

Role of pancreatic stent in reducing post ERCP pancreatitis in difficult biliary cannulation

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ABSTRACT

Background: Post endoscopic retrograde cholangiopancreatography pancreatitis is the most common and serious complication of ERCP. Difficult biliary cannulation can be a procedure-related risk factor for post-ERCP pancreatitis. Recent studies reported that a temporary prophylactic pancreatic stent can reduce the frequency and severity of post-ERCP pancreatitis. **Objective:** To evaluate the efficacy and usefulness of a temporary pancreatic stent to prevent post-ERCP pancreatitis in patients with difficult biliary cannulation. **Design:** single tertiary care center, randomized, prospective study. **Patients and methods:** In total, 150 patients with a difficult biliary cannulation were randomly divided into the pancreatic stent placement group (n 51) or the no stent group (n 99). Patients were prospectively followed for the incidence and severity of post-ERCP pancreatitis in the two groups (with or without pancreatic stent), spontaneous dislodgment of stents, Standardized criteria were used to diagnose and grade the severity of post-ERCP pancreatitis. **Interventions:** Endoscopic placement of a flanged pancreatic stent. **Results:** From 150 patients enrolled in the study, 35 patients got pancreatitis, 34 patients was in the non-stenting group and only one in the stenting group, the percentage of female and male patients who got pancreatitis were 26.5% (18 out of 68 females patients), and 20.7% (17 out of 82 male patients) respectively, 61% (19 out of 31 cases) of short length stents (5fr x 6cm) were migrated compared with only 10% (2 out of 20 cases) of long stents (5fr x 8cm). **Conclusions:** Prophylactic temporary PS placement in patients with a difficult biliary cannulation during ERCP seems to be a safe and effective method for reducing post ERCP pancreatitis.

Introduction:

Post-ERCP pancreatitis is the most common and serious complication of ERCP and occurs after 1% to 30% of procedures.

¹⁻⁵Recent studies reported that prophylactic placement of a pancreatic stent (PS) reduces the frequency and severity of Post-ERCP pancreatitis in various risk groups.⁶⁻²³ However, numerous questions remain concerning the ideal stent size, duration of stenting, and rate of spontaneous duodenal migration.^{24,26} It has been proposed that pancreatitis is precipitated by impaired drainage of the pancreatic duct leading to acinar injury, this may lead to intracellular activation of proteolytic enzymes, with enhanced local inflammation as indicated by increased levels of cytokines (IL 1, 8, and 6).²⁷ Pharmacologic prophylaxis in an attempt to block the initial insult and inflammatory response have been disappointing.^{25, 28-29} the suggested mechanisms for impaired drainage include papillary edema and/or spasm.³⁰

Placement of a pancreatic duct stent is, however, not without complications, failure of spontaneous intraluminal migration of the stent may require a

repeat endoscopic procedure for stent removal, proximal migration, occlusion, perforation, infection, duodenal erosions, and development of stent-induced pancreatic duct strictures and other stent-related complications may occur.¹¹ Pancreatic duct and parenchymal changes mimicking chronic pancreatitis have also been reported with prophylactic pancreatic duct stenting.³¹

Pancreatic plastic stents are made primarily of polyethylene materials,³² pancreatic stent sizes range from 2 to 25 cm in length and 3F to 11.5F in diameter; pancreatic stents are either straight, curved, wedge, or single pigtail. Most pancreatic stents have side holes throughout the length of the stent to facilitate drainage of the pancreatic side ducts. A winged stent allows pancreatic juice to drain around the stent rather than through the stent lumen. Various designs are available depending on the desired duration of stenting. Stents with an internal flange are used for prolonged stenting; stents with no internal flange are used to promote spontaneous migration for short-term stenting. Most pancreatic stents have a mechanism (distal flange, pigtail) to prevent internal migration.³²

