

# Clinical and epidemiological evaluation of complications associated with gallstones in a tertiary hospital

Ridson Guilherme Parente de **AGUIAR**<sup>1</sup>, Francisco Emanuel Albuquerque de **SOUZA JÚNIOR**<sup>1</sup>, José Leonardo Gomes **ROCHA JÚNIOR**<sup>1</sup>, Francisco Sérgio Rangel de Paula **PESSOA**<sup>2</sup>, Leidiane Pinho da **SILVA**<sup>1</sup> and Gardênia Costa do **CARMO**<sup>1,2</sup>

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**ABSTRACT – Background** – Gallstones are the presence of bile clay in the gallbladder or bile ducts. The disease can be asymptomatic or symptomatic and can lead to complications and consequently a worse prognosis, such as acute cholecystitis, choledocholithiasis, cholangitis, and acute pancreatitis. The risk of complications increases after the first episode of biliary colic. **Objective** – A clinical-epidemiological evaluation of patients admitted to a gastroenterology ward of a tertiary care hospital with gallstone-related complications. **Methods** – We evaluated 158 patients admitted through discharge reports and medical records analysis from January 1, 2013, to February 24, 2021. **Results** – The female sex was predominant (76.6%), and the mean age of patients was 51.6 years. Men were significantly older than women ( $P=0.005$ ). Most (57.6%) had some comorbidity, the most frequent being systemic arterial hypertension, diabetes mellitus, and obesity. The mean hospitalization time was 24 days, significantly longer in men ( $P=0.046$ ) but without a direct relationship with age ( $P=0.414$ ). The most frequent complication was choledocholithiasis, and 55.7% of patients without previous cholecystectomy had a report of biliary colic before admission, on average 1.5 years previously. A history of a prior cholecystectomy was present in 17.1% of those evaluated. Abdominal ultrasonography followed by magnetic resonance cholangiography was the most frequently performed exam for diagnostic definition. Regarding therapeutic measures, endoscopic retrograde cholangiopancreatography was necessary for 47.3% of patients without previous cholecystectomy and 81.4% of patients who have already had a cholecystectomy. Among patients not yet cholecystectomized, 84% underwent the procedure before discharge. **Conclusion** – The female patients were predominant. Men were significantly older than women and had more extended hospital stays. The most frequent complication was choledocholithiasis, and around half of the patients reported previous biliary colic. endoscopic retrograde cholangiopancreatography has been necessary for the majority of the patients.

**Keywords** – Gallstones; cholecystectomy; choledocholithiasis.

## INTRODUCTION

Gallstones are the presence of concretions, either calculi (>3 mm) or biliary clay (<3 mm) in the gallbladder (cholelithiasis), bile ducts, or both. These concretions consist of crystal deposits containing primarily cholesterol, bilirubin, or both and are most commonly formed in the gallbladder<sup>(1)</sup>. The formation of these stones occurs due to a multifactorial disorder of the bile ducts<sup>(2)</sup>. It is the most common biliary disease in Western countries and is more common in women. In the United States and Europe, the prevalence of gallstones can reach 20% of the adult population<sup>(1)</sup>.

Patients can present asymptotically or symptomatically. When symptomatic, the clinical picture may consist of nonspecific dyspeptic symptoms, appetite changes, abdominal pain in the right hypochondrium (biliary colic), nausea, vomiting, and even jaundice<sup>(3)</sup>. However, it is noteworthy that about 80% of patients with cholelithiasis are asymptomatic<sup>(4)</sup>. In addition, after the first episode of gallstone-associated pain, the risk of complications increases from 0.1 to 0.3% per year in asymptomatic gallstone carriers to

1–2% per year<sup>(2)</sup>. The main complications associated with gallstones are acute cholecystitis, choledocholithiasis, acute pancreatitis, and cholangitis, leading to liver abscesses<sup>(5)</sup>. These complications occur due to the calculus migration and its impaction into the cystic duct or the central bile duct (choledochal)<sup>(6)</sup>.

Gallstones are usually diagnosed incidentally in asymptomatic patients or detected during the investigation of patients with typical abdominal pain or with complications associated with gallstones<sup>(7)</sup>. Abdominal ultrasonography is the most commonly used initial method for diagnosing gallstones accurately<sup>(8)</sup>. In cases of diagnostic doubt or when there is clinical evidence of cholelithiasis complications, other techniques, such as abdominal computed tomography (CT), magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound (EUS), and endoscopic retrograde cholangiopancreatography (ERCP) are commonly used<sup>(9)</sup>. Currently, in ERCP, its use is much more for therapeutic purposes.

