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A Systematic review and Meta-analysis

# Preoperative biliary drainage for pancreatic head carcinoma: A systematic review and meta-analysis

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**Abstract**

The aim of this study is to carry out a meta-analysis and to systematically review the impact of preoperative biliary drainage in obstructive jaundiced patients for pancreatic head carcinoma compared with that of the direct early surgery group based on their postoperative clinical outcomes. Systematic search of publications were conducted electronically (PubMed, Embase, Web of Science, the Cochrane library from 2000-2015). Studies included were Randomized controlled trials, Case-control studies, Cohort studies were include if they investigated and compared the preoperative biliary drainage outcomes with surgery outcomes in patients with obstructive jaundice caused by a tumor of the pancreatic head. Meta-analysis showed significant difference in the incidence of intra-abdominal abscess in which six studies had reported results of the incidence ($p$=0.02) (RR=0.50, 95%CI [0.29, 0.88]). In summary, Preoperative biliary drainage group when compared with direct early surgery group showed increased incidence of intra-abdominal abscess for pancreatic head carcinoma patients.

**Keywords:** Preoperative biliary drainage, pancreatic head carcinoma, obstructive jaundice, risk ratio, confidence interval.

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## Introduction

According to researchers[1, 2] Pancreatic Cancer is said to be the fourth leading cause of cancer death in the United States of America (USA) with estimated deaths of 227 000 per year worldwide. The number of reported deaths and incidence caused by pancreatic tumors over the years has significantly increased, despite declines in incidence and mortality of other common cancers. Notwithstanding modern advancements over the years in the detection and management of pancreatic cancer, it is estimated that only 4% of diagnosed patients will live for five years based on life expectancy figures. Currently surgical resection provides a greater chance of longevity for patients with malignant disease of the pancreas and responds poorly to most chemotherapeutic agents. It was stated that, the after extensive hepatopancreatobiliary surgery, postoperative mortality has decreased from 20% to less than 5% in high experienced hospitals, and yet the overall morbidity remains high at around 40–60% [3,4,5,6,7]. Additionally, Pancreaticoduodenectomy is said to be the single most potentially curative form of treatment for pancreatic head tumors and other Periampullary lesions that usually becomes evident by the various degrees of Hyperbilirubinemia [8]. However, despite it being performed for several decades since first described by Whipple et al. in 1935, it is still highly regarded as a major surgical procedure, with relatively high morbidity (5%) and mortality (40–60%) rates, even in high-volume centers. Pancreaticoduodenectomy following its usage in surgery on patients with severe obstructive jaundice is thought to have increase the risk of postoperative complications and as such preoperative biliary drainage was introduced to further improve the postoperative outcome [9, 10]. A commonly found symptom in patients with periampullary cancer is obstructive jaundice that is found near the ampulla of vater or cancer of the pancreatic head. Thus, for patients with a resectable tumor who have no radiologic evidence of metastasis, surgical resection is the only option for cure [9]. Obstructive jaundice is known to be associated with hepatic dysfunction and disturbances in coagulation and cholangitis and preoperative biliary drainage (PBD) is either endoscopic or percutaneous which has been highly recommended to patients for surgery [8]. Nevertheless, it is widely recognized and acknowledged that routine PBD should not be recommended to patients with obstructive due to the high level of infectious complications that have been noted in these patients [8]. According to Eshuis et al. [11], patients classified as PBD had a significantly higher level of overall complication treatment than patients undergoing surgery without PBD, and further suggested that the application of PBD should not be routinely performed. In addition, due to logistical reasons preoperative biliary drainage may also be warranted when early surgery (ES) is no longer applicable. Many recent reports [9, 12, 13] comparing preoperative biliary drainage and surgery-first groups revealed that biliary drainage leads to more complications and fewer clinical benefits. In a comparative study [9] conducted in randomized fashion by a Dutch group where an endoscopic biliary drainage group was compared with a group comprising of early-surgery among patients with pancreatic head cancer were discovered that the rates of serious complications in

the biliary drainage group were significantly higher than those in the surgery-first group. Other studies also reported more postoperative complications, such as infections and fistula in PBD patients [14,15,16]. A recent Cochrane review [17, 18] of Six (6) randomized clinical trials evaluating the safety and effectiveness of PBD versus no PBD discovered that PBD in patients undergoing surgery for obstructive jaundice were also associated with similar mortality, but with increased serious morbidity when compared with no PBD.

