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Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy for the prevention of lymphocyst formation in women with gynaecological malignancies (Review)

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Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy for the prevention of lymphocyst formation in women with gynaecological malignancies (Review)

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[Intervention Review]

Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy for the prevention of lymphocyst formation in women with gynaecological malignancies

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ABSTRACT

Background

This is an updated version of an original Cochrane review published in Issue 6, 2014. Pelvic lymphadenectomy is associated with significant complications including lymphocyst formation and related morbidities. Retroperitoneal drainage using suction drains has been recommended as a method to prevent such complications. However, findings from recent studies have challenged this policy.

Objectives

To assess the effects of retroperitoneal drainage versus no drainage after pelvic lymphadenectomy on lymphocyst formation and related morbidities in women with gynaecological cancer.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, Issue 3, 2017) in the Cochrane Library, electronic databases MEDLINE (1946 to March Week 2, 2017), Embase (1980 to 2017 week 12), and the citation lists of relevant publications. We also searched the trial registries for ongoing trials on 20 May 2017.

Selection criteria

Randomised controlled trials (RCTs) that compared the effect of retroperitoneal drainage versus no drainage after pelvic lymphadenectomy in women with gynaecological cancer. Retroperitoneal drainage was defined as placement of passive or active suction drains in pelvic retroperitoneal spaces. No drainage was defined as no placement of passive or active suction drains in pelvic retroperitoneal spaces.

Data collection and analysis

We assessed studies using methodological quality criteria. For dichotomous data, we calculated risk ratios (RRs) and 95% confidence intervals (CIs). We examined continuous data using mean difference (MD) and 95% CI.

Main results

Since the last version of this review, we have identified no new studies for inclusion. The review included four studies with 571 women. Regarding short-term outcomes (within four weeks after surgery), retroperitoneal drainage was associated with a comparable rate of overall lymphocyst formation when all methods of pelvic peritoneum management were considered together (2 studies; 204 women; RR

0.76, 95% CI 0.04 to 13.35; moderate-quality evidence). When the pelvic peritoneum was left open, the rates of overall lymphocyst formation (1 study; 110 women; RR 2.29, 95% CI 1.38 to 3.79) and symptomatic lymphocyst formation (2 studies; 237 women; RR 3.25, 95% CI 1.26 to 8.37) were higher in the drained group. At 12 months after surgery, the rates of overall lymphocyst formation were comparable between the groups (1 study; 232 women; RR 1.48, 95% CI 0.89 to 2.45; high-quality evidence). However, there was a trend toward increased risk of symptomatic lymphocyst formation in the group with drains (1 study; 232 women; RR 7.12, 95% CI 0.89 to 56.97; low-quality evidence).

Authors' conclusions

Placement of retroperitoneal tube drains has no benefit in the prevention of lymphocyst formation after pelvic lymphadenectomy in women with gynaecological malignancies. When the pelvic peritoneum is left open, the tube drain placement is associated with a higher risk of short- and long-term symptomatic lymphocyst formation. We found the quality of evidence using the GRADE approach to be moderate to high for most outcomes, except for symptomatic lymphocyst formation at 12 months after surgery, and unclear or low risk of bias.

PLAIN LANGUAGE SUMMARY

Drains versus no drains after pelvic lymphadenectomy to prevent lymphocyst formation in women with gynaecological cancer

Background

This is an updated version of an original Cochrane review published in Issue 6, 2014.

Pelvic lymphadenectomy (removal of lymph glands found in the pelvis) is an important component of the surgical management of gynaecological cancers to see if the cancer has spread. However, it can lead to complications, especially lymphocyst formation (collection of lymphatic fluid in the pelvis). Lymphocysts can cause leg swelling, blockage of the ureter (a tube that carries urine from the kidney to the urinary bladder), pelvic pain, clot formation in the leg and pelvic vein, bowel motility disorder, and infection. Without clear evidence for its effectiveness, placement of suction drains to remove lymphatic fluids that build up in the operative area between the peritoneum and the posterior abdominal wall has been traditionally recommended to prevent such complications.

Review question

The aim of this review was to compare the effects of drains versus no drains in preventing lymphocyst formation following pelvic lymphadenectomy.

Main findings

We updated the main database searches in March 2017. We identified four studies (571 women) for inclusion. The women primarily had cancer of the cervix and endometrium, with only one study also including women with cancer of the ovary. Our findings demonstrated that placement of suction drains is not effective in preventing lymphocysts, especially when the peritoneum (pelvic lining) is left open. In fact, such practice increases the risk of short- and long-term lymphocyst formation with related symptoms.

Quality of the evidence

The review includes four moderate to high quality evidence (unclear or low risk of bias) clinical trials in its final analysis.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy for gynaecological malignancies

Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy for gynaecological malignancies

Patient or population: Women with gynaecological malignancies

Settings: hospital

Intervention: retroperitoneal drainage versus no drainage after pelvic lymphadenectomy

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy				
Short-term lymphocyst formation: both asymptomatic and symptomatic within 4 weeks after surgery	Study population		RR 0.76 (0.04 to 13.35)	204 (2 studies)	⊕⊕⊕ moderate ¹	
	172 per 1000	131 per 1000 (7 to 1000)				
	Medium-risk population					
	161 per 1000	122 per 1000 (6 to 1000)				
Short-term lymphocyst formation: symptomatic within 4 weeks after surgery	Study population		RR 3.25 (1.26 to 8.37)	237 (2 studies)	⊕⊕⊕⊕ high	
	43 per 1000	140 per 1000 (54 to 360)				
	Medium-risk population					
	36 per 1000	117 per 1000 (45 to 301)				
Short-term lymphocyst formation: both asymptomatic and symptomatic at 8 weeks after surgery	Study population		RR 0.72 (0.3 to 1.71)	180 (2 studies)	⊕⊕⊕⊕ high	
	112 per 1000	81 per 1000 (34 to 192)				

	Medium-risk population 110 per 1000 79 per 1000 (33 to 188)			
Long-term lymphocyst formation: both asymptomatic and symptomatic at 12 months after surgery	Study population	RR 1.48 (0.89 to 2.45)	232 (1 study)	⊕⊕⊕⊕ high
	171 per 1000 253 per 1000 (152 to 419)			
	Medium-risk population			
	171 per 1000 253 per 1000 (152 to 419)			
Long-term lymphocyst formation: symptomatic at 12 months after surgery	Study population	RR 7.12 (0.89 to 56.97)	232 (1 study)	⊕⊕⊕⊕ low ^{1,2}
	9 per 1000 64 per 1000 (8 to 513)			
	Medium-risk population			
	9 per 1000 64 per 1000 (8 to 513)			
Febrile morbidity	Study population	RR 1.76 (0.87 to 3.55)	571 (4 studies)	⊕⊕⊕⊕ high
	39 per 1000 69 per 1000 (34 to 138)			
	Medium-risk population			
	39 per 1000 69 per 1000 (34 to 138)			
Pelvic infection	Study population	RR 0.42 (0.11 to 1.62)	571 (4 studies)	⊕⊕⊕ moderate ²
	18 per 1000 8 per 1000 (2 to 29)			
	Medium-risk population			
	19 per 1000 8 per 1000			

(2 to 31)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **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.

