

THE VALUE OF A PREOPERATIVE SCORE TO ASSES THE RISK FOR IATROGENIC INJURY OCCURRED DURING CHOLECYSTECTOMY

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ABSTRACT:

THE PURPOSE OF THIS PAPER IS TO DEMONSTRATE THE VALIDITY OF A PREOPERATIVE SCORE MEANT TO DECREASE THE INCIDENCE OF IATROGENIC BILIARY DUCT INJURIES.

DESPITE THE INTRODUCTION OF NEW MININVASIVE TECHNIQUES – ENDOSCOPIC AND LAPAROSCOPIC – THE NUMBER OF ACCIDENTS AND INCIDENTS ENCOUNTERED INCREASED.

THE INCIDENCE OF EXTRAHEPATIC BILIARY LESIONS IS DOUBLE IN LAPAROSCOPIC SURGERY (0.4-0.6%) COMPARED TO OPEN SURGERY (0.2-0.3%), SEVERITY OF INJURIES CONSISTING OF SURGICAL REPAIR DIFFICULTIES.

THE PERSONAL EFFORT MADE BY PROSPECTIVE ANALYSIS TO CALCULATE A PREOPERATIVE RISK SCORE TO PREDICT THE POSSIBILITY OF IATROGENIC INJURY AND TO SET THE INDICATION TO PERFORM PREOPERATIVE OR INTRAOPERATIVE FURTHER INVESTIGATIONS.

I ENROLLED A TOTAL OF 62 PATIENTS WHO HAD INDICATION FOR CHOLECYSTECTOMY AND CALCULATED FOR EACH ONE THE PREOPERATIVE SCORE. THE RESULTS SHOWED THAT THE PATIENTS WITH A SCORE HIGHER THAN 5 POINTS HAVE A SIGNIFICANT RISK FOR IATROGENIC BILIARY LESION.

KEYWORDS: IATROGENIC BILIARY LESIONS, PREOPERATIVE SCORE BACKGROUND

The problem of iatrogenic lesions dates back thousands of years and is still out of date because of the social, medical, economic, legal issues that involve their occurrence . Etymologically iatrogenic = IATROS - doctor and genie - generators.

Although we are in the era of minimally invasive surgery the rate of occurrence of iatrogenic biliary lesions it is high, virtually double in laparoscopic cholecystectomy versus open cholecystectomy. Over time efforts have been made to prevent, diagnose and treat as early and as optimally these injuries. There is a no widely accepted consensus for all to achieve all these goals.

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MATERIAL AND METHOD

I proposed the use of a preoperative score in order to evaluate the risk of iatrogenic injury to bile ducts and establish indication of further investigation (used pre / during surgery) to decrease the rate of occurrence of these injuries.

The need to develop this score resulted from doctoral research that I have made during 2009-2013, in the paper entitled "Iatrogenic biliary duct lesions during cholecystectomy -diagnostic and therapeutic approach." In this retrospective study on a group of 2,707 patients who underwent laparoscopic or open cholecystectomy I have met 18 cases of iatrogenic lesions of the bile ducts. Iatrogenic lesions are a redoubtable complication of cholecystectomy representing "Achilles Heel" for surgeons who approach this region.

Remaining in the shadows at a time the incidence has increased with the introduction of minimally invasive techniques (laparoscopic and endoscopic).^{3 4 5}

The paper tried to answer the question: "Could it be avoided?" I searched for solutions and proposed new ways of tackling these injuries.

The number of cases and severity of the lesions encountered, along with new possibilities of laboratory and imagistic diagnosis used led me to deepen and establish criteria that will help reduce the incidence and severity of these lesions and lead to an early diagnosis and optimal treatment choice.

The conclusions of the doctoral research showed that iatrogenic biliary injuries can not be prevented completely and their appearance is the result of several factors (favoring, predisposing) rather than a single factor itself.

Decreasing the incidence of these injuries should be a constant concern for any surgeon who performs cholecystectomy and prevention of iatrogenic lesions depends also on the performance of intraoperative investigations.

Prevention is the main factor for decreasing the incidence of iatrogenic lesions of the bile ducts.

Based on data obtained from the study I have proposed an algorithm for calculating a preoperative risk score, based on which I have settled the new criterion to carry out further investigations (not routinely performed) preoperatively and especially intraoperatively.

Scoring tries to establish increased risk of iatrogenic injury and to determine the indication of performing imagistic investigations with the role to prevent these injuries.

