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THE PERCUTANEOUS USE OF THE WALLSTENT ENDOPROSTHESIS IN MALIGNANT BILIARY OBSTRUCTION

THE PERCUTANEOUS USE OF THE WALLSTENT ENDOPROSTHESIS IN MALIGNANT BILIARY OBSTRUCTION

De percutane toepassing van de Wallstent endoprothese bij maligne galwegobstruktie

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CONTENTS

ABBREVATIONS

CBD	common bile duct
-F	french or french gauge (= 0.3 mm)
LHD	left hepatic duct
PTBD	percutaneous transhepatic biliary drainage
RHD	right hepatic duct
US	ultrasound

1 AIM OF THIS THESIS

The aim of this work is to evaluate the efficacy of the percutaneously inserted metallic self-expandable Wallstent endoprosthesis in malignant biliary obstruction. Six years of experience with the Wallstent and the results of randomized trials justify an evaluation of the current status of the biliary Wallstent endoprosthesis.

The problems encountered with conventional plastic endoprostheses in the palliative treatment of malignant obstructive jaundice are discussed first (Chapter 2). The major problem with plastic stents is reduced patency caused by stent blockage. Possible solutions to prolong patency, which predominantly concern minor changes in stent diameter and stent material, are described. A landmark was the introduction of the expandable metal stent in the second half of the 1980s. The revolutionary design of the metal stent was promising and a more fundamental and improved progress in stent patency was anticipated.

Most experience with metal stents in malignant biliary obstruction concerns the Wallstent endoprosthesis. The clinical results with the Wallstent are the subject of this thesis. The early experiences are reported first (Chapter 3). The results of the Wallstent in hilar and distal strictures are subsequently described separately, as these involve different study populations (Chapters 4 and 5). Complications related to the use of the Wallstent are discussed, with emphasis on technical aspects of the use of the Wallstent in percutaneous stenting (Chapter 6). Finally, the place of the Wallstent in the treatment of malignant biliary obstruction will be defined (Chapter 7) and the important issues of this work are summarized.

2 INTRODUCTION

2.1 Introduction

Obstructive jaundice is a major symptom of cancer involving the biliary system. Pancreatic carcinoma is the most common cause; bile duct carcinoma, gallbladder carcinoma and metastatic disease are other frequent causes of malignant biliary obstruction. In 1989 almost 30,000 new cases of pancreatic carcinoma were diagnosed in the USA [1]. Gallbladder carcinoma occurred in approximately 10,000 patients and bile duct carcinoma in 4,500 cases [2,3]. In the Netherlands in 1992, 109 males and 114 females per 1,000,000 inhabitants died of pancreatic cancer while 18 males and 42 females per 1,000,000 inhabitants died of biliary tract cancer [4].
Curative surgery of malignant distal or hilar biliary strictures is possible in only a minority of patients [1,5-13]. In the remaining patients palliative biliary drainage should be considered to treat jaundice and the often accompanying pruritus [14]. Obstructive jaundice has profound systemic effects, such as on renal function and immunity, and may present as or evolve to cholangitis [15-25]. Several palliative treatment modalities should be considered: endoscopically inserted biliary endoprostheses, percutaneous biliary drainage or surgical biliary bypass.

2.2 Palliative biliary drainage

Surgical or non-surgical treatment
Surgical biliary bypass is one of the three palliative treatment modalities available in the management of patients with malignant obstructive jaundice. It is, however, associated with a considerable morbidity and mortality rate. A literature review of 20 years of palliative surgery of pancreatic carcinoma disclosed an overall surgical bypass mortality rate of 14% in the 1980s [26]. The ranges were, however, wide and the results improved according to more recent studies. Comparison of surgical bypass, percutaneous stents and endoscopic stents in this review disclosed comparable drainage success rates, but more early and less late complications in surgical bypass [26]. Recent studies on surgical bypass in pancreatic carcinoma report postoperative morbidity in 20-30% of cases [27-29]. A recent retrospective study of surgical biliary bypass and endoscopic

plastic endoprostheses at our institution advocates palliative endoscopic stenting of malignant pancreatic strictures in patients surviving less than six months and surgical bypass in patients expected to survive more than six months [30]. The patients treated by endoprostheses were significantly older than in the other group. Some surgeons prefer the surgical placement of tubes or stents which is, however, associated with a thirty-day mortality of approximately 10-15% [31]. Palliative surgery of hilar strictures has a mortality rate of approximately 20% with, however, wide ranges of 5-33% [5,32-34]. A retrospective study reports higher hospital mortality in non-surgical treatment compared to surgical bypass [33]. The small non-surgical group was, however, diversely treated and had significantly more concomitant medical problems before treatment. The thirty-day mortality of surgically placed tubes in patients with malignant hilar strictures is approximately 20% [5,35,36].

Comparison of the treatment modalities in this way is, however, influenced by patient selection. Debilitated patients are often considered unfit for surgery and are therefore referred for non-surgical drainage. Several randomized trials have been performed comparing surgical bypass and non-surgical, predominantly endoscopic, endoprostheses in pancreatic carcinoma [37-43]. These series included patients treated by cholecystostomy or choledochoduodenostomy. A randomized study on percutaneous endoprostheses and surgical bypass in inoperable pancreatic carcinoma demonstrated successful drainage in all patients [37]. The overall early complication rates were comparable but, with increasing percutaneous experience, less complications occurred in patients treated by percutaneous stenting. Thirty-day mortality and procedure-related mortality were less with percutaneous stents. The median hospital stay was significantly less with percutaneous stents, although no longer significant when readmissions for recurrent jaundice and duodenal obstruction were taken into account. Several randomized series on surgical bypass and endoscopic endoprosthesis demonstrate their equal effectiveness in drainage [38-42]. The early complication rate and thirty-day mortality were somewhat higher in patients treated by surgery. Post-procedural hospital stay tended to be longer in surgical treated patients, but readmissions occurred more often in the endoscopically treated group due to stent blockage.

Malignant tumors causing obstructive jaundice may also cause duodenal obstruction. The occurrence of duodenal obstruction requiring bypass surgery is influenced by the type of stricture and the survival of the patient. In a series of 1,153 endoscopically treated patients with malignant obstructive jaundice, surgical bypass was necessary in 7.5% of the patient population, varying from 2.4% in metastatic disease to 23% in ampullary strictures [44]. In pancreatic carcinoma, 9% of patients needed surgical

bypass while some other endoscopic series reported a lower incidence in pancreatic carcinoma [45-47]. Two reviews of surgical series after biliary bypass alone for pancreatic carcinoma report an average of 17-21% needing gastrojejunostomy at a mean of 8.6 months [1,26]. The lower incidence in the endoscopic series is probably due to patient selection, as patients are excluded from endoscopic drainage when duodenal stenosis is expected shortly after intervention. Patient survival is not significantly increased by either form of palliative drainage [48].

The introduction of non-surgical biliary drainage has changed the management of patients with inoperable biliary obstruction. In most hospitals, poor operative candidates and patients with inoperable cancer will be treated by non-surgical drainage. Reasonable operative candidates in whom unresectability cannot be proved definitely preoperatively and patients with duodenal obstruction are candidates for surgery.

Percutaneous or endoscopic drainage

Numerous non-comparative reports have been published describing the results of the endoscopic or percutaneous technique. Comparison is hampered by differences in patient populations, definitions of complication and success, and improvement in results due to continuous technical improvements. Comparison of recent data indicates no major differences in success and complication rates in distal biliary strictures [44,49,50]. In hilar strictures the overall success and complication rates of the studies have wider ranges, with a somewhat higher success rate and lower complication rate in percutaneous stenting [44,51-54]. A retrospective comparative study, including patients with catheter drainage, has reported preference for the percutaneous technique in hilar strictures, as early complications were less [51]. More solid conclusions might, however, be drawn in randomized trials. One such series has been performed [55]. The study population included patients with distal and hilar strictures. Stent insertion was, although not statistically significant, slightly more successful with endoscopic stents. When successful drainage was included as additional parameter the difference became significant (61% versus 81%). Early complication rate and thirty-day mortality were higher with percutaneous stents (67% versus 19%, and 33% versus 15%, respectively). The occurrence of other early complications, as well as late complications, were approximately comparable in both groups. As this study is the only randomized study comparing the results of the endoscopic and percutaneous technique it deserves special attention, especially as it is often referred to as proof of the superiority of the endoscopic technique. Some criticism on this study is, however, justified. The percutaneous technique used was not state-of-the-art as no ultrasound guidance was used, while a

caliber jump in size between the initial drainage catheter and the stent occurred [56,57]. This is probably the explanation for the low placement success rate and remarkable high percentage of bleeding and bile leakage. Although more patients with hilar stricture were randomized to the endoscopic technique, no reference was made to the type of hilar stricture and, therefore, the complexity of the strictures was ignored. The authors later reported comparable extent of hilar strictures in both groups, but did not expand on this statement [58,59]. One of the authors of this randomized trial stated: "the results of a randomized study thereby apply to the cohort of patients fitting the entry criteria, which may be only a small part of the spectrum, and only within the institution concerned" [60]. For several reasons it therefore seems not justified to use this randomized trail as the definite proof of the superiority of the endoscopic technique.

When the percutaneous or endoscopic technique or both fail, an alternative treatment is the combined percutaneous-endoscopic procedure or Rendez-vous procedure [61-63]. With this technique a percutaneously inserted guide wire is passed through the stenosis and grasped by the endoscopist who brings it outside the mouth. Control of both ends of the guide wire forms a stable track facilitating railroading of a stent. The combined procedure is often successful in cases not amenable to other non-surgical therapy with, however, an additional complication rate [64-66]. As with other new therapeutic techniques a learning curve exists, especially concerning too vigorous stent insertion resulting in liver parenchymal damage [67,68]. Other combination treatments have also been proposed, such as a fluoroscopically guided retrieval basket instead of employing an endoscope [69].

The choice between the endoscopic and percutaneous technique is dominated by diverging reported results and local circumstances. Endoscopic retrograde cholangiopancreatography (ERCP) will be part of the diagnostic work-up of patients with malignant distal biliary strictures. As endoscopic stent insertion can be performed in the same session and the results of percutaneous and endoscopic techniques are comparable, endoscopic stent insertion is the treatment of choice. When this fails, percutaneous stent insertion is the equal valuable alternative. In patients with hilar strictures, the choice is more debatable and often dictated by local circumstances. Overall published results indicate some preference for percutaneous stenting. In case of failure of one of the techniques the other technique, or the combined procedure, should be considered.

2.3 Percutaneous biliary drainage

History

Percutaneous transhepatic puncture of the intrahepatic biliary ducts was performed sporadically in the first half of this century. The first report of percutaneous transhepatic cholangiography dates from 1937 [70]. In these sporadic cases only diagnostic procedures were performed. The development of fluoroscopy and image intensification and the use of a cannular sheath facilitated the percutaneous procedure, which, therefore, became more popular in the 1950s and 1960s [70]. It was performed preoperatively with the sheath in place as external drainage before surgery. Leaving a sheath or catheter in place also prevented intraperitoneal bile leakage [71-73]. Kaude et al in 1969 were the first to describe prolonged drainage with this technique as palliative treatment of a malignant stricture [74]. This technique has, however, the disadvantage of prolonged external bile loss with its metabolic consequences, such as hypotension. A landmark in the development of percutaneous drainage was reported in 1974 by Molnar and Stockum who advanced a multiple side hole catheter through a stenosis, thereby establishing internal bile drainage [75]. As early experience was overshadowed by a considerable number of especially infectious complications (approximately 40%) further refinements were developed in the following years, giving better results [76-86]. Changes in puncture technique and catheters and the use of ultrasound guidance are examples of the progress in percutaneous biliary drainage [56,73,87].

The percutaneous technique

Parenteral antibiotic prophylaxis is given 12 h before and after each procedure [88]. Bleeding and clotting times should be checked and corrected when indicated [89]. The procedure is performed under sterile conditions with the ultrasound transducer wrapped in a sterile sleeve. Local anesthesia is established by lidocaine, while midazolam and fentanyl are used as systemic sedative and analgesic. Both midazolam and fentanyl have the advantage of rapid onset of action and short half-life [89]. A pulse oximeter and an automatic blood pressure monitor may be used to control oxygen saturation and blood pressure [90,91]. Some have advocated epidural anesthesia in percutaneous biliary intervention [92].

Use of the anterior approach to the left hepatic duct is preferred at our institution. This anterior approach avoids the risk of a transpleural puncture while a left-sided catheter gives less patient discomfort and has a reduced dislodgement risk [56,73,93-96]. The latter is also important for patients treated by endoprostheses as this is, in our institu-

tion, mostly performed as a two-stage procedure, especially in hilar strictures. A catheter will, therefore, be in place after the first procedure. A right lateral, preferably subcostal, ultrasound-guided approach may be indicated in hilar strictures when left hepatic lobe atrophy exists, or when multiple intubations are necessary in hilar disease. Ascites is a relative contra-indication for percutaneous drainage. Leakage of ascitic fluid along the catheter may occur and drainage of infected bile will cause peritonitis.

First, an appropriate bile duct will be localized by ultrasound and a puncture route will be chosen. An ultrasound transducer (3.5 MHz) with a sterile puncture adaptor is used. A skin incision is made at an appropriate site and a short, stiff 18 gauge needle [Spinocan, B Braun Melsungen AG, Germany] is inserted through the puncture adaptor and the skin. This needle prevents bending of the 22 gauge echo-tip design Chiba puncture needle [Cook Europe A/S, Bjaeverskov, Denmark] due to movements between the skin and the transducer. During breath hold the Chiba puncture needle is inserted into the biliary system. Correct position is confirmed by bile discharge after removing the stylet of the Chiba needle. In distal strictures a more central segmental duct can be punctured, but in hilar strictures a more peripheral entry should be used to allow for adequate overstenting and guide wire and catheter manipulation. A 0.046 cm (0.018 inch) Cope mandril stainless steel guide wire with platinum tip [Cook Europe A/S, Bjaeverskov, Denmark] is introduced through the Chiba needle into the biliary duct. This action is observed by ultrasound. The puncture needle is removed and a 22 gauge needle with a preloaded 7-F teflon sheath [Neff percutaneous access set, Cook Europe A/S, Bjaeverskov, Denmark] is introduced over the guide wire. The sheath will be pushed over the guide wire into the bile duct when the needle is inside the bile duct. The needle and the guide wire are withdrawn and, after aspiration of bile, water-soluble contrast agent is injected into the biliary system. Radiographs of the stricture will be made to document the stricture and to decide which treatment is most appropriate. In patients with cholangitis only external drainage will be established. In these cases the procedure will be stopped after an 8-F pigtail catheter [Cook Europe A/S, Bjaeverskov, Denmark] has been left for external drainage. Further manipulations will be performed in a second session when the cholangitis has disappeared. In all other patients an attempt will be made to pass the stricture at the initial session. An 0.035 inch hydrophilic-coated angled tip guide wire [Glide wire, Terumo Corporation, Tokyo, Japan], a 5-F cobra-head shaped angiographic catheter [Cordis Europe NV, Roden, The Netherlands] and a 0.035 inch modified Amplatz extra stiff guide wire [Cook Europe A/S, Bjaeverskov, Denmark] facilitate this procedure. An external 8-F pigtail catheter will be used in case of a failed attempt.

After several days the second stage of the procedure will be performed. When stricture passage has not been established during the initial procedure the second session will start by attempting to establish stricture passage. This attempt will often be successful. Because the external drainage has reduced the diameter of the prestenotic dilated bile duct, the lumen will be better matched to the stricture diameter facilitating guide wire and catheter passage. After stricture passage an endoprosthesis or catheter can be introduced. For the technique of percutaneous plastic endoprothesis insertion one is referred to the literature, while metal stent insertion is described in this chapter (2.6) [73].

In hilar strictures more than one catheter or endoprosthesis may be needed necessitating multiple punctures and stricture passages. The choice to perform multiple drainage procedures is influenced by several factors, such as the clinical condition of the patient, the life expectancy and the anticipated success of the procedure. Incomplete drainage will often be sufficient to treat distressing symptoms such as pruritis. Bilateral catheter drainage has been performed through a single percutaneous approach. Bilateral drainage by endoprostheses inserted through a single tract will, however, hamper reintervention [97-99]. A Y-shaped drainage catheter which can be inserted through a single percutaneous tract has been developed [99]. It functions as an endoprosthesis with a subcutaneous button.

A percutaneous access to the biliary tree allows several diagnostic and therapeutic procedures such as biopsy, cholangioscopy, intraluminal ultrasound or intraluminal radiotherapy [100-105]. In selected cases, an alternative percutaneous approach can be used such as a cholecystostomy or a transjejunal route [106,107].

2.4 Plastic endoprostheses

In the 1970s and early 1980s percutaneous catheter drainage had become an established method of palliative drainage of malignant obstructive jaundice. One aspect of this treatment, however, namely the permanent presence of a catheter, was considered a major disadvantage [108]. The catheter acts as a constant reminder of the underlying disease while it thereby requires daily care. This prompted the use of a tube crossing the stricture without external continuation: an endoprosthesis.

The first reports on the use of a percutaneously inserted biliary endoprosthesis were published at the end of the 1970s [109-111]. The first endoscopic report was published one year later [112-115]. Already early in the use of endoprostheses in non-surgical

biliary stenting major drawbacks became clear [116,117]. Early cholangitis occurred in up to 40%, while stent blockage by sludge occurred in 50-90 days implicating frequent reintervention. Occlusion of plastic endoprostheses is often clinically presented as cholangitis or jaundice [118]. To reduce the incidence of stent blockage experimental and clinical research has been done in order to identify factors contributing to stent blockage.

Research results

Analysis of the contents and surface of occluded stents has elucidated the mechanism of stent blockage. The initial event in stent blockage is bacterial adherence to absorbed proteins on the stent surface, with subsequent biofilm formation and bile crystals deposition [44,119-121]. Other factors such as duodenal reflux of food fibers add to this phenomenon [44,119,122,123]. Several stent characteristics, such as stent surface material, surface area and especially inner diameter, have been recognized as significant factors influencing the process of stent occlusion [108].

One of the methods to reduce stent blockage might be to prevent or reduce bacterial adherence by changing stent materials, or the introduction of a surface coating. However, contradictional experimental results have been reported on the influence of different stent materials on stent patency [124-127]. Differences in experimental design, such as using single or multiple bacteria strains, renewal of perfusion bile and stent diameter are major factors influencing these results. A small clinical comparative study on antibiotic-coated stents versus conventional stents did not demonstrate any advantage of antibiotic-coated stents [128]. An in vitro study has reported decreased bacterial adherence to silver-coated stent material [129]. Hydrophilic polymers in hydrogel coating might be useful, as less protein adherence is to be expected [108,129]. The high water content of the gels makes them, however, intrinsically weak [44]. Oral aspirin and doxycycline administration causes a modest decrease in sludge formation [130]. Surface smoothness influences patency. A 7-day in vitro study of the ultrasmooth polymer Vivathane demonstrated inhibition of bacterial growth and sludge formation [131]. Artificial defects created on the surface of this stent allowed bacterial adherence only in the area of surface irregularity, indicating the importance of surface smoothness.

More agreement exists in the experimental work on the relationship between stent diameter and stent patency. This has demonstrated higher bile flow and relatively less incrustation with larger inner diameter stents [124,125,132,133]. Clinical endoscopical studies give conflicting results, probably reflecting the difference in study populations and type of stents used, as well as the multifactorial mechanism of stent blockage [134-

139]. Although these clinical studies are inconclusive the majority of the studies report longer patency in larger diameter stents. This, together with the experimental findings and the experience of many radiologists and endoscopists, favor the use of stents of at least 10-F diameter. Some have advocated even larger stent diameters, such as 20-F [140,141]. The use of large diameter stents is, however, limited by patient discomfort, procedure time and increased costs. Also the risk of complications is expected to increase [108]. Thereby patient's anatomy often limits large diameter stenting [108]. A large diameter endoprothesis with a subcutaneous port for flushing has been developed, but has not gained much popularity [141].

Other factors influencing stent patency are the stent configuration, defects in stent manufacture and presence of side holes [123,124,127]. Endoprostheses with pigtails or sharp taper at the end demonstrate reduced bile flow rate [124]. Stents with side holes perform less well, as the bile flow is more disturbed [123,126,127,133,142]. Association between some clinical factors, e.g. high bilirubin levels before insertion and advanced age, and decreased patency have been reported [143].

