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Retrospective Study

Prospective single-center feasible study of innovative autorelease bile duct supporter to delay adverse events after endoscopic papillectomy

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Abstract

BACKGROUND

Conventional endoscopic papillectomy (EP) is safe and effective for the treatment of small papilla adenoma to even large laterally spreading tumors of duodenum lesions. As reported by some existing studies, temporarily placing a prophylactic stent in the pancreatic and bile duct can lower the risk of this perioperative complication.

AIM

To evaluate the usefulness, convenience, safety, and short-term results of a novel autorelease bile duct supporter after EP procedure, especially the effectiveness in preventing EP.

METHODS

A single-center comparison study was conducted to verify the feasibility of the novel method. After EP, a metallic endoclip and human fibrin sealant kit were applied for protection. The autorelease bile duct supporter fell into the duct segment and the intestinal segment. Specifically, the intestinal segment was extended by nearly 5 cm as a bent coil. The bile was isolated from the pancreatic juice using an autorelease bile duct supporter, which protected the wound surface. The autorelease bile duct supporter fell off naturally and arrived in colon nearly 10 d after the operation.

RESULTS

En bloc endoscopic resection was performed in 6/8 patients (75%), and piecemeal resection was performed in 2/8 of patients (25%). None of the above patients were

positive for neoplastic lymph nodes or distant metastasis. No cases of mortality, hemorrhage, delayed perforation, pancreatitis, cholangitis or duct stenosis with the conventional medical treatment were reported. The autorelease bile duct supporter in 7 of 8 patients fell off naturally and arrived in colon 10 d after the operation. One autorelease bile duct supporter was successfully removed using forceps or snare under endoscopy. No recurrence was identified during the 8-mo (ranging from 6-9 mo) follow-up period.

CONCLUSION

In brief, it was found that the autorelease bile duct supporter could decrease the frequency of procedure-associated complications without second endoscopic retraction. Secure closure of the resection wound with clips and fibrin glue were indicated to be promising and important for the use of autorelease bile duct supporters. Well-designed larger-scale comparative studies are required to confirm the findings of this study.

Key Words: Endoscopic papillectomy; Duodenal papilla; Bile duct stent; Adverse events; Endoscopic retrograde cholangiopancreatography

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Core Tip: In this study, a novel autorelease bile duct supporter was successfully inserted through a guide wire using endoscopic retrograde cholangiopancreatography in all patients after endoscopic papillectomy, during which an experienced operator was required for the insertion of the guide wire. The novel autorelease bile supporter entered the colon nearly 10 d after the endoscopic procedure with automatic shedding characteristics and decreased the frequency of procedure-related complications without a second endoscopic retraction.

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INTRODUCTION

Endoscopic sphincterotomy was first reported in 1981 as an endoscopic operative strategy for the treatment of ampullary tumors[1]. Conventional endoscopic papillectomy (EP) has been indicated to be safe and effective for small papilla adenoma (PA) to even large laterally spreading tumor (LST) of duodenum lesions[2]. The above lesions potentially undergoing the adenoma-carcinoma sequence are expected to be removed by endoscopy resection for curative therapy[3,4]. Compared with surgical management by either pancreaticoduodenectomy or duodenostomy, EP using a snare has less morbidity, less mortality, and shorter hospital stay, and it has been accepted as an effective first-line therapy for resecting ampullary tumors[5].

Before proceeding with attempted endoscopic resection, biopsy specimens from suspicious ampullary lesions are recommended and should be obtained to confirm the diagnosis and exclude carcinoid tumors or gangliocytic paragangliomas[6]. EP has been found to be effective and safe for experienced hands with success rates of nearly 80% for lesions benign ampullary adenoma, HGIN, and noninvasive cancer without intraductal tumor growth[7,8]. Ductography by endoscopic retrograde cholangiopancreatography (ERCP) with bile and pancreatic duct plays a vital role in the evaluation of any ampullary adenomas ductal extension. *En bloc* resection should be performed by endoscopic snares, because of its advantages of short procedure time, less cautery and complete tissue sample for pathology evaluation. EP is correlated with an increased risk of procedure-related acute pancreatitis.

