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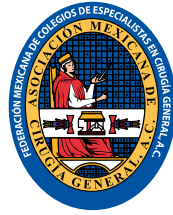
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# Zero Disruption (PDC2024) Policy and International Safe Cholecystectomy Crusade of the Mexican Association of General Surgery, A.C.

*Política Disrupción Cero (PDC2024) y Cruzada Internacional de Colecistectomía Segura de la Asociación Mexicana de Cirugía General, A.C.*

Marco Antonio Loera-Torres,<sup>\*</sup> Karina Sánchez-Reyes,<sup>‡</sup> José Luis Beristain-Hernández,<sup>§</sup> Eduardo Moreno-Paquentín,<sup>¶||</sup> Héctor F Noyola-Villalobos,<sup>||,\*\*</sup> Elena López-Gavito,<sup>||,‡‡</sup> Jordán Zamora-Godínez<sup>||,§§</sup>

## Keywords:

safe cholecystectomy,  
biliary duct  
disruption, critical  
view, laparoscopic  
cholecystectomy.

## Palabras clave:

colecistectomía  
segura, disrupción  
de la vía biliar;  
vista crítica,  
colecistectomía  
laparoscópica.

## ABSTRACT

Biliary tract disruption by cholecystectomy is a complication with catastrophic clinical consequences. Despite Safe Cholecystectomy Culture and numerous strategies to prevent this complication devised by various surgical associations around the world, incidence has not decreased. Unawareness of fully established preventive actions, lack of rescue strategies for difficult cholecystectomy, adoption of alternative high-risk procedures, and overconfidence of the surgical team, among other factors, contribute to biliary disruption by cholecystectomy remaining a reality in Latin America. Conscious of this reality, the Mexican Association of General Surgery, A.C. created the Zero Disruption Working Group to draft a set of evidence-based institutional directives called Zero Disruption Policy (PDC2024 AMCG) to raise awareness about its prevention, eradicate unsafe surgical practices, and unite collaborative efforts to teach the systematization of intraoperative actions, decision-making in different scenarios of difficult cholecystectomy, and materialize the International Safe Cholecystectomy Crusade. The objective of the PDC2024 AMCG is to achieve a 0% incidence of biliary disruption by cholecystectomy within five years.

## RESUMEN

La disrupción de la vía biliar por colecistectomía es una complicación de consecuencias clínicas catastróficas. A pesar de la enseñanza de la cultura de la Colecistectomía Segura y de las numerosas estrategias para prevenir esta complicación, diseñadas por distintas agrupaciones quirúrgicas alrededor del mundo, su incidencia no ha disminuido. El desconocimiento de medidas preventivas plenamente establecidas, la falta de apego a estrategias de rescate ante colecistectomía difícil, la adopción de procedimientos alternativos de alto riesgo, así como el exceso de confianza del equipo quirúrgico, entre otros factores, contribuyen a que la disrupción biliar por colecistectomía siga siendo una realidad presente en América Latina. Consciente de esta realidad, la Asociación Mexicana de Cirugía General, A.C. creó el Grupo de Trabajo Disrupción Cero para redactar un conjunto de directivas institucionales basadas en la evidencia científica existente, denominado Política Disrupción Cero (PDC2024 AMCG), para concientizar sobre su prevención, erradicar las prácticas quirúrgicas inseguras y unir esfuerzos de colaboración para enseñar la sistematización de las acciones intraoperatorias, la toma de decisiones ante diferentes escenarios de colecistectomía difícil y materializar la Cruzada Internacional de Colecistectomía Segura. El objetivo de la PDC2024 AMCG es alcanzar en cinco años una incidencia de 0% de disrupción biliar por colecistectomía.

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## INTRODUCTION

The disruption of the bile duct is a catastrophic complication of cholecystectomy, whatever its approach. It consists of section, obstruction by ligation, stapling, or diathermy damage of the main bile duct, right or left hepatic ducts, and the confluence of hepatic ducts or accessory hepatic ducts occurring during dissection of the hepatocystic triangle.<sup>1,2</sup>

The consequences of biliary disruption by cholecystectomy are hepatic atrophy, biliary stenosis, recurrent cholangitis, hepatic fibrosis, secondary biliary cirrhosis, portal hypertension or death, as well as the need for multiple invasive procedures or surgical reinterventions, liver resection or liver transplantation.<sup>3</sup> Biliary dysfunction is associated with surgical scenarios of acute or chronic cholecystitis with a large amount of firm, fibrous inflammatory adhesions in the gallbladder hilum, often involving colon, duodenum, or stomach and limiting safe dissection of the structures of the hepatocystic triangle. However, there are cases reported in surgical scenarios without severe local inflammation.<sup>4</sup> Its real incidence is unknown and often underreported, with a high empirical casuistry in hospitals of reference and concentration of hepatopancreatic biliary pathology in Latin America.<sup>2</sup>

Despite the efforts to teach and systematize the procedure that has been made in different surgical organizations (SAGES, ACS, Tokyo Group, AMCG) in congresses, courses, workshops, webinars, books, and articles on Safe Cholecystectomy, the incidence has not decreased. Cases of biliary tract disruption continue to be received in public and private health institutions due, on many occasions, to a lack of knowledge of rescue techniques in the face of difficult cholecystectomy or reluctance to adopt them, overconfidence, lack of surgical skill, lack of experience, clinical judgment and decision making, among other causes. It is common to observe surgical sites that promote risky techniques such as reduction of the number of working ports, single port, or surgery with magnets in cholecystectomy. Likewise, it is common to find general surgery resident training centers unfamiliar with the regular practice of rescue

techniques in difficult cholecystectomy, doublet view scoring, pre-operative and intraoperative predictive scales, critical view of safety and surgical pauses at “turning points” described in the literature and particularly in the Safe Cholecystectomy Program of SAGES, which leads to a non-unified language and confusion in the description of the surgical technique in the operative dictations and the systematization and teaching of decision making in difficult scenarios.

Aware of this reality, the Mexican Association of General Surgery, A.C., ordered in November 2023 the creation of the Zero Disruption Working Group to draft the **Zero Disruption Policy (PDC2024)** and create and materialize the institutional strategy called **the International Safe Cholecystectomy Crusade**.

## OPERATIONAL DEFINITIONS

For the purposes of this policy, the following definitions shall be understood as such:

- **Surgical patient safety culture:** global movement integrated by the set of institutional, individual, and collective policies to generate actions aimed at preventing and reducing near misses, adverse events, and sentinel events in surgical practice.
- **Patient-surgeon binomial (P.C. binomial):** dual and indivisible unit of shared effects composed of the patient and the surgeon.
- **Safe cholecystectomy:** cholecystectomy that ends without biliary disruption.
- **Difficult cholecystectomy:** cholecystectomy is performed in an inflammatory setting that prevents obtaining the critical view of safety and corresponds to the Parkland scale of 3 to 5.
- **Subtotal cholecystectomy:** is the procedure to remove portions of the gallbladder when the structures of the hepatocystic triangle cannot be safely identified in difficult cholecystectomies.
- **Zero Disruption Policy (PDC2024):** is the set of institutional directives of the *Asociación Mexicana de Cirugía General*, A.C. aimed at:



- To end the acceptance of bile duct disruption as a normal event in cholecystectomy.
  - Raise awareness about its prevention.
  - To eradicate unsafe surgical practices.
  - To commit to a unified effort where all general surgery resident training centers adopt systematize intraoperative actions and decision-making in complex cholecystectomy scenarios according to what is described in the international scientific literature.
  - To materialize its actions through the International Safe Cholecystectomy Crusade.
- **International Safe Cholecystectomy Crusade:** is the institutional, multi-front, staged, and permanently supervised operational strategy of the Mexican Association of General Surgery, A.C., created to materialize the PDC2024 and achieve the master objective of reducing, in five years, the incidence of biliary disruption by cholecystectomy in Mexico, Central and South America.

#### **ZERO DISRUPTION POLICY DIRECTIVES OF THE MEXICAN ASSOCIATION OF GENERAL SURGERY, A.C. (PDC2024 AMCG)**

The Associations, Universities, Hospitals, and General Surgery Resident Training Centers that adhere to PDC2024 of the AMCG commit themselves to teach, practice, and supervise all the following guidelines and operative concepts without modifying them or adopting them in part:

1. The degree of inflammation does not justify bile duct disruption.<sup>5,6</sup>
2. Incorporate in a mandatory manner in all training programs for General Surgery residents the teaching and evaluation in surgical simulators of all the directives contained in PDC2024, recording them in a portfolio of evidence integrated by Simulation Log, Rubric, and Checklist.<sup>7</sup>
3. Verify and record the surgical team's optimal physical and mental state before starting surgery.
4. Record the pre-operative Nassar score and prediction of difficult cholecystectomy in the pre-operative evaluation note.<sup>8-11</sup>
5. Always perform a laparoscopic cholecystectomy approach with four ports (one optical and three working ports). Abandon the three-port or less approach, magnet-assisted surgery, and single port approach.<sup>12</sup>
6. Perform B-SAFE orientation and visualization of the R4U line by traction of the vesicular fundus at the 11 o'clock radius and the vesicular infundibulum at the 7 o'clock radius, to keep the cystic perpendicular to the main bile duct and avoid its parallel alignment.<sup>13</sup>
7. Perform gentle dissection of the hepatocystic triangle until the critical safety view is obtained, safely identifying the anatomical structures, without forcing the dissection: "If it does not take off smoothly, do not insist...".<sup>5,14</sup>
8. Perform the "doublet view" maneuver and record it in the postoperative note, attaching the supporting photographs. Always record video.<sup>15,16</sup>
9. Perform five surgical breaks (time out) at turning points:<sup>8,17,18</sup>
  - a. Before starting surgery, verify that the patient is the right one, the correct procedure, and that the human resources of the surgical team and available material resources are adequate.<sup>19</sup>
  - b. At the time of the first B-SAFE and R4U line visualization.<sup>5,6</sup>
  - c. Upon achieving the critical safety vision or declaring the impossibility of realizing it.<sup>17,20</sup>
  - d. Before clipping and sectioning what appears to be the cystic duct and cystic artery.<sup>5</sup>
  - e. If there is any doubt about the anatomy.<sup>5</sup>
10. Use the Parkland intraoperative scale to classify the degree of vesicular and hepatocystic triangle inflammation.<sup>21</sup>
11. Before ligation and sectioning any structure, state aloud to the entire surgical team in the operating room the Parkland grade and doublet view score achieved after

- careful dissection and record it in the postoperative note.<sup>5,15,18</sup>
12. If, after gentle dissection of the hepatocystic triangle, a critical safety view can be performed and doublet view > 5 is achieved (Parkland 1 and 2), perform total cholecystectomy.<sup>15,20,22</sup>
  13. If, after gentle dissection of the hepatocystic triangle, safety-critical vision is NOT possible and doublet view < 4 is achieved, recognize early the danger of biliary disruption and perform a rescue procedure to complete the operation safely:<sup>14,23</sup>
    - a. Perform subtotal cholecystectomy at Parkland 3.<sup>6,20,24</sup>
    - b. Perform cholecystostomy with stone removal in Parkland 4.<sup>6,25</sup>
    - c. Discontinue the procedure and refer to a center of HPB expertise at Parkland 5.<sup>12,26</sup>
  14. Always place subhepatic drainage if subtotal cholecystectomy or cholecystostomy is performed.<sup>20</sup>
  15. Ask for help from a more experienced surgeon in case of difficult cholecystectomy.<sup>5,12</sup>
  16. Do not perform conversion to open surgery for routine Parkland 3 to 5. It is always preferable to perform a laparoscopic salvage procedure and only reserve conversion for intraoperative life-threatening situations.<sup>6,27,28</sup>
  17. Do not use monopolar energy (hook) in the skeletonization of the cystic duct and cystic artery. Reserve its cautious use for dissection of the perivesicular visceral peritoneum of the body and fundus.<sup>12,29</sup>
  18. Use bipolar energy (if available) in the gallbladder wall section of the subtotal cholecystectomy, not in the dissection of the gallbladder hilum.<sup>18,29</sup>
  19. Prepare the Informed Consent, recording Nassar and the possibility of difficult cholecystectomy, as well as the possible variants of the surgical technique of cholecystectomy according to intraoperative findings and the need for rescue procedures and placement of drains.<sup>8</sup>
  20. Do not use intraoperative cholangiography routinely, but selectively.<sup>12,29-31</sup>
  21. These guidelines do not apply to a life-threatening intraoperative emergency, in which case the surgical team is free to act according to its clinical judgment and criteria. They are equally applicable to laparoscopic, open, and robotic approaches.

### **INTERNATIONAL CRUSADE FOR SAFE CHOLECYSTECTOMY OF THE MEXICAN ASSOCIATION OF GENERAL SURGERY, A.C.**

The Associations, Universities, Hospitals, and General Surgery Resident Training Centers that adhere to the PDC2024 AMCG commit themselves to join their efforts with the Mexican Association of General Surgery, A.C. to materialize the institutional and staged strategy called International Safe Cholecystectomy Crusade to participate in the following action front:

1. **Signing of institutional agreements of adhesion** to the PDC2024 between the Mexican Association of General Surgery, A.C. and Associations, Universities, Hospitals, and Training Centers for General Surgery Residents in Mexico, Central, and South America for the teaching and local supervision of the intraoperative performance of surgeons during cholecystectomy, as well as the exchange of information to help achieve the master objective.
2. **Instructor training courses.**
3. **Disruption Zero Symposia:** are the set of face-to-face and online conferences to teach PDC2024.
4. **Training workshops in open and laparoscopic cholecystectomy simulation by scenarios.**
5. **Dissemination of informative and awareness-raising capsules** aimed at teaching PDC2024 through social networks, podcasts, radio programs, television, streaming, congresses, and academic sessions of AMCG and sister associations in Mexico, Central and South America.
6. **Appointment of International Coordinators and their integration into**

the International Team of Instructors who have presented and passed the Instructor Training Course of the PDC2024 of the Mexican Association of General Surgery, A.C.

7. **Permanent supervision program of the adherence to the PDC2024** in each General Surgery Resident training center and Hospitals in agreement in Mexico, Central and South America.

This policy represents the *Asociación Mexicana de Cirugía General, A.C.*'s international effort in Safe Cholecystectomy. It ratifies our commitment to surgical patient safety and to benefit patients with acute cholecystitis in Latin America.

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# Enhanced Surgical Recovery Program. Safe cholecystectomy

## Programa de Recuperación Quirúrgica Mejorada. Colecistectomía segura

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### Keywords:

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### Palabras clave:

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disrupción de vía  
biliar.

### ABSTRACT

In Mexico, cholecystectomy is the most common surgical procedure in general surgery. Enhanced recovery programs in surgery aim to provide efficient treatment based on the best scientific evidence. This document aims to optimize the outcome of patients undergoing cholecystectomy in our country based on a series of recommendations issued by experts from different institutions and based on the best scientific evidence available to date. It is aimed at surgeons working in public institutions and private sectors. It seeks to promote strategies for improved surgical recovery and a safe cholecystectomy to offer our patients the best possible surgical outcome.

### RESUMEN

En México, la colecistectomía es el procedimiento quirúrgico más frecuente en cirugía general. Los programas de recuperación mejorada en cirugía tienen como principal objetivo brindar un tratamiento eficiente basado en la mejor evidencia científica. El presente documento busca optimizar el desenlace quirúrgico de los pacientes sometidos a colecistectomía en nuestro país, a partir de una serie de recomendaciones emitidas por expertos de diferentes instituciones y basadas en la mejor evidencia científica disponible hasta este momento. Está dirigida tanto a cirujanos que trabajan en instituciones públicas como aquellos en el sector privado, además busca difundir estrategias para una recuperación quirúrgica mejorada y, ante todo, para una colecistectomía segura, con el objetivo de ofrecer a nuestros pacientes el mejor desenlace quirúrgico posible.

## INTRODUCTION

Gallbladder lithiasis is a frequent condition in our environment and the leading cause of cholecystitis and biliary colic. In Mexico, cholecystectomy is the most frequently performed surgical procedure in general surgery.<sup>1</sup> In spite of the technological advances and the different modifications in the conventional technique for performing cholecystectomy, the procedure continues to be

performed in our country both by conventional open and laparoscopic routes. The main objective of enhanced recovery programs in surgery is to provide efficient treatment based on the best scientific evidence to shorten the postoperative recovery time of patients, reduce the incidence of complications inherent to hospitalization and surgical treatment, and, consequently, reduce hospital costs. One of the initiatives of the Mexican Association of General Surgery (AMCG) A.C. is to issue a series

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of recommendations that support national surgeons to have better surgical results, with the sole objective of increasing the quality of care of the Mexican population.<sup>2,3</sup> The above applies to the different modalities of the procedure and in any type of institution in the country; these are general recommendations applicable to all cases.

## MATERIAL AND METHODS

This work aimed to reach a consensus of experts to issue recommendations during the preoperative, intraoperative, and postoperative periods to improve the surgical outcomes of patients who underwent cholecystectomy. All these recommendations are based on the best available scientific evidence and are oriented to general surgeons nationwide. For the purposes of these guidelines, a consensus was reached using the Delphi panel methodology, with the participation of two types of experts: firstly, surgeons with training in hepatopancreatobiliary surgery and/or transplant and/or oncologic surgery and with particular interest in this area; and secondly, general surgeons with extensive experience in cholecystectomy, who have performed more than 50 cholecystectomies per year during the last 10 years.<sup>4,5</sup> A total of 32 questions were developed, then submitted to the panel for consideration and answered based on the best available evidence. The answers were stated as statements and submitted electronically to an anonymous vote for electronic approval to ascertain the level of agreement with the statements. After three rounds, a consensus percentage of greater than 80% was reached in 28 statements; in one case, the agreement was 77%, and in three cases, there was no consensus. All the experts approved the final document. None of the authors declared a conflict of interest.

The recommendations are based on the level of evidence available, according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) classification: grade A, level 1 evidence corresponding to randomized clinical trials; grade B, corresponding to level 2 or 3 evidence, are cohort or case-control studies; grade

C, recommendations based on studies with level 4 evidence, that is, case series or cohort studies of poor quality; and grade D, which are recommendations based on level 5 evidence, corresponding to expert opinion. The quality of the evidence for each recommendation was classified as high, moderate, low, or very low. The grade of each recommendation was assigned as strong (recommended) or weak (suggested).<sup>2,6</sup>

## RESULTS

### Recommendations

#### Preoperative

#### 1. In which cases is cholecystectomy recommended for asymptomatic cholelithiasis?

At present, cholecystectomy is not recommended when incidental lithiasis is found.<sup>7-9</sup> Although there are circumstances in which the risk/benefit of prophylactic cholecystectomy can be evaluated, such as patients on transplant protocol, patients on the protocol for bariatric surgery, and regions with a high risk of gallbladder cancer, there is no consensus to date to recommend cholecystectomy in asymptomatic patients routinely.<sup>10-13</sup>

*Percentage of agreement: 61.5%. Level of evidence: 2, grade: B, recommendation: strong.*

#### 2. Is gallbladder dyskinesia an indication of cholecystectomy?

The diagnosis of biliary dyskinesia within the functional disorders of the gallbladder and biliary sphincter is based on the definition of Rome IV guidelines.<sup>14</sup> Although gallbladder dyskinesia is associated with concomitant gastrointestinal disorders, cholecystectomy can provide relief of symptoms secondary to functional gallbladder disorder in most adult patients (> 90%). Therefore, cholecystectomy is considered the standard treatment for biliary dyskinesia, as up to 90% of patients have symptomatic relief.<sup>15-18</sup>



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*Percentage of agreement: 92.3%. Level of evidence: 2, grade: B, recommendation: strong.*

### **3. Is the presence of gallbladder polyps an indication of cholecystectomy?**

In patients with vesicular polyps, treatment should be individualized, considering the size, number, and ultrasonographic characteristics of the polyps and the patient's symptomatology.<sup>20</sup>

In patients with gallbladder polyps larger than 10 mm, cholecystectomy is recommended due to the described risk of malignant transformation; in polyps smaller than 10 mm with concomitant biliary pathology (lithiasis) or biliary symptoms, surgical treatment is also recommended.<sup>20,21</sup>

In patients with asymptomatic polyps smaller than 10 mm, follow-up imaging (abdominal ultrasound) is recommended every six months; if growth is demonstrated or symptoms develop during follow-up, cholecystectomy is recommended.<sup>20-24</sup>

*Percentage of agreement: 92.3%. Level of evidence: 2, grade: B, recommendation: strong.*

### **4. What are the minimum preoperative studies (laboratory and imaging) recommended for elective and/or emergency cholecystectomy, and what are these studies' validity?**

In the case of elective surgery, it is recommended that complete blood count, blood chemistry, liver function tests (including bilirubin and liver enzymes), and coagulation tests be performed as part of the pre-surgical protocol in all patients. Among the imaging studies, liver and biliary tract ultrasound is suggested.<sup>3</sup> In patients over 50 years of age, chest X-ray and electrocardiogram are also suggested.<sup>25-27</sup>

The validity of these studies ranges from one to three months if the patient remains clinically stable.

In patients with acute cholecystitis who are considered for emergency cholecystectomy, pancreatic function tests (serum amylase and lipase) are also suggested.

*Percentage of agreement: 92.3%. Level of evidence: 5, grade: D, recommendation: strong.*

### **5. What are the recommended assessments prior to elective cholecystectomy scheduling?**

According to the American Society of Anesthesiologists (ASA) classification, anesthesiology evaluation is recommended prior to surgery for ASA I patients under 40 years of age.

Preoperative evaluation by an internist is recommended for ASA I patients over 40 and ASA II and older patients (regardless of age).

Depending on the patient's comorbidities, in the case of patients with known conditions (heart disease, lung disease, kidney disease, rheumatologic pathologies, and others), assessment by the corresponding specialty should be considered, especially in cases of decompensation of the underlying pathology.<sup>28,29</sup>

*Percentage of agreement: 92.3%. Level of evidence: 2, grade: B, recommendation: strong.*

### **6. In which cases is it recommended to have blood products for transfusion?**

It is recommended that blood products be available only to patients with known coagulation disorder or thrombocytopenia.<sup>3,30</sup>

*Percentage of agreement: 85%. Level of evidence: 2, grade: B, recommendation: strong.*

### **7. What is the ideal time for scheduling elective and emergency cholecystectomies?**

According to the 2018 Tokyo Guidelines, urgent cholecystectomy is recommended within 24 hours in cases of severe acute

cholecystitis. In cases of moderate acute cholecystitis, early cholecystectomy is suggested between 24 and 72 hours. In mild acute cholecystitis, early cholecystectomy is suggested within the first seven days of the onset of the symptoms to reduce the risk of complications.<sup>31-33</sup>

Surgical resolution is suggested in patients with chronic cholecystitis within 30 days<sup>34,35</sup> (Table 1).

*Percentage of agreement: 85%. Level of evidence: 2, grade: B, recommendation: strong.*

### 8. Is it recommended to perform cholecystectomies during the night shift?

Elective cholecystectomy at night is not recommended. In cases of acute cholecystitis, urgent cholecystectomy can be performed if the hospital has all the resources (medical and infrastructure) to offer a safe procedure.<sup>36-39</sup>

*Percentage of agreement: 85%. Level of evidence: 2, grade: B, recommendation: strong.*

### 9. Is antimicrobial prophylaxis recommended? In which cases?

Antimicrobial prophylaxis is recommended in all cases, with one dose before the incision.<sup>40-44</sup>

*Percentage of agreement: 92.3%.  
Level of evidence: 1, grade: A,  
recommendation: strong.*

Table 1: Ideal cholecystectomy scheduling time.	
Severity according to Tokyo Guidelines 18	Conduct
Cholecystitis	
Acute severe	First 24 hours
Moderate acute	Between 24 and 72 hours
Mild acute	First 7 days
Chronic	30 days

### 10. Is antithromboembolic prophylaxis recommended?

Antithromboembolic prophylaxis is only recommended in patients at high thromboembolic risk, with a score on the Caprini scale greater than or equal to 5 points.<sup>45-47</sup>

*Percentage of agreement: 92.3%. Level of evidence: 2, grade: B, recommendation: strong.*

### 11. What prehabilitation maneuvers are recommended for elective cholecystectomy?

In general, in all patients scheduled for elective cholecystectomy, control of comorbidities should be optimized (adequate glycemic and blood pressure control), and smoking should be suspended.

