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Prophylactic Pancreatic Stents in High-Risk Population and Post-Endoscopic Retrograde Cholangiopancreatography Pancreatitis

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Abstract

Background: Acute pancreatitis is a common complication of endoscopic retrograde cholangiopancreatography (ERCP). Several medical and surgical procedures have been analyzed in prevention of post-ERCP pancreatitis as a major post-ERCP complication, so we conducted a study to assess the role of prophylactic pancreatic stents on prevention and severity of post-ERCP pancreatitis.**Materials and Methods:** This case control studied adult patients undergoing ERCP at the ERCP unit of a referral educational hospital. Data of the case (stent, N=90) and control (non-stent) (N=105) groups were retrieved from medical records. In our center, sphincterotomy was performed for 103 patients of non-stent group and successful pancreatic stent placement was done in 86 patients of stent group in a standard fashion. In stent group, a 5F, 4 centimeter pancreatic stent was emplaced over a guide wire under fluoroscopic guidance. All post–ERCP pancreatitis and major complications of all patients were retrieved too.**Results:** Of 255 enrolled patients, 195 were at high risk of post-ERCP pancreatitis allocated in two groups of this study. Successful pancreatic stent placement was done in 86 patients (95.6%) of stent group. There was no major complication during procedures. The migration of pancreatic duct stent was diagnostic in 3 (3.5%) patients. The overall post ERCP pancreatitis was 4.0% and 16.6% in stent and non-stent groups, respectively. **Conclusion:** Based on our findings in this study, we strongly recommended pancreatic duct stent placement in high-risk patients; although the experience of endoscopist plays a crucial role. **[GMJ.2015;4(2):67-71]**

Keywords: Pancreatitis; Complications; Endoscopy; Pancreatic Stent

Introduction

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a common therapeutic procedure for the management of biliary tract stenosis. It could also provide profound understanding about biliary and pancreatic duct (PD) pathologies. This technique is accompanied by certain postoperative complications including acute pancreatitis, perforation, bleeding, and cardiopulmonary complications. Post-ERCP pancreatitis, as one of the most serious of these kinds of complications, has a rate of 1-10% in average-risk patients. This rate is more than 30% in high-risk patients [1]. Risk factors related to this condi-

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tion include female sex, difficult or prolonged cannulation, several attempts for cannulation, papillectomy, precut sphinctrotomy and dye injection into PD [2]. It has been hypothesized that pancreatitis occurs due to impaired drainage of PD as a result of papillary edema and spasm. However, preventing post-ERCP pancreatitis remains a critical subject in spite of many studies [3].

Many studies were carried out for preventing this problem [2, 4-6]. This way, different prophylactic pharmaceutical solutions were introduced [3] and also different surgical procedures were applied in many ERCP units [7]. Placement of PD stent is a somehow new effort to prevent post-ERCP pancreatitis applied in difficult situations [8]; however, there is no consensus on indication and necessity of prophylactic PD stent placement by all gastrointestinal societies. Therefore, we designed present study to assess the impact of PD stent insertion on the rate of post-ERCP pancreatitis.

Materials and Methods

Study Design and Patients

This case control study was conducted at an ERCP unit of a referral educational tertiary hospital on medical dossiers of August 2011 to June 2013. The protocol was approved by the Institutional Review Board (IRB) of local research ethic committee of Firoozgar Hospital, Iran University of Medical Sciences, Tehran, Iran.

The medical dossiers of adult patients at high risk of post-ERCP pancreatitis were recruited for this study. The inclusion criteria were precut sphincterotomy, previous history of post-ERCP pancreatitis sphincter of oddi dysfunction, PD cannulation, injection into PD, and difficult cannulation defined as more than 30 min of manipulation to achieve cannulation. Exclusion criteria were inability to access papilla, presence of acute or chronic pancreatitis at the time of procedure, inability to achieve PD, pregnancy and lactation and pancreatic divisium. Finally, a total of 189 patients were studied into a case of stent group (N=90) and a control (non-stent) group (N=105).

