Prophylactic Pancreatic Stent Placement for Endoscopic Duodenal Ampullectomy: A Single-Center Retrospective Study

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Background/Aims: We investigated the efficacy of prophylactic pancreatic stent placement for preventing postprocedure pancreatitis in patients undergoing endoscopic papillectomy. **Methods:** This retrospective study included 82 consecutive patients who underwent endoscopic papillectomy for benign ampullary neoplasm at Samsung Medical Center between August 2002 and June 2011. The patients were subdivided into two groups, namely, those who received prophylactic pancreatic stent placement and those who did not. Patient demographics, baseline blood test, tumor characteristics, and endoscopic treatment data were collected. The primary endpoint was postprocedure pancreatitis. **Results:** There was no difference in the development of postprocedure pancreatitis between the stent group and the no stent group (6/54, 10.5% and 2/28, 7.14%, respectively; p=1.00). At baseline, there were no significant differences between the two groups in terms of their risk factors for pancreatitis except pancreatic duct dye injection. The stent group was more likely to have dye injection than the nonstent group (100% vs 42.8%, p<0.001). However, in a logistic regression analysis, no significant difference was observed in the risk factors for pancreatitis including dye injection. **Conclusions:** Our data suggest that routine prophylactic pancreatic duct stent placement in all patients undergoing endoscopic papillectomy may not be necessary and that large-scale prospective studies are required to identify the subgroup of patients who would benefit. **(Gut Liver 2014;8:306-312)**

Key Words: Endoscopic papillectomy; Pancreatic stent; Postprocedure pancreatitis

INTRODUCTION

Endoscopic papillectomy, first reported in 1993,[1] is increasingly performed as a curative procedure for benign ampulla neoplasm with the advantages of avoidance of associated morbidity and mortality of surgical resection under general anesthesia. On the other hand, endoscopic papillectomy carries a high risk of pancreatitis.[2-4] A randomized prospective study in 2005 showed that a prophylactic pancreatic duct stent could reduce the postprocedure pancreatitis in endoscopic papillectomy patients.[5] However, in this prospective study, the total number of patients was small and no postprocedure pancreatitis developed in patients with pancreatic stent placement. In practice, postprocedure pancreatitis sometimes occurs after prophylactic pancreatic stent placement in endoscopic papillectomy. In several studies, postprocedure pancreatitis developed more frequently in patients with pancreatic stent placement than in those without stent placement.[2,6,7] The main aim of the present study was to evaluate the efficacy of the prophylactic pancreatic stent in preventing postprocedure pancreatitis in endoscopic papillectomy.

MATERIALS AND METHODS

1. Study population

From August 2002 to June 2011, we retrospectively reviewed 82 patients who underwent endoscopic papillectomy due to ampullary neoplasm at Samsung Medical Center. The medical records of the patients, which included preprocedural diagnosis work up, endoscopic papillectomy methods, placement or non-placement of prophylactic pancreatic stent, reason for no stent insertion, postprocedural outcomes, and complications were reviewed. Endoscopic papillectomy was performed in pathologic confirmed ampullary adenoma by endoscopic biopsy or cases of highly suspicious ampullary tumors by gross endoscopic exami-

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nation even if biopsies were not confirmative. Although small (<25 mm), obviously benign adenoma could be resected without extensive prepapillectomy work up,[8] we performed endoscopic ultrasound (EUS) or other imaging work up (such as computed tomography [CT] or magnetic resonance imaging [MRI]) in all patients before endoscopic papillectomy to assess the extent of the lesion, and the presence of lymph node metastasis. When intraductal extension was suspected, endoscopic retrograde cholangiopancreatography (ERCP) was performed at the time of planned papillectomy.

2. Endoscopic papillectomy and pancreatic duct stenting

Endoscopic papillectomy procedures were performed by three experienced pancreaticobiliary endoscopists (J.K.L., K.T.L., and K.H.L.) using a polypectomy snare that was advanced through the accessory channel of a TJF-200 or -240 side-viewing endoscope (Olympus, Tokyo, Japan). The ampullary lesion was grasped with the snare and removed using electrosurgical generator (ICC 200 or VIO 300D [ERBE, Tübingen, Germany]) in endocut mode. Lesions were excised en bloc or in piecemeal fashion, depending on the size and shape of the tumor. Submucosal injection (normal saline mixed with epinephrine) before resection was done in lesions with predominant lateral extrapapillary extension. A 5-Fr polyethylene pancreatic duct stent insertion was tried immediately after excision of the tumor to prevent postprocedure pancreatitis in every patient, except some who had patulous pancreatic duct opening and patent pancreatic duct (Fig. 1). Several days later, follow-up endoscopy was performed to remove the pancreatic stent.

