



Self-Expanding Metal Stents in Malignant Biliary Obstruction: Device Selection, Recurrent Obstruction, and Endoscopic Rescue

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Abstract

Background: Malignant biliary obstruction is a frequent consequence of pancreaticobiliary cancer and is often encountered when cure is no longer feasible. Durable biliary decompression is essential for relief of jaundice and pruritus, prevention of cholangitis, preservation of hepatic function, and delivery of systemic anticancer therapy. Self-expanding metal stents (SEMS) have become the principal endoscopic prostheses for palliation, but their clinical performance is shaped by stent design, obstruction level, tumor biology, deployment technique, and the mechanism of recurrent biliary obstruction. **Aim:** To examine SEMS-centered management of malignant biliary obstruction with particular attention to device selection, mechanisms of stent failure, post-deployment optimization, and endoscopic rescue. **Methods:** Evidence from clinical guidelines, randomized trials, cohort studies, systematic reviews, and key technical studies published through 2024 was integrated. **Results:** SEMS provide longer functional patency than plastic stents and reduce repeat procedures in patients expected to survive beyond a short interval. Covered and uncovered designs show different failure profiles: covering limits tumor ingrowth but increases migration, sludge-related dysfunction, and selected adverse events, while uncovered stents resist migration but can become embedded and difficult to revise. Hilar obstruction requires drainage planning based on functional liver volume rather than simple unilateral or bilateral labels. Recurrent obstruction should be treated according to its cause, using endoscopic cleaning, coaxial stenting, exchange of removable covered devices, intraductal ablation in selected patients, or EUS-guided rescue when transpapillary access is ineffective. **Conclusion:** SEMS therapy is best viewed as a longitudinal strategy rather than a single procedure; matching device properties and rescue options to anatomy and expected survival is central to durable palliation.

Keywords: Malignant biliary obstruction, Self-expanding metal stent, Recurrent biliary obstruction, ERCP

Introduction

Malignant biliary obstruction (MBO) is most often produced by pancreatic ductal adenocarcinoma, cholangiocarcinoma, gallbladder cancer, ampullary tumors, or metastatic disease involving the extrahepatic duct or hepatic hilum. The clinical burden extends beyond jaundice. Persistent cholestasis causes pruritus, anorexia, malabsorption, impaired hepatic drug handling, coagulopathy, infection, and progressive functional decline. In advanced disease, drainage is therefore a supportive oncologic intervention: it may permit chemotherapy, reduce the risk of cholangitis, and improve daily symptoms even when it does not alter the underlying cancer. Modern management depends on the level of obstruction, resectability, expected survival, anatomy after surgery, and local endoscopic expertise. [1]

The transition from plastic stents to self-expanding metal stents changed the natural history of palliative biliary drainage. A metal mesh can be delivered through a relatively small catheter and subsequently expand to a lumen substantially wider than that of a plastic prosthesis. The larger diameter delays clogging and reduces repeated endoscopic procedures, an advantage that becomes increasingly important as systemic therapy extends survival. The choice is no longer simply whether to drain, but how to construct a drainage strategy that will remain functional through months of cancer treatment and that can be revised if the first prosthesis fails. [2]

This shift has also exposed clinically important trade-offs. Uncovered SEMS integrate into the duct wall and resist migration, yet tumor or reactive tissue can grow through the mesh. Covered SEMS block ingrowth and may be removable, but the covering can promote migration, food or sludge accumulation, and obstruction of the cystic or pancreatic duct orifices. In hilar disease, the operator must additionally decide how much viable liver to drain and whether side-by-side or stent-in-stent configurations will facilitate future reintervention. These decisions make SEMS therapy a problem of device engineering, anatomy, oncology, and procedural planning rather than a single technical maneuver. [3]



Aim

To critically review SEMS-based management of malignant biliary obstruction, linking stent design and deployment to recurrent obstruction, adverse events, and practical endoscopic rescue strategies.

