

Rate of early complications of endoscopic retrograde cholangiopancreatography at the Hospital Nacional de Itaugua, Paraguay from 2013 through 2017

Incidencia de complicaciones precoces de la colangiopancreatografía retrógrada endoscópica en el Hospital Nacional de Itauguá. Periodo 2013-2017

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ABSTRACT

History: Endoscopic retrograde cholangiopancreatography (ERCP) is a very widely used technique very efficient to treat biliary and pancreatic duct obstruction. However, it is no stranger to risks for the patient. **Objectives:** To find out the rate of ERCP-related complications in patients from the Endoscopy Unit at Hospital Nacional de Itauguá, Paraguay from 2013 through 2017. **Materials and methods** Descriptive, retrospective, and cross-sectional study conducted in 945 ERCPs performed from 2013 through 2017 at the Endoscopy Unit from Hospital Nacional de Itauguá, Paraguay. **Results:** The rate of early post-ERCP complications was 5.2%, acute pancreatitis—the most common one—3.38% followed by hemorrhage (0.95%), acute cholangitis (0.42%), and perforation (0.31%). **Conclusions:** The rate of post-ERCP complications at Hospital Nacional de Itauguá, Paraguay is low, being acute pancreatitis the most common complication and conservative management the most widely used. No deaths were reported in this study and no laparotomy was necessary.

Keywords: Endoscopic retrograde cholangiopancreatography, complications, choledocholithiasis.

RESUMEN

Introducción: La colangiopancreatografía retrógrada endoscópica (CPRE) es una técnica muy utilizada y eficaz para el tratamiento de la obstrucción de la vía biliar y pancreática, pero la misma no está exenta de riesgos para el paciente. El **objetivo** fue conocer la incidencia de complicaciones de la CPRE en pacientes del Servicio de Endoscopia del

Hospital Nacional de Itauguá, en el periodo de 2013-2017. **Materiales y métodos:** Se realizó un estudio descriptivo, de tipo retrospectivo y de corte transversal en 945 CPRE, realizadas en el periodo del 2013-2017 en el Servicio de Endoscopia del Hospital Nacional de Itauguá. **Resultados:** La incidencia de complicaciones precoces post CPRE fue de 5,2%, siendo la pancreatitis aguda la más frecuente, 3,38%, seguido por la Hemorragia 0,95%, la colangitis aguda 0,42% y la perforación 0,31%. **Conclusiones:** La incidencia de complicaciones post CPRE en el Hospital Nacional de Itauguá es baja, la pancreatitis aguda es la complicación más frecuente y el manejo conservador es el más utilizado. no se reportaron óbitos en este estudio y no fue necesaria ninguna laparotomía.

Palabras clave: Colangiopancreatografía retrógrada endoscópica, complicaciones, coledocolitiasis.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic technique used in the diagnosis and treatment of biliopancreatic conditions.¹ It is indicated in patients with cholestatic jaundice, when conventional diagnosis methods such as ultrasound, contrast computed tomography scan, magnetic cholangio-resonance, and echoendoscopy are not enough to establish the cause¹ and to treat the following conditions:²

- Residual choledocholithiasis or with gallbladder in situ
- Stenosis or papillary dysfunction

General Surgery Resident

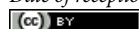
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- Acute cholangitis
- Dilatation of postoperative stenoses
- Dilatation of benign stenoses
- Placement of pancreatic prosthesis
- Hemobilia
- Biliary parasitosis
- Miscellanea

It also plays a palliative role in irresectable neoplastic conditions of the main biliary duct and the pancreas, where it allows the placement of prostheses to improve jaundice resulting from stenosis due to irresectable neoplasms.³

ERCP-related complications can be classified into direct and indirect. Direct complications can also be categorized into early (acute pancreatitis, cholangitis, post-sphincterotomy hemorrhage, and duodenal perforation), and late ones (post-sphincterotomy papillary stenosis, prosthesis migration or rupture).⁴

Indirect complications occur in organs far from the site where the technique is performed and are mainly of cardiopulmonary type. On many occasions they are associated with the sedative methods used and the patient's previous pathological condition.^{3,4}

Sphincter manipulation of the biliary duct causes papillary edema, which occludes the pancreatic fluid outflow causing the activation of intracellular proteolytic enzymes, and consequently pancreatic inflammation.⁵ Its severity can be classified based on Petrov's criteria.⁶