Thus, the present study aimed at the clinical-epidemiological evaluation of patients hospitalized in the Gastroenterology ward with gallstone-related complications. Therefore, in a single study,

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<sup>1</sup> Centro Universitário Christus (Unichristus), Fortaleza, CE, Brasil. <sup>2</sup> Hospital Geral de Fortaleza, Fortaleza, CE, Brasil.

Corresponding author: Ridson Guilherme Parente de Aguiar. E-mail: ridsong@gmail.com

this research seeks to analyze the epidemiological profile of patients hospitalized in the Gastroenterology ward due to complications associated with gallstones in non-cholecystomized and previously cholecystomized patients. According to the authors' search, none of the articles found addressed all these topics in a single study, with most articles found in the literature generally focusing only on a specific point of these mentioned topics. Furthermore, the authors found few previous articles on this topic with epidemiological information about the Northeast of Brazil and none with epidemiological information from Ceará.

## METHODS

This study is retrospective. Data were collected by analyzing discharge reports and medical records of patients hospitalized due to complications related to gallstones from January 1, 2013, to February 24, 2021. In addition, the authors used a specific form to record epidemiological and clinical information relevant to the study.

The inclusion criteria were: being over 16 years of age, being patients admitted to the Gastroenterology ward, having a diagnosis of clinical complications associated with gallstones, and having copies of the discharge report on file during the study period. Exclusion criteria were: patients who died during their stay in the Gastroenterology ward; patients in whom data had been mistakenly or incompletely recorded in the discharge reports, preventing retrieval of the medical records from complementing the data; patients in whom gallstones were not evidenced at the time of admission or previously; and patients whose entry did not occur due to gallstone-associated complications.

All generated data were recorded in an Excel spreadsheet, MICROSOF<sup>®</sup> (New York, NY, USA). Expressed quantitative data are presented as mean  $\pm$  standard deviation and median, while qualitative data are presented as absolute numbers or percentages. Data analysis was performed using statistical software GraphPad QuickCalcs online (Graphpad by Dotmatics Company, San Diego, CA, USA). We used paired *t*-test for statistical analysis among the groups, and *P* values  $<0.05$  were considered statistically significant. Linear regression analyses were also performed to evaluate the relationship between continuous variables, age, and length of hospital stay.

The Ethics Committee duly approved the study (CAAE 31146920.2.0000.5040), respecting the terms of Resolution No. 466, of December 12, 2012, of the National Health Council.

## RESULTS

A total of 199 discharge reports of patients admitted to the Gastroenterology ward for pancreatic and biliary tract diseases from January 2013 to February 2021 were evaluated. The discharge reports were filed in identified folders and stored in the Gastroenterology prescription room. Of the 199, seven reports were initially excluded due to incomplete information regarding patient identification, making it impossible to analyze the records. Of the remaining 192, twenty-three patients were excluded because, when evaluating the data from the discharge reports, we observed that the pathologies that led to hospitalization were no complications associated with gallstones. Thus, 169 patients were selected for chart analysis and completion of data collection forms. Eleven of these were excluded because, after a detailed analysis of the medical re-

ports, we verified that, although they were carriers of cholelithiasis, the reason for hospitalization was not due to complications related to it. Thus, 158 patients hospitalized for complications associated with gallstones were included in our study (FIGURE 1).

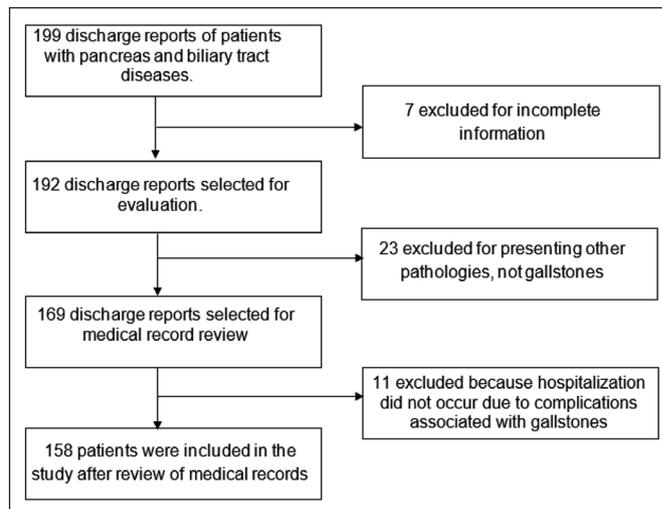


FIGURE 1. Selection of patients for the study.

