Palliation of Malignant Extrahepatic Biliary Obstruction With Plastic Versus Expandable Metal Stents: An Evidence-Based Approach

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Malignant extrahepatic (nonhilar) biliary obstruction is associated most commonly with pancreatic adenocarcinoma, but also may result from other pancreatic tumors, ampullary cancer, cholangiocarcinoma, gallbladder cancer, and malignant lymphadenopathy. The incidence of pancreatic adenocarcinoma is increasing, and it is estimated that >28,000 new cases will be diagnosed in the United States this year. Although it is the 10th most common malignancy, it is the 4th leading cause of cancer-related mortality and 2nd most common cause of cancer deaths for all gastrointestinal-related carcinomas.

Most patients with pancreatic cancer present late in their course, have either locally extensive or metastatic disease, and have a median survival of only 4–6 months. At the time of diagnosis, only 10%–20% of patients are candidates for curative resection. Late presentation, aggressive nature, and lack of effective therapies all contribute to the poor prognosis. Biliary obstruction develops in 70%–90% of patients and may lead to secondary complications, including jaundice, pruritus, hepatic cellular dysfunction, cholangitis, malabsorption, and coagulopathy. As a result, in most patients, the primary goal is to relieve biliary obstruction, which can be performed by surgical, radiological, or endoscopic means. These techniques are equally effective at relieving obstructive jaundice, with no difference in overall survival. Endoscopic stent insertion safely and effectively reestablishes bile flow, alleviates jaundice and pruritus, and may improve quality of life (QOL).

Endoscopically inserted plastic or metal stents are technically successful in ~90%–95% of patients with malignant extrahepatic biliary obstruction. Plastic stents commonly are used because of their efficacy and low cost. These stents are exchanged easily as long as duodenal narrowing does not prohibit passage of the endoscope. The major drawback of plastic stents is the formation of a bacterial biofilm, leading to stent obstruction, recurrent jaundice, and occasional cholangitis. As a result, a repeated endoscopic retrograde cholangiogram (ERC) and stent exchange are necessary in 30%–60% of patients with malignant extrahepatic biliary obstruction.

Efforts to prolong the patency of plastic stents have included alterations in stent design and administration of ursodeoxycholic acid, antibiotics, aspirin, or other agents. Unfortunately, these therapies have had minimal impact on stent patency and clinical outcomes. More recently, self-expanding metal stents (SEMS), which achieve a larger luminal diameter, have been used with the goal of prolonging stent patency. Comparative trials showed greater patency and overall cost-effectiveness for SEMS relative to plastic stents because of the need for fewer repeated interventions. However, they offer no survival advantage compared with plastic stents and have an uncertain influence on QOL. Therefore, selection of plastic stents versus SEMS for the relief of malignant extrahepatic biliary obstruction currently is debated.

This review summarizes the endoscopic method for plastic stent and SEMS insertion for relief of extrahepatic malignant biliary obstruction. Publications specific to this topic are reviewed, and evidence-based guidelines for palliation of malignant extrahepatic biliary obstruction in patients who are poor surgical candidates and those with unresectable disease caused by extensive locoregional spread or distant metastases.
regarding the indications, role, and outcomes of plastic versus metal endoscopic stent therapy are developed. Potential future areas of investigation are proposed when evidence is incomplete to base a firm recommendation.

**Review Methods**

A comprehensive literature review was undertaken using Ovid (http://www.ovid.com) and the “explode” version of each of the following key words: plastic stent, metal stent, biliary obstruction, bile duct obstruction, and obstructive jaundice. These terms were used to search MEDLINE from 1960 through 2003. Only studies published in English were included. Results of the search were augmented by a review of the references from each of these reports, with inclusion of additional articles considered germane to the topic.

**Plastic Biliary Stents**

Plastic stents were introduced in 1979 as a means to endoscopically relieve benign and malignant extrahepatic biliary obstruction. Plastic stents are inserted over a guide wire into a position that traverses the stricture, thereby restoring bile flow. They are available in a variety of shapes, lengths, and sizes. Most endoscopists typically use a 10 Fr straight polyethylene stent with side flaps at both ends that inhibit stent migration. A multifactorial process that is influenced by bacteria, proteins, bile viscosity, and stent properties limits the duration of stent patency. This process results in the deposition of sludge, which contains a bacterial biofilm and calcium bilirubinate and calcium palmitate crystals. Stent occlusion typically develops after 3–5 months and predisposes to biliary obstruction and occasionally results in cholangitis, thereby requiring a repeated ERC and stent exchange. The optimal strategy for plastic stent exchange has yet to be determined.

Whereas some endoscopists recommend stent exchange at the earliest sign of obstruction, others advocate prophylactic exchange on a scheduled basis to avoid potential complications of stent occlusion. Acceptance of prophylactic stent exchange is limited by the lack of data showing clinical or financial benefit of this approach and uncertainty regarding the optimal frequency of exchange. Furthermore, studies have shown that an ERC and stent exchange, when performed after the development of stent occlusion, seldom are associated with severe cholangitis. The absence of prospective comparative data limits the strength of either recommendation.

The literature documents a number of measures to attempt to prolong the patency of plastic stents. They include the following measures:

1. Use of larger caliber stents. Comparative trials have shown that stent patency is significantly prolonged by the use of larger caliber stents (10 and 11.5 Fr) versus smaller caliber stents (5, 7, and 8.5 Fr). However, there is no apparent advantage in regard to the use of 11.5 Fr stents compared with 10 Fr stents.