¹Wide confidence interval.

²Small number of events in the analysis.

BACKGROUND

This review is an update of a previously published review in the Cochrane Database of Systematic Reviews, Issue 1, 2010 (Charoenkwan 2014).

Pelvic lymphadenectomy, the removal of all or most of the lymph nodes surrounding major pelvic blood vessels, is an important component of the surgical management of gynaecological malignancies, particularly those originating from the cervix, endometrium, and ovary. Knowledge of the metastatic status of the removed pelvic lymph nodes provides valuable staging and prognostic information that guides postoperative adjuvant treatment. In addition, removal of both bulky and microscopic metastatic nodes can potentially improve treatment outcome. However, the procedure is associated with postoperative complications, among which lymphocyst formation and its related morbidities are important (Benedetti-Panici 1997; Yamamoto 2000).

A lymphocyst, defined as a collection of lymphatic fluid in the retroperitoneal space (the space between the peritoneum and the posterior abdominal wall), is well known as a specific complication of pelvic lymphadenectomy (Benedetti-Panici 1997; Ilancheran 1988; Livingston 1980; Petru 1989). The reported incidence of lymphocyst following gynaecological cancer surgery varies from 1% to 29% (Lopes 1995). These differences can be explained by the use of various surgical techniques (methods and instruments used to remove the lymph nodes and secure lymphatic vessels; sharp dissection with suture ligation or coagulation), the difference in extent of lymphadenectomy, and the use of different diagnostic methods (ultrasonography or computerised tomography (CT) scan) (Srisomboon 2002; Yamamoto 2000). The mechanism of lymphocyst formation is unknown. However, previous radiotherapy, node metastasis, and prophylactic heparin have been considered as possible risk factors (Yamamoto 2000). Most lymphocysts occur within the first two to four weeks after surgery (Conte 1990). Although frequently asymptomatic, lymphocysts can lead to leg oedema, ureteral obstruction, pelvic pain, deep venous thrombosis, ileus (intestinal stasis), secondary infection, and fistula (abnormal passage that connects an abscess, cavity, or hollow organ to the body surface or to another hollow organ) (Franchi 2007).

Retroperitoneal drainage has been traditionally recommended as a method to prevent lymphocyst formation and associated postoperative morbidities (Symmond 1961; Symmond 1966; Van Nagell 1976). The procedure is performed by the placement of passive or active suction drains to remove lymphatic fluid or blood that accumulates in the operative fields. This practice has become a surgical dogma. However, recent studies have challenged this policy by demonstrating that there is no advantage to the routine use of retroperitoneal drainage following radical hysterectomy and pelvic lymphadenectomy (Franchi 2007; Lopes 1995; Patsner 1995; Srisomboon 2002). In fact, the drain itself, as a foreign body, could disturb the reparative and absorptive functions of the peritoneum and contribute to the formation of lymphocyst (Maitland 1970).

Our aim was to determine whether there is clear evidence to support the omission of retroperitoneal drainage following pelvic lymphadenectomy in people with gynaecological malignancies.

OBJECTIVES

To assess the effects of retroperitoneal drainage versus no drainage after pelvic lymphadenectomy on lymphocyst formation and related morbidities in people with gynaecological cancer.

METHODS

Criteria for considering studies for this review

Types of studies

We considered randomised controlled trials (RCTs) that compared the effect of retroperitoneal drainage versus no drainage after pelvic lymphadenectomy in women with gynaecological cancer. However, we excluded quasi-RCTs. The trials that were included in the final analysis had clear random allocation criteria with appropriate allocation concealment. In addition, the included studies did not have significant violations of allocation procedure and exclusions after allocation.

Types of participants

Participants were women with gynaecological malignancies who had undergone pelvic lymphadenectomy with or without para-aortic lymphadenectomy as part of their surgical treatment, regardless of lymphadenectomy approaches (transperitoneal or extraperitoneal) and surgical approach (open or laparoscopic).

Types of interventions

Main intervention

Retroperitoneal drainage, defined as placement of passive or active suction drains in pelvic retroperitoneal spaces following pelvic lymphadenectomy, regardless of drainage route (transabdominal or transvaginal), surgical management of pelvic peritoneum (left open or sutured closed), and surgical management of vaginal stump (open or closed).

Comparison intervention

No drainage, defined as no placement of passive or active suction drains in pelvic retroperitoneal spaces following pelvic lymphadenectomy, regardless of surgical management of pelvic peritoneum (left open or sutured closed) and surgical management of vaginal stump (open or closed).

Types of outcome measures

We recorded the following outcomes where information was available.

Primary outcomes

Rate of lymphocyst formation; asymptomatic and symptomatic (categorical data). The diagnosis of lymphocyst must have been made by imaging studies such as ultrasound, computerised tomography (CT), or magnetic resonance imaging (MRI). The techniques used for diagnosis were described.

Secondary outcomes

1. Rate of related postoperative morbidities: febrile morbidity, wound infection, wound dehiscence, leg oedema, deep venous thrombosis, bowel obstruction, fistula formation (categorical data).

2. Blood transfusion (categorical data).
3. Change of related serum chemistry: protein and albumin level (continuous data), albumin infusion (categorical data).
4. Time to the return of bowel sound (continuous data).
5. Duration of surgery (continuous data).
6. Postoperative hospital stay (continuous data).

Search methods for identification of studies

Electronic searches

We obtained all articles that described RCTs of retroperitoneal drainage versus no drainage after pelvic lymphadenectomy in women with gynaecological cancer from the following sources.

