

## RISK FACTORS OF PANCREATITIS AFTER ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY – A RETROSPECTIVE COHORT STUDY

STANISŁAW GŁUSZEK<sup>1,2</sup>, JAROSŁAW MATYKIEWICZ<sup>1</sup>, DOROTA KOZIEŁ<sup>1</sup>,  
DARIUSZ KLIMER<sup>2</sup>, IWONA WAWRZYCKA<sup>1,2</sup>, ALEKSANDRA OGONOWSKA<sup>2</sup>

Faculty of Medicine and Health Sciences, Jan Kochanowski University in Kielce<sup>1</sup>

Kierownik: prof. dr hab. *S. Głuszek*

Department of General, Oncological and Endocrinological Surgery, Regional Hospital in Kielce<sup>2</sup>

Kierownik: prof. dr hab. *S. Głuszek*

Endoscopic retrograde cholangiopancreatography (ERCP) is the most important non-surgical procedure in serious pancreatic and biliary diseases, still burdened with the risk of severe complications. The objective of the study was to distinguish factors which could increase the risk of occurrence of ERCP complication in the form of pancreatitis.

**Material and methods.** The study included 452 patients who had undergone ERCP. Patients' records were retrospectively analyzed from the aspect of demographic data, indications for the procedure, type and course of the procedure, type and severity of complications, width of the common bile duct (CBD), concomitant diseases and administered medicines which might increase the risk of complications.

**Results.** In 35 patients (7.7%) a complication occurred in the form of pancreatitis (AP). A severe course was confirmed in 11 patients (31%). Cholelithiasis constituted approximately 2/3 of indications for ERCP. AP after ERCP was significantly more often observed in the group of patients aged under 40 (22.9% vs 8.6%;  $p < 0.05$ ). Narrow biliary ducts (3-8 mm) were the factor increasing the frequency of development of AP (25.9% vs 45%;  $p < 0.05$ ). Death occurred in 5 patients (1.1%), including 4 patients (0.96%) in the group without complications, and in 1 patient (2.85%) with complicated AP.

**Conclusions.** ERCP is a very valuable procedure in clinical treatment; however, it is burdened with the risk of complications, such as AP, bleeding, or duodenal perforation. A group especially exposed to the risk of complications in the form of AP are young patients aged under 40 with a narrow CBD.

**Key words:** endoscopic retrograde cholangiopancreatography, acute pancreatitis, complication

Endoscopic retrograde cholangiopancreatography (ERCP) is the most important non-surgical procedure in serious pancreatic and biliary diseases. The ERCP was first performed in 1968, and the first sphincterotomy carried out in 1974 (1). The main complications of ERCP are: acute pancreatitis (1-10%), bleeding from the duodenum, papilla of Vater and common bile duct (1-4%), perforations (1-2%), cholangitis (1-5%), and cardiopulmonary and sedation related events (2-6). In the cases of a high risk ERCP, determination of the risk factors allows the undertaking of endoscopic and pharmacological treatment aimed at minimizing the development of the complication, or even a change

of the management algorithm and replacement of this procedure by a surgical procedure.

An indication for the ERCP is most frequently mechanical jaundice caused by cholelithiasis, cancerous changes in the pancreatic-duodenal region (common bile duct, papilla of Vater and pancreatic head), narrowing of the papilla of Vater, and pro-inflammatory narrowing of the bile duct. The ERCP procedure is of great diagnostic importance because it allows differentiation of the above-mentioned changes also by taking specimens for microscopic examination. In addition, ERCP is very important in the diagnostics of iatrogenic bile duct injuries (7).

The therapeutic management covers the incision of the papilla of Vater – papillotomy, sphincterotomy, and insertion of a prosthesis which allows the decompression of jaundice. In gallstones, it enables the crushing and removal of the deposits. In the case of cancerous changes, the diagnostics is possible, including the collection of material for microscopic examination, and is a bridge procedure in preparation for surgery (elimination of jaundice). Complications related with ERCP still constitute an important clinical problem, presenting difficulties in treatment. In especially rare cases, pancreatitis, bleeding and perforation may end in death.

Thus, the question about factors of increased risk is up-to-date, in order to effectively apply the prophylaxis of complications, and in a clinical situation burdened with a high risk of complications, change the tactics of management and select a method which would allow the avoidance of the above-mentioned complications.