As reported by several studies, temporarily placing a prophylactic stent in the pancreatic and bile duct can lower the risk of this perioperative complication[9,10]. To date, no clear consensus relating to the parameter of pancreatic and bile duct stents has been reached.

This study assessed the usefulness, convenience, safety, and short-term results of a novel autorelease bile duct supporter after EP procedure, especially the effectiveness in preventing EP-related adverse events.

MATERIALS AND METHODS

Patients

In general, 8 patients were diagnosed histopathologically with PA and duodenum LST between March 2021 and September 2021 in the gastroenterology endoscopy center of Chinese PLA General Hospital (Beijing, China). All patients received abdominal computed tomography (CT) and pathological biopsy in before EP to evaluate the invasion depth. Exclusion criteria included suggestion of malignancy by pathological biopsy and suspicion of invasion into the pancreaticobiliary duct. Patients were sedated with a balanced propofol and maintained sedation with initial intravenous administration of midazolam. Carbon dioxide insufflation was conducted, and prophylactic antibiotics were permitted.

EP and stent drainage

The procedure of EP in combination with this novel autorelease bile duct supporter is described in [Figure 1](#). A submucosal injection with 1:10000 diluted epinephrine into the submucosa at 3 to 4 locations around the ampulla was performed to evaluate the lesion. Electrosurgical snare (SD-7P-1/SD-221L-25; Olympus, Tokyo, Japan) passed over the working channel of the duodenoscope. The snare was carefully deployed around the ampullary lesion, and it grasped all abnormal-appearing mucosal tissues. *En bloc* or piecemeal resection of the lesion was performed based on the “Forced Coag” mode and “Endocut” mode (VIO 300D; Erbe Elektromedizin GmbH, Tübingen, Germany), and any suspicious residual lesion after resection was ignited through argon plasma coagulation. Electric coagulation forceps were employed for hemostasis when required. The resected specimen was retrieved with either the snare or a grasper. A guidewire was inserted through the catheter into the bile duct. The wound was closed with endoscopic hemoclips. The autorelease bile duct supporter involved the duct segment and the intestinal segment, in which the intestinal segment was extended by nearly 5 cm as a bent coil. The novel autorelease bile duct supporter was inserted through a guide wire using ERCP ([Figure 2](#)) to ensure adequate pancreatobiliary drainage. The gravity of the curved coil of autorelease bile stent could ensure the automatic shedding characteristics of this novel bile duct supporter. Fibrin glue (S10959931; Human Fibrinogen, Shanghai, China) was sprayed on the wound. The resected specimen was sent immediately for histopathologic analysis through serial sectioning. The autorelease bile duct supporter fell off naturally and arrived in colon nearly 10 d after the operation.

Stent placement were rechecked under X-radiography. Fasting water, acid-inhibitory drugs, enzyme inhibitors (somatostatin), and total parenteral nutrition were given through intravenous infusion nearly 10 d after the operation. The autorelease bile duct supporter fell off naturally and arrived in colon about 10 d after the operation based on X-ray image examination.

Definitions

Early complications (*e.g.*, bleeding, perforation and acute pancreatitis) after the procedure were controlled by hot-biopsy forceps (Coagrasper; Olympus) hemoclips and somatostatin. Post-EP pancreatitis was set as a 3-fold increase in pancreatic enzymes with abdominal pain[7].

Perforation was recognized as a transmural defect by emergency gastroscopy or radiographic evidence of free retroperitoneal or intraperitoneal air by CT scan. Endoscopic success was defined as complete resection of the lesion without any residual tumor tissue, as well as when no recurrence was detected at the 3-mo and 6-mo follow-up after EP. The resection rate of the tumor, discharge of the autorelease stent, operative time, early complications, late complications and tumor recurrence were predicted.

RESULTS

[Table 1](#) lists the clinicopathological data and outcomes of 2 women and 6 men. The mean age was 55.5 ± 4.9 years. The size of adenomas ranged from 20-43 mm with mean (standard deviation) 28.1 mm. Preoperative pathological diagnosis was tubular adenoma in 3, tubulovillous adenoma with low-grade dysplasia in 1, as well as tubulovillous adenoma with high-grade dysplasia (HGD), HGD/inflammation, and neuroendocrine tumor in 2, 1, in 1, respectively ([Table 1](#)).