Endoscopic Procedures and Follow-up in our Center

Forty eight hours prior to ERCP, any medications that could affect the performance of the sphincter of Oddi were stopped. Before ERCP, spray of lidocaine 10% was used for local pharyngeal anesthesia and consequently, under the supervision of an anesthesiologist, intravenous midazolam 0.02 mg/kg, propofol 50 μg/kg/min with or without petedine hydrochloride (0.5 mg/kg) were used for anxiolysis and sedation. ERCP was performed in a standard fashion with a side-view duodenoscope (Olympus 240, Tokyo, Japan). Sphinctrerotomy was performed in a standard fashion [9]. In stent group a 5F, 4-centimeter pancreatic stent was emplaced over a guide wire under fluoroscopic guidance. The stent was placed after all necessary endoscopic interventions were performed. Patients were followed by daily abdominal radiography to evaluate their stent position. The stent was removed endoscopically if it remained on the third day. After ERCP, all patients were hospitalized for at least three days to assess post-ERCP pancreatitis or other complications [10].

Major complications were recorded in two groups including pancreatitis, stent migration, perforation, massive hemorrhage and infection. Post-ERCP pancreatitis was defined as presence of epigastria or periumbelical regions pain (pancreatic pain) and hyperamilasemia (≥3 times more than upper normal limit) within 24h after procedure. Severity of pancreatitis was defined as mild, moderate and sever based on Cotton's criteria.

Statistical Analysis

Continuous variables were present as mean ± SD. Comparisons between groups were evaluated by student t-test. The chi-square test was used for qualitative variables. A P values less than 0.05 were considered significant. All statistical analyses were performed by SPSS version 16.0.

Results

Two groups were not different regarding their demographic data (P>0.05). Characteristics of the patients and prevalence of reasons for

high-risk patients for post-ERCP pancreatitis are shown in Table 1.

PD placement was done in all patients successfully. There was no major complication during procedures. PD stent migration was diagnosed in 3 (3.5%) patients. The overall post-ERCP pancreatitis was 5.7.0% and 18.4% in stent and non-stent groups, respectively. The prevalence of mild, moderate and sever pancreatitis is illustrated in Table 2. Cholelitiasis was the most common final diagnosis in our study, cholangiocarcinoma hit second place and in the third turn, CBD mass was diagnosed. Final diagnosis of all patients in both groups are shown in Table 3.

Discussion

The present case-control study was designed to evaluate the effectiveness of PD stent in prevention of post-ERCP pancreatitis in high-risk groups. We placed pancreatic stent after any PD manipulation in 86 patients. The overall rate of post-ERCP pancreatitis in stent group was significantly lower than non-stent group and the incidence of post-ERCP pancreatitis decreased about 70%. Severe pancreatitis did not occur in stent group. In addition, our study demonstrated that PD stenting in high-risk patients was feasible and also reduced the severity of pancreatitis along with a decrease in hyper-amylasemia and post-ERCP discomfort. This result is comparable with other studies [8, 11-12].

Documents regarding the benefits of PD stent

Table 1. Demographic Data and Prevalence of Post-ERCP Pancreatitis Risk Factors

Variables	Group	
	Stent	control
Number of Patients	60	70
Mean Age ± SD	55.6 ± 19.8	54± 15.6
Gender (F/M)	29/31	40/30
Reasons of high risk		
Previous ERCP	-	-
PD cannulation	36(60.0%)	38(54.3%)
Difficult cannulation	11(18.3%)	13(18.6%)
Suspected SOD	1(1.6%)	1(1.4%)
Pre-Cut	26(43.3%)	29(41.4%)
Pancreatic Sphincterotomy	4(6.6%)	5(7.1%)
Pancreatic duct biopsy	-	-
Multiple attempt	24(39.8%)	22(31.4%)
Injection into PD	16(26.6%)	15(21.4%)

ERCP: Endoscopic Retrograde Cholangiopancreatography; **PD:**Pancreatic Duct; **SOD:** Sphincter of Oddi Disorder

