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[Intervention Review]

Prophylactic abdominal drainage for pancreatic surgery

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ABSTRACT

Background

The use of surgical drains has been considered mandatory after pancreatic surgery. The role of prophylactic abdominal drainage to reduce postoperative complications after pancreatic surgery is controversial.

Objectives

To assess the benefits and harms of routine abdominal drainage after pancreatic surgery, compare the effects of different types of surgical drains, and evaluate the optimal time for drain removal.

Search methods

For the last version of this review, we searched CENTRAL (2016, Issue 8), and MEDLINE, Embase, Science Citation Index Expanded, and Chinese Biomedical Literature Database (CBM) to 28 August 2016). For this updated review, we searched CENTRAL, MEDLINE, Embase, Science Citation Index Expanded, and CBM from 2016 to 15 November 2017.

Selection criteria

We included all randomized controlled trials that compared abdominal drainage versus no drainage in people undergoing pancreatic surgery. We also included randomized controlled studies that compared different types of drains and different schedules for drain removal in people undergoing pancreatic surgery.

Data collection and analysis

We identified six studies (1384 participants). Two review authors independently identified the studies for inclusion, collected the data, and assessed the risk of bias. We performed the meta-analyses using Review Manager 5. We calculated the risk ratio (RR) for dichotomous outcomes and the mean difference (MD) for continuous outcomes with 95% confidence intervals (CI). For all analyses, we used the random-effects model.

Main results

Drain use versus no drain use

We included four studies with 1110 participants, who were randomized to the drainage group (N = 560) and the no drainage group (N = 550) after pancreatic surgery. There was little or no difference in mortality at 30 days between groups (1.5% with drains versus 2.3% with no drains; RR 0.78, 95% CI 0.31 to 1.99; four studies, 1055 participants; moderate-quality evidence). Drain use probably slightly reduced mortality at 90 days (0.8% versus 4.2%; RR 0.23, 95% CI 0.06 to 0.90; two studies, 478 participants; moderate-quality evidence). We were uncertain whether drain use reduced intra-abdominal infection (7.9% versus 8.2%; RR 0.97, 95% CI 0.52 to 1.80; four studies, 1055 participants; very low-quality evidence), or additional radiological interventions for postoperative complications (10.9% versus 12.1%; RR 0.87, 95% CI 0.79 to 2.23; three studies, 660 participants; very low-quality evidence). Drain use may lead to similar amount of wound infection (9.8% versus 9.9%; RR 0.98, 95% CI 0.68 to 1.41; four studies, 1055 participants; low-quality evidence), and additional open procedures for postoperative complications (9.4% versus 7.1%; RR 1.33, 95% CI 0.79 to 2.23; four studies, 1055 participants; low-quality evidence) when compared with no drain use. There was little or no difference in morbidity (61.7% versus 59.7%; RR 1.03, 95% CI 0.94 to 1.13; four studies, 1055 participants; moderate-quality evidence), or length of hospital stay (MD -0.66 days, 95% CI -1.60 to 0.29; three studies, 711 participants; moderate-quality evidence) between groups. There was one drain-related complication in the drainage group (0.2%). Health-related quality of life was measured with the pancreas-specific quality-of-life questionnaire (FACT-PA; a scale of 0 to 144 with higher values indicating a better quality of life). Drain use may lead to similar quality of life scores, measured at 30 days after pancreatic surgery, when compared with no drain use (105 points versus 104 points; one study, 399 participants; low-quality evidence). Hospital costs and pain were not reported in any of the studies.

Type of drain

We included one trial involving 160 participants, who were randomized to the active drain group (N = 82) and the passive drain group (N = 78) after pancreatic surgery. An active drain may lead to similar mortality at 30 days (1.2% with active drain versus 0% with passive drain; low-quality evidence), and morbidity (22.0% versus 32.1%; RR 0.68, 95% CI 0.41 to 1.15; low-quality evidence) when compared with a passive drain. We were uncertain whether an active drain decreased intra-abdominal infection (0% versus 2.6%; very low-quality evidence), wound infection (6.1% versus 9.0%; RR 0.68, 95% CI 0.23 to 2.05; very low-quality evidence), or the number of additional open procedures for postoperative complications (1.2% versus 7.7%; RR 0.16, 95% CI 0.02 to 1.29; very low-quality evidence). Active drain may reduce length of hospital stay slightly (MD -1.90 days, 95% CI -3.67 to -0.13; one study; low-quality evidence; 14.1% decrease of an 'average' length of hospital stay). Additional radiological interventions, pain, and quality of life were not reported in the study.

Early versus late drain removal

We included one trial involving 114 participants with a low risk of postoperative pancreatic fistula, who were randomized to the early drain removal group (N = 57) and the late drain removal group (N = 57) after pancreatic surgery. There was no mortality in either group. Early drain removal may slightly reduce morbidity (38.6% with early drain removal versus 61.4% with late drain removal; RR 0.63, 95% CI 0.43 to 0.93; low-quality evidence), length of hospital stay (MD -2.10 days, 95% CI -4.17 to -0.03; low-quality evidence; 21.5% decrease of an 'average' length of hospital stay), and hospital costs (MD -EUR 2069.00, 95% CI -3872.26 to -265.74; low-quality evidence; 17.0% decrease of 'average' hospital costs). We were uncertain whether early drain removal reduced additional open procedures for postoperative complications (0% versus 1.8%; RR 0.33, 95% CI 0.01 to 8.01; one study; very low-quality evidence). Intra-abdominal infection, wound infection, additional radiological interventions, pain, and quality of life were not reported in the study.

Authors' conclusions

It was unclear whether routine abdominal drainage had any effect on the reduction of mortality at 30 days, or postoperative complications after pancreatic surgery. Moderate-quality evidence suggested that routine abdominal drainage probably slightly reduced mortality at 90 days. Low-quality evidence suggested that use of an active drain compared to the use of a passive drain may slightly reduce the length of hospital stay after pancreatic surgery, and early removal may be superior to late removal for people with low risk of postoperative pancreatic fistula.

PLAIN LANGUAGE SUMMARY

Drain use after pancreatic surgery

Review question

Can the use of a drain reduce postoperative complications after pancreatic surgery?

Background

The use of surgical drains has been considered mandatory after pancreatic surgery. However, the role of a drain in reducing complications after pancreatic surgery (called postoperative complications) is controversial.

Study characteristics

We searched for all relevant, well-conducted studies up to November 2017. We included six randomized controlled studies (an experiment in which participants are randomly allocated to two or more interventions, possibly including a control intervention or no intervention, and the results are compared). The six studies included 1384 participants who underwent pancreatic surgery. Four of the six studies randomized

1110 participants to drain use (number of participants = 560) or no drain use (N = 550). One trial randomized 170 participants to an active drain (drains with low or high pressure suction, N = 82) and passive drain (drains without suction, N = 78). One trial randomized 114 participants with a low risk of postoperative pancreatic fistula (a complication during which the pancreas is disconnected from the nearby gut, and then reconnected to allow pancreatic juice containing digestive enzymes to enter the digestive system) to early drain removal (N = 57) or late drain removal (N = 57).

Key results

There was probably little or no difference in death at 30 days (1.5% with drains versus 2.3% with no drains), overall complications (61.7% versus 59.7%), or duration of hospitalization (14.3 days versus 13.8 days) between the drain use and no drain use groups. Drain use probably slightly reduced death at 90 days (0.8% versus 4.2%). We were uncertain whether drain use reduced infections in the abdomen (7.9% versus 8.2%), or the need for additional radiological interventions for postoperative complications (10.9% versus 12.1%). Drain use may lead to similar wound infections (9.8% versus 9.9%), need for additional open procedures for postoperative complications (9.4% versus 7.1%), and quality of life scores (105 points versus 104 points) when compared with no drain use. There was one drain-related complication (the drainage tube was broken) in the drain use group (0.2%).

Active drains may lead to similar rates of death at 30 days (1.2% with active drain versus 0% with passive drain), and overall complications (22.0% versus 32.1%) when compared with no passive drain. We were uncertain whether active drains reduced intra-abdominal infections (0% versus 2.6%), wound infections (6.1% versus 9.0%), or the need for additional open procedures for postoperative complications (1.2% versus 7.7%). Active drains may slightly reduce duration of hospitalization (14.1% decrease of an 'average' duration of hospitalization).

There were no deaths in either group in one small study that examined early versus late removal of drains. Early drain removal may reduce overall complications (38.6% with early drain removal versus 61.4% with late drain removal), duration of hospitalization (21.5% decrease of an 'average' duration of hospitalization), and hospital costs (17.0% decrease of 'average' hospital costs). We were uncertain whether early drain removal reduced the need for additional open procedures for postoperative complications (0% versus 1.8%).

It was unclear whether routine drain use had any effect on the reduction of death 30 days, or postoperative complications. Routine abdominal drainage probably slightly reduced death at 90 days. Active drains appeared to be associated with earlier discharges from hospital than passive drains, and early removal appeared to be better than late removal for people with a low risk of postoperative pancreatic fistula.

Quality of the evidence

All studies were at high risk of bias (suggesting the possibility of overestimating the benefits or underestimating the harms). Overall, the quality of the evidence varied from very low to moderate.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Drain use versus no drain use for pancreatic surgery

Drain use versus no drain use for pancreatic surgery

Patient or population: people undergoing elective open pancreatic resections

Setting: hospital

Intervention: drain use

Comparison: no drain use

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no drain use	Risk with drain use				
Mortality Follow-up: 30 days	23 per 1000	18 per 1000 (7 to 46)	RR 0.78 (0.31 to 1.99)	1055 (4 studies)	⊕⊕⊕⊖ Moderate ^{1,2}	
Mortality Follow-up: 90 days	42 per 1000	10 per 1000 (3 to 38)	RR 0.23 (0.06 to 0.90)	478 (2 studies)	⊕⊕⊕⊖ Moderate ^{1,2}	
Intra-abdominal infection Follow-up: 30 days	82 per 1000	80 per 1000 (43 to 148)	RR 0.97 (0.52 to 1.80)	1055 (4 studies)	⊕⊖⊖⊖ Very low ^{1,2,3,4}	
Wound infection Follow-up: 30 days	99 per 1000	97 per 1000 (68 to 140)	RR 0.98 (0.68 to 1.41)	1055 (4 studies)	⊕⊕⊖⊖ Low ^{1,2,3}	
Drain-related complications Follow-up: 30 days	See comment	See comment	Not estimable	179 (1 study)	⊕⊕⊖⊖ Low ^{1,2,3}	There was 1 drain-related complication in the drainage group. The drainage tube was broken.
Morbidity Follow-up: 30 days	597 per 1000	614 per 1000 (561 to 674)	RR 1.03 (0.94 to 1.13)	1055 (4 studies)	⊕⊕⊕⊖ Moderate ^{2,3}	

Length of hospital stay Follow-up: 30 days	The mean length of hospital stay in the no drain groups was 13.8 days	The mean length of hospital stay in the drain groups was 0.66 days lower (1.6 lower to 0.29 higher)	MD -0.66 (-1.60 to 0.29)	711 (3 studies)	⊕⊕⊕⊖ Moderate 2,3	
Hospital costs Follow-up: 30 days	Not reported					
Additional open procedures for postoperative complications Follow-up: 30 days	71 per 1000	94 per 1000 (56 to 158)	RR 1.33 (0.79 to 2.23)	1055 (4 studies)	⊕⊕⊕⊖ Low 1,2,3	
Additional radiological interventions for postoperative complications Follow-up: 30 days	121 per 1000	105 per 1000 (48 to 227)	RR 0.87 (0.40 to 1.87)	660 (3 studies)	⊕⊕⊕⊖ Very low 1,2,3,4	
Pain Follow-up: 30 days	Not reported					
Quality of life Follow-up: 30 days FACT-PA questionnaire: scale 0 to 144, where higher values indicate better quality of life	The mean quality of life score in the no drain group was 104 points	The mean quality of life score in the drain groups was 105 points	Not estimable (see comment)	399 (1 study)	⊕⊕⊕⊖ Low 2,3,5	The study reported the mean quality of life score, without mentioning the standard deviation.

