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# *Endoscopic Biliary Stent: Experience in 57 Patients with Various Biliary Problems at Songklanagarind Hospital*

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**We report our experience in management and follow-up of 57 patients with biliary obstruction treated by endoscopic stent insertion or combined percutaneous and endoscopic technique between 1990 and 1995. There were 40 patients with malignant diseases and 17 patients with benign diseases. The stent was successfully inserted in 28 cases (70%) of malignant obstruction and in 17 cases (100%) of benign obstruction. Jaundice was improved in 88.9% in malignant group. Clinical improvement was achieived in 82% in benign group. Early complications occurred in 13 cases (benign = 4, malignant = 9). The mortality rate was 5.26 per cent with procedure-related mortality of 1.75 per cent. Median survival available in 23 patients with malignant obstruction was 11 weeks and 25 per cent survived more than 6 months. Endoscopic stent insertion is an alternative in the therapeutic options available. The procedure is a useful and safe method in the treatment of malignant and benign biliary obstruction but its role as compared with surgery in terms of efficacy, cost and quality of life in our setting remains to be evaluated in controlled study.**

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The technique of insertion of biliary stents was first described in 1979. Since then it has become an accepted method for the palliation of malignant biliary obstruction.[1-6] This is especially useful for patients with periampullary carcinoma and cholangiocarcinoma since few patients will be suitable candidates for surgery and also can

survive more than 5 years.[7-9] Indications for benign diseases include large common bile duct (CBD) stones with failed stone removal in high risk patient, sclerosing cholangitis, benign biliary stricture, and bile leakage from blown cystic duct stump or CBD injury after laparoscopic cholecystectomy (LC). We described our experience in using this stent in various biliary conditions in our hospital.

## MATERIALS AND METHODS

Fifty seven patients were treated by endoscopic stent insertion or combined technique. The data were retrieved, reviewed and extracted into standard data record forms (some were retrospective and some were prospective) from February 1990 to May 1995 in 55 cases and two cases from early attempts before this interval were included in the analysis.

The first two stents were home-made stent of 7 Fr gauge and the rests were 10 Fr stents (Wilson-Cook, Denmark) of suitable length to allow proximal tip to lie well above the stenosis. The standard ERCP preparation was used throughout the study period. Routine antibiotic prophylaxis with 1 g of cefoxitin or 750 mg of cefuroxime was given 30 minutes before the procedure except in patients currently receiving antibiotics or in some patients participating in the double-blinded randomized study comparing the efficacy of ampicillin plus gentamicin against placebo in the prevention of biliary infection associated with ERCP conducted in our unit. Diazepam 2-10 mg with pethidine 5-25 mg were given intravenously for sedation. Sphincterotomy was not used routinely except when two prostheses were inserted or deep cannulation was impossible without precut sphincterotomy.

Cholangitis was defined as 1) fever in the setting of biliary obstruction with or without jaundice and/or abdominal pain with no other sources identified or with positive bile culture, 2) fever after the procedure without other sources identified or bile culture was positive for organism. Pancreatitis was defined as compatible abdominal symptoms and elevation of serum amylase after the procedure. Improvement of jaundice was defined as > 50% declining of total bilirubin after stent insertion compared with the pretreatment level. Early complication was defined as complication occurred within one week after the procedure. Mortality was defined as death within the same admission of the procedure. Chi-square or Fisher's exact test were used for statistical analysis where appropriate.

## RESULTS

There were 29 male and 28 female patients with the mean age of 58.49 (SD=15.63) and a range of 15-92 years. Forty patients had malignant diseases with 22 males and 18 females and the mean age was 58.3 (SD=15.13) with a range of 15-92 years. Seventeen patients had benign diseases or undetermined diagnoses with 7 males and 10 females and the mean age was 58.94 (SD=17.24) with a range of 20-80 years. Stent insertion was successful in 45 of 57 patients (79%).

**Malignant diseases:** Stents were successfully inserted in 28 of 40 patients (70%); 24 patients by endoscopic mean and another 4 patients by combined percutaneous and endoscopic mean and another 4 patients by combined percutaneous and endoscopic method. Stents were inserted for bile drainage in cholangitis with or without jaundice in 6 cases, for obstructive jaundice in 22 cases including bile leakage after percutaneous transhepatic biliary drainage (PTBD) in one and as a stent exchange for blocked stent which had been inserted percutaneously elsewhere in another. The diagnoses of the malignant group were shown in Table 1. Endoscopic sphincterotomy (ES) was done in 12 of 28 cases.

Of the 6 patients with cholangitis; 3 responded to stent drainage included one who developed cholecystitis 6 days after stent insertion leading to cholecystectomy and 3 patients did not improve; one requested to be treated elsewhere, one was discharged with no further treatment and the other one had Whipple's operation which the fever subsided after the operation.

