



## Conversion of a Long-Lasting Percutaneous Internal-External Biliary Drainage into a Totally Implantable Device Using a PORT Chamber: Early Results

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### Abstract

**Purpose:** With the aim to improve the patient's quality of life and to minimize the complications related to a long-lasting indwelling catheter, we developed a new technique of connecting an internal-external (I/E) biliary catheter to a subcutaneous PORT chamber. In our study, the technique is described and the related clinical outcomes are analyzed.

**Materials and Methods:** This is a retrospective study on a clinical series of 27 patients affected by biliary stricture under treatment with expected long-lasting percutaneous I/E biliary drainage. A quality of life (QoL) questionnaire was applied to support the analysis of the outcomes.

**Results:** The cause of biliary stricture was benign in 24 patients and neoplastic in 3. The mean duration of the biliary PORT was 12.4 month (range 1.9-20.6) and the indications for its removal were stenosis resolution in 21 cases, subcutaneous infection questionnaires of the chamber site in 3 cases (11.1%), recurrent cholangitis in 2 cases. No cases of complete and not reversible biliary PORT obstruction occurred. In those cases who had the PORT removed due to complications, the substitution of the catheter with a percutaneous internal-external drainage was carried out without additional difficulties. The questionnaire on the QoL reported that the patients felt themselves less restricted by the PORT than by I/E drainage regarding personal hygiene, clothing sleeping, daily activities, social life, routine medication, and pain.

**Conclusions:** The procedure seems feasible and promising, particularly regarding the positive impact on the patient's quality of life. However, wider clinical series are needed for more conclusive results.

**Keywords:** Biliary stricture; PORT; Internal-external drainage; Biliary catheter; Quality of life

### Introduction

Several lesions may produce a biliary stricture and can be classified as malign or benign. Cholangiocarcinoma, gallbladder carcinoma, pancreatic carcinoma or liver metastasis are the most frequent malign causes. Benign stricture can have a post-traumatic, iatrogenic, inflammatory, ischemic, immunological, congenital or idiopathic etiology. Iatrogenic represents the most frequent form [1-5]. Laparoscopic cholecystectomy is complicated by biliary stricture in 0.2-0.7% of the cases, usually due to direct lesion by bile duct ligation or clipping, or due to bile duct wall ischemia from dissection and thermal injury [1-3]. Risk factors for stricture at a choledochojejunostomy are leakage of the anastomosis, small stoma size, ischemia and placement of stents at the stoma [1,3].

Biliary stenosis after liver transplantation is classified as anastomotic or non-anastomotic. Duct-to-duct anastomosis may complicate as a result of tension, kinking, ischemia, bile leakage or infection [1,2,4,6]. Non anastomotic strictures occur in form of multiple intrahepatic lesions. Related risk factors are ischemic injury due to hepatic artery thrombosis, long warm and cold ischemic times, reperfusion injury or immunological-induced injuries [1,2,4,6].

The cholestasis sustained by biliary strictures exposes the affected patients to severe complications as sepsis secondary to cholangitis and hepatic biliary cirrhosis [2,4,6].

The current therapeutic management of biliary stricture is primarily based on endoscopic or

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**Table 1:** Quality of life Questionnaire.

In which way did the following aspects of life change since you carry the PORT in comparison to the time when you had the internal/external catheter?			
	Improved	Unchanged	Worsened
A- Personal hygiene	88% (22)	12% (3)	0
B- Clothing	64% (16)	36% (9)	0
C- Sleep	48% (12)	40% (10)	12% (3)
D- Daily activities/ work activities	72% (18)	24% (6)	4% (1)
C-Social life	72% (18)	28% (7)	0
D- Routine medications	84% (21)	16% (4)	0
E- Pain/discomfort	64% (16)	32% (8)	4% (1)

**Table 2:** Demographic and clinical data of the study population (LT: Liver Transplantation).

Demographic and clinical data		
M:F		17:10
Age		65.8 years (range 41-79)
Liver transplanted patients		10 (37,04%)
Indication for LT	end-stage cirrhosis	5
	hepatocellular carcinoma	3
	sclerosing cholangitis	1
	fulminant hepatitis	1
Oncologic patients with advanced biliary tree cancer		3 (11,1%)
Localization	Hilar colangiocarcinoma	2
	Gallbladder carcinoma	1
Causes of biliary stricture		
	post bilioenterostomy Roux-en-Y loop	11 (40.74%)
	post duct-to-duct anastomosis in LT	7 (25.92%)
	iatrogenic injury secondary to laparoscopic cholecystectomy	5 (18.52%)
	advanced biliary tree cancer	3 (11,1%)
	iatrogenic injury secondary to ERCP	1 (3,7%)

percutaneous radiologic procedures which both aim to re-establish the patency of the bile duct and to calibrate the stricture by dilating it with a balloon and placing a stent or a catheter [1-3,5]. The effectiveness of the treatment depends particularly on the duration of the stent/catheter in situ at the biliary stricture [2,3,7]. However, the expected results are also related to the underlying cause of the stricture, thus being curative in case of benign lesion and palliative in case of malign lesion [4,8]. Both endoscopic and percutaneous approaches show advantages and disadvantages in terms of invasiveness of the positioning procedure, risks of infection or obstruction, possibility of clinical control of the draining function and comfort for the patient [1,2,6,7,9]. We present hereafter the preliminary results of a new technique of managing internal-external (I/E) biliary catheters by connecting them to a subcutaneous PORT chamber. The aim is to improve the patient's quality of life and to minimize the complications related to a long-lasting indwelling catheter.

