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META-ANALYSIS

Prophylactic intra-peritoneal drain placement following pancreaticoduodenectomy: A systematic review and meta-analysis

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Abstract

AIM: To conduct a meta-analysis comparing outcomes after pancreaticoduodenectomy (PD) with or without prophylactic drainage.

METHODS: Relevant comparative randomized and non-randomized studies were systemically searched based on specific inclusion and exclusion criteria. Postoperative outcomes were compared between patients with and those without routine drainage. Pooled odds ratios (OR) with 95%CI were calculated using either fixed effects or random effects models.

RESULTS: One randomized controlled trial and four non-randomized comparative studies recruiting 1728 patients were analyzed. Patients without prophylactic drainage after PD had significantly higher mortality (OR = 2.32, 95%CI: 1.11-4.85; P = 0.02), despite the fact that they were associated with fewer overall complications (OR = 0.62, 95%CI: 0.48-0.82; P = 0.00), major complications (OR = 0.75, 95%CI: 0.60-0.93; P = 0.01) and readmissions (OR = 0.77, 95%CI: 0.60-0.98; P = 0.04). There were no significant differences in the rates of pancreatic fistula, intra-abdominal abscesses, postpancreatectomy hemorrhage, biliary fistula, delayed gastric emptying, reoperation or radiologic-guided drains between the two groups.

CONCLUSION: Indiscriminate abandonment of intra-abdominal drainage following PD is associated with greater mortality, but lower complication rates. Future randomized trials should compare routine *vs* selective drainage.

Key words: Pancreaticoduodenectomy; Drain; Meta-analysis; Morbidity; Postoperative pancreatic fistula

Core tip: Routine prophylactic drainage remains standard practice following pancreaticoduodenectomy (PD) due to concerns that abandoning this would not be safe. Existing studies provide limited evidence regarding prophylactic drainage following PD. A systematic review addressing postoperative drainage following PD is therefore required. This study clarified that indiscriminate abandonment of intra-abdominal drainage following PD is associated with greater mortality, but lower overall and major complication rates. However, future randomized trials are needed to compare routine *vs* selective drainage.

Wang YC, Szatmary P, Zhu JQ, Xiong JJ, Huang W, Gomatos I, Nunes QM, Sutton R, Liu XB. Prophylactic intra-peritoneal drain placement following pancreaticoduodenectomy: A systematic review and meta-analysis. *World J Gastroenterol* 2015; 21(8): 2510-2521 Available from: URL: http://www.wjgnet.com/1007-9327/full/v21/i8/2510.htm DOI: http://dx.doi.org/10.3748/wjg.v21.i8.2510

INTRODUCTION

The routine use of intraperitoneal drain placement at the end of abdominal operations has been considered standard practice for many years. It can prevent build-up of intra-abdominal fluid collections and debris, as well monitor for anastomotic leaks and hemorrhage[1,2]. In recent years, however, a number of randomized controlled trials (RCTs) have demonstrated that prophylactic drainage at the operative bed is not associated with a reduction in postoperative complications in elective cholecystectomy[3], hepatectomy[4], gastrectomy[5] or colectomy[6]. As a result, surgeons are beginning to abandon this practice.

The role of prophylactic drain placement after pancreatic resection remains unclear. With a reported morbidity between 30% and 50% in pancreatic surgery, resulting in both prolonged hospital stay and increased cost[7,8], even a modest improvement in procedure can have great benefits for patients and hospitals alike. The commonest complication after pancreatic resection is postoperative pancreatic fistula (POPF), which has an incidence ranging from 2% to more than 30% and is thought to contribute to other complications such as hemorrhage, intra-abdominal abscess, sepsis, multisystem organ failure and death[7]. As drains allow early identification and management of these complications, their use following elective pancreatic resection has become routine[9,10]. There is, however, an ongoing debate regarding risks and benefits of their use in this setting. For example, it is argued that drainage tubes may impede wound healing, and that the pressure generated by closed-suction systems may even contribute to the formation of POPF[11]. Furthermore, given the significant improvements in quality and availability of diagnostic and interventional radiology services in recent years, a drain can be usually be safely placed percutaneously to deal with POPF or abdominal fluid collections should they develop. Therefore, the routine practice of drain placement after pancreatic resection is open to debate[12].

Existing studies provide limited evidence regarding the use of prophylactic drainage following pancreaticoduodenectomy (PD) as well as the optimal timing for drain removal[13,14]. Routine prophylactic drainage remains standard practice by the majority of pancreatic surgeons around the world[14,15] and many surgeons fear that abandoning this would not be safe. A systematic review addressing postoperative drainage or not following PD is therefore required. The current study was conducted to clarify this issue.

MATERIALS AND METHODS

Study selection

PubMed (MEDLINE), EMBASE and Science Citation Index Expanded databases and the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library were searched for RCTs and observational comparative studies on routine intraperitoneal drainage after PD up to and including May 2014. Search terms included: "drainage", "drain", "suction", "pancreaticoduodenectomy", "pancreatoduodenectomy", "Whipple", "pancreatoduodenal resection", "postoperative complications" and "pancreatic fistula". Reference lists of selected articles were also examined to find relevant studies not identified during the database searches. Investigators and experts in the field of pancreatic surgery were then contacted to ensure that all relevant studies were identified. Only comparative clinical trials with full-text descriptions were included. Final inclusion of articles was determined by consensus between two authors; where this failed, a third author adjudicated.

Inclusion and exclusion criteria

The PRISMA criteria[16] were used as guidelines in the construction of this analysis. Two authors screened the search results for potentially eligible studies. Inclusion criteria were: (1) English language articles published in peer-reviewed journals; (2) human studies; and (3) studies with at least one of the outcomes mentioned. Where multiple studies came from the same institute and/or authors, either the higher quality study or the more recent publication was included in the analysis.

Exclusion criteria were: (1) abstracts, letters, editorials, expert opinions, case reports, reviews and studies lacking control groups; (2) studies including patients undergoing distal or central pancreatectomy; (3) studies only comparing peripancreatic fixed drain and non-fixed drainage; and (4) studies only comparing early and delayed removal of drainage tube after PD.

