Endoscopic stenting of the biliary tract and pancreatic duct

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K HUIBREGTSE, S RIVERA-MACMURRAY. Endoscopic stenting of the biliary tract and pancreatic duct. *Can J Gastroenterol* 1993;7(1):15-22. Biliary and pancreatic drainage by endoscopic insertion of endoprotheses has become routine treatment for patients with malignant obstructions. This method is particularly indicated for patients with irresectable tumour or contraindications for surgery. However, accumulating data suggest this method is superior even to surgical palliative procedures. Endoscopic treatment of benign biliary and pancreatic strictures is more controversial and further studies are needed to establish its place among the other nonsurgical and surgical treatment modalities. A survey of possible indications, success rates and complication rates are discussed and compared with other treatment options.

Key Words: Bile duct strictures, Biliary drainage, Endoscopic retrograde cholangiopancreatography, Obstructive jaundice

Moulage endoscopique des voies biliaires et du canal pancréatique

RÉSUMÉ: Le drainage biliaire et pancréatique par insertion endoscopique d'endoprothèses est devenu un traitement de routine chez les patients atteints d'obstruction maligne. Cette méthode est particulièrement indiquée chez les patients porteurs de tumeurs impossibles à réséquer ou chez qui il est contre-indiqué d'intervenir chirurgicalement. Cependant, les données recueillies suggèrent que cette méthode serait même supérieure aux interventions chirurgicales palliatives. Le traitement endoscopique des rétrécissements bénins des voies biliaires et pancréatiques est plus controversé et d'autres études sont requises pour évaluer son rôle parmi les autres modalités thérapeutiques chirurgicales et non-chirurgicales. On procède à un survol des indications possibles, des taux de réussite et des taux de complication propres à différentes options thérapeutiques.

SINCE THE INITIAL DESCRIPTION BY Soehendra in 1980 of endoscopic insertion of a transpapillary stent (1), the procedure has gained wide acceptance and multiple applications (2). Indications, complications and success rates have been studied. Endoscopic stent placement in benign and malig-

nant biliary lesions, and management of pancreatic disorders are discussed.

TECHNIQUE OF STENT INSERTION

The authors use an endoscope with a large 4.2 mm instrumentation channel to start the procedure, although

others prefer to use a diagnostic endoscope with a 2.7 or 3.2 mm channel initially. Cannulation may be difficult because of tumour compression, displacement or fixation. On occasion a precut papillotomy may be needed to unroof the papilla and to gain access to the bile duct. After routine endoscopic retrograde cholangiopancreatography (ERCP) a 6 to 8 mm sphincterotomy is performed to facilitate stent insertion and subsequent exchanges. Cytology brushings are done at this point. Then a Teflon catheter containing an atraumatic flexible tip guidewire is inserted into the common bile duct up to the structure. The guidewire is manipulated across it by movements of the wire, the catheter and the endoscope as needed under fluoroscopy. Forceful pushing should be avoided so that false passages are not created.

Once the rigid part of the guidewire is well above the stenosis, the Teflon catheter is pushed above the stricture also. The stent is loaded on to the Teflon catheter and wire assembly and advanced to the tip of the endoscope with the pusher tube. The elevator bridge is opened when the stent is felt to be adjacent to it. The whole assembly (guidewire, Teflon catheter, stent and pusher tube) is then moved forward by advancing the pusher tube. The assistant secures and withdraws the guiding catheter/wire slightly as the endoscopist advances the pusher tube. The endoprosthesis is moved up the duct in a stepwise fashion as the endoscopist opens and closes the elevator bridge in coordination with elevation of the en-

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Figure 1) Endoprosthesis in duodenum with good bile flow

Figure 2) Patient with post cholecystectomy bile leakage due to a distal bile duct obstruction caused by a pancreatic cancer. **Left** Stricture in pancreatic duct due to pancreatic cancer. **Right** Bile leakage from cystic stump and biliary endoprosthesis

doscope tip towards the papilla. The right/left knob is in the locked position. Care should be taken to keep the distance between the papilla and the endoscope short. Bowing of the stent in the duodenum makes successful insertion unlikely. When the distal flap reaches the papilla, the assistant pulls the Teflon catheter and wire out as the

endoscopist holds the stent in place with the pusher tube. Once the stent is freed from the endoscope about 1 cm should be protruding from the papilla (Figure 1). After drainage is established endoscopically or under fluoroscopy the endoscope is withdrawn.

