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

Pietro Di Giorgio, Leonardo De Luca

INTRODUCTION

Endoscopic insertion of biliary stents is the preferred method of palliation for inoperable malignant biliary obstruction. 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.

METHODS:

From March 1996 to June 2001 172 consecutive patients who underwent placement of a single 10F polyethylene stent (PS) and to reduce the risk of pancreatitis. The aim of the study was to assess the possible advantages of ES before PS placement.

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.


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.

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. 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.

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INTRODUCTION

Endoscopic insertion of biliary stents is the preferred method of palliation for inoperable malignant biliary obstruction. 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). 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 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.

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developed.
Oclusion 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 $\chi^2$ 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

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

Table 2 Endoscopic technique results

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

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).

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[6-9] 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 3 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
cholestatics[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 stucture
(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 sphyncterotomy 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.

REFERENCES

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Edited by Wang XL  Proofread by Xu FM