* The basis for the **assumed risk** was the control group proportion in the study. **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the control group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **MD:** mean difference.

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

- 1 Downgraded one level for serious imprecision (very few events, confidence interval of risk ratio overlapped 0.75 and 1.25).
- 2 Publication bias could not be assessed because of the few number of studies.
- 3 Downgraded one level for serious risk of bias.
- 4 Downgraded one level for serious heterogeneity.
- 5 Downgraded one level due to serious imprecision (total population size was less than 400).

Summary of findings 2. Active drain versus passive drain for pancreatic surgery

Active drain versus passive drain for pancreatic surgery

Patient or population: people undergoing elective open pancreatic resections

Setting: hospital

Intervention: active drain

Comparison: passive drain

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with passive drain	Risk with active drain				
Mortality Follow-up: 30 days	1 per 1000	3 per 1000 (0 to 69)	RR 2.86 (0.12 to 69.06)	160 (1 study)	⊕⊕⊕⊕ Low ^{1,2}	There were no events in the control arm. A risk of "1 per 1000" was chosen for illustration. RR was calculated using a correction factor and should be interpreted with caution.
Mortality Follow-up: 90 days	Not reported					
Intra-abdominal infection Follow-up: 30 days	26 per 1000	5 per 1000 (0 to 100)	RR 0.19 (0.01 to 3.90)	160 (1 study)	⊕⊕⊕⊕ Very low ^{1,2,3}	
Wound infection	90 per 1000	61 per 1000	RR 0.68 (0.23 to 2.05)	160 (1 study)	⊕⊕⊕⊕ Very low ^{1,2,3}	

Follow-up: 30 days	(21 to 184)				
Drain-related complications	Not reported				
Follow-up: 30 days					
Morbidity	321 per 1000	218 per 1000	RR 0.68	160	⊕⊕⊕⊕
Follow-up: 30 days		(131 to 369)	(0.41 to 1.15)	(1 study)	Low 2,3,4
Length of hospital stay	The mean length of hospital stay in the passive drain group was 14.5 days	The mean length of hospital stay in the active drain group was 1.90 days lower (3.67 days to 0.13 days lower)	MD -1.90 (-3.67 to -0.13)	160	⊕⊕⊕⊕
Follow-up: 30 days				(1 study)	Low 2,3,5
Hospital costs	Not reported				
Follow-up: 30 days					
Additional open procedures for postoperative complications	77 per 1000	12 per 1000	RR 0.16	160	⊕⊕⊕⊕
Follow-up: 30 days		(2 to 99)	(0.02 to 1.29)	(1 study)	Very low 1,2,3
Additional radiological interventions for post-operative complications	Not reported				
Follow-up: 30 days					
Pain	Not reported				
Follow-up: 30 days					
Quality of life	Not reported				
Follow-up: 30 days					

* The basis for the **assumed risk** was the control group proportion in the study. **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the control group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **MD:** mean difference; **RR:** risk ratio.

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

- ¹ Downgraded two levels for very serious imprecision (small sample sizes, very few events, confidence intervals of risk ratios overlapped 0.75 and 1.25).
- ² Publication bias could not be assessed because of the few number of studies.
- ³ Downgraded one level for serious risk of bias.
- ⁴ Downgraded one level for serious imprecision (small sample sizes, very few events).
- ⁵ Downgraded one level due to serious imprecision (total population size was less than 400).

Summary of findings 3. Early versus late drain removal for pancreatic surgery

Early versus late drain removal for pancreatic surgery

Patient or population: people undergoing elective open pancreatic resections

Setting: hospital

Intervention: early drain removal

Comparison: late drain removal

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with late drain removal	Risk with early drain removal				
Mortality Follow-up: 30 days	There was no mortality in either group.			114 (1 study)	⊕⊕⊕⊖ Moderate ^{1,2}	
Mortality Follow-up: 90 days	Not reported					
Intra-abdominal infection Follow-up: 30 days	Not reported					
Wound infection Follow-up: 30 days	Not reported					
Drain-related complications Follow-up: 30 days	Not reported					
Morbidity	614 per 1000	387 per 1000	RR 0.63	114	⊕⊕⊖⊖	

Follow-up: 30 days	(264 to 571)		(0.43 to 0.93)	(1 study)	Low ^{1,2,3}
Length of hospital stay			MD -2.10 (-4.17 to -0.03)	114 (1 study)	⊕⊕⊕⊕ Low ^{1,3,4}
Follow-up: 30 days	The mean length of hospital stay in the late removal group was 10.8 days	The mean length of hospital stay in the early removal group was 2.1 days lower (4.17 days to 0.03 days lower)			
Hospital costs			MD -2069.00 (-3872.26 to -265.74)	114 (1 study)	⊕⊕⊕⊕ Low ^{1,3,4}
Follow-up: 30 days	The mean hospital costs in the late removal group was EUR 12140.00	The mean hospital costs in the early removal group was EUR 2069 lower (EUR 3872.26 lower to EUR 265.74 lower)			
Additional open procedures for post-operative complications	18 per 1000	6 per 1000 (0 to 141)	RR 0.33 (0.01 to 8.01)	114 (1 study)	⊕⊕⊕⊕ Very low ^{1,3,5}
Follow-up: 30 days					
Additional radiological interventions for postoperative complications	Not reported				
Follow-up: 30 days					
Pain	Not reported				
Follow-up: 30 days					
Quality of life	Not reported				
Follow-up: 30 days					

* The basis for the **assumed risk** was the control group proportion in the study. **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the control group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio.

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Publication bias could not be assessed because of the few number of studies.

- 2 Downgraded one level for serious imprecision (small sample sizes, very few events).
- 3 Downgraded one level due to serious risk of bias.
- 4 Downgraded one level due to serious imprecision (total population size was fewer than 400).
- 5 Downgraded two levels for very serious imprecision (small sample sizes, very few events, confidence intervals of risk ratios overlapped 0.75 and 1.25).

BACKGROUND

Description of the condition

See 'Glossary' for an explanation of terms ([Appendix 1](#)).

Pancreatic cancer ranks thirteenth in terms of the most common cancers and eighth as the cause of cancer death from a global viewpoint ([Anderson 2006](#); [Lowenfels 2006](#)). Regional differences exist in the incidence, and the number of new cases diagnosed per year ([Anderson 2006](#); [Kamisawa 2016](#)). The overall incidence of pancreatic cancer is approximately 4 to 10 cases per 100,000 people per year ([Dragovich 2017](#); [Torre 2015](#)). The most common cause of pancreatic cancer is heavy tobacco usage ([Kamisawa 2016](#); [Lowenfels 2006](#)).

Although the exact worldwide incidence of chronic pancreatitis is unknown, the estimated incidence of chronic pancreatitis is six cases per 100,000 people per year in Europe, and probably in all western countries ([Spanier 2008](#)). The prevalence of chronic pancreatitis per 100,000 people is 3 cases in the UK, 26 in France, 4 in Japan, and 114 to 200 cases in south India ([Bornman 2001](#); [Braganza 2011](#); [Garg 2004](#); [Lévy 2006](#)). The most common cause of chronic pancreatitis is alcohol abuse ([Kleeff 2017](#); [Spanier 2008](#)).

Pancreatic surgery is performed to treat various pancreatic and extra-pancreatic diseases, including pancreatic cancers, chronic pancreatitis, and biliary and duodenal malignancies ([Cheng 2014](#); [Cheng 2016a](#); [Cheng 2017](#); [Connor 2005](#); [Gurusamy 2013a](#)). Although mortality of pancreatic surgery has been reduced to less than 5% currently, overall morbidity is still high, ranging from 30% to 60% ([Bassi 2017](#); [Connor 2005](#); [Giovinazzo 2011](#); [Gurusamy 2013a](#); [Wente 2007a](#); [Wente 2007b](#)). The most common complications after pancreatic surgery include delayed gastric emptying (19% to 23%; [Wente 2007a](#); [Wente 2007b](#)), pancreatic fistula (2% to 30%; [Bassi 2017](#); [Cheng 2016a](#); [Hackert 2011](#); [Wente 2007a](#); [Wente 2007b](#)), intra-abdominal abscess (9% to 10%; [Wente 2007a](#); [Wente 2007b](#)), wound infection (5% to 15%; [Andrén-Sandberg 2011](#); [Halloran 2002](#)), and postoperative bleeding (1% to 8%; [Wente 2007a](#); [Wente 2007b](#)).

Description of the intervention

As a measure to reduce postoperative complications after pancreatic resections, prophylactic drains are traditionally placed in the subhepatic space near both the biliary and pancreatic anastomoses ([Conlon 2001](#); [Fisher 2011](#)). Abdominal drainage has been in use for over 1000 years ([Memon 2001](#)).

Surgical drains are artificial tubes used to remove blood, pus, or other body fluids from wounds ([Durai 2009](#)). There are two main types of surgical drains: open and closed ([Cheng 2015](#); [Durai 2009](#); [Gurusamy 2007a](#); [Wang 2015](#)). An open drain communicates with the atmosphere (e.g. corrugated drain, Penrose drain, sump drain; [Durai 2009](#); [Gurusamy 2007a](#); [Wang 2015](#)). A closed drain consists of a tube that drains into a collection bag or bottle, where the contents are not exposed to the atmosphere ([Durai 2009](#); [Gurusamy 2007a](#); [Wang 2015](#)). Closed drains may be either active (suction drains under low or high pressure, e.g. Jackson-Pratt drain, Redivac) or passive (drains without suction, e.g. Robinson drain, Pigtail drain; [Durai 2009](#); [Gurusamy 2007a](#); [Wang 2015](#)).

