# Retained common bile duct stones after endoscopic sphincterotomy: temporary and longterm treatment with biliary stenting

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La lithiase de la voie biliaire principale inextirpable : indications et résultat de la mise en place d'une endoprothèse biliaire.

LA TUNISIE MEDICALE - 2011; Vol 89 (n°04): 342 - 346

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#### RÉSUMÉ

**Prérequis :** La sphinctérotomie endoscopique avec extraction des calculs est le traitement endoscopique de choix de la lithiase de la voie biliaire principale. En cas d'échec d'extraction de calcul, l'insertion d'une prothèse biliaire peut constituer une alternative thérapeutique

But: Déterminer les caractéristiques épidémiologiques, cholangiographiques et évolutives à court et à long terme des patients traités par endoprothèse biliaire

**Méthodes :** Etude prospective colligeant toutes les cholangiopancréatographie par voie rétrograde (CPRE) indiquées pour lithiase de la voie biliaire principale de janvier 2005 à Janvier 2008 ont été inclus dans les lithiases de la voie biliaire principale (LVBP) traités par prothèse biliaire.

Résultats : 414 patients étaient adressés pour une prise en charge endoscopique d'une LVBP. La vacuité de la voie biliaire principale (VBP) était obtenue chez 363 patients (88%). Vingt cinq patients étaient adressés pour un traitement chirurgical de la lithiase de la voie biliaire principale. Chez 12 hommes et de 14 femmes d'âge moyen de 66.5 ans, une prothèse biliaire droite de 10 Fr a été insérée. Les indications de la mise en place de la prothèse étaient la présence d'une LVBP difficile chez des patients ayant une hypertension portale avec varices oesophagiennes avec trouble de la crase sanguine chez 35% des cas, la présence de comorbidités (tares ou cancers évolutifs) dans 34% des cas ou un âge > 80 ans dans 19% des cas. Dans les cas restants, il s'agissait d'échec de l'extraction des calculs lors de la CPRE première. La résolution des symptômes était obtenue chez 88% des patients. Nous avons pu obtenir la vacuité complète de la voie biliaire chez 6 patients soit 23% après trois tentatives en movenne, dans un délai moyen de 15 mois, allant de 1 à 48 mois. Chez trois patients, la prothèse était insérée au long cours. Les complications étaient dominées par l'angiocholite.

Conclusions: L'insertion d'une prothèse biliaire en cas de lithiase de la voie biliaire principale permet un drainage de la voie biliaire. Elle peut être insérée provisoirement jusqu'à obtention de la vacuité de la voie biliaire. La mise à demeure au long cours d'une prothèse biliaire est une bonne alternative thérapeutique pouvant être réservée aux patients à haut risque opératoire ou à espérance de vie limitée.

#### SUMMARY

**Background:** Endoscopic extraction of biliary tract stones is safe and effective. When the procedure is not successful, the use of a biliary stent can be a solution

**Aim:** To prospectively analyse the usefulness of a stenting in management of biliary obstruction due to choledocolithiasis.

**Methods:** All patients referred to our endoscopic unit from January 2005 to January 2008, for management of bile duct stone are studied. We included patients subjected to an endoscopic insertion of a biliary stent.

Results: Of 414 patients with choledocolithiasis, 51 failed to have their ducts cleared with the first endoscopic retrograde cholangiopancreatography (ERCP): 25 patients (6%) were referred to surgical stone removal. Twenty six consecutive patients had endoscopic insertion of a 10 Fr biliary stent: There were 12 men and 14 women ranging in age from 35 to 102 years (median age 68 years). The indications for stent placement in common bile duct stone were mainly the endoscopic portal hypertension, elderly patients or with a short life expectancy. Twenty four patients (88%) are symptom free after stenting. Six patients (23%) had duct clearance after a median of 3 sessions at a mean of 13 months (range 3-48 months). In 3 patients endoprosthesis was inserted as a permanent therapy of biliary obstruction. Cholangitis occurred in 5 patients, early in two cases and later at a mean of 18 months (range 6-24 months) in 3 patients and was managed endoscopically by stent replacement and fluid antibiotics.

Conclusions: These data favor temporary use of biliary endoprostheses in patients with endoscopically irretrievable bile duct stones until the definitive treatment is carried out. However, as a permanent therapy, late complications occur in many patients and the risk increases proportionally in time. Therefore, permanent biliary stenting should preferably be restricted to patients unfit for elective treatment at a later stage and with a short life expectancy.