3. Definitions

Postpapillectomy complications such as pancreatitis, bleeding, and cholangitis were defined according to the consensus criteria.[9] Pancreatitis was defined by elevation of pancreatic enzymes three times more than upper normal limit with significant abdominal pain for 24 hours after the procedure. Bleeding was defined by clinical (not just endoscopic) evidence of

bleeding that occurred after completion of the procedure and required transfusion or endoscopic or surgical intervention. Bleeding during the procedure was not considered as a complication. Cholangitis was defined by fever more than 38°C for 24 to 48 hours after papillectomy without other cause of fever. We compared patients with stent (stent group) with those without stent (no stent group) concerning development and risk factors of post-ERCP pancreatitis. The severity of complications was assessed according to consensus criteria. Among the reasons of nonplacement of pancreatic duct, cannulation failure was defined as the inability to inject contrast to the pancreatic duct and stent failure was defined as failure to insert stent after visualization of pancreatic duct. No stent was defined as nonplacement of pancreatic stent regardless of contrast injection.

4. Statistical analyses

Outcomes including risk factors of post-ERCP pancreatitis in patients with and without prophylactic pancreatic duct stent were compared by using chi-square, Fisher exact test, and logistic regression analysis. The data were analyzed using PASW statistics version 18 for Windows (IBM Co., Armonk, NY, USA). A two-sided p<0.05 was regarded as significant.

RESULTS

1. Patient characteristics

Between August 2002 and June 2011, 82 patients with ampullary neoplasm underwent endoscopic papillectomy (54 men and 28 women, 54.7±13 years [range, 27 to 80 years]) (Table 1). Among them, 43 patients had other medical problems including diabetes mellitus, hypertension, familial adenomatous polyposis syndrome, and previous operation history due to malignancy in other organs. None of the patients received anticoagulation medications. Ampulla of Vater adenoma was incidentally detected in 73 asymptomatic patients; 69 patients with screening endoscopy and four patients with follow-up CT scan for underlying disease. Eight patients had abdominal pain and one
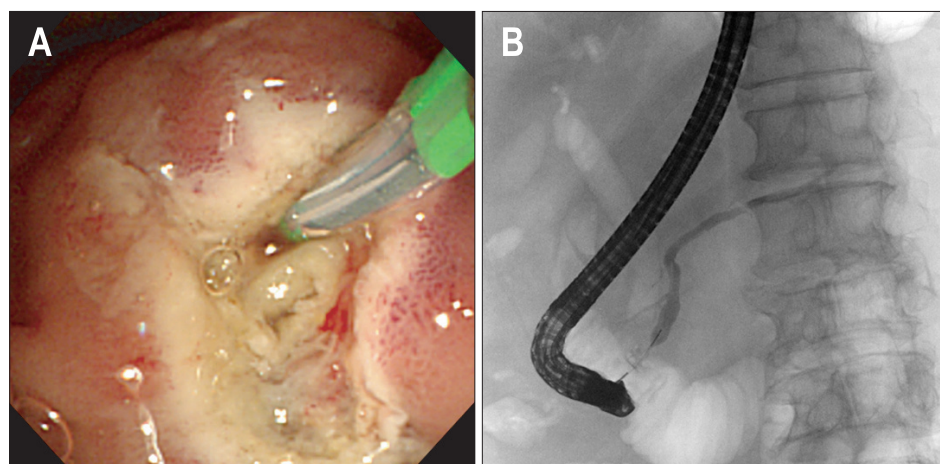

Fig. 1. (A) Patulous pancreatic duct opening was noticed after papillectomy and (B) there was no obstructive lesion in the pancreatogram.

Table 1. Demographic and Clinical Data on the Endoscopic Papillectomy Cases

Characteristic	Value
No. of patients	82
Mean age, yr	54.7 (27-80)
Male:Female	54:28
Symptoms	
No symptoms	73 (89)
Abdominal pain	8 (9.8)
Jaundice	1 (1.2)
Prepapillectomy pathology	
Adenoma	75 (91.5)
Atypical gland	4 (4.9)
Epithelial hyperplasia	2 (2.4)
Harmartoma	1 (1.2)
Size of tumor, cm	1.3 (0.4-3.0)
Submucosal injection	19 (23.2)
En bloc resection	63 (76.8)
P-duct contrast injection during the procedure	67 (81.7)
Postpapillectomy pathology	
Tubular adenoma	70 (85.4)
Low grade	57
High grade	13
Others*	12 (14.6)
Patients who underwent surgery after endoscopic papillectomy	10
Incomplete resection (margin positive)	6
Adenocarcinoma	4
Follow-up duration, median day	736.5
Adenoma recurrence	5
Complications	
Early	
Pancreatitis	8 (9.8)
Bleeding	10 (12.2)
Late	
Papillary stenosis	1 (1.2)

Data are presented as mean (range) or number (%).
*One harmartoma, one epithelial hyperplasia, one gangliocytic ganglioma, five tubulovillous adenoma, four adenocarcinoma.

patient visited the hospital for jaundice.

