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A culture of safety: a strategy to prevent bile duct injury

Cultura de seguridad, estrategia para prevenir la disrupción de la vía biliar

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Palabras clave:
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ABSTRACT

Introduction: Cholelithiasis has a frequency of up to 30% in Western populations. Cholecystectomy —particularly with a laparoscopic approach— is one of the surgical procedures most often performed in our country: 22,000 every year at the *Instituto Mexicano de Seguridad Social*. Its main associated complications should be well recognized; the one that most increases morbidity and mortality is bile duct injury, with a frequency of 0.1 to 0.4%. The practice of a culture of safety during cholecystectomy has been currently proposed as a strategy to prevent bile duct injury.

RESUMEN

Introducción: *La colelitiasis se presenta con una frecuencia de hasta 30% en la población occidental. La colecistectomía —y particularmente, el abordaje laparoscópico— es una de las cirugías que más se realizan en nuestro país: 22 mil al año en el Instituto Mexicano de Seguridad Social. Se deben conocer las principales complicaciones asociadas; una de las que más aumentan la morbilidad y mortalidad es la disrupción de la vía biliar, cuya frecuencia de presentación es de 0.1 a 0.4%. En la actualidad, se ha propuesto practicar una cultura de seguridad para colecistectomía como estrategia para prevenir la disrupción de la vía biliar.*

INTRODUCTION

Cholelithiasis (gallstone disease) is very frequent in our setting, and the main cause of cholecystitis and biliary colic. It has been reported in up to 30% of the Western population, and 20% of cases have symptoms.[1,2]

A great variety of treatments for cholelithiasis have been developed, but definitive therapy is cholecystectomy. Laparoscopic approach is currently considered the gold standard[1-4] and in Mexico, it is one of the most frequently performed surgeries: 22,528 in 2007 at the *Instituto Mexicano de Seguridad Social*.[4]

The first description of the surgical technique for cholecystectomy was made in the late 1880's, and the open approach was the gold standard for approximately 100 years, until the late 1980's. when the first laparoscopic cholecystectomy was performed.[1,5,6]

The advantages of minimally invasive surgery (laparoscopic cholecystectomy) include a lower metabolic response to trauma, a shorter hospital stay, less postoperative pain, faster patient return to daily life, and superior cosmetic results.[7-9]

Morbidity reported for laparoscopic cholecystectomy is lower than that of open cholecystectomy: 4-8% *vs* 14-18%.[10-12] The most frequent complications are bleeding at the incision site, infection of the surgical site and chronic pain. More severe complications, such as injury to the biliary tract, the bowel or the blood vessels, are less frequent; these may significantly compromise the patient's quality of life and may even lead to death.[8,13,14]

Biliary tract injury has a reported frequency of 0.1 to 0.2% in open cholecystectomy and 0.1 up to 0.4% in laparoscopic cholecystectomy.[3,7,8,11-13,15,16]

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It is worth noting that, in the first laparoscopic procedures, the frequency of bile duct injury once reached up to 2.8%, according to U.S. publications.[3,17] This number has significantly decreased, but it is still higher than with the open approach.[3,8,15]

Several factors associated to bile duct injury have been described: one of them is the surgeon's training and experience in laparoscopic cholecystectomy.[18] Some authors have reported that the training curve stabilizes the risk of bile duct injury from 1.7 to 0.17%, by procedure number 50.[11,19] The number of procedures required for a surgeon to be considered high-volume varies between 15 and 25 per year.[20,21]

Intraoperative factors associated with bile duct injury are acute cholecystitis, chronic inflammation, bleeding that obscures the surgical field, increased periportal fatty tissue, and anatomical variants. The frequency of bile duct injury has been reported to be greater in cases of laparoscopic cholecystectomy due to acute cholecystitis (0.5%),[18] compared to elective cholecystectomy (0.21%).[16]

Another factor to consider is the need for the equipment's quality to be optimal, particularly the lens and instrument isolation.[18]

There are currently several classifications of bile duct injury, whose main objective is to anatomically determine the type and site of the injury. Some also include vascular injuries. The following are some of the most used in our setting.

