Translated by A.P. Strelkova

Research Article

https://doi.org/10.23934/2223-9022-2024-13-1-37-42

Double Postbulbar Block in the Prevention of Postmanipulation Pancreatitis

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ABSTRACT The problems of preventing postmanipulation pancreatitis (PMP) remain the subject of debate and a lot of research from leading scientific clinics around the world. The article is devoted to the assessment of prevention methods of PMP in patients with lesion of the pancreaticobiliary zone who underwent transpapillary interventions.

AIM OF THE STUDY Evaluation of the effectiveness of the author's method of preventing PMP.

MATERIAL AND METHODS A prospective two-center randomized study included 545 patients treated in the Department of Liver Surgery and General Surgery in 2020–2022, who underwent ERCP and endoscopic papillosphincterotomy. There were 146 (26.8%) male patients, and 399 (73.2%) female patients, aged from 18 to 92 years, the mean age 62.7±7.4 years. Patients were divided into 3 groups according to the method of preventing PMP: in the 1st group, standard drug premedication was supplemented with two postbulbar blocks with a solution of lidocaine 0.5% 10 ml before and after the intervention (RF Patent No. 2779221, 09/05/2022), in the 2nd group standard premedication was combined with placebo was used, and in the comparison group 3 no submucosal injections were performed. The monitoring of clinical manifestations of PMP and the level of amylase was carried out every 12 hours until the parameters normalized. Statistical processing was carried out using program STATISTICA 6.1 for Windows.

RESULTS The frequency of mild pancreatitis, corresponding to the criteria for PMP, did not exceed 18% in groups 1 and 3 (p=0.3408), but was lower with pseudo postbulbar block, 9% (χ^2=2.83, p=0.0926), the difference was not statistically significant. The incidence of severe pancreatitis was significantly lower in group 1 with double postbulbar block where there were no cases of pancreatic necrosis among 143 patients (χ^2=6.19, p=0.0129). The mortality did not differ significantly among groups (χ^2=0.15, p=0.7004). The duration of the hospital period had significant differences between groups (Student's t-test 1.973, p=0.001). The hospital period with double postbulbar block turned out to be significantly shorter.

CONCLUSION 1. Double postbulbar blockade significantly reduces the risk of developing severe postmanipulation pancreatitis, regardless of existing risk factors. 2. Double postbulbar block significantly reduces the duration of the hospital period after endoscopic papillosphincterotomy. 3. Pseudo postbulbar block using saline requires further evaluation as a possible way to prevent mild pancreatitis.

Keywords: hyperamylasemia, postbulbar block, postmanipulation pancreatitis, prevention of pancreatitis

For citation Frolov PA, Korotkevich AG. Double Postbulbar Block in the Prevention of Postmanipulation Pancreatitis. *Russian Sklifosovsky Journal of Emergency Medical Care.* 2024;13(1):37–42. https://doi.org/10.23934/2223-9022-2024-13-1-37-42 (in Russ.)

Conflict of interest Authors declare lack of the conflicts of interests

Acknowledgments, sponsorship The study had no sponsorship

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2PBB – double postbulbar blockade
EPST – endoscopic papillosphincterotomy
ERCP – endoscopic retrograde cholangiopancreatography
IM – intramuscular
IV – intravenously
PBB – postbulbar block
PMP – post-manipulation pancreatitis
pseudoPBB – pseudopostbulbar block

INTRODUCTION

Postmanipulation pancreatitis (PMP) is the most common serious side effect of endoscopic retrograde cholangiopancreatography (ERCP), consistently occurring in approximately 8% of cases (range 2.7 to 37%) [1–4]. PMP is associated with mortality in 0.2% (0.1–0.5%) of cases and annual costs of several hundred million dollars per year [1, 4, 5]. Pancreatitis after ERCP is most often mild or, rarely, moderate in severity, but in approximately 10% of cases (about 0.4–0.6% of procedures performed) it is severe and potentially fatal. In addition, asymptomatic hyperamylasemia occurs in 35–70% of patients undergoing ERCP. The wide range of published incidence of pancreatitis may be explained by and depends on the criteria used for diagnosis and the type and duration of follow-up of patients.

The problems of preventing PMP remain the subject of debate and many studies from leading scientific clinics around the world [1, 6–8]. The rectal use of nonsteroidal drugs, recommended for routine use, turns out to be ineffective in preventing moderate and severe forms of PMP [1, 2, 8].

Aim of the study: to evaluate the effectiveness of the author 's method of preventing PMP.