Another, although less frequent, problem with plastic stents is stent migration. Several stent designs have been developed to reduce migration, such as spiral-shaped stents, mushroom-tipped stents and stents with anchoring threads to a subcutaneous button [144-146]. A simple and effective method is the use of side flaps, as in the Huibregtse endoprosthesis [147]. The risk of migration is also reduced using long stents but the risk of stent blockage might increase [148-150]. A Y-shaped endoprosthesis was especially developed for hilar strictures, but has not gained much popularity outside Germany [151].

Differences in occurrence of early cholangitis in studies are influenced by the presence of cholangitis before the procedure and routine use of antibiotics during placement. Antibiotics decrease the risk of cholangitis after manipulation but do not prevent occlusion and subsequent cholangitis [130].

Recent clinical results

Technical developments and growing experience have improved the results of percutaneous and endoscopic drainage in the 1980s. Evaluation of the current status of plastic endoprosthesis should, therefore, be directed to more recent studies using state-of-the-art techniques.

Comparing the results of several studies to evaluate the efficacy of the plastic stent is hampered by differences in study design and patient population. Patients with hilar and distal biliary strictures are often lumped together as one group, sometimes even

combined with patients with benign strictures. The site of the biliary stricture should be taken into account as the difficulty of biliary intervention and thereby complication rate is increased with hilar strictures. The results of studies should, therefore, be considered separately for hilar and distal (non-hilar) strictures.

Insertion and drainage

Successful percutaneous or endoscopic endoprosthesis insertion and drainage will be achieved in approximately 90-95% of the patients with a distal stricture [43,44,47,49,50,148,152]. In hilar strictures successful percutaneous insertion and drainage is accomplished in 90% or more of the patients [50,51,152-154]. Endoscopical drainage may be less favorable in hilar strictures with overall success percentages of 53-93% [44,47,51,52,54,58,117,155-157]. In one endoscopic series insertion of the stent was successful in 97%, but included patients treated by the percutaneous technique after endoscopic failure [157]. The more complex the stricture the less successful the attempt will be [44,157]. The success rate is thereby also influenced by the choice for complete or incomplete drainage [54,157-159].

Early complications

Early complications are generally defined as complications occurring within 30 days after stent insertion. They occur in approximately 10-20% of the non-surgical treated patients, with more complications in patients with hilar strictures than with distal strictures [44,50,116,148,152]. The major early complication is cholangitis, occurring in 10-15% of the patients with distal strictures and in approximately 20-30% of the patients with hilar strictures. The occurrence is influenced by several factors such as preexisting cholangitis and the complexity of the stricture [47,157,160-164]. Other relatively frequent early complications are stent migration (approximately 1-4%), bleeding (approximately 2%), perforation (<1%), pancreatitis (<1%), abscess (<1%) and bile leakage (<1%) [44,50,148,152,157,165-167].

Thirty-day mortality rate is approximately 10-20% with a 1-5% procedure-related mortality [41,44,49,51,148,152,153].

Late complications

Late complications of plastic endoprostheses, other than stent blockage, occur in approximately 3-5%. This includes stent migration, acute cholecystitis, stent fracture and perforation of bile duct or duodenum [44-47,150,168-178].

Stent blockage occurs in 20-40% with a median patency of approximately five months

in distal strictures and a median patency of approximately three months in hilar strictures [44,45,47,152,179]. Patients with hilar strictures have more frequent recurrent jaundice than patients with distal strictures. This is predominantly caused by tumor progression with subsequent obstruction of segmental radicles.

Plastic stents: current status

Blockage of plastic stents remains, despite much efforts, a significant problem in biliary stenting [108,117]. As new types of plastic stents do not give the solution other ways to prevent stent occlusion and cholangitis should be found.

A percutaneous alternative could be to treat all patients with catheters and to abandon the endoprosthesis [180,181]. Although catheters require daily care and have their complications they have one major advantage: they are easy to exchange, while blocked endoprostheses necessitate a new intervention. A disadvantage of catheters is the periodical catheter exchange to prevent blockage. Patients generally react in one of two ways to a catheter [108]. One group sees the catheter as a "life line" and considers the daily care of the catheter as their part of the management of their disease. The other group sees the catheter as an unpleasant reminder of their impending death. In the former group there may be a place for catheter drainage depending on several factors, such as life expectancy.

Another comparable solution that has been proposed is prophylactic endoscopic stent replacement [137,182]. This is, however, not a very attractive solution as it may well subject a large number of patients with a short life expectancy to an unnecessary procedure. The choice at which interval this stent exchange should occur is crucial. A recent report advises to increase the initially used interval of three months to six months [182].

A more basic solution which would result in a real progress in stent patency is, however, more attractive. This led some workers to look for essentially other types of stents to overcome the diameter limitation. The design of metal expandable intravascular stents was promising as they seemed to overcome some of the limitations of the plastic stents [183-187].

2.5 Metal expandable biliary stents

Corresponding characteristics of all expandable metal stents are the relatively small-sized delivery systems, the large diameter of the expanded stent, the small surface area and fixation against the wall. Differences are the kind of metal used, the delivery

mechanism and the way expansion of the stent is achieved - by its intrinsic radial force or after balloon dilation. The large diameter and the small surface area are important factors preventing stent occlusion by sludge. The fixation against the wall and subsequent incorporation in the wall will prevent stent migration.
The promising characteristics of the expandable metal stents prompted their introduction in biliary stenting. The first clinical results were published in 1989 [187-190]. Several types of metal stents are available. The most commonly used biliary stents are, in order of popularity: the Wallstent, the Gianturco stent and the Strecker stent (Fig. 2.1).

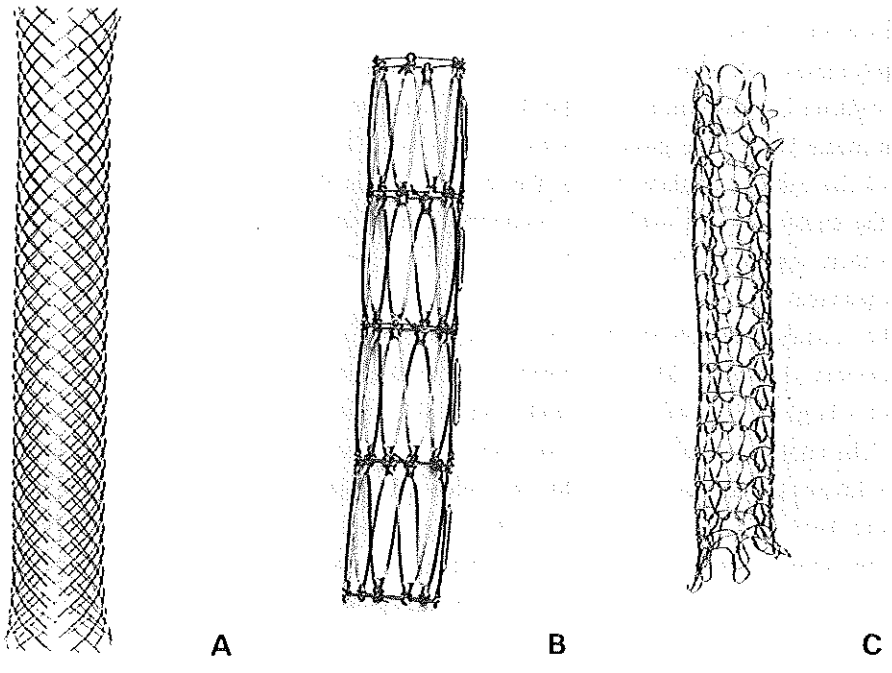

Figure 2.1 Most commonly used expandable metallic stents for biliary stenting.
(a) Wallstent. (b) Gianturco stent. (c) Strecker stent.

The stents can be divided into two main categories: self-expandable and balloon-expandable. Self-expandable stents deploy by the intrinsic expanding force, while balloon-expanding stents are dilated to their final size by balloon dilation.

Self-expandable metal stents

Wallstent

The Wallstent (Schneider, Bülach, Switzerland and Minneapolis, Minn, USA) is a self-expandable stainless steel alloy stent with a meshlike construction (Fig. 2.1a). The filaments of the stent are 0.12-0.14 mm in diameter. The interlocking weave of the filaments allows flexibility around curved surfaces. The stent is introduced in compressed form loaded on the distal end of a delivery system (Fig. 2.2). The delivery system has two coaxially arranged shafts with the stent mounted on the inner shaft. The outer shaft has an outer plastic rolling membrame as distal extension compressing and elongating the stent.

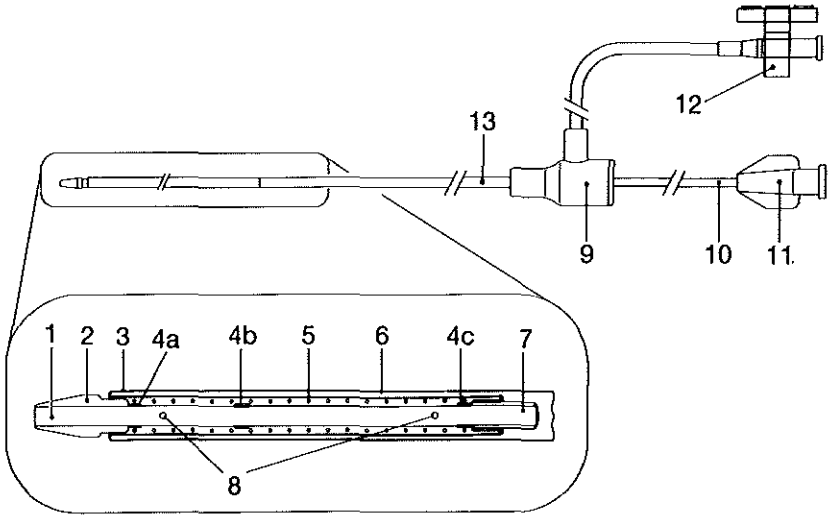

Figure 2.2 Wallstent loaded on the introduction catheter. **(1)** Central lumen. **(2)** Tip. **(3)** Micropore. **(4a)** Distal radio-opaque marker. **(4b)** Central radio-opaque marker. **(4c)** Proximal radio-opaque marker. **(5)** Wallstent. **(6)** Rolling membrane. **(7)** Inner shaft. **(8)** Holes in the inner shaft. **(9)** T-Connector. **(10)** Stainless steel tube. **(11)** Luer lock injector. **(12)** Luer stopcock. **(13)** Outer sheath.
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The percutaneous delivery system has a diameter of 7-F, the endoscopic system a diameter of 9-F. A 9-F sheath [Cook Europe A/S, Bjaeverskov, Denmark] is used in our institution to facilitate easy access to the biliary system. Correct positioning of the

delivery catheter across a stricture is facilitated by radiopaque markers delineating the proximal and distal ends of the compressed stent. Stent release occurs when pressure is applied to the potential space between the outer and inner rolling membrane while pulling back the outer shaft. Membrane failure during deployment may occur, therefore modifications to prevent this problem were developed [191,192]. A hydromer coating between the membranes and the Unistep-system both proved to be successful solutions. With the Unistep-system the compressed stent is released by progressive withdrawal of an enclosing sheath. With each type of introduction system the distal end of the Wallstent opens first, allowing repositioning. The stent shortens considerably (up to 40%) while expanding [192-194]. The diameter after full expansion is 8-10 mm, the available lengths vary from 3.5-10 cm. Balloon dilation to full expansion immediately after deployment is not necessary as the radial recoil force of the stent will result in full expansion [195]. This can take several days, or even longer [192]. Clinical results of the biliary Wallstent will be discussed in the following chapters.

Gianturco-Rösch Z-stent

The Gianturco Z-stent stent (Cook Europe A/S, Bjaeverskov, Denmark and Cook, Bloomington, Ind., USA) is a self-expandable stainless steel stent with a zigzag structure (Fig. 2.1b). The stainless steel wire is 0.08-0.1 mm in diameter. Six zigzag bends are soldered together to form a cylinder. It is firmer and has less longitudinal flexibility than the Wallstent. The delivery system requires an entry of at least 11-F. The stent is released by withdrawing the enclosing sheath while the pusher is held in place. It tends to deploy abruptly and move forward as it deploys. The diameter used in the bile ducts is 10 mm, the length of the stent is varied by connecting two or more bodies (of three cm each). Several modifications have been performed, such as side-barbs to prevent migration and a nylon suture running through the eyelets at each end to control stent diameter [188,196,197]. The latter is the Rösch modification which is usually used in biliary stenting [197,198]. A relocatable modification of the Gianturco stent has also been developed [199]. The Gianturco stent has the largest radial force of the commonly used biliary stents. Several clinical studies on biliary Gianturco stents have been published [188,189,200-204]. A series of 16 patients with malignant strictures reports on eight patients with reobstruction with a mean patency of 5.25 months (range three weeks-eight months) and one patient with stent migration after 24 hours [190]. The majority of the patients in this series had a distal stricture. The rather disappointing results are propably caused by the large mesh, allowing tumor ingrowth [188,200]. Another series including 16 patients with, predominantly hilar, malignant strictures has

shown better results with a 6% reobstruction rate after six months. Two other patients possibly also had reobstruction with therefore possible increase of the reobstruction rate to 19% [188]. An extension of this study reports on 100 patients including 46 patients with malignant obstruction, all but one with hilar strictures [205]. Reobstruction occurred in seven of the 46 patients (15%). Five cases (24%) of reobstruction after a median interval of 15 weeks occurred in a study of twenty-one patients with a malignant biliary stricture treated by a Gianturco stent [201]. The survival was short: fifteen patients had died after a median survival of 11 weeks (range 0-59 weeks). Two patients needed reintervention in a series of 11 patients [203]. A new modification of the Gianturco stent with a coating and tapered ends has been developed to prevent tumor ingrowth and to reduce papillary mucosal hyperplasia at the ends of the stent [206]. No clinical data concerning this stent are available to date.

Nitinol coil spring stent

Recently initial clinical experience with an interesting new type of stent has been published [207]. The stent is a coil spring self-expandable stent made of a nickel-titanium alloy wire which has elastic and memory proporties (Instent Inc, Israel and Eden Priarie, Minn, USA). This alloy stent has more radial force than stainless steel stents [207]. The introduction catheter is 12-F (3,5 mm) in diameter and maximum stent diameter is 8 mm. The authors report that the stent can be removed when reobstruction occurs. After a mean follow-up period of 4.5 months two cases of reobstruction occurred in 10 patients, tumor ingrowth and sludge were the causes. A new prototype with closer loops and a stronger radial force is developed.

Balloon-expandable metal stents

Strecker stent

The Strecker stent (Boston Scientific, Watertown, MA, USA) is a balloon mounted stent made of tantalum (Fig. 2.1c). The diameter is 7 mm, the lengths varies from 4-8 cm. It is delivered through a 7-F sheath. The stent does not change length when released. The stent is radiopaque. A major advantage is its flexibility. A disadvantage, especially in tight strictures, is the absence of intrinsic radial force. To date the reported experience with the Strecker stent is limited. A percutaneous study on Strecker stents and Wallstents reports on partial collapse of the Strecker stent in 30% of the patients [208]. In two randomized series comparing plastic stents and metal stents in hilar and distal malignant strictures the results of the Strecker stent and the Wallstent are lumped

together, precluding further analysis [209,210]. A study on technical failures of the Wallstent and the Strecker stent reports on six (18%) technical failures of the Strecker stent, predominantly difficult balloon removal and partial expansion [191].

Palmaz stent

The Palmaz stent (Johnson and Johnson Interventional Systems, Warren, NJ, USA) is a balloon-expandable stent made of partially compressed diamond-shaped stainless steel lattices. The wall of the stent is 0.015 inches thick. The delivery system with the stent compressed around a deflated balloon has an outer diameter of 9-10-F. The maximal diameter after dilation is 7-12 mm; length varies, depending on the diameter used, from 2-3 cm. Minimal shortening occurs during deployment. The stent is rigid, limiting its use in angulated segments. In these cases multiple stents should be used with sufficient overlap. A design modification has been made which allows articulation of the center of the stent at a slight angle [211]. At the articulation point only two strands of the lattice are present allowing angulation but, unfortunately, tumor ingrowth might be anticipated. A polymer-coated modification has been developed to reduce ingrowth [186]. An experimental study on these polymer-coated Palmaz stents in dogs has demonstrated good biologic tolerance, however mucosal hyperplasia did occur [186]. The Palmaz stent has not become popular so far, propably because of its rigidity [197].

2.6 Percutaneous placement of the Wallstent endoprosthesis

In most patients in our institution Wallstent insertion is performed as a two-stage procedure. At the initial visit an attempt will be made to pass the stricture, except in patients with cholangitis. When this attempt is successful an 8.5-F modified multiple side hole Ring-Ferrucci catheter with only proximal side holes for external drainage [Cook Europe A/S, Bjaeverskov, Denmark] will be introduced. When the attempt to pass the stricture fails, an 8-F pigtail catheter [Cook EuropeA/S, Bjaeverskov, Denmark] will be left for external drainage and the stricture will be passed at the second visit. When a catheter has passed the stenosis a 0.035 inch modified Amplatz extra stiff guide wire [Cook Europe A/S, Bjaeverskov, Denmark] is introduced through the stricture into the duodenum. The catheter is exchanged for a 9-F sheath [Cordis Europe NV, Roden, The Netherlands]. This sheath allows an easy access to the biliary system. The optimal length of the stent is chosen based on the cholangiographic findings and expected shortening of the stent. The Wallstent, loaded on the delivery catheter, is introduced

into the biliary system and is positioned across the stricture. Radiopaque markers on the delivery catheter indicate the proximal and distal end of the compressed Wallstent. Delivery catheters with hydromer coating between the membranes are used at our institution. Stent release occurs when pressure is applied to the potential space between the outer and inner rolling membrane of the delivery catheter together with withdrawing the outer shaft. The distal end of the stent is released first. At this moment withdrawal of the partly opened stent into a more favorable proximal position if desired is possible. With progressive release repositioning becomes more difficult, while it is impossible after release. After stent release correct stent position is controlled. Enough overstenting has to be present to allow for prolonged drainage. No balloon dilation after stent placement is necessary as the stent continues to expand to an adequate inner diameter. A safety catheter above the stent can be left in place for a few days when desired.

2.7 Conclusion

Endoprostheses are the palliative treatment of choice in the majority of patients with malignant biliary obstruction. Adequate drainage will be established in almost all patients. Until the late 1980s plastic endoprostheses were used which had one major drawback: reduced stent patency by sludge. The mechanism of stent blockage by sludge has been elucidated and several attempts have been made to use this information to design a plastic endoprosthesis with prolonged patency. Although some improvements occurred, reduced stent patency remained a major problem with plastic stents. A major breakthrough was anticipated with the introduction of metal expandable stents as these stents have a large inner diameter. Several metal stents are available today but the Wallstent endoprosthesis is the most commonly used. The reported clinical experience with all other types of metal stents in biliary stenting is limited or absent.
Results from the literature concerning the Wallstent, together with data of our own series, will be analysed in the following chapters to determine the place of the Wallstent in current percutaneous stenting. Our results are based on a non-comparative study design. Although the drawbacks of such a study design were recognized it was found appropriate for several reasons. The initial results with the Wallstent demonstrated a much easier introduction which facilitated the procedure for patient and radiologist. The majority of the patients had a previous failed endoscopic attempt, therefore to subject these patients to a second procedure which would be more painful than necessary was not found appropriate. The endoscopic failures were partly caused by unsuccessful

conventional stent introduction. The use of the during introduction smaller Wallstent seemed for this reason advantageous. Our results described in Chapters 3-6 were based on experience in a growing study population. Each three months until death a questionnaire was send to the patient's physician concerning the occurrence of jaundice, fever, or other complications. In case of possible complications further information was obtained from the doctor and from the hospital to which the patient was referred.

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3 INITIAL PERCUTANEOUS EXPERIENCE WITH THE WALLSTENT ENDOPROSTHESIS IN MALIGNANT BILIARY OBSTRUCTION

3.1 Abstract

A total of 83 self-expandable metallic stents were placed percutaneously in 69 patients for palliation of malignant biliary obstruction to achieve palliation. Stent diameter was 1 cm; lenght, 3.5-10.5 cm. Of the 41 patients with a common bile duct stenosis 27 died 0.2-12 months (median, 3.2 months) after stent insertion. Two patients developed recurrent jaundice and cholangitis after 6 and 12 months, respectively. One patient underwent reintervention. Fourteen patients were alive without jaundice 1-8 months (median, 6.3 months) after stent placement.

Of the 28 patients with hilar lesions, 13 died 0.7-7.6 months (median 4.3 months) after stent placement. Fifteen were alive 1-15.5 months (median, 8.1 months) afterward. Recurrent jaundice and cholangitis were seen in eight patients of the 28 patients after 1-6 months (median, 3.6 months). The cause of malfunction of the stent(s) was tumor ingrowth in one patient, tumor overgrowth at the proximal end in five patients and overgrowth at the distal end in two patients. Reintervention was performed in five patients (18%). Stent related complications were seen in four patients.

