Iatrogenic Major Bile duct Injuries Injury

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Through out the last decade we used to receive at ibn Sina Hospital a steady rate of referrals of iatrogenic major bile duct injuries (IMBDIs) which had been inflicted mainly during open cholecystectomy[1]. This was the real motivation for designing this review to reflect on the situation in the international literature. The WHO in 1948 defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity"[2]. Towards the eve of the last century globalization had led the way towards best quality in all professions with special reference to quality of life[3, 4]. Infection and bleeding are the recognized complications of surgery. However, IMBDI remains the most disastrous complication that leads to major morbidities and sometimes mortality. Bile duct injury was estimated as 0.1-0.3% and 0.4- 0.6% in open and laparoscopic cholecystectomy respectively[5, 6, 7, 8, 9]. This rate may reach 1.4%[10,11] with mortality as high as 11%[12]. The best management ought to be based on the best evidence, personal expertise and available facilities. Hence, we started collecting the relevant data for this review.

Key words: Iatrogenic, Bile duct injuries, Cholecystectomy, Hepatico-jejunostomy.

Objectives: To verify the current rate of IMBDI, evaluate its outcome and find the evidence of the best surgical management in the international literature.

Methods: Search of Medline and Pubmed for studies on iatrogenic major bile duct injuries. Because of the lack of single and double blind randomized controlled trials in such disastrous injuries we searched for category 2 evidence according to Howes et al[13]. We concentrated on evidence on correct incidence, new interpretation of aetiology of IMBDIs and out come of the best management.

Inclusion criteria: Peer reviewed articles, multi-centric and large population studies followed by surgeon's series were searched for incidence and outcome of management.

Exclusion criteria: Biliary strictures complicating liver transplantation, chronic pancreatitis, malignancy, bile duct injury due to trauma other than surgery were excluded. Also, minor bile duct injuries and bile leak treated with endoscopic stenting with or without rendezvous technique[14] (rail-roading of strictures combining PTC and ERCP) were excluded. Small size surgical series that reflect personal experience which does not add to best evidence were as well excluded.

Reviews

Six prospective studies, 36 retrospective population-based retrospective audits and major case series with more than 94 major hospitals and eight national population based studies of open and laparoscopic cholecystectomies were reviewed. Bias of some studies was found out. Main pros and cones of intraoperative cholangiogram (IOC) were clarified. Update of the aetiological understanding with regards to training competences, and complication rate after construction was calculated and the evidence of best management of IMBDIs was worked out.

Incidence of IMBDIs

Gentileschi P et al.[15] in 2004 reported the magnitude of IMBDI in Rome province. They compared results of a questionnaire designed to collect data from 13 centres in a retrospective limb from 1994 to 1998 with a prospective limb of data collection in an audit that ended in December 2001. They found that there were no differences in rate of IMBDI, conversion and mortality rate between the two groups. They found that in 137 18 laparoscopic cholecystectomies (LCs) there were 33(0.24%) IMBDIs (half of them in each limb) resulting in a total of 4 (12.1%) deaths. Elective calcular cholecystitis was the diagnosis in 9(27.3%) of the 33 IMBDIs with no adhesions or congenital anomalies. Direct injury occurred in 24(72.7%), diathermy in 7(21.2%) and wrong clipping in 2(6.1%). There was no significant difference in the retrospective limb and prospective audit. The bias in this study is the lower number of responses in the retrospective limb. This is probably because the surgeons who had had injuries do not like to expose their failures. Nusso G[9] reported the incidence of bile duct injury (BDI) as 0.45% (and 0.36% for IMBDI). Nevertheless, this data shows that there is no differences in outcome of laparoscopic cholecystectomy in eight years time suggesting that IMBDI is a ***"stable phenomenon[14]"*** because ***"increasing experience in the prospective audit did not affect the overall incidence of bile duct injury[14]"***. High incidence was reported after analysis of 1011 open cholecystectomies (OCs) and 4332 LCs to be o.7% and o.8% respectively16. Higher incidence

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of 5% was reported in a review of >114000 patients from 40 different case studies[17].

Impact of training

IMBDI witnessed a sharp rise during the shift from open to laparoscopic cholecystectomy (OC, LC), thereafter, it declined in a low plateau level. This was well shown in a cohort[18] of 30211 patients who had either OC or LC resulting in 47 IMBDIs at a rate that increased "from0.04% in 1989 to 0.24 in 1991, then decreased to 0.11 in 1993".

