

## INTRA-AND POST ERCP MORBIDITY AND MORTALITY AFTER 500 CASES IN ASSIUT

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المعدل المرضى والوفيات أثناء وبعد  
منظار القنوات

المرارية لحمسمانة حالة فى أسبوط  
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أسبوط

يعتبر منظار القنوات المرارية  
البنكرياسية من أنفع الوسائل للتشخيص والعلاج  
المنظاري لأمراض القنوات المرارية والبنكرياس  
ولكنه لا يخلو كغيره من التداخلات المنظارية  
الطبية من بعض المضاعفات التي لا تتعدى النسبة  
الصغيرة جدا مقارنة بما تقدمه من خدمات فى  
مجال التشخيص والعلاج ونحمد الله أن الوفيات  
والمضاعفات الخطيرة نادرة الحدوث بالنسبة  
لمنظار القنوات المرارية البنكرياسية.

وفى هذه الدراسة تم أخذ عينة  
عشوائية من مرضى وحدة المناظير للقنوات  
المرارية البنكرياسية وعددها ٥٠٠ مريض  
لدراسة هذه المضاعفات المرضية.

بينت الدراسة أن نسبة المضاعفات  
الناجمة عن قطع العضلة الضامة للقنوات المرارية  
البنكرياسية مثل النزيف وإصابات قنوات  
البنكرياس وثقب الإثنى عشر الخلف بريتونى فى  
حوالى ٨% من الحالات. ومضاعفات استخراج  
حصوات القنوات المرارية مثل النزيف وفشل  
تكسير الحصوات وكذلك انحسار السلة  
المنظارية والحصوات فى داخل القنوات المرارية  
بنسبة ٦.٩% من الحالات مضاعفات ما بعد  
المنظار التي تم حصرها فى هذه الدراسة تشمل  
التهاب البنكرياس فى ٣% من الحالات.

وكان ارتفاع نسبة أنزيم الأميليز بالدم  
فى ٤% من الحالات، التهاب القنوات المرارية فى  
٣.٦% من الحالات وكذا مضاعفات الدعامات

المرارية مثل تحركها وسقوطها. وعدم قيامها  
بوظيفتها أو انسدادها فى ٣.٢% من الحالات  
ولحسن الحظ أن الوفيات أثناء عمل المنظار لم  
تحدث أثناء الدراسة ولكن وصلت النسبة إلى  
٠.٤% خلال ٤٨ ساعة بعد المنظار والوفيات  
خلال ثلاثين يوما بعد المنظار لا تتعدى ٠.٨% من  
الحالات. وهذا يثبت جدوى منظار القنوات المرارية  
البنكرياسية كوسيلة آمنة فعالة للتشخيص والعلاج.

### SUMMARY

*Endoscopic retrograde  
cholangio-pancreatography has  
become one of the most useful  
diagnostic and therapeutic tools for  
biliary-pancreatic diseases and is  
considered as the gold standard  
approach in this aspect.*

*However, ERCP carries some  
risks and complications, fortunately,  
major and serious complications are  
extremely rare. In this work, 500 cases  
undergoing ERCP were randomly  
selected to study these complications  
the study reveals that most of these  
complications are mild, and of low  
incidence.*

*Complications encountered  
during ERCP included complications of  
sphincterotomy in the form of bleeding,  
pancreatic duct injury and  
retroduodenal perforation in about 8%  
of cases, complications of stone  
extraction as bleeding, failed  
lithotripsy, or basket impaction was  
encountered in 6.9% of cases.*

*Post ERCP complications  
encountered were pancreatitis in 3%,  
hyperamylasemia in 3%, cholangitis in  
3.6% and stent complications as  
migration, slipping, malfunction or  
early closing in 3.2% of cases.*

*Fortunately, mortality during  
the procedure was zero percent, within  
48 hours after ERCP 0.4% and 30 days  
mortality was 0.8% of cases.*

### INTRODUCTION

### AND AIM OF THE WORK

Endoscopic retrograde cholangio-pancreatography (E.R.C.P) has many applications in patients with known or suspected biliary and pancreatic diseases. (Cotton, 1996) and it is considered the gold standard in diagnosis and treatment (Shimizu et al., 1999).

However, ERCP carries some risks and complications, that are broadly similar to those of routine upper gastrointestinal endoscopy, and major complications are extremely rare (Sameh,1993).

The aim of this work is to detect and study the complications following ERCP for a randomly selected sample of 500 patients in Assiut University Hospital either during the procedure or following the procedure.