Outcomes of interest and definitions

Primary outcome was mortality, which was defined as death from any cause, prior to discharge from hospital or within 30, 60 or 90 d. Secondary outcomes included the incidence of POPF, biliary fistula, delayed gastric emptying, intra-abdominal abscess formation, post-pancreatectomy hemorrhage, reoperation, re-admission and need for radiologic-guided drains. POPF was defined using the International Study Group on Pancreatic Fistula (ISGPF) definition[17] or other definitions. Overall complications were defined as the sum of the aforementioned complications from operation to discharge. Major complications were defined as grade Ⅲ-Ⅳ according to the Clavien Classification of Surgical Complications[18]. Whenever relevant information was lacking, the following definitions were applied. Biliary fistula was defined as a bilirubin-containing discharge of typical color or as determined by fistulography. Delayed gastric emptying was defined as the need for nasogastric decompression beyond ten days after surgery, or as proposed by the International Study Group of Pancreatic Surgery[19]. Intra-abdominal abscess formation was defined as an intra-abdominal fluid collection associated with fever requiring drainage and subsequently yielding positive cultures. Post-pancreatectomy hemorrhage was defined as per the International Study Group of Pancreatic Surgery definition[20]. Reoperation was defined as the need for laparotomy as a consequence of the first operation. Readmission was defined as the need for hospital admission for any reason.

Data extraction and quality assessment

Data were extracted by two independent researchers using standardized forms. The qualitative assessment of the RCTs was based on the Jadad *et al*[21] scoring system that took into consideration the randomization and double-blinding process and the description of withdrawals or dropouts. Note was also made of sample size calculation, sequence generation, allocation concealment, and definitions of outcome parameters. The non-RCTs were assessed on the basis of McKay *et al*[22] method that included assessment of the following parameters: prospective *vs* retrospective data collection; assignment to drain group or no drain group by means other than the surgeon's preference; and an explicit definition of POPF or leak (studies were given a score of 1 for each of these areas; score 1-4).

Statistical analysis

The meta-analyses were performed using Review Manager Version 5.1 software (The Cochrane Collaboration, Oxford, United Kingdom). Pooled odds ratios (ORs) with 95%CIs were calculated using fixed or random effects models. Heterogeneity was evaluated by means of the χ^2 test, with $P < 0.1$ considered to represent a significant difference. I^2 values were used for the evaluation of statistical heterogeneity; an I^2 value of $\geqslant$ 50% indicated the presence of heterogeneity[23]. The fixed effects model was initially calculated for all outcomes[24], but if the test rejected the assumption of homogeneity of studies, a random effects analysis was performed[25]. If data were considered to be inappropriate for meta-analysis in the included studies, some outcomes were presented in a descriptive way. Sensitivity analyses were performed by removing individual studies from the data set and analyzing the effect on the overall results to identify sources of significant heterogeneity. Subgroup analyses were undertaken by including studies with the ISGPF definition or quality score $\geqslant$ 2 to present cumulative evidence. Funnel plots[26] were constructed to evaluate potential publication bias based on POPF.

RESULTS

Description of included trials in the meta-analysis

The search strategy initially generated 288 relevant clinical trials. A total of 12 full text articles[12,27-37] were identified for detailed investigation. Of these, seven studies[12,14,28,29,31,32,34] were excluded: one study only compared peripancreatic fixed drain and non-fixed drainage[29], two studies[14,28] only compared early and delayed removal of drainage tube, three studies[12,31,34] included patients undergoing central and distal pancreatectomy, and one study[32] focused on distal pancreatectomy alone. Figure 1 shows the process of selecting comparative studies included in our meta-analysis. The study characteristics and quality assessments are shown in Table 1 and the definition of POPF in Table 2. Postoperative outcomes are listed in Table 3.

In total, five studies (1728 patients) were included: 945 and 783 patients in the no drain and drain group, respectively. The number of patients in each study ranged from 54 to 739. There was only one RCT[37] and four observational comparative studies with prospective[35]or retrospective designs[30,33,36]. The ISGPF definition of POPF was used in three studies[33,36,37]. Three studies[30,35,36] did not comment on timing of complications, but one study[33] reported 90 d complication rate and another[37] reported 30 and 60 d rates.

Primary outcomes

Results of the analyses are shown in Figure 2 and summarized in Table 4. Four studies[33,35-37] reported mortality. Because Van Buren *et al*[37] reported 30, 60 and 90 d mortality rates, analyses were repeated using each time point individually. Using the 30 d mortality rate, there was higher mortality in the no drain group (OR = 2.32, 95%CI: 1.11-4.85; $P = 0.02$). This finding persisted using both 60 d (OR = 2.36,

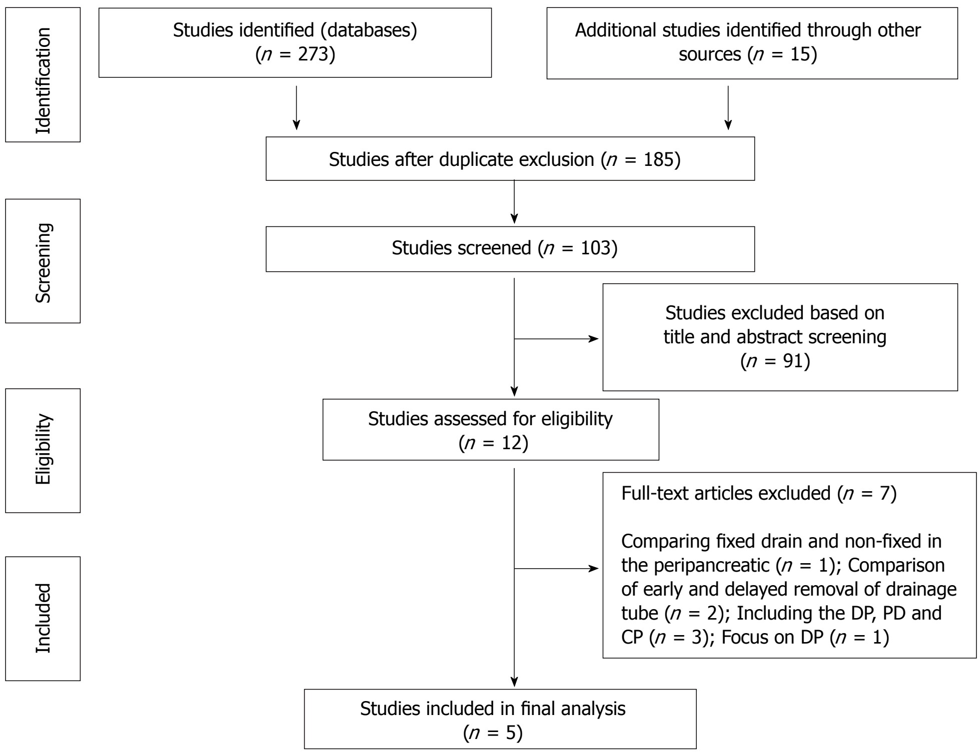


Figure 1 Flow diagram depicting the study selection. CP: Central pancreatectomy; DP: Distal pancreatectomy; PD: Pancreaticoduodenectomy.

