

Comparison of treatment outcomes between biliary plastic stent placements with and without endoscopic sphincterotomy for inoperable malignant common bile duct obstruction

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Abstract

AIM: Considerable controversy surrounds the adoption of endoscopic sphincterotomy (ES) to facilitate the placement of 10F plastic stents (PS) and to reduce the risk of pancreatitis. The aim of the study was to assess the possible advantages of ES before PS placement.

METHODS: From 3/1996 to 6/2001, 172 consecutive patients, who underwent placement of a single 10F polyethylene stent for inoperable malignant strictures of the common bile duct, were randomly assigned to 2 groups. In group A (96 patients), a ES was performed before PS placement. In Group B, 96 patients had PS directly. Early complications (within 30 d) and late effects (from 30 d to stent replacement) were assessed. Patency interval was defined as the period between PS placement and obstruction or death. The success of stent replacement in the 2 groups was evaluated.

RESULTS: Stent insertion was successful in 95.8%(92/96) of the pts in group A and in 93.7%(90/96) of the patients in group B ($P>0.05$). Early complications were more frequent in patients who underwent ES (6.5% vs 4.4%) but the data were not significant ($P>0.05$). In group A pancreatitis developed in two patients and bleeding in three; whereas pancreatitis occurred in 2 patients in group B. Complications were managed conservatively. No procedure related mortality occurred. All late complications were acute cholangitis due to stent occlusion. We performed a stent replacement in 87 patients that was successful in 84 cases without differences between groups.

CONCLUSION: Sphincterotomy does not seem to be necessary for placement of 10F-PS in patients with malignant common bile duct obstruction.

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INTRODUCTION

Endoscopic insertion of biliary stents is the preferred method of palliation for inoperable malignant biliary obstruction^[1-3]. It

efficiently relieves jaundice and improve quality of life in patients with malignant obstructive biliary disease. The endoscopic approach is more cost-effective than the operative approach.

The use of plastic stents (PS) is nowadays recommended in patients with poor prognosis (less than 5-6 mo)^[4-6]. Initial endoscopic placement of a metal stent is a cost-saving strategy only in patients expected to survive longer than six months.

Controversy exists regarding the use of endoscopic sphincterotomy (ES) before placing 10F stents. Endoscopists who preferred to perform ES pointed out that it was easier to place stents and substitute. Also ES would decrease also post-procedure pancreatitis. Antagonist to ES aim to eliminate risks of complications due to ES. The purpose of this study was to evaluate the potential advantages for ES before PS placement.

MATERIALS AND METHODS

From March 1996 to June 2001 172 consecutive patients who underwent placement of a single 10F polyethylene stent (Cotton Leung biliary stent) for inoperable malignant stricture of the common bile duct, were randomly assigned to two groups (Table 1). In group A (96 patients) an ES was performed before PS was placed.

Group B (96 patients) received PS placement without ES.

The following patients were excluded namely those who had already had ES, precut papillotomy or stent placements, those with previous Billroth II resection and, also, those suffering from coagulopathy. Those with ampullary tumours were not included, either.

The diagnosis and poor prognosis of the patients were established by various imaging methods (US, EUS, TAC, MRC) and on the basis of age.

Patients were randomised by using sealed opaque envelopes. Randomisation was done only after diagnostic cholangiography had been performed.

This study reviewed and approved by the ethics committee of our hospital, was carried out in accordance with the Helsinki Declaration as revised in 1989. All patients were included after they had given their written informed consent on ethics committee forms.

All patients underwent operative endoscopic retrograde cholangiopancreatography (ERCP) with a duodenoscope (JF 140 Olympus) performed by 2 experienced endoscopists. A standard 0.035-inch guidewire to perform deep cannulation of the biliary tree and to pass through the strictures.

Occasionally a hydrophilic guidewire was used. In every patient we also aimed to visualize the pancreatic duct.

The success the technique was evaluated as a correct placement of the stent with good drainage of bile from the bile duct into the duodenum as visualized endoscopically. Early complications (occurring within 30 d) and late effects (from 30 d to stent replacement or death) were assessed. Complications of papillotomy were considered according to the criteria of Cotton^[7] Stents were not replaced routinely and patients were treated if occlusion of the stent or cholangitis

developed.

Occlusion was considered in patients with jaundice.

Patency interval was defined as the period between PS placement and obstruction.

Analysis of data was performed with the statistical package SPSS/PC version 4.0 (M.J. Norusis Chicago, Ill). Rate differences were tested by using the χ^2 analysis with Yates' correction and Fisher's exact test, when appropriate. The Mann whitney *U* test was used to compare median values of variables between the two groups. Values of $P < 0.05$ were regarded as statistically significant.

RESULTS

Patient characteristics did not differ between groups (Table 1). A histological diagnosis was obtained in 104 patients (54.1%) using biliary brushing and biopsies, and FNA-US. In the other cases we presume diagnosis using morphologic criteria.

A similar mean stents length among groups indicated a similar localization of biliary strictures.

Results of endoscopic treatment are shown in Table 2. The mean follow up time was 115±95 d (mean±SD).

