

Papillectomy for ampullary neoplasm: results of a single referral center over a 10-year period



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Background: Tumors arising from the duodenal papilla account for approximately 5% of GI neoplasms, but are increasingly identified.

Objective: To describe the clinical characteristics and outcomes in a large single-center experience with patients referred for ampullary lesions.

Design: A retrospective review of the Virginia Mason Medical Center endoscopy and hospital service database.

Setting: Tertiary referral center.

Patients: One hundred ninety-three patients referred for ampullary lesions from 1997 to 2007.

Interventions: Endoscopic management of ampullary lesions.

Main Outcome Measurements: The relationship of demographic and clinical data with endoscopic treatment and clinical outcomes in these patients.

Results: One hundred ninety-three patients underwent endoscopy for ampullary lesions. Fifteen juxta-ampullary lesions and 10 normal variants were excluded. Among 168 patients, there were 112 (67%) adenomas, 38 (23%) adenocarcinomas, and 18 (10%) nonadenomatous lesions. There were 88 men and 80 women, with a mean age of 64 years. Clinical presentation included cholestasis/choolangitis (72 patients), abdominal pain (54 patients), incidental/asymptomatic (51 patients), pancreatitis (9 patients), and bleeding (7 patients). Of the 57 patients referred to surgery, 42 were sent directly without papillectomy, and 16 were sent after papillectomy. Papillectomies were performed in 102 patients with adenomatous lesions. The mean tumor size was 2.4 cm (range 0.5-6 cm). The papillectomy complication rate was 21%: mild pancreatitis in 10 (10%) patients, cholangitis in 1, retroperitoneal perforation in 1 (adenocarcinoma), intraperitoneal perforation in 1 (lateral extension), bleeding in 5 (lateral extension in 2 of these 5), and delayed papillary stenosis in 3. Recurrences were seen in 8%. The endoscopic success rate was 84%. Factors affecting success were a smaller adenoma size and the absence of dilated ducts.

Conclusions: Most ampullary adenomas are amenable to endoscopy. Underlying malignancy and lateral extension may be risk factors for bleeding and perforation. Smaller lesion size and the absence of dilated ducts are factors favorably affecting success. (Gastrointest Endosc 2009;70:923-32.)

Neoplasms of the duodenal papilla are rare, with a reported prevalence of 0.04% to 0.12% in autopsy series.^{1,2} Ampullary adenomas and adenocarcinomas are

Abbreviations: APC, argon plasma coagulation; FAP, familial adenomatous polyposis.

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increased 200- to 300-fold in genetic polyposis syndromes, especially familial adenomatous polyposis (FAP) and its variants.³ They can arise from the surface epithelium or the inner lining of the ampulla.⁴ Historically, these lesions presented late with a high incidence of underlying malignancy.⁵ Endoscopic management in the early years consisted mainly of palliative maneuvers such as stent placement for obstructive jaundice. These lesions are, however, being increasingly recognized at earlier stages with lower incidences of underlying malignancy.⁶

Symptoms often appear when the lesions grow large enough to cause obstruction, leading to cholestasis,

pancreatitis, nonspecific abdominal pain, and, less commonly, bleeding. Asymptomatic lesions are being recognized more commonly in patients undergoing endoscopy for other symptoms such as GERD and dyspepsia or, alternatively, in patients with FAP undergoing surveillance.⁶⁻⁸

The extensive experience with removing colorectal polyps with snare polypectomy, in conjunction with reports of transduodenal resections being adequate treatment for benign disease, led to the recognition that the bulk of benign adenomas are endoscopically amenable.⁴ The real issue today is not can we resect adenomas endoscopically, but rather in whom should we do it?

In 2004, Catalano et al⁹ reported a retrospective multicenter experience in the management of ampullary adenomas in 103 patients over a 4-year period. In 2005, Bohnacker et al² reported their experience prospectively in 106 patients over 15 years looking at benign ampullary tumors with and without intraductal extension. There are a few other studies that have critically evaluated papillectomy for ampullary neoplasms with a much smaller number of patients.^{6,10-12} We report a large single-center experience with patients referred for endoscopic management of ampullary neoplasms over the past decade and specifically evaluate the outcomes in patients with ampullary adenomatous lesions.

PATIENTS AND METHODS

Between September 1997 and September 2007, 193 patients were referred to gastroenterology at Virginia Mason Medical Center for the management of ampullary lesions (82% outside referrals, 18% internal referrals). Preprocedural, procedural, and postprocedural data were collected and reviewed retrospectively (Table 1).

All patients undergoing papillectomy had previous abnormal biopsy results. Cross-sectional imaging and/or EUS (42% cases) was performed pre-procedure when metastasis or invasive cancer was suspected either at the time of the initial referral or after performing the first ERCP. EUS was not performed for most adenomas smaller than 2 cm, for which endoscopic and ERCP criteria were used to determine resectability. Features of unresectability were friability, ulceration, more than 50% lateral extension, obvious duodenal infiltration, and intraductal extension of more than 1 cm at ERCP. Four gastroenterologists performed papillectomies at our institution (all with >10 years of pancreaticobiliary experience), with 73% being performed by one of the providers. The technique, in general, was as follows (Fig. 1): A pancreatogram and a cholangiogram were obtained initially. A standard, braided polypectomy snare using blended electrosurgical current was used to tighten around the lesion and transect it at its base. For tumors smaller than 2 cm, performance of a single papillectomy was attempted, whereas

Capsule Summary

What is already known on this topic

- Ampullary adenomas are increasingly recognized at earlier stages with lower incidences of underlying malignancy.

