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To Stent or Not to Stent: An Evidence-Based Approach to Palliative Procedures at the End of Life

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Abstract

Patients near the end of life often undergo invasive procedures, such as biliary stenting for obstructive jaundice, with the intent of relieving symptoms. We describe a case in which the medical team and a patient and family are considering a second palliative biliary stent despite the patient's limited life expectancy. We review available evidence to inform the decision, focusing on the specific question of whether the benefits of palliative biliary stents in patients with advanced cancer outweigh the risks. We then apply the evidence to the issue of how the primary and/or palliative care team and the interventionist communicate with patients and their families about the risks and benefits of palliative procedures. Review of the evidence found several prospective case series without control groups that measured patient-centered outcomes. Studies had high attrition rates, results for improvements in symptoms and quality of life were mixed, and rates of complications and short-term mortality were high. In conclusion, the limited evidence does not support that the benefits of palliative biliary stents in this population outweigh the risks. We propose that primary care teams consider and discuss the larger picture of the goals of care with patients and families when considering offering these procedures, as well as benefits and potential harms, and consider involving palliative care services early, before consultation with an interventionist.

Keywords

Biliary stenting; palliative care; palliative procedures; advanced cancer; end of life; obstructive jaundice

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Disclosures

The authors declare no conflicts of interest.

Introduction

The Case

Mrs. W. is a 78-year-old woman with cholangiocarcinoma, first diagnosed a year ago and involving the porta hepatis. She declined surgery but opted for chemotherapy. She has undergone multiple courses of chemotherapy with some response but on a recent scan was found to have progression with new pulmonary nodules.

Over the past six months, Mrs. W. has had five subsequent hospitalizations for jaundice, with biliary stent placement and/or revision by both gastroenterology and interventional radiology. She has received eight cycles of gemcitabine but has had to undergo dose reduction because of thrombocytopenia and fatigue. During her most recent oncology visit, she was feeling even more fatigued, with abdominal bloating and poor appetite. She had been resting in bed about 50% of the time and was having four to five loose stools each day. On exam, she was cachectic, with a moderately distended abdomen. Her oncologist did not recommend further chemotherapy at this time and discussed home hospice. The patient agreed with the oncologist's recommendation. Her daughter and son-in-law, her main caregivers, were not present.

She is now admitted to the general medicine service again, presenting with jaundice and worsening upper abdominal pain. Her daughter states that they did not start hospice because she wants her mother to come to the hospital for her fevers. Her last stent procedure was approximately three weeks prior. During this admission, she undergoes stent placement by gastroenterology to the left biliary tree, but the right biliary tree is unable to be drained because of tumor progression. Gastroenterology then refers the patient to interventional radiology for percutaneous drainage of the right side. The patient currently has an internal-external drain there, so interventional radiology decides to revise that. After the stent revision, the patient remains markedly fatigued with no appetite.

At this point, the general medicine team is concerned that the patient is no longer benefiting from the repeated biliary stent placements and that her quality of life (QOL) is poor. The gastroenterologists and the interventional radiologists are willing to continue with additional procedures for now but also think it would be reasonable to stop intervening. The daughter states that these biliary stents help her mother to feel better. The patient is deferring decision making to her daughter but does state that she is tired and does not want aggressive treatments at this point.

The team asks the following questions: What is the evidence on the risks and benefits of palliative biliary stenting in a patient like Mrs. W.? How should we use this evidence to approach the decision-making process with this patient, her daughter, and the interventional radiologist?

Biliary Stenting

Patients with advanced illnesses frequently have symptoms that might be improved by invasive procedures, such as percutaneous gastrostomy tubes for drainage with malignant bowel obstruction, or indwelling drainage catheters for pleural effusions. Often, little

evidence exists on the risks and benefits of palliative procedures in patients near the end of life or on comparative effectiveness of noninvasive alternatives for symptom management. Because of lower functional reserve and higher disease burden, these patients may be more likely to suffer complications from procedures and less likely to regain prior functional status after a stressful procedure or complications.

