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Original Research Article

Comparison of the incidence of post-ERCP pancreatitis between combined rectal indomethacin and sublingual nitroglycerin with that of rectal indomethacin alone

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is now widely accepted as a therapeutic modality for benign and malignant diseases of the pancreaticobiliary tree. Acute pancreatitis is the most common and feared complication of ERCP, associated with substantial morbidity and mortality. This study aimed to compare the incidence of post-ERCP pancreatitis in combined rectal indomethacin and sublingual nitroglycerin with that of rectal indomethacin alone.
Methods: This was a randomized controlled trial conducted in the Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh during the period from July, 2019 to September, 2020. In this study, 100 hospitalized patients of >18 years age undergoing ERCP based on clinical indication and proper investigation were included. The study population was randomly divided into two groups - group A (patients who were given indomethacin suppository plus sublingual glyceryl trinitrate) and group B (patients who were given indomethacin alone).
Results: In this study, we found that PEP developed in 11 out of 100 patients (11%). Post-ERCP pancreatitis developed in 2 (4%) in group A and 9 (18%) in group B (p=0.025), which was statistically significant. Mild PEP developed in none in group A and 4 (8%) in group B whereas moderate in 2 (4%) in group A and 3 (6%) in group B. Severe pancreatitis occurred in none in group A and 2 (4%) in group B (p=0.231) which was not statistically significant.
Conclusions: This study showed that the combination of indomethacin suppository and sublingual GTN is superior to indomethacin suppository alone in preventing post-ERCP pancreatitis.

Keywords: Comparison, Rectal indomethacin, Sublingual nitroglycerin, ERCP, PEP

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is now widely accepted as a therapeutic modality for benign and malignant diseases of the pancreaticobiliary tree. But, as an invasive procedure, it carries significant risks to the patient.[1] Acute pancreatitis is the most common and feared complication of ERCP,

associated with substantial morbidity and occasional mortality.[2] Tenner et al showed that asymptomatic hyperamylasemia occurs in 35% to 70% of post-ERCP cases. Clinical acute pancreatitis occurs in 5% of diagnostic ERCPs, 7% of therapeutic ERCPs, and 25% with having previous history of post-ERCP pancreatitis (PEP).[3] In other studies, the most common complication of ERCP is reported to be acute pancreatitis occurring in 2-10% of patients.[4,5] A prospective observational study by Alam et al found post-ERCP pancreatitis in 3.57% of cases.[6] Another study found it as the most common complication of ERCP in 2.99% of cases.[7]

Although most episodes of PEP are mild (80-90%), a small proportion of patients develop severe acute pancreatitis, requiring prolonged hospitalization, a long stay in the ICU, and utilization of major hospital resources.

These patients carry increased morbidity and mortality rates.[8] Due to the clinical and economic burden of PEP, extensive research efforts have been devoted to its prevention.[9,10] Among the most promising measures to prevent PEP is the use of peri-procedural rectal administration of non-steroidal anti-inflammatory drugs (NSAIDs).[11,12]

Several randomized trials including a high-profile multicenter study have confirmed the efficacy of rectal indomethacin to prevent post-ERCP pancreatitis. NSAIDs inhibit phospholipase-A2 and subsequently arachidonic acid products and platelet-activating factors which play a pivotal role in the initial inflammatory cascade of acute pancreatitis. NSAIDs may also be important for the production of anti-inflammatory agents such as interleukin-10, which may reduce the incidence of PEP.[13]

Indomethacin has been used extensively since 2012 following the publication of a randomized, placebo-controlled trial on high-risk patients showing that a single 100 mg rectal indomethacin reduced PEP from 16.9% to 9.2%.[14] Recent meta-analyses have shown that rectal indomethacin reduces the risk of PEP by about 40 to 45%.[15]

