



Management of Postoperative Bile Leak: Tertiary Centers Experience

Mohammed A Omar^{1*} and Alaa A Redwan²

¹Department of Surgery, Qena Faculty of Medicine, South Valley University, Qena, Egypt

²Department of Surgery, Sohag Faculty of Medicine, Sohag University, Sohag, Egypt

Abstract

Background: Bile duct leak is an infrequent but serious disorder. The great majority occurs after hepatobiliary surgery. Early recognition and adequate multidisciplinary approach is the cornerstone for the optimal final outcomes. Traditionally, surgery has been the gold standard for the management of bile leak, but it is associated with significant morbidity and mortality. Biliary endoscopic procedures have become the treatment of choice, as simple, noninvasive procedure, with low morbidity and mortality, short hospital stay, and cost effective, with demonstrated results comparable to those achieved with surgery. We aim to evaluate the optimal management of postoperative bile leak.

Methods: In the period from January 2014 to October 2016, 155 patients with postoperative bile leak referred to our tertiary specialized centers were managed and evaluated.

Results: The definitive management of bile leak was done within 0-143 days. Patients were managed accordingly using, endoscopy in 116 patients (plus percutaneous techniques in 4 patients) and surgery in 39 patients. The endoscopic treatment proved very effective in 94.7% of the patients with simple bile leak and 44.2% of the patients with complex bile leak.

Conclusion: Endoscopic treatment substituted surgery in all simple bile leak cases as a competitive treatment. Surgical treatment was the definitive treatment of complex bile leak; however endoscopy was a mandatory complementary tool in initial management.

Keywords: Bile leak; Post operative; Percutaneous

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*Correspondence:

Mohammed Ahmed Omar,
Department of General Surgery, Qena
Faculty of Medicine, South Valley
University, 83511 Qena, Egypt, Tel:
(002) 0965228628; Mobile: (002)
01064184848;
E-mail: mohamed_ali@med.svu.edu.eg

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Introduction

Bile duct leak is an infrequent but serious disorder. The cause of bile duct leak can be either iatrogenic or more rarely, traumatic [1]. The great majority (95%) occurs after hepatobiliary surgery and the most common cause is related to open and laparoscopic cholecystectomy [2]. Biliary injury occur in 0.1% - 0.2% and 0.3% - 0.8% after open and laparoscopic cholecystectomy respectively [3]. Postoperative bile leak is usually the result of oblivious injury to the bile ducts, inappropriate ligation of the cystic duct stump, or leakage from the liver bed or the drainage site and usually precipitated with a distal block from residual stones or strictures [4]. Minor leakage may stop spontaneously while major leakage may be a serious problem to the patient [5]. These patients present with external or internal biliary leakage resulting in localized or generalized biliary peritonitis [6] 11% - 23% of biliary injuries are diagnosed intraoperatively while the remaining is diagnosed postoperatively or after discharge [7].

Early management in a specialized center is the cornerstone for satisfactory results. Inadequate management usually results in serious co-morbidities and a more difficult repair [8]. Surgery is the best method for the treatment, but it is associated with serious complications and great mortality [9]. Preoperative management ranges from simple drainage and early transfer up to bilio-enteric anastomosis [10]. Minimally invasive endoscopic procedure with evidenced results equal to surgical outcomes became the treatment of choice [9,11]. As compared to surgery, endoscopic treatment may require many sessions, and is not effective in all cases [12]. What is the best management (surgical versus endoscopic) of postoperative bile leak still the major challenging facing surgeons and this work presents the experience of two major tertiary referral centers in Egypt trying to answer this question.

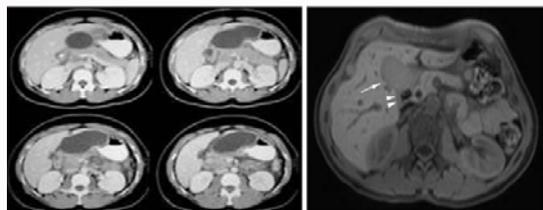


Figure 1: Post cholecystectomy leakage and biloma collection as seen by CT (left) and MRI (right).



