

## Use of PTFE Ring For Partial Substitution of the Extrahepatic Main Bile Duct

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## 1. Introduction

Since Von Winiwarter's first biliodigestive anastomosis in 18801, several procedures have been tried intending to replace the main bile duct. Some of them were the performance of aponeurotic flaps, and the interposition of ureter, arteries and veins, cecal appendix, jejunum, gallbladder and tubes from different synthetic materials, as well as the adoption of various biliodigestive bypass procedures [2-24]. The malignant stenosis of the main bile duct represents a therapeutical problem for surgeons, although there are currently different treatment possibilities. These generally appear in an advanced stage, therefore, surgery ends up being a palliative procedure in most cases, unfortunately. The most widely used surgical procedure is the biliodigestive anastomosis. When biliodigestive anastomosis are used for treatment of a benign pathology with a high survival probability, particularly in stenosis or iatrogenic injuries of the main bile duct, the outcome is the loss of the sphincter of Oddi and an alteration in the normal physiology of the bile flow. This may produce complications, including cholestasis, cholangitis, stenosis and fistulae [25-27]. This investigation is developed within the conceptual framework of proposing a physiological solution, respecting the continuity of the biliary tree and the sphincter of Oddi for a stenosis or iatrogenic injury of the extrahepatic main bile duct. The object of our study is to compare the interposition of PTFE prosthesis with the creation of a biliodigestive Roux-en-Y bypass in the restoration of the bile flow.

## 2. Material and Methodology

Twenty sheep, both male and female were used, which weighted between 30 and 35 kg. They received proper care, analgesia and anesthesia, strictly following the recommendations of the code [clincicsurgery.com](http://clincicsurgery.com)

of animal protection used in the Experimental Surgery Lab. The study was carried out following strict sterility conditions.

During the preoperative stage, a liver function and enzymes test was carried out, together with prophylactic antibiotic therapy with Ampicillin - Sulbactam 1.5 gr i/v. Animals were anaesthetized with Pentobarbital Sodium and the abdomen was reached by transverse incision in the right hypochondrium. Afterwards, a liver biopsy was performed, the main bile duct was identified, dissected, its caliber was measured and we proceeded to the circumferential resection of a 1 cm-piece of common bile duct. Each animal was randomly assigned to one of two groups.

Group 1 (n=9): A 6 mm-diameter PTFE ring prosthesis with 1.5 cm long thin walls and end-to-end anastomosis was placed with polypropylene continuous suture 7-0.

Group 2 (n=11): A Roux-en-Y biliodigestive biliary-jejunal bypass, end-to-side was performed, with polypropylene continuous suture 6-0.

The wall was closed by planes. Clinical tests were carried out: weight, appearance of jaundice, bile in urine and white stools; and paraclinical tests (5 months later): liver function and enzymes, and radioisotopic cholescintigraphy (qualitative study performed with Mebrofenin and Technetium 99, in which sequential images were obtained for 1 hour, assessing hepatocyte function and main bile duct permeability).

Ten months later, the animals underwent another surgery. Liver function and enzymes tests were repeated as well as the liver biopsy; the extrahepatic main bile duct was removed in all of them and the pieces were sent to pathologic anatomy. The animals were put

down with overdoses of Pentobarbital.

### 3. Results

#### 1) Mortality

In Group 1 (PTFE - n=9), there were two deaths. One 24 hours after surgery due to biliary peritonitis (the animal was ruled out from the project). Another 5 months after the surgery due to acute and septic cholangitis.

In Group 2 (biliodigestive bypass - n=11) there were no deaths.

#### II) Clinical

Group 1: 7 out of 8 animals gained weight as expected. In the animal dead from septic acute cholangitis, stenosis of the biliopro-

thetic anastomosis was found.

Group 2: All the animals gained weight as expected. No clinical elements indicative of main bile duct obstruction were found.

#### III) Lab- Biochemical tests: Liver function and enzymes test (total bilirubin, TB)

Group 1: TB was normal in 8 of the assessed animals 5 and 10 months after surgery. In the animal deceased after 5 months, a hyperbilirubinemia due to the obstruction of the bilioprothetic anastomosis was found (refer to chart).

Group 2: TB was normal after 5 and 10 months in all of the animals (Table 1).

**Table 1:**

Group 1	TB (0 - 0.42 mg/dl)			Group 2	TB (0 - 0.42 mg/dl)				
	Sheep	Preop.	5 months		10 months	Sheep	Preop.	5 months	10 months
1		0.54	0.15	0.354	1		0.44	0.209	1.13
2		0.076	0.063	0.16	2		0.448	0.201	0.323
3		x	x	x	3		0.586	1.18	0.47
4		0.475	0.18	0.391	4		0.108	0.17	0.33
5		0.197	0.108	0.24	5		0.4	0.3	0.02
6		0.24	0.332	0.09	6		0.33	0.282	0.09
7		0.28	0.281	0.15	7		0.48	0.373	0.33
8*		<b>0.25</b>	<b>5.8</b>	x	8		0.29	0.22	0.13
9		0.345	0.35	0.43	9		0.26	0.321	0.323
					10		0.55	0.44	0.48
					11		0.43	0.423	0.4

#### IV) Morphological

##### A - Macroscopic findings:

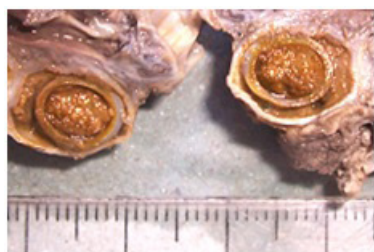
The transverse section of the common bile duct showed, 10 months later:

Group 1: In all of them, lithiasic material was found, which precipitated over the PTFE in all of the studied pieces. Outside the PTFE a fibrous scar tissue was formed, which allowed for the recanalization of the common bile duct, keeping the permeability of the main bile duct (Figures 1-3).