## PATIENTS AND METHODS

In this work, a randomly selected sample of 500 patients was taken from the therapeutic endoscopy unit, general surgery department, Assiut university hospital. All of them were undergoing endoscopic retrograde cholangio pancreatography (E.R.C.P) for variable indications without specification. No specific inclusion criteria for this work apart from ERCP indication.

For all patients:

Premedication was done using:

- midazolam I.V.
- propofol drip.

Standard ERCP procedure was done using side viewing pentax videoendoscope (EMP 3300) side channel 4.2mm. using different types of instruments that is currently available in the endoscopy unit.

## RESULTS

### 2. Failure of cannulations:

500 patients were studied in this work were categorized as follows:

#### General findings

- The shape of the papilla:

papillary shape was variable as shown in table (2) to be either normal papilla, or abnormal. This abnormality included distortion by fibrosis previous manipulation, unsupported or gravid papilla and infiltration. All these abnormalities have their great impact on procedure success and also on the incidence of complications.

These abnormalities were overcome by:

- a. Trial of free cannulation using sphincterotome.
- b. Pancreatic duct wiring to fix the papilla.
- c. The use of precut knife.
- d. Combined percutaneous-endoscopic (Rendez-vous) technique (rarely indicated).

#### Regular cannula versus sphincterotome cannulations:

In this work, sphincterotome was preferred for cannulations as it provides a great malleability in negotiating the papilla, especially if it was distorted or abnormal.

Double or triple lumen type was preferred over regular type.

#### Complications and difficulties encountered during E.R.C.P.

##### 1. Failure to reach the papilla:

It was encountered in 9 cases (1.8%) due to:

Post operative esophageal stricture in 2 cases

Cicaterized pylorus in 6 cases.

Pyloric carcinoma (incidentally discover-ed) in 1 case.

For these cases, dilatation and E.R.C.P. was done in 5 cases, and the other 4 cases were managed surgically.

Was encountered in 10 cases (2%) due to:

- Malignant ampullary growth in 4 cases
- Para ampullary diverticulae in 4 cases
- Abnormal papilla in 2 cases

For those patients, Rendez-Vous technique was done in 7 cases, and percutaneous transhepatic drainage (P.T.D.) was done in the 3 remaining cases.

### 3. Complications of sphincterotomy

Sphincterotomy was performed in 370 cases. In this work in 74% of cases, of them precut knife sphincterotomy was used in 95 cases (19% of cases).

Complications were encountered in minority of patients. (30 patients about 8% of cases), most of these complications were encountered with the use of precut knife sphincterotomy (in 19 cases, about 64 % of cases).

- Bleeding was of mild type, controlled during the procedure and therapeutic maneuvers continue. Unfortunately, in 2 cases the procedure was stopped and one unit of fresh blood transfusion was needed and re-do ERCP was done 3 days later, but no life threatening

bleeding was encountered during this work.

- Mild pancreatitis in the form of mild abdominal pain, and hyperamylasaemia was encountered following pancreatic duct injury, but it was a self limited problem, resolved within 3 days without any sequelae or complications.
- Retroduodenal perforation and false passage was encountered in 7 cases. In 3 cases. It was necessary to stop technique and re-do ERCP after 3 days due to masking of normal anatomical landmarks.

### 4. Mortality during ERCP procedures

Zero

No mortality encountered during the procedures

### Therapeutic maneuvers:

I. Management of pancreatic problems (25/500): Table 4-6)

II- Management of malignant obstructive jaundice (150/500): Table (7-10)

III- Choledocholithiasis (188/500): Table (11-13)

IV- Benign biliary stricture (117/500): Table (14-16)

V- Postoperative biliary injury with leakage (20/500): Table (17-19)

Post E.R.C.P complications: Table (20)

Post E.R.C.P mortality> Table (21)

Table (1): Categories of the studied patients.