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The overall success rate for selective biliary cannulation during ERCP ranges from 90% to 95%, even when performed by experts⁷. During biliary cannulation, the rate of post-ERCP pancreatitis increases when cannulation is difficult and prolonged³. However, few data are available concerning the effect of a prophylactic pancreatic duct stent on this technical difficulty with respect to cannulation time or frequency of papillary contacts. In addition, the sizes and lengths of stents are variable, and no guideline or consensus yet exists regarding which type or length of PS is optimal.¹⁶⁻¹⁸ The definition of pancreatitis and the grading of its severity were based on consensus criteria,³³ the criteria proposed by Cotton et al. have been widely employed in the published literature, post-ERCP pancreatitis was diagnosed when new-onset or increased abdominal pain lasted for more than 24 hours, caused an unplanned hospitalization of an outpatient for more than 1 night, or prolonged a planned hospitalization of an inpatient and was associated with an increase in the serum amylase level of at least 3 times greater than the normal upper limit at approximately 18 hours after procedure. The severity was graded mild when hospitalization lasted 2 to 3 days, moderate when 4 to 10 days, and severe when hospitalization was prolonged for more than 10 days or any of the following occurred: hemorrhagic pancreatitis, pancreatic necrosis, pancreatic pseudocyst, or a need for percutaneous drainage or surgery³³.

Patients and methods:

Study population and design:

Consecutive consenting 150 patients referred for therapeutic ERCP between January 2013 and March 2014 was included from single academic tertiary GIT referral center in Baghdad (GIT hospital). All patients underwent abdominal US, CT scans, and/or magnetic resonance cholangiopancreatography before ERCP. Patients who satisfied the following inclusion criteria were enrolled: age 18 years and older, difficult biliary cannulation, which was defined as failure to achieve selective biliary access despite 10 minutes of attempted cannulation, more than 5 attempted unintentional pancreatic cannulation, or frequent papillary contact of more than 10 times, whichever occurred first.³⁴ Papillary contact was defined as sustained contact between the catheter and the ampulla of Vater for at least 3 to 5 seconds.^{4,34}

Exclusion criteria were the following: age younger than 18 years, successful deep biliary cannulation without difficulty, surgically altered anatomy (Billroth II gastrectomy or Roux-Y anastomosis), previous biliary or pancreatic sphincterotomy, radiological and clinical evidence of acute pancreatitis at the time of the procedure,

pancreatic divisum, pre-cut papillotomy, and pancreatic sphincterotomy. In total, 150 patients with difficult biliary cannulations were enrolled, and patients who met the eligibility criteria were randomly assigned into two groups: pancreatic plastic stent inserted versus non-stent group. Written informed consent was obtained from all enrolled patients.

Endoscopic procedure:

All patients underwent ERCP with a standard duodenoscopes (Pentax KPI 5000). The procedure was performed after the patient fasted overnight, was placed in the prone position, and was sedated with intravenous diazepam (5 mg) and/or pethidin (50 mg). Prophylactic antibiotics were permitted. All procedures started with a standard double-lumen sphincterotome or conventional catheter, the endoscopic approach to PS placement involved passing a 0.021-inch/480-cm guidewire (Cook Endoscopy, Winston-Salem) deep into the PD, at least past the genu. Pancreatography was not performed in all cases. Then, a single flanged straight type pancreatic stent (Cook Endoscopy) with a caliber (5fr) and 6 or 8 cm in length was placed over the guidewire. Successful PS placement was achieved when the stent was appropriately positioned within the PD and its distal end was positioned in the duodenal lumen. Cannulation was attempted in the NS group until successful biliary cannulation was achieved. If biliary cannulation failed within 20 minutes, the procedure was completed without PD stenting. Pre-cut papillotomy (infundibulotomy) was performed as a rescue method for selective common bile duct cannulation but those patients were not included in the study.

After the ERCP procedure, patients were admitted for observation and fasted until physical examination and tests (if necessary) on the following day confirmed that no complications had occurred, including pancreatitis. Follow-up plain abdominal radiographs were obtained to assess spontaneous stent dislodgment and to exclude internal migration, if the stent had not passed spontaneously by 7 days, endoscopic removal was performed.

Definition of outcomes:

The primary outcome measurements for both groups were the frequency and severity of post-ERCP pancreatitis; we also evaluated the success rate of PS placement, the rate of spontaneous pancreatic stent dislodgment, and complications in both groups. ERCP-related pancreatitis were classified and graded according to Cotton consensus guidelines³³. Serum amylase levels were measured 24 hours after the procedure. Pancreatitis was considered mild if hospitalization was extended 2 to 3 days after the procedure, moderate if hospitalization was extended

4 to 10 days after the procedure, and severe if hospitalization was extended for more than 10 days. Spontaneous dislodgment of the PS was defined when the entire stent completely migrated from the PD within 7 days without any intervention³³.

