A "Nondislodgeable" Endoprosthesis for Nonsurgical Drainage of the Biliary Tract

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In patients with obstructive jaundice, biliary decompression can be achieved by an endoprosthesis inserted by a percutaneous transhepatic approach. The prosthesis sometimes becomes dislodged and thus additional percutaneous transhepatic procedures may be required. To avoid this problem, a nondislodgeable endoprosthesis has been developed. The prosthesis is constructed with a layer of biocompatible material (hydrogel) on its surface. The hydrogel is located in grooves around the endoprosthesis and has the ability to absorb liquid, which increases its size. By placing the rings of hydrogel on either side of the obstruction, dislodgement of the prosthesis can be prevented. The nondislodgeable endoprosthesis has been inserted into 11 patients with biliary obstructions due to malignant strictures. No dislodgement has occurred and the established internal drainage reduced serum bilirubin levels without any major complications.

Percutaneous Transhepatic Cholangiography (PTC), together with nonsurgical drainage of an obstructed bile duct has now been in use for more than 20 years. Early diagnosis and treatment of obstructive jaundice is of vital importance, since otherwise irreversible damage to the liver may occur. Furthermore, since there is an increased risk of postoperative complications after laparotomy and a doubling of the mortality rate after pancreaticoduodenectomy in patients with obstructive jaundice, preoperative biliary drainage in connection with the PTC procedure has been suggested by several authors. This can be performed either as an external biliary drainage or as an internal biliodigestive shunt, which was described in 1974. One of the advantages of an internal biliodigestive shunt (through an endoprosthesis) compared to external drainage is that no depletion of bile salts, electrolytes, or water occurs. Thus the endoprosthesis can be used as an ideal treatment to reduce the bilirubin serum levels and to restore the enterohepatic circulation either in patients about to undergo major surgery or as a definitive palliative procedure. However, in 4–38% of cases, the endoprosthesis is dislodged. In order to overcome this problem, we have constructed a new endoprosthesis that automatically fixes itself in position. The purpose of the present report is to describe this new "nondislodgeable" endoprosthesis and to present our experience with it.

Patients and Methods

Eleven consecutive jaundiced patients with a median age of 76 years (range 52–83) were included because they needed either a permanent palliative shunt or a temporary procedure before surgical treatment. The diagnosis was carcinoma of the bile ducts or gall bladder in six cases and carcinoma of the pancreas in five cases. The diagnoses were confirmed in all patients either by a fine needle biopsy or at operation.

The PTC procedure was carried out under fluoroscopic control according to the technique described by Wiechel 1964. The procedure was performed under general anesthesia, with apnoea in the midinspiratory position in order to minimize the risk of the catheter being fed out during or after the investigation. The puncture with a PTC instrument (Wiechel-Stille, Stockholm, Sweden), was performed in the mid-axillary-line on the right side, with the guidance of the pleural sinus, the lower contour of the liver, and the possible presence of gas in the duodenal bulb often in the direction to vertebræe Th XI–Th XII. After puncture of an intrahepatic bile duct and withdrawal of the mandrin, a small amount of contrast medium (Isoopaque 150 mg I/ml, Nyegaard and Co. A/S, Oslo, Norway) was injected before the catheter was secured by the guide-wire technique. Subsequently, another more peripheral intrahepatic bile duct was punctured and, after contrast medium injection through the secured catheters, a flexible guide-wire (PE 160, Surgimed A/S, Denmark) was passed through the obstruction. A polyethylene catheter (PE 205) was passed.

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silicone), containing a cross-binding triacrylate, was grafted-polymerized into the grooves of the PVC tube by radiation ($^{60}\text{Co}$ 450 krad/h during 2 h). The endoprosthesis was then sterilized (3.2 Mrad during 10–12 h), which at the same time causes a complete hardening of the polymer. This procedure has been developed in collaboration with T. Reitberger, Dr. Techn., at the Department of Nuclear Chemistry, Royal Institute of Technology, Stockholm, Sweden. This technique has been used in the present study but the endoprosthesis will in the future be commercially available (Astra Meditec, Mölndal, Sweden).