Twenty four of 27 patients (88.9%) with available data showed improvement of jaundice and the remaining 3 cases did not improve, one due to inadequate drainage and died of uncontrolled sepsis, one for unknown reason, and the other one, despite the cessation of bile

leakage, jaundice did not change due to advanced liver metastasis and carcinomatosis, and died shortly after the stent insertion.

Excluding two patients with curative operation, the available data of 23 patients were analyzed for survival. The Kaplan-Meiter analysis (Figure 1) showed the median survival of 11 weeks with a range of 1-49 weeks. Six of 23 patients (25%) survived beyond 28 weeks. The status of these patients at the time of analysis were 3 alive, 8 dead and 12 unknown.

Blockage of stent was documented in 7 of these 23 patients. In one patient, stent was blocked twice over a 35 weeks period and stent changes improved the symptoms. In another 5 cases, stents were blocked at 8,15,17,28,37 weeks, respectively and stent changes were done in four except the first case who was too sick to undergo stent change and he died of liver failure. The four who had stent changed; the first one died of ruptured liver abscess, the next two cases improved, and the remaining one who had stent blockage at 37 weeks died within 24 hours of severe cholangitis. The last patient had stent blockage for unknown period and died of uncontrolled sepsis.

The location of obstruction and the result of stent insertion related to the site of the obstruction were shown in Table 2. The failure rate was high in distal bile duct obstruction but the difference was not statistically significant (Chi-square, p=0.196). The number of sphincterotomy in patients with successful stent insertion is lower than in those who failed stent insertion (12/28 vs 8/12). However, the difference was not statistically significant (Fisher's exact test, p=0.30).

**Benign diseases:** Stent insertion was successful in all 17 cases (100%). The indications were cholangitis in 9, obstructive jaundice in 4, jaundice of undetermined cause in 2, biliary colic

**Table 1** The Diagnoses of Biliary Obstruction.

| Diagnosis | No. of cases | Pathology confirmed |
|---|---|---|
| **Malignant diseases** | | |
| Cholangio CA | 20 | 3 |
| Pancreatic CA | 11 | 3 |
| Periampullary CA | 5 | 4 |
| CA gallbladder | 3 | 3 |
| Metastatic colonic CA | 1 | 1 |
| **Total** | **40** | **14** |
| **Benign diseases** | | |
| CBD stones | 7 | |
| Biliary stricture | 4 | |
| Papillary stenosis | 1 | |
| Tubulovillous adenoma of ampulla | 1 | |
| Jaundice of unknown cause | 2 | |
| Undetermined | 2 | |
| **Total** | **17** | |

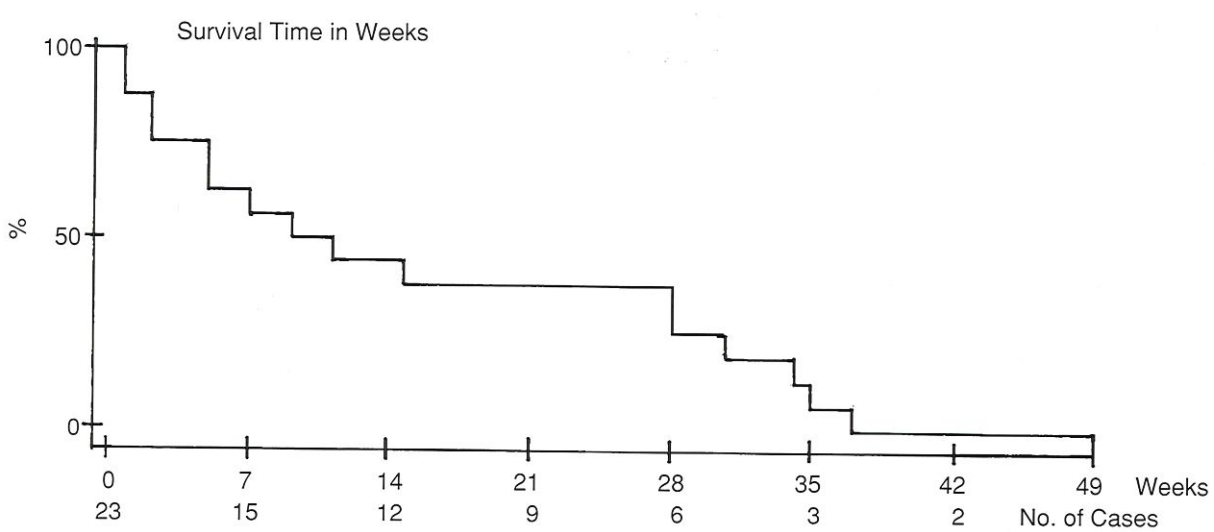


**Fig 1** Survival curve of malignant diseases.

in one and as sphincterotomy guide in one. Stent insertion was done by endoscopic mean in 16 and combined technique in one. The diagnoses of the benign diseases were shown in Table 1.