Biliary stenting is a frequently performed palliative procedure for relieving obstructive jaundice in advanced cancer. Biliary obstruction may be associated with pruritus, jaundice, nausea, and anorexia. Stent procedures involving internal (endoscopic) or external (percutaneous) drainage are used to reduce elevated bilirubin levels to reduce symptoms, as well as to enable future chemotherapy.¹ However, these procedures also have common complications, including biliary leaks, infections, hemorrhage, perforation, and stent migration causing duodenal obstruction.² Stent occlusion and recurrent jaundice, leakage, or infection are common and lead to consideration of stent revision/replacement.³ This may require urgent procedures or repeat hospitalizations, which can cause further complications and burden.

To address the key issue for this case, we asked the following question: What is the evidence for the risks, benefits, and general approach to biliary stenting in patients with advanced cancer, including outcomes such as survival, disease progression, receipt of further chemotherapy, QOL, symptoms (pruritus, abdominal pain, and anorexia), and complications? We performed a literature search directed at this question, described the relevant evidence, and critically appraised two key articles. We then addressed the implications of our findings through a general approach to decision making in palliative procedures and coordinating with interventionists near the end of life.

Methods

Literature Search

We performed a search in MEDLINE and the Cochrane Database for peer-reviewed English language articles from 1995 through November 2010. We conducted searches using the search term “biliary stent*” with the search terms “palliative,” “quality of life,” or “symptoms” or the MeSH term “Palliative Care” [MeSH]. We cross-referenced the palliative care terms with search terms for the relevant subspecialists, “gastroenterologist*” and “interventional radiologist*.” We included studies with outcome data addressing the risks and benefits of biliary stents in patients with advanced disease and studies comparing biliary stenting with noninvasive approaches to palliating obstructive jaundice. We included only studies that had data on survival/disease progression, receipt of chemotherapy, QOL, symptoms, and/or complications, and excluded studies that only addressed bilirubin levels or successful biliary drainage because guiding therapy for patients with limited life expectancy requires patient-centered outcome data.

We evaluated the data for both patient-reported benefits (QOL and symptoms) and risks (complications and mortality), focusing on studies designed to evaluate these issues in patients with advanced disease. We also selected one study and performed a critical

appraisal of the methods, including inclusion and exclusion criteria, power, and selection of measurement instruments.

Results

What Is the Evidence for Benefits and Risks of Biliary Stents in Advanced Disease?

Benefits: QOL and Symptoms—We identified a number of studies examining stent outcomes for malignant biliary obstruction; however, most focused on comparisons among surgical, percutaneous, and endoscopic drainage, or metal vs. plastic stents, and did not collect patient-oriented data.^{4–6} Only one of the trials comparing percutaneous with endoscopic stenting measured QOL outcomes over time.⁷ Neither study arm ($n = 27$ in each) showed significant changes after stenting on either the overall World Health Organization Quality of Life Questionnaire or the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30 (EORTC QLQ-C30) at one month follow-up; of nine symptom scores, only fatigue in the percutaneous arm was significantly improved.

We identified four studies evaluating QOL and symptoms. All were single-arm case series with no control group and only reported changes over time after stenting; we identified no studies comparing stenting with a palliative noninvasive approach. Luman et al.⁸ described 47 patients with jaundice as a result of extrahepatic biliary malignant strictures and unresectable disease. They were assessed at baseline (within 48 hours of stenting) and one month after endoscopic stenting with the EORTC QLQ-C30 and two questions assessing jaundice and pruritus. Thirty-eight patients completed the study; nine died before the one month assessment. The study found significant improvement in emotional, cognitive, and global health ($P < 0.01$) in the patients who survived to follow-up, improvement in pruritus and jaundice ($P < 0.01$), and improved anorexia, diarrhea, and sleep ($P < 0.01$). A study of endoscopic stents in 40 patients with malignant biliary obstruction⁹ found statistically significant improvements after two weeks in EORTC QLQ-C30 global health function (from 30 to 48; $P = 0.003$) and in symptoms, including pain and pruritus. A third study examined 109 patients (94% with advanced disease) and found a statistically significant improvement in pruritus at one month (2.26–0.75; $P < 0.01$), using a visual analogue scale, but a significant decrease in QOL (101.3–94.7; $P < 0.01$), using the Functional Assessment of Cancer Therapy-Hepatobiliary instrument.¹⁰