What this study adds to our knowledge

- In a retrospective series of 102 patients with ampullary adenomas undergoing endoscopic papillectomy, the success rate was 84% and the complication rate was 21%.
- Lesions <2 cm and the absence of dilated ducts favor successful outcome.
- The sensitivity of endoscopic biopsies was 53%.

lesions larger than 2 cm were mostly done piecemeal to decrease the chance of involving the deeper layers in the resection. Three of the 4 providers performed dual sphincterotomies after the papillectomy (this included the majority of the papillectomies performed), whereas one of the providers performed the dual sphincterotomies before the papillectomy. A biliary sphincterotomy was performed with blended current, whereas the pancreatic sphincterotomy was done with pure cut current by using a monofilament papillotome. Saline solution lift was performed only for lesions with lateral extensions (>25% of circumference of the duodenum at the level of the papilla) and very flat lesions. Pancreatic stenting (3F × 8 cm) and biliary stenting (10F × 5 cm straight, 7F × 3 cm double pigtail) was routinely attempted in all patients, irrespective of the ease of drainage of contrast at the end of the procedure. All tissue was retrieved and sent for histopathologic evaluation. If needed, thermal energy (argon plasma coagulation [APC]) was used to treat any residual tissue. All patients were admitted for an overnight stay. All patients returned 4 to 8 weeks after the initial papillectomy for stent removal, routine biopsies, and further treatment, if needed. Follow-up was then performed at 3- to 6-month intervals for as long as 2 years for the incidental/sporadic group of patients. The FAP patients were followed based on their C-loop polyp burden.

Inclusion criteria were patients older than 18 years of age who underwent papillectomy for preprocedure biopsy-proven adenomatous lesions and who had at least 1 year of follow-up. Ninety percent of these cases had more than 2 years of follow-up. Patients undergoing thermal therapy only, patients with any prepapillectomy diagnosis of invasive cancer or obvious metastasis, and patients lost to follow-up were excluded from the analysis. Results were reported as residual lesion, recurrence, success, failure, and complications. A residual lesion was one in which gross or microscopic adenomatous tissue was still present on a subsequent endoscopy. To be called a recurrence, at least 1 endoscopy with a biopsy specimen

TABLE 1. Preprocedural, procedural, and postprocedural data points collected on patients presenting with ampullary lesions at our institution**Preprocedural data points**

Sex
Age
Personal history of CRC/adenomatous polyps
FAP
Family history of CRC
Clinical presentation
Preprocedure imaging (if done)

CT of abdomen

EUS

Previous ERCP

Pathology

Procedural data points

Endoscopist
Date of procedure
Type of sedation
Location
Major ampulla
Minor ampulla
% Circumferential
Lesion size
Associated C-loop adenomas
PD/CBD

Sphincterotomy

Stenting

Intraductal extension

Removal

Single/piecemeal

Complete/incomplete

Lateral extension

Use of thermal energy

Postprocedural data points

Complications

Bleeding

Early

Late

Pancreatitis

Mild

TABLE 1 (Continued)

Moderate

Severe

Perforation

Retroperitoneal

Intraperitoneal

Cholangitis

Papillary stenosis

Pathology

On ampullectomy specimen

On surgical specimen

Referral to surgery

Without ampullectomy

Obvious cancer

After ampullectomy

Invasive cancer

Intraductal recurrence/residual lesion

Multiple local recurrences

Follow-up endoscopy and pathology

CRC, Colorectal cancer; FAP, familial adenomatous polyposis; PD, pancreatic duct; CBD, common bile duct.

demonstrating no residual tissue was required, and a 3-month interval between the end of the treatment and the diagnosis of a recurrence was required. Success was defined as a complete excision of the lesion irrespective of the number of procedures required, in the absence of a recurrence on long-term follow-up. Failure was defined as an inability to completely remove the lesion endoscopically regardless of the number of procedures, invasive malignancy on histopathology, or a recurrence that was no longer endoscopically amenable. Lesion size was determined by pathology reports. Dilated ducts were defined as a common bile duct larger than 8 mm pre-cholecystectomy and larger than 10 mm post-cholecystectomy and a pancreatic duct larger than 4 mm, with the patient's age also being taken into consideration. Complications included pancreatitis, bleeding, perforation, and delayed papillary stenosis. Pancreatitis was defined by a threefold increase in serum amylase or lipase with abdominal pain. This was further categorized as mild, if the hospital stay was 3 days or less with complete resolution of symptoms and enzymes; severe, if the hospital stay was longer than 10 days with complications, necrosis, or pancreatic fluid collections requiring treatment; and moderate for a hospital stay of 4 to 10 days. Bleeding was defined as