3.2 Introduction

In patients with inoperable malignant biliary obstruction in whom endoscopic drainage of the bile ducts fails, percutaneous transhepatic biliary drainage (PTBD) is the method of choice for palliative treatment [1,2]. Because these patients have a very short life expectancy the procedure should be safe, effective, and performed only once. There is little question that internal drainage by means of endoprostheses is the ideal way to treat these patients. There are, however, several problems with the currently available endoprostheses, and blockage by sludge or tumor is the most frequent. This occurs several weeks to more than one year after stent placement, with a mean of five months

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in common bile duct (CBD) obstructions and three months in obstructions in the hilar region, when 10-F polyethylene endoprostheses are used [3].
Blockage of the endoprosthesis is influenced by several factors, one of which is diameter [4]. The larger the diameter of the endoprosthesis, the longer it will stay patent. The use of self-expandable stents combines the advantages of a small delivery catheter (7-F) and a large stent diameter (1cm).
In this article the long-term results of percutaneous placement of self-expandable stents in patients with malignant biliary obstruction are reported.

3.3 Patients and Methods.

From April 1989 through September 1990, 83 self-expandable stents (Wallstent; Medinvent, Lausanne, Switzerland) were implanted via a percutaneous transhepatic route in 69 patients (30 men and 39 women) with inoperable malignant biliary obstruction. The mean age was 67 years (range, 36-89 years). Pancreatic carcinoma was the cause of jaundice in 32 patients, cholangiocarcinoma in 16 patients, gallbladdercarcinoma in seven patients, extrahepatic metastases of various malignancies in 10 patients and intrahepatic metastases in the remaining four patients. The diagnoses were proved with either cytologic or histologic examination in 55 of 69 patients (80%).
For 28 patients (41%) the percutaneous drainage was the second biliary intervention, after either endoscopically performed drainage or after bilioenteric bypass surgery. In all others, endoscopic drainage was not possible for technical or anatomic reasons. In 41 patients the obstruction was in the CBD. Hilar obstruction was present in 28 patients. Of these 28 patients, five had a Bismuth type I lesion (stenosis in the common hepatic duct); nine, a type II lesion (involvement of both hepatic ducts); 11, a type III lesion (involvement of both hepatic ducts, including segmental ducts in one lobe); and three, a type IV lesion (extension to segmental ducts in both lobes) [5].
All PTBD procedures were performed under sonographic and fluoroscopic guidance. The stents were placed 5-7 days after the initial drainage procedure. The technique of stent placement has been described in detail [6]. In patients with hilar obstruction who needed two stents (one in the right and one in the left biliary duct), the delivery catheters were first placed through the stenoses, and the stents were released one after another. Patients with three stenoses in the hilar region needed four stents to achieve complete drainage. In these patients, we first placed a short stent in the distal part of the CBD. Two stents were then placed in such a way that their distal parts ended in the

already inserted stent. Finally, one long stent was released from the delivery catheter that was already positioned through the third stenosis.

The length of the stents varied from 6.8 to 8.5 cm in patients with CBD obstruction and from 3.5 to 10.5 cm in hilar obstructions. All stents had a diameter of 1 cm. Balloon dilation of the stenosis prior to stent insertion was performed only in the first five patients. Plain abdominal radiography to evaluate the position and the degree of expansion of the stents was performed 1-14 days after placement.

The effects on jaundice and the post-procedural and late complications were recorded in all cases.

3.4 Results

The survival rates of the patients and the data on stent malfunctioning are listed in Table 3.1.

Table 3.1 **Survival after Stent Placement, Number of Recurrences of Jaundice and Cholangitis, Causes of Stent Malfunctioning, and Number of Reinterventions in 41 Patients with CBD Obstruction and 28 Patients with Hilar Obstruction**

	CBD Obstruction (n = 41)		Hilar Obstruction (n = 28)	
Finding or Procedure	Died (n = 27)	Alive (n = 14)	Died (n = 13)	Alive (n = 15)
Median survival after stent placement in months *	3.2 (0.2 - 12)	6.3 (1 - 8)	4.3 (0.7 - 7.6)	8.1 (1 - 15.5)
Recurrent jaundice with cholangitis	2	0	6	2
Tumor ingrowth	1	0	0	1
No established cause	1	0	0	0
Tumor overgrowth	0	0	6	1
Reintervention	1	0	3	2

* Numbers in parentheses are ranges

Common bile duct obstruction

Six patients (14%) died within one month after stent placement. One died after massive pulmonary embolism, two died of upper gastrointestinal tract bleeding, and two died of disseminated malignancy. Pancreatitis was the cause of death in the other patient, an 86-year old patient with pancreatic carcinoma. Endoscopic retrograde cholangio-pancreatography had already disclosed a pseudocyst in the tail of the pancreas. An

endoscopic attempt at drainage failed, and the patient developed fever. After successful percutaneous drainage and subsequent stent insertion, the plasma bilirubin level dropped in one week from 506 to 170 μmol/L (normal range, 4-14 μmol/L), but sepsis persisted and the patient died. Autopsy disclosed severe pancreatitis of the tail of the pancreas.
All patients had a decrease in serum bilirubin levels. Of the 27 patients who died, five had persistent high bilirubin levels or developed recurrent jaundice shortly before death. One of these five had clinical signs of cholangitis and dilated bile ducts at sonography 12 months after stent insertion. No definite cause was established, but ingrowth might have been the cause. The general physical condition of the patient at that stage prevented further invasive treatment. One patient underwent reintervention 6 months after stent placement. A catheter with multiple side holes was passed through the stent, which had become occluded by tumor ingrowth. The patient died without jaundice 3.5 months later. At this writing, no recurrent jaundice has developed in the 14 patients who are still alive.

Hilar obstruction
One patient (4%) died with signs of an acute abdomen within one month. Of the 15 patients who were still alive at the end of this study three survived longer than one year: two with the expandable stents functioning well and one with a catheter bypassing a blocked stent.
Complete drainage was achieved in all five patients with type I and in five patients with a type II lesions. In three of these patients, the distal ends of the stents were positioned in a suprapapillary location. Drainage was complete in only two of 14 patients with type III or IV lesions. Of the 16 patients with incomplete drainage, 13 had one stent and three had more than one stent. The stent position was suprapapillary in eight and transpapillary in six patients.
Bilirubin levels returned to normal in all patients with type I or II lesions. In five patients with type III or IV lesions, bilirubin levels remained above 50 μmol/L, although the drainage had a satisfactory effect on pruritus. Recurrence or worsening of the jaundice was seen in eight patients (29%) 1-6 months (median, 3.6 months) after stent placement. All these patients had signs of cholangitis. The cause of recurrent jaundice was tumor overgrowth at the proximal end of the stent(s) in five patients, tumor overgrowth at the distal end in two patients and tumor ingrowth in one patient.
Five patients underwent percutaneous reintervention: two underwent external catheter drainage, one underwent internal catheter drainage and in two patients with distal tumor overgrowth the stents were extended into the duodenum. Two of these patients were still

alive after 14 and 12 months. Three patients with stent blockage died without undergoing further interventions.

Complications

Septicaemia after the initial PTBD occurred in eigth patients, all of whom had preexisting cholangitis. Balloon dilation of a stenosis caused by a pancreatic carcinoma in one case resulted in bleeding for which the patient required blood tranfusions. Stent insertion itself never caused complications. In two patients, bleeding from the transhepatic tract was controlled by leaving the drainage catheter in place for another two weeks after stent placement.

Late complications other than recurrent jaundice occurred in five patients. Two patients with hilar obstruction developed acute cholecystitis; one of these patients underwent cholecystectomy, and the other percutaneous gallbladder drainage.

Duodenal ulceration caused by constant pressure of the stent against the opposite mucosa was seen twice, once after placement of one stent and once after placement of two stents through the papilla into the duodenum. Both patients had upper abdominal pain and mild intestinal blood loss. A lethal complication occurred in a patient with cholangiocarcinoma, in whom two stents were placed through the papilla after internal irradiation with Iridium-192 wires. He presented with acute abdominal pain after 21 days and died despite acute laparotomy. At autopsy it was found that only one stent had a transpapillary position. The malpositioned stent had perforated the tumorous wall of the CBD.

3.5 Discussion

Recurrent jaundice or cholangitis due to clogging of endoprostheses is a major complication in the palliative treatment of malignant biliary obstruction. Few long-term follow-up studies of stent patency have been published, and the frequency of blockage of percutaneously placed endoprostheses varies greatly, from 6% to 23% [7,8]. The reintervention rate after endoscopic placement of endoprostheses in a large series of 969 patients with malignant biliary obstruction was reported to be 35% [9].

Besides the diameter of the endoprosthesis, the site of the stenosis seems to be an important determinant. In a series of 49 patients with hilar cholangiocarcinoma who received percutaneous treatment 45% of the patients needed a reintervention for blocked endoprostheses [10].

In our study, one of the patients with CBD obstructions (2%) and five of the patients with hilar lesions (18%) underwent reinterventions. These numbers compare favorably

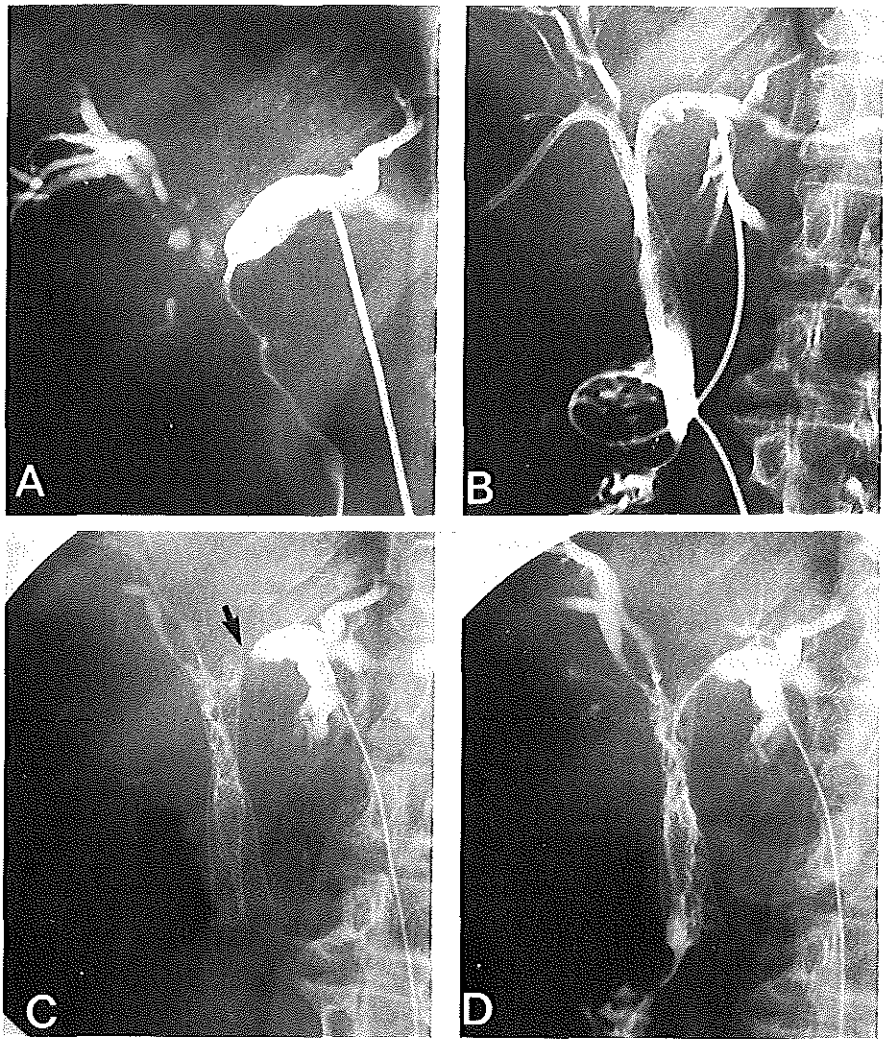

Figure 3.1 (a) Cholangiogram of an 89-year old patient with carcinoma of the gallbladder. (b) Cholangiogram obtained immediately after stent insertion. (c) The patient remained well for four months and then developed cholangitis. Cholangiogram shows tumor overgrowth on the left side (arrow). (d) Because of the angulation at the junction of the stent and the left hepatic duct, the stent could only be entered with a small catheter through the mesh of the stent. Only external drainage was possible. The patient died six weeks later.

with the previously mentioned data from the literature. A main cause of blockage is the presence of biliary sludge in the lumen of the stent. The larger diameter of the self-expandable stent and the small surface area of the stainless steel wires offers a less chance of sludge formation. Another cause of malfunction, such as migration of the endoprosthesis, is highly unlikely when expandable stents are used, because the wires are fixed to the wall by the expansive force. The mesh of the self-expandable stent does not prevent tumor ingrowth. However, with the large diameter used (1 cm), stent blockage due to tumor ingrowth occurs late. We did not observe this blockage within six months after stent insertion in our patients.

The most important cause of recurrent jaundice and cholangitis after stent placement in hilar lesions is tumor extending beyond the length of the stent (seven of eight patients). Therefore, as a general rule, these stents should extend well proximal and distal to the obstructing lesion. However, the characteristic spread of many hilar malignancies eventually overgrows any stent at its proximal end and invariably occludes segmental ducts. In our study, this phenomenon was the most frequent type of overgrowth in patients with hilar lesions (five patients). Depending on the general condition of the patient at that stage, attempts can be made to correct this situation. An external catheter drainage to treat cholangitis is often the best treatment possible in these cases (Fig. 3.1).

Although the open mesh of the stent can be considered as a disadvantage as far as tumor ingrowth is concerned, this small mesh seems to garantee drainage of secondary radicles

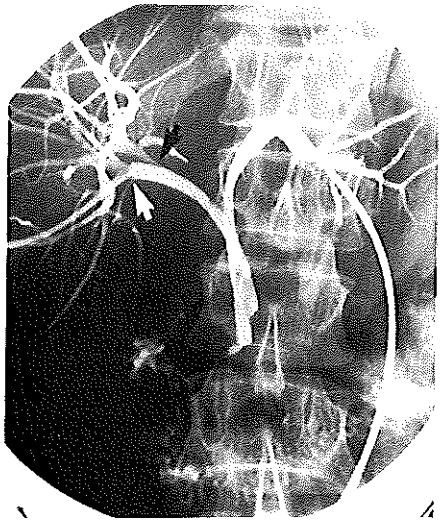

Figure 3.2 Cholangiogram of a patient with hilar obstruction due to metastasis from colorectal cancer. Two short stents were placed in this type IV lesion. Bile ducts (arrow) entering the edge of the mesh on the right side can be seen. Note the suprapapillary position of the distal parts of the stent. The patient was alive and without jaundice four months after stent insertion.

within the intrahepatic system that end up on the edge of the stent. Thus, these stents work better than conventional stents, which all have relatively few side holes. This is especially important in draining type III and IV hilar lesions (Fig. 3.2).
Since endoscopic exchange of these metallic stents is not possible, a suprapapillary positioning of the stent in hilar lesions should be considered to preserve papillary function and prevent ascending cholangitis. In a well drained biliary system, infected bile will not cause septic complications. However, in patients with Type III or IV hilar lesions, complete drainage of all ducts often cannot be achieved. A drawback of this approach is that tumor overgrowth at the distal end of the stent can occur. This occured in two of our patients, both of whom had carcinoma of the gallbladder, and in both cases the stents were extented into the duodenum in a second percutaneous intervention (Fig. 3.3).

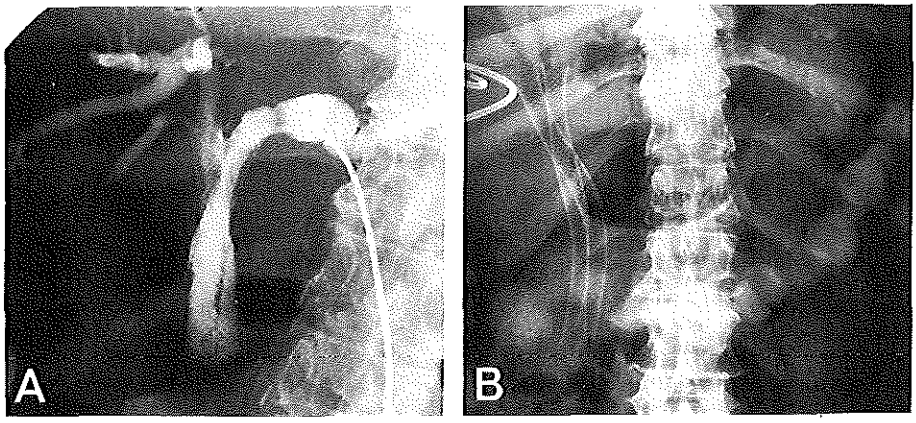

Figure 3.3 **(a)** Cholangiogram of a patient with gallbladder carcinoma and recurrent jaundice two months after stent placement. Cholangiogram was obtained after drainage of the left lobe hepatic bile ducts and shows blockage at the distal end of the stents. After drainage of the right lobe hepatic bile ducts, both stents and the stenosis distal to the stents were passed. Another two stents were then placed. **(b)** Abdominal radiograph obtained after extension of both stents into the duodenum. The right-sided catheter was removed after it became clear that the stents were functioning well.

A disadvantage of the self-expandable stent is the sharp wires on both ends. These wires were believed to have caused duodenal ulcerations in two patients, and a lethal CBD perforation in one patient. To what extent the intraluminal Ir-192 irradiation contributed to this latter serious complication is not clear. Radiation therapy followed by placement

of conventional endoprostheses has, to our knowledge, never resulted in perforation, nor was this complication reported to result from the use of expandable stents.
It is important to realize that self-expandable stents shorten by 40% while they are expanding. This so-called understenting was the cause of recurrent jaundice in seven out of 19 cases in a previous report [6]. With lengths up to 10.5 cm this problem can be avoided. Despite its expansive force, the self-expandable stent is subjected to another force that will straighten it. Eventually the stent may not retain the form of the bile duct. The proximal end of the stent will become occluded by the wall of the bile duct (Fig. 3.4). Drainage will then be possible only through the open mesh of the stent.

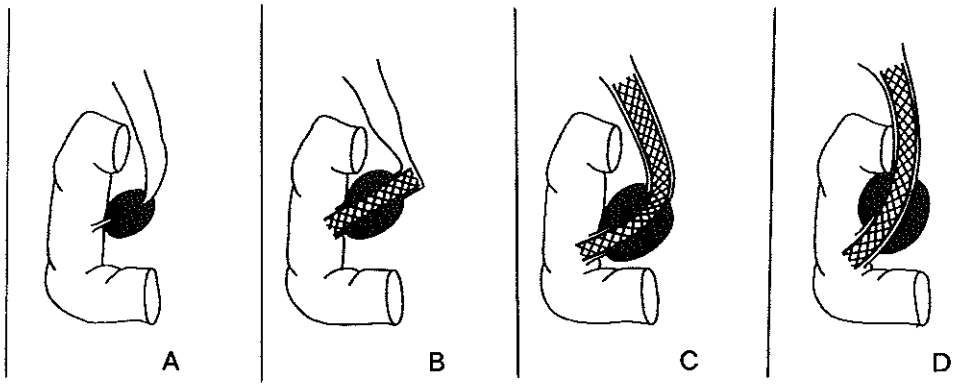

Figure 3.4 **(a and b)** Acute angulation at junction of the stent and the normal duct can occur when short stents are used. **(c and d)** This problem can be prevented by using long stents.

Furthermore, the chance of damage to the bile duct epithelium by the sharp, wires will increase. In a distal stenosis, this can be prevented by using a stent of adequate length and "overstenting" the lesion at the proximal site (Fig. 3.5). However, in hilar lesions angling of the stent axis, especially in the left hepatic duct, is difficult to prevent, because "overstenting" can be done only to a limited degree (Fig. 3.1).
The use of self-expandable stents increase the cost of biliary drainage. Balloon dilation of the stenosis before and after insertion of the stent, as recommended, increases the costs even more. When we observed the natural tendency of these stents to continue expanding for a few days, we abandoned balloon dilation. Theoretically, the selfexpandable stent can be placed in one session, thereby reducing the costs of hospitalisation.