The final study by Abraham et al.¹¹ assessed 50 patients with inoperable disease and malignant obstruction but without overt liver metastases, at baseline and one month after endoscopic stent insertion using the SF-36[®] QOL questionnaire. Complete outcome data were available on only 51% of patients: six patients died before the one month visit, six were withdrawn because of stent blockage, one had stent dislodgement, two declined follow-up, and three underwent surgery before the one month mark. Patients with successful drainage (78% of patients), defined as a 20% drop in bilirubin seven days postprocedure, had significant improvement in QOL in social function and mental health but no significant change in the other six domains, including pain or physical functioning. Patients with baseline bilirubin < 13 mg/dL also had a statistically significant improvement in social function scores but none in other domains.

This study had several limitations similar to the other three studies and several additional methodological issues. In several studies, baseline symptom and QOL measurement could have been performed right after the procedure, when patients could have had procedure-related symptoms. In all these studies, significant attrition and the lack of a control group are major limitations; QOL often improves significantly over time in responders in palliative care studies with high attrition. Abraham et al. also did not report overall results but excluded patients with stent blockage and only reported outcomes for patients with successful drainage, rather than an intent-to-treat analysis or results for the available sample. Finally, the QOL questionnaire, the SF-36, was designed for the general population and may not be sensitive enough to pick up subtle QOL changes in terminally ill cancer patients. Improvements were seen only in social function scores, likely unrelated to stenting.

Risks: Complications and Mortality—Studies demonstrate high complication rates and significant short-term mortality in patients receiving biliary stents, with 30 day mortality ranging from 10% to 43%.^{10,12,13} Of two studies that we identified describing complications, a prospective trial¹² found that 63% had major complications, defined as complications requiring more than one night postprocedure hospitalization, and 31% had minor complications. Two percent died as a result of the procedure, one patient from an arterial bleed and one from sepsis. The second study, a retrospective analysis,¹³ found that patients required a mean of 2.4 procedures and found a 62% incidence of complications, including a 19% incidence of cholangitis; 10% of patients died during the hospitalization for the procedure.

Discussion

In limited uncontrolled studies, we found mixed results for the benefits of percutaneous or endoscopic biliary stenting in advanced disease, with high rates of complications. Of four case series that focused on QOL and symptoms in patients with advanced disease, two showed improvements in both QOL and symptoms, one did not report overall outcomes but did not show relevant benefits in a limited group, and one showed a significant improvement in pruritus but a significant decrease in QOL. Short-term mortality was high, and patients' survival was limited; two-thirds of patients had complications, often requiring postprocedure hospitalizations.

The mixed findings on QOL, despite some improvement in pruritus, may be attributable to patient selection (in studies that reported the indication for the procedure, the indication for most patients was not pruritus), the burden and complications of the procedure, and the advanced stage of patients undergoing these procedures, as well as methodological limitations of the studies. Discussion with Mrs. W. and her surrogate would present the low-quality mixed evidence for improved symptoms and QOL with this intervention, and evidence that complications are frequent and significant, and could cause further decline. Additionally, shared decision making would include discussion of noninvasive symptom management options and focus on goals of care. This would put any anticipated benefits of repeating a stent procedure into perspective.

Although we did not identify any studies analyzing the decision to provide palliative biliary stenting, this situation is analogous to the decision on whether to insert a percutaneous endoscopic gastrostomy (PEG) for artificial feeding. For PEG placement, existing guidelines encourage dialogue between gastroenterologists and their referring colleagues about immediate and long-term risks and benefits at the time of referral¹⁴ and suggest that interventionists take more responsibility for the decision beyond providing the technical expertise.^{15,16}

