

Study of patients undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP) at Tishreen University Hospital in Lattakia – Syria

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Abstract: Objective: The aim of this study is to evaluate the indications, findings, and complications of performing Endoscopic Retrograde Cholangiopancreatography (ERCP).

Patients and Methods: A Prospective Observational Descriptive study conducted for the period from January 2020 to January 2021, 167 consecutive ERCP were performed at Tishreen University Hospital in Lattakia-Syria.

Results: The median age was 58 years, 59.30% of patients were female. The most common indications for ERCP were common bile duct stones (44.9%) and obstructive jaundice (44.3%). The median number of attempts for cannulation was 2 counts, and 74.3% of the procedures were graded as with difficulty grade 1. The most common abnormal findings were common bile duct dilation (50.3%) and bile duct stones (43.7%). The most therapeutic endoscopic interventions were sphincterotomy (64.7%) and stone extraction balloons (68.9%). The therapeutic success rate was 93.5% with repeated the procedure and complications occurred in (10.8%) of patients. The most frequent complication was mild pancreatitis (6%). Death was reported in five cases (3%), one of them (0.6%) was due to ERCP.

Conclusion: ERCP is a potential risk for complications, so physicians should be adept at recognizing and treating any complications as soon as they arise.

Keywords: Endoscopic Retrograde Cholangiopancreatography, ERCP, Post –ERCP pancreatitis, sphincterotomy.

دراسة مرضى التنظير الراجع للطرق الصفراوية والبنكرياسية في مستشفى تشرين الجامعي في اللاذقية - سوريا

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المستخلص: هدفت الدراسة إلى تقييم الاستطبابات، الموجودات وتواتر الاختلاطات المرتبطة باستخدام التنظير الراجع للطرق الصفراوية والبنكرياسية (ERCP).

طريقة البحث: دراسة رصدية وصفية مستقبلية أجريت على مدى سنة واحدة (كانون الثاني 2020-كانون الثاني 2021)، تم إنجاز 167 تنظير راجع للطرق الصفراوية والبنكرياسية في مستشفى تشرين الجامعي في اللاذقية-سوريا عند مرضى مع استطباب مناسب.

النتائج: معدل العمر كان 58 سنة، 59.3% من المرضى إناث. مثلت حصيات القناة الجامعة الصفراوية (44.9%) واليرقان الانسدادي (44.3%) الاستطبابات الأكثر شيوعاً. بلغ العدد الوسطي لمحاولات تنبيب الحليمة 2 محاولة (1-25 محاولة) وكانت درجة صعوبة الإجراء من الدرجة الأولى لدى 74.3% من عينة البحث. مثل توسع القناة الصفراوية (50.3%) وحصيات القناة الصفراوية (43.7%) أكثر موجودات الإجراء ملاحظة، وأن خزع الحليمة الداخلي (64.7%) واستخدام بالون سحب الحصيات (68.9%) كانت أكثر التداخلات العلاجية. بلغ معدل نجاح الإجراء العلاجي 83.5% وارتفع إلى 93.5% مع تكرار المحاولات مع حدوث الاختلاطات في 10.8% من المرضى، ومثل التهاب البنكرياس الخفيف (6%) الاختلاط الأكثر شيوعاً، مع وفيات بمعدل 3%. الاستنتاج: يعتبر التنظير الراجع للطرق الصفراوية والبنكرياسية خطراً كامناً لحدوث الاختلاطات لذلك يتوجب على الأطباء تمييز وعلاج هذه الاختلاطات مباشرة عند حدوثها.

الكلمات المفتاحية: التنظير الراجع للطرق الصفراوية والبنكرياسية، التهاب البنكرياس التالي للتنظير الراجع للطرق الصفراوية والبنكرياسية، خزع الحليمة الداخلي

Introduction.

Endoscopic Retrograde Cholangiopancreatography (ERCP) is an endoscopic technique in which a specialized side-viewing upper endoscope is guided into the duodenum, allowing for instruments to be passed into the bile and pancreatic ducts [C handrasekhara V et al 2017, Coelho-Prabhu N et al].

