

Peripheral cutting balloon in the management of resistant benign ureteral and biliary strictures: long-term results

Eli Atar, Gil N. Bachar, Mor Eitan, Franklyn Graif, Haim Neyman, Alexander Belenky

PURPOSE

To report the long-term follow-up results of peripheral cutting balloon incision and dilatation (PCBID) after failed high-pressure balloon dilatation in patients with benign ureteral and biliary strictures.

MATERIALS AND METHODS

The study included 9 patients (5 males and 4 females) who underwent successful PCBID procedures. Of these, 4 patients had biliary strictures; 2 of them had choledocho-choledochal anastomosis after liver transplantation, one at the choledocho-jejunal anastomosis, and the other at the papilla of Vater after failed endoscopic papillotomy. Of the 5 patients with ureteral strictures, 2 occurred following kidney transplantation, one after local radiation, and 2 had pelvic metastases compressing the urinary tract. The duration of follow-up, both clinical and radiological, was 24 months.

RESULTS

The 9 patients who underwent successful PCBID procedures represented 82% of the original group treated by PCBID, which we reported in a previous publication. There were no periprocedural complications. The rate of primary patency, which was confirmed clinically and ultrasonographically at the end of follow-up, was 55% (5/9), and the secondary patency rate was 78% (7/9). Choledocho-choledochal restenosis occurred in 2 patients, 5 and 9 months after liver transplantation, who were treated percutaneously; one by balloon angioplasty (secondary patency for 19 months) and the other by PCBID (patency for 15 months). The remaining 2 patients (both with pelvic metastases) had restenosis 5 and 6 months postprocedure and were successfully treated by the insertion of double-J ureteral stents.

CONCLUSION

PCBID is a simple and safe option for the treatment of ureteral and biliary strictures after failed high-pressure balloon dilatation, which demonstrated a two-year primary patency rate of 55% and a secondary patency rate of 78%.

Key words: • common bile duct • ureter • balloon dilatation

Ischemic and fibrotic benign strictures of the biliary and urinary systems are usually initially treated percutaneously by sequential high-pressure balloon dilatation and tube upsizing. This procedure, however, has relatively high primary and secondary failure rates, mainly in patients with post-transplant anastomotic strictures caused by highly-resistant fibrotic changes (1–4). Recently, we described the short- and mid-term results of peripheral cutting balloon incision and dilatation (PCBID) for the treatment of nonvascular strictures following the failure of high-pressure balloon dilatation in 11 patients (5). The aim of the present study was to describe the long-term follow-up results.

Materials and methods

Patient group

Between January and August 2003, 11 patients (6 males and 5 females) with ureteric and biliary stenoses and strictures that were resistant to conventional high-pressure balloon dilatation were treated with peripheral cutting balloon (Boston Scientific, Natick, MA, USA) incision dilatation. Ages ranged from 30 to 82 years (mean, 53.3 years). Following kidney transplantation, 3 patients had a tight distal ureteric stenosis, 3 patients following liver transplantation had a tight stenosis at the choledocho-choledochal (CBD-CBD) anastomosis, 3 patients had pelvic metastases near the ureter, one patient had a tight stricture at the choledocho-jejunal anastomosis, and one patient presented with a tight stricture at the papilla of Vater after failed endoscopic papillotomy. None of the stenoses was longer than 1.5 cm. Total obstructions were evident in 5 cases.

Of the original 11 patients, 9 had successful PCBID and were followed for 24 months.

Technique

All patients initially underwent percutaneous balloon dilatation with high-pressure angioplasty balloons (Blue Max, Boston Scientific, Natick, MA, USA, and Powerflex, Cordis, Warren, NJ, USA), which were inflated several times up to 20 atmospheres. In all cases, repeated injections of contrast media demonstrated insufficient width. PCBID was performed during the same session as the failed high-pressure balloon dilatations in 4 patients, and within 3 to 7 days in 7 patients. The PCBID technique is detailed in our preliminary report (5); all PCBIDs were performed without sedation.

Technical success was defined as an increase in luminal diameter more than 70% compared to the adjacent normal lumen diameter and was determined by cholangiography or antegrade urography. Clinical success was defined as an alleviation of symptoms, no need for external drains, and normal bilirubin levels in the patients undergoing bile duct dilatation.

From the Departments of Radiology (E.A. ✉ atareli@hotmail.com, G.N.B., H.N., A.B.), Organ Transplantation (M.E.), and Surgery (F.G.), Rabin Medical Center Affiliated to the Sackler Faculty of Medicine, Tel Aviv University, Petah Tiqwa, Israel.

