

The Role of Sphincterotomy on the Outcome of Post Endoscopic Retrograde Cholangiopancreatography Pancreatitis

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Abstract

Background: Post-Endoscopic retrograde cholangiopancreatography [ERCP] pancreatitis is one of the most frequent and feared complications following ERCP and can lead to significant morbidity as well as occasional mortality. Endoscopic sphincterotomy is a procedure of ERCP that is either used solely for the treatment of diseases of the papilla of Vater, such as sphincter of Oddi dysfunction or to facilitate subsequent therapeutic biliary interventions such as stone extraction or stenting and decrease the possible.

Aim of Study: To evaluate the effect of sphincterotomy in reducing or increasing post ERCP pancreatitis.

Patients and Methods: A prospective cohort study was conducted in General surgery, Gastro-enterology and Hepatology Department Faculty of Medicine, Assiut University Hospital on 100 patients aged from 15 to 70 years from both sexes eligible for ERCP for extraction of common bile duct stones, treatment of papillary stenosis and facilitation of endotherapy [i.e. stent placement, tissue sampling and stricture dilation] allocated into 2 equal groups [50 patients each]; group A, in which ERCP was performed with cannulation of the common bile duct and group B in which ERCP was performed with sphincterotomy. Pre-operative assessment included full history, physical examination, serum amylase and lipase and pelvi-abdominal ultrasound.

Results: There were no statistically significant differences between both groups as regarding postoperative ultrasound findings and post-operative results of laboratory investigations including: Lipase and amylase.

Conclusion: Sphincterotomy can be performed safely and effectively during ERCP without fear of an increased risk of post-ERCP pancreatitis.

Key Words: *Endoscopic – Pancreatitis – Retrograde cholangiopancreatography – Sphincterotomy.*

Introduction

IN 1968, endoscopic retrograde cholangiopancreatography [ERCP] introduced for the first time by

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McCune et al., and later on become one of the important techniques in the diagnosis of different biliary and pancreatic disease [1].

One of the most frequent indication of ERCP was choledocholithiasis secondary to gallstones disease affects, it affecting about 20 million adults in the united state of America. According to the American Society for Gastrointestinal Endoscopy [ASGE], only patients with high suspension criteria and risk factor were considered as appropriate candidate for ERCP to allow immediate diagnosis and proper treatment [2].

In 1988, Neoptolemos and Carr-Locke et al., examined the role of early ERCP in gallstone pancreatitis which presented within less than or equal to 72h for the first time as previously, ERCP was contraindicated in similar situation. Their results reported that, only patients with severe disease benefited according to the modified Glasgow criteria was had therapeutic benefits from ERCP. Although incidence of mortality not decreased despite of early ERCP, but the incidence of overall complications in the ERCP group [24%] significantly lower than cases received conventional supportive treatment [61%] [3].

One of most common complication after ERCP was development of post-ERCP pancreatitis [PEP], with incidence of 5-30%. Its incidences affected by patients health status, procedures [4].

The Atlanta criteria-based definition of pancreatitis based on the presence of two of three of the following criteria to diagnose pancreatitis; abdominal pain in the epigastrium with or without radiation to the back, at least three-fold increase in the serum amylase and/or lipase, and imaging features suggest the pancreatitis [5].

Post-ERCP pancreatitis had different presentation according to the severity graded according to consensus definitions based on the hospitalization duration and need for invasive intervention ranged from mild interstitial to severe necrotizing disease with multiorgan failure and even death. Because of induced papillary edema, difficult cannulation was a risk factor of Post-ERCP pancreatitis. Other risk factors include multiple injection of the contrast in pancreatic duct, the time and dose of injection and deep insertion of used guidewire into the pancreatic duct [6].

In 1974, the introduction of endoscopic papillotomy [EP] with precut or needle-knife papillotomy was reported with one of their possible complications developed secondary to the entrance of guidewires to common bile duct [CBD] without initial selective cannulation [7,8].

