Postoperative bile leakage: endoscopic management

P H P Davids, E A J Rauws, G N J Tytgat, K Huibregts

Abstract
Bile leakage is an infrequent but serious complication after biliary tract surgery. This non-randomised single centre study evaluated the endoscopic management of this problem in 55 consecutive cases. Treatment consisted of standard sphincterotomy and, if needed, subsequent stone extraction with or without endoprostheses placement. The aim of all treatments was to facilitate bile flow into the duodenum. The biliary tract and the site of the leakage were visualised during endoscopic retrograde cholangiopancreatography (ERCP) in 98%. There was distal obstruction in 33 – caused by retained gall stones in 15 patients and concomitant strictures in 18. Overall, 48 of 55 patients were treated endoscopically. An excellent outcome (clinical and radiological resolution of the bile leak) was achieved in 43 patients (90%). Five patients (10%) had continuing sepsis from which they died. Postoperative bile leakage can be diagnosed safely and effectively by ERCP and subsequent endoscopic management is successful in most cases.

(Gut 1992; 33: 1118–1122)

Postoperative bile leakage leading to internal and external fistulas is an infrequent but serious complication of biliary tract surgery. It is usually the result of inadvertent surgical damage to the bile duct, inadequate closure of the cystic stump, leakage from the gall bladder bed, or leakage from the T tube site. There is often distal obstruction of the common bile duct because of residual stones or strictures. These patients present soon after surgery with external biliary drainage or an internal biliary-peritoneal leakage, resulting in biloma, peritonitis, or abscess formation.

In the past this complication has been treated by surgical repair, but lately non-operative methods of improving biliary drainage have also been investigated. This study gives a detailed analysis of the endoscopic management (sphincterotomy, stone extraction, and endoprostheses placement) and long term follow up in a consecutive series of patients.

Methods
Between 1982 and 1990, 55 patients were referred for endoscopic assessment of postoperative bile leaks and fistulas; there were 28 women and 27 men with a mean age of 55 years (range 22–82). Indications for the initial surgery included cholecystitis in 51 and ampullary carcinoma, peptic ulcer, blunt abdominal trauma, and a hepatocellular carcinoma. The surgical procedures performed included: open cholecystectomy (n=35), open cholecystectomy and common bile duct (CBD) exploration (n=13), CBD exploration with abscess drainage (n=1), cholecystostomy with stone extraction (n=1), duodenopancreatectomy (n=1), partial gastrectomy (n=1), right hemihepatectomy (n=2), and explorative laparotomy (n=1). Damage to the extrahepatic bile duct was noted during operation in 10 patients; local repair was performed in three patients, end to end anastomosis in two, and in the remaining five the torn cystic duct was irretrievable. T tubes were used in 17 patients, resulting in dislodgement in four and perforation of the distal CBD in one. Two patients had undergone prior endoscopic sphincterotomy.

The patients presented with a biliary-cutaneous fistula (n=27), peritonitis (n=10), recurrent intra-abdominal abscess formation (n=5), progressive jaundice (n=7), cholangitis (n=5), or pancreatitis (n=1). In 20 patients, bile was flowing through a sump drain, in five through a tube drain, and in two through the abdominal wound. The quantity of bile leakage ranged from 100 to 800 ml/day.

The mean interval between the initial surgery and presentation with complications was 37 days (range 5–292). During this period 12 patients underwent one or more subsequent laparotomies, comprising surgical extraction of retained CBD stones in three, abscess drainage in six, haematoma drainage in two, and cholecystectomy after initial cholecystostomy in one. Percutaneous abscess drainage under ultrasound guidance was performed in two patients.

The method of endoscopic retrograde cholangiopancreatography (ERCP) using a (video) duodenoscope (Olympus), sphincterotomy, and subsequent placement of a biliary endoprosthesis has been described in detail elsewhere. Antibiotics were given before the procedure in patients with cholangitis or sepsis.