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Follow-up

The patients in whom PBCID was successful underwent sonographic follow-up examinations, and in those who had bile dilatation, bilirubin levels were checked at 3, 6, 12, 18, and 24 months. The criteria for a normal sonographic examination in the patients with biliary strictures were absence of intrahepatic biliary dilatation and a patent CBD-CBD anastomosis. The criteria for the patients with ureter strictures were the absence of hydronephrosis or ureteral dilatation.

Institutional review board approval was not required for this study.

Results

There were no major or minor procedure-related complications, and the dilatations were relatively painless according to patient reports. Contrast extravasation was not evident after use of the cutting balloon. There were 2 failures of PCBD, one in a ureteral stricture following kidney transplantation and one in a CBD-CBD anastomotic stricture following liver transplantation. Both of these patients underwent corrective surgery shortly afterwards, and the surgeons reported severe fibrosis around the stenotic region.

Sonographic follow-up was available in the 9 patients (82%) that had successful PCBD; 12- and 24-month primary patency rates were both 55% (5/9 patients). CBD-CBD restenosis occurred in the 2 remaining liver-transplant patients, 5 and 9 months post-procedure. Both underwent percutaneous retreatment; balloon angioplasty in one patient and PCBD in the other. Patency was maintained for 19 months and 15 months, respectively; thus, the 24-month secondary patency rate was 78%. Restenosis also occurred in 2 patients with pelvic metastases, 5 and 6 months postprocedure. Treatment in these cases consisted of insertion of double-J ureteral stents; follow-up examination revealed no sequelae 9 and 8 months postprocedure, respectively. None of the 4 patients with restenosis had periprocedural complications.

Discussion

Resistant ureteral and biliary stenotic lesions are relatively frequent complications of kidney (1, 2) and liver transplantation (3), which lead to allograft dysfunction and failure in up to 10% of patients. Post surgical fibrotic adhe-

sions, rejection, infection, and, especially, local ischemia may lead to strictures that reduce and even obstruct fluid passage, thereby increasing morbidity (2, 3). A recent study showed that hepatic artery patency is a significant prognostic factor for biliary anastomotic dilatation outcome (4).

Percutaneous transhepatic or transrenal repeated high-pressure balloon dilatation has a long-term success rate of only 16%-62% for ureteral stenoses, especially when performed more than 3 months after transplantation (6-8), and of 33% to 73% for biliary stenoses (4, 8-11). Metallic stents may be used primarily or after failed balloon dilatations with virtually the same results (9).

Several studies have described endourologic interventions for ureteral anastomosis performed under general anesthesia with electric-powered incision cutting balloons. The recurrence rate was 32% and the one-year patency rate was 77% for ureterovesical junction obstructions, and 71% for ureteropelvic obstructions (12). There was some risk of a full-thickness incision leading to urinary extravasation (2). Nephrostomy and ureteral stenting, if possible, may improve symptoms, but they also increase morbidity.

Endoscopic retrograde cholangiography is used to identify the presence of biliary strictures and to determine which treatment to use; stenting alone or combined with percutaneous balloon dilatations. Success rates are high (3, 12); however, this method is not suitable for all patients and it requires good technical skills.

Cutting balloons are surgical microtomes mounted on angioplasty balloons. They were originally introduced for the treatment of fibrosis or intimal hyperplasia. The system is low-profile and flexible, and is therefore easily directed. The blades are sufficiently small so as not to overdisrupt the neointimal or fibrotic tissue, but large enough to break the tissue at the stenosis and allow dilatation where regular balloons fail. Cutting balloons are accepted for use in the vascular system, especially for dialysis-related arteriovenous fistulas and venous anastomotic strictures after failed high-pressure balloon angioplasty. Data are also accumulating on the advantages of cutting balloon angioplasty over simple balloon angioplasty for tight strictures or calcified

lesions, stent placement, or surgery (12-16). There are also reports on its use in lower limb arterial bypass grafts (17) and in-stent restenosis (18). We first reported the use of PCBD of non-vascular tubes in the biliary and urinary system in 2005 (5), with a primary patency rate of 82% at 6 months postprocedure. Continued follow-up of this group in the present study revealed a primary patency rate of 55% at 1 and 2 years postprocedure, and a secondary patency rate of 78%. The higher rate of patency compared to simple balloon dilatation may be explained by the controlled blade incisions in ischemic areas, which cause less tissue response and hyperplasia.

Limitations of this study include a small and heterogeneous group of patients, lack of a control group, and imaging follow-up only by ultrasound. More studies are needed to determine how best to use cutting-balloon angioplasty in the treatment of benign biliary and urinary stenoses.

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