2. Use of stents without side holes. The Tannenbaum stent (Wilson-Cook, Winston-Salem, NC) was designed without side holes, with the goal of reducing turbulence and optimizing bile flow. Although some reported prolonged patency with this stent, others found that neither the lack of side holes nor the use of Teflon itself prolongs stent patency or improves clinical outcome. Furthermore, these stents theoretically may occlude more quickly because of stent impaction against the bile duct wall.

3. Modification of the stent surface. As opposed to the more commonly used polyethylene material, Teflon and other new polymers that are ultrasmooth (low coefficient of friction) may reduce bacterial adhesion and sludge formation, thereby prolonging stent patency. Although in vitro studies have yielded promising results, they have not been duplicated in clinical trials.

4. Varying positioning of the stent. Placement of the distal end of the plastic stent above an intact biliary sphincter has been shown in animal studies to inhibit biofilm formation; however, subsequent human trials failed to duplicate these findings.

5. Administration of choleretic agents and/or antibiotics. Various agents, including ursodeoxycholic acid, antibiotics, and aspirin, have been administered in an attempt to prolong stent patency. Antibiotics have been used for the purpose of inhibiting and/or preventing bacterial colonization, an important early step in the process of stent occlusion. In addition, such choleretic agents as ursodeoxycholic acid or rowachol may be administered to enhance bile flow to improve stent patency. A recent meta-analysis failed to show a benefit of ursodeoxycholic acid and/or antibiotics for the prevention of biliary stent occlusion.

Unfortunately, the only strategy found to reliably prolong stent patency is the use of larger caliber stents. This finding has led to use of SEMS technology.

**Metal Biliary Stents**

More recently, SEMS have been used with the goal of delaying stent occlusion and minimizing the need for reintervention that commonly occurs with plastic stents. SEMS are composed of either stainless steel or
nickel shape-retaining titanium (Nitinol). More recently, covered metal stents have been introduced with the goal of prolonging stent patency by inhibiting tumor ingrowth through the interstices. However, the initial experience suggests that covered stents do not improve patency.60–64 Furthermore, covered stents, in particular, fully covered stents, are prone to early migration. These stents also may occlude the cystic duct or a contralateral hepatic duct, thereby predisposing to secondary complications.61,65 Partially covered stents, although less likely to migrate, are prone to develop a bacterial biofilm in the covered areas and mucosal hyperplasia in the uncovered areas, which induce stent occlusion.61

As opposed to plastic stents, SEMS occlude as a result of: (1) tumor ingrowth through the stent mesh, (2) tumor overgrowth around the proximal or distal end of the stent, (3) mucosal hyperplasia into the stent as a result of a chronic inflammatory reaction to the stent mesh, and, less commonly, (4) biliary sludge.66–68 Therapeutic options for managing SEMS occlusion include mechanical cleaning, insertion of a plastic stent within the SEMS, or deployment of another SEMS within the first. Initial studies suggest a cost benefit for plastic stent insertion to manage SEMS occlusion.59

SEMS are delivered into the bile duct while constrained (“captured”) by a sheath, allowing insertion as a small-circumference delivery system (typically 7.5–10 Fr). When the sheath is retracted, the wire mesh stent expands to a diameter up to 10 mm (30 Fr) when fully deployed. The larger internal caliber relative to plastic stents leads to prolonged stent patency (~5–10 months).20–24 Wallstents (Boston Scientific, Natick, MA) and Diamond stents (Boston Scientific) shorten by one third during deployment. The process of foreshortening necessitates accurate wire positioning and stent measurement. Stents are available from 40–80 mm, allowing tailoring of the stent length to a particular stricture. The Memotherm (Bard, Billerica, MA), Spiral Z stent (Wilson Cook, Winston-Salem, NC), ZA stent (Wilson Cook), and Zilver stent (Wilson Cook) do not foreshorten during delivery (i.e., maintain the same length whether captured or deployed), which may facilitate more accurate insertion. SEMSs are designed to be permanent and are used only in patients with unresectable malignant disease or non–surgical candidates. However, once placed, SEMS occasionally may be removed with difficulty and risk patient injury. Another disadvantage of SEMS is the greater cost relative to plastic stents.

In a retrospective analysis by Schmassmann et al.,25 patients treated with SEMS had significantly longer survival than those receiving plastic stents (6.5 vs. 4.0 months; \( P < 0.05 \)). The investigators used historic controls to compare survival in patients with plastic stents versus SEMS. Although SEMS prolonged survival, better patient compliance is believed to have accounted for their findings. Despite the initial optimism, prospective comparative trials have failed to replicate their findings, and the body of evidence does not support a survival advantage for SEMS.20,23,24,70

**Head to Head Comparative Trials of Plastic Stents With SEMSs for Malignant Extrahepatic Biliary Obstruction**

Five randomized controlled trials20–24 and 1 retrospective study25 compared endoscopically placed plastic stents with SEMS for relief of malignant extrahepatic biliary obstruction. Primary results of these trials are listed in Tables 1 through 5. The most commonly used SEMS is the Wallstent, for which the majority of the literature pertains, including each of the listed studies. These studies uniformly confirm the longer patency of SEMS versus plastic stents in this patient population, with a decreased need for hospital readmission and endoscopic reintervention for recurrent obstruction. Whether these results are applicable to other SEMS is uncertain.