Since its introduction in 1968, ERCP has become a commonly performed endoscopic procedure [Adler DG et al 2005]. The diagnostic and therapeutic utility of ERCP has been well demonstrated for a variety of disorders, including management of choledocholithiasis, diagnosis and management of biliary and pancreatic neoplasms, and the postoperative management of biliary perioperative complications [Cohen S et al 2002, Cotton PB 2006]. The evolution of the role of ERCP has occurred simultaneously with that of other diagnostic and therapeutic modalities, most notably magnetic resonance imaging (MRI)/MRCP (Magnetic resonance cholangiopancreatography) [Maple JT et al 2010]. The appropriate use of ERCP and avoidance of this procedure when it is contraindicated or when there are alternative diagnostic procedures is a quality issue for gastrointestinal endoscopists [Zuckerman M] et al 2007].

The most frequent complications of ERCP are pancreatitis, cholangitis, hemorrhage, and duodenal perforation [Vandervoort J et al 2002]. Also, a number of less common adverse events have been described including cardiopulmonary complications, contrast allergy, impaction of a retrieval basket, and numerous other events reported in only small numbers of patients. These uncommon adverse events, which may be difficult to manage, can be associated with significant morbidity and mortality [Anderson MA et al 2012, Mallery JS et al 2003].

Numerous studies have helped to determine the expected rates of complications, potential contributing factors for these adverse events, and possible methods for improving the safety of ERCP. The aim of the study is to evaluate the indications, findings, and frequency of complications of ERCP.

Patients and Methods

This is a Prospective Observational Descriptive study of a group of patients who underwent ERCP procedures in the Department of Gastroenterology at Tishreen University Hospital in Lattakia-Syria during one year (January 2020 to January 2021).

The demographic characteristics (age, sex) were recorded. Indications, findings, and difficulty of ERCP according to Schultz's grading system were also investigated [Schutz SM 2011]. Exclusion criteria were patients with one of the following: active pancreatitis, patients who underwent ERCP to remove stents after cholecystectomy, and presence of gastric outlet obstruction. Patients were followed for 30 days, and post ERCP complications were defined based on those described by Cotton et al and recorded [Cotton PB et al 1991].

Statistical Analysis

Statistical analysis was performed by using IBM SPSS version20. Basic Descriptive statistics included means, standard deviations (SD), median, frequency, and percentages. Differences of distribution were examined by using chi- square test or Fisher exact test if it needs. An independent t student test was used to compare two independent groups. P- value <0.05 was considered statistically significant.

Results.

A total of 191 patients who presented to the Department of Gastroenterology from January 2020 to January 2021, 24 patients were excluded according to the exclusion criteria. 167 consecutive patients underwent therapeutic ERCP, and the baseline characteristics of patients are as given in table (1). The median age of patients who enrolled in the study was 58 years, and 59.30% were female. There was a previous history of ERCP in 41.3% and sphincterotomy in 39.5%. The most common indications for ERCP were common bile duct stones (44.9%) and Obstructive jaundice (44.3%). Some patients may have more than one indication for performing ERCP.

Table (1) Demographic characteristics and Indications of ERCP of the study population

Variables	
Age(years)	58(13-86)
<u>Sex</u>	
Male	68(40.7%)
Female	99(59.30%)
History of ERCP	41.3%
Previous sphincterotomy	39.5%

Variables	
<u>Indications of ERCP</u>	
Common bile duct stones	75(44.9%)
Obstructive jaundice	74(44.3%)
Suspicion of tumor	31(18.6%)
Stent replacement	15(9%)
Cholangitis	13(7.8%)
Biliary pancreatitis	10(6%)
Chronic pancreatitis	7(4.2%)
Bile duct leaks(post-surgery)	5(3%)
Traumatic injury	3(1.8%)
Pancreatic cyst	2(1.2%)

The median manipulation time around the papillary orifice was 5 minutes (range:1-45 minute). The median number of attempts was 2 counts (range:1-25), with a number of attempts <5 times in 75.4% and difficulty in cannulation in 24%. The median time of the ERCP process was 35 minutes (range:15-100 minute). 74.3% of the procedures were graded as with difficulty grade 1 with normal major papilla in 57.5%, Table (2).

