



## Treatment of Biliopancreatic Diseases by Endoscopic Retrograde Cholangiopancreatography. Retrospective Analysis of Twenty-five Years in a Tertiary Reference Center

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### Abstract

**Introduction:** The Endoscopic retrograde cholangiopancreatography (ERCP) is the main therapeutic procedure at the present time like complement of the minimally invasive surgery of the biliary tracts and of the pancreas, non-exempt of complications.

**Aims:** Show the level of competence and performance achieved in the treatment of 14,213 biliopancreatic diseases by ERCP during 25 years at the CNCMA.

**Methods:** Retrospective and descriptive study of 14,462 ERCP records taken from the database of the CNCMA, which were carried out from January 4, 1995 to February 5, 2020.

**Results:** Of 14,462 ERCP records, 14,213 they remained for analysis; 5,148 (38%) male and 8,224 (62%) female, ages 18 to 93 years; 4,548 (34%) diagnostic and therapeutic ERCPs were performed, 8,824 (66%). The primary indication was the study of jaundice in 8,690 (65%) and the main diagnosis was choledocholithiasis (5,799 patients [43%]), followed by malignant bile duct strictures (3,685 patients, [27%]). The most widely used intervention was endoscopic sphincterotomy (6,236) to remove stones (3,267), and the placement of prostheses in the bile duct was frequently followed (3,138). Complications occurred in 449 cases, 348 (4%) during 8824 therapeutic procedures and 101 (2.2%) in diagnoses. There was a mortality of 0.19% (28 patients), 24 (0.3%) in therapeutic procedures and four (0.08%) in diagnoses.

**Conclusions:** Our results demonstrate the high level of competence and performance achieved and the high diagnostic value and therapeutic success of ERCP, with minimal complications.

**Keywords:** Endoscopic Retrograde Cholangiopancreatography; Sphincterotomy; Choledocholithiasis

### Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) was introduced in Cuba in the 1970s, but it was not until the 1980s and 1990s that it began its development in different and specialized centers in Havana, reporting its first experiences [1-7].

The development of the techniques associated with this procedure and laparoscopic gallbladder surgery makes this the main

diagnostic and therapeutic resource as a complement to the treatment of gallstones and the complications of surgical treatment [8-15].

The National Center for Minimally Access Surgery since its inception was designed as work objectives, the development and introduction of novel techniques related to ERCP. The development of the techniques associated with this procedure make it the main

diagnostic and therapeutic resource as a complement to minimally invasive surgery of the bile ducts and pancreas, as well as the complications of its surgical treatment [16-20].

The objective of this report is to show the results of 25 years of medical practice by our group where the experience achieved in the endoscopic treatment of patients with biliopancreatic affections by ERCP is revealed, with a minimum of risks and complications.

### Material and Methods

A retrospective descriptive study of 14,462 ERCP files taken from the CNCMA database was reviewed; data were carried out from January 4, 1995 to February 5, 2020. The clinical data, indications, diagnoses and complications obtained during the procedure were analyzed. Those files that were not complete were excluded. 14,213 documents were left for analysis. Results were described in percent rounded to the nearest decimal. Equipment and accessories Olympus (Olympus®Co, Tokyo, Japan) were used to perform ERCP, and the different procedures Electrosurgery unit ERBE® (ERBE-GmbH®, Berlín, Germany) and Fluoroscopy equipment Phillips y Toshiba (Toshiba Medical Co Ltd, Otawara, Japan).

### Results

A total of 14,462 ERCP records were reviewed, leaving 14,213 for analysis. Of the total, 5,148 (38%) were male and 8,224 (62%)

female. The mean age of the studied group was 58 (age limits 18 to 93 years).

Of the total ERCP attempted (14,213), only the cannulation of the desired duct was achieved in 13,372 for a 94% rate, being failed or could not be cannulated in 841 (6%) procedures. Of these, 4,548 (34%) were diagnostic ERCPs and 8,824 (66%) were therapeutic (Table 1).

The most frequent pathological personal history found in the files were: history of biliary surgery, 1,325 (10%); signs of cholangitis, 2,761 (20%), and tumors in 237 patients (2%).The indications for the procedure and the main diagnoses that were obtained from the files analyzed are shown in table 2.