Figure 2: Cystic duct leakage evident by ERCP, treated by sphincterotomy and stent.

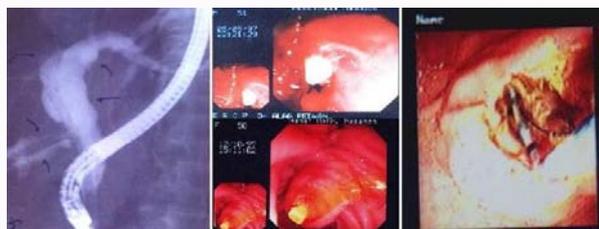


Figure 3: Leakage around misplaced T-tube with papillitis; treated by tube extraction and sphincterotomy and stent.



Figure 4: Minor CBD laceration leakage, treated by endoscopic sphincterotomy and stent.

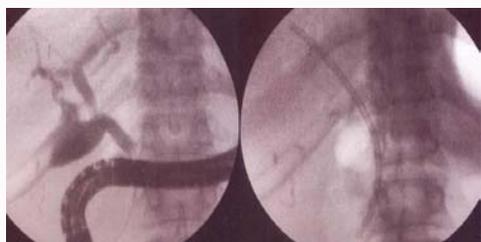


Figure 5: Major CBD laceration leakage, treated by endoscopic sphincterotomy and stent.

Methods

A 155 patients suffering from postoperative bile leak referred to our centers during the period from January 2014 to October 2016, was enrolled in this study. We exclude patients with bile leak from trauma, rupture, associated biliary malignancy or vascular injury.



Figure 6: Major CBD laceration leakage, treated by endoscopic sphincterotomy and stent effluxing pus.



Figure 7: Partial CBD transection injury; treated by endoscopic sphincterotomy and stent.

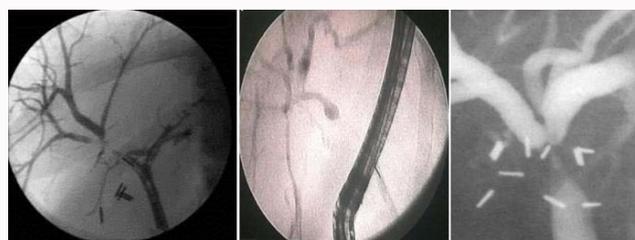


Figure 8: Complex injury cannot be negotiated endoscopically as Rt. Anterior duct transection (left), Rt. sectorial duct transection (middle), CBD transection with loss segment (right).

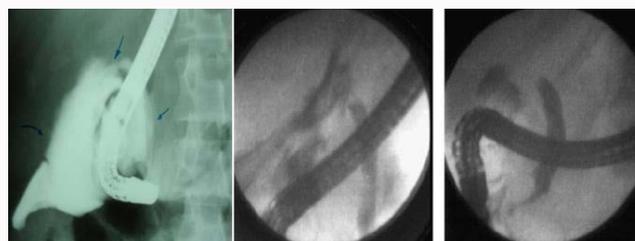


Figure 9: Complex injury cannot be negotiated endoscopically as massive CBD transection injury with loss of CBD continuity.

History, clinical examination, and routine investigations (complete blood count, liver function tests, coagulation parameters and ultrasonography) were done for all patients. Computed tomography (CT) or magnetic resonance imaging (MRI) was done in some selected cases (Figure 1). Bile leak was diagnosed clinically (abdominal pain, fever, distension, nausea, tenderness, jaundice) and radiologically (US and/or CT scan) and was re-confirmed by cholangiogram. Patients were classified simply according to cholangiographic and operative findings into two groups; simple bile leak which include liver bed leak, cystic duct leak (Figure 2), accessory duct leak, leakage around T-tube (Figure 3), and leak with partial laceration of the ductal system (Figures 4-7) and complex bile leak which include complete duct transection (Figure 8 and 9), retained stone (Figure 10 and 11), stricture (Figures 12-14) or anastomotic leak (Figure 15). Patients were managed gradually, starting with the minimally invasive (endoscopic treatment alone or with percutaneous technique) to

