

## Treatment of malignant biliary obstruction using one metallic stent per patient

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**Background:** Drainage of malignant jaundice by percutaneously inserted stents is an established method in inoperable neoplasms. In a group of consecutive patients with malignant biliary obstruction, an attempt was made to drain the bile using only one metallic stent (MS) per patient. This study examines the results of this approach.

**Patients and methods:** In 23 men and 18 women (mean age 61.6 years) with obstructive jaundice caused by inoperable neoplasm, 43 shape-memory metallic stents (SMMS) were percutaneously inserted.

**Results:** In one case, two SMMS were used for the drainage of the two segmental ducts of the right hepatic lobe. In the remaining 40 patients, the stents were successfully released in the proper position in 38 patients and in an incorrect position in 2 patients. Their final length after their adjustment to the bile duct was increased by 20-30% resulting in protrusion of 8 MS into the duodenum. The serum bilirubin level before the intervention was 9 to 40 (mean 19.6) mg/dl while the lowest value after the drainage was 2 to 15 (mean 4.3) mg/dl. Serious complications were observed in 14,6% of patients whilst the 30-day mortality was 5%. Seven patients underwent reintervention because of significant aggravation of jaundice.

**Conclusion:** Treatment of malignant biliary obstruction with the use of only one SMMS of considerable size is feasible and effective; the main drawback is the inability to accurately estimate the final position of the distal end of the stent.

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The method of choice for the drainage of obstructive jaundice caused by an inoperable neoplasm is the insertion of a stent by endoscopy as this technique has considerably lower morbidity and mortality than the surgical or percutaneous draining procedures<sup>1</sup>. However, when due to a preceding choledochostomy or other reasons the retrograde catheterization of the bile ducts is not feasible, the solution is provided by the percutaneous insertion of a draining catheter or a metal stent (MS)<sup>2</sup>. In the last decade, metal stents are preferred because they drain sufficiently, for a long period of time and improve patient's quality of life<sup>3</sup>. Their greater disadvantage is their high cost which is further substantially increased when a second stent is needed, an occurrence that is not rare<sup>4,5</sup>.

In a group of patients we attempted to drain the bile using only one MS, of the shape-memory type, per patient. In this study we analyze the results of this approach, the problems encountered and the cause of failure.

### Patients and Method

In a group of 41 patients, 43 shape memory metallic stents (nitinol stents, by Bard-Angiomed) with a diameter of 8-12 mm and length 4-12 cm were used. The group consisted of 23 men and 18 women (mean age 61,6 years). A tissue diagnosis was available in 17 patients from a previous surgical procedure and in 2 patients from percutaneous biopsy. The obstruction was

diagnosed to be due to metastatic neoplasm in 8 patients, to pancreatic cancer in 6, to cholangiocarcinoma in 3 and due to hepatocellular carcinoma in 2 patients.

In 6 patients a choledochostomy had previously taken place which was subsequently obstructed, while in 21 cases an attempt to drain the bile with plastic stents preceded the current procedure; this attempt either failed or the inserted stents were in less than a month obstructed.

In 14 patients the MS was inserted in one session, while in the rest insertion of a catheter was initially performed and implantation of the stent followed, after ensuring the success of the drainage. This gradual approach was selected in cases with a poor prognosis, such as high levels of bilirubin (>20 mg/dl) or multiple hepatic metastases. Placement of the stent was performed after local infiltration with lidocaine and intravenous administration of pethidine, a technique described in earlier reports<sup>6,7</sup>. In 28/41 patients after the insertion of the MS the draining catheter remained in place for a few days until the bilirubin had begun to decrease.

In 35/41 patients (85%) the right lobe was selected for drainage because it was larger and more easily accessed. In those patients with an infiltrated by the tumor or atrophic right lobe, an approach through the epigastrium was undertaken. There was usually communication between the two hepatic ducts so that one stent was sufficient for the drainage of both lobes.