The median tumor area of the tumors was measured as 7.57 mm² (ranging from 4.7-11.6 mm²). All PA with positive lifting sign after submucous injection was considered a criterion of lower superficial invasion. The resection was histopathologically performed in all patients. *En bloc* endoscopic resection was performed in 6/8 patients (75%), and piecemeal resection was performed in 2/8 of patients (25%). After EP, the autorelease bile duct supporter was placed. The average operation time was recorded as 47.1 ± 6.7 min. Tumor was confined to the mucosal layer in 5 cases and invaded the submucosa in 2 cases. In 1 case, tumor invaded the muscularis mucosa. None of the above patients were reported to be positive for neoplastic lymph nodes or distant metastasis.

There was only 1 case with positive lateral margin lesion after EP, and no treatment was added, except for endoscopic follow-up. The final histopathological diagnoses of the endoscopic specimens consisted of 3 cases of tubular adenoma, 3 cases of tubulovillous adenoma, 1 case of hamartomatous

Table 1 Baseline characteristics of patients with papillary adenoma

No.	Sex	Age in yr	Tumor size in mm	Biopsy pathology
1	M	59	20	Tubular adenoma
2	M	60	15	Tubular adenoma and HGD
3	M	49	32	Adenomatoid hyperplasia and LGD
4	M	44	20	Tubular adenoma
5	M	50	10	Neuroendocrine tumor (stage G1)
6	F	86	40	HGD
7	M	56	43	Tubular adenoma and HGD
8	F	52	20	Tubular adenoma

M: Male; F: Female; LGD: Low-grade dysplasia; HGD: High-grade dysplasia.

polyp, 1 case of adenocarcinoma, and 1 case of atypical juvenile polyposis with tubulovillous adenoma (Table 2). Among the 3 cases of tubular adenomas, 2 were correlated with HGD, in which the depth of invasion was limited to the mucosa. In the 3 cases of tubulovillous adenoma, HGD was found with submucosa invasion. The case of neuroendocrine tumor was confirmed to be G2 stage based on pathologically immunohistochemical staining. 1 patient had postoperative abdominal pain, which was resolved with antibiotic and somatostatin.

All cases were reported without any mortality, hemorrhage, delayed perforation, pancreatitis, cholangitis or duct stenosis with conventional medical treatment. The autorelease bile duct supporter in 7 of 8 patients fell off naturally and arrived in colon 10 d after the operation. One of this autorelease bile duct supporter was successfully removed with forceps or snare under endoscopy.

This neuroendocrine patient was referred for surgery and received pylorus-preserving pancreaticoduodenectomy after multidisciplinary diagnosis and treatment. No recurrence was identified during the 8-mo (ranging from 6-9 mo) follow-up.

DISCUSSION

With a thin, highly vascular wall, the major papilla refers to the site of the confluence of the pancreatic and bile duct orifices, which can increase the risk of bleeding, pancreatitis, perforation and other complications after EP[11]. In this study, 8 patients with ampullary adenoma were treated with an autorelease bile duct supporter to investigate the parameters that might define this novel stent without second endoscopic retraction as an effective method. Adenoma of the major duodenal papilla is recognized as a type of benign lesion that requires complete resection for the potential premalignant in patients with reasonable life expectancy[12]. Compared with traditionally surgical segmental or whipple resection, EP exhibits significant advantages in reducing complications (*e.g.*, acute pancreatitis, bleeding and perforation), attendant cost, morbidity, as well as potential mortality risk[2,13]. The overall reported incidence of complication rate changed from 0.4% to 7.9% for bleeding, perforation, cholangitis and pancreatitis[14].

Some closing and covering methods were employed to avoid the exposure of digestive juices for the mitigation of the delayed complications (*e.g.*, clips and stents). Proper closure of the mucosal with clips and fibrin glue could mitigate the complication and improve the EP outcomes[15,16]. Poor operability of clips under duodenoscope after papilla resection might be technically challenging to extend the lesion fully and perform appropriate suturing, whereas we still strongly recommend adopting endoscopic clips to suture the duodenal mucosal wound. Accidental closure of the pancreatic or bile duct might result in pancreatitis or jaundice during the above process with clips.