How the intervention might work

Surgeons have routinely used drains after pancreatic surgery because of the possible collection of bile, pancreatic juice, or blood, which may require additional procedures. The primary reasons for placing abdominal drains after pancreatic resections are: (1) drainage of established intra-abdominal collections (e.g. bile, pancreatic juice, pus); (2) prevention of further fluid accumulation; and (3) identification and monitoring of any fistula or bleeding. Theoretically, abdominal drainage has the potential to prevent or control postoperative complications (e.g. intra-abdominal abscess, pancreatic or biliary fistula, bleeding; [Adham 2013](#); [Bassi 2010](#); [Conlon 2001](#); [Correa-Gallego 2013](#); [Fisher 2011](#); [Giovinazzo 2011](#); [Heslin 1998](#); [Jeekel 1992](#); [Kawai 2006](#); [Lim 2013](#); [Mehta 2013](#); [Paulus 2012](#); [Van Buren 2014](#); [Van Buren 2017](#)). The use of surgical drains has been considered mandatory after pancreatic surgery since the mid-1930s ([Allen 2011](#)).

However, some surgeons have argued that abdominal drainage may fail to reduce postoperative complications because a drain may become sealed off and ineffective within a few days after pancreatic surgery ([Heslin 1998](#); [Paulus 2012](#)). The drain itself appears to act as a foreign body, and may interfere with wound healing ([Correa-Gallego 2013](#); [Fisher 2011](#); [Paulus 2012](#)). The drainage tube creates a pathway for contamination, and may increase the risk of postoperative infectious complications ([Inoue 2011](#); [Jeekel 1992](#)). In addition, the use of a drain may be associated with an increased length of hospital stay ([Fisher 2011](#); [Mehta 2013](#); [Paulus 2012](#); [Van Buren 2017](#)). Abdominal drainage may be also associated with some rare adverse events, such as bowel perforation, hernia, and bleeding ([Cameron-Strange 1985](#); [Henkus 1999](#); [Makama 2010](#); [Nomura 1998](#); [Reed 1992](#); [Sahu 2008](#); [Srivastava 2007](#); [Van Hee 1983](#)). Studies have suggested that routine placement of prophylactic abdominal drains may be unnecessary, and may be associated with an increased complication rate ([Adham 2013](#); [Correa-Gallego 2013](#); [Fisher 2011](#); [Giovinazzo 2011](#); [Heslin 1998](#); [Jeekel 1992](#); [Lim 2013](#); [Mehta 2013](#); [Paulus 2012](#)).

Why it is important to do this review

Routine use of prophylactic abdominal drainage in people undergoing pancreatic surgery is controversial. This is an update of a previous Cochrane Review assessing the role of prophylactic abdominal drainage for pancreatic surgery ([Cheng 2016a](#)).

OBJECTIVES

To assess the benefits and harms of routine abdominal drainage after pancreatic surgery, compare the effects of different types of surgical drains, and evaluate the optimal time for drain removal.

METHODS

Criteria for considering studies for this review

Types of studies

We included all randomized controlled trials (RCTs), regardless of sample size, language, or publication status, which compared (1) drain use versus no drain use, (2) different types of drains, or (3) different schedules for drain removal in people undergoing pancreatic surgery. We excluded quasi-randomized studies, in which the allocation was performed on the basis of a pseudo-random sequence (e.g. odd or even hospital number or date of

birth, alternation, and non-randomized studies) because of the potential for bias (Reeves 2011).

Types of participants

We included people, regardless of age, sex, or race, who underwent elective pancreatic resections (open or laparoscopic) for any pancreatic or extra-pancreatic disease.

Types of interventions

1. Drain use versus no drain use.
2. One type of drain versus another.
3. Early versus late drain removal (no more than four days versus more than four days).

Types of outcome measures

Primary outcomes

1. Mortality:
 - a. 30-day mortality;
 - b. 90-day mortality.
2. Infectious complications:
 - a. intra-abdominal infection;
 - b. wound infection.
3. Drain-related complications.

Secondary outcomes

1. Morbidity as defined by study authors. We classified morbidity by the Clavien-Dindo classification of surgical complications (Clavien 2009).
2. Length of hospital stay.
3. Hospital costs.
4. Additional procedures for postoperative complications:
 - a. open procedures;
 - b. radiological interventions (radiological drainage requiring insertion of drain or percutaneous aspiration).
5. Pain.
6. Quality of life.

The main reason to justify abdominal drainage was the assumption that it would reduce the infectious complication rate and subsequent mortality and morbidity rates. Other clinical outcomes were chosen to assess whether abdominal drainage resulted in earlier discharge from hospital, fewer reoperations, and improvement in health-related quality of life and cost effectiveness.

Reporting of the outcomes listed here was not an inclusion criterion for the review.

Search methods for identification of studies

Before searching, we designed the search strategies with the help of the Cochrane Upper Gastrointestinal and Pancreatic Diseases (UGPD) Information Specialist. We placed no restrictions on the language of publication when searching the electronic databases or reviewing reference lists in identified studies.

Electronic searches

For the last version of this review, we searched the Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 8) in the

Cochrane Library, MEDLINE (1946 to 28 August 2016), Embase (1980 to 28 August 2016), Science Citation Index Expanded (1900 to 28 August 2016), and Chinese Biomedical Literature Database (CBM; 1978 to 28 August 2016; Cheng 2016b; Peng 2015). For this updated review, we searched the following electronic databases from 2016 to 15 November 2017, with no language or date of publication restrictions:

1. the Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 11) in the Cochrane Library (searched 15 November 2017; Appendix 2);
2. MEDLINE Ovid (2016 to 15 November 2017; Appendix 3);
3. Embase Ovid (2016 to 15 November 2017; Appendix 4);
4. Science Citation Index Expanded (Web of Science; 2016 to 15 November 2017; Appendix 5); and
5. Chinese Biomedical Literature Database (CBM; 2016 to 15 November 2017; Appendix 6).

Searching other resources

We checked reference lists of all primary studies and relevant review articles that were identified during the search for RCTs for additional references. We contacted authors of identified studies and asked them to identify other published and unpublished studies.

We searched PubMed for errata or retractions of eligible studies, and reported the date this was done in the results section (www.ncbi.nlm.nih.gov/pubmed). We also searched the meeting abstracts via the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES; www.sages.org/; accessed 15 November 2017) and Conference Proceedings Citation Index to explore further relevant clinical studies.

Clinical trials registers/trial result registers

We searched the following databases to identify ongoing studies (accessed 15 November 2017):

1. World Health Organization International Clinical Trials Registry Platform search portal (apps.who.int/trialsearch/);
2. ClinicalTrials.gov (www.clinicaltrials.gov/);
3. Current Controlled Trials (www.controlled-trials.com/);
4. European (EU) Clinical Trials Register (www.clinicaltrialsregister.eu/);
5. Chinese Clinical Trial Register (www.chictr.org/).

Data collection and analysis

We conducted this systematic review according to the *Cochrane Handbook for Systematic Reviews of Intervention* (Higgins 2011), and the Cochrane UGPD Group Module (Forman 2011).

Selection of studies

Two review authors (WZ, SH) independently screened the titles and abstracts of all the reports we identified as a result of the search, and coded them as 'retrieve' (eligible, potentially eligible, or unclear) or 'do not retrieve'. We retrieved the full-text study reports and publications of identified reports, and two review authors (WZ, SH) independently screened the full text, identified studies for inclusion, and identified and recorded reasons for exclusion of the ineligible studies. We resolved any disagreements through discussion, or if required, we consulted a third review author

(ZL). We identified and excluded duplicates and collated multiple reports of the same study, so that each study, rather than each report, was the unit of interest in the review. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram and a 'Characteristics of excluded studies' table (Moher 2009).

Data extraction and management

We used a standard data collection form for study characteristics and outcome data, which had been piloted on at least one study in the review. Two review authors (JX, ML) extracted the following study characteristics from included studies:

1. methods: study design, total duration of study and run in, number of study centers and location, study setting, withdrawals, and date of study;
2. participants: number (N), mean age, age range, gender, severity of condition, diagnostic criteria, inclusion criteria, and exclusion criteria;
3. interventions: intervention, comparison;
4. outcomes: primary and secondary outcomes specified and collected, time points reported;
5. notes: funding for trial, notable conflicts of interest of trial authors.

Two review authors (JX, ML) independently extracted outcome data from included studies. We noted in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We resolved disagreements by consensus, or by involving a third review author (ZL). One review author (SH) copied the data from the data collection form into Review Manager 5 (RevMan 2014). We double-checked that the data were entered correctly by comparing the study reports with how the data were presented in the systematic review. A second review author spot-checked study characteristics for accuracy against the trial report.

Assessment of risk of bias in included studies

Two review authors (WZ, SH) independently assessed risk of bias for each study, using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreements by discussion, or by involving a third review author (ZL). We assessed the risk of bias according to the following domains:

1. random sequence generation;
2. allocation concealment;
3. blinding of outcome assessment;
4. incomplete outcome data;
5. selective outcome reporting;
6. other bias.

We graded each potential source of bias as high, low, or unclear risk, and provided a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We summarized the 'Risk of bias' judgements across different studies for each of the domains listed. We considered blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be different than for a participant-reported pain scale). Where information on risk of bias related to unpublished data or

correspondence with a trialist, we noted this in the 'Risk of bias' table.

When considering treatment effects, we took into account the risk of bias for the studies that contributed to that outcome.

Assessment of bias in conducting the systematic review

We conducted the review according to the published protocol, and reported any deviations from it in the 'Differences between protocol and review' section of the review (Cheng 2013).

Measures of treatment effect

We analyzed dichotomous data as risk ratio (RR) and continuous data as mean difference (MD) or standardized mean difference (SMD) with 95% confidence intervals (CI). We ensured that higher scores for continuous outcomes had the same meaning for the particular outcome, explained the direction to the reader, and reported where the directions were reversed, if this was necessary.

We undertook meta-analyses only where this was meaningful, that is, if the treatments, participants, and underlying clinical question were similar enough for pooling to make sense.

A common way that trialists indicate when they have skewed data is by reporting medians and interquartile ranges. When we encountered this, we noted that the data were skewed and considered the implication of this.

Where multiple trial arms were reported in a single trial, we included only the relevant arms. If two comparisons (e.g. drug A versus placebo and drug B versus placebo) were entered into the same meta-analysis, we halved the control group to avoid double-counting.

Unit of analysis issues

The unit of analysis was the individual participant. We did not find any cross-over or cluster-randomized studies.

Dealing with missing data

We contacted investigators or study sponsors in order to verify key study characteristics and obtained missing numerical outcome data when needed (e.g. when a study was identified as abstract only). We did not get a response. Thus, we only used the available data in the analyses.

Assessment of heterogeneity

We used the I^2 statistic to measure heterogeneity among the studies in each analysis (Higgins 2003). When we identified substantial heterogeneity (greater than 50%), we explored it by prespecified subgroup analysis, and we interpreted summary effect measures with caution.

Assessment of reporting biases

We did not perform funnel plots to assess reporting biases because there were fewer than 10 included studies (Sterne 2011).

Data synthesis

We performed the meta-analyses using Review Manager 5 software (RevMan 2014). For all analyses, we used a random-effects model.

Subgroup analysis and investigation of heterogeneity

We had intended to perform the following subgroup analyses, but were unable to because of limited data:

1. RCTs with low risk of bias versus RCTs with high risk of bias;
2. different etiologies (pancreatic cancer, chronic pancreatitis, and others);
3. type of operation (proximal, distal, and central pancreatectomy).