Research Gap

Most studies compare devices at the moment of first placement, while real clinical benefit depends on the entire course of care: adequate initial expansion, preservation of side branches, compatibility with later reintervention, and the ability to restore drainage after tumor progression. Evidence is also uneven across distal and hilar obstruction, and technical practices such as selective balloon expansion after deployment remain less standardized than stent choice itself. A clinically useful synthesis should therefore evaluate the stent as part of a longitudinal drainage pathway rather than as an isolated implant.

Why Durable Biliary Drainage Matters

The immediate objective of biliary drainage is biochemical and symptomatic recovery, but the broader goal is continuity of cancer care. Hyperbilirubinemia can delay chemotherapy, complicate drug dosing, and worsen nutrition and performance status. Cholangitis can produce emergency admissions, treatment interruption, and death. For patients with unresectable disease, each episode of recurrent biliary obstruction can therefore consume a meaningful proportion of remaining life. Contemporary guidelines frame drainage as a therapeutic endpoint in itself and recommend tailoring the route and prosthesis to obstruction level, resectability, and the expected need for prolonged patency. [4]

Endoscopic retrograde cholangiopancreatography (ERCP) remains the most established route for transpapillary drainage of distal obstruction. When anatomic access is possible, it offers internal drainage without an external catheter and permits tissue sampling and stent placement in one session. European guidance favors SEMS for palliative drainage because of longer patency and fewer reinterventions compared with plastic stents, while also recognizing that short life expectancy, uncertain diagnosis, or a need for temporary drainage may modify this choice. [5]

SEMS Architecture and Expansion Mechanics

A SEMS is a cylindrical metallic lattice, commonly manufactured from nitinol or related alloys, that is compressed within a delivery sheath and expands after release. The final lumen is usually close to 8-10 mm, far exceeding the diameter of standard plastic biliary stents. The mesh pattern, cell size, wire thickness, covering membrane, shortening behavior, radial force, and axial force all influence deployment and long-term function. The device must generate enough outward force to oppose a malignant stricture while remaining conformable enough to follow the bile duct without excessive pressure on adjacent structures. [6]

The earliest metallic biliary endoprostheses established the feasibility of self-expansion for malignant obstruction and demonstrated why a large-caliber lumen could improve drainage. Subsequent designs moved from stainless-steel constructs toward nitinol systems with more predictable deployment and flexibility. These engineering changes are clinically relevant: a stiff stent may straighten the distal duct, impinge on the duodenal wall, or alter the position of its distal end, whereas inadequate radial force may permit persistent waist formation and delayed full expansion across a tight tumor. [7]

Covered devices add a polymeric membrane over all or part of the mesh. The membrane acts as a mechanical barrier against tumor ingrowth, but it also reduces tissue fixation. Fully covered devices are consequently easier to remove or exchange, a major advantage when treatment strategy may change, while partially covered designs attempt to combine resistance to ingrowth with anchoring at uncovered ends. No design eliminates all failure modes, so device selection is best understood as choosing the most acceptable failure profile for a particular patient rather than identifying a universally superior stent. [8]

How Stent Outcomes Should Be Measured

Meaningful comparison of biliary stents requires standardized endpoints. The TOKYO criteria replaced the narrow concept of 'stent occlusion' with recurrent biliary obstruction (RBO), which includes both occlusion and migration, and introduced time to recurrent biliary obstruction as a key time-to-event outcome. This distinction matters because covered and uncovered devices can fail through different mechanisms. A study that counts only luminal occlusion may therefore favor a covered device while overlooking clinically important migration.



Reporting technical success, clinical success, adverse events, cause of RBO, and reintervention provides a more clinically coherent description of stent performance. [9]

Metal Versus Plastic Stents

The strongest practical advantage of SEMS is reduced need for repeat drainage. Plastic stents have a small internal diameter and are vulnerable to bacterial biofilm, sludge deposition, and early clogging. In malignant distal strictures, modern comparative data consistently show longer patency with SEMS and fewer episodes of recurrent obstruction. A 2022 analysis of malignant distal biliary strictures found self-expanding metal stents superior to plastic stents for key clinical outcomes, reinforcing the shift toward metal devices when palliation is expected to extend beyond a brief interval. [10]

