Retrograde endoscopic cholangiopancreatography: Analysis of the epidemiological profile and complications

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ABSTRACT

Introduction: Endoscopic retrograde cholangiopancreatography (ERCP) is an important diagnostic and therapeutic tool used in the management of hepatobiliary and pancreatic diseases. Post-ERCP pancreatitis is the most common complication of this procedure. We evaluated the results of patient procedures found at ERCP in a reference service of the SUS, determining a success rate, epidemiological profile and frequency of complications. Methods: Retrospective and cross-sectional study carried out from August 2019 to December 2020, with a final sample of 217 patients. Information was collected from the database of the Santa Casa de Maceió Endoscopy Service, using a semi-structured questionnaire containing age, gender and data regarding: indication of the ERCP procedure, success rate, in addition to complications. The description of the data obtained was presented using descriptive statistics. Results: We observed a predominance of females (70.5%), with a mean age of 53.9 years. All therapeutic procedures and choledocholithiasis represent the main indication (76.4%). The most common procedures were: biliary cannulation for stone removal (62.2%), passage of biliary stent (19.8%) and removal of biliary stent (10.5%). The procedure success rate

was 92.6%, complications occurred in 6.45%, the main one being acute pancreatitis in 3.7%. Conclusion: The study concluded that the main indication for performing ERCP was biliary obstruction by calculus. The observed success rate of the procedure was 92.6%. Complications after ERCP were infrequent (6.45%), with the highest frequency being acute pancreatitis, with an incidence of 3.7%.

Keywords: Endoscopic Retrograde Cholangiopancreatography, Postoperative complications, Acute pancreatitis, Quality indicators in health care.

1 INTRODUCTION

ERCP is an invasive technique that combines endoscopy with fluoroscopy in the diagnosis and treatment of diseases of the biliary and pancreatic ductal systems1. Currently, the use of this procedure has been restricted to therapeutic purposes due to lower costs, lower rate of adverse effects, high technical improvement and increased accuracy of other diagnostic techniques, such as endoscopic ultrasound, computed tomography and magnetic resonance cholangiopancreatography, in the detection of biliopancreatic complex diseases2,3.

Therapeutic indications for ERCP include: removal of stones, sphincterotomy and dilation of stenosis, endoscopic insertion of prostheses or biiliar drain, and resection of adenomatous lesions of the greater duodenal papilla4,5. This procedure, however, is not risk-free, and may present complications ranging from 4% to 10% and eventually lead to mortality (0.4 to 1.4%) 6,7. The National Commission for the Incorporation of Technologies in the SUS (CONITEC)[8] has recommended the performance of preoperative ERCP in cases of choledocholithiasis and subsequent laparoscopic cholecystectomy in order to ensure a free duct without obstruction, reducing the risk of other procedures in the postoperative period.

To perform ERCP safely, experienced professionals with training in specialized services are needed, as well as trained medical staff, evaluation of preoperative conditions, and stratification of risk factors in order to implement preventive measures, reducing morbidity and mortality related to the procedure9,10.

The most common complications of ERCP are acute pancreatitis, infections, hemorrhage, acute cholecystitis, and duodenal perforation11. The incidence of pancreatitis after ERCP ranges from 3% to 10%, and in high-risk patients this rate can reach up to 15%[12]. Post-ERCP pancreatitis (PPCPRE) is characterized by abdominal pain, elevated amylase levels greater than three times the reference value, or radiological findings compatible with acute pancreatitis1, and its pathogenic mechanism remains unclear12,13. It should also be noted that asymptomatic hyperamylasemia after ERCP is related to pancreatic duct injury and is more frequent than acute pancreatitis, with an incidence of 7.7% to 70%, so it is recommended that this enzyme should not be used alone for the diagnosis of pancreatitis1.

Risk factors associated with post-ERCP pancreatitis are: suspected dysfunction of the sphincter of Oddi, previous history of post-ERCP pancreatitis, female gender, age < 55 years, normal serum

bilirubin level, history of recurrent acute pancreatitis, and pregnancy[10,14]. Chronic pancreatitis, on the other hand, is considered a protective factor, since pancreatic atrophy reduces the exocrine function of the pancreas, with a decrease in enzyme production.