Sensitivity analysis

We performed sensitivity analyses, defined a priori, to assess the robustness of our conclusions. This involved:

1. changing between a fixed-effect model and a random-effects model;
2. changing between RR, risk differences (RD), and odds ratios (OR) for dichotomous outcomes;
3. changing between MD and SMD for continuous outcomes;
4. changing between worst-case and best-case scenario analyses for missing data.

If the results did not change, they were considered to have low sensitivity. If the results changed, they were considered to have high sensitivity.

Reaching conclusions

We based our conclusions only on findings from the quantitative or narrative synthesis of included studies for this review. We avoided making recommendations for practice, and tried, in our implications for research, to give the reader a clear sense of where the focus of any future research in the area should be and what the remaining uncertainties were.

'Summary of findings' table

We created 'Summary of findings' tables for all considered outcomes. We used the five GRADE considerations (study

limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of a body of evidence based on the studies that contributed data to the meta-analyses for the prespecified outcomes. We used the methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and used GRADEpro GDT software (GRADEpro GDT). We justified all decisions to downgrade or upgrade the quality of the evidence using footnotes, and made comments to aid the reader's understanding of the review, where necessary. We considered whether there was any additional outcome information that we were unable to incorporate into meta-analyses, and noted this in the comments. We noted whether it supported or contradicted the information from the meta-analyses for each outcome, including any subgroup analysis or sensitivity analysis.

RESULTS

Description of studies

See 'Characteristics of included studies' and 'Characteristics of excluded studies' tables.

Results of the search

For this updated review, we identified 278 records through the electronic searches of CENTRAL (25 records), MEDLINE Ovid (74 records), Embase Ovid (88 records), Science Citation Index Expanded (Web of Science; 80 records), and Chinese Biomedical Literature Database (CBM; 11 records). We did not identify any records by scanning reference lists of the identified RCTs. We excluded 51 duplicates and 225 clearly irrelevant records through reading titles and abstracts. The remaining two records were retrieved for further assessment. We excluded one study for the reasons listed in the [Characteristics of excluded studies](#) table. In total, one RCT fulfilled the inclusion criteria for this update. We have shown the study flow diagram in [Figure 1](#).

Figure 1. Study flow diagram: 2018 review update

Included studies

The last published version of this review included five studies, published between 2001 and 2016 ([Bassi 2010](#); [Conlon 2001](#); [Jiang 2016](#); [Van Buren 2014](#); [Witzigmann 2016](#)). We added one recently published study to this update ([Van Buren 2017](#)). Therefore, we included six studies (1384 participants), all of which provided data for the analyses. We listed details of the studies in the 'Characteristics of included studies' table.

Drain use versus no drain use

Four studies randomized 1110 participants who underwent elective pancreatic resections (604 pancreaticoduodenectomy, 439 distal pancreatectomy, and 67 other pancreatic surgery) to those

who had drainage tubes inserted postoperatively (N = 560), and those who did not (N = 550). Three of these studies were conducted in the USA ([Conlon 2001](#); [Van Buren 2014](#); [Van Buren 2017](#)), and one in Germany ([Witzigmann 2016](#)). The mean age was 63.9 years. One or two drainage tubes were placed near the pancreatic anastomoses or pancreatic stumps. These studies measured mortality, morbidity, wound infection, intra-abdominal infection, various postoperative complications, reoperation, additional radiological intervention, length of hospital stay, and quality of life ([Conlon 2001](#); [Van Buren 2014](#); [Van Buren 2017](#); [Witzigmann 2016](#)).

One type of drain versus another

One study randomized 160 participants undergoing elective pancreaticoduodenectomy to the active drain group or the passive drain group (Jiang 2016). This trial was conducted in China. One drainage tube was placed near both the biliary and pancreatic anastomoses. The mean age was 59.6 years. The outcomes reported were mortality, morbidity, wound infection, intra-abdominal infection, various postoperative complications, reoperation, operation time, and length of hospital stay.

Early versus late drain removal

One study randomized 114 participants with low risk of postoperative pancreatic fistula undergoing elective pancreatic resections (75 pancreaticoduodenectomy and 39 distal pancreatectomy) to the early drain removal group or the late drain removal group (Bassi 2010). This trial was conducted in Italy. Two drainage tubes were placed near both the biliary and pancreatic anastomoses. One drainage tube was placed near the pancreatic stump after distal pancreatectomy. The mean age was 56.6 years. The outcomes reported were pancreatic fistula, abdominal complications, pulmonary complications, reoperation, length of hospital stay, hospital readmission, postoperative mortality, morbidity, and hospital costs.

Excluded studies

We excluded 12 studies. We listed the details in the 'Characteristics of excluded studies' table. One trial was excluded because it focused on pancreatic duct drainage (Lee 2009); the rest were not RCTs.

Ongoing studies

We found one ongoing study (Čečka 2015). Two hundred and twenty-three participants undergoing pancreatic resection will be randomized to closed suction drain or closed gravity drain. This trial is currently recruiting participants. It is being performed in Czech Republic, and was initiated in October 2013. The primary outcome is the rate of postoperative pancreatic fistula. The secondary outcomes are postoperative morbidity, including wound infection, intra-abdominal collections, delayed gastric emptying, postoperative hemorrhage, pneumonia, abdominal rupture, cardiac events, and neurological complications.

Risk of bias in included studies

Figure 2 and Figure 3 show the risk of bias of the included studies. All six studies were at high risk of bias (Bassi 2010; Conlon 2001; Jiang 2016; Van Buren 2014; Van Buren 2017; Witzigmann 2016).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bassi 2010	+	?	-	+	+	+
Conlon 2001	?	?	?	+	+	+
Jiang 2016	+	?	?	+	+	+
Van Buren 2014	+	?	-	-	+	+
Van Buren 2017	+	?	-	-	+	+
Witzigmann 2016	+	+	?	-	+	+

Allocation

Random sequence generation was at low risk of bias in five studies (Bassi 2010; Jiang 2016; Van Buren 2014; Van Buren 2017; Witzigmann 2016). Allocation concealment was at low risk of bias in one trial (Witzigmann 2016).

Blinding

Blinding of outcome assessment was at high risk of bias in three studies (Bassi 2010; Van Buren 2014; Van Buren 2017).

Incomplete outcome data

There were some dropouts in three studies, but the data were not analyzed on an intention-to-treat basis, therefore, we assessed

these three studies at high risk of bias regarding incomplete outcome data (Van Buren 2014; Van Buren 2017; Witzigmann 2016).

Selective reporting

Selective reporting was at low risk of bias in all six studies (Bassi 2010; Conlon 2001; Jiang 2016; Van Buren 2014; Van Buren 2017; Witzigmann 2016).

Other potential sources of bias

Baseline imbalance was at low risk of bias in all six studies.

Effects of interventions

See: [Summary of findings for the main comparison Drain use versus no drain use for pancreatic surgery](#); [Summary of findings 2](#)

Active drain versus passive drain for pancreatic surgery; **Summary of findings 3** Early versus late drain removal for pancreatic surgery

See: [Summary of findings for the main comparison](#), [Summary of findings 2](#), [Summary of findings 3](#).

Drain use versus no drain use

Four studies (1110 participants) compared drain use with no drain use ([Conlon 2001](#); [Van Buren 2014](#); [Van Buren 2017](#); [Witzigmann 2016](#)). Five hundred and sixty participants were randomized to the drainage group, and 550 participants to the no drainage group. See: [Summary of findings for the main comparison](#).

Mortality (30 days)

The 30-day mortality was 1.5% (8/532) in the drainage group, and 2.3% (12/523) in the no drainage group. The estimated risk ratio (RR) for 30-day mortality was 0.78 (95% confidence interval (CI) 0.31 to 1.99; four studies, 1055 participants; [Analysis 1.1](#)). We downgraded the quality of evidence from high to moderate due to serious imprecision.

Mortality (90 days)

The 90-day mortality was 0.8% (2/242) in the drainage group, and 4.2% (10/236) in the no drainage group. The estimated RR for 90-day mortality was 0.23 (95% CI 0.06 to 0.90; two studies, 478 participants; [Analysis 1.2](#)). We downgraded the quality of evidence from high to moderate due to serious imprecision.

Intra-abdominal infection

The intra-abdominal infection rate was 7.9% (42/532) in the drainage group, and 8.2% (43/523) in the no drainage group. The estimated RR for intra-abdominal infection rate was 0.97 (95% CI 0.52 to 1.80; four studies, 1055 participants; [Analysis 1.3](#)). We downgraded the quality of evidence from high to very low due to high risk of bias, serious imprecision, and inconsistency in the direction and magnitude of effects across the studies ($I^2 = 52\%$).

Wound infection

The wound infection rate was 9.8% (52/532) in the drainage group and 9.9% (52/523) in the no drainage group. The estimated RR for wound infection rate was 0.98 (95% CI 0.68 to 1.41; four studies, 1055 participants; [Analysis 1.4](#)). We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Drain-related complications

One trial (179 participants) reported this outcome ([Conlon 2001](#)). There was one drain-related complication (broken drain) in the drainage group. We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Morbidity

The morbidity was 61.7% (328/532) in the drainage group and 59.7% (312/523) in the no drainage group. The estimated RR for morbidity was 1.03 (95% CI 0.94 to 1.13; four studies, 1055 participants; [Analysis 1.5](#)). We downgraded the quality of evidence from high to moderate due to high risk of bias.

Length of hospital stay

The estimated mean difference (MD) for length of hospital stay was -0.66 days (95% CI -1.60 to 0.29; three studies, 711 participants; [Analysis 1.6](#)). We downgraded the quality of evidence from high to moderate due to high risk of bias.

Hospital costs

None of the studies reported this outcome.

Additional open procedures for postoperative complications

A total of 87 participants needed additional open procedures for postoperative complications. The rate of additional open procedures for postoperative complications was 9.4% (50/532) in the drainage group and 7.1% (37/523) in the no drainage group. The estimated RR for the need of additional open procedures was 1.33 (95% CI 0.79 to 2.23; four studies, 1055 participants; [Analysis 1.7](#)). We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Additional radiological interventions for postoperative complications

A total of 75 participants needed additional radiological interventions for postoperative complications. The rate of additional radiological interventions for postoperative complications was 10.9% (36/330) in the drainage group and 12.1% (40/330) in the no drainage group. The estimated RR for the need of additional radiological interventions was 0.87 (95% CI 0.40 to 1.87; three studies, 660 participants; [Analysis 1.8](#)). We downgraded the quality of evidence from high to very low due to high risk of bias, serious imprecision, and inconsistency in the direction and magnitude of effects across the studies ($I^2 = 64\%$).

Pain

None of the studies reported on pain.

