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Beyond Haemostasis

Clinical Case Study

"Treatment of Bleeding After Endoscopic Sphincterotomy Using a New Haemostatic Gel"

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VŠEOBECNÁ FAKULTNÍ NEMOCNICE V PRAZE
1. LÉKAŘSKÁ FAKULTA Univerzita Karlova
3-D MATRIX MEDICAL TECHNOLOGY

AUTHORS

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INTRODUCTION

Bleeding after endoscopic sphincterotomy (ES) is among the most common complications of ERCP (endoscopic retrograde cholangiopancreatography). Significant bleeding manifesting as melaena or enterorrhagia tends to occur in 2-5 % of the procedures.
The most common endoscopic haemostasis methods include diluted adrenaline injection, application of haemoclips, and coagulation methods.
PuraStat is one of the new haemostatic products for the treatment of minor vascular and capillary bleeding in the gastrointestinal tract.

GOAL

To assess the safety and efficacy of a new haemostatic gel in the treatment of acute and delayed bleeding after endoscopic sphincterotomy or precut.

METHODOLOGY

PuraStat gel was applied to patients at our centre in the period from 08/2022 to 08/2023 after they had endoscopic sphincterotomy or precut (Intervention Group). We compared the incidence of significant bleeding manifesting as melaena, haematemesis or enterorrhagia with the previous period from 06/2021 to 06/2022 when PuraStat wasn't available (Control Group). Other monitored parameters included the incidence of post-ERCP pancreatitis and cholangitis, the number of urgent gastroscopies and recurrent bleeding occurrences. Data were processed using logistic regression models.

RESULTS

In the Intervention Group (PuraStat group), 102 endoscopic sphincterotomy and 21 precuts (83% and 17%) were performed in 117 patients; in the Control Group, 125 endoscopic sphincterotomy and 19 precuts (87% and 13%) were performed in 140 patients. (Refer to Fig. 1-2)
The groups were not differentiated by the average age profile (66,6 ± 16,2; 70,6 ± 15,2), gender (m/f 55/85; 50/76), or aetiology. (Refer to Table 1)

Fig.1 Bleeding after sphincterotomy

Fig.2 Application of PuraStat gel

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TABLE 1

CHARACTERISTICS	WITHOUT PURASTAT (N = 140)	WITH PURASTAT * (N = 117)
Gender (males; females)	55/85	50/67
Age ± SD	70,6 ± 15,2	66,6 ± 16,2
Papillosphincterotomy (%)	125 (86,8)	102 (82,9)
Precut (%)	19 (13,2)	21 (17,1)
AETIOLOGY		
Choledocholithiasis (%)	82 (58,5)	62 (53)
Pancreatic cancer (%)	23 (16,4)	29 (24,7)
Cholangiogenic cancer (%)	7 (5)	2 (1,7)
Gallbladder cancer (%)	2 (1,4)	2 (1,7)
Other cancers (%)	13 (9,2)	11 (9,4)
Leak after Cholecystectomy CCY (%)	5 (3,5)	3 (2,5)
PSC (%)	2 (1,4)	2 (3,4)
Chronic pancreatitis (%)	1 (0,7)	2 (1,7)
Other (%)	5 (3,5)	4 (3,4)
LABORATORY		
INR (CI)	1.05 (1.03; 1.06)	1.06 (1.04; 1.09)
Platelets (CI)	226.06 (212.35; 240.66)	218.27 (201.87; 235.99)
Bilirubin (CI)	53.46 (44.23; 64.62)	58.88 (47.38; 73.18)
CRP (CI)	23.49 (18.38; 30.02)	19.05 (14.35; 25.28)

*p= NS in all parameters

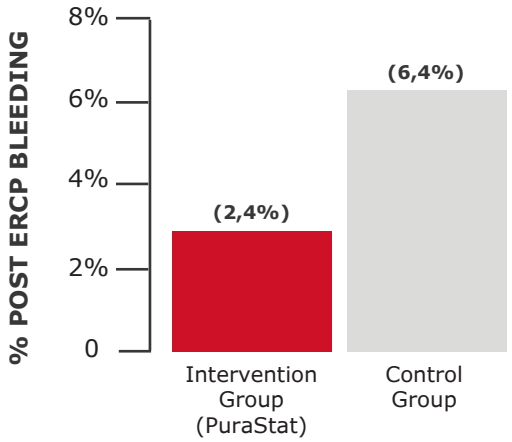
RESULTS CONTINUED

Post-ERCP bleeding in the Intervention Group (PuraStat group) was significantly less common compared to the Control group (3 patients 2,4% vs. 9 patients 6,4%; OR 0.15; p=0.031). (Refer to Table 2 and Graph 1) Urgent gastroscopy due to manifested bleeding after ERCP was performed in 2 patients in the Intervention group, and in 7 patients in the Control group, respectively. No recurrent bleeding was observed. The incidence of post-ERCP pancreatitis and cholangitis did not differ significantly in the two groups (p=0.473 and p=0.411).

TABLE 2

COMPLICATIONS	WITHOUT PURASTAT (N = 140)	WITH PURASTAT (N = 117)	STATISTICAL EVALUATION
Significant bleeding (%)	9 (6,2)	3 (2,4)	p=0,031
Mild	2	0	
Moderate	7	2	
Severe	0	1	
Urgent Gastroscopy (%)	7 (4,8)	2 (1,6)	p=0,144
Recurrent bleeding	0	0	
Post-ERCP Cholangitis (%)	5 (3,4)	6 (4,8)	p=0,473
Post-ERCP Pancreatitis (%)	7 (4,8)	4 (3,2)	p=0,411

POST ERCP BLEEDING GRAPH 1*



(*) The graph displayed has been adapted from its original version for presentation purpose

CONCLUSION

Using a new haemostatic product represents an **easy**, **safe**, and **effective method for treating bleeding after endoscopic sphincterotomy**. Other benefits include the **gel's transparency** so that it does not limit the **potential continuation of the procedure**, as well as the option of **combining it with other haemostatic methods**.
Due to the cost-benefit effectivity, it is advisable to consider the application of PuraStat gel in patients with risk factors for bleeding after ES.

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INDICATIONS FOR USE

PuraStat is indicated for haemostasis in the following situations encountered during surgery, when haemostasis by ligation or standard means is insufficient or impractical(*):

- Bleeding from small blood vessels and oozing from capillaries of the parenchyma and surrounding tissues of solid organs
- Oozing from vascular anastomoses to native or artificial vessels, on the surface of blood vessels and surrounding tissues
- Bleeding from small vessels and oozing from capillaries of the GI tract and surrounding tissues following surgical procedures and endoscopic procedures
- PuraStat is also indicated for the reduction of delayed bleeding following gastrointestinal endoscopic submucosal dissection (ESD) procedures in the colon

(*) PuraStat IFU 007 Rev2, PuraStat IFU-011 Rev2

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PuraStat is a class III medical device, CE marked according to European council directive 93/42/EEC on medical devices and its relatives

CE 2797 BSI

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