Earlier randomized data already showed the same direction of effect. In patients with malignant common bile duct obstruction, metal stents remained functional longer than plastic stents, although the initial device cost was higher. The clinical relevance of this trade-off is straightforward: a more expensive first procedure may still be preferable if it prevents repeated ERCP, anesthesia exposure, hospital visits, and episodes of cholangitis. [11]

Cost should therefore be considered across the whole period of care. A multicenter randomized trial comparing plastic, uncovered metal, and partially covered metal stents found markedly longer functional stent time with both metal strategies; total costs over follow-up were not significantly higher because repeat interventions were reduced. This observation is especially important in health systems where device price can dominate the initial decision even though reintervention is the larger downstream burden for patients and hospitals. [12]

Covered Versus Uncovered SEMS in Distal Obstruction

Covered and uncovered SEMS achieve similar rates of initial biliary decompression, but their modes of failure diverge. In a randomized multicenter study, covered nitinol stents reduced tumor ingrowth but did not deliver an unequivocal global advantage because migration and other causes of dysfunction offset that benefit. The clinical message is that covering changes the mechanism of RBO more consistently than it changes overall survival. [13]

A systematic review and meta-analysis of randomized trials likewise found no simple superiority of one design for all distal malignant strictures. Covered stents reduce ingrowth, while migration, sludge formation, and overgrowth can become more prominent. The balance may favor a removable covered device in a patient likely to undergo reintervention, while an uncovered stent can be attractive when stable fixation is prioritized and the anatomy makes later removal unlikely to be required. [14]

More recent evidence has refined the comparison between fully and partially covered designs. A 2024 meta-analysis found that these devices differ in several mechanisms of recurrent obstruction, but the available evidence does not support treating membrane coverage as the only determinant of patency. Stent platform, anti-migration features, tumor type, duct diameter, and the location of the cystic and pancreatic duct orifices all modify outcomes and should be considered before the device is deployed. [15]

Large cancer-center experience also illustrates the same trade-off. In a cohort of 749 patients, covered and uncovered SEMS had comparable overall patency and survival, but tumor ingrowth was far more frequent with uncovered devices, whereas migration and pancreatitis were more frequent with covered devices. These patterns are useful at the bedside because they identify the complications that should be anticipated and the type of rescue that is likely to be feasible. [16]

Patient and Tumor Factors That Influence Patency

Stent performance is not determined by the prosthesis alone. Tumor bulk, length and tightness of the stricture, residual stones or sludge, stent length, persistent hyperbilirubinemia, duodenal obstruction, and cancer progression can all shorten functional patency. A 2023 study found tumor size, biliary stones or sludge at placement, an 8-cm SEMS, and bilirubin remaining above 2 mg/dL one month after the procedure to be associated with stent dysfunction. These findings support close early biochemical follow-up rather than assuming that technically successful deployment guarantees durable drainage. [17]

A large multicenter analysis of more than 1,400 patients with malignant distal obstruction further showed



that adverse events and RBO are strongly linked to anatomy and device type. An intact papilla, lack of pancreatic duct involvement, and transpapillary SEMS placement were associated with pancreatitis, tumor involvement at the cystic duct orifice predicted cholecystitis, covered devices were associated with food impaction or sludge, fully covered stents with migration, and uncovered stents with tumor ingrowth. The data argue for individualized device selection based on the anatomy visible before ERCP. [18]

Preventing Migration

Migration is one of the defining limitations of fully covered SEMS. Because the covering prevents tissue embedding, the stent can move distally into the duodenum or proximally into the bile duct. Anti-migration strategies include flared ends, anchoring fins, variable radial force, and placement of a coaxial double-pigtail plastic stent. In malignant distal strictures, a randomized study found that an internal anchoring plastic stent can reduce migration of a fully covered SEMS, providing a relatively simple option when the risk of displacement is considered high. [19]