On the other hand, according to the American Society for Gastrointestinal Endoscopy (ASGE), the use of rectal indomethacin (a non-steroidal anti-inflammatory drug, which acts by inhibiting cyclooxygenases and a potent inhibitor of phospholipase A2, playing a role in the pathogenesis of acute pancreatitis) and intravenous hydration with lactated Ringer' s is recommended, aiming to reduce the severity and risk of pancreatitis after ERCP in high-risk populations2, 12.

In a randomized multicenter clinical study, post-ERCP pancreatitis was shown to occur in 9.2% of the group using indomethacin rectally and 16.9% in the placebo group when administered immediately after the procedure, indicating a decrease in relative risk of approximately 46%[15]. In addition, aggressive intravenous hydration with lactated Ringer's solution has also been shown to be effective in reducing post-ERCP pancreatitis13. In the randomized study conducted by Shaygan-Nejad et al.[15] Post-ERCP pancreatitis was observed in approximately 5% of the group receiving aggressive lactated Ringer's hydration compared to 22% of the standard hydration group.

Thus, it is known that ERCP is a technique for accessing the pancreatobiliary pathway, subject to some complications, requiring well-trained professionals to perform it. The importance of recognizing risk factors associated with prophylactic measures in the prevention of severe complications of this procedure has been well demonstrated. Thus, this study aims to analyze the results of procedures of patients undergoing ERCP in a SUS referral service, analyzing the epidemiological profile, success rate and frequency of complications.

2 METHODOLOGY

This is a retrospective, cross-sectional, observational and analytical study, approved on 08/11/2021 by the Research Ethics Committee (CEP) of the Jayme de Altavila Educational Foundation/Cesmac University Center, under registration number 067649/2021, in accordance with resolution 466 of 2012 of the National Health Council, via Plataforma Brasil.

The research was carried out through data analysis in electronic medical records of patients who underwent ERCP, in the period from August 2019 to December 2020 at Hospital Santa Casa de Misericórdia de Maceió, in the endoscopy service, reference for the SUS (Unified Health System), in Maceió-AL.

All patients included in the study underwent prophylaxis of complications (acute pancreatitis), as recommended by the American Society for Gastrointestinal Endoscopy (ASGE) with vigorous hydration and rectal indomethacin suppository, except for those who reported allergy to the medication.

The convenience sample consisted of 221 patients. Patients over 18 years of age, regardless of gender, were included. Patients with incomplete medical records that made the analysis impossible were excluded from the study, as well as patients in the gestational or puerperial period, and four patients were excluded. The final sample resulted in 217 patients.

Data collection was performed through a semi-structured questionnaire researching data related to the indication of ERCP, age, gender, signs and symptoms reported after the procedure. The procedure was considered successful when the indication for ERCP was achieved.

Complications were assessed through signs and symptoms reported after the procedure; In patients with abdominal pain suggestive of acute pancreatitis, amylase determination was requested to confirm the diagnosis. In addition, the presence of other complications such as hemorrhage, perforation, and bacterial infections were systematically investigated.

The description of the clinical data is presented by means of descriptive statistics. Categorical variables were expressed as percentages and continuous variables as mean and standard deviation or median.

3 RESULTS

The study sample consisted of 221 patients, four of whom were excluded because they had incomplete data in the medical records, with a final sample of 217 patients.

Considering the final sample, 153 patients (70.5%) who underwent the procedure were female. The age of the study participants ranged from 18 to 91 years, with a mean age of 53.9 years (standard deviation: 17.84) and a median of 54 years. The epidemiological characteristics, indications, and procedures performed are described in Table 01.

The main indications for ERCP observed were choledocholithiasis (76.4%), cholangitis (8.7%), periampullary neoplasia (8.7%), postoperative bile duct stenosis (4.6%) and removal or replacement of biliary prosthesis (4.6%), some patients had more than one indication. The procedures performed during ERCP were: stone removal (62.2%), plastic biliary prosthesis (19.8%), biliary prosthesis removal (10.5%), papilla biopsy (1.8%), pancreatic prosthesis (0.9%) and others (1.3%).

The goal of the procedure was successfully achieved in 201 patients (92.6%), and in only 16 patients (7.4%) this goal was not achieved. Procedural failures were observed in cases of large gallstones (>12mm) that occurred in 7 patients (3.2%), obstructive neoplastic disease in 6 patients (2.8%) and other conditions in 3 patients (1.4%).

Table 01 - Clinical characteristics, indications and procedures performed.

