

# EC GASTROENTEROLOGY AND DIGESTIVE SYSTEM Research Article

# Endoscopical Retrograde Cholangiopancreatography. A Big Success? Multicentre Study in México

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Received: May 23, 2022; Published: June 13, 2022

# **Abstract**

**Introduction:** Endoscopic Retrograde Cholangiopancreatography is defined as a specialized medical procedure that combines technical elements of gastrointestinal endoscopy with radiological technical elements, in diagnostic and treatment scenarios, of diseases of the digestive system at the level of the biliary tract and pancreas, allowing visualization of the bile ducts and pancreatic ducts.

**Method:** It is a study with retrospective, longitudinal, comparative, observational and descriptive design. The presentation of the results is carried out through descriptive biostatistical procedures, through which the census data of works and studies compiled from all the patients who underwent Endoscopic Retrograde Cholangiopancreatography due to biliary pathology and/or pancreas in the endoscopy services of nine hospitals of second and third level of health care in Mexico.

Results: There were a total of 2,272 patients, of whom 1,362 were women (60%) and 910 men (40%). With an age range of 17 to 90 years, with an average of 44 years of age, at a bimodal value of 38 and 46 years. A number of failed Endoscopic Retrograde Cholangiopancreatographies is described in 153 representing 7%. On the other hand, in 180 patients (8%) post-procedure complications were reported. Despite what was previously described, success in the diagnostic-therapeutic objective is reported, in a range of 88 to 98% and an average of 94%.

**Conclusion:** Endoscopic Retrograde Cholangiopancreatography is currently a very successful pillar in the diagnosis and treatment of pancreatobiliary diseases, with minimal morbidity, as well as mortality; (Thanks to the advancement of medical technology, this study is positioned, significantly, above surgical procedures of yesteryear and obsolete techniques, in the context of pancreatobiliary disease, in terms of diagnosis and treatment.

Keywords: Endoscopic Retrograde Cholangiopancreatography; Procedure. Endoscopy; Biliary Pathology; Pancreatic Pathology

# Introduction

Endoscopic Retrograde Cholangiopancreatography (ERCP) is defined as a specialized medical procedure that combines technical elements of gastrointestinal endoscopy with radiological technical elements, in diagnostic and treatment scenarios, of diseases of the digestive system at the level of the biliary tract and pancreas, allowing visualization of the bile ducts and pancreatic ducts [1]. It consists of accessing, from the patient's mouth, the duodenum, with a duodenoscope-type endoscope, locating and cannulating the duodenal papilla with a small catheter, to instill radiological contrast material, allowing, by taking the radiological study, visualization of the bile ducts and the ducts of the pancreas [2]. The first ERCP is documented in 1968 [3] and the first sphincterotomy of the duodenal papilla, 5 years later [4,5].

# Aim of the Study

To describe the experience and results of the endoscopy services of nine different hospitals of second and third level of health care in the United Mexican States (Mexico) in the performance of ERCPs, in relation to the success and associated complications, within the period 2013. to January 2022, with a statistical, deductive, critical, logical and impartial analysis.

#### Methods

It is a study with retrospective, longitudinal, comparative, observational and descriptive design. The presentation of the results carried out through descriptive biostatistical procedures, where the work and files of all the patients who undergo ERCP for biliary and/or pancreatic pathology in the Endoscopy services of nine second and third-grade hospitals are reviewed. level of health care in Mexico:

- 1. General Hospital "Dr. Ruben Lenero. Secretary of Health of Mexico City. Country: MEXICO. 2<sup>nd</sup> level.
- 2. Juarez Hospital in Mexico. Federal Health Secretariat. Mexico City. Country: MEXICO. 3rd level [6].
- 3. Xoco General Hospital. Secretary of Health of Mexico City. Country: MEXICO. 2<sup>nd</sup> level [7].
- 4. Villa General Hospital. Secretary of Health of Mexico City. Country: MEXICO. 2nd level [7,8].
- 5. Juarez Hospital of the Center. Federal Health Secretariat. Mexico City. Country: MEXICO. 2nd level [7].
- 6. Tacuba General Hospital. Institute of Security and Social Services for State Workers. Mexico City. Country: MEXICO. 2nd level [9,10].
- 7. General Hospital of Mexico "Dr. Eduardo Liceaga". Federal Health Secretariat. Mexico City. Country: MEXICO. 3rd level [11,12].
- 8. General Hospital of Iztapalapa "Dr. Juan Ramon De La Fuente. Secretary of Health of Mexico City. Country: MEXICO. 2<sup>nd</sup> level [13].
- 9. General Hospital "Dr. Ernesto Ramos Bours". Secretary of Health of the State of Sonora. Hermosillo City. Country: MEXICO. 2<sup>nd</sup> level [14].