There have been some meta-analysis focusing on the effects of preoperative biliary drainage for tumors causing obstructive jaundice that have been carried out by several researchers, however the goal of this study was to carry out a systematic review and meta-analysis on the effects of preoperative biliary drainage specifically in obstructive jaundiced patients due to pancreatic head carcinomas.

**Materials and Methods**

All published and unpublished journal articles regarding preoperative biliary in patients who have obstructive jaundice due to pancreatic head carcinoma from 2000 to this present day were selected. We followed the meta-analysis of observational studies in epidemiology (MOOSE) guidelines for searching and reporting, and this investigation was approved by the ethics committee of the Affiliated Zhongda Hospital of Southeast University Medical College. Computer research was done in database of Pubmed, Embase, Cochrane Library and other relevant databases.

**Search strategy**

Systematic search of publications were conducted electronically (PubMed, Embase, Web of Science, the Cochrane library from 2000-2015). For the first search, text key words were "preoperative biliary drainage", "pancreatic cancer", "pancreatic head cancer", and "obstructive jaundice".

**Study selection**

Randomized controlled trial, Case-control studies, Prospective and retrospective cohort studies were include if they investigated and compared the preoperative biliary drainage outcomes with surgery outcomes in patients with obstructive jaundice caused by a tumor of the pancreatic head.

**Inclusion criteria**

Patients with obstructive jaundice and a Bilirubin level of 40 to 250umol per liter (2.3 to 14.6mg per deciliter) of age 18-85 years and with no evidence on computed tomography (CT) of distant metastasis or local vascular involvement (which was defined as tumor surrounding portal or mesenteric vessels for more than 180 degrees of their circumference or an irregular vessel margin).

**Exclusion criteria**

The patients with coexisting illness (Karnofsky performance score, <50 [on a scale of 0 to 100, with higher scores indicating better performance]), cholangitis, or previous preoperative biliary drainage with stenting by means of (ERCP) or (PTC) were excluded. Current receipt of neoadjuvant chemotherapy or the presence of serious gastric outlet obstruction (tumor-related duodenal stenosis, which was defined by vomiting and an oral intake of <1 liter per day) was also excluded as well as all patients that provided written consent.

The assessment of study quality used the following criteria:

1. The Jadad score was introduced to evaluate the quality of randomized controlled trials (RCTs). Trials scored one point for each area addressed in the study design (randomization, blinding, concealment of allocation, reporting of withdrawals, and generation of random numbers) with a possible score of between 0 and 5 (highest level of quality). "Good" was defined as a Jadad score ≥4; "fair," a Jadad score of 3; and "poor," defined as a Jadad score <3.
2. The Newcastlee-Ottawa Scale was used to assess the quality of observational studies based on the following nine questions: (1) representativeness of the exposed cohort; (2) selection of the non-exposed cohort; (3) ascertainment of exposure; (4) demonstration that the outcome was not present at outset of study; (5) comparability; (6) assessment of outcome; (7) length of follow-up sufficient; (8) Adequacy of participant follow-up; (9) total stars. Maximum score on this scale is a total of 9.28 "Good" was defined as a total score of 7-9; "fair," a total score of 4-6; and "poor," defined as a total score of ≤ 4.

**Statistical analysis**

To perform this systematic meta-analysis, we used Review Manager (RevMan) [Computer program], Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014. A test (chi-square test) was performed to test the heterogeneity between the included studies. However, in cases where there was no significant heterogeneity ($P > 0.05$), the fixed effect model was applied for follow-up analysis; also, if there was significant heterogeneity ($P < 0.05$), the random effects model was considered. The effect sizes for summary were the ratios of overall postoperative complications, Overall Infection, Overall mortality,

the incidence of wound infection, the incidence of intra-abdominal abscess and the incidence of pancreatic fistula or bile leak between two groups to be compared. That is, the corresponding Risk ratio (RR). Statistical significance level was set at 0.05.

## Results

Quality assessment and characteristics of the studies included.

Based on inclusion criteria and exclusion criteria, 10 studies were enrolled in this study. Year published ranged from the year 2000 to this year 2015, and a total of 2113 patients. Among these patients 930 underwent preoperative biliary drainage procedure and 832 underwent direct early surgery (**Table 1**).

