

Management of Bile Duct Injuries Secondary to Laparoscopic and Open Cholecystectomy. The Experience of a Single Surgical Department

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Rezumat

Managementul leziunilor biliare iatrogene secundare colecistectomiei laparoscopice sau deschise. Experiența unui singur centru chirurgical

Colecistectomia reprezintă una dintre cele mai frecvente operații întâlnite în chirurgia generală. Introducerea colecistectomiei laparoscopice a fost asociată cu o creștere a incidenței leziunilor de căi biliare. Scopul studiului este de a atrage atenția asupra riscului permanent de apariție a acestor leziuni, asupra dificultăților de rezolvare și identificarea celor mai bune soluții terapeutice.

Metodă: Au fost analizate retrospectiv și prospectiv toate cazurile internate și operate în Clinica Chirurgie 3 Cluj Napoca cu diagnosticul de leziune iatrogenă a căilor biliare în perioada 1987-2008

Rezultate: Distribuția pe ani a arătat o creștere a numărului de leziuni biliare adresate și rezolvate în Clinica Chirurgie 3 Cluj Napoca. 81% din leziunile iatrogene ale studiului nostru s-au produs după o colecistectomie laparoscopică, 19% fiind secundare unei colecistectomii deschise. 136 de pacienți au prezentat leziuni biliare majore (clasele D, E după Strasberg Soper), iar 47 pacienți au avut leziuni minore (clasele A-C). Durata medie a spitalizării a fost de 17 zile. 83 de pacienți au avut nevoie de una, două sau trei intervenții chirurgicale înainte de rezolvarea definitivă a leziunii. Cea mai frecventă

dintre complicații a reprezentat-o supurația de plagă (12.5%). Complicațiile cardio-reno-pulmonare au fost prezente la 8.7% din pacienți iar abcesul intraabdominal la 3.8% pacienți. Fistula anastomotică a fost prezentă la 11% din pacienții operați, iar mortalitatea globală a fost de 6%.

Concluzii: Leziunile iatrogene ale căilor biliare sunt caracterizate de o evoluție complicată, cu intervenții seriate și evoluție progresivă a stenozei biliare. Întârzierea reparației biliare definitive și numărul mare de intervenții efectuate înaintea adresării pacienților în centre de referință pentru chirurgia hepato-biliară, cresc morbiditatea și costurile spitalizării.

Cuvinte cheie: colecistectomie, leziune biliară, complicații, management chirurgical

Abstract

Cholecystectomy is one of the most performed surgical interventions in general surgery. Laparoscopic cholecystectomy was associated with an increasing occurrence of biliary ducts lesions. The aim of this study is to draw the attention towards the permanent risk of these kind of complications, the curative difficulties and identifying the best therapeutic solution in order to obtain favorable results on long term.

Method: There were retrospectively and prospectively analysed all the cases with diagnosis of iatrogenic biliary ducts lesion hospitalized and operated during 1987-2008 in the Surgical Clinic No 3 Cluj Napoca.

Results: The yearly distribution showed an increasing number of biliary lesions operated in the Surgical Clinic No 3 Cluj-Napoca. 81% of the iatrogenic lesions in our study occurred postlaparoscopic cholecystectomy, and 19% secondary to an open cholecystectomy. One hundred thirty-six patients

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had major biliary lesions (D, E classes according to Strasberg Soper) and 47 patients had minor lesions (A-C classes). The medium hospitalization range was 17 days. Eighty – three patients (45.3%) needed one, two or three surgical interventions before the complete cure of the lesions. The most frequent complication was plague suppuration (12.5%). The cardio-renal-pulmonary complications were present in 8.7% of the patients and the intra-abdominal abscess in 3.8% of the patients. The anastomotic fistula was present in 11% of the operated patients and 6% global mortality.

Conclusions: The iatrogenic lesions of the biliary ducts are characterized by a complicated evolution, with series of interventions and progressive evolution to biliary stenosis. Delaying the final biliary treatment and the high number of interventions performed before patients were referred to hepato-biliary specialised centres lead to an increasing morbidity and hospitalization costs.

Key words: cholecystectomy, bile duct injuries, complications, surgical management

Introduction

The introduction of laparoscopic cholecystectomy represented a true “revolution” in the surgical management of the gallbladder. This is a minimally invasive technique, it reduces postoperative pain and pulmonary dysfunctions, it offers a faster recovery, a shorter hospitalization, and as a whole, the reduction of the hospitalization costs (1,2).