Group 2: In all the pieces, a permeability of the main bile duct was observed. No stenosis, biliary sludge or lithiasis was observed in any of the pieces.



**Figure 1:** Recanalization of the common bile duct and prosthesis.



**Figure 2:** Recanalized common bile duct, prosthesis and biliary sludge inside



**Figure 3:** Prosthesis with precipitation of bile salts in the exterior surface (oval gallstone)

##### Microscopic findings:

Group 1: In 4 animals, the recanalization of the main bile duct was performed by multiple channels, all of which were coated with biliary epithelium. In the other 3, biliary epithelium completely covered the internal surface of the scar tissue, causing a uniform flow of bile outside the prosthesis and inside the replacement tissue.

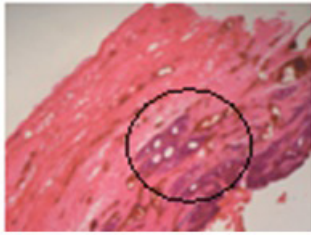
B - Hepatic biopsy: The general histoarchitecture, centrilobular vein, hepatocyte and portal space with its cells, blood vessels and cholangiole were assessed. The mentioned structures were kept irrespective of the evolution time in all of the animals in both groups.

#### IV) Imaging

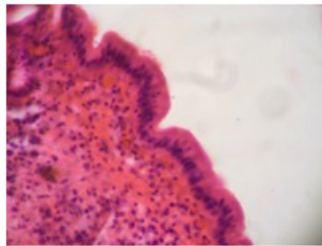
##### Radioisotopic cholecintigraphy

Both in Group 1 and in Group 2, times of excretion and arrival of the radiopharmaceutical product in the small intestine were kept regarding control times (35 min.).

These pictures show the hepato jejunal transit of the radiocolloid (Figure 4 and 5).



**Figure 4:** Recanalization of common bile duct by multiple channels all covered in biliary epithelium.



**Figure 5:** Internal surface of scar tissue covered with biliary epithelium.

#### V) Permeability

An adequate release of bile into the digestive track was observed in both groups and all of the animals after 10 months. No statistically significant differences were found with regard to the permeability of the main bile duct in any of the two groups ( $p = 0.421$  - Fisher's Exact Test).

#### 4. Discussion

Repairs of the main bile duct may be done through different procedures, some of them surgical and others endoscopic with Stening or endoscopic stent. These non-surgical procedures are controversial, very expensive and frequently they do not bring a solution as they involve a certain morbidity in the immediate, mediate and long term [28-30]. This fact, added to the fact that the biliodigestive bypass is not always considered the first option for the repair of injuries in the main bile duct were the bases to carry out this work.

In the animals of Group 1, bile precipitated in the prosthetic surface, forming biliary sludge, gallstones and partially occluding its light. At the same time, a fibrous scar tissue developed outside the PTFE, which allowed for the recanalization of the common bile duct.

The fact that the internal sector of this scar tissue is covered with biliary epithelium (simple columnar) was surprising, causing that in 7 animals, release of bile was observed with no consequences either in the function or in the histology of the liver. We believe that this anatomopathological situation is the explanation for an appropriate release of bile into the digestive tract 10 months later.

An animal died 24 hours after surgery due to a technical failure in the performance of the suture and that resulted in it being ruled out of the work, as it was not possible to assess the effect of the interposition of the prosthesis on the main bile duct in the given time. No bile leaks were detected in the rest of the animals.

Another animal died 5 months after surgery due to a septic acute cholangitis produced by the proximal stenosis of the bilioprosthetic anastomosis.

The decision of making a Roux-en-Y biliodigestive bypass in Group 2 was based in the fact that this is the traditional method for the repair of stenosis in the main bile duct. Facing the existence of stenosis or severe injuries in the main bile duct, the biliodigestive bypass is still one of the therapeutical options [31]. Drawbacks of this method stem from the suppression of the sphincter of Oddi, the endoscopic access to the main bile duct gets complicated and the performance of a biliodigestive bypass becomes difficult in patients with previous abdominal surgeries [25]. We should also consider that it is a complex technicosurgical resource for biliary reconstruction, added to the fact that its complications imply a difficult therapeutical problem.

The interposition of the PTFE in the main bile duct restores the physiological continuity of the biliary tree and keeps the sphincter of Oddi. Plus, it allows, not only an endoscopic assessment but also a transparietohepatic one, for future diagnostic and possible therapeutics [25].

This procedure for replacement of the main bile duct with PTFE could become a valid option among the therapeutical armory of options for the handling of these situations. Its possibilities for clinical usage could extend in case of successful solution of the lithiasis of the "new common bile duct".

#### 5. Conclusions

- The natural evolution of the replacement of the main bile duct with PTFE prosthesis after 10 months is the development of biliary sludge and formation of gallstones organized on the prosthesis itself.
- After 10 months, a recanalization of the main bile duct was observed, which allowed for its permeability and lack of cholestasis.
- The sector of recanalized common bile duct was covered in biliary epithelium, which gave functionality to that sector.
- No statistically significant differences were found regarding permeability between the two groups.
- These results turn the studied method into a valid alternative in the short and medium term for the repair of stenosis or injuries in the main bile duct.

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