Of the patients included in the study, 121 (76.6%) were female, and 37 (23.4%) were male. The mean age at the hospitalization time was  $51.6 \pm 21$  years and a median of 52 years. Male inpatients were significantly older, with a mean age of 60 years, while females were 49 years old ( $P=0.005$ ).

Most evaluated patients had at least one comorbidity, 24.7% had one, and 32.9% had two or more comorbidities. The three most prevalent comorbidities, either alone or in association, in our sample were: hypertension (36.7%), diabetes mellitus (15.1%), and obesity (13.9%). Identified current or previous history of significant alcoholism in 24.6% and important smoking history in 29.7% of the studied individuals.

We observed that the mean length of stay was  $24.4 \pm 21.3$  days and an average of 19.5 days. Male patients had a longer mean length of stay ( $30.5 \pm 31.1$  days) than female patients ( $22.6 \pm 16.9$  days),  $P=0.046$ . The size of stay had no direct relation with the age of patients in the total sample studied ( $P=0.414$ ), as shown in FIGURE 2. There was no significant difference when

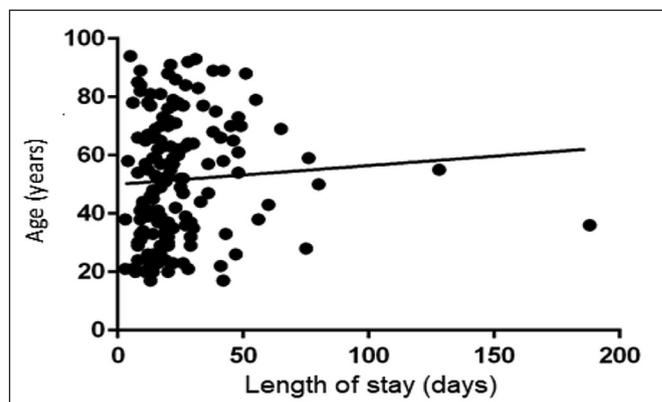


FIGURE 2. Linear regression graph showing the relationship between the length of hospital stay and the age of the studied patients ( $P=0.414$ ).

comparing the mean length of stay of patients with and without comorbidities ( $P=0.761$ ) or with and without a history of prior cholecystectomy ( $P=0.196$ ).

Patients admitted with complications associated with gallstones were divided into two groups: patients not yet cholecystectomized (complicated cholelithiasis) and patients previously cholecystectomized (primary or secondary choledocholithiasis). No differences in mean age ( $P=0.125$ ) or gender predominance ( $P=0.213$ ) were observed between the groups.

### Patients who have not undergone a previous cholecystectomy

Complicated cholelithiasis was the reason for hospitalization in 82.9% of the studied population. The complication most often evidenced, either alone or associated, was choledocholithiasis (53.4%), followed by acute pancreatitis (41.9%), acute cholecystitis (32.8%), cholangitis (29.7%), cholangitis liver abscess (4.5%), and gallbladder adenocarcinoma (0.7%), as shown in FIGURE 3. According to the clinical history at admission to the gastroenterology ward, 55.7% of these patients had, before entry, self-limited episodes of symptoms compatible with biliary colic. The mean time between the onset of these symptoms and the outbreak of complications that led to hospitalization was  $1.55 \pm 1.76$  years (median one year). It is noteworthy that in 10 patients with symptoms compatible with biliary colic before the complication, the exact time of onset of these symptoms was not reported in the medical record; thus, it was impossible to include them in this analysis. Eleven (8.3%) patients had already presented previous complications and were clinically managed in other hospitals.