**Table 1: Quality assessment and characteristics of the studies included**

| Study | Published Year | Type of Design | Number of Patients Studied | Average Age (ES/ PBD) | Sex (ES/PBD) (Male) | Study Quality |
|---|---|---|---|---|---|---|
| Niels A. van der Gaag et al | 2010 | RCT | 202 | 64.7±9.5/64.7±10.5 | 119M | Good |
| Wietse J. Eshuis et al | 2010 | RCT | 185 | 64.6±9.5/64.7±10.3 | 114M | Good |
| James J.Mezhir et al | 2009 | Pros | 340 | 71 | 163M | Fair |
| Tobin J.Strom et al | 2015 | Retro | 193 | 67-69/69 | 98M | Good |
| Paolo Limongelli et al | 2007 | Pros | 220 | 52.7/59.6 | 131M | Good |
| Stephen et al | 2006 | Pros | 104 | 63 | 57M | Good |
| Nikolaos Arkadopoulos et al | 2014 | CCT | 240 | 58±11/57±12 | 95M | Fair |
| Yoshiaki Murakami et al | 2014 | Retro | 160 | 69 | 84M | Good |
| Pamela Hodul et al | 2003 | Retro | 212 | 64±10/66±11 | 128M | Fair |
| Marcos E. et al | 2000 | Retro | 257 | 64/69 | 140M | Good |

**RCT,** randomized controlled trial; **CCT**, case control study; **Pros**, prospective study; **Retro,** restrospective study

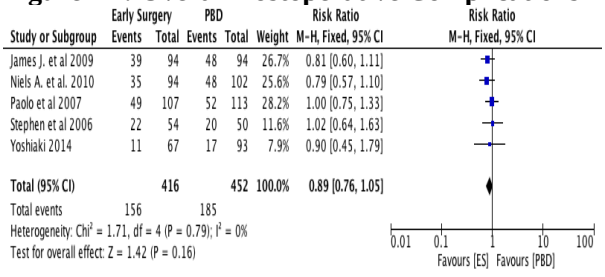
* **Study quality** was assessed using Jadad Score for the 2 randomized controlled trials (the studies by Niels A. van de Gaag et and Wietse J. Eshuis et al.) with a possible score of between 0 and 5 (highest level of quality), and "Good" was defined as a Jadad ≥4; "fair," a Jadad score of 3; and "poor," defined as a Jadad score <3. And the Newcastle- Ottawa Scale (NOS) was used to assess the quality of other 16 observational studies. Maximum score on this scale is a total of 9. "Good" was defined as a total score of 7-9; "fair," a total score of 4-6; and "poor," defined as a total score of ≤ 4.

## Meta-analysis

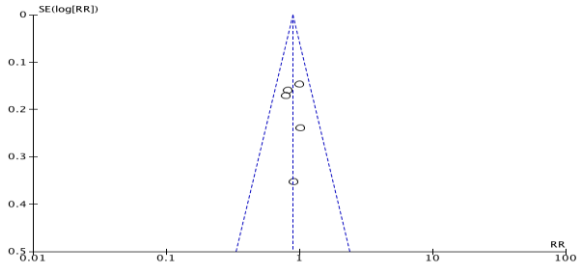
### Overall Postoperative Complications

From all included studies, five studies reported overall postoperative complications. There was no significant heterogeneity among the studies ($p$=0.79) in which the fixed effect model was used instead of random effect. Meta-analysis results showed that the overall postoperative complications did not differ significantly between the group of Early Surgery and of PBD (Risk Ratio [RR] =0.89, 95% Confidence Interval [CI] (0.76, 1.05) (**Figure 1A, 1B**).

**Figure 1A: Overall Postoperative Complications**



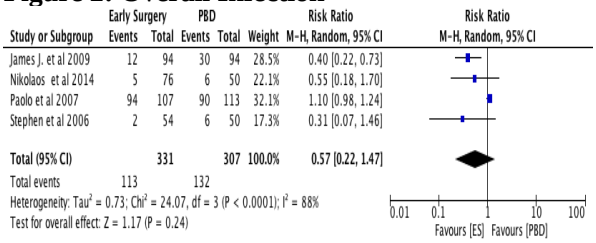

**1B**



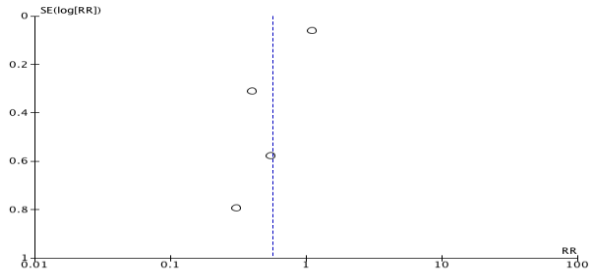

### Overall Infection

Four studies reported an overall infection. Meta-analysis showed significant heterogeneity among the studies, in which random effect model was used ($p$<0.0001). The overall infection did not differ significantly in these two compared groups (RR=0.57, 95%CI [0.22, 1.47]) (**Figure 2A, 2B**).