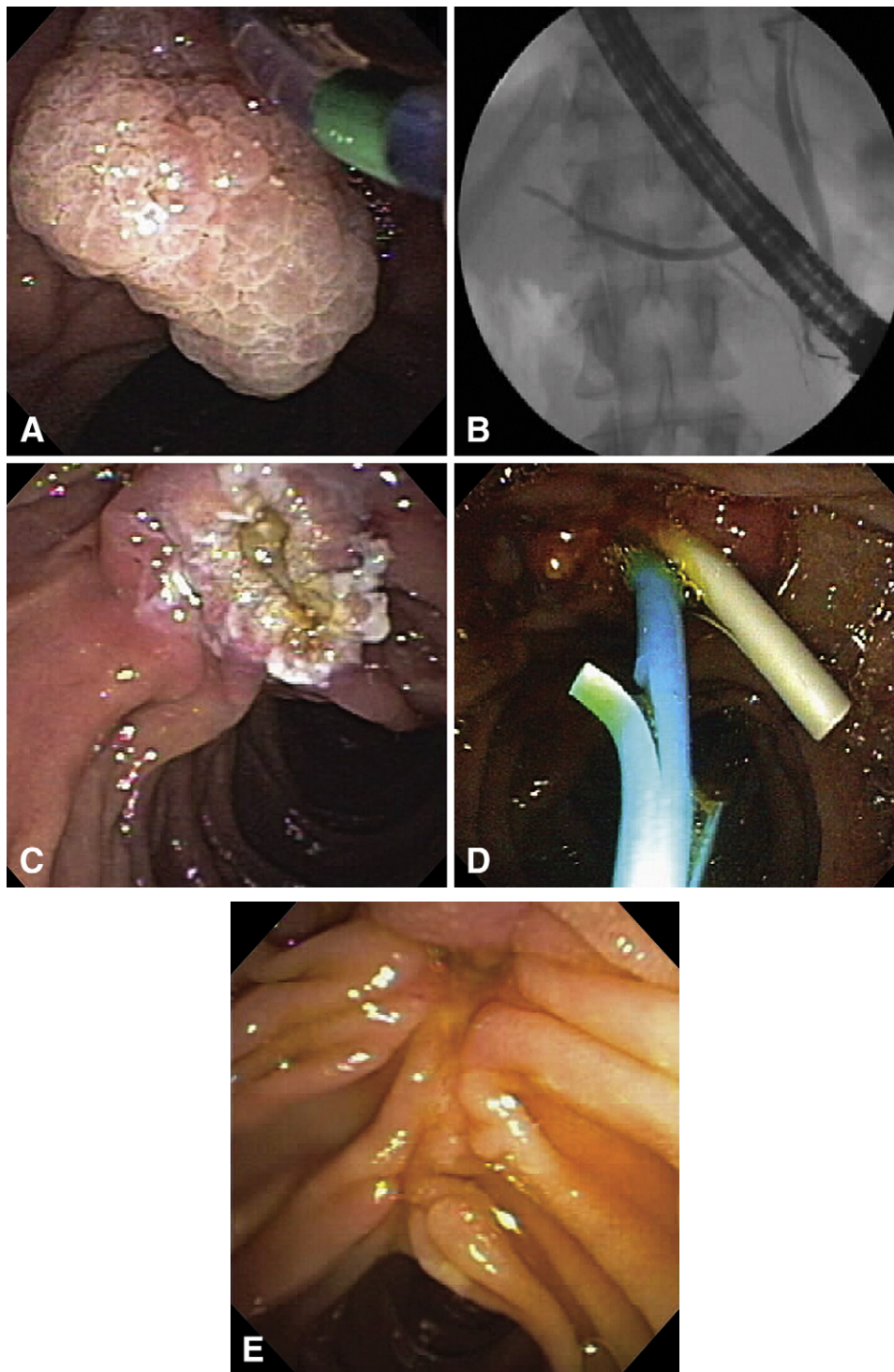


Figure 1. A-D, Patient with a 2.5-cm ampullary adenoma undergoing ERCP and ampullectomy. E, Same patient 8 weeks after papillectomy.

a decrease in hemoglobin of at least 2 g and/or the need to perform an endoscopy based on a clinical suspicion for a postpapillectomy bleed. Patients were also analyzed as 2 different groups: the FAP group and the incidental group (ie, patients with sporadically occurring ampullary adenomatous lesions with no history of FAP and not meeting any

clinical criteria for FAP or its variants). Mean follow-up for patients undergoing papillectomy was 32 months for the incidental group (range 2-68 months) and 48 months for the FAP group (range 3-88 months).

Univariate statistical methods included descriptive statistics, χ^2 test, Fisher's exact test, and the paired *t* test.