Then at 1989, the wire-guided sphincterotomy became widely accepted modality of treatment to avoid precut papillotomy especially in difficult selective cannulation of the common bile duct. Although, biliary sphincterotomy allow the access the bile duct to remove bile duct stones, and/or facilitate introduction of accessories into the biliary system, one of the most common and dangerous drawbacks was related to higher risks of bleeding, postpancreatitis, and perforation [9].

Endoscopic sphincterotomy [EST] associated with successful stone extraction in about 85-98% of cases, but still had a risk of bleeding, perforation and pancreatitis with permanent loss of the sphincter function and higher risk of free bacterial translocation in to the bile duct leading to recurrent stone formation [10].

So, one of developed alternative to EST was endoscopic balloon dilation of the native papilla [EBD] to decreased the risk of postoperative complication and preserve the sphincter function [11].

This study aimed to evaluated the effect of sphincterotomy in reducing or increasing post ERCP pancreatitis.

Patients and Methods

This was a prospective cohort study was conducted in General Surgery, Gastro-Enterology and Hepatology Department Faculty of Medicine Assiut University Hospital during the period January 2018 - June 2019 on 100 patients aged from 15 to 70 years from both sexes eligible for ERCP for extraction of common bile duct stones, treatment of papillary stenosis and facilitation of endotherapy [i.e. stent placement, tissue sampling and stricture dilation].

Study protocol received approval from Institutional Review Board [IRB] - Al-Azhar Faculty of Medicine, Assiut branch and administrative approval and official permissions were obtained prior to data collection after written informed consent was obtained from patients included in the study following guarantee of data confidentiality to them.

Patients have risk factor for pancreatitis [diabetes, raised amylase and lipase], past history of pancreatitis, Congenital biliary abnormalities or any other complication as perforation and bleeding were excluded from the study.

Patients were randomly allocated into 2 equal groups [50 patients each]; group A, in which ERCP was performed with cannulation of the common bile duct and group B in which ERCP was performed with sphincterotomy.

Pre-operative assessment included full history taking of previous attacks of pancreatitis as well as comorbidities e.g. diabetes, physical examination, laboratory investigations including complete blood picture [CBC] [to exclude anaemia, leukocytosis], international normalized ratio [INR], renal function tests [creatinine], liver function tests [liver enzymes, total and direct bilirubin], serum amylase and lipase and radiological investigations include pelvi-abdominal ultrasound. Post-operative follow-up for 48 hours for vital signs and drains, serum amylase and lipase and pelvi-abdominal ultrasound to exclude presence of any collection or oedema before discharge.

Discharge criteria included normal results of laboratory investigations i.e. CBC, serum amylase and lipase, INR & prothrombin time [PT], liver and kidney function tests and abdomino-pelvic ultrasound free of collection.

Statistical analysis:

The collected data was tabulated and statistically analyzed by SPSS program [Statistical Package for Social Science] for windows version 20 [SPSS Inc., Chicago, IL, USA]. The qualitative data were presented as number and percentages and quantitative data was presented as mean with standard deviations. Comparison between the qualitative data in two groups were conducted by Chi-square test and Fisher exact test was used when the expected count less than 5 in any cell. Independent *t*-test was used to compared between the quantitative data in two groups. The confidence interval was set to 95% and the margin of accepted error was 5%. So, the significance of *p*-value was considered if $p < 0.05$.

Results

Males represented 54% of group A and 50% of group B whereas females represented 46% and 50% of group A & B respectively. The mean age of group A patients was 44.58 ± 15.33 years versus 42.82 ± 15.43 in group B. However, no statistically significant differences were found between both groups as regards gender or age ($p=0.689$ & 0.569 respectively).

There were no statistically significant differences between both groups as regarding the presence of chronic calcular cholecystitis, non-calcular cholecystitis or common bile duct stones (Table 1).

Table (1): Findings in patients in the study groups.