Table 1 Characteristics of the included studies

Ref.	Year	Country	Design	Drain	*n*	Sex (male/female)	Age (yr)	Type of surgery	Disease (M/B)	Score[1]
Heslin *et al*[30]	1998	United States	Retro	Yes	51	18/20	65 ± 2	PD	47/4	1
				No	38	19/32	65 ± 2	PPPD	31/7	
Lim *et al*[33]	2013	France	Retro	Yes	27	8/19	62 (40-76)	PD	20/7	1
				No	27	8/19	62 (38-78)	PPPD	20/7	
Mehta *et al*[36]	2013	United States	Retro	Yes	251	130/121	60.0	PD	162/89	1
				No	458	222/236	62.5	PPPD	289/169	
Correa-Gallego *et al*[35]	2013	United States	PNR	Yes	386	NA	NA	NA	282/104	2
				No	353				257/96	
Van Buren *et al*[37]	2014	United States	RCT	Yes	68	37/31	62.1 ± 11.7	PD	45/23	3
				No	69	38/31	64.3 ± 12.6		50/19	

[1]Scoring for RCT was according to Jadad scoring system, and the method of McKay *et al*[22] was used for non-randomized studies. B: Benign; M: Malignant; NA: Not available; PD: Pancreaticoduodenectomy; PNR: Prospective nonrandomized observational study; PPPD: Pylorus-preserving pancreaticoduodenectomy; RCT: Randomized controlled trial; Retro: Retrospective observational study.

Table 2 Definition of pancreatic fistula

Ref.	Definition of postoperative pancreatic fistula
Heslin *et al*[30]	> 30 mL/d pancreatic fluid drainage for more than 1 wk
Lim *et al*[33]	International study group on pancreatic fistula definition
Mehta *et al*[36]	International study group on pancreatic fistula definition
Correa-Gallego *et al*[35]	Clinical signs and symptoms with amylase-rich drainage > 50 mL/d after postoperative day 10
Van Buren *et al*[37]	International study group on pancreatic fistula definition

95%CI: 1.15-4.84; *P* = 0.02) and 90 d rates (OR = 2.34, 95%CI: 1.17- 4.67; *P* = 0.02).

Secondary outcomes

Results of the analyses are shown in Figures 3 and 4 and summarized in Table 4. There was no statistically significant difference in rates of POPF between the drain and no drain groups, analyzing both the 30 d (OR = 0.61, 95%CI: 0.33-1.12) and 60 d (OR = 0.59, 95 %CI: 0.33-1.05) rates in the Van Buren *et al*[37] study. There was, however, significant heterogeneity (I^2 = 63%) when using the 60 d time point.

As for the other complications, there were no statistically significant differences in the rates of intra-abdominal abscess formation (OR = 1.80, 95%CI: 0.82-3.97), post-pancreatectomy hemorrhage (OR = 1.55, 95%CI: 0.60-3.99), biliary fistula (OR = 0.32, 95%CI: 0.03-3.14), delayed gastric emptying

Table 3 Postoperative outcomes

Ref.	Drain	Complications Overall	Complications Major	POPF	BF	DGE	IAA	POH	Mortality	Reoperation	Readmission	RGD
Heslin *et al*[30]	Yes	23	14	3	NA	NA	3	NA	NA	1	NA	2
	No	15	8	1	NA	NA	0	NA	NA	3	NA	1
Lim *et al*[33]	Yes	19	5	5	0	3	1	2	1	2	0	1
	No	15	2	0	0	4	1	2	1	1	1	1
Mehta *et al*[36]	Yes	171	62	41	NA	NA	NA	0	5	14	44	21
	No	248	75	35	NA	NA	NA	0	11	26	75	29
Correa-Gallego *et al*[35]	Yes	NA	139	104	NA	NA	NA	NA	3	2	107	68
	No	NA	105	59	NA	NA	NA	NA	11	2	73	49
Van Buren *et al*[37]	Yes	50/50[1]	19/21[1]	7/8[1]	3/3[1]	16/16[1]	7/8[1]	6/6[1]	0/1/2[2]	2	16	6
	No	52/55[1]	28/28[1]	14/14[1]	1/2[1]	26/29[1]	17/18[1]	10/13[1]	4/6/8[2]	6	12	16

[1]After postoperative 30/60 d; [2]after postoperative 30/60/90 d. BF: Biliary fistula; DGE: Delayed gastric emptying; IAA: Intra-abdominal abscess; NA: Not available; POPF: Postoperative pancreatic fistula; POH: Postoperative hemorrhage; RGD: Radiologic-guided drains.

