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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.

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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.[1,2]

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.[3] 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.[4] 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.[2]

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.[5,6]
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.[7]
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.[8-11]
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.[12]
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.[13]
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...".[5,14]
8. Perform the "doublet view" maneuver and record it in the postoperative note, attaching the supporting photographs. Always record video.[15,16]
9. Perform five surgical breaks (time out) at turning points:[8,17,18]
   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.[19]
   b. At the time of the first B-SAFE and R4U line visualization.[5,6]
   c. Upon achieving the critical safety vision or declaring the impossibility of realizing it.[17,20]
   d. Before clipping and sectioning what appears to be the cystic duct and cystic artery.[5]
   e. If there is any doubt about the anatomy.[5]
10. Use the Parkland intraoperative scale to classify the degree of vesicular and hepatocystic triangle inflammation.[21]
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.[5,15,18]

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.[15,20,22]
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:[14,23]
    a. Perform subtotal cholecystectomy at Parkland 3.[6,20,24]
    b. Perform cholecystostomy with stone removal in Parkland 4.[6,25]
    c. Discontinue the procedure and refer to a center of HPB expertise at Parkland 5.[12,26]
14. Always place subhepatic drainage if subtotal cholecystectomy or cholecystostomy is performed.[20]
15. Ask for help from a more experienced surgeon in case of difficult cholecystectomy[5,12]
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.[6,27,28]
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.[12,29]
18. Use bipolar energy (if available) in the gallbladder wall section of the subtotal cholecystectomy, not in the dissection of the gallbladder hilum.[18,29]
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.[8]
20. Do not use intraoperative cholangiography routinely, but selectively.[12,29-31]
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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