Diagnosis	Number	Percentage (%)
I. Pancreatic problem	25	5
II. Malignant obstructive jaundice	150	30
III. Choledocholithiasis	188	37.6
IV. Benign biliary stricture	117	23.4
V. Post operative leakage.	20	4
Total	500	100

**Table (2):** Various Shapes of the Papilla encountered.

Shape of papilla	Number	Percentage (%)
Normal papilla	190	38
Distorted papilla	45	9
Growth or infiltration	60	12
Para ampullary diverticulae	95	19
Unsupported papilla	80	16
Gravid papilla	30	6
Total	500	100

**Table (3)** shows number and percentage of these complications

Item	Number	Percentage (%)
Bleeding	15	4
Injury of pancreatic ducts & pancreatitis	8	2
Retroduodenal perforation and false passage	7	2
Total	30	8

**Table (4)** shows the presentation of those patients:

Item	Number	Percentage (%)
Pseudocyst.	5	20
Chronic pancreatitis	8	32
Gall stone pancreatitis	12	48
Total	25	100% (25 patient)

**Table (5)** shows management procedures for pancreatic problems

The procedure	Number	Percentage (%)
Eendoscopic cystogastrostomy & stenting	5	20
Sphincterotomy	14	56
Pancreatic stenting	5	20
Pancreatic stone extraction	1	4

**Table (6)** shows complications encountered within 2 weeks after the maneuvers.

Item	Number	Percentage (%)
Cystogastrostomy stent occlusion by debris	1	4
Slipped stent and infection	1	4
Total	2	8

Table (7) shows cholangiographic diagnosis of the malignant stricture.

Malignancy site	Number	Percentage (%)
Ampullary stricture	28	18.7
Low CBD stricture	65	43.4
Mid CBD stricture	8	5.3
Upper CBD stricture	15	10
Hepatic duct stricture	21	14
Combined stricture	12	8.6
Total	150	100

**Table (8)** shows management of malignant obstruction

Management	Number	Percentage (%)
Precut knief	29	12.6
Sphincterotomy	59	39.3
Stenting procedures:		
- 7 & 8 French stent	5	3.3
- 10 French stent	91	60.7
- 11.5 & 12 French stent	30	20
- expandable metal stent	3	2
Dilatation only	4	2.7
Stone extraction	3	2
Biopsy of accessible lesion	69	46
Bile aspiration or brush cytology	35	23.3
Stent retrieval and restenting	70	46.7

**Table (9)** shows difficulties and complications encountered

Complications	Number	Percentage (%)
Failure to reach the papilla	3	2
Bleeding	3	2
Failure to cannulate ampullary growth	4	2.7
Failure to dilate tough stricture	3	2
Stent slipping	2	1.3
Proximal migration	2	1.3
Total	24	16

**Table (10)** shows average functioning period of stents and their exchange

Item	Minimum period	Max. period
7 fr. Stent	3 weeks	3 months
8 fr. Stent	3 weeks	3.5 months
10 fr. Stent	2 months	14 months
11.5 fr. stent	4 months	18 Months

**Table (11)** shows presentations of those patients with choledocholithiasis

Item	Number	Percentage (%)
• Jaundice		
- post cholecystectomy	55	29.3
- with chcalc. Cholecystitis	52	27.6
- haemolytic anemia	3	1.6
• Biliary colic	28	14.9
• Cholangitis	18	9.6
• Biliary pain	6	3.2
• Post.op. bile leak	12	6.4
• T. cholangiogram abnormality	14	7.4
Total	188	100

**Table (12)** shows therapeutic manquvers done

Item	Number	Percentage (%)
• Sphincterotomy	153	81.4
• Balloon sphincteroplasty	21	11.2
• Basket extraction	78	41.5
• Balloon extraction	67	35.6
• Lithotrepsy	26	13.8
• Stenting for:		
- failed stone extraction	6	3.2
- major leakage	1	0.5
- mirrizi's syndrom	4	2.1
- haemobilia	1	0.5
- bad general conditions	7	3.7
- severe cholangitis	7	3.7
- associated stricture	25	13.2
• Dilatation	8	4.3

**Table (13)** shows complications encountered

Complications	Number	Percentage (%)
Bleeding during manipulation	3	1.6
Failure to extract the stone	5	2.7
Failed lithotrepsy	4	2.1
Basket impaction	1	0.5
Total	13	6.9

**Table (14)** shows presentation of patients

Presentation	Number	Percentage (%)
Post cholecystectomy jaundice	46	39.3
Cholangitis	26	22.2
Post.cholecystectomy leakage	26	22.2
Biliary pain	9	7.7
Cholangiogram abnormality	10	8.6
Total	117	100

**Table (15)** shows therapeutic manquvers

Therapeutic procedure	Number	Percentage (%)
• Sphincterotomy	72	61.5
• Balloon sphincteroplasty	20	17.1
• Stricture dilatation		
- Balloon	33	28.2
- bougie	57	48.7
• Stenting procedure		
- 12 French stent	18	15.4
- 11.5 fr. Stent	17	14.5
- 10 fr. Stent	29	24.8
- double stent	13	11.1
- 8 fr. Stent	5	4.3
• Other procedures		
- stone extraction	6	5.1
- biopsy of suspicious masses	5	4.2
- stent retrieval and restenting	30	25.6