Seventy-five patients were pathologically confirmed as adenoma before endoscopic papillectomy, but the remaining seven patients underwent endoscopic papillectomy based on highly suspicious endoscopic and imaging findings of adenoma. Prepapillectomy diagnosis of these seven patients consisted of four atypical glands, two benign epithelial hyperplasias, and one harmartoma. The postpapillectomy diagnosis of the patient with

prepapillectomy diagnosis of harmartoma was harmartoma and those of the other six patients were adenoma except one case gangliocytic paraganglioma.

All patients underwent an imaging work up to evaluate regional lymph node before endoscopic papillectomy. Thirty-seven patients underwent EUS and CT (45%), and 34 patients underwent CT only (41.5%). The other six patients received MRI or an ultrasonogram. No patient had regional lymph node metastasis.

2. Endoscopic resection

The mean size of the tumors was 13.0 mm (range, 4 to 30 mm). Endoscopic papillectomies were performed without submucosal injection in 63 patients. In 19 patients who had flat lesions with lateral extension, submucosal injection of normal saline mixed with epinephrine was performed to facilitate grasping and to lessen the risk of perforation. *En bloc* resection was done in 64 cases and piecemeal resection in 18 cases. Immediate or potential bleeding spots observed after papillectomy were managed using argon plasma coagulation and/or hemoclips in 20 patients (24.4%). Prophylactic 5-Fr pancreatic duct stent was placed in 54 patients to prevent pancreatitis and biliary stent placement was performed in 24 patients. Biliary and pancreatic sphincterotomy were not performed in any patient during the procedure. In six patients, the pancreatic stent was passed out spontaneously. In the remaining patients, the stents were endoscopically removed later (mean 3.3 days after resection; range 1 to 88 days). The no stent group consisted of 28 patients; stent insertion was tried but failed in 20 patients and stent insertion was not tried in the other eight patients.

3. Final pathology and follow-up

Histopathologic evaluation of the resected specimens revealed 75 cases of tubular adenoma (57 cases of low grade and 13 cases of high grade). The remaining specimens were five cases of tubulovillous adenoma (four low grade cases and one high grade case), one case of harmartoma, one case of surface epithelial hyperplasia, one case of gangliocytic paraganglioma, and four cases of adenocarcinoma. The prepapillectomy diagnosis of epithelial hyperplasia was low grade adenoma. In six patients, resection margin was positive for adenomatous tissue, and these patients underwent transduodenal papillectomy. Remained adenoma was confirmed in surgical specimens after transduodenal papillectomy in all six patients. Four patients with adenocarcinoma underwent radical pancreatoduodenectomy. Malignant tissue was completely resected and there was no lymph node metastasis. Median follow-up duration was 736.5 days including patients underwent surgery. During follow-up an 80-year-old male patient died from unknown cause 3.3 years after papillectomy. Adenoma recurred in five patients. Two of them underwent transduodenal papillectomy: one patient received surgery due to recurred high grade dysplasia and the other pa-

tient desired surgical management. The other three recurrent low grade adenomas were addressed by a repeat endoscopic papillectomy.

4. Complications

Perforation and cholangitis did not develop in any patient. Bleeding developed in 10 patients (10/82, 12.2%) after endoscopic papillectomy, and was managed by endoscopic treatment. Pancreatitis developed in eight patients and was fully resolved with conservative management. Recurrent pancreatitis due to postpapillectomy papillary stenosis developed in a 57-year-old female patient in the no stent group. The stent was not placed for stent failure due to acute angulation of pancreatic duct. Acute pancreatitis developed 3 and 5 months after papillectomy in this patient. Pancreatic duct stent was tried but failed, so we performed transduodenal papillectomy 6 months after endoscopic papillectomy to prevent recurrent obstructive pancreatitis.