## Material and Methods

Between 2010 and 2014, 27 patients with an I/E biliary drainage due to biliary stricture were submitted to subcutaneous implant of a PORT chamber connected to the biliary catheter. Clinical indication

for the procedure was biliary stenosis under treatment with expected long-lasting percutaneous I/E biliary drainage. All clinical data of the patients and the postoperative complications were prospectively recorded and analyzed. A procedure-related complication or failure was considered in case of PORT site infection, recurrent cholangitis or obstructive jaundice, catheter dislodgement or obstruction.

The aim was to analyze the effect on the quality of life of converting a percutaneous catheter to a totally implantable device, all the patients were required to answer a series of questions regarding their functional status 6 month after the procedure. The study-specific questionnaire was derived from a previously published study [10] which compared the impact on the quality of life of peripherally inserted central venous catheter (PICC) versus subcutaneously implanted port-chamber catheter (Table 1).

The questions focused on 8 items of the daily life which could be altered or hindered by the presence of an invasive medical device (A- personal hygiene, B- clothing, C-sleep, D- daily activities/work activities, E- social life, F-routine medications and controls, G- pain/discomfort). Therefore, the patients were asked to assess qualitatively as "improved", "worsened" or "unchanged" the specific aspects of

**Table 3:** Outcomes of the biliary PORT.

Biliary PORT outcomes	
Mean duration of the biliary PORT	12.4months (range 1.9-20.6)
Indication for PORT removal:	total: 25/27
stricture resolution	21 (84%)
subcutaneous infection of the PORT site	2 (7,4%)
recurrent cholangitis	1 (3,7%)
cholangitis and subcutaneous infection of the PORT site	1 (3,7%)

their present functional status with the PORT in comparison to the previous period with the I/E catheter.

### The technique

The procedure was performed under local anesthesia by a Senior Surgeon and a Senior Interventional Radiologist. After the substitution of the biliary catheter (Flexina 10F Boston Scientific, Boston, US) a subcutaneous pouch was created in the right abdominal upper quadrant with an incision of 3 cm. The catheter was thereafter tunneled from the percutaneous access to the pouch site. The connection of the catheter to the Power Port (Bard Medical, Louisville, GA) required milling the locking system of the PORT with a 4 mm drill bit in order to fit the chamber to catheter's caliber. Thus the PORT was inserted in the pouch and the wound was closed as usual with subcuticular resorbable stitches. An antibiotic prophylaxis with quinolones was given for 10 days to minimize the risk of wound infection. Seriated clinical controls with PORT wash-out with 20-40cc normal saline solution via a Huber needle were attained every 2 months. The status of the stricture was evaluated with cholangiography trans-PORT every 6 months or on demand.

### Results

The study population constitutes of 10 women and 17 men with a mean age of 65.8 years (range 41-79) (Table 2).

Ten patients had received liver transplantation (LT) (37%); among these, the initial hepatic disease was end-stage cirrhosis in 5 cases, hepatocellular carcinoma in 3 cases, sclerosing cholangitis and fulminant hepatitis in 1 case respectively.

Overall, the cause of biliary stenosis was anastomotic stricture post bilio enterostomy Roux-en-Y loop in 11 cases (40.74%), anastomotic stricture post duct-to-duct anastomosis in LT in 7 cases (25.92%), iatrogenic injury secondary to laparoscopic cholecystectomy (LC) in 5 cases (18.52%) or after ERCP in 1 case (3.7%), advanced gallbladder carcinoma and stage IV hilar cholangiocarcinoma in 1 (3.7%) and 2 (7.41%) cases respectively.

The bilio enterostomy was used as a second-line salvage surgical procedure for the treatment of a previous biliary stricture (anastomotic or LC related) in 4 cases.

In all cases the stenosis was located in the extrahepatic biliary system. In 2 patients with anastomotic stricture post duct-to-duct anastomosis in LT, there were also multiple intrahepatic stenosis due to ischemic type biliary lesion (ITBL).

In 3 cases there was also a cholelithiasis associated with the strictures. Previous recurrent cholangitis were reported in 16 cases and 14 had been submitted to ERCP-guided stenting or ballooning dilatation without effect.

The mean duration of the PORT was 12.4 months (range 1.9-20.6) and the indications for PORT removal were stenosis resolution in 21 cases, subcutaneous infection of the PORT site in 3 cases (11.1%), and recurrent cholangitis in 2 cases (1 case with concomitant cholangitis and PORT site infection) (Table 3). At 1 year control a trans-PORT cholangiography demonstrated persistence of the biliary stricture in 17 cases. Therefore the PORT was maintained considering the increased surgical risk in case of reoperation and the absence of signs of cholestasis or PORT malfunction/complications.