Stent geometry also matters. Comparative work on fully covered devices has shown that anchoring flaps can improve fixation compared with flared ends. Although much of the early design literature included benign strictures, the mechanical lesson carries into malignant disease: secure fixation must be achieved without creating excessive trauma or making later removal impossible. Device selection should therefore account for duct diameter, stricture length, the amount of stent extending below the papilla, and whether future exchange is anticipated. [20]

Sludge, Biofilm, and Duodenobiliary Reflux

Plastic stent occlusion is closely linked to bacterial colonization and biofilm, but biofilm and sludge also remain relevant after SEMS placement. Food material, bacterial products, calcium bilirubinate, and tumor debris can accumulate within the metal lumen, particularly after the papillary barrier has been traversed. Microbiologic studies of biliary prostheses show that polymicrobial biofilm formation is a central process in stent clogging, which explains why mechanical clearance alone may provide only temporary benefit if an underlying reflux problem persists. [21]

Antireflux valves were developed to reduce retrograde entry of duodenal contents into the biliary tree. A randomized trial reported a lower risk of cholangitis with an antireflux metal stent in malignant strictures, supporting the biological plausibility of this approach. In practice, valve design must preserve easy bile flow while resisting food reflux, and any added mechanism can itself become a source of resistance or malfunction. [22]

A separate randomized pilot study of a newly designed antireflux valve stent also demonstrated technical feasibility and reduction in duodenobiliary reflux. These devices are conceptually attractive for patients with recurrent sludge or food impaction, particularly when survival is long enough for reflux-related dysfunction to become clinically relevant. Their uptake has remained limited because results vary across platforms and manufacturing refinements are still needed. [23]

Pilot experience with antireflux metal stents similarly suggests potential value but does not establish a universal first-line role. The broader lesson is that the duodenal environment becomes part of stent physiology once the prosthesis crosses the papilla. Patients with duodenal narrowing, impaired gastric emptying, or repeated food impaction may therefore need both biliary and luminal assessment when RBO occurs. [24]

SEMS Strategy in Malignant Hilar Obstruction

Hilar MBO is fundamentally different from distal obstruction because a single stricture can isolate multiple intrahepatic sectors. Drainage planning should be based on the volume and function of liver that will actually be decompressed. The ASGE guideline suggests bilateral drainage for unresectable malignant hilar obstruction in the absence of liver atrophy, while allowing either endoscopic or percutaneous approaches according to anatomy, expertise, and patient preference. The practical goal is adequate drainage of viable liver without opacifying ducts that cannot subsequently be drained, which can provoke cholangitis. [25]

Asia-Pacific consensus recommendations similarly stress that hilar drainage must be planned from cross-sectional imaging before ERCP. Bismuth classification remains useful, but volumetric thinking is more clinically informative because atrophic, portal-vein-compromised, or extensively tumor-infiltrated segments



may contribute little functional benefit. Selective drainage also affects later chemotherapy, because persistent cholestasis in undrained segments can continue despite an apparently successful stent on fluoroscopy. [26]

The traditional debate between unilateral and bilateral stenting is therefore an imperfect surrogate for a more important question: how much functional liver has been drained? A multicenter randomized trial comparing unilateral and bilateral strategies in unresectable hilar obstruction showed that the drainage plan influences subsequent metal stent placement and clinical outcomes. The decision should be made before contrast injection and should anticipate the route of reintervention if one branch later occludes. [27]

When bilateral metal drainage is chosen, side-by-side and stent-in-stent techniques are both established. A prospective comparison found that both can achieve effective drainage, but they differ in technical sequence and the ease of later access. Side-by-side placement keeps two parallel lumens available but can be demanding at the papilla; stent-in-stent placement uses the cells of the first SEMS to access the second hepatic system and may be limited by mesh geometry. [28]

Meta-analytic evidence indicates that neither configuration is consistently superior across all endpoints. Stent-in-stent may offer higher technical success and fewer early adverse events in some datasets, whereas side-by-side placement has shown longer patency or lower re-obstruction in others. The operator should therefore choose a configuration that fits the hilar anatomy, available stent platform, and local rescue expertise rather than applying one technique to every Bismuth III or IV lesion. [29]

