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A Meta-Analysis of Randomized Trials: Immediate Stent Placement vs. Surgical Bypass in the Palliative Management of Malignant Biliary Obstruction

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Abstract

Context—Many patients with unresectable pancreatic and peripancreatic cancer require treatment for malignant biliary obstruction. We performed a meta-analysis of randomized trials comparing immediate biliary stent placement and immediate surgical biliary bypass in patients with unresectable pancreatic and peripancreatic cancer.

Objectives—To conduct a meta-analysis of the English language literature (1985 through 2011) comparing those two treatments and analyze hospital utilization patterns.

Methods—After identifying five randomized controlled trials comparing immediate biliary stent placement and immediate surgical biliary bypass, we performed a meta-analysis for dichotomous outcomes, using a random effects model. We compared resource utilization in terms of the number of hospital days before death, by reviewing high-quality literature.

Results—379 patients were identified. We found no statistically significant differences in success rates between the two treatments (risk ratio [RR], 0.99; 95% confidence interval [CI], 0.93 to 1.05, $P = 0.67$). Major complications and mortality were not significantly higher after surgical bypass (RR, 1.54; 95% CI, 0.87 to 2.71; $P = 0.14$). Recurrent biliary obstruction was significantly less frequent after surgical bypass than after stent placement (RR, 0.14; 95% CI, 0.03–0.63; $P < 0.01$). Despite similar overall survival rates, longer survival was associated with more hospital days before death in stent patients than in surgical patients.

Conclusions—Nearly all patients with unresectable pancreatic cancer benefit from some procedure to manage biliary obstruction. Patients with low surgical risk may benefit more from surgery because the risk of recurrence and subsequent hospital utilization are much lower than for stent patients.

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Keywords

pancreatic cancer; biliary bypass; biliary stent

Introduction

Despite the advent of multidisciplinary cancer therapy, pancreatic adenocarcinoma and peripancreatic cancer are still among the most morbid and lethal cancers in the United States. The only potential for cure remains resection, but even after a presumably curative resection, the median survival time is only 25 to 34 months.[1–3] The 5-year survival rate of patients whose cancer is deemed unresectable for cure (per radiologic imaging or intraoperative findings) is less than 5%.[2, 4]

Biliary obstruction is a major potential consequence of pancreatic and peripancreatic cancer. At the time of diagnosis, more than 70% of patients have biliary obstruction and require intervention.[5, 6] Since the late 1970s, endoscopic management of biliary obstruction has been increasingly used, rather than open abdominal surgical procedures.[7, 8] But the recent literature has suggested that biliary stent placement, followed by a planned surgical biliary bypass for curative resection after metabolic correction, may be associated with worse outcomes than early or immediate surgical biliary bypass.[9] Up to 50% of patients with unresectable pancreatic cancer eventually require an intervention for gastric outlet obstruction as well.[5, 10]

Surgical management of biliary obstruction typically consists of a bypass from the common bile duct or gallbladder to the duodenum or jejunum.[6, 11] Endoscopic or percutaneous stent procedures typically include placement of a covered or uncovered metal or plastic stent from the proximal or mid common bile duct into the duodenum.

For our meta-analysis, we examined published randomized trials to determine the ideal treatment for biliary obstruction in patients with unresectable pancreatic or peripancreatic cancer. Specifically, we performed a meta-analysis of randomized controlled trials comparing stent placement and surgical bypass in the palliative management of malignant biliary obstruction due to pancreatic or peripancreatic cancer. We also performed a meta-analysis of inpatient utilization rates to estimate whether those 2 treatments differ in costliness.

