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IMPLATED OF COVERED BILIARY PROSTHESES THROUGH ULTRASOUND-GUIDED ACCESS: PRELIMINARY RESULTS AND REVIEW OF THE LITERATURE

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ABSTRACT

The purpose of the study is to describe the percutaneous management and the safety and efficacy results of the implantation of covered biliary stents positioned in the main biliary tract in patients suffering from obstructive hyperbilirubinemia caused by unresectable neoplasms. We also performed a comparison between the procedural data of right or left percutaneous hepatic access. A monocentric retrospective study was performed from January 2015 to August 2020, in which we examined 27 patients who had severe hyperbilirubinemia (values > 7 mg / dL) and unresectable neoplasms with indication for palliative therapy**.** The treatment was performed through an interventional radiology procedure. The technical success was considered as release of the covered prosthesis. Therapeutic success was considered as patency of the metal prosthesis through reduction in bilirubin by > 4 mg / dL and the frequency of cholangitis episodes in the follow-up of the study. Overall, 7 of the 27 procedures performed from January 2015 to August 2020 were included in the study. In 2 of the 7 patients there was a microperforation of the biliary tract with spread of contrast medium. In all cases, the technical success of the procedure was observed. There were no statistically significant differences between the results of accesses from the right and left lobe. Our study suggests that the interventional radiology procedure is a safe and effective procedure. The study is limited by the small number of patients studied and needs further studies.

1. Introduction

Obstructive biliary tract disease represents an important cause of mortality and morbidity affecting more than 3 million people overall in our country. In 90% of cases, however, the cause of the obstruction is a benign pathology and only in the remaining 10% a malignant neoplasm[1]. In most cases, it is a carcinoma of the head of the pancreas, less frequently a cholangiocarcinoma, a carcinoma of the gallbladder, lymphadenopathy of the hepatic hilum, tumors and metastases of the liver. The placement of the biliary stent represents the fundamental therapeutic choice in the management of the patient with unresectable neoplasm and symptomatic compression of the biliary tract. The purpose of the study is to describe the percutaneous management and the safety and efficacy results of the implantation of covered biliary stents in the main biliary tract in patients suffering from obstructive hyperbilirubinemia caused by unresectable neoplasms.

2. Material and methods

Population

This is a monocentric retrospective study performed from January 2015 to August 2020, in which we examined the medical records and image storage systems available to interventional radiology of 27 patients who had severe hyperbilirubinemia (values > 7 mg / dL) and unresectable neoplasms with indication for palliative therapy. The data collected include: age, family history for hepatic and pancreatic tumors, blood count, coagulation index, inflammation indexes, liver, cardiac, renal function index, total and fractionated bilirubin values, therapy with anticoagulants and antiplatelet agents; finally, we evaluated the implantation date of the prosthesis as well as the size at the implant site of biliary prostheses.

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The study inclusion criteria are: unresectable cholangiocarcinoma III-IV according to Bismuth classification, unresectable pancreatic head tumor, hyperbilirubinemia (> 7 mg / dL), covered stent in the main biliary tract, failure of the endoscopic procedure through ERCP, cardio-respiratory compensation, coagulation compensation, platelet count compensation, and absence of drug-allergy to anesthetics. No dimensional characteristics of the prosthesis were used to select the trans-hepatic interventional procedure. The exclusion criteria are: implantation of plastic prostheses and uncovered biliary stent. Written informed consent on the risks and benefits of the procedure was obtained from all patients prior to the treatment which was performed in accordance with national and European guidelines. The authorization of the ethics committee was requested and obtained.