**Statistical method:** Through descriptive biostatistics studies with a sample of consecutive cases, making 2 x 2 contingency tables, with cohort designs and odds ratio, the difference between groups was analyzed using Fisher's exact probability and Pearson's X2, with a package SPSS 25 statistic. The 95% confidence interval is calculated using the normal approximation of the binomial distribution. In some values, the Mantel-Haenszel-Yates corrections are applied to increase reliability.

The period in which the included and analyzed studies were carried out, comprises from January 2013 to January 2022. Age, sex, risk factors for complications, comorbidities, average duration of the procedure, type of procedure were taken into account. anesthesia

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applied, or the evasion of its use with each ERCP, success and failure rates, morbidity due to complications of each ERCP, due to factors related to the disease or patient comorbidity, diagnostic indications, general morbidity, mortality and finally special remarks.

#### Results

Of the total of 2,272 patients, 1,362 (60%) were women and 910 (40%), men, with an age range of 17 to 90 years, with an average of 44 years, at a bimodal value of 38 and 46 years. 153 failed ERCPs are described, that is, 7%; caused by intolerance to the study, since in more than 70% they are carried out without anesthetic management, the rest of the causes are sporadic, such as poor preparation, lack of fasting, hemodynamic instability; among others). On the other hand, the number of post-study complications occurred in 180 patients who they are 8%. Despite what was previously described, success in the diagnostic-therapeutic objective is reported, in a range of 88 to 98% and an average of 94%. See table 1. The diagnostic indications for performing an ERCP were grouped into six categories, where choledocholithiasis is the main and most frequent suspected diagnosis, with a much higher number of cases than the others by 83% (1,896) (Figure 1). Second place is occupied by residual choledocholithiasis, comprised of only 6% (144 patients), and third place is cholangitis in 5% (120 cases). Various neoplasms were confirmed in 64% patients, 3% of the study population. See table 2. Regarding the associated comorbidities of patients who underwent ERCP, obesity is documented as the most frequent in 27%, followed by diabetes mellitus in 13% and in third place arterial hypertension in 12. %, see more detail in table 3.

Comorbidity/Studies	CR	Н	M	CF	CO	% E
1. Moreno., et al.	524/23	246/47	278/53	11/2	52/10	98
2. Fuentes., et al.	172/8	59/34	113/66	24/14	23/13	91
3. Perez., et al.	621/27	258/42	363/58	90/14	0	98
4. Zurita., et al.	216/10	83/38	133/62	6/7	37/17	93
5. Macedo., et al.	73/3	35/48	38/52	3/4	9/12	99
6. Verdezoto., et al.	240/4	86/36	154/64	6/3	7/3	98
7. Goroztieta., et al.	148/7	61/41	87/59	2/1	22/15	93
8. Hurtado., et al.	176/8	48/27	128/73	5/3	25/14	96
1. Scotus., et al.	60/3	21/35	39/65	3/5	2/3	90
2. Terán., et al.	42/2	13/31	29/69	5/12	3/7	88
Total	2272	910/40	1362/60	155/7	180/8	94

Table 1: General data of endoscopic retrograde cholangiopancreatography by number/percentage (%).

ACOT:

CR: ERCP Performed; H: Men; W: Women; CF: Failed ERCP; OC: Complications; E: Success.

