain relief. Stents can be removed in most patients after a period of in situ dilation followed by continued pain relief. Endoscopic treatment of pancreatic duct obstruction due to a dominant stricture should be considered as an effective and safe alternative to surgery for the long-term management of pancreatitis pain. The role of endoscopic treatment relative to surgery remains to be established in prospective studies, but the data from this study support endoscopic drainage as a first-line treatment, followed by resective surgery in nonresponders.

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