1. The Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (2017, Issue 3) in all fields ([Appendix 1](#)).
2. The MEDLINE electronic database (1946 to March week 2, 2017) ([Appendix 2](#)).
3. The Embase electronic database (1980 to Week 12, 2017) ([Appendix 3](#)).

We performed the latest searches on 22 March 2017.

Searching other resources

1. We searched the following sources for ongoing trials: WHO International Clinical Trials Registry Platform (WHO ICTRP) (www.who.int/ictcp/en/) and ClinicalTrials.gov (www.clinicaltrials.gov).
2. We searched electronic databases including GreyNet.org (www.greynet.org/), the Ohio College Library Center (OCLC) WorldCat dissertations and theses (www.oclc.org/support/services/firstsearch/documentation/dbdetails/details/WorldCatDissertations.en.html), and index to theses (ProQuest Dissertations & Theses: UK & Ireland) to identify the possible relevant conference abstracts and proceedings.
3. We handsearched reports of conferences from the following sources: Gynecologic Oncology (Annual Meeting of the Society of Gynecologic Oncology); International Journal of Gynecological Cancer (Annual Meeting of the International Gynecologic Cancer Society); Annual Meeting of the European Society of Medical Oncology (ESMO); and Biennial Meeting of the European Society of Gynaecologic Oncology (ESGO).
4. We searched the citation lists of relevant publications, systematic reviews, review articles, abstracts of scientific meetings, and included studies.
5. We conducted personal communication with experts, specialists in the field, and the study authors of relevant publications in an attempt to identify unpublished studies.

We performed the latest searches of these resources on 20 May 2017.

Data collection and analysis

Selection of studies

Both review authors (KC and CK) undertook the study selection. Both review authors screened the titles and abstracts of articles

identified by the search. We discarded studies that were clearly ineligible but aimed to be overly inclusive rather than risk losing relevant studies. Next we obtained full-text copies of the eligible articles. Both review authors independently assessed whether the studies met the inclusion criteria, resolving any disagreements by discussion. We sought further information from the study authors of papers containing insufficient information to make a decision about eligibility.

Data extraction and management

The review authors independently extracted information using a pre-designed data extraction form. We resolved any discrepancies by discussion. For each included trial, we collected information regarding the location of the study, methods of the study, the participants (age range, eligibility criteria), nature of the interventions, and data relating to the outcomes specified above. Where possible, we sought missing data from study authors.

Assessment of risk of bias in included studies

Methodological quality

The two review authors then independently assessed the quality of all eligible studies, following the guidelines of the *Cochrane Handbook of Systematic Reviews of Interventions* ([Higgins 2008](#)) and resolving any discrepancies by discussion. We conducted the assessment by detailed description of the following standardised items.

- Was the assigned treatment adequately concealed prior to allocation? ([Appendix 4](#))
- Were the treatment and control group comparable at entry?
- Were the outcomes of participants who withdrew or were excluded after allocation described and included in an intention-to-treat analysis?
- Were the participants blinded to assignment status following allocation?
- Were the treatment providers blinded to assignment status?
- Were the care programmes, other than the trial options, identical?
- Were the outcome assessors blinded to assignment status?
- Were the withdrawals or loss to follow-up less than 10% of the study population?

We rated each item as follows:

- clearly yes: rate A;
- not sure: rate B (seek details from study authors);
- clearly no: rate C.

The information regarding methodological quality is presented graphically, providing a context for discussing the reliability of the results ([Figure 1](#); [Figure 2](#)). We examined the funnel plot for each outcome for the possibility of publication bias.

Figure 1. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias): Lymphocyst formation	Blinding (performance bias and detection bias): Postoperative morbidities and recovery	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Benedetti-Panici 1997	+	+	+	?	+	?
Franchi 2007	+			?	+	
Lopes 1995	+	+	?	?	+	+
Srisomboon 2002	+	+	+	-	+	+

Data synthesis

We performed statistical analysis in accordance with the guidelines for statistical analysis developed by The Cochrane Collaboration (Deeks 2008).

Subgroup analysis and investigation of heterogeneity

We examined heterogeneity (variations) between the results of different studies by inspecting the forest plot of a meta-analysis for variation in effects. We also considered formal statistical tests, such as the statistical tests of homogeneity of 2 x 2 tables and the I^2 value, in conjunction with the graphical approaches to determine between-study differences.

For categorical data, we expressed results for each study as a risk ratio (RR) with 95% confidence interval (CI) and combined these for meta-analysis using Review Manager 5 software (RevMan 2012).

For continuous data, we expressed results from each study as a mean difference (MD) with 95% CI and combined these for meta-analysis using Review Manager 5 software. Meta-analytic methods for continuous data assume that the underlying distribution of the measurements is normal. Where data were clearly skewed and results reported in the publication as median and range with non-parametric tests of significance, we reported the results separately in the Results section of the review.

For meta-analysis, we used the fixed-effect or random-effects model depending on the outcome of the tests of homogeneity.

Sensitivity analysis

We planned to perform sensitivity analyses where there was uncertainty or disagreement regarding inclusion of studies, data extraction, and missing data/dropouts.

GRADE rating and Summary of findings

Both review authors (KC and CK) rated the quality of the evidence based on the approach proposed by the GRADE Working Group (GRADE 2013). We used the GRADE checklist and GRADE Working Group quality of evidence definitions (Meader 2014). We downgraded the evidence from high quality by one level for each serious (or by two for each very serious) limitation. Definitions used for grading of evidence included:

- High quality: Findings of the review provide a very good indication of the likely effect. The likelihood that the effect will be substantially different is low.

- Moderate quality: Findings of the review provide a good indication of the likely effect. The likelihood that the effect will be substantially different is moderate.
- Low quality: Findings of the review provide some indication of the likely effect. However, the likelihood that it will be substantially different is high.
- Very low quality: Findings of the review do not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different is very high.

We presented the main results in a 'Summary of findings' table generated using GRADEpro software (GRADEpro). We presented the following outcomes in the 'Summary of findings' table:

- Short-term lymphocyst formation
- Long-term lymphocyst formation
- Febrile morbidity
- Pelvic infection

RESULTS

Description of studies

The database searches up to March 2017 and trial registries in May 2017 identified 196 records. After removing duplicates, we screened 160 titles and abstracts records and excluded 148.