Bismuth-Corlette (1982): this classification has the primary purpose of anatomically determining the site of bile duct injury. It is simple and is based on the distance between the injury and the hepatic duct confluence. It guides the surgeon in selecting the type of repair required. It is worth noting that this classification was established prior to the introduction of laparoscopic surgical approaches *(Table 1)*.[8,22-25]

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Strasberg (1995): this classification was created after the introduction of the laparoscopic approach, and it complements the Bismuth classification. It includes the most common injuries in laparoscopic cholecystectomy. It offers the advantage of being simple and widely known *(Table 2 and Figure 1)*.[8,22-24]

Stewart-Way (2003): this classification takes into account the anatomical level of the injury, its likely mechanism and, besides, any associated arterial injury.[8,22-24] Injury to the right hepatic artery has been associated with greater proximal extension of the injury, with no impact on mortality or on the repair's success. An important factor in the repair's outcome is whether it is hepato-pancreato-biliary (17% *vs* 94%).[26] Another advantage is focusing on prevention, since this classification describes the mechanism of the bile duct injury *(Table 3)*.[25]

Since the introduction of laparoscopic cholecystectomy, several recommendations have been made to decrease the risk of bile duct injury. A number of associations and surgical groups have proposed strategies specifically aimed at performing safe surgical procedures. The Society of American Gastrointestinal Endoscopic Surgeons (SAGES) launched an initiative to improve the safety of laparoscopic cholecystectomy, headed by the Safety in Cholecystectomy Task Force, with the aim of fostering a culture of safety. A two-phased consensus took place. Nominal group technique: this is a highly structured process for the generation of concepts, avoiding personal bias. By combining the ideas approved by the majority, it highlighted the most important

Table 1: Bismuth-Corlette classification of bile duct stenosis.

Type	Description
1	Low stenosis, more than 2 cm from the confluence of the hepatic ducts
2	Proximal stenosis, less than 2 cm from confluence of the hepatic ducts
3	Hilar stenosis at the confluence, but both hepatic ducts remain communicated
4	Hilar stenosis involving the confluence, with loss of communication of the hepatic ducts
5	Stenosis of aberrant sectorial hepatic duct, with or without stenosis of the common hepatic duct

Table 2: Strasberg classification for bile duct injury during laparoscopic surgery.

Type	Description
A	Leak from the cystic duct or a small duct in the hepatic bed
B	Occlusion of a posterior or aberrant hepatic duct not communicated with the common bile duct
C	Leak from posterior or aberrant hepatic duct not communicated with the common bile duct
D	Occlusion or leak due to partial section of the common bile duct
E1	Complete section of the common bile duct more than 2 cm from the confluence of the hepatic ducts
E2	Complete section of the common bile duct less than 2 cm from the confluence of the hepatic ducts
E3	Complete section of the common bile duct at the confluence, without loss of communication of the hepatic ducts
E4	Complete section of the common bile duct at the confluence with loss of communication of the hepatic ducts
E5	Complete section of the common bile duct plus occlusion of the right posterior or an aberrant hepatic duct (+ Type 3)