**Figure 2: Overall Infection**




**2B**

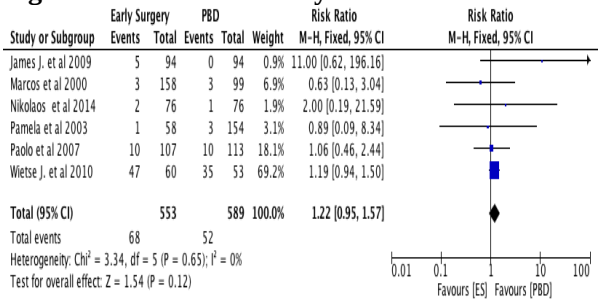



### Overall mortality

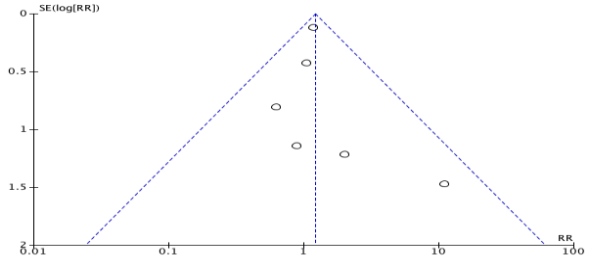
Six studies pointed out overall mortality results. There was no significant heterogeneity among the studies ($p$=0.65), thus; fixed effect model was

considered. Meta-analysis revealed that the overall mortality did not differ significantly between the two compared groups (RR=1.22, 95%CI [0.95, 157]) (**Figure 3A, 3B**).

**Figure 3: Overall mortality**



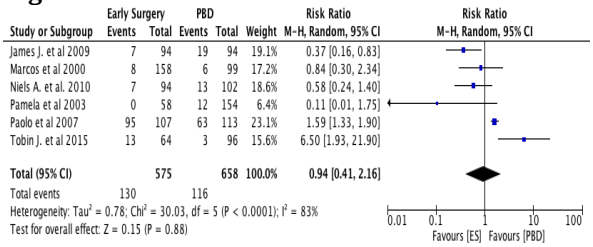

**3B**



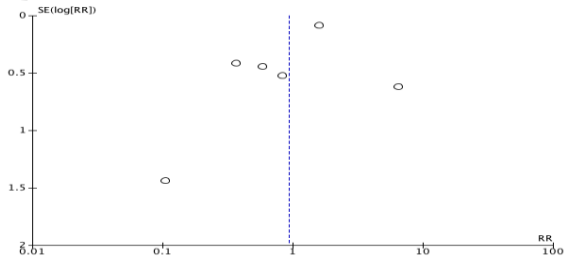

**Incidence of wound infection**

Six studies reported wound infection incidence. There was significant heterogeneity between the studies therefore random effect model was used ($p$<0.0001). Meta-analysis showed that the incidence of wound infection did not differ significantly between the two compared groups (RR=0.94, 95%CI [0.41, 2.16]) (**Figure 4A, 4B**).

**Figure 4: Incidence of wound infection**



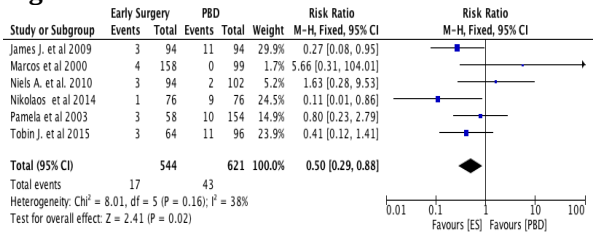

**4B**



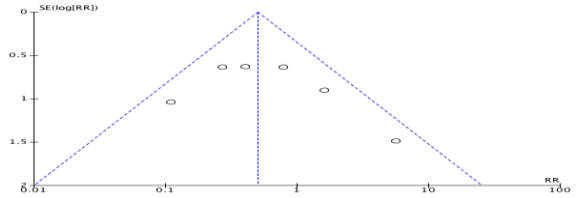

**Incidence of intra-abdominal abscess**

Six studies pointed out incidence of intra-abdominal abscess. There was no significant heterogeneity among the studies ($p$=0.16), therefore, fixed effect model was considered. Meta- analysis showed that the incidence of intra-abdominal did significantly differ between the two groups ($p$ = 0.02) (RR=0.50, 95%CI [0.29, 0.88]) (**Figure 5A, 5B**).