In the initial report from Amsterdam,20 105 patients with unresectable malignant extrahepatic biliary obstruction were randomly assigned to placement of either a metal \(( n = 49 )\) or plastic stent \(( n = 56 )\). Mean duration of patency for SEMS was significantly longer than for plastic stents (273 vs. 126 days; \( P = 0.006 \)). However, survival duration did not differ between groups (median, 149 days). The prolonged patency of SEMSs led to a 28% reduction in ERCS per patient, which, despite the greater cost for SEMS, resulted in an overall cost benefit. They also performed an incremental cost-effectiveness analysis. The cost of an ERC and initial stent placement only differed with respect to the price of the stent: $900 for the Wallstent vs. $20 for the plastic stent. Therefore, the incremental price for placement of a Wallstent versus a plastic stent was $880. The cost was measured relative to stent effectiveness, which was expressed as mean number of ERCS per patient. Initial Wallstent use resulted in 1.3 ERCs/patient compared with 1.8 ERCs/patient for a plastic stent, with a resulting incremental effectiveness of 0.5. The resulting cost-effectiveness ratio therefore was $880 \( \div 0.5 = \$1760/ERC \) prevented. Therefore, the investigators considered placement of a Wallstent more economical when ERC-related costs exceeded $1760/ERC based on their assigned values. Of note, their anal-
Table 1. General Information of Trials Reviewed

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study arm</th>
<th>No. of patients</th>
<th>Type stent</th>
<th>Stricture location</th>
<th>Stent placement successful (%)</th>
<th>Median follow-up (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davids et al.,20 1992</td>
<td>Metal</td>
<td>49</td>
<td>Wallstent</td>
<td>Extrahepatic</td>
<td>100^</td>
<td>124 d (1–450 d)^2</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>56</td>
<td>10 Fr polyethylene</td>
<td></td>
<td>100^</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carr-LOCKE et al.,21 1993</td>
<td>Metal</td>
<td>86</td>
<td>Wallstent</td>
<td>Hilar</td>
<td>98^</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>78</td>
<td>10 or 11.5 Fr</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KNYRIM et al.,22 1993</td>
<td>Metal</td>
<td>31</td>
<td>Wallstent (70%)</td>
<td>Extrahepatic</td>
<td>100^</td>
<td>5 mo^</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>31</td>
<td>Streck-Stent^i (30%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRAT et al.,23 1998</td>
<td>Metal</td>
<td>34</td>
<td>Wallstent</td>
<td>Extrahepatic</td>
<td>97^</td>
<td>143 d (0–596 d)^2</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>34</td>
<td>11.5 Fr polyethylene</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>33</td>
<td>11.5 Fr polyethylene</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KAASSIS et al.,24 2003</td>
<td>Metal</td>
<td>59</td>
<td>Wallstent</td>
<td>Extrahepatic</td>
<td>100^</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>59</td>
<td>10 Fr Tannenbaum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCHMASSMANN et al.,25 1996</td>
<td>Metal</td>
<td>95</td>
<td>Wallstent</td>
<td>Intrahepatic or hilar (28%)</td>
<td>100^</td>
<td>3.3 yr^ (minimum, 1.4 yr)</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>70</td>
<td>10 or 12 Fr polyethylene</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ERCP, endoscopic retrograde cholangiopancreatography.
^Extrahepatic includes strictures in the common bile duct and/or common hepatic duct, does not include strictures in the hilar region.
^Stent placement technically successful irrespective of the success of biliary decompression.
^Three patients (6.1%) required a second ERCP for metal stent placement. Five patients (8.9%) required a second ERCP and 2 patients (3.6%) required a third ERCP for successful insertion of a plastic stent.
^Information given for the combined group (metal and plastic stents).
Information excluded concerning the number of ERCPs required to insert a metal or plastic stent.
^Seven patients (22.6%) in the metal-stent group and 5 patients (16.1%) in the plastic-stent group required combined percutaneous-endoscopic insertion after an initial endoscopic attempt at insertion failed.
^Streck-Stent, Boston Scientific, Natick, MA.
^Information given for the combined group (metal and plastic stents). Of 105 patients initially included, stent insertion failed in 3 patients (2.9%), and they were excluded from the study.
^Stent exchanged (prophylactically) every 3 months with or without evidence of stent dysfunction.
^Stent exchanged (as needed) on evidence of stent dysfunction.
^Information given for the combined group (metal and plastic stents). Three patients (2.5%) required a second ERCP for stent insertion.
^Information given for the combined group (metal and plastic stents). Eighteen patients (10.9%) required a second ERCP (n = 8) or combined percutaneous ERCP approach (n = 10). A nasobiliary stent was initially inserted in 12 patients (7.3%) until non resectability was established, followed by repeated ERCP and successful insertion in all 12 patients.

Analysis did not include the cost of the delivery device, albeit small, which is necessary when deploying a plastic stent.

Their group also attempted to identify factors that may predict stent patency by conducting an univariate analysis after stratifying both treatment groups. Variables correlating with decreased patency were found only in the SEMS group. They included the presence of jaundice for at least 14 days before stent placement (P = 0.01) and a bilirubin value > 300 μmol/L (P = 0.03). Unfortunately, the investigators did not include a complete list of potential prognostic factors evaluated, but only reported those found to correlate with stent patency.

The Wallstent Study Group multicenter trial is the largest comparative study to date, but was published in abstract form only.23 It included 163 patients with either a hilar (n = 48) or common duct (n = 115) malignant obstruction randomly assigned to placement of either a 10–11.5 Fr plastic stent (n = 78) or a Wallstent (n = 86). Unfortunately, details regarding initial stent placement and timing were not included. Of note, 30% of all patients previously had had a plastic stent placed and were returning for stent replacement. Plastic stents were successfully placed in 74 of 78 patients (95%), and SEMSs, in 84 of 86 patients (98%). Although the number of patients who developed stent occlusion before death or at the last follow-up was equal for both groups (10 of 78 patients [13%], plastic; 11 of 86 patients [13%, metal], median time until obstruction was shorter with plastic stents than SEMSs (62 days for plastic vs. 111 days for metal). The 30-day mortality rate (5%) did not differ between groups.

