The effect of Nafamostat Mesilate Infusion after ERCP for Post-ERCP Pancreatitis

Joo Seong Kim, Sang Hyub Lee, Namyoung Park, Gunn Huh, Jung Won Chun, Jin Ho Choi,
In Rae Cho, Woo Hyun Paik, Ji Kon Ryu, Yong-Tae Kim
Department of Internal Medicine, Seoul National University College of Medicine, Seoul, Korea

DISCLOSURES

- Nothing to disclose

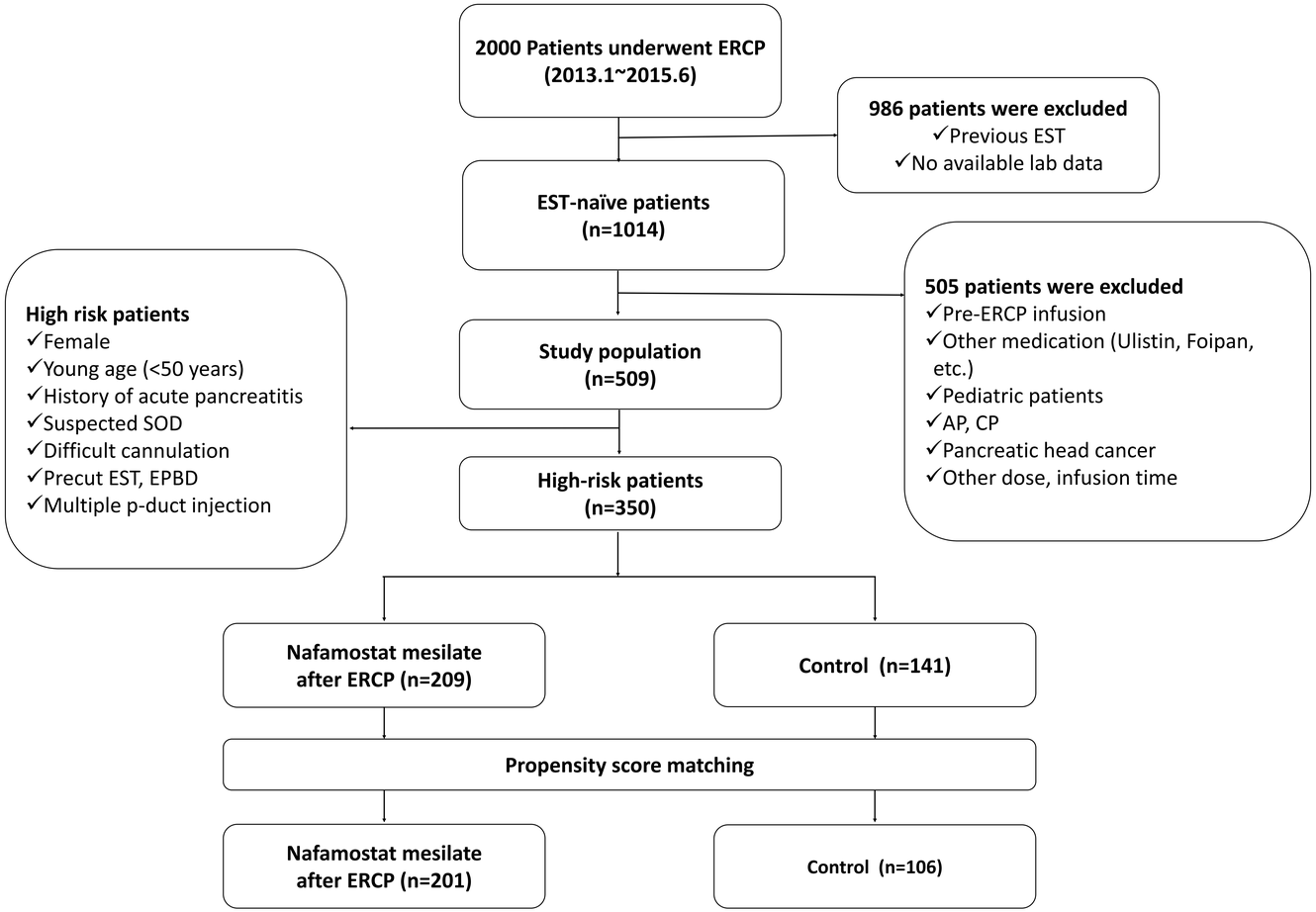
Background / Aims

- Nafamostat mesilate decreases the incidence of pancreatitis after endoscopic retrograde cholangiopancreatography (ERCP).
- However, no studies have administered nafamostat mesilate after ERCP.
- So we investigated if the infusion of nafamostat mesilate after ERCP can affect the post-ERCP pancreatitis (PEP) in high-risk patients.

METHODS

- In a tertiary hospital, 350 high-risk patients of PEP were reviewed retrospectively. Among them, 201 patients received nafamostat mesilate after ERCP.
- Patient-related and procedure-related risk factors for PEP were collected.
- We performed a propensity score matching to adjust for the significant different baseline characteristics.
- The incidence and severity of PEP were evaluated according to the infusion of nafamostat mesilate.
- The risk factors of PEP were also analyzed by multivariate logistic regression.

METHODS


2000 Patients underwent ERCP
(2013.1~2015.6)
986 patients were excluded
✓Previous EST
✓No available lab data
EST-naïve patients
(n=1014)
505 patients were excluded
✓Pre-ERCP infusion
✓Other medication (Ulistin, Foipan, etc.)
✓Pediatric patients
✓AP, CP
✓Pancreatic head cancer
✓Other dose, infusion time
Study population
(n=509)
High risk patients
✓Female
✓Young age (<50 years)
✓History of acute pancreatitis
✓Suspected SOD
✓Difficult cannulation