Quality of life

[Van Buren 2017](#) used the pancreas-specific quality of life questionnaire (FACT-PA) to assess quality of life. The FACT-PA is a scale of 0 to 144, with higher values indicating better quality of life. The mean quality of life score at 30 days after pancreatic surgery was 105 points in the drainage and 104 points in the no drainage group. The study reported the standard deviation of the quality of life score. We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Active drain versus passive drain

One trial (160 participants) compared active drain versus passive drain ([Jiang 2016](#)). Eighty-two participants were randomized to the active drain group and 78 participants to the passive drain group. See: [Summary of findings 2](#).

Mortality (30 days)

The 30-day mortality was 1.2% (1/82) in the active drain group and 0% (0/78) in the passive drain group. We downgraded the quality of evidence from high to very low due to high risk of bias and very serious imprecision.

Mortality (90 days)

The trial did not report this outcome.

Intra-abdominal infection

The intra-abdominal infection rate was 0% (0/82) in the active drain group and 2.6% (2/78) in the passive drain group. We downgraded the quality of evidence from high to very low due to high risk of bias and very serious imprecision.

Wound infection

The wound infection rate was 6.1% (5/82) in the active drain group and 9.0% (7/78) in the passive drain group. The estimated RR for wound infection rate was 0.68 (95% CI 0.23 to 2.05; one study, 160 participants; [Analysis 2.3](#)). We downgraded the quality of evidence from high to very low due to high risk of bias and very serious imprecision.

Drain-related complications

The trial did not report this outcome.

Morbidity

The morbidity was 22.0% (18/82) in the active drain group and 32.1% (25/78) in the passive drain group. The estimated RR for morbidity was 0.68 (95% CI 0.41 to 1.15; one study, 160 participants; [Analysis 2.4](#)). We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Length of hospital stay

The estimated MD for length of hospital stay was -1.90 days less (14.1% decrease of an 'average' length of hospital stay) in the active drain removal group (95% CI -3.67 to -0.13; one study, 160 participants; [Analysis 2.5](#)). We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Hospital costs

The trial did not report this outcome.

Additional open procedures for postoperative complications

Seven participants needed additional open procedures for postoperative complications. The rate of additional open procedures for postoperative complications was 1.2% (1/82) in the active drain group and 7.7% (6/78) in the passive drain group. The estimated RR for the need of additional open procedures was 0.16 (95% CI 0.02 to 1.29; one study, 160 participants; [Analysis 2.6](#)). We downgraded the quality of evidence from high to very low due to high risk of bias and very serious imprecision.

Additional radiological interventions for postoperative complications

The trial did not report this outcome.

Pain

The trial did not report this outcome.

Quality of life

The trial did not report this outcome.

Early versus late drain removal

One study (114 participants with low risk of postoperative pancreatic fistula) compared early versus late drain removal ([Bassi 2010](#)). Fifty-seven participants were randomized to the early drain

removal group and 57 participants to the late drain removal group. See: [Summary of findings 3](#).

Mortality (30 days)

There was no mortality reported in either group.

Mortality (90 days)

The study did not report this outcome.

Intra-abdominal infection

The study did not report this outcome

Wound infection

The study did not report this outcome

Drain-related complications

The study did not report this outcome.

Morbidity

The morbidity was 38.6% (22/57) in the early drain removal group and 61.4% (35/57) in the late drain removal group. The estimated RR for morbidity was 0.63 (95% CI 0.43 to 0.93; one study, 114 participants; [Analysis 3.1](#)). We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Length of hospital stay

The estimated MD for length of hospital stay was 2.10 days less (21.5% decrease of an 'average' length of hospital stay) in the early drain removal group (95% CI -4.17 to -0.03; one study, 114 participants; [Analysis 3.2](#)). We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Hospital costs

The estimated MD for total hospital costs was EUR 2069.00 less (17.0% decrease of 'average' hospital costs) in the early drain removal group (95% CI -3872.26 to -265.74; one study, 114 participants; [Analysis 3.3](#)). We downgraded the quality of evidence from high to low due to high risk of bias and serious imprecision.

Additional open procedures for postoperative complications

One participant needed an additional open procedure for postoperative complications. The rate of additional open procedures for postoperative complications was 0% (0/57) in the early drain removal group and 1.8% (1/57) in the late drain removal group. The estimated RR for the need of additional open procedures was 0.33 (95% CI 0.01 to 8.01; one study, 160 participants; [Analysis 3.4](#)). We downgraded the quality of evidence from high to very low due to high risk of bias and very serious imprecision.

Additional radiological interventions for postoperative complications

The trial did not report this outcome.

Pain

The trial did not report this outcome.

Quality of life

The trial did not report this outcome.

Subgroup analysis

We did not perform any of the planned subgroup analyses because this review included only five studies.

Sensitivity analysis

We performed the following planned sensitivity analyses:

1. changed between a fixed-effect model and a random-effects model;
2. changed statistics among RR, RD, and OR for dichotomous outcomes;
3. changed statistics between MD and SMD for continuous outcomes;
4. changed between worst-case and best-case scenario analyses for missing data.

We observed no change in the results by changing between a fixed-effect and a random-effects model, calculating the RD and OR for dichotomous outcomes, or calculating the SMD for continuous outcomes. There were 101 postrandomization dropouts in three studies (Van Buren 2014; Van Buren 2017; Witzigmann 2016). We observed no change in the results by changing between worst-case and best-case scenario analyses for missing data, except for the outcome 'mortality ((90 days)'; [Analysis 4.1](#); [Analysis 4.2](#)).

DISCUSSION

Summary of main results

Evidence from six studies with 1384 people undergoing pancreatic surgery contributed data to the outcomes of interest for this review. For the comparison of drain use versus no drain use (four studies, 1110 participants), we found that there was probably little or no difference in mortality at 30 days or in postoperative complications between groups. Although drain use probably slightly reduced mortality at 90 days, it may have led to drain-related complications.

One trial (160 participants) compared the use of an active drain versus a passive drain. We found that an active drain was associated with earlier discharge from hospital.

Data comparing early versus late drain removal were available from one trial (114 participants). We found that they favored early drain removal for people with low risk of postoperative pancreatic fistula.

Overall completeness and applicability of evidence

All of the studies included people undergoing elective pancreaticoduodenectomy (N = 839, 60.6%), distal pancreatectomy (N = 478, 34.6%), and other pancreatic surgery (N = 67, 4.8%) for various pancreatic and extra-pancreatic diseases, including pancreatic cancers, ampullary cancers, chronic pancreatitis, biliary and duodenal malignancy. The majority (58.1%) of the participants had either pancreatic cancers (46.8%) or chronic pancreatitis (11.3%). Only two of the studies included 163 participants (11.8%) who underwent laparoscopic pancreatic resections, therefore, the results of this review are not applicable to people undergoing laparoscopic pancreatic resections, and the role of abdominal drainage after laparoscopic pancreatic resections requires further

assessment. Therefore, the results of this review are only applicable to people undergoing elective open pancreaticoduodenectomy, distal pancreatectomy, and other pancreatic surgery for various pancreatic and extra-pancreatic diseases, especially for pancreatic cancers or chronic pancreatitis.

Quality of the evidence

None of the studies were at low risk of bias. There were too few studies included under each comparison to assess inconsistency and publication bias. There was no indirectness of evidence because the studies did not perform the indirect comparison of one type of drain versus another. The confidence intervals of the majority of outcomes were wide, indicating that the estimates of effect obtained were imprecise. Overall, the quality of the evidence was considered to be very low to moderate ([Summary of findings for the main comparison](#); [Summary of findings 2](#); [Summary of findings 3](#)).

Potential biases in the review process

There were some unavoidable potential biases of note in the review process. First, when we contacted some investigators to request further information, we did not get a reply. The missing data may introduce bias to this review. Additionally, we were unable to explore publication bias because we did not have access to protocols for two studies (Conlon 2001; Jiang 2016), and the studies included in each comparison were too few.

Agreements and disagreements with other studies or reviews

There is increasing evidence in Cochrane Reviews that routine abdominal drainage after various abdominal operations is not mandatory (Cheng 2015; Rolph 2004; Gurusamy 2007a; Gurusamy 2007b; Gurusamy 2013b; Wang 2015). The routine use of surgical drains has also been questioned in other areas, including thyroid, gynaecological, and orthopaedic surgeries (Charoenkwan 2017; Gates 2013; Parker 2007; Samraj 2007).

The routine use of drains has been considered surgical dogma after a pancreatic resection. Jeekel and coworkers first challenged the dogma in the 1990s (Jeekel 1992). They reported a cohort in which 22 people underwent pancreaticoduodenectomy without undue complications after abandoning abdominal drainage. They concluded that abdominal drainage after pancreaticoduodenectomy may be omitted. Since then, several non-randomized studies (Adham 2013; Correa-Gallego 2013; Fisher 2011; Giovino 2011; Heslin 1998; Kawai 2006; Lim 2013; Mehta 2013; Paulus 2012), and one RCT (Conlon 2001), have tested drain use versus no drain use after pancreatic resections. All of the studies found a similar or higher complication rate in the drainage group over the no drainage group. In addition, the routine use of surgical drains was associated with an increased length of hospital stay (Fisher 2011; Mehta 2013; Paulus 2012). Some authors suggested that routine prophylactic drainage after pancreatic resections could be safely abandoned (Adham 2013; Correa-Gallego 2013; Mehta 2013). Twenty-two years after the first reports of a 'no drain' policy and 13 years after the first RCT (Conlon 2001), Van Buren and coworkers conducted an RCT that compared drain use versus no drain use after pancreatic resections (Van Buren 2014). They found that pancreaticoduodenectomy without drain use was associated with an increased rate and severity of complications. They questioned the safety of not routinely

placing drains in all participants after pancreaticoduodenectomy. In contrast, Witzigmann and colleagues performed another RCT on this topic (Witzigmann 2016). They found that pancreatic resection without drain use was superior to drain use in terms of clinically relevant pancreatic fistula and fistula-associated complications. They suggested that there was no need for routine prophylactic drainage after pancreatic resection. Recently, Van Buren and coworkers conducted another RCT that compared drain use and no drain use after pancreatic resections (Van Buren 2017). They found that distal pancreatectomy without drain use had mortality and postoperative complications similar to the procedure with drain use.

One systematic review that compared drain use with no drain use in people undergoing pancreatic resections concluded that the routine use of abdominal drains after pancreatic resection may result in a higher risk for major complications (Van der Wilt 2013). They included three studies that we had considered for this review (Conlon 2001; Fisher 2011; Heslin 1998). Two of these studies were non-randomized, so were not included in this review. Another recent systematic review also compared drain use with no drain use after pancreatic resections (Hüttner 2017). The review included a total of three randomized controlled studies (Conlon 2001; Van Buren 2014; Witzigmann 2016). The authors of the systematic review concluded that drain use and no drain had similar results in mortality, morbidity and re-intervention. Our review did not make any specific recommendation because the quality of the current evidence about drain use after pancreatic surgery is low.

Another systematic review compared early drain removal with late drain removal in people undergoing pancreatic resection (Diener 2011), and included two studies that we had considered for this review (Bassi 2010; Kawai 2006). One of the studies was not randomized, so we did not include it (Kawai 2006). The authors of the systematic review concluded that early drain removal seemed to be superior to late drain removal (Diener 2011). Our results concluded that early drain removal seemed to be superior to late drain removal for people with low risk of postoperative pancreatic fistula.