Among the main perioperative risks associated with smoking are an increased risk of myocardial infarction, arrhythmia, and stroke. The risk of postoperative pneumopathy doubles; there is an alteration of skin healing, increased postoperative pain and postoperative consumption of opioids, and risk of withdrawal syndrome.<sup>3,48-51</sup>

*Percentage of agreement: 92.3%. Level of evidence: 2, grade B, recommendation: strong.*

#### Transoperative

### 12. What is the recommended anesthetic technique for elective and/or emergency cholecystectomy?

General anesthesia is considered the technique of choice for cholecystectomy. It is less uncomfortable for the patient with the changes in position required for the procedure because it facilitates mechanical respiratory support and relaxation of the abdominal wall during surgery. Although regional anesthesia has proven to be equally effective in the patient's recovery process, hemodynamic stability, and lower risk of respiratory problems, the consensus recommendation is to opt for general anesthesia.<sup>3,9,51,52</sup>

*Percentage of agreement: 100%. Level of evidence: 1, grade: A, recommendation: strong.*

### **13. Is infiltration with local anesthetics recommended?**

Infiltration of laparoscopy ports with local anesthetics is recommended.<sup>53-55</sup>

*Percentage of agreement: 100%. Level of evidence: 1, grade: A, recommendation: strong.*

### **14. Which surgical approach (open or laparoscopic) is recommended for elective and/or urgent cholecystectomy?**

In all cases, as long as the resources and experience are available, the laparoscopic approach is recommended; among the most frequent contraindications for a laparoscopic approach are anatomical alterations or adhesions from previous abdominal procedures and the inability to tolerate pneumoperitoneum; however, depending on each case, the feasibility of this approach should be evaluated as long as all the resources are available to perform the procedure safely.<sup>1,3,9,25,26,31,33,56-58</sup>

*Percentage of agreement: 100%. Level of evidence: 2, grade: B, recommendation: strong*

### **15. In the case of laparoscopic cholecystectomy, how many access ports should be used?**

Laparoscopic cholecystectomy with four ports is considered the gold standard since it allows for better exposure to the surgical field and facilitates obtaining a critical safety view, decreasing the risk of biliary tract disruption. Although techniques with three, two, or only one port have been described, studies report that the fewer the ports, the less postoperative pain, greater technical difficulty, longer surgical time, and greater risk of bleeding have also been reported. These techniques with less than four ports require a longer learning curve, and in some cases, they will not be feasible and will require "conversion" to conventional laparoscopy (four ports) by placing additional trocars, and in the long-term follow-up they

are associated with a higher risk of incisional hernia (mainly in single port). On the other hand, there are no significant differences in terms of hospital stay, analgesic requirement, conversion rate to open procedure, or immune response to surgical stress compared to the four-port technique.

Therefore, although these techniques may have comparable results in selected patients and with experienced surgeons, the consensus recommendation is four-port laparoscopic cholecystectomy.<sup>59,60</sup>

*Percentage of agreement: 100%. Level of evidence: 2, grade: B, recommendation: strong.*

### **16. In the case of laparoscopic cholecystectomy, what is the recommended entry technique for pneumoperitoneum insufflation?**

In general, there is no completely safe entry technique; closed techniques have been described, such as the use of the Veress needle, or open techniques, such as the Hasson technique; however, to date, there is no consensus as to the ideal technique for access to the abdominal cavity and for pneumoperitoneum insufflation. Each surgeon should perform the technique with which he/she was trained and with which he/she is familiar, to reduce the risk of complications.<sup>61-63</sup>

*Percentage of agreement: 54%. Level of evidence: 2, grade: B, recommendation: weak.*

### **17. In which cases is the conversion from a laparoscopic to an open approach recommended?**

Conversion should be considered as a strategy to perform a safe procedure and for the resolution of transoperative complications; within the indications for conversion should be considered those derived from systemic complications (as in the case of patients who cannot tolerate pneumoperitoneum), complications attributable to local inflammation (multiple adhesions, fibrosis that makes it difficult to correctly identify the anatomy or inflammatory processes that are difficult to

dissect) or transoperative complications (such as bleeding that is difficult to control, intestinal perforation or any that cannot be resolved by laparoscopy).<sup>56,64,65</sup>

Before conversion, when obtaining a critical view of safety is impossible, it is suggested to consider salvage procedures, such as subtotal cholecystectomy (fenestrated or reconstituted).<sup>64,66-70</sup>

Conversion should also be considered in cases of technical failure of the equipment when there is a need to explore the biliary tract, when there is no adequate equipment to perform it laparoscopically, and when the surgeon is uncomfortable with the approach or exposure in laparoscopy.<sup>64-66,71-73</sup>

*Percentage of agreement: 100%.  
Level of evidence: 2, grade: B, grade  
of recommendation: strong.*

#### 18. In which cases is it recommended to perform the “critical safety overview”?

Always. Strasberg’s critical view of safety has three dissection goals, which are maintained as the first recommendation for the culture of safe cholecystectomy. These goals consist of 1) complete dissection (anterior and posterior) of the hepatocystic triangle freeing fatty and fibrous tissue to observe and identify, in a complete manner, the cystic artery and cystic duct, 2) exposure of the lower third of the gallbladder bed, and 3) observe two and only two tubular structures entering the gallbladder corresponding to the cystic artery and cystic duct.<sup>66</sup>

By obtaining this safety-critical view, within this dissection space, up to 95% of the vascular variations and more than 80% of the anatomical variants of the extrahepatic bile duct can be identified.

If this critical safety view is not possible, it is recommended a salvage procedure, such as subtotal cholecystectomy and drainage, derivative cholecystostomy, or conversion to open surgery be considered.<sup>1,56,66,69,70,74-80</sup> (Figure 1).

*Percentage of agreement: 100%.  
Level of evidence: 1, grade: A, grade  
of recommendation: strong.*

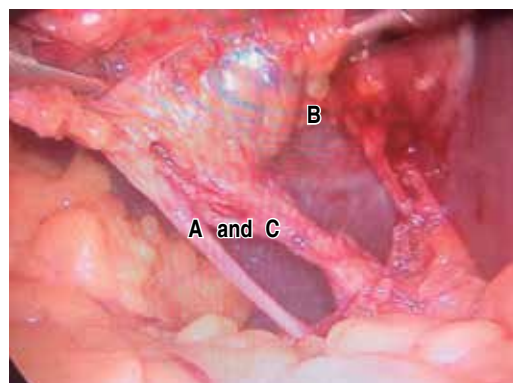
#### 19. In which cases is transoperative cholangiography indicated?

The use of transoperative cholangiography is recommended in those patients with uncertainty of the biliary anatomy and in those with suspected choledocholithiasis (dilatation of the cystic duct and main bile duct, obstructive jaundice, or alteration in liver function tests). In cases of suspected bile duct disruption, transoperative cholangiography allows for the characterization of the extent of the disruption.<sup>56,70,77-79</sup>

*Percentage of agreement: 100%.  
Level of evidence: 2, grade: B, grade  
of recommendation: strong.*

#### 20. In which case is a salvage procedure (subtotal cholecystectomy/cholecystostomy/conversion) indicated?

Depending on the surgeon’s experience, whenever a critical safety view is not possible, a rescue procedure, such as subtotal cholecystectomy and drainage, derivative cholecystostomy, or conversion to open surgery, is recommended.



**Figure 1:** Critical safety view. **A)** Complete dissection (anterior and posterior) of the hepatocystic triangle, freeing fatty and fibrous tissue to completely observe and identify the cystic artery and cystic duct. **B)** Exposure of the lower third of the vesicular bed. **C)** Observe two and only two tubular structures entering the gallbladder corresponding to the cystic artery and cystic duct.

These salvage procedures should be considered when it is impossible to identify the structures of the hepatocystic triangle in acute or chronic inflammatory processes that are difficult to dissect and in unstable septic patients.

In patients with high surgical risk and severe cholecystitis, derivative cholecystostomy (percutaneous or surgical) can be considered as an alternative procedure for resolution of the septic process, with scheduling of interval cholecystectomy.<sup>1,56,65,66,69,70,74,75</sup>

*Percentage of agreement: 100%.  
Level of evidence: 1, grade: A, grade  
of recommendation: strong.*

## 21. What other safety strategies are recommended for cholecystectomy?

Among the strategies to achieve a correct identification of the structures and to achieve a safe cholecystectomy, the following are recommended:

1. Strategies for anatomical orientation: B-SAFE, Rouviere's sulcus, R4U, and asking for a second trans-operative opinion in difficult cases (ask for help from a more experienced colleague).
2. Intraoperative imaging techniques: conventional transoperative cholangiography, infrared fluorescent cholangiography (indocyanine green), and intraoperative ultrasound.
3. Conversion: In cases in which tactile discrimination allows resolving doubts regarding the anatomy, a conversion to an open procedure can be chosen.
4. Fundus first: fundocystic or antegrade cholecystectomy has been associated with a higher risk of vasculobiliary lesions, mainly of the right hepatic artery. It is, therefore, no longer recommended except in exceptional cases.
5. Finally, in cases in which a safe procedure is not possible, the procedure can be aborted, and deferred cholecystectomy can be performed at another level of care with more experience and resources (Table 2).<sup>78,80-87</sup>

*Percentage of agreement: 85%.  
Level of evidence: 2, grade: B, grade  
of recommendation: strong.*

## 22. In which cases is the placement of drains recommended?

In general, drains are not routinely recommended in uncomplicated cholecystectomy; however, they are recommended in patients in whom a salvage procedure has been performed, those with septic processes (necrotic/emphysematous cholecystitis/pyocholecystitis), or when there is suspicion of biliary leakage.

Depending on the center's availability, in those cases in which it is decided to leave drainage, this should ideally be a closed and soft drainage, or in its absence, open and soft drainage. The placement of rigid drains is not recommended.<sup>88-90</sup>

*Percentage of agreement: 100%.  
Level of evidence: 1, grade: A, grade  
of recommendation: strong.*

## Postoperative

## 23. What are the recommendations for optimal postoperative analgesia?

In the transoperative period, infiltration of the laparoscopic access ports with local anesthetics is suggested. Postoperatively, most patients can be managed with paracetamol plus nonsteroidal anti-inflammatory analgesic with a schedule. On an individual basis, a stepwise approach is recommended, reserving opioid analgesia for selected cases.<sup>53-55,91-93</sup>

*Percentage of agreement: 100%.  
Level of evidence: 1, grade: A, grade  
of recommendation: strong.*

## 24. What would be the ideal postoperative recommendations for an improved recovery?

After anesthetic recovery and in the absence of nausea or vomiting, the following measures for an improved recovery are recommended: initiation of the oral route, early ambulation,



and bathing. Bandaging is not recommended for laparoscopic surgery.

Hospital discharge can be performed the same day at the surgeon’s discretion, as long as the following discharge criteria are met: pain control with oral analgesics according to the analog pain rating scale (VAS) of less than 4, adequate tolerance to the oral route, ambulation, ability to urinate, hemodynamic stability, full mental recovery, surgeon’s approval, and absence of nausea and vomiting.<sup>3,48-51</sup>

*Percentage of agreement: 85%. Level of evidence: 2, grade: B, recommendation: strong.*

**25. In which cases is the histopathological study of the gallbladder recommended**

Histopathological studies are currently recommended in all cholecystectomy surgical specimens. If neoplasia is documented similarly,

the patient should be referred to surgical oncology for complete staging and, if required, complete oncologic treatment.<sup>94</sup>

*Percentage of agreement: 100%. Level of evidence: 2, grade: B, recommendation: strong.*

**26. What is the recommended postoperative follow-up after hospital discharge?**

In general, an evaluation 7-10 days after discharge is recommended to know the postoperative evolution, to rule out complications, to review the histopathological study, and, if necessary, to remove the stitches. According to the evolution and at the surgeon’s discretion, an assessment at 30 days for discharge is suggested.<sup>25</sup>

*Percentage of agreement: 61%. Level of evidence: 5, grade: D, recommendation: weak.*

**27. How many days of incapacity for work are recommended after elective and/or emergency cholecystectomy?**

Depending on whether the procedure was open or laparoscopic and whether there were any complications, 10 to 28 days are suggested. The type of work the patient performs should also be considered.<sup>25</sup>

*Percentage of agreement: 77%. Level of evidence: 5, grade: D, recommendation: weak.*

**Special considerations**

**28. In which cases is cholecystectomy indicated during pregnancy?**

Cholecystectomy during pregnancy is indicated exclusively in patients with acute cholecystitis.

Although laparoscopic cholecystectomy is considered safe and effective during all trimesters of pregnancy, in the third trimester, its feasibility should be carefully evaluated given the presence of the pregnant uterus..<sup>95-99</sup>

*Percentage of agreement: 92.3%. Level of evidence: 3, grade: B, recommendation: strong.*

Table 2: Safety strategies.	
Strategies for anatomical orientation	Critical Safety Overview B-SAFE Rouviere’s groove R4U Second transoperative opinion
Intraoperative imaging techniques	Conventional transoperative cholangiography Infrared fluorescence cholangiography (indocyanine green) Intraoperative ultrasound
Subtotal cholecystectomy	Reconstituted Fenestrated
Conversion	In cases in which tactile discrimination allows the resolution of doubts regarding anatomy
Fundus first	It has been associated with an increased risk of vasculobiliary lesions, so it is only recommended in exceptional cases
Delayed cholecystectomy	In cases where a safe procedure is not possible, it may be aborted, and the patient may be referred to another level of care with more expertise and resources
R4U = Rouvière sulcus segment 4.	



**Table 3: Cholecystectomy scheduling time in acute pancreatitis of biliary origin.**

Severity according to Atlanta classification	Conduct
Mild acute pancreatitis	During the same hospitalization
Moderately severe acute pancreatitis without local complications	Once the systemic inflammatory response is controlled and there is no evidence of pancreatic necrosis
Moderately severe acute pancreatitis with local complications	It is recommended to defer cholecystectomy until the need for surgical resolution of complications (necrosis, pseudocyst) is determined
Severe acute pancreatitis without local complications	Once organic failures are resolved and the patient's clinical conditions allow them, surgery can be performed in the same hospitalization
Severe acute pancreatitis with local complications	Even when the organic failures are resolved and the patient's clinical conditions allow them, it is recommended to defer cholecystectomy until the need for surgical resolution of the complications is determined

### 29. In cases where cholecystectomy is required during pregnancy, what is the recommended approach?

Laparoscopic cholecystectomy is considered safe and effective during all trimesters of pregnancy; therefore, laparoscopic cholecystectomy is recommended in the first and second trimesters of pregnancy; however, in the third trimester, its feasibility should be assessed, and an open approach should be considered due to the presence of the pregnant uterus.<sup>95-99</sup>

*Percentage of agreement: 100%. Level of evidence: 3, grade: B, recommendation: strong.*

### 30. In patients with acute pancreatitis of biliary origin, when is cholecystectomy recommended?

In patients with acute pancreatitis of biliary origin, the performance of cholecystectomy will depend on the severity of the pancreatitis,

the presence or absence of local complications, and the patient's general condition.

In patients with mild acute pancreatitis, according to the Atlanta criteria (without local or systemic complications), cholecystectomy is suggested during the same hospitalization to reduce the risk of recurrence.<sup>100-103</sup>

In moderately severe acute pancreatitis, the timing of cholecystectomy will depend on the presence of local complications; when there are no local complications, cholecystectomy can be performed once the systemic inflammatory response is controlled and there is no evidence of pancreatic necrosis. If local complications develop, it is recommended that cholecystectomy be deferred until the need for surgical resolution of the complications is determined.<sup>104-105</sup>

In severe acute pancreatitis, without local complications, surgery can be performed in the same hospitalization once the organic failures are resolved, and the patient's clinical conditions allow it. However, if pancreatic necrosis or other local complications develop, it is recommended to defer cholecystectomy until the need for surgical resolution of the complications is determined (*Table 3*).

*Percentage of agreement: 85%. Level of evidence: 1, grade: A, grade of recommendation: strong.*

### 31. Which patients should be referred to as a third level of care for cholecystectomy?

Cholecystectomy is considered a procedure that can be safely performed at a second level of care; however, in some cases, referral to a third level is recommended when the cholecystectomy has preoperative risk factors for being a problematic cholecystectomy, and the resources (medical and infrastructure) are not available to resolve it, in patients with icteric syndrome of unstudied etiology or with suspected gallbladder cancer.

Referral is also suggested in patients with underlying pathologies that merit third-level management.<sup>3,25,28,29,32,56</sup>

*Percentage of agreement: 92.3%. Level of evidence: 5, grade: D, recommendation: weak.*

### 32. What special considerations should the informed consent for cholecystectomy have?

It should be as detailed as possible and include minor and major risks associated with the patient's characteristics, those attributable to anatomical variants, inflammatory alterations, and technical failures of the equipment. It is suggested to specify bleeding risk, risk of biliary tract disruption or involvement of other organs, the possibility of conversion (in the case of laparoscopy), and even the possibility of not concluding the procedure due to

technical difficulties and of performing a rescue procedure and/or subsequent referral to a center with hepatopancreatic biliary surgery or a third level of care.<sup>106-109</sup> (Figure 2).

*Percentage of agreement: 92.3%. Level of evidence: 5, grade: D, recommendation: strong.*

## CONCLUSIONS

This document seeks to optimize the outcome of patients undergoing cholecystectomy in our country based on a series of recommendations issued by experts from different institutions and based on the best scientific evidence available at this time. It is aimed both at surgeons working in public institutions and those in the private sector. It seeks to disseminate strategies for improved surgical recovery and, above all, for a safe cholecystectomy, seeking to offer our patients the best possible surgical outcome.

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ASOCIACIÓN MEXICANA DE CIRUGÍA GENERAL FEDERACIÓN MEXICANA DE COLEGIOS DE ESPECIALISTAS EN CIRUGÍA GENERAL NOMBRE DE LA INSTITUCIÓN AL QUE PERTENEZCA EL ESTABLECIMIENTO	
Consentimiento bajo información para Colectistomía Vía Laparoscópica	
CON FUNDAMENTO EN LA LEY GENERAL DE SALUD, ARTÍCULO 77 BIS, REGLAMENTO DE LA LEY GENERAL DE SALUD MATERIA DE PRESTACIÓN DE SERVICIOS DE ATENCIÓN MÉDICA, ARTÍCULOS 80, 81, 82, 83 Y A LA NORMA OFICIAL MEXICANA NOM-004-SSA3-2002(06), EXPEDIENTE CLÍNICO FRACCIONES 10.1.1.1, A LA 10.1.1.4.	
Nombre	Edad
Lugar	Fecha
Servicio o Médico tratante	Cama
Mediante este procedimiento se accede a la cavidad abdominal mediante unas incisiones pequeñas, la introducción de trocares creando un espacio en la cavidad abdominal tras la introducción de un gas (CO <sub>2</sub> ). La intervención quirúrgica se realizará con la introducción de un lente especial conectado a una videocámara, y de instrumental especial a través de los trocares. Esto evita las incisiones grandes. La técnica quirúrgica no difiere de la habitual que consiste en identificar y ligar con grapas especiales el conducto y arteria cística, posteriormente la extracción de la vesícula biliar, sacándola a través de una de las pequeñas heridas. En casos en que, teóricamente, por hallazgos intraoperatorios o por complicaciones no sea posible concluir la cirugía por esta vía, se procederá a realizar la incisión habitual y abordaje convencional para su resolución. También cabe la posibilidad de que durante la cirugía haya que realizar modificaciones del procedimiento por los hallazgos intraoperatorios para proporcionar un tratamiento más adecuado. Existe la posibilidad, que por complicación de la enfermedad, sea necesario realizar una exploración de la vía biliar, efectuando una pequeña incisión en la pared del conducto colédoco, la colocación de una sonda de drenaje (Sonda en "T") que sale a través de la pared abdominal por un tiempo, la utilización de medio de contraste para estudio radiográfico llamado colangiografía. En ocasiones es necesaria la colocación de otros tubos de drenajes a través del abdomen. El tipo de anestesia requerida será la indicada por el Médico Anestesiólogo.	
Yo _____ Nombre y firma del paciente o representante	
Manifiesto mi libre voluntad para autorizar los procedimientos diagnósticos, terapéuticos y quirúrgicos que se me indiquen o apliquen después de haberme informado de manera clara, oportuna, suficiente y veraz sobre mi enfermedad y estado actual, además de los beneficios, los posibles riesgos, complicaciones y secuelas. Se me ha comunicado las alternativas existentes y disponibles, el derecho a cambiar mi decisión en cualquier momento antes del procedimiento o intervención. También otorgo mi autorización al personal de salud para la atención de contingencias y urgencias derivadas del acto médico señalado, atendiendo al principio de libertad prescriptiva. Con el propósito de que mi atención sea adecuada, me comprometo a proporcionar información completa y veraz, así como seguir las indicaciones médicas.	
Diagnóstico	Tipo de intervención Urgente ( ) Electiva ( )
Riesgos más frecuentes de la Colectistomía Vía Laparoscópica: A pesar de la técnica y de su correcta realización, pueden presentarse efectos indeseables, tanto los comunes derivados de toda intervención y que pueden afectar a todos los órganos y sistemas, como los debidos a la situación vital del paciente (diabetes, cardiopatía, hipertensión, edad avanzada, anemia, obesidad, y los específicos del procedimiento: Poco graves y frecuentes: extensión del gas al tejido subcutáneo u otras zonas, infección o sangrado de las heridas quirúrgicas, dolores referidos, habitualmente al hombro, dolor prolongado en la zona de la operación. Poco frecuentes y graves: lesión de vasos sanguíneos y hemoperitoneo, laceración o perforación de vísceras al introducir los trocares, embolia gaseosa, neumotórax, trombosis en extremidades inferiores. Complicaciones específicas en relación a la vía biliar, como laceración, estenosis tempranas y tardías, amputación de los conductos biliares, fuga de bilis, biliperitoneo, formación de fistulas. Algunas de estas complicaciones, habitualmente, se resuelven con tratamiento médico (medicamentos, sueros, etc.), pero pueden llegar a requerir una reintervención, en algunos casos de urgencia. Ningún procedimiento invasivo está absolutamente exento de riesgos importantes, incluyendo el de mortalidad, si bien esta posibilidad es bastante infrecuente. Pueden presentarse alteraciones cardiorrespiratorias, renales, embolias. Puede requerir transfundir sangre o hemoderivados. Riesgos Personalizados: También es necesario que advierta de posibles alergias medicamentosas, alteraciones de la coagulación, resultados adversos por antecedentes de enfermedades previas, adicción a drogas, existencia de prótesis, marcapasos, medicaciones actuales o cualquier otra circunstancia. Beneficios: Mediante este procedimiento se logra en la mayoría de los casos la extracción de la vesícula biliar en menor tiempo, evitando incisiones mayores a la pared abdominal, el dolor postoperatorio es menor y la recuperación es muy rápida en comparación a la cirugía abierta convencional.	
Procedimientos Alternativos: El abordaje quirúrgico abierto convencional	
Nombre y Firma del Testigo	Nombre y firma del Médico
Revocación del Consentimiento: Yo después de ser informado de la naturaleza y riesgos del procedimiento propuesto, manifiesto de forma libre y consciente mi denegación/revocación (tachése lo que no proceda) para su realización, haciéndome responsable de las consecuencias que puedan que puedan derivarse de esta decisión.	
Nombre y Firma del Paciente o Representante	Nombre y firma del testigo

Figure 2: Informed consent letter.

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# Utility of routine drainage after elective laparoscopic cholecystectomy. A prospective randomized study

## Utilidad del drenaje rutinario después de colecistectomía laparoscópica electiva. Estudio prospectivo aleatorizado

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### Keywords:

drainage, Penrose, cholecystectomy, complication, randomized.

### Palabras clave:

drenaje, Penrose, colecistectomía, complicación, aleatorizado.

### ABSTRACT

**Introduction:** the use of prophylactic drains after elective laparoscopic cholecystectomy is a common practice; however, its utility is still controversial. **Objectives:** to determine whether the use of routine drains after laparoscopic cholecystectomy can modify postoperative morbidity, hospital stay, the need for rescue analgesia, or the requirement for antiemetics. **Material and methods:** a randomized study evaluated patients undergoing elective laparoscopic cholecystectomy at the General Hospital of Mexico over 36 months (December 2016 to December 2019). Two groups were formed: group A with prophylactic Penrose drain and group B without drainage. **Results:** 400 patients were included in the randomization process, of which 209 belonged to group A and 191 to group B. No significant differences were found in the incidence of complications (1.9% vs. 0.5%,  $p = 0.24$ ), rescue analgesia (54.9% vs. 48.3%,  $p = 0.19$ ), or the requirement for antiemetics (36.8% vs. 34.1%,  $p = 0.29$ ). The average hospital stay (31.1 vs 27.3 hours,  $p = 0.001$ ) and prolonged hospital stay (11.9% vs 3.6%,  $p = 0.0001$ ) were significantly higher in group A. The behavior of patients excluded from the randomization process due to the use of drainage at the surgeon's discretion for difficult cholecystectomy was analyzed, forming a third group (group C) with 63 patients. This group showed a higher incidence of complications compared to groups A and B (12.6% vs 1.25%,  $p = 0.0001$ ) and greater severity of complications ( $p < 0.0001$ ). **Conclusions:** the routine use of drains associated with cholecystectomy is not justified. Its utility lies in selective use under the surgeon's discretion.

### RESUMEN

**Introducción:** el uso de drenajes posterior a una colecistectomía laparoscópica electiva es una práctica común, sin embargo, su utilidad aún es controvertida. **Objetivos:** determinar si el uso de drenajes rutinarios después de una colecistectomía laparoscópica puede modificar la morbilidad postquirúrgica, estancia hospitalaria, necesidad de analgesia de rescate o requerimiento de antieméticos. **Material y métodos:** estudio aleatorizado que evaluó a pacientes sometidos a colecistectomía laparoscópica electiva en el Hospital General de México en un periodo de 36 meses (diciembre de 2016 a diciembre de 2019). Se conformó un grupo A con drenaje tipo Penrose y un grupo B sin drenaje. **Resultados:** se incluyeron 400 pacientes en el proceso de aleatorización, de los cuales, 209 pertenecieron al grupo A y 191 al grupo B. No se encontraron diferencias significativas en la incidencia de complicaciones (1.9% vs 0.5%,  $p = 0.24$ ), analgesia de rescate (54.9 vs 48.3%,  $p = 0.19$ ) o requerimiento de antieméticos (36.8% vs 34.1%,  $p = 0.29$ ). El promedio de estancia hospitalaria (31.1 vs 27.3 horas,  $p = 0.001$ ) y la estancia hospitalaria prolongada (11.9 vs 3.6%,  $p = 0.0001$ ) fueron significativamente mayores en el grupo A. Se analizó el comportamiento de los pacientes excluidos del proceso de aleatorización debido al uso de drenaje a conveniencia por colecistectomía difícil conformando un tercer grupo (grupo C) con 63 pacientes, encontrando una mayor incidencia de complicaciones respecto a los grupos A y B (12.6 vs 1.25%,  $p = 0.0001$ ) y una mayor severidad de éstas ( $p < 0.0001$ ). **Conclusiones:** el uso rutinario de drenajes asociados a colecistectomía no está justificado. Su utilidad se encuentra en un uso selectivo bajo el criterio del cirujano.