The surface of the endoprosthesis has the same diameter along the whole of its length during the percutaneous, transhepatic passage to the obstructed area. The two bands of hydrogel give the endoprosthesis a unique property, since the hydrogel increases in size by absorbing bile, thus rising above the surface of the prosthesis (Fig. 1). This fixes the prosthesis with one hydrogel band on each side of an obstruction, as can be seen in Fig. 2.

Two 1-cm wide grooves were cut in the tube 4 cm apart. After dehydrochlorization and cleaning with ethanol a biocompatible hydrogel polymer (vinylpyrol-
A NONDISLODGEABLE ENDOPROSTHESIS

Results

The insertion of the endoprosthesis was successful in all patients. In four cases the introduction of the prosthesis was carried out 3 to 5 days after the PTC procedure, since cannulation of the tumor area was not possible at the first attempt due to edematous swelling around the tumor with a dilated choledochus. One patient had two endoprostheses inserted within 2 days as two segments of the liver needed separate drainage. The plasma bilirubin concentrations returned to normal within 2 to 3 weeks, regardless of the initial degree of jaundice (Fig. 3). The plasma bilirubin levels remained normalized in all patients except in one, with a temporary obstruction of the prosthesis that spontaneously reopened. No dislodgement or permanent obstruction of the endoprosthesis occurred; this was verified at autopsy in six patients, at operation in two patients, and by radiological investigation in the remaining three patients. The median survival time was 3 months (range 1 week–7 months). Six patients could leave the hospital and be at home for a median time of 4 months (range 3–7 months).
the head of the pancreas (Fig. 6). The endoprosthesis was introduced, over a guide-wire, with its hydrogel rings above and below the tumor (Fig. 7). After 3 weeks the patient was anicteric and the bile ducts were normalized (Fig. 8). She subsequently underwent a Whipple procedure.

**Discussion**

The outlook for patients with carcinoma of the pancreas or of the biliary tree is poor, with a resectability rate of about 20%. Therefore the majority of such patients may only need a palliative procedure. PTC is a procedure, with a good chance of making a correct diagnosis, that carries little risk of complications. Cholangitis is often described as a complication of the PTC procedure and has been reported to occur in 20% of cases. However, we do not regard cholangitis as a complication, since over 40% of patients with obstructive jaundice have bacterial growth in the bile already at the time of the PTC. Furthermore, the insertion of an endoprosthesis for bile duct obstruction is relatively easy and seems to involve little risk. This new endoprosthesis is designed to eliminate one of the complications that

**Case Reports**

**Case 1**

Case 1 was a 52-year-old man who had been operated upon for a histologically verified carcinoma of the bile duct with a palliative choledochoduodenostomy one year earlier. He was now jaundiced with severe itching. PTC revealed a total obstruction at the confluence with dilated intrahepatic ducts (Fig. 4). After the passage of a guide-wire and a catheter, an endoprosthesis was inserted, with normalization of the dilated intrahepatic bile ducts (Fig. 5). There was a fall in plasma bilirubin levels, together with a disappearance of the pruritus. The patient was discharged from the hospital and went back to work. After 7 months he is still at home and nonicteric.

**Case 2**

Case 2 was a 69-year-old woman with a history of jaundice, itching, pain, and weight loss. PTC revealed a typical picture of carcinoma at the head of the pancreas (Fig. 6). The endoprosthesis was introduced, over a guide-wire, with its hydrogel rings above and below the tumor (Fig. 7). After 3 weeks the patient was anicteric and the bile ducts were normalized (Fig. 8). She subsequently underwent a Whipple procedure.
By introducing an endoprosthesis at the same time that the PTC procedure is carried out, an unnecessary intraoperative bypass procedure with a high mortality risk can thus be avoided. The aim in this patient group must be to relieve jaundice and pruritus and to reduce pain and anorexia, which will improve the patients' general condition and reduce the time spent in hospital.

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References