Reintervention planning is particularly important in hilar disease because uncovered SEMS become embedded and crossing an occluded mesh can be difficult. Reviews of ERCP in malignant hilar obstruction recommend mapping the ducts, minimizing unnecessary contrast injection, using guidewire access to planned segments before deployment, and considering whether future stent-through-stent access will remain possible after the first procedure. A technically elegant initial configuration can become clinically poor if it blocks access to an undrained sector later. [30]

Incomplete Expansion and the Role of Balloon Dilation

A newly deployed SEMS may show a residual waist because of severe tumor compression, duct angulation, or the gradual nature of nitinol expansion. Many stents continue to enlarge over several hours, so immediate complete opening is not always required. Balloon dilation can accelerate luminal expansion and may help when the delivery system has crossed a very tight stricture but the stent remains markedly constrained. Evidence in unresectable malignant obstruction shows that balloon dilation before SEMS placement can be performed effectively, yet it also highlights the need to balance easier deployment against bleeding, perforation, and pancreatobiliary trauma. [31]

Post-deployment dilation is less standardized. Mechanistically, a balloon can oppose the mesh to the duct wall, reduce a severe residual waist, and potentially improve immediate bile flow, but it also transmits radial force directly to friable malignant tissue. Dilation should not be automatic. It is most defensible when there is clear fluoroscopic underexpansion associated with poor drainage, when the stent design permits balloon expansion, and when the operator can avoid excessive balloon diameter or pressure. In the absence of such findings, allowing spontaneous expansion may reduce procedural trauma. This remains an area where practice often runs ahead of comparative evidence. [6]

Mechanisms of Recurrent Biliary Obstruction

RBO after SEMS placement should trigger a search for mechanism rather than immediate empiric restenting. Tumor ingrowth, tumor overgrowth beyond the stent ends, sludge, food impaction, migration, kinking, inadequate initial length, and progression in a previously undrained hilar branch require different solutions. Uncovered stents are particularly vulnerable to ingrowth; covered stents are more likely to migrate or accumulate debris. Cross-sectional imaging can identify proximal ductal dilatation or tumor progression, while ERCP defines intraluminal obstruction and permits therapy in the same session. [32]

Malfunctioning SEMS can often be treated endoscopically even when the original device cannot be removed. Techniques include balloon sweeping, mechanical clearance, insertion of a plastic stent through the metal stent, or deployment of a second SEMS coaxially. Covered SEMS may sometimes be removed and exchanged, while embedded uncovered devices usually require an in-stent strategy. Early work on endoscopic



removal and rescue of malfunctioning metallic stents established the practical foundation for this approach and remains directly relevant to current reintervention algorithms. [33]

A broader review of biliary metal stents confirms that device failure is best managed according to the cause and original platform. In an occluded uncovered SEMS, placing a second metal stent can restore a wide lumen but may make later procedures more complex. A plastic stent is inexpensive and easily exchanged but may clog sooner. For a migrated fully covered SEMS, retrieval followed by replacement with a better-anchored design may be preferable. The expected remaining survival and the likelihood of another procedure should shape the rescue choice. [34]

Intraductal Ablation as an Adjunct to Stenting

Endobiliary radiofrequency ablation (RFA) uses a catheter-mounted bipolar electrode to deliver controlled thermal energy to malignant tissue. The technique can be used before stenting to debulk the stricture or within an occluded SEMS to treat tumor ingrowth. A systematic review and meta-analysis found that RFA combined with biliary stenting was associated with improved stent patency and survival compared with stenting alone, although the included studies were heterogeneous and many were nonrandomized. RFA is therefore an adjunct for selected patients rather than a replacement for effective drainage. [35]

Randomized evidence in unresectable extrahepatic cholangiocarcinoma has supported the biological and clinical potential of RFA. A trial comparing RFA plus stenting with stenting alone reported longer survival and acceptable safety. The effect may be greatest when local tumor growth is a dominant cause of recurrent obstruction, while benefit is less certain in rapidly progressive metastatic disease where death is driven by systemic tumor burden rather than local ductal failure. [36]