The iatrogenic biliary lesions represent the most important cause of postoperative morbidity and mortality. The studies showed that contrary to expectations, after a certain learning curve, the number of biliary lesions secondary to laparoscopic cholecystectomy, remain relatively constant instead of decreasing. If the percentage of biliary lesions was of 0.1 - 0.2% in the period of open cholecystectomies, it has reached a percentage of 0.5-0.7% in the USA and 0.33% in Europe, in the era of laparoscopic cholecystectomies (3,4).

Material and Method

The study included all the patients hospitalized in the Surgical Clinic No. 3 Cluj Napoca with post-cholecystectomy (both laparoscopic and open) iatrogenic bile duct lesions during the period 1987 – 2008. This is a retrospective and prospective study looking at the surgical management of these patients. Data from 183 patients with iatrogenic biliary lesions secondary to cholecystectomy have been analysed.

Stenoses or biliary lesions emerging after benign inflammatory processes (chronic pancreatitis, lithiasis, oddian stenosis, vicinity ulcers) or malignant stenoses have been excluded.

The lesions were divided into two categories: minor lesions comprising lesions from the classes A,B,C according to

Strasberg-Soper, and respectively major lesions comprising the classes D and E of the classification.

Thus major lesions included the complete sections of the choledochus, of the common hepatic duct or of the left or/and right hepatic ducts, as well as partial lesions of the main biliary duct and main bile duct stenoses. Minor lesions comprised leaks from the level of the vesicular bed or of the cyst duct stump and leaks secondary to the sectioning of the aberrant biliary ducts.

The evaluation of the patients was carried out on the basis of the anamnesis, clinical examination, biological samples, and data existing in the surgical protocols correlated with the ones observed biliary restorative procedures. The data obtained by the clinical observations on the evolution of these cases was added to these.

The imagistic explorations most frequently used for the diagnosis were abdominal ultrasound, ERCP, computer tomography and to the lowest degree, cholangio-MRI, HIDA scan, spiral CT.

The use of ultrasound, of the abdominal CT and of the ERCP allowed in the majority of cases the establishing of the diagnosis and the adopting of the best therapeutic solutions. Abdominal ultrasound was the most frequently used diagnosis method, with a diagnosis rate of up to 85% of the cases. With the ultrasound we were able to highlight intraabdominal collections especially subhepatically, the dilation of the biliary tree superjacent to the lesions or areas of discontinuity of the bile ducts. ERCP highlighted the distal extremity of the biliary tree, the area of stenosis or the section area with the extravasation of the contrast substance at the level of the lesion.

The statistical processing was carried out with the SPSS 17 software, with the use of the statistical Chi-Square Test; the statistical estimation was made for a minimal significance threshold of $p=0.05$, corresponding to a statistical precision of 95% and where $p < 0.05$ means a significant difference.

Results

Data from 183 patients with iatrogenic biliary lesions situated in the classes A-E according to Strasberg and Soper were analyzed, the study comprising all patients hospitalized in The Surgery Clinic No. 3 from Cluj Napoca with the diagnosis iatrogenic lesion of the biliary duct after the carrying out of the cholecystectomy, coming both from tertiary centers with experience in laparoscopic techniques, as well as patients operated in the territory.

The annual distribution of the patients shows an increase of the number of cases solved in The Surgery Clinic No. 3 Cluj Napoca, proving the importance of solving these types of lesions in centers with experience in hepato-biliary surgery (Fig. 1).

The incidence of biliary lesions was evaluated according to gender. In our study, the reemergence according to genders (F/M = 142/41) shows a prevalence of the lesions for the female gender (77.6% versus 22.4%). This could be explained by the increased incidence of vesicular lithiasis at the female

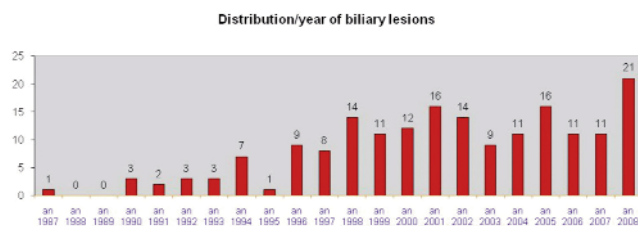


Figure 1. The yearly distribution of biliary lesions

gender and thus a larger number of laparoscopic cholecystectomies carried out as compared to the male gender. The ages of the patients varied between 22 and 83 years, the maximum incidence of biliary lesions being recorded in the 5th and 6th decades of life.