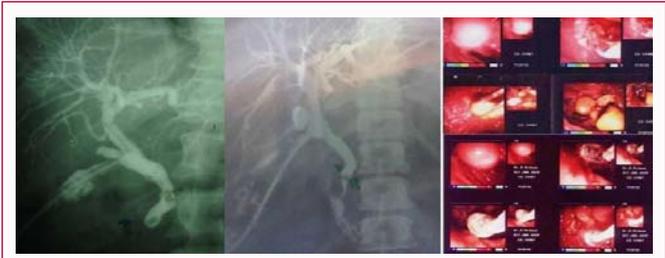


Figure 10: Leakage due to distal CBD obstruction by stones; treated by endoscopic sphincterotomy, stone retrieval by basket and balloon and stent.

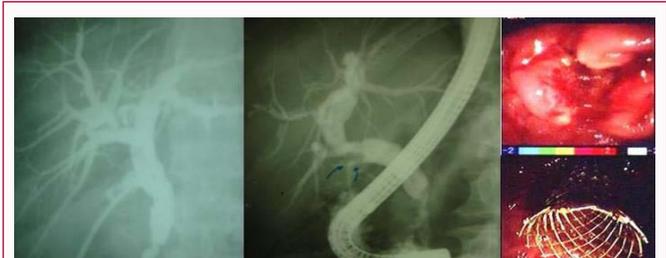


Figure 14: Major leakage due to distal CBD stricture; treated by endoscopic sphincterotomy, dilatation and self expandable metal stent.



Figure 11: Leakage associated with distal CBD retained stones (left), and retained hepatic duct stone (right).



Figure 15: Operative picture for anastomotic leakage treated by redo anastomosis, and post operative MRCP.

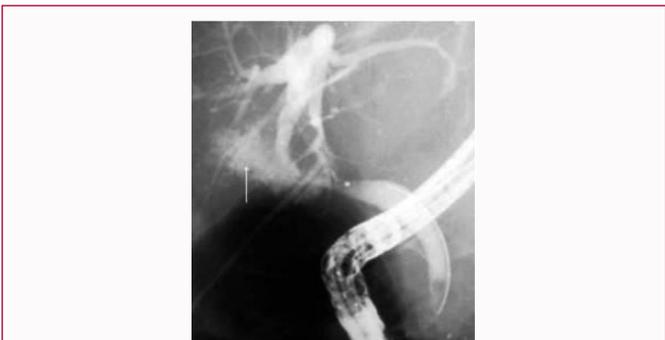


Figure 12: Leakage associated with mid CBD stricture.

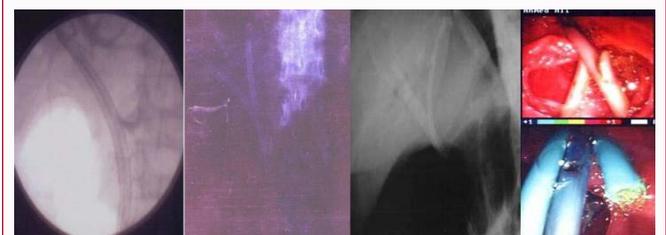


Figure 16: Stents applied for CBD injury was upgraded in size and number as 2, 3 or more CBD stents.



Figure 13: Delayed leakage with stricture/fistula formation (left, middle), treated by endoscopic sphincterotomy, dilatation and stent.



Figure 17: Operative photograph of biliary leakage with a common bile duct stone, treated by drainage, choledocholithotomy and repair over T-tube.

the more invasive surgical technique. Some patients underwent a combination of these procedures. The study protocol was approved by the ethical committee of our hospitals. Also, a written informed consent was obtained from all the patients.

