Endoscopic palliation of malignant obstructive jaundice using resterilized accessories: an audit of success, complications, mortality and cost

V SANTHI SWAROOP, V DHIR, K M MOHANDAS, S D WAGLE, K F VAZIFDAR, GAYATHRI GOPALAKRISHNAN, O P SHARMA, P FAGANATH, L J DESOUZA

Division of Medical Gastroenterology and Departments of *Radiology and **Surgery, Tata Memorial Hospital, Mumbai 400 012

Objective: To assess the success, complications and cost of endoscopic endoprosthesis placement for palliation of obstructive jaundice caused by malignancy. Methods: Four hundred and two consecutive patients with obstructive jaundice due to nonresectable malignancy undergoing endoscopic stenting were studied. Commercial or homemade 7F or 10F endoprostheses were placed using minor modifications of the standard technique. The accessories were sterilized and reused. Results: Endoprosthesis placement was successful in 291 patients (72.4%, 95% CI 67.7-76.7) — 241 in one attempt, 49 in two attempts, and one in three attempts. Fifty-nine patients (14.6%, 95% CI 11.4-18.8) had procedure-related complications, including cholangitis (30), pancreatitis (15), perforation (3) and bleeding (11). The incidence of cholangitis was significantly higher in bifurcation blocks than in other lesions (17.6% vs 4.7%, p=0.0005). The success rate did not differ between distal and proximal lesions (68.1% vs 72.9%). The procedural cost per patient could be reduced from Rs 14,850 to Rs 5,555 by using endoprostheses after sterilization, and using home-made stents. Conclusions: Endoscopic endoprosthesis placement is a safe and effective method for palliation of malignant obstructive jaundice. Preparation of indigenously made stents and reuse of accessories can reduce the cost of the procedure by over 50%. [Indian J Gastroenterol 1997; 16: 91-93]

Key words: Biliary tract, cholangitis, endoscopy, endoscopic retrograde cholangiography

Obstructive jaundice due to irresectable malignancy has a grim prognosis, with a median survival of 3-5 months.1,2 Endoscopic palliation is done for relief of symptoms and nutritional disturbances. No large studies on endoscopic biliary stenting have been published from India.

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Cost-efficiency is of paramount importance in palliative procedures undertaken for advanced cancer. In a previous study,3 we had shown that indigenously made stents were as useful as commercial stents for palliation. Accessories for stent placement, like guide wire, glide wire, and catheters are expensive and need to be imported. Sterilization and reuse of these accessories could reduce the cost of this procedure.

We present an audit of the short-term efficacy and cost of biliary endoprosthesis placement for palliation of malignant obstructive jaundice by reusing sterilized accessories.

Methods

From January 1990 to December 1995, 302 patients with irresectable malignancy were referred for endoprosthesis placement. Informed consent was obtained from all patients. Side-viewing endoscopes (TF-E-20 and TJF-10, Olympus Corporation, Tokyo) were used. Intravenous pentazocine (15-30 mg) and diazepam (5-10 mg) were used for sedation. Patients were administered one dose of ciprofloxacin 200 mg intravenously 30 minutes before the procedure. Since 1994, ciprofloxacin was replaced by amikacin (250 mg intravenous) in view of our hospital data showing high resistance to the former. Further antibiotic coverage was determined by adequacy of drainage.

Procedure

No attempt was made to obtain a pancretogram routinely. Cholangiogram was obtained by injecting sufficient contrast to visualize the stricture and dilated biliary system, and complete opacification of intrabiliary system was avoided. A precut needle knife papilotome was used in patients in whom selective cannulation of the bile duct was not possible. No attempt was made to enhance success by substituting a new accessory for a reused one.

A 380-cm glide wire (Terumo Inc, Japan) was used to traverse the stricture. The wire was modified by stripping its hydrophilic coating, leaving only 20 cm of the flexible tip covered. Stripping improved its maneuverability through the catheters and allowed repeated sterilization. The biliary strictures were dilated using 10F Soehendra dilators (Wilson-Cook, Salem, USA) over the guide wire. Straight Amsterdam-type prostheses (7F to 12F, Wilson-Cook, Salem, USA, or home-made) were passed over a 0.035" guide wire (Wilson-Cook) without a guiding catheter. The size of the endoprostheses was determined after
defining the length of the stricture at cholangiography. An
indigenous 15-cm-long plastic stent (Devon, Bangalore)
was shortened to the required length and clips were added.

The patients were observed for 24 hours and then
discharged. The accessories such as guide wire, glide wire,
catheters and dilators were sterilized by ethylene oxide
before reuse.

Stent placement was considered successful if serum
bilirubin levels dropped by more than 20% one week after
the procedure. Pancreatitis was defined as post-ERCP
abdominal pain along with five-fold increase in amylase
after 24 hours. Bleeding was considered significant when
it did not stop during endoscopic observation or transfu-
sions were needed. Patients with failed endoscopic drain-
age were referred for either surgical bypass or percutane-
ous drainage.

Statistical analysis

Statistical significance was determined using \( \chi^2 \) test and
Fisher's exact test. For the purpose of analysis, patients
with primary cancer of pancreas and ampulla of Vater
were said to have distal blocks, while patients with bifur-
cation strictures had proximal blocks.