**Table (16)** shows difficulties and complications encountered.

Complications	Number	Percentage (%)
Ligated CBD with failure of procedure	8	6.8
Failure of stenting of tough stricture	3	2.6
Proximal stent migration	1	0.9
Stent slipping	1	0.9
Total	13	11.1

**Table (17)** shows presentations of patients

Presentation	Number	Percentage (%)
Post cholecystectomy	14	70
Post chole. & CBD exploration	3	15
Post traumatic	3	15
Total	20	100

**Table (18)** shows therapeutic maneuvers

Procedure	Number	Percentage (%)
Sphincterotomy	14	70
Stenting procedure		
- 12 fr. Stent	2	10
- 11.5 fr. Stent	3	15
- 10 fr. stent	7	35

**Table (19)** shows complications encountered

Complications	Number	Percentage (%)
C.B.D transection with procedure failure	2	10
Slipped stent	1	5
Residual stricture	1	5
Total	4	20

**Table (20)** shows these complications and their incidence

Complications	Number	Percentage (%)
• Pancreatitis		
- Mild cases	8	1.6
- Moderate	4	0.8
- Severe cases	3	0.6
• Hyperamylasaemia	15	3
• Upper abdominal pain and discomfort	13	2.6
• Stent complications		
- Migration to liver	2	0.4
- Slipping	3	0.6
- Malfunction	5	1
- early clogging	6	1.2
• Cholangitis		
- mild cases	11	2.2
- moderate cases	5	1
- severe cases	2	0.4
Total	77	15.4

**Table (21)** shows mortality rate

Item	Number	Percentage (%)
Mortality during the procedure	-	-
Mortality during 48 hours after ERCP	2	0.4
Mortality within 30 days	4	0.8
Total	6	1.3

**Fig. (1):ERCP showing malignant stricture at lower C.B.D.? cancer of pancreatic head, treated by stenting.**



**Fig. (2):ERCP showing malignant stricture? Cholangiocarcinoma at upper C.B.D treated by stenting.**

**Fig. (3):ERCP showing Basket extractions of multiple stones from C.B.D. in post. Cholecystectomy patient.**

**Fig. (4):ERCP showing malignant growth at the ampulla? Ampullary carcinoma treated by stenting & biopsy.**

**Fig. (5):The same case treated by double stenting.**

**Fig. (6):ERCP showing malignant stricture lower C.B.D.? Ampullary carcinoma with metastatic deposit stricture at porta hepatis.**

**Fig. (7):The same case treated by Ballon extractions after shincterotomy.**

**Fig. (8):ERCP showing stone filling defect in the C.B.D. in post cholecystectomy patient.**

**Fig. (9):The same case with protrusion of the lower end of the T.tube from the papillary orifice, obstructing it.**

**Fig. (10):ERCP showing post operative leakage due to badly placed T.tube, that does not drain and obstruct C.B.D.**

**Fig. (11):ERCP showing bleeding as a complication following sphincterotomy.**

**Fig. (12):ERCP showing post. Cholecystectomy leakage at the site of cystic duct treated by sphincterotomy.**

**Fig. (13):The same case as shown by P.T.C showing severely injured C.B.D? partial transection a ligation at upper C.B.D.**

**Fig. (14):ERCP showing arrest of the dye at upper C.B.D. in post-cholecystectomy patient, with failure to continue.**

**Fig. (15):The same case with complete maneuver, and endoscopic placement of stent was done stradeling the area of injury or ligations.**

**Fig. (16):The same case as Rendez-vous technique was done and wire in seen passing per cutaneously through the injured or ligated area to the duodenum.**

## **DISCUSSION**

### **Complications during E.R.C.P**

#### **1. Bleeding:**

Bleeding complicates endoscopic sphincterotomy in 2.5-5% of cases. (Cotton et al., 1991). However, some degree of bleeding ranged from oozing to severe bleeding is seen at the time of sphincterotomy in about 10-30% of cases (Freeman et al., 1996). Usually obvious and occurs immediately after sphincterotomy, but can lag behind the procedure by several days (Finnie et al., 1990), as long as ten days after sphincterotomy (Freeman et al., 1996). Clinically significant hemorrhage is usually defined as melena or haematemesis with fall in hemoglobin, or any bleeding that requires secondary intervention such as endoscopy or

blood transfusion (Cotton et al., 1991).