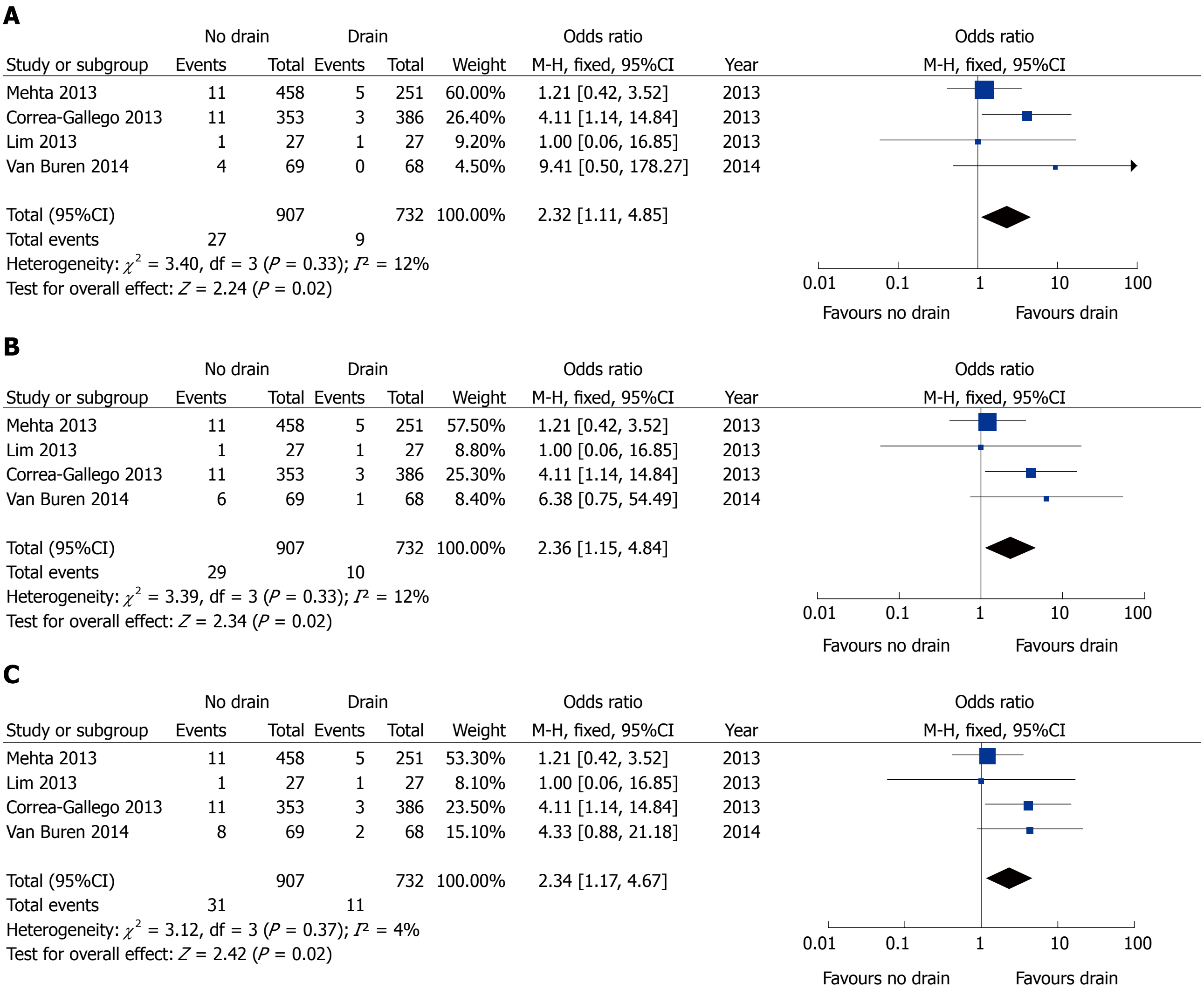


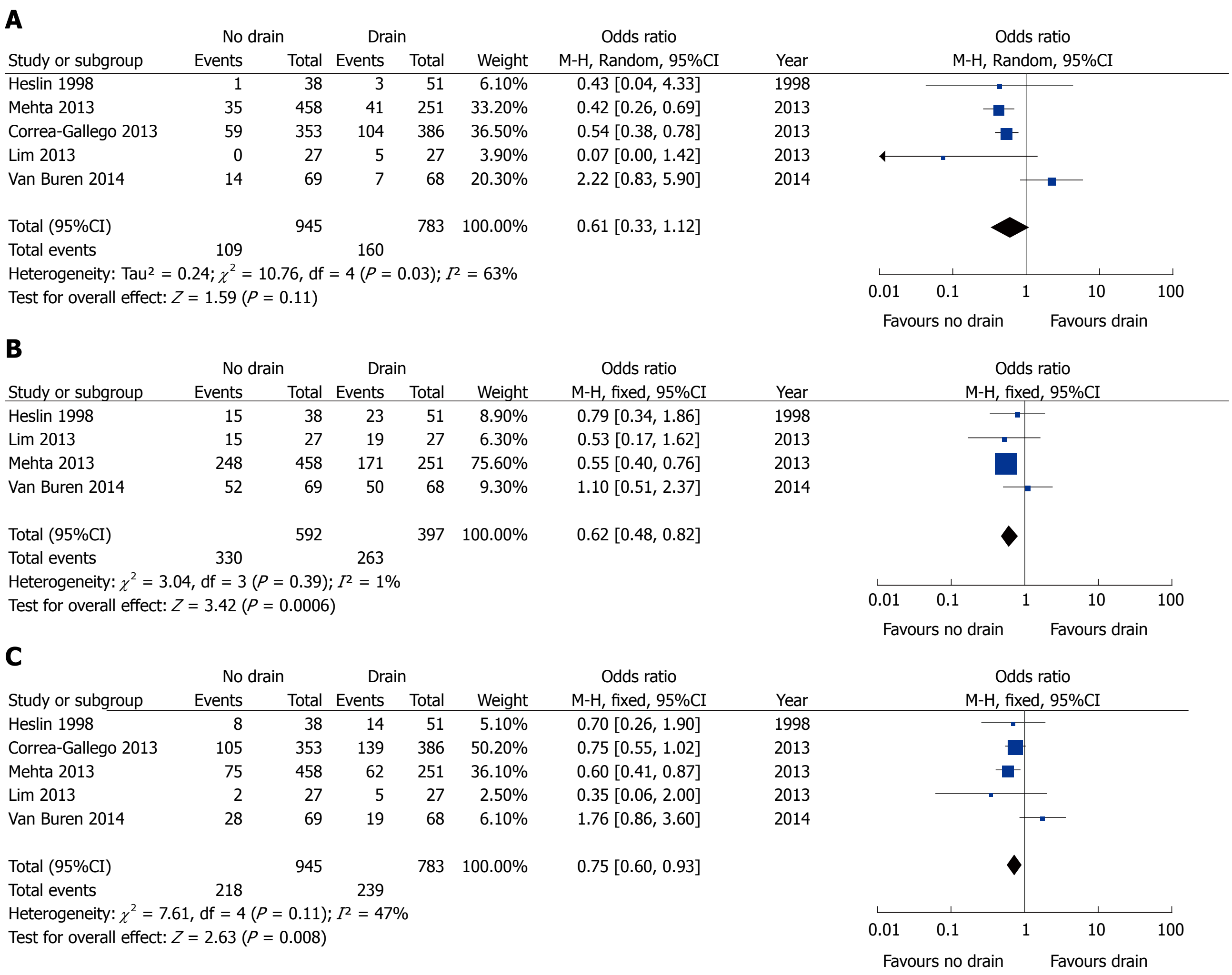
Figure 2 Forest plots illustrating meta-analysis of primary outcomes comparing drain with no drain after pancreaticoduodenectomy. Pooled odds ratios (ORs) with 95%CIs were calculated using the fixed effects models to analyze outcomes at A: 30 d; B: 60 d; and C: 90 d.