Comorbidity/Studies	COLE	CANC	PANC	FIST	CO-RE	COLA
1	449/86	17/3	2/1	4/1	38/7	14/3
2	160/93	4/2	0	2/1	6/4	0
3	544/88	14/2	1/1	13/2	28/4	21/3
4	145/67	8/4	0	1/1	14/6	48/22
5	61/83	3/4	0	3/1	4/5	2/3
6	169/70	4/2	9/4	6/3	24/10	28/12
7	128/73	5/3	0	2/1	13/9	0
8	160/91	4/2	0	3/2	6/3	3/2
9	54/90	3/5	0	0	3/5	0
10	26/62	2/5	0	2/3	8/19	4/9
Total	1896/83	64/3	12/1	36/2	144/6	120/5

**Table 2:** Diagnostic indications for performing ERCP with endoscopic retrograde cholangiopancreatography by number/percentage (%). ACOT:

COLE: Choledocholithiasis; CANC: Cancer; PNC: Pancreatitis; FIST: Fistula; CORE: Residual Choledocholithiasis; COLA: Cholangitis.

ACOT:

Comorbidity/Studies	HAS	DM	0	IRC	С	AR	Н	D
1	79/15	94/18	114/21	1/1	3/1	1/1	1/1	31/6
2	11/6	29/17	76/44	0	0	0	0	0
3	67/11	71/11	126/11	2/1	2/1	2/1	0	11/2
4	37/17	23/11	85/39	1/1	0	1/1	0	3/1
5	6/8	4/5	39/53	1/1	2/3	0	1/1	2/3
6	12/5	21/9	66/28	0	0	0	0	4/2
7	24/16	18/12	30/20	2/1	1/1	0	5/3	2/1
8	15/9	26/15	51/29	1/1	2/1	2/1	1/1	0
9	9/15	6/10	17/28	0	0	0	0	1/2
10	8/19	2/5	9/21	2/5	1/2	1/2	1/2	0
TOTAL	268/12	294/13	613/27	10/1	11/1	7/1	9/1	54/2

 $\textbf{\textit{Table 3:}} \ Associated \ comorbidities \ in \ patients \ with \ endoscopic \ retrograde \ cholangiopan creatography \ by \ number/percentage.$ 

DM: Diabetes Mellitus; SAH: Systemic Arterial Hypertension; OR: Obesity; CKD: Chronic Kidney Failure; C: Heart Disease; RA: Rheumatoid Arthritis; H: Liver Disease; D: Various.

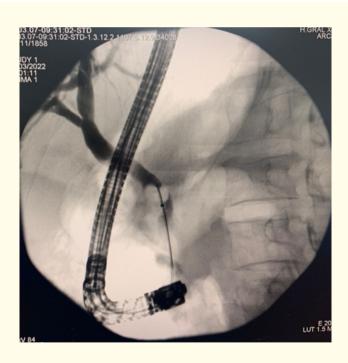


Figure 1: Cholangiography: Stone in distal third of common bile duct.

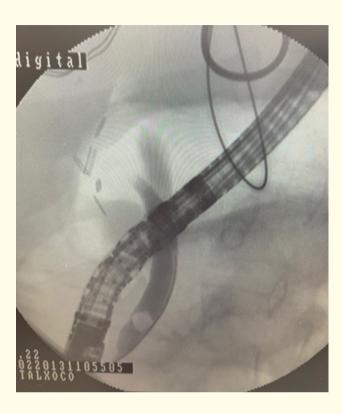


Figure 2: Cholangiography: Residual choledocholithiasis.

313 patients are exposed as a diagnosis of normal ERCP, which represent 14% of the total number of studies carried out and an average of 35 minutes without anesthesia and 42 minutes with it were timed. Intraoperatively, it averaged 110 minutes with cholecystectomy.

Post-ERCP complications reported with an average percentage less than 8% are broken down, with acute pancreatitis becoming the most frequent, covering 70% of all cases. Of these acute pancreatitis, only two cases required Intensive Care for severe acute pancreatitis and ARDS (Acute Respiratory Insufficiency Syndrome). Fifteen cases of post-study bleeding are documented, requiring only conservative management. Ten perforations are reported, seven postoperative (performed during surgery) and three typical of ERCP, with aggressive and immediate surgical management in six patients and the rest with the use of endoprostheses and/or conservative management. When complications after ERCP are compared, in each of the hospitals in this study, using the X² test, no significant statistical evidence was demonstrated at a likelihood ratio of 2850, and 34 cases with cholangitis less than 1% were tabulated. See table 4. On the other hand, morbidity was minimal, two cases presented nosocomial pneumonia, as well as three patients urinary tract infection and four presented surgical wound infection. Mortality was below 1%, which occurred in four patients, due to intestinal perforation in three of them and in the last due to severe acute pancreatitis with ARDS. The ordinal groups are compared in a multivariate analysis, mortality was associated with the complication of the underlying disease such as cholangitis, acute pancreatitis, cancer, with Fisher's exact probability and X² without being able to show statistical difference (p = 0.019), between one hospital from another.