Results of the search

We considered 12 studies to be relevant and chose them for further assessment. We obtained copies of the full-text of these potentially relevant references, and both review authors independently assessed them for eligibility.

We excluded six studies because they were not RCTs (see Characteristics of excluded studies).

We excluded two RCTs because the randomisation was not between retroperitoneal drainage and no drainage after pelvic lymphadenectomy. Franchi 1997 compared closure of pelvic and parietal peritoneum (with placement of a T-shape suction drain through the vagina) to no peritoneal closure (but the vagina closed and two abdominal drains placed). Morice 2001 compared placement of a low-pressure drain in the aortic area to no placement of para-aortic drain after complete para-aortic lymphadenectomy. However, most participants had suction drains placed in the pelvis.

We included four RCTs in the meta-analysis (Benedetti-Panici 1997; Franchi 2007; Lopes 1995; Srisomboon 2002) (see Figure 3 and Characteristics of included studies).

Figure 3. PRISMA flow diagram.

Included studies

Participants

The review included a total of 571 women. The number of women in the included studies was 100 ([Lopes 1995](#)), 137 ([Benedetti-Panici 1997](#)), 100 ([Srisomboon 2002](#)), and 234 ([Franchi 2007](#)). The countries represented were the United Kingdom ([Lopes 1995](#)), Italy ([Benedetti-Panici 1997](#)), and Thailand ([Srisomboon 2002](#)). [Franchi 2007](#) is a European Organisation for Research and Treatment of Cancer-Gynaecological Cancer Group (EORTC-GCG) multi-institutional trial that recruited participants from 12 European cancer centres. In three studies ([Franchi 2007](#); [Lopes 1995](#); [Srisomboon 2002](#)), the majority of women had early-stage cervical carcinoma. In [Benedetti-Panici 1997](#), the women's diagnoses was almost equally distributed between endometrial (early), cervical (early and locally advanced), and ovarian carcinoma (all stages). Baseline characteristics of the women were comparable between the two groups in all studies.

Interventions

For women randomised to the use of drains, two suction drains were placed retroperitoneally alongside the site of node dissection and brought out through the abdominal wall in [Benedetti-Panici 1997](#), [Lopes 1995](#), and [Srisomboon 2002](#). In [Franchi 2007](#), two passive or active suction drains were placed in the retroperitoneal fossa and inserted via the vagina or the abdominal route, according to the institution's policy. The drains were removed when the loss was less than 50 mL in 24 hours in three studies ([Benedetti-Panici 1997](#); [Franchi 2007](#); [Srisomboon 2002](#)), and less than 100 mL in 24 hours in [Lopes 1995](#).

In three studies, the pelvic peritoneum was left open in all cases ([Benedetti-Panici 1997](#); [Franchi 2007](#); [Lopes 1995](#)). In [Srisomboon 2002](#), the pelvic peritoneum was closed in the drain group and left open in the no-drain group.

In [Benedetti-Panici 1997](#), [Franchi 2007](#), and [Srisomboon 2002](#), the vaginal cuff was primarily closed in all women. In [Lopes 1995](#), the vaginal cuff edge was oversewn, leaving the vaginal vault open.

Outcomes

Three studies provided data on short-term lymphocyst formation rate ([Lopes 1995](#) (overall; asymptomatic and symptomatic together); [Benedetti-Panici 1997](#) (overall and symptomatic); [Srisomboon 2002](#) (overall; asymptomatic and symptomatic together)). However, the surveillance schedule appeared to differ among studies. In [Lopes 1995](#), an abdominal ultrasound scan was performed approximately eight weeks after the surgery to identify any asymptomatic lymphocysts. In [Srisomboon 2002](#), transabdominal and transvaginal ultrasounds were performed at four, eight, and 12 weeks after surgery to detect lymphocyst formation. Weekly abdominal and pelvic ultrasounds were performed on 110 of 137 women to detect lymphocyst formation in [Benedetti-Panici 1997](#). Lymphocysts were followed up in order to assess their clinical behaviour. When no lymphocysts were detected at the third examination, monitoring was discontinued.

The only study that provided data on rate of long-term lymphocyst formation (both asymptomatic and symptomatic) was [Franchi 2007](#).

Risk of bias in included studies

Allocation

Allocation concealment was clearly adequate in [Srisomboon 2002](#), in which randomisation was performed by using sequentially numbered, sealed, opaque assignment envelopes. We considered the concealment of allocation potentially adequate in [Benedetti-Panici 1997](#) and [Lopes 1995](#), although we did not obtain further details. In [Lopes 1995](#), the random allocation was done using numbered envelopes kept in the operating theatre. However, the authors did not specifically describe whether or not the envelopes were sealed and opaque. In [Benedetti-Panici 1997](#), it was stated that "Randomization was centralized and computer-based". [Franchi 2007](#) recruited participants from 12 European cancer centres; no detailed explanation on allocation concealment method was provided.

Blinding

For the outcome of lymphocyst formation, the outcome assessors were unaware of the ongoing study in [Benedetti-Panici 1997](#), and unaware of the group allocation in [Srisomboon 2002](#). The blinding of outcome assessors was not reported in [Lopes 1995](#) and [Franchi 2007](#).

For the rate of related postoperative morbidities the blinding of participants, treatment providers, and outcome assessors was not documented in [Benedetti-Panici 1997](#), [Franchi 2007](#), and [Lopes 1995](#). In [Srisomboon 2002](#), the participants, treatment providers, and outcome assessors were not blinded.

Incomplete outcome data

All studies addressed incomplete data for the lymphocyst formation outcome (see the corresponding 'Risk of bias' tables under [Characteristics of included studies](#)).

Selective reporting

In [Lopes 1995](#) and [Srisomboon 2002](#), the outcomes prespecified in the [Methods](#) section were reported. In the other two studies, the rate of asymptomatic lymphocyst formation and the rate of asymptomatic and symptomatic lymphocyst formation at one month after surgery were not specifically reported ([Benedetti-Panici 1997](#); [Franchi 2007](#)).

The 'Risk of bias' graph and 'Risk of bias' summary are shown in [Figure 1](#) and [Figure 2](#).

Effects of interventions

See: [Summary of findings for the main comparison Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy for gynaecological malignancies](#)

For the outcomes with data available, the number of studies contributing usable data ranged from one to four. When compared to no drainage, retroperitoneal drainage after pelvic lymphadenectomy was associated with the following.