(OR = 1.85, 95%CI: 0.94-3.62), reoperation (OR = 1.26, 95%CI: 0.73-2.17) or use of radiologic-guided drains (OR = 0.98, 95%CI: 0.57-1.66) between the two groups when using the 30 d rates reported by Van Buren *et al*[37]. However, overall complications (OR = 0.62, 95%CI: 0.48-0.82; $P < 0.01$), major complications (OR = 0.75, 95%CI: 0.60-0.93; $P = 0.01$) and rate of readmission (OR = 0.77, 95%CI: 0.60-0.98; $P = 0.04$) were fewer in the no drain group. Similar findings were obtained using the 60 d

Table 4 Summary results of drain *vs* no drain after pancreaticoduodenectomy

	Outcome	Studies (*n*)	Patients (*n*)	OR (95%CI)	*P*	Heterogeneity	
						P	I^2
All studies	Overall complications	4	989	0.62 (0.48-0.82)	< 0.01	0.39	1%
	Major complications	5	1728	0.75 (0.60-0.93)	0.01	0.11	47%
	Postoperative pancreatic fistula	5	1728	0.61 (0.33-1.12)	0.11	0.03	63%
	Biliary fistula	2	191	0.32 (0.03-3.14)	0.33	NA	NA
	Delayed gastric emptying	2	191	1.85 (0.94-3.62)	0.07	0.70	0%
	Intra-abdominal abscess formation	3	280	1.80 (0.82-3.97)	0.14	0.19	40%
	Post-pancreatectomy hemorrhage	2	191	1.55 (0.60-3.99)	0.36	0.63	0%
	Mortality	4	1639	2.32 (1.11-4.85)	0.02	0.33	12%
	Reoperation	5	1728	1.26 (0.73-2.17)	0.41	0.51	0%
	Readmission	4	1639	0.77 (0.60-0.98)	0.04	0.56	0%
	Radiologic-guided drains	5	1728	0.98 (0.57-1.66)	0.93	0.13	43%
ISGPF definition	Overall complications	3	900	0.61 (0.46-0.81)	< 0.01	0.26	26%
	Major complications	3	900	0.82 (0.34-1.98)	0.66	0.02	74%
	Postoperative pancreatic fistula (ISGPF B/C)	3	900	0.61 (0.14-2.66)	0.51	0.01	81%
	Intra-abdominal abscess formation	2	191	2.57 (1.05-6.29)	0.04	0.49	0%
	Mortality	3	900	1.68 (0.68-4.18)	0.26	0.40	0%
	Reoperation	3	900	1.16 (0.64-2.09)	0.63	0.36	3%
	Readmission	3	900	0.89 (0.62-1.27)	0.52	0.61	0%
	Radiologic-guided drains	3	900	1.34 (0.43-4.19)	0.61	0.05	66%
Quality score ≥ 2	Major complications	2	876	1.08 (0.47-2.46)	0.85	0.03	78%
	Postoperative pancreatic fistula (ISGPF B/C)	2	876	1.02 (0.26-4.00)	0.98	0.01	86%
	Mortality	2	876	4.88 (1.52-15.69)	0.01	0.61	0%
	Reoperation	2	876	2.10 (0.62-7.12)	0.23	0.42	0%
	Readmission	2	876	0.68 (0.50-0.93)	0.02	0.99	0%
	Radiologic-guided drains	2	876	1.42 (0.36-5.66)	0.62	0.01	85%

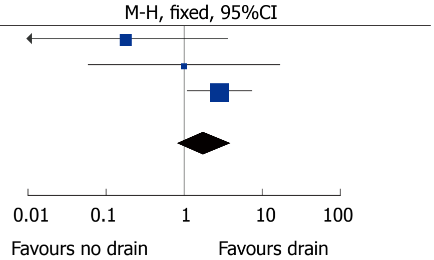
ISGPF: International Study Group on Pancreatic Fistula; OR: Odds ratio.



D

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Heslin 1998	0	38	3	51	32.10%	0.18 [0.01, 3.59]	1998
Lim 2013	1	27	1	27	10.40%	1.00 [0.06, 16.85]	2013
Van Buren 2014	17	69	7	68	57.50%	2.85 [1.10, 7.40]	2014
Total (95%CI)		134		146	100.00%	1.80 [0.82, 3.97]	
Total events	18		11				

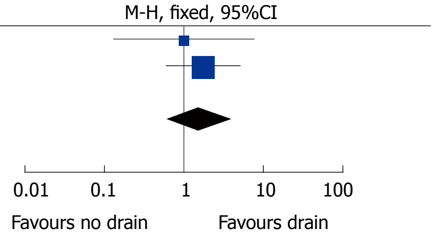
Heterogeneity: χ^2 = 3.33, df = 2 (P = 0.19); I^2 = 40%
Test for overall effect: Z = 1.46 (P = 0.14)



E

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Lim 2013	2	27	2	27	26.40%	1.00 [0.13, 7.67]	2013
Van Buren 2014	10	69	6	68	73.60%	1.75 [0.60, 5.12]	2014
Total (95%CI)		96		95	100.00%	1.55 [0.60, 3.99]	
Total events	12		8				

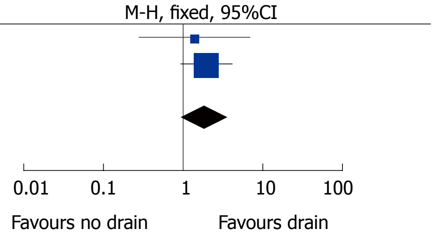
Heterogeneity: χ^2 = 0.23, df = 1 (P = 0.63); I^2 = 0%
Test for overall effect: Z = 0.91 (P = 0.36)



F

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Lim 2013	4	27	3	27	20.30%	1.39 [0.28, 6.91]	2013
Van Buren 2014	26	69	16	68	79.70%	1.97 [0.94, 4.13]	2014
Total (95%CI)		96		95	100.00%	1.85 [0.94, 3.62]	
Total events	30		19				