# Mots-clés

Lithiase de la voie biliaire principale, sphinctérotomie endoscopique, prothèse biliaires.

# Key-words

Common bile duct stones, endoscopic sphincterotomy, biliary stenting.

Since its introduction, in 1974, endoscopic sphincterotomy has become a well-etablished therapeutic modality for common bile duct stones. Endoscopic sphincterotomy and subsequent stone extraction can clear the bile ducts in 85% to 90% of patients (1). Removal of common bile duct stones can be difficult in patients with large or multiple stones. Therefore, if endoscopic sphincterotomy and conventional stones extraction fail, further treatment is mandatory. New therapeutic interventions like extracorporeal shock-wave lithotrypsy, electrohydraulic or laser lithotripsy and chemical dissolution have been introduced. Consequently, if endoscopic stone extraction proves unsuccessful, patients are often referred for operative management. Insertion of an endoprostheses achieves temporary drainage and reduces the risk of stone impaction.

The aim of this prospective study was to evaluate the usefulness of a stenting in management of biliary obstruction due to choledocolithiasis and to draw results and complications during early and long term follow-up of the insertion of biliary endoprostheses in a cohort of 26 patients with unsuccessful endoscopic stone removal.

#### **METHODS**

All patients referred to our endoscopic unit from January 2005 to January 2008, for management of bile duct stone are prospectively studied. The patients are mainly in-patients of gastroenterology department of Habib Thameur hospital or drawn from other centers. We included patients subjected to an endoscopic insertion of a biliary stent. Endoscopic retrograde cholangiography (ERCP) was performed with a side wiewing duodenoscope with a large accessory channel in a standard manner. Standard sphincterotomy and subsequent stone extraction with balloon or basket was performed in 22 patients. Straight 10 Fr polyethylene endoprosthesis with side flaps were used throughout. The proximal end of a 7 to 12 endoprosthesis was positioned above the stones and, whenever possible, wedged in the intrahepatic ducts to prevent dislodgement. The distal end of the endoprostheses was placed in the duodenum (figure 1).

Figure 1: Endoscopic vue: stent inserted for stone in the common bile duct.



The endoprosthesis was inserted without preceding sphincterotomy because of major hemostatic disorders in 4 patients. No sphincteroclasia was performed.

Follow-up compassed an analysis of the short-term efficacy and early complications of stent insertion in all patients.

Follow-up comprised analysis of all complications during the stented period and results and complications during long-term follow-up.

#### RESULTS

A total of 414 patients underwent endoscopic retrograde cholangiography for treatment of common bile duct stones. Duct clearance was accomplished in 363 of cases (88%) after a nasobiliary drain insertion in 92 patients. This gives an overall incidence of retained stones of 12%. Of the remainder, 25 patients are referred for a surgical management. In twenty six patients complete clearance were not achieved immediately and a stent was inserted for temporary biliary drainage before further endoscopic attempts at duct clearance or as a permanent drainage.

There were 12 men and 14 women ranging in age from 35 to 102 years (median age 68 years). Patients presented with pain in the upper abdomen jaundice, fever, abnormal liver functions tests or dilatation of the biliary tract alone or in combination. Eiting patients (73%) presented with cholangitis.

• Clinical history and epidemiological characteristics (table 1): Patients are either > 65 years of age or younger with in majority a serious debilitating disease. Thirty-five percent of patients had a portal hypertension with oesophageal varices. After endoprosthesis was positioned, patients were reassessed about every three months in the out patients clinics and whenever necessary. During follow-up special attention was directed at episodes of cholangitis and episodes of abdominal pain. Figure 2 shows the clinical outcome of the 414 patients with common bile duct stone referred to endoscopic retrograde cholangiography treatment.

