ORIGINAL ARTICLE

Relationship of Postoperative Complications from Preoperative Biliary Stents after Pancreaticoduodenectomy. A New Cohort Analysis and Meta-Analysis of Modern Studies

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ABSTRACT

Context Debate still continues as to the effects of preoperative biliary stents on postoperative complications after pancreaticoduodenectomy. Some studies have documented increased wound infection rates, while others have not. The importance of this issue rests on whether these postoperative complications are detrimental enough to not recommend preoperative chemoradiation in the treatment of pancreatic cancer. **Objective** This study is in two parts: 1) a retrospective review of patients who underwent pancreaticoduodenectomy at Henry Ford Hospital; and 2) a meta-analysis of published studies on the effects of preoperative biliary stents. **Methods** In the retrospective portion, all patients who underwent pancreaticoduodenectomy from January 1st, 1997 through December 31st, 2006 were included in the study. **Main outcome measures** Data gathered included gender, age, pathologic diagnosis, use of preoperative biliary stent (either ERCP or PTC), all postoperative complications, and in-hospital mortality. In the meta-analysis portion, all studies published from 1990 with either a randomized or quasi-randomized allocation of patients were included. Endpoints analysis were peri-operative mortality, wound infection rate, intra-abdominal abscess rate, and overall morbidity rate. **Results** In the retrospective portion, 181 patients were studied, with 123 (68.0%) of these having preoperative biliary stents. Patients with and without stents had no significant difference in wound infection rate (19.5% *vs*. 17.2%, respectively), intra-abdominal abscess rate (16.3% *vs*. 22.4%), any postoperative complication (50.4% *vs*. 51.7%) and in-hospital death (2.4% *vs*. 1.7%). Fifteen studies were included in the meta-analysis. There was variation in both the definitions of complications as well as the incidence of all postoperative endpoints among the studies. For peri-operative mortality and wound infection rate, the relative difference favored the no stent group by 0.5% (95% confidence interval: -0.4% to 1.4%) and 5.8% (95% confidence interval: 3.6% to 8.0%), respectively. For intra-abdominal abscess and overall morbidity rate, the relative difference favored the stent group by 2.0% (95% confidence interval: -0.3% to 4.3%) and 0.06% (95% confidence interval -3.8% to 3.9%), respectively. **Conclusion** Although the use of a preoperative biliary stent increases the postoperative wound infection rate by about 5%, there is no overwhelming evidence that it either promotes or protects from the other complications. As there was variation in the definitions used in these studies, a more uniformed system of complication reporting is required.

INTRODUCTION

For years, obstructive jaundice has been associated with higher postoperative morbidity and mortality rates [1, 2]. It was felt that is was due to hyperbilirubinemia-induced impairment of immunity [3, 4] and nutritional status [5]. Because of this, it was felt that hyperbilirubinemia was associated with a higher incidence of postoperative complications. This lead to a practice of obtaining preoperative biliary drainage, either with a percutaneously placed transhepatic catheter or an endoscopically placed biliary stent. However, since the mid-1980's, studies have questioned the value of this practice. Reports have documented that preoperative correction of hyperbilirubinemia have not lead to reductions in postoperative complications [6, 7]. In facts, reports began to appear in the 1990's suggesting that preoperative biliary stents lead to increased surgical site infections, specifically wound infections and intra-abdominal abscesses [8].

After these initial reports, others have also published retrospective cases series which have demonstrated both increased and decreased postoperative complications related to preoperative biliary stents. This is not an insignificant issue, especially if treatment for pancreatic adenocarcinoma includes preoperative chemotherapy and radiation therapy, which requires preoperative biliary drainage [9]. Two meta-analyses have been published to help clarify this problem. These

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meta-analyses only assessed overall morbidity, postoperative morbidity, and overall mortality, without determining the effect on surgical site infections specifically [10, 11]. In addition, one report included only studies with more than 80% of cases treated with endobiliary stents in order to limit the effects of percutaneous stents [10]. The other report included proximal biliary lesions, so that not all patients would have been planned to undergo pancreatic resection [11].