Comorbidity/Studies	PAN	COR	COL	SAN	PER	cos
1	45/9	3/1	12/2	0	0	0
2	7/4	0	8/5	5/3	3/2	0
3	0	0	0	0	0	0
4	25/12	0	8/4	2/1	0	2/1
5	2/3	0	3/4	2/3	2/3	0
6	2/1	0	2/1	1/1	2/1	0
7	16/11	0	1/1	3/2	1/1	0
8	19/11	3/2	1/1	1/1	1/1	0
9	0	1/2	0	1/2	0	1/2
10	2/5	1/2	0	0	1/2	0
Total	118/5	8/1	34/1	15/1	10/1	3/1

**Table 4:** Complications of performing endoscopic retrograde cholangiopancreatography by number/percentage (%). ACOT:

PAN: Acute Pancreatitis; COR: Residual Choledocholithiasis; COL: Cholangitis; NAS: Bleeding; PER: Drilling; SOC: Cholecystitis.

#### Discussion

Choledocholithiasis is the most common and frequent pathology of the bile ducts in humans, an affirmation that is documented in the results presented in this work, and one of the options for its treatment is the successful use of ERCP; that is why ultrasound in the first place is the ideal study for a diagnostic first (with the disadvantage of being operator-dependent) [15] secondly, due to economic costs and infrastructure, nuclear magnetic resonance imaging or improved computed tomography, but with an unequivocal role, ERCP is the definitive diagnostic and therapeutic weapon [16] the question is, at what time is it indicated to perform this procedure (ERCP) in patients with choledocholithiasis? And the answer is that most authors agree to perform an immediate laparoscopic cholecystectomy after ERCP, in an average time of no more than 72 hours [17-20].

There are special scenarios to perform an ERCP, one of them is in the pediatric population [21,22]. Another indication is to be able to evaluate the efficacy, feasibility, and safety of postoperative anatomy in liver transplant patients [23-25]. A further guideline is in pregnant women as it is a safe procedure during pregnancy, however, radiation-free techniques seem to reduce rates of non-pregnancy related complications, but not those of fetal complications, it is therefore essential to assess risk-benefit [26]. Other special cases is performing ERCPs in periampullary diverticula, which are asymptomatic and are increasingly frequent in the elderly population, translating into a technical challenge, since the location and orientation of the ampulla could be altered, increasing thus the risk of complications (Figure 3) [27-29]. Finally, one more indication that has evolved is transoral endoscopic access to the pancreaticobiliary system, which is a challenge after Roux-en-Y gastric bypass, becoming a viable option to treat patients with symptomatic choledocholithiasis [30-33].

Distinguishing between the studies that are necessary and those that are not is essential for patient safety. For this reason, the American Society for Gastrointestinal Endoscopy (ASGE) classifies the probability of choledocholithiasis into three risk groups: low risk, intermediate risk, and high risk. high; In the same way, some time later, the British Society of Gastroenterology (BSG) carried out specific recommendations to avoid carrying out studies in an unjustified manner, which have been documented in up to 40% of the published works [20,34,35]. On the other hand, intraoperative imaging is decisive in cholecystectomy, avoiding Thus, an unjustified ERCP, such as

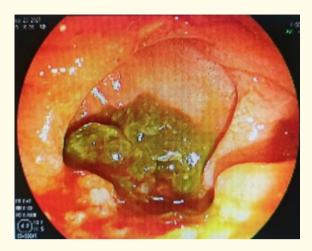


Figure 3: Periampular duodenal diverticulum.