Implantation of pancreatic duct stent has been generally the preferred route for the palliative drainage with fewer pancreatitis after EP[7,12,17,18]. Endoscopic bile drainage tube can also effectively prevent delayed complications for shunting bile and pancreatic juice to avoid erosion exposure of the duodenal ulcer[19-21]. As mentioned in our previous study, the mixture of bile and pancreatic juice could activate the trypsinogen to achieve a high digestive capacity. Active trypsin in the pancreatic duct would induce pancreatitis and erode the duodenal wound[22,23].

Kim *et al*[12] used wire-guide EP, requiring the insertion of a guide wire to the pancreatic duct before the papillectomy, to increase the success rate of pancreatic duct stenting.

However, a guide wire could also impede the expansion and angle of the snare, while making it difficult to resect larger adenomas[12]. Zolotarevsky *et al*[24] performed an RCT targeting pancreatic duct stents, and the spontaneous removal rates in 2 wk were obtained as 68.4% and 75.0% for 3-Fr (*n* =

Table 2 Endoscopic resection results at baseline and follow-up

No.	Tumor size in mm ²	Lifting sign	Operation time in min	En bloc or piecemeal	Autorelease at 2 wk	Complications	R0 resection	Depth of invasion	Lesion pathology
1	5.495	(+)	11	En bloc	(+)	(-)	(+)	Mucosa	Tubulovillous adenoma/HGD
2	8.635	(+)	27	En bloc	(-)	(-)	(-)	Submucosa	Tubulovillous adenoma/HGD
3	9.734	(+)	21	En bloc	(+)	(-)	(+)	Mucosa	Adenomatoid hyperplasia/LGD
4	6.28	(+)	8	En bloc	(+)	(-)	(+)	Mucosa	Tubular adenoma
5	4.71	(+)	16	En bloc	(+)	(-)	(+)	Mucosa	Neuroendocrine tumor, stage G2
6	9.42	(+)	25	Piecemeal	(+)	(-)	(+)	Muscularis mucosa	Tubular adenoma/HGD
7	11.618	(+)	16	Piecemeal	(+)	(-)	(+)	Submucosa	Tubulovillous adenoma/HGD
8	4.71	(+)	13	En bloc	(+)	(-)	(+)	Mucosa	Tubular adenoma/LGD

LGD: Low-grade dysplasia; HGD: High-grade dysplasia.

40) and 5-Fr ($n = 38$) after EP, respectively. In this study, the novel autorelease bile duct supporter was successfully inserted in all patients through a guide wire using ERCP after EP, during which an experienced operator was required for the insertion of the guide wire. The gravity of the curved coil ensured the automatic shedding characteristics of this novel bile stent in 2 wk. No severe or fatal bleeding occur in the above 8 patients. The literature on ampullary papillectomy was examined, and it was found that the insertion of duct stent has been widely recommended by numerous endoscopists to reduce the risk of pancreatitis[25-27]. The autorelease bile duct supporter in 7 of 8 patients fell off naturally and arrived in colon nearly 10 d after the operation.