In addition, since the 2002 meta-analyses, there have been several more reports addressing this issue in a "modern era" of more advanced preoperative and postoperative care. Therefore, further analysis of these existing data with emphasis on peri-operative mortality and surgical site infections is warranted. We will further present on our experience with pancreatico-duodenectomy in patients with and without preoperative biliary drainage and add this to the meta-analysis.

METHODS AND MATERIALS

Retrospective Cohort Analysis

Patients who underwent pancreaticoduodenectomy for periampullary tumors or chronic pancreatitis from January 1st, 1997 through December 31st, 2006 were included in this study. The medical records were reviewed for age, gender, date of operation, pathology (pancreatic adenocarcinoma, other periampullary tumor, chronic pancreatitis), placement of preoperative internal or external biliary stent, and the occurrence of complications. Patients did not undergo operation if an existing infection was suspected.

The definitions of the specific complications were as follows. "Peri-operative death" was defined as death occurring during the hospitalization for the operation or any death within 30 days of the operation. "Wound infection" was defined as purulent drainage from the operative incision with or without growth from bacterial culture, any drainage which was culture positive, or wound-related physical signs suspicious enough for the surgeon to initiate antibiotic therapy. "Intra-abdominal abscess" was defined as purulent or culture positive intra-abdominal fluid treated with percutaneous or operative drainage and/or antibiotics. "Any complication" was defined as any postoperative adverse event meeting Clavien *et al*. [12] criteria for a class II or higher event.

Meta-Analysis

Studies included in this meta-analysis included published reports comparing patients who underwent pancreaticoduodenectomy for benign or malignant disease and who either had or had not had a preoperative placed biliary stent (endoscopic or percutaneous) placed. Studies excluded from analysis were studies published prior to 1990, studies not comparing postoperative complications in patients with and without biliary stents, and studies including resections other than pancreaticoduodenectomy (such as for proximal cholangiocarcinoma).

Each study was reviewed for the number of patients operated upon for biliopancreatic disease with and without preoperative biliary stenting, the number and type of postoperative complications, and the definition of each complication. Comparisons were made for peri-operative death, postoperative wound infection, postoperative intra-abdominal abscess and any postoperative complication.

STATISTICS

Retrospective Cohort Analysis

Statistical analysis was performed using the Stata statistical software program [13]. A chi-squared test with Yates' correction was used for nominal data. A P value of less than 0.05 was considered significant.

Meta-Analysis

The data was pooled in the manner of DerSimonian and Laird [14]. Data will be presented as the relative difference in frequency of occurrence of the event favoring either preoperative stent placement or no stent placement with the 95% confidence interval of this difference.

ETHICS

This study has been approved by the Institutional Review Board of the Henry Ford Health System.

RESULTS

Retrospective Cohort Analysis

From January 1st, 1997 through December 31st, 2006, 181 patients underwent pancreaticoduodenectomy for both benign and malignant disease. Of these, 114 patients (63.0%) had endoscopic-placed biliary stents, while 9 (5.0%) had percutaneous transhepatic biliary stents.

Overall, there was no statistically significant difference in wound infection rates between patients who had preoperative biliary stents placed compared to those who did not (24/123, 19.5% *vs*. 10/58, 17.2%, respectively, P=0.872), intra-abdominal abscess (20/123, 16.3% *vs*. 13/58, 22.4%, respectively P=0.427), in-hospital or 30-day mortality (3/123, 2.4% *vs*. 1/58, 1.7%, respectively, P=1.000), or any postoperative complication (62/123, 50.4% *vs*. 30/58, 51.7%, respectively, P=0.995). There were no significant differences between the endoscopically-placed and percutaneously-placed stents (data not shown).

Meta-Analysis

Including the retrospective cohort analysis just presented, 15 studies were included in the meta-analysis [15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28]. All studies used were retrospective except that of Lai *et al*. [22], which was the only prospective, randomized trial. Table 1 presents the definitions of the postoperative adverse events recorded in this study.

There was variation in the definition of the events. For example, some studies recorded the frequency of post-operative death, without defining what this meant. Others defined a postoperative death as a death within 30 days of the operation, while other defined it as any in-hospital death or death within 30 days. With regard to wound infection, some studies based the diagnosis purely on clinical evaluation, while others required a positive bacterial culture. Yet, others did not record this event. This variation in definition also occurred with respect to intra-abdominal abscess. Many studies did not define a category of "any complication." Most just listed the complications that occurred with or without definitions.