Description of the procedure

The operators who performed the procedure have more than 15 years of extra-vascular interventional radiology experience. The examination is performed in ordinary hospitalization. The interventional strategy has always been planned through available radiological imaging in order to optimally evaluate the target and the access site [2-3]. For this evaluation, all patients underwent a CT examination with contrast medium, an ultrasound examination and MRI cholangiography. Coagulation and platelet counts were monitored for each procedure and corrected if possible. The SIR-CIRSE guidelines were respected for bleeding risk procedures[4-5]. Administration of clopidogrel and aspirin was suspended 5 days before the procedure. Anticoagulants were suspended according to drug kinetic and drug dynamic profile. The radiological device used for the study was a SIEMENS controlled table and a SIEMENS ultrasound system with Convex probe. The access kit used was Accu-Stick Introducer System, Boston Scientific®. The X-ray dose was reduced as much as possible using the lowest principles as reasonably achievable (ALARA) by minimizing X-rays in preferring fluoroscopy, applying beam collimation, and increasing the distance from patient to the beam source. After positioning the patient on the fluoroscopic table, a preliminary liver ultrasound examination was performed to identify the site of the access. The procedure was performed by administering local anesthesia at the access site (Carbosen 2%). During the procedures, monitoring of saturation, blood pressure, heart rate and respiratory rate was performed. After disinfection, local anesthesia was performed at the target access site through ultrasound guidance. The liver capsule was anesthetized. The right and left lobes were perforated with intercostal and subcostal epigastric accesses, respectively, to reduce the risk of bleeding. The bile duct was punctured through an ultrasound-guided procedure with a 22-gauge needle. A 0.018-inch guide wire was inserted. With the Seldinger technique, an introducer of 6 Fr was advanced and the biliopasty was performed. A 7 Fr armored valve introducer with a length of 40 cm was positioned before occlusion. Subsequently, a super-stiff rigid guide was used to cross the obstruction, an entire-external biliary drainage was inserted when it was possible to cross the biliary stenosis. In case of distal occlusion of the biliary tract, an external drain was placed with a subsequent second procedural session at approximately 48-36 hours to attempt to cross the lesion.

The procedure ended with the execution of a cholangiography. The drainage was fixed through sutures. Subsequently, clinical, liver ultrasound examination and laboratory tests (the blood count, inflammation indices and bilirubin) were carried out at 12-24-36 hours.

The biliary drainage was then removed, and the metal biliary prosthesis covered in the main biliary tract was released. The metal stents used are in Nitinol, self-expandable, with a diameter between 8 and 10 mm and a length between 6 and 10 cm. A bilioplasty was then performed with a ballon of variable caliber (8 - 10 mm) a length between 6 and 10 cm. A biliary drainage and cholangiography were implanted. Subsequently, clinical, liver ultrasound examination and laboratory tests (the blood count, inflammation indices and bilirubin) were carried out at 12-24-36 hours. Follow-up with the same exams was performed at 30 days (with the removal of the drainage) at 60 days, 6 months, and a year. Contrast CT imaging was performed at 6 months and at one year.

Procedural factors

The procedural factors evaluated were the safety of the procedure in accordance with the CIRSE Standard criteria for the classification of complications[4]: the frequency of vaso-vagal reactions, hematomas, and bleeding. The technical success was considered as a reduction in bilirubin (> 4 mg / dl) and frequency of cholangitis in the follow-up. We subsequently evaluated statistically significant differences between the procedural data of access to the right and left biliary duct.

Statistical analysis

All statistics were developed in MATLAB® (Mathematics Works, Inc., Natick, Massachusetts, USA). We evaluated statistically significant differences between the procedural data of access to the right and left biliary duct and between the removal of 1 or more prostheses: the differences in terms of safety and efficacy were considered statistically significant if p value <0,05, using Student's t-test or Wilcoxon's sign-rank test.

3. Results

7 of the 27 procedures performed from January 2015 to August 2020 were included in the study. Of the 20 patients excluded: 14 patients had a plastic biliary stent implant; 6 patients had uncovered biliary stent implant. Patients ranged in age from 70 to 89 years (mean, 76). The treated patients had pancreatic cancer (75%), cholangiocarcinoma (10%) and liver metastasis (5%). 5 patients had recent or previous episodes of cholangitis. In 2 of the 7 patients there was a microperforation of the biliary tract with spread of contrast medium. (Figure 1a). Only one patient presented, on ultrasound examination, a small peri-hepatic subfascial hematoma. (Figure 1b). In 6 patients, an external-internal biliary drain was placed before the covered biliary prosthesis was released. In only one patient, an external biliary drainage was first placed due to the impassable obstruction (Figure 2a and 2b) and then an internal and external biliary drainage before the covered biliary prosthesis was released.

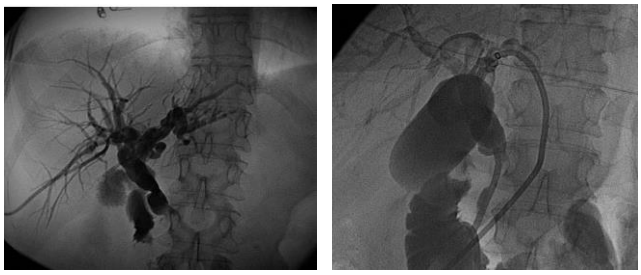

Figure 1 A (left) and B (right). Figure a) shows the parabilary spreading of MDC due to a small tear in the biliary tract. In b) an area of contrastgraphic alteration can be seen referable to the perihepatic hematoma.