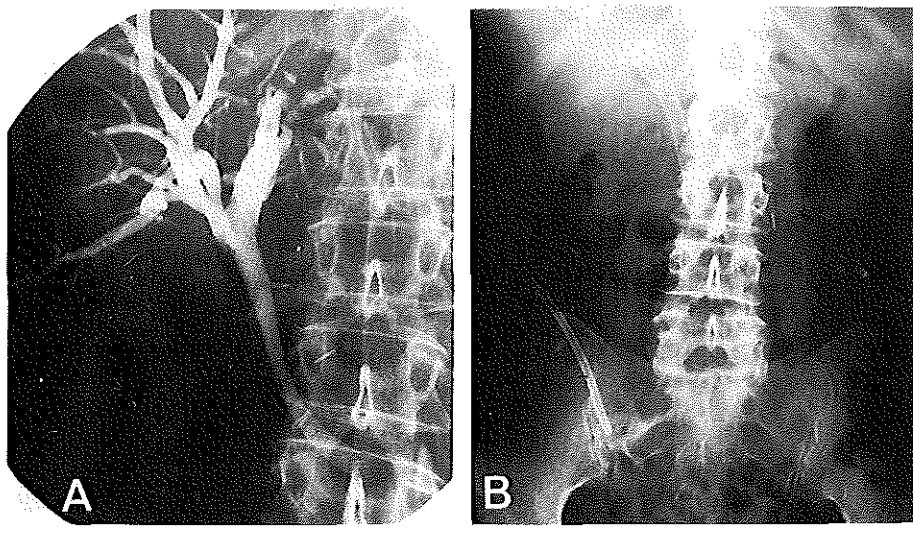

Figure 3.5 Images from a patient with inoperable pancreatic carcinoma and a blocked endoprosthesis placed by means of endoscopy. **(a)** The stenosis in the distal part of the CBD is "overstented" from the hilar region to the duodenum. **(b)** Plain radiograph obtained five days later shows that the stent has almost fully expanded. The shortened stent retains the form of the CBD. The blocked endoprosthesis, which was pushed into the duodenum, is now seen in the right lower quadrant of the abdomen.

In the majority of our patients, the presence of cholangitis or complex biliary strictures was the reason that stent placement was performed as a two stage procedure.

In conclusion, placement of the self-expandable stent in patients with malignant CBD and hilar obstruction who are referred for percutaneous drainage is safe and effective. The rate of reinterventions is low and compares favorably with rates in previous studies with conventional endoprotheses.

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4 THE PERCUTANEOUS USE OF THE WALLSTENT ENDOPROSTHESIS IN MALIGNANT HILAR BILIARY OBSTRUCTION

4.1 Abstract

Forty-five patients with malignant hilar obstruction were treated with a total of 68 percutaneously inserted self-expandable endoprostheses (Wallstents) for palliative biliary drainage. The stent diameter was 1 cm; the length was 3.5-10.5 cm. Early complications occurred in seven patients (16%), including cholangitis in four patients (9%). The 30-day mortality rate was 9%, with two procedure-related deaths (4%).
Of the 45 patients, 29 died between 10 and 550 days (median, 126 days) after stent insertion. Reobstruction occurred in 13 of these patients after 26 to 184 days (median, 105 days). Sixteen patients were alive 44 to 737 days (median, 305 days) after stent insertion. Reobstruction occurred in four patients after 142 to 279 days (median, 246 days). The cause of reobstruction was proximal overgrowth in seven patients; distal overgrowth in four patients; and tumor ingrowth and proximal overgrowth, tumor ingrowth, hemobilia, and angling of the stent in one patient each. The cause of reobstruction was not established in two patients. Reintervention was performed in 14 patients (31%).
Because reobstruction of Wallstent endoprostheses is primarily not stent-related but rather is caused by tumor progression, and because insertion and reintervention is easier, we consider the use of the Wallstent in malignant hilar biliary obstruction advantageous in comparison with plastic stents.

4.2 Introduction

Malignant biliary obstruction of the hilus of the liver is caused by a heterogeneous group of tumors for which curative surgery is possible in a limited number of patients. Percutaneously inserted endoprostheses are one of the recognized options of palliative biliary drainage in the remaining patients [1,2]. The ideal endoprothesis should be easily insertable with no complications or only a limited number of complications, should

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remain in place, and should stay open until death. The currently available plastic endoprostheses do not satisfy these requirements primarily because of stent blockage [3-5]. Several new designs of plastic endoprostheses have been developed in an attempt to overcome these difficulties, but several problems, such as stent patency, remain [3]. The introduction of self-expandable biliary endoprostheses is the next attempt to come closer to the ideal endoprothesis. It combines the advantages of a small delivery catheter, large stent diameter and fixation of the stent against the wall. This paper reports our two-year experience with percutaneously inserted metallic self-expandable endoprostheses in malignant hilar lesions.

4.3 Patients and Methods

From April 1989 through April 1991, 47 patients with inoperable malignant hilar biliary obstruction were treated by percutaneous drainage. Routine management at our institution is initial catheter drainage, with Wallstent insertion after several days. This provides the opportunity to evaluate the effect of the drainage. In 45 patients a total of 68 metallic self-expandable endoprostheses (Wallstent, Medinvent, Lausanne, Switzerland) were inserted. Two patients not included in this study remained on catheter drainage because of persistent cholangitis after the initial drainage procedure.

Table 4.1 Diagnosis and Type of Hilar Stricture in 45 Patients with Hilar Strictures

		Type of Obstruction *			
Diagnosis		I	II	III	IV
Cholangiocarcinoma	(n = 22)	1	3	12	6
Gallbladder carcinoma	(n = 9)	2	2	5	0
Liver metastasis	(n = 7)	0	1	3	3
Periportal lymphoma	(n = 3)	1	2	0	0
Other causes #	(n = 4)	2	1	0	1
Total		6	9	20	10

* Type of hilar stricture according to Bismuth et al.[6]

\# Other causes include the following: one infiltrating gastric carcinoma, one local recurrence of a pancreas carcinoma after a Whipple procedure, one local recurrence after resection of a renal cell tumor, and one hepatocellular carcinoma.

The study population comprised 23 men and 22 women with a mean age of 65 years (range, 36-89 years). Diagnosis and type of hilar stricture, according to Bismuth, Castaing, and Traynor are listed in Table 4.1 [6]. A Bismuth type I lesion is a stenosis in the common hepatic duct, a type II lesion has involvement of both hepatic ducts, a type III lesion has extension to segmental ducts in one lobe, and a type IV lesion has extension of tumor to segmental ducts in both lobes. Histologic or cytologic proof of the diagnosis was obtained in 34 of the 45 patients (76%), whereas in the remaining 11 patients the diagnosis was based on clinical and radiologic findings; follow-up left no doubt concerning the diagnosis.

In 32 patients, endoscopic placement of an endoprosthesis was attempted previously, but it failed to achieve initial drainage in 22 patients or failed to replace a previous plastic endoscopic stent in 10 patients. One patient had a previous percutaneous plastic stent. Twelve patients had previous biliary surgery, which included the following: three patients had a hepaticojejunostomy, one patient had a Whipple procedure, one patient had a peroperative stent, six patients had a total or partial cholecystectomy, and one patient had a cholecystojejunostomy. Radiotherapy was performed in 19 patients (15 cholangiocarcinoma, two gallbladder carcinoma, and two metastases). Thirteen patients received external and intraluminal radiotherapy, four received patients external radiotherapy and two patients received intraluminal radiotherapy. In two patients this radiotherapy was given several months to one year before stent insertion. Twelve patients had cholangitis before the percutaneous procedure. The blood bilirubin concentration before the procedure was 9 - 555 μmol/L (mean, 230 μmol/L; normal range, 4 to 14 μmol/L).

All percutaneous transhepatic biliary drainage procedures were performed using sonographic and fluoroscopic guidance. Broad-spectrum antibiotics were given for 12 hours before and after each procedure. The stents were placed five to seven days after the initial drainage procedure when cholangitis, when present, had disappeared. One patient with cholangitis in this series had placement of the Wallstent at the initial visit because of percutaneously drained ascites. This patient had persistent cholangitis after the procedure and developed an abscess in the right liver lobe. In patients who needed two stents (one in the right and one in the left biliary duct), the delivery catheters were first placed through the stenoses, and the stents were released one after another. Patients with three stenoses needed four stents to achieve complete drainage. In these patients a short stent was first placed in the distal part of the common bile duct. Two stents were then placed in such a way that their distal parts ended in the already inserted stent. Finally, one long stent was released from the delivery catheter that was already

positioned through the third stenosis.
All stents had a diameter of 1 cm, the length varied from 3.5 to 10.5 cm. No balloon dilation was performed before stent insertion. Prepapillary position of the stent was especially considered in patients with incomplete drainage to prevent direct communication between the gut and the biliary system, which might lead to ascending cholangitis. Plain abdominal radiography to evaluate the position and degree of expansion of the stents was performed 1 to 14 days after insertion. The effect on jaundice, the complications, and follow-up were recorded for all patients. Early complications were defined as complications occurring within 30 days after stent placement. Cholangitis was defined as a temperature greater than 38° C, in the absence of any other obvious explanation. The blood bilirubin concentration was recorded approximately one month after stent placement. The patency period of the stent was taken as the interval between the insertion of the prosthesis and the time of biliary obstruction, as defined by clinical symptoms, ultrasound, and cholangiographic findings.

4.4 Results

Wallstent insertion was successful and uneventful in all patients. Preexisting cholangitis disappeared in all patients except one.
Complete drainage was established in all six patients with a type I hilar obstruction, in five patients with a type II lesion, and in six patients with a type III lesion (Fig. 4.1).
The other 28 patients had incomplete drainage (Fig. 4.2). The stent had a transpapillary position in 25 patients, whereas, of the 20 patients with a prepapillary positioned stent, only eight had an intact papilla of Vater. Adequate stent expansion was seen in all patients. The stents expanded in general to an upper limit of 8 mm in the hepatic ducts, and full expansion occurred in the common bile duct. Jaundice decreased in all patients, although one patient with sclerosing cholangitis, complicated by cholangiocarcinoma, showed jaundice and bilirubin increase only days after initial decrease. Blood bilirubin analysis after stent insertion was available for 36 of the 45 patients. Bilirubin decrease was found in all of them, with bilirubin falling to less than twice the upper limit of normal in 22 patients.
Seven patients (16%) had early complications. Early cholangitis occurred after the initial drainage in four patients, all of whom had incomplete drainage. The cholangitis was treated successfully by antibiotics in three patients, and no sepsis occurred. The fourth patient, who had Wallstent placement at the initial visit, died of cholangitis and

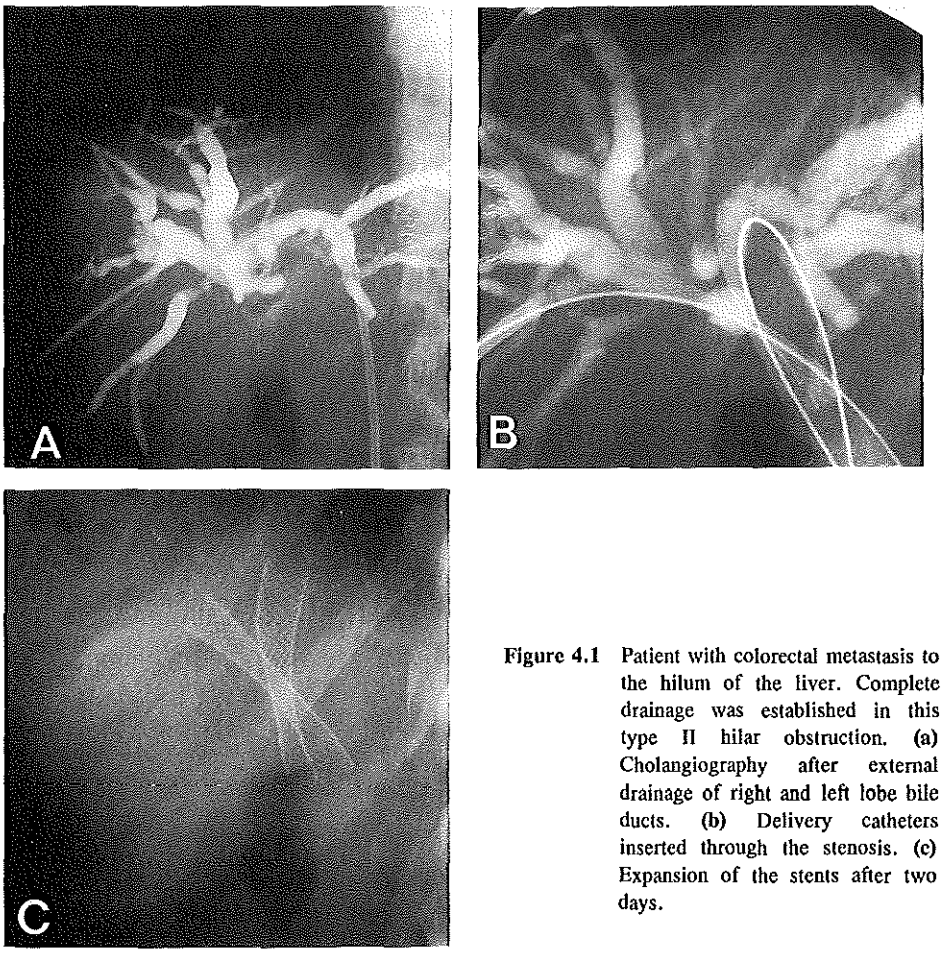

Figure 4.1 Patient with colorectal metastasis to the hilum of the liver. Complete drainage was established in this type II hilar obstruction. **(a)** Cholangiography after external drainage of right and left lobe bile ducts. **(b)** Delivery catheters inserted through the stenosis. **(c)** Expansion of the stents after two days.

sepsis caused by an abscess in the undrained right lobe. This patient had cholangitis before percutaneous intervention after an endoscopic attempt at stent insertion. A subhepatic abscess occurred in a patient after removal of the percutaneous biliary catheter by the ward physician before stent placement. This abscess was treated by percutaneous drainage. One patient with hepatocellular carcinoma had persistent hemobilia after the initial drainage procedure. Occlusion of the stent occurred after 26 days and was treated by a left-sided catheter. This catheter again revealed blood stained bile and occluded after five days. A new catheter remained in place until death. This

patient also developed acute cholecystitis 11 days after Wallstent placement, which was drained percutaneously. He died with jaundice, but without fever, 79 days after stent insertion. One patient died 21 days after stent placement due to a malpositioned Wallstent [7]. This patient had been treated with iridium-192 brachytherapy and had two parallel transpapillary Wallstents. At autopsy only one stent had a transpapillary position, and the other had perforated the tumorous common bile duct wall.

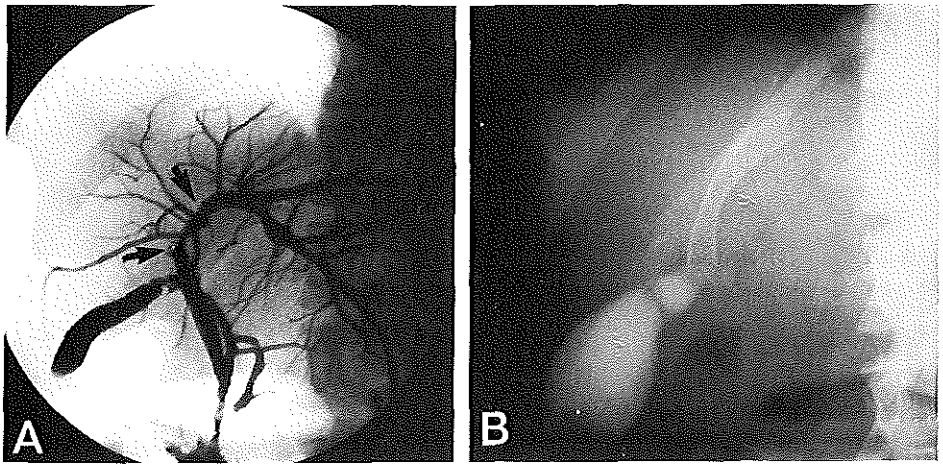

Figure 4.2 Type III malignant hilar obstruction in a patient with colorectal metastasis to the liver hilus. Incomplete drainage was established. (a) Cholangiography after placement of internal drainage catheter. Arrows indicate the length of the stenosis. (b) Stent expansion after one day.

Four patients died within 30 days (9%), including two procedure-related deaths (4%), which have been described above. The other two patients died of disseminated malignancy.

Late complications other than recurrent jaundice occurred in four patients. One patient developed cholecystitis five months after stent insertion and was treated by cholecystectomy. Another patient with cholecystitis was treated by percutaneous drainage. Pressure ulceration of the duodenum opposite to the Wallstent was seen endoscopically in a patient who presented with upper abdominal pain and mild intestinal blood loss 32 days after stent placement. The fourth patient, who initially had a type I lesion, developed an abscess in the right liver lobe, which was treated by a percutaneous catheter. This patient died with sepsis and peritonitis.

Sixteen patients are alive, with a median follow-up of 305 days after stent placement

Table 4.2 Survival after Stent Placement, Number of Reobstructions, Period between Stent Placement and Reobstruction and Number of Reinterventions in 45 Patients with Hilar Stricture Treated by Wallstents

Finding or procedure	Deceased (n = 29)	Survived (n = 16)
Median survival after stent placement * (days)	126 (10 to 550)	305 (44 to 737)
Reobstruction	13	4
Median period between stent placement and reobstruction * (days)	105 (26 to 184)	246 (142 to 279)
Reintervention	10	4

* Numbers in parentheses are ranges.

(Table 4.2). Four of the 16 patients had biliary reobstruction after a median period of 246 days after insertion. Twenty-nine patients have died, with a median survival of 126 days after stent insertion, which includes the four patients who died within 30 days. Five of them had jaundice without fever in the terminal phase. Four had incomplete drainage and liver metastasis, and the fifth had sclerosing cholangitis. It remains unclear whether stent obstruction attributed to the jaundice. One other patient with liver metastasis developed progressive jaundice. An ultrasonography shortly before the patient's death revealed no biliary obstruction. This patient had fever at death. Biliary reobstruction occurred after a median period of 105 days in 13 of the 29 patients who died.

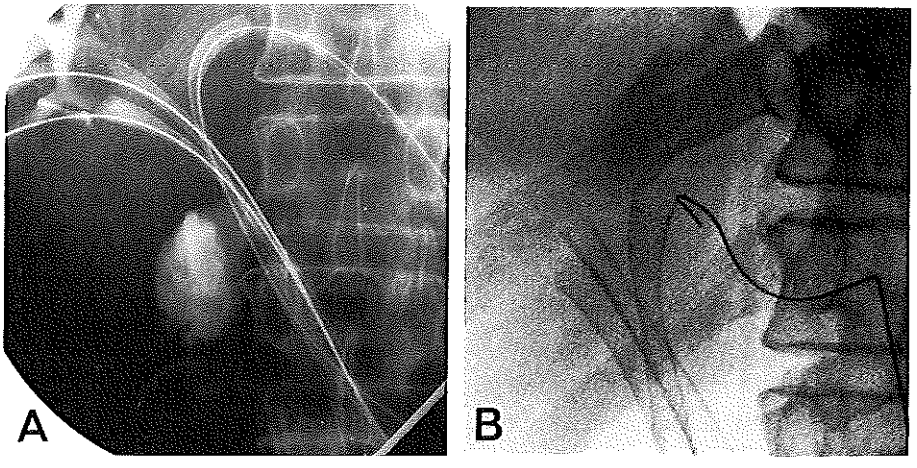

Figure 4.3 Patient with a type III cholangiocarcinoma. Complete drainage was established. (a) Cholangiography during stent placement. The stent in the left hepatic duct will retain the form of the duct. (b) Situation after six months. The stent in the left hepatic duct has an angulated position. The course of the left hepatic duct is indicated by the guide wire.

The cause of the biliary reobstruction was established in 15 of the 17 patients affected. Tumor overgrowth at the proximal end of the stent occurred in seven patients, distal overgrowth occurred in four patients, tumor ingrowth and proximal overgrowth occurred in one patient, tumor ingrowth occurred in one patient, hemobilia occurred in one patient, and another patient had obstruction caused by angling of the stent combined with sludge (Fig. 4.3). Cytologic confirmation was obtained in one patient with tumor ingrowth. All four patients with distal overgrowth had prepapillary stents. Two of the four patients had cholangiocarcinoma, one had liver metastases and, one had periportal lymphoma. Biliary reobstruction occurred in nine of the 17 patients with complete drainage, in eight of the 28 patients with incomplete drainage, in nine of the 25 patients with a transpapillary stent, and eight of the 20 with a prepapillary stent. Three of the eight patients with a prepapillary stent had an intact papilla of Vater. Table 4.3 demonstrates biliary reobstruction in relation to the diagnosis and type of hilar stenosis.