	Group A (No.=50)		Group B (No.=50)		Chi square test	
	No.	%	No.	%	χ^2	<i>p</i> -value
Chronic calcular cholecystitis	20	40.0	19	38.0	1.388	0.500
Non calcular cholecystitis	18	36.0	14	28.0		
Stone in common bile duct	12	24.0	17	34.0		

Also, both groups were comparable in complete blood picture (CBC) results [including haemoglobin, white blood cells (WBC) and platelets], pre-operative results of creatinine level and liver function tests serum glutamic-oxaloacetic transaminase [serum glutamic-oxaloacetic transaminase (SGOT) and Serum glutamic pyruvic transaminase (SGPT)], lipase, amylase, direct and total bilirubin (Table 2).

Table (2) Laboratory results in the study groups.

	Group A (No.=50)		Group B (No.=50)		Independent <i>t</i> -test	
	Mean	SD	Mean	SD	<i>t</i>	<i>p</i> -value
Hemoglobin	12.24	1.65	11.71	1.77	1.550	0.124
WBCs	11.10	3.31	10.73	3.81	0.525	0.601
Platelets	271.34	96.51	297.30	88.52	-1.402	0.164
Creatinine	0.96	0.28	0.96	0.30	0.000	1.000
SGOT (ui/l)	129.52	42.32	132.38	43.57	-0.333	0.740
SGPT (ui/l)	226.02	97.72	222.86	91.64	0.167	0.868
Lipase	93.35	14.88	91.97	7.04	0.593	0.555
Amylase	59.92	13.40	61.00	14.12	-0.393	0.695
Direct bilirubin (mmol/l)	41.56	12.14	42.12	12.22	-0.230	0.819
Total bilirubin (mmol/l)	56.82	12.49	56.16	12.85	0.260	0.795

WBC : White blood cells.
 SGOT : Serum glutamic-oxaloacetic transaminase.
 SGPT : Serum glutamic pyruvic transaminase.
 SD : Stander deviation.

Table (3) showed that no statistically significant differences were found between both groups as regards pre-operative and post-operative ultrasound findings.

Table (3): Pre-operative and postoperative ultra-sound in the study groups.

Preoperative	Group A (No.=50)		Group B (No.=50)		Chi square test	
	No.	%	No.	%	χ^2	<i>p</i> -value
Chronic calcular cholecystitis with dilated CBD	20	40.0	16	32.0	0.694	0.405
Non calcular cholecystitis	30	60.0	34	68.0		
<i>Postoperative:</i>						
Edema and collection	5	10.0	7	14.0	0.379	0.538
Normal	45	90.0	43	86.0		

CBD: Common bile duct.

There were no statistically significant differences were found between both groups as regards the post-operative results of laboratory investigations including: Lipase and amylase (Table 4).

Table (4): Post-operative results of laboratory investigations in the study groups.

	Group A (No.=50)		Group B (No.=50)		Independent <i>t</i> -test	
	Mean	SD	Mean	SD	<i>t</i>	<i>p</i> -value
Lipase	78.32	43.77	66.72	45.01	1.307	0.194
Amylase	131.19	69.78	112.93	73.39	1.275	0.205

SD: Stander deviation.

Discussion

The present study revealed that no statistically significant differences were found between both groups as regards gender or age. As the males represented 54% of group A patients and 50% of group B patients whereas females represented 46% of group A patients and 50% of group B patients. The mean age of group A patients was 44.58 ± 15.33 years whereas it was 42.82 ± 15.43 in group B patients.

These findings are comparable to those published by Mohammad et al., [12] who performed their retrospective review database-based study on 780 patients who had undergone diagnostic and therapeutic ERCP as they found that 50.4% of the patients were males and that the mean age of patients was 57.5 years.

The present study revealed no statistically differences were found between both groups as regards

the presence of chronic calculous cholecystitis, non-calculous cholecystitis or common bile duct stones. This finding comes in line with what was published by Solomon and Baillie, [13] that ERCP remains a mainstay in the treatment of choledocholithiasis.