Nitrates also have a role in the prevention of PEP. The influence of sublingual nitrates on the reduction of PEP was assessed in multiple meta-analyses. Sublingual glyceryl trinitrate (GTN) is a strong sphincter of Oddi (SO) relaxant, demonstrates its effects within 1–2 min, and maintains for 30 min.[16] It helps intubation by relaxing the sphincter of pancreatic and bile ducts when ERCP is performed. It reduces the spasm of the sphincter of Oddi and keeps ducts open for contrast agent and pancreatin drainage, as a result, reduces post-ERCP pancreatitis.[17]

Moreover, nitrates produce nitric oxide that causes dilation of the microvascular vessels, which may improve pancreatic tissue circulation and nutrition. These effects of nitrate may reduce the incidence of PEP.[18] The papillary instrumentation during ERCP may cause a spasm of the sphincter of Oddi and result in transient pancreatic duct obstruction and subsequent development of PEP.[19] Meta-analysis showed that the prophylactic use of GTN is an effective and relatively safe intervention for preventing PEP and hyperamylasemia.[20]

As a measure of preventing PEP Sotoudehmanesh et al conducted a randomized trial with a combination of sublingual nitrates and indomethacin vs indomethacin alone and found absolute risk reduction, relative risk reduction, and number needed to treat for the prevention of PEP were 8.6% respectively. Nitrates should be considered as adjunctive therapy to rectal NSAIDs in high-risk patients who do not receive a prophylactic pancreatic duct stent.[13,21]

Moreover, recent randomized trials have shown better efficacy of combined rectal indomethacin and sublingual nitrate in comparison to rectal indomethacin alone. But to date, there is no published data in this regard from our perspective. So, this study aimed to compare the incidence of post-ERCP pancreatitis in combined rectal indomethacin and sublingual nitroglycerin with that of rectal indomethacin alone.

Objectives

General objective

General objective was to compare the incidence of PEP in combined rectal indomethacin and sublingual nitroglycerin with that of rectal indomethacin alone.

Specific objectives

Specific objectives were to assess the efficacy of combined rectal indomethacin and sublingual nitroglycerin before ERCP in reducing the risk of post-ERCP pancreatitis; to assess the efficacy of rectal indomethacin before ERCP in reducing the risk of post ERCP pancreatitis; to compare the clinical outcome of post ERCP pancreatitis between two groups.

METHODS

This was a randomized controlled trial conducted in the Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh during the period from July, 2019 to September, 2020. In this study, 100 hospitalized patients were included who were >18 years of age undergoing ERCP based on clinical indication and proper investigation. Study population was randomly divided into two groups - Group A (Patients who were given indomethacin suppository plus sublingual glyceryl trinitrate) and Group B (Patients who were given indomethacin alone).

Inclusion criteria

Patients undergoing ERCP based on clinical indication and proper investigation, and patients aged >18 years of both sexes.

Exclusion criteria

a) Patients with recent (within 4 weeks) gastrointestinal (GI) hemorrhage; b) Patients with coagulopathy or received anticoagulant within 3 days before ERCP; c) Patients with previous sphincterotomy; d) Patients with known allergy/hypersensitivity to NSAIDs and nitrates; e) Patients with chronic calcific pancreatitis, ampullary tumor, and pancreatic malignancy; f) Patients with any history of acute illness (e.g., renal or pancreatic diseases, ischemic heart disease, asthma, COPD etc.) were excluded from our study.

Study procedure

Group A was given an indomethacin suppository (Indomet100 mg) plus sublingual glyceryl trinitrate (Anril spray 5 puff) and Group B was given indomethacin alone (Indomet100mg) 5 minutes before ERCP. The ERCP procedures were performed with the patient after administration of sedation (propofol and fentanyl) intravenously, with dosage at the discretion of the endoscopist. Patients received complementary oxygen (3 to 5 l/min) through a nasal cannula and infusion of 500 ml to 1000 ml of 0.9 % normal saline. The material used to perform ERCP consisted of a video duodenoscope model TJF-150 (Olympus™), conventional wire sphincterotome for selective cannulation of the bile duct, needle knife to perform the precut sphincterotomy, hydrophilic guide wire via catheter through the bile duct cholangiogram or stenting, Dormia basket and/or stone extraction balloon or trapezoid lithotripsy basket for stone extraction, plastic biliary stents and self-expandable metal stents (SEMS) for drainage and dilation of benign and malignant biliary stricture and nonionic water-soluble contrast Inj. Iopamiro in concentration of 370 mg/ml (BRACCO™ 370) for opacification of the biliary and pancreatic ducts. All accessories that were used for ERCP from Olympus™ or Boston Scientific. All patients were monitored continuously during the procedure, with measurements of blood pressure, heart rate, respiratory rate and arterial oxygen saturation.