1. Comparable rate of overall (asymptomatic and symptomatic) lymphocyst formation within four weeks after surgery, when all methods of pelvic peritoneum management (left open in all cases or closed in the drain group) were considered together (2 studies ([Benedetti-Panici 1997](#); [Srisomboon 2002](#)); 204 women;

- risk ratio (RR) 0.76, 95% confidence interval (CI) 0.04 to 13.35 (Analysis 1.1)). However, when the pelvic peritoneum was left open in all cases, the rate of overall lymphocyst formation within four weeks after surgery was significantly higher in the drain group (1 study (Benedetti-Panici 1997); 110 women; RR 2.29, 95% CI 1.38 to 3.79 (Analysis 1.1)).
2. Significantly higher rate of symptomatic lymphocyst formation within four weeks after surgery when all methods of pelvic peritoneum management (left open in all cases or closed in the drain group) were considered together as well as when the pelvic peritoneum was left open in all cases (2 studies (Benedetti-Panici 1997; Srisomboon 2002); 237 women; RR 3.25, 95% CI 1.26 to 8.37 (Analysis 1.2)).
 3. Comparable rate of overall (asymptomatic and symptomatic) lymphocyst formation at eight weeks after surgery, either when all methods of pelvic peritoneum management (left open in all cases or closed in the drain group) were considered together (2 studies (Lopes 1995; Srisomboon 2002); 180 women; RR 0.72, 95% CI 0.30 to 1.71 (Analysis 1.3)) or when each method of peritoneum management was considered separately (1 study (Lopes 1995) with pelvic peritoneum left open in all cases; 91 women; RR 0.89, 95% CI 0.35 to 2.26 (Analysis 1.3) and 1 study (Srisomboon 2002) with pelvic peritoneum closed in the drain group; 89 women; RR 0.19, 95% CI 0.01 to 3.79 (Analysis 1.3)).
 4. Comparable rate of overall (asymptomatic and symptomatic) lymphocyst formation at 12 weeks after surgery when the pelvic peritoneum was closed in the drain group (1 study (Srisomboon 2002); 83 women; RR 0.13, 95% CI 0.01 to 2.38 (Analysis 1.4)).
 5. Comparable rate of overall (asymptomatic and symptomatic) lymphocyst formation at 12 months after surgery (1 study (Franchi 2007); 232 women; RR 1.48, 95% CI 0.89 to 2.45 (Analysis 1.5)) and a trend toward increased risk of symptomatic lymphocyst formation at 12 months after surgery (1 study (Franchi 2007); 232 women; RR 7.12, 95% CI 0.89 to 56.97 (Analysis 1.6)) when the pelvic peritoneum was left open in all cases.
 6. Comparable rate of postoperative febrile morbidity, regardless of the methods of pelvic peritoneum management (4 studies (Benedetti-Panici 1997; Franchi 2007; Lopes 1995; Srisomboon 2002); 571 women; RR 1.76, 95% CI 0.87 to 3.55 (Analysis 1.7)).
 7. Comparable rate of postoperative pelvic infection regardless of the methods of pelvic peritoneum management (4 studies (Benedetti-Panici 1997; Franchi 2007; Lopes 1995; Srisomboon 2002); 571 women; RR 0.42, 95% CI 0.11 to 1.62 (Analysis 1.8)).
 8. Comparable rate of postoperative wound infection when all methods of pelvic peritoneum management (left open in all cases or closed in the drain group) were considered together (2 studies (Franchi 2007; Srisomboon 2002); 334 women; RR 0.29, 95% CI 0.07 to 1.18 (Analysis 1.9)). However, when the pelvic peritoneum was left open in all cases, there was a significant decrease in the rate of postoperative wound infection in the drain group (1 study (Franchi 2007); 234 women; RR 0.13, 95% CI 0.02 to 0.98 (Analysis 1.9)).
 9. Comparable rate of wound dehiscence (2 studies (Benedetti-Panici 1997; Lopes 1995); 237 women; RR 0.99, 95% CI 0.14 to 6.89 (Analysis 1.10)), fistula formation (3 studies (Benedetti-Panici 1997; Franchi 2007; Lopes 1995); 471 women; RR 1.24, 95% CI 0.34 to 4.57 (Analysis 1.11)), bowel obstruction (2 studies (Franchi 2007; Srisomboon 2002); 334 women; RR 0.20, 95% CI 0.01 to 4.12 (Analysis 1.12)), leg oedema (1 study (Benedetti-Panici 1997); 137 women; RR 2.71, 95% CI 0.75 to 9.77 (Analysis 1.13)), deep venous thrombosis (2 studies (Benedetti-Panici 1997; Franchi 2007); 371 women; RR 2.02, 95% CI 0.38 to 10.84 (Analysis 1.14)), symptomatic ascites (1 study (Benedetti-Panici 1997); 137 women; RR 0.68, 95% CI 0.12 to 3.92 (Analysis 1.15)), and need for blood transfusion (2 studies (Benedetti-Panici 1997; Srisomboon 2002); 237 women; RR 0.91, 95% CI 0.68 to 1.21 (Analysis 1.16)).
 10. Comparable duration of surgery (1 study (Srisomboon 2002); 100 women; mean difference (MD) 4.20 minutes, 95% CI -15.35 to 23.75 (Analysis 1.17)). Similarly, there was no significant difference in duration of surgery in the two studies that reported this outcome as a median (10 minutes; 190 minutes in the drain group, 180 minutes in the no-drain group in Benedetti-Panici 1997 and 5 minutes; 240 minutes in the drain group, 245 minutes in the no-drain group in Franchi 2007).
 11. Comparable time interval to the return of bowel sounds (1 study (Srisomboon 2002); 100 women; MD 0.14 day, 95% CI -0.11 to 0.39 (Analysis 1.18)). Similarly, there was no significant difference in the time interval to the return of bowel sounds in the two studies that reported this outcome as a mean only (Lopes 1995, 0.02 day; 1.04 day in the drain group, 1.02 day in the no-drain group) and as a median (Franchi 2007, 0 day; 2 days in the drain group, 2 days in the no-drain group).
 12. Comparable postoperative decrease of total protein (-0.1 mg%; 0.6 mg% in the drain group, 0.7 mg% in the no-drain group) and albumin (-0.1 mg%; 0.5 mg% in the drain group, 0.6 mg% in the no-drain group) in the only study that reported this outcome as a median (Benedetti-Panici 1997).
 13. Comparable duration of postoperative hospital stay (2 studies (Lopes 1995; Srisomboon 2002); 200 women; MD 0.20 day, 95% CI -0.34 to 0.74 (Analysis 1.19)). However, postoperative hospital stay was significantly longer in the drain group in a study that reported this outcome as a median (4 days; 11 days in the drain group, 7 days in the no-drain group) (Benedetti-Panici 1997).