Table 4.3 Number of Biliary Reobstructions in Relation to the Diagnosis and Type of Stricture in 45 Patients with Hilar Stricture Treated by Wallstents

Diagnosis		Type of obstruction *				Total
		I	II	III	IV	
Cholangiocarcinoma	(n = 22)	0	2	4	1	7
Gallbladder carcinoma	(n = 9)	1	0	3	0	4
Liver metastasis	(n = 7)	0	0	1	0	1
Periportal lymphoma	(n = 3)	1	1	0	0	2
Other causes	(n = 4)	1	1	0	1	3
Total		3	4	8	2	17

* Type of hilar stricture according to Bismuth et al. [6]

Reintervention was performed in 14 patients (31%). Eight of these patients were treated by catheter drainage, three patients were treated by a new Wallstent that stented the distal tumor overgrowth in two patients and proximal overgrowth in one patient, and left internal catheter drainage and segmental external catheter drainage was established in another patient. One patient initially treated by catheter drainage was eventually treated by a Wallstent and a left segmental external catheter. An endoscopic attempt to reestablish patency by guide wire manipulation through the stent lumen caused relief of symptoms in another patient. Cholangitis occurred in two patients after reintervention, including the patient with the endoscopic guide wire manipulation. Ten of the 14 patients

died 46 to 366 days (median, 96 days) after reintervention, and four patients were alive after 30 to 272 days (median, 99 days). Although 12 of the 14 patients initially benefited from the biliary reintervention, eight had recurrence of jaundice or fever.

4.5 Discussion

Jaundice recurrence after endoprosthesis insertion is a major problem in palliative biliary drainage. Several attempts have been made to improve the stent design. Until the late 1980s, stents differed mainly in geometric design and, to a lesser extent, in stent materials [3]. A larger inner diameter was recognized as an important factor for prolonged patency but was associated with increased risk of complications [3,8]. In recent years several studies have been published concerning the use of metal self-expandable endoprostheses in the biliary tree [9-19]. Most studies were concerned with the Wallstent endoprostheses, as in this study [12-19]. These endoprostheses have a small delivery catheter (7-F), large inner diameter (1 cm), and fixation of the stent against the wall. Drainage of second-order radicles, which end up on the edge of the stent, is possible through the mesh of the stent.

Percutaneous or endoscopic insertion of plastic endoprostheses in hilar strictures has been successful in a large number of patients. The type of stricture is an important factor influencing the success rate, with an insertion success rate up to 90% or more in achieving incomplete drainage [20-23]. Insertion seems even more successful with the use of self-expandable endoprostheses [9-19]. Effective biliary drainage is accomplished in this way in most patients.

Both the success rate and complication rate are influenced by the choice for complete or incomplete drainage. Supporters of complete drainage emphasize the risk of cholangitis and inadequate drainage in incomplete drainage. Others advocate incomplete drainage because of the expected lower risk of complications and because adequate palliation can be achieved by drainage of only 25% of the liver [22]. These opinions are reflected in the literature, with studies favoring one approach or the other [20,22-24]. Drainage is complete with one stent in every type I lesion, whereas complete drainage is hard to establish in type IV lesions. The choice between complete and incomplete drainage therefore concerns type II and III lesions. The progression of the malignancy will, at a certain moment, change each complete drainage into an incomplete drainage.

The major problem in incomplete drainage, and most common early complication in biliary drainage, is cholangitis. Several studies report different rates, but occurrence in

approximately 10% of the patients is a common finding, and some studies report up to 40 to 50%, depending on the complexity of the stricture and whether complete drainage was established [20,22-25]. Four patients (9%) in this study had early cholangitis, all with incomplete drainage. One of these patients died of cholangitis and sepsis caused by an abscess in an undrained right liver lobe. No early cholangitis occurred in patients with complete drainage. These findings, although concerning a limited number of patients, support the hypothesis of increased occurence of cholangitis in incomplete drainage. One might expect more procedure-related complications in complete drainage, but none occurred in this study. Initial catheter drainage is routine at our institution, with Wallstent insertion after several days. This provides the opportunity to evaluate the effect of the drainage. In the only patient where this routine was not applied an abscess developed in the undrained right lobe. In two patients not included in this study this management prevented Wallstent insertion because adequate drainage was not established. The 30-day mortality rate (9%, procedure-related in 4%) and late complications not related to jaundice recurrence (7%) in this study are comparable with recent studies on plastic or metal endoprostheses [11,12,17,20,23].

The most common late complication and major drawback of biliary stenting is jaundice recurrence by stent occlusion. It occurs in 10% to 50% of plastic endoprostheses for distal biliary strictures, with a mean patency of approximately five months [6,20,26-28]. Plastic stents perform less favorably in hilar strictures, with a mean jaundice recurrence in approximately three months [26]. One study observed a tendency, although not statistical significant, for longer patency in less advanced cholangiocarcinoma compared with more extensive cholangiocarcinoma [20].

Experience with stenting of malignant hilar strictures by self-expandable stents is limited and predominantly concerns Wallstents. Comparison of studies is, as with conventional stenting, hampered by several factors. One of the major obstacles is that most of the studies have not documented the type of hilar strictures and have not related complications and patency to the type of stricture. Despite this lack of documentation, some tendencies can be identified. Jaundice recurs more frequently in hilar strictures than in distal strictures, as is the case with conventional stenting [13,19]. Jaundice recurrence has been documented in only 5% to 11% of patients with distal strictures treated by Wallstents [14,19]. In one study, jaundice recurrence with or without sepsis was reported in 45% of patients with hilar strictures treated by Wallstents [13]. Another study concerning Wallstent endoprostheses in hilar strictures reported no jaundice recurrence, but this study had a short follow-up period of two months [16]. Several other studies [12,17,18] include patients with hilar strictures, but patency has not been grouped

separately for hilar strictures. One of these studies reports a jaundice recurrence of 17%, with stent patency of 78% after 200 days [18].

In our study, there was recurrence of jaundice by biliary obstruction in 17 of the 45 patients (38%). It is not completely certain, however, whether some of the patients with jaundice attributed to liver metastasis should be included in this group, thereby increasing the occlusion rate. Tumor overgrowth was the major cause of biliary reobstruction in this study. Distal overgrowth occurred in four patients, all of whom had a prepapillary positioned stent. This can be prevented by longer initial stents. Proximal overgrowth is more difficult to treat. The hilar malignancies will inevitably progress, with stricturing of segmental ducts and second-order radicles. Tumor ingrowth through the mesh of the Wallstent occurs, but it has not been identified as a major cause of biliary obstruction in Wallstents as in our study [18,19]. Sludge and stent migration are not important causes of biliary reobstruction in metal stents because of their large inner diameter and fixed position against the wall.

The patency rate of Wallstent endoprostheses in malignant hilar strictures in this study is encouraging. The expected low incidence of reobstruction by sludge is demonstrated in this and other series, whereas it is identified as a major cause of reobstruction in only one study [13]. The major cause of reobstruction is proximal overgrowth, which is inherent in the diseases. This can be partly prevented by more proximal overstenting, but this is limited by the number and size of the affected ducts and would not prevent obstruction of smaller ducts, that end up on the stent because of tumor progression. Reobstruction is therefore primarily a sign of progressive disease, and stent-related causes are less common in Wallstents compared with plastic stents. One of the specific characteristics of the Wallstent is the straightening force of the stent. This may lead to angling of the stent against the wall, which may cause reobstruction, as occurred in one patient in this series (Fig. 4.3) [19]. In our opinion one of the most important advantages of the Wallstent, as compared with plastic stents, is the easier reintervention because it can be performed without stent removal. The large inner diameter of the stent allows placement of another stent or catheter through the lumen. Meaningful comparison between complete and incomplete drainage, prepapillary or transpapillary stent position, and type of stricture or diagnosis with regard to stent patency is difficult in this study because of the relatively small number of patients. Comparisons are also influenced by the predominance of incomplete drainage and prepapillary stent position in more extensive strictures. No clear difference exists in the occurence of reobstruction between prepapillary and transpapillary stents, whereas reobstruction does occur more frequently with complete drainage and in low-type strictures. This may be explained by the fact that

survival in low-type stricture, with predominantly complete drainage, is longer. Reobstruction was relatively uncommon in cholangiocarcinoma and liver metastases.

In comparing the use of Wallstent endoprostheses with plastic stents, although superior patency rate is not proven and procedure costs are increased with Wallstents, we consider the latter to be the stent of choice, because of the ease of insertion and the ease of reintervention [29].

4.6 References

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5 THE PERCUTANEOUS USE OF THE WALLSTENT ENDOPROSTHESIS IN MALIGNANT DISTAL BILIARY OBSTRUCTION

5.1 Abstract

Seventy-five patients with malignant distal biliary obstruction were treated by percutaneously placed self-expandable Wallstent endoprostheses for palliative drainage. Stent diameter was 1 cm and its length 3.5-10.5 cm. Early complications occurred in 16 patients (21%), they were related to the endoprosthesis in five patients (7%) and serious in six patients (8%). The thirty-day mortality was 15%, with 1% procedure-related mortality rate. Sixty-five patients died six-365 (median 87) days after stent insertion and four had recurrence of obstruction after 21-341 (median 152) days. Reobstruction was the result of tumor ingrowth in one patient, angling of the stent in one and an unestablished cause in two. Ten patients were alive without obstruction 31-383 (median 65) days after stent insertion. Percutaneous use of the Wallstent endoprosthesis allows easy insertion; reobstruction is rare.

5.2 Introduction

Inoperable malignant non-hilar biliary obstruction may be palliated by endoscopic or percutaneous insertion of an endoprosthesis. Currently available plastic prostheses frequently block with sludge and, less commonly, migrate. Changes in stent design to reduce blockage rates have met with only limited success [1].

Self-expandable metallic endoprostheses have recently been introduced [2]. These have a large inner diameter after release; this is an important factor in prolonging stent patency [3]. The expansile force of the stent against the bile duct wall prevents migration. The Wallstent endoprosthesis (Wallstent, Schneider, Bülach, Switzerland) used in the present study is composed of a stainless steel braided self-expandable mesh and is loaded in compressed form on a small (7- F) delivery catheter, to be released by progressive withdrawal of the enclosing membrane.

Experience with the Wallstent endoprosthesis and its role in the stenting of malignant distal biliary strictures are described.

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5.3 Patients and methods

Between 1989 and 1991, 75 patients with inoperable malignant biliary obstruction distal to the liver hilum were treated by percutaneous insertion of a Wallstent endoprosthesis. There were 36 men and 39 women with a median age of 72 (range, 36-91) years. Fifty-three patients had pancreatic carcinoma, four cholangiocarcinoma, 12 periportal metastasis and six obstruction due to miscellaneous malignant causes. Histological or cytological confirmation of the diagnosis was obtained in 47 patients (63%). In the remaining 28 patients the diagnosis was based on clinical and radiological findings, and follow-up gave no doubt concerning the diagnosis. The majority of patients had treatment before percutaneous stenting (Table 5.1). Eighteen patients had cholangitis before the percutaneous procedure. The serum bilirubin concentration was measured before stent placement in 67 patients and the median value was 185 μmol/L (range, 29-566 μmol/L; normal range, 4-14 μmol/L).

Table 5.1 **Previous Therapy in 75 Patients Treated by Percutaneous Wallstent Endoprosthesis Insertion**

Failed endoscopic attempt	50
Failed endoscopic replacement	12
Previous percutaneous endoprosthesis	1
Palliative biliary bypass	5
Whipple's procedure	1
Cholecystectomy	1
Gastroenterostomy	5
External radiotheraphy	5

All percutaneous transhepatic biliary drainage procedures were performed under ultrasonographic and fluoroscopic guidance. Broad-spectrum antibiotics were used during the 12 h before and after each procedure. All stents had a diameter of 1 cm; the length varied from 3.5 to 10.5 cm. Balloon dilation was performed before stent insertion in the first five patients. This was subsequently abandoned as the prostheses continued to expand for a few days after placement. Plain abdominal radiography confirmed the position and degree of expansion of the stents 1-14 days after insertion.
The effect on jaundice, complications and follow-up were recorded for all patients. Early complications were those occurring within 30 days of stent placement. Cholangitis was defined as fever above 38°C in the absence of other explanations. Bleeding was assumed after a haemoglobin reduction of 0.5 mmol Fe^{2+}/L or more in the absence of other explanations. The serum bilirubin concentration was recorded approximately one

month after stent placement. The patency period of the prosthesis was taken as the interval between its insertion and the occurrence of biliary obstruction, as defined by clinical symptoms, and ultrasonographic and cholangiographic findings.

5.4 Results

Wallstent insertion (Fig 5.1) was successful and uneventful in all patients. Stent expansion to more than 80 % of the maximal diameter was seen in all cases. Preexisting cholangitis resolved in all but two patients. Serum bilirubin concentration after stent insertion was measured in 47 patients, and showed decrease in all, with a level measured of less than twice the upper limit of normal in 21 patients after 30 days.

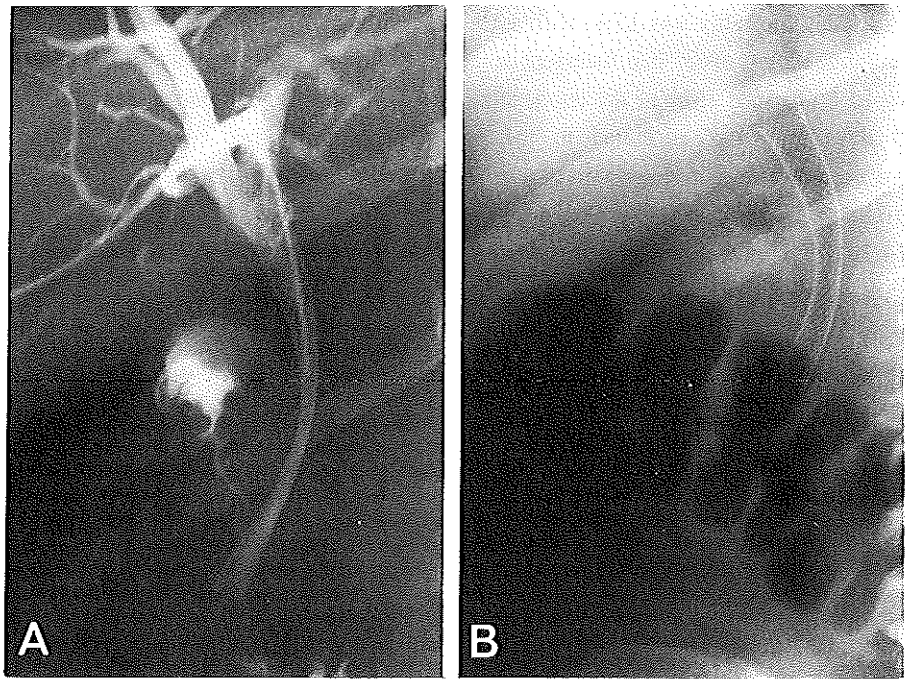

Figure 5.1 (a) Cholangiogram after insertion of a Wallstent endoprosthesis in a patient with pancreatic carcinoma. (b) Plain abdominal radiograph four days after insertion demonstrates further expansion of the stent.

Early complications occurred in 16 patients (21%); they were related to the stent in five (7%) and serious in six (8%) (septicaemia, four; pleural empyema, one; reobstruction, one). Seven patients had cholangitis, including four patients with preexisting cholangitis.

Four of these seven had septicaemia but all recovered following antibiotic administration. In four patients bleeding of the transhepatic tract was noticed during catheter manipulation, and controlled by leaving the drainage catheter in place for two weeks after stent insertion. Bleeding, bile leakage along the catheter and catheter dislocation occurred in one patient each and were treated conservatively. A debilitated patient with a transpleural catheter developed a pleural empyema; no therapy was performed as the patient was terminally ill. Reobstruction due to angling of the stent occurred in one patient 21 days after insertion. A patient with a pancreatic carcinoma had an aggrevation of a preexisting pancreatitis after an endoscopic attempt at drainage. Septicaemia persisted after successful percutaneous biliary drainage. The septicaemia was attributed to the pancreatitis and not to the percutaneous procedure. This was confirmed at autopsy.

The thirty-day mortality was 15%, with a 1% procedure related mortality rate.

Late complications, other than recurrent jaundice, occurred in two patients. One patient developed a pressure ulcer of the duodenum opposite the stent and another had melaena at 45 days that was attributed to the prosthesis as no other cause was found. Gastroenterostomy was necessary in two patients.

Recurrent jaundice due to stent obstruction occurred in four patients after 21, 127, 176 and 341 days. Tumor ingrowth caused reobstruction in one patient and angulation of the stent caused recurrent jaundice in another. The first patient was treated by catheter drainage, the second by proximal lengthening of the stent. There was clinical suspicion of reobstruction in two terminally ill patients but no definitive cause was established.

Ten patients remain alive after a median follow-up of 65 (range, 31-383) days, with no recurrence of obstruction so far. The other 65 patients died, with a median survival of 87 (range, 6-365) days after stent placement. The four patients with reobstruction occurred in this group.

5.5 Discussion

Curative surgery is often not feasible in patients with malignant distal biliary obstruction. Palliative biliary bypass may be performed, but non-surgical drainage by stent insertion has proved an important alternative and provides better results than biliary surgery in many institutions [4-7]. Efforts have been made to design an endoprosthesis that is easy to insert and remains patent until death. The major disadvantage of the plastic stents currently available is reobstruction by sludge. Increase

of stent diameter might prolong patency but is limited by several factors, such as more difficult manipulation and the possibility of more complications. The design of the self-expandable Wallstent endoprosthesis, with its small delivery catheter, large inner diameter, relatively small surface area and fixation against the wall, seems advantageous in theory, but trial results are required.

Before comparing the present study with other (especially endoscopic) studies on biliary stenting, the differences in study populations should be considered. The majority of the patients in the present study had one or more failed endoscopic attempts. This increases the risk of early complications, especially cholangitis, and this patient group is probably more difficult to treat, as one method has already failed.

Early complications in this series, predominantly cholangitis, occurred in 21% of patients, a rate comparable to plastic stents [7-11]. The majority of the early complications were caused by the initial catheter drainage and most of these patients had a previous failed endoscopic attempt, thus increasing the risk of cholangitis. Most complications were minor complications and other studies concerning the Wallstent endoprosthesis have reported a wide range of early complications [2,12-14].

Reobstruction of plastic stents in malignant distal stricture occurs in approximately 20-40% of cases after 3-5 months [4,5,7,10,11,15] and therefore the rate (5%) associated with the Wallstent in this present series compares favourably. Blockage by sludge, the major problem in biliary stenting, has become a rare cause of reobstruction [2,12-14,16-19]. Tumor overgrowth seldom causes reobstruction when stents of an adequate length are used. Tumour ingrowth through the mesh of the stent occurs but, since the inner stent diameter is large and survival is short, stent obstruction will remain a relatively rare event.

Besides its expanding force the Wallstent prosthesis has a straightening force; this may result in the stent not retaining the form of the bile duct, with subsequent occlusion of the proximal end of the stent by the bile duct wall, as occurred in one patient in the present study. This problem can be treated by proximal lengthening of the stent and prevented by using longer stents initially. Reintervention is more easily performed than with plastic prostheses, because another stent or catheter can be placed through the lumen, without the need for stent removal.

The use of the Wallstent endoprosthesis increases the cost of the procedure, and this must be weighed against the reduction in the rate of reobstruction and consequent decrease in the costs of reintervention and rehospitalization [20]. Percutaneous insertion of the Wallstent endoprosthesis to establish definitive biliary drainage without recurrence of jaundice by reobstruction was accomplished in most patients in this study.

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6 COMPLICATIONS OF THE PERCUTANEOUSLY INSERTED WALLSTENT ENDOPROSTHESIS IN MALIGNANT BILIARY OBSTRUCTION

6.1 Abstract

Purpose: Complications were assessed during and after percutaneous Wallstent endoprosthesis insertion in patients with inoperable malignant biliary obstruction.
Patients and methods: Two hundred seven Wallstents were inserted in 176 patients: 74 had hilar strictures and 102 had distal strictures. Median survival after stent placement was 95 days.
Results: Early complications occurred in 12 patients (7%), predominantly cholangitis and reobstruction. Thirty-day mortality was 12%; 2% of deaths (three patients) were procedure related. Late complications, predominantly reobstruction, occurred in 36 patients (20%). Obstruction recurred in 33 patients (19%) after a median period of 135 days; 27 had a hilar stricture. Tumor overgrowth was the major cause of reobstruction (n=19), especially proximal overgrowth. Tumor ingrowth caused reobstruction in three patients. Other causes were rare. No reobstruction due to sludge occurred. Reintervention was performed in 25 patients. Nineteen of the 25 patients benefited from repeated intervention.
Conclusion: The use of the Wallstent is preferable to use of a plastic stent, as the major complication - reobstruction - is not stent related predominantly but is caused by tumor progression.