The impact of training on the incidence of IMBDIs was obtained from a questionnaire to 3657 USA surgeons either qualified between 1980 and 1990 i.e. trained in LC after completion of the residency program (group A) or 1992-1998 i.e. trained in LC during their residency program (Group B) aiming at finding out whether residency training modifies the learning curve and decreases IMBDIs and to find out the relation of IOC with IMBDIs[19]. Only 1661(45%) surgeons responded. During the first 50 LCs group A had 40% of the injuries compared to 22% in group B. On the other hand 30% of injuries in group A and 32.9% in group B occurred after >200LCs. IMBDIs were recognized during surgery using IOC compared omitting IOC in 80.9% and 45.1% respectively. The high non-respondents rate might have reduced the rate of IMBDIs in the study. Yet, residency program seems to reduce the frequency of injuries but trained residents are not immunized against IMBDIs. This is probably validated by retrospective study of Nuzzo G et al[9] which was conducted in 184 hospital in 56591 LCs resulting in 235(0.42%) bile duct injuries among which there were 188 cases with no obvious risk factor for the injury i.e. unacceptable injuries. They reported "*The incidence of BDI significantly decreased with increasing number of LCs performed, ranging from 0.9% for surgeons who had performed fewer than 150 LCs in the 3-year period to 0.3% for those who had performed more than 450 LCs*". On the contrary, it seems that IMBDIs after 200LCs are not related to lack of experience but reflect an inherited problem in the LC. This is supported by a population based study[10] that concluded "*increasing experience (during 5 years period) was not related to the incidence of biliary tract injury during LC*" and a community survey[20] that proved the learning curve is not really important for timing the injury. Accordingly, bile duct injury was explained by Stewart L et al[21] to be due to errors of visual perception. However, difficult dissection in acute inflammation, dense adhesions and bleeding are incriminated to the major predisposing factors IMBDIs[22].

Role of IOC

IOC was reported in survey of 9,000 LCs in Belgium[23] to detect 68% of bile duct injuries compared to 32% when it was not done, and in a prospective study of 10,174 patients in Switzerland[23] IOC was able to help recognizing 75% of cases of bile duct injuries. It was also reported that IOC detected 81% of bile duct injuries compared to 45% detection rate in those who didn't undergo IOC[14]. Thus, in a total of 22,831 IOCs in the above three studies[19, 23, 24] it was possible to recognize an average of 74.6% bile duct injuries during the primary surgery. This gives good clinical evidence that IOC helps early detection of bile duct injuries, early repair; reduced costs related to prolonged hospitalization, further morbidities and reduce chances of facing a legal charge of negligence and incompetence. On the other hand, a controlled study of 2038 LCs reported excellent results without performing IOC[25]. This bring us back to the hypothesis of bile duct injuries as inherited problem due to errors of visual perception[21] that trigger a sequence of avoidable tragic morbidities which may culminate in death. For this reason, bile duct injuries should not be considered as a recognized complication of biliary surgery but as a result of lack of attention, reluctance to convert when it is difficult and/or unnecessary high speed and over confidence.

A retrospective cohort in Washington State Hospital from 1991 through 1998 on 30,360 LCs performed by 3,447 surgeons in 138 hospitals, resulted in 76 IMBDIs (1: 400) were identified after search for reconstruction up to 90 days after LC[26]. There was no significant difference between patients in the bases of demographics or hospital variables. The experience of the surgeons was classified into early <20 middle 21-36 and high 37-75 operations. IMBDIs occurred in 3.2/1000 LCs in the early case order of surgeons compared with 1.7/1000 in the high group (P 0.01) , but there was no significant differences after case order greater than 20. The rate of IMBDIs in LCs without intraoperative cholangiogram (IOC) was 3.3/1000 compared with 2.0/1000 LCs with IOC (P 0.02). However, surgeons using IOCs in >75% of LCs had an injury rate of 2.2/1000compard to 1.8/1000 among those who use IOCs in >90% of LCs. The injury rate among those who use IOCs in >75% of LCs was 1.6/1000 compared with 6.3/1000 among those who do not use IOCs. Therefore surgeon's experience and IOC were