Knyrim et al.22 prospectively randomly assigned 62 patients with malignant common bile duct obstruction to endoscopic insertion of either an SEMS (n = 31) or plastic stent (n = 31). An initial attempt was made to place the stents endoscopically. A combined percuta-
ous-endoscopic approach was performed because endoscopic insertion failed in 7 patients (22%) in the SEMS group and 5 patients (16%) in the plastic-stent group. During the first 30 days after stent insertion, 1 patient with a plastic stent experienced stent migration and no patient in either group developed stent occlusion. Longer follow-up (>30 days) was available for 27 patients in the SEMS group and 28 patients in the plastic-stent group.

Stent occlusion was more common in the plastic-stent (36%) than SEMS group (22%) after a shorter period (4.6 ± 0.7 vs. 6.2 ± 1.9 mo; P = not significant) for the plastic-stent versus SEMS groups, respectively. The re-intervention rate for managing stent occlusion was significantly greater in the plastic-stent group compared with the SEMS group (1.5 ± 0.4 vs. 0.8 ± 0.4 re-interventions; P = 0.038). Duration of hospitalization for stent failure (occlusion and/or migration) was 11.8 ± 3.0 vs. 4.0 ± 1.9 days for the plastic-stent versus SEMS groups (P < 0.05). Comparing cost, their group reported the cost in terms of the Deutsche mark (DM). For the purpose of this review, we converted from DMs to US dollars ($) by using the exchange rate of DM1 = $0.62 from January 1, 1993. The cost of retreatment because of stent failure was significantly greater in the plastic-stent group compared with the SEMS group ($3658 ± $940 vs. $1283 ± $606; P < 0.028). However, there was no significant difference in overall costs (for the stent and hospitalization) between groups ($3720 ± $930 vs. $2480 ± $585) for the plastic-stent versus SEMS groups, respectively.

Subsequently, Prat et al.23 evaluated 101 patients with malignant extrahaepatic biliary strictures. Patients were randomly assigned to placement of either a plastic stent (11.5 Fr, polyethylene) to be exchanged on evidence of dysfunction (n = 33; group 1), a plastic stent to be replaced prophylactically every 3 months (n = 34; group

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**Table 2. Treatment Outcomes**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study arm</th>
<th>No. of patients</th>
<th>First stent occlusion</th>
<th>P</th>
<th>First stent patency (mo)</th>
<th>P</th>
<th>Relief of jaundice</th>
<th>P</th>
<th>Median survival (range in mo)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davids et al.,20 1992</td>
<td>Metal</td>
<td>49</td>
<td>16 (33%)</td>
<td>NR</td>
<td>9.1b (0.5–12.1)</td>
<td>0.0006</td>
<td>47 (96%)</td>
<td>NR</td>
<td>5.8b (0.03–15)</td>
<td>0.45</td>
</tr>
<tr>
<td>Carr-Locke et al.,21 1993</td>
<td>Plastic</td>
<td>56</td>
<td>30 (54%)</td>
<td>NR</td>
<td>4.2b (0.20–16.1)</td>
<td>0.0007</td>
<td>53 (95%)</td>
<td>NR</td>
<td>4.9 (0.5–14.1)</td>
<td>NR</td>
</tr>
<tr>
<td>Plastic</td>
<td>86</td>
<td>11 (13%)</td>
<td>3.7</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Plastic</td>
<td>78</td>
<td>10 (13%)</td>
<td>2.1</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Plastic</td>
<td>31</td>
<td>6 (22%)</td>
<td>6.2 ± 1.9</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Plastic</td>
<td>31</td>
<td>10 (36%)</td>
<td>4.6 ± 0.7</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Plastic</td>
<td>34</td>
<td>NR</td>
<td>NR</td>
<td>4.8</td>
<td>&lt;0.05c</td>
<td>34 (100%)a</td>
<td>NS</td>
<td>4.5</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Plasticf</td>
<td>34</td>
<td>NR</td>
<td>3.2d</td>
<td>33 (100%)a</td>
<td>NS</td>
<td>5.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasticg</td>
<td>33</td>
<td>NR</td>
<td>3.2d</td>
<td>34 (100%)a</td>
<td>NS</td>
<td>4.8</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Kaassiss et al.,24 2003</td>
<td>Plastic</td>
<td>59</td>
<td>11 (19%)</td>
<td>&lt;0.007</td>
<td>Median not reached</td>
<td>0.007</td>
<td>NR</td>
<td>NR</td>
<td>5.1</td>
<td>NS</td>
</tr>
<tr>
<td>Plastic</td>
<td>59</td>
<td>22 (37%)</td>
<td>5.5</td>
<td>NR</td>
<td>NR</td>
<td>3.3</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Schmassmann et al.,25 1996</td>
<td>Plastic</td>
<td>95</td>
<td>16%</td>
<td>&lt;0.005</td>
<td>10d</td>
<td>&lt;0.001</td>
<td>98%</td>
<td>NS</td>
<td>6.5d</td>
<td>&lt;0.05f</td>
</tr>
<tr>
<td>Plastic</td>
<td>70</td>
<td>38%</td>
<td>4.0</td>
<td>95%</td>
<td>97%</td>
<td>88</td>
<td>m</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NR, not reported; NS, not significant.

aRelief of jaundice (biliary decompression) for patients in whom stent insertion was successful.

bConverted to months from reported days by dividing by 30.

cGroup 1 versus groups 2 and 3.

dDecrease in bilirubin level by >20% at 48 hours after stenting and air visualized in bilateral intrahepatic ducts on plain films of the abdomen.