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## INTRODUCTION

**D**rains are used after cholecystectomy as a protective measure for a condition that does not exist but could exist. Their hypothetical usefulness is reducing complications by providing an exit route for hematic, biliary, or purulent collections and facilitating early diagnosis.

On the other hand, it has been described that there is a risk of complications inherent to their presence, such as infection, pain, bleeding, and hernias in the site through which they are externalized; they can also favor the formation of adhesions, intestinal lesions or fragment and require interventional maneuvers for their removal.<sup>1-5</sup> These complications are described with a very low frequency, and the cause-and-effect relationship with the presence of drainage can be complicated to demonstrate.

The reality is that, despite being routine practice for some surgeons, the evidence regarding its risks and benefits could be more consistent and sometimes contradictory.<sup>6</sup> *Table 1* summarizes the results of randomized studies that have evaluated the routine use of drains associated with laparoscopic cholecystectomy.

## MATERIAL AND METHODS

In 36 months from December 2016 to December 2019, patients undergoing laparoscopic cholecystectomy (LC) at the Hepatopancreatobiliary Surgery Clinic (HPB) of the General Hospital of Mexico were analyzed using an accidental non-probabilistic sampling. Patients over 18 years of age who underwent scheduled LC with the diagnoses of symptomatic gallbladder stones, gallbladder polyps, or with a history of complications associated with stones (choledocholithiasis and acute pancreatitis of biliary origin) were included. A computer randomization system decided the placement of ½ inch caliber Penrose drain. The surgeon knew the result of the randomization once the gallbladder had been removed and any hemostasis maneuvers had been completed. Patients with drainage constituted Group A or the experimental group,

and patients without drainage constituted Group B or the control group.

Patients with conversion to open surgery, development of transoperative complications, and the need to place a drain for convenience were excluded; that is when the surgeon considered its use necessary and placed it outside the randomization process. The determinants for the use of convenience drains were established as evident biliary leakage, suspicion of biliary tract involvement, and a friable cystic duct.

The use of antiemetics (metoclopramide 10 mg IV) was selective and was only administered in subjects with nausea or vomiting. In all cases, intravenous paracetamol 500 mg was used for pain control, and metamizole was escalated to rescue analgesia when the intensity exceeded 3 points on the visual analog scale (VAS). Both antiemetics and rescue analgesics were administered in response to patient demand or when found necessary in systematic assessments every four hours. The incidence and severity of complications were recorded using the Clavien-Dindo (CD) classification.

A prolonged hospital stay was defined as spending more than one night. All patients were evaluated in the outpatient clinic seven days after discharge, where a record sheet was completed.

During the protocol's development and outside the objectives set at the beginning, it was considered relevant to record and analyze the behavior of the patients with exclusion criteria due to the placement of drains at convenience and to form a third group (group C), whose evolution was contrasted with that of groups A and B.

Descriptive statistics consisted of means and percentages. Analytical statistics were performed using the Student's t-test for continuous quantitative variables with normal distribution and the Mann-Whitney U test for those with non-normal distribution. Qualitative variables were analyzed using  $2 \times 2$  contingency tables, where statistical significance was determined by  $\chi^2$  when all frequencies were greater than five and by Fisher's exact test for frequencies less than 5.

Table 1: Utility of the use of routine drainage associated with cholecystectomy in randomized studies.								
Author (year)	Sample	Type of Surgery	Post-surgical morbidity	Pain	IHS	Nausea or vomiting	Subhepatic collections	Other
Nursal (2003) <sup>7</sup>	69	Elective and urgent	Similar	Similar	NA	More severe without drainage	NA	Reduced amount of subdiaphragmatic gas post-surgery –
Uchiyama (2007) <sup>8</sup>	120	Elective	Similar	More severe with drainage	Similar	NA	NA	–
Tzovaras (2009) <sup>9</sup>	565	Elective	Similar	More severe with drainage	Similar	NA	NA	–
Georgiou (2011) <sup>10</sup>	116	Elective	Similar	More severe with drainage	Longer with drainage	Similar	Similar	Longer surgical time with drains (6.9 min)
El-Labban (2012) <sup>11</sup>	160	Elective	Similar	Similar	Longer with drainage	Similar	Similar	–
Picchio (2012) <sup>12</sup>	106	Elective	NA	Similar	NA	NA	Similar	–
Shamim (2013) <sup>13</sup>	155	Elective	NA	NA	Longer with drainage	NA	Longer with drainage at 24 hours. Similar at 72-hours	–
Park (2015) <sup>14</sup>	159	Urgent	Similar	NA	Longer with drainage	NA	Similar	–
Kim 2015 <sup>15</sup>	193	Urgent	Similar	More severe with drainage	Similar	NA	NA	–
Qiu 2018 <sup>16</sup>	212	Urgent	Similar	Similar	Longer with drainage	NA	NA	Less incapacity without drainage

IHS = In-hospital stay. NA = not available.

## RESULTS

Out of an initial sample of 499 patients who met the inclusion criteria, two patients (0.4%) were excluded due to noted transoperative complications (in both cases, biliary tract affections), two (0.4%) due to conversion to open surgery, 32 (6.4%) due to inconsistent data in the collection sheets, and 63 (12.6%) due to the placement of drains at convenience (constituting group C). The final sample was 400 patients; 209 comprised group A and 191 group B.

### General analysis

The mean age of the patients in groups A and B ( $n = 400$ ) was 43.1 years (range 18 to 83), 79.5% ( $n = 318$ ) were women and 20.5% ( $n = 82$ ) were men. The incidence of complications was 1.25% ( $n = 5$ ), and all of them were considered mild as they were classified as type I DC. No patient was reintervened, and there were no deaths. The mean hospital stay was 29.3 hours, and 8% of the patients had a prolonged hospital stay ( $n = 32$ ).

The variables needed for rescue analgesia and the requirement of antiemetics were reliably collected in 378 and 377 patients, respectively, so this analysis was performed with samples of smaller magnitude: 51.8% (196 of 378 patients) required rescue analgesia,

and 35.5% (134 of 377 patients) required antiemetics.

### Group analysis

The average length of hospital stay and the incidence of prolonged stay were significantly higher in group A than in group B. The other variables analyzed showed no significant differences between groups. The complications that occurred were bleeding from a port, biliary leak, and vomiting (considered a complication when it generated a prolonged hospital stay), classified as mild complications in all cases (CD type I). The results are shown in [Table 2](#).

The causes that conditioned a prolonged hospital stay were nausea, abdominal pain, drainage appearance, and undetermined reasons when the cause was not collected. The results are shown in [Figure 1](#).

Serobiliary, serohematic, and high serous output only appear as causes of prolonged stay in group A since, in the absence of drainage in group B, eventual hematic or biliary leaks were not noticed.

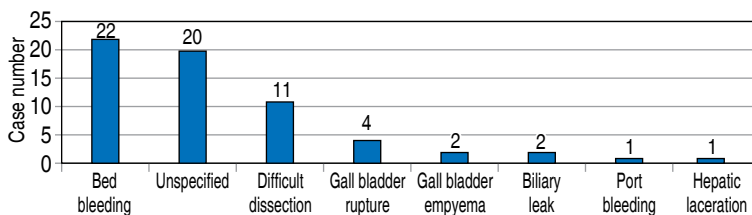
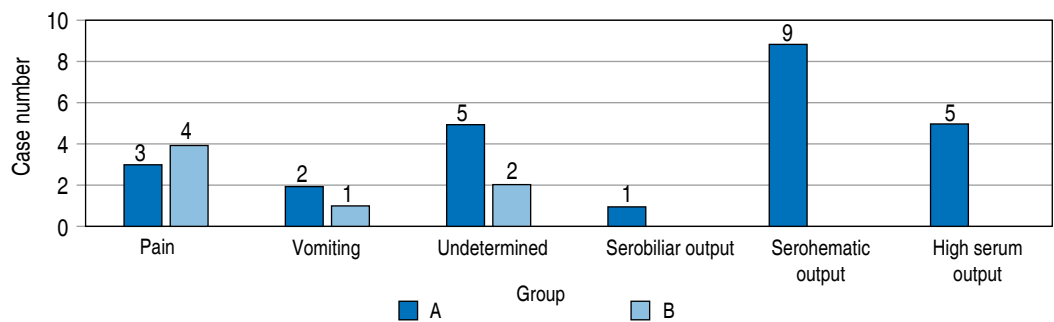
### Group C analysis

Group C consisted of 63 patients. When the causes for the placement of drains at convenience were analyzed, only two cases (3.2%) did the decision adhere to the elimination criteria established during the planning phase

**Table 2: Results of group A vs group B.**

	<b>Group A</b> <b>N = 209</b> <b>n (%)</b>	<b>Group B</b> <b>N = 191</b> <b>n (%)</b>	<b>p</b>
Age (years)*	43.7 [18-83]	42.8 [19-81]	0.56
Female gender	159 (76.1)	159 (83.3)	0.076
Complications	4 (1.9)	1 (0.5)	0.24
Hospital stay (hours)*	31.1 [19-127]	27.3 [18-56]	<b>0.001</b>
Prolonged hospital stay	25 (11.9)	7 (3.6)	<b>0.0001</b>
Rescue analgesia	111/202 (54.9)	85/176 (48.3)	0.19
Antiemetic requirement	75/204 (36.8)	59/173 (34.1)	0.59

\* Values expressed as mean [range].

**Figure 1:***Causes of prolonged hospital stay.***Figure 2:** Causes of drain placement at convenience (N = 63).

(biliary leak), and in 41 cases (65%) the reasons were different from those pre-established. In 20 (31.8%), the surgeon did not specify the causes. The results are shown in [Figure 2](#).

A higher incidence of post-surgical complications (12.6 vs 1.25%,  $p = 0.0001$ ) and incidence of prolonged hospital stay (28.6 vs 7.25%,  $p \leq 0.0001$ ) were observed in this group for groups A and B. The results are shown in [Table 3](#).

In the presence of complications in group C patients, Penrose drainage was considered beneficial diagnostically in all eight cases (100%) and therapeutically in six cases (75%) since it allowed conservative management by flushing out hematic and biliary collections without additional intervention. Bleeding was the most common complication (five patients); in two of them (40%), transfusion of blood products was required, and in two (40%), surgical reintervention for hemostasis (one case due to port bleeding and another due to bleeding from the surgical site). [Table 4](#) shows the behavior of these patients.

## DISCUSSION

The routine use of drainage after laparoscopic cholecystectomy is a common practice,

which is performed to reduce the incidence of postoperative complications or to facilitate early diagnosis. There are clinical trials that have evaluated the performance of the routine use of these drains with contradictory and inconsistent results, being performed in most cases with modest casuistry, which frequently prevents reaching significant and conclusive results, although with a constant tendency to dismiss their usefulness.<sup>7-10</sup>

As part of their nature, clinical trials are conducted under strict inclusion, exclusion, and elimination criteria to ensure that the effect of their variables can be reliably interpreted and the results can be reproducible. However, it should be kept in mind that excluding patients creates groups that will not be considered in the final analysis, so their behavior will not be known. These cases are part of routine clinical practice, and omitting their clinical course may result in considerable bias.<sup>9</sup> Previously, no study had analyzed the evolution of the excluded cases due to the placement of drains for convenience nor the factors that conditioned this behavior.

A Penrose drain may or may not be innocuous for the patients. One of the objectives established as a priority was to estimate the association of the Penrose with pain intensity since its effect as a foreign body or its capacity to evacuate the pneumoperitoneum (after the closure of surgical wounds, the Penrose maintains an escape route to the exterior) could have a favorable or unfavorable relationship with pain intensity.<sup>12</sup> Being a validated, standardized, and widely accepted instrument, we initially considered using the VAS scale as the unit of measurement; however, we concluded that implementing



it would be impractical since it allows us to estimate pain only at an exact moment in time. Determining that moment would be arbitrary and fallible. Thus, we opted for a dynamic system where analgesics were administered at the patient's request based on the World Health Organization (WHO) analgesic scale, and the results were collected as the need for rescue analgesia. We also sought to evaluate the relationship of Penrose with the incidence of nausea and vomiting, for which a similar

system was used where antiemetics was used only on demand.<sup>9-12</sup>

Analysis of the results suggests no link between the presence of a Penrose drain and pain intensity. Nor is there any link between drains and the incidence of nausea or vomiting.

The main objective was to determine the relationship between the Penrose drain and postoperative morbidity, its effect on the incidence, and its possible therapeutic role in the face of complications. The conclusion

**Table 3: Results of group A + B vs group C.**

	<b>Groups A + B</b> <b>N = 400</b> <b>n (%)</b>	<b>Group C</b> <b>N = 63</b> <b>n (%)</b>	<b>p</b>
Age (years)* A	43.3 [18-83]	45.17 [18-91]	0.56
Female gender	318 (79.5)	45 (71.4)	0.076
Complications	5 (1.25)	8 (12.6)	<b>0.0001</b>
Severity of complications	CD I: 5 (1.25)	CD I: 3 (4.8) CD II: 2 (3.2) CD IIIb: 3 (4.8)	<b>&lt; 0.0001</b>
Hospital stay (hours)*	29.3 [18-127]	40.12 [23-192]	0.06
Prolonged hospital stay	32 (8.0)	18 (28.6)	<b>&lt; 0.0001</b>

CD = Clavien-Dindo classification.  
\* Values expressed as mean [range].

**Table 4: Penrose behavior in group C in patients who developed complications.**

<b>Morbidity</b>	<b>CD</b>	<b>Hospital stay (hours)</b>	<b>Resolution</b>	<b>Diagnostic usefulness</b>	<b>Therapeutic usefulness</b>
1) Hemorrhage*	II	126	Conservative	Yes	Yes
2) Hemorrhage <sup>‡</sup>	IIIb	58	Reintervention	Yes	No
3) Biliary leakage <sup>§</sup>	I	96	Conservative	Yes	Yes
4) Biliary leakage (Strasberg A)	I	100	Conservative	Yes	Yes
5) Hemorrhage*	II	132	Conservative	Yes	Yes
6) Hemorrhage*	I	72	Conservative	Yes	Yes
7) Hemorrhage <sup>¶</sup>	IIIb	150	Reintervention	Yes	No
8) Biliary leakage (Strasberg D)	IIIb	192	ERCP	Yes	Yes

CD = Clavien-Dindo classification. ERCP = endoscopic retrograde cholangiopancreatography.  
\* The origin of the hemorrhage was not determined. <sup>‡</sup> Laparoscopic port hemorrhage. <sup>§</sup> The origin of the biliary leak was not determined.  
<sup>¶</sup> Vesicular bed bleeding.

is that, with post-surgical morbidity of 1.9% versus 0.5% for groups A and B, respectively ( $p = 0.24$ ), the presence of the Penrose does not significantly impact its incidence. Interestingly, cases of biliary leakage and post-surgical hemorrhage (classified as CD I) were diagnosed in group A and absent in group B. This result can be understood only as the ability to notice an eventuality due to the clinically irrelevant drainage and not as a cause-effect relationship.

Although the routine use of drains did not represent a risk or a benefit in terms of morbidity, it was associated with a higher incidence of prolonged hospital stay (11.9 vs. 3.6% /  $p = 0.0001$ ). This use was interpreted as the surgeons' response to an expense through the drain whose appearance generated concern and motivated them to prolong the hospital observation period.<sup>12,13</sup> Therefore, the routine use of drains after cholecystectomy is not justified since it does not benefit the patient and represents a risk of prolonged hospital stay.

Even though in the planning stage, we tried to establish objective exclusion criteria for convenience when deciding to place a drain, during the execution of the protocol, we found that it was impossible to make objective the conditions that merit the placement of these drains and that despite the attempt to standardize these conditions, in most cases it is a subjective decision of the surgeon, since of the 63 cases that were presented, only in two (3.2%) the reason for placing a drain followed the pre-established standards.

When contrasting the morbidity between groups A and B (subjected to randomization) with group C (drainage by convenience), we can affirm that the surgeon's subjective criterion for the decision to place a drain is correct since the analysis of group C shows significantly higher postoperative morbidity compared with groups A and B. Furthermore, morbidity in group C was significantly higher. However, it was also related to more severe complications ( $p < 0.0001$ ), which confirms that the surgeon's criterion to detect a complex surgery that warrants the placement of a drain is an acceptable and correct practice.<sup>12,15</sup>

It would be interesting to determine the role played by using Penrose drainage as a therapeutic instrument in the presence of

a complication. Unfortunately, the results obtained in this study do not allow this analysis. However, it should not be omitted that 75% of the complications encountered in group C ( $n = 6$ ) were resolved conservatively, the role of the Penrose drain being fundamental to evacuating the hemoperitoneum or bilioperitoneum (depending on the case), avoiding the need for additional interventions. Thus, even though we do not have a control group or a statistical test that allows a categorical statement, we can say without a doubt that the Penrose drainage played a fundamental diagnostic and therapeutic role in managing the cases that developed complications.<sup>16</sup>

## CONCLUSIONS

The results affirm that the routine use of a Penrose after elective laparoscopic cholecystectomy does not modify the incidence of post-surgical complications, the requirement of antiemetics, or the need for rescue analgesia. However, it represents a risk factor for a prolonged hospital stay, so we do not find grounds for its routine use. However, it is justified selectively at the surgeon's discretion when he/she notices a complex surgery, which, in the case of our patients, avoided reoperation in 75% of the cases.

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# Progressive biliary dilation via percutaneous transhepatic access for benign biliary strictures associated with cholecystectomy. Long-term results

*Dilatación biliar progresiva por acceso transhepático percutáneo para estenosis biliares benignas asociadas a colecistectomía. Resultados a largo plazo*

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## Keywords:

injury, biliary,  
stenosis, benign,  
dilatation,  
percutaneous.

## Palabras clave:

afección, biliar,  
estenosis, benigna,  
dilatación,  
percutánea.

## ABSTRACT

**Introduction:** post-cholecystectomy bile duct injury is the most common cause of benign biliary stricture. Surgical diversion through a hepaticojejunostomy has shown the best outcomes; however, approximately 13% of cases will progress to stenosis of the diversion. In this scenario, percutaneous dilation protocols exist to restore the patency of the anastomosis. **Material and methods:** we report a series of cases of progressive bile duct dilation via percutaneous transhepatic access in patients with benign biliary stenosis associated with hepaticojejunostomy secondary to post-cholecystectomy bile duct injury. **Results:** 14 patients with biliary stenosis associated with post-cholecystectomy bile duct injury were included in a progressive bile duct dilation via percutaneous transhepatic access protocol over 13 years (2004-2017). With an average follow-up of 43 months (12 to 192), 11 patients (78.6%) maintained biliary patency, while 3 patients (21.4%) developed re-stenosis of the hepaticojejunostomy, diagnosed 22 months after the end of the dilation protocol (3 to 33). **Conclusion:** the progressive bile duct dilation via percutaneous transhepatic access technique is effective in resolving benign bile duct strictures in 78.6% of cases in long-term follow-up.

## RESUMEN

**Introducción:** la afección de vía biliar postcolecistectomía es la causa más común de estenosis biliar benigna. El tratamiento que ha mostrado los mejores resultados es la derivación quirúrgica a través de una hepato-yeyuno-anastomosis; sin embargo, alrededor de 13% de los casos evolucionarán con estenosis de la derivación. Ante este escenario, existen protocolos de dilatación percutánea como una estrategia para recuperar la permeabilidad de la anastomosis. **Material y métodos:** se reporta una serie de casos de dilatación biliar progresiva por acceso transhepático percutáneo en pacientes con estenosis biliar benigna asociada a hepato-yeyuno-anastomosis secundaria a afección de vía biliar postcolecistectomía. **Resultados:** 14 pacientes con estenosis biliar asociada a afección de vía biliar postcolecistectomía fueron incluidos en un protocolo de dilatación biliar progresiva por acceso transhepático percutáneo a lo largo de 13 años (2004-2017). En un seguimiento promedio de 43 meses (12 a 192), 11 pacientes (78.6%) mantienen permeabilidad biliar, mientras que tres pacientes (21.4%) evolucionaron con reestenosis de la hepato-yeyuno-anastomosis, la cual se diagnosticó 22 meses después del término del protocolo de dilatación (3 a 33). **Conclusión:** la técnica de dilatación biliar progresiva por acceso transhepático percutáneo es efectiva para resolver las estenosis benignas de los conductos biliares en 78.6% de los casos en un seguimiento de largo plazo.

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## INTRODUCTION

Benign biliary strictures are a condition that may be due to inflammatory or post-surgical processes. They require multidisciplinary evaluation and management, where treatment goals will be to alleviate the symptoms of biliary obstruction, preserve liver function and recover patency of the affected duct for as long as possible.<sup>1</sup>

The most frequent cause of benign biliary strictures is postcholecystectomy biliary tract disease (PCBD). Its incidence is estimated between 0.4 and 1.33%,<sup>2,3</sup> with Roux-en-Y hepatojejunum-anastomosis (HYA) being the treatment that has shown the best long-term results according to the type of condition considering the Bismuth classification. However, about 13% of HYA will develop recurrent stricture<sup>4,5</sup> and up to 40% when the confluence has been lost.<sup>6,7</sup> Radiological, endoscopic, and surgical interventions are available to restore biliary patency.

Radiological interventions by percutaneous access have undergone a continuous evolution. In 1921, Professor Burckhardt in Germany described for the first time the radiological visualization of the biliary tract by puncture of the gallbladder. In 1978, Molnar reported the first case series of percutaneous transhepatic balloon dilatation (PTBD),<sup>8</sup> and in 1986, Mueller reported the first large case report with 76 patients.<sup>9</sup> Since then, the percutaneous transhepatic approach has been positioned as an alternative to surgical remodeling with a less invasive body; however, it requires, as a necessary condition, the introduction of a biliary catheter that manages to cross the stenosis, which is not always achieved.

The objective of the percutaneous dilatation protocol is, in most cases, to achieve secondary biliary patency in patients with a history of a bilioenteric bypass who have evolved with stenosis.<sup>10</sup> However, it is occasionally possible to achieve primary biliary patency in patients with AVBPC without a previous attempt at repair.

## MATERIAL AND METHODS

We present a retrospective observational study of patients with a history of AVBPC

and secondary stricture who underwent a progressive biliary dilatation protocol by percutaneous transhepatic access (DBPATP) developed at the *Hospital General de México* (HGM), over 13 years (2004 and 2017).

The DBPATP protocol consists of the installation of a mixed biliary catheter, i.e., one that manages to frank the stricture and place fenestrae in both the biliary and intestinal lumen (*Figure 1*), usually with an initial diameter of 8.5 or 10 Fr that is replaced every two months by a larger French (Fr) (2 Fr of advance per session) until reaching a variable diameter depending on the stenosed duct, 14 Fr if it is only a right or left duct and between 18 and 22 Fr if it is the confluence. The catheter is kept closed because its mixed position allows biliary flow into the intestine through the fenestrations and is only opened when cholangitis is suspected.

Adequate biliary patency is thought to have been achieved in cases where there is a functional biliary tree, without endoprosthesis, without the need for invasive interventions, without post-treatment cholangitis, without hepatic abscess, without jaundice or external biliary fistula. It is considered primary biliary patency if it is achieved after an index treatment (surgery or dilatation) and secondary biliary patency if it is completed after the failure of



**Figure 1:** Percutaneous transcatheter cholangiography of left bile duct bypass with mixed placement (up to duodenum).



Table 1: Patients with exclusion criteria.

Criteria	n (%)
Short-term follow-up*	2 (16.7)
Did not attend follow-up (untraceable)	2 (16.7)
Still in the process of dilatation	6 (50.0)
Technical failure	2 (16.7)
Total	12 (100.0)

\* The dilatation protocol came to term with biliary patency demonstrated by cholangiography, but follow-up is <12 months.

a previous intervention as in the case of our patients.<sup>11</sup>

The procedure can be performed under sedation or general anesthesia. Antisepsis of the right costal region is performed, the puncture site will generally be at the level of the posterior axillary line, at a variable height between the eighth and tenth intercostal space, depending on the diaphragmatic ablation and having as a priority to avoid pleural lesions. Simple lidocaine is infiltrated at 2%, and with the assistance of ultrasound and fluoroscopy, a fine 21 or 22 g Chiba needle is punctured, which advances. At the same time, the contrast medium is injected until accessing a branch of the right hepatic duct. A 0.018 g Cope-type platinum-tipped guidewire is introduced through the needle using an introducer system. The needle is removed, and a 5 Fr plastic dilator is passed, sliding over the guidewire, which is replaced by a larger gauge to favor the passage of the dilator through the obstructed area. Finally, a metal positioner is used to place a multifenestrating catheter that advances to the small bowel.

In all cases, biliary stricture was suspected clinically by jaundice or biochemically by cholestasis and confirmed by direct cholangiography by percutaneous access, magnetic resonance imaging (MRI), or endoscopic retrograde cholangiopancreatography (ERCP). We excluded patients in whom the catheter was positioned externally, that is, where the stricture was not crossed, and its location was exclusively in the bile ducts, and those with a follow-up of fewer than 12 months from the

end of the intervention. Cases of stenosis due to malignant etiology were not considered.