5. Comparison of pancreatitis between the stent group and no stent group

All patients were classified into two groups: stent group (pancreatic duct stent was placed, n=54) and no stent group (not placed, n=28). There was no difference in development of postprocedure pancreatitis between stent group and no stent group (6/54, 10.5% and 2/28, 7.14%, respectively; p=1.00). In univariate analysis (Table 2) and multivariate analysis, there was no significant difference in the risk factors of post-ERCP pancreatitis including younger age, female sex, pancreatic duct dye injection, and normal serum bilirubin level. Stent insertion, submucosal injection, and tumor size were not significantly different between two groups also. The severity of pancreatitis was mild to moderate as consensus criteria without significant difference between two groups: one mild and five moderate pancreatitis patients in stent group and two moderate pancreatitis patients in no stent group. All patients were fully recovered after conservative management.

The most common cause of no stent insertion was technical difficulty (Table 3): cannulation failure (n=13/28) followed by stent failure due to acute angulation or tortuous pancreatic duct (n=6/28). Stent reinsertion was impossible due to loss of sight of pancreatic duct opening after bleeding control in a patient (Fig. 2). We did not try stent insertions in eight patients: patent pancreatic duct opening and smooth flow of dye after endoscopic papillectomy were observed in three patients and postprocedure

Table 2. Comparison of Pancreatic Risk Factors between the Stent Group and No Stent Group (Univariate Analysis)

	OR	95% CI	p-value
Age ≤60 vs >60	0.38	0.04–3.47	0.55
Gender (male vs female)	0.23	0.04–1.35	0.19
Pancreatic duct injection (no vs yes)	1.13	0.12–10.44	0.81
Stent insertion (no vs yes)	1.04	0.18–6.06	0.72
Submucosal injection (no vs yes)	1.74	0.29–10.30	0.99
Size (each 1 cm increase)	0.21	0.03–1.72	0.08
Bilirubin (each 1 unit increase)	0.29	0.02–5.16	0.61

OR, odds ratio; CI, confidence interval.

Table 3. Causes of No Stent Insertion

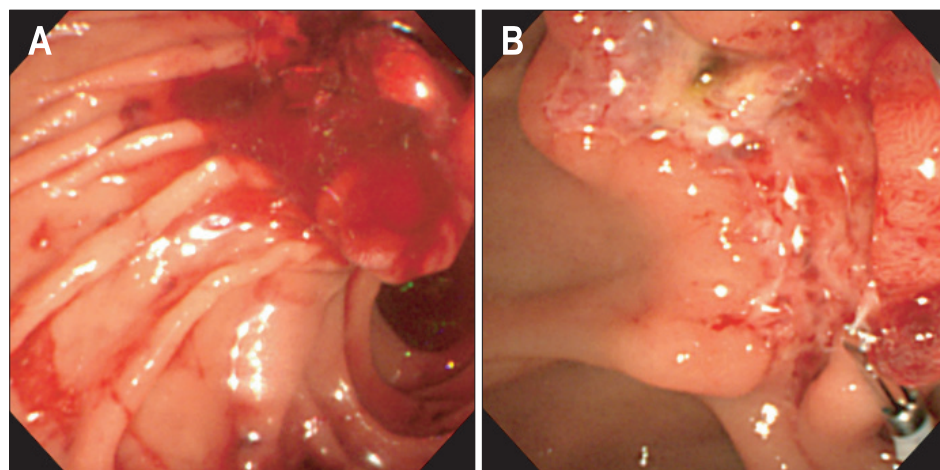|	Number
Cannulation failure	13
Stent failure:Acute angle or tortuous P-duct	6
Pancreas divisum	1
Bleeding	1
Patulous P-duct opening	3
No trial due to no concept of P-duct stent (before 2005)	4
Total	28

Fig. 2. (A) Bleeding occurred immediately after papillectomy and (B) pancreatic duct opening, which was not observed after hemostasis.

pancreatitis did not develop in these patients. There was one patient with pancreas divisum and there were four patients who received endoscopic papillectomy before the concept of protective effect of prophylactic pancreatic stent. These eight patients may have low risk of pancreatitis, so we tried univariate and multivariate analysis between stent (n=54) and no stent group (n=20) again except these eight patients. In the results, there was no difference in development of postprocedure pancreatitis between stent group (6/54) and no stent group (1/20). And there was no significant difference in the risk factors of post-ERCP pancreatitis between two groups also.

DISCUSSION

Acute pancreatitis is one of most common and potentially severe complications of ERCP. There have been attempts to find effective measures to prevent post-ERCP pancreatitis through mechanical or pharmacological interventions. Among them, temporary prophylactic placement of pancreatic duct stent is highly recommended to prevent pancreatitis due to pancreatic duct obstruction.[2-4,10-14] In our center, we also explored the use of prophylactic pancreatic stent placement after endoscopic papillectomy to prevent pancreatitis. However, several patients developed pancreatitis even after pancreatic stent placement (6/54, 10.5%) and the development rate of pancreatitis was not significantly different compared to patients without stent placement (2/28, 7.14%, p=1.00).