Most stents are straight 10 Fg. Nine centimetre stents are often used for dis-

tal common bile duct strictures, 11 cm stents for mid common bile duct strictures, 14 cm stents for bifurcation and 19 cm stents for intrahepatic strictures.

INDICATIONS IN BENIGN BILIARY LESIONS

Postoperative bile leakage: Inadvertent damage to the bile duct during surgery can result in biliary-cutaneous or biliary-peritoneal fistulas, or high output from T-tubes if present. Inadequate closure of the cystic stump can have the same effect. Traditionally patients have undergone surgical repair, but in the past few years several groups have obtained good results with endoscopic treatment (3,4).

The authors' experience with 55 patients was recently reviewed (4). Patients presented with biliary-cutaneous fistulae, peritonitis, intraabdominal abscess, increasing jaundice, cholangitis or pancreatitis. At ERCP, extravasated contrast flowed from the cystic duct stump (31 patients), the common hepatic duct (six patients), the common bile duct (six patients), a hepatic radical (four patients) and from a surgical anastomosis (one patient). ERCP failed in one patient with a Billroth II. Eventual closure of the leaks or fistulae was achieved in 43 of the 48 patients (90%) treated endoscopically. Most closed within 1 to 10 days. Five patients died of persistent sepsis (10%). Obstruction distal to the site of bile leakage due to residual stones or strictures was seen in 10% of the patients (Figure 2).

The purpose of treatment is to facilitate bile flow into the duodenum by eliminating resistance at the sphincter of Oddi. Patients were treated in the following way. If the cystic stump or hepatic radicle leakage was seen without distal obstruction only a sphincterotomy was done. If stones were seen in the common bile duct, they were extracted after sphincterotomy. If there was a history of operative biliary trauma, or a stricture was observed, or if all stones could not be extracted, a 10 Fg stent was placed. The prosthesis is helpful in dilating a narrowed area during the healing phase, thereby decreasing the risk of late stricture for-

mation. In patients in whom a stricture was found one or two stents were placed for about one year. There were no early complications. Late complications included cholangitis in two patients (despite trimonthly stent exchanges) and recurrent stricture after stent removal in one patient.

Endoscopic evaluation and intervention is a valuable tool in the diagnosis and management of postoperative bile leakage and should be performed as soon as it is suspected.

Postoperative and benign biliary strictures: Postoperative biliary strictures occur in 2 to 5% of patients after biliary tract surgery (5). The choice of drainage procedures includes biliary enteric bypass surgery and percutaneous or endoscopic stenting and balloon dilatation. There are no randomized controlled studies comparing the three options.

Series from major centres reveal good results with endoscopic stents. Geenen et al (6) reported excellent or good response in 25 patients (88%) who underwent balloon dilation and/or stent placement over a mean follow-up of 48 months. There was no significant morbidity or mortality associated with the procedure. In reviewing the present authors' experience with 70 patients, 83% had a good or excellent response (7). Seventeen percent had recurrence of the stricture after stent removal over a mean follow-up of 42 months. There was 2.5% 30-day mortality.

These numbers compare very favorably with those from a recent study (8) which showed that expert surgery achieved results in 80 to 90% of cases over a five-year follow-up. A non-surgical approach may be the best initial procedure with surgery reserved for those with recurrences.

These patients are usually managed by placing one stent for six weeks (Figure 3), after which two 10 Fg stents are inserted. They are left in place for one year, replaced every three months (or earlier) if cholangitis ensues. They are kept in place for one year. Antibiotics are administered if cholangitis is present or if successful drainage is not obtained. Because of the tight fibrotic nature of the strictures, 21% of patients require dilation before stent placement.

Figure 3) Patient with liver cirrhosis due to a post operative biliary stricture. **Left** Postoperative stricture at the bifurcation. **Right** Endoprosthesis is inserted for stricture dilation

Balloon catheters (4 to 8 mm outside diameter) or metal tipped dilating catheters can be used. Balloon dilation alone (without stenting) has not been found to be beneficial, by these authors, although others have reported good results with dilation only.

Finally, after removal of the stents, the stricture is considered sufficiently dilated if a 1 cm balloon can be pulled through easily or if rapid drainage is seen under fluoroscopy.

Other benign strictures can be treated in the same manner but care must be taken to ensure that they are indeed benign. A lack of a tumour 'shelf' or even negative cytology brushes do not rule out malignancy.

Endoscopic biliary drainage is also used for patients with chronic pancreatitis who have intrapancreatic biliary strictures causing jaundice. These strictures are usually longer, smoother and easier to intubate than those caused by pancreatic cancer. The natural history of these strictures is unclear. Biliary

drainage provides an adequate temporary measure while the patient undergoes further evaluation. It also serves as an alternative to surgery in high risk patients.