The present study revealed that no statistically differences were found between both groups as regards CBC results [including haemoglobin, WBCs and platelets]. Haemoglobin level is measured before endoscopic procedures since severe anaemia is found in <1% of asymptomatic patients and unsuspected severe anaemia was a risk factor of tissue hypoxia during the perioperative period in many patients and required pre-operative proper treatment. Moreover, the baseline hemoglobin level useful marker to predict the needs of blood transfusion in patients with significant risk for intraoperative blood loss. In addition, Hb levels less than 8g/dL also associated with significant increased incidence of postoperative cardiac morbidity and mortality [14].

The incidence of abnormal platelet counts before elective procedures in previous study was about 0.9% and it strongly correlated with the management [15]. Meanwhile, an elevated WBC count is an indicator of acute cholecystitis [16].

The present study revealed also that no statistically differences were found between both groups as regards the pre-operative results of liver and kidney function tests. The significance of measuring creatinine level is that high serum creatinine is a well-known unfavorable prognostic parameter in acute pancreatitis and that elevated creatinine at 48 h after admission was recently described as a marker for pancreatic necrosis [17]. On the other hand, invasive procedures as ERCP can result in elevated liver function tests [18].

The present study revealed that that no statistically differences were found between both groups as regards the pre-operative lipase and amylase as well as direct and total bilirubin. Also, no statistically differences were found between patients in both groups of this study as regards pre-operative ultrasound findings. Balance between both groups in the baseline characteristics [age, gender, history, pre-operative results of laboratory investigations and ultrasound findings] provides the basis for comparison between the study groups as it helps to minimize bias.

The present study revealed no statistically differences were found between both groups as regards post-operative ultrasound findings and lipase and amylase, indicating no statistically significant

differences between ERCP performed with cannulation of the common bile duct and ERCP performed with sphincterotomy as regards the incidence of post-ERCP pancreatitis. Post-ERCP pancreatitis might be recognized early after the procedure by assessing the serum amylase or lipase levels [19].

According to a Minakari et al., [20] study assessment of the serum amylase and lipase level 2-4h post-ERCP were useful in early prediction of post-ERCP pancreatitis at cut off of 241 IU/L [normal range: 28-100 IU/L], serum amylase had a very high negative predictive value [NPV] value equal to [98.7%] but with poor positive predictive value [49.2%].

That is why guidelines have suggested to test serum amylase or lipase 2-6h after ERCP procedures in patients suffering from abdominal pain and who are to be discharged on the day of ERCP and the patients can be discharged safely if serum amylase level is less than 1.5 times the upper limit of normal or lipase value is less than 4 times the upper limit of normal [21].

The limitation of the current study included a relatively small sample size did not provide much statistical power for the results, and our data report the practice in a tertiary center, which are possibly not generalizable. Also, long term complications of the procedure were not included in this study.

Conclusion:

It can be concluded that sphincterotomy was not associated with an increased incidence of post-ERCP pancreatitis when compared with cannulation of the common bile duct. Future researchers were recommended to replicate this study on a wider scope and with longer follow-up periods.

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دور قطع المصرة الغائره أثناء عملية تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع على حدوث الإلتهاب الحاد للبنكرياس

إن تقنية تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع هي مزيج بين تقنيات التنظير الباطنى والتنظير الفلورى التى تستخدم لفحص قنوات البنكرياس والقنوات الصفراوية. وتتمثل دواعى إجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع فى اليرقان الإندسادى، علاج الأمراض المتعلقة بجهاز القنوات البنكرياسية والصفراوية أو أخذ عينات من أسجتها، عند الشك فى وجود سرطان البنكرياس، إلتهاب البنكرياس غير معلوم السبب، تركيب دعامة صفراوية لوجود ضيق أو تسريب، تصريف الاكياس الكاذبة بالبنكرياس بالإضافة لتوسيع حليلة الإثنى عشر أو ضيق القنوات باستخدام البالون.