Follow-up

Patients were kept under surveillance in the endoscopy recovery area for 3 hours after ERCP. Measurement of serum amylase and lipase was performed 3 times: before ERCP, 2 hours, and 24 hours after ERCP. Patients who developed abdominal pain during this observation period were generally kept in the hospital to exclude procedural complications, including pancreatitis and perforation. The decision to prolong hospitalization was left to the discretion of the endoscopist and clinical service, respectively. Patients who developed PEP were also observed to evaluate PEP-related or unrelated complications.

Data analysis

All data were recorded systematically in preformed data collection form. Quantitative data was expressed as mean and standard deviation and qualitative data was expressed as frequency distribution and percentage. Median and interquartile range (IQR) were reported if the distribution of variables was not normal. The differences between groups were analyzed by unpaired t-test, chi-square (X2) test, fisher's exact test, Mann-Whitney U test, etc. A p-value <0.05 was considered as significant. Statistical analysis was performed by using SPSS 23 (Statistical Package for Social Sciences) for Windows version 10. The study was approved by the Ethical Review Committee of Bangabandhu Sheikh Mujib Medical University.

RESULTS

A total of 100 patients who underwent ERCP and fulfilled the selection criteria, were included in this study. The result of the study is presented in the following tables.

Table 1: Demographic profile of the study subjects (n=100).

Demographic profile	Group A (rectal indomethacin + sublingual GTN) N (%)	Group B (rectal indomethacin) N (%)	P value
Age (years)			
≤30	7 (14.0)	11 (22.0)	
31-40	3 (6.0)	8 (16.0)	
41-50	14 (28.0)	9 (18.0)	
51-60	17 (34.0)	7 (14.0)	
>60	9 (18.0)	15 (30.0)	
Mean±SD	50.78±14.24	48.40±17.33	0.455
Gender			
Male	22 (44.0)	24 (48.0)	0.688
Female	28 (56.0)	26 (52.0)	

Table 2: Indications of ERCP of the study subjects (n=100).

Indication of ERCP	Group A (%)	Group B (%)
Choledocholithiasis	18 (36.0)	20 (40.0)
Cholangiocarcinoma	13 (26.0)	16 (32.0)
Benign biliary stricture	8 (16.0)	11 (22.0)
Carcinoma GB infiltrating biliary tree	9 (18.0)	3 (6.0)
Recurrent pyogenic cholangitis	2 (4.0)	0 (0.0)

Table 3: Biochemical parameters of the study subjects (n=100).

Parameters	Group A (Mean±SD)	Group B (Mean±SD)	P value
Serum creatinine (mg/dl)	0.92±0.54	0.67±0.23	0.004
Serum calcium (mg/dl)	9.88±0.69	9.41±0.81	0.003
Serum albumin (g/l)	39.82±6.49	33.96±6.44	<0.001
Serum bilirubin (mg/dl)	8.27±7.57	12.35±4.40	0.001
Alkaline phosphatase (IU/l)	388.48±245.70	511.52±230.82	0.011
Random blood sugar (mmol/l)	7.69±4.21	6.45±0.88	0.044
C-reactive protein (CRP)	2.58±2.24	2.96±1.84	0.366

Unpaired t- test was done to measure the level of significance

Table 4: Serum amylase before and after ERCP (N=100).