The duration of the intervention was defined as the time elapsed from the placement of the first biliary catheter to the removal of the last one. Technical failure was those cases in which a dilatation protocol was initiated but not completed due to persistent stenosis or inability to advance the catheter caliber.

Patients who developed restenosis or technical failure underwent surgical remodeling.

## RESULTS

In 26 patients a percutaneous biliary catheter was placed in a mixed position in the context of AVBPC with secondary stenosis with the aim of recovering biliary patency; 14 of them were considered for the final analysis and 12 had exclusion criteria (Table 1).

Technical failure occurred in two patients (16.7%), due to inability to progress the catheter caliber in one case, and intrahepatic lithiasis in another, so they abandoned the dilatation protocol after an average of eight months (six and 10) and underwent surgical remodeling.

Of the final sample (n = 14), three patients were male (21.4%) and 11 (78.6%) were female, with a mean age of 40.5 years (range 26 to 69 years). The initial level of the condition was classified as Bismuth 1 to 3 in 11 patients (78.6%), 4 in two patients (14.3%) and 5 in one patient (7.1%). One case with type 4 condition required double catheterization due to stenosis of both sectoral ducts. The duration of the dilatation protocol was 19.9 months on average, with a range of 9 to 49 months.

In 11 patients (78.6%) long-term biliary patency was achieved, with an average follow-up of 43 months (range 12 to 192 months), while in three patients (21.4%) restenosis occurred after an average of 21.5 months (3 to 33 months) following the end of the dilatation protocol (Table 2).

In the cases in which biliary patency was achieved, the most frequent antecedent was a stenosis of an HYA performed by AVBPC (9/81.8%), of which, stenosis at the level of the biliary confluence was the most common (6/54.5%), followed by stenosis of the CHD (2/18.2%), and of both ducts in one patient with

double bypass (1/9.1%). In two patients (18.2%) primary biliary patency was achieved in the presence of AVBPC without a previous repair attempt. The duration of the intervention was 21.4 months (nine to 45), with a mean of 6.2 catheters required (four to eight). Cases where

the dilatation target was sectoral conduits (right or left), the maximum caliber was 14 Fr, and 18 or 22 Fr when the target was confluence (Table 2).

Most patients achieved grade B patency (n = 5/45.4%), followed by grade C patency (n

**Table 2: Patients with successful DBPATP protocol.**

Age	Sex	History	Intervention duration (months)	Total catheters	Final diameter	Type of patency	Degree of patency	Follow-up (months)
26	Female	HYA due to AVBPC/CHD stenosis	21	6	18 Fr	PS	C	18
54	Male	HYA due to AVBPC/confluence stenosis	19	6	18 Fr	PS	C	30
38	Female	AVBPC Bismuth 5	17	8	22 Fr	PP	A	48
27	Female	Double HYA shunt by AVBPC with loss of confluence/CHD stenosis	16	4	14 Fr	PS	B	21
31	Male	Double HYA shunt for AVBPC with loss of confluence/ stenosis of both conduits (required 2 catheters)	12	6/6	18/18 Fr	PS	B	22
30	Female	HYA due to AVBPC/confluence stenosis	21	6	18 Fr	PS	C	24
62	Female	HYA due to AVBPC/confluence stenosis	12	7	20 Fr	PS	B	27
47	Female	HYA due to AVBPC/confluence stenosis	16	8	22 Fr	PS	B	20
40	Female	HYA due to AVBPC/confluence stenosis	48	8	22 Fr	PS	D	192
42	Female	AVBPC Bismuth 2	45	6	16 Fr	PP	D	12
39	Male	HYA due to AVBPC/confluence stenosis	9	4	22 Fr	PS	B	72

DBPATP = progressive biliary dilatation by percutaneous transhepatic access. HYA = Hepato-jejunum-anastomosis.

AVBPC = postcholecystectomy bile duct involvement. CHD = right hepatic duct. Fr = French. PS = secondary patency. PP = primary patency.

Table 3: Patients with unsuccessful DBPATP protocol.

Age	Sex	History	Intervention duration	Total catheters	Final diameter	Cause of failure	Interval (months)
64	Female	AVBPC Bismuth 3	16	8	22 Fr	Restenosis	30
40	Female	HYA by AVBPC	16	8	22 Fr	Restenosis	33
69	Female	HYA by AVBPC	11	5	16 Fr	Restenosis	3

DBPATP = progressive biliary dilatation by percutaneous transhepatic access.

AVBPC = postcholecystectomy bile duct involvement. HYA = Hepato-jejunum-anastomosis. Fr = French.

= 3/27.3%), grade D (n = 2/18.2%) and grade A (n = 1/9.1%).

In the cases that evolved with restenosis (3/21.4%), the duration of the intervention was 14.3 months (11 to 16), with a mean of seven catheters required (five to eight) and a final diameter of between 16 and 22 Fr (Table 3).

## DISCUSSION

Since their inception in 1895, percutaneous approach procedures have offered an exceptional window into the comprehensive management of patients through diagnostic and therapeutic procedures. Using needles, guidewires, and catheters directed by ultrasound, tomography, or fluoroscopy, it is possible to route instruments through the body to specific areas, offering an alternative to a surgical approach with less body invasion.<sup>12</sup>

They are now a fundamental part of the multidisciplinary approach to AVBPC patients. The aim is to achieve secondary biliary patency in patients with a history of bilioenteric shunting who have evolved with stricture. However, occasionally, it is possible to attain primary biliary patency in patients with AVBPC without a previous attempt at repair. The standard protocol consists of DBTP percutaneous transhepatic biliary dilatation, which is performed with serial high-pressure balloon cholangioplasty and a catheter that is maintained throughout the procedure both for radiological control and to keep the access route for future sessions. The number and interval of these sessions are determined by institutional

preference. The literature reports an average of between two and 7.8 sessions per patient, with intervals of six to 12 weeks between each one, and a duration of the intervention with an extensive range between 1.1 and 19.9 months. The incidence of restenosis is 13.2 to 39%, which increases proportionally with follow-up time.<sup>12-19</sup>

Some groups have implemented interventions of short duration, with three sessions over five days, removing the biliary catheter after the last session. The results have been discouraging, with new strictures of 59% at three years.<sup>20</sup> Yun et al.<sup>21</sup> reported a variant with a temporary metallic stent with coverage, which migrates spontaneously and is expelled without any intervention, achieving superior results compared to those achieved with balloon angioplasty regarding restenosis (13 vs 54.5%).

To date, no technique ensures long-term biliary patency. Percutaneous dilatation eventually leads to restenosis because once the cholangioplasty has been performed, a new scarring process is stimulated because of the aggression to the tissues. This is why at MGH, we have opted to maintain a transanastomotic biliary catheter that is replaced by a progressively wider caliber, as an attempt to ensure that scar remodeling always develops limited by the caliber of the catheter. In addition, each new cholangioplasty progresses little concerning the diameter reached in the previous procedure, thus seeking minimum aggression to the tissues with each session.

The duration of the intervention with the DBPATP technique should be less than 21 months in its most extensive variant. It starts with an 8.5 Fr caliber catheter and ends with a 22 Fr catheter, with three-month intervals and a total of seven replacements. However, the patient's ability to achieve this continuity was inconsistent, so the intervention time was considerably extended.

We have achieved good long-term results with this technique, like those obtained by other authors. However, it is difficult to contrast the experience between groups due to the lack of a standardized definition of biliary patency in the context of dilatation protocols. This definition should consider clinical and biochemical variables, the need for reinterventions, and a minimum temporal delimitation, as the definition of a successful intervention may differ between groups.

In 2018, Dr. Strasberg et al.<sup>11</sup> proposed a definition of biliary patency applicable to surgical, endoscopic, and radiological interventions to facilitate comparison between approaches and centers. Under this definition, which we have adopted in this report, biliary patency does not allow the presence of jaundice, cholangitis, hepatic abscesses, external fistulas or the need for new interventions.

The follow-up period should be considered a fundamental variable when determining the incidence of restenosis when evaluating a dilation strategy, with an inversely proportional relationship between follow-up time and the success of the intervention. Since restenosis occurred on average 14.3 months after the end of the intervention, we considered it most correct to exclude patients with a follow-up of less than 12 months, thus showing a realistic expectation of long-term success.

No variant in the percutaneous dilatation techniques has shown reliable superiority, and in all cases, there is a risk of restenosis. Therefore, the existence of a standard technique cannot be concluded. In this case series, we present a variant in the dilatation technique, with which we have achieved good long-term results, although the number of patients is small.

## CONCLUSION

Based on the results of this research, we can say that the DBPATP technique is effective in resolving benign bile duct strictures in 78.6% of cases at long-term follow-up.

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# Prognostic value of red blood cell distribution width for severity in acute biliary pancreatitis

## Valor pronóstico del ancho de distribución eritrocitaria para severidad en pancreatitis aguda biliar

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### Keywords:

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### Palabras clave:

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### ABSTRACT

**Introduction:** acute biliary pancreatitis is the most common disease of the exocrine pancreas worldwide. Its morbidity and mortality are directly related to the severity of the disease, so one of the main goals at hospital admission is to identify those patients at higher risk of developing complications. The red cell distribution width (RDW) measures the cell blood count, showing prognostic value in septic or critically ill patients. **Objective:** to determine whether levels of RDW on admission were associated with the prognosis of severity in acute biliary pancreatitis. **Material and methods:** in a nested case-control study in a cohort of patients with acute biliary pancreatitis, a total of 106 patients, grouped according to the classification of Atlanta 2012, were studied. **Results:** RDW values at admission were compared between groups, and a statistically significant difference was found between them. ROC curve analysis was performed, with an area under the curve of 0.834, 95% CI 0.707-0.961; with an RDW cut-off value of 14.95%, an Odds Ratio of 10.421 ( $p = 0.001$ ) was obtained, with a sensitivity and specificity of 73.3 and 79.1% for developing severe pancreatitis. **Conclusions:** we found an association between RDW value on admission and severity of acute biliary pancreatitis. Patients with  $RDW > 14.95\%$  on admission are at increased risk of developing severe pancreatitis, so knowing this value will allow early identification of patients with an increased risk of developing systemic complications.

### RESUMEN

**Introducción:** la pancreatitis aguda es la patología más frecuente del páncreas exocrino en el mundo. Su morbimortalidad está directamente relacionada con la severidad del cuadro, por lo que uno de los principales objetivos al ingreso hospitalario es identificar aquellos pacientes con mayor riesgo de desarrollar complicaciones. El ancho de distribución eritrocitaria (ADE) es un índice de la biometría hemática que ha demostrado tener valor pronóstico en pacientes sépticos o críticamente enfermos. **Objetivo:** determinar si los niveles del ADE al ingreso se asocian con el pronóstico de severidad en pancreatitis aguda biliar. **Material y métodos:** estudio de casos y controles anidado en una cohorte de pacientes con diagnóstico de pancreatitis aguda biliar. Se estudiaron 106 casos, agrupados de acuerdo con la clasificación de Atlanta 2012. **Resultados:** se compararon los valores del ADE al ingreso entre los grupos, encontrando una diferencia estadísticamente significativa entre ellos. Se realizó análisis mediante curva ROC (área bajo la curva de 0.834, IC95% 0.707-0.961) y con un valor de ADE de 14.95%, se obtuvo una razón de momios de 10.421 ( $p = 0.001$ ) para desarrollar pancreatitis grave (sensibilidad de 73.3%, especificidad de 79.1%). **Conclusiones:** encontramos asociación entre el valor del ADE al ingreso y la severidad de la pancreatitis aguda biliar. Los pacientes con un  $ADE > 14.95\%$  al ingreso tienen mayor riesgo de cursar con un cuadro de pancreatitis grave, por lo que conocer este valor al ingreso permitirá identificar tempranamente aquellos con mayor riesgo de desarrollar complicaciones sistémicas.



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## INTRODUCTION

Acute pancreatitis is the most frequent disease of the exocrine pancreas worldwide; it comprises a broad clinical spectrum ranging from self-limited pancreatic involvement, with resolution of the inflammatory picture and complete recovery in a few days, to systemic involvement that can trigger sepsis, multiple organ failure and patient's death.<sup>1</sup> The most frequent etiology in our environment is biliary.<sup>2-4</sup>

It is considered that 80% of the cases will have mild disease (mortality < 1%), while the remaining 20% will present severe disease with mortality up to 50%; that is, 90% of the deaths occur in patients with severe acute pancreatitis.<sup>5,6</sup>

The most widely used classification at present is the Atlanta classification; the latest revision of this classification in 2012 aims to unify the diagnostic criteria in acute pancreatitis, define local and systemic complications, and propose a new classification according to the pathophysiology and evolution of the cases, recognizing three degrees of severity: In this context, severe acute pancreatitis is defined as that which presents with persistent organ failure (greater than 48 hours); this organ failure develops during the early phase of pancreatitis, triggering a systemic inflammatory response that perpetuates the organ failure, which may be single or multiple, and may or may not be accompanied by local complications. In these patients, mortality is reported to be as high as 36-50%.<sup>6</sup>

Early determination of the severity of pancreatitis is crucial to recognize those at higher risk of complications and those requiring intensive monitoring and treatment.<sup>1,7,8</sup> To this end, several clinical and biochemical scales have been described; however, most require multiple laboratory determinations and the performance of several laboratory studies; most are expensive and unavailable in all hospital units.<sup>6,8-15</sup>

The erythrocyte distribution width (EDW) is a parameter of cell blood count that describes the percentage of heterogeneity in the size of erythrocytes and is part of the complete test.<sup>16,17</sup> It is calculated by dividing the standard

deviation (SD) by the mean of the mean corpuscular volume (MCV) and multiplying this value by 100 ( $ADE = [SD/VCM] \times 100$ ). It is routinely included in automated blood counts and is therefore available in clinical practice at no additional cost. The physiological ADE value in our population is  $12.8 \pm 0.7$  in women and  $12.6 \pm 0.7$  in men. The higher the value, the greater the heterogeneity. An RDW of more than 15% implies an abnormally heterogeneous cell population, i.e., anisocytosis.<sup>18</sup>

In addition to being a useful parameter in the study of anemias, in recent years, various studies have shown its prognostic value in subjects with heart failure, acute myocardial infarction, pulmonary thromboembolism, pneumonia, critically ill patients and cardiac arrest, as well as in other chronic diseases.<sup>19-28</sup>

The mechanisms involved in this association need to be better clarified. It has been described that the systemic inflammatory response, the presence of inflammatory cytokines, and nutritional deficits lead to increased ADE values. Similarly, an association between ADE-bacteremia and ADE-sepsis has been reported, so it has been used as a biomarker of underlying conditions, inflammatory processes, oxidative damage, and malnutrition.

In 2013, Kolber<sup>29</sup> published the first study to describe an association between increased RDW and mortality in acute pancreatitis. Subsequently, Senol<sup>30</sup> also described the usefulness of ADE as an independent prognostic marker of mortality in cases with acute pancreatitis. These observations were also reported by Yao<sup>31</sup> and Zhang,<sup>32</sup> who described higher levels of RDW in non-survivors concerning survivors with acute pancreatitis and healthy controls.

Objective: to determine whether RDW levels at hospital admission correlate with prognostic severity in acute biliary pancreatitis.

## MATERIAL AND METHODS

A prospective nested case-control study in a cohort of patients admitted to the general surgery service diagnosed with acute pancreatitis of biliary etiology from May 2013 to January 2014, which were grouped according to the Atlanta 2012 classification, was performed.

With the difference of proportions formula, a sample size of 110 cases was calculated. Demographic variables, laboratory values, ADE at admission, with follow-up of the evolution to three months, local and systemic complications and their duration, days of hospital stay, and deaths, if any, were recorded.

Adults of both genders with a diagnosis of acute pancreatitis of biliary origin were included. Pregnant patients, oncologic patients, patients from other units with complications of acute pancreatitis but without acute symptoms, patients with a history of blood transfusion in the last 120 days, or patients diagnosed with anemia or other hematologic diseases were excluded. Patients with incomplete records or those in whom it was impossible to complete the follow-up were eliminated.

*Ethical aspects:* the Ethics and Research Committees of the Hospital General de México reviewed the protocol approved by the Directorate of Research, with registration code DI/13/305/03/042. Informed consent was obtained in all cases, and the information was handled confidentially.

*Statistical analysis:* we analyzed descriptive and inferential statistics, finding normal distribution in our variable. A general linear model, ANOVA with Bonferroni post hoc test, considering a statistically significant a value of  $p < 0.05$ , ROC curve, diagnostic validation tests and contingency tables with calculation of odds ratio. SPSS® version 22 was used for the statistical analysis.

## RESULTS

A total of 106 cases with acute pancreatitis of biliary origin were included. The study sample consisted of 80 women (75.5%) and 26 men (24.5%), with a mean age of 41.41 years (range 18 to 88) with an SD  $\pm 19.38$ . The most frequent comorbidities were: overweight and obesity (37.7% and 26.4%), followed by systemic arterial hypertension (16%) and diabetes mellitus (4.7%).

They were grouped according to the 2012 Atlanta classification criteria ([Table 1](#)). ADE values at admission were compared between groups through the ANOVA test, finding a significant difference ( $p < 0.001$ ). The Bonferroni test showed that patients with severe acute pancreatitis had significantly higher RDW values ( $p < 0.001$ ) than those with mild and moderately severe acute pancreatitis.

Nineteen subjects recorded the presence of local complications. When comparing the ADE between cases without local complications and those with local complications, no significant difference was found between the two groups ( $p = 0.105$ ) ([Table 2](#)).

Regarding systemic complications, a distinction was made between subjects where the systemic complication resolved in less than 48 hours (transient failure) and those where it persisted for more than 48 hours (persistent failure). Within the group with transient complications, 34 cases (32.1%) were found; renal and metabolic failure (metabolic acidosis and hyperglycemia) were the most frequent, followed by pulmonary and decompensation of previous heart disease. When comparing the ADE between patients without complications and those with transient systemic complications, no significant

**Table 1: Erythrocyte distribution width values by group according to the Atlanta 2012 classification.**

Atlanta	Erythrocyte distribution width	
	n (%)	mean $\pm$ SD
Mild	54 (50.9)	14.04 $\pm$ 1.11
Moderately severe	37 (34.9)	14.51 $\pm$ 0.98
Severe	15 (14.2)	15.99 $\pm$ 1.51

**Table 2: Comparison of erythrocyte distribution width according to the presence of local complications.**

	Erythrocyte distribution width	
	n (%)	mean $\pm$ SD
Absent	87 (82.07)	14.38 $\pm$ 1.23
Present	19 (17.92)	14.92 $\pm$ 1.52

**Table 3: Comparison of erythrocyte distribution width according to systemic complications.**

	Erythrocyte distribution width	
	n (%)	mean $\pm$ SD
Absent	54 (50.9)	14.04 $\pm$ 1.09
< 48 hours	34 (34.9)	14.55 $\pm$ 0.99
< 48 hours	15 (14.2)	15.99 $\pm$ 1.51

difference was found between the values in both groups (14.04 vs. 14.55%;  $p = 0.116$ ).

Within the group with persistent systemic complications, 15 patients were found; renal failure was the most frequent complication, followed by pulmonary, hematologic, metabolic, and sepsis conditions. When comparing the RDW between patients without complications and those with persistent systemic complications, a statistically significant difference was found between the values in both groups (14.04 vs. 15.99%,  $p < 0.001$ ).

When comparing the ADE between those with transient systemic complications and those with persistent systemic complications, the difference between the values in both groups was also statistically significant with  $p < 0.001$  (Table 3).

By means of a general linear univariate model, it was observed that there was a higher RDW value at admission in subjects with severe pancreatitis ( $p < 0.001$ ).

A ROC curve was performed to determine the RDW value at patient admission, with greater diagnostic utility to detect cases with severe acute pancreatitis, obtaining an area under the curve of 0.834, a standard error of 0.065 and a  $p < 0.001$ , with a 95% confidence interval of 0.707-0.961. When analyzing the coordinates of the curve, we observed that with an ADE value at admission of 14.95% or higher, we obtained a sensitivity of 73.3% and a specificity of 79.1% to predict severe acute pancreatitis and an odds ratio of 10.421 (significant with a  $\chi^2$  value 17.461 and  $p < 0.001$ ) (Table 4 and Figure 1).

ADE levels were analyzed at admission, 48, 72, and 168 hours in patients with these

measurements ( $n = 82$ ). A high correlation ( $R = 0.88$  at 48,  $R = 0.801$  at 72, and  $R = 0.728$  at 168 hours) was found between values at admission and on days two, three, and seven of hospital stay.

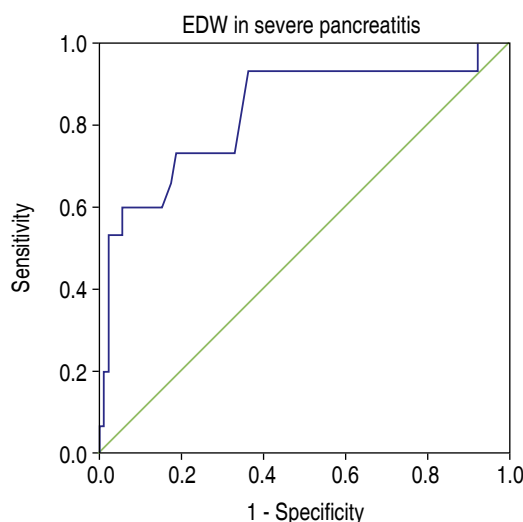
## DISCUSSION

Within the treatment of cases with acute pancreatitis, it is of vital importance to determine when an acute pancreatitis event is going to become severe; this allows the identification

**Table 4: Diagnostic test value.**

Variable	Percent
Erythrocyte distribution width	> 14.95
Sensitivity	73.33
Specificity	79.12
PPV	36
NPV	94
Overall Value	78

PPV = positive predictive value.  
NPV = negative predictive value.



**Figure 1: Receiver Operating Characteristic (ROC) curve for erythrocyte distribution width in severe pancreatitis. Ties generate diagonal segments. EDW = erythrocyte distribution width.**

of the most vulnerable patients, who require a more aggressive therapeutic approach, referral to a third level or admission to an intensive care unit, to maximize life support and prevent irreversible organ dysfunction. Risk factors for developing severe pancreatitis have been described to date, such as advanced age, associated comorbidities, and obesity. Much of the research in acute pancreatitis is directed to the search for a biomarker that allows early identification of those who will evolve to severe forms, such as C-reactive protein, D-dimer, determination of metalloproteinases, or serum amyloid A.

This study established the usefulness of RDW as a predictor of severity in acute pancreatitis of biliary origin, explored the prognostic correlation between RDW and the severity of biliary pancreatitis, and proposed a cut-off point for screening and early identification of patients at risk. Unlike other scales or risk markers currently used in acute pancreatitis, RDW is routinely performed as part of the blood cell count measure. Hence, its determination upon patient admission to an emergency department is fast, automated, and inexpensive, and its availability is practically universal.

RDW was determined in all patients on admission to the emergency department, even before confirming the diagnosis of acute pancreatitis. When comparing the RDW values of patients with severe acute pancreatitis versus those who developed mild or moderately severe forms, we found an association between the admission levels and the severity of pancreatitis. There is a tendency to have higher levels in patients who developed persistent systemic complications; when analyzing the mean difference between the three groups, we found that this was statistically significant in the severe pancreatitis group concerning the other two groups (14.04 vs. 14.51 vs. 15.99%).

We sought to establish an ADE value at admission that would predict severe acute pancreatitis, defined according to the 2012 revision of the Atlanta classification as the presence of persistent organ failure, regardless of the presence of local complications. Using the ROC curve, it was found that with a cut-off point of 14.95%, the ADE has a sensitivity of 73.3% and a specificity of 79.1% to predict

severe pancreatitis. With this cut-off point, it was observed that patients with an ADE value at admission > 14.95% have a 10-fold increased risk of developing severe acute pancreatitis compared to cases with a lower ADE at admission.

Even though there are no studies on the usefulness of RDW as a predictor of severity, these results are consistent with previous studies by Senol,<sup>30</sup> Yao<sup>31</sup> and Kolber,<sup>29</sup> who established its usefulness as a predictor of mortality in pancreatitis. In our study, only two deaths were recorded, corresponding to an overall mortality rate of 1.88%, like that reported in the literature. Both cases were in the severe pancreatitis group, which gives us mortality for this group of 13.3%, like that reported in the international literature. Since the number of deaths was low in this study, it was impossible to establish whether the ADE had prognostic value for predicting mortality in our population, as suggested by other authors.

We did not observe differences in RDW levels at admission about local complications. Even when these complications are caused by extensive local tissue destruction, they do not impact mortality. This supports the theory that RDW is a biomarker of pre-existing systemic inflammatory conditions rather than the acute inflammatory response caused by pancreatitis. Thus, elevated RDW will be associated with systemic conditions that favor the development of severe pancreatitis independently of local inflammatory damage.

When analyzing the levels of RDW at admission, 48, 72, and 168 hours, a high correlation was found, suggesting that its determination in the first seven days of pancreatitis' evolution will present few variations; this low variability supports the theory that the modifications are due to underlying chronic clinical conditions.

## CONCLUSIONS

An elevated RDW on admission to the emergency department allows us to identify vulnerable cases with a higher risk of developing severe acute pancreatitis of biliary origin.

Although we do not know the pathophysiology of anisocytosis in these



patients, these observations indicate that it is possible to use RDW as an early marker of severity in patients with acute pancreatitis of biliary origin; these results are compatible with observations made in other parts of the world. We know that early identification of severe cases of acute biliary pancreatitis allows modifying the evolution, seeking to improve the prognosis; in this sense, ADE can become a tool available to any hospital unit for initial screening, thus optimizing its treatment.