6.2 Introduction

The introduction of metallic self-expandable endoprostheses has changed percutaneous biliary stent placement substantially. The self-expandable stents have advantages over plastic stents, as they can be introduced on a small delivery catheter, have a large inner diameter, and have a fixed position after release. Several types of self-expandable endoprostheses are used in biliary stent placement; most percutaneous experience concerns the Wallstent (Schneider [Pfizer], Minneapolis, Minnesota, USA and Bülach,

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Switzerland) [1-7]. In many institutions, the Wallstent is preferred over plastic stents because percutaneous insertion and reintervention are more easily performed and because obstruction by sludge is rare [2-7]. A recent randomized endoscopic study comparing use of Wallstents and plastic stents in patients with malignant distal biliary obstruction has demonstrated superior patency of the Wallstent [8].
Stent-related complications are assessed in 176 patients with malignant biliary obstruction who where treated with percutaneous Wallstent endoprostheses in our institution.

6.3 Patients and Methods

From April 1989 through October 1992, 176 consecutive patients with inoperable malignant biliary obstruction treated with use of a total of 207 percutaneously inserted Wallstent endoprostheses were studied retrospectively. The study population comprised 81 men and 95 women, with a median age of 70 years (range, 34-91 years). Median survival after stent placement was 95 days (range, 6-1,204 days). Hilar obstruction was present in 74 patients, distal obstruction was present in 102 patients; pancreatic carcinoma, cholangiocarcinoma and metastatic disease were the main causes (Table 6.1).

Table 6.1 Diagnosis in 176 Patients with Malignant Biliary Obstruction Treated with Percutaneously Placed Wallstents

Diagnosis	Hilar Stenosis (n = 74)	Distal Stenosis (n = 102)	Total (n = 176)
Pancreatic carcinoma	3	70	73
Cholangiocarcinoma	36	5	41
Gallbladder carcinoma	15	1	16
Metastatic disease	13	17	30
Miscellaneous causes	7	9	16

Histologic or cytologic confirmation of the diagnosis was available in 124 patients (70%). Among patients with hilar obstruction, 12 had a type I lesion, 13 had a type II lesion, 36 had a type III lesion, and 13 had a type IV lesion [9]. Endoscopic biliary drainage was attempted unsuccessfully in 137 patients (78%). Twenty-nine patients (16%) had undergone biliary surgery, and 33 patients (19%) had undergone radiation therapy. Thirty patients underwent external radiation therapy directed on the hilum of the

liver and the hepatoduodenal ligament; in 20 patients this was combined with intraluminal radiation therapy (iridium-192). Three patients underwent intraluminal radiation therapy (Ir-192) only.

Technique

All procedures were performed under sonographic and fluoroscopic guidance. Broad-spectrum antibiotics were administered 12 hours before and after each procedure. Initial catheter drainage is routine at our institution, especially in hilar lesions, with Wallstent insertion after several days. This permits evaluation of the effect of drainage. No stent is placed before preexisting cholangitis has disappeared. A 9-F sheath is inserted over the guide wire before the delivery catheter is introduced to give an easy access to the biliary system. Balloon dilation was performed before stent placement in the first five patients. This was abandoned, as the stents continue to expand spontaneously over several days. The stent is introduced in compressed form on a 7-F delivery catheter and is released by progressive withdrawal of the enclosing membrane. On release, the stent expands and shortens. No balloon dilation was performed after stent placement. All stents had a maximum diameter of 1 cm after release; length varied from 3.5-10.5 cm. A modified Wallstent with improved membrane withdrawal was used in the last five patients. The stent or stents had a prepapillary position in 41 patients with a hilar lesion. Twenty-nine patients with hilar lesions received more than one stent. Two parallel stents were present in 24 patients, while three patients had two segmental stents, which overlapped a previously placed stent in the common bile duct. Two right-sided segmental stents, which overlapped a third stent in the common bile duct, and a long left-sided stent were present in two patients.

Complications

Early complications were defined as those occurring within 30 days after stent placement. Cholangitis was defined as fever above 38°C, in the absence of any other explanation. Bleeding was defined as a hemoglobin decrease of 0.5 mmol Fe^{2+}/L or more, in the absence of any other explanation.

A questionnaire was send every three months to the patient's physician concerning the occurrence of jaundice, fever, or other complications. If complications had occurred, further information was obtained from the doctor and from the hospital to which the patient was referred.

The patency period of the stent was considered the interval between the insertion of the stent and the time of biliary obstruction, as defined by means of clinical symptoms,

ultrasound (US), and cholangiographic findings. The source of reobstruction was determined with US and cholangiographic findings. Obstruction of bile ducts proximal to the stent, tumor mass around the proximal end of the stent, and progression of tumor mass were used as the main indicators of proximal tumor overgrowth. Distal overgrowth was defined as tumor mass around the distal end of the stent and progression of tumor mass. Tumor ingrowth was defined as obstruction present at stent level along with progression of tumor mass around the stent.

6.4 Results

Wallstent insertion was successful in all patients, although incomplete membrane withdrawal of the delivery catheter occurred with all stents longer than 6.8 cm. Partial release outside the patient with introduction in a long sheath and subsequent release in the patient solved this problem. Early complications occurred in 12 patients (7%); one of these patients experienced two early complications (Table 6.2).

Table 6.2 Early Complications in 176 Patients Treated with Percutaneously Placed Wallstents

Complication	Hilar stenosis (n = 74)	Distal Stenosis (n = 102)	Total (n = 176)
Cholangitis	2	4	6
Hepatic abscess	1	0	1
Reobstruction *	3	1	4
Acute cholecystitis *	1	0	1
Common bile duct and duodenum perforation	1	0	1
Total	8	5	13

* One patient with hemobilia had acute cholecystitis and reobstruction.

Six patients developed cholangitis after insertion, which was serious in two patients. Another patient with a hilar lesion had cholangitis after attempted endoscopic biliary drainage. Normal routine of initial catheter drainage was abandoned, as ascites was present. Ascites was drained percutaneously with Wallstent insertion at the initial visit; he developed an abscess in the undrained right liver lobe and died of sepsis. A patient with a hepatocellular carcinoma had persistent hemobilia with acute cholecystitis after 11 days and Wallstent occlusion after 26 days; both were treated by means of percutaneous catheter drainage. Obstruction recurred in three other patients within 30 days.

A malpositioned Wallstent caused the death of a patient 21 days after stent placement. This patient had two parallel transpapillary Wallstents in the common bile duct and had been treated with Ir-192 intraluminal radiation therapy before stent insertion. At autopsy only one of the stents was in a transpapillary position; the other had perforated the common bile duct and duodenal wall [10]. In a patient with a distal stenosis, pancreatitis was aggrevated after an endoscopic attempt at drainage. Septicaemia persisted after successful percutaneous biliary drainage. The septicaemia was attributed to the pancreatitis and this complication was therefore probably not related to the percutaneous procedure. This was confirmed at autopsy. Thirty-day mortality was 12%; deaths were related to the procedure in three patients (2%), including a debilitated patient who died of a pleural empyema after a transpleural catheter placement.

Complete follow-up was available in all patients. Late complications other than reobstruction occurred in seven patients (4%). Three patients developed acute cholecystitis 16 weeks, five months, and 21½ months, respectively, after stent placement; treatment was by percutaneous drainage in two patients and by cholecystectomy in one. A duodenal pressure ulcer developed in two patients five weeks and six weeks, respectively, after stent insertion. Another patient was admitted six weeks after stent placement with melena; because no gastrointestinal bleeding source was found and hemobilia could not be excluded, this was attributed to the Wallstent. An abscess developed in the right liver lobe of a patient who had initially a type I lesion. The abscess was treated by percutaneous drainage. The patient died with sepsis and peritonitis. Reobstruction, the major late complication, occurred in 33 patients (19%) after a median period of 135 days (range, 6-395 days). Six of these 33 patients had a distal obstruction, and 27 had a hilar obstruction. The latter group consisted of five patients with a type I lesion, five with a type II lesion, 13 with a type III stenosis, and four with a type IV lesion. Obstruction recurred most frequently in patients with a hilar

Table 6.3 Diagnosis in 33 Patients with Reobstruction after Wallstent Insertion

Diagnosis		Hilar Stenosis (n = 74)	Distal Stenosis (n = 102)	Total (n = 176)
Pancreatic carcinoma	(n = 73)	1	1	2
Cholangiocarcinoma	(n = 41)	12	1	13
Gallbladder carcinoma	(n = 16)	7	0	7
Metastatic disease	(n = 30)	4	1	5
Miscellaneous causes	(n = 16)	3	3	6
Total		27	6	33

Table 6.4 Causes of Reobstruction in 33 Patients Treated with Percutaneously Placed Wallstents

Cause	Hilar Stenosis (n = 74)	Distal Stenosis (n = 102)	Total (n = 176)
Proximal overgrowth	14	1	15
Proximal overgrowth and ingrowth	1	0	1
Distal overgrowth	4	0	4
Tumor ingrowth	1	1	2
Stent angulation	1	1	2
Inadequate positioning	1	0	1
Hemobilia	1	0	1
Inadequately functioning Roux loop	1	0	1
No established cause	3	3	6
Total	27	6	33

stenosis caused by cholangiocarcinoma or gallbladder carcinoma (Table 6.3). The major cause of reobstruction was tumor overgrowth, especially proximal overgrowth (Table 6.4). Other causes were rare, while sludge did not cause reobstruction in this series. Pathologic confirmation was obtained in two patients with tumor ingrowth; in the other patients, no attempt was made to obtain histologic or cytologic specimens. Reintervention was performed in 25 patients (14% of the total study population, 76% of the patients with reobstruction). Seven patients were treated with placement of an additional Wallstent (in two, stent placement was combined with catheter drainage), six with internal catheter drainage, six with external catheter drainage, three with combined internal and external catheter drainage. One patient developed a small liver abscess as a sequela of the reobstruction. This abscess was aspirated percutaneously.

One patient was treated with a plastic endoscopically placed stent because of ascites, while another was treated with antibiotics. In both patients symptoms disappeared. Endoscopic guide wire manipulation was performed in one patient, with a short-lasting beneficial effect. Reintervention caused complications in four patients (16%). Cholangitis occurred in three patients, and a subphrenic fluid collection occurred in one. The cholangitis was treated successfully in two patients, while one patient had recurrent cholangitis after endoscopical guide wire manipulation. The fluid collection was treated by means of percutaneous drainage.

Nineteen of the 25 patients (76%) who underwent reintervention benefited from the procedure; 11 patients remained symptom-free until death.

Multiple reinterventions for reobstruction were performed in six patients. Twenty-nine patients died after a median period of 61 days (range, 2-523 days) after reobstruction.

Four patients are alive, with a median survival of 60 days (range, 30-448 days) after reobstruction.

6.5 Discussion

The self-expandable Wallstent endoprosthesis was introduced several years ago in an attempt to solve the problem of limited patency of plastic stents due to sludge formation. It has become the stent of choice in many institutions, as insertion is more easily performed and reobstruction by sludge is rare [2-7]. Although the use of the Wallstent for percutaneous stent placement is advantageous, some problems may occur during and after stent placement.

Stent release and placement

The improvement of the delivery catheter design with a hydromer coating between the membranes and the introduction of the Unistep system have solved the problems encountered with release of stents longer than 6.8 cm. The visibility of the Wallstent at fluoroscopy during and after release in obese patients is often poor [7]. Radiographs are then needed for adequate delineation of the stent, which is important for accurate placement. The manufacturer is planning to integrate more radiopaque wires in the mesh to solve this problem.

Stent behaviour over time

After placement, additional shortening and expanding of the stent occurs. The stents expand in the common bile duct to or near its maximum diameter. In the hilar region, incomplete expansion up to 7 - 8 mm is not uncommon. The additional expansion after release may occur over a long period, which makes stent behaviour somewhat unpredictable, especially in complex stent configurations.

In our first five patients who needed two or more stents, a Y stent configuration was used. In three patients with this configuration, at least one of the proximal stents lost contact with the distal one, despite an overlap of at least 1.5 cm. This was noticed on radiographs taken three weeks to six months after stent placement (Fig. 6.1). Despite the disturbed stent configuration, the communication between the dislodged stents remained intact. The expanding, shortening, and straightening force of the Wallstent, together with respiratory and other movements, cause the filaments at the end of the inner one of two stents to climb the mesh of the outer one in a proximal direction, which will lead to a

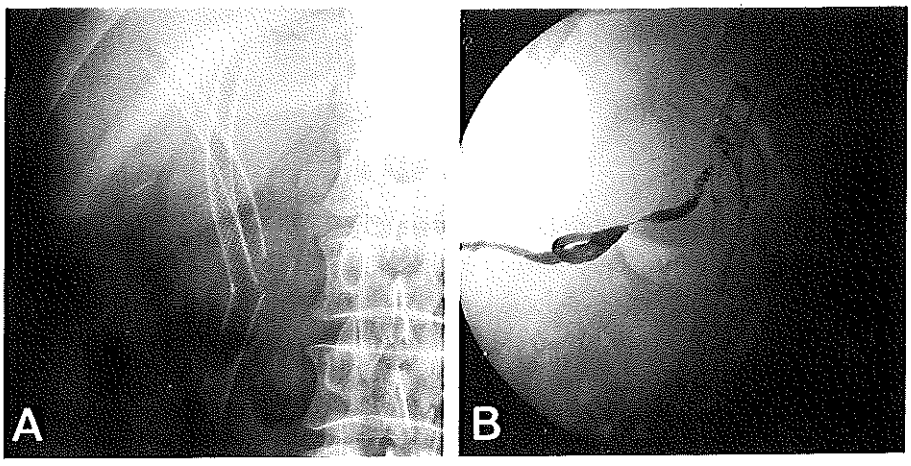

Figure 6.1 Patient with a type III hilar stricture caused by cholangiocarcinoma. **(a)** Radiograph obtained six weeks after placement of three stents in a Y configuration reveals additional shortening of the stents with poor alignment. No signs or symptoms of reobstruction were present. **(b)** Acute cholecystitis occurred 21½ months after stent insertion and was treated by means of percutaneous gallbladder drainage. Recovery of cystic duct patency is seen on the cholecystogram obtained 2½ weeks after drainage. Additional shortening of the stents is visible, with a closer relationship between the stents.

dislodgement in the direction of the liver hilus (Fig. 6.1). Because of this observation the use of the Y configuration was abandoned, and currently two parallel Wallstents are placed in the hepatocholedochal duct. In our experience, this is a stable configuration. Communication between the parallel stents remains intact for a long period (Fig. 6.2b).

Effects on anatomical structures

The Wallstent, as with other biliary stents, has an effect on surrounding tissues. A recent histologic study demonstrates mucosal destruction of the bile duct epithelium in the early phase and mild-to-moderate fibrosis in the later stages [11]. One patient in this study died of perforation of the common bile duct and duodenal wall by one of two parallel stents. This patient had undergone intraluminal radiation therapy before stent placement [10]. A case of Wallstent erosion through the medial duodenal wall was reported in an endoscopic study; no definite cause was reported in that article [12].

In our series, two of 135 patients with a transpapillary stent had a duodenal pressure ulcer. Intestinal blood loss was the reason for endoscopy in these patients. One endoscopic study of 103 patients treated with Wallstents describes two patients with a

pressure ulcer [13]. A possible explanation of this phenomenon is a fixed duodenal wall opposite a transpapillary stent, causing repetitive trauma of a small area of the duodenum.

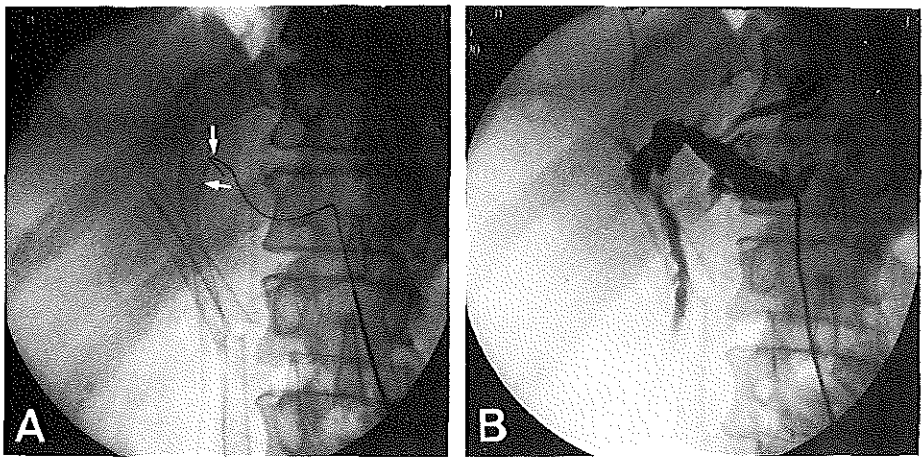

Figure 6.2 Type III hilar stricture in a patient with cholangiocarcinoma, which was treated with complete drainage by using a right-sided Wallstent Y configuration and a long Wallstent on the left. After eight months symptoms recurred. **(a)** Radiograph demonstrates angling of the left-sided Wallstent (arrows indicating angulation). The guide wire indicates the more distal part of the left hepatic duct. The relationship between the right segmental stents and the distal stent has changed; one has lost contact with the distal stent. **(b)** Cholangiogram by the left-sided catheter reveals contrast material in right lobe ducts indicating communication between the parallel stents.

The structure of the Wallstent allows drainage of the cystic duct through the mesh. Impaired drainage through the mesh may occur with tumor progression, sludge, or hemobilia. Acute cholecystitis may result, which occurred in four patients in this series. Hemobilia was the cause in one patient, while in at least one of three other patients it was stent related, as repeated cholangiography of the percutaneous cholecystostomy revealed recovery of cystic duct patency after 2½ weeks (Fig 6.1b).

Stent occlusion

Stent occlusion by sludge has become a rare cause of reobstruction since the use of Wallstents [2-7]. Most cases of reobstruction are now caused by tumor progression, especially tumor overgrowth in patients with hilar stricture (Table 6.4). This can be prevented in part by proximal overstenting, but this carries its own limitations and disadvantages. First, the number and size of segmental ducts limit the possibilities of

sufficient overstenting. Second, a stent will cover side branches which might become obstructed due to the stent. Third, reintervention is more difficult when important ducts are covered by a Wallstent (Fig. 6.3). One study concerning five patients has reported continuous drainage of side branches through the mesh [14]. In our population we also noticed small ducts draining through the mesh immediately after placement, but no long-term results are available [5]. We are reluctant to perform peripheral stent placement as the number in the referred study is small and reintervention is hampered.

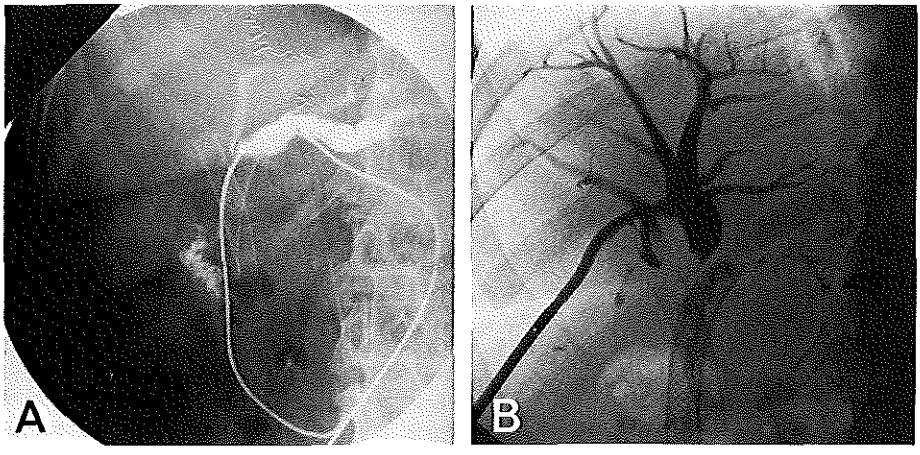

Figure 6.3 Incomplete drainage was established through two parallel Wallstents in a patient with a type III hilar stricture caused by cholangiocarcinoma. Reobstruction due to proximal overgrowth occurred after 1 year. **(a)** Cholangiogram demonstrates segment VIII draining in the left hepatic duct through the edge of the left Wallstent. An additional Wallstent was inserted in the left hepatic duct because of the overgrowth. **(b)** A second reintervention was performed after six weeks because of recurrence of symptoms. External drainage of segment VIII could be established, no internal drainage catheter could be passed through the mesh.