Procedures	Performed
Total ERCPs attempted	14,213
ERCP performed	13,372
ERCP failed	841
Cannulation index	94%
ERCP diagnostics	4,548 (34%)
ERCP therapeutics	8,824 (66%)

**Table 1:** Distribution of ERCPs performed.

ERCP: Endoscopic Retrograde Cholangiopancreatography, Source: Database EndoSorex - ProGastro v12.11.14.94. CNCMA 1995-2020.

Indications	Ptes	%	Diagnostics	Ptes	%
Jaundice study	8690	65	Biliary lithiasis	5799	43
Pain with elevation of enzymes (aminotransferases, amylase, alkaline phosphatase, gammaglutamil trans-peptidase).	2761	20	Malignant obstruction of the bile duct.	3685	27
Biliary surgery complications	1325	10	Benign obstruction of the bile duct.	932	7
Pancreatic disease study	280	2	Chronic pancreatitis	665	5
Biliopancreatic tumors study	237	2	Oddi's sphincter dysfunction	624	5
Intraoperative ERCP	79	1	Normal	703	5
			Post surgical bile duct injury	406	3
			Pancreatic pseudocysts	251	2
			Tumors of the main pancreatic duct (Wirsung)	116	1
			Others (primary sclerosing cholangitis, biliary cysts, parasitosis)	110	1
			Ampulary tumors	81	1
Total	13,372	100	Total	13,372	100

**Table 2:** Indications and Diagnostics of ERCP performed (n = 13,372).

ERCP: Endoscopic Retrograde Cholangiopancreatography.

Source: Database EndoSorex - ProGastro v12.11.14.94. 1995-2020.

A total of 8,824 therapeutic ERCPs (66%) were performed in the resolution of the entities where different modalities of endoscopic treatment were used and in which endoscopic sphincterotomy was the standard endoscopic technique that preceded other procedures related to it, which were shown in table 3.

Of the total of 14,213 patients with ERCP analyzed, 348 (4%) had complications related to therapeutic ERCP, while 101 (2%)

had complications in diagnostic ERCP. In total, we had 28 (0,2%) deaths, 24 (0,3%) in the therapeutic and 4 (0.1%) in the diagnostic ERCP. The different causes are described in table 4.

The above results allow us to establish levels of competence and performance for ERCP of our working group, taking into account international standards established (Table 5).

Therapeutic Procedures	n.	%	Complementary techniques	n.	%
Biliary sphincterotomy	6236	71	Bile duct Stone extraction	3267	37,2
Papillary precut	1024	12	Biliary prosthesis placement	3138	35,5
Pancreatic sphincterotomy	196	2,2	Biliary prosthesis changes	817	9,2
Gastroduodenal cystostomy	46	0,5	Prosthesis removal	294	3,3
Ampulectomies	23	0,3	Main pancreatic duct prosthesis placement.	108	1,2
			Mechanical biliary lithotripsy	82	1
			Cystic endoprosthesis placement	82	1
			Biliary stenosis dilation.	52	0,5
			Nasobiliary drainage	50	0,5
			Stones extraction of the pancreatic duct.	33	0,3
			SEMS placement in the biliary duct	33	0,3

**Table 3:** ERCP therapeutic procedures performed (n = 8,824).

\*Each patient can have accomplished more than one therapeutic procedure.

SEMS: Self-Expandable Metallic Stent.

Source: Database EndoSorex - ProGastro v12.11.14.94. 1995-2020.

Complications	ERCP diagnostics (n = 4,548)		ERCP therapeutics (n = 8,824)	
	n	%	n	%
Haemorrhage	0		167	2
Perforation	0		69	1
Pancreatitis	56	1	63	1
Cholangitis	28	1	12	0,1
Anesthetics	13	0,3	13	0,1
Death	4	0,1	24	0,3
Total	101	2	348	4

**Table 4:** Complications in ERCP performed.

ERCP: Endoscopic Retrograde Cholangiopancreatography.

Source: Database EndoSorex - ProGastro v12.11.14.94. 1995 - 2020.