The same mechanism can cause an increased intracholedocal pressure and biliary flow stasis, which facilitates bacterial proliferation, contamination, and consequently ascending cholangitis.⁵

Bleeding observed during sphincterotomy is a common finding. However, it does not represent in itself an adverse result for the patient if there is no clinically significant blood loss.⁵

Regarding perforations, it is important to spot them early during the endoscopic act or within the first few hours after being performed since they can be managed with watchful waiting and only a few of them will eventually need surgery.⁷

At the Endoscopy Unit of Hospital Nacional de Itauguá, Paraguay, indications for therapeutic ERCP are limited, according to the predicting criteria established by the American Society for Gastrointestinal Endoscopy (ASGE) 2010 (see Figure 1).⁸

This study has the objective of getting to know the rate of ERCP complications in patients from the Endoscopy Unit at Hospital Nacional de Itauguá, Paraguay from 2013 through 2017.

METHODOLOGY

Descriptive, observational, retrospective, cross-sectional study. A non-probabilistic sample of consecutive cases was conducted in all the patients with a diagnosis of obstructive jaundice of non-neoplastic origin who met all the ASGE 2010 predictive criteria to undergo an ERCP with diagnostic and/or therapeutic purposes due to the high chances of choledocholithiasis, at Hospital Nacional de Itauguá Digestive Endoscopy Unit from 2013 through 2017. Patients whose past medical histories were complete for the variables needed in the study were selected. A total of 945 records from patients who met the study inclusion criteria were included. The classifications used for the complications were for acute pancreatitis, the 2013 Petrov severity criteria,⁶ for acute cholangitis the 2018 Tokyo classification criteria,⁹ and for perforations, the 2000 Stapfer classification.¹⁰

Data collected were organized in a Microsoft Excel spread-

sheet, and frequency (%) tables were used, as well as dispersion measurements (SD) and Flow Histograms.

Bioethical principles were respected: the information obtained was analyzed confidentially. Codes were used for each patient's records. Informed consent was not required because the data obtained were taken from the records. There was no risk of maleficence or discrimination. No conflicts of commercial interest were declared.

RESULTS

Out of the 945 patients, sex prevalence was 41.9% men (396 patients), and 58.1% (550) women. The patients came from rural areas [68.5% (648)], and 31.5% (297) from urban areas. Regarding distribution by age groups, 3.4% (32) were between 15 and 24 years, 6.9% (66) between 25 and 34 years, 69.9% (660) between 35 and 44 years, and 19.8% (187) over 45 years. No patients > 60 years were reported in our series (see Table 1). The median age was 40 years with a SD of ± 3 years.

Out of the 945 patients, complications were reported in 5.3% (50) of the cases. No deaths were reported. Among the complications, the most common was acute pancreatitis in 3.4% (32 patients) followed by hemorrhage in 1% (9), acute cholangitis in 0.4% (4), perforations in 0.3% (3), and indirect complications in 0.2% (2) (See Table 2).

Out of 32 patients with acute pancreatitis categorized according to the 2013 Petrov criteria, most of the patients developed mild acute pancreatitis in 71.9% (23) followed by moderate in 15.6% (5), severe in 9.4% (3), and critical in 3.1% (1). In all of them computed tomography scans with control contrast between the fourth and fifth day after the ERCP were performed, mild pancreatitis received conservative management with analgesic drugs and fluid therapy. The moderate ones required antibiotic treatment; severe pancreatitis were treated with anti-

PREDICTORS	
VERY STRONG	
1. Choledocholithiasis	
2. Clinical cholangitis	
3. Bilirubin > 4 mg/dL	
STRONG	
1. Dilated choledochus > at 6 mm in gallbladder in situ and > at 10 in cholecystectomized ones.	
2. Bilirubin between 1.8 and 4 mg/dL at the expense of the direct one	
MODERATE	
1. Alteration of liver enzymes in addition to bilirubin	
2. > 55 years	
3. Acute lithiasic pancreatitis	
RISK	
Presence of any very strong predictor	HIGH
Presence of 2 strong predictors	HIGH
No predictors	LOW
All the remaining patients	INTERMEDIATE

Figure 1. Predicting criteria of choledocholithiasis risk, ASGE 2010.

Table 1. Distribution of patients who underwent ERCP between 2013 and 2017 according to socio-demographic data (N = 945).