Criteria for calculating the score:

1. Patient's age :
 - > 50 years..... 1 point
 - > 70 years..... 2 points
2. Patient's sex :
 - Female.....2 points
 - Male1 point
3. Obesity (ranked as BMI)
 - BMI> 30..... 1 point
4. Billiary symptoms > 2 years or history of billiary interventions1 point
5. Elevated preoperative inflammatory tests (leukocytosis, raised CRP)1 point
6. Indication for laparoscopic intervention.....1 point
7. Surgical team's experience

³ Cuschieri A, Dubois F, Mouil J et al. *The European experience with laparoscopic cholecystectomy*. Am J Surg 1991; 161: 385-387

⁴ Moosa A.R, Mayer A.D., Stabile B., *Iatrogenic injury to the bile duct*, Arch Surg 25:1028, 1990

⁵ *NIH Consensus Development Panel on Gallstones, Laparoscopic Cholecystectomy* (1993) Gallstones and laparoscopic cholecystectomy Surg Endosc 7:271-279

- Low (<50 gallbladder interventions made) 1 point
- 8. ultrasound criteria
- Gallbladder wall thickening.....1 point
- Distended gallbladder 1 point
- Murphy sign.....1 point

The value of this score may vary between 1 and 12 points.

It's simple and convenient calculated based on historical data, basic clinical and laboratory data.

For values of this score > 5 points I propose:

- Further investigation performed preoperative (Colangio-MRI, ERCP)
- Making mandatory intraoperative cholangiography (or intraoperative ultrasound)

Subsequently, during postdoctoral research I applied this score system on patients undergoing cholecystectomy admitted in the Surgery Clinic I work in. In the period June 2014 - February 2015 I made a lot of 62 patients who underwent cholecystectomy for biliary suffering. Demographic lot structure was : 37 women representing 59.67% and 25 men representing 40.3%, with an average age of 56 years (range between 29 and 85 years).

Surgical interventions were performed in classic open way in 2 cases (as per primam indication), and in 60 cases using laparoscopic approach. In 3 cases the laparoscopic interventions were converted to open way (1 case of necessity because of bile leak appearance).

For the entire group of patients I calculated the preoperative score, obtaining values between 2 and 11 points, the number of patients with scores above 5 being 17 (27.4% of the group).

In these 17 patients I have conducted further investigations (2 cholangioMRI preoperative and 15 intraoperative cholangiography).

Cholangio MRI was performed in a patient with a score of 11 points, the result being chronic sclerous cholecystitis , with a short cystic duct and probability for a bilio-biliary fistula. In this case the surgery took place in classical open way. The second cholangioMRI was a case of a patient with unclear medical history, the patient stated history of gastric and biliary surgery but unable to specify the type of surgery performed. The investigation showed a chronic cholecystitis with a single large calculus, the main bile duct of about 8 mm, but uninhabited, with wide passage into the duodenum (so probably was ERCP). In this case the surgical intervention was performed laparoscopic way.

Intraoperative cholangiography was performed in 15 patients for one of its setting the diagnosis of iatrogenic injury to bile ducts. Is the case of a patient in whom laparoscopic surgery began, but was found bile leak in the operating field, probably from the cystic stump. The surgery was converted and intraoperative cholangiography was performed and was detected lesion of the main biliary duct . Subsequently wound was sutured and a type Kehr biliary drainage was inserted (which has been maintained 6 weeks postoperatively, with favorable evolution).

In other cases the criterion for performing cholangiography was established preoperative by risk score calculation; in 7 patients being particularly useful for determining the local anatomy and possible anatomic variations encountered. There have been detected 2 anatomical variations: origin of cystic duct from the right hepatic bile duct and an accessory bile duct.

RESULTS

There were found two Iatrogenic lesions : one type D Strasberg (lateral lesion of the main biliary duct) which was diagnosed intraoperatively and a type A Strasberg lesion (bile leak from accessory hepatic duct). Both patients evolved favorably postoperative and no surgical re intervention was required. Similarly, both patients were part of the batch with a score more than 5 points and that further investigation was imposed intraoperatively.

When performing intraoperative cholangiography on criteria established by the proposed algorithm I got the diagnostic of biliary lesion in 2 cases and prevented the appearance of biliary lesions in the group of patients in whom: was established indication open for intervention per primam (1 case),and was clarified biliary duct anatomy during surgery (7 patients).