Tumor ingrowth is a recognized phenomenon in Wallstents. The rate of tumor ingrowth is influenced by the growth pattern of the tumor, with more ingrowth in cell-rich tumors [11]. Ingrowth is, however, not a frequent cause of reobstruction as the inner diameter is large and the survival is short. The development of partly or completely coated stents may prevent tumor ingrowth, but this will prevent the reported prolonged drainage of side branches or the cystic duct through the stent [14]. With adequate stent position and length, distal overgrowth appears to be a rare phenomenon. Another potential cause of reobstruction is mucosal hyperplasia. The presence of a stent may induce proliferation of the wall which may cause reobstruction. Until now this has not been recognized as a significant cause of reobstruction in the use of Wallstents in malignant biliary obstruction

[1-8,11]. In this series no reobstruction due to mucosal hyperplasia was diagnosed.

In addition to an expanding and shortening force, the Wallstent has a force that will straighten the stent. This may result in the stent not retaining the often curved shape of the bile duct. This will subsequently lead to occlusion of the proximal end of the stent by the overlying bile duct wall, as occurred in two patients in this series (Fig. 6.2a) [5]. This phenomenon is also reported in the randomised comparitive study of plastic stents and Wallstents in malignant distal biliary obstruction [8]. Two cases of reobstruction by kinking occurred in that series concerning 49 patients treated by a Wallstent. A large angle between the longitudinal axis of the stenosis and the bile duct and the use of a relatively short, rigid, large-diameter stent predispose for this phenomenon. This problem can be prevented with the use of a longer stent, or a stent with a smaller diameter and thereby less expanding force.

Reintervention should be considered in all cases of reobstruction, as 76% of our patients benifited from such a procedure. Several factors should be considered in this decision, such as the clinical condition of the patient and the complexity of the biliary stricture at that time.

In our opinion only tumor ingrowth and impaired stent function due to angulation and incorrect placement can be classified as stent-related causes of reobstruction. All others, especially tumor overgrowth, are the result of the expected inevitable progress of the tumor.

Despite some inadequacies, placement of the Wallstent is a safe and well tolerated procedure. The most important complication of endoprosthesis insertion in malignant biliary obstruction - reobstruction - is predominantly not stent related but is caused by the expected progression of the malignant tumor.

6.6 References

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7 DISCUSSION AND CONCLUSION

7.1 Introduction

Endoprostheses have become the treatment of choice in the majority of patients with inoperable malignant biliary obstruction [1-7]. Until the late 1980s several types of plastic endoprostheses have been used, but all had the major disadvantage of limited patency by sludge [8-10]. Several factors were identified influencing stent patency, stent diameter being a major one [11]. Increase of stent diameter was, however, limited by several factors such as more difficult insertion and possibly more complications. A less frequent problem was stent migration.
In the mid and late 1980s the promising design of metallic self-expandable endoprostheses prompted their use in biliary stenting to overcome the limitations of the plastic endoprostheses. These metal stents have a small delivery catheter, small surface area, large diameter after release and fixation against the wall. Most experience with metal stents concerns the Wallstent endoprosthesis. The aim of this chapter is to review the literature on biliary Wallstents and to determine the place of the percutaneous Wallstent in malignant biliary obstruction.

Since the introduction of the biliary Wallstent in 1988 several uncontrolled studies and some controlled studies have been published [12-46]. A review of the literature on Wallstents in malignant biliary obstruction is hampered by several factors. Almost all studies are non-comparative retrospective studies. These have inherent problems such as underscoring of complications while the relationship with the results of the plastic stents in the same population remains uncertain. In the majority of studies the results in patients with benign and malignant strictures, hilar and distal biliary strictures, or different types of metallic stents are presented together without the possibility to convert the results to subgroups. Patient selection for percutaneous treatment, as primary therapy or only after failed endoscopic drainage, is not always evident. In two of the randomized series Wallstent and Strecker stents are used and compared with plastic stents.

This chapter is a modified version of the paper: JS Laméris, J Stoker. Metal stents for malignant biliary obstruction. Digestive diseases 1994; in press.

7.2 Insertion and drainage

The outer diameter of the delivery catheter of a Wallstent (7-F) is smaller than the outer diameter of a plastic endoprosthesis (12-F). Easier percutaneous insertion of a Wallstent in distal and hilar biliary obstruction is therefore expected and also reported in several studies [21,25,39,41]. Although not always appreciated by every radiologist, percutaneous placement of large bore polyethylene endoprostheses, which requires multiple dilations, has always been a painful experience for the patient. The ease with which insertion of metal stents can be done, has been for many interventionalists the main reason to switch from polyethylene to metal stents. Theoretically metal stents can be placed percutaneously in one session, thereby reducing the cost of hospital stay [21,33]. However cholangitis, complex biliary strictures, or pending the decision on surgical therapy are motives to perform the placement in a two-stage procedure. In case of ascites some have advocated the transjugular insertion of a Wallstent, but ascites drainage or the endoscopic route are more obvious [47]. Other less common routes may be used in special cases [48]. The stent shortens considerably (up to 40%) during expansion [45,49,50].

Unlike in percutaneous use, metallic stents have not facilitated the endoscopic placement procedure. Although important improvements were carried out, the long delivery devices are more prone to mechanical failure. Pre-cut papillotomy may still have to be done to enable successful delivery [34]. Inadequate stent release occurred in approximately 10% of the Wallstents of the original design [16,18,21,25,33-35,37,45,52]. It was caused by inability to retract the enclosing membrane, membrane leak, or by an acute angulation of the delivery catheter. The introduction of hydromer coating and the Unistep system solved this problem. Difficulty in removing the delivery catheter in hilar strictures may be encountered in endoscopic Wallstent insertion [53]. The funnel-shaped flange of the tip of the delivery catheter has a slightly larger diameter than the compressed stent. When no sufficient expansion of the intrahepatic tip of the stent occurs, this will prevent catheter withdrawal. This has been reported in stents with the proximal tip of the delivery catheter in a small intrahepatic duct or a stenotic duct. Mechanical failure for other reasons is rare [54]. A new design Wallstent with gold wires has increased the visibility of the stent during fluoroscopy.

Distal strictures

Plastic stents or Wallstents have a comparable insertion and initial drainage success rate

in distal strictures. The insertion and drainage success rate of plastic stents is approximately 90-95%. Percutaneous or endoscopic Wallstent insertion is successful in almost 100% of the patients, while successful drainage will be established in approximately 95% of the patients [13,18,41]. The two randomized comparative studies confirm these uncontrolled studies [34,35].

Hilar strictures

Successful insertion and drainage is in general more difficult to obtain in hilar strictures. In plastic stents percutaneous placement will be successful in 90% and with endoscopy in 50-95%. Insertion of the Wallstent is successful in approximately 100% [20,21,36,38,39]. Successful drainage will be established in 95-100% of the patients. The only comparative study concerning only 20 patients demonstrates successful placement of Wallstents in all patients but of plastic stents in eight out of nine patients (89%) [36]. The success rates of the stents and techniques will be influenced by the choice for complete or incomplete drainage.

Percutaneous placement of multiple stents in hilar obstruction can easily be done, the delivery catheters are first passed through the strictures and then released one after another. Ending the two Wallstents next to each other inside the common bile duct is well tolerated. Reports on perforation are rare. A Y shaped configuration, as proposed by some, has not proved to be always stable [45,55]. Whereas the effect of one lobe drainage can be awaited when plastic stents are used, the choice between partial or complete drainage is almost irreversible when metal stents are used. Placement of a second metal stent for the other lobe at a later stage is extremely difficult and in most cases impossible. Bilateral endoscopic metal stent placement in hilar lesions is extremely difficult and has been reported only occasionally [7,19].

A prepapillary position of the distal end of the stents has the advantage of preserving the papillary function and minimizing the risk of ascending cholangitis. The outcome of reinterventions for obstructed pre-papillary metal stents is not hampered by this strategy.

7.3 Early complications

Early complications are defined as complications occurring within 30 days after stent placement and are generally regarded as procedure-related complications. Cholangitis is the most common early complication in palliative biliary stenting with plastic stents as

well as with Wallstents. Stent migration is rare as the stent is fixed against the wall after release and becomes embedded in the wall. The histopathological changes produced by the wires on the bile duct wall consist mainly of focal denudation and mild submucosal inflammation with edema [56]. In two months the stent is covered by a fibrogranulomatous tissue layer, or in some cases an epithelium-like cell formation covers the stent surface. Pressure necrosis, especially related to the edges of the stent, has also been noticed and can occasionally lead to perforation of the bile duct and duodenal ulcerations [13,55,57].

Distal strictures

The early complication rates of plastic stents and Wallstents are comparable with a tendency to a slightly lower early complication rate with Wallstents.

Table 7.1 Results of Two Prospective Randomized Controlled Trials of Plastic versus Metallic Stents for Malignant Distal Biliary Obstruction

	Davids et al (34)		Knyrim et al (35)	
	Plastic (n = 56)	Metal (n = 49)	Plastic (n = 31)	Metal ■ (n = 31)
Early complications	6 (11%)	6 (12%)	1 (3%)	1 (3%)
cholangitis	5	6	-	1
stent migration	-	-	1	-
cholecystitis	1	-	-	-
Thirty-day mortality	2 (4%)	7 (14%)	3 (10%)	4 (13%)
Median survival (days)	147	175	n.a.	n.a.
Late obstruction	30 (54%)	16 (33%)	12 (39%)	6 (19%)
sludge	29	4	10	2#
tumor ingrowth	-	10	-	4
stent migration	1	-	2	-
bile duct kinking	-	2	-	-
Patency (days)				
median	126	273	n.a.	n.a.
mean	n.a.	n.a.	140	189

n.a. data not available

■ including nine patients treated with Strecker stents

\# concerns two patients with a Strecker stent

With plastic endoprostheses early complications occur in approximately 10-20%; with early cholangitis being the most frequent early complication (10-15%). The early

complication rate with Wallstent endoprostheses is 0-20%, with early cholangitis in 0-10% [17,21,26,33,37,41]. Bleeding, bile leakage and kinking of the Wallstent are other early complications which are rare and partly related to the procedure before Wallstent insertion [41,58]. The rare occurrence of early reobstruction is often caused by kinking or angling of the Wallstent [34,41]. The two randomized trials report comparable early complication rates (Table 7.1) [34,35]. Wallstent migration is rare.

Hilar strictures

Early complications occur in 10-20% of the patients with hilar strictures treated by Wallstents. Early cholangitis is the most frequent early complication (5-10%). With plastic stents the early complication rate is higher with early cholangitis in 20-30%. Complications other than cholangitis with Wallstents are rare [20,21,36,39,59].

Migration of a Wallstent is rare and predominantly occurs during or directly after placement [21,24,60,61].

7.4 Thirty-day mortality rate and procedure-related mortality rate

The thirty-day mortality rate for patients with Wallstent for distal strictures is 5-15% and for hilar strictures 5-10% [17-19,21,22,25,26,34-37]. The procedure-related mortality rate is 2% for distal and hilar strictures. With plastic stents the results are similar, with a thirty-day mortality rate of 10-20% and a procedure-related mortality rate of 1-5%. The randomized series on hilar stents gives similar results for both types of stents [36]. The two randomized series on Wallstents in distal strictures give a higher thirty-day mortality rate for metal stents [34,35]. In one of those series it could not be explained by stent-related causes and was not considered to be clinically significant [34]. In the other series this difference is not further explained.

7.5 Late complications

Reobstruction

The Wallstent endoprosthesis was introduced to overcome the major drawback of the plastic endoprosthesis, namely reobstruction by sludge. This occurs in 20-40% of the patients treated by plastic stents, with a median patency of approximately five months in distal strictures and three months in hilar strictures.

Early results of percutaneous placement were not encouraging and appeared to be no better than results with polyethylene stents [12,17]. A 40% rate of recurrent jaundice and cholangitis was reported, with a median patency of four months in hilar strictures and of 4.5 months in distal strictures. The use of short vascular stents combined with the intrinsic shortening were probably responsible for these disappointing results. Recent reports on Wallstents have shown better results (Table 7.2). The data of a large randomised comparative endoscopic study of plastic stents and Wallstents are until now only reported in an abstract [40]. This study comprising 48 patients with hilar strictures and 115 patients with distal strictures, reports similar reobstruction rates of both stents (13%). The median time to obstruction was 62 days in plastic stents and 111 days with Wallstents.

Table 7.2 Long Term Results of Treatment of Malignant Biliary Obstruction with Wallstents

Authors	Ref.	No. of Patients	Survival (months) Median	Survival (months) Mean	Reob-struction	Patency rate (months) Median	Patency rate (months) Mean	
Gillams et al 1990	(17)	40	-	-	40 %	-	hilar distal	4.1 4.5
Lammer et al 1990	(18)	53	-	-	11 %	-		-
Adam et al 1991	(21)	41	3.4	-	5 %	-		-
Neuhaus et al 1991	(22)	35	3.9	-	14 %	- #		-
Huibregtse et al 1992	(26)	103	4.7	-	17 %	4		-
Gordon et al 1992	(25)	50	-	7.5	24 %	-		5.8
Dertinger et al 1992	(28)	65	-	5.1	21 %	- □		-
Salomonowitz et al 1992	(31)	39	4.4	-	28 %	-		-
Stoker et al 1993 *	(39)	45	4.5	-	38 %	5		-
Nicholson et al 1993	(37)	77	-	7.2	9 %	-		-
Lee et al 1993 *,■	(38)	22	-	-	27 %	-		2.5
Stoker et al 1993 ○	(41)	75	3	-	5 %	5		-
Wagner et al 1993 *,■	(36)	11	-	-	18 %	-		-
Becker et al 1993 *	(42)	39	-	-	33 %	- •		-

* only patients with hilar obstruction
■ including a minority of the patients treated by other metal stents
○ only patients with common duct obstruction
\# stent patency probability 78% after 6.5 months
□ stent patency probability 81% after 6 months
• stent patency probability 46% after 12 months

Experimental studies on Wallstents, Gianturco-Rösch Z-stent and Palmaz stents have demonstrated mucosal hyperplasia of the bile duct wall after stent placement [62-65]. Until now this has not been recognized as a major cause of reobstruction in the clinical

use of Wallstents. A histological analysis of bile duct tissue from fifteen patients treated by Wallstents has not demonstrated hyperplastic biliary epithelium [56].

Distal strictures

The reobstruction rate and patency rate of Wallstents in distal strictures are superior to plastic stents. Uncontrolled studies of patients with distal strictures or predominantly patients with distal strictures reported a reobstruction rate of 5-15% after approximately five months [18,26,30,37,41,42]. The two controlled studies report a higher reobstruction rate (19% and 33%) but also a higher than expected reobstruction rate of plastic stents (39% and 54%) (Table 7.1) [34,35]. The polyethylene stents used were 11.5-F and 10-F in diameter. Reobstruction in these series occured in the Wallstent after 6.2 and 7.5 months and in plastic stents after 4.6 and 3.5 months. These differences in reobstruction between plastic stents and Wallstents were statistically significant in one of these series [34]. The results of a percutaneous comparative study on distal strictures have been presented as an oral presentation [44]. Reobstruction occurred in 22% (10/46) of the patients treated with Wallstents and in 32% (14/44) of the patients with plastic Carey-Coons stents. Median patency of the Wallstent was significantly longer (346 days) than of plastic stents (approximately 135 days). Patient selection with differences in survival is probably a major cause for the discrepancy between the controlled and the uncontrolled studies [34,41].

The major cause (approximately 50-60%) of reobstruction of distal Wallstents is tumor ingrowth [18,26,27,34,35,37,41,66]. Covering of the stent to prevent this tumor ingrowth seems attractive, but no clinical studies on covered Wallstents in distal strictures have been published to date. An experimental study in dogs has demonstrated the potential usefulness of elastomeric coated Wallstents in the biliary tree [65]. The coated stents did not migrate in this study and were not embedded in the bile duct wall. These stents may be removable, which is only an important advantage in stenting of benign strictures. An endoscopic study has reported the use of Dacron covered Gianturco stents in four patients [67]. In two patients migration of the stent during installment occurred, probably because the fixation of a covered stent to the bile duct wall is less firm. An experimental study on Gianturco stents with several different types of covering demonstrated the feasibility of the stents, but mucosal hyperplasia at the ends occurred [64]. The use of a half silicon-covered stent with tapered ends prevented this problem. Proximal or distal tumor overgrowth is the second most frequent cause of reobstruction. This problem can generally be prevented by the use of long stents. Sludge is a minor cause of reobstruction. A relatively rare cause of reobstruction is angling or kinking of the bile

duct by the straightening force of the stent. Although the Wallstent is flexible, the stent is subjected not only to a radial recoil force but also to a force that will straighten it. This results in a limited pliability along the longitudinal axis which can cause kinking of the stent with the bile duct [23,27,34,45,55,68,69].

Hilar strictures

Recurrent jaundice and cholangitis after stent placement is seen more often (20-38%) in patients with hilar lesions [21,36,38,39,42]. Wallstent patency will be approximately 4-5 months but data are very limited (Table 7.2). In one controlled study long-term stent failure in patients with hilar lesions who were treated with percutaneously placed metallic stents was 18% vs 50% in polyethylene stents [36]. Although the treatment of patients with hilar strictures has always been difficult, the difference in results to distal structures can not be explained by poor stent positioning. The natural course of many malignant strictures in the hilar region is characterized by tumor spread along the intrahepatic bile ducts. This explains the high incidence of tumor overgrowth, especially at the proximal site of the stent [21,36,38,39,45]. The proximal overgrowth might be prevented by more proximal overstenting, but this has disadvantages and limitations [45]. The anatomical situation often precludes sufficient overstenting, while future reintervention might be jeopardized by covering important side branches. The side branches may become obstructed by the stent itself, although a study on five patients has demonstrated continuous drainage of side branches through the mesh [42,70]. Stent malfunction due to tumor ingrowth is relatively less commonly seen in hilar lesions than in common bile duct disease [45]. Sludge is a rare cause of reobstruction as well as stent angulation [38,45]. The Wallstent has additional expansion after release, which may occur over periods of months [45]. This makes stent behavior somewhat unpredictable, especially in complex hilar stent configurations. Stent malfunction might theoretically be the result of this phenomenon. As with plastic stents, reobstruction seems to occur more often in lower type hilar strictures and complete drainage [39,71]. This probably reflects the longer survival of patients with lower type stricture and complete drainage. Kinking is a rare cause of reobstruction.

Although large comparative studies are lacking the use of Wallstents in hilar strictures seems preferable as reobstruction is primarily caused by tumor progression and not by stent dysfunction [39].

Reintervention

In case of reobstruction reintervention should be considered, as the majority of the patients will benefit from such a procedure [25,45,72]. Certain factors may, however, preclude reintervention such as the clinical condition of the patient and the complexity of hilar strictures.

The comparative studies on plastic stents and Wallstents have demonstrated a significant lower reintervention rate in the metal stent group [34-36].

Metal stents become permanently embedded in the bile duct wall and can not be removed. Generally, this does not hamper successful reintervention for stent malfunction. It even facilitates percutaneous and endoscopic attempts to restore bile drainage because there is no need for stent removal. Although diathermic cleaning, radiotherapy, laser or placement of a second metal stent have been advocated, insertion of a polyethylene stent or an indwelling catheter has proved to be very effective [19,45,72-75]. Davids et al. observed no recurrent jaundice after insertion of a polyethylene stent through a blocked stent, whereas after polyethylene stent exchange, the second stent clogged in almost 50% of patients [34]. They assumed that friction between the plastic stent and the content of the metal stent creates enough space to allow bile flow along even a blocked plastic stent. A solution for reobstruction by tumor ingrowth is electrocoagulation which, however, has the potential complication of melting and fracture of the stent when the probe is in contact with the stent [19,76,77]. Reentering the stent with plastic stents or catheters through the mesh after dilating the mesh-holes has been advocated by some, but long-term results of these efforts are not known [78,79]. Withdrawal of an occluded plastic stent through the mesh may not always be an easy procedure [80].

Restoring internal bile drainage in hilar disease is more problematic than in distal disease. Tumor overgrowth at the proximal edge of the stent is the most common cause of recurrent jaundice and in these cases the only option is often a percutaneous reintervention. In many cases external catheter drainage of obstructed second order bile ducts, merely to treat septic complications, is the only realistic treatment. Bilateral Wallstents inserted through a single percutaneous approach may hamper reintervention as in plastic stents [20,29,81-83].

