

Volume Issue IV Version I Year 013 2

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Abstract

Background: Iatrogenic biliary duct injury is a rare but potentially devastating condition associated with significant morbidity and mortality. Related data are limited in developing countries. This study aimed to analyse the clinical presentation, diagnosing and type of biliary injuries, and management proposed and in a population treated at a tertiary care centre. Method : Retrospective and prospective analysis of patients who sustained IBDI, and presented to the Gastroenterology surgical department at the National Centre Of Gastroenterology and Liver Disease Sudan , between the period of October 2010 to September 2013 (three years period).

Index terms— open cholecystectomy, biliary injury, strasberg classification .

Abstract -Background: Iatrogenic biliary duct injury is a rare but potentially devastating condition associated with significant morbidity and mortality. Related data are limited in developing countries. This study aimed to analyse the clinical presentation, diagnosing and type of biliary injuries, and management proposed and in a population treated at a tertiary care centre.

Method : Retrospective and prospective analysis of patients who sustained IBDI, and presented to the Gastroenterology surgical department at the National Centre Of Gastroenterology and Liver Disease Sudan , between the period of October 2010 to September 2013 (three years period).

Results : Total of 40 patients diagnosed as IBDI, 36 were females and 4 were males. Their mean age was 41 years (range 23-72) years. IBDI were due to 90% (n=36) post OC and due to 10% (n= 4) post LC. 65% presented with obstructive jaundice, 20% presented with biliary peritonitis, 15% presented with biliary cutaneous fistula (bile leak). The identification rate of intra-operative injury was 10% and 90% in the post-operative group. Time of presentation ranged between 2 days and 3 years the median was 12 days .According to Strasberg type E I, II, III and type D injuries, 20%, 37.5%, 35%, 7.5% were seen in patients, respectively. 87.5% of patients (n=35) underwent Roux en Y HJ. 5% of patients (n=2) underwent ERCP stenting, 2.5% underwent end to end anastomosis , 2.5% underwent primary repair T tube insertion.. Fifteen patients (40.5%) had complications during their hospital stay. Total hospitalization days, ranged between 14 days and 1 months the median was 18 days. Mortality was 12.5% (n=5).

1 Conclusion :

Open cholecystectomy is the main cause of IBDI in our study. In most of the cases surgical reconstruction with hepaticojejunostomy was required as the definitive treatment. ERCP should only be attempted when there is biliary continuity. Intra-abdominal abscess is the most common cause of death. Early referral to a tertiary centre with experienced hepatobiliary surgeons is necessary to assure optimal results.

2 Introduction

cholecystectomy is one of the most performed surgical procedures in general surgery. Iatrogenic biliary duct injury is a rare but potentially devastating condition associated with significant morbidity and mortality. The vast majority of these injuries occur as rare complication of both open and laproscopic cholecystectomies [1].

Iatrogenic injury may also occur during gastrectomy, pancreatectomy or ERCP, Trauma and duodenal ulcer are less common causes. A multidisciplinary approach including surgery, endoscopy and interventional radiology specialists is required to properly manage this complex disease [1].

Management depends on the timing of recognition of injury, the extent of bile duct injury, the patient's condition and the availability of experienced hepatobiliary surgeons. Immediate detection and repair are associated with an improved outcome, and the minimum standard of care after recognition of a bile duct injury is immediate referral to a surgeon experienced in bile duct injury repair.

The goal of surgical repair of the injured biliary tract is the restoration of a durable bile conduit, and the prevention of short- and long-term complications such as biliary fistula, intra-abdominal abscess, biliary stricture, recurrent cholangitis and secondary biliary cirrhosis [2].

The success rate of biliary reconstruction for iatrogenic bile duct injuries depended on complete eradication of abdominal infection, complete cholangiography, use of correct surgical technique, and repair by an experienced biliary surgeon. If these objectives were achieved, the repair could be performed at any point with the expectation of an excellent outcome [3].

In general data about IBDI in Sudan is lacking, there are no records of IBDI incidence per year. Although there is a recognized rise in IBDI cases presenting to tertiary centres. Records are not just deficient in Sudan but also in other developing countries especially African countries. Developing countries are in III.

3 Patients and Methods

4 Study Design

It is a Retrospective prospective descriptive analytical study.