In cases with planned ERCP, when a considerable localized collection was defined, a radiologically guided drainage was done, while when the collection was large and diffuse, open or laparoscopic drainage was done, either before or after the procedure. For simple bile leak, patients underwent combined endoscopic sphincterotomy (ES) plus plastic stent (10F, 9 cm - 12 cm), straddling the site of the leak (Figures 2-7). For patients with bile leak and retained stones, a sphincterotomy, stone removal, and stent insertion was done

(Figure 10 and 11). For patients with bile leak and duct stricture, dilatation and a plastic stent(s) was done (Figure 13 and 14). Repeat ERCP for assessment and stent removal was performed 2-3 months after improvement. Cholangiography was performed to confirm healing and absence of stricture or residual stones and they were managed accordingly (Figure 16). The percutaneous intervention was done in cases of failure of ERCP either in the form of percutaneous transhepatic drainage (PTC) prior surgery or a part of combined procedures (Rendezvous technique). Surgery was done either urgently with large and diffuse collection not suitable for percutaneous drainage or electively after failed (Figure 8 and 9) or inappropriate nonsurgical tools treatment (Figure 17 and 18). Follow up: Third generation cephalosporin antibiotics were given for

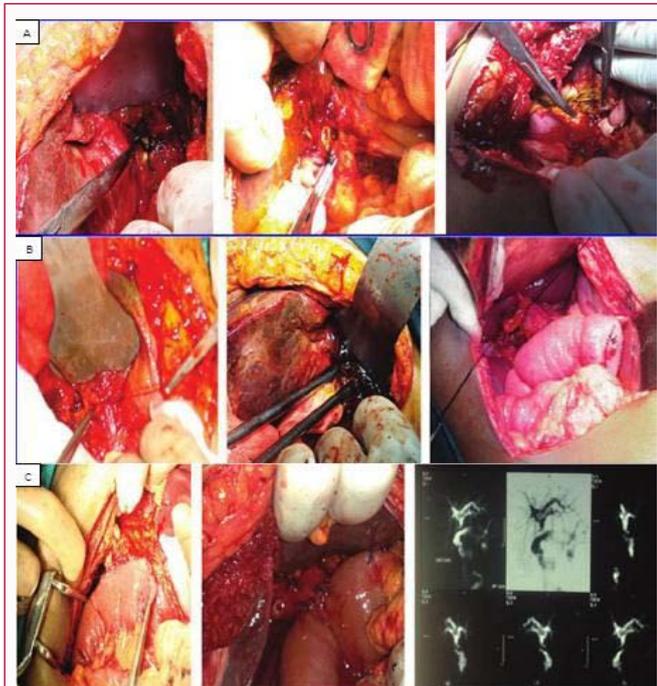


Figure 18: A: Operative field showing ligated, excised common bile duct with many stitches in the porta hepatis; B: Operative dissection of hepatic ducts with Roux-en Y loop hepaticojejunostomy anastomosis; C: Roux-en-Y hepaticojejunostomy completed with postoperative MRCP assurance.

all patients. Patients were discharged from the hospital with clinical and radiological improvement and they were followed up in the outpatient clinic. Main outcome measurements: Successful management was defined by clinical and investigatory improvement and normal ERCP with stent removal with no further complications. Statistical analysis: Statistical analysis was made using the Statistical Package for Social Sciences (SPSS) version 16. Descriptive data are expressed as mean - standard deviation or medians and ranges for continuous variables and as number and percent for categorical variables.

