Bile Duct Anastomosis Supplied With Biodegradable Stent in Liver Transplantation: The Initial Experience

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ABSTRACT

Background. The most common biliary complications after orthotopic liver transplantation are bile leaks, anastomotic and intrahepatic strictures, stones, and ampullary dysfunction. These complications can occur in up to 10% to 30% of liver transplant recipients. Leaks occur early in the posttransplant period; the stricture formation typically graduates over time.

Methods. Ten patients underwent transplantation in our preliminary study: 5 were randomized to the group with stent placement and 5 to the control group. We investigated the role of an absorbable biliary stent with the goal of proving patency of duct-to-duct biliary anastomosis. The stents are made of machine-knitted polydioxanone monofilaments.

Results. Our initial results show that duct-to-duct biliary reconstruction using an absorbable internal stent had good patency in all 5 patients. There were no signs of biliary leakage accompanying the anastomoses in any of the cases, and there was no stone formation observed after liver transplantation. The biliary stent was completely absorbed, with no adverse effects.

Conclusions. Based on our initial experience and data, we concluded that biodegradable stents can be successfully and safely used in clinical practice. Further large prospective randomized studies are needed to estimate the efficacy of the bioabsorbable stents.

THE INCIDENCE of biliary complications after liver transplantation remains the reason why there is increased morbidity in liver transplant patients, with the incidence varying between 10% and 30% [1,2]. The risk factors for biliary complications are as follows: donor type (cardiac death), technical aspect of the liver transplantation (partial graft), severity of the ischemia-reperfusion injury, small size bile duct (<4 mm), ischemia of the bile duct, type of anastomosis performed, original liver disease recurrence and/or infection, ABO incompatible transplantation, and graft rejection episode. In general, 2 types of biliary complications occur: leak and/or stricture. Bile leaks either from the bile duct anastomosis or from the resection surface of the liver, and eventually both. The stricture occurs either in the bile duct anastomosis or anywhere on the extrahepatic or intrahepatic bile duct tree. About one third of the biliary complications become clinically significant during the first month after the transplantation. Some 80% of the complications occur during the first 6 months [3].

There is a wide spectrum of clinical signs for bile duct complication. Patients may have the typical upper right quadrant abdominal pain with fever and paralytic ileus along with nonspecific mild abdominal signs in cases of early-stage biliary peritonitis. In some cases, the clinical signs might be hidden due to the immunosuppressive therapy and also because of liver graft denervation. The diagnosis of biliary complications is made on the basis of clinical investigations and blood test results. Possible graft rejection must be assessed by using fine needle biopsy. Abdominal ultrasound, magnetic resonance cholangiography, and/or endoscopic retrograde cholangiopancreatography are used for both diagnosis as well as treatment in some cases.

A wide spectrum of possible bile duct surgical reconstruction techniques in liver transplantation has been

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described in the literature. The majority of these techniques offer a decreased risk of biliary complications. The most commonly used techniques for the biliary tree reconstruction are end-to-end or side-to-side bile duct anastomosis. Some prefer the T-drain support or intraoperative stent insertion. There are more options; some of the techniques are barely used today, mainly because of technical difficulties, and some because the expected low incidence of biliary complications was not proven. In contrast, other techniques exhibited extra, unexpected complications related to the stent or tube removal; the incidence of these complications varies between 10% and 20% [4–6].

In our department, we use the end-to-end choledocho-choledocho anastomosis or hepaticojejunostomy for selected patients. If the bile duct is small and fragile, we tend to use the intraoperatively inserted tube stent. In our liver transplant series, the incidence of biliary complications rises to 18% [7]. There were few biliary tree reconstruction techniques within the liver transplantations described, and there is still no uniformity. The stent usage remains controversial as well [8]. Some experiments did show a benefit and a lower rate of biliary complications when biodegradable stents are used [9,10]. Such reports are rare, and the trials were based on small research groups. The biodegradable stents were not used, and they have not yet been tested in clinical practice of liver transplantation.

Fig 1. Bile duct stent.

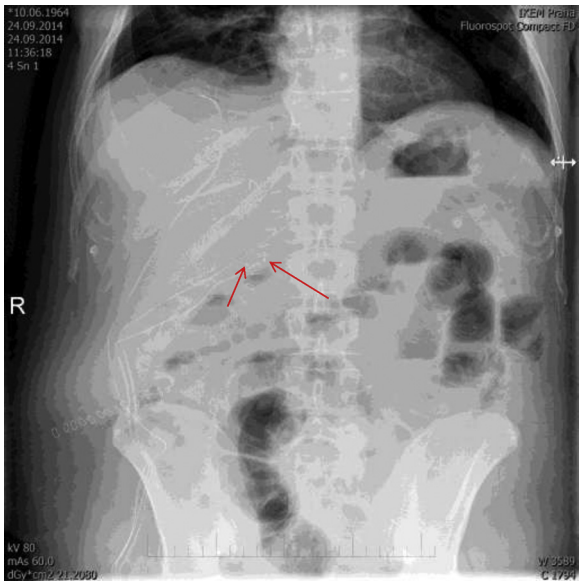

Fig 2. Stent placement; arrows point to the ends of the stent with RTG contrast marks.

The goal of the present article was to describe our initial experience with an absorbable biliary stent, with the goal of proving the patency of duct-to-duct biliary anastomosis and confirming the biodegradable stent's biological and clinical tolerance as well as assess possible side effects.

PATIENTS AND METHODS

The trial was designed as a prospective randomized trial in 10 patients. We wanted to confirm the clinical tolerance of the biodegradable stent as well as to assess its possible side effects. The study was reviewed by the appropriate ethics committee and was therefore performed in accordance with the ethical standards provided in an appropriate version of the 1964 Declaration of Helsinki. All patients gave their informed consent before their inclusion in the study. Patients were randomized into 2 groups (with and without a biliary stent). The stent is made of coated knitted polydioxanone

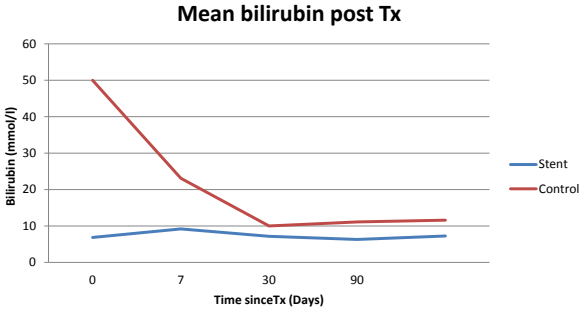

Fig 3. Mean bilirubin test results post-transplantation (Tx).