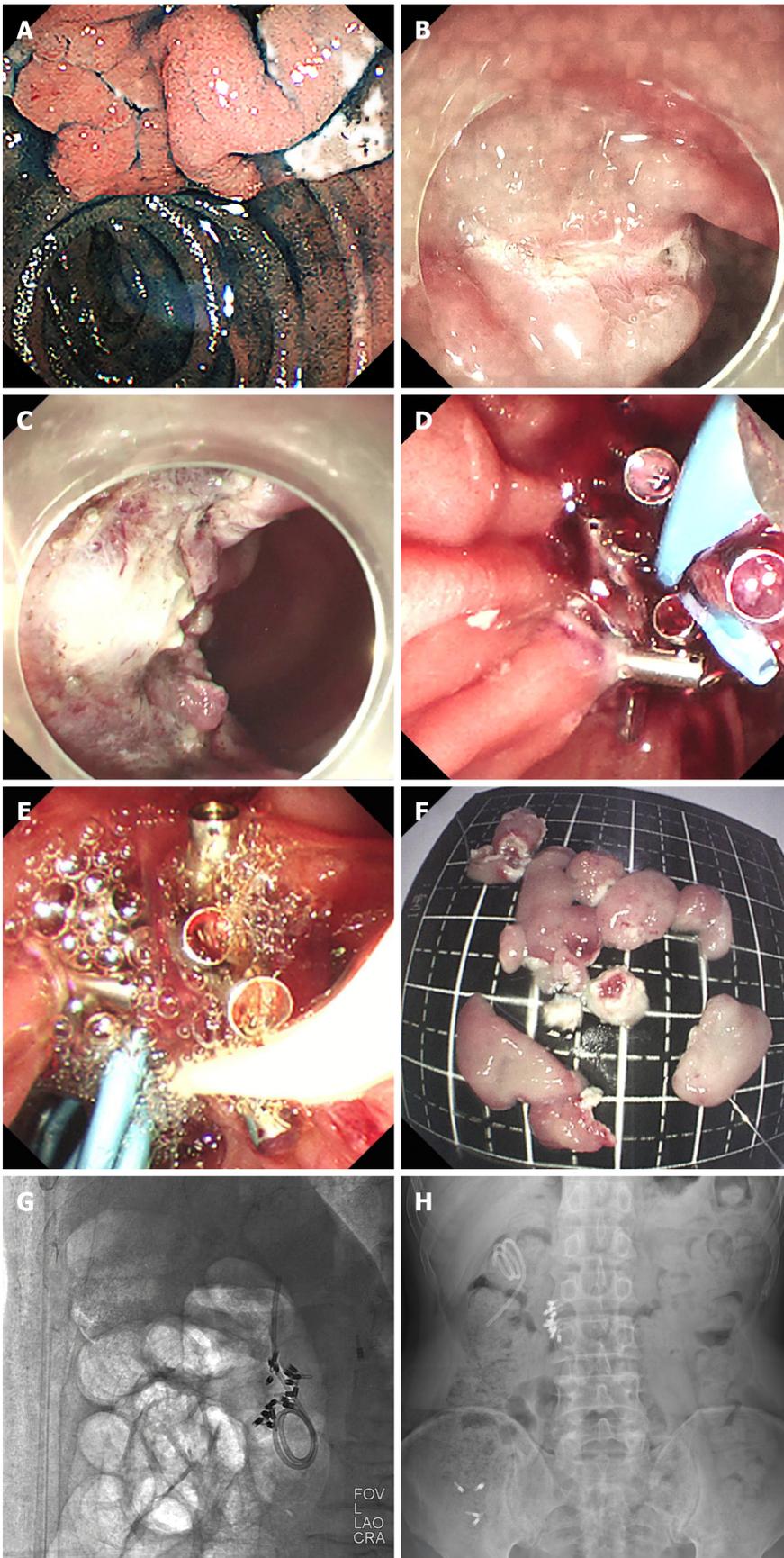
Acid-inhibitory drugs, enzyme inhibitors (somatostatin) and total parenteral nutrition were given through intravenous infusion till 7 d after EP. With the recovery of diet and bile secretion after 7 d, we presume that autorelease bile duct supporter start to liberate from bile duct and then arrived in colon nearly 10 d after EP. With the separation effect of bile stent shunting bile and pancreatic juice and secure closure by fibrin glue, no pancreatitis was detected in the postoperative period in this small-sample study with this autorelease bile duct.

Accordingly, novel autorelease bile duct supporter might be a safe method to prevent severe or fatal pancreatitis without removal by endoscopy. However, patients should be carefully monitored for pancreatitis after EP with giant tumor or greater manipulation around the orifice of the pancreatic duct for the effect arising from the pancreatic opening and pancreatic juice outflow.

The main limitations of this study were the small sample size (EP with a novel autorelease bile duct supporter conducted at a single center by an experienced endoscopist) and the relatively short follow-up time. Well-designed comparative studies are required to assess the findings of this study. For instance, one autorelease bile duct supporter did not come off successfully by itself, whereas it was removed by endoscopy, which could be attributed to the deep plastic wing opening and the improving friction. However, this has been the first study reporting the endoscopic pancreaticobiliary drainage with autorelease bile duct supporter to prevent delayed complications after EP.