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**Ethical aspects:** the protocol was reviewed by the Ethics and Research Committees of the Hospital General de México and approved by the Directorate of Research under registry number DI/13/305/03/042. Informed consent was obtained in all cases and the information was handled confidentially.

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# Radial sphincterotomy in endoscopic retrograde cholangiopancreatography for the management of choledocholithiasis of large elements, institutional experience

*Esfinterotomía radial en colangiopancreatografía retrógrada endoscópica para manejo de coledocolitiasis de grandes elementos, experiencia institucional*

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## Keywords:

choledocholithiasis,  
large stones,  
endoscopic retrograde  
cholangiopancreatography,  
radial  
sphincterotomy,  
common bile duct.

## Palabras clave:

coledocolitiasis,  
litos de gran tamaño,  
colangiopancreatografía  
retrógrada  
endoscópica,  
esfinterotomía radial,  
vía biliar común.

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## ABSTRACT

**Introduction:** sphincterotomy is commonly used to remove stones from the bile duct and has a high success rate in stones < 10 mm; however, this decreases when larger stones appear; applying the radial sphincterotomy technique increases the surface area of the bile duct outlet, so its usefulness in the extraction of stones with large elements is the subject of this study. **Objective:** to describe the experience of using radial sphincterotomy in large element choledocholithiasis in our hospital. **Material and methods:** a longitudinal, retrospective, observational, and clinical study in patients diagnosed with large element choledocholithiasis who underwent endoscopic retrograde cholangiopancreatography and radial sphincterotomy between April 2021 and April 2023. Study variables: incidence, age at diagnosis, sphincterotomy results, and complications. **Results:** 35 records of patients diagnosed with large element choledocholithiasis were reviewed. An institutional incidence of 13% was obtained. The average age at diagnosis was 58.2 years. It was satisfactory in 85% of the cases. Complications occurred in 8% of cases, pancreatitis being the most common. **Conclusions:** radial sphincterotomy presents percentage gains in the geometric area compared to conventional sphincterotomy, which is why it has proven helpful in managing stones > 10 mm in the bile duct without increasing the rate of complications in this hospital.

## RESUMEN

**Introducción:** la esfinterotomía es comúnmente utilizada para remover litos de la vía biliar y tiene una alta tasa de éxito en litos < 10 mm; sin embargo, ésta disminuye al presentarse litos de mayor tamaño; aplicando la técnica de esfinterotomía radial se presenta un aumento en el área de superficie de salida de la vía biliar, por lo que su utilidad en la extracción de litos de grandes elementos es el tema de este estudio. **Objetivo:** describir la experiencia en el uso de esfinterotomía radial en coledocolitiasis de grandes elementos en nuestro centro hospitalario. **Material y métodos:** estudio retrospectivo, observacional y clínico en pacientes con diagnóstico de coledocolitiasis de grandes elementos sometidos a colangiopancreatografía retrógrada endoscópica a los cuales se les realizó esfinterotomía radial entre los meses de abril de 2021 a abril de 2023. Variables de estudio: incidencia, edad al momento de diagnóstico, resultado de esfinterotomía y complicaciones. **Resultados:** se revisaron 35 expedientes de pacientes con diagnóstico de coledocolitiasis de grandes elementos. Se obtuvo una incidencia institucional de 13%. Edad promedio al momento del diagnóstico 58.2 años. Fue satisfactoria en 85% de los casos. Se presentaron complicaciones en 8% de los casos, la más común fue la pancreatitis. **Conclusiones:** la esfinterotomía radial, presenta porcentajes de ganancia en el área geométrica en comparación con la esfinterotomía convencional, por lo que ha demostrado utilidad para manejo de litos > 10 mm en la vía biliar, sin aumentar la tasa de complicaciones en este centro hospitalario.



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#### Abbreviation:

ERCP = endoscopic retrograde cholangiopancreatography.

## INTRODUCTION

The high worldwide prevalence of gallbladder stones (10-20%) has conferred an inherent risk of developing choledocholithiasis, followed by primary choledocholithiasis, which has an incidence of 4-10% of the population. Endoscopic retrograde cholangiopancreatography (ERCP), as a diagnostic and therapeutic tool, began to be used in 1968, followed by the first sphincterotomy in 1974, becoming the gold standard in the management of common bile duct stones as it is a highly effective, minimally invasive, and safe procedure. Common duct stone removal techniques include sphincterotomy, mechanical lithotripsy, papillary balloon dilatation, and cholangioscopy-guided lithotripsy.<sup>1</sup> However, several factors make stone removal difficult, including large stones, which is defined as a stone greater than or equal to 10 mm. Because of this, the risk of a failed ERCP, with no possibility of removing the common bile duct stone, is 10-15%. Anatomically, Oddi's sphincter is divided into bile duct and pancreatic sphincter, followed by a common segment and the ampulla. The latter is usually located in the second portion of the duodenum and appears as a nodular prominence on the lateral wall. It is a site where sphincterotomy is performed in search of access to the bile duct to remove the duodenum. This technique has been widely described and has been shown to be close to 100% effective in stones smaller than 10 mm. However, the success rate decreases up to 12% in stones larger than 15 mm.<sup>2</sup> Therefore, the management of large choledocholithiasis still represents a challenge and involves the risk of advanced endoscopic techniques or surgery with bile duct exploration, which, if unsuccessful, will lead to the development of complications such as cholangitis and sepsis in the patient. The aim of this study is to present the experience in a hospital center for the management of large element choledocholithiasis with radial sphincterotomy.

## MATERIAL AND METHODS

*Objective:* to describe the experience in using radial sphincterotomy during endoscopic retrograde cholangiopancreatography (ERCP) to manage large element choledocholithiasis in our hospital center. In a retrospective, observational, and clinical study performed in patients diagnosed with large element choledocholithiasis, from April 2021 to April 2023, 252 endoscopic retrograde cholangiopancreatography (ERCP) procedures were performed. The diagnosis was confirmed at the time of the procedure during cannulation and fluoroscopy of the biliary tract. Patients with common bile duct stones > 15 mm who underwent radial sphincterotomy were included. The information was obtained from medical records and notes, and endoscopic reports.

*Variables analyzed:* incidence, sex, age at diagnosis, sphincterotomy result, and complications.

*Statistical analysis:* for data management, means between independent groups were recorded, and a parametric statistical test was applied. Categorical variables are reported in frequency and percentages.

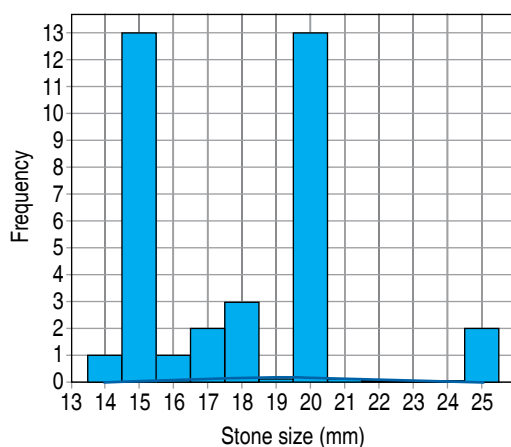
## RESULTS

Of the 252 patients who underwent ERCP, 35 were found and included in this report. They had a diagnosis of large element choledocholithiasis, presenting an incidence of 13%; 25 of the cases were women, and only 10 were men. The average age at presentation was 58.2 years; however, the age ranged from 20 to 91. All subjects underwent endoscopic retrograde cholangiopancreatography (ERCP), with the same frequency of 15 mm lithiasis with 13 cases and 13 cases of 20 mm lithiasis; the rest ranged from 14 to 25 mm. Radial sphincterotomy was performed in all patients. The removal of common bile duct stones was successful in 30 cases, while the stone could not be removed in five patients, which corresponds to a success rate of 85%. In most cases (33), a balloon was used to remove the stone. Only in two cases was a Dormia basket used. Complications were reported in only three patients, two of whom

developed pancreatitis, while one of them developed cholangitis.

## DISCUSSION

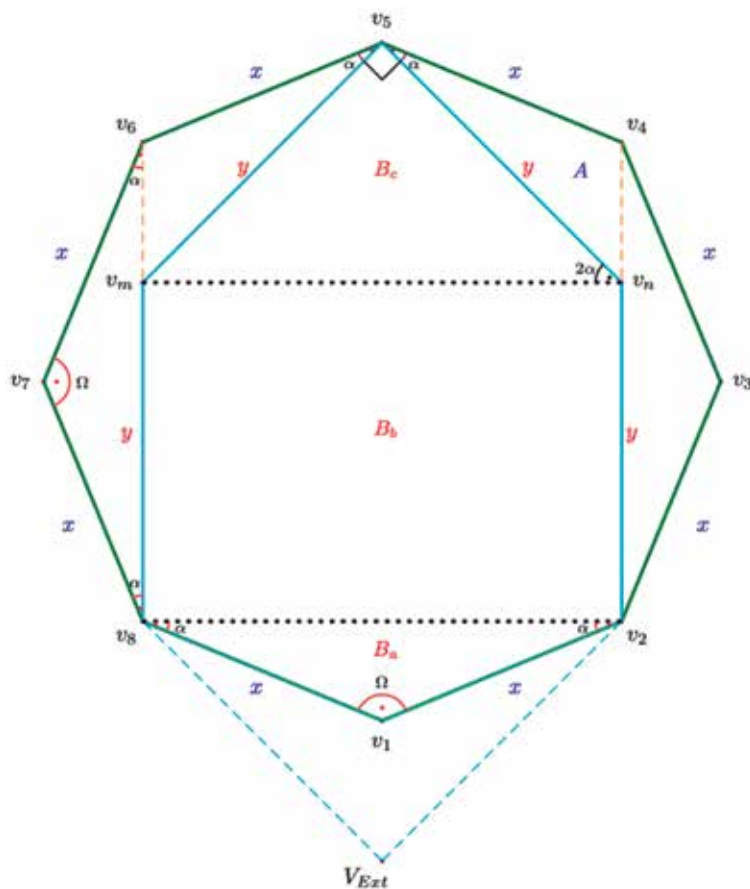
Choledocholithiasis most frequently results from the migration of bile from the gallbladder into the biliary tree. They are formed as a consequence of cholesterol saturation in the bile, inadequate bile salt function, and decreased contractility of the biliary epithelium.<sup>3</sup> One of the risk factors for the development of lithiasis is related to being female; 25 of the 35 files analyzed belonged to this group, while the remaining ten were male, as reported in our study, age over 40 years, obesity, and rapid weight loss.<sup>4</sup> Choledocholithiasis has a concomitant incidence with gallbladder lithiasis of 7-12%. The size of the stones varies from small (1-2 mm) to large (15-30 mm); this study focused on stones > 14 mm, with 15- and 20-mm stones being more frequent comprising 75% (Figure 1). Their management represents an important clinical problem. Endoscopic retrograde cholangiopancreatography (ERCP) with the use of a Dormia basket or balloon has become the standard management for this condition, and it is estimated that 85-95%<sup>5</sup> of choledocholithiasis resolved satisfactorily by this endoscopic method.



**Figure 1:** Frequency of common bile duct stone size.

Multiple factors have been reported to hinder the success of ERCP removal of lithiasis. It is estimated that approximately 10-15% are related to difficulty in accessing the bile duct (periampullary diverticulum, sigmoid morphology of the common bile duct, postgastrectomy Billroth II anatomy, Roux-en-Y gastrojejunostomy), large number of stones (> 10), large size of stones (> 15 mm), unusual shape of stones or abnormal location (intrahepatic, cystic duct, proximal structures).<sup>6</sup> However, stone size is the most challenging factor, and multiple studies have demonstrated that stone size is inversely proportional to the clearance of the bile duct during ERCP.<sup>7</sup> Successful bile duct stone removal depends on two general principles: decreasing the size of the stone and increasing the surface area of the bile duct outflow orifice.<sup>8</sup> Because of this, sphincterotomy combined with balloon dilatation has become the first-line approach. Standard sphincterotomy has been extensively detailed and consists of an electrocautery incision in the 11, 12, or 1 o'clock direction, depending on the papilla's anatomy and the stone size. Subsequently, a balloon sweep or the use of a cannula can be performed to extract the stone. The maximum length of the incision depends on the length of the longitudinal fold from the papilla to the first transverse fold.<sup>9</sup> The safe, natural anatomic boundaries are around the papilla, which makes it an insufficient incision for large element (< 15 mm) stones. Because of this, in 2020 Kenan Yusif-Zade described and compared the improved method for radial sphincterotomy, in which multiple incisions are performed in a single session towards 11, 12, and 1 o'clock conventional clock positions; this provides a larger total cross-sectional area, at least 1.5 times larger, compared to conventional sphincterotomy.<sup>10</sup> Figure 2 depicts the radial sphincterotomy surface as proposed in the referenced article, which is bounded by the vertices in the interval [V1-V8]; the area of this surface is taken as A. Similarly, the standard sphincterotomy geometry is formed by the surface of vertices V1, V2, Vn, Vm, V8; the area of this surface is taken as B. To





**Figure 2:** Geometric comparison of conventional sphincterotomy area vs radial sphincterotomy.

verify the area gain factor, the trigonometric analysis was replicated to compare areas A and B in much the same way as performed by Kenan Yusif-Zade. The gain  $\sigma$  is defined by the relation (1) (Figure 3), where area A is directly proportional to area B and the gain factor  $\sigma$ . If the edges bounding each vertex  $v_i$  of A, have length  $x$ , and the top four edges of B are worthy, leaving everything a function of a single variable is convenient. We have information:  $\Omega = 135^\circ$  and  $\alpha = \Omega / 6$ . It is straightforward to determine the relationship between the variables  $x$  and  $y$  in Figure 2, where the geometric segment bounded by the vertices  $v_2$ ,  $v_3$ ,  $v_4$ , and  $v_5$  is shown. Adding the Euclidean distance  $v_{no} + ov_2$  results in equation (2) (Figure 3). Area A is a regular octagon, but with B, dividing

each area section into known geometries,  $B_a$ ,  $B_b$ ,  $B_c$ , and applying corresponding formulas is convenient. From this analysis, equations (3), (4), and (5) are determined (Figure 3) for each area section, all as a function of a single variable, the length of edge  $x$ . If the gain  $\sigma$  is calculated by the geometric ratio of area A between area B, where  $B = B_a + B_b + B_c$ , then the resulting factor is 1.333333..., i.e., the area of A is approximately 4/3 greater than area B, or A represents 33.33% more area than B. Thus, it can be deduced that increasing the sphincter exit area by 1.333333 allows larger volume stones to exit. The success rate demonstrated in this study corresponds to 85%, with satisfaction in 30 procedures concerning the five that were not satisfactory in large element choledocholithiasis, representing a significant increase compared to that reported in the literature, ranging from 15-20%. Like any procedure, it is not exempt from developing complications, and despite the indication and population, mortality and morbidity rates after sphincterotomy are reported in the literature to be approximately 10%.<sup>11</sup> In this regard and in relation to this study, we can define any adverse event related to ERCP in which sphincterotomy was performed as a complication. In the literature, between 7 and 10% of patients undergoing ERCP had any complication<sup>12</sup> which corresponds to the complications presented in the population of this study (Figure 4). Post-ERCP pancreatitis is defined as the presence of abdominal pain and

$$(1) \sigma B = A$$

$$(2) y = x(\cos \alpha + \sin \alpha)$$

$$(3) B_a = \frac{x^2 \sin \Omega}{2}$$

$$(4) B_b = x^2 \frac{\sin \Omega}{\sin \alpha} (\cos \alpha + \sin \alpha)$$

$$(5) B_c = x^2 \sin \Omega \cos \alpha (\cos \alpha + \sin \alpha)$$

**Figure 3:** Trigonometric analysis of area in sphincterotomy.

elevation of pancreatic enzymes, which usually leads to a course of mild pancreatitis in 42% of cases,<sup>13</sup> both in the literature and in this study. It was found to be the most frequent complication and generally presented in its mild form, with satisfactory resolution with supportive management and allowing patients to leave the hospital an average of three days after the procedure. Hemorrhage is defined as bleeding data such as melena or hematemesis associated with a decrease of 2 g in hemoglobin concentration and did not occur in this group of patients.<sup>14</sup> It is necessary to

compare different techniques for bile duct clearance. However, it is worth considering radial sphincterotomy as a therapeutic option, with a high possibility of success in patients with this pathology.

## CONCLUSIONS

Radial sphincterotomy during the performance of endoscopic retrograde cholangiopancreatography (Figure 5) presents an area gain factor of 1.333 demonstrated by replicating the trigonometric analysis, which represents an increase in the surface maneuvering margin, which represents a difference in the diameter of the segment for the extraction of the stone. The mathematical analysis has demonstrated the theoretical increase in the area for extraction. The complication rate is similar and remains within the expected parameters, like conventional sphincterotomy, while the success rate rises to 85% for large element choledocholithiasis in this study. It is convenient to carry out further studies to compare other techniques for biliary tract clearance in cases of large element choledocholithiasis, as well as to know the limit of the tissue enlargement field due to the thickness of the walls and their elasticity without representing risks for the structures involved, nor for the patient.

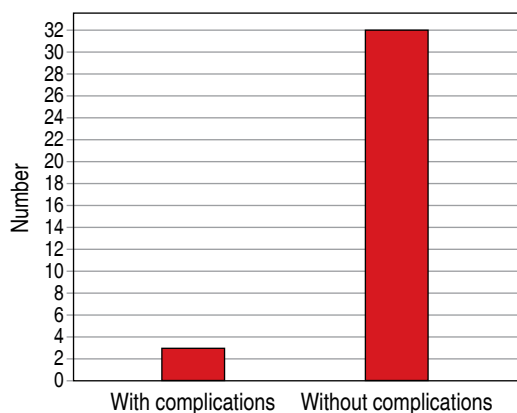


Figure 4: Frequency of complications.

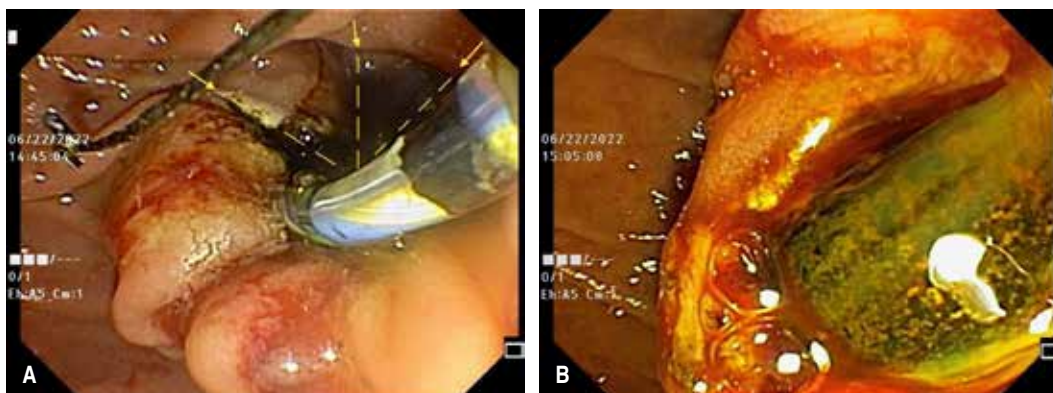


Figure 5: A) Radial sphincterotomy technique in endoscopic retrograde cholangiopancreatography. B) Clarification of the biliary tract with the exit of a large bile duct stone through the Oddi sphincter.

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# Gallbladder's adenomyomatosis. Critical aspects for surgical decision

## Adenomiomatosis de la vesícula biliar. Aspectos críticos para la decisión quirúrgica

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### Keywords:

adenomyomatosis,  
gallbladder,  
gallbladder cancer,  
cholecystectomy,  
biliary tract.

### Palabras clave:

adenomiomatosis,  
vesícula biliar;  
cáncer vesícula,  
colecistectomía,  
sistema biliar.

### ABSTRACT

Adenomyomatosis of the gallbladder is a benign, pseudotumoral pathology, frequently diagnosed incidentally and rarely considered in clinical practice. The interest of this communication is to establish an accurate diagnosis of gallbladder adenomyomatosis, considering common risk factors with gallbladder cancer to evaluate the safe indication of cholecystectomy in a condition defined as benign. This paper is a retrospective, observational series of cases of 13 patients with a diagnosis of gallbladder adenomyomatosis that studies clinical and imaging diagnosis, surgical procedure performed, morbidity, and mortality. This study included eight women and five men with a mean age of 65.7 years. Nine cases (69.2%) were symptomatic; 46.1% had signs of biliary dysfunction, and 23.3% suffered pain and nonspecific digestive symptoms. The remaining 15.3% were asymptomatic, and another 15.3% were incidental findings during hepatectomies. Ultrasound was diagnostic in 92.3% of patients. Laparoscopic cholecystectomy was performed in 76.9% of cases, conventional cholecystectomy in 15.3%, and one patient chose conservative management. There was no mortality or significant complications. The indication of cholecystectomy for adenomyomatosis with asymptomatic or incidental clinical presentation in the absence of gallstones is only justified in the case of persistent uncertainty diagnosis.

### RESUMEN

La adenomiomatosis de la vesícula biliar es una patología pseudotumoral, benigna, de diagnóstico frecuentemente incidental y poco considerada en el ámbito clínico. El interés de esta comunicación se vincula con la necesidad de establecer el diagnóstico preciso a los efectos de indicar la colecistectomía, considerando que existen factores de riesgo comunes con el cáncer de vesícula en una patología definida como benigna. Se realizó un análisis retrospectivo, observacional, de 13 pacientes con diagnóstico de adenomiomatosis vesicular; se analizó: diagnóstico clínico e imagenológico, procedimiento realizado y morbimortalidad. Fueron incluidos ocho mujeres y cinco hombres con edad media de 65.7 años. Fueron sintomáticos 69.2% de los casos; 46.1%, tenían signos de disfunción biliar y 23.3% sufrían dolores y síntomas digestivos inespecíficos. El 15.3% eran asintomáticos y otro 15.3% fueron hallazgos incidentales en el curso de hepatectomías. La ecografía fue diagnóstica en 92.3% de los pacientes. Se realizó colecistectomía laparoscópica en 76.9% de los casos, convencional en 15.3% y un paciente optó por manejo conservador. No existieron mortalidad ni complicaciones significativas. La indicación de colecistectomía por adenomiomatosis en las formas asintomáticas o incidentales y en ausencia de litiasis vesicular sólo se justifica frente a la incertidumbre diagnóstica persistente.

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### Abbreviations:

18FDG = 18-fluorodeoxyglucoside.  
ADM/GB = adenomyomatosis of the gallbladder.  
MRI = magnetic resonance imaging.  
RA sinuses = Rokitsansky-Aschoff sinuses.  
CT = computerized tomography scan.

### INTRODUCTION

In routine clinical practice, the most frequent gallbladder pathologies are lithiasis and cancer; however, there are other diseases of lower incidence, but with clinical

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and healthcare aspects of great interest. Adenomyomatosis of the gallbladder (ADM/GB) is a degenerative and proliferative pathology of controversial pathogenesis linked to inflammatory and mechanical factors derived from its frequent association with gallstones. Its origin is postulated in epithelial growth stimulated by chronic inflammation secondary to lithiasis or excessive bile absorption at the gallbladder wall level. It is considered a benign disease and is little known by clinicians. Its diagnosis is usually incidental during liver ultrasound.

When faced with the diagnosis of ADM/GB, the main aspects to consider are a) to achieve diagnostic certainty based on a pseudotumorous imaging pattern in a nonspecific or asymptomatic clinical context; b) to evaluate the existence of risk factors common to GB cancer; c) the patient's fear of a gallbladder "tumor" and d) the surgeon's certainty to safely assume the decision to perform cholecystectomy.

The aim of this report is related to the need to make an accurate diagnosis of ADM/GB, considering that it has common risk factors with GB cancer to establish the indication for cholecystectomy for a benign and sometimes asymptomatic disease.

## MATERIAL AND METHODS

This is a retrospective, observational review of a series of 13 patients with a diagnosis of ADM/GB, analyzing age, sex, clinical and imaging diagnosis, procedure performed, and morbimortality. An analysis was made of the literature on the subject, the current definition and pathogenesis of ADM, its possible risk of GB cancer, as well as the need to establish a safe preoperative diagnosis, which allows informing the patient and making a surgical decision with the right elements of technical judgment and safety.

The present work has the approval of the CASMU-IAMPP Ethics Committee, the signed consent of the patients included in the study, and is registered in the MSP (No. 7649061). The authors declare that they have received no funding and have no conflict of interest.

## RESULTS

In the period between March 2012 and July 2020, 6,872 cholecystectomies were performed in the Department of Surgery of CASMU-IAMPP; among them, an imaging diagnosis of ADM/GB was made in 13 cases (0.18%); eight women and five men. The ages ranged from 41 to 87 years (mean 65.7). Nine cases (69.2%) were symptomatic; six of them (46.1%) had signs suggestive of biliary dysfunction and three cases (23.3%) had nonspecific digestive pain and symptoms; two cases (15.3%) were asymptomatic, and two others (15.3%) were incidental findings in the course of hepatectomies for cancer: one metastasis of colorectal carcinoma and one hepatocellular carcinoma.

With ultrasonography the diagnosis was made in 12 cases (92.3%); in the remaining case, a confirmatory magnetic resonance cholangiography was performed due to diagnostic doubt. One patient with nonspecific symptoms opted for follow-up.