AUTHORS' CONCLUSIONS

Implications for practice

It is unclear whether routine abdominal drainage has any effect on the reduction of mortality at 30 days or on postoperative complications after pancreatic surgery. Moderate-quality evidence suggested that routine abdominal drainage probably slightly reduced mortality at 90 days. Low-quality evidence suggested that an active drain may slightly reduce hospital stay over a passive drain after pancreatic surgery, and early removal may be superior to late removal for people with a low risk of postoperative pancreatic fistula.

Implications for research

More studies with sufficient sample size are necessary to assess the benefits and harms of abdominal drainage for people with high risk of postoperative pancreatic fistula.

Future studies should report the rate and grade of the postoperative complication according to the Clavien-Dindo Classification (Clavien 2009; Dindo 2004).

Future studies should analyze the data on an intention-to-treat basis in the case of postrandomization dropouts.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bassi 2010

Methods	Randomized controlled trial
Participants	Country: Italy Number randomized: 114 Postrandomization dropout: 0 (0%) Mean age: 56.6 years Females: 55 (48.2%) Pancreatic cancer: 56 (49.1%) Biliary cancer: 2 (1.8%) Ampullary cancer: 7 (6.1%) Chronic pancreatitis: 3 (2.6%) Other: 46 (40.4%) Pancreaticoduodenectomy: 75 (65.8%) Distal pancreatectomy: 39 (34.2%) Other pancreatic surgery: 0 (0%) Inclusion criteria: 1. Participants had undergone either pancreaticoduodenectomy (reconstruction by pancreaticojejunostomy) or distal pancreatectomy 2. An amylase value in drains on postoperative day 1 < 5000 IU/L Exclusion criteria:

Bassi 2010 (Continued)

1. Reconstruction of the pancreatic remnant by pancreaticogastrostomy
2. Clinical suspicion of post-pancreatectomy haemorrhage or re-laparotomy within 72 hours from index operation
3. Appearance of drain effluent or clinical suspect of biliary fistula within 72 hours of index operation
4. Peripancreatic fluid collection > 5 cm (maximum diameter) at a routine transabdominal ultrasound performed

Interventions	<p>Participants (N = 114) were randomly assigned to 1 of 2 groups</p> <p>Group 1: early drain removal (postoperative day 3; N = 57)</p> <p>Group 2: late drain removal (postoperative day 5 or later; N = 57)</p>
Outcomes	Pancreatic fistula, abdominal complications, pulmonary complications, reoperation, length of hospital stay, hospital readmission, postoperative mortality, morbidity, and hospital costs
Notes	Two drainage tubes (Penrose drains) were placed in relation to the pancreatic and biliary anastomoses through separate skin incisions after pancreaticoduodenectomy. One drainage tube was placed in relation to the pancreatic stump through separate skin incisions after distal pancreatectomy.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "eligible patients were randomized by a computer-generated allocation schedule"
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Masking: Open Label" in the protocol
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no postrandomization dropouts
Selective reporting (reporting bias)	Low risk	Comment: the study protocol was available (NCT00931554). All of the study's prespecified outcomes were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Conlon 2001

Methods	Randomized controlled trial
Participants	<p>Country: USA</p> <p>Number randomized: 179</p> <p>Postrandomization dropout: 0 (0%)</p> <p>Mean age: 65.4 years</p> <p>Females: 90 (50.3%)</p> <p>Pancreatic cancer: 142 (79.3%)</p>

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Conlon 2001 (Continued)

Biliary cancer: 3 (1.7%)

Duodenal cancer: 10 (5.6%)

Ampullary cancer: 24 (13.4%)

Chronic pancreatitis: 0 (0%)

Pancreaticoduodenectomy: 139 (77.7%)

Distal pancreatectomy: 40 (22.3%)

Other pancreatic surgery: 0 (0%)

Inclusion criteria:

1. Adults
2. People with peripancreatic tumors
3. People who had undergone either pancreaticoduodenectomy or distal pancreatectomy

Exclusion criteria:

1. People who had undergone a recent exploration before presentation
2. People who had evidence of intra-abdominal sepsis

Interventions	<p>Participants (N = 179) were randomly assigned to 1 of 2 groups</p> <p>Group 1: drainage (N = 91)</p> <p>Group 2: no drainage (N = 88)</p>
Outcomes	Mortality, morbidity, wound infection, intra-abdominal infection, various postoperative complications, reoperation, additional radiological intervention, and length of hospital stay
Notes	Two drainage tubes (Jackson-Pratt closed suction drains) were placed in relation to the pancreatic and biliary anastomoses through separate skin incisions after pancreaticoduodenectomy. One drainage tube was placed in relation to the pancreatic stump through separate skin incisions after distal pancreatectomy.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information provided
Allocation concealment (selection bias)	Unclear risk	<p>Quote: "patients were randomized during surgery by the envelope method"</p> <p>Comment: no information was provided whether the envelope was opaque or not</p>
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no postrandomization dropouts
Selective reporting (reporting bias)	Low risk	Comment: all of the study's prespecified outcomes in the method section were reported

Conlon 2001 (Continued)

Other bias	Low risk	Comment: the study appeared to be free of other sources of bias
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Jiang 2016

Methods	Randomized controlled trial	
Participants	<p>Country: China</p> <p>Number randomized: 160</p> <p>Postrandomization dropout: 0 (0%)</p> <p>Mean age: 59.6 years</p> <p>Females: 42 (26.3%)</p> <p>Pancreatic cancer: 53 (33.1%)</p> <p>Biliary cancer: 36 (22.5%)</p> <p>Duodenal cancer: 28 (17.5%)</p> <p>Ampullary cancer: 33 (20.6%)</p> <p>Chronic pancreatitis: 5 (3.1%)</p> <p>Pancreaticoduodenectomy: 160 (100%)</p> <p>Distal pancreatectomy: 0 (0%)</p> <p>Other pancreatic surgery: 0 (0%)</p> <p>Inclusion criteria:</p> <p>1. People with planned pancreaticoduodenectomy</p> <p>Exclusion criteria:</p> <p>1. People who had undergone explorative laparotomy</p> <p>2. People who had undergone distal pancreatectomy</p>	
Interventions	<p>Participants (N = 160) were randomly assigned to 1 of 2 groups</p> <p>Group 1: active drain (N = 82)</p> <p>Group 2: passive drain (N = 78)</p>	
Outcomes	<p>Mortality, morbidity, wound infection, intra-abdominal infection, various postoperative complications, reoperation, readmission, additional radiological intervention, and length of hospital stay</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "we randomized our patients using a computer-generated random number"

Jiang 2016 (Continued)

Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Patients were prospectively assigned a code and data were recorded in a database by two nurses" Comment: no information provided whether the 2 nurses were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no postrandomization dropouts
Selective reporting (reporting bias)	Low risk	Comment: all of the study's prespecified outcomes in the method section were reported
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Van Buren 2014

Methods	Randomized controlled trial
Participants	Country: USA Number randomized: 137 Postrandomization dropout: 3 (2.2%) Mean age: 63.2 years Females: 62 (45.3%) Pancreatic cancer: 67 (48.9%) Biliary cancer: not mentioned Duodenal cancer: not mentioned Ampullary cancer: 17 (12.4%) Chronic pancreatitis: 15 (10.9%) Pancreaticoduodenectomy: 137 (100%) Distal pancreatectomy: 0 (0%) Other pancreatic surgery: 0 (0%) Inclusion criteria: <ol style="list-style-type: none"> 1. The participant had a surgical indication for distal pancreatectomy 2. In the opinion of the surgeon, the participant had no medical contraindications to pancreatectomy 3. Aged ≥ 18 years 4. The participant was willing to consent to randomization to the intraperitoneal drain or no drain group 5. The participant was willing to comply with 90-day follow-up and answer quality-of-life questionnaires per protocol Exclusion criteria: <ol style="list-style-type: none"> 1. People who refused to be randomized 2. People who withdrew their consent before surgery

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Van Buren 2014 (Continued)

3. People who were found to have unresectable disease at the time of exploration, or had an enucleation, or a total pancreatectomy rather than a pancreaticoduodenectomy

Interventions	Participants (N = 137) were randomly assigned to 1 of 2 groups Group 1: drainage (N = 68) Group 2: no drainage (N = 69)
Outcomes	Mortality, morbidity, wound infection, intra-abdominal infection, various postoperative complications, reoperation, readmission, additional radiologic intervention, and length of hospital stay
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed using a computerized randomization system at the coordinating center"
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Masking: open label"
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "There were 3 cases for which the randomization group assignment was inadvertently not followed"
Selective reporting (reporting bias)	Low risk	Comment: the study protocol was available (NCT01441492). All of the study's prespecified outcomes were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Van Buren 2017

Methods	Randomized controlled trial
Participants	Country: USA and Canada Number randomized: 399 Postrandomization dropout: 55 (13.8%) Mean age: 61.0 years Females: 205 (60.0%) Pancreatic cancer: 171 (49.7%) Biliary cancer: not mentioned Duodenal cancer: not mentioned Ampullary cancer: not mentioned

Van Buren 2017 (Continued)

Chronic pancreatitis: 33 (9.6%)

Pancreaticoduodenectomy: 0 (0%)

Distal pancreatectomy: 344 (100%)

Other pancreatic surgery: 0 (0%)

Inclusion criteria:

1. The participant had a surgical indication for distal pancreatectomy
2. In the opinion of the surgeon, the participant had no medical contraindications to distal pancreatectomy
3. Age $\geq$ 18 years
4. The participant was willing to consent to randomization to the intraperitoneal drain or no drain group
5. The participant was willing to comply with 30-day and 60-day follow-up in the office and answer quality-of-life questionnaires per protocol
6. The participant was willing to comply with 90-day follow-up by phone

Exclusion criteria:

1. People who refused to be randomized
2. People who withdrew their consent before surgery
3. People who were found to have unresectable disease at the time of exploration, or had an enucleation, or a total pancreatectomy rather than a pancreaticoduodenectomy
4. People who required any type of pancreas resection other than a distal pancreatectomy
5. In the opinion of the surgeon, the participant had medical contraindications to distal pancreatectomy
6. Age < 18 years
7. The subject was not willing to consent to randomization to the intraperitoneal drain or no drain group
8. The subject was not willing to comply with 30-day and 60-day follow-up in the office and answer quality-of-life questionnaires per protocol
9. The subject was not willing to comply with 90-day follow-up by phone

Interventions	<p>Participants (N = 399) were randomly assigned to 1 of 2 groups</p> <p>Group 1: drainage (N = 202)</p> <p>Group 2: no drainage (N = 197)</p>
Outcomes	Mortality, morbidity, wound infection, intra-abdominal infection, various postoperative complications, reoperation, readmission, additional radiologic intervention, length of hospital stay, and quality of life
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomized preoperatively to DP with or without intraperitoneal drain placement using a computerized randomization system at the coordinating center"
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Masking: open label"