The data concerning the type of the cholecystitis for which the surgical intervention was needed, the environment of origin of the patients and the place where the cholecystectomy was carried out were studied.

The demographical data of the patients are presented in (Table 1).

The indications of the cholecystectomy were gallbladder lithiasis and cholesterototic polyps.

Out of the 183 patients taken in study, in 81% the iatrogenic lesions of our study emerged after a laparoscopic cholecystectomy, the rest of 19% being secondary to an open cholecystectomy. The classification of biliary lesions was carried out using the Strasberg – Soper classification of iatrogenic lesions. Thus the lesions were grouped into two categories: major biliary lesions and minor biliary lesions. 136 patients presented major biliary lesions, corresponding to the classes D and E according to Strasberg Soper, and 47 patients had minor lesions belonging to the classes A-C (Table 2).

The clinical manifestations in patients with biliary lesions were represented by abdominal pain, nausea and vomiting associated with jaundice, choleperitoneum or biliary leaks and the asthenic syndrome (Table 3).

Jaundice was present in 59% of the patients, and in 73% respectively 29% of the patients fever and angiolitic phenomena were present. Choleperitoneum was present in 73 patients, its presence influencing the prognosis of the patients. The diagnosis was established before surgery by the paraclinical examinations and confirmed during surgery.

The largest part of the biliary lesions taken into study came from another surgical service than that of the Surgical Clinic No. 3 Cluj Napoca. Of the total number of 183 patients with biliary lesions, in 119 patients the lesions were produced in another surgical service, and in 64 cases the lesions were produced at the Surgical Clinic No. 3 (65%

Table 1. The demographic data of patients with biliary duct lesions

Demographical data	Number	Percentage %
Age		
Limits	22 - 83	
Average	52	
The gender of the patients		
Female	142	78 %
Male	41	22 %
Environment of origin		
Urban	134	73%
Rural	49	27%
Initial surgery		
External Surgical Clinic No. 3	119	65%
Surgical Clinic No. 3 Cluj Napoca	64	35%
The type of surgery		
Laparoscopic cholecystectomy	147	81%
Classical cholecystectomy	35	19%
Type of cholecystitis		
Acute cholecystitis	85	46%
Chronic cholecystitis	78	43%
Scleroatrophic cholecystitis	20	11%

Table 2. The distribution of patients with lesions according to the surgical technique and the type of the lesion

Cholecystectomy/Lesion	Number	Percentage
The type of the cholecystectomy	183	
Laparoscopic cholecystectomy	148	81%
Open cholecystectomy	35	19%
The type of biliary lesion	183	
Major (classes D-E)	136	74%
Minor (classes A-C)	47	26%

versus 35%) (Fig. 2).

From the point of view of the complexity of the lesions, the patients coming from outside the Surgical Clinic No. 3 in the majority of cases presented major biliary lesions. 110 cases (92%) were lesions of the classes D-E Strasberg Soper. These needed a series of surgical interventions to be solved. 60% of the lesions produced in the Surgical Clinic No. 3 were minor lesions belonging to the classes A-C (Fig. 3).

Out of 119 biliary lesions produced outside the Surgical Clinic No. 3, in 67 patients (56%) it was attempted to solve the lesion at the level of the surgical center where the lesion was produced, a variable number of reparatory interventions being necessary (1-3 interventions). Finally it was necessary to address the cases towards the tertiary center for the final solving of the lesion. 52 cases (44%) were addressed to the Surgical Clinic No. 3 immediately after the establishing of the diagnosis being solved at first attempt.

Table 3. The clinical manifestations of patients with biliary lesions

	Jaundice	Fever	Chole-peritoneum	Angiolcolitis	Weight loss	Asthenia	Vomiting
Number	108	133	73	53	28	99	84
Percentages	59%	73%	40%	29%	15%	54%	46%