Primary sclerosing cholangitis: Primary sclerosing cholangitis is a chronic fibrosing inflammatory disease of the intra- and extrahepatic bile ducts resulting in areas of strictures and dilations forming the classic 'beading' pattern. Its pathogenesis is unknown but evidence suggests an autoimmune process. Evaluation of endoscopic treatment is hampered by the small numbers of patients reported and the variability of interindividual disease patterns.

The disease can affect intrahepatic, extrahepatic or both ductal systems to varying degrees. Nonetheless, treatment of patients with cholangitis and jaundice who have dominant strictures (classified as major ductal strictures in primary branches of large intra- or extrahepatic ducts) is advocated (2,9). Stones and debris are removed and the

Figure 4) Patient with recurrent pancreatitis and pancreas divisum. **Top** Highly dilated dorsal pancreatic duct. **Bottom** Endoprosthesis (10 Fg) is inserted via minor papilla

strictures either dilated with balloons or stented. Follow-up of 35 patients treated with combinations of stents and dilations showed significant improvement in rates of hospitalization for cholangitis and in laboratory data (9). Antibiotics should be given before and for several days after treatment. Nasobiliary drainage should be used if dilation or stent placement is not immediately possible. Follow-up attempts can then be performed safely a few days later. One study found that if adequate dilation could be obtained with Gruntzig balloons or Soehendra dilating catheters, stents should probably not be placed as they appear to increase the risk of subsequent cholangitis (9).

Biliary endoprotheses in gallstone disease: Occasionally very elderly or very high risk patients have common bile duct stones that are either too large or too numerous for endoscopic clearance. Despite the many treatment modalities available, several studies

have shown that stenting is a reasonable long term alternative in this subgroup of patients (10,11). One study of 63 patients treated with permanent endoprosthesis reported good results in a one- to five-year follow-up with only 14 patients requiring stent exchange (12). The exchange is not routine, and should be performed only if patients become symptomatic. The stent, if possible, should be 19 cm long in order that it can be positioned high in the biliary tree so it does not migrate out. Its purpose is to prevent stone impaction and thus cholangitis.

Pancreatic drainage: Because therapeutic endoscopy of the pancreas is technically difficult and chronic pancreatitis is uncommon, most studies have been conducted at the few centres with the necessary expertise. Treatment can consist of pancreatic sphincterotomy, stone extraction, stricture dilation, nasopancreatic drainage or stent placement (13-16) (Figure 4). Studies in-

volving a total of 54 patients with chronic pancreatitis in whom a stent was placed in the main duct across a dominant stricture showed improved pain control in 91% (17). Several other studies have shown decreased signs and symptoms in patients with pancreas divisum who had a stent placed in the dorsal duct. Although the results of stent placement are encouraging there are potential risks, such as inducing further ductal changes, that must be studied (18). Because so many questions remain as to optimal duration of therapy and patient selection, general clinical use of pancreatic stents is not recommended at present.

MALIGNANT BILIARY STRICTURES

Malignant bile duct obstruction is a disease mainly of the elderly (19). By the time clinical signs and symptoms occur and patients present to physicians, spread to the liver, nodal bed and adjacent vascular structures has frequently occurred (20). Because of the late presentation of the malignancy and the concomitant physiologic dysfunction of the elderly, few can undergo curative resection. Palliative surgical intervention has an overall operative mortality of 20 to 30% (21,22). Surgical intervention, however, offers the only chance of a cure. Therefore, careful consideration for surgical intervention is warranted on an individual basis, taking into consideration the type and extent of the tumour, and a patient's physiological status. For the majority of patients endoscopic therapy offers the best method of palliation. The rationale for palliative intervention is the relief of pruritus, malaise, occasional cholangitis, multiple organ dysfunction and physiological impact of jaundice.

Because of its deleterious effects on multiple organ systems, obstructive jaundice is thought to increase surgical morbidity and mortality. Three randomized studies with percutaneous drainage have not shown benefit (23-25). Whether endoscopic drainage with its lower risk of complications will show any benefits remains to be studied.