Table 2 lists the frequency of complications for each category of adverse event recorded for each study. Again, there is a great deal of variation of the frequency of complications among the studies. In addition, there is not consistency that the stented or unstented groups have lower complication rates.

Table 1. Definitions of postoperative complications.

Study	Death	Wound infection
Lai, 1994 [22]	Not defined, event recorded	Not defined or recorded
Karsten, 1996 [27]	In-hospital death or as a direct result of a postoperative complication	"Infectious complications" defined, no comparison made
Heslin, 1998 [20]	Not defined, event recorded	Erythema necessitating opening and packing the wound
Marcus, 1998 [23]	Death within 30 days of operation	Not defined, event recorded
Sohn, 2000 [17]	Death during the index hospitalization or within 30 days	A diagnosis of infectious complications required fever as well as positive cultures. Wound infection required purulent drainage which necessitated opening the wound
Pister, 2001 [16]	Death during hospital stay or within 30 days	Not defined, event recorded
Sewnath, 2002 [11]	Death occurring during hospital admission or as a direct result of a postoperative complication	Not defined, event recorded
Martignoni, 2001 [25]	Not defined, event recorded	Not defined, "wound sepsis" recorded
Srivastava, 2001 [26]	Not defined, event recorded	Purulent discharge from the wound or serous discharge, positive for bacterial growth
Hodul, 2003 [21]	In-hospital death or death within 30 days of surgery	Purulent drainage from incision with necessity to open the wound
Gerke, 2004 [19]	Not specifically defined, although "complications occurring during same admission or within 30 days were considered postoperative complications." Event recorded	Purulent drainage and/or wound changes that required re-operation or early removal of staples or suture or initiation of antibiotic therapy
Mullen, 2005 [15]	Death within the first 30 days after surgery or during the hospital stay for surgery	Not defined, event recorded
Jagannath, 2005 [28]	Any in-hospital mortality	Culture positive collection resulting in >2- week hospitalization
Howard, 2006 [18]	Death during the index hospitalization or within 30 days after surgery	Area of erythema or purulent drainage which yielded pus and grew bacteria
Present study	Any in-hospital mortality or death within 30 days of the operation	Purulent drainage with or without bacterial culture positive, or any drainage which was culture positive. Erythema with antibiotic therapy

Table 1. Continued.

Study	Intra-abdominal abscess	Any complication
Lai, 1994 [22]	Not defined or recorded	Not defined, event recorded
Karsten, 1996 [27]	"Infectious complications" defined, no comparison made	Postoperative complications during hospitalization classified as infection, hemorrhage, symptomatic anastomotic leak, and complications requiring intervention
Heslin, 1998 [20]	Intra-abdominal fluid associated with fever requiring percutaneous or open draining yielding positive cultures	A list of "any complication" was given
Marcus, 1998 [23]	Not defined, event, recorded	A list of "any complication" was given
Sohn, 2000 [17]	Intraabdominal fluid collection on computed tomography	A list of complications was given
Pister, 2001 [16]	Postoperative fluid collection with positive fluid culture results	A list of complications was given
Sewnath, 2002 [11]	Not defined, event recorded	A list of complications was given
Martignoni, 2001 [25]	Not recorded	Not defined, event recorded
Srivastava, 2001 [26]	Collection on ultrasound or CT scan or at re-operation, which was positive on culture following percutaneous or surgical drainage	Not defined, event recorded
Hodul, 2003 [21]	Need for drainage of intra-abdominal fluid collection with positive cultures	Not defined, "None," under complications, recorded
Gerke, 2004 [19]	Not specifically defined, although "complications occurring during same admission or within 30 days were considered postoperative complications." Event recorded	Not specifically defined, although "complications occurring during same admission or within 30 days were considered postoperative complications." Event recorded
Mullen, 2005 [15]	Postoperative fluid collection with positive fluid culture results	A list of complications was given
Jagannath, 2005 [28]	Abscess not defined, "infectious complication" defined and recorded	Not defined or recorded
Howard, 2006 [18]	Postoperative intra-abdominal fluid collection identified by imaging associated with a fever or leukocytosis that grew bacteria on culture	Not defined, but recorded as a list of individually defined complications
Present study	Purulent or culture positive intra-abdominal fluid treated with percutaneous or operative drainage and/or antibiotics	Any complication meeting Clavein class II or higher