✓Precut EST, EPBD
✓Multiple p-duct injection
High-risk patients
(n=350)
Nafamostat mesilate
after ERCP (n=209)
Control (n=141)
Propensity score matching
Nafamostat mesilate
after ERCP (n=201)
Control (n=106)

RESULTS

Table 1. The Baseline Characteristics in the Nafamostat Mesilate and the Control Groups.

	Nafamostat (n=201)	Control (n=149)	Total (N=350)	*P value*
Age, y, median (range)	68 (55-75)	66 (54-74)	66 (55-75)	0.436
Male (%)	74 (36.8)	59 (39.6)	133 (38.0%)	0.596
History of AP (%)	3 (1.5)	0	3 (0.9%)	
SOD (%)	2 (1.0)	0	2 (0.6%)	
Purpose of ERCP (%)				
Choledocholithiasis	120 (59.7)	81 (54.4)	201 (57.4%)	0.318
Malignant biliary stricture	67 (33.3)	56 (37.6)	123 (35.1%)	0.410
Benign biliary stricture	11 (5.5)	8 (5.4)	19 (5.4%)	0.966
Biliary leakage	0	1 (0.7)	1 (0.3%)	
Pancreatic cyst	1 (0.5)	2 (1.3)	3 (0.9%)	0.577
Other indication [illegible]	2 (1.0)	1 (0.7)	3 (0.9%)	0.745
Procedures (%)				
Difficult cannulation	115 (57.2)	59 (39.6)	174 (49.7%)	0.001
P-duct manipulation	69 (34.3)	44 (29.5)	113 (32.3%)	0.342
Precut EST	70 (34.8)	42 (28.2)	112 (32.0%)	0.188
Pancreatic EST	44 (21.9)	20 (13.4)	64 (18.3%)	0.043
EPBD	21 (10.4%)	18 (12.1%)	39 (11.1%)	0.631
ERPD	43 (21.4%)	20 (13.4%)	63 (18.0%)	0.055

Data are presented as median (range) or number (%)
AP, acute pancreatitis; SOD, sphincter of Oddi dysfunction; ERCP, endoscopic retrograde cholangiopancreatography; P-duct, pancreatic duct; EST, endoscopic sphincterotomy; EPBD, endoscopic papillary balloon dilatation; ERPD, endoscopic retrograde pancreatic drainage. *Intraductal papillary neoplasm of bile duct, Mirrizi's syndrome

RESULTS

Table 2. The Baseline Characteristics in the Nafamostat Mesilate and the Control Groups After Matching.