The treatment protocol was as follows. Sphincterotomy was performed with a standard papillotome where a cystic stump or hepatic radical leakage was present but there was not any evidence of distal obstruction of the CBD. If residual stones were seen in the CBD, sphincterotomy was followed by stone extraction using a Dormia basket. A straight polyethylene endoprosthesis (10 FG) was placed when there was a history of operative biliary trauma, when a benign or malignant stricture was present, or when not all the stones could be removed. A nasobiliary tube was introduced only when the clinical condition of the patient did not improve after stenting and the leakage persisted. The aim of all the types of treatment was to facilitate bile flow from liver into the duodenum.

To evaluate the outcome of the endoscopic treatment, two groups were defined according to response. Patients were considered excellent
TABLE I  Radiographic features, therapy, and outcome (n=48)

<table>
<thead>
<tr>
<th>Leakage site*</th>
<th>CDS  (n=32)</th>
<th>CBD (n=6)</th>
<th>CHD (n=5)</th>
<th>HR  (n=4)</th>
<th>A  (n=1)</th>
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</thead>
<tbody>
<tr>
<td><strong>Stones:</strong></td>
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<tr>
<td>Distal</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Hilum</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Total (%)</td>
<td>12 (38)</td>
<td>1</td>
<td>-</td>
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<tr>
<td><strong>Stenosis:</strong></td>
<td></td>
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<tr>
<td>Distal</td>
<td>5</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>-</td>
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<tr>
<td>Mid</td>
<td>5</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>4</td>
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<tr>
<td>Hilum</td>
<td>1</td>
<td>-</td>
<td>4</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Total (%)</td>
<td>11 (36)</td>
<td>2</td>
<td>1</td>
<td>5</td>
<td>-</td>
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<tr>
<td><strong>Therapy:</strong></td>
<td></td>
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<tr>
<td>P</td>
<td>7</td>
<td>1</td>
<td>-</td>
<td>2</td>
<td>-</td>
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<tr>
<td>P &amp; S</td>
<td>9</td>
<td>-</td>
<td>1</td>
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<tr>
<td>P &amp; E</td>
<td>11</td>
<td>2</td>
<td>4</td>
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<tr>
<td>P &amp; S &amp; E</td>
<td>3</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>P &amp; NBD &amp; E</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td><strong>Outcome:</strong></td>
<td></td>
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<tr>
<td>Excellent (%)</td>
<td>30</td>
<td>4</td>
<td>4</td>
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</tr>
<tr>
<td>Poor (%)</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>-</td>
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</tr>
</tbody>
</table>

*CDS=cystic duct stump; CBD=common bile duct; CHD=common hepatic duct; HR=hepatic radical; A=surgical anastomosis.
†P=papillotomy; S=stone extraction; E=endoprosthesis; NBD=nasobiliary drain.

Results

The biliary tract was visualised during ERCP in 54 of 55 patients (98%, Table I). The papilla could not be located in a patient with a Billroth II gastrectomy. Cholangiography showed extravasation of contrast material originating from: the cystic duct stump (n=37), the common hepatic duct (n=6), the CBD (n=6), a hepatic radical (n=4), and a surgical anastomosis (n=1). Retained gall stones were present in 15 patients and stricture of the extrahepatic bile ducts was present in 18 patients (16 as a result of surgery, two because of pancreatic head carcinoma).

Endoscopic treatment was attempted in 49 of 54 patients. Five patients had total bile duct obstruction caused by a surgical clip or ligature and concomitant bile leakage (level: mid-CBD (n=4) and hilus (n=1)). These patients were referred for further surgery. Successful drainage was achieved in 48 of 49 patients (number of ERCP procedures: mean 1.25 (range 1–3)). Placement of an endoprosthesis failed in a 65 year old woman with gall bladder carcinoma and bile leakage after cholecystectomy. She died of cachexia 34 days after the procedure.