**Figure 5: Incidence of intra-abdominal abscess**



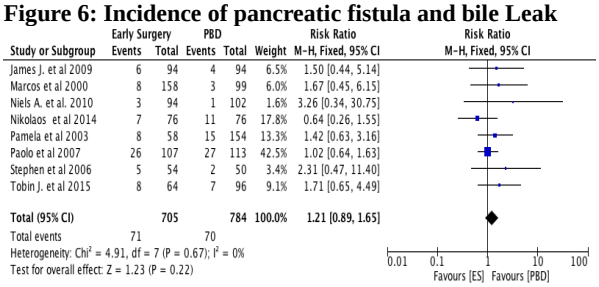

**5B**



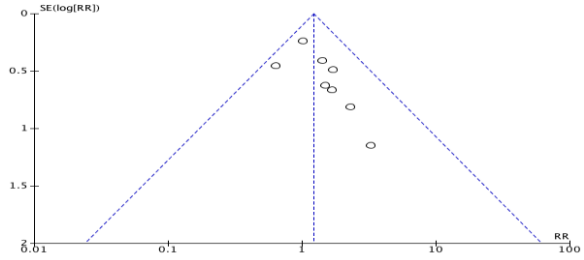

**Incidence of pancreatic fistula and bile Leak**

Eight studies reported the incidence of pancreatic fistula and bile leakage. Among the studies heterogeneity was not significant ($p$=0.67), therefore, fixed effect model was used. Meta-analysis showed that between the two compared groups the incidence of pancreatic fistula and bile leak did not differ significantly (RR=1.21, 95% CI [0.89, 1.65]) (**Figure 6A, 6B**).

**Figure 6: Incidence of pancreatic fistula and bile Leak**




**6B**




**Publication bias**

Funnel plots were present to assess the potential publication bias among included studies. For the small number of studies included for all outcomes. It is hard to assess the symmetry of funnel plot, so conclusion on publication bias cannot be made according to the funnel plots.

**Discussion**

The concept of PBD was developed with an attempt to reduce the postoperative morbidity and mortality in patients with obstructive jaundice, caused by a suspected pancreatic or periampullary malignancy. This Procedure either endoscopic or percutaneous is associated with an increased incidence of postoperative morbidity, mostly infectious complications and postoperative mortality when performed prior to a pancreaticoduodenectomy. Furthermore, the different technique of PBD has its own complications. A study [19] reported harmful and damaging effect, which to some extent is a result of complications associated with the drainage procedure. In one drainage study, Speer et al. [20] reported that patients had a significantly higher success rate for jaundice relief (81% vs. 61%, p=0.017) and significantly lower 30-day mortality (15% vs. 33%, p=0.016) in a randomized endoscopic method compared with those in the percutaneous drainage group. Liver puncture complications were associated with higher mortality after percutaneous stenting, which were hemorrhage and bile leaks. A 2012 Cochrane meta-analysis by Fang et al. [18] reported that PBD group had a significantly higher occurrence of serious morbidity compared to the early surgery group (RR, 1.66; 95% CI, 1.28 to 2.16; p=0.0002). In another study Martignoni et al. [21] reported that preoperative biliary drainage group had 47% postoperative morbidity, 4.3% reoperation rate and 2.3% mortality rate. Additionally, it was further noted that there was no difference in the total morbidity, infectious complications, reoperations rate, mortality or long-term survival between patients with or without PBD. However, contrary to the views of some research there are several other studies which strongly points to evidences that supports PBD. Coss A et al. [22] claimed that PBD is clearly indicated in the presence of cholangitis or significant hepatic dysfunction secondary to prolonged obstruction, both of which may be expected to increase perioperative complications and that biliary drainage can be considered if surgery is delayed for logistical reasons or to permit delivery of neoadjuvant chemoradiotherapy, particularly in patients with deep jaundice or pruritus. This was attributed to an association between hyperbilirubinemia and increased perioperative complications. Furthermore, some experimental studies conducted on jaundiced animals revealed the benefits of biliary drainage, especially internal biliary drainage with restoration of enterohepatic circulation of biliary salts [23, 24]. Again, other multiple retrospective studies showed that PBD decreases postoperative complications, exclusive of improvement in mortality or survival [25-28].