The objective of the study was to distinguish the factors which might increase the risk of occurrence of ERCP complication in the form of pancreatitis.

## MATERIAL AND METHODS

The study covered 452 patients who had undergone ERCP performed by a single endoscopist (D.K.), whose total experience is 3700 procedures. Data concerning patients were collected retrospectively based on medical history and surgical records. The data contained demographic information – age, gender, clinical history taking, biochemistry blood tests, imaging examinations – abdominal ultrasound (USG), abdominal computed tomography (CT), or magnetic resonance (MR), magnetic resonance cholangiopancreatography (MRCP), according to the indications, type and course of ERCP procedure, type and severity of complications. In detailed analyses, the type of pathology was considered (cholelithiasis, choledocholithiasis, presence of tumour mass, pancreatic cysts). The ERCP procedure was performed under general anaesthesia or analog sedation (midazolam, fentanyl). In individual cases, atropinum sulphuricum was administered. For the opacification of the ducts, Omnipaque 300 mg/1 ml (GE Health-

care) was applied in the amount of 10-20 ml. According to the clinical situation, sphincterotomy of various extent and removal of deposits was performed, lithotripsy, and insertion of prosthesis, collection of specimens for microscopic examination. After the ERCP procedure, the patient remained fasting for 12-24 hours, blood was collected at 8 and 24 hours after the procedure for amylase test, blood cell count and ionogram. All patients were hospitalized for at least 1 day after ERCP.

Diagnosis of mild, moderate, or severe acute pancreatitis (SAP) according to the Atlanta 2012 classification was the criterion for inclusion in this research. The diagnosis of AP was based on a joint interpretation of medical history, physical examination, and targeted laboratory tests. The diagnosis requires the fulfilment of 2 of the following 3 criteria: 1) abdominal pain of an acute onset, often radiating towards the back; 2) lipase or amylase activity in serum >3-times exceeding the upper limit of normal; 3) results of imaging examinations allowing the obtaining of cross-sectional images: computed tomography (CT), magnetic resonance (NMR), or ultrasound scan (USG). Bleeding was defined as bleeding during the ERCP procedure, or during the period up to 2 weeks after ERCP. Cholangitis was diagnosed based on elevation of temperature above 38°C, and the accompanying symptoms: chills, and increasing jaundice. Duodenal perforation was diagnosed based on clinical symptoms and radiological examination with a contrast agent soluble in water.

### Clinical problems

1. What is the frequency of occurrence of AP after ERCP?
2. Are age and gender the risk factors of AP after ERCP?
2. What is the difference in the frequency of deaths after ERCP complicated and non-complicated by AP?
4. What is the effect of the width of CBD ducts on the frequency of AP after ERCP?

### Statistical analysis

Analysis of the difference in the proportions of patients with AP after ERCP in the groups

of males and females was performed by using the single-tailed Z-test for comparing two proportions.

The relationships between the occurrence of complications after ERCP and the occurrence of a particular event of interest (for example, narrow bile ducts) were analysed by using Fisher's exact test with the data sets displayed in the form of 2x2 contingency tables. Odds ratio (OR) were used as a measure that compares the odds of the specific event occurrence in the group of patients with complications after ERCP vs. the group of patients without complications after ERCP. The limits of 95% confidence intervals for ORs were also reported.

## RESULTS

In the group of 452 who had undergone ERCP at the age from 17-93 (median 65) there were 250 females (55.3%) aged 17-88 (median 66.5), and 202 males (44.7%) aged 25-93 (median 63). In 35 patients (7.7%) aged 24-87 (median 59) there occurred a complication in the form of pancreatitis (AP), including 23 females aged 24-84 (median 61), who constituted 9.2% (23/250) of the total number of women, and in 12 males aged 25-87 (median 51.5), who constituted 5.9% (12/202) of the total number of males after ERCP. Among 35 patients who had undergone ERCP complicated with AP, in 11 patients (31%) a severe course was confirmed, and in 24 (69%) a light course of acute pancreatitis.

The difference in the proportions of patients with AP after ERCP in the groups of males and females was not statistically significant ( $p=0.14$ ). Death occurred in 1 patient with complicated AP (1/35- 2.85%), and in 4 patients

in the group without complications (4/417 -0.96%). The direct causes of death in the group not complicated with AP were most frequently cardiologic disorders – severe arrhythmia in patients at advanced age, advanced cancerous disease, and complications related with the consequences of iatrogenic bile duct injuries. The cause of death in the group complicated with AP was multiple organ dysfunction syndrome.