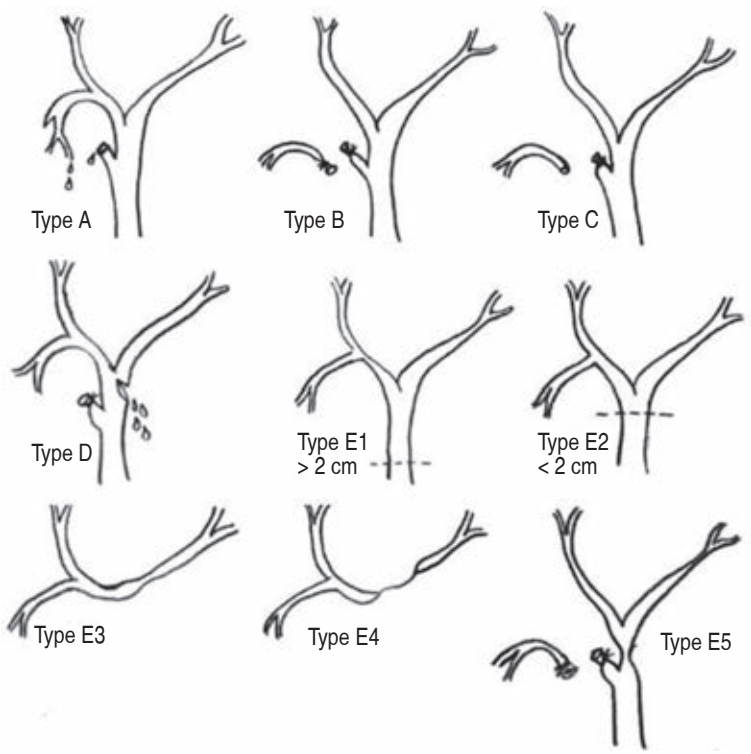

Figure 1: *Strasberg classification of bile duct injury.*

factors for a safe laparoscopic cholecystectomy. The SAGES members were subsequently invited to participate by email, to select the most relevant factors by Delphi consensus. Furthermore, the five most pertinent factors for resident training, performance evaluation and research were also stated. In the first round, 39 initial parameters were reduced to 26, and at the end of the second round, 15 remained *(Table 4)*.

SAGES published the following strategies as part of the culture of safety in cholecystectomy, in order to decrease the risk of bile duct injury.

1. Use the Critical View of Safety (CVS) method of identification of the cystic duct and cystic artery.
   a. Dissect the hepatocystic triangle (cystic duct, common hepatic duct and the inferior edge of the liver). The common bile duct must not be dissected.
   b. Dissect the lower one-third of the gallbladder to expose the cystic plate.
   c. Only two structures should be seen entering the gallbladder. This must be confirmed by anterior and posterior visualization.
2. During surgery, consider a time-out with all members of the surgical team prior to clipping, cutting or transecting any structure.
3. In all cases, consider the possibility of aberrant anatomical variants.
4. Use intraoperative cholangiography in case of doubts on the anatomy.
5. Consider the possibility of performing a subtotal cholecystectomy, cholecystostomy or conversion to an open approach.
6. Request help from another surgeon if difficulties arise.

CONCLUSION

Currently, gallstone disease is highly prevalent in Mexico. Therefore, cholecystectomy is one of the most frequently performed surgeries in the country. Thus, its associated complications must be well understood, and the appropriate measures to reduce them must be implemented in our setting. The proposal by SAGES is aimed at establishing a safety culture to decrease these

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Table 3: Stewart-Way classification of bile duct injury during laparoscopic surgery.

Class	Description	Associated injury to RHA*
I	Incomplete section of the bile duct with no tissue loss Common bile duct mistaken for cystic duct, but error corrected before sectioning Extension of the cystic duct section for intraoperative cholangiography or for T-tube	5%
II	Lateral stenosis of the bile duct Thermal injury or injury due to inadvertent clip placement Associated to bleeding and poor visibility	20%
IIIA	Complete section of the common bile duct with hepatic duct remnant	35%
IIIB	Complete section of the bile duct at the confluence	
IIIC	Complete section of the bile duct at the confluence, with loss of communication of hepatic ducts	
IIID	Section above the confluence	
IV	Section of right or aberrant hepatic duct with injury to the right hepatic artery Right hepatic duct mistaken for cystic duct and collateral injury by electrocautery or clipping	60%

* RHA: right hepatic artery.
\+ The proposed mechanism in class III is inadvertently mistaking the common bile duct for the cystic duct, frequently with tissue loss.

Table 4: Relevant factors for a safe laparoscopic cholecystectomy.

Proposed parameters to perform a safe laparoscopic cholecystectomy (SAGES, Delphi Consensus, 2015).	
• Use the Critical View of Safety (CVS) method	• Safeguard the cystic duct
• Understand anatomical variants	• Appropriate decision-making to go on with the surgery
• Appropriate traction and exposure	• Rational use of energy devices by the surgeon
• Know when to ask for help	• Ability to perform and interpret an intraoperative cholangiography
• Recognize when to convert or perform an alternative procedure	• Appropriate handling of tissues
• Recognize post-surgical complications or a change in the expected course	• Appropriate hemostasis
• Adequate experience of main surgeon	• Avoid injury to the hepatic artery
• Initiate dissection of Calot's triangle in the upper gallbladder portion	

injuries since, undoubtedly, prevention is the best strategy.

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