Table (2) Characteristics of ERCP procedure

<u>Manipulation time around papillary orifice(min)</u>	
< 5	63(37.7%)
5-10	66(39.5%)
>10	38(22.8%)
<u>Number of cannulation attempts</u>	
< 5	126(75.4%)
5-10	19(11.4%)
>10	22(13.2%)
<u>ERCP difficulty grading</u>	
Grade 1	124(74.3%)
Grade 2	37(22.2%)
Grade 3	6(3.6%)
<u>Major papilla morphology</u>	
Normal	96(57.5%)
Small	32(19.2%)
Edematous	24(14.4%)
Tumoral	15(9%)

As shown below (Table 3), the most common abnormal findings were common bile duct dilation (50.3%) and bile duct stones (43.7%), with normal findings in 7.2%. Some patients may have more than one abnormal finding of ERCP.

Table (3) Findings of ERCP procedure

Findings	N (%)
Normal	12(7.2%)
Common bile duct dilation	84(50.3%)
Common bile duct stones	73(43.7%)
<u>Bile duct stricture</u>	40(24%)
benign	15(9%)
Malignant	25(15%)
Sphincter of oddi dysfunction (SOD)	7(4.2%)
Chronic pancreatitis with/ without pancreatic stones	5(3%)
Bile duct leaks	5(3%)
Common bile duct stones with Mirizzi syndrome	2(1.2%)
Peripapillary abscess	1(0.6%)

Tumors were found in 31(18.6%) patients, most of them were cholangiocarcinoma (7.78%) followed by pancreatic cancer (4.79%).

Sphincterotomy was performed on 108(64.7%) patients and stone extraction balloons in 115(68.9%). Stent placement was applied during ERCP on 89 (53.3%) patients, and plastic stents were used frequently, Table (4). Some patients may undergo more than one therapeutic endoscopic intervention.

Table (4) Therapeutic endoscopic interventions during ERCP

Sphincterotomy	108(64.7%)
Pre-cut	30(18%)
<u>Stone extraction balloons</u>	115(68.9%)
Removal of stones	65(38.9%)
Sludge	21(12.6%)
Stones, Sludge, pus	3(1.8%)
Pus	2(1.2%)
None	24(14.4%)
<u>Stent placement</u>	89(53.3%)
<u>Bile duct stent</u>	83(49.7%)
Plastic	4(2.4%)
metal	2(1.2%)

<u>Pancreatic duct stent(plastic)</u>	
Stent removal	38(22.8%)
Balloon dilation of papilla	16(9.6%)
Tissue sampling from papilla	7(4.2%)

The rate of bile duct cannulation success was 95.8%. ERCP therapeutic success rate for the first time was (83.5%) which increased to (93.5%) with the repeated procedures.

The total rate of complications was (10.8%). The most common complication was mild pancreatitis (6%), followed by cholangitis (3%) and bleeding (1.2%) which occurred in association with cholangitis and common bile duct perforation. A single event of bile duct perforation was occurred after multiple manipulations of guidewire insertion to pass a fibrotic stricture due to surgical injury of the bile duct. The contrast medium leakage occurred during the procedure and developed bleeding later necessitating blood transfusion and surgery. Some patients may have more than one complication post-ERCP.

The 30-day mortality rate was (3%), one case was related to ERCP and four cases were non-related to ERCP (3 cases due to progressive metastatic disease and one case because of cardiac arrest after procedure immediately), Table (5).

Table (5) Complications of ERCP procedure

complication	N (%)
<u>Post –ERCP pancreatitis</u>	<u>11(6.6%)</u>
Mild	10(6%)
Moderate	1(0.6%)
<u>Post –ERCP cholangitis</u>	<u>5(3%)</u>
Mild	2(1.2%)
Moderate	2(1.2%)
Severe with acute purulent cholecystitis	1(0.6%)
Post –ERCP bleeding	2(1.2%)
Post –ERCP perforation (Bile duct)	1(0.6%)
Post –ERCP cardiac vascular complication	1(0.6%)
Total of mortality within 30 days	5(3%)
ERCP- specific mortality	1(0.6%)
Non- ERCP- mortality	4(2.4%)

ERCP therapeutic failure rate was associated with the presence of bile stones (64.9% vs. 37.7%, p: 0.003). The total time of procedure was significantly longer in non- survivors (65±25.1 vs. 38.8±16.5, p: 0.002).