Methods

Search strategy

We searched PubMed, CINAHL [Cumulative Index to Nursing and Allied Health Literature], and Web of Science for articles, using combinations of these relevant keywords: biliary bypass, biliary stent, biliary obstruction, and pancreatic/peripancreatic cancer. Limits we placed on the search included English language, randomized controlled trials, and human studies. In addition, we sought referenced articles if they existed outside of those 3 major databases. Publication dates for inclusion were 1985 through 2011. We followed the PRISMA [Preferred Reporting Items for Systematic Reviews and Meta-Analyses] protocol, which evolved from the QUOROM [*QU*ality *O*f *R*eporting *O*f *M*eta-analyses] protocol for systemic reviews and meta-analyses.[12]

Article selection

Initially, we found 24 publications (Figure 1). We excluded articles with nonrandomized study designs, review articles, articles containing an unspecified number of patients with pancreatic or peripancreatic cancer, and articles comparing only different types of stents or only different types of surgical operations.

Major outcomes

The major outcomes that we investigated were technical success of the procedures, major complications of the procedures, mortality, and recurrent biliary obstruction. All of the articles that we included defined technical success and major complications. Major complications included life-threatening hemorrhage, pneumonia, liver failure, pulmonary embolus, cholangitis, severe acute renal failure, and peritonitis. Biliary recurrence was defined by the need for any biliary procedure (surgical or endoscopic), for any reason, after the index procedure.

Statistical analysis

To perform our meta-analysis, we used Review Manager version 5.1.1 (Cochrane Collaboration, Copenhagen, Denmark). We coded outcomes as dichotomous variables and used the Mantel-Haenszel statistical method with a random effects model. We assumed that small random differences between studies were likely due to variations in local practices, variations in patient health patterns across the world, and variation in treatments over time. To compare the median survival time and the total number of hospital days, we used a paired Student *t* test. Statistical significance was set at $\alpha \leq 0.05$.

Results

Randomized controlled trials

For our meta-analysis, 5 randomized controlled trials[13–17] met the final inclusion criteria (Figure 1). The total number of patients was: 191 in the surgical arm and 188 in the stent arm. Variations in the technical aspects of the surgical procedures and in the types of stents are highlighted in Table 1. One of the trials compared surgery to percutaneous stent placement,[15] while the other 4 compared surgery to endoscopic stent placement. In addition, the surgical procedures were slightly different in each trial: overall, 60.9% of surgical patients underwent gastric bypass (either simultaneous with or subsequent to biliary bypass), and 27.9% of stent patients underwent gastric bypass.[15–17] We do not know whether such procedures were prophylactic or therapeutic. Nor do we know whether endoscopic (i.e., gastroduodenal) maneuvers were performed initially or during follow-up.

Technical success

The 2 treatments had essentially equal technical success rates: surgical bypass, 89.5% (171/191) and stent placement, 91.0% (171/188) (*P* = 0.67, Figure 2). Neither treatment was demonstrated to be technically superior to the other (all 95% CIs included 1.0). The 5 trials were not heterogeneous in terms of technical success (I^2 = 0%, *P* = 0.67).

Mortality, morbidity, and survival time

According to our meta-analysis, the 30-day mortality rate for surgical patients was 15%; for stent patients, 12% (*P* = 0.40). About 39% (75/191) of surgical patients had major complications or died, as compared with 21.2% (40/188) of stent patients (RR, 1.54; 95% CI, 0.87 to 2.71; *P* = 0.14; Figure 3). The 5 trials were not heterogeneous in terms of major complications or death (I^2 = 61%, *P* = 0.03). We analyzed recurrent biliary obstruction as a separate endpoint, not as a major complication.

The average survival time after randomization was 120 ± 37 days for surgical patients; 129 ± 27 days, for stent patients. The difference was not statistically significant (*P* = 0.57). Complications in the endoscopic group include gastrointestinal bleeds, cholangitis, renal failure and pneumonia. Complications in the surgical group include gastrointestinal bleeds, wound infections, and gastrointestinal obstructions, pulmonary embolus, and stroke. In one article, bleeding was more common in the endoscopic group while non-cholangitis infections were more common in the surgery group.[15]

Recurrent obstruction

Of the 5 trials, 4 demonstrated that recurrent biliary obstruction was more frequent after stent placement than after surgical bypass; 1 trial demonstrated no difference (Figure 4). Overall, the RR was 0.14 (95% CI, 0.03 to 0.63) in favor of less frequent obstruction after surgical bypass, as compared with stent placement; the difference was statistically significant (*P* = 0.01). The 5 trials were heterogeneous (I^2 = 63%, *P* = 0.04) in terms of recurrent obstruction. According to our meta-analysis, only 3.1% (6/191) of surgical patients had recurrent obstruction (requiring re-intervention), as compared with 28.7% (54/188) of stent patients (Figure 4). The incidence was 9 times higher in stent patients.