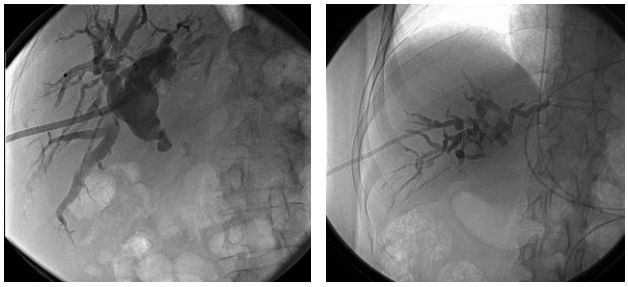

Figure 2 A (left) and B (right). Image a) shows ectasia of the intrahepatic biliary tract and choledochus up to the middle third site of obstruction. In b) the obstruction is instead localized at the confluence of the hepatic ducts. In both cases it was not possible to cross the obstacle and therefore a DBE was positioned.

In all 7 patients, a 12 Fr brace drain was placed at the end of the procedure in order to preserve the transit of bile.

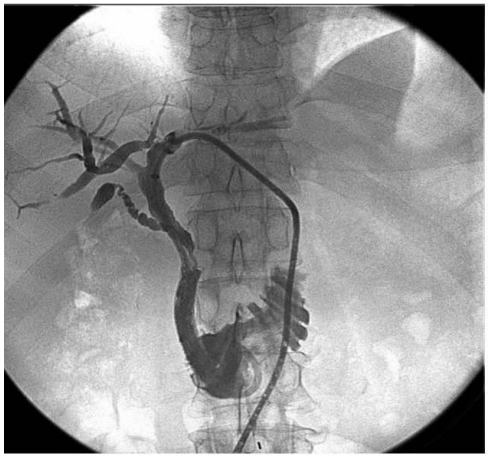

Figure 3. The image shows the presence of a metal stent at the distal choledochus. It is also possible to observe a narrowing / occlusion upstream of the stent and the placement of an external-internal drainage catheter.

The residence time of the biliary drain was 30 days. In 5 patients it was necessary to replace the drainage tube as it was occluded 15 days after the procedure; in 4 patients, this replacement took place using the hydrophilic guide and without losing the biliary pathway. In one patient, a new percutaneous access of the biliary tract was performed. At six months, 2/7 patients treated with the covered biliary stent showed hyperbilirubinemia due to stent occlusion due to disease progression. 2/7 patients treated with biliary stent developed cholangitis and non-reduction of bilirubin resolved in the hospital observation week. In 1 patient there was no reduction in bilirubin due to dislocation of the prosthesis at 60 days confirmed by CT examination with contrast. In 2 patients there was an occlusion of the biliary tract lumen, both upstream at 6 months. (Figure 3). No statistically significant differences were found between the results of accessing the right and left biliary duct.

4. Discussion

Obstructive biliary tract disease is a condition characterized by an obstacle to the outflow of bile and consequently the regurgitation of conjugated bilirubin into the blood. The cause of this obstruction can be benign or malignant in nature. The most important benign causes are represented by: lithiasic and a-lithiasic cholecystitis, cholecysto-choledocholithiasis, parasitosis, chronic pancreatitis, cholangitis, sclerodditis, benign post-surgical stenosis and spasm of the sphincter of Oddi. Less frequently (10% of cases), malignant disease is at the origin of the biliary tract obstruction. The most important malignant obstructive pathologies are represented by: neoplasms of the pancreas head, neoplasms of the intrahepatic biliary tract, of the hepatic hilum, of the extra-hepatic and ampullary biliary tract, carcinoma of the gallbladder, lymphadenopathy of the hepatic hilum, tumors and metastases of the liver. As a result of biliary obstruction, patients may develop cholangitis, with fever and pain in the right hypochondrium and jaundice known as Charcot's triad. Symptoms due to the concomitant and responsible pathology of the obstructive condition must clearly be added to these manifestations. In any case, a careful evaluation based on imaging methods is essential before implementing any therapeutic intervention. This makes the pre-operative diagnostic phase an essential moment for the success of the therapeutic intervention. The diagnostic algorithm must begin with a careful clinical and ultrasound evaluation: the obstruction and the increase in pressure determine the dilation of the biliary tract. Ultrasonography identifies biliary obstruction in 78-98% of cases. It allows the level of obstruction to be identified up to 95%[6]. Computed tomography allows definition of the local extension of the intra and extra hepatic masses. The administration of contrast medium effectively highlights the intra and extrahepatic biliary tracts through the opacification of the vessels and of the hepatic parenchyma. It allows evaluation of the dilation and thickness of the biliary tract walls. In case of obstruction, the segmental bile ducts appear dilated. The accuracy of CT in determining the presence and level of obstruction was 85-94% and 88-92% [7-8], respectively. MR-cholangiography protocols have been developed for the biliary tree through the development of T2-weighted rapid sequences and the availability of biliary excretion paramagnetic contrast agents. MRI cholangiography is based on the use of superfast T2-weighted sequences which result in an increase in the signal of normal static liquids such as bile[9]. (Figure 4).