Rabeneck et al¹⁵ proposed an algorithm for PEG decision making that has many similarities to biliary stenting. They base their guidelines on principles of patient benefit, from the strictest definition of physiological benefit for a patient who is well but cannot eat and then increasing by steps as clinical benefit becomes more uncertain. In some situations, there is no benefit and the procedure should not be offered: in the PEG example, this is the patient with anorexia-cachexia syndrome but no dysphagia; a PEG tube will not improve nutritional status (the premise of physiological benefit) or QOL. In other situations, such as a permanent vegetative state, a PEG tube may provide physiological benefit but offers no improvement in QOL; in this situation, the decision depends on patient/family preferences. There are circumstances when the benefits of the procedure are clear, such as a patient with significant life expectancy but difficulty taking in nutrition, and others where the risks and benefits of the procedure are equivocal. The authors challenge the premise that gastroenterologists are simply providing a technical service and encourage both referring physicians and gastroenterologists to use their guidelines and provide both directive and collaborative counseling to patients and families. As with the difficult decision to place a PEG tube, the patient's and family's expectations, and the risks/benefits of a procedure, should be carefully reviewed in advance of sending the patient to the interventional radiology suite. Campbell and Roenn¹⁷ propose a palliative care-oriented framework for the interventional radiologist to use goals of care to discuss the appropriateness of procedures with patients.

When faced with a patient with advanced illness or frailty and a potentially correctable problem, it is tempting to consult a specialist with a question such as “Should this patient have a stent?” However, for patients with advanced illness and frailty and potentially limited prognosis, or when considering procedures with poor risk/benefit profiles, the primary care team should take responsibility for considering the big picture. An intervention-oriented specialist usually does not have the training or assume the role of judging the overall benefits of the procedure on the patient's health and how it fits in with the patient's overall goals. Interventionists usually focus their discussion on the informed consent process and risks of the procedure, assuming that the primary care team has already considered the patient's prognosis, goals of care, and potential to benefit from the procedure. Understanding these realities, the primary care team should not consult a specialist until they are reasonably confident that the procedure, if done, could benefit the patient and that the benefit-risk ratio fits with the patient's preferences. If this is not clear, the consult could be framed as informational in nature: “Can you quantify for us the risks and benefits of this procedure for this patient and the likelihood of success?” The team could also consider a palliative care consult to help address these larger issues.

In the case of Mrs. W., the primary care team, when possible with the help of palliative care consultants, should take the lead in any discussion about the risks and potential benefits of another biliary stent, with input from the interventionist and any other consultants. The issue of pain must be addressed, informing the patient and family that pain can be aggressively managed with or without stent placement. Unless he or she has had special training in the discussion of end-of-life issues and pain control, the interventional radiologist may not be comfortable addressing these larger concerns and may feel that these are issues for the primary and palliative care teams. The long-term (days to weeks) risks and benefits of the procedure need to be presented to the patient and family before the procedure is scheduled; in our current system, the interventionist's role is to inform them of the more immediate risks. Primary care teams should also discuss with the patient/family their overall goals of care in light of having a limited prognosis and place the intervention within that framework. Palliative care consultants can help primary teams with these complex conversations. In this case, the team should facilitate a discussion with Mrs. W. and her daughter to provide a forum to clarify the goals of Mrs. W. and discuss options for symptom relief, including the risks and potential benefits of another stent. Because the risk for mortality and complications of Mrs. W. are high if the procedure is performed and the evidence for benefits for QOL and symptoms are equivocal, the patient's goals, preferences, and alternative options will be important in the team's recommendation and shared decision making.

Conclusions

Patients, families, and physicians are often tempted to do something as patients approach the end of life. Although biliary stents can reduce hyperbilirubinemia in patients with advanced disease, evidence is mixed for benefits on symptoms or QOL in uncontrolled studies, and the risks of complications and hospitalizations are high. Given this equivocal data on whether the benefits of this procedure are likely to exceed the risks in patients with advanced disease, the application of consultation guidelines, in which primary (or palliative) care teams take the lead in determining whether considering the procedure is appropriate, may improve the care a patient receives at the end of life. Ideally, when the procedure may be appropriate, the primary or palliative care team should take the lead in discussing the overall benefits and potential for harm of the procedure with the patient and family and give the interventionist needed information about the case, including prognosis and goals, allowing the interventionist to provide adequate informed consent.

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