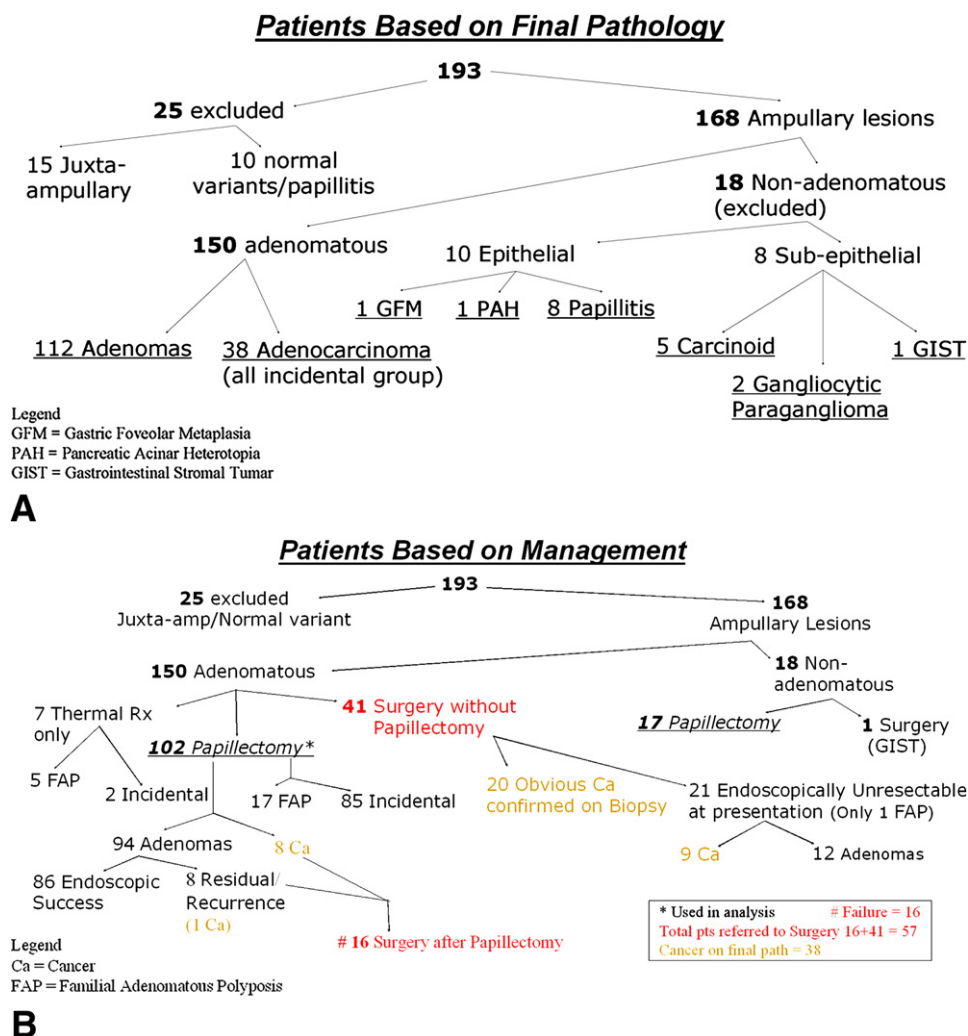


Figure 2. A, Final pathology results of the patients with ampullary lesions seen at our institution. **B,** Management of the patients with ampullary lesions seen at our institution.

Parsimonious, multivariable, logistic regression models for papillectomy outcome (success/failure) were determined by backward elimination of potential covariates.

RESULTS

From September 1997 to September 2007, 193 patients underwent endoscopy for ampullary lesions at our institution. Fifteen patients had juxta-ampullary lesions. These were treated as duodenal adenomas and were excluded from the analysis. There were 10 patients with normal endoscopic variants of the ampulla in whom only a biopsy was performed; they were also excluded.

Of the 168 patients (88 men, 80 women) with ampullary lesions, there were 112 (67%) adenomas (7 patients with major and minor ampullary adenomas), 38 (23%) adenocarcinomas, and 18 (10%) nonadenomatous lesions.

The 18 nonadenomatous lesions of the ampulla were subdivided into 2 categories: subepithelial lesions and

epithelial lesions. The subepithelial lesions included 5 carcinoids, 2 gangliocytic paragangliomas, and 1 GI stromal tumor. All of these lesions were removed endoscopically except the GI stromal tumor. The epithelial lesions included 1 pancreatic acinar cell heterotopia, 1 gastric metaplasia, and the remaining 8 with papillitis (all of which were associated with biliary stenting and/or bile duct stones). These nonadenomatous lesions had been referred with biopsy suggesting adenomas performed at outside institutions. These 18 nonadenomatous lesions were also excluded from the analysis.

All 38 adenocarcinomas were found in the incidental/sporadic group. Of these 38 patients, 20 patients were referred directly to surgery after endoscopy and biopsy confirming adenocarcinoma. Another 10 patients were referred to surgery because of endoscopic unresectability as the indication with initial biopsies only demonstrating adenoma, but on the surgical specimens, the final histopathology confirming adenocarcinomas. Eight patients underwent papillectomy, which demonstrated invasive

cancer, and were then referred to surgery. These 8 patients were considered failures (Fig. 2).

Of the 150 patients with ampullary adenomas or adenocarcinomas, 23 patients had a known diagnosis of FAP, and 127 patients had no known history of FAP (incidental/sporadic group). Excluding the 23 FAP patients, there was a personal history of adenomatous colon polyps in 31% and colorectal cancer in 3% (total 34%). There was also a strong family history of colon cancer in these patients, with 11% having a first-degree relative with colon cancer.