The post-procedural therapy and follow-up were carried out by the referring clinicians whereas the radiologists were consulted in cases of complications of the drainage.

### Results

In all cases the propulsion of the introducing catheter through the stenosis was feasible, provided that the stenotic lesion had been successfully traversed by the guide wire. Characteristically, in one case where the course of the bile ducts in combination with the hardness of the neoplasm did not allow the catheterization of the stenosis with the guide wire, we decided to traverse the stenosis with the introducing catheter and eventually succeeded.

Deployment of the stent was successful without any dislodgement in all cases; however drainage failed in two cases of hilar tumors. Failure was attributed to the presence of additional obstruction at the distal end of the common bile duct. In the first case a second MS was placed, its distal end protruding into the lumen of the duodenum. In the second case, endoscopy followed which revealed extensive infiltration of the duodenal wall and the patient was treated with catheter placement. In this study, we included a 42-year-old woman with cholangiocarcinoma and obstruction at the junction of the segmental ducts of the right lobe; in this patient two stents were inserted in the respective obstructed segmental ducts as the left lobe was atrophic and these stents drained adequately for 10 months. With the exception of the two cases described above, in all other patients only one stent was placed. Therefore the proportion of stents to patients was 43/41 (1.05 stent/patient). Excluding the woman with the cholangiocarcinoma, in whom insertion of two stents was planned from the beginning, successful drainage of the bile with one stent was achieved in 38/40 patients (95%).

The immediate self-expansion of the stents was satisfactory with their diameters measuring >5 mm. After the release, depending on the degree of expansion, the length of the stents was increased resulting in protrusion of their distal end into the lumen of the duodenum in some cases.

In all cases the bilirubin level decreased significantly. Jaundice responded in all patients except for one with extensive neoplasm and substantially elevated bilirubin (40 mg/dl) who remained icteric in spite of the considerable fall in bilirubin level (15 mg/dl). In this patient, despite the poor response to the insertion of a draining catheter, a MS was finally placed as the catheter was frequently obstructed by debris from tumor necrosis. Bilirubin levels before the procedure were 9-40 (mean 19.6) mg/dl while the lowest level measured after the procedure was 2-15 (mean 4.3)mg/dl.

### Complications

In the first days after stent insertion, serious complications related to the procedure were observed in 6 patients (14.6%). Two patients presented with high

fever and chills that lasted for a few hours; one of them had concomitant infection at the site of skin puncture which was uneventfully treated. Although the majority of patients had slightly prolonged prothrombin time (2-3 sec) only 2 patients presented with haemorrhage that needed transfusion. After stent placement some patients complained of abdominal pain which was treated with anti-inflammatory drugs and antibiotics. In two of these patients clinical and ultrasound examination revealed cholecystitis; this complication was treated conservatively in one while in the other percutaneous cholecystostomy was performed which drained bile mixed with pus.

The 30-day mortality was 2/41 (5%) and was due to the combination of infection and haemorrhage. In one patient haemorrhage was caused from injury to a portal vein branch during the insertion of a draining catheter and cholangitis followed. The haemorrhage was successfully treated with tamponage. However, since the patient was in danger of cholangitis and septicaemia, a stent was percutaneously placed but it failed to save the patient.

During the three years that this study lasted, 7/41 patients (17%) were referred for recurrence of jaundice (rise in bilirubin levels >10 mg/dl). Five of them were referred to the radiological department; percutaneous cholangiography revealed stent obstruction to be complete in 3 patients and incomplete in the other two. In these 5 patients, two with symptoms of cholangitis, an internal-external drainage catheter was inserted. In one patient, although the catheterization of the MS failed, the manipulations performed resulted in restoration of the patency for some weeks. Placement of a catheter improved patency and helped treatment of cholangitis but did not result in considerable decrease in bilirubin level. In 2/7 patients plastic stents were successfully endoscopically inserted.