Ten (76.9%) laparoscopic cholecystectomies were performed, and in the two cases associated with cancer, the procedure was conventional surgery. The anatomopathological studies showed focal ADM in two patients, and in the other 10, it was located in the vesicular fundus. No malignant cells were found in any case. Gallbladder lithiasis was observed in five cases (38.4%), which represents 0.07% of the total number of cholecystectomies in the period.

There was no mortality or complications except for a urinary tract infection. In the operated cases, hospital discharge was granted in the first two postoperative days in 10 cases, and no evolutionary controls were indicated once the pathologic diagnosis of ADM was confirmed. Patients with hepatectomies were discharged on the fourth and sixth postoperative days. The case that did not undergo surgery was submitted to clinical and ultrasound control and is asymptomatic and without imaging changes after 53 months of follow-up.

## DISCUSSION

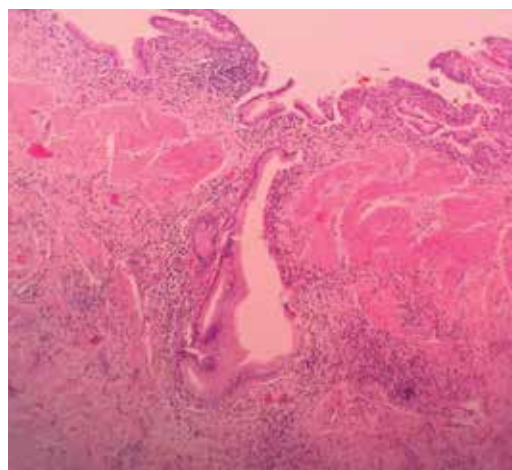
Prior to 1960, multiple terms were accepted to nominate ADM/GB (hyperplastic adenomatosis,



adenomyoma, cystic cholecystitis, proliferative glandular cholecystitis, intramural diverticulosis, hamartoma) until the publication of Jutras,<sup>1</sup> who defined it as a degenerative and proliferative disease of the GB. Adenomyomatosis is now the sole term, although “adenomyosis” is still frequently used. It is considered to be a benign disease, although, in 1988, Katoh<sup>2</sup> reported a noninvasive, localized carcinoma in the breast of a ADM/GB female patient, which prompted interest relating to cancer.

ADM/GB predominates in adults over 50 years of age. This study shows a higher mean age (65.7 years) and the finding of between 1 and 9% of the population aged 65.7 years<sup>3</sup> of the cholecystectomy specimens in this series was much lower (0.07%). In this report, the incidence of associated vesicular lithiasis (38.4%) is in accordance with the literature, which shows an incidence between 36 and 95%.<sup>4</sup> Inflammatory and mechanical mechanisms are postulated in the pathogenesis of ADM/GB. The association between gallbladder stones and the chronic inflammatory changes they produce suggests that epithelial growth is stimulated by permanent inflammation.<sup>5</sup> However, it is also postulated that excessive bile absorption at the level of the vesicular wall generates inflammation that stimulates epithelial growth. Other origins of parietal inflammation have been cited, such as chronic pancreatic/vesicular reflux, especially in patients with abnormal implantation of the Wirsung duct at the level of the common bile duct.<sup>6,7</sup> In addition, alterations in vesicular motility due to neuromuscular hyperactivity increase intraluminal pressure, push the epithelium towards the muscular layer, and produce its transformation to diverticulum, forming the Rokitansky-Aschoff sinuses (RA sinuses) (Figure 1).<sup>8</sup>

The diagnosis of ADM in our series was preoperative in 92% of the cases; in all cases, an ultrasound scan was the first study. The diagnostic efficacy of ultrasound is related to the high incidence of gallbladder stones and the high level of training in the identification of biliary anatomy in our environment. ADM does not have exclusive symptoms; they overlap with those of cholelithiasis, and it is difficult to differentiate between the two. The incidental finding of ADM is discovered in the



**Figure 1:** Gallbladder (H&E 2x). The microscopic appearance of a Rokitansky-Aschoff diverticulum within marked muscular hypertrophy, characteristic of vesicular adenomyomatosis, is shown.

pathological examination of cholecystectomy specimens for symptomatic gallbladder lithiasis and is observed in 7% of the autopsy series.<sup>9</sup> Cholecystectomy may be a therapeutic test when it presents without associated lithiasis and nonspecific symptomatology. Exceptionally, it may present as an acute picture of acalculous cholecystitis.<sup>10</sup> Consequently, imaging is critical for definitive and differential diagnosis.

Associated with the diagnosis of ADM, it is important to rule out GB cancer, and the immediate question emerges: How reliable is imaging to accomplish this with certainty?<sup>11</sup> The efficacy of abdominal ultrasound and computed tomography (CT) scan are similar; both can accurately diagnose ADM. Ultrasonography has a sensitivity of about 65%. Vesicular wall thickening (defined as greater than 3 mm) is a suggestive sign of ADM, always present but not very specific and seen in 25% of cases.<sup>12,13</sup> Other related entities, including cancer, xanthogranulomatous cholecystitis, polyps, lipomas, adenomas, and even acute cholecystitis, should be considered. Consequently, imaging evaluation should rule out the diagnosis of GB cancer, whether the wall thickening is localized or diffuse.<sup>5</sup>

Other signs suggestive of ADM are pseudocystic mural images corresponding to AR sinuses and acoustic artifacts due to intramural

calcific lithiasis with a “comet tail” appearance,<sup>5</sup> which is a particular sign of ADM. Anechoic luminal content can usually be visualized due to biliary mud or lithiasis.<sup>14</sup> There are different types of images associated with parietal thickening that characterize ADM: a) diffuse type, encompassing the entire organ and wall, containing multiple cysts corresponding to the RA sinuses and “kite tail” artifacts; and b) segmental type with annular wall thickening, focused to the medial part that gives the GB an hourglass appearance. In short, the most reliable diagnosis of ADM in a thickened wall is when associated with large AR sinuses, i.e., larger than 3 mm.<sup>11</sup>

Endoscopic ultrasound improves sensitivity for differential diagnosis of GB cancer, but it is an invasive test that must be accurately indicated.<sup>15</sup> It has recently been reported that high-resolution ultrasound would be particularly effective for the diagnosis of GB cancer, with a sensitivity equivalent to magnetic resonance imaging (MRI).<sup>16</sup> The use of contrast-enhanced ultrasound (intravenous injection of hyperechoic microbubbles) has also been reported to enhance the differential and definitive diagnosis of ADM. This technique is inexpensive, avoids radiation and nephrotoxic contrast agents, but is highly operator dependent.<sup>17</sup>

CT scan has a sensitivity of 50-75% for the diagnosis of ADM,<sup>18</sup> but it is not a very effective study for differentiating ADM from GB cancer.<sup>19</sup> Still, some tomographic images are particular, for example, the “pearl necklace rosary” sign, which is produced by the combination of a non-contrast proliferating muscular layer surrounding proliferative mucosal epithelium enhanced by intramural diverticula and the “cotton ball” sign, which consists of gray dots enhanced in a thickened wall on contrast-enhanced CT and is more evident when the RA sinuses are small.<sup>11,16,20</sup>

MRI can provide greater precision in case of diagnostic doubt (*Figure 2*). In fact, it has a higher sensitivity (73 vs. 80.3%) and specificity (96.3 vs. 98.2%) than ultrasound.<sup>16</sup> Here, GB wall thickening can be evidenced on T1 and T2 scans. RA sinuses typically appear hyperintense on T2 and hypointense on T1, showing no contrast enhancement. The conjunction of

parietal thickening and intramural diverticula with the “string of pearls sign” distinguishes ADM from other etiologies and is seen on T2 as multiple high-intensity cavities in the vesicular wall. This pearl sign is more notorious on cholangio-MRI.<sup>21,22</sup>

On positron emission tomography (PET scan), the ADM usually does not uptake 18-fluorodeoxyglucose (18FDC) and has lower uptake compared to the liver ( $SUV < 2.5$ ). It is useful for differential diagnosis because GB cancer is usually hypermetabolic. However, the acute inflammatory reaction surrounding AR sinuses can generate an increased 18FDC uptake and result in a false-positive result. The PET scan is not indicated for the diagnosis of ADM but can help to rule out cancer when the uptake of the marker is low.<sup>23</sup>

In short, due to the diagnostic efficacy that arises from the conjunction of different types of images, anatomopathological studies are usually omitted in the presence of previously analyzed signs, and biopsy is not postulated as necessary.<sup>5</sup>

A second issue is the malignant potential of genuine ADM/GB. While it is difficult to assert that ADM is a cancer risk factor, the inflammatory condition underlying its origin has been considered a potential carcinogen.<sup>24,25</sup>



**Figure 2:** Cholangio-MRI. View of a fundus segmental adenomyomatosis. Parietal thickening with hypercapillary foci in the fundus is seen. In T2, the Rokitsky-Aschoff sinuses can be visualized (arrow) to differentiate adenomyomatous hyperplasia from vesicular carcinoma.

Some authors have reported a relationship between GB cancer and ADM/GB in up to 25% of cases.<sup>26</sup> Although, in general, ADM is not considered to have malignant potential, both entities have in common factors that favor oncogenesis.

When surgery is indicated due to increased pain or other symptoms, an accurate differential diagnosis between ADM and GB cancer is an important element in choosing the appropriate procedure and avoiding influencing the oncologic prognosis.

The absence of cholelithiasis is an independent risk factor linked to GB cancer. The Moon paper<sup>27</sup> shows that the group of patients with ADM had a significantly higher rate of gallstones compared to the group with GB cancer, suggesting that the absence of stones in cases of unclear imaging diagnosis allows inferring the existence of gallbladder cancer.

Morikawa,<sup>3</sup> in 93 cholecystectomies with ADM/VG confirmed by pathology, mentions that 79.6% had associated gallbladder lithiasis, and in 3.2%, an early gallbladder carcinoma was detected, without any preoperative image suggesting it. In the present study, 61.6% of the cases were not associated with gallbladder lithiasis; however, malignancy was not verified in the specimens studied.

A well-established aspect is that GB cancer usually develops in the segmental type of ADM, in the distal fundus sector, and that this location can be considered a precancerous condition (Figure 3).<sup>2</sup> Therefore, the difficulty in early diagnosis of GB cancer in the setting of ADM with gallbladder stones is evident, and physicians should be aware of the same when planning the sequence of studies.<sup>2,28</sup>

Therapeutic decision-making in asymptomatic cases without associated vesicular pathology is complex and controversial because, despite its proliferative characteristics -pseudotumorous- ADM is a lesion with low malignant potential. In this case, the tendency is to avoid surgical treatment to minimize the risks of surgery, which allows a "watch and wait" strategy with periodic controls.<sup>5</sup>

When assuming the indication for surgery, one must consider the surgeon's conviction and certainty that he/she has completed a



**Figure 3:** Image of the open and evacuated gallbladder with pseudotumoral aspect. A parietal thickening may be due to extensive muscular hypertrophy and intramural cavities.

process that allows him to guarantee the diagnosis of ADM and the patient's consent and understanding in terms of overcoming his fears in a situation whose most practical solution is cholecystectomy, but over with the risk of a particularly serious complication such as surgical lesion of the biliary tract, which is observed in a low percentage of cases, but whose transcendence and poor prognosis cannot be avoided.

## CONCLUSIONS

The present analysis verifies that ADM/GB is an incidental imaging finding, usually associated with gallbladder lithiasis, with high diagnostic safety efficacy by ultrasound, CT scan, and MRI. It is considered a disease with low malignant potential, even though it shares risk factors with GB cancer. This series shows the absence of neoplasia in all the pieces studied. The indication of cholecystectomy in asymptomatic forms without lithiasis is only justified in the face of persistent diagnostic doubt.

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# Prevalence of pancreatic neoplasms and their surgical management

## Prevalencia de neoplasias pancreáticas y su manejo quirúrgico

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Luis Arturo Chávez-Balanza, \*¶ Karina Sánchez-Reyes \*¶

### Keywords:

neoplasia, pancreas,  
cancer, Whipple,  
prevalence.

### Palabras clave:

neoplasia, páncreas,  
cáncer; Whipple,  
prevalencia.

### ABSTRACT

**Introduction:** pancreatic neoplasms present a prevalence of 10% internationally; however, at the national level, it is unknown. Therefore, it is essential to know which are the most common neoplasms so that an appropriate diagnostic and therapeutic approach can be performed for each particular case. **Objective:** to investigate the prevalence of pancreatic neoplasms and diagnostic and therapeutic strategies in a tertiary-level hospital. **Material and methods:** a retrospective, observational, descriptive, and cross-sectional study of patients diagnosed with pancreatic neoplasia at the Siglo XXI National Medical Center Specialty Hospital. **Results:** from 2016 to 2020, 206 cases of pancreatic neoplasms were identified, and 69 cases were included; the average age was 56 years. Pancreatic adenocarcinoma was the most frequent type, 36%; the most performed surgical procedures were pancreatoduodenectomies. Trans and post-surgical morbidity was 27.5%, local and systemic complications occurred in 22.5 and 27.5%, respectively. **Conclusions:** there is a high prevalence of patients diagnosed with pancreatic neoplasms in our unit, where surgical interventions of high technical complexity are performed; the morbidity reported in this study compares with that reported nationally and internationally.

### RESUMEN

**Introducción:** las neoplasias de páncreas presentan una prevalencia de 10% a nivel internacional, sin embargo, a nivel nacional se desconoce; es indispensable conocer cuáles son las neoplasias más comunes con el fin de realizar un abordaje diagnóstico y terapéutico apropiado para cada caso en particular. **Objetivo:** conocer la prevalencia de las neoplasias de páncreas, abordaje diagnóstico y terapéutico en un hospital de tercer nivel. **Material y métodos:** estudio retrospectivo, observacional, descriptivo y transversal del hospital de especialidades del Centro Médico Nacional Siglo XXI de pacientes con diagnóstico de neoplasia de páncreas. **Resultados:** de 2016 a 2020 se identificaron 206 casos de neoplasias de páncreas, se incluyeron 69 casos, la edad promedio fue de 56 años, el adenocarcinoma de páncreas fue el tipo más frecuente 36%, los procedimientos quirúrgicos más realizados fueron las pancreatoduodenectomías, la morbilidad trans y postquirúrgica fue de 27.5%, las complicaciones locales y sistémicas se presentaron en 22.5 y 27.5%, respectivamente. **Conclusiones:** existe una alta prevalencia de pacientes con diagnóstico de neoplasias de páncreas en nuestra unidad, donde se realizan intervenciones quirúrgicas de alto grado de complejidad técnica, la morbilidad reportada en este estudio se compara con la reportada a nivel nacional e internacional.

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### Abbreviations:

ERCP = endoscopic retrograde cholangiopancreatography.  
MRCP = magnetic resonance cholangiopancreatography.  
COPD = chronic obstructive pulmonary disease.  
CKD = chronic kidney disease.  
MRI = magnetic resonance imaging.  
CT = computerized tomography scan.

### INTRODUCTION

The prevalence of pancreatic neoplasms has increased thanks to the advances in diagnostic methods that have made it possible to identify them promptly; it is essential to know which are the most common neoplasms

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in our environment and thus be able to make an appropriate diagnostic and therapeutic approach for each case. In summary, the most frequent neoplastic pathologies of the pancreas will be discussed.

### Cystic neoplasms

Cystic lesions of the pancreas present as a well-defined lesion with dilatations of the main pancreatic duct or its branches; their incidence increases with age, and they are frequently diagnosed as incidental lesions depending on the imaging method used: 2.6% in CT, 13.5% in MRI and 44.7% in MRCP. In 2008, Laffan et al. reported the incidence of asymptomatic cystic lesions in 2.6% of cases identified by imaging studies, reaching up to 30% in specialized centers.<sup>1</sup> The most common cystic lesions are inflammatory pseudocysts (90%); the other 10% of the total is represented by serous cystadenoma, mucinous cystic neoplasm, mucinous papillary intraductal neoplasm, among others, which are more frequent in young women and represent 1% of pancreatic tumors.<sup>2-4</sup> Serous cystadenoma represents the most frequent cystic neoplasm (30%) of benign behavior; it occurs predominantly in women between the sixth and seventh decade of life, and its most frequent location is in the body and tail of the pancreas (60%). Clinically, most of them are asymptomatic.<sup>5-8</sup> Mucinous papillary intraductal neoplasia most frequently affects males between 60 and 70 years of age, who may present symptoms of chronic or recurrent acute pancreatitis attributable to obstruction of the pancreatic duct by mucin; they are mainly located in the head and uncinate process.<sup>9,10</sup>

### Neuroendocrine tumors

Pancreatic neuroendocrine tumors are a heterogeneous group of neoplasms originating from multipotential epithelial cells in the pancreatic ducts. They account for 1-3% of pancreatic neoplasms, although their prevalence in necropsy studies ranges from 0.5-10%. Of the functioning tumors, the most frequent are insulinomas (70%), followed by gastrinomas (25%).<sup>11,12</sup>

### Malignant neoplasms

The most frequent exocrine neoplasm of the pancreas is ductal adenocarcinoma, which comprises more than 75% of pancreatic cancers. They often are hard, poorly differentiated tumors. There are no screening or early detection tests. However, several studies have been suggested, such as biochemical markers, endoscopic ultrasound, or CT scan from age 40 in those at high risk. Surgical options depend on the location of the tumor and vary from distal pancreatectomies to central pancreatectomies and pancreatoduodenectomies. Due to the complexity of pancreatoduodenectomy and its high morbidity rate, it should be performed by surgeons familiar with hepatopancreatobiliary surgery in high-volume centers, performing more than 20 procedures per year. The accepted mortality is less than 5%, while morbidity is around 40%.<sup>13-16</sup>

Cancers of the ampullary region represent only 0.2% of gastrointestinal tract cancers. The most frequent tumor is adenoma, and its progression to adenocarcinoma is admitted in the same sense as the adenoma-carcinoma sequence of colon polyps. Most ampullary carcinomas are adenocarcinomas, but histology can be variable, including papillary, adenosquamous, mucinous, and adenocarcinoma tumors.<sup>17</sup>

This study aims to know the prevalence as well as the demographic and epidemiological characteristics, the main clinical manifestations, the approach and imaging modalities used for diagnosis, the surgical interventions performed for each type of neoplasm, the local and systemic post-surgical complications, and the follow-up of patients with a diagnosis of pancreatic neoplasms treated in the period from January 01, 2016 to December 31, 2020 at the Hospital de Especialidades del Centro Médico Nacional Siglo XXI.

### MATERIAL AND METHODS

All patients with a diagnosis of pancreatic neoplasia that were hospitalized and operated on at the Gastro Surgery Service of the *Hospital de Especialidades "Dr. Bernardo Sepúlveda"* of the *Centro Médico Nacional Siglo XXI*, during the

period from January 1, 2016, to December 31, 2020, were included. Electronic and physical records were reviewed to obtain the patients' clinical and epidemiological characteristics, including age, gender, clinical manifestations, diagnostic method, histology, intervention, and complications. Inclusion criteria were established as male and female patients over 18 years of age treated in the unit. The exclusion criteria were under 18 years of age, not having undergone surgery in the unit, not having a histopathological report, and lost to follow-up. A descriptive and inferential statistical analysis was performed. For quantitative variables, the Kolmogorov-Smirnov normality test was applied. For qualitative variables, frequencies and maximum and minimum percentages were used; in the bivariate analysis, the t-Student test and Mann-Whitney U test were used.

The authors declare that this article complies with the policies and standards of our institutional ethics committee. It does not present personal information or patient identification.

## RESULTS

In the mentioned period, a total of 204 cases with a diagnosis of pancreatic neoplasia were obtained, of which only 69 met the inclusion criteria; in the rest of the cases, pancreatic pathology was ruled out; they were operated on in another unit or did not undergo surgical management. The mean age of the patients was  $56 \pm 17$  years, with an age range of 18 to 87 years, being more prevalent the diagnosis in the female gender with 60 (41) and 40% (28) for the male gender. About the family history of pancreatic neoplasia, this was found in only 7% (5) of the cases. The comorbidities present at the time of diagnosis of pancreatic neoplasia were diabetes mellitus as the main one in 28% (20) of the patients, followed by systemic arterial hypertension in 26% (18); concerning breast cancer, heart disease, and liver cirrhosis constituted 5% (4) each, and in the case of COPD and CKD 2% (2). About the clinical manifestations present, abdominal pain was found as the main symptom in 73% (51), jaundice 57% (40), nausea 43% (30), weight loss 40% (28), vomiting 24% (17), cholangitis 18%

(13), hypoglycemia 15% (11); oral intolerance was the least frequent symptom 14% (10).

The histopathological types reported were: ampuloma in 24 patients (35%), adenocarcinoma in 21 patients (30%), cystic neoplasms in 13 patients (19%), insulinoma in 6 patients (9%), and nesidioblastosis in 5 patients (7%). The mean in-hospital stay from diagnosis to discharge was  $21 \pm 13$  days ([Table 1](#)).

The imaging modalities used during the diagnostic approach in the preoperative period were abdominal CT scan in 100% (69) of the cases, endoscopic ultrasound in 79% (54), abdominal ultrasound in 72% (46), nuclear magnetic resonance in 34% (23) and ERCP in 32%. In the review of each imaging modality used according to each subtype of neoplasm, it was found that abdominal CT scan and endoscopic ultrasound were the most used modalities in adenocarcinomas (100 and 90% respectively), in ampulomas (80 and 71%), cystic neoplasms (92 and 77%), insulinoma (57 and 57%) and in nesidioblastosis (80 and 100%), with ERCP being the least used modality in general. The anatomical location where the tumors were found in the study group was distributed as follows: head of the pancreas and ampulla of Vater 36% (25) followed by the uncinate process 15% (11), neck 5% (4), tail of the pancreas 4% (3), and pancreatic body 1% (1).

Regarding tumor size, the patients were grouped into five groups for analysis, with a range of 1 to 100 mm, and were defined as follows: the first group with a size of 10-20 mm corresponding to 46% (32) of the cases, being the most frequent; the second group, had tumors larger than 41 mm 24% (17), the third group of 21-30 mm and the fourth of 31-40 mm corresponded to 13% (9), and the fifth group with a tumor size of 1-9 mm occupying 2% (2) of the total number of cases. The most frequently performed surgical procedure was pancreatoduodenectomy without pylorus preservation and open pylorus preservation in 22 (32%) and 8 (12%) cases, as shown in [Figure 1](#). [Figure 2](#) describes the procedure according to the underlying pathology.

Trans operative complications were 39%, with hypovolemic shock the most frequent at 35% (grade 1: 8%, grade 2: 23%, grade 3:

**Table 1: Demographic characteristics. N = 69.**

	n (%)
Age, (years)*	56 ± 17
Sex	
• Female	41 (60)
• Male	58 (40)
Family history of pancreatic neoplasia	5 (7)
Comorbidities	
• T2D	20 (28)
• HBP	18 (26)
• Breast cancer	4 (5)
• Heart disease	4 (5)
• Liver cirrhosis	4 (5)
• COPD	2 (2)
• ERC	2 (2)
Clinical manifestations	
• Abdominal pain	51 (73)
• Jaundice	40 (57)
• Weight loss	28 (40)
• Cholangitis	13 (18)
• Nausea	30 (43)
• Vomiting	17 (24)
• Hypoglycemia	11 (15)
• Intolerance to the oral route	10 (14)
Histopathological diagnosis	
• Ampuloma	24 (35)
• Adenocarcinoma	21 (30)
• Cystic neoplasms	13 (19)
• Insulinoma	6 (9)
• Nesidioblastosis	5 (7)
Days of in-hospital stay*	21 ± 13

\* Values presented as mean ± standard deviation.  
T2D = type 2 diabetes. COPD = chronic obstructive pulmonary disease. CKD = chronic kidney disease.  
HBP = high blood pressure.

1%, and grade 4: 1%); cardiogenic shock at 3% and vascular disruption in 1%. Regarding local complications, they were pancreatic fistulas (20%), surgical site infection (19%), and surgical wound dehiscence (9%), occurring mainly in patients diagnosed with ampuloma or adenocarcinoma who underwent open pancreatoduodenectomy, as shown in [Table 2](#).

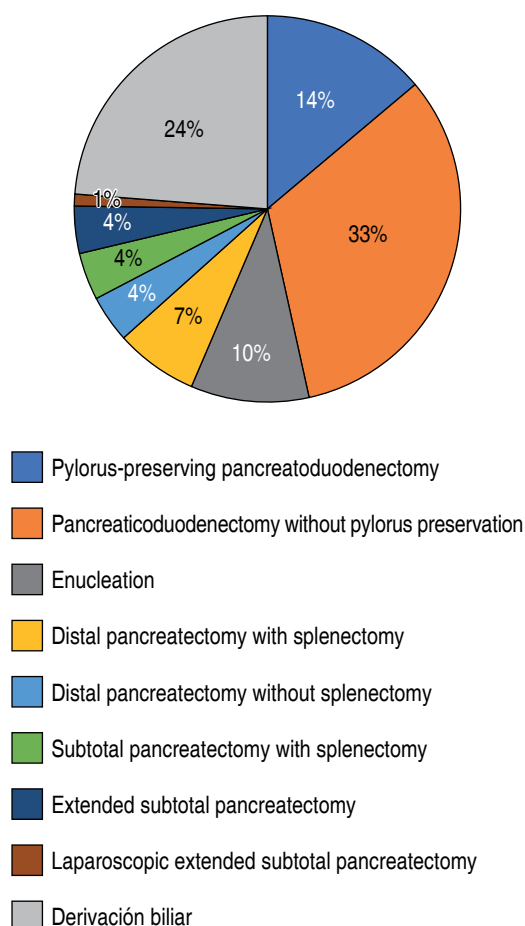
## DISCUSSION

Pancreatic neoplasms are very diverse and involve both benign and malignant diseases, manifesting themselves clinically in a similar way and almost always late, which increases the complexity of medical-surgical management, with a high percentage of morbidity and mortality in the case of malignant neoplasms. This percentage has been improved thanks to advances in diagnostic imaging modalities, with which they are often detected incidentally and, in other cases, allow planning of the appropriate surgical management according to the type and location of the tumor at the pancreatic level.