Table 2. Post-ERCP Pancreatitis Among Case and Control Groups

	Case Group	Control Group	P value
Number of patients	60	70	NA
Hyperamylasemia: N(%)	21(35)	27(38.6)	0.1
Average serum amylase level (IU/L)	746	842	0.07
Post-ERCP Pancreatitis			
Mild: N (%)	3(5)	8(11.4)	0.02
Moderate: N (%)	1(1.7)	3(4.3)	0.03
Sever: N (%)	0.0	1(1.4)	0.01

ERCP: Endoscopic Retrograde Cholangiopancreatography

Table 3. Final Diagnosis Among Both Groups' Subjects

	Case Group N (%)	Control Group N (%)
CBD Stone ±GB Stone	39(65)	47(67.1)
CBD Stone ±GB Stone	4(6.6)	4(5.7)
CBD Stone ±GB Stone	5(8.3)	6(8.6)
CBD Stone ±GB Stone	2(3.3)	2(2.8)
CBD Stone ±GB Stone	5(8.3)	6(8.6)
CBD Stone ±GB Stone	1(1.6)	1(1.4)
CBD Stone ±GB Stone	4(6.6)	4(5.7)

CBD: Common Bile Duct; **GB:** Gallbladder; **SOD:** Sphincter of Oddi Disorder

in reducing post-ERCP pancreatitis are increasing. In this context, some case control studies revealed that PD stent insertion considerably reduced the incidence of post-ERCP pancreatitis certainly among high-risk patients [1, 4, 8, 10, 13]. On the other hand, other studies revealed opposite results [2]. In general, meta-analysis on efficacy of PD stent placement for prophylaxis has illustrated that PD stent placement significantly decreases the rate of post–ERCP pancreatitis as well as hyper-amylasemia. According to these reports, some gastrointestinal societies recommended PD stent insertion for prophylaxis of post-ERCP pancreatitis in high-risk patients. Furthermore, PD stent has some other advantages which make it cost-effective in high-risk patients. This is totally related to success rate and post ERCP hospitalization. This issue was controversial in other patients [8, 14].

However, there are some unclear issues concerning PD stent such as risk factors and side effects of PD stent and their management. Moreover, size, timing of stent placement and removal require more specific studies [9, 15-16]. The size of stent was subject for many studies too. Some studies revealed that 3f and 5f diameter stents have the same outcome although, the rate of and also success of 5f stent insertion is more common. Furthermore, placement of 3f stent needs more experience along with a small-caliber guide wire [9-10, 15]. Previous studies showed that long stent placement is more difficult and is accompanied by more spontaneous dislodgement and migration. In this study, we used a 5f, 4cm stent for all patients. Spontaneous removal of this type of stent rarely happened [17]. Stent related complications include migration, in present study, was very low and just occurred in three patients (3.5%), and occlusion did not happen which is comparable with recent reports [8, 18]. Furthermore, in current study, we placed PD stent without failure in all patients. The failure rate in previous studies was about 5-10%. This result could be related to expertise of endoscopists as well as good selection of patients. In addition, type of stents might play a role in this setting; we did not evaluate the effects of size of stent on outcome though. It should be noted that, based on previous reports, successful placement of PD stent and low rate complications are related to experience of endoscopists and their familiarity with techniques of PD stent placements [2, 4, 8]. These finding could suggest the routine usage of short, 5f diameter PD stent at active ERCP centers.

Our study had several limitations; first, we could not evaluate the design of stent regarding size and shape because a uniform stent was administered for all patients. Second, this study is a single blind study in which observation bias could not be ruled out. Third, because we extracted a majority of stents through second ERCP, we could not evaluate post-ERCP complications in spontaneous dislodgement of PD stent group.

Conclusion

We strongly recommend pancreatic stenting in high-risk patients, as to decrease the incidence of post-ERCP pancrititis about 70%. To confirm PD stent as a routine procedure in ERCP of high-risk individuals, the expertise of another ERCP unit and the evaluation by another endoscopists' techniques are required.

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Conflicts of Interest

None declared.

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