Obstruction of the MS is mainly caused by tumor overgrowth at the proximal or distal end of the stent, by tumor ingrowth through the mesh openings and by bile sludge encrustation. Other causes have also been described; these include obstruction from blood clot, from food particles, from infiltration of the duodenum by the tumor and mucosal hyperplasia<sup>4,8-11</sup>. Based on the radiological findings alone, it was not possible to undoubtedly attribute the MS obstruction to one or more of the above causes.

### Discussion

The wide application of the MS is due to their easy positioning and to the longer duration of drainage in comparison to the plastic endoprosthesis<sup>12-15</sup>. For these reasons MS are used by endoscopists in spite of their higher cost which is their significant drawback. In some studies relevant parameters such as the duration of drainage, the cost, the complication rate and the quality of life were evaluated. The results showed that for patients with life expectancy less than 4-6 months plastic stents are indicated. For patients with longer life expectancy MS are preferred because of their lower frequency of occlusion



**Figure 1:** Patient with cystadenocarcinoma of the pancreas and obstructive jaundice. Through the left hepatic lobe a MS of considerable length (12cm) and diameter (10mm) was inserted, which expanded the common hepatic and bile duct. Contrast medium was administered through the external catheter and flowed freely into the intestine.

and consequent rare need for reintervention<sup>12,13,16,17</sup>. This rule is valid only for patients appropriate for endoscopic stenting; if this is not possible the percutaneous method is used and the MS are preferred as the complication rate of percutaneous plastic stent placement is high. Moreover the cost rises even more if the first stent does not succeed to drain and a second stent is used, immediately after the insertion of the first one or later in case of occlusion<sup>4,5</sup>. To lower the cost a continuous effort is under way to improve the technical characteristics of stents, the technique of stenting and to carefully select the patients who are suitable candidates for this procedure.

In this series we tried to accomplish the best result with the lower number of stents per patient. For this purpose we used a new type of stent made by nitinol which has thermal shape memory. The characteristic of these stents is that following their deployment in the environment of the body temperature they exert tension on the stenosis until they take the original shape they are given at their construction<sup>5,18</sup>. Another merit of these stents is that they have non-traumatic ends with radiopaque markers made from tantalum<sup>18,19</sup>.



**Figure 2:** Patient with metastases from colon cancer that caused obstructive jaundice. After placement of the MS through the right hepatic lobe and its self-expansion, contrast medium was injected and flowed without any obstruction towards the intestine. The MS protrudes into the duodenum and its distal end is indicated by the radiopaque tantalum markers.

The use of one only stent per patient is based on the fact, which is well acknowledged by our experience, that drainage of a portion of the liver parenchyma is sufficient to confront the jaundice successfully<sup>20</sup>. In our patients we chose to drain the lobe with the largest volume of healthy parenchyma even if we had to drain the left lobe which is technically challenging.

In our series the ratio of stents per patient was 1.05 (43/41). In other publications the proportion of stents to patients is reported to be 1,1<sup>21</sup>, 1,2<sup>9</sup>, 1,3<sup>22</sup>, 1,4<sup>23</sup> and 1,6<sup>24</sup>. The lower ratio in the present series is due mainly to the technique we followed and will be discussed latter. However it should be mentioned that in the reported studies more than one MS were used for independent drainage of the 2 lobes<sup>9,24</sup>. The data about the need to drain both lobes is contradictory; some investigators think that draining both lobes prolongs survival<sup>25,26</sup> and

reduces the rate of cholangitis<sup>27</sup> however others consider the drainage of only one lobe as sufficient<sup>29</sup>. Moreover all writers insist that in selected patients with cholangiocarcinoma both lobes should be stented because these patients have long survival and a good quality of life is warranted<sup>9,24</sup>; this is the task we followed too.

The technical characteristics and the technique contribute to the long patency of the stents. The evaluation of the MS showed that they were easily forwarded through the stenosis if the catheterization with a guide wire had been successfully done. The deployment mechanism worked uneventfully and no transposition or other malfunctioning occurred and therefore no loss of any stent ensued. In all cases the stents' shape adapted to the course of the biliary duct without distortion that could cause occlusion.