Statistical analysis:

Data were collected and analyzed using SPSS version 10.0 for windows (SPSS, Chicago, Illinois, and USA). The significance of relationship between groups was examined by Chi square test, the risk estimated by odds ratio. P value < 0.05 was considered as statistically significant.

Result:

During the study period from January 2013 - March 2014, 150 patients were enrolled, 82 patients (54.7%) were male and 68 (45.3%) were female, with mean age of 49.6 and standard deviation of 16.6, with minimum age included was 18 year and maximum age was 85 years.

The histogram below demonstrates the age distribution which shows that most cases in the study were between 40-60 years old.

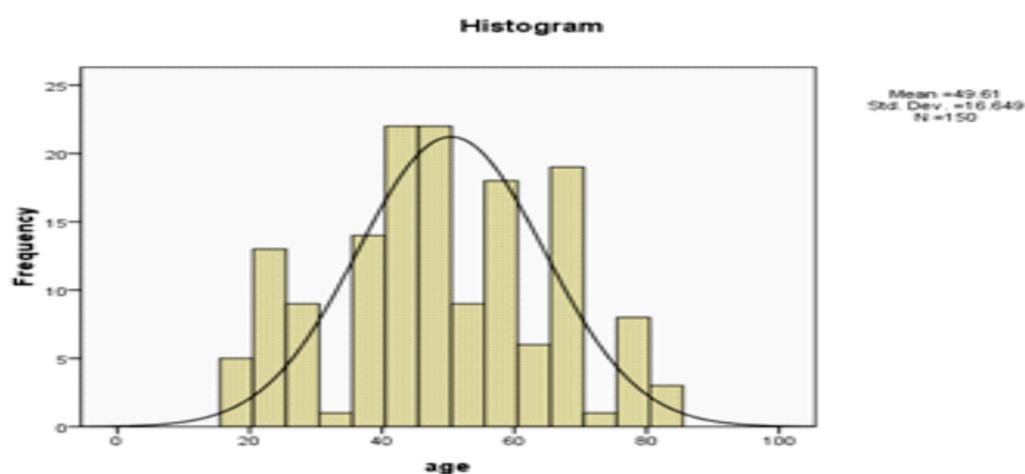


Figure 1: Histogram showing the ages of the 150 cases included in the study.

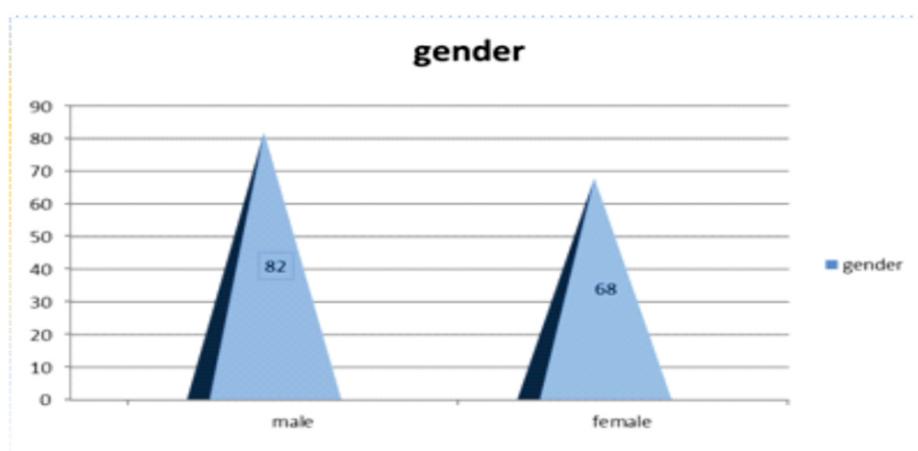


Figure 2: Relative frequency of males and females included in the study. Showed the males enrolled in the study are 82 patients (54.7%) which was slightly more than females 68 (45.3%).