Stents were inserted to drain CBD in 7 cases of CBD stone with good clinical response in all. One of these underwent operation after clinical symptoms subsided, one patient refused surgery. In one patient, the stone was removed endoscopically, whereas 3 patients failed from stone extraction due to large stones had stents placed for drainage and surgery was subsequently performed. Stent was inserted in one case with CBD stone after LC which served as a guide for sphincterotomy by needle papillotome due to the papilla located in a duodenal diverticulum and the stone was then removed endoscopically.

Stent insertion was done in 4 patients with benign biliary stricture, 2 cases associated with gallstones, one due to previous CBD exploration and the other of undetermined cause. Three of these, stents were placed for preoperative drainage. In one patient, stent insertion was used as non-operative treatment of the stricture because the stricture was judged by a surgeon to be technically difficult for surgical repair. All 4 patients showed clinical improvement after stent drainage.

Two patients had stent drainage as a preoperative measure. In one patient, papillary stenosis was diagnosed based on prompt relief of jaundice after drainage and surgery failed to show any tumor of the periampullary region. Surgical sphincteroplasty was done with the patient doing well with the follow-up of 72 weeks. The other patient underwent Whipple's operation with the operative specimen showed tubulovillous adenoma of pancreas.

Two patients with jaundice of uncertain cause, stents were inserted for drainage without improvement. One of the two, liver biopsy showed reactive hepatitis of unknown cause.

Two patients with unknown diagnoses were treated by stent insertion. One of these with obstructive jaundice, ERCP showed a dilated CBD so stent was inserted to drain the bile duct but no data available thereafter. The other patient presented with clinical pictures of cholangitis. ERCP revealed a dilated CBD of unknown cause. Stent insertion was done to drain the CBD. The clinical condition improved slightly for 2 days then deteriorated. At operation, empyema of acalculous gallbladder and blood clot in the CBD were found. The patient expired one week after the operation. No definitive diagnosis was established.

Sphincterotomy was performed in 7 patients; CBD stones in 4, benign stricture in one, jaundice of unknown cause in one and unknown diagnosis in the remaining one case. The status of the patients was concluded as one dead, 4 alive, and 12 unknown.

**Complications:** Early complications occurred in 6 cases in malignant group with successful stent insertion. Bleeding from puncture site occurred in one patient and 3 units of blood transfusion were required. Cholangitis occurred in 3 patients; 2 responded to antibiotics treatment, one with Bismuth type IV tumor and inadequate stent drainage died of uncontrolled sepsis. One developed cholangitis and pneumonia which responded to antibiotics treatment. One patient with the initial stent placed in the left intrahepatic duct developed cholecystitis 6 days after stent insertion leading to cholecystectomy with a stormy postoperative course including abscess formation and bile leakage. Stent exchange was required to drain the right intrahepatic duct to obtain the closure of the leakage.

In 12 patients who failed stent insertion, complications occurred in 3 cases; 2 had catheter-induced perforation but needed no intervention. One patient had minimal bleeding and mild pancreatitis which resolved with conservative treatment.

Data ere available in 15 patients with be-

**Table 2** The Locations of Obstruction in Malignant Diseases and Results of Stent insertion.

| Site | Successful | Failed |
|---|---|---|
| Distal CBD | 8 | 7 |
| Mid BD | 6 | 2 |
| Proximal BD | 8 | 3 |
| Bifurcation or higher | 6 | 0 |
| **Total** | **28** | **12** |

**Table 3** Complications of Stent Insertion and Mortality of the Groups.

| Complications | Benign | Malignant |
|---|---|---|
| **Early complications** | | |
| Bleeding from puncture site | - | 1 |
| Cholecystitis | 1 | 1 |
| Cholangitis | 1 | 3 |
| Stent pushed into CBD | 1 | - |
| Postoperative bleeding & pancreatitis | - | 1 |
| Catheter perforation | - | 2 |
| Empyema of GB and hemobilia | 1 | - |
| Cholangitis and pneumonia | - | 1 |
| **Total** | **4** | **9** |
| **Late complications** | | |
| Cholecystitis | 1 | 1 |
| Cholangitis | 1 | - |
| Stent migrated into CBD | - | 1 |
| **Total** | **2** | **2** |
| Mortality | 1 | 2 |
| Procedure-related mortality | 1 | - |
| **Total mortality%** | **5.26** | |
| **Total procedure-related mortality%** | **1.75** | |

nign diseases. Early complications occurred in 4 patients, one case with empyema of gallbladder with hemobilia, one case with the stent pushed into the CBD and sphincterotomy was done to remove the stent. In one patient with large CBD stone, elective surgery was done uneventfully. In one patient with benign stricture, stent insertion was accomplished by combined technique after failure of two endoscopic attempts. Bile leakage from the puncture site with fever and abdominal pain occurred. However, the patient recovered after conservative treatment. The overall early complication rate was 13 out of 57 (22.80%).