Results

From January 2014 to October 2016, 155 cases of postoperative bile leak were incorporated in this study. There were 70 male and 85 female. 21 cases (13.5%) were previously operated in our centers. The median time for the referral to our hospitals was 8 days (2-87 days) after the first operation. During this period 18 patients (11.6%) underwent one or more subsequent endoscopy or laparotomy. The amount of bile leak ranged from 100-880 ml/day, and the commonest site (56.1%) of external bile follow was the abdominal drain. 149 cases were diagnosed by cholangiogram while the remaining 6 cases were operated urgently without a cholangiogram. Patient’s demographic data were shown in Table 1. Management: 18 patients were initially treated before referral either endoscopically (3 cases) or surgically (15 cases). The definitive management was done within 0-143 days (median 8 days) after the injury. Treatment was done either by ERCP alone or in combination with the percutaneous technique in some cases or surgically (Table 2). Simple bile leak (94 patients): 93 patients were subjected firstly to endoscopic treatment. Successful management was achievable in 89 cases (3 cases assisted with the percutaneous route) and failure to control the leak after a reasonable time occurred in 4 patients where they managed surgically. The last case was subjected firstly to urgent surgery due to biliary peritonitis. Endoscopic treatment exhibited a 94.7% success rate. The leak was controlled in all patients in a mean

Table 1: Patients data.

Characteristics	No. (%)
Patients (M, F)	155 (70, 85)
Age Mean, Range	41.25, 18-73
Previous surgical procedure	
Open cholecystectomy	79 (50.9)
Lap cholecystectomy	34 (21.9)
Open cholecystectomy and exploration of CBD	24 (15.5)
Lap cholecystectomy and exploration of CBD	4 (2.6)
Hepatic resection	8 (5.2)
Whipple procedures	4 (2.6)
Liver abscess surgery	2 (1.3)
Site of external leak	
Surgical drain	87 (56.1)
Abdominal wound	38 (24.5)
T-tube tract	19 (12.3)
No external leak (Biloma)	11 (7.1)
Cholangiographic and operative findings	
Simple bile leak	94 (60.6)
Complex bile leak	61(39.4)
Bile leak with stone(s)	33 (21.4)
Bile leak with stricture	12 (7.7)
Bile leak with duct transection	12 (7.7)
Anastomotic leak	4 (2.6)

period of 3.7 (range 1-19) days. The number of ERCP sessions: mean 1.1 (range 1-3). Percutaneous drainage of bile collections was performed in 11 patients (before ERCP in 8 patients, after ERCP in 3 patients). Complex bile leak (61 patients): 27 cases (44.2%) were managed endoscopically while 34 patients (55.8%) were managed surgically. Bile leak with complete transection of the bile ducts (12 patients): These patients managed surgically (2 cases urgently and 10 cases electively) with Roux-en-Y hepatico-jejunostomy and choledochoduodenostomy as a reconstructive repair. Bile collections was initially drained percutaneously (2 cases) or surgically (2 cases), to stabilize the patient’s condition in cases with removed or slipped drain. Bile leak with stone (33 patients): From 28 patients who were subjected firstly to ERCP, 20 patients were managed definitively with ES, stone extraction, and biliary stent while the remaining 8 cases were managed initially with ES and biliary stent due to intra-hepatic stones, or hugely dilated CBD requiring drainage. After cessation of bile leak, these patients were treated definitively with reconstructive surgery. The other 5 cases were managed firstly by urgent surgery due to biliary peritonitis in the form of choledocholithotomy and repair over T-tube (4 cases) and peritoneal drainage followed by elective HJ (1 case). The number of ERCP sessions: mean 1.6 (range 1-3). Percutaneous drainage of bile collections was performed in 3 patients (before ERCP in 2 patients, after ERCP in 1 patient).