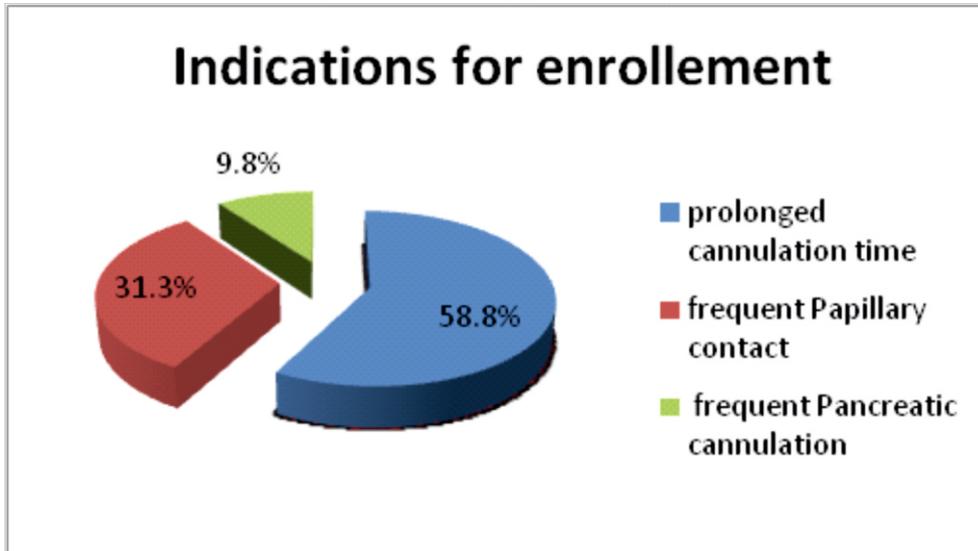


Figure 3:Shows the indication for enrollment .

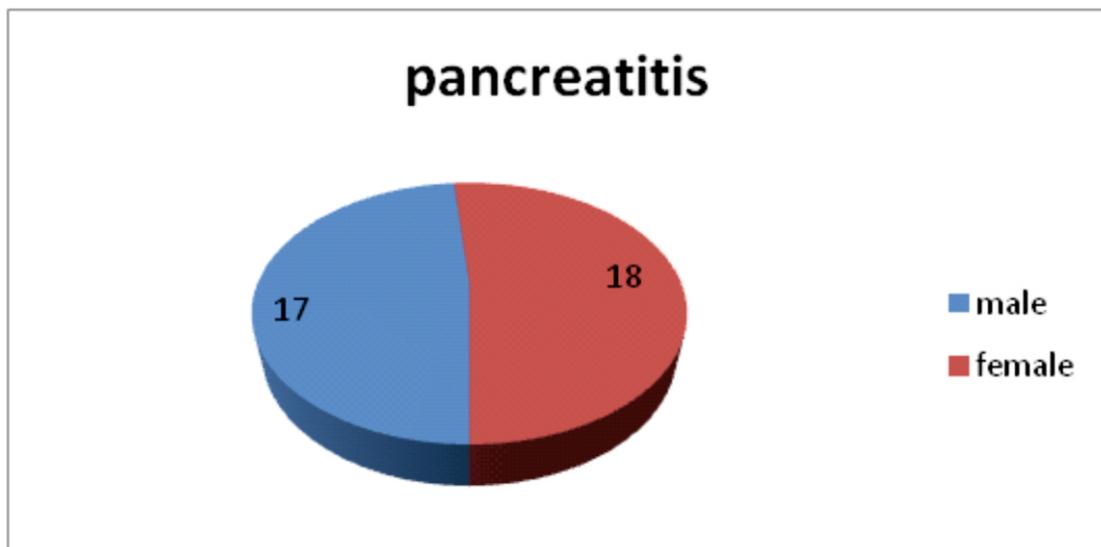


Figure 4: Number of male and female patients who developed pancreatitis.