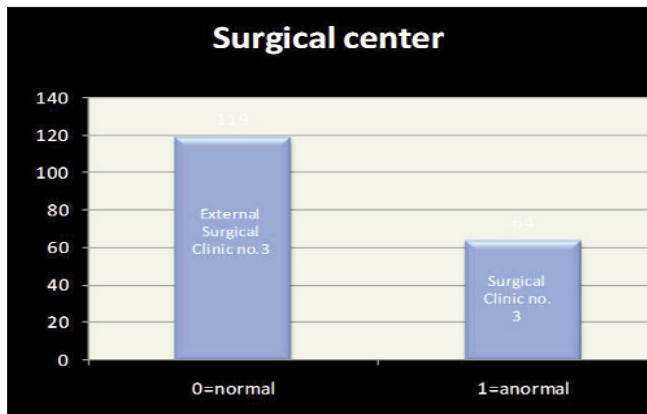


Figure 2. The nature of the center where the lesion emerged

The operatory moment for the solving of the biliary lesions was established according to the presentation of the patients in the Surgical Clinic No. 3. The lesion was recognized during surgery in 11 patients (6%), in 45 (25 %) the attempt to repair was carried out within the first 7 days from the production of the lesion. In 56 (31%) patients the attempt to repair was carried out within the first 30 days from the production of the lesion, in 32 (17%) the moment of the surgery was at an interval between 1 month to 1 year from the emergence of the lesion, and in 39 patients (21%) the moment of the surgery was more than one year after the emergence of the lesion.

In patients who addressed our clinic after more than 1 month from the production of the biliary lesion, the incidence of cholangitis was significantly higher ($p < 0.01$). A decrease of the incidence of postoperative biliary leaks ($p < 0.01$) was recorded in patients who addressed within the first 30 days from the lesion. The intraoperative and immediate postoperative recognition rate of biliary lesions with their immediate repairing was significantly higher ($p < 0.01$) for the lesions from the Surgical Clinic No. 3 as compared to those produced in other surgical services. The average duration of the hospitalization was of 17 days, with limits between 4 and 83 days.

Out of the total number of cases, 83 patients (45.3%) needed one, two or three surgical interventions before the final solving of the lesion (Table 4). The maneuvers used for the solving of the lesions were represented by the endoscopic approach in 10% of the cases, in 29% a biliodigestive anastomosis was attempted and in 43% Kehr type drainage and respectively suture.

After the addressing of the cases in the tertiary center, the therapeutic attitude was variable according to each case. This was influenced by the level of the lesion with the involvement of the biliary tree, by the presence of sepsis and the general state of the patient.

In 53 cases (29%) the surgical solution consisted of a biliodigestive anastomosis carried out between the digestive segment and the choledochus or the common hepatic duct. In 20 cases the anastomosis was carried out at the level of the confluence between the right hepatic duct and the left hepatic duct and in 30 cases it was necessary to lift the hilar

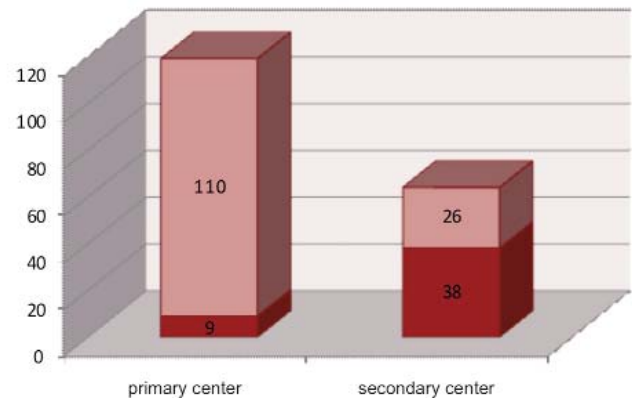


Figure 3. Distribution according to centers of the types of biliary lesions

Table 4. Attempts of bile repairs before addressing the case to the Surgical Clinic no. 3

Types of surgical interventions used to repair the lesion	No. of cases
ERCP, SE \pm endoscopic stent	8
Biliodigestive anastomosis (using choledochus or Common hepatic duct)	21
Biliodigestive anastomosis at the level of the confluence of the bile ducts	2
Hepp Couinaud anastomosis	1
Kehr type drainage, suture, ligature, clipping, abdominal drainage	36
The association of several types of surgical maneuvers	15

plaque and carry out the biliodigestive anastomosis with the left hepatic duct (Hepp Couinaud anastomosis). In 67 (36.6%) of the cases the solving of the lesion was carried out by the mounting of a Kehr drainage at the level of the biliary tree or by the suture, clipping and ligature of the wounded area and abdominal drainage. In 3 cases the management of the lesions was not surgical, the solving of the lesions being carried out by ERCP, endoscopic sphincterectomy or biliary stenting.

In 10 cases (5.5%), the solving of the biliary lesion needed several types of surgical interventions. In 11 cases (6%) the protection of the biliodigestive anastomosis was carried out by a transanastomotic drainage (Table 5).