In 3 patients the underlying cause of biliary stricture was neoplastic: one patient developed a PORT site infection under chemotherapy treatment 2 months after the implant and consequently the PORT was removed and substituted with an I/E catheter; the other 2 patients maintained the biliary PORT for 9.2 and 12 months respectively without complications until they died due to tumor progression.

No cases of complete and not reversible PORT obstruction occurred. In those cases that had the PORT removed due to complications, the substitution of the catheter with a percutaneous internal external drainage was carried out without additional difficulties.

As 2 patients had the PORT removed before the 6-months' check up on quality of life (QoL), the analysis was conducted on the remaining 25 patients.

Regarding the impact of converting the I/E drainage into a subcutaneous PORT, the questionnaires on the QoL reported that the patients felt themselves less restricted by the PORT than by I/E drainage at all the 8 investigated items of the daily life. The greatest improvement was registered for personal hygiene (88%) and routine medication (84%). 3 patients reported a worsening of the sleep. A closer analysis of the result in these cases allowed to record that the patients felt less worried for the risk of accidentally remove the catheter while sleeping but the presence of the PORT somehow forced them to change their usual sleeping position. In the only patient who referred a worsening of the discomfort and of the capability to attain to the daily activity, the PORT was probably placed too close to the costal considering that the patient was really slim and that his daily activities implied sitting at a desk for several hours per day. However, the overall results outlined that, as expected, the PORT placement determined a significant improvement in the social life and daily activities. Patients felt relieved from the concern of having a dressing under the clothes and from the worry of any complication of the indwelling catheter.

### Discussion

Whether endoscopic retrograde biliary drainage or percutaneous transhepatic biliary drainage is chosen as treatment after diagnosis of a biliary stricture depends on the status of the biliary stricture and the patient's condition [6]. The endoscopic treatment is favored as the first line approach but there are several conditions which hinder its execution such as the presence of a biliodigestive anastomosis or a tight low biliary stenosis [1-3,5,11]. In these cases or when the endoscopic treatment has already been unsuccessful, there is the indication for a percutaneous approach [1,3,6,8]. The main advantage of this procedure is the easily and rapidly available access to the biliary stricture for external decompression, lavage or contrastographic control [3,6,7,11]. On the other hand the presence of a percutaneous catheter is afflicted by common complications such as catheter dislodgement, catheter infection or bile leak around the tube, and

by the discomfort of a long-lasting indwelling catheter which all negatively impact the quality of life of the patients [1,3,6,8,9,11].

The connection of a percutaneous internal-external biliary drainage to a PORT chamber is a newly proposed procedure targeted to convert a long-lasting indwelling catheter into a totally implanted subcutaneous device. The reported preliminary result demonstrates that the procedure was not associated with major complications and was effective in terms of improvement of the quality of life.

The rate of bile-PORT infection was 11.1% which might represent the most critical result in the outcome of the device implantation.

As a term of comparison, the rate of catheter-related infections in long-term central venous access catheters is reported to range from 0.6 to 27%, depending on the catheter type and location and the patients' health status [12]. Immunosuppressed patients with port systems were found to have a median of 0.2 infections per 1000 catheter-days (range 0–2.7 per 1000 catheter-days) [12] and in oncologic patients PORT-related infection are reported with a mean prevalence of 8.7% (range 1.3 – 30%) [13].

In our series, the patients who developed the PORT infection were respectively 3 liver transplanted patients (i.e under immunosuppressant therapy) and 1 patient with advanced biliary tract cancer, thus having all an increased risk of developing infectious complications.

Moreover, the implant of a PORT chamber guaranteed the possibility of hold the advantages of a percutaneous access to the biliary tracts: routine washing reduced the risk for infection or cholelithiasis (thus avoiding the necessity of cyclic substitution of the catheter) and cholangiographic controls of the stricture were not hindered by the PORT chamber. All these procedures would have not been possible for instance with an internalized stent unless with a new percutaneous puncture.

Additionally to the aforementioned clinical advantages, a crucial element for the evaluation of the bile-PORT performance was the effects on the patient's quality of life. In fact nowadays this is an important clinical task to account in the therapy planning. The application of a simple QoL questionnaire demonstrated a positive trend in the physical and psychological well-being of the patients associated with the implantation of the bile PORT.

The present study shows several limits: the small number of cases, the necessity to mill the locking system of the PORT in order to fit the chamber to catheter's caliber due to the actual unavailability of a specific for-the-use PORT and the use of a non-validated QoL questionnaire.

## Conclusions

To the best of our knowledge, this is the first report of a newly

developed technique in the management of biliary stricture by percutaneous biliary drainage. Anyway, more extensive studies of a large study population are necessary. The procedure seems feasible and promising, particularly regarding the positive impact on the patient's quality of life.

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