

M1371**Preventative Effects of Ulinastatin On Post-ERCP Pancreatitis in High Risk Patients**

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Background and Objectives: Previous studies showed that ulinastatin may be effective in preventing pancreatitis after endoscopic retrograde cholangiopancreatography (ERCP). However, routine use of ulinastatin to all patients is not likely to be cost effective. To evaluate the effectiveness of low dose ulinastatin to prevent pancreatitis in the patients who were at high risk for post-ERCP pancreatitis. Methods: Prospective, double-blind, randomized, placebo-controlled trial, comparing active drug (100,000 U of ulinastatin) with placebo. Results: From December 2004 to June 2006, 227 patients were enrolled (119 in the ulinastatin group and 108 in the placebo group). There was no significant difference in the incidence of pancreatitis between placebo- and ulinastatin- treated patients (5.6% vs. 6.7%). There were also no differences in the occurrence of hyperamylasemia in ulinastatin-treated patients compared with those given a placebo. Conclusions: low dose prophylactic ulinastatin immediately after ERCP is ineffective at preventing post-ERCP pancreatitis in high risk patients.

Incidence of hyperamylasemia and acute pancreatitis in the treatment groups

	Placebo group (n = 108)	Ulinastatin group (n = 119)	Total (n = 227)	p value
Hyperamylasemia	9 (8.3%)	13 (10.9%)	22 (9.7%)	0.510
Acute pancreatitis	6 (5.6%)	8 (6.7)	14 (6.2%)	0.715
Mild	5	7	12	
Moderate	1	1	2	
Severe	0	0	0	

M1372**ERCP with Pancreatotomy and Electrohydraulic Lithotripsy (EHL) for Calcific Pancreatitis**

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Background: A predominant component of pain in patients with calcific pancreatitis is intraductal hypertension secondary to obstructing pancreatic duct (PD) stones. Pancreatotomy with EHL permits stone fragmentation and removal during the same procedure, a potential advantage over ESWL. We evaluated pancreatotomy with EHL for PD stones. Methods: Patients undergoing pancreatotomy for known or suspected PD stones were prospectively collected. Opioid use, hospitalizations, pain scores, weight, and ductal clearance were recorded. Follow-up was obtained by chart review and patient contact. EHL was performed through the pancreatoscope in selected patients with PD stones and fragments were retrieved using baskets and balloons. Associated strictures were dilated and stented. Follow-up assessment included reduction in pain over 50%, reduction in opioid requirements, weight change, and surgical intervention. Results: Between January 2000 and November 2006, 27 patients (12M, 15F, mean age 54 years) underwent pancreatotomy for PD stones via the major (N = 24) and minor (N = 3) papilla. Etiology of pancreatitis: alcohol (56%), idiopathic (30%), and other (14%). Prior to pancreatotomy, patients had pain requiring hospitalization (N = 24, 89%), weekly opioid use (N = 15, 56%), weight loss (N = 6, 22%), had a mean of 2.0 (± 1.5) ERCPs, and prior ESWL (N = 3, single sessions). A mean of 1.9 (± 1.0) pancreatotomies were performed. 17/27 (63%) patients had EHL sessions (mean 1.5 \pm .7), 4/27 (15%) had stone extraction without EHL, and 6/27 (22%) had failed pancreatotomy due to obstruction from stricture or impacted stone. PD clearance: complete (N = 16, 59%), partial (N = 5, 19%), failed (N = 6, 22%). Follow-up was obtained in all patients for a mean of 18.3 (± 16.9) months. Overall, pain improved in 16/27 patients (59%) for a mean duration of 17.6 months (± 14.1). In patients with complete PD clearance: 11/16 (69%) had pain improvement, none had an increase in opioid use, 6 (38%) reported a decrease in opioid use, 15 (94%) had stable or increased weight, and 2 (7%) had developed pancreatic cancer. 2 patients with partial PD clearance underwent pancreaticojejunostomy with incomplete relief of symptoms. Conclusions: 1. Pancreatotomy with EHL results in complete clearance of PD stones in the majority of referred patients with calcific pancreatitis 2. Complete clearance of the PD is associated with intermediate-term improvement in pain but only modest reduction in opioid requirements. 3. Intraductal obstruction by stricture or stone immediately upstream of the ampulla may limit successful pancreatotomy.