eThe degree to which serum bilirubin levels decreased was similar (metal, 41%; routine exchange of plastic, 34.3%; and as needed exchange of plastic, 35.4%).

fStent exchanged (prophylactically) every 3 months with or without evidence of stent dysfunction.

gData not reported separately.

hStent exchanged (as needed) on evidence of stent dysfunction.

iSubgroup analysis found no significant difference among stricture locations (common bile duct versus hilar or intrahepatic).

jStent placement resulted in an initial decline in bilirubin level >20% of the preintervention value.

kSurvival was similar for both the metal-stent and plastic-stent groups after excluding 29 patients (8 patients, metal stent; 21 patients, plastic stent) who died secondary to untreated stent dysfunction.

lThe improved survival was believed to occur as the result of greater compliance in the metal-stent group.

mJaundice free at 3–6 weeks after stent placement.
2), or a Wallstent (n = 34; group 3). Patients were followed up for a mean of 166 days (range, 0–596 d). The group of patients randomly assigned to elective plastic stent changes or Wallstent insertion had a significantly longer asymptomatic interval (4.8 vs. 3.2 months; *P* < 0.05) and shorter hospitalization compared with the group undergoing on-demand stent exchange. Although those undergoing scheduled plastic stent exchange had a more prolonged symptom-free interval than group 1 (on-demand placement), they also required more ERCs than group 1 (85 vs. 57 ERCs; *P* = 0.05). A cost analysis was performed that considered the expense of the stents, accessory devices, drugs, laboratory, x-rays, anesthetist’s and endoscopist’s fees, and institutional fees. An overall cost advantage was seen for SEMSs versus prophylactic or as-needed plastic stent exchange (median cost, $4643 vs. $6770 vs. $5547, respectively). However, if all patients with survival < 3 months received a plastic stent, the estimated cost would have been $3,715 compared with $4,246 for an SEMS. The calculated difference in costs for patients surviving < 6 months was similar for each group. The investigators concluded that placement of an SEMS is less expensive than placement of a plastic stent in patients surviving > 6 months.

Most recently, Kaassis et al.24 conducted a multicenter study comparing the efficacy and cost of plastic stents and SEMS (Wallstent) in 118 patients with malignant extrahepatic biliary obstruction. Time to initial obstruction was longer for those in the SEMS group versus the plastic-stent group (median not reached vs. 5.5 months; *P* = 0.007). Stent occlusion developed in 33 patients (plastic stent, 22 patients; SEMS, 11 patients). In total, there were 49 episodes of stent occlusion; 37 episodes in the plastic-stent group and 12 episodes in the SEMS group. For this subgroup in which stent occlusion occurred, the number of additional days of hospitalization, duration of antibiotic therapy, and number of ERCs were all significantly (*P* < 0.05) greater in those receiving a plastic stent. There was no difference in duration of survival between groups.

Schmassmann et al.25 conducted a retrospective study involving 156 patients with unresectable malignant extrahepatic obstruction (72%) and intrahepatic or hilar obstruction (28%). They found that SEMS offered more

### Table 3. Adverse Outcomes

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study arm</th>
<th>No. of patients</th>
<th>Perioperative 30-d mortality</th>
<th><em>P</em></th>
<th>Complications</th>
<th><em>P</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Davids et al.,20 1992</td>
<td>Metal</td>
<td>49</td>
<td>7 (14%)</td>
<td>0.04</td>
<td>6 (12%)a</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>56</td>
<td>2 (4%)</td>
<td></td>
<td>6 (11%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cachexia (n = 4)</td>
<td></td>
<td>Cholangitis (n = 6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cardiac failure (n = 2)</td>
<td></td>
<td>Cholangitis/sepsis (n = 1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cholangitis (n = 2)</td>
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<td>Cholangitis (n = 5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cachexia (n = 2)</td>
<td></td>
<td>Cholecyctitis (n = 1)</td>
<td></td>
</tr>
<tr>
<td>Carr-Locke et al.,21 1993</td>
<td>Metal</td>
<td>86</td>
<td>5%</td>
<td>NS</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>78</td>
<td>5%</td>
<td></td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cholangitis (n = 4)</td>
<td></td>
<td>Cholangitis (n = 4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cardiac failure (n = 2)</td>
<td></td>
<td>Cholangitis (n = 10)</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cholangitis (n = 10)</td>
<td></td>
<td>12 (11.9%)b</td>
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</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>31</td>
<td>NR</td>
<td></td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Biliary sepsis (n = 2)</td>
<td></td>
<td>Hemorrhage (n = 1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hemorrhage (n = 2)</td>
<td></td>
<td>Transient renal failure (n = 1)</td>
<td></td>
</tr>
<tr>
<td>Prat et al.,23 1998</td>
<td>Metal</td>
<td>34</td>
<td>3.9% (for all groups)</td>
<td>NS</td>
<td>4 (7%)</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Plasticc</td>
<td>34</td>
<td></td>
<td></td>
<td>Pancreatitis (n = 3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Plasticd</td>
<td>33</td>
<td></td>
<td></td>
<td>Hemorrhage (n = 1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cholangitis (n = 1)</td>
<td></td>
</tr>
<tr>
<td>Kaassis et al.,24 2003</td>
<td>Metal</td>
<td>59</td>
<td>NR</td>
<td></td>
<td>4 (7%)</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>59</td>
<td></td>
<td></td>
<td>Pancreatitis (n = 3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hemorrhage (n = 1)</td>
<td></td>
</tr>
<tr>
<td>Schmassmann et al.,25 1996</td>
<td>Metal</td>
<td>95</td>
<td>2%</td>
<td>NS</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>70</td>
<td>3%</td>
<td></td>
<td>NR</td>
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</tbody>
</table>