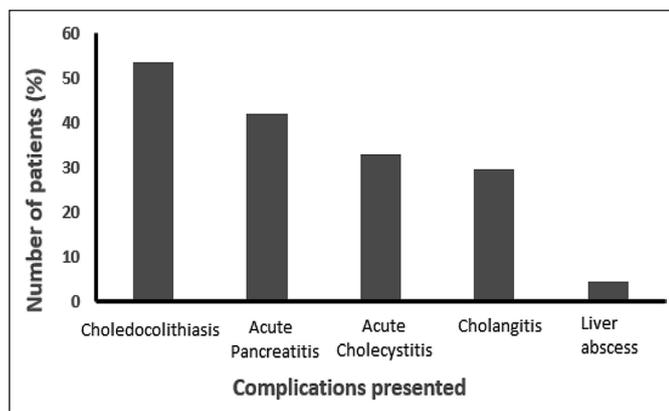


FIGURE 3. Current complications led to hospitalization in the group of patients who had not yet undergone cholecystectomy.

The following imaging exams were performed for a diagnostic definition in this group of patients: USG in 93.8%, MRCP in 53.4%, CT in 37.4%, and EUS in 11.4%. Regarding the therapeutic procedures used to control the complication during hospitalization, 47.3% of patients required ERCP, and 4.5% needed to perform endoscopic or percutaneous drainage of peri-pancreatic or hepatic collection. Before hospital discharge, cholecystectomy was possible in 84% of the patients, and six of them required an associated biliodigestive shunt. Twenty-one patients did not undergo cholecystectomy before release, a definitive therapeutic method that would avoid further complications. This decision was made due to the high surgical risk of the patient at that moment, either by age, presence of comorbidities, or current clinical status.

### Previously cholecystectomized patients

Of the patients admitted to the gastroenterology ward for complications associated with gallstones, 17% (27/158) had previously undergone cholecystectomy. Thus, the admissions occurred because of clinical manifestations (abdominal pain, jaundice, or both) or complications associated with the presence of choledocholithiasis, either primary or secondary. Nineteen of them (70%) had primary choledocholithiasis. They had been submitted to cholecystectomy more than two years before (mean and median of 10 years). As complications associated with choledocholithiasis, 37% of them presented with cholangitis, 26% with acute pancreatitis, and 7% with cholangitis liver abscess, as represented in FIGURE 4. In two patients who presented with cholangitis, no choledochal calculi were evident in the imaging exams performed.

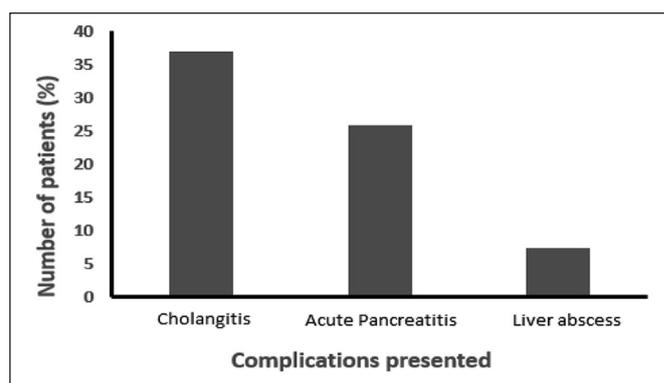


FIGURE 4. Complications are present in the group of patients who have already undergone cholecystectomy.

The following imaging exams were performed for a diagnostic definition in this group of patients: USG in 81.4%, MRCP in 70.3%, CT in 48.1%, and EUS in 3.7%. Regarding the therapeutic procedures used to control the complication during hospitalization, 81.4% of patients required ERCP, and 7.4% needed a biliodigestive shunt. The three patients, who did not undergo invasive therapeutic procedures, evolved with a complete improvement of symptoms only with clinical management.

### DISCUSSION

In the current study, the mean age at admission was 51.6 years, which agrees with the literature since the evidence shows that the presence of gallstones is ten times more likely in people aged 40 years or older, which is explained by a decline in the activity of cholesterol 7  $\alpha$ -hydroxylase, an essential enzyme for cholesterol metabolism. Women are generally at higher risk of cholelithiasis than men due to factors such as naturally higher estrogen levels in women, intake of estrogen-based oral contraceptives, or multiparities<sup>(10,11)</sup>. Therefore, it may justify that we found that the men who were admitted to the hospital for gallstone-associated complications were significantly older than the women.