**Figure 2 :** Clinical outcome of the 414 patients presenting with common bile duct stone.

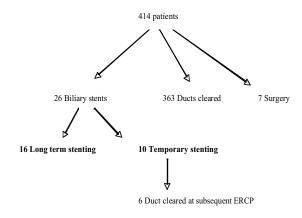


Table 1: Demographic data

Patient	Age	Gender	Assocciated medical conditions	Cholecystectom	Presentation
1	46	M	Cirrhosis Child C, O V grade III	у	Cholangitis
2	94	M		No	Cholangitis
3	90	F		No	Biliary colic
4	81	F		Yes	Cholangitis
5	77	F	Cirrhosis Child B, O V grade III	No	Cholangitis
6	40	M	Cirrhosis Child C, O V grade III	Yes	Biliary colic
7	54	M		No	Cholangitis
8	60	M		Yes	Cholangitis
9	57	M	Cirrhosis Child B, O V grade III	Yes	Cholangitis
10	55	M	Suprarenal carcinoma	No	Cholangitis
11	72	F	Heart failure	No	Biliary colic
12	84	F		Yes	Cholangitis
13	83	M	Heart failure	No	Cholangitis
14	46	F	Portal cavernoma, OV grade III, duct stenosis	Yes	Biliary colic
15	43	F	Cholangite sclérosante primitive, VO grade III	Yes	Cholangitis
16	68	M		No	Cholangitis
17	80	F		Yes	Biliary colic
18	90	F	Heart failure	Yes	Biliary colic
19	53	F	Galbladder Carcinoma	Yes	Biliary colic
20	70	F	Cirrhosis Child C, O V grade III	Yes	Cholangitis
21	40	F		Yes	Cholangitis
22	72	M	Cirrhosis Child B, O V grade III	Yes	Cholangitis
23	75	F	Heart failure	No	Cholangitis
24	102	M	Heart failure	No	Cholangitis
25	66	F	Heart failure	No	Cholangitis
26	35	F	Portal cavernoma- duct stenosis	No	jaundice
				No	

• Cholangiography data (table 2):

Multiple large common bile duct stones was found in 15 patients (65%). Mean size stone was 15mm, ranging from 8 to 30mm (figure 3).

Figure 3: Stent removed with stone fragments.

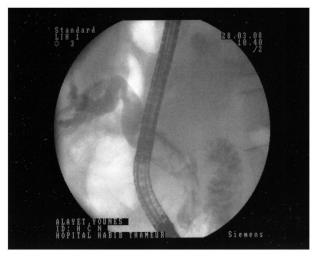


- Early results of stent insertion: Intraductal stent insertion was achieved in all patients. Intravenous fluids antibiotics (amoxicillin- A. clavulanic) before and after ERCP was administrated to patients. A successful biliary drainage, defined as resolution of jaundice, fever and cholestasis was observed in 24 patients. Two patients (8%) had early cholangitis, managed by endoscopy in one patient and by surgery in other. No death occurred by stent insertion.
- Complete stone removal was achieved in 6 patients after at mean 3 ERCP. So, duct
- clearance in this group was obtained in about two thirds of patients (23%). A mean of 13 months (range 3-48) elapsed before treatment was completed. In one patient symptom free intraductal migration of the stent was observed managed by extraction with basket (figure 4).
- In 3 patients the endoprosthesis was considered a permanent treatment. After insertion of the stent an expectant policy was followed with stent exchange only in case of recurrent problems. Late cholangitis was observed in 3 patients (12%) managed with fluid antibiotics and stent removal. Table 2 shows long term follow-up and number of ERCP required. No duodenal perforation occurred.
- In 12 patients there is no follow up.

Table 2: Repeat procedures required to establish biliary drainage

Patient	ERCP 1	Sphincterotomy	Number ERCP	Evolution	delay
1	Numerous stones	no	2	Numerous stones stent replaced	24 months
2	1 large stone	yes	2	No follow-up	
3	Numerous stones	no	1	No follow-up	
4	Numerous stones	no	1	No follow-up	
5	Numerous stones	yes	4	Clear duct	48 months
6	1 large stone	yes	4	Numerous stones stent replaced	28 months
7	Numerous stones	yes	1	No follow-up	
8	Numerous stones	no	1	No follow-up	
9	Numerous stones	yes	3	Numerous stones stent replaced	6 months
10	1 large stone	yes	1	No follow-up	
11	3 large tones	yes	1	No follow-up	
12	Numerous stones	yes	3	No follow-up	
13	Numerous stones	yes	4	Clear duct	18 months
14	1 large stone	yes	1	No follow-up	
15	2 large stones	yes	2	Cystic obstruction	02 days
16	Numerous stones	yes	2	Clear duct	6 months
17	Numerous stones	yes	3	Clear duct	4 months
18	Numerous stones	yes	2	No follow-up	
19	Numerous stones	yes	2	No follow-up	
20	Numerous stones	yes	3	Surgery	3 months
21	Numerous stones	yes	2	Surgery	7 days
22	Numerous stones	no	1	No follow-up	
23	Numerous stones	yes	2	Clear duct	3 months
24	Numerous stones	yes	1		1 months
25	Numerous stones	yes	2	Intraductal migration- clear duct	1 months
26	Numerous stones	no	1		