The patients presented one or more local or general complications. The most frequent of the complications was represented by the wound suppuration (12.5%). Cardio-renal-pulmonary complications were present in 8.7% of the patients and the intraabdominal abscess in 3.8% of the patients. The anastomotic fistula was present in 11% of the operated patients, 66.6% of these fistulas being associated to the patients from outside the clinic, 78.6% of these having one or more attempts of surgical repair before addressing the tertiary center. The complication rate was statistically significantly higher with these patients ($p < 0.01$).

The emerging of the fistula was correlated statistically with the type of repairs carried out in the primary center,

Table 5. Final repairs carried out in tertiary center

Types of surgical interventions used to repair the lesion	No. of cases
ERCP, SE +/- endoscopic stent	3
Biliodigestive anastomosis (using choledochus or Common hepatic duct)	53
Biliodigestive anastomosis at the level of the confluence of the bile ducts	20
Hepp Couinaud anastomosis	30
Kehr type drainage, suture, ligature, clipping, abdominal drainage	67
The association of several types of surgical maneuvers	10

where the lesion was produced as well as with the number of these interventions ($p=0.004$), being more frequently encountered with these patients.

The death rate was influenced by the number of repair attempts carried out before addressing the case to the tertiary center, being proportional with their number ($p<0.01$). The data processing shows a statistical correlation between the laboratory data and the presence of complications. The presence of the hepatic cytolysis and cholestasis syndrome, as well as anemia negatively influenced the emerging of complications ($p<0.01$).

According to the type of surgical intervention, the rate of complications was of 15% for the cases where the solving of the lesion was carried out by the mounting of a Kehr drainage or by suture, the clipping of the wounded area or abdominal drainage, being more frequent for the lesions produced outside our clinic ($p<0.01$). For the biliodigestive anastomoses using the Roux-en-Y loop, the complication rate was of 13% with a higher frequency in lesions produced outside the Surgical Clinic No. 3 and directly proportional with the number of attempts of biliary repairs carried out before addressing the case towards the tertiary center. Hepp Couinaud anastomosis was used successfully as an alternative in patients with multiple repairing interventions in antecedents, with favorable final results ($p<0.01$).

Discussions

Iatrogenic lesions of the biliary ducts represent a severe complication associated with high long term morbidity and with the decrease of the quality of life. The real incidence of these lesions is not fully known because the clinical manifestations of biliary lesions may emerge even a few months after the production of the lesion, and the number of these lesions could be under-reported, as most of the time they are secondary to surgical negligence (5). The question which persists is if laparoscopic cholecystectomy is as safe for the patient as the classical method, or "the golden standard" (6,7) refers only to the short duration of the hospitalization, the low costs and the quick reintegration of the patient in activity.

In a study carried out by Cuschieri in 7 European centers with the involvement of 20 surgeons who carried out 1236 laparoscopic cholecystectomies, the incidence of iatrogenic

biliary lesions was of 0.33% (8) and in a study carried out by The Southern Surgeons Club on 1518 laparoscopic cholecystectomies, the incidence of biliary lesions was of 0.5% (9). In another study, the incidence of iatrogenic biliary lesions varies between 0.3-0.9%, representing a double frequency as compared to the ones in open cholecystectomy (10).

Because the main cause of biliary lesions is represented by the removal of the cholecyst without a correct identification of the anatomy of the Calot triangle, it is essential to identify, as a first gesture, before sectioning any element, the common hepatic duct and the choledochus. To this the checking of the integrity of the bile ducts is added also after the removal of the cholecyst. The immediate recognition of the biliary lesion and its repair offers the best long term results in these patients. The advantage is offered by the fact that the work is done on supple tissues, with no fibrous tissue and in the absence of local and regional inflammatory processes. The major disadvantage is given by the lack of dilation of the bile ducts, thus increasing the risk of subsequent stenoses.

Out of 119 biliary lesions produced outside the Surgery Clinic No. 3, in 56% of the patients it was attempted to solve the lesion at the level of the surgical center where the lesion was produced, a variable number of reparatory interventions (1-3 interventions) being necessary. 66.6% of the biliary fistulas are associated to patients from outside the clinic, 78.6% of these having one or more attempts of surgical repair before addressing the tertiary center ($p<0.01$).

The moment of biliary repairs remains controversial. 75% of the primary surgeons tried to solve the biliary lesions produced, by themselves. Stewart and Way report an increased rate of complications after other new attempts of biliary repair (11). The success of biliary repairs is influenced by the number of interventions carried out on the biliary tree and by who carried out the first repair attempt.