Van Buren 2017 (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "There were 55 patients who were excluded from the study after randomization and were not followed. Four patients, 2 in each group, were lost to follow-up and excluded from the analysis".
Selective reporting (reporting bias)	Low risk	Comment: the study protocol was available (NCT01441492). All of the study's prespecified outcomes were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Witzigmann 2016

Methods	Randomized controlled trial
Participants	<p>Country: Germany</p> <p>Number randomized: 438</p> <p>Postrandomization dropout: 43 (2.2%)</p> <p>Mean age: 63.4 years</p> <p>Females: 139 (35.2%)</p> <p>Pancreatic cancer: 159 (40.3%)</p> <p>Biliary cancer: 23 (5.8%)</p> <p>Duodenal cancer: 5 (1.3%)</p> <p>Ampullary cancer: 19 (4.8%)</p> <p>Chronic pancreatitis: 101 (25.6%)</p> <p>Pancreaticoduodenectomy: 328 (83.0%)</p> <p>Distal pancreatectomy: 0 (0%)</p> <p>Other pancreatic surgery: 67 (17.0%)</p> <p>Inclusion criteria:</p> <ol style="list-style-type: none"> 1. Aged ≥ 18 years 2. People planned for pancreatic head resection with pancreaticojejunal anastomosis for benign or malignant tumors, chronic pancreatitis, or other indications <p>Exclusion criteria:</p> <ol style="list-style-type: none"> 1. People who underwent extended resection 2. People who had a cardiac infarction within 6 months before operation 3. Malignancy that had not responded to treatment within 5 years before operation 4. Lack of compliance 5. Pregnancy or lactation 6. Participation in another trial that may interfere with the intervention or outcome
Interventions	<p>Participants (N = 395) were randomly assigned to 1 of 2 groups</p> <p>Group 1: drainage (N = 202)</p> <p>Group 2: no drainage (N = 193)</p>

Witzigmann 2016 (Continued)

Outcomes Mortality, morbidity, wound infection, intra-abdominal infection, various postoperative complications, reoperation, operation time, and length of hospital stay

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A random list was created by GWT-TUD Ltd"
Allocation concealment (selection bias)	Low risk	Quote: "The random allocation sequence was implemented by the use of sequentially numbered opaque envelopes"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "A total of 438 patients were randomized. Forty-three patients (9.8%) were excluded because no pancreatic resection with consecutive pancreatico-jejunal anastomosis was performed. Thus, the intention-to-treat population consisted of 395 patients". Comment: there are 43 postrandomization dropouts. The study did not perform an intention-to-treat analysis which included the 43 dropouts.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol was available (ISRCTN04937707). All of the study's prespecified outcomes were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

DP: distal pancreatectomy; IU: international unit; N: number of participants.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Adham 2013	A non-randomized study
Behrman 2015	A non-randomized study
Correa-Gallego 2013	A non-randomized study
Fisher 2011	A non-randomized study
Giovinazzo 2011	A non-randomized study
Heslin 1998	A non-randomized study
Jeekel 1992	Case series
Kawai 2006	A non-randomized study
Kunstman 2017	A non-randomized study

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Study	Reason for exclusion
Lee 2009	Randomized controlled trial about pancreatic duct drainage
Lim 2013	A non-randomized study
Mehta 2013	A non-randomized study
Paulus 2012	A non-randomized study

Characteristics of ongoing studies [ordered by study ID]

Čečka 2015

Trial name or title	DRAPA Trial - Closed-suction drains versus closed gravity drains in pancreatic surgery: study protocol for a randomized controlled trial
Methods	Randomized controlled trial
Participants	Country: Czech Republic Number of enrolment: 223 Inclusion criteria: <ol style="list-style-type: none"> 1. People scheduled for primary pancreaticoduodenectomy or distal pancreatic resection in participating centers 2. Aged ≥ 18 years 3. Signed informed consent provided Exclusion criteria: <ol style="list-style-type: none"> 1. No pancreatic resection performed: non-resectable tumor 2. Total pancreatectomy, central pancreatectomy, or enucleation 3. Multivisceral resection 4. Laparoscopic procedure 5. Resection of the portal vein and reconstruction with a graft 6. Lack of compliance, informed consent not provided, or refusal to participate
Interventions	Participants are randomly assigned to 1 or 2 groups Group 1: closed suction drain (active drain) Group 2: closed gravity drain (passive drain)
Outcomes	Primary outcome: rate of postoperative pancreatic fistula Secondary outcomes: postoperative morbidity, including wound infection, intra-abdominal collections, delayed gastric emptying, postoperative hemorrhage, pneumonia, abdominal rupture, cardiac events, and neurological complications
Starting date	October 2013
Contact information	Principal investigator: Filip Čečka, Department of Surgery, University Hospital Hradec Kralove, Hradec Kralove, Czech Republic, 50005 Tel: +42049583 ext 4272 Email: filip.cecka@seznam.cz

Čečka 2015 (Continued)

Notes

DATA AND ANALYSES

Comparison 1. Drain use versus no drain use

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality (30 days)	3	711	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.31, 1.99]
2 Mortality (90 days)	2	478	Risk Ratio (M-H, Random, 95% CI)	0.23 [0.06, 0.90]
3 Intra-abdominal infection	4	1055	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.52, 1.80]
4 Wound infection	4	1055	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.68, 1.41]
5 Morbidity	4	1055	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.94, 1.13]
6 Length of hospital stay (days)	3	711	Mean Difference (IV, Random, 95% CI)	-0.66 [-1.60, 0.29]
7 Additional open procedures for postoperative complications	4	1055	Risk Ratio (M-H, Random, 95% CI)	1.33 [0.79, 2.23]
8 Additional radiological interventions for postoperative complications	3	660	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.40, 1.87]

Analysis 1.1. Comparison 1 Drain use versus no drain use, Outcome 1 Mortality (30 days).

Analysis 1.2. Comparison 1 Drain use versus no drain use, Outcome 2 Mortality (90 days).

Analysis 1.3. Comparison 1 Drain use versus no drain use, Outcome 3 Intra-abdominal infection.

Analysis 1.4. Comparison 1 Drain use versus no drain use, Outcome 4 Wound infection.

Analysis 1.5. Comparison 1 Drain use versus no drain use, Outcome 5 Morbidity.

Analysis 1.6. Comparison 1 Drain use versus no drain use, Outcome 6 Length of hospital stay (days).

Analysis 1.7. Comparison 1 Drain use versus no drain use, Outcome 7 Additional open procedures for postoperative complications.

Analysis 1.8. Comparison 1 Drain use versus no drain use, Outcome 8 Additional radiological interventions for postoperative complications.

Comparison 2. Active drain versus passive drain

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality (30 days)	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
2 Intra-abdominal infection	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
3 Wound infection	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4 Morbidity	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
5 Length of hospital stay (days)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
6 Additional open procedures for postoperative complications	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 2.1. Comparison 2 Active drain versus passive drain, Outcome 1 Mortality (30 days).

Analysis 2.2. Comparison 2 Active drain versus passive drain, Outcome 2 Intra-abdominal infection.

Analysis 2.3. Comparison 2 Active drain versus passive drain, Outcome 3 Wound infection.

Study or subgroup	Active drain n/N	Passive drain n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Jiang 2016	5/82	7/78		0.68[0.23,2.05]
Favours active drain				Favours passive drain

Analysis 2.4. Comparison 2 Active drain versus passive drain, Outcome 4 Morbidity.

Study or subgroup	Active drain n/N	Passive drain n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Jiang 2016	18/82	25/78		0.68[0.41,1.15]
Favours active drain				Favours passive drain

Analysis 2.5. Comparison 2 Active drain versus passive drain, Outcome 5 Length of hospital stay (days).

Study or subgroup	Active drain		Passive drain		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Jiang 2016	82	12.6 (4.4)	78	14.5 (6.7)		-1.9[-3.67,-0.13]
Favours active drain			Favours passive drain			

Analysis 2.6. Comparison 2 Active drain versus passive drain, Outcome 6 Additional open procedures for postoperative complications.

Study or subgroup	Active drain n/N	Passive drain n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Jiang 2016	1/82	6/78		0.16[0.02,1.29]
Favours active drain				Favours passive drain

Comparison 3. Early versus late drain removal

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Morbidity	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
2 Length of hospital stay (days)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
3 Hospital costs (EUR)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Additional open procedures for postoperative complications	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected

Analysis 3.1. Comparison 3 Early versus late drain removal, Outcome 1 Morbidity.

Study or subgroup	Early removal n/N	Late removal n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Bassi 2010	22/57	35/57		0.63[0.43,0.93]
Favours early removal			0.1 0.2 0.5 1 2 5 10	Favours late removal

Analysis 3.2. Comparison 3 Early versus late drain removal, Outcome 2 Length of hospital stay (days).

Study or subgroup	Early removal N	Early removal Mean(SD)	Late removal N	Late removal Mean(SD)	Mean Difference Random, 95% CI	Mean Difference Random, 95% CI
Bassi 2010	57	8.7 (4)	57	10.8 (6.9)		-2.1[-4.17,-0.03]
Favours early removal			-5 -2.5 0 2.5 5			Favours late removal

Analysis 3.3. Comparison 3 Early versus late drain removal, Outcome 3 Hospital costs (EUR).

Study or subgroup	Early removal N	Early removal Mean(SD)	Late removal N	Late removal Mean(SD)	Mean Difference Random, 95% CI	Mean Difference Random, 95% CI
Bassi 2010	57	10071 (2700)	57	12140 (6400)		-2069[-3872.26,-265.74]
Favours early removal			-1000 -500 0 500 1000			Favours late removal

Analysis 3.4. Comparison 3 Early versus late drain removal, Outcome 4 Additional open procedures for postoperative complications.

Study or subgroup	Early removal n/N	Late removal n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Bassi 2010	0/57	1/57		0.33[0.01,8.01]
Favours early removal			0.001 0.1 1 10 1000	Favours late removal

Comparison 4. Drain use versus no drain use sensitivity analysis for missing data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality (90 days) - worst-case scenario	2	536	Risk Ratio (M-H, Random, 95% CI)	2.15 [0.05, 89.11]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Mortality (90 days) - best-case scenario	2	536	Risk Ratio (M-H, Random, 95% CI)	0.07 [0.00, 1.01]

Analysis 4.1. Comparison 4 Drain use versus no drain use sensitivity analysis for missing data, Outcome 1 Mortality (90 days) - worst-case scenario.

Analysis 4.2. Comparison 4 Drain use versus no drain use sensitivity analysis for missing data, Outcome 2 Mortality (90 days) - best-case scenario.