Clinical presentation included cholestasis/cholangitis (72 patients), abdominal pain (54 patients), incidental/asymptomatic (51 patients), pancreatitis (9 patients), bleeding (7 patients), and weight loss (28 patients). Weight loss (> 10 lb) was seen in 22 patients with invasive cancer compared with 6 patients with adenomas ($P < .01$). Although cholestasis and abdominal pain were statistically more common in patients with adenocarcinoma compared with adenomas ($P < .01$), their clinical utility to differentiate adenocarcinoma from adenoma was very limited because of a low positive predictive value. An incidental presentation, conversely, was seen in only 2 of the 38 patients with adenocarcinoma, making this a more useful clinical clue of benignity ($P < .001$). Of the 51 patients presenting incidentally, screening or surveillance for Barrett's esophagus was the most common reason for endoscopy, accounting for 75% of these cases. All 23 FAP patients were asymptomatic, and Barrett's esophagus was found on screening or as a part of their surveillance.

Fifty-seven patients were referred to surgery. All patients ultimately undergoing surgery were staged with cross-sectional imaging (CT/magnetic resonance imaging) and EUS. Twenty patients were sent directly to surgery after endoscopy and biopsy without papillectomy because of the high suspicion for cancer (friable, ulcerated lesions > 5 cm). Twenty-one patients were sent because of endoscopically unresectable lesions (> 1 cm intraductal extension in 12 patients, extensive lateral extension in 7 patients, and other reasons in 2 patients). Of these 21 lesions, 9 of them were found to have adenocarcinoma on surgical resection and the remaining 12 to have adenomas, 8 of which had high-grade dysplasia. The remaining 16 patients were referred to surgery after papillectomy (invasive cancer in 8 patients, intraductal recurrence/residual in 7 patients, multiple local recurrences in 1 patient). Three patients with intraductal recurrence were documented with cholangioscopy, one of whom had an extension all the way to the cystic duct take-off (Figs. 3 and 4).

Papillectomies on biopsy-proven adenomas were performed in 102 patients, with 2 undergoing minor and major papillectomies. There were 5 other FAP patients with minor and major ampullary adenomas, but because the adenomas were small, these patients only underwent biopsy and surveillance. Fourteen patients underwent more than 1 papillectomy for residual or recurrent lesions (total 141 papillectomies). Of the patients undergoing repeat papillectomy, most required 2 to 3 procedures to completely

remove the adenoma, with 1 patient, who was a poor surgical candidate, requiring 6 procedures before failure of endoscopic therapy was declared. The mean tumor size was 2.4 cm (range 0.5-6 cm) among patients undergoing papillectomy. Lateral extension of the polyp from the ampulla was seen in 17 patients. Thermal therapy, predominantly in the form of APC, was used in 22 patients.

Endoscopic success was seen in 86 of 102 patients with suspected ampullary adenomas who underwent papillectomy. Failure was seen in 16 patients (intraductal recurrence/residual in 8 and invasive cancer in 8). Intraductal recurrences or residual lesions larger than 1 cm were found in 8 patients who were referred to surgery. The pathology after surgery demonstrated adenoma in 7 patients and invasive cancer in 1. All of these patients underwent successful pancreaticoduodenectomy. The other 8 failures were patients with cancer noted after papillectomy. On univariate analysis, factors affecting success were a smaller lesion size (< 2 cm) ($P < .001$), the absence of dilated ducts ($P < .001$), younger age (younger than 45 years) ($P < .05$), and a lack of lateral extension ($P < .05$). On multivariate analysis, however, only a smaller lesion size ($P < .001$) and the absence of dilated ducts ($P < .001$) were associated with a successful outcome (Table 2).

Of the 150 patients with ampullary adenomatous lesions, 23 were FAP patients and 127 patients had incidental/sporadic lesions (Table 3). As expected, the mean age was younger and the mean size of the lesions was smaller in the FAP group. Six of the 7 patients with minor and major ampullary adenomas were in the FAP group, and associated C-loop adenomas were also seen almost exclusively in the FAP group. Endoscopic unresectability at presentation was seen in 20 patients in the incidental group, whereas only 1 FAP patient had an unresectable lesion at presentation and underwent successful pancreaticoduodenectomy. Endoscopic success rates were similar in the 2 groups. There was a trend toward more complications in the FAP patients. This did not reach statistical significance for overall complication rates, but was significant with regard to pancreatitis (FAP 24% vs incidental 6%) ($P < .05$).

There were 21 complications from papillectomies performed in 102 (21%) patients and 21 (15%) from 141 procedures in patients with ampullary adenomatous lesions (Table 4). Two patients had both pancreatitis and an early bleed. One of these patients had a clot occluding the pancreatic duct stent. The 10 cases of pancreatitis were all mild. The one patient with cholangitis did not have biliary stenting and was managed with stenting and antibiotics. One retroperitoneal perforation was recognized at the time of endoscopy, immediately after papillectomy, in a patient with a 2-cm lesion that on final pathology was classified as T3 N1 M0 adenocarcinoma. This patient, who did not have an EUS scan before attempted papillectomy, also had a significant bleed requiring angiography and embolization. She was managed conservatively and 2 months later underwent a successful pancreaticoduodenectomy. The 1 patient