independent predictors for IMBDIs. After controlling patients and surgeons factors in another nationwide retrospective study of 1,570,361 cholecystectomies reported 7,911 (0.5%) BDIs. 2,380(0.39%) BDIs in 613,706 cholecystectomies with IOC compared to higher rate of 5,531 (0.58%) BDIs in 956, 655 cholecystectomies without IOC[27]. A population-based study in 2006 composed of 152,776 Cholecystectomies in the Swedish Inpatient Registry resulting in 613(0.4%) BDIs concluded that "*Older age and male sex increased the risk of BDI, whereas intraoperative cholangiography was protective*"[28]. Unfortunately, IOCs is usually performed to detect CBD stones but not to find whether IOC prevents IMBDI or not. To find out whether IOC prevents bile duct injury or not requires a double blind prospective study that may breech ethics. However, the large population studies[25,26,29] and the previously discussed three studies[19,23,24,28] gave good evidence based advice that surgeons have to perform IOC to reduce the frequency of IMBDIs, but this does not spare the need for attention, and careful demonstration dissection to avoid bile duct injuries. Usually IOC is performed for detection of CBD stones and to clarify the biliary anatomy, but, this is not a guarantee that BDI will not occur in the subsequent events of surgery. This is supported by Thomas R et al[30] who reported in 2006 in a retrospective review of public malpractice database that 15% of LCs were converted to open cholecystectomies. Of these conversions 60% were to repair BDI, but unfortunately ended in compensations average of $570,956 in favor of the plaintiff. However, in the rest of the 40% the decision to convert was to allow better exposure. In the latter group the verdict was in favor of the surgeon. This indicates that one should not hesitate to convert to open surgery. They concluded that "*the nature of the bile duct injuries suggest that routine IOC is unlikely to make LC safer*", and that "*To minimize the risk of litigation after LC, they recommended that the threshold for conversion to open procedure should be lowered*" Also, a review of 46 IMBDIs 11 out of 16 IOCs were misinterpreted resulting in a total of 80% missed injuries during cholecystectomy[31]. In the Italian National Survey of 184 hospitals which had performed a total of 56,591 LCs it was found that routine IOCs was performed in 10.4 of the units in which 25(0.32%) BDIs occurred (14 recognized during surgery, seven before performing IOC and seven during the ICO procedure itself) compared to selective IOC in 89.7% of the units with 210(0.43%) BDIs (93 detected during surgery, 14 at cholangiography) but there was no statistical difference in incidence of BDIs in the two groups[9]. Similarly, the Physicians Insurers Association of America stated that "*This should concern surgeons, because when LC litigation data are compared with litigation data for open cholecystectomy, it appears patients are much more willing to sue for an adverse outcome after LC*[32]". The same association reviewed 324 LC claims and found 67% due to IMBDIs. 80% of these injuries were missed during surgery. 50% of the claims ended in the favor of the plaintiff for an average of $236,384. Another retrospective review by Kern[33] for public database containing malpractice verdicts and settlements found that in out of 44 legal abstracts 27(61%) cases of IMBDIs ended in 16% mortality rate. In 25 out of the 44 legal abstracts the claims were settled in the favor of the plaintiff for average of $438,000. Both PIAA and Kern reflect that the learning curve theory is not applicable to today's surgeons and all possible efforts should be exerted to prevent bile duct injuries probably by early conversion. This is supported by the fact that open cholecystectomy is associated with 50% lower incidence of BDIs[34, 35]. In contrast, a retrospective study on open and laparoscopic surgery outcomes for discharge data of acute care hospitals in Maryland concluded that "*the operative mortality associated with laparoscopic cholecystectomy was less than that with open cholecystectomy*"[36]. On the other hand The Southern Surgeons Club[37] reported in a prospective analysis of 1,518 laparoscopic cholecystectomies, complication rate comparable to that of open cholecystectomy. Also, in a review of 40 series with sum of 11,4005 LCs the frequency of IMBDIs was 561(0.5%) with 41.8% ending in biliary-enteric anastomosis[38]. This study concluded that "*the mortality and morbidity of LC are similar to that of OC*". The relative short follow up period probably reflect some weaknesses in these studies because as time passes more bile duct strictures tend to appear, and further re-strictures, biliary cirrhosis and recurrent cholangitis occur in the previously repaired ducts.

Outcome of repair

The outcome of management of bile duct injury is proportionately related to the severity of the injury. The severity of injury has been classified by different researchers like MICHEK J et al[39] and Bismuth[41]. Subsequently A four-grade rating system was published [5,42,43] classifing

injuries from type A to type E which made Bismuth's classification much more comprehensive. Type A is bile leak from minor ducts like cystic duct and duct of Lushka. Type B is stricture of the aberrant right sectoral hepatic duct. Type C is transaction of bile duct. Type D a lateral injury to an extrahepatic bile duct, potentially requiring a major reconstruction. Type E was further subclassified into E1 to E5.

Injuries occurring at LC are more severe than in open cholecystectomy. Strasberg E3 to E5 injuries occur in 31% of LC against 12% of open cholecystectomy[44]. Nevertheless, the majority of these injuries will be missed during OC and LC even when IOC is performed. This is evident in a review of 131 IMBDIs (62 in OC and 64 in LC)[43].