the risks that it entails for the patient, with more days of hospital stay, an exponential increase in economic and healthcare costs in the event of a complication, or failure to extract the stone, evoking residual choledocholithiasis, added to that more than half of patients with asymptomatic choledocholithiasis are detected on intraoperative cholangiography and that they pass the stones spontaneously [36]. In addition, it is essential to perform a cholecystectomy within seven days after an event of acute pancreatitis with this probable etiology, reducing readmissions, morbidity, and mortality [17,20,37,38]. It is to date, 40 years later, what role does ERCP play, since it is still controversial in the treatment of acute pancreatitis of probable biliary etiology, evaluating risk-benefit for its indication in the first 24 to 72 hours in severe acute pancreatitis, but not so, there is still no study backed by enough statistics to make the decision or not to indicate it [39-41].

On the other hand, the training of endoscopist surgeons in hospitals in certain countries uses simulators for training and gaining experience, shortening the learning curve of the physician responsible for performing ERCP [42]. In the process of performing an ERCP, it is inconceivable today, that in the vast majority of hospitals involved in this investigation, there is still a lack of moderate and conscious sedation, which is the enlightened standard to carry out. carried out an ERCP study, so failed studies are reported in up to 7% (155 patients) and 99% are due to patient intolerance for this reason [43].

Intraoperative laparoscopic cholangiography with exploration of the common bile duct and endoscopic retrograde cholangiopancreatography ERCP are two therapeutic techniques to treat choledocholithiasis. However, surgical management is more effective with fewer complications, readmissions, and procedures than the endoscopic option alone [19,20]. At the same time, it happens in residual and recurrent choledocholithiasis, that when performing cholecystectomy surgery with intraoperative cholangiography and confirming disease in the common bile duct, its resolution in the operating room is more feasible, effective and safe than of performing a subsequent ERCP, since it presents a recurrence/residual, of surgery only 2% against the study of 8.9% [19,20,44,45]. It is important to mention that, technically, it has been innovatively combined to perform laparoscopic or conventional cholecystectomy and at the same time perform intraoperative ERCP, successfully and with no complications of pancreatitis [46-48]. In addition, the technological advancement of endoscopic ultrasound in transgastric ERCP directed by this method is documented, making it a most effective and highly efficient procedure, not to mention that endoscopic ultrasonography-guided bile duct drainage has become the standard of care in tertiary referral centers for failed ERCP cases, with metal or plastic stents, as well as, in patients with Bismuth III/IV malignant biliary obstruction [20,49-52].

The factors that have been detected in a multivariate analysis were six predictors of early complications: periampullary precut (Figure 4 and 5), difficult cannulation, the time of care of the procedure (Figure 6 and 7), choledocholithiasis of large elements, the cannulation time and the total duration of the study [53-55] ERCP is safe in critically ill patients in the ICU (Intensive Care Unit) as it does not increase the overall mortality rate and has a relatively low rate of procedure-associated complications [56]. It is mentioned that age (> 65 years) did not increase the risk of developing pancreatitis after ERCP, however, if other factors were detected in the elderly, such as female gender, sphincter of Oddi dysfunction (Figure 8) and the presence of a duodenal or periampullary diverticulum, which slightly increase the risk [57].



Figure 4 and 5: Vater ampule sphincterotomy.



Figure 6 and 7: Difficult cannulation of the ampula of vater.



Figure 8: Cholangiography: With dilation of the extrahepatic bile route vs sphincter of oddi dysfunction.

In the aspect of infections and the endoscopic study, it has been determined that antibiotics before ERCP, especially in the presence of an obstructed biliary system, have been managed with fourth-generation quinolones and third-generation cephalosporins, proving that these have decreased the complications of cholangitis and sepsis, with no differences in the results due to the type of medication; In addition, it was recorded, When there is failed cannulation in ERCP, a significant reduction in general and infectious complications is shown when prophylactic antibiotics are administered [58-60]. It is worth mentioning that the rectal non-steroidal anti-inflammatory is of high prophylactic value in complications due to this interventional study, as well as the use of statins, they have shown a protective action and are currently being evaluated as preventive, in the incidence of acute pancreatitis after ERCP [61-63].