Two of 32 patients with bile leakage from the cystic duct stump had a poor result. An 81 year old man had an aortic graft inserted because of a bleeding aneurysm four days after cholecystectomy and choledochotomy and bile leaked through the T tube tract after surgery. During ERCP, cystic duct stump leakage and a distal CBD stenosis were visualised (Fig 1). An endoprosthesis was inserted but the patient died of cardiac failure five days after the endoscopic procedure. Autopsy showed carcinoma of the pancreatic head. The other patient was referred three weeks after cholecystectomy with severe septic shock because of bile leakage from the cystic duct stump. Despite placement of an endoprosthesis and subsequently a nasobiliary tube, the patient died of multiple organ failure.

In seven patients treated with a standard sphincterotomy and nine with additional stone extraction, all fistulas closed within one week of endoscopic intervention (Fig 2). Thirteen patients treated with an endoprosthesis showed fistula closure 2–25 days (median 10 days) after insertion. Gall stone extraction was performed concurrently in three patients. A short period of nasobiliary drainage stopped the bile leakage in

responders when bile leakage was found to have stopped both clinically and radiologically. The result was considered poor when death occurred despite adequate endoscopic therapy.

Figure 1: Cystic duct stump leakage and concomitant malignant distal common bile duct stenosis.

Figure 2: Cystic duct stump leakage and balloon (arrow) extraction of distal concrement. Percutaneous drain in situ.
one patient with a tight stricture and facilitated positioning of an endoprosthesis.

After bile leakage from the CBD, four patients had an excellent result after sphincterotomy, stone extraction, or stent placement (Fig 3). Two patients had a poor result: one patient presented with sepsis after cholecystectomy and CBD exploration and died of cardiac failure despite endoprostheses and subsequent nasobiliary tube placement (Fig Fig 4). The other patient developed gangrene of the cystic stump after the initial surgery. At further laparotomy one week later, multiple areas of necrosis were visible. Sphincterotomy, further stone extraction, and endoprosthesis placement were performed, but the patient eventually died of septic complications. Bile leakage from the common hepatic duct occurred in five patients. Four were treated with endoprostheses because of a stricture, and leakage stopped within one week. One patient presented with continuing sepsis six weeks after cholecystectomy and further laparotomy. An ERCP showed residual stones and an internal fistula. Extraction was performed but the patient died of multiple organ failure after five further surgical interventions.

In two patients leakage from a hepatic radical was successfully treated by standard sphincterotomy. A benign stricture necessitated endoprostheses placement in two other patients.

In one patient external bile leakage occurred after radical resection of a papillary carcinoma by duodenopancreatectomy. Cholangiography showed a fistula at the site of the hepaticojejunostomy but this closed four days after endoprosthesis placement.

ENDOPROSTHESIS

All 16 patients with benign postoperative biliary strictures and concomitant biliary fistulas were treated according to the following protocol: initial placement of one and if possible two 10 FG stents, with elective exchange every three months for one year to avoid clogging induced cholangitis. The stricture was considered to be sufficiently dilated after successful passage of a 1 cm balloon or because rapid emptying of the intrahepatic biliary tree was seen on fluoroscopy.

In 13 patients the stents were removed after a mean period of 297 days (range 91–725) and the bile duct remained patent in all but one. This mentally retarded patient developed recurrent cholangitis after definitive stent removal. After replacement of two endoprostheses his clinical condition remained excellent.

The five patients treated with an endoprosthesis without concomitant stricture had their stent removed after a median period of 40 days (range 9–475). The indication for removal was clinical and radiological resolution of bile leakage.

COMPLICATIONS

No early complications related to the sphincter-
otomy or stone extraction were noted. One patient developed septic shock after removal of a T drain during endoscopy. Recovery was achieved rapidly after conservative treatment. Late complications occurred only in the group with benign postoperative strictures and consisted of cholangitis caused by stent clogging in two patients despite the three monthly stent changes. Replacement of the stents was always effective.