Sample collection time	Group A (Mean±SD)	Group B (Mean±SD)	P value
Serum amylase level (IU/l)			
Before ERCP	38.90±7.75	40.00±12.18	0.591
2 hours after ERCP	64.46±20.07	68.58±15.75	0.256
24 hours after ERCP	64.00±17.48	67.12±11.49	0.294
Serum lipase level (IU/l)			
Before ERCP	46.92±10.96	44.88±8.99	0.311
2 hours after ERCP	62.98±20.09	64.60±8.37	0.600
24 hours after ERCP	58.06±14.63	61.10±9.61	0.222

Tests done to measure the level of significance- a. Unpaired t- test, b. Mann-Whitney U test; IQR-Interquartile range

Table 5: Post-ERCP pancreatitis and severity of pancreatitis (n=100).

Pancreatitis	Group A, N (%)	Group B, N (%)	P value
Present	2 (4.0)	9 (18.0)	0.025
Absent	48 (96.0)	41 (82.0)	
Severity of pancreatitis			
Mild	0 (0.0)	4 (8)	0.231
Moderate	2 (4)	3 (6)	
Severe	0 (0.0)	2 (4)	

Chi-Square test was done to measure the level of significance

Table 1 shows that most of our patients (34%) in group A were aged between 51-60 years and in group B majority of patients were more than 60 years old. We found the mean age of group A was 50.78±14.24 years and group B was 48.40±17.33 years. Among our study subjects, females were predominant in both groups (Table 1).

Table 2 shows the most common indication of ERCP of the study subjects was choledocholithiasis18 (36%) in group A and 20 (40%) in group B. The next common was cholangiocarcinoma 13 (26%) in group A and 16 (20) in group B, followed by benign biliary stricture 8 (16%) in group A and 11 (22%) in group B.

Table 3 shows that most of the biochemical variables have a significant difference between the two groups and p-values were significant except CRP. Serum creatinine, Serum calcium, Serum Albumin, and RBS were significantly higher in group A than in group B while Serum Bilirubin and Alkaline phosphatase were significantly higher in group B than in group A. There were no significant differences between the CRP of groups A and B.

Table 4 shows the mean value of serum amylase (IU/L) and serum lipase (IU/L) before ERCP, there was no significant difference between the two groups and the p-

value was not significant. Median values 2hrs and 24hrs after ERCP have no significant difference between the 2 groups and p values also were not significant.

In this study, PEP after ERCP was found in 2 (4%) patients of group A and 9 (18%) in group B with a p value of 0.025, which was statistically significant.

We found that there was no significant difference in the severity of pancreatitis in both groups. In group B there were 4 mild, 3 moderate, and 2 severe cases of PEP while in group A there were only 2 cases of moderate PEP (Table 5).

Table 6 shows the most common symptoms after ERCP were abdominal pain followed by radiation of pain to the back and nausea/vomiting but only nausea/vomiting was statistically significant (p value 0.001).

We found the most common side effect was a fall in systolic blood pressure followed by dizziness and headache were more common in group A but none of the variables were statistically significant (Table 6).

Table 6: Common gastrointestinal symptoms and drug-induced adverse effects (n=100).

	Group A N (%)	Group B N (%)	P value
Symptoms			
Abdominal pain after ERCP	5 (10.0)	12 (24.0)	0.062
Radiation of pain in the back	2 (4.0)	5 (10.0)	0.240
Nausea/vomiting	1 (2.0)	13 (26.0)	0.001
Adverse effects			
Fall of SBP	3 (6)	0 (0)	0.242
Dizziness	2 (4)	1 (2)	1.00
Headache	1 (2)	3 (6)	0.617

DISCUSSION

In this study, the most frequent indication of ERCP was choledocholithiasis, observed in 18 cases (36.0%) in group A and 20 cases (40%) in group B, followed by cholangiocarcinoma 13 (26%) in group A and 16 (32%) in group-B. Sotoudehmanesh et al, Tomoda et al, and Sarkeshikian et al also found that choledocholithiasis is the most common diagnosis followed by the malignant biliary obstruction, which is consistent with this study.[13,22,23]