DISCUSSIONS

Performing further investigation (cholangioMRI, intraoperative cholangiography, intraoperative ultrasound, choledocscopy) has raised many discussions, considering the costs of these investigations, the risks (allergies, able to produce injuries themselves), extending operating time.

Therefore there is controversy in the literature especially in terms of the type of investigation chosen and the time of performing it. In the previous study I demonstrated the superiority of 2 investigations: cholangioMRI (considered the gold standard in the diagnosis of iatrogenic biliary lesions) and intraoperative cholangiography. The other possible investigations (intraoperative ultrasound, choledocscopy, endoscopic retrograde cholangiopancreatography) have numerous disadvantages, among which: increased cost, need for expensive equipment, trained staff, slow learning curve, technical difficulties.^{6 7 8}

Of all investigations intraoperative cholangiography is the easiest, with cheap cost, well known by all surgeons or having a quick learning curve, extends the operating time in average with 20 minutes (range 15-45 minutes).

Another discussion in literature refers to the criteria for routinely or selective intraoperative cholangiography.

I do not support routinely performing of this maneuver because has disadvantages: increases costs and duration of surgery, if false positive result leads to non- required biliary tract exploration. However, in carrying out routinely has the advantage of surgical team training and leads to a correct identification of the anatomy of the biliary tree.

I sustain making this maneuver on selective basis - preoperative or intraoperative criteria.⁹ The criteria that justify conducting intraoperative cholangiography are:

- Unclear local anatomy, anatomical anomalies identification
- The presence of stones in the cystic duct or cystic dilated than 4 mm
- Suspected iatrogenic injury (bile leak, identify several " cystic channels")
- Suspicion of common bile duct stones

⁶ Soper, Dunnegan, R.N, *Routine versus selective intraoperative cholangiogram during laparoscopic cholecystectomy*. World Journal of Surgery 16, 1133 – 1140, 1992:

⁷ A Ragozzin, Rosaria De Ritis, A Mosca, V Iaccarino and M Imbriaco *Value of MR Cholangiography in Patients with Iatrogenic Bile Duct Injury After Cholecystectomy* AJR 2004, Volume 183, Number 6

⁸ Callery MP. *Avoiding biliary injury during laparoscopic cholecystectomy: technical considerations*. Surg Endosc. 2006; 20: 1654–1658

⁹ Davidoff AM, Pappas TN, Murray EA et al : *Mechanisms of major biliary injury during laparoscopic cholecystectomy*, Ann Surg 1992, 215(3):196-202

I have demonstrated, analysing the cases studied that performing intraoperative cholangiography may have a protective effect in case of iatrogenic biliary injuries. This is consistent with data reported in the literature:¹⁰ "Making intraoperative cholangiography can reduce the rate and severity of iatrogenic biliary lesions and may help diagnosing them earlier" (SAGES Guidelines).

Several observational studies demonstrate that reduces by 50% the rate of iatrogenic lesions (Australia in 1988-1994)¹¹ or on the contrary, a study of 30 630 discharged patients who underwent cholecystectomy between 1991-1998, Washington showed a 61% higher rate of biliary lesions when cholangiography was not made.¹² Also it can limit the severity of a lesion already produced already (eg. avoid cutting the bile duct after clipping it wrong).

CONCLUSIONS

Performing intraoperative cholangiography on selective criteria has an important role in preventing iatrogenic biliary lesions.

Establishing preoperative criteria for making this investigations (the proposed scoring system) identifies patients at highest risk of suffering an iatrogenic injury and establishes preoperative indication for performing them.

CholangioMRI recognized as the gold standard in the diagnosis of iatrogenic lesions has proven its value in terms of preventing possible iatrogenic injuries when it is performed preoperatively.

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¹⁰ *Guidelines for the Clinical Application of Laparoscopic Biliary Tract Surgery*, 2010, www.sages.org

¹¹ Fletcher DR, Hobbs MST, Tan P, Valinsky LJ, Hockey RL, Pikora TJ, Knuiman MW, Sheiner HJ, Edis A. *Complications of cholecystectomy: risks of the laparoscopic approach and protective effects of operative cholangiography*. *Ann Surg*. 1999;229:449–57.

¹² Flum DR, Koepsell T, Heagerty P, et al – *Common bile duct injury during laparoscopic cholecistectomy and the use of intraoperative cholangiography: adverse outcome or preventable error?* *Arch. Surg.* 2001;136:1287-92

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