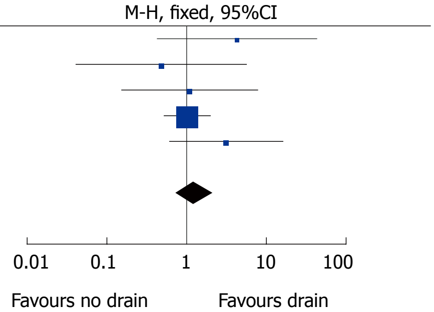
Heterogeneity: χ^2 = 0.15, df = 1 (P = 0.70); I^2 = 0%
Test for overall effect: Z = 1.79 (P = 0.07)



G

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Heslin 1998	3	38	1	51	3.30%	4.29 [0.43, 42.92]	1998
Lim 2013	1	27	2	27	8.20%	0.48 [0.04, 5.64]	2013
Correa-Gallego	2	353	2	386	8.10%	1.09 [0.15, 7.81]	2013
Mehta 2013	26	458	14	251	72.60%	1.02 [0.52, 1.99]	2013
Van Buren 2014	6	69	2	68	7.80%	3.14 [0.61, 16.16]	2014
Total (95%CI)		945		783	100.00%	1.26 [0.73, 2.17]	
Total events	38		21				

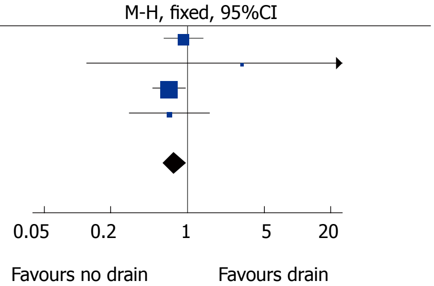
Heterogeneity: χ^2 = 3.28, df = 4 (P = 0.51); I^2 = 0%
Test for overall effect: Z = 0.82 (P = 0.41)



H

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Mehta 2013	75	458	44	251	33.40%	0.92 [0.61, 1.39]	2013
Lim 2013	1	27	0	27	0.30%	3.11 [0.12, 79.87]	2013
Correa-Gallego 2013	73	353	107	386	56.90%	0.68 [0.48, 0.96]	2013
Van Buren 2014	12	69	16	68	9.30%	0.68 [0.30, 1.58]	2014
Total (95%CI)		907		732	100.00%	0.77 [0.60, 0.98]	
Total events	161		167				

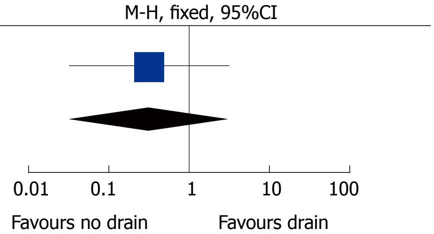
Heterogeneity: χ^2 = 2.04, df = 3 (P = 0.56); I^2 = 0%
Test for overall effect: Z = 2.08 (P = 0.04)



I

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Lim 2013	0	27	0	27		Not estimable	2013
Van Buren 2014	1	69	3	68	100.00%	0.32 [0.03, 3.14]	2014
Total (95%CI)		96		95	100.00%	0.32 [0.03, 3.14]	
Total events	1		3				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.98 (P = 0.33)



J

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, Random, 95%CI	Year
Heslin 1998	1	38	2	51	4.40%	0.66 [0.06, 7.58]	1998
Lim 2013	1	27	1	27	3.30%	1.00 [0.06, 16.85]	2013
Correa-Gallego	49	353	68	386	41.40%	0.75 [0.51, 1.12]	2013
Mehta 2013	29	458	21	251	32.70%	0.74 [0.41, 1.33]	2013
Van Buren 2014	16	69	6	68	18.30%	3.12 [1.14, 8.54]	2014
Total (95%CI)		945		783	100.00%	0.98 [0.57, 1.66]	
Total events	96		98				

Heterogeneity: Tau² = 0.14; χ^2 = 7.03, df = 4 (*P* = 0.13); I^2 = 43%

Test for overall effect: *Z* = 0.09 (*P* = 0.93)

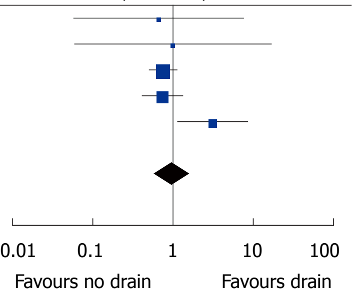


Figure 3 Forest plots illustrating meta-analysis of secondary outcomes comparing drain with no drain after pancreaticoduodenectomy. Pooled odds ratios (ORs) with 95%CIs were calculated using fixed or random effects models to analyze outcomes at 30 d. A: Pancreatic fistula; B: Overall complications; C: Major complications; D: Intra-abdominal abscess; E: Postoperative hemorrhage; F: Delayed gastric emptying; G: Reoperation; H: Readmission; I: Biliary fistula; J: Radiologic-guided drain.

complication rates reported by Van Buren *et al*[37], with no statistically significant differences in intra-abdominal abscess formation (OR 1.75, 95%CI: 0.81-3.77), biliary fistula (OR = 0.65, 95%CI: 0.10-4.00) and post-pancreatectomy hemorrhage rates (OR = 2.02, 95%CI: 0.81-5.01). Rates of delayed gastric emptying (OR = 2.15, 95%CI: 1.10-4.19; *P* = 0.02), however, were lower in the drain group. The no drain group still had fewer overall (OR = 0.64, 95%CI: 0.49-0.84; *P* < 0.01) and major (OR = 0.74, 95%CI: 0.59-0.92; *P* = 0.01) complications.

Statistical analysis

Sensitivity analyses were carried out by excluding each study from each outcome measure. These exclusions did not alter the results obtained from cumulative analyses. The subgroup analyses were undertaken for all outcome measures by including studies with ISGPF definition or quality score ≥ 2. Results of the analyses are summarized in Table 4.

Publication bias

The funnel plot based on the incidence of POPF is shown in Figure 5. None of the studies lie outside the limits of the 95%CI and hence, there was no evidence of publication bias. However, there was a somewhat asymmetric distribution around the vertical axis with an absence of smaller studies favoring PD with no drain.

