

MULTIMODAL MANAGEMENT OF BILE DUCT INJURIES AND ITS IMPACT ON QUALITY OF LIFE.

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Aim: The aim of this study is to present long-term results of endoscopic and surgical management of patients with bile duct injury (BDI) and the impact of such injury on quality of life.

Patients and methods: Patients with BDI during the period 2000-2004 received either endoscopic or surgical therapy according to the type of BDI diagnosed at ERCP. Patients were clinically, laboratory, ultrasonographically followed-up to assess the functional outcome of such multimodal management. The SF-36 quality of life questionnaire was used to assess their quality of life and was compared with a matched control group who had undergone an uncomplicated cholecystectomy.

Results: Surgical, endoscopic, and combined management was offered to 17 (53%), 12 (37.5%), 3 (9.5%) patients, respectively. Management outcome was excellent to good in 19 (59.4%) patients and fair in 13 (40.6%) patients. Biliary leak was encountered in 4 (21.1%) postoperative and liver abscess in one patient post-endoscopic treatment. A total number of 8 (25%) patients required reintervention as a result of initial treatment failure or restenosis. Analysis of actuarial survival in relation to type of injury, type of management and management outcome revealed that outcome was the only factor that significantly affected survival. Quality of life of all patients regardless of outcome was significantly lower than corresponding patients with uncomplicated cholecystectomy.

Conclusion: Although good functional outcome with no mortality can be achieved from multimodal management of patients with BDI, long-term results are characterized by recurrent morbidity, short survival, and a low quality of life.

Keywords: iatrogenic, stents, hepaticojejunostomy

INTRODUCTION

Although cholecystectomy is one of the most common surgeries performed by general and hepato-biliary specialists it is still carries a considerable risk for injuring the bile duct. The reported incidence of bile duct injury (BDI) with open cholecystectomy ranges from 0.1% to 0.9%. Moreover, the incidence of BDI has increased since the introduction of laparoscopic cholecystectomy to an alarming level ranging from 0.2% to 2.4%.⁽¹⁻⁶⁾ Initially this increase has been attributed to the learning curve of laparoscopic cholecystectomy. However, the incidence has not declined after the learning phase as a substantial number of injuries, exceeding 30%, still occur after acquiring adequate experience.⁽⁷⁻⁹⁾

In theory, numerous mechanisms are responsible for BDI but in practice the main cause is misidentification of the

bile duct, which has been reported to be responsible for around 40% of injuries.⁽¹⁰⁾ However, still, a large number of injuries reaching up to 30%, the mechanism of injury remains unknown.⁽¹¹⁾ A recently established risk factor for bile duct injury, especially with laparoscopic cholecystectomy, is operating on patients with acute cholecystitis.^(12,13)

Re-establishing adequate continuity of the biliary tree after precise assessment of the degree of injury is the ultimate goal of management which, nowadays, can be achieved through a multi-modal approach.⁽¹⁴⁾ In this approach endoscopy in the form of endoscopic retrograde cholangiopancreatography (ERCP) is used for the initial assessment of injury followed by either immediate endoscopic therapy in the presence of communication with the proximal biliary tree or surgery when proximal communication is found to be lost.

Reports of surgical repair report satisfactory functional results with approximately 25% of patients requiring redo surgery.⁽¹⁵⁾ However, long-term follow-up has shown a sustained reduction in quality of life (QoL). Patients with BDI, even in the presence of excellent functional results, have lower quality of life affecting both the physical and emotional domains.⁽¹⁶⁻¹⁸⁾

The aim of this study is to present the functional results of multimodal approach to BDI and the impact of such an approach on QoL through a prospective analytical study.

PATIENTS AND METHODS

Patient population. The study population was composed of all patients referred to the Endoscopy and Motility Unit, Department of Experimental and Clinical Surgery, Medical Research Institute, University of Alexandria for initial assessment and definitive multimodal management during the period 2000-2004.

Exclusion criteria. Patients were excluded from the study if they were found on ERCP to suffer from cystic duct leakage secondary to a missed (undiagnosed preoperatively) stone in the bile duct.

Clinical and diagnostic work-up. Patients were interviewed, clinically and ultrasonographically examined in order to assess mode of presentation and presence or absence of leakage, biliary dilatation, intra-abdominal collection and/or sepsis (peritonitis).

Laboratory investigations. Blood samples were withdrawn for routine haematological and liver function tests and used for initial and follow-up assessment.

Injury severity assessment. The severity of the injury was classified during the cholangiographic phase of ERCP according to the Amsterdam criteria⁽¹⁹⁾:

Type A lesion was defined as leakage from the cystic duct or peripheral hepatic radicals.