FEATURES (N=217)	
	Mean ± standard deviation
Age	53.9 ± 17.84
	N (%)
Gender	
Female	153 (70,5%)
INDICATIONS	
	N (%)
Choledocholithiasis	166 (76,4%)
Cholangitis	19 (8,7%)
Neoplasia periampular	19 (8,7%)
Post-surgical bile duct stenosis	10 (4,6%)
Biliary prosthesis removal/replacement	10 (4,6%)
Other	8 (3,6%)
PROCEDURES PERFORMED	
	N (%)
Calculation Withdrawal	135 (62,2%)
Passage of plastic biliary prosthesis	43 (19,8%)
Removal of biliary prosthesis	23 (10,5%)
Dilatation of stenosis	6 (2,7%)
Papilla biopsia	4 (1,8%)
Pancreatic prosthesis passage	2 (0,9%)
Other	3 (1,3%)
SUCCESS IN THE PROCEDURE	
	N (%)
Yes	201 (92,6%)
PROCEDURE FAILURE (N=16)	
	N (%)
Large calculations (>12mm)	7 (3,2%)
Obstructive neoplastic disease	6 (2,8%)
Other	3 (1,4%)

The most frequent signs and symptoms that occurred in the post-procedure period were epigastralgia in 30.7% of the cases (16 patients), nausea and vomiting in 19.2% (10 patients) and abdominal pain in 17.3% (nine patients), described in Table 02.

Table 02 - Post-procedure signs and symptoms and associated complications.

SIGNS AND SYMPTOMS (N = 52) – 23.9%	
	N (%)
Epigastralgia	16 (30,7%)
Nausea and vomiting	10 (19,2%)
Abdominal gold	9 (17,3%)
Respiratory distress	4 (7,6%)
Fever	3 (5,7%)
Hypotension	3 (5,7%)
Abdominal distention	2 (3,8%)
High digestive hemorrhage	2 (3,8%)
Other	3 (5,7%)
COMPLICATIONS (N = 14)	
	N (%)
Pancreatite aguda	8 (3,7%)
Infections	4 (1,8%)
Haemorrhage	1 (0,5%)
Drilling	1 (0,5%)
Pancreatite marital-CPRE (N=8)	
	N (%)
Sexo female	8 (100%)
Age < 55 years	4 (50%)

A complication rate of 6.45% was observed. Complications were more frequent in females, equivalent to 71.5% of the cases, against 28.5% in males, nine (64.2%) were over 60 years of age. There were no deaths related to the procedure. The main complications were acute pancreatitis in 3.7% (eight cases), infections in 1.8% (four cases), hemorrhage in 0.5% (one case) and perforation in 0.5% (one case). Of the eight patients who developed pancreatitis, 100% were female and 50% were younger than 55 years, as shown in Table 02.

4 DISCUSSION

ERCP combines endoscopy with fluoroscopy in the diagnosis and treatment of diseases of the biliary ductal and pancreatic system1. Currently, the use of this procedure has been restricted to therapeutic purposes8, with choledocholithiasis being the most common indication for this procedure.

Our study included 217 patients, with a predominance of females, representing 70.5% of the patients, and with ages ranging from 18 to 91 years, with a mean age of 53.9 years (standard deviation: 17.84). Our results are similar to those of Matos et al.[16], since the presence of gallstones in the bile duct is more common in women, with incidence between 35 and 55 years of age, increasing with age17.

Vitale et al.,18 in their study conducted in Guatemala with 1874 patients, showed that the 3 main indications for ERCP were: choledocholithiasis (78.8%), bile duct tumor (12.2%) and bile duct stenosis after cholecystectomy (3.8%). Our results were similar to those reported in this study, however, Vitale et al.[18] does not mention cholangitis or removal/replacement of biliary prostheses as frequent indications. In our study, these two indications corresponded to 8.7% and 4.6% of the cases, respectively.

In specialized centers, biliary cannulation is successful in up to 95-99% of cases. In this study, the success rate of the procedure reached values of 92.6%, with results similar to those found in specialized centers. Our biliary cannulation result was slightly higher than that reported by Matos et al.[16,] in the state of Ceará, Brazil, which evaluated 56 patients undergoing ERCP due to choledocholithiasis and obtained a success rate of 89%. In the study by Antonello et al.[4], we analyzed the data of ERCP performed at the National Cancer Institute (INCA) in Rio de Janeiro and the success of the procedure was achieved in 85.3%, which was slightly lower than that found in our center, but without significant differences when compared to our results.