DISCUSSION

Routine drainage after surgery has been a hotly debated topic since the advent of surgical drains. Over the past 30 years, however, its application has declined due to the relative ease and safety of computed tomography-guided drainage[38] and literature demonstrating increased frequency of complications with routine drainage[39]. There are divided opinions over routine drainage following pancreatic resections because of the high frequency of clinically significant complications, many of which relate to POPF. Routine drain placement potentially allows early detection of POPF and potentially gives clues that allow differentiation between POPF, intra-abdominal abscess formation, intra-abdominal fluid collections and anastomotic leaks, allowing for early, targeted management[17,31].

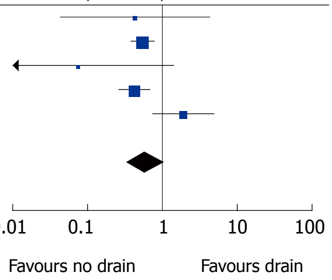
Our own analyses reveal two significant yet apparently contradictory results: there is greater mortality in the no drain group, and yet fewer overall and major complications as well as a lower readmission rate. Firstly, one has to note that most of the observed differences in mortality stem from a single study[37], which happened to be the only RCT included in our analysis. In this study, there is a significantly greater proportion of intra-abdominal abscess formation, intra-abdominal fluid collections and diarrhea in the no drain group, providing us with some insight as to the cause of mortality. The remaining studies, which are non-RCTs, report similar mortality rates, yet lower overall complication rates in the no drain group. Serious complications such as bowel perforation and/or fistulation has been reported from intra-abdominal suction drains[40,41] and these devices are often associated with increased pain and prolonged hospital stay, suggesting possible mechanisms for these findings. Notably, however, analyses of individual clinically significant, PD-specific complications do not reveal statistically significant differences, apart from delayed gastric emptying. This may indicate variability in definitions between studies and highlights the drawbacks of comparative meta-analyses.

Furthermore, the indication for postoperative drainage and the type of drain could affect the incidence of complications and prognosis of patients. From the non-randomized studies included in our analysis, one reported that intra-abdominal drain placement was at the discretion of the attending surgeon[36], while another suggested that routine abdominal drainage was dependent on pancreatic texture (soft) and pancreatic duct diameter (< 3 mm)[33]. In patients with a hard pancreas and/or a dilated (> 3 mm) main pancreatic

A

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, Random, 95%CI	Year
Heslin 1998	1	38	3	51	5.40%	0.43 [0.04, 4.33]	1998
Correa-Gallego 2013	59	353	104	386	37.50%	0.54 [0.38, 0.78]	2013
Lim 2013	0	27	5	27	3.50%	0.07 [0.00, 1.42]	2013
Mehta 2013	35	458	41	251	33.60%	0.42 [0.26, 0.69]	2013
Van Buren 2014	14	69	8	68	20.00%	1.91 [0.74, 4.90]	2014
Total (95%CI)		945		783	100.00%	0.59 [0.33, 1.05]	
Total events	109		161				

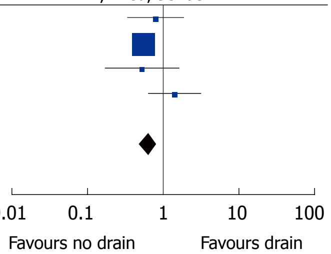
Heterogeneity: Tau² = 0.19; χ^2 = 9.64, df = 4 (P = 0.05); I^2 = 59%
Test for overall effect: Z = 1.79 (P = 0.07)



B

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Heslin 1998	15	38	23	51	9.00%	0.79 [0.34, 1.86]	1998
Mehta 2013	248	458	171	251	76.80%	0.55 [0.40, 0.76]	2013
Lim 2013	15	27	19	27	6.40%	0.53 [0.17, 1.62]	2013
Van Buren 2014	55	69	50	68	7.80%	1.41 [0.64, 3.14]	2014
Total (95%CI)		592		397	100.00%	0.62 [0.48, 0.82]	
Total events	333		263				

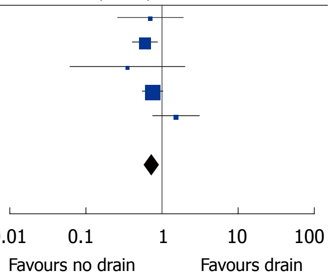
Heterogeneity: χ^2 = 4.97, df = 3 (P = 0.17); I^2 = 40%
Test for overall effect: Z = 3.23 (P = 0.001)



C

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Heslin 1998	8	38	14	51	5.00%	0.70 [0.26, 1.90]	1998
Mehta 2013	75	458	62	251	35.80%	0.60 [0.41, 0.87]	2013
Lim 2013	2	27	5	27	2.50%	0.35 [0.06, 2.00]	2013
Correa-Gallego 2013	105	353	139	386	49.90%	0.75 [0.55, 1.02]	2013
Van Buren 2014	28	69	21	68	6.70%	1.53 [0.76, 3.09]	2014
Total (95%CI)		945		783	100.00%	0.74 [0.59, 0.92]	
Total events	218		241				

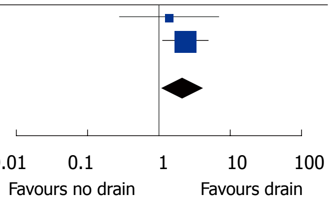
Heterogeneity: χ^2 = 6.03, df = 4 (P = 0.20); I^2 = 34%
Test for overall effect: Z = 2.74 (P = 0.006)



D

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Lim 2013	4	27	3	27	21.50%	1.39 [0.28, 6.91]	2013
Van Buren 2014	29	69	16	68	78.50%	2.36 [1.13, 4.92]	2014
Total (95%CI)		96		95	100.00%	2.15 [1.10, 4.19]	
Total events	33		19				

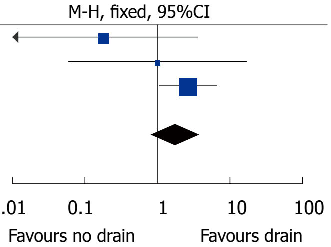
Heterogeneity: χ^2 = 0.34, df = 1 (P = 0.56); I^2 = 0%
Test for overall effect: Z = 2.25 (P = 0.02)