Hospital days

The total medical costs of all interventions to treat biliary obstruction are based on multiple factors and thus will vary widely. Nonetheless, the total number of hospital days to treat index and recurrent biliary obstruction can be a useful marker for the relative total costs between the 2 treatment modes (surgical bypass and stent placement), because the number of hospital days represents the most costly category of medical care utilization. In the 5 trials, the average length of stay for the index surgical bypass was 21.8 ± 5.8 days, as compared with 14.6 ± 9.3 days for the index stent placement (*P* = 0.026). We do not have data regarding the total number of hospital days from the index procedure until death. But in our literature review, we noted a 2-fold increase, for stent patients, in the total number of hospital days from the index procedure until death (Table 2).

Discussion

According to our meta-analysis of 5 randomized controlled trials, surgical biliary bypass and biliary stent placement are equivalent in efficacy, with similar average survival times and with statistically equivalent rates of major morbidity and mortality. Currently, in most institutions, stent placement is standard for patients with biliary obstruction due to tumors, even if a curative resection in the future is likely. A 3rd option is medical management, consisting of pain control, symptom control, and palliative care. It is an alternative for patients who are too sick for either stent placement or surgical bypass or for patients who elect to not endure further interventions. Chemotherapy for palliation or down-staging is another option but none of the articles utilized in this meta-analysis investigated this approach.

However, in our meta-analysis, we found that stent patients (as compared with surgical bypass patients) were 9 times more likely to experience recurrent biliary obstruction and to need further procedures, such as endoscopic biliary stent revision. (Figure 4, Table 2). Furthermore, according to our literature review, other studies have shown that the total number of hospital days from the index procedure until death was higher in stent patients (Table 2).[18–23]

While surgical biliary bypass is clearly an inpatient procedure necessitating a considerable hospital stay (22 days), it is surprising that the length of stay for stent procedures was nearly 15 days. While many current stent procedures may be accomplished on an out-patient or short hospital stay, in these studies the LOS associated with stent placement may also be related to a patient population with cancer-related biliary obstruction. In addition, while LOS may be a surrogate for cost, it has clear limitations that only a prospective trial can delineate.

Of the 5 trials in our meta-analysis, only the most recent trial (Artifon et al., 2006[14]) used metal stents; the other 4 used plastic stents. This represents a limitation of our literature review and meta-analysis. It is possible that the use of modern covered metal endoscopic stents could improve results. According to a meta-analysis by Moss et al. of 13 studies,[24] metal stents were associated with a mean patency of 165 days, as compared with only 123 days for plastic stents ($P < 0.05$). Still, surgical bypass is associated with far fewer recurrent obstructions and increased patency rates; the idea that modern metal stents are far superior to older metal stents (and perhaps to surgical bypass) has not been demonstrated in the literature.

Another limitation of our meta-analysis was that so few trials—only 5— met our strict inclusion criteria. Specifically, we limited our search to full reports of randomized controlled trials, and thus excluded published abstracts and prospective cohort studies. We analyzed only high-quality studies. In addition, the studies analyzed (Table 1) were heterogeneous, with no de facto standard for the biliary bypass procedure. Procedure-specific variations may well be the reality of clinical practice, but they clearly make comparisons difficult. Since the articles utilized were all randomized trials, heterogeneous patient populations and selection bias (i.e., selecting patients with poor fitness for stent over surgery) are an unlikely source of bias. However, the relatively small patient population in this analysis remains a potential limitation.