Photodynamic therapy (PDT) represents a different form of local treatment. After systemic administration of a photosensitizer, intraductal laser illumination produces localized cytotoxicity. Early clinical studies suggested improved palliation and prolonged survival in advanced bile duct cancer, providing proof that local control within the bile duct can have clinically meaningful effects when combined with drainage. [37]

A randomized prospective study of nonresectable cholangiocarcinoma also demonstrated survival benefit with PDT plus stenting compared with stenting alone. The practical limitations are substantial: photosensitivity, cost, specialized equipment, and the logistics of repeated treatment. For that reason, PDT has remained concentrated in selected centers, while RFA has gained wider procedural interest because it is easier to integrate into ERCP. [38]

Radioactive and Drug-Eluting Stent Concepts

Attempts to transform the biliary stent from a passive scaffold into a local anticancer platform have included radioactive seed-loaded devices. A preliminary clinical study of iodine-125 seed-loaded biliary stents reported encouraging patency and survival outcomes compared with conventional stents. The concept is attractive because continuous low-dose radiation is delivered directly to the tumor while maintaining ductal drainage, potentially limiting local ingrowth. [39]

A later comparative study of percutaneous stenting with or without iodine-125 seeds also reported improved outcomes in malignant biliary obstruction. These approaches remain outside routine endoscopic practice because dosimetry, radiation handling, device standardization, and access route vary among centers. Drug-eluting stents have faced similar barriers: local drug delivery is biologically appealing, but consistent gains in patency or survival have not yet matched the simplicity and reliability required for widespread adoption. [40]

EUS-Guided Rescue and the Changing Role of ERCP

When ERCP fails because the papilla cannot be reached or cannulated, endoscopic ultrasound-guided biliary drainage (EUS-BD) has become a major alternative to percutaneous drainage. EUS-guided choledochoduodenostomy, hepaticogastrostomy, rendezvous, and antegrade techniques create internal drainage pathways that bypass the obstructed papilla. The ESGE therapeutic EUS guideline recognizes EUS-BD as an established rescue approach in expert centers, and the availability of dedicated SEMS and lumen-apposing metal stents has improved technical reproducibility. [41]

Comparative evidence after failed ERCP favors EUS-BD over percutaneous transhepatic drainage in appropriately equipped centers. A systematic review found similar technical success but higher clinical success,



fewer adverse events, and fewer reinterventions with EUS-guided drainage. This matters for patients with advanced cancer, because an external catheter can impair mobility, sleep, body image, and quality of life, while repeat exchanges create additional procedural burden. [42]

The role of EUS-BD is now moving from rescue toward primary drainage for distal MBO. A 2024 meta-analysis of randomized trials found similar technical and clinical success compared with ERCP, with lower risks of reintervention, post-procedure pancreatitis, and tumor-related stent dysfunction and a shorter hospital stay. These findings do not make ERCP obsolete, but they expand the menu of first-line strategies when expertise in therapeutic EUS is available. [43]

A second 2024 meta-analysis focused on primary malignant distal obstruction reached a similar conclusion: EUS-BD achieved comparable drainage with an almost absent risk of procedure-related pancreatitis and lower stent dysfunction. The choice between ERCP and EUS-BD should therefore consider papillary accessibility, duodenal invasion, anticipated tumor progression, the desired stent route, and the operator's ability to manage EUS-specific adverse events. [44]

SEMS in the Neoadjuvant and Potentially Resectable Setting

Metal stents are increasingly used before surgery when prolonged preoperative drainage is required, especially during neoadjuvant therapy. In pancreatic cancer, patients may remain jaundiced for weeks or months before resection, and plastic stent failure can interrupt chemotherapy or lead to cholangitis. Cohort data have shown favorable outcomes with SEMS in this setting, including fewer episodes of obstruction without clear evidence that the metal prosthesis prevents subsequent surgery. [45]