E

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Heslin 1998	0	38	3	51	30.00%	0.18 [0.01, 3.59]	1998
Lim 2013	1	27	1	27	9.70%	1.00 [0.06, 16.85]	2013
Van Buren 2014	18	69	8	68	60.30%	2.65 [1.06, 6.59]	2014
Total (95%CI)		134		146	100.00%	1.80 [0.82, 3.97]	
Total events	19		12				

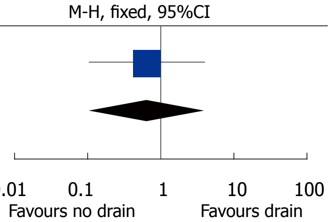
Heterogeneity: χ^2 = 3.16, df = 2 (P = 0.21); I^2 = 37%
Test for overall effect: Z = 1.42 (P = 0.16)



F

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Lim 2013	0	27	0	27		Not estimable	2013
Van Buren 2014	2	69	3	68	100.00%	0.65 [0.10, 4.00]	2014
Total (95%CI)		96		95	100.00%	0.65 [0.10, 4.00]	
Total events	2		3				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.47 (P = 0.64)



G

Study or subgroup	No drain Events	No drain Total	Drain Events	Drain Total	Weight	Odds ratio M-H, fixed, 95%CI	Year
Lim 2013	2	27	2	27	26.40%	1.00 [0.13, 7.67]	2013
Mehta 2013	0	0	0	0		Not estimable	3013
Van Buren 2014	13	69	6	68	72.60%	2.4 [0.85, 6.74]	2014
Total (95%CI)		96		95	100.00%	2.02 [0.81, 5.01]	
Total events	15		8				

Heterogeneity: χ^2 = 0.56, df = 1 (P = 0.45); I^2 = 0%

Test for overall effect: Z = 1.51 (P = 0.13)

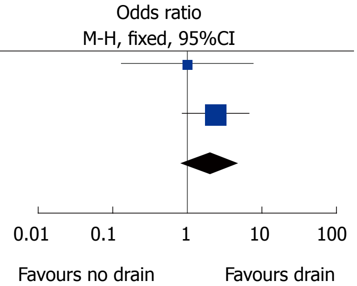


Figure 4 Forest plots illustrating meta-analysis of secondary outcomes comparing drain with no drain after pancreaticoduodenectomy. Pooled odds ratios (ORs) with 95%CIs were calculated using fixed or random effects models to analyze outcomes at 60 d. A: Pancreatic fistula; B: Overall complications; C: Major complications; D: Delayed gastric emptying; E: Intra-abdominal abscess; F: Biliary fistula; G: Postoperative hemorrhage.

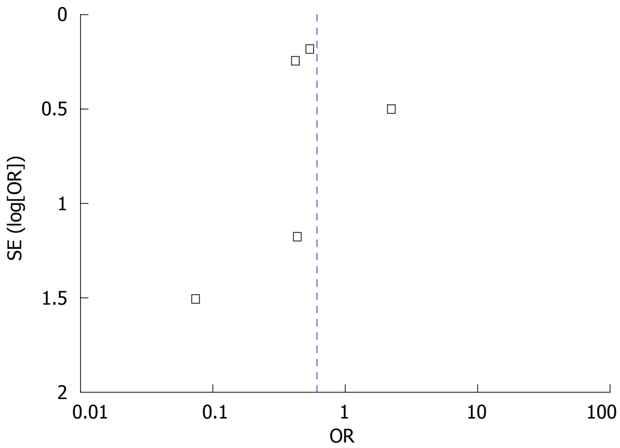


Figure 5 Funnel plot to investigate publication bias.

duct, the decision regarding the use of abdominal drainage was at the surgeon's discretion. Two studies[30,35] did not report the indications for drainage, however in one of these studies, drains were more likely to be placed following resections for cholangiocarcinoma or ampullary cancer than resections for pancreatic ductal adenocarcinoma or cystic neoplasms[35].

The lack of adequately powered prospective studies is also a significant limiting factor in this field. The increasing use of "prospectively set-up databases" and subsequent data analysis does not overcome the inherent shortcomings of retrospectively designed studies, such as selection bias. Technical differences in pancreaticojejunostomies performed may further affect the reported complication rates. A further potential source of heterogeneity in the studies was the type of drains used. Studies either reported predominant use of closed-suction drains[30,35,37] or multichannel open-channel silicone drains[33], or did not comment at all on the type used. One study specified the use of intra-peritoneal Jackson-Pratt drains[35], which is a brand of closed-suction drain. Different types of drains (especially suction *vs* no suction) can impact complications such as fluid collections, and may also differentially affect the efficacy of such devices (*e.g.*, rates of drain blockage). Differences in definitions used for major complications also presents a challenge for meta-analyses, which is why the attempt to introduce a common language for major complications such as POPF[17] is a welcome addition to the field.

Accepting the small number of studies available, in particular the scarcity of prospective studies, our analysis cannot safely favor or condemn the use of an intraperitoneal drain following PD. Indeed, looking at the only RCT designed to address this question, one is drawn to the conclusion that abandoning postoperative drainage indiscriminately following PD leads to an increase in complication rate and higher mortality. However, looking at our analysis overall there appears to be a select group of patients in whom prophylactic drainage is advantageous to avoid complications and mortality, and another in whom routine drainage is detrimental. Patients at low risk of POPF (*i.e.*, hard pancreas, large pancreatic duct, short operative time, little intra-operative blood loss and no other concerning factors) may benefit from avoiding routine intra-abdominal drainage[33]. Further RCTs are therefore required to clarify this question in a definite manner and should be designed to compare routine with selective drainage.

COMMENTS

Background

Previously, prophylactic placement of surgical drains following abdominal surgery has been considered standard practice. However, drainage after pancreatic resection continues to be controversial especially following pancreaticoduodenectomy (PD).

Research frontiers

The purpose of this present work was to conduct the first meta-analysis comparing outcomes after PD with or without prophylactic drainage.

Innovations and breakthroughs

Based on this meta-analysis, patients without prophylactic drainage after PD had significantly higher mortality, despite being associated with fewer complications, major complications and readmissions overall.

Applications

Indiscriminate abandoning of intra-abdominal drainage following PD appears to be associated with greater mortality, but selective use can lead to lower overall and major complication rates. Future randomized trials should compare routine *vs* selective drainage.

Peer-review

In the future, routine prophylactic intra-abdominal drainage may be deemed unnecessary. This is a well-written study that may be of interest for pancreatic surgeons worldwide.

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