Post –ERCP pancreatitis was significantly associated with the presence of difficult cannulation (p:0.0001), inserting a guidewire into the pancreatic duct(p:0.001), and Pre –cut (p:0.01) Table (6).

Table (6) Correlation between Post –ERCP pancreatitis rate and the variables of study populations

Variable	Post –ERCP pancreatitis		p-value
	Present	Absent	
<u>Sex</u>			
Male	5(45.5%)	63(40.4%)	0.6
Female	6(54.5%)	93(59.6%)	
Age (years)	44[34-73]	58[13-86]	0.1
Difficult cannulation	8(72.7%)	32(20.5%)	0.0001
<u>ERCP difficulty grading</u>			
Grade 1	9(81.8%)	115(73.7%)	0.7
Grade 2	2(18.2%)	35(22.4%)	
Grade 3	0(0%)	6(3.8%)	
Peripapillary diverticulum	1(9.1%)	22(14.1%)	0.6
Stone extraction balloons	7(63.6%)	108(69.2%)	0.6
Bile stones	4(36.4%)	69(44.2%)	0.6
Inserting a guidewire into the pancreatic duct	8(72.7%)	39(25%)	0.001
Pre -cut	6(54.5%)	24(15.4%)	0.01
Sphincterotomy	8(72.7%)	100(64.1%)	0.5

Discussion

In the last years, ERCP has evolved from a diagnostic to a predominantly therapeutic procedure, and the use of this tool seems to be increasing. Even though considered safe, ERCP is among the endoscopic procedures associated with the highest rate of complications [Costamagna G et al 2008, Masci E et al 2007].

The subject of the research is well known in Syria, but for the first time, the procedure is studied in a detailed analytical manner, as well as the study of complications. All previous studies focused on complications mainly.

Our study demonstrated that common bile duct dilation and bile duct stones were the most frequent findings on ERCP. In addition, tumors were found in 18.6%, most of them were cholangiocarcinoma. The major endoscopic interventions applied during ERCP were sphincterotomy, stone extraction balloons, and stent placement. Our data also demonstrated that ERCP had a good therapeutic success rate in the first time which increased with the repeated procedures. The frequency of

complications in this study was (10.8%), and pancreatitis was the most common complication of ERCP with a high mortality rate (3%). Post –ERCP pancreatitis was significantly associated with the presence of difficult cannulation, inserting a guidewire into the pancreatic duct, and Pre –cut. These results are comparable to the findings reported by previous studies.

Dinesh *et al* (2003) at Auckland Hospital in New Zealand found that successful diagnostic and therapeutic ERCP was performed in 93% with an overall complication rate of 9.5%. The incidence of pancreatitis was 4.76% without the occurrence of procedure- related mortality [Dinesh L *et al* 2003].

Alireza *et al* (2019) in Shahroud, Iran demonstrated that the bile duct cannulation success rate was 92.3% and the therapeutic success rate was 88.5%. The complications rate was 18.7%. Mild pancreatitis was the most common complication (7.7%) and risk factors associated with Post –ERCP pancreatitis were difficult cannulation and inserting a guidewire into the pancreatic duct [Alireza *et al* 2019].

Tarikci *et al* (2019) in Istanbul, Turkey found that the bile duct cannulation success rate was 97.45% and the therapeutic success rate was 90.3%. Choledocholithiasis was found in 65.45%, post-ERCP pancreatitis was observed in 4%, and the mortality rate was 1.64% [Tarikci *et al* 2019].

Choudhury *et al* (2020) in North East India found that cannulation of the desired duct was successful in 89.2% of ERCP and the therapeutic success rate was 82.6%. The most common indication was choledocholithiasis (63.97%) followed by malignancy (26.3%). Post ERCP complications developed in 9.2% and pancreatitis was the most common complication [Choudhury *et al* 2020].

In summary, ERCP is an important method for managing the pancreatic-biliary diseases, Identification of risk factors for post- ERCP complications is crucial in reducing its occurrence.

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