Systematic review data in pancreatic cancer undergoing neoadjuvant chemoradiotherapy also favor metal over plastic stents for reducing recurrent obstruction and reintervention. This is a clinically distinct population from purely palliative disease: the stent must remain reliable during oncologic treatment but should not complicate the planned operation. Covered SEMS are attractive because they are removable, although the final choice depends on surgeon preference, anatomy, and whether the stent will traverse the future resection field. [46]

Preoperative drainage should not be performed reflexively in every jaundiced patient. Meta-analytic data show that routine biliary stenting before immediate surgery can increase infectious and procedural complications in some settings. Drainage is most defensible when cholangitis is present, bilirubin is very high, surgery will be delayed, neoadjuvant therapy is planned, severe pruritus is present, or hepatic dysfunction prevents safe treatment. The device should therefore be selected only after the treatment timeline is known. [47]

Clinical Follow-up After SEMS Placement

Technical deployment is only the first checkpoint. Clinical success should be confirmed by symptom improvement and a clear fall in bilirubin, while fever, pain, or persistent jaundice should prompt early evaluation for incomplete drainage, cholangitis, cholecystitis, pancreatitis, or stent underexpansion. The ACG guideline on biliary strictures underscores the importance of matching drainage to anatomy and maintaining a high index of suspicion for complications when biochemical improvement does not occur as expected. [4]

For longer-term follow-up, patients and oncology teams should be given a simple failure plan: recurrent jaundice, dark urine, fever, rigors, pale stools, or worsening pruritus warrant urgent reassessment. Imaging should determine whether the original drainage territory is dilated and whether new segments have become obstructed. A rapid pathway back to ERCP or EUS can prevent sepsis and reduce interruptions in anticancer therapy. The value of SEMS lies not only in longer median patency but also in making the entire drainage pathway predictable and recoverable when failure eventually occurs. [48]

Quality of Life and Treatment Continuity

For advanced pancreaticobiliary cancer, patient-centered benefit is often better captured by days free of jaundice, infection, hospitalization, and external drains than by small differences in laboratory values. MBO can markedly impair quality of life, and durable internal drainage can restore appetite, sleep, mobility, and tolerance of systemic therapy. Reviews of malignant biliary obstruction consistently place symptom control and treatment continuity at the center of palliative endoscopy, which is why minimizing avoidable reintervention is a clinically meaningful endpoint even when overall survival is dominated by cancer biology. [49]



The same principle explains why local expertise should influence the initial choice. A sophisticated hilar SEMS configuration or EUS-guided bypass is only valuable if the center can rescue it when complications occur. Conversely, a technically simpler strategy that permits reliable reintervention may be preferable in a patient expected to receive prolonged therapy. The best stent is therefore the device embedded within the best service pathway: appropriate imaging, experienced deployment, structured follow-up, and immediate access to rescue drainage. [50]

Stent Length, Position, and Side-Branch Preservation

Stent length should cover the entire malignant stricture with an adequate margin while avoiding unnecessary extension across normal duct. A short device risks tumor overgrowth at the proximal or distal end; an excessively long device can complicate access to the cystic duct, pancreatic duct, contralateral hepatic ducts, or future surgical planes. Distal positioning also deserves attention. Too much intraduodenal protrusion can promote food impaction or mucosal trauma, while a proximal position that barely traverses the stricture can become ineffective as the tumor progresses. In practice, fluoroscopic measurement should be integrated with cross-sectional imaging and the anticipated direction of tumor growth rather than based on a single cholangiographic frame. [17]

Side-branch preservation is particularly important when a covered SEMS is used. If the cystic duct orifice is involved by tumor, a covering membrane may further impair gallbladder drainage and increase the risk of cholecystitis. In the distal duct, transpapillary stenting can also compress the pancreatic orifice and contribute to post-ERCP pancreatitis in susceptible anatomy. The 2024 multicenter adverse-event study provides a practical framework: tumor involvement at the cystic duct orifice was strongly linked to cholecystitis, while an intact papilla and lack of pancreatic duct involvement were associated with pancreatitis. These relationships should be reviewed before the stent is released because they are difficult to reverse once the device has fully expanded. [18]