DISCUSSION

Summary of main results

The incidence of lymphocyst formation varied among the included studies. This could be due to different surgical techniques, as well as different methods and criteria for diagnosis. The available evidence suggests that placement of retroperitoneal drains does not reduce the incidence of lymphocyst formation after pelvic lymphadenectomy in women with gynaecological cancer. In fact, if the pelvic peritoneum is not closed, the drain placement is associated with a higher incidence of symptomatic lymphocyst formation within a month and potentially so at 12 months following surgery. This could be explained by the drain itself acting as a foreign body and interfering with the reparative and absorptive function of the pelvic peritoneum. The practice of leaving the pelvic peritoneum open appears to be an effective alternative method of pelvic retroperitoneal drainage that allows lymphatic fluid to be reabsorbed by the peritoneal surface without the need to insert foreign material into the surgical site. Of note, when the pelvic peritoneum is left open, fluid produced from the pelvic lymphadenectomy area may freely circulate in the abdominal cavity. Ascites could develop as a result of an imbalance between fluid production from the retroperitoneal area and fluid absorption by the peritoneal surface. Having the tube drain in place might lower the risk of developing ascites. However, the rate of

symptomatic ascites was evidently the same between women with a drain (3%) and without a drain (4%) ([Benedetti-Panici 1997](#)).

Cost-effectiveness is an important issue that has not been adequately addressed in studies on effects of drainage on lymphocyst formation. However, one would assume that drainage requires more materials, more personnel, and more time to spend supervising postoperative care. All of these together increase healthcare costs. In addition, women's comfort is another issue that needs special attention. It could be assumed that women without a drain would be more comfortable and more ambulant.

Leaving the vaginal vault open is another method of passive retroperitoneal drainage. In one included study ([Lopes 1995](#)), this practice was applied in combination with non-closure of the pelvic peritoneum. That study found that women without tube drains had a higher incidence of serosanguinous fluid loss through the vagina in the first postoperative day (12% versus 4%). After the first day, the loss continued in 4% of the women without the tube drains and 2% of those with the tube drains. There are no data on the effect of leaving the vaginal vault open alone as a preventive measure for lymphocyst formation following pelvic lymphadenectomy.

Overall completeness and applicability of evidence

The number of eligible studies that examined the effects of retroperitoneal drainage following pelvic lymphadenectomy was limited. In addition, only a small number of studies contributed data for individual outcome measures. Furthermore, there were differences in the details of the surgical procedures among the included trials, for example in method of pelvic peritoneum management (open or closed), vaginal vault management (open or closed), type of drains (active or passive), route of drains (abdominal or vaginal), exact location for placement of drains, and criteria for removal of drains. One important discrepancy of surgical technique among the included studies should be noted. In [Srisomboon 2002](#), the pelvic peritoneum was sutured closed in the drain group and left open in the no-drain group, whereas in the other three included studies the pelvic peritoneum was left open in all women regardless of the group allocation. Closing the pelvic peritoneum in the group with drains and leaving it open in the group without drains is the comparison of two sets of surgical management strategies that consider both placement of the tube drains and management of the pelvic peritoneum together, not the drain placement alone. When this study is combined with the other studies in the final analysis, the result should therefore be interpreted with this discrepancy in mind, and bias in favour of the drain group is expected. However, the results of the final analysis appear to be in the same direction whether this study was included or excluded. This finding would confirm that placement of retroperitoneal tube drains has no benefit in preventing lymphocyst formation. This information should be applicable to a wide range of gynaecological cancer operations that include pelvic lymphadenectomy as a part of the entire procedure.

Quality of the evidence

In general, the methodological quality of the included studies was acceptable, with some limitations. The allocation concealment appeared adequate or potentially adequate in all trials. All studies addressed incomplete data on the main outcome, that is lymphocyst formation. The important limitation of the included studies was the process of blinding. Given the nature of the

study intervention (retroperitoneal tube drainage), blinding of participants and care providers is difficult. On the other hand, blinding of outcome assessors is possible. However, for the diagnosis of lymphocyst formation by ultrasound, blinding of the outcome assessors was clearly documented in only two of the four included studies ([Benedetti-Panici 1997](#); [Srisomboon 2002](#)). Although there are objective criteria for ultrasound diagnosis of pelvic lymphocyst, the final diagnostic decision sometimes involves a subjective component. In such a case, lack of blinding could introduce bias into the results. Also, for the rate of related postoperative morbidities, the blinding of participants, treatment providers, and outcome assessors was not documented in [Benedetti-Panici 1997](#), [Franchi 2007](#), and [Lopes 1995](#). In [Srisomboon 2002](#), the participants, treatment providers, and outcome assessors were not blinded.

The possibility of publication bias should be kept in mind. In an attempt to assess its presence, we examined the funnel plots for all main outcomes. The findings were not suggestive of publication bias. However, we did not reach a meaningful conclusion on this issue due to the limited number of included studies.

We found the quality of evidence using the GRADE approach to be moderate to high for most outcomes except for symptomatic lymphocyst formation at 12 months after surgery (see [Summary of findings for the main comparison](#)). The quality of the evidence regarding symptomatic lymphocyst formation within 4 weeks after surgery, both asymptomatic and symptomatic lymphocyst formation at 8 weeks and 12 months after surgery, and febrile morbidity were high. We downgraded the evidence to moderate for both asymptomatic and symptomatic lymphocyst formation within 4 weeks after surgery and pelvic infection due to a wide confidence interval. Based on a wide confidence interval and small number of events in the analysis, we downgraded the evidence to low quality for symptomatic lymphocyst formation at 12 months after surgery.