	Nafmostat (n=201)	Control (n=106)	Total (N=307)	*P value*
Age, y, median (range)	68 (55-75)	66 (54-74)	66 (55-75)	0.436
Male (%)	74 (36.8)	59 (39.6)	133 (38.0%)	0.596
History of AP (%)	3 (1.5)	0	3 (0.9%)	
SOD (%)	2 (1.0)	0	2 (0.6%)	
Purpose of ERCP (%)				
Choledocholithiasis	120 (59.7)	81 (54.4)	201 (57.4%)	0.318
Malignant biliary stricture	67 (33.3)	56 (37.6)	123 (35.1%)	0.410
Benign biliary stricture	11 (5.5)	8 (5.4)	19 (5.4%)	0.966
Biliary leakage	0	1 (0.7)	1 (0.3%)	
Pancreatic cyst	1 (0.5)	2 (1.3)	3 (0.9%)	0.577
Other indication	2 (1.0)*	1 (0.7)	3 (0.9%)	0.745
Procedures (%)				
Difficult cannulation	115 (57.2)	59 (39.6)	174 (49.7%)	0.001
P-duct manipulation	69 (34.3)	44 (29.5)	113 (32.3%)	0.342
Precut EST	70 (34.8)	42 (28.2)	112 (32.0%)	0.188
Pancreatic EST	44 (21.9)	20 (13.4)	64 (18.3%)	0.043
EPBD	21 (10.4%)	18 (12.1%)	39 (11.1%)	0.631
ERPD	43 (21.4%)	20 (13.4%)	63 (18.0%)	0.055

Data are presented as median (range) or number (%)
AP, acute pancreatitis; SOD, sphincter of Oddi dysfunction; ERCP, endoscopic retrograde cholangiopancreatography; P-duct, pancreatic duct; EST, endoscopic sphincterotomy; EPBD, endoscopic papillary balloon dilatation; ERPD, endoscopic retrograde pancreatic drainage. *Intraductal papillary neoplasm of bile duct, Mirrizi's syndrome

RESULTS

Table 3. Incidence and Severity of Post-ERCP Pancreatitis According to the Usage of Nafamostat Mesilate After Matching.

	Nafamostat (n=201)	Control (n=106)	Total (N=307)	*P value*
PEP (%)	35 (17.4)	11 (10.3)	46 (15.0)	0.141
Mild (%)	30 (85.7)	5 (45.5)	35 (76.1)	0.006

Data are presented as number (%)
PEP, post-ERCP pancreatitis.

RESULTS

Table 4. Univariate and Multivariage Analysis of the Risk Factors of Post-ERCP Pancreatitis

	Univariate		Multivariate	
	OR (95% CI)	*P value*	OR (95% CI)	*P value*
Age <50	2.14 (1.07-4.28)	0.031	2.69 (1.28-5.66)	0.009
Female	2.60 (1.28-5.31)	0.009	3.25 (1.54-6.86)	0.002
P-duct manipulation	1.89 (1.01-3.53)	0.046	2.11 (0.62-7.19)	0.234
Precut biliary EST	0.62 (0.31-1.23)	0.172		
Pancreatic EST	2.05 (1.04-4.03)	0.038	1.32 (0.47-3.77)	0.598
EPBD	0.75 (0.25-2.24)	0.607		
ERPD	1.87 (0.94-3.72)	0.075	1.12 (0.40-3.10)	0.832
Nafamostat mesilate	1.63 (0.81-3.29)	0.171	1.66 (0.79-3.48)	0.182

Multivariate analysis included variables with *P*-value <0.1 in univariate analysis. PEP, post-ERCP pancreatitis; OR, odds ratio; CI, confidence interval; P-duct, pancreatic duct; EST, endoscopic sphincterotomy; EPBD, endoscopic papillary balloon dilatation; ERPD, endoscopic retrograde pancreatic drainage.

CONCLUSION

- The administration of nafamostat mesilate after ERCP in high-risk patients was not effective in preventing PEP, but may attenuate the severity of PEP.