Type B lesion was defined as leakage from the common bile duct with or without concomitant biliary strictures.

Type C lesion was defined as a stricture of the CBD without leakage.

Type D lesion represented a complete transection of the CBD, with or without loss of a segment of the bile duct.

Multimodal protocol. Patients with type A injury were endoscopically managed by inserting a 10 French 9-11 cm long stent for six weeks. If a stricture was observed to develop when removing the stent after six weeks the following protocol designed for type B and Type C was then applied. Patients with type B and type C injury were initially endoscopically managed with balloon dilatation of their stricture, if present, up to 8 mm. Two 10 French 9-11 cm stents were then inserted to maintain biliary dilatation. The stents were then exchanged every three months for a

period of one year. If a residual stricture was seen after one year patients were advised to undergo surgery. Patients with type D injury were surgically managed with no preoperative percutaneous transhepatic biliary drainage. Three type of repairs were performed: direct repair, choledochoduodenostomy, or hepaticojejunostomy.

Clinical follow-up. Objective outcomes (re-interventions, hospital admission, ultrasound examination, and laboratory data) were assessed by reviewing data collected at the regular outpatient visits. Patients were asked whether they suffered from attacks of pain, fever, chills, or jaundice.

Quality of life. Quality of life was assessed by the Short Form Health Survey (SF-36) questionnaire. Patients were asked to fill the SF-36 questionnaire after hospital discharge and settlement at home among family members. The SF-36 questionnaire consists of eight subscales: Physical Functioning, Role Functioning, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. On the basis of these subscales, component summary scores can be calculated to provide a global measure of physical and mental functioning, respectively. The Physical Component Summary (PCS) consists of the subscales Physical Functioning, Role Functioning, Bodily Pain, and General Health; the Mental Component Summary (MCS) comprises the subscales Vitality, Social Functioning, Role-Emotional, and Mental Health. QoL scores of patients with BDI were compared with scores from a matched control group of patients who had undergone uncomplicated cholecystectomy.

Statistical analysis. Fisher's exact test was used for comparison of nominal data and is presented. The unpaired t-test used for comparison of two continuous unmatched data sets and is presented as mean \pm standard deviation. Actuarial survival data was plotted using Kaplan-Meier technique and comparisons between subgroups using Log rank test. All comparisons were two tailed and a 5% level of significance was chosen.

Ethical considerations and informed consent. The study protocol was approved by the local ethical committee. The study was explained to each patient and his/her informed consent obtained prior to entry into the study.

RESULTS

Patient population. A total number of 32 patients were referred to the unit in the five year period. Their mean (\pm SD) age was 40.19 (\pm 11.9) years. Most of the patients were females representing 81.25% of the patient population as shown table 1. Only 3 (9.5%) patients had BDI secondary to laparoscopic cholecystectomy.

Clinical presentation and ultrasonographic findings. The most common presentation was jaundice which was present in 26 (81.5%) patients followed by biliary leakage in 14 (43.75%) patients. The various combinations of presentations are shown in Table 1. Ultrasonographic examination was able to detect positive findings in 22 (68.75%) patients in the form of proximal dilatation of the biliary tree or fluid collection (bilomas) as shown detail in Table 1.

Laboratory findings. Patients presenting with jaundice, apart from elevated mean serum bilirubin, had markedly elevated mean alkaline phosphatase and mean liver enzymes as shown in Table 2. On the other hand, patients not presenting with jaundice had a slight increase in mean alkaline phosphatase and normal mean liver enzymes as shown in Table 2.

ERCP findings. Radiological evaluation of the severity of the bile duct injury performed at ERCP revealed that 6 (18.8) patients suffered from biliary leakage from the main bile duct (Type B), 7 (21.9%) patients with bile duct stricture (Type C), and 19 (59.3%) patients with bile duct transaction (type D) of which 8 patients had concomitant biliary leak from the proximal transected proximal biliary tree.

Management. Seventeen patients with Type D injury were surgically managed with a bile duct repair in 5 patients and with a bilio-digestive anastomosis in 12 patients as shown in Table 3. Twelve patients were endoscopically managed as they suffered from type B and C injury (Table 3). Three patients had combined therapy of which two patients with Type D injury had initial surgical management (bile duct direct repair and choledcho-duodenostomy) followed by endoscopic management. The third patient with type C injury had a bile duct repair after initial endoscopic therapy.

Procedure related events. There was no procedure-related mortality. Postoperative biliary leakage occurred in 4/19 (21.1%) patients who had surgery; the biliary leak resolved spontaneously in all four patients. One patient who was managed endoscopically developed a large liver abscess in the right hepatic lobe which was successfully surgically drained.