Table (1)
Frequency and severity of pancreatitis in relation to gender.

gender		pancreatitis			no	total
		Mild	Moderate	severe		
female		13	4	1	50	68
	Percentage within gender	19.1%	5.9%	1.5%	73.5%	100.0%
male		11	6	0	63	82
	Percentage within gender	13.4%	7.3%	.0%	76.8%	100.0%

P value 0.58 was statistically insignificant

Table (2)
Cross tabulation between pancreatic plastic stent insertion and frequency And severity of pancreatitis.

Pancreatic stent versus pancreatitis Crosstabulation							
Pancreatic stent		pancreatitis				Total	
		severe	mild	moderate	no		
no stent	Count	1	23	10	67	101	
	%within pancreatitis	100.0%	96.0%	100.0%	57.5%	67.1%	
with stent	Count	0	1	0	48	49	
	%within pancreatitis	.0%	4.0%	.0%	42.5%	32.9%	
Total		Count	1	24	10	113	150
		%within pancreatitis	100.0%	100.0%	100.0%	100.0%	100.0%

P value 0.001 was statistically significant

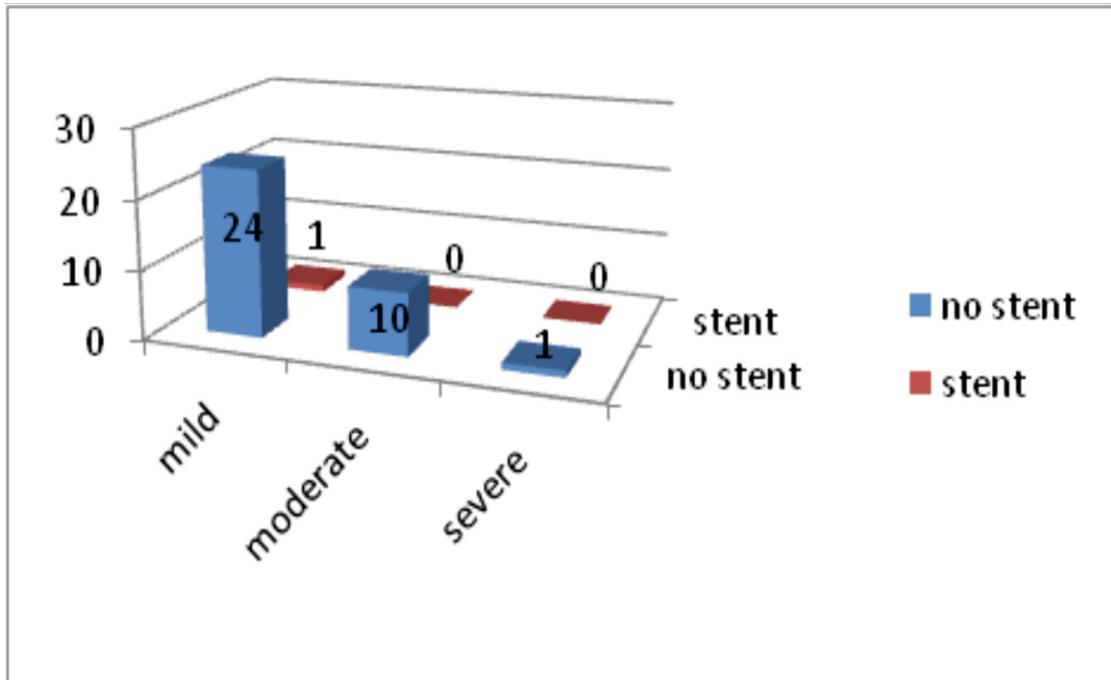


Figure 5: Shows the frequency and severity of pancreatitis in stented and non-stented groups.