MATERIAL AND METHODS

A prospective two-center randomized study included 545 patients with pathology of the pancreaticobiliary zone who were treated in the department of hepatic surgery and general surgery in 2020–2022, who underwent ERCP and endoscopic - papillosphincterotomy (EPST). There were 146 (26.8%) men, 399 (73.2%) women, aged from 18 to 92 years, average age 62.7±7.4 years. The structure of the pathology included: choledocholithiasis in 172 patients, obstructive jaundice in 204 cases, stenosis of the major duodenal papilla in 125 cases, cholecystitis in 24 cases, pancreatitis in 20 cases. ERCP was performed under sedation in 275 patients (50.1%). The study was carried out in compliance with the requirements of the Declaration of Helsinki, adopted by the XVII session of the World Health Assembly in 1964 and its subsequent editions. The study protocol was approved by the local independent ethics committee. Before the intervention, patients signed an informed consent for inclusion in the study and, according to the method of preventing PMP, were divided into three groups: group 1 for standard drug premedication (Atropine sulfate 0.1%–1 ml once a day intramuscularly (i/m), *Dimedrol* 1% 1 ml i/m once a day, *Octreotide* 0.01% 1 ml once a day intravenously (i/v), *Diclofenac* 2.5% 3 ml once a day i/m, *Nitrosorbide* 10 mg 1 time per day sublingually) supplemented with two postbulbar blockades with lidocaine solution 0.5%–10 ml before and after the intervention (RF Patent No. 2779221, 09/05/2022), group 2 for standard premedication was combined with placebo (2 blockades with NaCl solution 0.9%), group 3 without submucosal injections. The groups were comparable in gender, age, disease structure and nature of the intervention. Monitoring of clinical manifestations of PMP and the level of amylasemia was carried out every 12 hours until the parameters normalized.

Statistical processing was carried out using the application package *STATISTICA* 6.1 *for Windows* (*StatSoft*, Russian Federation). The study used Mann–Whitney (*U*) tests to compare

two independent groups and Kruskal–Wallace tests to compare *k*-independent groups (*k* >2) of ordinal characteristics, and also used Chi-square (χ^2) and *z*-tests for comparison independent groups of - qualitative characteristics. The normality of distributions of quantitative characteristics was checked by calculating the characteristics of asymmetry and kurtosis. With a normal distribution, the mean (*M)* with a standard deviation σ. In the absence of normality - median and quartiles. The null hypothesis (H_0) assumes that the differences in the compared groups are statistically insignificant. Differences were considered significant (H_0 was rejected) at a significance level of difference $p < 0.05$.

RESULTS

The incidence of mild pancreatitis, corresponding to the criteria for PMP [7, 9], did not exceed 18% in groups 1 and 3 (p = 0.3408), but was lower in case of pseudoPBB, 9% (χ^2 = 2.83 , p =0.0926), the difference is statistically insignificant (Fig. 1).

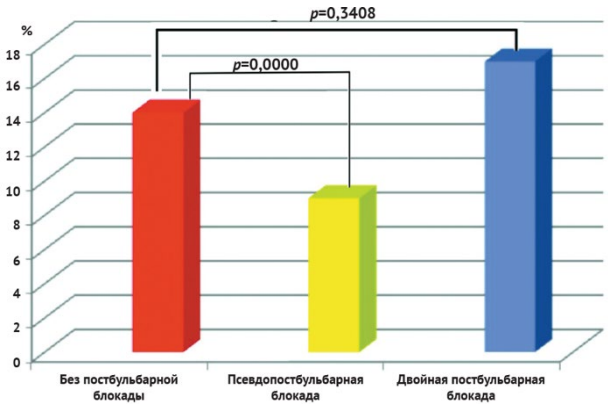

Fig. 1. Frequency of mild post-manipulation pancreatitis in groups (%)

The incidence of severe pancreatitis was significantly lower in group 1, 2PBB, where among 143 patients there were no cases of pancreatic necrosis (χ^2 =6.19, p =0.0129) (Fig. 2).

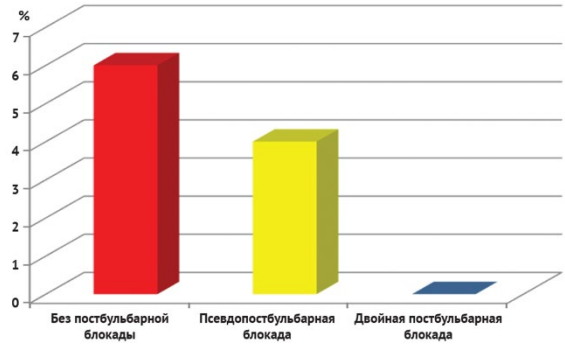

Fig. 2. Frequency of severe post-manipulation pancreatitis in groups (%)

The mortality did not differ significantly among groups (χ^2 =0.15, p =0.7004) (Fig. 3). However, among the causes of mortality in group 1, comorbid diseases were noted, myocardial infarction, pneumonia, decompensation of chronic obstructive pulmonary disease. In groups 2 and 3, multiple organ failure and sepsis were also noted among the causes of death. There were no differences in comorbidity in the comparison groups.