Outcome. As shown in Table 3; 19 (59.4%) patients had good to excellent results requiring no further intervention while 13 (40.6%) patients had fair results with recurrent bouts of jaundice necessitating redo intervention in 5 (15.63%) patients (3 surgery and 2 endoscopy) with ultrasonographically proven postoperative biliary dilatation secondary to re-stricture.

Quality of life. Patients with BDI attained significantly lower scores in all eight subscales of the SF-36 quality of life questionnaire than corresponding patients who had an uncomplicated cholecystectomy as shown in Table 4. Patients with bile duct injury, regardless of management type or outcome, scored significantly less in both physical and mental component scales than patients who had an uncomplicated cholecystectomy, 50 ± 24 versus 71 ± 18 (unpaired t-test: $p < 0.01$) and 49 ± 26 versus 79 ± 15 (unpaired t-test: $p < 0.01$), respectively as shown in Fig. 1.

Patient survival. After a median of 26.8 (min – max: 3.9 – 60.9) months of follow-up 12 (37.5%) patients died. Most of the mortality occurred in the early phase of follow-up as 10 (31.25%) patients died during the first year of follow-up. Analysis of actuarial survival in relation to type of injury, type of management and management outcome revealed that outcome was the only factor that significantly affected survival (Log rank test: $p < 0.05$) as shown in Fig. 2.

Table 1. Patient characteristics (32 patients).

Item	
Mean \pm SD age in years	40.19 \pm 11.9
Male : Female	6 : 26
Laparoscopic cholecystectomy (%)	3 (9.5)
Presentation (%)	
Jaundice	15 (46.9)
Jaundice and biliary leak	9 (28.1)
Biliary leak	5 (15.6)
Failed repair	2 (6.3)
Sepsis	1 (3.1)
Ultrasound findings (%)	
Bile duct dilatation	19 (59.4)
No specific findings	10 (31.2)
Bile duct dilatation with biloma	2 (6.3)
Biloma	1 (3.1)

Table 2. Liver function tests* (32 patients).

Item	Jaundice at presentation No. = 26	No jaundice at presentation No. = 6
Serum bilirubin	9.4 ± 7.3	0.7 ± 0.1
Alkaline phosphatase†	911 ± 812.7	174 ± 221.2
SGOT	89.9 ± 76.9	35.2 ± 13.9
SGPT	81.3 ± 57.1	35.0 ± 12.0

* Data in mean ± SD

† Normal: 3-13 King Armstrong Units

Table 3. Injury severity, management and outcome.

Item	
Injury severity (%)	
Type B	6 (18.8)
Type C	7 (21.9)
Type D	19 (59.3)
Management (%)	
Surgical	17 (53.0)
Endoscopic	12 (37.5)
Combined	3 (9.5)
Type of surgery* (%)	
Direct repair	7 / 20 (35)
Choledochoduodenostomy	4 / 20 (20)
Hepaticojejunostomy	9 / 20 (45)
Outcome (%)	
Excellent	11 (34.4)
Good	8 (25.0)
Fair	13 (40.6)

* Including patients with combined management.

Table 4. Quality of life assessment.

SF-36 domain scores	BDI	Ch	P value
Physical functioning	60 ± 28	86 ± 14	< 0.01
Physical limitations	36 ± 40	73 ± 35	< 0.05
Emotional limitations	36 ± 43	78 ± 35	< 0.01
Vitality	48 ± 27	70 ± 13	< 0.05
Mental health	57 ± 21	77 ± 12	< 0.01
Social functioning	54 ± 34	91 ± 15	< 0.01
Bodily pain	62 ± 31	85 ± 18	< 0.05

* Data are given as mean ± SD

Abbreviations: BDI, bile duct injury; Ch, uncomplicated cholecystectomy

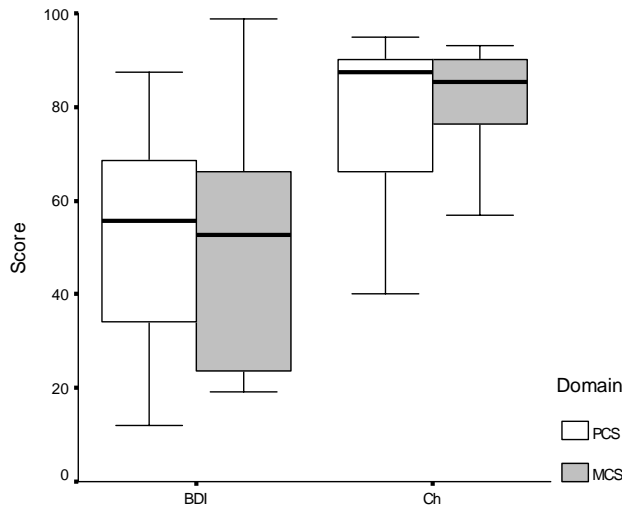


Fig 1. Quality of life scores for the physical component scale (PCS) and mental component scale (MCS). BDI; bile duct injury, Ch; uncomplicated cholecystectomy