Table 1 Patients characteristics

	Group A With ES	Group B w/o ES	Total
Patients	96	96	192
Median Age (±SD)	72±6	75±6	73±7
Gender (M/F)	51/35	47/39	98/74
Bilirubine (mg/dL)	13.5	11.9	12.7
Stent length(cm)	6.78	6.76	6.79
Visualization of pancreatic duct	77	79	156
Pancreatic cancer	64 (66.6 %)	67 (69.8 %)	131 (68.2%)
Cholangiocarcinoma	31 (32.3 %)	28 (29.1 %)	59 (30.7 %)
Metastatic lymph nodes	1 (1.1%)	1 (1.1%)	2 (1.1 %)

Table 2 Endoscopic technique results

	Group A With ES (%)	Group B w/o ES (%)	<i>P</i>
Successful stent insertion	92/96 (95.8)	90/96 (93.7)	0.745
Early complications	6/92 (6.5)	4/90 (4.4)	0.772
Pancreatitis	2/92 (2.2)	2/90 (2.2)	0.629
Bleeding	3/92 (3.7)	0/90	0.252
Clogging	1/92 (1.2)	2/90	0.985
Procedure related mortality	0	0	
Late complications	16/92 (17.4)	15/90 (16.6)	0.946
Migration	3/92 (3.2)	3/90 (3.3)	0.698

Four cases of pancreatitis were treated successfully with conservative therapy.

In all the 3 cases bleeding stopped after papillar needle infiltration with adrenaline solution.

In three cases we have early clogging of the prostheses and we performed an urgent stent replacement. No procedure related mortality occurred. In 6 cases (6.5%) stents migrated proximally. 86 patients died before stent occlusion (8 during the first month but non related to endoscopic therapy). Nine patients did not come for follow-up after the first period of 30 d.

Late complications in all cases were acute cholangitis due to stent occlusion.

Eighty-seven patients (47.8%) needed a stent replacement which was successful in 95.4% of the cases (Table 3).

Table 3 Stents replacement

	Group A with ES	Group B w/o ES	<i>P</i>
Patients (<i>n</i>)	41	46	
Successful stent replacement	39/41	45/46	0.919
Patency (median±SD)	109±15	110±18	0.765

DISCUSSION

Our data showed no differences between two groups in regard to success of stent insertion, incidence of early and late complications and patency. Our data were similar to those of literature^[8-9] limited to common bile duct obstructions.

In a retrospective study, Margulies^[10] considered the effect of sphincterotomy on acute and chronic complications of 10F stent therapy in 130 patients. The incidence of acute complications was higher in patients undergoing sphincterotomy 8.3% vs 1.2% ($P=0.04$). A gastrointestinal bleeding was seen in 3 cases (6.2%) in whom ES was performed. There were no inclusive criteria reported in this study, therefore we do not know whether patients with coagulopathy were considered.

In our experience the incidence of bleeding was lower. We had three cases of bleeding in the ES group (3.1%) which were treated successfully with endoscopic therapy.

Coagulopathy has been found to be an independent risk factor for hemorrhage after ES^[11] and its incidence increases in cholestasis^[12,13].

In a retrospective study, Tarnasky^[14], found that the rate of pancreatitis following transpapillary stenting without ES increased in patients with a proximal biliary stenosis because this kind of lesion worked as a fulcrum leading to a distal deflection of the stent and a consequential compression of the pancreatic orifice. Patients with proximal biliary strictures were at significantly increased risk for postprocedure pancreatitis (4 of 24) versus those with distal or no stricture (0 of 59) ($P=0.006$).

In our study the incidence of pancreatitis was not significantly different between the two groups (Group with ES: 2/92, Group without ES 2/90), probably because our patients did not have proximal stenosis.

Johanson^[15] examined multiple risk factors associated with stent migration such as stent diameter and length. In his study the odds ratio of proximal migration in patients with ES was 3.9, and 0.3 in patients without ES.

The association between sphincterotomy and proximal migration was not statistically significant, but the authors concluded if ES was not performed the risk of proximal migration might decrease.

Lahoti^[16] examined retrospectively 2 993 procedures for insertion of biliary or pancreatic duct stents. Thirty-three proximally migrated duct stents and twenty-six proximally migrated pancreatic duct stents were identified. All patients except one had a sphincterotomy.

Margulies^[10], on the other hand, found an increased incidence of migration in patients who had stents placed without ES. Stent migration was seen in 8.5% of patients in the no ES group.

In our experience, the incidence of proximal or distal migration was not so high and we didn't find differences between the groups.

Stent replacement was possible in 97.8% (45/46) of the patients who had not undergone ES, probably owing to the persistent dilation of the papilla caused by the presence of the stent.

In conclusion, according to our prospective study, placement of a 10 F biliary stent for common bile duct stenosis without ES is safe and has the same success rate of the ES technique.

No ES can avoid the risk of perforation and bleeding. ES must not be performed in patients with coagulation problems which are frequent in patients with cholestasis due to neoplastic biliary obstruction. If we consider long term complications of sphincterotomy whose range was 5.8-24%^[17-18] ES should not be performed in patients with non neoplastic pathology (bile leaks, non malignant strictures). We did not find any difference in stent replacement between patients with ES and those without.

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