NR, not reported; NS, not significant.

aComplications were measured 7 days after the procedure.

bInformation includes combined results of all 3 groups. The cause of morbidity was not given for 2 other patients.

cStent exchanged (prophylactically) every 3 months with or without evidence of stent dysfunction.

dStent exchanged (as needed) on evidence of stent dysfunction.
prolonged stent patency than plastic stents (10 vs. 4 mo; $P < 0.001$) and a decreased need for additional endoscopic procedures (20% vs. 58%; $P < 0.005$). In addition, this is the only study to find a survival advantage for SEMS (6.5 vs. 4.0 months; $P < 0.05$). However, better compliance in the SEMS group is thought to have led to the improved survival duration. An incremental cost-effectiveness analysis also was performed. The cost for the first stent placed only differed with respect to the price of the stent: $900 for the Wallstent vs. $100 for the plastic stent and delivery device. Therefore, the incremental price for placement for use of a Wallstent was $800. The cost was measured relative to stent effectiveness, which was expressed as mean number of ERCs per patient for those receiving a Wallstent (1.2) versus those with a plastic stent ($n = 1.58$). The resulting cost-effectiveness ratio was $800 \div 0.38 = $2105/ERC prevented. Therefore, the investigators concluded that placement of a Wallstent was more economical when ERC-related costs exceeded $2105/ERC based on their assigned values.

**Endoscopic Management of Unresectable Malignant Extrahepatic Biliary Obstruction**

There are no universally accepted recommendations for choosing plastic stents or SEMS for palliating unresectable malignant extrahepatic biliary obstruction. However, most endoscopists use SEMS in patients expected to survive >4–6 months.23,24,65,71–73 This rationale is based on the prolonged patency offered by SEMS, thereby often avoiding the need for a repeated ERC in patients with relatively prolonged survival who outlive the patency of their plastic stent. Use of plastic stents in this setting may lead to greater overall cost because of the expense associated with repeated ERCS and stent exchanges, antibiotic therapy for cholangitis, and resulting

### Table 4. Resource Utilization and Cost Analysis

<table>
<thead>
<tr>
<th>Study arm</th>
<th>Reference</th>
<th>No. of patients</th>
<th>No. of ERCs/patient</th>
<th>Median hospital days (range)</th>
<th>Cost analysis</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal</td>
<td>Davids et al.,20 1992</td>
<td>49</td>
<td>1.3</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Plastic</td>
<td>Knyrim et al.,22 1993</td>
<td>78</td>
<td>NR</td>
<td>0.8 ± 0.4c</td>
<td>0.038</td>
<td>4.0 ± 1.9d</td>
</tr>
<tr>
<td>Plastic</td>
<td>Prat et al.,23 1998</td>
<td>31</td>
<td>1.5 ± 0.4</td>
<td>11.8 ± 3.0</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Metal</td>
<td>Kaassis et al.,24 2003</td>
<td>59</td>
<td>0.1c</td>
<td>1.4d</td>
<td>0.05</td>
<td>NR</td>
</tr>
<tr>
<td>Metal</td>
<td>Schmassmann et al.,25 1996</td>
<td>95</td>
<td>1.2</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Plastic</td>
<td>Schmassmann et al.,25 1996</td>
<td>70</td>
<td>1.58</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
</tbody>
</table>

NA, not applicable; NR, not reported; NS, not significant; ERCP, endoscopic retrograde cholangiopancreatography.

*Total number of ERCPs per patient.
*Cost savings of $1760/ERC prevented.
*Number of repeated ERCP per patient to evaluate and/or treat stent occlusion.
*Hospital duration for stent failure (stent occlusion and/or migration).
*Mean cost of complications, defined by hospital duration. Cost is converted from Deutsche mark (DM) to US dollars by using the exchange rate of DM1 = US $0.62 from January 1, 1993.
*Mean cost of complications and for stents. Cost is converted from Deutsche mark (DM) to US dollars by using the exchange rate of DM1 = US $0.62 from January 1, 1993.
*Analysis of variance.
*Total hospital duration (d).
*Group 1 versus 2, $P < 0.01$; group 2 versus 3, $P < 0.05$; group 1 versus 3, not significant.
*Mean (range) for overall resource utilization costs. Includes cost for stents, accessory devices, drugs, laboratory, x-rays, anesthetist’s and endoscopist’s fees, and institutional fees.
*Stent exchanged (prophylactically) every 3 months with or without evidence of stent dysfunction.
*Stent exchanged (as needed) on evidence of stent dysfunction.
*Results of the cost analysis are not included because of discrepancies in the information provided.
*Cost savings of $2105/ERC prevented.
hospitalization. SEMS may be preferred for patients with impending duodenal obstruction, noncompliant patients, repeated plastic stent occlusion, and those living in a geographically remote location.

Although the majority of patients with newly diagnosed unresectable pancreatic cancer survive for only 4–6 months, a small percentage survive only a few weeks, whereas others live >1 year. This highlights the importance of identifying factors that reliably predict patient survival that can serve as a guide for stent selection. In such an effort, Prat et al.74 evaluated 7 criteria, including patient age, sex, tumor size, tumor histological characteristics, serum bilirubin level, liver metastases, and percentage of weight loss, to determine their value in predicting patient survival. In univariate analysis, only weight loss (P < 0.05) and tumor size > 3 cm (P < 0.01) significantly correlated with survival. In multivariate analysis, only tumor size > 3 cm independently correlated with survival (P < 0.01). Median survival for patients with tumors > 3 cm was 3.2 vs. 6.6 months for patients with a smaller tumor. Therefore, insertion of a plastic stent was recommended for patients with tumors > 3 cm.