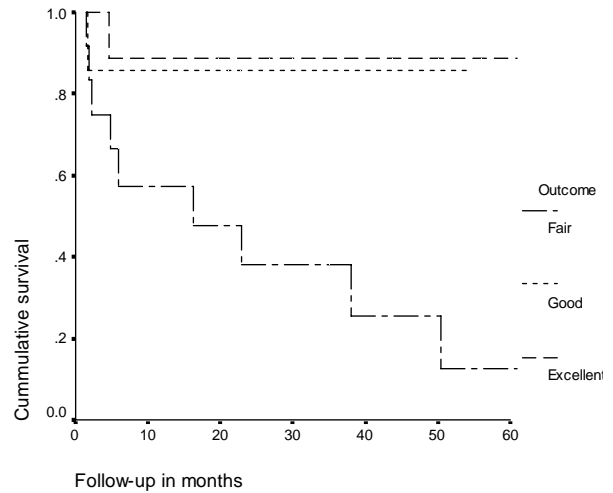


Fig 2. Actuarial survival in relation to management outcome. Log Rank test: $p = 0.015$

DISCUSSION

Although BDI is a benign condition it has a malignant course manifested by its long-term detrimental effect on patients' wellbeing and survival in addition to its large financial burden on the health system. In this series, a small proportion of patients not exceeding 10% sustained a BDI secondary to laparoscopic cholecystectomy, nevertheless, with the continuous increase in the use of laparoscopy the number of patients suffering from BDI is expected to increase. Therefore, every effort should be pursued to prevent or minimize its occurrence.

Awareness of the magnitude of the problem and the fact that BDI is not specific to the learning phase of a surgeon career are primary key points for its prevention. In addition, risk factors and mechanisms leading to injury should be well understood and stressed upon in professional development programmes. The use of intraoperative cholangiography, although does not totally prevent BDI, leads to a significant reduction in its occurrence and should be encouraged at all cost as its maximum effect is only achieved when routinely used.⁽²⁰⁾

Procedure or operative related mortality associated with management of bile duct injury is low, however, morbidity is still high even from specialized centres.⁽¹⁻⁴⁾ A large number of patients suffer from biliary leakage, abscess formation, cholangitis and restenosis which requires reintervention. In this series, a total of 8 (25%) patients required combined management or repeat intervention as a result of initial treatment failure or restenosis. Such high reintervention rates seem to be a constant feature of

patients with BDI when followed from time of injury up to their definitive successful outcome.^(15,25) Multimodal management offers suitable modalities of treatment in such a situation as recurrent endoscopic procedures are well-tolerated and can salvage surgical management in case access to the bile duct is preserved as with a direct repair or a choledochoduodenostomy. However, this should deter surgeons from aiming at creating a hepaticojejunostomy, which is still the preferred method of surgical management as it is associated with the least incidence of restenosis.^(9,26)

QoL after BDI seems to be permanently affected in both its physical and mental domains. This lower QoL is constant regardless of type of management or even its outcome. All published studies which have used the SF-36 questionnaire in the assessment of the QoL of patients with BDI have reported significantly diminished scores in all domains in comparison to a matched control group of patients with uncomplicated cholecystectomy.^(16,18) On the other hand, studies using QoL questionnaires apart from the SF-36 have reported significantly reduced psychological quality of life.⁽²⁷⁾ These findings further stress the importance of preventing the occurrence of BDI as endoscopic or surgical correction, although, capable of producing excellent functional results do not guarantee patients the return of a normal quality of life.

An alarming feature of patients with BDI is their high mortality during the first year of follow-up after hospital discharge. In this series, 31.25% of patients died during the first post-operative year in spite of no in-hospital deaths. This figure is not unique to this study as it is close to what has been found in a nation-wide report on 7911 patients

with BDI from the United States where 26.1% of them died during the first-postoperative year.⁽²⁸⁾ These figures emphasize again the malignant course of BDI and strongly argue for a period of pre-operative biliary drainage during which the associated liver insult and acute inflammation resulting from peri-hepatic bile leak would resolve.^(29,30)

In conclusion, BDI is a serious problem which should be best avoided at all cost. Most patients who sustain an injury to their bile duct will have acceptable functional results. However, BDI will have a sustained detrimental effect on their quality of life.

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