The introduction of a biliary excretion MD (Gd-BOP-TA, Gd- EOB-TA) produces, in addition to a hepatic enhancement usable for diagnostic purposes, a significant hyperintensity in the T1-weighted sequences, then an MRI cholangiography for evaluation morphology of the biliary tree. (Figure 5).

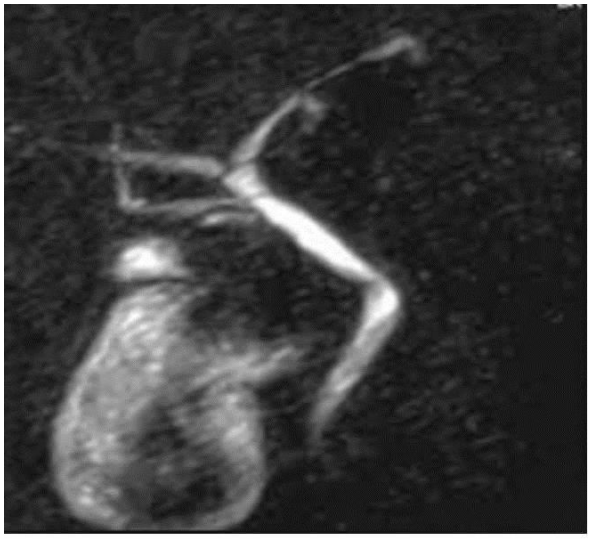

Figure 4. MRI direct cholangiography. It is an image obtained by turbo-SE sequences markedly T2- weighted in apnea. The hyperintensity of the bile allows imaging of the gallbladder and biliary tract to be obtained.

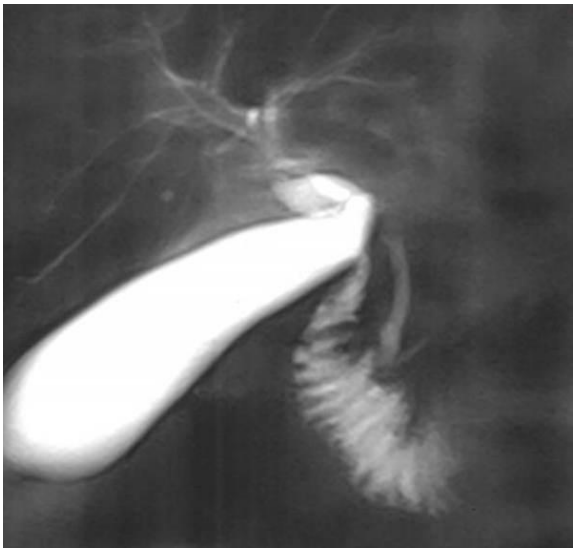

Figure 5. MRI cholangiography with paramagnetic MDC with biliary excretion. One hour after the start of the iv infusion, the MDC is significantly concentrated in the gallbladder and biliary tract causing hyperintensity in T1-weighted sequences.

Biliary endoprostheses can be divided into plastic or metal. The advantages and disadvantages of plastic prostheses and of metal stents compared to plastic prostheses are summarized.