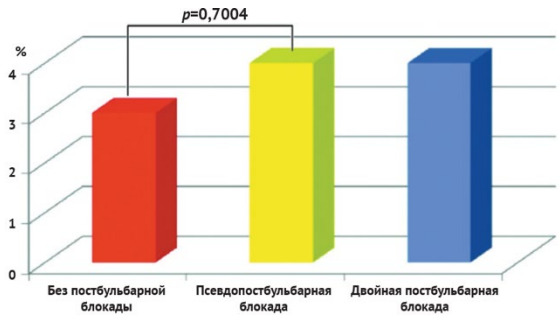

Fig. 3. Mortality among groups (%)

The length of the hospital period had significant differences between groups (Student's *t* -test 1.973, *p* = 0.001) (Fig. 4). The hospital period with 2PBB turned out to be significantly shorter.

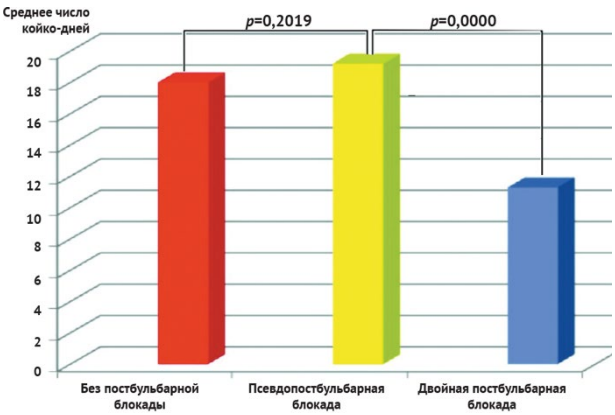

Fig. 4. Duration of hospital stay in groups

DISCUSSION

Known methods for preventing PMP are diverse and differ in cost, risk to the patient and effectiveness [2]. Non-steroidal anti-inflammatory drugs recommended for routine use have proven effective in reducing the incidence of mild forms of PMP, but an effective reduction in the incidence of moderate and severe forms of pancreatitis has not been achieved [1, 2, 8]. It is severe forms of pancreatitis that are accompanied by consistently high mortality and require the search for measures to reduce their frequency after ERCP [5]. The technology we proposed in a randomized study showed its effectiveness in preventing severe forms of pancreatitis.

Prophylactic stenting is recommended to prevent severe PMP in high-risk patients and even in routine use, but there are reports of a risk of PMP in association with pancreatic duct stenting [2, 4, 10]. This contradiction, in our opinion, indicates limited indications for stenting in high-risk patients with the introduction of contrast into the pancreatic duct and multiple cannulation of the pancreatic duct [11], as well as the need to find effective methods for the prevention of PMP [8, 9]. The cost of prophylactic stenting is also high.

Measures to prevent PMP are especially relevant for unchanged papilla in the absence of biliary hypertension [7, 12, 13]. Such situations often occur in asymptomatic choledocholithiasis and the absence of biliary hypertension. In our observations, almost half of the patients had such conditions. On the other hand, a history of PMP remains a proven risk factor for complications of ERCP [14].

Despite the same mortality rate, in group 2PBB the main causes of death were somatic causes from comorbid diseases. Also, 2PBB significantly reduced the length of the hospital period. Of course, the fact of a decrease in the incidence of mild pancreatitis when using pseudoPBB—submucosal administration of saline solution—requires explanation. Perhaps local hydration of the head of the pancreas with preserved lymphatic drainage from the duodenum somehow affects the pathogenesis of PMP?

There is no doubt that the prevention of PMP is a multifaceted process, including cannulation technique, time of access and intervention, type of anesthesia, combination of medications, etc. [2, 15, 16].

However, our results indicate the high effectiveness of a new method of preventing PMP, which can be used routinely for all known and proven risk factors for PMP [17].

CONCLUSION

The study found that double postbulbar blockade significantly reduces the risk of developing severe postmanipulation pancreatitis, regardless of existing risk factors. It has also been demonstrated that dual postbulbar blockade significantly reduces the length

of hospital stay after endoscopic papillosphincterotomy. Sham postbulbar block using saline requires further evaluation as a possible way to prevent mild pancreatitis.

CONCLUSIONS

1. According to the study, the frequency of mild pancreatitis did not exceed 18% in the groups (p = 0.3408), but was lower with false postbulbar blockade – 9% (χ^2 = 2.83, p = 0.0926), the difference is statistical insignificant.

2. The use of double postbulbar blockade led to a statistically significant decrease in the incidence of severe pancreatitis (χ^2 =6.19, p =0.0129)

3. The inclusion of double postbulbar blockade in addition to drug prevention of post-manipulation pancreatitis made it possible to statistically significantly reduce the length of hospitalization of patients (Student's t -test 1.973, p = 0.001).

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Received on 03/03/2023
Review completed on 05/04/2023
Accepted on 05/10/2023