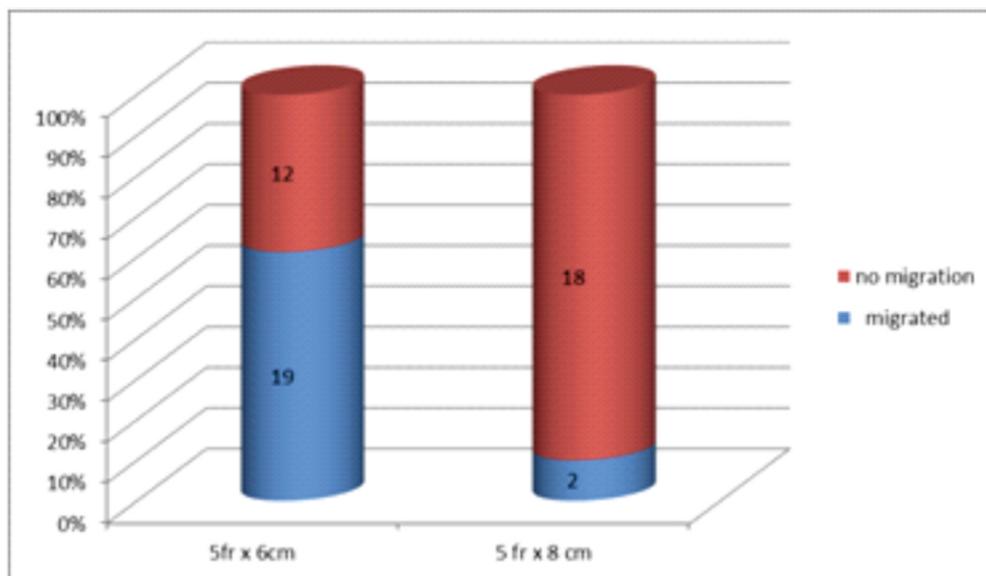


Figure 6: The number and percentage of pancreatic plastic stent intraluminal migration according to stent length.

Table 3
Percentage of spontaneous intraluminal pancreatic stent migration according to its length.

length		migration		Total
		migrated	non migrated	
6cm	Count	19	12	31
	% within length	61.3%	38.7%	100.0%
8cm	Count	2	18	20
	% within length	10.0%	90.0%	100.0%
Total	Count	21	30	51
	% within length	41.2%	58.8%	100.0%

P value =0.00 was statistically significant

Discussion:

The total number of patients included in our study were 150 patients, Figure 1 clearly demonstrate that the minimum age included was 18 years and maximum age included was 85 years and most of the cases lie between 40-60 years old with the mean age 49.6, the males included 82 (54.7%) cases were slightly more than females 68 (45.3%) as can be seen in Figure 2. The most common indications for enrollment in our study was due to prolonged biliary cannulation (lasting more than 10 minutes) as seen in Figure 3 where it represent 58.8% of cases (78 out of 150 cases) ,followed by frequent papillary contacts 31.1 % (48 out of 150) and then repeated pancreatic cannulation 9.8 % (15 out of 150)and this is suspected in our study because we perform the study in a training center in which trainees are involved in the ERCP procedure.

In Figure 4, the percentage of female patients who got pancreatitis were 26.5 % (18 out of 68 females patients) which is higher than the percentage of male patients 20.7 % (17 out of 82 male patients) and this finding is similar to fact that females are considered as independent risk factors for post- ERCP pancreatitis as can be seen in many studies.^{1, 2, and 3} however another study was not able to confirm that the cannulation of the female papilla is more troublesome than the cannulation of the male papilla.³⁵ We are comparing male and females patients who got pancreatitis with the severity of pancreatitis in Table 1, and the result was

approximately comparable were mild pancreatitis occurred slightly more in females 13 cases (19.1 %) than males 11 cases(13.4 %) while moderate pancreatitis appeared higher in male patients 6 cases (7.3 %) than females 4 cases (5.9%), but the only case of severe pancreatitis enrolled was female had CBD stone in the control group (had no pancreatic plastic stent inserted) she got bilateral pleural effusion with intraperitoneal hemorrhage with complicated pelvic abscess and required 15 days of hospitalization , the relationship between gender and severity of pancreatitis was statistically insignificant with a P value of 0.58 and that mean females are more than males at risk for post ERCP pancreatitis but not necessarily associated with higher severity , however there is no other studies comparing these factors. Obviously the plastic stent role in preventing post ERCP pancreatitis in patient with difficult biliary cannulation clearly demonstrated by Table 2 and Figure 5 where only one patient with pancreatic plastic stent insertion 2.8% (out of 35 cases of pancreatitis) has got pancreatitis which was mild while all other 34 cases of pancreatitis 97.2% (out of 35) were in the control group which was statistically significant with a P value of 0.001 and this finding is similar to other studies , Multiple clinical trials and a meta-analysis

that demonstrate placing PS in high-risk patients effectively reduces the incidence of post-ERCP pancreatitis^{8-15,29}, however There are limited data evaluating stenting in patients who underwent excessive manipulation of the papilla.