Agreements and disagreements with other studies or reviews

There are a few retrospective and prospective non-RCTs examining the effect of retroperitoneal tube drainage on the prevention of lymphocyst formation after pelvic lymphadenectomy in women with gynaecological cancer. The results and conclusions from these studies are in keeping with the findings from the present review. In [Jensen 1993](#), the records of 115 women with early-stage cervical cancer were retrospectively reviewed. There was no difference between the participants with drains and without drains in mean operative time, mean estimated blood loss, transfusion rate, febrile morbidity rates, incidence of pelvic cellulitis, length of postoperative ileus, and total hospital stay. However, the participants with drains had an increased rate of rehospitalisation and morbidity directly related to the presence of the drains. [Patsner 1995](#) is a prospective non-RCT comparing the effects of closed-suction drainage versus no drainage after radical abdominal hysterectomy and bilateral pelvic lymphadenectomy for 120 women with stage IB cervical cancer. In this study, all operations were performed in a uniform manner by one surgeon. The vaginal cuff was closed and the pelvic peritoneum was left open in all cases. In addition, an omental J-flap was brought into the pelvis in all women and secured to the pelvic floor. There was no increase in postoperative lymphocyst formation, pelvic infection, and fistula in the group without drains. Of note, the rate of lymphocyst formation was 6.7% in the drain group and 0% in the no-drain group. The

exact role of the omental J-flap in the prevention of lymphocyst formation is unknown. In another prospective non-RCT comparing the effects of closed suction pelvic drainage versus no suction drainage following pelvic/pelvic-para-aortic lymphadenectomy for 143 participants with various gynaecological malignancies (Bafna 2001), rates of lymphocyst formation were comparable between the study groups (7.3% in the drain group and 2.7% in the no-drain group). The pelvic peritoneum was sutured closed in the drain group and left open in the no-drain group.

AUTHORS' CONCLUSIONS

Implications for practice

We found no new studies for inclusion since the last published version of this review (Charoenkwan 2014). The findings of this review demonstrated that retroperitoneal tube drain placement has no benefit in the prevention of lymphocyst formation after pelvic lymphadenectomy in women with gynaecological malignancies. Furthermore, the evidence suggests that when the pelvic peritoneum is left open, the tube drain placement is associated with a higher risk of short- and long-term symptomatic lymphocyst formation. The practice of leaving the

pelvic peritoneum open appears to be an effective alternative method of pelvic retroperitoneal drainage.

Implications for research

Due to the consistent data on the effect of retroperitoneal tube drain placement for the prevention of lymphocyst formation, further research on this issue would be unnecessary. However, the role of leaving the vaginal vault open and using the omental transposition/omental J-flap alone or in combination with no closure of the pelvic peritoneum in reducing lymphocyst formation and related morbidities are interesting topics for future research.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Benedetti-Panici 1997

Methods	RCT. Randomisation was determined using a computer-based method. The groups were comparable at entry. There was no exclusion after allocation and no withdrawal. Weekly abdominal and pelvic ultrasound was performed on 110 of 137 women to detect lymphocyst formation.
Participants	Women with FIGO stage I-IV ovarian carcinoma (43 women), stage IB-III cervical carcinoma (45 women), and stage I-II endometrial carcinoma (49 women). The women underwent intensive surgical staging/tumour reductive surgery/second-look laparotomy (ovarian carcinoma) or Piver type I/II radical hysterectomy (endometrial carcinoma) or Piver type III/IV radical hysterectomy (cervical carcinoma) plus bilateral pelvic or pelvic and para-aortic lymphadenectomy. Study setting: the Catholic University of Rome and the Hospital San Carlo di Nancy, Rome, Italy
Interventions	Women were randomised intraoperatively to the use of drains (68 women) or no drain (69 women). For those randomised to drains, 2 retroperitoneal low-pressure closed-suction drains were placed. For pelvic/para-aortic lymphadenectomy, the first drain was placed at the insertion of the mesenteric artery down to the left external iliac artery, and the second drain at the level of the paracaval area from the point where the ovarian vein enters the cava down to the right external iliac artery. For pelvic lymphadenectomy, the cranial part of the drains was at the level of the ipsilateral common iliac vessels. The drains were removed when the loss was less than 50 mL in 24 hours.
Outcomes	There was a significant increase in complications (43% versus 22%) in the drain group, mainly related to lymphocyst. The hospital stay was shorter in the group not drained.

Benedetti-Panici 1997 (Continued)

Notes In all cases, the pelvic peritoneum and the peritoneum along the paracolic gutters were left open.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	It was stated that "Randomization was centralized and computer-based."
Allocation concealment (selection bias)	Low risk	It was stated that "Randomization was centralized and computer-based." The allocation concealment was probably adequate.
Blinding (performance bias and detection bias) Lymphocyst formation	Low risk	Weekly ultrasound pelvic and abdominal examinations were performed; the ultrasound operator was unaware of the ongoing study.
Blinding (performance bias and detection bias) Postoperative morbidities and recovery	Unclear risk	The blinding of participants, treatment providers, and outcome assessors was not documented.
Incomplete outcome data (attrition bias) Short-term lymphocyst formation	Low risk	It was stated that the weekly ultrasound examinations to detect lymphocyst formation were performed on 110 women operated on at the Catholic University (of 137 women in the study).
Selective reporting (reporting bias)	Unclear risk	The rate of asymptomatic lymphocyst formation was not specifically addressed.

Franchi 2007

Methods	Multicentre RCT (12 European cancer centres). Randomisation was determined using a computer-based method. Stratification was performed per centre. The groups were comparable at entry. There was no exclusion after allocation and no withdrawal. Ultrasonography or CT scan was performed at 1 and 12 months postoperatively on all women to identify lymphocyst formation.
Participants	Women with FIGO stage IA1-IIA cervical carcinoma (198 women), endometrial carcinoma (35 women), and vaginal carcinoma (1 woman). All had radical hysterectomy and bilateral pelvic lymphadenectomy. Study setting: European cancer centres (the EORTC trial)
Interventions	Women were randomised following surgery to either pelvic drainage (117 women) or no drainage (117 women). For those randomised to drains, 2 passive or active suction drains were placed in the retroperitoneal fossa and inserted via the vagina or the abdominal route, according to the institution's policy. The drains were removed when the loss was less than 50 mL in 24 hours.
Outcomes	The study found no difference in the incidence of postoperative lymphocyst formation or postoperative complications between the 2 groups. The late (12 months) incidence of symptomatic lymphocysts was 5.9% in the drain group versus 0.9% in the no-drain group (P = 0.06).
Notes	In all cases, the vaginal cuff was primarily closed and the pelvic peritoneum was left open.