Regarding social habits, the current or previous significant history of alcoholism or smoking was identified in a minority of the patients studied, occurring in 24.6% and 29.7% of them, respectively. Data in the literature indicate that alcohol consumption appears to confer protection against gallstone formation<sup>(12)</sup>, with an inverse association reported between increased alcohol consumption and the risk of gallstones<sup>(11,13)</sup>. However, several other studies have failed

to find such an association, including evidence that alcohol abuse would increase the risk of gallstone synthesis; in addition, alcoholic liver cirrhosis appears to be a decisive, independent risk factor for gallstone formation<sup>(11)</sup>. Thus, physicians need to be cautious when recommending beverages for gallstone prevention<sup>(14)</sup>.

The studies that have evaluated the association between smoking and gallstone formation are also controversial. There is evidence that smoking more than 35 cigarettes per day may be a decisive risk factor for women developing gallstones. A large population-based study also confirmed that smoking is a significant risk factor for developing symptomatic gallstones in women. However, some other studies found no relationship between smoking and gallstone development<sup>(11-13)</sup>. A meta-analysis of studies linking smoking and the risk of gallbladder disease confirms an increased relative risk of 19% among current smokers<sup>(15)</sup>.

The most prevalent comorbidities in the patients studied were systemic arterial hypertension, diabetes mellitus, and obesity. According to the literature, dyslipidemia, diabetes mellitus, insulin resistance, and metabolic syndrome are often present in patients with gallstones. In insulin-resistant individuals with type 2 diabetes mellitus, the prevalence of gallstones has been observed to increase two- to threefold. Thus, due to its ability to increase bile cholesterol saturation, insulin resistance has been suggested as a causal link in the development of gallstones<sup>(11)</sup>.

In our study, around half of patients who had not yet undergone cholecystectomy reported symptoms consistent with biliary colic before hospitalization, and the meantime to the onset of symptoms was one and a half years<sup>(5)</sup>. This percentage is close to the rate of another study conducted, in which 57% of not cholecystectomized patients had biliary colic before presenting with gallstone complications<sup>(16)</sup>. There is evidence in the literature that most patients who evolve with complications associated with gallstones have previously presented episodes of biliary colic<sup>(16)</sup>. Thus, cholecystectomy is recommended, when possible, for patients with gallstones who present with biliary colic to prevent the onset of complications<sup>(17)</sup>.

The mean time between the onset of biliary colic and the episode of complication leading to hospital admission was  $1.55 \pm 1.76$  years (median one year). A study in the UK shows a similar time course from gallstones to some complications, in which 127 patients with gallstones were indicated for cholecystectomy for biliary colic, waiting 12 months for surgery. Over those 12 months, 37 of 127 of these patients were admitted to the emergency department in 47 admissions, of which 32 were for biliary colic, 13 for acute cholecystitis, and two for acute pancreatitis<sup>(18)</sup>.

It was observed that acute cholecystitis was the third most observed complication, preceded by choledocholithiasis and acute pancreatitis. According to the literature, the main complications of gallstones are acute cholecystitis, choledocholithiasis, acute pancreatitis, and cholangitis<sup>(17)</sup>, with acute cholecystitis being the main complication of gallstones, accounting for 3 to 10% of cases of abdominal pain<sup>(19)</sup>. Choledocholithiasis can occur in 10–20% of patients with gallstones and be found in 5–18% of patients undergoing elective cholecystectomy<sup>(17,20)</sup>. The presence of choledocholithiasis can cause cholangitis, whose prevalence in patients with gallstones ranges from 6 to 9% and is a medical emergency whose treatment is immediate biliary decompression<sup>(17,21)</sup>, and acute pancreatitis that can occur in 3 to 7% of patients with gallstones<sup>(22)</sup>. This difference in the prevalence of complications in our findings compared to the literature may have occurred because the research was conducted in a tertiary hospital, which receives, in its

emergency department, patients who more often have more severe complications and require specialized multidisciplinary evaluation (clinician, endoscopist, and digestive tract surgeon), as happens in choledocholithiasis and acute pancreatitis. Many cases of acute cholecystitis alone are often managed in secondary care hospitals and do not require admission to tertiary care hospitals. Furthermore, patients admitted to the hospital where the research was conducted are often referred to from other secondary hospitals in the city or the countryside, as they need more complex exams and procedures, which brings a high cost to the Unified Health System.