5 Study area

This study was done at National Gastroenterology & Liver Disease Centre (NGLDC).

6 Study duration:

September 2012 to October 2013.

7 Study population

Cases diagnosed as postcholecystectomy biliary injuries admitted from the period of October 2010 to September 2013 (three years period).

8 Sample size

Total of 40 patients presenting to the Gastroenterology surgical department at the NCGLD, diagnosed as postcholecystectomy biliary injury.

9 Inclusion criteria

Patients who had injury iatrogenic biliary injury during cholecystectomy done by either laproscopic or open method.

10 Exclusion criteria

Patient who sustained their biliary injuries either through trauma or during some other procedure.

11 Sampling

Non probability sample.

12 Research & technique

This study was conducted in the surgical department at the National Center of Gastroenterology and Liver Disease (NCGLD) -Sudan.

Analysis was done retrospectively and prospectively from the records of patients files, patients charts and operation notes, demographic info, history of presenting illness, date of cholecystectomy surgery, symptoms and signs after surgery, imaging, drainage procedures, course of the illness, type of injury according to (Strasburg classification), management proposed and postoperative complications. Patient were also contacted through the telephone contact.

13 Data Collection Tools

A well-constructed predesigned questionnaire including demographic info, history, and clinical examination, investigation, mode of management, patient will be followed up in the refer, through their admission, and through telephone contact.

14 Data Variables

Questionnaire including, age, sex, gender, BMI, Operation (laproscopic or open cholecystectomy), signs and symptoms of biliary injury presentation(early and late),decompression procedure(open or US), investigations laboratory and radiological MRCP, type of injury according to Strasburg classification, definitive managements endoscopic and surgical, postoperative complications and postoperative mortality, days of admission in the hospital.

15 Data analysis

All the data was analyzed using computer program SPSS 19. Significance will be used with probability of P value will be considered significant if ≤ 0.05 .

16 Consent

Verbal consent to be taken from all patients after explanation of the study, its nature, the confidential keeping of data & to quit at any time during the study. Ethical clearance: Will be obtained from Sudan National Summit Board, Ethical Clearance committee.

17 IV.

18 Results

19 Sample number

Forty patients sustained postcholecystectomy IBDI, were admitted in the Gastroenterology surgical department, at the NCGLD from October 2010 to September 2013.

20 Age and gender

The mean age of patients is 41 years old (S.D. $\pm$ 11.8).Sixty five percent of patients' ages were between 30 and 50 years. The age range is (23-72years old).

Thirty six patients were females (90%) and four male s (10%), with a female to male ratio of 9:1.

21 Previous Operation

Thirty six patients (90%) underwent open cholecystectomy, while only four patients (10%) underwent laparoscopic cholecystectomy.

Intraoperative detected injuries were in four patients (10%), two of them in our centre, none of them were LC biliary injury. Postoperative detected injuries in 36 patients (90%); they were referred from other hospitals, two patients detected postoperatively in our centre. c) d) e) f) g) h) i) j) k) l) m) a) b) c)

22 Clinical Presentations

There is a realized increase in patients with IBDI presenting to the centre, nearly half of the patients (n=19) presented in the last year.

Twenty six patients (65%) presented with obstructive jaundice, eight patients (20%) presented with biliary peritonitis (fever, vomiting, generalized abdominal tenderness), six patients (15%) presented with biliary cutaneous fistula (bile leak).

Of the 26 patients presenting with obstructive jaundice, 15 patients (37.5%) presented with complete clipping or ligation of the CHD or CBD, and 11 patients (27.5%) presented with strictures, many month after the surgery.

23 Time of presentation since operation (Referral Delay)

Between 2 days and 3 years the mean 45 weeks(SD+242.8) the median is 12 days, 2 patients refused reconstructive surgery but appeared after 3 years .

Although two patients presented to our centre, diagnosed as intraoperative detected major bile injury by their surgeons they were referred after 8 days.

Only 2 patients diagnosed as postcholecystectomy injury after 2 days of injury, they sustained their injury at our centre, and underwent reconstructive Roux n y surgery after one day (immediate reconstruction).

Decompression was done for 10 patients, for all of the patients with biliary peritonitis 8 patients (20%), and in 2 patients (5%) with biliary cutaneous fistula due to a significant bilioma on MRCP.