There are four typical or most frequent complications after performing ERCP: acute pancreatitis, post-sphincterotomy hemorrhage, sepsis of biliary origin (cholangitis and cholecystitis) and perforation, both of the papillary area due to sphincterotomy, and of the duodenum by endoscope or by biliary stents [21,54,64-68] and manifest with less than 1% mortality [69,70]. Another factor to take into account is sphincter of Oddi dysfunction or dyskinesia, as they are associated with a high risk of post-ERCP pancreatitis, as well as cholangitis, crampy pain, and jaundice. due to cholestasis. However, these biliary complications have not been sufficiently evaluated [71]. Bile duct bleeding has led to biliary obstruction, with an incidence of sporadic presentation [72]. Or that of an unusual case of multifocal pyogenic abscess formation after the study; therefore, they consider the use of prophylactic antibiotics by the authors [73].

There are determinants that involve performing ERCP, such as the placement of a stent in the pancreatic duct in high-risk patients, managing to prevent post-study pancreatitis, however, it does not work in patients with sphincter of Oddi dysfunction [74]. Expandable metal stents are used to prevent hemorrhage by pre-cutting the sphincter after ERCP, effectively and safely [75,76]. Also essential is the successful therapeutic role played by ERCP with the use of stents, in intraperitoneal bile leak, in bilioma, in biliary fistula and/or type II Stapfer perforation, due to traumatic, surgical or traumatic aetiology. idiopathic; with prior diagnostic confirmation [77-79]. On the contrary, the very use of stents (in benign or malignant pathology) has complications such as migration, which has been reported in 4%, which is why ERCP is by itself, the most effective therapeutic form for its extraction [80]. Another problem that is documented is benign

biliary stenosis after hepatobiliary surgery or liver transplantation, untreatable with endoscopy, where they undergo a cycle of percutaneous treatment consisting of a 20-min balloon dilation session on day one, repeating days three and five, with successful results [80].

Currently, technological advances have resolved the problem of the lack of endoluminal vision of the bile and pancreatic ducts by peroral cholangioscopy, achieving diagnostic fineness and certainty, as well as fewer complications [81]. The other advance in applied technology is 3D image-enhanced Computed Tomography, in combination with ERCP, allowing a detailed intraductal, anatomical, and structural view of biliary disease, for accurate planning, greater success, and fewer complications. in your treatment [82].

### The authors describe the following observations:

- 1. Acute pancreatitis after ERCP is overdiagnosed, a situation associated with various factors such as: abdominal pain after the aforementioned invasive procedure, which in some hospitals is performed without anesthesia, as well as the identification of an increase in enzymes amylase or lipase is not enough, it is considered that the lack of studies such as dynamic pancreatography becomes a key and determining factor for the correct diagnosis and management of this complication.
- 2. Technology, although it tries to facilitate diagnostic-therapeutic procedures for the surgeon, it is notable that surgical skill has also been displaced every day, a clear example is the way in which choledocholithiasis and/or remnants of biliary pathologies are approached. -pancreatic, prioritizing ERCP and leaving in the background a surgical approach reflected in the training of new generations of surgeons with inexperience, expertise and lack of surgical decision, ultimately affecting the patient.
- 3. Some relatively new procedures or studies become fashionable, and the Surgeon, in seeking to update, tends to displace studies such as ultrasound, in particular; a low-cost, accessible study, with high sensitivity and specificity among many other advantages, or to perform an intraoperative cholangiography, an "ancestral technique", which allows anatomical detailing of the bile duct, ruling out anatomical aberrations, surgical injuries and diagnosing in a timely manner a choledocholithiasis avoiding an unnecessary ERCP.
- 4. What is referred to in the previous numerals becomes an act of reflection for current and future generations of surgeons, who as a surgical guild must avoid incomplete, deficient or poor quality surgical medical praxis.

## Conclusion

ERCP is currently a very successful pillar in the diagnosis and treatment of pancreaticobiliary diseases with minimal morbidity and mortality. Thanks to the advancement of medical technology, this study is positioned, significantly, above surgical procedures of yester-year and obsolete techniques, in the context of pancreatobiliary affection, in terms of diagnosis and treatment. ERCP is currently a brutally effective and efficient weapon in the ongoing battle against disease, with invaluable benefits for physician and patient.

# **Conflict of Interests**

The authors declare that they have no conflict of interest.

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