M1373**Protocol Based Management of Post-ERCP Pancreatitis Is Associated with Better Outcomes**

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Background: While several studies have evaluated outcomes pertaining to ERCP complications, no study has evaluated outcomes on management of post-ERCP pancreatitis. Aim: Evaluate the effectiveness of a standard treatment protocol for management of post-ERCP pancreatitis. Methods: Retrospective study of consecutive patients managed for post-ERCP pancreatitis using a standard treatment protocol over a 3-yr period. By protocol, patients received only intravenous fluids (D5 1/2 NS at 200 cc/hr), narcotics and analgesics for the first 24-72 hrs. Oral intake was attempted when white cell count was normal or revealed a downward trend, abdominal pain was absent or minimal without need for narcotics over a 12 hr period and serum lipase was less than three times normal range. For patients hospitalized beyond 72 hrs, an abdomen CT was obtained at days 4 and 10 to guide management based on severity index. Intravenous antibiotics were administered only for patients with pancreatic necrosis. Enteral feeding via jejunum and a PCA meperidine pump for pain control were initiated in symptomatic patients at day 4. Effectiveness of the treatment protocol was evaluated by comparing clinical outcomes of patients managed by protocol with those managed outside protocol. Data on ERCP complications was collected prospectively and graded per consensus criteria. Results: 45 of 1976 patients (2.27%) who underwent ERCP developed post-ERCP pancreatitis. Rate of post-ERCP pancreatitis was higher in those undergoing treatment for SOD and pancreatic diseases compared to other diagnoses (21.6% vs. 1.7%; $p < 0.001$). Of 45 (females 39; mean age 43 yr) patients with post-ERCP pancreatitis, 32 were managed by protocol and 13 outside protocol. There was no difference in demographics, procedural indications, comorbidity, endotherapy and pancreatic stenting among both groups. Rate of moderate or severe pancreatitis was lower in patients managed by protocol versus those managed outside protocol (12.5% vs. 61.5%; $p = 0.002$). One patient managed outside protocol died from severe pancreatitis. When compared to patients managed outside protocol, median duration of hospital stay (7 vs. 3 days; $p = 0.01$), number of CT (100% vs. 15.6%; $p < 0.001$), and use of antibiotics (50% vs. 9.4%; $p = 0.01$) was significantly lower in those managed by protocol. By multivariate logistic regression, only protocol based management was independently associated with less severe disease (adjusted OR 18.7; 95% CI = 2.6-132.1; $p = 0.003$) when adjusted for age, comorbidity, endotherapy and pancreatic stenting. Conclusion: A standard protocol based management was associated with better outcomes in patients with post-ERCP pancreatitis.

M1374**Endoscopic Ultrasound Guided Transmural Debridement of Organized Pancreatic Necrosis: A Retrospective Cohort Study**

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Introduction: Pancreatic necrosis is a severe complication of acute pancreatitis. Surgery has been the mainstay of treatment once intervention was necessary. Surgical management is however associated with significant morbidity and mortality. By the time necrosis becomes organized endoscopic therapy has the potential to offer an alternative treatment. However, due to rapid blockage of stent or naso-cystic catheter by necrotic material, endoscopic drainage of pancreatic necrosis is often considered contraindicated. This could be overcome by adding endoscopic debridement to transmural drainage. We have performed a retrospective study on our prospectively collected cohort of patients evaluating the results and complications with this new technique. Aim was to evaluate its safety and efficacy and to identify procedural aspects that may improve outcome. Patients and Methods: All consecutive patients who underwent endoscopic debridement of pancreatic necrosis in our hospital between January 2003 and July 2006 were included. In all patients the treatment was started with EUS-guided transmural drainage of the collection with placement of multiple stents and naso-cystic catheter. The next step consisted of balloon dilatation up to 18 mm, advancement of an endoscope into the retroperitoneal cavity and endoscopic debridement of the collection under direct vision. Endoscopic debridement was repeated every 2 days until most necrotic material was evacuated. Additionally, naso-cystic catheter irrigation was performed manually with saline 6-8 times a day. The endpoint of treatment was complete resolution of the necrotic collection and related symptoms. Results: 25 patients (13 women, 12 men) were identified, who had undergone debridement of 27 collections. After the initial stent placement, in eleven collections (41%) one, in 13 (48%) two, in 2 (7%) three and 1 (4%) four endoscopic debridement procedure(s) were performed. There was no mortality. Severe complications occurred in 2 patients (7%) and required surgery: Hemorrhage in one case and perforation of cyst wall in the other. During a median follow up of 16 (range 3-38) months, the overall clinical success rate with resolution of the collection and related symptoms was 93%. Two patients (7%) developed an asymptomatic recurrent pseudocyst of 5.6 and 3 cm. Conclusion: In this study we have shown that endoscopic debridement is an effective and relatively safe minimally invasive therapy in patients with symptomatic organized pancreatic necrosis. Further comparative studies need to define its definitive role in the management of these patients.