International parameters established ERCP	International Parameters.**	Results achieved in 25 years CNCMA
Cannulation rate and effective completion of procedures.	80-85%	94%
Complication index.	Morbidity 5-10% Mortality 0,1-1%	Morbidity 3% Mortality 0,2%
ERCP induced pancreatitis.	1-7%	1%
Post-sphincterotomy hemorrhage	2%	2%
Cholangitis	1%	0,3%
Perforation.	1%	1%

**Table 5:** Level of competence and performance in realization endoscopic therapy in ERCP\*.

\*ERCP: Endoscopic Retrograde Cholangiopancreatography; CNCMA: National Center Minimal Access Surgery.

\*OMED Guidelines for Credentialing and Quality Assurance in Endoscopy. Gastroenterology and Hepatology. 2010, 6 (4) : 216- 217.

\*NIH state-of-the-science statement on endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy. NIH Consensus State Sci Statements. 2002 Jan 14-16; 19(1):1-23.

## Discussion

In our series, the behavior of sex and age groups were similar to those reported in other national and foreign studies, in which female sex and age above 40 years are factors that condition the performance of these procedures, in which the presence of a history of biliary surgery, the study of jaundice and the presence of gallstones presented with a high frequency. in accordance with that observed in other ERCP publications [2-5,7,11-16,19] (Table 1).

In our study we had a greater amount of therapeutic ERCP performed, in accordance with the current consensus on the use of this technique for the solution of biliopancreatic diseases, where its use as a diagnostic element has been declining, using other less invasive imaging techniques [10,21,22].

Regarding the indications that motivated the performance of ERCP, the study of jaundice was the main cause, originated by the minimal possibilities in our country of non-invasive studies, such as nuclear magnetic resonance, as well as the limited possibility of computed tomography and conventional ultrasound to carry out treatment, that in most cases it is limited to pointing out when there is dilation of the biliary tree, and that ERCP makes it possible during the same act to carry out therapeutic procedures, often definitive [13-18,23-26].

The study of abdominal pain with enzyme elevation was the second reason for performing ERCP in this case series, due to the

difficulty that exists in medical practice to discriminate the origin of this symptom. In addition, due to not having an sphincter of Oddi manometry study to rule out biliary or pancreatic dysfunction, nor are the aforementioned imaging studies to be definitive (Table 2).

The performance of this technique for the diagnosis of post-surgical lesions of the bile duct is undoubtedly of great value because of the possibility of solving them at the time of their identification, avoiding the patient reoperations that would decrease their quality of life. Likewise, the clarification of chronic pancreatic diseases and the study of biliopancreatic tumors not only made it possible to diagnose but also made it possible to carry out palliative procedures *in situ*, as reported in the literature [16-20].

Regarding the diagnoses observed in our study, biliary lithiasis was the main entity detected, behaving the same as that observed in other studies reported in our country [13-15,24,26] and in large international series [8,9,11,12,23], following in order of frequency, benign and malignant obstruction of the bile duct. Both benefit from this method, due to the possibility of acting on it by performing definitive or palliative therapeutic procedures, such as biliary sphincterotomy and stone extraction in the first, placement of stents in the second and different combinations of procedures in the different entities, which are shown in table 3.

Regarding the complications observed, these were similar to those obtained by other national and foreign working groups [2-

7,19,20,27-29], finding a higher proportion in cases of endoscopic therapy, where hemorrhage (2%), perforation (1%) and pancreatitis (1%) occupy the main consequences of the practice of these procedures due to their complexity on many occasions and the condition of the patient. As to diagnostic ERCP, pancreatitis and cholangitis (1%) were the main causes of complications, hence the importance of performing this procedure in those who would actually benefit from it, either as a diagnostic or therapeutic procedure (Table 4).

When comparing our results with the level of competence and performance established by the OMED Guidelines [30] and in international consensus in the performance of the ERCP [10], we can see that our work group complies with them, allowing us to classify as an institution capable of the treatment and training of specialists in carrying out these procedures (Table 5).

## Conclusion

We can conclude that our working group has obtained good results in the development of this technique, backed by the results shown, with a low morbidity and mortality in these twenty-five years, which allows us to be an institution for the treatment and training of specialists in carrying out these procedures. However, this procedure should be considered as a therapeutic tool and consider other alternatives for diagnosis as it is not without risk.

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