Non-Inferiority of Pharmacologic Prophylaxis vs. Pancreatic Duct Stenting for Prevention of Post-ERCP Pancreatitis - An Interim Report

View Session Detail

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Abstract: Background/aims: Acute pancreatitis is the most feared adverse event of endoscopic retrograde cholangiopancreatography (ERCP). The aim of this study is to assess the non-inferiority of a combination of pharmacological measures as compared to pancreatic duct stenting (PDS) for the prevention of post-ERCP pancreatitis (PEP).
Patients and methods: Patients at high risk for PEP received a combination of rectal indomethacin, sublingual isosorbide dinitrate and intravenous hydration with Ringer's lactate. They were randomized to pharmacological prophylaxis alone (group A) or pharmacological prophylaxis + PDS (Group B). Serum amylase levels and clinically pertinent measurements were performed in all patients after ERCP. The sample size was calculated to be 400 subjects.
Results: At the time of this writing 190 patients were enrolled. 94 received pharmacological prophylaxis alone and 96 pharmacological prophylaxis + PDS. Twenty-seven patients developed pancreatitis: 14 (14.9%) in group A and 13 (13.8%) in group B (p=0.84). Severe acute pancreatitis occurred in one patient in group A (1.1%) and two patients in group B (2.1%). A statistically significant difference was not observed in mean serum amylase levels after 24 hours between the two groups (336 ± 586 vs. 304 ± 448.6, U/L, p=0.67). There were no adverse events related to the prophylactic measures used in either group.
Conclusions: The combination of rectal indomethacin, sublingual nitrate and hydration appears to effectively reduce the risk of PEP. The addition of PDS offers no significant added value.