Tae Hoon Lee, et al in a multicentric, prospective, randomized study, 101 patients with a difficult biliary cannulation were randomly divided into the 3fr french PS placement group (n 50) or the non-stent group (n 51), the stented group had a significantly lower rate of post-ERCP pancreatitis (6% for stenting group versus 15% for non-stenting group).³⁴ In another 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 x 2 cm pancreatic stent, a nasopancreatic drain, or no drainage.²

The two stented groups had a significantly lower rate of post-ERCP pancreatitis (5 for stenting group versus 28 for non-stenting group).¹¹

The exact mechanism by which PS might reduce post-ERCP pancreatitis risk is not well understood, the stents probably preserve pancreatic drainage that otherwise might be impaired by mechanical injury to the pancreatic sphincter from catheter and guidewire manipulations.

To date, a consensus holds that prophylactic PS placement is beneficial for preventing post-ERCP pancreatitis in high-risk individuals.²⁰⁻²³

Patients with difficult cannulation, such as a longer duration cannulation and frequent papillary contacts, should be considered a risky group for post-ERCP pancreatitis.

At present, the routine use of PS in high-risk cases at advanced centers has changed ERCP, reducing the incidence and severity of post-ERCP pancreatitis to a more acceptable level; this may relax some of the fear factor surrounding a previously prohibitively high-risk patient population. Two length of plastic stents were used in our study (as shown in Figure 6 and Table 3) 5fr x 6cm and 5fr x 8cm in order to assess the impact of stent length on the spontaneous intraluminal migration and the study shows that 61% (19 out of 31 cases) of small length stents were migrated compared with only 10% (2 out of 20 cases) of large length stents are migrated and these results were highly statically significant with a P value of 0.0001.

However, controversy exists regarding which type or length of PS is best.

An ideal PS should completely prevent the occurrence of post-ERCP pancreatitis, dislodge spontaneously, deploy easily, and not cause stent-induced ductal or parenchymal pancreatic changes.³⁴

A large retrospective study suggested that unflanged, longer length (8-10 cm) 3fr polyethylene stents with

a single duodenal pigtail are associated with significantly higher spontaneous dislodgment rates compared with larger caliber, shorter length unflanged 4fr and 5fr stents. That study also reported a lower incidence of post-ERCP pancreatitis in patients who received a 3fr stent compared with patients who received a 5fr stent, although the difference was not statistically significant.¹⁶ however there is another study done by Chahal et al comparing long 3fr stents with short 5fr stents showed that the spontaneous dislodgment rate of unflanged, short-length 5fr PS (98%) was significantly higher than that for unflanged, long length, 3fr stents (88%) after 14 days in patients at high-risk of post-ERCP pancreatitis (P value 0.0001)¹⁷, this decreased the need for endoscopic removal, a higher rate of PS placement failure and post ERCP pancreatitis, but without statistical difference (14% in 3fr group and 9% in 5fr group), was observed in patients with 3fr stents. Recently, Zolotarevsky et al reported that placement of a 5fr compared with a 3fr PS for post-ERCP pancreatitis prophylaxis is easier and faster and requires fewer wires.¹⁸ However, there was no statistically significant difference in spontaneous passage rates (5fr group, 68.4%; 3fr group, 75.0%; P value 0.617) and post-ERCP pancreatitis rates.¹⁸

Conclusions:

Prophylactic temporary PS placement in patients with a difficult biliary cannulation during ERCP seems to be a safe and effective method for reducing post ERCP pancreatitis

Recommendation:

Because of ominous complications of post-ERCP pancreatitis we recommend:

1. As the study performed in the training center we need to use simulator for learning the tricks of selective biliary cannulation.
2. Insertion of pancreatic plastic stent in any patient with difficult biliary cannulation.
3. Use of short length pancreatic plastic stent measured 5fr x 5 cm in order to increase the rate of spontaneous intraluminal migration of the stent without the need for a second session of ERCP for pancreatic plastic stent removal.

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