SOCIAL- DEMOGRAPHIC CHARACTERISTICS	FREQUENCY	RATE
GENDER		
Men	396	41.9%
Women	549	58.1%
TOTAL	945	100%
ORIGIN		
Rural	648	68.5%
Urban	297	31.5%
TOTAL	945	100%
AGE		
15 to 24	32	3.4%
25 to 34	66	6.9%
35 to 44	660	69.9%
Over 45	187	19.8%
TOTAL	945	100%

Table 2. Rate of complications in total number of patients who underwent ERCP between 2013 and 2017. (N = 945)

FINDING	FREQUENCY	RATE
Acute pancreatitis	32	3.4%
Hemorrhage	9	1.0%
Cholangitis	4	0.4%
Perforation	3	0.3%
Indirect complications	2	0.2%
No complications	895	94.7%
TOTAL	945	100.0%

otic therapy and percutaneous drainage, and those classified as critical needed—on top of antibiotic therapy and percutaneous drainage—in-hospital therapy. No deaths were reported. Out of the 9 patients with hemorrhage, all hemorrhages were treated with adrenalin during the procedure, with spontaneous resolution in all the cases; late bleeding was not reported in our series. Out of the 4 patients diagnosed with postoperative acute cholangitis, 75% (3) had the mild form of the disease, and the remaining 25% (1) the moderate form of the disease, which required biliary stent implantation. No cases of severe post-ERCP cholangitis were described, according to the 2018 Tokyo classification. Out of the 3 patients with a diagnosis of duodenal perforation 66.6% (2) had type II and 33.3% (1) type IV according to the 2000 Stapfer classification. None of them required surgical treatment. All of them received conservative management and no deaths were reported in our series.

DISCUSSION

Among the patients that underwent ERCP, in our sample, it was found that there was predominance of women (58.1%) with a mean age of 40 years \pm 3 SD; similar data were published by Gomez et al, who found a 2:1 woman-man ratio, with a mean age a little over 49 years.¹¹ In their work on ERCP

Table 3. Classification of severity according to each complication described

Post-ERCP acute pancreatitis according to Petrov's classification		
FINDING	FREQUENCY	RATE
Mild	23	71.9%
Moderate	5	15.6%
Severe	3	9.4%
Critical	1	3.1%
TOTAL	32	100

Post-ERCP acute cholangitis according to the 2018 Tokyo criteria		
FINDING	FREQUENCY	RATE
Mild	3	75%
Moderate	1	25%
TOTAL	4	100

Post-ERCP perforation according to Stapfer's classification		
FINDING	FREQUENCY	RATE
Type I	0	0%
Type II	2	67%
Type III	0	0%
Type IV	1	33%
TOTAL	3	100

complications regarding digestive emergencies where the mean age with which ERCP was performed, Olazábal et al. found different data with a mean age of 60 years and the predominant sex being women with 64.9%.¹³ This is consistent with what was reported by the medical literature worldwide that indicates that women are more often affected by lithiasis, both vesicular lithiasis and that due to secondary gallbladder stones in the choledochus. That is why they have a higher risk of undergoing this procedure. The same thing happens regarding age with mild increasing tendencies being reported in other papers.^{1,3,5}

Of the overall number of patients (n=945), complications were reported in 5.2% (50), a percentage that is greater compared to the study conducted by García L., which showed a 4% rate of complications.¹³ And similar to Gómez, R's in Lima, Perú with a 5.9% rate of complications.¹¹ However, it was higher compared to the rate found by Reyes et al. at the Regional Hospital of Mexico between 2002 and 2011 in 1145 patients in whom the rate of complications was just 2.1%.¹⁴

The most common complication in all the patients was acute pancreatitis in 3.4%, data that are similar to those published by Gonzalez et al. in Guatemala where post-ERCP pancreatitis occurred in 3.26%,¹⁵ and Gómez R., with an overall rate of

post-ERCP acute pancreatitis of 3.4%.¹¹ Our numbers are higher compared to those reported by Garcia et al. in a study conducted among 11 497 patients in Mexico over a period of 12 years where acute pancreatitis occurred in 2.6%.¹³

Of the total number of patients that had complications with post-ERCP pancreatitis, 71.9% had mild pancreatitis whose management was conservative with analgesic drugs and fluid therapy. A total of 15.6% had moderate pancreatitis that required antibiotic treatment. A total of 9.4% of the patients had severe complications that required antibiotic therapy and percutaneous drainage. In 3.1%, pancreatitis was critical and required in-hospital therapy. No deaths were reported. These results vary in proportion from those published by Kochar et al. who, among 8857 patients with post-ERCP pancreatitis, found a 58.8% rate of mild pancreatitis with a similar therapeutic management, a 34% rate of moderate pancreatitis with antibiotic management, and a 7.2% rate of severe pancreatitis that required antibiotics (carbapenem) and percutaneous drainage.¹⁶