Late complications apart from stent blockage occurred in 2 patients in malignant group. One was admitted with a diagnosis of acute cholecystitis based on clinical ground. He responded to antibiotics treatment without surgery. Stent migrated into the CBD in one case and stent exchange failed to improve the symptoms of cholangitis, she was taken home and died shortly thereafter. Late complications occurred in 2 patients in benign group; one cholecystitis 4 weeks after stent insertion and one cholangitis after stent slipped off. The overall late complication rate was 4 out of 57 (7%).

**Mortality rate:** Two patients in the malignant group and one in undetermined group died. The mortality of the whole group was 5.26 per cent. Only one procedure-related mortality occurred (1.75%).

The summary of complications and mortality of the whole group was shown in Table 3.

## DISCUSSION

Resection for carcinoma of head of pancreas can carry a considerable mortality and morbidity rates and the prognosis even after curative operations remains poor, with 10 per cent overall survival rate at 2 years. Bypass surgery is far from harmless particularly in elderly and severely ill patients. For cholangiocarcinoma the figures are equally bad. Alternative non-operative method therefore aroused much interests. The first method available was PTBD. The result in relief of jaundice was as effective as bypass operation. However, it unfortunately carried many serious hazards relating to transhepatic route, notably hemorrhage and bile leakage from the puncture site.[10-12]

Endoscopic biliary stent was an alternative to PTBD. The prosthesis allowed bile to re-enter the bowel and offered a more attractive physiologic method than external transhepatic draiange. Furthermore, it is much more appealing and comfortable for the patient.

The use of pre-operative drainage is controversial. Many studies have failed to demonstrate any advantage. This may be due to many risks related to PTBD which may mask any advantages. If ERCP is used for preoperative examination of jaundiced patients, endoscopic stent is an essential part of the examination.[10,12,13,17]

The role of stent in the treatment of benign biliary obstruction has emerged recently and these included benign biliary stricture, large CBD stone, sclerosing cholangitis and bile leakage or fistula after surgery.[13-18] The success rate of stent insertion in 17 benign cases was excellent and clinical improvement achieved in 14 patients (82%) was impressive. This finding and results of other reports support the value of stent

in these circumstances.

Operation for CBD stones carry high risks in elderly people18 and internal prosthesis is a valuable adjunct to sphincterotomy if all stones can not be removed because of large size or duct stricture.[19] With our limited experience in two patients, the long term result of stent was not as good as reported in the literature.[20-25]

Success rate for stent insertion in malignant group was 70 per cent which was lower than report from center with more experience.[26] Endoscopically visible extrinsic invasion by a malignancy in the pancreatic head is the major reason for failed stent insertion in one study.[14] However, most of our failures were due to failure to pass the guide-catheter through the stricture and were not influenced by the site of lesions. The type of lesion was found to affect the successful drainage by stent. Bismuth type I lesion had the highest successful drainage whereas type III had the worst.[15] Of 27 patients with malignant disease, jaundice was improved in 24 cases (88.9%) so the efficacy of stent was good in our series and was similar to results of other reports.[27-31] However, the median survival of 11 weeks in our patients was rather short but was close to those of other reports.[27-31] The efficacy of stent in cholangitis was rather low in malignant group while the efficacy in benign group was impressive. The poor result in the malignant group may be explained by inadequate drainage of the infected bile particularly in the complex obstruction by tumor at the level of bifurcation.

The early complication rate of 13 from 57 cases (22.80%) was slightly higher than other reports.[2,3,12,28-31] This may signify that we are still in the learning curve. Cholangitis was the most serious complication found in one report and inadequate drainage was the main reason leading to unfavorable outcome.[15] Stent blockage is a major drawback. The patency-time of the stents was similar to the reports of others.[26,32,33] Stent replacement increased the cost of treatment by stent in long-term. Controlled studies have shown that stent drainage increased number of hospital admission more than surgery but the overall cost is similar.[27] The long term result regarding quality of life was reported to improve in one study.[31] The overall mortality in our series was similar to other reports.[23,28-30] and the procedure-related mortality was closed to the reported mortality of therapeutic ERCP in general.[33]

Our study has underscored the value of stent in biliary diseases. The role of stent as an adjunctive treatment in benign diseases is appreciated. The actual role of this procedure in the management of malignant biliary diseases compared with surgery in our community remains to be seen, although the data from western countries have shown that both were comparable for distal biliary obstruction.[23,32]

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