The relationship between the occurrence of complications after ERCP and the occurrence of death was insignificant – the p-value from the Fisher's exact test was 0.33 (tab. 1).

Cholelithiasis in both groups complicated and non-complicated with AP constituted approximately 2/3 indications for ERCP. Without cholelithiasis – 151 patients (36.2%) in the group not complicated, and 11 patients (31.4%) in the group complicated with AP.

In the group of patients with complications, patients aged under 40 constituted 8/35 (22.9%), compared to the group without complications 36/417 (8.6%). The relationship between the occurrence of complications after ERCP and the age of patients (under 40 or 40+) was statistically significant – the p-value from the Fisher's exact test was  $<0.01$ . Complication in the form of AP developed in 21.7% (5/23) of females and 25% (3/12) of males aged under 40. In the group of patients with pancreatitis, the presence of a tumour change in USG, CT, and NMR was observed in 25.8% (9 patients) and 21.9% (91 patients) in the group without complications. A cyst in imaging examinations was confirmed in 8.6% (3 patients) in the group with complications, and 1.2% (5 patients) in the group without complications. As many as 80% of patients with complications (28/35) were hospitalized for a period longer than 7 days.

Table 1. Characteristics of patients

	Patients without AP	Patients with AP	p	OR (95% CI)
No. of patients	417	35		
Gender (male/female)	190/227	12/23	0,14	-
Age (median±SD)	65 (±14,9)	57,5 (±18,4)	0,21	-
Death	4 (0,96%)	1 (2,86%)	0,33	3,02 (0,06-31,7)
Choledocholithiasis	101 (24,2%)	4 (11,4%)	0,09	0,40 (0,10-1,18)
Cholelithiasis	54 (12,9%)	12 (34,3%)	<0,001	3,49 (1,49-7,83)
Choledocholithiasis and cholelithiasis	112 (26,9%)	8 (22,9%)	0,69	0,80 (0,30-1,89)
Tumour change	91 (21,9%)	9 (25,8%)	0,67	1,23 (0,49-2,85)
Cyst	5 (1,2%)	3 (8,6%)	<0,05	7,65 (1,13-41,40)

The width of the common bile duct in patients who had undergone ERCP was assessed in imaging examinations (USG, CT, MRCP) to be from 3 mm – 2 cm. In the group without complication AP – the narrowest ducts – 3-5 mm were noted in 14/417 (3.4%), and 6-8 mm in 94/417 (22.5%). Together, this group of patients constituted more than 25% of patients qualified for ERCP, and among those with AP complications an analogous group constituted 45% (3-5 mm – 4/35 (11.4%), 6-8 mm -12/35 (34.3%), respectively). Narrow ducts most probably constituted an important risk factor increasing the frequency of occurrence of the complication in the form of AP. The obtained OR estimate, equal to 2.4, indicates that the odds of the event that the bile ducts are narrow in the group of patients with complications after ERCP, are 2.4 times higher than in the group of patients without complications after ERCP. The relationship between the occurrence of narrow bile ducts and the occurrence of complications after ERCP was statistically significant: p-value from the Fisher's exact test – <0.01 (tab. 2).

The narrow bile ducts and age  $\leq 40$  years together had a significant impact on the incidence of AP (p <0.05) (tab. 3).

In the group analyzed, no clinically significant bleedings were observed in the postop-

erative course, nor any ERCP-related perforations. In cholangitis, empirical antibiotic therapy was applied, after the previous collection of blood for bacteriological tests and antibiogram. In patients who had additionally applied percutaneous drainage, bile was collected for bacteriological test. In special, rare cases (5 patients), it was necessary to perform a repeated ERCP in order to exchange prosthesis (obstruction or prolapse of prosthesis from bile ducts).

The type of ERCP procedure had no significant association with the incidence of AP, other than exclusively incision of papilla. This procedure may have a significant impact on the incidence of AP (p <0.01) (tab. 4).