In a total of 41 patients failure to drain resulting from imperfect positioning was observed in 2 patients and was due to the fact that only part of the stenotic lesion was covered. Successful drainage using 1 stent/patient was accomplished in 95% of cases. This is in accordance with other studies where different types of MS were used and success rates between 90%-100% were reported<sup>5,9,19,21-24,30</sup>. In the beginning of our study we realized that leaving the end of the biliary duct uncovered is a cause of failure of the drainage. Therefore we decided that in any case where doubt existed about the extent of the neoplasm, the whole length of the biliary duct should be covered using a lengthy stent. In each case this approach was used, immediate drainage was achieved. Hatzidakis et al. report that this practice reduces the rate of cholangitis<sup>21</sup>. The disadvantage of this approach is that the stent frequently protrudes into the duodenum. Protrusion into the intestine may cause injury and haemorrhage<sup>8,31</sup>. Follow-up of our patients did not disclose any sign of hemorrhage from the gastrointestinal tract, possibly because the ends of the stents used are non traumatic and their junctions flexible. However it is probable that retention of food in the protruding end of the stent could cause obstruction<sup>21</sup>.

In our patients the 30-day mortality after the intervention was 5%; one of the deaths was mostly caused by the attempt to insert a drainage catheter rather than stent placement. The corresponding rate in other contemporary reports varies between 0-20%<sup>5,8,9,11,19,21,22,30,32-34</sup>. The rate of major complications was 14.6%. In the literature equivalent rates between 0-20% are reported<sup>4,21,24,30</sup>. Comparison of mortality and complication rates between different reports is not easy as different methods are employed and the findings are grossly depended on different parameters which cannot be standardized. For example in our department, as is the case elsewhere 21, patients with major clinical problems or patients who did not respond to the drainage are treated with catheters and not with stents. As a consequence patients with shorter life expectancy and severe complications are excluded from some studies.

The occlusion of stents is a major problem not easily



**Figure 3:** Reintervention with insertion of an internal-external drainage catheter after 5 months of adequate drainage of bile through the MS. Since the left lobe contained a greater proportion of healthy parenchyma than the right one, we decided to insert the catheter through the left hepatic duct. The lumen of the MS is filled with material of unknown origin.

solved. Presently the research is aiming mainly toward the construction of covered stents<sup>34,35</sup>. In published studies the stent patency lasts from 2,3 up to 12 months<sup>4,5,9-11,19,30</sup> and usually exceeds the mean survival of the patients<sup>9,11,22</sup>, which means that most of the stents remain patent until the death of the patient. In most studies follow-up of the patients in the terminal stage was done with periodic visits or phone calls. In our study for practical reasons it was not possible for an accurate estimation of the stent patency to be done. We believe that although it is possible that some patients in the terminal stage experienced recurrence of jaundice, the stents placed remained patent for an adequate period of time since reintervention was requested for 7 patients only.

We think that this satisfactory long patency of the stents is due to the characteristics of MS, primarily their large diameter and length. Extension of the stent beyond the edges of the neoplasm is an advantage because it covers the area which will be probably soon invaded by the neoplasm. However we believe that the large mesh openings in the stents used is a disadvantage because they permit the intrusion of the neoplasm through them, as other writers have also noticed<sup>4</sup>.

A drawback of our study is that the patients included were followed by clinicians in different clinics and as a consequence different protocols were used; for many patients a scheduled follow up could not be achieved. Another significant disadvantage was that a histological diagnosis of

the obstructing neoplasm was not available in the majority of patients while tumor staging was not meticulously done, which is also the case in similar studies.

We conclude that drainage of malignant jaundice with one per patient memory stent of large diameter and length is efficacious with low rates of mortality and morbidity. The most significant problem in their use is the protrusion of their distal end into the intestine.

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