Post-papillotomy bleeding occurred in 1% of the patients. This figure is greater to that reported by Garcia et al. where hemorrhages occurred in 0.3% of the patients.¹⁶ While Olazábal et al. reported a 2% rate bleeding in 114 procedures.¹² Regarding management, all the cases were classified as mild hemorrhages, and they were resolved with adrenalin infiltration. In all the cases control endoscopic vision was required. This management is similar to the one reported by F. J. Gallego-Rojo, performed by the Andalusian Society of Digestive Diseases who, in cases of mild bleeding, follow a wait-and-see approach and if the bleeding becomes persistent, they perform adrenalin infiltration or sclerosis.¹⁷

The rate of cholangitis reported in our study was 0.4%, a figure that is lower compared to that reported by Macías C. in his report on complications at the Buenos Aires Italian Hospital, Buenos Aires, Argentina where it occurred in 2% to 4% of the complications.¹⁸

Of the total number of patients with complications with post-ERCP cholangitis, the most common form of presentation was mild cholangitis in 75% (3), which required antibiotic treatment. This follows the Tokyo guidelines.⁹ When moderate cholangitis occurred in 25% of the cases (1) the management required by the patient was biliary stent implantation. In our series no severe post-ERCP cholangitis was reported.

Perforations (open windows) had an incidence rate of 0.3% (3). This rate is low compared with that described by Retuerta J et al. at the Navarra Hospital facility in Navarra, Spain. Over a period of two years, they found 12 cases of post-ERCP perforations, numbers that are quite large.¹⁹ According to Stapfer's classification, 66.7% (2) of these complications were papillary perforations, Stapfer's Type II while the remaining 33.3 % (1) were Stapfer's perforations Type IV. They all required conservative management with good clinical evolution.¹⁰ An experience that is similar to that described by E. Perea del Pozo et al. who described a 9.4 % mortality rate in type II perforations without surgical treatment and a 38% mortality rate in those who did receive surgical treatment.²⁰

This study has limitations: the size of the sample compared to other studies in the region is very small. Therefore, the re-

sults cannot be generalized; additionally, patients with jaundice of neoplastic etiology or suspected neoplastic etiology were not considered, which would increase the rate of complications. On the other hand, this was a retrospective study conducted in one center only. Moreover, there was no mid- or long-term follow-up of the patients, which would have enabled us to evaluate complications away from post-ERCP, and the evolution of the complications.

Different research lines are recommended, with a longitudinal and analytical approach, to better correlate the variables, and with a larger sample that would enable us to generalize the results to the population.

CONCLUSION

Of the 945 ERCPs performed at the Hospital Nacional de Itauguá during the years 2013-2017 the most prevalent sex regarding complications was females and the mean age was 40 years.

The rate of early post-ERCP complications is low with 5.2%, acute pancreatitis being the most common, 3.38% followed by hemorrhages, 0.95%, acute cholangitis, 0.42%, and perforations, 0.31%. Most pancreatitis are mild. Hemorrhages during the procedure are mild and most of them are easy to be taken care of with hemostatic control. Post ERCP cholangitis have mild evolution in 75% of the cases. Perforations are rare and most of them do not require surgical treatment.

In view of the onset of any post-ERCP complication, conservative non-surgical management with analgesic drugs, fluid therapy, sclerosis, and antibiotic therapy was not associated with deaths.

Conflicts of Interest: the authors declare that there are no conflicts of interest among the authors and that they respect ethical conducts and good publishing practices. No external financial support was received.

Authors' contributions:

MAAW: he provided substantial contributions to the conception or design of data collection and analysis, and was involved in the bibliographic search, drafting of the paper and reviewing it critically looking for relevant intellectual content, and final approval; he was responsible for all the aspects of the article to guarantee that questions having to do with the precision or integrity of any part of the paper were properly looked into and eventually resolved.

GIPG: he provided substantial contributions to the conception or design of data collection and analysis, and was involved in bibliographic search, drafting of the paper and its final approval.

CPB: she provided the study idea, data analysis, and created graphics and tables, design and drafting of the paper and its final approval.

CRAG: he provided substantial contributions to the original idea and was involved in the methodological design of the study; the critical review of the content, and also made significant intellectual contributions, critical reviews, and the manuscript final approval.

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