Bile leak with stricture (12 cases): 11 patients were subjected firstly to ERCP. Endoscopic treatment was successful in 7 cases (1 cases assisted with percutaneous rout), and 4 cases were failed dilatation to enough size (8 Fr). They were managed with percutaneous trans-hepatic drainage and elective surgical treatment in the form of HJ after 2-3 months. The last case was managed urgently by drainage followed by elective HJ. Drainage of bile collections was performed in 3 patients, all before (2 patients) or during initial treatment (1 patient). The number of ERCP procedures: mean 2.7 (range 1-5). Anastomotic leak (4 cases): They were treated with redo the anastomosis (HJ), 1 cases urgently and 3 cases electively after drainage (percutaneous = 1 case, surgical = 2 cases). Surgical treatment for bile leak (Table 3 and 4): Definitive surgical treatment was done within 36 days (range 1-98) from injury in 39 patients with 46 surgical procedures. Complications: The median follow-up was 11.5 months (range, 0-30 months). 40 patients (25.8%) showed, at least, one postoperative complication

Table 2: Definitive management of bile duct injury.

Type of bile leak	ERCP	PTC and ERCP	Surgery	Total
	No. (%)	No. (%)	No. (%)	No. (%)
Simple bile leak	86 (91.5)	3 (3.2)	5 (5.3)	94 (60.6)
Complex bile leak	26 (42.6)	1 (1.6)	34 (55.8)	61 (39.4)
Bile leak with bile duct transection	0	0	12 (100)	12 (7.7)
Bile leak with stone(s)	20 (70)	0	13 (30)	33 (21.4)
Bile leak with stricture	6 (50)	1 (8.3)	5 (41.7)	12 (7.7)
Anastomotic leak	0	0	4 (100)	4 (2.6)
Total	112 (72.2)	4 (2.6)	39 (25.2)	155 (100)

Table 3: Type and time of surgery.

Type of leak	Urgent Surgery		Elective Surgery
	Preliminary	Definitive	Definitive
Simple leak			
Complex leak	0	1	4
Bile leak with bile duct transection	2	2	10
Bile leak with stone(s)	1	4	9
Bile leak with stricture	1	0	5
Anastomotic leak	2	1	3
Total	6	8	31

Table 4: Surgical procedures for bile leak.

Surgical treatment for bile leak	No.
Drainage and peritoneal toileting only for biliary peritonitis	7
Drainage, and CBD repair over T-tube	3
Drainage, choledocholithotomy and repair over T-tube	4
Drainage, ligation of slipped cystic duct ligature	1
Drainage, ligation of accessory duct	1
Bilio-enteric anastomosis	
• Hepatico- jejunostomy	28
• Choledocho- duodenostomy	2
Total	46

(range 1-3). Complications were classified according to the Dindo classification system [13]. Short-term complications occurred in 13 patients (11.2%) with the endoscopic treatment and in 15 patients (38%) with the surgical maneuver, while long-term complications developed in 6 patients (5.2 %) with the endoscopic maneuver, and in 6 patients (15.4%) with the surgical maneuver. The mortality rate was 0.9% (1 patient), one patient in the endoscopic group (0.4%), and 2 patients in the surgical group (5.1%), (Table 5 and 6). Treatment outcomes: The mean time from diagnosis to cure was 5.6 ± 3 days (range 4-17 days) in the endoscopic group and 66 ± 35 days (range 7-105 days) in the surgical group (Table 7).

Discussion

The incidence of postoperative bile leak cannot be assessed accurately as many cases may heal spontaneously [14]. Postoperative bile leak usually occurs from the liver bed or bile duct injury [15], as a result of pressure gradient created by the sphincter of Oddi