Initially decompression was done either by open decompression (60%) or U.S guided decompression (40 %).All of patients who underwent U.S guided drainage got blocked within a few days and so open decompression was done in all the patients.

Regarding diagnosis all of the patients with IBDI injuries, were diagnosed by MRCP, the distal and proximal biliary tree was clearly identifiable, and amount of bilioma was detectable, MRCP was not done for the patients who sustained intraoperative injury at our centre.

24 Classification of injury

According to MRCP results patients injuries were classified by Strasberg classification, eight patients diagnosed as E I (20%), fifteen patients diagnosed as E2 (37.5%), fourteen patients diagnosed as E3 (35%) , three patients diagnosed as type D (7.5%).

Patients with drains and biliary cutaneous fistula, in total were 14 patients (35%) ,have intraabdominal infections, definitive surgery was deferred until inflammation subsided ,added to that decrease of biliary cutaneous fistula till reaching dryness or semidryness, and proximal stump fibrosis and dilatation of biliary system with appearance of jaundice, differed from patient to patient,70% of patients reached dryness and appearance of jaundice within 3months . The mean duration for fistula dryness was 2.6 month(SD+-1.60), median was 3 month.

25 Definitive management

Out of 40 patients, thirty five patients (87.5%) patients underwent Roux.en.Y HJ(Rodney Smith rechnique). Two patients (5%) underwent ERCP stenting, one patient (2.5%) underwent end to end anastomosis of CHD were injury detected intraoperatively, one patient (2.5%) with type D underwent primary repair T tube insertion were injury detected intraoperatively, one patient (2.5%) didn't come back for surgery.

The method of biliary drainage and stenting was either external transhepatic stenting for 31 patients(88.6%) or external T drainage which was done in 4 patients (11.4%) according to surgeon preference. Eight patients (22.8%) of the 35 patients with transected or ligated CHD, had previous attempts of ERCP stenting but failed. Seven patients (63.6%) of the 11 patients diagnosed as strictures managed initially by ERCP stenting and dilatation more than 3 times, but failed to dilate the stricture, six patients (54.5%) had an episode of cholangitis during their stent management at least for once.

26 Injury-intervention time gap

The time between the injury and definitive management, the mean is 5 months and median 2 months (SD± 10.9) .

27 Early postoperative complications

Regarding the postoperative period, out of the 37 patients who underwent definitive surgical management, 20 had a normal postoperative period during their hospital stay, with no complications. Fifteen patients (40.5%) had sustained complications during their hospital stay.

Wound infection. Four patients (10.8%) developed wound infection in the postoperative period. Fistula, five patients (13.5%) developed fistula, 2 patients from them developed intra abdominal abscess. AnastamoticDe-hiscense, one patient (2.7%), the only patient who underwent primary end to end anastomosis. Liver failure, three patients (8.1%) developed liver failure. Pulmonary embolism. One patient (2.7%) developed pulmonary embolism.

Acute renal failure. One patient (2.7%) developed acute renal failure.

28 Mortality

Five patients (12.5%) unfortunately died, all in the postoperative period.

Three patients (7.5%) died due to sepsis condition started as fistula formation, followed by intraabdominal abscess collection.

29 Volume XIII Issue IV Version I

d) e) f) g) h) i) j)

One patient (2.5%) died due to massive pulmonary embolism. One patient (2.5%) died to hepatic failure, deterioration in liver functions and hepatic encephalopathy.

Hospitalization ranged between 14 days and 1months the median was 18 days.

V.

30 Discussion

Iatrogenic biliary duct injuries are a major concern to general surgeons everywhere, since it's an iatrogenic inflicted injury.

In general data about IBDI in Sudan is lacking, there is no records of IBDI incidence per year , although there are few centers which are specialized in gastroenterology and liver surgery and these centers receive all of the IBDI in Sudan .

Information about IBDI incidence is not just deficient in Sudan but also in other developing countries especially African countries. One of the causes maybe due to sensitivity of the surgeons' community to the condition, which leads to less reporting, the exact reason is not clear.

NCGLD have been receiving IBDI for a long time. There is an increase in the referred patients in comparison with the pervious study done in the late 90's(MAM Ibnouf et al)4, the referred patents have doubled and even

tripled in the last year 2013 .According to IbnOuf et al 5, IMBDI is a stable phenomenon because increasing experience of surgeons did not affect the overall incidence of bile duct injury.