A systematic review of 11 studies comparing PBD (five percutaneous, six percutaneous or endoscopic) or no PBD in patients with hilar cholangiocarcinoma (klastin tumor) did not prove a decrease in mortality or postoperative hospital stay in patients experiencing PBD. There was an increase in postoperative complication rates (36–100% vs 28–72%) and infectious morbidity (18–52% vs 0–27%) in the PBD group [29].

A recent multicenter retrospective study similarly showed no decrease in overall postoperative morbidity and mortality in patients with hilar cholangiocarcinoma (HC) undergoing PBD; however, a subgroup study verified significant reduction in postoperative mortality in patients undergoing right hepatectomy, advocating patients with type IIIa may benefit from PBD [26].

Other older studies [10, 30] have supported the importance of biliary drainage prior to tumor resection in which operative mortality was decreased from 28% to 8%. Although there are evidences supporting PBD, there are arguments based on the different methods of PBD. Studies [9, 31] have shown an increased rate of perioperative morbidity following ERCP stent placement, including early stent occlusion, need for stent exchange, pancreatitis, cholangitis, perforation, hemorrhage, bile leak, and wound infection. Tobin J. Strom et al. [32] in their study concluded that, PTBD patients had an independently worse overall survival, likely a result of advanced locoregional disease on presentation, as well as an increased rate of hepatic metastases. However, notwithstanding this, not all stents have equal benefit, plastic stents have been shown to occlude more rapidly and are unable to maintain patency long enough for neoadjuvant chemoradiotherapy for pancreatic carcinoma than that of metal stents [33, 34]. Combined data from retrospective studies [9, 12, 35-41] published over the past few years have shown equivalent rates of 30-day mortality after pancreaticoduodenectomy (PD) in those who have undergone PBD and those who have not. Infectious complication rates were also similar in the two groups; nevertheless, the outcome measures have not been identical and the absence of complete data on complications following preoperative drainage made direct comparisons difficult and biased [42].

Consequently, the overall conclusion not to routinely perform preoperative biliary drainage seems evident; however, there still remain some selected obstructed jaundiced patients with pancreatic cancer whom could still benefit from biliary drainage as a temporizing measure. These include patients whom surgery could be delayed

because of the need for preoperative staging and clinical evaluation, those with correction of underlying comorbid medical illnesses, also for those with whom there is a postponement because of the administration of neo-adjuvant therapy. A delay in surgery may be indeed an effective decision for selected patients undergoing curative-intent surgery (CIS).

Additionally, a prospective randomized trial addressing the effects of PBD is required to find out whether or not PBD should be routinely performed in jaundiced patients prior to pancreatoduodenectomy.

In this systematic review and meta-analysis study we focused mainly on overall postoperative complications, overall infections; overall wound infections, the incidence of intra-abdominal abscess, overall mortality and the incidence of pancreatic fistula or bile leak. Early surgery group was compared with Preoperative Biliary Drainage group. There was no significant heterogeneity in the subgroup studies included except for one of the incidence of wound infection (RR=0.94, 95%CI [0.41, 2.16]), but meta-analysis showed that the incidence of wound infection did not differ significantly. Between the two compared groups, meta-analysis was significantly different in the incidence of intra-abdominal abscess only in which six studies had reported results of the incidence. ($\alpha$ = 0.02) (RR=0.50, 95%CI [0.29, 0.88]) (Fig. 5).

This study has some limitations such as: the quality of each study was not equally the same; only 2 studies were randomized clinical trial, one case control study and the others were cohort studies; studies included did not focus on the same outcome parameters.

Thus, in light of the forgoing limitations; it is strongly suggested that a high quality randomized controlled trial for obstructed jaundiced patients caused by pancreatic head carcinoma should be carried out in order to accomplish best and most effective treatment method in such patients.

## Conclusion

Preoperative biliary drainage group when compared with direct early surgery group showed increased incidence of intra-abdominal abscess for pancreatic head carcinoma patients.

## Conflicts of interest statement

There were no conflicts of interest among the authors in this study.

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