[16]. The commonest cause of postoperative bile leak was post-cholecystectomy and the commonest site was the cystic duct stump, and this was comparable with the previously published results [17]. Cholangiogram was the standard method of the diagnosis in most cases, however, the leak was minimal and not evident in 5 cases, such cases may heal spontaneously according to the literature [18]. Treatment options available for bile leak include surgical repair, percutaneous biliary drainage, and endoscopic biliary drainage. It is important to select the appropriate therapeutic approaches according to the setting. Resorting to surgery as a primary approach for therapy should not be the standard practice. On the other hand, strict adherence to a conservative approach, which employs non-surgical methods and excludes surgery, is associated with an obligatory 9% conversion to surgery at an advanced stage of the disease, together with a mortality rate of 3.5% [19]. Surgery may be required for 2 goals: 1) drainage of collections in uncontrolled fistulas, and 2) definitive treatment. Two reasons place drainage as an early essential step: Firstly, an intra-abdominal collection may predispose to serious septic complications unless promptly drained and secondly, final repair should not be attempted at this early stage, since the affected bile duct(s) are collapsed, friable and are usually embedded within a severe local inflammatory reaction. As a definitive therapy, surgery is indicated when: 1) there is no bilio-enteric continuity, 2) failure of non-surgical methods with bilio-enteric continuity, and 3) surgery is the primary line of treatment for an associated pathology, e.g. malignancy [20]. Earlier, bile leak has been treated by surgical repair, and it is associated with high morbidity (22% - 37%) and mortality (3% - 18%). Also percutaneous transhepatic biliary drainage carries a high morbidity rate owing to hemorrhage and bile leak related to liver puncture [21]. Endoscopic therapy became the standard method for definitive treatment of postoperative bile leak [22], in the form of Nasobiliary Drainage (NBD), sphincterotomy, or stent insertion [23,24], with no consensus regarding optimal endoscopic intervention [23-27]. The principle of endoscopic techniques is the abolition or reduction of the pressure gradient and bile diversion away from the site of injury, resulting in the closure of the fistula [28]. We follow the policy of crossing the stent above the site of the leak with the conflicting results [29,30] regarding the strategy of stent insertion, There are no

Table 5: Follow-Up and Complications.

Type of leakage	Endoscopic maneuver			Surgical maneuver		
	Early Morbidity	Late Morbidity	Mortality	Early Morbidity	Late Morbidity	Mortality
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Simple bile leak (89,5)	8 (9)	2 (2.2)	0 (0)	1 (20)	1 (20)	0 (0)
Complex bile leak (27,34)	5 (18.5)	4 (14.8)	1 (3.7)	14 (41.2)	5 (14.7)	2 (5.9)
Bile duct transection	0 (0)	0 (0)	0 (0)	5 (14.7)	1 (2.9)	1 (2.9)
Bile leak with stone	2 (7.4)	2 (7.4)	0 (0)	5 (14.7)	2 (5.9)	0 (0)
Bile leak with stricture	3 (11.1)	2 (7.4)	0 (0)	2 (5.9%)	1 (2.9)	0 (0)
Anastomotic leak	0 (0)	0 (0)	1 (3.7)	2 (5.9%)	1 (2.9)	1 (2.9)
Total	13 (11.2)	6 (5.2)	1 (0.9)	15 (38.5)	6 (15.4)	2 (5.1)

Table 6: Dindo classification of postoperative complications (morbidity and mortality).

Grade	Endoscopic maneuver		Surgical maneuver	
	Complication	NO. (%)	Complication	NO. (%)
I	Fever	1 (0.9)	wound infection	2 (5.1)
II	PEP Cholangitis, UTI,	4 (3.4)	wound infection,	2 (5.1)
		4 (3.4)	cholangitis,	2 (5.1)
		1 (0.9)	pneumonia,	2 (5.1)
			paralytic ileus, DVT	1 (2.6) 1 (2.6)
111a	Leakage, stricture, Basket trapping	1 (0.9)	stricture	2 (5.1)
		2 (1.7)	abscess,	1 (2.6)
		1 (0.9)	cholangitis	1 (2.6)
IIIb	Stricture	4 (3.4)	stricture	1 (2.6)
			incisional hernia,	1 (2.6)
			Abscess,	1 (2.6)
			Primary hemorrhage, bowel obstruction,	1 (2.6) 1 (2.6)
IV a	ARDS	1 (0.9)	ARDS	1 (2.6)
IVb		0 (0)	Septic shock with multiorgan failure	1 (2.6)
V	Sever Arrhythmia	1 (0.9)	Pulmonary embolism septic shock	1 (2.6) 1 (2.6)
Total		20 (17.2)		23 (59)

PEP: Post ERCP Pancreatitis; UTI: Urinary Tract Infection; ARDS: Acute Respiratory Distress Syndrome; DVT: Deep Venous Thrombosis

Table 7: Treatment outcomes.