Management of IMBDIs

Before construction patients must be stabilized and bile leak should be drained. The type of injury dictates the type of repair. Biliary-enteric anastomosis is a demanding surgery. The mean mortality rate of 15 case series[45] composed of a total of 602 IMBDIs with a follow up period ranging from 12-80.4 months was 17(2.8%). In presence of excellent experience good results will be expected with early repair. On the contrary, poor results are associated with delayed referrals, biliary peritonitis and associated vascular injury or other co-morbid factors resulting in as high as 9.4% mortality rate[22]. Pellegrini CA[46] et al studied 50 patients with post–reconstruction (hepaticojejunostomy and hepaticoduodenostomy) in bile duct strictures in whom 40% suffered recurrent cholangitis, 30% obstructive jaundice and 17% pain. Symptoms appeared in 67% within two years and 90 % within seven years resulting in 25% chance of recurrence after the initial reconstruction with two (4%) post operative mortalities. They concluded that there was no evidence that prolonged stenting had contributed to a good result. Similarly it was reported[47] that the mortality rate in 39 cases of Bisthmus type III and IV to be 25%. Delayed diagnosis leads to death due to sepsis[48] and with time some patients develop either cholangitis or liver fibrosis[49]. The best time for management is during surgery as validated by the combined 3 years retrospective (25,007LCs) and 8 years prospective(6,488LCs) study[50]. Although hepaticojejunostomy is the gold standard treatment for IMBDI, its commonest complication is stricture at the anastomotic line. The higher the injury the most frequent and most difficult is the resulting stricture[51] (Table 1).

Table 1: Outcome of IMBDIs

Series	Follow up period	IMBDI	Complications	Mortality
Barrow PJ et al 2007[56]	13 (1-64 months)	11	1 (Stricture)	1(9%)
Wu JS et al 2007[59]	3.4(0.25-10 yrs)	103	22(12.5%)	--
Bektas H et al 2007[60]	---	74	35(26%)	3(3%)
Conzo G 2005[58]	---	51	----	5(10%)
Ersumo T[62]	6 yrs	22	Frequent	3(13.6%)
Yang FQ et al[63]	6 months - 9 yrs	182	11(6%)	10(5.4%)
Mercado MA et al[64]	---	180	17(3.8%)	3(1.7%)
et al[65]Palacio-Vélez F	12 months	54	3(5.5%) reoperated	4(7.2%)
Al-Ghnaniem R et al[55] 2002	80.4 months	48	11(22.9%)	1(2%)
Abdel wahab M et al1996[67]	36 months	33	4(11%)	2(6%)

In long-term follow-up, most of the surgically repaired injuries will have a successful outcome as measured by standard clinical parameters, but, unexpected morbidities will be picked in studies of standard quality of Life. In such studies a standardized questionnaire to100 healthy well matched post LC controls and 89 patients who had successful surgical repair of IMBDI at the Johns Hopkins Hospital between 1990 and 2000 was studied[43]. QOL scores were comparable in the two groups in physical and social domains but were significantly different in the psychological domain. All QOL domain scores were significantly lower in the patients who pursued a lawsuit versus those who did not. The decreased QOL assessment in the psychological dimension may be attributable to the prolonged, complicated, and unexpected nature of these injuries. However, Sarmiento JM[32] in his five year follow up of 59 patients of repaired IMBDIs couldn't demonstrate such a difference.

Working models and protocols should be developed to prevent BDIs. Such models were successful to reduce BDI from 0.27% in early cases (6/2224) to zero (0/2967)[52]. Great care

should be taken because the prolonged hospitalization for repair and the high morbidity may not only double the cost of treatment 4.5 to 26 times the cost of successful cholecystectomy[66]

but doubles the chance of death three times the rate of death in successful cholecystectomy in the following few years[67] (Table 2).

Table 2: Complication rate of repair of IMBDIs

Series	Number of repaired IMBDI	Complication rate (Stricture and/or cholangitis
Walsh RM et al [34] 1998	34(47%)	18(25%)
Walsh RM[53] 2004	133	46(35%)
*MacFadyen BV Jr[38] 1998	561(0.5%)	(4.9%)
Topal B et al[47] 1999	16	4(25%) one of them died
Johnson SR et al[49] 2000	21(77.8%)	7(33.3%)
Tsalis KG et al [54]	7/12	2(25%) one of them died
Slater K et al [44]	131	2(1.5%) one of them died
Chaudhary A et al[51]	41	3(7%) one of them died
Karvonen J 2007[57]	14(0.38%)	3(26%) one of them died
Al-Sebaye MI[61]	17	7(41%)

*Review of 40 published case series (total of 114005 cases

Conclusion

Cholecystectomy should not be regarded as simple operation even in expert hands. IMBDI occurs at a rate of 0.4%- 1.4%. It is due to visual malperception and resistance to convert to open cholecystectomy. Factors that predispose to litigation include resistance to convert to open surgery, failure to recognize the injury intraoperatively, treatment failures in immediately recognized injuries, complications that result from delays in diagnosis, and misinterpretation of abnormal cholangiogram. The Outcome of postcholecystectomy biliary injury is related to the technique and timing of the surgical repair. However, complications of repair of IMBDIs increase with time and may culminate in death at earlier time than expected.

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