In 2005, a prospective randomized study[5] reported a markedly reduced rate of pancreatitis in endoscopic papillectomy patients who received prophylactic pancreatic duct stent placement (0/10, 0%) compared with patients who did not receive a stent (3/9, 33%, p=0.02). Since the publication of this study, most physicians have performed prophylactic pancreatic stenting for endoscopic papillectomy.[15-17] However, the study involved a small number of patients and the reason for statistical significance despite this small number was the absence of pancreatitis in patients who received prophylactic pancreatic duct stent placement. In common with the study of Harewood et al.,[5] two retrospective studies showed no postprocedure pancreatitis development in patients with prophylactic pancreatic stent placement.[18,19] However, there were some differences in the procedures between two of three studies and this study. We did not perform the biliary sphincterotomy, however in the study of Harewood et al.,[5] biliary sphicterotomy was performed routinely, and in the study of Desilets et al.,[18] routine biductal sphincterotomy was performed. In the study of Harano et al.,[19] bile duct stenting was routinely done. In some other studies, postprocedure pancreatitis developed in patients who received prophylactic pancreatic stent.[2,6-8,20-22] In these studies, as in our study, routine biliary sphincterotomy, pancreatic sphincterotomy, and routine biliary stent insertion were not performed.

In the present series, why was the postprocedure pancreatitis differently reported in papillectomy cases according to prophylactic pancreatic stent? Some mechanisms have been considered for the induction of pancreatitis after endoscopic papillectomy.[23] These are obstruction to outflow of pancreatic juice, foreign substances in the pancreatic duct, contrast dye injection into pancreatic duct,[24] and electrical current injury during papillectomy and/or sphincterotomy.[25] In cases of no stent group, pancreatitis may develop more commonly than in stent group due to obstruction. While endoscopic ampullary tumor is resected, the sphincter is also resected. Therefore, the risk of obstruction in papillectomy might be lower compared to other ERCP procedures. In contrary, pancreatic duct stent may cause enzymatic activation leading to pancreatitis as a foreign body. In the studies with no difference of pancreatitis according to stent, less coagulation current was used only during papillectomy. This might lessen the coagulation effect leading to pancreatic duct damage and obstruction in no stent group. In our study, we did not perform a routine pancreatogram before papillectomy because detailed work up of pancreatic duct was possible due to progress of CT and EUS. This might lessen the risk of pancreatitis in no stent group more profoundly. These may be the reasons for no difference in pancreatitis development between two groups with and without pancreatic stent after papillectomy unlike the only prospective study.

Even for experienced endoscopists, pancreatic duct cannulation and stent placement are not always successful. Several prospective studies from advanced centers have reported failure rates of 4% to 10%.[26-29] The success rate may be lower in endoscopic papillectomy than other ERCP procedure due to bleeding, edema, or cautery artifact after resection. In a study of endoscopic papillectomy by Harano et al.,[19] the success rate was 82% (23/28). In our study, the pancreatic stent insertion success rate was 72% (54/74) and one case of postprocedure pancreatitis developed in one of 20 patients for whom pancreatic stent placement failed, due to cannulation failure.

A papillary stenosis developed in only one patient without prophylactic stent placement during follow-up in our study. In a retrospective study, papillary stenosis after papillectomy occurred more with statistical significance in patients without pancreatic duct stents (1/12 vs 2/91).[21] However the number of papillary stenosis was very small, in another study, papillary stenosis after endoscopic papillectomy developed in a patient with prophylactic pancreatic duct stent placement.[20] So, it is hard to conclude that papillary stenosis develop after endoscopic papillectomy more in patient without pancreatic stent before definite evidence.

Our study has some limitations as retrospective study, and while the patient number was somewhat larger compared to previous study, the patient size was still small. Furthermore there may be a statistical error due to the huge difference of

number of cases between the two groups.

In conclusions, the routine insertion of pancreatic duct stent in patients undergoing endoscopic papillectomy needs to be avoided considering comflicting outcomes of prophylactic pancreatic stent placement, potential injury of pancreatic duct stent, and progress of imaging and equipment. Large-scale prospective studies are required to find the subgroup who get the benefit of prophylactic pancreatic duct stent to prevent postprocedure pancreatitis and papillary stenosis after endoscopic papillectomy.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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