Speculation of the exact reason is not possible, the rise of IBDI is probably due to many factors, possibly one of them is the amount of cholecystectomies which has definitely increased in the last years.

Of the admitted patients female percentage is higher than males similar to the result in (MAM Ibnouf et al)4 and (JayasundaraJAet al)6. Mean age and age range is also similar to results in 4 and 6 and but less in comparison to results of SicklickJK et al7.

Injuries due to open cholecystectomy were 90%, while laproscopic cholecystectomy were just 10%. Similar to the results ofIbnouf et al4 which results showed post OC were 95% and LC 5%, this shows that there is no advancement in introducing laproscopic surgery to our hospitals in the last 12 years .Although worldwide the routine cholecystectomy surgery done is LC, still in Sudan the common practice is the open cholecystectomy. OC injuries are still reported reaching approximately half of the patients according to Seeliger H et al8, and 40.3% according to Jayasundara JA6 but they are less than LC.

There is delay in the referral time median is 12 days,and mean is 45 weeks. this finding is very similar between MAM Ibnouf et al4 and our results and it show less delay in comparison to Sicklick et al7 results, median is 21 days,and results of Seeliger H816 days but comparing the mean of delayed referral results of Sicklick et al7 results shows 29.1 week and our study shows 45 weeks, due to 2 patients in our study who refused surgery for years and eventually came back. Delayed referral is a major problem most of the patients are referred at the maximum time of inflammation making surgery impossible, and so patients definitive surgery is deferred till inflammation subsides.

Presentations of patients in our study, similar to the presentations MAM Ibnouf et al4 and comparable to Sicklick et al7, but in contrast to results of M.shamimi et al9and SlaterK et al10were patients presenting were biliary peritonitis and bile leak (57%) and (70%) respectively.

All of the patients were diagnosed by MRCP, except for the intraoperative detected injuries in our centre ,MRCP is considered a new technology and proved to be of high sensitivity and specificity in detecting abnormalities of the biliary system according Bujanda L et al 11and Yeh TS et al12.Before the invention of MRCP diagnosis was made by ERCP and PTC ,ERCP detect low injuries and PTC detect high injuries ,PTC have disadvantage of possibility of failure when the biliary system is not dilated according to results of MAM IbnOuf et al4, Bujanda L et al 11and Yeh TS et al12.

MRCP have completely replaced ERCP and PTC in the diagnosis of biliary injury, ERCP should not be considered as tool of diagnosis, unless MRCP is not available.

Regarding classification of IBDI injury,In our study EII and EIII, together were 72.5% and E1 were 20%, similar to results of IbnOuf et al4 were portahepatis injuries were 62.5% and injuries at the level of the cystic duct E1 26.3% , In comparison to Jayasundara JAet al6 results which showed both EII and EIII 57% significantly less than our injuries and a higher rate of E 1 were 27% which is more than our E I injury,and also showed EIV injuries in 16% of patients ,there was no EIV injuries in our study .This is probably because of difference between mode of injury in OC and LC according to Ibnouf et al 4. Open cholecystectomy injuries is associated with high ductal injuries specially just below the confluence and portahepatis collectively EII and EIII, while laproscopic cholecystectomy is associated with diathermy heat transfer, late tissue necrosis affecting unpredictable length of biliay system can reach to the right and left hepatic ducts i.e EIV injuries . However in both LC and OC overtraction may lead to inappropriate placing of clips or ligatures. There are overall commonalities of injuries when comparing them to Seeliger H et al 8and Woods MS et al13, although specific type E classification was not reported.