Other late complications

Late complications other than reobstruction are rare with Wallstents. Stent migration was a relatively frequent early and late complication with plastic stents. Migration of the Wallstent is, however, very rare and when it occurs this will be during or directly after insertion [21,24,61]. The firm fixation against the wall after release and the incorporation

in the bile duct wall will prevent migration [56]. Acute cholecystitis caused by the Wallstent is rare as with plastic endoprostheses [31,42,45,71,84-86]. The mesh structure of the stent will generally allow drainage through the stent wall. This will in general also prevent pancreatitis [31,59]. A pressure ulcer of the duodenal wall opposite the stent is rare [26,31,45].

7.6 Costs

The use of metal stents results in an at least tenfold increase in the cost of the procedure. The price of a conventional stent ranges between $60-$160 vs the cost of the Wallstents of more than $1000 [87]. However, since reobstruction is encountered less frequently, long-term cost reduction is obtained by a decrease in hospital readmissions for stent change or insertion of other drainage modalities [34-36]. The three randomized comparative studies have demonstrated that the use of the Wallstent is more economical than the use of plastic stents [34-36]. Davids et al. performed an incremental cost effectiveness analysis [34]. In this study initial placement of a metal stent in 100 patients would have prevented 50 endoscopic procedures for reintervention. The other two comparative studies also demonstrated a decrease in the cost of complications when metallic stents were used [35,36]. Despite all this, the short-term economic considerations constitute the major obstacle for widespread use of metal stents. In many institutions, the endoscopic use is therefore limited to patients who require second stent placement due to blocked plastic stents.

7.7 Comparison of the Wallstent with other metal stents

The limited experience with other metal stents and the absence of comparative studies precludes a definite comparison between the Wallstent and other metal stents, but some advantages and disadvantages can be identified. The major disadvantages of the Gianturco-Rösch Z-stent stent are its larger diameter introduction catheter, limited longitudinal flexibility and tumor ingrowth between the struts. The costs of the Wallstent may thereby also be advantageous compared to the Gianturco-Rösch Z-stent, as in most cases one long Wallstent will provide good drainage. With the use of the shorter Gianturco-Rösch Z-stent and also the Palmaz stent more than one stent may be required, making the Wallstent more economical to use [24]. The rigidity makes the Palmaz stent unsuitable for hilar strictures.

The stent design most comparable to the Wallstent is the Strecker stent. The diameter of the introduction catheter is 7-F with both systems and both stents are flexible enough to allow use in angled segments. An advantage of the Strecker stent compared to the Wallstent is that no shortening occurs during release. The Strecker stent has the disadvantage of no intrinsic expanding force. Collapse of the endoprosthesis has been reported in a considerable number of cases [27]. The reported clinical experience with the nitinol coil spring stent is too limited to review its usefulness. Modification of several metal stents have been introduced to overcome some disadvantages, such as tumor ingrowth, but data are lacking to compare these modified stents with the Wallstent.

The Wallstent has several advantages over other metal stents and is, therefore, the stent of choice in percutaneous treatment of malignant biliary obstruction. In the future a modified nitinol Strecker stent with intrinsic radial force or a coated Gianturco-Rösch Z-stent might be alternatives to the Wallstent.

A new development in Wallstent design is the partial covered Wallstent [65]. This will prevent tumor ingrowth, but may have the disadvantage of occluding the cystic duct or segmental bile ducts. There may be a place for a partial coated Wallstent in distal strictures, as tumor ingrowth is the major cause of reobstruction in these strictures. The partial coated Wallstent is not yet available for percutaneous use.

7.8 Conclusion

The introduction of the Wallstent endoprosthesis is a major innovation in stenting of malignant biliary obstruction. Substantial progress has been made in preventing stent blockage by sludge with subsequent increased patency rates. However, the Wallstent is not the ideal endoprosthesis. The ideal stent for the palliative treatment of malignant biliary obstruction should guarantee easy insertion and relief of jaundice until death [88]. Although insertion is facilitated by the Wallstent, reobstruction remains a significant problem. This is predominantly caused by progressive disease. Innovations in stent design, such as partly covered stents to prevent tumor ingrowth, may be a further step towards the ideal endoprosthesis. The problem of proximal overgrowth by progressive disease can only be partially prevented by proximal overstenting and remains a limitation of the success of palliative treatment of hilar strictures.

Although the Wallstent has shortcomings, there are several arguments to support the use of this stent rather than conventional endoprostheses. For percutaneous use, the simplifi-

cation of the placement procedure and the decreased need for reinterventions are of overriding importance. An important argument for both percutaneous and endoscopic use is the more favourable longterm patency rate, resulting in less readmissions, less reinterventions and reduced costs.

7.9 References

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SUMMARY

In *Chapter 1* the aim of the thesis is defined: namely, to evaluate the efficacy of the metallic self-expandable Wallstent endoprosthesis in the percutaneous treatment of malignant obstructive jaundice.

Chapter 2 is an introduction to the important topics in the field of palliative biliary drainage. The three major palliative treatment modalities of malignant obstructive jaundice are discussed: surgical bypass, and percutaneous or endoscopic endoprosthesis insertion. Surgical treatment is generally performed in patients with potentially resectable tumors, or in patients with duodenal obstruction. Most patients will undergo non-surgical techniques employing plastic endoprostheses.
The major drawback to the use of plastic stents is reobstruction caused by sludge blocking the stent, necessitating reintervention. Several factors influencing patency such as stent inner diameter, stent surface area, stent material, and stent design are discussed. Recent studies using optimized plastic stents are described which report a reobstruction rate of 20-40%, with a median patency of approximately five months in distal strictures and approximately three months in hilar strictures. Stent migration is a less common, but significant, drawback in the use of plastic stents.
Against this background of scepticism regarding the use of plastic stents, interest in the use of metal expandable stents in biliary stenting has increased. These stents have the advantage of a small diameter introduction catheter, a large diameter after release, fixed position after release, and a small surface area. The experience with expandable biliary stents predominantly concerns the self-expandable Wallstent endoprosthesis. The percutaneous use of this stent is the subject of this thesis.

Our initial results with the percutaneously inserted Wallstent endoprosthesis in 69 patients with malignant biliary obstruction are described in *Chapter 3*. A distal stricture was present in 41 patients and a hilar stricture was present in 28 patients. The results of the Wallstent with regard to reobstruction by sludge were encouraging, as this did not occur. The problem of reobstruction was, however, not solved as tumor ingrowth, and especially tumor overgrowth, were recognized causes of reobstruction. In distal strictures reobstruction occurred in 2 of 41 patients (5%) after 6 and 12 months, respectively. Reobstruction occurred after a median period of 3.6 months in 8 of 28

patients (29%) with hilar strictures. Use of Wallstents with sufficient length is important. First because the Wallstent will shorten while expanding, and second because long stents will prevent kinking of the bile duct by the straightening force of the Wallstent.

In *Chapter 4*, results of the percutaneously inserted Wallstent in 45 patients with hilar strictures are described. Wallstents were easier to insert than plastic endoprostheses, as the outer diameter of the introduction catheter is smaller than the outer diameter of plastic stents (7-F vs 12-F). Percutaneous placement of more than one stent in hilar strictures is easier performed with Wallstents than with plastic stents.
Reobstruction occurred in 17 of the 45 patients (38%) after a median period of five months. The major cause of reobstruction was proximal tumor overgrowth by progressive disease. This problem can only be partially prevented by overstenting and remains a limitation to the success of palliative biliary drainage. No reobstruction by sludge occurred. Reintervention was performed in 14 patients (31%); this was easier than with plastic stents, as no stent removal was needed. Because stent insertion and reintervention are easier, and reobstruction is not primarily stent-related, the percutaneous use of the Wallstent in hilar strictures is preferred to plastic stents.

Chapter 5 presents our results in 75 patients with distal strictures. As in hilar strictures, insertion and reintervention were easier with the Wallstent than with plastic stents. Reobstruction was rare: occurring in four patients after 21, 127, 176, and 341 days, respectively. Tumor ingrowth was the cause of reobstruction in one patient and bile duct kinking by the stent in another patient. The cause was not established in two patients.
With the use of the Wallstent, definitive palliative biliary drainage could be established in the majority of patients with distal strictures.

The limitations and complications of the percutaneously inserted Wallstent endoprosthesis in 176 patients with malignant obstructive jaundice are discussed in *Chapter 6*. Changes in design have solved initial problems with visibility of the stent during fluoroscopy and stent release of the introduction catheter. Additional expansion of the stent after release makes stent behavior over time somewhat unpredictable, especially in complex stent configurations. For this reason, two parallel stents should be used when more than one Wallstent is needed; in our experience this has proved a stable configuration. Effects of the stent on surrounding structures generally remain restricted to early mucosal destruction and, later, fibrosis. However, in one patient bile

duct perforation occurred, while a duodenal pressure ulcer developed in two other patients. The mesh structure of the stent allows drainage of bile ducts and cystic duct through the stent wall, but tumor progression may interfere with this drainage. In this extended study population, the causes and the occurrence rate of reobstruction are similar to those in the smaller study population described in the previous three chapters.

A review of the literature addressing the Wallstent in malignant obstructive jaundice is discussed in *Chapter 7*. Our results, described in Chapters 3-6, are for the most part confirmed by the results reported in the literature.

Early published experience with the Wallstent endoprosthesis with regard to reobstruction was disappointing as jaundice recurrence and cholangitis occurred in 40% of the patients, with a median patency of 4.5 months in distal strictures and 4 months in hilar strictures. More recent studies, using longer stents, have demonstrated the superiority of the Wallstent endoprosthesis. Numerous uncontrolled series have reported the occurrence of reobstruction after approximately five months in 5-15% of the patients with distal biliary strictures treated by Wallstents. The reobstruction rates of plastic stents and Wallstents in randomised studies are higher: approximately 45% and 25%, respectively. With plastic stents reobstruction occurs in these series after approximately four months and with Wallstents after seven months. The major cause of reobstruction is tumor ingrowth through the mesh of the stent. This problem may be prevented in the future by covered stents. Data on patients with hilar strictures are limited, but also indicate a more favorable patency of the Wallstent. The major cause of reobstruction in this group of patients is tumor overgrowth by progressive disease, which can only be partial prevented by overstenting. The reintervention rate in the reported studies is lower for Wallstents than for plastic stents, while reintervention is facilitated as there is no need for stent removal. The limited reported experience with other metal stents precludes a definite comparison, but the results with the Wallstent seem favorable.

The only major drawback of the Wallstent is the higher short-term costs. The overall costs are, however, reduced as the more favorable patency rate results in less readmissions, less reinterventions and, therefore, reduced long-term costs.

There were no major differences between our results and those reported in the literature. The somewhat unpredictable stent behavior in complex stent configurations is, however, rarely described. This is probably due to the small number of studies concerning patients with hilar biliary strictures. These patients are thereby commonly treated by one stent. Kinking of the hepatocholedochal duct is also seldom reported.

The Wallstent endoprosthesis is for several reasons the stent of choice in the percutaneous palliative treatment of malignant obstructive jaundice. First, insertion and reintervention are easier performed. Second, the reobstruction rate is decreased and reobstruction is mainly due to non stent-related causes. Finally, the overall costs over time are decreased.

SAMENVATTING

In *hoofdstuk 1* wordt het doel van dit proefschrift beschreven, het beoordelen van de effectiviteit van de percutaan geplaatste Wallstent endoprothese bij de palliatieve behandeling van patiënten met maligne obstruktie-icterus.

Hoofdstuk 2 is een beschrijving van de belangrijkste onderwerpen bij de palliatieve behandeling van maligne galwegobstruktie. De drie belangrijkste behandelingsvormen worden beschreven: chirurgische bypass en percutaan of endoscopisch geplaatste endoprothesen (stents). De chirurgische behandeling wordt toegepast bij mogelijk curatief te behandelen patiënten en bij patiënten met duodenumobstruktie. De meerderheid van de patiënten zal echter met niet-chirurgische geplaatste endoprothesen worden behandeld.
Het grootste nadeel van endoprothesen is het optreden van recidieficterus door verstopping van de endoprothese met galmodder. Dit maakt veelal het plaatsen van een nieuwe stent noodzakelijk. Verschillende factoren die van invloed zijn op het ontstaan van verstopping van de endoprothese door galmodder worden vervolgens in dit hoofdstuk beschreven. Het gaat hierbij om de inwendige diameter van de stent, het stent oppervlak, het stent materiaal en het ontwerp van de stent. Recente onderzoekingen met de beste plastic endoprothesen melden een re-obstruktie percentage van 20-40% na een mediane interval van ongeveer vijf maanden bij distale tumoren; bij hilaire tumoren bedroeg dit drie maanden. Een minder frequent probleem bij het gebruik van plastic endoprothesen is dislokatie van de stent.
Gezien de tegenvallende resultaten met plastic endoprothesen, ontstond er een toenemende belangstelling voor het gebruik van metalen expanderende endoprothesen in de galwegen. Deze endoprothesen hebben het voordeel van een kleine diameter van de introduktiecatheter, een grote diameter van de stent na plaatsing, een gefixeerde positie van de stent tegen de wand en een klein stent oppervlak. De ervaring met dit type stents is voornamelijk opgedaan met de zelfexpanderende Wallstent endoprothese. De percutane toepassing van deze endoprothese is het onderwerp van dit proefschrift.

Onze eerste ervaringen met de percutaan geplaatste Wallstent endoprothese bij 69 patiënten met maligne galwegobstruktie worden beschreven in *hoofdstuk 3*. De resultaten van de Wallstent met betrekking tot het optreden van re-obstruktie door

galmodder waren bemoedigend, re-obstruktie door galmodder trad niet op. Het vóórkomen van re-obstruktie was daarmee niet geheel verholpen, omdat tumoringroei en bij hilaire tumoren met name tumorovergroei re-obstruktie veroorzaakten. Bij distale stenosen trad re-obstruktie op bij 2 van de 41 patiënten (5%) na respectievelijk 6 en 12 maanden. Bij hilaire stenosen trad re-obstruktie op bij 8 van de 28 patiënten (29%) na een mediane periode van 3,6 maanden. Het is belangrijk dat Wallstents met een voldoende lengte worden gebruikt. Ten eerste wordt de stent korter tijdens de expansie en ten tweede wordt op deze wijze voorkomen dat de galweg "kinkt" door de longitudinale kracht van de Wallstent.

In *hoofdstuk 4* worden de resultaten van de percutaan geplaatste Wallstent bij 45 patiënten met hilaire galwegstenosen beschreven. Het plaatsen van de Wallstent was gemakkelijker dan het plaatsen van een plastic stent, omdat de buitendiameter van de introduktiecatheter van de Wallstent kleiner is dan de buitendiameter van een plastic endoprothese (7-F versus 12-F). Tevens is de percutane plaatsing van meerdere endoprothesen gemakkelijker uitvoerbaar met Wallstent endoprothesen dan met plastic stents.
Re-obstruktie trad op bij 17 van de 45 patiënten (38%) na een mediane periode van 5 maanden. De belangrijkste oorzaak van re-obstruktie was proximale tumorovergroei door tumorprogressie. Dit probleem is maar ten dele door het gebruik van langere stents (overstenten) te voorkomen. Dit vormt derhalve een beperking van palliatieve galweg-drainage. Er trad geen re-obstruktie ten gevolge van galmodder op. Re-interventie was noodzakelijk bij 14 patiënten (31%). Dit was gemakkelijker uitvoerbaar dan met plastic stents, die immers eerst moeten worden verwijderd.
Bij de percutane behandeling van hilaire stenosen heeft de Wallstent endoprothese om bovengenoemde redenen de voorkeur boven de plastic endoprothese.

In *hoofdstuk 5* worden onze resultaten bij 75 patiënten met distale galwegstenosen beschreven. Ook bij deze patiëntengroep is plaatsing en re-interventie gemakkelijker dan met plastic stents. Re-obstruktie kwam sporadisch voor, namelijk bij vier patiënten na respectievelijk 21, 127, 176 en 341 dagen. Tumoringroei was de oorzaak van re-obstruktie bij één patiënt en "kinken" van de galweg door de stent bij een andere patiënt. Bij de twee andere patiënten werd de oorzaak niet vastgesteld. Met de Wallstent endoprothese kon bij de meerderheid van de patiënten een probleemloze palliatieve galwegdrainage worden bewerkstelligd.

De beperkingen en de complicaties van de percutaan geplaatste Wallstent endoprothese bij 176 patiënten met maligne hilaire of distale galwegobstruktie worden beschreven in *hoofdstuk 6*. De aanvankelijk aanwezige problemen met de zichtbaarheid van de stent tijdens röntgendoorlichting en het loslaten van de stent van de catheter tijdens plaatsing, zijn inmiddels door wijzigingen in het ontwerp verdwenen. De voortgaande expansie van de stent na plaatsing zorgt voor een wat onvoorspelbaar stentgedrag, met name bij complexe stentconfiguraties. Om deze reden verdient het de voorkeur, indien meerdere stents geplaatst dienen te worden, twee parallelle stents te gebruiken. Dit is een stabiele stentconfiguratie gebleken. Effekten van de stent op omgevende structuren blijven veelal beperkt tot destruktie van de mucosa in een vroeg stadium en fibrosering in een later stadium. Bij één patiënt trad galwegperforatie op. Bij twee patiënten was sprake van een duodenumdrukulcus ten gevolge van de stent. Drainage van zijtakken van de galwegen en ductus cysticus is mogelijk door de mazen van de stent. Tumorgroei kan dit echter verhinderen. In de patiëntenpopulatie beschreven in dit hoofdstuk waren de oorzaken en de frekwentie van re-obstruktie ongeveer gelijk aan de kleinere patiëntenpopulatie beschreven in de vorige drie hoofdstukken.

Een literatuuroverzicht van de resultaten van de Wallstent bij maligne galwegobstruktie is het onderwerp van *hoofdstuk 7*. In de literatuur worden onze ervaringen met de Wallstent, zoals beschreven in de hoofdstukken 3 tot en met 6, grotendeels bevestigd.
De eerste gepubliceerde ervaringen met de Wallstent endoprothese met betrekking tot het optreden van re-obstruktie waren teleurstellend. Recidiefícterus en cholangitis traden op bij 40% van de patiënten met een mediane interval van 4,5 maanden bij distale tumoren en 4 maanden bij hilaire tumoren. Recenter onderzoek, waarbij langere stents werden gebruikt, heeft echter aangetoond dat re-obstruktie minder vaak optreedt. Een groot aantal niet-vergelijkende studies melden optreden van re-obstruktie na ongeveer vijf maanden bij 5-15% van de patiënten met distale galwegtumoren. Vergelijkende gerandomiseerde studies melden hogere re-obstruktie percentages van zowel plastic stents als Wallstents, namelijk 45% en 25%. De re-obstruktie treedt op na vier maanden bij plastic stents en na zeven maanden bij Wallstents. De belangrijkste oorzaak van re-obstruktie blijkt tumoringroei door de mazen van de stent te zijn. Het gebruik van beklede stents zal dit probleem mogelijk doen afnemen. De literatuurgegevens over de Wallstent bij patiënten met hilaire tumoren zijn beperkt, maar wijzen ook op een minder vaak optreden van re-obstruktie dan bij plastic stents. De belangrijkste oorzaak voor re-obstructie bij deze groep patiënten is tumorovergroei door progressie van de ziekte. Het gebruik van langere stents (overstenten) kan dit probleem maar ten dele voorkomen. Uit

verschillende studies blijkt dat re-interventie minder vaak noodzakelijk is bij patiënten met Wallstents dan met plastic stents. De re-interventie wordt daarbij vereenvoudigd, omdat geen endoprothese verwijdering nodig is. De gepubliceerde ervaring met andere typen metalen stents is te beperkt voor een grondige vergelijking. De resultaten van de Wallstent endoprothese ten opzichte van andere expanderende stents lijken echter vooralsnog gunstig.
Het enige belangrijke nadeel van de Wallstent, zowel in onze eigen ervaring als in de literatuur, is gelegen in de initieel hogere kosten. De totale kosten per patiënt zijn echter lager, doordat het minder vaak optreden van re-obstruktie minder ziekenhuisopnamen en minder re-interventies tot gevolg heeft.
Belangrijke verschillen tussen onze bevindingen en de literatuur zijn niet aanwezig. Wel wordt het door ons gevonden wat onvoorspelbare stentgedrag bij complexe stent-configuraties nauwelijks beschreven. Dit wordt waarschijnlijk veroorzaakt door het gering aantal studies met patiënten met hilaire galwegstenosen, die dan daarbij veelal met één stent worden behandeld. Ook het "kinken" van de ductus hepatocholedochus ten gevolge van de stent wordt weinig beschreven.

De Wallstent endoprothese is om verschillende redenen de endoprothese van eerste keuze bij de percutane behandeling van maligne obstructie-icterus. Plaatsing en re-interventie zijn gemakkelijker uitvoerbaar, het re-obstruktie percentage is kleiner en de totale kosten per patiënt zijn lager.

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