The Figure 1 shows the results of the meta-analysis for all four complication rates studied. The difference in rates favors no stenting with respect to postoperative death by 0.5% (95% confidence interval: -0.4% to 1.4%) and wound infection by 5.8% (95% confidence interval: 3.6% to 8.0%). The differences in rates favors stenting with respect to intra-abdominal abscess by 2.0% (95% confidence interval: -0.3% to 4.3%) and any complication by 0.06% (95% confidence interval: -3.8% to 3.9%). However, only in the difference in wound infection rate does the 95% confidence interval not include 0, implying that this is the only statistically significant difference.

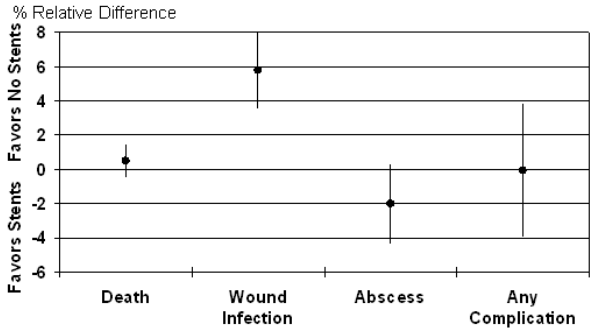

Figure 1. Results of meta-analysis. The data is presented as the difference in rates between the stented and unstent groups with the 95% confidence interval of this difference.

DISCUSSION

The results of this meta-analysis help explain the continued controversy in the use of preoperative biliary stents. Except for wound infection, there does not appear to be statistically significant differences in postoperative death, intra-abdominal abscess or total complication rates. The use of stents appears to increase the occurrence of wound infections by 5%. Therefore, the use may have more to do with local institutional variation and treatment protocols than on the adverse effects of the stents. However, we must acknowledge that only one of the studies used in the meta-analysis was a randomized trial, therefore, this must be viewed as a weakness in this meta-analysis and a deficit in our knowledge on this subject.

There is a wide variation in the reported occurrences of the complications studied. There may be several potential causes. Firstly, this is variation is the definitions of what event actually constitutes a complication. Those studies which have a more narrow definition of a complication will have a lower complication rate, while those which have a broader definition will have a higher rate. The issue of the definitions of specific risk factors and complications is not new. The National Surgical Quality Improvement Program takes great efforts to insure that uniformed definitions are used throughout participating hospitals because what gets counted as a complication varied so widely among these hospitals [29]. Nevertheless, this will not explain the differences of rates between the stented group and unstented group within each study as the definitions should be internally consistent. Secondly, there may be local institutional variation in care which may affect the complication rates independent of the use of stents. For example, the relative use of internal (i.e., endoscopically-placed) and external (radiologically-placed) stents may affect postoperative complications [30]. Other institutions which routinely used preoperative stents may have practices in place which lead to lower complications [31]. Lastly, there may be variations in preoperative and postoperative care between institutions that decrease overall complication rates, regardless of the use of preoperative stents. Given these variations, it may be difficult to dissect the effects of preoperative stents from the effects of these other processes of care.

It is argued, by those who suggest that preoperative stenting leads to postoperative complications, that contamination of the biliary system by bacteria introduced during the stenting process is the cause of postoperative infectious complications. There appears to be a relationship between bactibilia and postoperative septic complications [18]. Indeed, in this meta-analysis, the only postoperative complication that was statistically significant was wound infection,

Table 2. Incidence of complications in each study.