Pain control as a component of quality life is an important issues that the articles in this meta- analysis did not explore. For patients undergoing surgery, chemical celiac block is an optional adjunct during the operation while post operative celiac blockade can be performed by interventional radiologists or with ionizing radiation therapy.[5] In some studies, operative celiac plexus ablation is associated with decreased pain, narcotic use, and increase quality of life for up to 12 months after surgical identification of unresectable pancreatic cancer.[5, 25] Furthermore, long-term benefit is seen in up to 90% of patients without major complications.[26] Percutaneous and endoscopic approaches performing the above are often complimentary to surgical celiac plexus chemical ablation in that they can be performed postoperatively if inadequate pain relief is initially found or if pain later develops.

Finally, the treatment of gastric outlet obstruction was unclear in the 5 trials investigated. About 20% of patients treated for biliary obstruction will eventually require therapy for gastric outlet obstruction;[20, 22, 28, 29] the rate is as high as 50% in some centers.[5, 10] Concurrent gastric bypass at the time of biliary bypass could theoretically increase benefits, with minimal increases in operative risk, and could even decrease the total number of hospital days if gastric outlet obstruction is averted.[30] While not an endpoint of the studies in this meta-analysis, 45%–85% of patients undergoing biliary bypass had some sort of simultaneous enteric bypass as well in these studies.[13, 15–17]

Survival time is typically predicted by portents of a poor prognosis: high levels of CA19-9/CEA tumor markers, rapid tumor growth, ascites or peritoneal carcinomatosis, hypoalbuminemia, elevated Ki-67 expression, and elevated VEGF expression.[28, 29, 31] Each of those factors independently decreases survival by about 3 to 4 weeks, and these factors may help clinicians recommend specific therapies based on the presence of these factors in a given patient.

Our meta-analysis provides the first evidence that surgical biliary bypass may be more cost-effective than endoscopic biliary stent placement. A significant limitation to this conclusion is the use of LOS as the marker for cost. It is the only marker of costs consistently described in the articles and remains a fairly objective measurement. Our major finding is that recurrent biliary obstruction is significantly more likely after stent placement than after surgical bypass. Importantly, percutaneous transhepatic biliary stent placement may be even more cost-effective than surgery,[32] indicating the need for further study to pinpoint the “gold standard” treatment for patients with unresectable pancreatic and peripancreatic cancer.

Conclusion

Even though most patients with pancreatic and peripancreatic cancer present too late for curative resection, nearly all will benefit from procedures to manage biliary obstruction, thereby improving the quality of their remaining life. For pancreatic and peripancreatic cancer patients expected to live at least 6 months, we recommend surgical biliary bypass with a concomitant gastric emptying procedure. However, if survival is expected to be under 4 months, we recommend therapeutic endoscopic stent placement, since such patients are unlikely to outlive a covered metal biliary stent. If survival is expected to be between 4 and

6 months, the appropriate treatment is unclear; covered metal biliary stents might last long enough, but other types of stents likely would not.