COMPARISON OF EXCELLENT AND POOR RESPONDERS

Longterm follow up, available in all patients, was mean (range) 39 (3–93) months. In patients with an excellent result no adverse effects of the endoscopic treatment were noted. Poor responders were all admitted to an intensive care unit before endoscopic treatment. Statistical analysis of factors predictive of a more or less favourable outcome showed no significant differences (Table II). All patients with a poor result were older than 50 years. The interval between the initial operation and the ERCP tended to be longer in the excellent responder group. Four of the five poor responders had a T drain in situ.

Discussion

The true incidence of postoperative bile leakage is unknown since many leaks heal spontaneously. Bile duct injury during conventional cholecystectomy is reported to be 0·1 to 0·2%, but injury during laparoscopic cholecystectomy is reported to be higher, resulting in more postoperative bile leakage in the present era.

Surgical options are limited especially in the acute phase. The morbidity is considerable and the mortality from any intervention may reach 8%. Drainage of the biliary tree via the percutaneous transhepatic approach has been reported to be effective. The main risks, however, relate to liver puncture with large bore stents, with potential haemorrhage and bile leakage. In addition, puncturing a non-dilated biliary tree can be troublesome.

Endoscopic treatment, including standard sphincterotomy and subsequent stone extraction if needed, with or without endoprosthesis placement, can lead to resolution of bile leaks and postoperative fistulas as our results confirm. Overall, 48 of 54 patients (89%) were treated endoscopically. Clinical improvement and eventual closure of the leaks or fistulas were achieved in 43 patients (90%). Despite adequate treatment, however, five patients (10%) died of persistent sepsis.

The clinical manifestations of postoperative bile duct trauma include biliary fistula and abscess formation, peritonitis, sepsis, or severe metabolic disturbances. Most patients in this study were referred after conventional cholecystectomy with or without CBD exploration because of gall stones. One half of the patients presented with biliary-cutaneous fistulas and the other half had bile flow to the abdominal cavity resulting in peritonitis and abdominal abscess formation.

Although no significant factors predictive of a more or less favourable outcome could be defined, the clinical condition at the time of referral seemed to be of discriminant importance. All poor responders had been admitted to an intensive care unit before endoscopic treatment. The interval between the initial operation and the ERCP tended to be longer in the excellent responder group.

Evidence of obstruction distal to the site of bile leakage because of residual stones or strictures was diagnosed in nearly 70% of the patients. When stones were present, extraction after sphincterotomy led to excellent results in almost all patients. Similar results were reported in earlier limited studies. All patients with a concomitant benign biliary stricture showed closure of their fistulas after placement of an endoprosthesis.

The use of biliary stents serves several important functions in treating bile leakage. It provides a conduit past the site of leakage and bridges the defect at the site of the extravasation. The endoprosthesis may physically occlude the defect in the bile duct wall. In addition, the prosthesis is helpful in dilating and splitting a narrowed area during the healing phase, thereby contributing to the prevention of late strictureing. In this study only one patient (6%) developed a recurrent stricture after stent removal.

The short term impact of biliary tract surgery on the function of the sphincter of Oddi is not well understood. Preoperative passage of gall stones or peroperative trauma might result in papillary stenosis. Some patients may develop biliary dyskinesia in the postoperative phase because of unintended use of spasmogenic drugs, especially during intensive care treatment. These factors and the presence of a lower pressure in the intra-abdominal cavity can divert bile flow through the proximal defect. Theoretically, when bile leakage occurs in the absence of distal obstruction, standard sphincterotomy should be sufficient to decompress the biliary tree. Our results confirm this hypothesis: when leakage from the cystic duct stump or a hepatic radical was present, sphincterotomy always yielded a favourable outcome. In this situation some advocate temporary stenting of the sphincter zone, believing that sphincterotomy may have long term disadvantages as well as short term risks. In this study no side effects were encountered.

When bile leakage is suspected in the postoperative period close collaboration between surgeons and endoscopists is essential. Immediate visualisation of the biliary tract by ERCP is mandatory to confirm the diagnosis, to locate the exact site of the defect, and to elucidate the eventual presence of any distal obstruction. Subsequently, adequate endoscopic treatment can restore bile flow with good results.

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