In this work, bleeding was encountered in 15 cases (4%), and it is intimately related to the use of precut knief. Such bleeding was mild and controlled during the procedure in 13 cases (3.5%), and in 2 cases it was moderate, necessitated stoppage of procedure and blood transfusion of one unit of blood (0.5%), and re-do ERCP after 48 hours, no severe bleeding or life threatening bleeding was encountered. This is in agreement with Cotton (1996), who stated that the incidence of bleeding is 5% of which 3% are mild, 1% moderate and 1% severe.

#### **2. Retroduodenal perforation and false passage**



Perforation is reported in 1% or less of sphincterotomy procedures (Cotton and Williams, 1990). Perforation due to sphincterotomy itself generally results from extension of the incision beyond the intramural portion of the bile duct or pancreatic duct (Freeman et al., 1997). It is generally related to the use of needle knife sphincterotomy (Freeman et al., 1996), and computed tomography is a very sensitive method for detecting perforation (Cotton and Williams, 1996).

In this work, retroduodenal perforation, and false passage was encountered in 2% of patients and diagnosed during the procedure, and the procedure was stopped in half of the cases for re-do ERCP after 3 days. No surgery was needed for these patients.

### **3. Pancreatitis**

Pancreatitis is the commonest complication of E.R.C.P procedure. It has been reported in 1% to 40% of cases, and should be distinguished from transient asymptomatic hyperamylasemia which occurs in up to 70% of patients (Andriulli et al., 2000).

Following pancreatography, benign hyperamylasemia with hyperamylasuria lasting 24-48 hours commonly occur in the absence of pain or any other indication of pancreatitis (Skude et al., 1976), its severity is graded by length of hospital stay and the need for surgical or radiological intervention (Cotton et al., 1991).

In this work, pancreatitis was encountered in 15 cases (3%), varied from mild condition (8 cases), moderate severity in 4 cases and

severe condition in 3 cases however no major complication was encountered as pancreatic abscess or necrosis.

In contradistinction to hyperamylasemia which was encountered in 15 patients (3%) pancreatitis may be attributed to many factors either mechanical, chemical, hydrostatic, enzymatic, microbiological and thermal. (Sherman, 1994) and a study by Freeman et al. (1996) identified five factors that were significantly related to post ERCP pancreatitis. These include suspected sphincter dysfunction, younger age, difficult cannulation, repeated injection of contrast medium into pancreatic ducts and the use of precutting techniques. Vandervoort et al. (1997) has confirmed these findings. Fortunately, the majority of patients respond well to conservative treatment. (Venu and Geenen, 1992) and surgical or radiologic intervention is reserved for pseudocyst or abscess formation (Gordon and Shapiro, 1990).

### **4. Cholangitis**

Cholangitis (ascending bile duct infection) is a potential complication or sequela of sphincterotomy (Cotton et al., 1991). Possible mechanisms are contamination by instillation of contrast media, or by duodenobiliary reflux and bactobilia (Freeman, 1997). It can be prevented by prophylactic antibiotics (Geenen, 1982 & Sauter et al., 1990) and good clearance of C.B.D (Gordon and Shapiro, 1990), or complete drainage (Freeman, 1997)

Microbial contamination of the biliary system affects 50-100% of

patients after sphincterotomy (Bergman et al., 1997). However, cholangitis in single or repeated episodes develops in as much as 7-9.6% of patients. And without evidence of biliary obstruction, it is reported in 1.9-3.4% of patients (Prat et al., 1996).

In this work, cholangitis was encountered in 3.6% of cases (18 patients), including mild cholangitis in 11 cases, moderate in 5 cases and severe cholangitis in 2 cases.

### **5. Complications with stone manipulation**

Impaction of basket during endoscopic bile duct stone removal is rare, and seen only in 0.8-5.9% of cases (Siegel, 1992). If a common duct stone is encountered that is relatively large in relation to the distal biliary orifice, or of an awkward shape, a Dormia basket may become impacted, making removal by simple pulling maneuvers impossible (Siegel, 1992).

In this work, failure to extract the stone was encountered in 5 cases (2.7%) due to abnormal distorted shape, lower stricture or non-dilatable segment of intra-pancreatic C.B.D. Whereas, lithotripsy failure was encountered in 4 cases (2.1%) due to hard missed stone, all managed by stenting. Basket impaction was encountered in one case (0.5%) and managed endoscopically by lithotripsy. Although in the past, retained basket was considered primarily a surgical problem (Landreneau et al., 1990).