## DISCUSSION

In recent decades, success in the development of the therapy of bile duct diseases has been unequivocal. Previously, many clinical situations in the area of pathology of bile ducts (choledocholithiasis, pro-inflammatory narrowing of the papilla of Vater, cholangitis) had been solved by open surgery methods. At present, these procedures are performed extremely rarely. The ERCP is of a capital importance also in cancers of the head of pancreas, bile

Table 2. Risk factors of pancreatitis after ERCP

	Patients without AP n=417	Patients with AP n=35	p – value	OR	95% CI
Age (y)					
<40	36 (8,6%)	8 (22,9%)	p<0,05	3,1	1,14-7,75
>40	381 (91,4%)	27 (77,1%)			
Width of ducts (mm)					
3-5	14 (3,4%)	4 (11,4%)	p<0,05	2,4	1,11-5,14.
6-8	94 (22,5%)	12 (34,3%)			
>8	309 (74,1%)	19 (54,3%)			

Table 3. Age and width of the bile ducts in patients undergoing ERCP complicated and uncomplicated acute pancreatitis

Age (y)/ Width of ducts (mm)	Patients without AP	Patients with AP	p – value	OR	95% CI
$\leq 40$					
3-8	20 (55,6%)	8 (100%)	0,03	infinity	1.13-infinity
>8	16 (44,4%)	-			
>40					
3-8	128 (33,6%)	13 (48,1%)	0,14	1,832	0,77-4,34
>8	253 (66,4%)	14 (51,9%)			

Table 4. Type of ERCP procedure

Type of ERCP procedure	Patients without AP	Patients with AP	p – value	OR	95% CI
Incision of papilla + removal of residues + insertion of prosthesis	306 (73,4%)	23 (65,7%)	0,33	0,69	0,31-1,59
Incision of papilla + removal of previous prosthesis + removal of residues	17 (4,1%)	1 (2,9%)	1	0,69	0,01-4,69
Incision of papilla + removal of previous prosthesis + insertion of new prosthesis	27 (6,5%)	-	0,25	0	0-1,72
Incision of papilla	58 (13,9%)	11 (31,4%)	<0,01	2,83	1,18-6,38
Incision of papilla + removal of previous prosthesis + insertion of new prosthesis + removal of residues	9 (2,2%)	-	1	0	0-6,17

ducts, and the papilla of Vater. Very often, imaging examinations bring the problem closer from the diagnostic point of view; however, they are not able to define the type of disease. The ERCP enables the decompression of mechanical jaundice, collection of specimens for microscopic verification, and is a type of bridging therapy for carcinoma of the papilla of Vater, cancer of the common bile duct and head of the pancreas. As a result of the application of the procedure, the yellow discoloration may be eliminated in a patient, an improvement of the state of nutrition and metabolic balance may be achieved, as well as the elimination of infection and sepsis, stabilization of the renal function and the coagulation system. In such a difficult clinical situation, bridging therapy plays a very important role in the reduction of the risk of postoperative complications. On the other hand, it is known that that patients who are stable from the cardiovascular and respiratory aspects, with a normal coagulation system, without the features of sepsis, with jaundice due to cancerous pathology within the hepatoduodenal ampulla, may be operated on without increasing the risk of postoperative complications. However, the present state of a patient should be considered, infection, potential cholangiogenic sepsis, efficiency of the coagulation system, the kidneys and heart, and only after such an analysis may decisions be made concerning primary surgical resection, or the qualification for ERCP as a bridging therapy.

Despite many advantages of the ERCP, the risk of complications after these procedures must not be ignored. Katsinelos et al. (4) performed a multifactor analysis of 2,715 therapeutic ERCPs performed by a single endosco-

pist, and established the following risk factors of complications: in medical history an acute pancreatitis, difficult cannulation, needle-knife papillotomy, trans-pancreatic sphincterotomy, opacification of first- and second-order bile ducts. However, antiplatelet drugs and anticoagulants were not the independent risk factors of bleeding after ERCP. Therefore, it is important to indicate the factors increasing the risk of complications threatening death during the post-operative period, and to enable preventive management during the preoperative, perioperative, and postoperative period.

In literature (2, 3, 4), the fact is reported concerning a higher frequency of complications after ERCP among young women, with a narrow common bile duct, who show symptoms of the character of choledocholithiasis or acute pancreatitis. In addition, a prolonged ERCP procedure, an attempt at cannulation, false cannulations or penetrations, administration of a larger amount of contrast agent into the bile and pancreatic ducts, also constitute a risk factor of complications in the form of AP (2, 3, 4, 8). A complication in the form of AP occurred in 9.2% of all females and 5.9% of all males, without statistically significant differences. Cholelithiasis was the most frequent indication for ERCP, both in the complicated and non-complicated groups. In the group examined, the frequency of AP was 7.7%. In the group with complications, patients aged under 40 constituted 8/35 (22.8%), compared to the group without complications 36/417 (8.6%). Statistically significant differences were found between these groups. Patients aged under 40 were the group at higher risk.