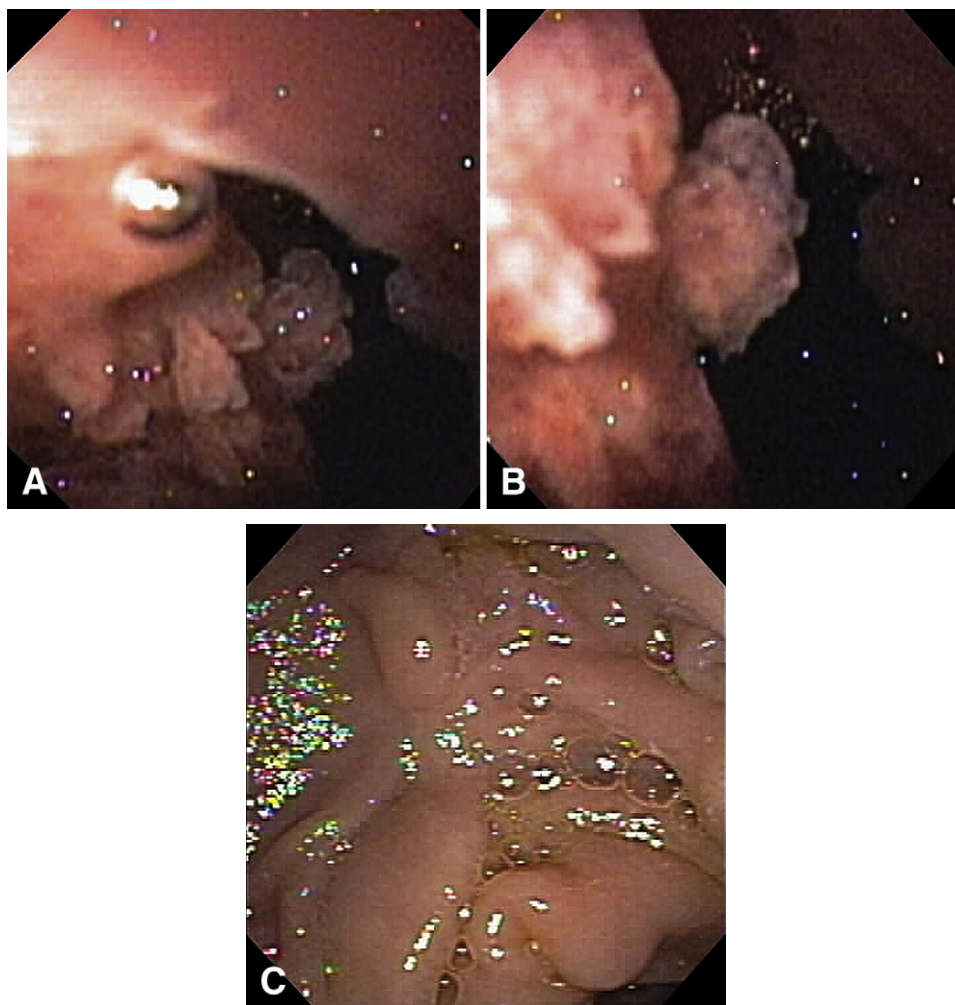


Figure 3. A, B, Intraductal recurrence noted at cholangioscopy in a patient with no further lesion seen on the duodenal side. C, Duodenal view of same patient with intraductal recurrence to cystic duct.

with an intraperitoneal perforation had a 3-cm tubulovillous adenoma with significant lateral extension. Symptoms developed 6 hours after the endoscopy. He underwent successful surgical repair and was discharged 9 days later. He was found to have residual adenoma on 2 subsequent endoscopies, but has repeatedly refused surgery. His local residual tumor has been managed endoscopically for the past 7 years with no evidence of disease progression. Bleeding was seen in 5 patients, including 2 patients with significant lateral extension. There was early bleeding (< 48 hours) in 3 patients and delayed bleeding (> 48 hours) in the other 2. Apart from 1 patient who had a retroperitoneal perforation and an early bleed that was treated by interventional radiology embolization, the other 4 patients were managed endoscopically. Delayed biliary papillary stenosis, manifested by elevated liver function tests and dilated bile ducts (type 1), was seen in 3 patients, despite placement of 10F × 5-cm biliary stents at papillectomy. All 3 patients responded well to a single endoscopic treatment with no recurrence of the papillary stenosis.

DISCUSSION

With the high morbidity and mortality associated with radical surgery and the adequacy of local resection for ampullary adenomas, endoscopic papillectomy, as demonstrated by this study, has established itself as a safe and effective alternative to surgery.