Successful drainage rates and complications vary with the site of obstruc-

TABLE 1
Results of biliary endoprosthesis in 1153 patients (38)

	Success rate	30-day mortality	Cholangitis	Bilirubin decrease	Stent clogging	Duodenal stenosis	Median survival
Bifurcation	85%	23	25%	86%	28%	2%	95 (1 to 2319)
Gallbladder carcinoma (biopsy proven)	86%	16	11%	93%	40%	6%	123 (3 to 1255)
Pancreatic carcinoma	92%	11	7%	97%	29%	9%	149 (0 to 934)
Papillary carcinoma	97%	1	5%	98%	53%	23%	409 (12 to 2365)

Median survival is in days (range)

tion (Table 1). The management of distal, mid common duct and proximal biliary tree lesions is described.

Distal lesions: Papillary carcinoma is the cause of malignant jaundice in 8% of cases. The tumour can be seen as a fleshy, friable, exophytic growth, as ulcerated tumours around the papilla, or as a mass behind the papillary opening covered with normal-looking mucosa (26).

Because the tumour has a better prognosis than other biliary tree malignancies (with five-year survival after surgery in some 30 to 50% of cases) and because almost 25% will develop duodenal obstruction (27), surgery is the optimal treatment for these patients. Endoscopic drainage is reserved for patients with contraindications to surgery such as extensive metastases or high surgical risk. Because the tumour is frequently very friable, it is preferable to insert a stent without a sphincterotomy although smaller firmer tumours can initially be treated effectively with sphincterotomy only.

A sphincterotomy may be needed to access tissue for biopsy diagnosis. Successful drainage can be achieved in over 95% of cases with no procedure related mortality and little morbidity. Late complications, such as stent clogging, which result in jaundice, pain or cholangitis are resolved by stent exchange.

Cancer of the pancreatic head is the most frequent cause of malignant distal bile duct obstruction, accounting for more than 50% of cases (Figure 5) (28). The median age of onset is 70 years. Less than 30% of tumours are resectable and five-year survival is a dismal 1%. The mortality of palliative bypass surgery has been reported as high as 43 to 59% in patients with extensive

Figure 5) Patient with adenocarcinoma of the pancreas. **Left** Pancreatic duct obstruction and bile duct obstruction. **Right** Endoprosthesis in common bile duct with flow of contrast to the duodenum

metastatic disease (29). Three randomized prospective trials of endoscopic versus surgical bypass intervention have been reported (Table 2) (30-32). Patients who had unresectable distal bile duct malignancy but were otherwise operative candidates were randomized to either endoscopic stent placement or surgical bypass. Endoscopic therapy was equally effective in relieving jaundice with less complications and lower 30-day mortality. Survival in both groups was the same, indicating that the advantage lies in

the shorter initial hospital stay (two to five days versus the reported three weeks of postoperative hospitalization) and the lower mortality. On the other hand, re-admissions for stent exchange or duodenal obstruction may be intolerable for some patients and quality of life studies of the treatment arms have not been reported.

Tumour growth near the papilla may distort the common bile duct and make cannulation and sphincterotomy difficult. Nonetheless, stent placement is successful in over 90% of patients

TABLE 2

Results of three prospective randomized trials comparing endoscopic stenting with surgical bypass for obstructive jaundice (30-32)

	Shepherd et al (30)		Andersen et al (31)		Dowsett et al (32)	
	Stent	Surgery	Stent	Surgery	Stent	Surgery
Number of patients	23	25	25	19	101	103
Successful drainage	91%	92%	96%	84%	94%	91%
Complications	22%	40%	NA	NA	10%	28% [†]
30-day mortality	9%	20%	NA	NA	7%	17% [†]
Duodenal bypass	0%	0%	0%	0%	6%	1% [†]
Recurrent jaundice	17%	2%	28%	16%	18%	3% [†]
Median survival (range)	152 days (39-411)	125 days (52-354)	84 days (3-498)	100 days (10-642)	5 months*	5 months*

*Mean survival; [†]Statistically significant. NA Not available

Figure 6) Type I bifurcation stricture. Right Two 10 Fr endoprostheses inserted through the tumour

with procedure related mortality of 2.5%, 30-day mortality of 10% and average hospital stay of two to five days. Although cases must be judged individually as to the benefit of surgical bypass versus endoscopic drainage, the latter is felt to be the best method in patients without impending duodenal obstruction.

Mid common duct obstruction: Gallbladder carcinoma and cholangiocarcinoma are the more frequent causes of

mid duct obstruction; 15 to 20% of patients with malignant jaundice will have a lesion at this level. By the time jaundice becomes manifest, over 15% of patients have liver and nodal bed involvement, while less than 15 to 25% have resectable disease. Palliative surgical procedures have produced mortality rates of 15 to 20% and do not prolong survival beyond a mean of four to six months. Nearly 25% of patients undergoing surgical palliations die within 30

days of surgery (33). Indeed, tumour extension beyond the submucosa predicts a poor prognosis.