The overall incidence of PEP in this study was 11% which is consistent with the studies done by Lv et al and Sotoudehmanesh et al found 10.19% and 11.1% respectively.[13,24]

This study showed that the pre-ERCP median serum amylase level in group A was 38.90±7.75 IU/l, and in group B was 40.0±12.20 IU/l, p=0.591 and there is no significant difference between two groups. Loza et al showed 53.56±22 IU/l, and 56.56±22.8 IU/l respectively. (p = 0.38), which is consistent with this study.[25] Sotoudehmanesh et al found median serum amylase 2 hours before ERCP in group A 97 IU/l (IQR: 52.5-258.5) and in group B 130 (IQR: 62-355) and there is no significant difference between the two groups, which is consistent with this study.[13]

Median serum amylase level 2 hours after ERCP was 64.46±20.07 IU/l in group A and 68.58±15.75 IU/l in group B. After 24 hours median serum amylase was 64.00±17.48 IU/l in group A and 67.12±11.49 IU/l in group B showing no significant difference between two groups which is consistent with the study of Sotoudehmanesh et al. i.e.108 IU/l (IQR: 56.0-335.0) in group A and 130 (IQR: 62.5-353.0) in group B (P = 0.83).[13]

In this study, PEP developed in 4% of group-A and 18% of group-B (p=0.025) which is consistent with the study of. Sotoudehmanesh et al who found 6.7% in group A and 15.3% in group B (p=0.016) and Tomoda et al found 5.6% and 9.5% respectively (p=0.03).[13,23] Another study by Sarkeshikian et al found it 5.1% and 5.6% respectively.[2]

All 11 patients with PEP were followed up until discharge from the hospital to assess the severity of pancreatitis. According to Cotton's classification, the PEP was mild in none in group A and 4 (8.8%) in group B.[19]

In this study, moderate PEP developed in 2 patients (4%) in group A and 3 (6%) patients in group B, whereas severe PEP occurred in none in group A and 2 (4%) in group B.

Sotoudehmanesh et al found that pancreatitis was mild in eight (5.3%) patients and moderate to severe in two patients (1.3%) in group A. In group B, mild pancreatitis occurred in 19 cases (12.7%) and moderate to severe pancreatitis in four patients (2.7%).[13]

In contrast, Elmunzer et al found the secondary outcome of moderate or severe post-ERCP pancreatitis occurred in 40 patients: 13 (4.4%) in the indomethacin group and 27 (8.8%) in the placebo group. So, the difference is significant (P = 0.03) between both groups.[14] That reveals Elmunzer et al found indomethacin suppository is effective in reducing the severity of post-ERCP pancreatitis which is not consistent with this study.[14]

Mild adverse effects concerning the use of nitrate, including dizziness, headache, or transient fall of SBP were detected in this study, which is consistent with the study of Moreto et al.[26]

One reason for the lower incidence of headaches may be related to the potent analgesic effect of indomethacin,

which overcomes this adverse effect. This might be another benefit of combining NSAIDs and nitrates for the prevention of PEP.

This study has few limitations. This was a single-center study with small sample size due to short study period. The study was done during the COVID-19 pandemic, so there was lack of availability of the patients. After evaluating those patients, long term follow-up with them was not possible.

Limitations

This was a single-center study with small sample size due to short study period. The study was done during the COVID-19 pandemic, so there was lack of availability of the patients. After evaluating those patients, long term follow up with them was not possible.

CONCLUSION

This study showed a significant difference between the efficacy of combined rectal indomethacin and sublingual GTN with that of indomethacin alone. The combination of indomethacin suppository and sublingual GTN is superior to indomethacin suppository alone in preventing post-ERCP pancreatitis. Although the difference in the severity of pancreatitis was not statistically significant among the treatment groups, a trend toward less severe pancreatitis was seen in the combination therapy group than in the monotherapy group.

Recommendations

A further study with a prospective and longitudinal study design including a larger sample size needs to be done to strengthen the study report and establish the efficacy of combined rectal indomethacin and sublingual GTN over rectal indomethacin alone in preventing post-ERCP pancreatitis.

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