In imaging examinations, the width of the common bile duct in patients who had under-

gone ERCP was assessed to be from 3 mm – 2 cm. In the group without complication with AP, the narrowest ducts – 3-5 mm – were found in 14/417 (3.4%), and 6-8 mm in 94/417 (22.5%). Together, this group of patients constituted more than 25% of patients qualified for the ERCP, and from among those complicated with AP, an analogous group constituted 45% (3-5 mm – 4/35 (11.4%), 6-8 mm – 12/35 (34.3%), respectively). A narrow CBD is an important risk factor increasing the frequency of occurrence of a complication in the form of AP. Other factors seem to be less important, and do not increase the risk of complications after ERCP. However, such factors as age under 40, and the necessity to perform ERCP in a patient with narrow CBD, should be a kind of alarm for increased awareness in performing this procedure, and use of techniques preventing complications, such as stenting of the pancreatic duct and administration of NSAIDs.

In the presented study, it was confirmed that such patients are especially burdened with the risk of complications. Also, the course of AP was especially severe in a considerable number of young patients after ERCP. Katsinelos et al. (4) registered 4.9% in a group of 2,715 cases of ERCP, did not confirm that young age, female gender and ampullary diverticula increase the risk of AP after ERCP. Care, attention and experience while performing ERCP may in difficult clinical situations eliminate the risk of complication (AP). Pre-cutting in the ERCP procedure increases the risk of complication, which is also confirmed by previous reports (9, 10, 11). A highly selective cannulation, insertion of the pancreatic stent and cautious, adequate incision, minimize the risk of complications (12).

The risk of AP after ERCP stimulated for seeking actions protecting against this complication (13-16). Nicolas-Perez et al. (17) analyzed 300 patients for a period of 1 year after ERCP. The strategy in the groups of patients who did not develop AP after ERCP was considered effective. The results of studies indicate that prophylactic strategy decreases the risk of AP after ERCP: the odds ratio of an episode of post-ERCP acute pancreatitis after pancreatic stent placement was 1.33 (95% CI 0.68-2.61); after stent plus indomethacin, it was 1.40 (95% CI, 0.72-2.73), and after no prophylaxis – 2.49 (95% CI, 1.35-4.59).

Thus, a rectal NSAID administration proved to be the most cost-effective prophylactic strategy used to prevent post-ERCP pancreatitis. Also Akbar et al. (18) while summing up metanalysis (29 studies, including 22 concerning pancreatic duct stents and 7 NSAIDs) discovered that rectal NSAIDs alone are superior to PD stents also in preventing post-ERCP pancreatitis, and should be considered as a first-line therapy for selected patients. However, these findings were limited by the small number of studies assessed (only 29 studies), potential publication bias, and the indirect nature of the comparison. High-quality, randomized, controlled trials are needed to compare these 2 interventions and confirm these findings. Insertion of a stent into the pancreatic duct is considered by many researchers as an important management preventing pancreatitis after ERCP, especially in the case of more difficult procedures (15-19).

Summing up, in the light of own studies and reports from literature, it may be presumed that such factors as age under 40 and necessity to perform ERCP in a patient with narrow CBD should be an alarm for increased watchfulness while performing this procedure, and use of techniques preventing complications, such as stenting of the pancreatic duct and administration of NSAIDs. The presented study confirmed that such patients are especially burdened with the risk of complications. Also, the course of AP was especially severe in a considerable number of young patients after ERCP. The results of metaanalysis by Katsinelos et al. (4) should also be borne in mind. In medical history: acute pancreatitis, difficult cannulation, needle-knife papillotomy, trans-pancreatic sphincterotomy, opacification of first- and second-order bile ducts, constitute an increased risk of postoperative complications, which are not known to the end, before undertaking the ERCP procedure.

## CONCLUSIONS

ERCP is a very valuable clinical procedure which, however, is burdened with the risk of complications, such as AP. A special group at risk of complications in the form of AP are young patients aged under 40, with a narrow CBD.

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Adress correspondence: 25-369 Kielce, ul. Żeromskiego 5

e-mail: sgluszek@wp.pl