Cholecystitis, Pancreatitis, and Procedure-Related Harm

Cholecystitis after SEMS placement is clinically important because it can convert a palliative procedure into an urgent drainage problem. The risk is not determined by coverage alone; tumor invasion of the cystic duct orifice, gallbladder opacification, and anatomic obstruction of the cystic duct are major contributors. When high risk is recognized, the operator should minimize unnecessary contrast filling of the gallbladder and consider whether an uncovered device or a covered design that avoids the cystic duct orifice is feasible. Once cholecystitis develops, antibiotics alone may be insufficient, and percutaneous or EUS-guided gallbladder drainage may be required in patients who are poor surgical candidates. [18]

Post-ERCP pancreatitis remains another relevant adverse event in distal obstruction. The mechanism may include papillary trauma, pancreatic duct compression by the expanding metal stent, contrast injection, or difficult cannulation. Covered SEMS have shown higher pancreatitis rates in some comparative studies, although patient anatomy modifies the risk substantially. Standard ERCP prevention measures still apply, including careful cannulation technique and evidence-based prophylaxis when appropriate. From a device perspective, the key point is that a stent chosen solely for long-term patency may be suboptimal if it creates an avoidable early complication that delays chemotherapy or prolongs hospitalization. [16]

A Practical Reintervention Algorithm

A structured approach to recurrent obstruction can shorten the time from presentation to effective drainage. First, define whether the problem is intraluminal, migratory, or anatomically new. Sludge and food impaction can be treated by balloon sweeping and irrigation, followed by assessment of the underlying stent. Tumor ingrowth through an uncovered SEMS usually requires coaxial placement of another stent, whereas overgrowth may require extension beyond the involved end. A migrated fully covered device should be retrieved when possible and replaced with a more stable platform. If transpapillary access is impossible or the duodenum is obstructed, EUS-guided drainage can bypass the failed route. [33]

Reintervention also provides an opportunity to reconsider the original strategy. Repeated short-lived plastic stents inside an occluded SEMS may be reasonable for a patient with very limited survival, but a second SEMS may be preferable when several months of treatment remain. In hilar obstruction, reintervention should target



the liver segment responsible for persistent cholestasis rather than simply reopening the easiest duct. The operator should avoid creating additional undrained contrast-filled segments and should preserve guidewire access across complex mesh whenever possible. When tumor ingrowth repeatedly compromises the lumen, RFA can be considered before restenting in carefully selected patients. [30]

Future Directions

Future stent development is likely to focus on controlled radial and axial force, antireflux function, more reliable anti-migration systems, biodegradable or selectively removable coverings, and surfaces that resist bacterial adhesion. Clinical trials should report time to recurrent biliary obstruction, mechanism of failure, number of reinterventions, days outside hospital, ability to deliver planned chemotherapy, and quality of life rather than relying only on technical success. More head-to-head studies are also needed to define when post-deployment balloon expansion adds benefit and when it simply adds trauma. [9]

The rapid growth of therapeutic EUS will also change how SEMS research is framed. Transpapillary and transmural stents have different exposure to tumor ingrowth, papillary reflux, pancreatitis, and migration. Future algorithms may select the drainage route first and the stent platform second, especially in distal obstruction with duodenal invasion or difficult papillary access. Trials comparing ERCP with EUS-BD should include rescue complexity and subsequent oncologic procedures so that technical success is not mistaken for durable clinical benefit. [43]

Conclusion

Self-expanding metal stents are central to modern palliation of malignant biliary obstruction, but durable success depends on more than choosing metal over plastic. The level of obstruction, expected survival, tumor behavior, membrane coverage, mechanical properties, side-branch anatomy, and feasibility of later rescue all influence outcome. Covered and uncovered devices exchange one set of failure mechanisms for another, while hilar disease requires planned drainage of functional liver rather than a purely numeric approach to stent number. Recurrent obstruction should be treated according to cause, with cleaning, exchange, coaxial stenting, intraductal therapy, or EUS-guided drainage used selectively. A longitudinal strategy that anticipates failure at the time of the first ERCP offers the best chance of sustained biliary decompression and uninterrupted cancer care.

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