More recently, Kaassis et al.24 evaluated 23 variables assessed at the time of study inclusion. They included 8 clinical variables (jaundice, pruritus, cholangitis, hepatomegaly, American Society of Anesthesiologists grade, ascites, vomiting, and pain), 4 ultrasonographic/radiological variables (lymph node metastases, presence of liver metastases, number of liver metastases [0, 1–5, and >5], and size of liver metastases), 8 biochemical variables (total bilirubin level, alkaline phosphatase level, alanine aminotransferase level, α-glutamyl transpeptidase level, hemoglobin level, white blood cell count, creatinine level, and albumin level), and 3 ERC variables (site of obstruction of common bile duct, pancreatic duct obstruction, and duodenal invasion by tumor). By univariate analysis, serum albumin level and leukocytosis correlated (P = 0.05 and P = 0.02, respectively) with survival. However, on multivariate analysis, only the presence of liver metastases independently correlated with survival (P < 0.0005). In their group of 118 patients, median survival of all patients was 4.2 months; 2.7 months in those with hepatic metastasis compared with 5.3 months in patients without hepatic metastasis. Survival did not correlate with type of stent inserted. Although some found tumor size to correlate with survival, their group did not evaluate this factor and therefore can neither support nor refute others’ findings.

Although there is no consensus regarding factors that predict shortened survival, evidence seems to suggest that increased tumor size14,23,74,76–79 and presence of hepatic metastases are useful predictors.14,23,24,48 There also is limited evidence that advanced age,14 male sex,14 hypoalbuminemia,23,80 poor performance status,23 and the choice not to administer chemotherapy81–83 may portend shortened survival. These patients may be served more ideally with plastic stents.

When considering the use of plastic stents or SEMS for palliation of malignant extrahepatic biliary obstruction, it is important to take into account financial aspects. Cost analyses indicate that SEMS are more cost-effective for palliation of malignant extrahepatic biliary obstruction in patients living > 6 months.23,25,84 Arguedas et al.84 used QOL outcome measures to design a cost-effectiveness model and determined that patient survival has the most influence on their decision model. They designed a model of the natural history of pancreatic carcinoma, which is the most common cause of malignant extrahepatic biliary obstruction. They compared 2 strategies: (1) initial plastic stent placement and (2) initial endoscopic SEMS placement. After evidence of occlusion, a plastic stent was exchanged (group 1) or inserted within the SEMS (group 2). Initial insertion of

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**Table 5. Factors Influencing Stent Patency and Patient Survival**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Factors influencing stent patency</th>
<th>Factors influencing patient survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davids et al.,20 1992</td>
<td>Univariate analysisa</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Jaundice (&gt;14 d before stenting; P = 0.01)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bilirubin (&gt;300 μmol/L; P = 0.03)</td>
<td></td>
</tr>
<tr>
<td>Carr-Locke et al.,21 1993</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Knyrim et al.,22 1993</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Prat et al.,23 1998</td>
<td>None (other than stent type)</td>
<td>Univariate analysis</td>
</tr>
<tr>
<td>Kaassis et al.,24 2003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schmassmann et al.,25 1996</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR, not reported.

aVariables associated with decreased patency were identified only in the metal-stent group.
a plastic stent resulted in a total cost of $13,879/patient and 1.799 quality-adjusted life-months compared with $13,466/patient and 1.832 quality-adjusted life-months for initial SEMS use. They determined that SEMS are financially beneficial as long as the SEMS occlusion rate is 1.65 times less than that for plastic stents. They concluded that the ideal cost-savings strategy is to initially place an SEMS, particularly in patients with > 6 months expected survival.

Not only do duration of patient survival and stent patency influence the financial benefit of a particular strategy, but also cost of the SEMS relative to ERC. Yeoh et al.72 compared the cost of 3 strategies for palliating malignant obstructive jaundice that involved initial placement of: (1) a plastic stent, with exchange for another plastic stent on occlusion; (2) an SEMS, with coaxial plastic stent insertion on occlusion; and (3) a plastic stent, with SEMS exchange on occlusion. When the cost of an SEMS is relatively expensive compared with an ERC (cost ratio of SEMS-ERC > 0.7), initial plastic stent insertion is favored (group 1). Conversely, when the cost of an SEMS is relatively inexpensive compared with an ERC (cost ratio of SEMS-ERC < 0.5), initial placement of an SEMS is favored (group 3). They also correlated cost with expected survival and found that for patients surviving < 4 months, initial insertion of a plastic stent is more cost-effective.

Two other trials using the number of ERCs prevented as the primary outcome measure favored the use of SEMS. For the 2 studies, initial use of a plastic stent resulted in a greater total number of ERCs compared with initial SEMS use (1.8 and 1.3 vs. 1.3 and 1.2 ERCs, respectively). Diminished need for a subsequent ERC resulted in a calculated cost-effectiveness ratio of $1760 and $2105 per ERC prevented.20,25 Neither study considered the influence of patient survival in their cost analysis. However, exclusion of this factor is unlikely to have influenced their findings given the similar life expectancy for the plastic-stent and SEMS groups.