Cost

Cost of an uncomplicated procedure was estimated by adding
charges for equipment, professional care, radiology, hospi-
talization, and drugs and intravenous fluids. The equip-
ment cost per patient was determined by dividing the cost
of the equipment or accessory by the number of times it
was used before being discarded. As ours is a govern-
ment-aided hospital, the charges levied to the patient are
lower than the actual cost; part of the overall cost is borne
by the hospital. For paying patients, a flat rate of Rs 1500
is charged towards equipment and professional expenses,
while no equipment or professional charges are levied on
nonpaying patients. An estimate was made of the actual
charges paid by the paying and nonpaying patients.

Results

Patients

The study included 222 men and 180 women with a me-
dian age of 56 years (range 35-82). The primary site of
cancer was pancreas (33), ampulla of Vater (52), bile duct
(66), gall bladder (112), biliary bifurcation (85), duode-
nun (2) and retroperitoneum (1). Selective bile duct can-
nulation was achieved in 319 patients (79.3%); of these,
56 cannulations (17.5%) were done following a precut
papillotomy.

Success

Endoprosthesis placement was successful in 291 patients
(72.4%, 95% CI 71.3-76.7) — 241 in one attempt, 49 in
two attempts, and one in three attempts. Endoprosthesis
could not be placed in 111 patients because of duodenal
stenosis in 28 patients (18 pancreatic cancer, 3 ampullary
cancer, 1 duodenal cancer, 4 gall bladder cancer, 2 bifur-
cation blocks), failure of bile duct cannulation (55 pa-
tients), and inability to place a glide wire or a 7F stent
across hard and tight strictures (28). Two stents were placed
in 12 patients (4 with distal block, 8 with bifurcation block).
The success rate in distal blocks (68.1%) did not differ
from that in proximal blocks (72.9%).

Complications

Post procedure complications developed in 95 patients
(14.7%, 95% CI 11.4-18.6), nine (2.2%) of whom died.
The complications included cholangitis [n=30 (7.5%, 95%
CI 5.2-10.6)], pancreatitis [15 (3.7%, 95% CI 2.2-6.2)],
bleeding [11 (2.7%, 95% CI 1.4-4.8)], and perforation [3
(0.7%, 95% CI 0.2-2.4)]. Of the nine deaths, one each was
due to pancreatitis, perforation and bleeding, while six
deaths were due to cholangitis.

Cost

The estimated cost differed according to the type of ac-
cessories used. When single-use imported accessories were
used only once, the mean cost per procedure was esti-
mated to be Rs 14,850. We found that a catheter could be
used for a median of five times, a guide wire five times,
and a glide wire 20 times after stripping. The home-made
stent cost us Rs 200. When the accessories were home-
made and reused, the mean cost per procedure was re-
duced to Rs 6565 (Table 1). The actual charges paid by
the paying and nonpaying patients are shown in Table 2.

Discussion

Western countries are working toward cost containment;
this is of paramount importance for developing countries
with economic constraints. Stent placement would be an
ideal palliative procedure for malignant obstructive jaun-
dice, if it was economical.

Our short-term results are comparable to other pub-
lished studies.5,6,7 Our low success rate relative to reports

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<th>Table 1: Mean cost per procedure</th>
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<td><strong>Single-use accessory</strong></td>
</tr>
<tr>
<td>Endoscope</td>
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<td><strong>Total</strong></td>
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<td>14,850</td>
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All values in Indian rupees (1 US $ = Rs 35 approx)
* reused five times, + home-made stents, ^ reused twenty times
** 2 days same private ward
Table 2: Charges levied to patients

<table>
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<th>Nonpaying patient</th>
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<tr>
<td>Accessories</td>
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<td>Drugs and fluids</td>
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<tr>
<td>Total</td>
<td>5,450</td>
<td>850</td>
</tr>
</tbody>
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All values in Indian rupees (1 US$ = Rs 35 approx)

from some established centers can be attributed to learning curves. Our success rate in the initial 150 procedures was 56%, while that in the last 80 procedures was 84%. It is possible that repeated use of resterilized accessories might be the cause of failure in some patients. Since the study is essentially an audit, comparison of success and complications with new versus reused accessories was not possible because of lack of complete information; a prospective study would be required to answer this question. Nonetheless, we believe that this difference would not be high. Our overall success rate for distal block was comparable to that for proximal blocks, unlike other studies where success rate is higher for distal blocks. The complication rates and mortality were higher in proximal blocks compared to distal blocks, a feature found in other studies also. Sterilized and reused accessories have not increased the complication rate in our study compared to other studies.

We estimated the cost of the procedure and the charges levied to the patient separately. Cost analysis revealed that stent placement can be expensive if the accessories are imported and used only once. However, the use of home-made stents and reuse of accessories after sterilization can together reduce the cost of the procedure by 37%. It is obvious that with the existing fee structure in a hospital like ours, the procedure is cost-effective only if the accessories are sterilized and reused, and stents are home-made. The procedure can become even cheaper if home-made accessories are used. While some accessories like catheters, dilators or stent can be prepared locally, preparation of guide wires and glide wires requires sophisticated technology.

With the availability of small, relatively cheap ethylene oxide sterilizers, sterilization of accessories in the endoscopy room has become possible. Since ERCP can lead to life-threatening infectious complications, it is imperative that high standards be maintained during the sterilization procedure. Meticulous mechanical cleansing and thorough drying of the accessories before packing for sterilization is essential. In the absence of good sterilization facilities, single-use accessories are the safer option.

References


Correspondence to: Dr Dhir
Received November 5, 1995. Received in final revised form February 13, 1997. Accepted February 28, 1997.

Indian Journal of Gastroenterology 1997 Vol 16 93