CONCLUSION

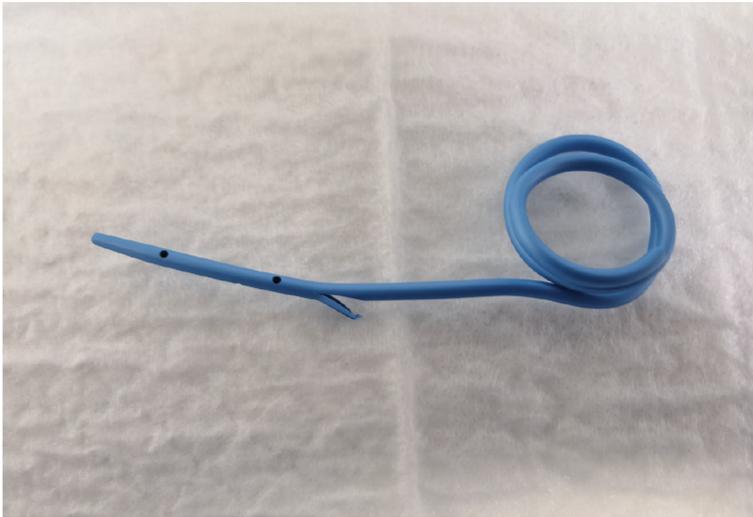
In brief, it was confirmed that autorelease bile duct supporter could decrease the frequency of procedure-associated complications without second endoscopic retraction. Secure closure of the resection wound with clips and fibrin glue was indicated to be promising and important for the use of autorelease bile duct supporter. Well-designed larger-scale comparative studies are required to assess the finding of this study.



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Figure 1 Endoscopic views of endoscopic papillectomy and autorelease biliary supporter placement in a patient with a laterally spreading tumors of the major duodenal papilla. A: Duodenal papilla tumor was examined by duodenoscopy with indigo carmine staining; B: Submucosal injection was performed to lift the lesion; C: Muscularis propria wound after piecemeal submucosal resection with duodenal papilla; D: The wound was closed with

endoscopic hemoclips, and the novel autorelease bile stent was inserted *via* a guide wire by endoscopic retrograde cholangiopancreatography; E: Fibrin glue was sprayed to cover the wound; F: Specimen of piecemeal papilla polypectomy; G: X-ray image showed autorelease biliary stents were successfully placed; H: The autorelease biliary supporter fell off naturally and arrived in colon about 10 d after this operation.



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Figure 2 The novel autorelease bile supporter was inserted through a guide wire using endoscopic retrograde cholangiopancreatography.

ARTICLE HIGHLIGHTS

Research background

Conventional endoscopic papillectomy (EP) has been indicated to papilla adenoma of duodenum lesions. Temporarily placing a prophylactic stent in the pancreatic and bile duct can lower the risk of this perioperative complication.

Research motivation

A new bile duct stent may help with the complication after EP and streamline the procedure.

Research objectives

We evaluated the usefulness, convenient, safety, and short-term results of a novel autorelease bile duct supporter after EP procedure.

Research methods

After EP, metallic endoclip and human fibrin sealant kit were applied for protection. The autorelease bile duct supporter fell into the duct segment and the intestinal segment. The bile was isolated from the pancreatic juice using an autorelease bile duct supporter, which protected the wound surface.

Research results

The autorelease bile duct supporter in 7 of 8 patients fell off naturally and arrived in colon 10 d after the operation. One of this autorelease bile duct supporter successfully removed using forceps or snare under endoscopy. No recurrence was identified during the 8-mo (ranging from 6-9 mo) follow-up.

Research conclusions

Autorelease bile duct supporter could decrease the frequency of procedure-associated complications without second endoscopic retraction.

Research perspectives

Well-designed larger-scale comparative studies are required to assess the finding of this study.

FOOTNOTES

Author contributions: Liu SZ and Chai NL contributed equally to this work; Liu SZ, Chai NL, Li HK, and Linghu EQ designed the study; Liu SZ, Gao F, Feng XX, and Wang SS performed the research; Gao Y and Wang NJ contributed new reagents and analytic tools; Liu SZ and Chai NL analyzed the data and wrote the manuscript; All authors have read and approved the final manuscript.

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