**Figure 4:** Retrograde cholangiography showing straight stent with large multiple stone in the common bile duct.



### DISCUSSION

This study confirms that single 10 Fr straight temporary or permanent stent provide effective biliary drainage when common bile duct clearance fails after endoscopic sphincterotomy or without sphincterotomy in cases of portal hypertension, and that surgical intervention can be avoided. In over two thirds of patients with a temporary biliary stenting we have a successful clearance after a mean of 3 ERCP in a mean of 13 months. Sixty percent of the original group of patients with choledocolithiasis remained with common bile duct stones and long term stents. Most were elderly, with portal hypertension or frail.

Since 1983-1984, biliary endoprosthesis are introduced in the treatment of patients with endoscopically irretrievable common bile duct stone especially in elderly and high-risk patients or patients with cholangitis. In these cases, duct clearance is not mandatory immediately and further endoscopic attempts should be programmed. The endoprosthesis offers a better comfort compared to nasobiliary drainage mainly in restless patients (2). The role of biliary endoprosthesis in the treatment of patients with endoscopically irretrievable common bile duct stones is twofold. First, placement of an endoprosthesis results in immediate biliary drainage, essential for treatment and prevention of cholangitis. This enables elective surgical or endoscopic treatment when the patient is in better general condition and at lower risk compared with emergency surgery or protracted endoscopic treatment (2, 3). In fact, sushil and al

and W.Chan and al. found that bile duct stones become significantly smaller after median periods of 30 days and 60 days respectively, of stent placement. Moreover, an additional benefit of stent placement that we also observed in 6 of our patients is fragmenting of large stone, leading to either spontaneous passage or to easy extraction at a later procedure permitting complete ductal clearance in about two third of patients (4). Presumably, respiration and other biliary movements cause the stent grinding against the stone, which may lead to mechanical disintegration. Changes in the biochemistry of the bile during stenting may also facilitate dissolution of the stones (5, 6). Ursodeoxycholic acid given orally may facilitate this process (3, 7).

Second, the endoprosthesis can serve as a definitive treatment in elderly patients who are poor candidates not only for direct surgical intervention but also for elective therapy at a later stage. Despite endoprosthesis will inevitably occlude after 3 to 5 months in situ, its presence is believed to prevent impaction of stones in the distal part of the common bile duct and this to maintain biliary flow (8). The greatest drawback of a long-term indwelling biliary endoprosthesis is the risk of recurrent cholangitis rapported in 3.5 to 40% of patients. The median time to onset of cholangitis seems to be around 16 weeks occurred mainly in patients with gallbladder in situ or in case of prosthesis insertion without sphincterotomy. In general, these complications were effectively managed endoscopically (6).

In our study, the choice of a single 10 Fr straight stent was purely practical. We also usually use stenting in endoscopic management of bile duct stone in patients with portal hypertension (35%) to prevent oesophageal varice bleeding by nasobiliary drain. As might be expected, with both stones and a

stent remaining in the common bile duct, there is a significant incidence of cholangitis. Five episodes of cholangitis occurred in the 26 patients (18%) managed by intravenous antibiotics, fluids and early but not emergency, stent replacement in 4 patients and by surgery in one case. There was no mortality related.

However, in view of the lond-term risk of cholangitis this technique, as a definitive treatment for choledocolithiasis, should be used principally in elderly and high-risk patients with short life expectancy. In other circumstances it was recommended replacement of the prosthesis about every six months, and then only if risks of biliary tract surgery or other techniques of bile duct clearance continues to outweigh those of recurrent ERCP (9, 10).

#### CONCLUSION

Insertion of a single 10 Fr biliary stent is an effective method of establishing temporary biliary drainage in patients with retained common bile duct stones after endoscopic sphincterotomy. Further endoscopic attempts at bile duct clearance are successful in most cases and small stones may pass spontaneously. If endoscopic stone extraction is not achieved a single biliary stent is a safe alternative to surgery particularly in the frail and elderly. Long term biliary stenting seems to give satisfactory symptom relief in such patients but the techniques requires prolonged evaluation and follow up. The main risk is cholangitis but this complication can be treated endoscopically. Surgical exploration can be then limited to the younger, fitter subjects with inextricable stones after, perhaps two or three unsuccessful endoscopic attempts.

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