Recent reports indicate that non operative attempts at retrieval are usually successful, and Sauter and others (Sauter et al., 1995) have

successfully treated this problem endoscopically in conjunction with various forms of lithotripsy (Neuhaus et al., 1992).

### **6. Complications with stricture manipulation**

Although surgical therapy has been the major treatment modality for benign biliary strictures with 70-90% long term success rate (Davidoff et al., 1992), yet a defined morbidity and mortality have prompted attempts at alternative therapies (Richard A, Kozarek, 1994).

Endoscopic management of biliary stricture requires continuity of the biliary tree (Ricardo et al., 1994). In this series, ERCP failure was encountered in 8 cases of ligated or clipped C.B.D. and in 2 cases of post operative C.B.D. transection as C.B.D. continuity is disturbed.

Complications of stricture management are those associated with all therapeutic ERCP procedures, plus the additional potential complications of stricture management perse, as major complications rate of 1-2%, and minor complication rate of 5-10% (Smith et al., 1995).

In this work, total complications encountered with stricture manipulation was 11.1%, with overall failure rate about 9.4% of cases to place biliary endoprosthesis. On the other hand, Davids et al., 1993 reported that successful endoprosthesis placement was accomplished in 94% with benign stricture with failure rate about 6%.

In this work, failure to dilate biliary stricture was encountered in 3 cases of benign stricture and 3 cases

of malignant stricture, in these situations, percutaneous trans-hepatic approach can be useful (Martin, 1994) or combined approach (Smith, 1995).

In this work, mostly all our patients outcome after endoscopic stricture manipulation were good as Walden et al., 1993 and Geenen et al., 1989 reported that long term outcome of endoscopic stenting of biliary benign stricture were similar to those of surgical treatment. So, this technique of endoscopic stricture manipulation can be considered as the primary option for management (Prat et al., 1997).

### **7. Complications encountered with stents**

Endoscopic stenting was done for various indications in this work.

Most authorities recommended 10 french straight stent (Gilbert et al., 1992). However, a non-randomized retrospective comparison of 10 and 11.5 french stents showed no significant differences in duration of patency, cholangitis, stent migration, or pancreatitis (Sherman et al., 1994).

Stent complications encountered in this work include migration in 2 cases (0.4%), slipping in 3 cases (0.6%), malfunction in 5 cases (1%) or early clogging in 6 cases (1.2%).

Stent migration was observed in 2-5% of patients, but the most significant problem is stent clogging which usually occurs after 4-5 months (Sung and Chung, 1995) with accompanying cholangitis which occurs in a mean of 4-6 months in about 20% of patients (Spear et al., 1988) and the median stent patency was about 83 days (Van Berkel et al., 1998).

The mechanism of stent clogging is multifactorial and include bacterial attachment via a fibrillous material (Biofilm), deposition of calcium bilirubinate crystals and food debris (Speer et al., 1988 and Sung & Chung, 1995).

Factors which may contribute to stent clogging include smaller stent diameter (i.e under 10 french), (Rey JF, 1985), stent shape (Pigtail tapered ends) (Leung et al., 1985), the presence of side holes (Coene et al., 1985), and roughness of the stent surface. The length of the stent and the location of tumor treated appear to be unrelated to the duration of stent patency (Matsuda et al., 1991).

Various strategies to prevent stent clogging are under investigation. Antibiotic coating of stent failed to impede the rate of stent clogging (Brown et al., 1990). Silver impregnation of stent markedly decreased accumulation of bacteria in an in vitro study (Leung et al., 1990). Stent made of an ultrasMOOTH polymer inhibited bacterial growth and biliary sludge accumulation in a 7-day in vitro trial (McAllister et al., 1991). Prophylactic antimicrobial agent, bile salts, new stent material and new stent design may help to decrease clogging (Sung and Chung, 1995).

### **Procedure related mortality**

In this work, mortality during the procedure was zero percent. However 2 patients (0.4%) died 48 hours after ERCP due to hepatorenal failure, and no response to conservative measures after successful stenting for massive malignant obstruction and 30 days mortality was 0.8% (4 patients).

Procedure related mortality was variable about 0.1% (Bilboa et al., 1976) up to 2% (Soehendra et al., 1980) and 30 days mortality of about 14% (Van Berkel et al., 1998).

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