Careful patient selection in centers with substantial pancreaticobiliary experience remains integral to this success. In 2005, Bohnacker et al² reported their experience with endoscopic resection of ampullary adenomas without and with intraductal extension in 75 and 31 patients, respectively. The overall success rate was 73%, the complication rate was 15%, and recurrence rate was 15%. In 2004, Catalano et al⁹ reported a combined 4-center experience in 103 patients with ampullary adenomas undergoing papillectomy. They were successful in 80% of patients, with a 20% recurrence rate and a 10% complication rate. Several other investigators reported similar experiences at centers of pancreaticobiliary excellence in smaller

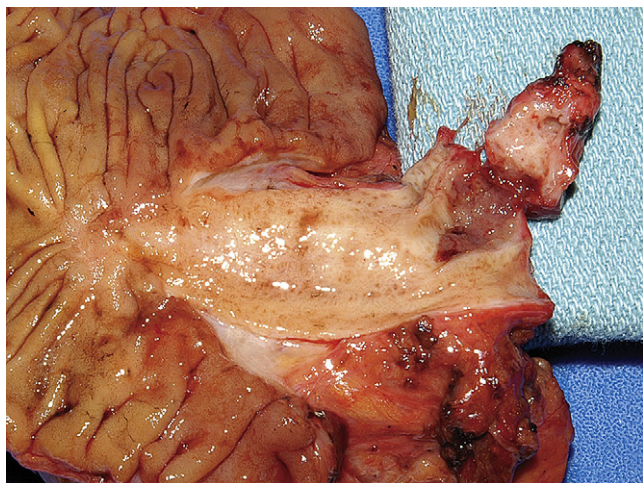


Figure 4. Intraductal recurrence versus new adenoma at the cystic duct take-off. No residual tumor seen at the site of previous papillectomy. This counted as one of the failures.

TABLE 2. Factors affecting success in patients undergoing ampullectomy for ampullary adenomas

Factors affecting success	P value
Univariate analysis	
Smaller size (<2 cm)	.001
Younger age (<45 y)	.018
Absence of dilated ducts	.001
Lack of lateral extension	.013
Multivariate analysis	
Smaller size (<2 cm)	.001
Absence of dilated ducts	.001

Thermal therapy, familial adenomatous polyposis, and lateral extension did not affect success.

numbers of patients with success rates varying from 62% to 92% (mean rate 81%) and complication rates from 10% to 30% (mean rate 22%).^{6,10,15-16} In our series of 102 patients with ampullary adenomatous lesions undergoing papillectomy, the success rate was 84% with a complication rate of 21%. The factors affecting success in our study were smaller lesion size (<2 cm) and the absence of dilated ducts, suggesting that an earlier lesion was not likely to have involved the ducts.

A common reason given for the surgical management of these patients is the lack of sensitivity of endoscopic biopsies to rule out cancer. As seen in our study, this remains true to an extent because only 20 (53%) of 38 total cancers were confirmed on biopsy. However, despite the absence of invasive cancer on biopsy, an additional 10 patients were clearly not candidates for endoscopic

removal. Of the 8 (7%) of 102 patients who underwent papillectomy and were found to have invasive cancer, 2 patients, including the 1 patient who had a retroperitoneal perforation, were in fact referred by the surgeons because of their high surgical risk. In this patient and the patient who sustained an intraperitoneal perforation, the endoscopist had previously made the determination that they would be better served with surgery because of the lateral spread of tumor in 1 patient and a large friable lesion in the other. Thus, there were only 6 (5%) of 102 papillectomies demonstrating invasive cancer that seemed to the endoscopist to be endoscopically amenable. We conclude that although it is true that biopsy alone has a definable miss rate in diagnosing invasive cancer, nevertheless only a minority of patients with invasive cancer seem to have endoscopically resectable lesions. Some authors propose that an EUS scan in selected patients could help decrease this miss rate to an even lower rate, with many centers performing EUS routinely for all ampullary adenomas.^{17,18} Our strategy from a cost efficacy standpoint is to perform EUS on patients with high-grade dysplasia or intramucosal cancer revealed on biopsy, patients with features of unresectability (friability, ulceration, or fixation), or patients with lesions larger than 2 cm. Another feature that was associated with a risk of underlying malignancy was weight loss (>10 lb), seen in 58% of patients with invasive cancer and only 5% of patients with adenomas. This should also prompt cross-sectional evaluation with a CT scan of the abdomen as well as an EUS scan before consideration of a papillectomy.

In our study, residual adenomas were seen in 14% of patients and required 2 or more sessions to complete treatment. The recurrence rate, requiring surgery to complete treatment, was 8%. Recurrences were all found within the first 14 months after the initial papillectomy. There were 3 cases in which the recurrences ascended the biliary tree without any visible lesion on the duodenal side, and in 1 case, recurrence was all the way up to the cystic duct take-off (Fig. 3). Cholangioscopy was helpful in confirming these findings. Catalano et al⁹ noted a 20% recurrence rate, with all recurrences within the first year, and made recommendations for surveillance in patients with incidental ampullary adenomas. They recommended endoscopy at 6-month intervals for a minimum of 2 years, with at least 2 examinations with negative findings after initial complete endoscopic removal. A cholangiogram and a pancreatogram should be routinely obtained during surveillance to rule out the possibility of intraductal residual or recurrent lesions.