In the United Kingdom, the rate of duct cannulation is around 84%, which is slightly lower than in other centers, an outcome that is probably related to the fact that the country performs the procedure in low-volume centers, resulting in less experience with the procedure19. The guidelines of the Joint Advisory Group (JAG), published in 2009, which promote frequent auditing of the quality and safety of each endoscopy modality, advise that Completion of the intended therapeutic procedure should be achieved in at least 80% of cases, and the values found in this study were within the recommended range20.

In our sample, the main causes of procedural failure were conditions inherent to the patient himself, large stones (>12mm) were observed in 3.2%, obstructive neoplastic disease in 2.8% and other conditions in 1.4%. In the study by Matos et al.[16], the presence of large stones was also a factor associated with a higher failure rate in the procedure. One factor that may have contributed to this rate

is the unavailability of adequate material for the management of larger stones (absence of direct cholangioscopy - Spyglass - with or without laser lithotripsy)[21].

Although ERCP is considered a safe procedure, it is related to higher complication rates compared to other endoscopic examinations22. In the present study, a complication rate of 6.45% (14 cases) was observed, ranging from 4% to 15.9% in the literature, a variation generally related to the methodology used in the studies23,24.

Acute pancreatitis is the most frequent complication related to ERCP, with an incidence rate ranging from 1.3 to 15.9%12,25. In our analysis, acute pancreatitis after ERCP accounted for 3.7% of cases. Other studies reported a slightly higher rate than ours, in Borges et al.[9] the rate of post-ERCP pancreatitis was 6.5%, whereas in Kochar et al.[26], this rate corresponded to 9.7%. Female gender and age < 55 years are considered risk factors associated with the development of this complication[13]. Our sample was very limited in relation to the analysis of these data, which allows us only to describe the results. All patients with pancreatitis (eight) were female and only 50% were 55 years < age. The mortality rate for this condition ranges from 0 to 1%, but in our analyses we did not observe any deaths associated with post-ERCP pancreatitis12,24.

ERCP-related infections are associated with enteric bacteria, species *Escherichia coli* and *Klebsiella*, *Alpha hemolytic Streptococcus, Pseudomonas aeruginosa, Enterococcus* and *Staphylococcus epidermidis27*. The rate of post-ERCP infection ranges from 0.3 to 1.5% and is associated with a mortality rate of approximately 1%[3,27,28]. In this study, we found an infection rate of 1.8%, similar to that described in previous studies3.

Post-procedure hemorrhage was observed in 0.5% of the cases, slightly lower than the data in the literature, which range from 0.76 to 3.7%, with a mortality rate of 0.3%[29,30]. Post-ERCP hemorrhage is considered an uncommon complication and, according to Ferrari Jr et al.[25,] is almost always associated with biliary and/or pancreatic sphincterotomy, in addition to any bleeding during the procedure. In this study, in the case in which this complication occurred, sphincterotomy was performed. Some defined risk factors for bleeding associated with the patient are: pre-existing coagulopathy, use of anticoagulants and pre-existing cholangitis25. However, none of these factors were observed in the sample.

Perforations may occur most commonly after sphincterectomy, guidewire maneuvers, balloon dilation, and lesions caused by the endoscope tip. In the literature, a perforation rate ranging from 0.08-0.6% is observed, with a mortality rate of 0.06%, which is compatible with the outcome of this study, in which the perforation rate reached 0.5%[10].

One limitation of this study was the retrospective study design and the inclusion of only a single center in the sample for analysis of the results, and there may be bias in the selection of the sample, which included more severe patients due to the repressed demand for the procedure in the SUS.

However, it is noteworthy that the results, success rate and complications were similar to those reported by specialized centers. thus demonstrating the effectiveness and safety of ERCP in biliopancreatic complex diseases in our service.

5 CONCLUSION

The analysis of the results allows us to conclude that the epidemiological profile of the patients submitted to ERCP was compatible with that reported in the literature, with a predominance of females, with a mean age of 53.9 years.

The main indication for ERCP was the clearance of the bile ducts caused by gallstones.

It was also observed that the success rate achieved in the service was (92.6%), and complications after the procedure were infrequent (6.45%), with acute pancreatitis being the most common, with an incidence of 3.7%.

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