The timing and applicability of a biliary metal stent should be evaluated based on the characteristics of the individual patient. However, consensus guidelines have been introduced, that recommend the correction of the INR to a value below 1.5, the suspension of heparin in case of a PTT 1.5 times higher than the normal value, and finally the suspension of aspirin and clopidogrel for 5 days and of fractionated heparin for 24h or up to two doses before the procedure[10]. Major complications of percutaneous radiological procedures include sepsis, cholangitis, hemorrhage, pleural puncture, and death. Complication rates range from 3% to 10% and procedural mortality ranges from 0.1% to 0.8%. The most frequent major complications are sepsis and haemorrhage with an incidence of 2.5% [11]. In reference to infectious risk, biliary tract surgery is a clean / contaminated procedure according to the National Academy of Sciences, therefore the guidelines of the Society of Interventional Radiology recommend the use of antibiotic prophylaxis in all patients undergoing biliary interventional therapy [12-13]. Hemobilia is common immediately after the procedure and usually disappears within 24 hours. A persistent hemobile condition may be due to involvement of a portal or hepatic venous branch. This complication can be diagnosed through trans-catheter contrast injection and treated by repositioning the catheter in order to obtain a tamponade. The choice of the metal stent implant in malignant biliary obstruction depends on the patency rate of the stent used, which must exceed the patient's life expectancy in order to minimize the use of multiple and repeated surgeries. For example, for inoperable pancreatic adenocarcinoma, the median survival ranges from 6 to 11 months[14], while for patients with metastatic disease it drops to 2-6 months [15]. Based on these survival rates, the stent patency rate therefore appears to be comparable to the life expectancy of most patients. As part of the choice of the most appropriate type of stent to use, metal stents are commonly preferred to plastic stents, in line with published data that show a higher clinical success rate, patency and lower indirect [16]. According to published data from a multicenter European study of 240 patients by Rossi et al, the patency rates were 78% and 67% for biliary stents made of nitinol and steel, respectively, in a population of patients with a survival to 25 and 50 weeks, respectively by 42% and 16% [17] Freeman and Overby conducted a prospective study evaluating unilateral stent placement in 35 patients with hilar obstruction, finding a clinical success rate of 77% and a median patency of 5.4 months [18] .The technical aspects of the placement of stents can be identified and planned during the preoperative imaging evaluation process, this evaluation is indispensable in case of malignant obstruction. The stent improves the patient's quality of life, leading to the disappearance of symptoms and avoiding the patient’s discomfort deriving from the presence of a drainage tube. Precisely to overcome this complication, numerous studies have evaluated the benefits deriving from the use of self-expandable and covered metal stents (Figure 6 and 7) describing their long-term patency rates. With reference to the last listed conditions, further therapeutic perspectives could be represented by the use of dedicated biliary stents arranged in a Y in the main biliary tract and in the choledochus so as to counteract neoplastic infiltration. All this in order to steadily increase the percentage of patients who, although no longer are susceptible to resolutive therapeutic treatment, can still benefit from procedures capable of significantly improving their quality of life.

In conclusion, the present study, although not very large and limited in time, suggests that the implantation of metal biliary stents is a safe and effective procedure.

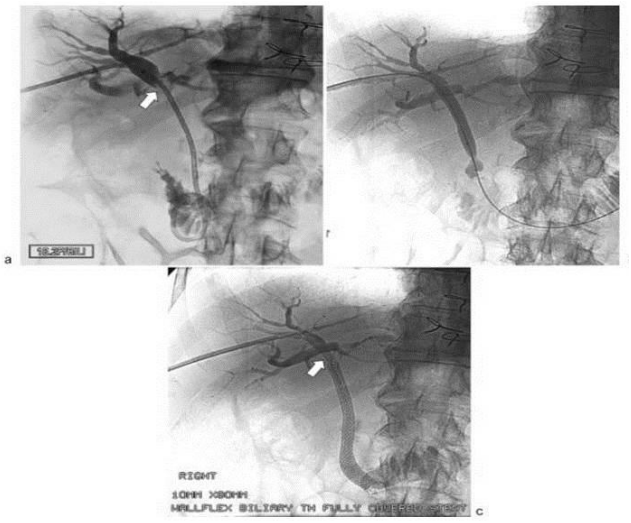

Figure 6. Percutaneous cholangiography of a malignant biliary obstruction caused by invasive gastric cancer. In a) it is possible to observe the positioning of a percutaneous biliary drainage. In b) it is possible to observe the percutaneous bilioplasty procedure. In c) the placement of a covered biliary stent that goes beyond the sphincter of Oddi due to its involvement.

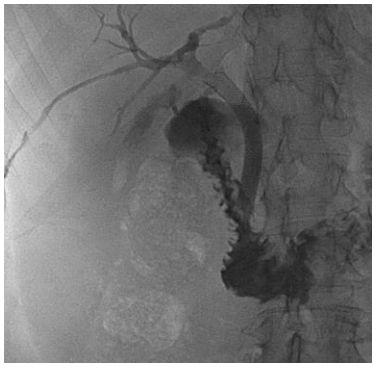

Figure 7. The figure shows a metal stent extending from the confluence of the main bile ducts to the papilla.

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