To obtain favorable long term results, it is important that the reparatory surgical intervention be carried out in centers specialized in hepato-biliary surgery. 52 cases (44%) addressed the Surgical Clinic No. 3 immediately after the establishing of the diagnosis being solved at first attempt. Each millimeter of healthy bile duct shall be preserved, as there is no guarantee that a new stenosis will not emerge in the future. Each relapse shall determine a stenosis localized even higher than the previous one and more difficult to repair (12,13,14).

Addressing the case with biliary lesion to the tertiary center and to the hepato-biliary surgeon reduces the number of surgical interventions, offers a final solution to the case and reduces the rate of complication and death.

A rigorous anamnesis associated with a complete objective exam suggests the diagnosis for the majority of patients with biliary lesions and imposes the sequence of investigations. The history of the disease brings important elements not only about the symptomatology, but also about the relationship with the prior surgical intervention and the starting time of the problems. Previous hospital release forms bring important diagnosis elements, but often are not available or have omissions related to the surgical data. For this the targeted

questioning of the patients is necessary about the presence of some prolonged drains, aspects of the secretions, the duration of the hospitalizations.

In our study jaundice was present in 59% of the patients, and in 73 % respectively 29 % of the patients fever and angiolithic phenomena were present. Choleperitoneum was present in 73 de patients (40%), its presence influencing the prognosis of the patients. Functional hepatic tests were routinely followed in the patients of the study. TGO and TGP were drawn, alkaline phosphatase, gamma GT, LDH, total and direct bilirubin. The minor modifications of these must not be ignored, because they may mask obstructions of the biliary tree. The laboratory data were completed by the imagistic exams. The use of ultrasound, abdominal CT and ERCP allowed in most cases the establishing of the diagnosis and the adoption of the best therapeutic solution.

The diagnosis of lesions of the bile ducts must be taken into discussion if after a cholecystectomy one or more of the following signs should appear: jaundice during the peri- and postoperative period, signs of localized or generalized peritonitis, abdominal puncture positive for bile, abdominal distension with abdominal ileus, biliary leaks in the drain tubes, imagery with the dilation of the biliary tree or unclear anatomy of the extrahepatic ducts.

In our study we used the Strasberg-Soper classification of biliary lesions (15). From the point of view of the complexity of the lesions, the patients coming from outside the Surgical Clinic No. 3 in most cases presented major biliary lesions, 92% being lesions of the classes D-E. 60% of the lesions produced in the Surgical Clinic No. 3 were minor lesions belonging to the classes A-C.

Robinson reported a rate of complications of 20%, 30 days after surgery and Innes a rate of fistulas of 5% (16,17). In a study carried out at the The Johns Hopkins Medical Institution USA on 200 patients with major biliary lesions, the rate of death was of 1.7% and that of complications of 42.9% the latter comprising anastomotic fistulas (4.8%), wound suppurations (8%), cholangitis (5.7%) and intra-abdominal abscesses, bilomas (2.9%) (18).

The most frequent of the complications was represented by wound suppuration (12.5%). Cardio-renal-pulmonary complications were present in 8.7% of the patients and intra-abdominal abscess in 3.8% of patients. The anastomotic fistula was present in 11% of the operated patients. The global mortality in our study was of 6%. The results are similar to other studies published by other surgical centers in the country, Turcu giving a mortality of 6% (19). Flum (20) reported a mortality of 2.7% and Warren in a study on 5000 cases for which 7643 interventions were carried out reported a mortality of 8.6% (21).

The use of the hepato-jejuno-anastomosis on Roux-en-Y loop represents the favorite approach in the re-establishing of biliary continuity. This is associated with a success rate of 92% as opposed to other therapeutic modalities (dilation with balloon with a success rate of 64% or T-T anastomosis protected with Kehr tube which according to Stewart and Way was accompanied by relapses in all cases). Hepp Couinaud anastomosis represents a safe, durable anastomosis and a final

solution for biliary lesions. Bismuth cites in 10 years excellent results for 93% of the patients with biliary lesions solved by Hepp Couinaud anastomosis. This proves that Hepp Couinaud anastomosis brings the best postoperative results, offering the final solution also for patients with multiple reparatory interventions in antecedents, with recurrent stenoses and where each new stenosis determined a higher lesion than the previous one. (22)

Iatrogenic lesions of the bile ducts remain a serious complication of cholecystectomies determining on the long run an important morbidity rate, a decrease of the survival rate and a decrease of the life quality of patients with such a health problem.

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