ويترتب على تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع العديد من المضاعفات التى تتمثل فى حدوث إلتهاب بالبنكرياس، حدوث عدوى بالقنوات الصفراوية أو المرارة، حدوث نزيف، حدوث رد فعل غير طبيعى للمهدئ المستخدم متمثلاً فى مشاكل تنفسية أو قلبية، حدوث ثقب بالقنوات الصفراوية أو البنكرياسية أو الإثنى عشر بالإضافة لتضرر الأنسجة من إستخدام الأشعة السينية. ويعد إلتهاب البنكرياس أحد أخطر المضاعفات التى تحدث بعد إجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع وأكثرها شيوعاً حيث يؤدى إلى مشاكل صحية فضلاً عن الوفاة فى بعض الأحيان. ويحدث إلتهاب البنكرياس ما بعد إجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع فى ٢-١٠٪ من الحالات وتصل النسبة إلى ٤٠٪ من الحالات التى بها عوامل خطورة والتى يمكن تقسيمها إلى: عوامل خطورة متعلقة بالمريض وعوامل خطورة متعلقة بمقدم الخدمة وعوامل خطورة متعلقة بالإجراء ذاته.

إن قطع المصرة الغائره بإستخدام المنظار هو إجراء أثناء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع والذى يتم إجراؤه إما لعلاج أو لتسهيل إجراء تدخلات علاجية لاحقة بالقنوات الصفراوية مثل إستخراج حصوة أو تركيب دعامة. وتحدث المضاعفات مع هذا الإجراء فى ٢.٥ - ١١.٨٪ من الحالات وتتمثل فى حدوث نزيف، ثقب، إلتهاب البنكرياس ويعد التشخيص المبكر لهذه المضاعفات والتعامل معها أساسياً.

وهذه الدراسة هي دراسة مستقبلية، تم إجراؤها على مائة مريض مؤهلين لإجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع بهدف دراسة تأثير قطع المصرة الغائره من حيث تقليل أو زيادة احتمالية حدوث إلتهاب بالبنكرياس ما بعد إجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع. وقد تم تقسيم المرضى عشوائياً إلى مجموعتين حيث تم إجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع للمجموعة أ من خلال قنينة القناة الصفراوية المشتركة فى حين تم إجراؤه للمجموعة ب من قطع المصرة الغائره بالمنظار، وقد تمت متابعة المرضى لمدة ٤٨ ساعة بعد الإجراء من خلال فحص مستويات الأميلين والليباز بالدم بالإضافة للفحص بالموجات فوق الصوتية على البطن والحوض. وقد تم إجراء هذه الدراسة بقسم جراحة الجهاز الهضمى والكبد بمستشفى الأزهر الجامعى بأسسيوط وذلك خلال الفترة من يناير ٢٠١٨ حتى يونيو ٢٠١٩.

تمت مراجعة البيانات التى تم تجميعها وتكويدها والتعامل معها وتحليلها بإستخدام برنامج الحزمة الإحصائية للعلوم الإجتماعية (SPSS) لنظام التشغيل ويندوز النسخة ٢٠ مع إستخدام الإختبار الملائم لإجراء المقارنة بين المجموعتين وقد تم إعتبار ($p < 0.05$) ذات دلالة إحصائية و ($p < 0.01$) ذات دلالة إحصائية عالية و ($p < 0.001$) ذات دلالة إحصائية عالية جداً.

وكانت أبرز نتائج هذه الدراسة هي عدم وجود إختلاف ذى دلالة إحصائية بين إجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع من خلال قطع المصرة الغائره بالمنظار أو من خلال قنينة القناة الصفراوية المشتركة من حيث نتائج الفحص بالموجات فوق الصوتية على البطن والحوض أو مستويات الأميلين والليباز بالدم ما بعد الإجراء، ولكن هذه النتيجة تسرى فقط على الـ ٤٨ ساعة الأولى ما بعد الإجراء.

وقد خلصت الدراسة إلى أن قطع المصرة الغائره بالمنظار لم يكن مصحوباً بزيادة فى معدلات حدوث إلتهاب البنكرياس ما بعد إجراء تصوير البنكرياس والأقنية الصفراوية بالتنظير الباطنى بالطريق الراجع وذلك مقارنة بإجرائه من خلال قنينة القناة الصفراوية المشتركة.