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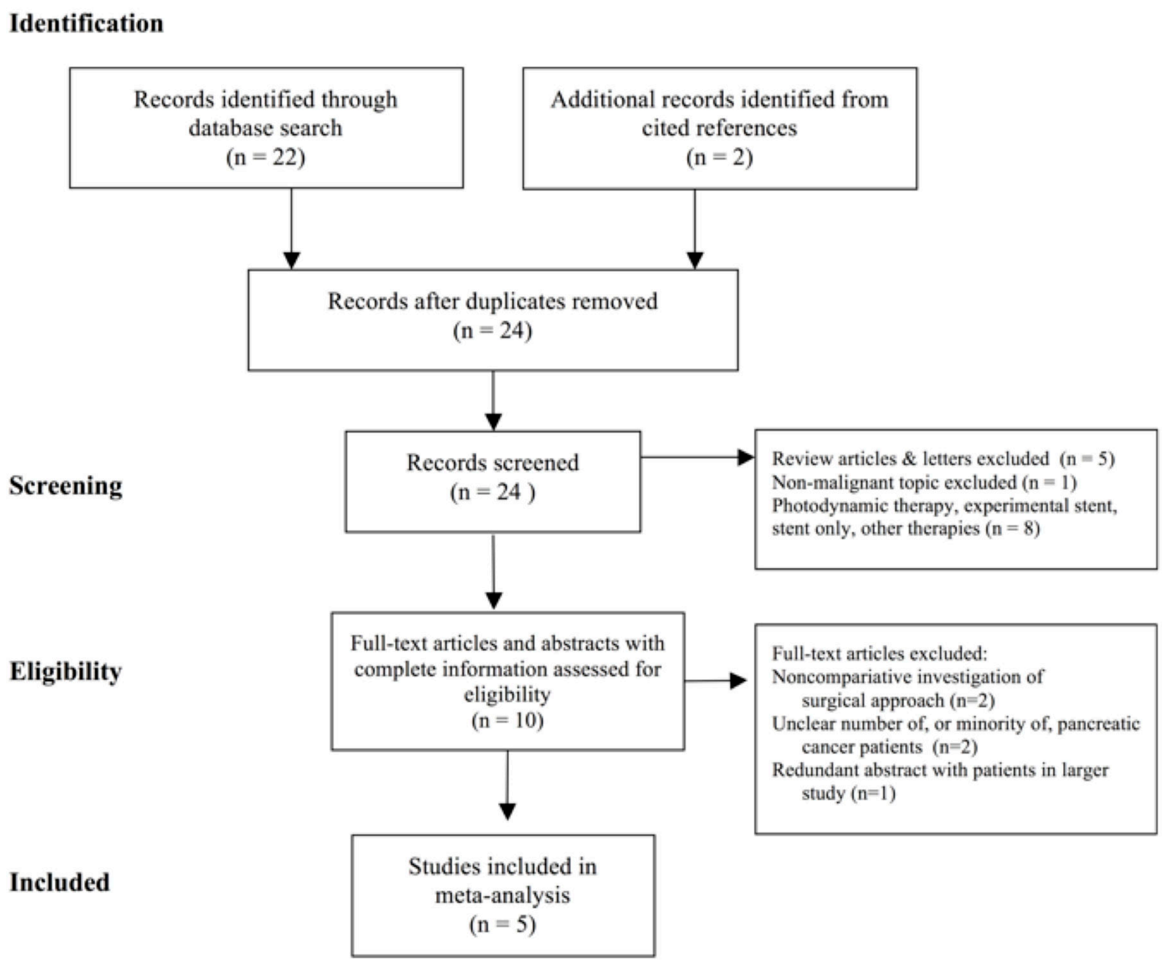

Figure 1.

Search Strategy and Article Inclusion/Exclusion Criteria (Modified from Moher et al., *PRISMA Statement*, 2009[12])

Study or Subgroup	Surgery Events	Surgery Total	Stent Events	Stent Total	Weight	Risk Ratio M-H, Random, 95% CI
Andersen 1989	22	25	24	25	13.2%	0.92 [0.78, 1.08]
Artifon 2006	15	15	15	15	23.4%	1.00 [0.88, 1.13]
Bornman 1986	19	25	21	25	4.7%	0.90 [0.68, 1.20]
Shepherd 1988	23	25	19	23	7.5%	1.11 [0.89, 1.39]
Smith 1994	92	101	92	100	51.3%	0.99 [0.91, 1.08]
Total (95% CI)		**191**		**188**	**100.0%**	**0.99 [0.93, 1.05]**
Total events	171		171			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.35$, df = 4 (P = 0.67); $I^2 = 0\%$

Test for overall effect: Z = 0.43 (P = 0.67)

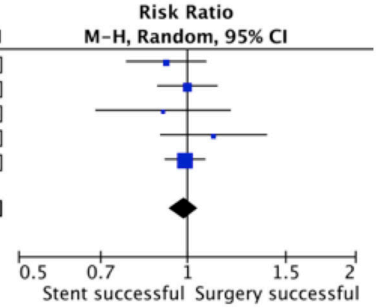

Figure 2.