Patients who underwent definitive managements were 39 patients ,our results were similar to results of Sicklick et al7which showed 86% underwent Roux en Y HJ reconstruction,(11%) underwent stenting for partial injuries,(1.5%) underwent end to end anastomosis. Also there is commonalities between our results and Seeliger H et al 8results showing 76% underwentRoux en Y HJ including CHD transection and strictures and 22% underwent stenting for Type A and Type D and cystic duct leaks. In comparison to Woods MSet al13, 18% underwent endoscopic stenting including all of type A and type D .Sixty five% underwent Roux en Y HJ (including 93% of complete transections and 60% of strictures), while 21% underwent end to end anastomosis (including 40%of strictures and 7% of transections), 36% of patients who underwent end to end anastomosis due to stricture required additional treatment and 52% of patients who underwent end to end anastomosis due to transections required further surgical intervention. In comparison to results of Karvonen Jet al14 69% of patients were treated surgically byRoux en Y HJ. Ninety eight percent of them were major injuries, including tangential lesions of common bile duct and total transections, were treated operatively.4% treated primary repair over T tube.. All the cystic duct leaks (8%) of injuries were treated endoscopically with a 90% success rate. 19 % of patients had strictures of bile duct 88% of them were treated successfully with ERCP stenting and dilataion. According to preference and availability of radiological expertise there are specialized centers which advocates stenting for strictures and resort to surgery when it fails, while other centers advocates surgical therapy for strictures, since ERCP stenting and dilatation has significant failure rates.

In Ibnouf et al4 only 50% underwent Roux n y HJ, and 50% of patients were stented , that's because ERCP was needed for diagnosis at that time and MRCP wasn't available and attempt for stenting was done even if injury is complete injury, stent was inserted even in completely transected CBD or CHD.

In our study seven patients (63.6%) of the 11 patients diagnosed as strictures managed initially by ERCP stenting and dilatation more than 3 times, but failed to dilate the stricture, six patients(54.5%) had an episode of cholangitis during the management at least for once. In many studies of radiological management of IBDI complete transections were referred for direct surgery as in Mohammed Salih et al¹⁵ Ahmed Abdel-Raouf et al¹⁶. ERCP stenting should only be done in patients with biliary continuity and better to refer patients with complete transections to surgical unit for surgical reconstructions.

In our study fifteen patients (40.1%) developed complication, similar to Sicklick et al⁷, were (42.9%) sustained at least 1 postoperative complication. In comparison to Sicklick et al⁷our results showed higher wound infection, but similar intra abdominal suppuration, and higher fistula formation.

In comparison to Mihăileanu et al¹⁷ our results showed lower intraabdominal suppuration, wound infection, and cardio-renal-pulmonary complications, while fistula formation in our result was higher.

Wound infection was treated with frequent dressings cultures and antibiotics Three of our patients who developed biliary cutaneous fistula, their biliary fistula closed within 2 months, their transhepatic drain was left for 2 months in these patients rather than 6 weeks.

Patient who underwent primary end to end anastomosis of CHD, developed anastamotic dehiscence after 3 days of surgery ,she developed massive biliary peritonitis with 7 days, patient was then explored, ischemia and retraction of ends of CHD, T tube was still connecting the two ends. Peritoneal wash and two drains were put in the right hypochondrium, patients condition stabilized within four days.

Mortality rate is 12.5% in our study. In comparison to Siclick et al⁷(1.7%) and Mihăileanu et al¹⁷(6%) and (1.6%) Slater K et al¹⁰andKarvonen J et al (3%)¹⁴, our mortality is higher.

Three patients (7.5%) died due to sepsis condition started as fistula formation, followed by intra abdominal abscess collection. One of these patients sustained the biliary injury two years back but refused definitive surgery she had liver cirrhosis and intraoperative hepatolithiasis was detected during the reconstructive surgery. The other 2 patients sustained their injury 1 and a half month prior to their surgery.

One patient (2.5%) died due to massive pulmonary embolism 4 hours after surgery. One patient (2.5%) died postoperatively due to hepatic failure: deterioration in liver functions and hepatic encephalopathy. Patient presented 1 months after injury with cholangitis and liver multiple abcess, and large amount of pus in the biliary tree reconstructive surgery was done for her after 4 months most of liver was found cirrhosed, patient developed deterioration of liver function and hepatic encephalopathy, after surgery she developed deterioraion in liver function ,impaired conscious level patient died after 11 days of operation. Total hospitalization days ranged between 14 days and 1months, the median was 18 days comparable to prompt evaluation of liver function followed by imaging. ? Early referral to a tertiary care center with experienced hepatobiliary surgeons and skilled interventional radiologists is necessary to assure optimal results. ? ERCP should only be attempted when there is biliary continuity evident on MRCP. ? Roux en Y HJ reconstruction using the Rodney Smith technique is the most used modality of management. ^{1 2}

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Figure 1: ?

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