Endoscopic biliary drainage not only relieves jaundice and pruritus, but there is increasing evidence that it effectively improves other symptoms and QOL.17–19 Ballinger et al.,17 evaluated 19 patients with pancreatic head cancer before and after insertion of a biliary stent (type unspecified). They assessed symptoms by means of the Rotterdam Symptom Checklist85 (with 2 questions added to evaluate jaundice and pruritus) and the Hospital Anxiety and Depression Scale.86 Biliary stent placement led to significant improvements not only in jaundice and pruritus, but also for other symptoms, including anorexia (at 1 and 12 weeks, P < 0.01), indigestion (at 1 and 12 weeks, P < 0.01), and overall QOL. A later study by Luman et al.18 evaluated 47 patients before and 1 month after stent placement (type unspecified) for extrahepatic biliary obstruction. They were assessed with the aid of the European Organization for Research and Treatment of Cancer QOL questionnaire.87 In addition to the expected improvement in jaundice and pruritus, they also reported significant improvement in emotional (P < 0.01), cognitive (P < 0.01), and global health scores (P < 0.001). Significant improvement in fatigue (P < 0.01), difficulty sleeping (P < 0.01), anorexia (P < 0.001), and diarrhea (P < 0.001) also were noted.

Abraham et al.,19 in addition to quantifying change in QOL after endoscopic drainage, evaluated clinical characteristics to identify those with the greatest negative impact on QOL. A plastic stent was inserted in 50 patients with unresectable extrahepatic and hilar malignant biliary obstruction. QOL was evaluated by means of the 36-Item Short-Form Health Survey questionnaire88 at baseline and 1 month after stent insertion. In both univariate and multivariate analysis, the presence of weight loss and elevated bilirubin level at baseline had the greatest negative impact on preprocedure QOL. Complete follow-up information was available for only 51% of patients. In this subgroup, biliary decompression significantly improved 2 of 8 QOL domains (social function and mental health). This benefit was less pronounced for patients with a baseline bilirubin level > 13 mg/dL. These studies, although varying in methods and measured outcomes, support the contention that endoscopic drainage alleviates many secondary symptoms and improves QOL in patients with malignant extrahepatic biliary obstruction.

**Appraisal of Comparative Efficacy of Plastic Stents versus SEMSs by Using Evidence-Based Medicine Criteria**

The available data are summarized using the classification system (Table 6) and definitions for level of evidence (Table 7) adopted by the American Heart Association. The classification system categorizes data as follows. Class I indicates conditions for which there is evidence or general agreement that a given procedure or treatment is useful and effective; class II, conditions for which there is conflicting evidence or a divergence of opinion about the usefulness/efficacy of a procedure or treatment (class IIa, weight of evidence/opinion is in favor of usefulness/efficacy; class IIb, usefulness/efficacy is less well established by evidence/opinion); and class III, conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and, in some cases, may be harmful. Addition-
Although some found improved outcomes after scheduled prophylactic stent exchange should be performed or stent exchange should be delayed until there is evidence of stent occlusion. For patients with biopsy-proven unresectable malignant obstruction or poor surgical candidates with >6 months expected survival, the weight of evidence favors initial insertion of an SEMS. For patients with expected survival ≤6 months, the literature supports insertion of a plastic stent. In both cases, the level of evidence is category A. SEMS also may be preferred for patients with ≤6 months expected survival in the presence of impending duodenal obstruction, noncompliant patients, repeated early plastic stent occlusion, and those living in geographically remote locations who do not have easy access to health care. The recommended use of SEMS in these situations is not based on formal study, but rather expert opinion (level of evidence category C).

It is unclear whether scheduled prophylactic stent exchange should be performed or stent exchange should be delayed until there is evidence of stent occlusion. Although some found improved outcomes after scheduled stent exchange, others delayed an ERC and stent exchange until after the development of stent dysfunction because doing so seldom leads to severe cholangitis. However, there are too few data from which to make a formal recommendation in this regard. For logistical purposes, patients without readily available stent exchange because of geographic considerations and noncompliant patients also benefit from scheduled exchange of their plastic stents. In addition, it is important to initially insert a plastic stent for good surgical candidates. An exception is when a tissue diagnosis has not been obtained, except in such select cases as poor surgical candidates, especially when imaging studies are highly suggestive of an unresectable malignant process, when surgical intervention is not planned.

The need for preoperative biliary drainage in good surgical candidates with potentially resectable tumors has been debated. Although some found no effect of stent placement on morbidity and mortality, others reported a positive or negative influence on patient outcomes. Recent meta-analyses found neither a beneficial nor harmful effect of preoperative biliary stent placement on the outcome of surgery for patients with pancreatic cancer. The weight of evidence does not support the practice of routine preoperative biliary stent placement in patients with potential resectable tumors who are good surgical candidates. An exception is when a patient’s comfort is compromised because of significant jaundice or pruritus, particularly when surgical intervention will be delayed.

### Future Research

Future research efforts aimed at improving patient outcomes and cost-effectiveness must focus on identifying factors that reliably predict survival and stent patency. This information is crucial in identifying patients who will benefit most from initial placement of an
expandable SEMS, as opposed to those who would be equally well palliated with a less expensive plastic stent. We also must develop new or improve existing technologies to prolong stent patency. Plastic stent patency might be enhanced through various means, including using of larger internal caliber stents, developing self-expanding nonmetallic stents, and creating an ultra-smooth surface design. Future SEMS options may include coated stents that do not migrate. Newer technologies include biodegradable stent material, drug-eluting stents, and removal of larger diameter devices. On the horizon are novel endoscopic approaches for bypassing malignant extrahepatic biliary obstruction, including endoscopic choledochoduodenostomy and hepaticojejunostomy.

**Conclusion**

Comparative trials show the efficacy and safety of plastic stents and SEMSs for relieving malignant extrahepatic biliary obstruction. Neither stent type offers patients a survival advantage. As a result, other factors, such as expected length of survival, QOL, cost, and physician expertise, continue to be important issues in stent selection.

**References**


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