In our study, 17% of the patients admitted were already cholecystectomized and were taken in due to clinical manifestations or complications probably associated with the presence of choledocholithiasis, most of them in the primary form. Only two patients presented with cholangitis, but no choledochal calculi were evidenced by the imaging exams performed. These findings may be explained because the patients may have had the post-cholecystectomy syndrome, which can affect 10 to 15% of patients who undergo cholecystectomy<sup>(23)</sup>, or even because the calculus has spontaneously migrated to the intestine, clearing the bile duct<sup>(24,25)</sup>.

The current study found an average length of stay of 24.4 days. When evaluating data already published, we found that there is a reference that the average length of hospital stays in the United States for patients with acute cholecystitis in the year 2012 was approximately four days<sup>(26)</sup>, and the average length of stay for patients hospitalized for choledocholithiasis between the years 1998 to 2013 ranged between 3 and 4 days<sup>(27)</sup>. A survey in Japan between 2014 and 2018 showed that the length of hospitalization for cholangitis was  $5.7 \pm 4.2$  days and ranged from 3 to 45 days<sup>(28)</sup>. Moreover, in a survey conducted in Spain, it was observed that the mean length of stay for biliary pancreatitis in a tertiary care hospital in 2014 was  $10.6 \pm 5.9$  days, with a range of 4 to 25 days<sup>(29)</sup>. Compared to these other studies, the prolonged hospital stays found in this study may be related to a higher prevalence of complications such as acute pancreatitis and cholangitis. These are usually associated with an increased risk of serious infections, requiring the use of longer-term broad-spectrum antibiotics and commonly requiring more diagnostic tests and invasive procedures. Male patients had a longer mean length of stay than female patients; this finding may be associated with the fact that the men evaluated are significantly older than the women, which may have contributed to the appearance of other clinical complications that prolonged the length of stay. Nevertheless, there was no evidence of a significant correlation between length of stay and increasing age, presence of comorbidities, or history of the previous cholecystectomy.

Thus, it is essential to emphasize that if it were possible to perform cholecystectomy early and electively, soon after the first episode of biliary colic and before the onset of more severe complications, we could have avoided, for the patient and the Unified Health System, costs related to prolonged hospitalizations and use of tertiary resources. There are many cost implications associated with increased length of hospital stay.

Although the diagnosis of symptomatic cholelithiasis and its complications is primarily clinical, imaging studies are necessary to document the presence of calculi in the gallbladder and bile ducts. In our study, most patients underwent USG as the initial examination for diagnosis, both in the group not yet cholecystectomized and in the group already cholecystectomized, 93.8% and 81.4%, which followed the recommendation that this method represents the first-line imaging test.

Taking into consideration that choledocholithiasis was the most frequent complication in this current study, it is justified that MRCP was the second most requested exam, being necessary for more than 50% of the patients who had not had a cholecystectomy and in more than 70% of those who had already had one. EUS was performed in only 11.4% of patients evaluated, which may be justified because it is less available in our service and more invasive than the other modalities because it involves sedation. However, there is evidence that EUS is better than MRCP in detecting the presence or absence of stones in the biliary ducts, avoiding unnecessary ERCP<sup>(30)</sup>.

In our study, regarding the therapeutic approach, in the non-cholecystectomized group, more than 50% of patients had evidence of choledocholithiasis, with almost 30% of them having cholangitis criteria ERCP was required in 47.3% of cases to clear the bile duct. Current guidelines recommend emergency ERCP in patients with biliary pancreatitis and concomitant cholangitis; furthermore, they suggest that ERCP may benefit patients with cholestasis and evidence of choledocholithiasis on imaging tests<sup>(31)</sup>. After resolving the current complication, over 80% of those evaluated could undergo cholecystectomy before discharge, possibly leading to lower rates of possible complications in the future<sup>(9)</sup>.

In the group already cholecystectomized, 81.4% of patients required ERCP for biliary tract clearance, and 7.4% of this group eventually needed a biliodigestive shunt due to the impossibility of resolving the condition only with ERCP. This finding agrees with data from the literature, which shows that only a small number of patients with choledocholithiasis require biliodigestive shunting<sup>(32)</sup>.

## CONCLUSION

In this study, the female sex was predominant. Men have been significantly older than women and have had significantly longer hospital stays. The most frequent complication was choledocholithiasis, and around half of the patients reported previous biliary colic. Abdominal ultrasonography followed by magnetic resonance cholangiography was the most frequently performed exam for diagnostic definition. Endoscopic retrograde cholangiopancreatography has been necessary for over half of patients without previous cholecystectomy and most patients with a previous cholecystectomy. The majority of the patients not yet cholecystectomized could undergo the procedure before discharge.