There were 23 patients with confirmed FAP in our study, of whom only 1 had an endoscopically unresectable lesion at presentation. He had not been enrolled in an endoscopic surveillance program. In contrast to the Catalano et al⁹ study, in our series, there was no difference in the success rates between the 2 groups. Lifelong surveillance of these patients should continue based on their associated C-loop

TABLE 3. Comparison between the familial adenomatous polyposis group and incidental/sporadic group of patients with ampullary adenomatous lesions**Incidental vs FAP group**

	No. patients	Age (y), mean (range)	Mean size (cm)	Major and minor ampullary adenomas	Associated C-loop adenomas	Initial endoscopic unresectability	Thermal therapy only
Incidental	127	65 (37-94)	2.4	1 (1%)	1 (1%)	20 (16)	2 (2%)
FAP	23	49 (28-85)	1.3	6 (26%)	11 (48%)	1 (4)	5 (22%)
<i>P</i> value		<.01	<.01	<.01	<.01	0.0	<.01

Incidental vs FAP group

	Ampullectomy	Invasive cancer post-ampullectomy*	Recurrence/ residual post-ampullectomy*	Success of ampullectomy	Complications	Mean F/U (mo)
Incidental	85 (67%)	8 (12%)	5 (6%)	72/85 (85%)	15 (18%)	32
FAP	17 (74%)	0 (0%)	3 (17%)	14/17 (82%)	6 (35%)	48
<i>P</i> value	.8	<.01	.7	.9	.4	.24

FAP, Familial adenomatous polyposis; F/U, follow-up.

*Failure = invasive cancer + recurrence/residual requiring surgery to complete treatment.

TABLE 4. Complications in patients undergoing ampullectomy for ampullary adenomatous lesions

Complication	Count	Comments
Pancreatitis (all mild)	10	9 stented, 1 failed stenting
Bleeding		2 lateral extensions
Early	3	
Late	2	
Perforation		
Retroperitoneal	1	Adenocarcinoma
Intraperitoneal	1	Lateral extension
Cholangitis	1	
Papillary stenosis	3	
Total	21/102 (21%) patients	
	21/141 (15%) procedures	
Mortality	0	

adenoma burden, with the interval never being any longer than 2 to 3 years after eradication of all visible adenomas. The FAP group showed a slight trend toward a higher rate of residual lesions, but this did not reach statistical significance, nor did it affect the final outcome. There was also a trend toward a higher complication rate in the FAP patients versus the incidental adenoma patients, and when specifically looked at from a pancreatitis rate, this difference

reached statistical significance. Possible explanations for this higher rate of pancreatitis in patients with FAP may be the younger age of these patients and a lower incidence of chronic ductal obstruction. Of note, the patients without FAP had a slightly higher incidence of a first-degree relative with colon cancer, approximately twice that noted in the general population.¹⁹

Complication rates, even in the most experienced of pancreaticobiliary centers, remain high for papillectomy, approximating 22%.^{2,5,9,10,12,13,15} Pancreatitis occurs at a rate of approximately 8%, and there has been 1 death from severe necrotizing pancreatitis reported to date.¹³ Routine pancreatic duct stenting has been shown in other settings to reduce post-ERCP pancreatitis, especially severe pancreatitis, and should be routinely performed. Our success rate for pancreatic duct stenting was 92%. There was only 1 case of pancreatitis in a patient in whom pancreatic duct stenting was unsuccessful, but there were 2 cases in which a blood clot was found occluding the pancreatic duct stent. All our 10 cases of pancreatitis were mild. There was 1 severe case of cholangitis, after which routine performance of biliary stenting was undertaken at our institution. Justification for biliary stenting can be made based on the fact that a repeat ERCP is performed at 4 to 8 weeks to evaluate the completeness of the papillectomy, at which time the bile duct stent can be removed. The 2 perforations that occurred were in patients with extensive lateral extension of the lesion and invasive cancer, respectively, making these potential risk factors for the above complications. In the study by Catalano et al,⁹ there was an association between the failure of pancreatic duct stenting and the occurrence of delayed papillary stenosis and subsequent pancreatitis. Although not seen in our study, the 3 cases of

papillary stenosis in our series were mild and responded promptly to a single endoscopic intervention.

This large retrospective series of endoscopic papillectomies of 102 adenomatous lesions of the ampulla adds to the small body of literature on this uncommon condition. Based on the results of this study, we agree with the guidelines proposed by Catalano et al⁹ to include endoscopic treatment every 2 to 3 months until complete resection, followed by surveillance every 6 to 12 months for at least the next 2 years. If no evidence of recurrence is seen at this time, follow-up should be based on symptoms in patients with sporadic/incidental adenomas. Other authors recommend annual surveillance for as long as 5 years after completion of the papillectomy.¹⁵ For patients with FAP, surveillance after eradication of the lesion should be based on the associated C-loop polyp burden, but at least should be done every 2 to 3 years if all polyps have been eradicated. Routine pancreatic duct stenting should be performed to decrease the incidence of pancreatitis and possibly delayed papillary stenosis. In our opinion, biliary stenting decreases the small associated risk of cholangitis, making it a worthwhile intervention, given the need for repeat ERCP within the next 4 to 8 weeks. For selected patients, cross-sectional imaging and EUS should be undertaken before consideration of papillectomy, especially if there is associated weight loss; dilated ducts; large, friable, or lateral spreading lesions; or high-grade dysplasia or carcinoma on biopsy. Complications should be carefully looked for and anticipated in what is potentially one of the more challenging endoscopic procedures. The cornerstone of successful endoscopic treatment in these patients should lie in careful patient selection and management at high-volume pancreaticobiliary centers.

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