Study	Death		Wound infection		Abscess		Any complication	
	Stent	No stent	Stent	No stent	Stent	No stent	Stent	No stent
Lai, 1994 [22]	14.6% (41)	13.6% (44)	-	-	-	-	39.0% (41)	40.9% (44)
Karsten, 1996 [27]	-	-	-	-	-	-	55.4% (184)	61.4% (57)
Heslin, 1998 [20]	2.6% (39)	0% (35)	12.8% (39)	2.9% (35)	5.1% (39)	0% (35)	59.0% (39)	34.3% (35)
Marcus, 1998 [23]	0% (22)	6.7% (30)	0% (22)	4.5% (30)	0% (22)	9.1% (30)	36.4% (22)	63.3% (30)
Sohn, 2000 [17]	1.7% (408)	2.5% (159)	10.0% (408)	3.8% (159)	3.9% (408)	6.3% (159)	35.0% (408)	30.2% (159)
Pister, 2001 [16]	0.6% (172)	1.1% (93)	13.4% (172)	4.3% (93)	6.4% (172)	10.7% (93)	87.8% (172)	86.0% (93)
Sewnath, 2002 [11]	1.3% (232)	0% (58)	7.3% (232)	8.6% (58)	15.5% (232)	15.5% (58)	50.4% (232)	55.2% (58)
Martignoni, 2001 [25]	3.0% (99)	1.9% (158)	-	-	-	-	49.5% (99)	44.9% (158)
Srivastava, 2001 [26]	14.8% (54)	10.4% (67)	42.6% (54)	23.9% (67)	27.8% (54)	14.9% (67)	48.1% (54)	44.8% (67)
Hodul, 2003 [21]	1.9% (154)	1.7% (58)	7.8% (154)	0% (58)	6.5% (154)	6.3% (58)	33.1% (154)	43.1% (58)
Gerke, 2004 [19]	5.2% (58)	0% (14)	29.3% (58)	21.4% (14)	12.1% (58)	14.3% (14)	70.7% (58)	50.0% (14)
Mullen, 2005 [15]	0.6% (170)	2.2% (92)	6.5% (170)	4.3% (92)	2.4% (170)	6.5% (92)	-	-
Jagannath, 2005 [28]	4.1% (74)	8.6% (70)	20.2% (74)	22.9% (70)	-	-	-	-
Howard, 2006 [18]	2.3% (86)	1.9% (52)	14.0% (86)	1.9% (52)	2.3% (86)	7.7% (52)	43.0% (86)	36.5% (52)
Present study	2.4% (123)	1.7% (58)	19.5% (123)	17.2% (58)	16.3% (123)	22.4% (58)	50.4% (123)	51.7% (58)

The total number of cases of each study is shown within parentheses

where there was a difference in rates favoring no stenting. It is curious that intra-abdominal abscess was not associated with the use of stents. However, this may be explained by the fact that most intra-abdominal abscesses are more related to pancreatic leak, which presumably occurs independently of preoperative stenting. Understanding the causative organisms related to preoperative stenting may lead to more appropriate choices of prophylactic antibiotics.

What drives the use of preoperative biliary stenting in most institutions is not the correction of hyperbilirubinemia prior to resection, but the use of preoperative chemoradiation [9, 31]. As preoperative treatment generally requires 4 to 6 weeks of treatment, followed by restaging, then resection 2 to 4 weeks after completion of neoadjuvant therapy, it is simply not practical to have these patients remain jaundice for that long. In fact, in those institutions experience in preoperative chemoradiation, biliary stent related complications between drainage and restaging occurs approximately 15% of the time [31]. As all patients who undergo preoperative chemoradiation must have a pathologic diagnosis of pancreatic adenocarcinoma, this difference could also be interpreted that patients with cancer may have a lower rate of stent-caused postoperative complications than a group of patients with mixed malignant and benign diagnoses.

In summary, despite the variation in definitions and complication occurrence rates, the use of preoperative biliary stents probably increases the rates of postoperative wound infection by 5%. However, postoperative death, intra-abdominal abscess and total complication rates do not appear affected. Therefore, there is no overwhelming reason to use or avoid preoperative biliary stents. Nevertheless, there may be very good reasons to use biliary stents preoperatively. For example, patients who are to undergo preoperative chemoradiation prior to resection, patients who may have some question of cholangitis, or patients with severe jaundice-related pruritus requiring symptom relief prior to resection. The use of preoperative biliary remains an individual decision by the physicians care for patients with periampullary tumors. However, only a well-designed randomized controlled trial with a large number of patients will truly resolve this issue.

Conflict of interest The authors have no potential conflicts of interest

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