Meta-Analysis of Technical Success

Study or Subgroup	Surgery Events	Surgery Total	Stent Events	Stent Total	Weight	Risk Ratio M–H, Random, 95% CI
Andersen 1989	5	25	9	25	17.3%	0.56 [0.22, 1.43]
Artifon 2006	9	15	6	15	21.1%	1.50 [0.71, 3.16]
Bornman 1986	8	25	6	25	18.0%	1.33 [0.54, 3.29]
Shepherd 1988	10	25	5	23	17.9%	1.84 [0.74, 4.58]
Smith 1994	43	101	14	100	25.6%	3.04 [1.78, 5.20]
Total (95% CI)		**191**		**188**	**100.0%**	**1.54 [0.87, 2.71]**
Total events	75		40			

Heterogeneity: $Tau^2 = 0.25$; $Chi^2 = 10.37$, df = 4 (P = 0.03); $I^2 = 61\%$
Test for overall effect: Z = 1.49 (P = 0.14)

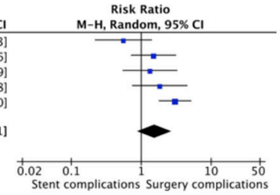

Figure 3.

Meta-Analysis of Major Complications and Mortality

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Study or Subgroup	Surgery Events	Surgery Total	Stent Events	Stent Total	Weight	Risk Ratio M–H, Random, 95% CI
Andersen 1989	0	25	0	25		Not estimable
Artifon 2006	0	15	3	15	16.5%	0.14 [0.01, 2.55]
Bornman 1986	4	25	8	25	35.3%	0.50 [0.17, 1.45]
Shepherd 1988	0	25	7	23	17.0%	0.06 [0.00, 1.02]
Smith 1994	2	101	36	100	31.2%	0.06 [0.01, 0.22]
Total (95% CI)		**191**		**188**	**100.0%**	**0.14 [0.03, 0.63]**
Total events	6		54			

Heterogeneity: $Tau^2 = 1.33$; $Chi^2 = 8.07$, df = 3 (P = 0.04); $I^2 = 63\%$

Test for overall effect: Z = 2.56 (P = 0.01)

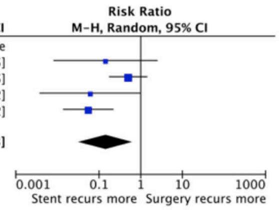

Figure 4.

Meta-Analysis of Recurrent Obstruction

Table 1

Randomized Controlled Trials[18–23]: Biliary Stent Placement vs. Surgical Biliary Bypass for Obstruction

Authors	Year	N (surgery)	Surgical Procedure	N (stent)	Stent Type
Andersen et al.	1989	25	Choledochoduodenostomy	25	Endoscopic Teflon
Artifon et al.	2006	15	Choledochojejunostomy	15	Endoscopic Metal
Bornman et al.	1986	25	Cholecystenterostomy or hepaticojejunostomy	25	Percutaneous Polyethylene
Shepherd et al.	1988	25	Cholecystostomy or choledochoduodenostomy	23	Endoscopic Polyethylene
Smith et al.	1994	101	Choledochoduodenostomy or cholecystojejunostomy	100	Endoscopic Teflon
Total patients		*191*		*188*	

Table 2

Meta-Analysis and Literature Review of Nonrandomized Clinical Trials[18–23]: Outcomes after Index Procedures for Biliary Obstruction

Index Procedure	**Stent Placement**	**Surgical Bypass**
Estimated obstruction rate after index procedure until death	29% (range, 10%–40%)	3% (range, 0%–10%)
Treatment for recurrence		
Surgical	18%	<1%
Endoscopic/percutaneous	82%	75%
Medical	<1%	25%
Total hospital days from index procedure until death (range)	30–35 days	10–22 days