Treatment outcomes	Endoscopic maneuver	Surgical maneuver	P value
Time from diagnosis to cure (Mean ± SD)	5.6 ± 3 days (Range 4-17 days)	66 ± 35 days (Range 7-105 days)	<0.0001
Hospital stay (Mean ± SD)	5 ± 2 days (Range 3-11 days)	14.5 ± 6 days (Range 3-31 days)	<0.001
No. of re-intervention (Mean ± SD)	1.34 ± 0.494 (Range 1-3)	1.19 ± 0.395 (Range 1-2 days)	0.78
Morbidity	19 (16.4%)	21 (53.9%)	<0.001
Mortality	1 (0.9%)	2 (5.1%)	<0.01

evidenced data regarding the optimal number, diameter, shape, type and length of stent necessary for optimal treatment of postoperative bile leak [31-33]. We did not use NBD because of patient's discomfort and this agrees with many papers. In cases with simple bile leak, endoscopic treatment was very effective in the treatment of 94.7% of patients though 11.7% required combined external drainage and these results were comparable with those published by many authors [34-36]. We can say that endoscopic treatment replaced surgery in all simple bile leak cases as a competitive definitive treatment. In cases with complex bile leak, endoscopic treatment was less effective in comparison to surgical treatment (44.2% vs. 55.8%). Although, endoscopic treatment proved effective in 70% and 58.3% of cases with bile leak associated with retained stone or stricture respectively, it has many defects: 1) generally, it is less effective than in case of a simple bile leak; 2) the duration may be very long; 3) stent complications; and 4) long-term follow-up which may be not done. Thus on contrast of many reports [37,38] we can say that surgery is the preferable treatment for cases with bile leak associated with retained stone or stricture only in surgically suitable patients.

Many recent studies concluded that there was no role for endoscopic treatment in patients with transected CBD or anastomotic leak. Similarly, our results showed that surgical treatment was the only definitive treatment of such problems; however endoscopy was a mandatory integral tool in the initial management either alone, or with percutaneous techniques. Without doubt, surgery has its associated morbidity and mortality, prerequisites, and necessary facilities. The overall successful endoscopic treatment was 74.8% with variable rates for each problem and this was comparable with different reports

detecting variable endoscopic success ranging from 78% to 94% of cases [39-41]. Roux-en-Y hepaticojejunostomy is the best biliary reconstruction procedure [42], however, choledochorrhaphy over T-tube and choledochoduodenostomy were also indicated in some cases [43]. Unlikely these operations are so complex and advanced, particularly when the anastomosis is done on a normal duct that is technically very difficult especially with the associated fibrosis and infection [44]. Early surgical reconstruction can be done after proper assessment and before the spread of infection; however, most cases present late, where surgery is very difficult but still may be done. Early referral to specialized centers with expert surgeons results in a better surgical outcomes [45,46]. Complications occurred in 72.3% of patients treated early versus 27.7% of patients treated electively. Also, 73.3% complication rate was encountered in patients initially treated before their referral in comparison to 38.8% in patients treated initially in our centers by experienced hepatobiliary surgeons. For these results, it is better to refer such patients early to a specialized center with expert surgeons. The outcome of surgical treatment is affected by many factors [47], but our series is too small to perform a multivariate analysis for their evaluation.

Conclusion

Endoscopic treatment replaced surgery in all simple postoperative bile leak cases as an identical definitive treatment. Surgical treatment was the definitive treatment of complex postoperative bile leakage; however endoscopy was a mandatory complementary tool in the initial management. Early referral to tertiary care centers with expertise in hepatobiliary surgery may limit further morbidity and mortality.

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