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## Authors' contribution

Aguiar RGP: investigation, methodology, data collection, search execution, writing of the manuscript. Supervision, visualization, project administration, and writing-review and editing. Souza Júnior FEA: Investigation, methodology, data collection, search execution, writing of the manuscript and writing-review and editing. Rocha Júnior JLG: methodology, investigation, data collection, search execution, writing of the manuscript. Pessoa FSRP: proposed the theme of the research, conceptualization, revised the final report. Project administration. Resources. Silva LP: statistical analysis, supervision. Writing of the manuscript. Investigation. Visualization Methodology. Project administration. Carmo GC: conceptualization, statistical analysis, supervision and writing of the manuscript. Project administration. Investigation. Visualization Methodology. Writing-review and editing. Validation. Methodology.

## Orcid

Ridson Guilherme Parente de Aguiar: 0000-0003-1493-5299.  
Francisco Emanuel A. de Souza Júnior: 0000-0002-2239-4886.  
José Leonardo Gomes Rocha Júnior: 0000-0002-3567-0480.  
Francisco Sérgio R. de Paula Pessoa: 0000-0001-6025-5601.  
Leidiane Pinho da Silva: 0000-0002-8825-945X.  
Gardênia Costa do Carmo: 0000-0003-4491-865X.

Aguiar RGP, Souza Júnior FEA, Rocha Júnior JLG, Pessoa FSRP, Silva LP, Carmo GC. Avaliação clínica-epidemiológica de complicações associadas à litíase biliar em um hospital terciário. *Arq Gastroenterol.* 2022;59(3):352-7.

**RESUMO – Contexto** – A litíase biliar pode ser definida como a presença de cálculo ou barro biliar na vesícula e/ou nos ductos biliares. A doença pode ser assintomática ou sintomática, podendo levar a complicações e, conseqüentemente, a um pior prognóstico, como colecistite aguda, coledocolitíase, colangite e pancreatite aguda. O risco de complicações aumenta após o primeiro episódio de cólica biliar. **Objetivo** – Avaliação clínica-epidemiológica dos pacientes internados em enfermaria de gastroenterologia de um hospital terciário, com complicações relacionadas à litíase biliar. **Métodos** – Foram avaliados 158 pacientes internados no período de 1º de janeiro de 2013 a 24 de fevereiro de 2021, por meio de análise de relatório de alta e prontuário. **Resultados** – Houve uma predominância do sexo feminino (76,6%), e a média de idade dos pacientes foi de 51,6 anos. Homens eram significativamente mais velhos que as mulheres ( $P=0,005$ ). A maioria (57,6%) apresentava alguma comorbidade, sendo as mais frequentes: hipertensão arterial sistêmica, diabetes *mellitus* e obesidade. A média de tempo de internação foi de 24 dias, sendo significativamente maior para os homens ( $P=0,046$ ), mas sem relação direta com a idade ( $P=0,414$ ). A complicação mais frequente foi a coledocolitíase, e 55,7% dos pacientes sem colecistectomia prévia apresentaram relato de cólica biliar antes da internação, em média, 1,5 anos antes. Histórico de colecistectomia prévia estava presente em 17,1% dos avaliados. Ultrassonografia abdominal, seguida de colangioparessonância magnética foram os exames complementares mais frequentemente realizados para definição diagnóstica. Em relação às medidas terapêuticas, a colangiopancreatografia endoscópica retrógrada (CPRE) foi necessária em 47,3% dos pacientes sem colecistectomia prévia e 81,4% dos pacientes com colecistectomia prévia. Dos pacientes ainda não colecistectomizados, 84% deles puderam ser submetidos ao procedimento antes da alta. **Conclusão** – Houve predomínio do sexo feminino. Os homens foram significativamente mais velhos do que as mulheres e tiveram uma permanência hospitalar consideravelmente mais longa. A complicação mais frequente foi a coledocolitíase, e cerca de metade dos pacientes relatou cólica biliar prévia. A CPRE foi necessária para a maioria dos pacientes.

**Palavras-chave** – Litíase biliar; colecistectomia; coledocolitíase.

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