The surgical techniques used for the resection of pancreatic tumors are twofold: one consisting of tumor enucleation indicated only for small benign pancreatic tumors that do not affect any adjacent structure or the pancreatic duct, and the other in which extensive pancreatic resections such as cephalic, total, or distal duodenopancreatectomy are performed.

Pancreatic resection is a surgery with a mortality rate in most hospitals with a certain degree of experience that does not exceed 6%. However, postoperative morbidity continues to be high, being reported up to 50-60%, among them the medical and surgical complications common to any postoperative major abdominal surgery (Clavien-Dindo classification), others belonging to a specific group concerning these procedures, such as pancreatic fistula, hemorrhage and delayed gastric emptying as defined by the group of experts of the "International Study Group of Pancreatic Surgery" (ISGPS), which is why many authors recommend performing such management in high volume centers to reduce postoperative morbidity. Comparing with the results published in a German study on mortality in patients undergoing pancreatic resections performed in hospitals with low and high surgical volume, they report 11.8 vs. 8.6% mortality, respectively, which shows a significant decrease in mortality in specialized centers where at least 5 pancreatic procedures are performed per year.<sup>18,19</sup>

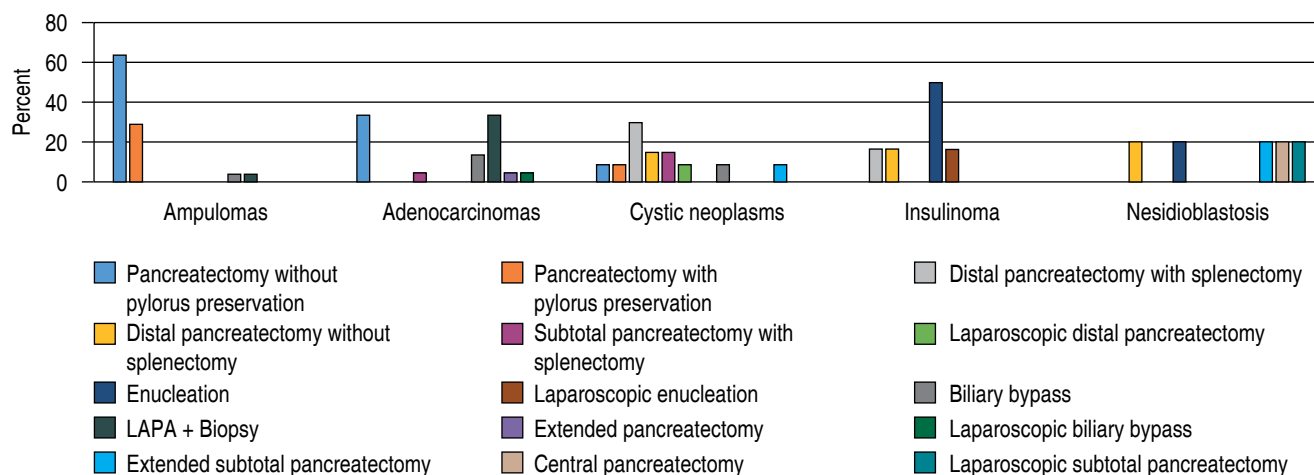
At present, in our country, there are no national statistical reports on the prevalence of this diagnosis; there are only reports from reference centers such as the *Hospital de*



**Figure 1:** Surgical procedures performed at the Hospital de Especialidades del Centro Médico Nacional Siglo XXI.

*Oncología del Centro Médico Nacional Siglo XXI and the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, where several pancreatic resections are performed, reporting morbidity and mortality rates similar to those registered in specialized centers at the international level, which are 5% and between 20-40% respectively, are associated to the high degree of surgical technical complexity since it involves partial or total resections of one or more organs, vascular dissection and complex digestive anastomosis.*

In our study, 69 cases of pancreatic neoplasms were reported, ampulomas and adenocarcinomas of the pancreatic head the most frequent, unlike the international literature, where only pancreatic adenocarcinoma is mentioned as the most frequent histology, being therefore open pancreatoduodenectomies the most frequent surgical interventions performed as surgical management, which represent a high degree of complexity with high morbimortality. In our unit a total post-surgical morbidity rate of 39% was reported, being pancreatic fistula (20% of the cases) the most frequent at the local level and at systemic level with 21% of the cases, surgical site infection, pneumonia associated to health care and urinary infections the most frequent, same complications reported at international level by high volume centers, with which it is identified that in our unit we have a morbidity rate below the range reported at national and international level.<sup>20</sup>



**Figure 2:** Surgical procedures performed based on the type of pancreatic neoplasm.

Table 2: Transoperative and postoperative local complications related to the procedure.

	Total n (%)	Trans QX n (%)	Anastomotic n (%)	Intestinal n (%)	Bleeding n (%)	Sepsis n (%)	Pancreatic fistula n (%)	Other n (%)
Palliative	15 (22)	3 (4)		1 (1)				3 (4)
Central pancreatectomy/ enucleation	5 (7)	2 (2)				1 (1)	1 (1)	
Laparoscopic approach	4 (6)							1 (1)
Distal subtotal pancreatectomy + splenectomy	11 (16)	4 (5)					1 (1)	
Distal subtotal pancreatectomy without splenectomy	4 (6)							
Open pancreatoduodenectomy	30 (43)	17 (24)	16 (23)	1 (1)	2 (2)	1 (1)	12 (17)	5 (7)

As mentioned, a higher incidence of ampuloma and adenocarcinoma was found in the female sex, which differs from the international literature; a recent study reported an increased incidence of pancreatic cancer, especially in younger women; however, this has not been externally validated. Accordingly, the exact cause of the trend among younger women is unclear. It may be due to disproportionate gender exposure or response to known or yet-to-be-explored risk factors, such as increased body mass index (BMI), which favors a pro-inflammatory state.<sup>21</sup>

In our hospital center, minimally invasive surgical techniques have increased to reduce operative time and post-surgical complications, including pain control, reduction of bleeding, and lower incidence of pancreatic fistula. The aim is to reduce morbidity and improve patient's quality of life in our hospital, which is considered a high-volume center for complex pancreatic resections.

## CONCLUSIONS

Pancreatic neoplasms can be both solid and cystic; other studies have reported that the most frequent neoplasms are of the solid type; however, a difference to what has already been published is that in our population, ampuloma was more prevalent, followed by adenocarcinoma (35% and 30% respectively), these findings justify the presence of abdominal pain as the main

symptom (73%). Women were more affected. It would be useful in a later study to evaluate the use of tobacco and alcohol as well as BMI to identify if the increase in BMI is more frequent in women as well as any drug addiction that could justify the increase of this type of lesions in the female gender, unlike what has been published, which indicates that the main gender affected by these neoplasms are men. Contrast computed tomography and magnetic resonance imaging help diagnose any of these lesions.

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# Idiopathic giant pancreatic pseudocyst

## *Pseudoquiste pancreático gigante idiopático*

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Mauricio Javier Valerdi-Cadena, <sup>\*,§</sup> Fernando Caballero-Castro <sup>\*,§</sup>

### Keywords:

pancreas, pancreatic  
pseudocyst,  
pancreatitis,  
neoplasms,  
laparoscopy.

### Palabras clave:

páncreas,  
pseudoquiste  
pancreático,  
pancreatitis,  
neoplasias,  
laparoscopia.

### ABSTRACT

Pancreatic cystic lesions are classified into inflammatory pancreatic fluid collections, true cysts, and cystic pancreatic neoplasms. Their characterization is crucial to determining the therapeutic approach. Pancreatic pseudocyst is a frequent complication of pancreatitis and requires a comprehensive evaluation to determine its origin. We present the case of a female patient with a previous diagnosis of pancreatic pseudocyst with no history of pancreatitis. She had an epigastric tumor, and imaging studies were compatible with this pathology. The pancreas was visible with two ovoid lesions, well-defined lobulated borders, and tumor markers in normal ranges. Laparoscopic cystogastroanastomosis was performed. Idiopathic giant pancreatic pseudocyst is a poorly documented complication. We ruled out true cysts and cystic pancreatic neoplasms in this case before definitive treatment.

### RESUMEN

Las lesiones quísticas pancreáticas se clasifican en colecciones inflamatorias de líquido pancreático, quistes verdaderos y neoplasias pancreáticas quísticas. Su caracterización es crucial para determinar el abordaje. El pseudoquiste pancreático es una complicación frecuente de pancreatitis y requiere de una evaluación integral que determine su origen. Se trata de paciente femenino con diagnóstico previo de pseudoquiste pancreático sin antecedente de pancreatitis. Presenta tumor epigástrico y estudios de imagen compatibles con dicha patología. Páncreas con dos lesiones ovoideas de bordes lobulados bien definidos, marcadores tumorales en rangos normales. Se realiza cistogastroanastomosis laparoscópica. El pseudoquiste pancreático gigante idiopático es una complicación poco documentada. En este caso descartamos quistes verdaderos y neoplasias pancreáticas quísticas previo a tratamiento definitivo.

## INTRODUCTION

Pancreatic cystic lesions can be pathologically classified into inflammatory pancreatic fluid collections, non-neoplastic pancreatic cysts, and neoplasms. Accurate characterization of the pancreatic cystic lesion is crucial because it determines the approach strategy. Acute inflammatory pancreatic lesions represent a frequent local complication of pancreatitis.<sup>1</sup>

A pancreatic pseudocyst (PP) is a collection of encapsulated fluid formed by digestive enzymes, pancreatic juice, and hematic content. The pseudocyst may be surrounded by a non-epithelialized wall formed by granulation tissue and fibrosis in the pancreatic tissue; 90% of it

is usually unique. It is mainly a complication of pancreatitis or pancreatic trauma and is rarely idiopathic. The size of a PP varies from small (< 2 cm), medium (2-6 cm), and large (> 6 cm) size, and a PP with a diameter ≥ 10 cm is called giant.<sup>2-4</sup>

The incidence of PP is reported to be one per 100,000 adults per year, with a prevalence of 6-18.5%. In 20-40% of cases, it occurs after chronic pancreatitis; in 70-78%, it is associated with acute alcoholic pancreatitis; in 6-16% with chronic idiopathic pancreatitis; and 6-8% with chronic pancreatitis of biliary origin.<sup>4-7</sup>

Multiple complications have been described with PP, such as rupture in the peritoneal cavity, infection, hemorrhage, fistula with a nearby

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organ, and compression of the biliary tract or adjacent organs.<sup>8,9</sup>

Diagnosing PP requires a comprehensive evaluation, with direct questioning, physical examination, imaging studies, and laboratory tests to determine the origin of the PP. Biochemical parameters are of limited value because they are nonspecific, and most patients have elevated amylase and lipase concentrations. On the other hand, common symptoms are usually pain and a feeling of fullness or early satiety, indicating the need for surgical treatment because of its direct proportional relationship with the dimensions of the PP and the compression exerted on adjacent organs.<sup>4,5</sup>

Most PPs do not require drainage; however, surgery is currently the best alternative for PPs with a diameter > 6 cm, who do not show changes in their dimensions for more than eight weeks, or in whom there is complication or persistence of symptoms. The procedures include percutaneous drainage, cystogastroanastomosis, cystojejunostomy, and open or laparoscopic pancreatectomies. Cystogastroanastomosis provides continuous drainage of the PP into the gastric cavity, which avoids compression of adjacent structures and possible complications.<sup>4</sup>

Few cases of idiopathic giant pancreatic pseudocysts (IGPP) have been reported in the literature; even with radiological imaging, the diagnostic approach is challenging due to the absence of a history of pancreatitis, pancreatic disease or trauma, specific signs or symptoms.<sup>2,10</sup>

This paper aims to describe the case of a woman with a giant pancreatic pseudocyst without evidence of pancreatitis or pancreatic trauma, its diagnostic approach, and subsequent evolution after surgical treatment.

## PRESENTATION OF THE CASE

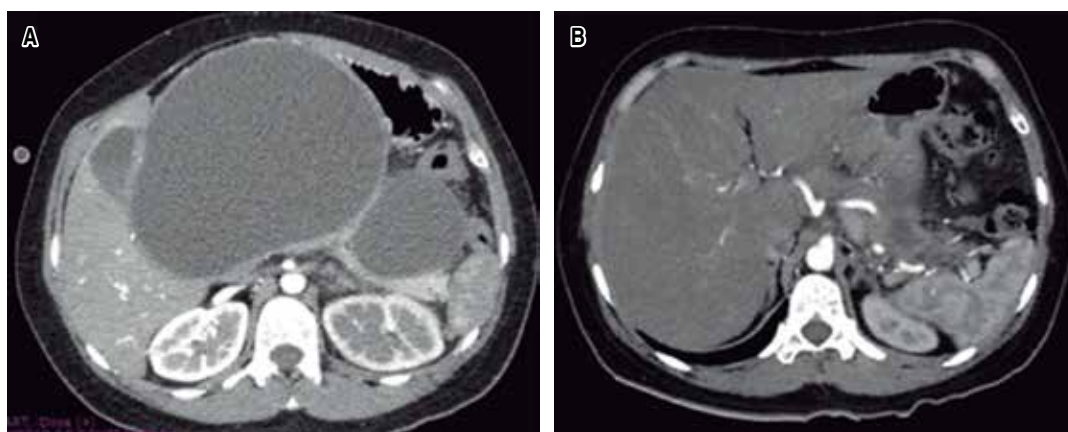
We present the case of a female patient, 40 years old, native and resident of Mexico City, with no chronic degenerative history, with a surgical history of cesarean section in 2020 due to dystocia and bilateral tubal obliteration in the same surgical time without complications. Alcohol consumption, smoking, and illicit drug

addictions were denied. She denied a history of pancreatitis, biliary colic, or abdominal trauma. Her current condition began six months ago when she noticed a palpable tumor covering the epigastrium and mesogastrium, which progressively increased in volume, adding postprandial fullness, hyporexia, and unintentional weight loss of 10 kg, so she started a study protocol. Imaging studies revealed pancreatic pseudocyst. Subsequently, the patient was admitted to the Emergency Department with symptoms characterized by colicky pain in the epigastric region, with a VAS (visual analog scale) 10/10, and irradiation to the right scapular region, without extenuating or aggravating factors, accompanied by nausea and vomiting of gastrobiliary contents on eight occasions. The patient was seen on physical examination with a nasogastric tube connected to derivation and gastrobiliary output. The abdomen was distended at the expense of abdominal mass in the epigastric region that was denoted indurated, non-fluctuant, measuring 18 × 15 cm in its longitudinal and transverse axes, normal peristalsis, without data of peritoneal irritation, with no other alteration to report (*Figure 1*).

Laboratory studies on admission with a white blood cell count of 10.35 K/ $\mu$ l, neutrophils 9.34 K/ $\mu$ l, lymphocytes 0.65 K/ $\mu$ l, hemoglobin



**Figure 1:** An epigastric, indurated, non-fluctuant tumor measuring 18 × 15 cm in its longitudinal and transverse axes.



**Figure 2:** Abdominal CT scan with intravenous contrast showing the pancreas enlarged by head and body-dependent ovoid lesions, measuring  $229 \times 137 \times 182$  mm with an approximate volume of  $2.899 \text{ cm}^3$ , and a second lesion measuring  $100 \times 57 \times 82$  mm with an approximate volume of  $238 \text{ cm}^3$ . **A)** Cross section at its largest diameter. **B)** Postoperative abdominal tomography (one month).

9.5 g/dl, hematocrit 33.2%, platelets  $474 \text{ K}/\mu\text{l}$ , glucose 147 mg/dl, creatinine 0.51 mg/dl, urea 29.9 mg/dl, amylase 309 U/l, total cholesterol 143.7 mg/dl, triglycerides 110.4 mg/dl, very-low-density lipoprotein (VLDL) cholesterol 22.08 mg/dl, high-density lipoprotein (HDL) cholesterol 43 mg/dl, low-density lipoprotein (LDL) cholesterol 78.62 mg/dl, and serum electrolytes in normal ranges.

An abdominal CT scan with intravenous contrast was performed with a report of an enlarged pancreas with ovoid lesions on the head and body, measuring  $229 \times 137 \times 182$  mm with an approximate volume of  $2,899 \text{ cm}^3$  and a second lesion measuring  $100 \times 57 \times 82$  mm with an approximate volume of  $238 \text{ cm}^3$ , with homogeneous density, thin walls, compatible with cystic lesions. The gallbladder measured  $80 \times 43 \times 35$  mm and had a thin wall with heterogeneous content due to a liquid-liquid level of biliary sediment (*Figure 2*).

A magnetic resonance cholangiography was performed during her hospitalization. As a preoperative diagnostic approach, the following was found: a non-dilated intrahepatic biliary tract, a choledochal duct measuring 5.9 mm, a gallbladder of usual size with heterogeneous content due to the presence of multiple polyhedral images concerning biliary stones, and an extrahepatic tract displaced laterally by a lesion compatible with pancreatic pseudocysts.

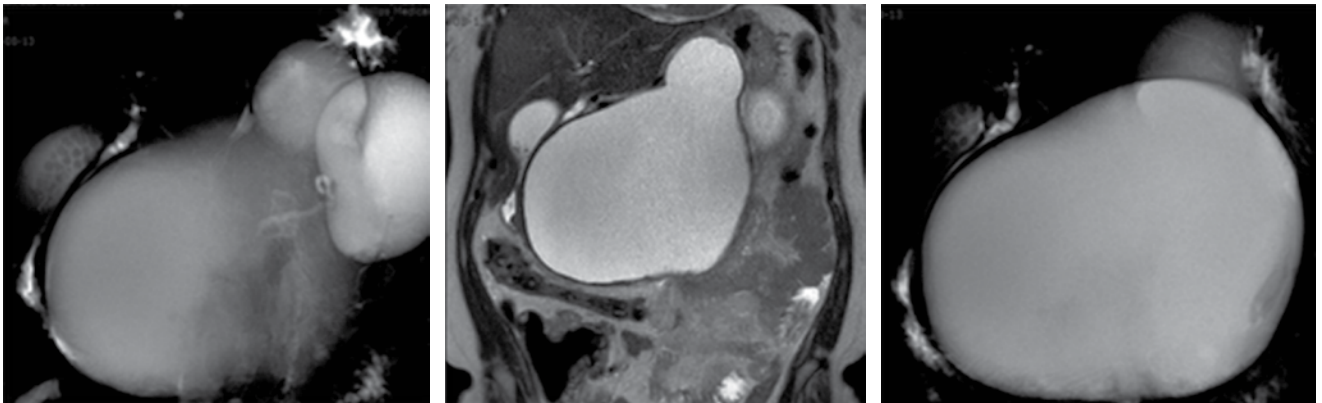
The pancreas had an altered morphology at the expense of two ovoid lesions, with well-defined lobulated borders, homogeneous hyperintense content in the T2 sequence, and a volume effect conditioning the opening of the duodenal arcade with lateral displacement of the stomach, limiting gastric distension. The largest lesion measured  $178 \times 179 \times 155$  mm with an approximate volume of  $2,089 \text{ cm}^3$ , and the smallest lesion measured  $56 \times 76 \times 95$  mm in its principal axes with an approximate volume of  $213 \text{ cm}^3$ . Before the surgical procedure, serum tumor markers showed an alpha-fetoprotein (AFP) 0.79 ng/mL, CEA 1.16 ng/mL, human chorionic gonadotropin (HCG)  $< 0.10 \text{ mIU/ml}$ , CA-125 17.37 U/ml, CA15-3 16.2 U/ml and CA19-9 8.25 U/ml (*Figure 3*).

After informed consent, a laparoscopy was performed. The stomach was bulging and displaced by a retro gastric tumor (pseudocyst) of approximately  $200 \times 180 \times 170$  mm and a Parkland 2 gallbladder; macroscopically, the liver was normal, and the rest showed no alterations. We proceeded to perform cystogastroanastomosis with an endo GIA stapler, obtaining abundant liquid with a rusty appearance. The aspirated liquid from the pancreatic pseudocyst was approximately  $2,000 \text{ cm}^3$ . The pseudocyst cavity was checked, and scarce necrotic tissue was found; blunt debridement of necrotic tissue was performed

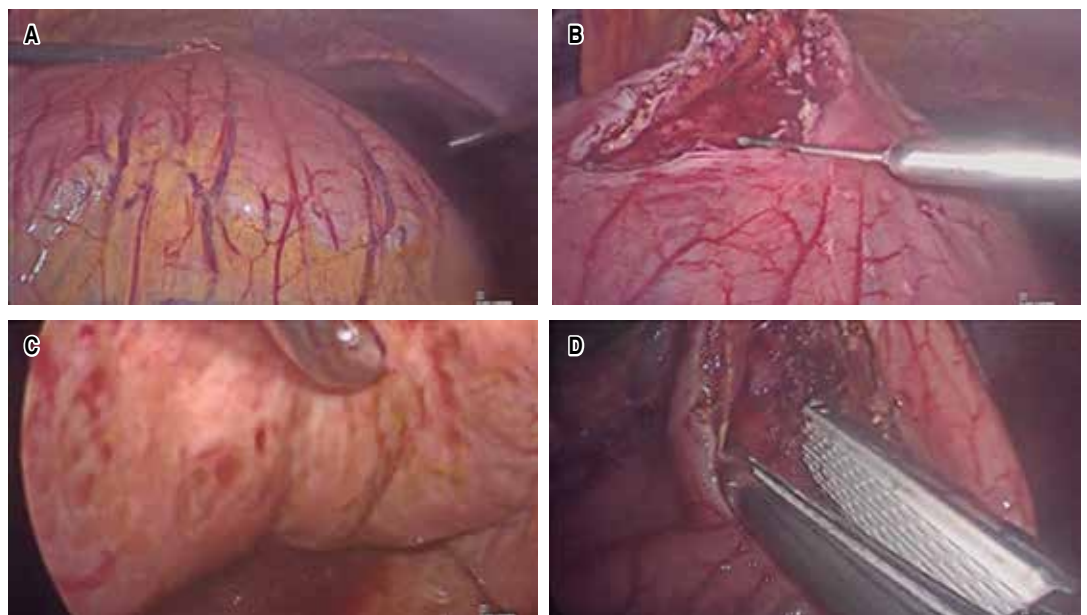


with gauze, the liquid was drained from the small pseudocyst, and approximately 200 cm<sup>3</sup> of liquid was obtained. An anterior gastrostomy was closed in two planes, and leaks were verified. Subsequently, laparoscopic cholecystectomy was performed conventionally; Penrose-type drains were placed towards the vesicular bed and proximal to the gastrostomy (Figure 4).

The cystic wall was sent to pathology, as well as the pseudocyst fluid to cytochemistry, obtaining amylase 2,261 IU/ml, albumin 2.6 mg/dl, glucose 49.6 mg/dl, creatinine 0.51 mg/dl, blood urea nitrogen (BUN) 13.6 mg/dl, urea 29.1 mg/dl, lactate dehydrogenase (LDH) 587 mg/dl, CEA 3.27 ng/ml, CA-125 4.67 U/ml, CA-19.9 631.9 U/ml, CA-15.3



**Figure 3:** Cholangiorresonance with a report of the pancreas with altered morphology due to two ovoid lesions, with well-defined lobulated borders, with volume effect that conditions opening of the duodenal arcade and lateral displacement of the stomach conditioning limitation to gastric distension.



**Figure 4:** Cystogastroanastomosis. **A)** Panoramic view of pancreatic pseudocyst through the stomach. **B)** Anterior gastrostomy with an ultrasonic scalpel and drainage of the major cyst. **C)** Gastrostomy of the posterior gastric wall. **D)** Cystogastroanastomosis with Endo GIA linear endoscopic linear stapler.



12.86 U/ml. Culture showed no bacterial growth, the cytology study was negative for neoplastic cells, and the pathology analysis was compatible with a histology characteristic of pancreatic pseudocyst.

Due to successful postoperative evolution, the patient was discharged eight days after the surgical procedure. Drains were removed, and she tolerated the oral route without pain; the bowel movements and uresis were normal. A control CT scan was performed one month after surgery, which reported post-surgical changes and a residual collection of 5 cm<sup>3</sup>, and the rest without alterations.

## DISCUSSION

The clinical case presented describes a type of giant bilobed PP without evidence of pancreatitis or pancreatic trauma. PPs are the most common pancreatic cystic lesions (75%) and should be differentiated from true cysts and cystic pancreatic neoplasms. Most acute PPs resolve spontaneously within 4-6 weeks; those that persist may require drainage or percutaneous endoscopic or surgical resection if they increase in size, are symptomatic, or have complications.<sup>2,11,12</sup>

PPs are commonly associated with a history of pancreatitis; in this case, the patient did not report a history of pancreatitis, biliary colic, or abdominal trauma. To achieve an adequate diagnostic approach, we used imaging tests that reported imaging characteristics of pancreatic pseudocyst and serum laboratory parameters that did not report amylase elevation or suggest an obstructive biliary pattern.