APPENDICES

Appendix 1. Glossary of terms

Abscess: a collection of pus that has built up within the tissues of the body

Active drain: drains that suction under low or high pressure

Adverse events: untoward side effects

Anastomosis: connection between two organs (e.g. stomach and small intestine) created by surgery

Biliary: related to the bile duct

Chronic pancreatitis: long-standing inflammation of the pancreas

Delayed gastric emptying: a medical condition consisting of paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for an abnormally long time

Duodenal: related to the first section of the small intestine

Drainage: the process or system by which water or waste liquid flows away

Incidence: the rate at which something happens

Morbidity: the proportion of people with any postoperative complications

Mortality: the proportion of deaths after surgery

Pancreas: the organ in the body that produces insulin and a liquid that helps your body to use the food that you eat

Pancreatic: relating to the pancreas

Pancreatic anastomoses: the surgical connection of the bile-pancreatic duct and gut to form a continuous channel

Pancreatic fistula: a complication whereby the pancreas is disconnected from the nearby gut, and then reconnected to allow pancreatic juice containing digestive enzymes to enter the digestive system

Pancreaticoduodenectomy: a major surgical operation involving the pancreas, duodenum, and other organs

Passive drain: drains without suction

Postoperative: relating to the time after someone has had a medical operation

Prevalence: the total number of people with an illness at a designated time

Prophylactic: protective or preventive

Randomized controlled trials: an experiment in which participants are randomly allocated to two or more interventions, possibly including a control intervention or no intervention, and the results are compared

Subhepatic: under the liver.

Appendix 2. EBM Reviews Ovid - Cochrane Central Register of Controlled Trials (CENTRAL; 2016 to 15 November 2017)

1. exp Pancreas/
2. common bile duct/ or "ampulla of vater"/ or "sphincter of oddi"/ or exp Duodenum/
3. pancrea*.ab,ti.
4. or/1-3
5. carcinoma/ or adenocarcinoma/ or exp Neoplasms/
6. (carcino* or cancer\$ or neoplasm* or tumour\$ or tumor\$ or cyst\$ or growth\$ or adenocarcinoma* or malign*).tw.
7. 5 or 6
8. 4 and 7
9. pancreatic neoplasms/ or exp carcinoma, islet cell/ or carcinoma, pancreatic ductal/ or Duodenal Neoplasms/ or Common Bile Duct Neoplasms/ or exp Pancreatitis/
10. 8 or 9
11. General Surgery/
12. (surger* or operatio* or operative therap* or resection*).tw.
13. 11 or 12
14. 10 and 13
15. pancreatectomy/ or pancreaticoduodenectomy/ or pancreaticojejunostomy/
16. (pancreatectom* or pancreaticojejunostom* or pancreaticoduodenectom* or pancreaticogastrostom* or duodenopancreatectom*).ab,ti.
17. or/14-16
18. drainage/ or negative-pressure wound therapy/ or suction/
19. (drain* or suction*).ab,ti.
20. 18 or 19

21.17 and 20

Appendix 3. MEDLINE Ovid search strategy (2016 to 2 November 2017)

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
- 10.exp animals/ not humans.sh.
- 11.9 not 10
- 12.exp Pancreas/
- 13.common bile duct/ or "ampulla of vater"/ or "sphincter of oddi"/ or exp Duodenum/
- 14.pancrea*.ab,ti.
- 15.or/12-14
- 16.carcinoma/ or adenocarcinoma/ or exp Neoplasms/
- 17.(carcino* or cancer\$ or neoplasm* or tumour\$ or tumor\$ or cyst\$ or growth\$ or adenocarcinoma* or malign*).tw.
- 18.16 or 17
- 19.15 and 18
- 20.pancreatic neoplasms/ or exp carcinoma, islet cell/ or carcinoma, pancreatic ductal/ or Duodenal Neoplasms/ or Common Bile Duct Neoplasms/ or exp Pancreatitis/
- 21.19 or 20
- 22.General Surgery/
- 23.(surger* or operatio* or operative therap* or resection*).tw.
- 24.22 or 23
- 25.21 and 24
- 26.pancreatectomy/ or pancreaticoduodenectomy/ or pancreaticojejunostomy/
- 27.(pancreatectom* or pancreaticojejunostom* or pancreaticoduodenectom* or pancreaticogastrostom* or duodenopancreatectom*).ab,ti.
- 28.or/25-27
- 29.drainage/ or negative-pressure wound therapy/ or suction/
- 30.(drain* or suction*).ab,ti.
- 31.29 or 30
- 32.11 and 28 and 31

Appendix 4. Embase Ovid search strategy (2016 to 15 November 2017)

1. random:.tw. or placebo:.mp. or double-blind:.tw.
2. pancreas/ or "islets of langerhans"/ or pancreas, exocrine/ or pancreatic ducts/
3. exp common bile duct/ or exp Vater papilla/ or exp duodenum/
4. pancrea*.ab,ti.
5. 2 or 3 or 4
6. carcinoma/ or adenocarcinoma/ or exp neoplasm/
7. (carcino* or cancer\$ or neoplasm* or tumour\$ or tumor\$ or cyst\$ or growth\$ or adenocarcinoma* or malign*).tw.
8. 6 or 7
9. 5 and 8
- 10.pancreas islet cell tumor/ or exp pancreas cancer/ or exp duodenum cancer/ or exp duodenum carcinoma/ or exp Vater papilla tumor/ or exp Vater papilla carcinoma/ or exp bile duct cancer/ or exp pancreatitis/
- 11.9 or 10
- 12.surgery/
- 13.(surger* or operatio* or operative therap* or resection*).tw.

- 14.12 or 13
- 15.11 and 14
- 16.exp pancreas resection/ or exp pancreaticojejunostomy/ or exp pancreaticoduodenectomy/
- 17.(pancreatectom* or pancreaticojejunostom* or pancreaticoduodenectom* or pancreaticogastrostom* or duodenopancreatectom*).ab,ti.
- 18.or/15-17
- 19.exp drain/ or exp suction/ or exp abscess drainage/ or exp abdominal drainage/ or exp wound drainage/ or exp surgical drainage/ or exp vacuum assisted closure/ or exp negative pressure wound therapy/
- 20.(drain* or suction*).ab,ti.
- 21.19 or 20
- 22.1 and 18 and 21

Appendix 5. Science Citation Index Expanded search strategy (2016 to 15 November 2017)

1. Topic=(pancrea* or (common bile duct*) or (ampulla of vater) or (sphincter of oddi) or duodenum) AND Topic=(carcino* or cancer* or neoplasm* or tumour* or tumor* or cyst* or growth* or adenocarcinoma* or malign*)
2. Topic=((surger* or operatio* or operative therap* or resection*)) OR Topic=((pancreatectom* or pancreaticojejunostom* or pancreaticoduodenectom* or pancreaticogastrostom* or duodenopancreatectom*))
3. Topic=(drain* or suction*) OR Topic=(negative-pressure wound therap*) OR Topic=(vacuum assisted closure*)
4. #3 AND #2 AND #1
5. Topic=(single blind* or double blind* or clinical trial* or placebo* or random* or controlled clinical trial* or research design or comparative stud* or controlled trial* or (follow up stud*) or prospective stud*)
6. #5 AND #4

Appendix 6. Chinese Biomedical Literature Database (CBM) search strategy (2016 to 15 November 2017)

1. 主题词:随机对照试验/全部树/全部副主题词
2. 主题词:临床对照试验/全部树/全部副主题词
3. 主题词:临床试验/全部树/全部副主题词
4. 主题词:病例对照研究/全部树/全部副主题词
5. 主题词:随机分配/全部树/全部副主题词
6. 主题词:对比研究/全部树/全部副主题词
7. 主题词:前瞻性研究/全部树/全部副主题词
8. 主题词:安慰剂/全部树/全部副主题词
9. 全部字段:随机
- 10.全部字段:单盲
- 11.全部字段:双盲
- 12.全部字段:盲法
- 13.(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12)
- 14.主题词:胰腺肿瘤/全部树/全部副主题词
- 15.主题词:胰腺疾病/全部树/全部副主题词
- 16.全部字段:胰腺占位
- 17.全部字段:胰腺癌
- 18.全部字段:胰头癌
- 19.主题词:胆总管肿瘤/全部树/全部副主题词
- 20.全部字段:胆总管下端占位
- 21.全部字段:胆总管下端肿瘤
- 22.全部字段:胆总管下端癌
- 23.主题词:肝胰管壶腹/全部树/全部副主题词
- 24.全部字段:壶腹部占位
- 25.全部字段:壶腹部肿瘤
- 26.全部字段:壶腹癌
- 27.全部字段:vater壶腹癌
- 28.主题词:十二指肠肿瘤/全部树/全部副主题词
- 29.主题词:十二指肠疾病/全部树/全部副主题词

- 30.全部字段:十二指肠占位
- 31.全部字段:十二指肠乳头腺癌
- 32.主题词:胰腺炎/全部树/全部副主题词
- 33.主题词:胰腺炎,慢性/全部树/全部副主题词
- 34.(#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33)
- 35.主题词:外科手术/全部树/全部副主题词
- 36.主题词:吻合术, 外科/全部树/全部副主题词
- 37.全部字段:手术治疗
- 38.全部字段:手术
- 39.全部字段:切除术
- 40.(#35 OR #36 OR #37 OR #38 OR #39)
- 41.(#34 AND #40)
- 42.主题词:胰腺/全部树/SU
- 43.主题词:胰腺切除术/全部树/全部副主题词
- 44.主题词:胰十二指肠切除术/全部树/全部副主题词
- 45.全部字段:胰体尾切除术
- 46.全部字段:胰腺部分切除
- 47.全部字段:胰十二指肠吻合术
- 48.全部字段:胰头十二指肠吻合术
- 49.全部字段:Whipple术式
- 50.全部字段:Child术式
- 51.(#41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50)
- 52.主题词:引流/全部树/全部副主题词
- 53.主题词:抽吸/全部树/全部副主题词
- 54.主题词:负压伤口治疗/全部树/全部副主题词
- 55.全部字段:腹腔引流
- 56.全部字段:引流管
- 57.全部字段:手术引流
- 58.全部字段:伤口引流
- 59.全部字段:负压引流
- 60.(#52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59)
- 61.(#13 AND #51 AND #60)

WHAT'S NEW

Date	Event	Description
15 November 2017	New citation required but conclusions have not changed	Searches rerun, one additional trial found
15 November 2017	New search has been performed	One trial added; new evidence incorporated

CONTRIBUTIONS OF AUTHORS

Conceiving the review: WZ.

Designing the review: SH.

Co-ordinating the review: ZL.

Designing search strategies: WZ, SH.

Study selection: WZ, SH.

Data extraction: JX, ML.

Writing the review: WZ, SH.

Providing general advice on the review: NC.

Securing funding for the review: ZL.

Performing previous work that was the foundation of the current study: YC.

DECLARATIONS OF INTEREST

WZ: none known.

SH: none known.

YC: none known.

JX: none known.

ML: none known.

NC: none known.

ZL: none known.

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Internal sources

- Chongqing Medical University, China.

Provided funding for the review

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Because overall infectious complications were not reported, we chose two types of infectious complication (intra-abdominal infection and wound infection) for the 'Summary of findings' table.

INDEX TERMS

Medical Subject Headings (MeSH)

Abdomen; Device Removal [adverse effects] [mortality]; Drainage [*methods] [mortality]; Length of Stay; Pancreas [*surgery]; Postoperative Complications [mortality] [*prevention & control]; Randomized Controlled Trials as Topic; Time Factors

MeSH check words

Humans