In the authors' series endoscopic drainage was successful in 84% of patients. Procedure related mortality was 3.1% and 30-day mortality was 14.5% (33). Overall mean survival of 23 weeks was comparable to that achieved with surgical palliation of advanced disease. Given the dismal outcome of the disease, endoscopic management provides palliation at a lower mortality, morbidity and cost than surgical bypass.

Bifurcation tumours: Malignant growths involving the bifurcation may arise from adjacent organs, lymphoma or metastases from the colon or breast. They account for 20 to 25% of cases with malignant jaundice. This type of malignant obstruction is difficult to treat by any intervention and often requires co-operation between the radiologist, surgeon and gastroenterologist.

Patients with primary hilar bile duct cancer should be evaluated for surgery in hope for a cure. Surgical series note resectability rates of 20% (34), 22% (35) and even 47% (36). A recent review of 499 patients who underwent resections showed an operative mortality of 12% and a five-year survival of 13%. The median survival was 14 to 18 months. Palliative surgical bypass has an operative mortality of 33% (34). Cholangitis is a frequent complication of hepaticojejunostomies.

Endoscopic stent placement across these often tortuous and asymmetric strictures is technically demanding (Figure 6). The usual cause of failure is inability to pass a guidewire or dilating

TABLE 3
Results of endoscopic treatment of hilar lesions by Bismuth classification

	Number of patients	Successful drainage	Early complications	30-day mortality	Median survival (weeks)
Polydorou et al (39)					
Type I	58	91%	7%	14%	21
Type II	54	83%	15%	15%	12
Type III	78	73%	31%	32%	10
Total	190	82%	19%	22%	12
Coene (38)					
Type I	63	94%	7%	14%	20
Type II	72	93%	17%	16%	17
Type III	62	85%	29%	32%	11
Type IV	60	53%	40%	33%	6
Total	257	85%	25%	23%	13

Figure 7) Left The constrained wallstent is inserted through a distal bile duct stricture. Middle The wallstent is completely deployed. Right Optimal flow of contrast through the stent

catheter through a stricture. Overall successful drainage rates are 80 to 85% (37-39). The Bismuth classification is useful in reporting results of intervention. Type I tumours involve the common hepatic duct within 2 cm of the bifurcation, but not the right and left duct. Type II lesions extend to involve both main hepatic ducts. In Type III tumours, the right, left and intrahepatic ducts are involved. The more extensive the disease (ie, Type III) the higher the morbidity and mortality rates (Table 3). All rates are worse in cases of metastases from distant malignancies. Type III lesions from metastatic disease had successful drainage in 71% of cases, complications in 71%, 30-day mortal-

ity in 42% and median survival of 1.5 months in one report (40). In patients with extensive intrahepatic strictures the benefit of any intervention is questionable.

The major early complication is cholangitis which has been reported in 7 to 19% of cases. Although all cases are performed with antibiotic coverage, adequate drainage is the critical element. This may entail more than one attempt at stent placement or a combined percutaneous/endoscopic approach. Controversy exists as to the need to drain all obstructed liver segments. Some do so aggressively (37) but others have obtained good results with just one stent draining at least 25% of

the liver parenchyma (39). A second stent is placed only in those with cholangitis from suspected undrained segments (38).

Early and late complications of endoprosthesis: Early complications occur less than one week after the procedure while late complications can occur from eight days to 15 months after insertion (38). The main complication is clogging which occurs in 21 to 36% of cases. Patients present with a 'flu-like' syndrome, malaise, low grade fever or increasing liver enzymes. If symptoms are not recognized promptly, frank jaundice and cholangitis will ensue. Symptoms respond promptly to stent exchange. Studies on the mechanisms of clogging and possible solutions are ongoing. Self expanding wire-mesh 30 Fg stents are being evaluated with promising initial results (Figure 7) (41).

CONCLUSIONS

Endoscopic endoprostheses offer a good alternative to surgical intervention, producing low mortality and morbidity rates in many situations. Therefore, an increasing need for these procedures can be expected. In a recent report of the British Society of Gastroenterology this need was calculated as 50 ERCP procedures per 100,000 inhabitants per year, of whom 16 per 100,000 need a biliary drainage procedure (42). Good training of endoscopists and cooperation between interventional radiologists, surgeons and gastroenterologists are prerequisites for optimal treatment of the patient with obstructive jaundice.

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