Giant PP, in the absence of evidence of acute pancreatitis or trauma, is a poorly documented complication; being rare, we consider a diagnostic approach in search of other types of pancreatic collections, ruling out true cysts and cystic pancreatic neoplasms. Cystic fluid amylase is usually elevated in PPs, serous cystadenomas, and mucinous neoplasms. On the other hand, a low amylase in cyst fluid (< 250 IU/L) reports a sensitivity of 98% to exclude a PP. Carcinoembryonic antigen (CEA) is low in pseudocysts and elevated (> 400 ng/mL) in cystadenomas; this elevation has a sensitivity of 65% for

mucinous neoplasms (mucinous cystadenoma and intraductal papillary mucinous neoplasm) from non-mucinous neoplasms; however, CEA is not helpful to differentiate malignant from benign true pancreatic cysts. In our patient, cytology of the cyst fluid showed no cellular malignancy, and cystic fluid amylase was elevated (> 2,000 IU/L), confirming the pseudocyst diagnosis.<sup>13</sup>

In the context of its treatment, cystogastroanastomosis is a technique that offers minimal modification of the digestive tract anatomy and lower morbidity, and mortality compared to pancreatic resection.

## CONCLUSIONS

Giant idiopathic PP is a poorly documented complication. In this case, we ruled out true cysts and cystic pancreatic neoplasms before definitive treatment.

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# Type IVA common bile duct cyst based on Todani classification

## Quiste de colédoco tipo IVA basado en la clasificación de Todani

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### Keywords:

common bile duct cyst, Todani classification, cholangioresonance, Roux-en-Y biliary reconstruction.

### Palabras clave:

quiste de colédoco, clasificación de Todani, colangiorresonancia, reconstrucción biliar en Y de Roux.

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### ABSTRACT

Cystic dilations of the common bile duct are a rare congenital anomaly that allows bile reflux, causing dilatation of the bile ducts in various forms. In the last five years (2018-2022), the general surgery service of the Civil Hospital of Guadalajara "Fray Antonio Alcalde" attended a total of 5,886 patients, among which only two cases of choledochal cyst (premalignant lesions) were found, with an incidence rate of 0.03%, presenting a low frequency of this pathology in our region compared to western nations and an even lower incidence concerning the Asian population. We present the case of a 36-year-old female patient from the state of Hidalgo with a biliary cystic lesion staged as IVA, according to the modified Todani classification, with a magnetic cholangioresonance study. After a complete preoperative evaluation, the cystic lesion was resected, and the biliary tract was reconstructed with jejunal and Roux loops; she evolved satisfactorily and was discharged on the eighth postoperative day. She was seen in the outpatient clinic with hepatic functional tests and a new magnetic cholangioresonance reported as normal and with good biliary drainage.

### RESUMEN

Las dilataciones quísticas del colédoco son una anomalía congénita infrecuente que permite el reflujo de bilis, ocasionando la dilatación de las vías biliares en diversas formas. En los últimos cinco años (2018-2022) el servicio de cirugía general del Hospital Civil de Guadalajara "Fray Antonio Alcalde" atendió un total de 5,886 pacientes entre los cuales se encontraron sólo dos casos de quiste de colédoco (lesiones premalignas), con una tasa de incidencia de 0.03%, presentando una baja frecuencia de esta patología en nuestra región en comparación con naciones occidentales y una incidencia aún más baja en relación a la población asiática. Se presenta el caso de una femenina de 36 años derivada del estado de hidalgo con una lesión quística biliar, la cual se estadificó como IVA, de acuerdo con la clasificación modificada de Todani, con estudio de colangiorresonancia magnética. Previa valoración completa preoperatoria se resecó la lesión quística y se reconstruyó la vía biliar con asas de yeyuno en Y de Roux; evolucionando de forma satisfactoria y siendo dada de alta al octavo día postoperatorio, vista en consulta externa con pruebas funcionales hepáticas y nueva colangiorresonancia magnética cuyo reporte resultó completamente normal y con buen drenaje biliar.

### INTRODUCTION

The first description of cystic dilatation of the biliary tree was attributed to Vater in 1720. Subsequently, several reports have referred to cases of patients with the triad of jaundice, pain,

and abdominal mass suggestive of cystic lesions of the biliary tract.<sup>1</sup>

Choledochal cysts have an incidence in Western countries of 1:13,500 and in Asian populations of 1:1,000, with type IV being the most frequent in adults.<sup>2</sup> In addition, it is

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suggested that the prevalence in both Western and Eastern women is 4:1.<sup>1</sup>

According to the literature, the most accepted theory regarding etiology is the presence of an anomalous pancreaticobiliary junction that allows reflux and a consequent increase in pressure that causes dilatation, inflammation due to activation of pancreatic enzymes, biliary cholestasis, and epithelial damage.<sup>3</sup>

Clinical manifestations vary between adults and infants, and although most cases of common bile duct cysts are diagnosed during

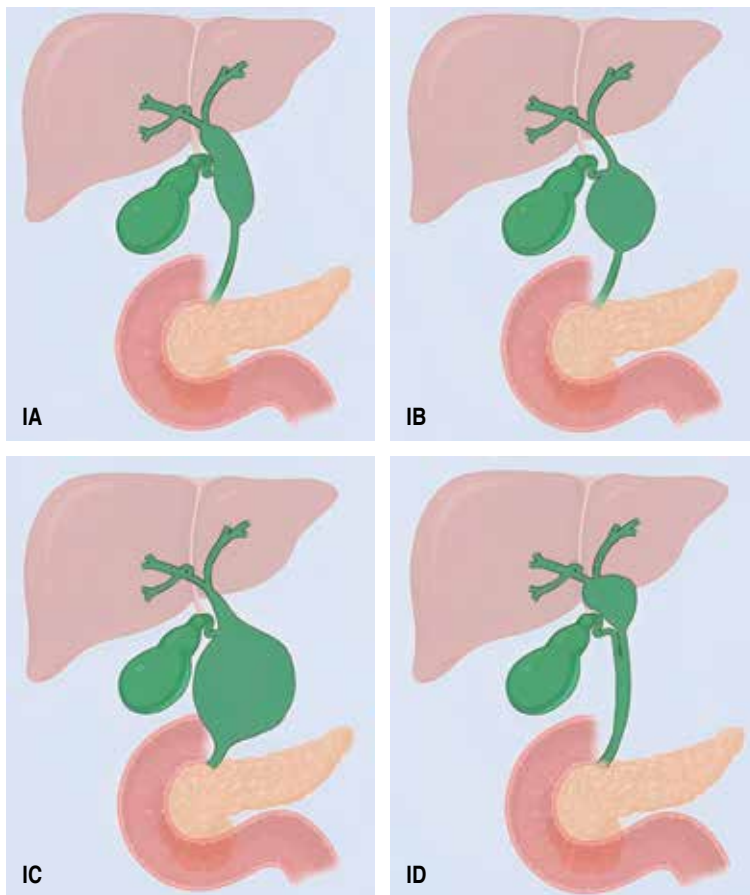
childhood, 25% are discovered in adulthood. Abdominal pain, palpable abdominal mass, and jaundice, also known as the classic triad of common bile duct cysts, are found in only 20% of cases. Adults often present with nonspecific symptomatology, such as right upper quadrant abdominal pain, jaundice, nausea, vomiting, and fever.<sup>4</sup>

Diagnosis is based on studies, including blood cytology, electrolytes, liver function tests, International Normalized Ratio (INR), and tumor markers. In addition, abdominal ultrasound (USG) allows visualization of hepatic and pancreatic structures. However, endoscopic retrograde cholangiopancreatography (ERCP) and magnetic cholangioresonance (M-CR) have become the gold standard for proper diagnosis and classification.<sup>5,6</sup>

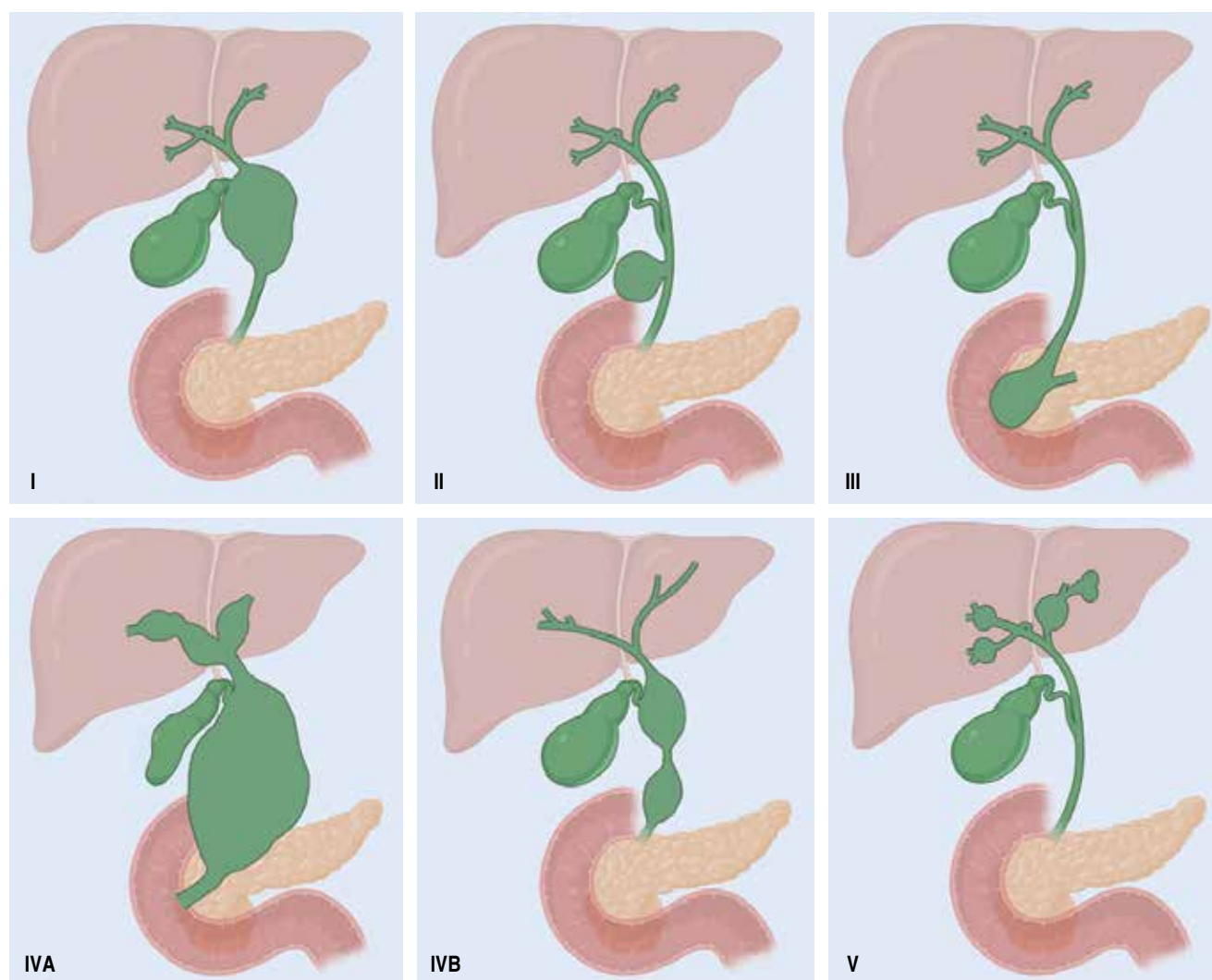
In 1959, Alonso-LEJ and collaborators attributed the term common bile duct cyst. They classified them into three types, among which the following stand out: congenital cystic dilations, congenital diverticulum of the common hepatic (CH) duct, and congenital choledochocoele.<sup>5</sup>

Later, in 1977, Todani and associates added two more types and several subtypes to the classification, being updated by the same authors in 1997 and 2003.<sup>7,8</sup> The most recent Todani classification subdivides type I being the most frequent (> 90%); variation IA involves dilatation of the entire extrahepatic bile duct, unlike type IB which includes dilatation of a segment of the common bile duct below the cystic implantation and type IC comprises a fusiform or cylindrical dilatation of the entire extrahepatic common bile duct.<sup>7,8</sup> Finally, subtype ID was proposed and added to the Todani classification modified in 2008 by Calvo-Ponce and colleagues, which is a segmental dilatation above the cystic and bifurcation of the hepatic ducts (Figure 1).<sup>9</sup>

In type II, there are diverticula throughout the extrahepatic duct. Type III is a choledochocoele, and type IVA has the presence of multiple cysts in the intrahepatic and extrahepatic bile duct. In type IVB, multiple cystic dilations of the extrahepatic bile duct are present. Type V (Caroli's disease) involves dilatation of one



**Figure 1:** Subclassifications of modified Todani type I common bile duct cyst. Subclassifications of type I choledochal cyst: (IA) cystic dilatation involves the entire extrahepatic biliary system, (IB) involves only a portion of the extrahepatic bile duct, (IC) spindle-shaped expansion of the whole of extrahepatic bile ducts, along with widening of the intrahepatic ducts, (ID) extrahepatic fusiform dilatation at the biliary confluence, with a non-dilated intrahepatic biliary tree and no pancreatobiliary malunion.<sup>2</sup>



**Figure 2:** Modified Todani classification: (I) subclassified in four ways mentioned in Figure 1, (II) corresponds to a diverticular sac in the common bile duct, (III) also called choledochocoele, consisting of an intramural dilatation of the distal segment of the common bile duct, (IVA) consists of dilatation of the bile ducts both inside and outside the liver, (IVB) exclusively extrahepatic bile ducts show expansion at different points, (V) existence of single or multiple dilatations that are limited to the bile ducts within the liver, also called Caroli's disease.<sup>2</sup>

or several segments of the intrahepatic ducts (Figure 2).<sup>5,10</sup>

In 2004, Visser and associates proposed a modification and distinguished the following designations: common bile duct cyst, diverticulum, and Caroli's disease.

In 2011, Michaelides and collaborators reported and proposed a new variant called type ID; in this new variant, in addition to the dilatation of the HC, there is a dilatation of

the central portion of the cystic duct, giving a bicornuate configuration to the cyst.<sup>2</sup>

The treatment of choice is surgical resection, avoiding drainage of the cyst or incomplete resection, especially of the mucosa of the affected segment of the bile duct to prevent dysplasia and postoperative malignant degeneration,<sup>11</sup> since common bile duct cysts are precancerous lesions with a malignancy rate that ranges from 2.5 to 28%, increasing with age.<sup>2</sup>



## PRESENTATION OF THE CASE

A 36-year-old woman, originally from the state of Hidalgo, Mexico, underwent surgery at the general surgery service of the Hospital Civil de Guadalajara “Fray Antonio Alcalde” (HCGFAA) in Jalisco, Mexico, on November 28, 2022, due to the presence of a common bile duct cyst type IVA according to the modified Todani classification (QC-IVA-Todani-modified). She had an evolution of two months characterized by epigastric abdominal pain, early satiety, and anorexia without nausea, vomiting, fever, or jaundice.

In her home, a hepatic and biliary tract ultrasound (HBVUS) was performed to

interpret the presence of a hepatic cyst. Later, an M-RC was performed in Pachuca, Hidalgo, which confirmed the general surgeon’s diagnosis of a common bile duct cyst. Due to a lack of resources, the surgeon referred her to the HCGFAA. Laboratory tests were performed (Table 1), and a new CR-M was performed (Figures 3 and 4), which showed a modified QC-IVA-Todani cyst (Figure 2).

Findings: an atrophic gallbladder without the presence of gallstones, a 7.6 mm cyst in the cystic duct, saccular dilatation of the intrahepatic and extrahepatic bile duct with a diameter of 18 mm in the right hepatic, 15 mm in the left hepatic duct and a confluence

Table 1: Pre- and post-surgical laboratory tests and six-month follow-up.

Laboratory tests	Pre-surgical	Post-surgical	Six-month follow-up
Blood cytology	Hemoglobin: 14.3 g/dl Platelets: 185,000 mm <sup>3</sup> Leukocytes: 5.3 Neutrophils: 2.7	Hemoglobin: 16.6 g/dl Platelets: 174,000 mm <sup>3</sup> Leukocytes: 20.5 Neutrophils: 18.5	Hemoglobin: 13.6 g/dl Platelets: 130,000 mm <sup>3</sup> Leukocytes: 7.0 Neutrophils: 62% Htc: 41.8% MCV: 91 fL MCHC: 31 pg Lymphocytes: 32% Monocytes: 3% Basophils: 0% Eo: 3% Segmented: 62% Bands: 0%
Blood chemistry	Glucose: 95 mg/dl Urea: 13 mg/dl Creatinine: 0.58 mg/dl	Glucose: 75 mg/dl Urea: 23 mg/dl Creatinine: 0.51 mg/dl	Glucose: 102 mg/dl Urea: 29 mg/dl Creatinine: 0.78 mg/dl
Liver function tests	GGT: 23 U/l AST: 20 U/l ALT: 16 U/l TB: 0.28 mg/dl DB: 0.04 mg/dl IB: 0.24 mg/dl	GGT: 194 U/l AST: 19 U/l ALT: 29 U/l TB: 0.54 mg/dl DB: 0.17 mg/dl IB: 0.37 mg/dl	GGT: 24 U/l AST: 30 U/l ALT: 25 U/l TB: 0.50 mg/dl DB: 0.20 mg/dl IB: 0.30 mg/dl

ALT = alanine aminotransferase. AST = aspartate aminotransferase. DB = direct bilirubin. IB = indirect bilirubin. TB = total bilirubin. MCHC = mean corpuscular hemoglobin concentration. Eo = eosinophils. GGT = gamma-glutamyl transpeptidase. Hct = hematocrit. MCV = mean corpuscular volume.



**Figure 3:** *Magnetic resonance cholangiography. Coronal section of magnetic resonance cholangiography; (1) common bile duct cyst (70 mm) with interspersed areas of stenosis and added intrahepatic dilatation that classifies it as type IVA. (2) Normal-sized gallbladder with a thin wall.*

zone of 33 mm (carina) was seen. A maximum dilatation of the common bile duct of 70 mm, distal common bile duct of 23 mm, and the duct of Wirsung with normal dimensions were observed.

Elective resection was scheduled laparoscopically (Figure 5) after completing a thorough preoperative protocol. Intraoperative findings evidenced a QC-IVA-Todani-modified, with an atrophic gallbladder. Dissection of the cyst capsule was initiated by attempting to separate it from the vascular structures (portal vein and hepatic artery). It was decided to open the cyst to facilitate its dissection. However, due to its strong adhesion and vascularization, with scarce but continuous bleeding, it was converted to open surgery through a Kocher-type incision.

Dissection of the cyst was continued by separating it from the portal vein without damaging it. A Bakes dilator was introduced through the cyst opening to identify and canalize the dilated right and left hepatic ducts. Then, the removal of the common bile duct cyst was performed from the bifurcation of both intrahepatic ducts to the duodenal

border, where a continuous suture with polydioxanone was performed, including the last centimeter of the common bile duct, thus performing a complete removal of the cyst, including the gallbladder. Finally, a Roux-en-Y biliodigestive bypass was performed, with a jejunal loop of 50 cm from the Treitz angle and a biliary drainage loop of 50 cm, using a 60 mm linear stapler in the hepatic-jejunal anastomosis.

The jejunum-jejunal anastomosis was performed manually with a continuous suture of Vicryl® 4-0, leaving an anastomotic diameter of 30 mm. Hemostasis was verified; a gauze count was performed, and a closed drain of 19 Fr was installed. A bleeding of 800 cc was recorded, so a globular package was transfused during the trans-operative period. The patient was given antibiotic therapy with ceftriaxone 1 g every/12 hours and metronidazole 500 every 8 hours. On the following postoperative day, she started on a liquid diet and ambulation, and on the third postoperative day, she was given a mixed diet.

The cyst was sent to pathology evaluation with the following findings: a cyst wall



**Figure 4:** *Magnetic resonance cholangiography. 3D reconstruction of magnetic resonance cholangiography: widening of the common bile duct up to 70 mm, dilatation of the right hepatic duct with 18 mm and 15 mm of the left hepatic duct, and 30 mm in the confluence zone.*

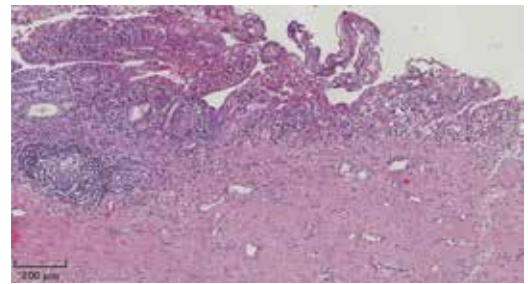
composed of dense fibroconnective tissue lined by simple columnar epithelium accompanied by acute and chronic inflammatory infiltrate. A lamina propria with vasodilatation and acute and chronic infiltrate extending to the cyst wall was seen. Focal papillary hyperplasia of the mucosa, areas of focal ulceration, and a secondary lymphoid follicle formation (Figure 6) were shown.

The patient had a good clinical evolution and was discharged on postoperative day 8 with no evidence of early surgical complications. Laboratory studies continue to be performed.

There were six-month follow-up appointments with laboratory tests, including blood cytology, blood chemistry, and liver profile, which found the patient clinically stable and physical examination without jaundice, cardiopulmonary problems, and abdomen with good surgical healing process. The patient will continue to be followed up with a CT scan with intravenous water-soluble contrast and determination of tumor markers: carcinoembryonic antigen (CEA) and CA 19-9 at 12 months post-surgery.

## DISCUSSION

In the last five years, the general surgery service of the HCGFAA attended 5,886 patients, of

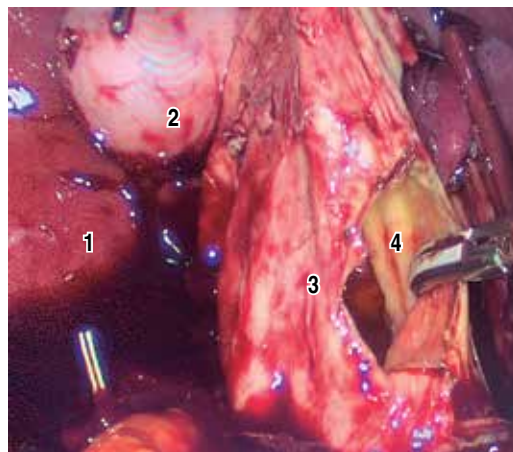


**Figure 6:** Laminoma. Focal papillary hyperplasia of the mucosa, with chronic and acute inflammatory infiltrate, areas of focal ulceration. Formation of a secondary lymphoid follicle.

which only two cases of common bile duct cysts were found in adults. The incidence of this pathology in HCGFAA was 0.03%, low compared to Western countries and even lower concerning the Asian population. Choledochal cysts are more commonly found in Eastern countries, with a prevalence of 1:1,000 persons, with type IV being the most frequent in adults.<sup>2</sup> The sex ratio is reported to be more frequent in women in both Eastern and Western countries, 4:1.<sup>1</sup>

Due to the inherent pathophysiology of common bile duct cysts, the scientific literature mentions a malignancy rate that varies between 2.5 and 28%, which increases with age.

The variety of common bile duct cysts leads us to divide their management according to their classification; surgical resection for type I and IV cysts is the therapeutic option of choice, either by laparoscopic, robotic, or open surgery. The use of the laparoscopic and robotic routes entails a considerably lower risk of both immediate and late complications, according to Miron et al.<sup>2</sup> Among the most common surgical complications are bleeding and dehiscence of the anastomosis, which could result in the appearance of leaks leading to local or generalized sepsis of the abdominal cavity. This situation requires immediate treatment according to the current protocols for managing the dehiscence in biliodigestive anastomoses. For type II cysts, diverticulectomy plus primary closure of the common bile duct can be chosen. If necessary,



**Figure 5:** Laparoscopic view. Opening of the common bile duct cyst at its anterior wall; (1) right hepatic lobe; (2) gallbladder; (3) anterior serosa wall of the cyst; (4) posterior mucosa wall of the cyst.

management can be limited to transduodenal excision for type III cysts by endoscopic management with respective sphincterotomy and sphincteroplasty.

However, due to the firm adhesion of the posterior wall of the cyst to the vascular structures, mainly to the portal vein, laparoscopic resection was not possible, and it became an open surgery through a Kocher-type incision. In this way, its total extirpation was achieved, leaving a remnant of the duct in the intrapancreatic portion of about 5 mm. The literature indicates that this remnant can be the cause of dysplasia.<sup>11,12</sup> However, we do not fully agree with this statement because the physiopathology of the cyst is modified when most of the cystic lesion is removed, thus eliminating the increase of pressure in the biliary tract.

Zheng and colleagues debated whether VATS cysts in adults require additional hepatic resection because of concomitant intrahepatic dilatation; in this case, hepatic resection is unfeasible since the reported dilatations involve the initial portion of both hepatic ducts. Therefore, resection should be limited to specific segments that do not increase the morbimortality of the patient due to extensive hepatic resection. This situation is replicated in pediatric patients since they have a much milder inflammatory evolution and less malignant transformation than adults, less lithiasis formation, and a lower risk of cholangiocarcinoma in general.<sup>10</sup>

In the present case, the patient was followed up for 10 months. Her evolution will continue to be monitored by CT scan with water-soluble intravenous contrast and determination of tumor markers: carcinoembryonic antigen (CEA) and CA 19-9 every six months until five years postoperatively, to ensure the non-recurrence or malignant transformation of the unresected cystic remnant.

## CONCLUSIONS

Giant common bile duct cyst, a rare condition worldwide, may present with nonspecific symptoms, leading to its

diagnosis going unnoticed, highlighting the importance of resorting to imaging techniques such as ERCP or M-CR for timely evaluation and staging. In addition, long-term postoperative monitoring is required to prevent complications, particularly malignant transformation. The latter can affect the bile ducts, gallbladder, and even the pancreas in advanced stages, decades after the initial intervention.

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