Risk of bias

Bias	Authors' judgement	Support for judgement
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Franchi 2007 (Continued)

Random sequence generation (selection bias)	Low risk	
Blinding (performance bias and detection bias) Postoperative morbidities and recovery	Unclear risk	The blinding of participants, treatment providers, and outcome assessors was not documented.
Incomplete outcome data (attrition bias) Short-term lymphocyst formation	Low risk	

Lopes 1995

Methods	RCT. Randomisation was determined using a random number table. The groups were comparable at entry. There was no exclusion after allocation and no withdrawal. An abdominal ultrasound scan was performed approximately 8 weeks after the surgery to identify any asymptomatic lymphocysts.	
Participants	Women with FIGO stage IA-IIB cervical carcinoma (95 women) and stage IIB endometrial carcinoma (5 women). All had Piver type II radical hysterectomy and bilateral pelvic lymphadenectomy. Study setting: Regional Department of Gynaecological Oncology, Gateshead, United Kingdom	
Interventions	Women were randomised immediately before abdominal closure to the use of drains (51 women) or no drain (49 women). For those randomised to drains, 2 suction drains were inserted, 1 through each iliac fossa, and placed alongside the site of node dissection. The drains were usually removed when the loss was less than 100 mL in 24 hours.	
Outcomes	The detection of lymphocysts by ultrasound and clinical examination in the drains group (15.6% and 5.9%, respectively) did not differ significantly from the group not drained (17.4% and 6.1%, respectively). Postoperative morbidity did not differ between the groups.	
Notes	In each case, the vaginal cuff edge was oversewn, leaving the vaginal vault open, and the pelvis was not reperitonised. Of the 100 women randomised, 8 defaulted their ultrasound scan: 5 were in the drained group and 3 were not. Of these 8, 2 (1 in each group) were assessed further; 1 had a magnetic resonance imaging scan and another had a laparotomy, both showing no evidence of lymphocysts.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was determined using a random number table.
Allocation concealment (selection bias)	Low risk	The random allocation was done using numbered envelopes kept in the operating theatre. The allocation concealment was probably adequate, although the authors did not specifically mention whether or not the envelopes were sealed and opaque.
Blinding (performance bias and detection bias) Lymphocyst formation	Unclear risk	An abdominal ultrasound scan was performed approximately 8 weeks after surgery to identify any asymptomatic lymphocysts. Also, the clinical detection of lymphocysts at subsequent review visits was documented. However, any attempt to blind outcome assessors was not mentioned.

Lopes 1995 (Continued)

Blinding (performance bias and detection bias) Postoperative morbidities and recovery	Unclear risk	The blinding of participants, treatment providers, and outcome assessors was not documented.
Incomplete outcome data (attrition bias) Short-term lymphocyst formation	Low risk	It was stated that "Of the 100 women randomized, eight defaulted their ultrasound scan; five were in the drained group and three were not." Also, it was stated that "the scan was reported as unsatisfactory in one patient who had been drained."
Selective reporting (reporting bias)	Low risk	—

Srisomboon 2002

Methods	RCT. Randomisation was conducted by block randomisation. The groups were comparable at entry. There was no exclusion after allocation and no withdrawal. Transabdominal and transvaginal ultrasound were performed at 4, 8, and 12 weeks after surgery to detect lymphocyst formation.	
Participants	Women with FIGO stage IA2-IIA cervical carcinoma (100 women). All had Piver type II/III radical hysterectomy and bilateral pelvic lymphadenectomy. Study setting: Chiang Mai University Hospital, Chiang Mai, Thailand	
Interventions	Women were randomised immediately before abdominal closure to the use of drains with closure of pelvic peritoneum (52 women) or no drain with pelvic peritoneum left open (48 women). For those randomised to drains, 2 low-pressure closed-suction drains were placed along the side of node dissection and brought out extraperitoneally through the anterior abdominal wall lateral to the rectus muscle margins. The drains were removed when the loss was less than 50 mL in 24 hours.	
Outcomes	Asymptomatic lymphocysts were sonographically detected at 4, 8, and 12 weeks postoperatively in 6.8%, 4.6%, and 7.7% of women, respectively, in the group not drained, whereas none were found in the drain group ($P = 0.2$). Postoperative morbidity did not differ significantly between the 2 groups.	
Notes	The vaginal vault was primarily closed in all cases. Of the 52 women in the drain group, 50, 46, and 44 women had ultrasound done at 4, 8, and 12 weeks after surgery, respectively, as scheduled. Of the 48 women in the no-drain group, 44, 43, and 39 women underwent ultrasound examination at each scheduled visit.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The method of block randomisation was used.
Allocation concealment (selection bias)	Low risk	The random allocation was done using sealed, numbered envelopes kept in the operating theatre.
Blinding (performance bias and detection bias) Lymphocyst formation	Low risk	The operators of transabdominal and transvaginal ultrasound to detect lymphocyst formation were not aware of the group allocation.
Blinding (performance bias and detection bias)	High risk	The participants, treatment providers, and outcome assessors were not blinded.

Srisomboon 2002 (Continued)

Postoperative morbidities
and recovery

Incomplete outcome data (attrition bias) Short-term lymphocyst formation	Low risk	The number of participants who had postoperative ultrasound performed at each visit as scheduled was reported. Accordingly, the number of missing cases was known.
Selective reporting (reporting bias)	Low risk	—

CT: computerised tomography

EORTC: European Organisation for Research and Treatment of Cancer

FIGO: International Federation of Gynecology and Obstetrics

RCT: randomised controlled trial

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Bafna 2001	Not an RCT
Franchi 1997	RCT comparing closure of pelvic and parietal peritoneum (with placement of a T-shape suction drain through the vagina) to no peritoneal closure (but the vagina closed and 2 abdominal drains placed)
Jensen 1993	Not an RCT
Morice 2001	RCT comparing placement of a low-pressure drain in the aortic area to no placement of para-aortic drain after complete para-aortic lymphadenectomy. However, most participants had suction drains placed in the pelvis.
Orr 1986	Not an RCT
Patsner 1995	Not an RCT
Patsner 1999	Not an RCT
Yamamoto 2000	Studied the effect of the procedure on preventing vaginal shortening on lymphocyst formation. A closed-suction drain was placed in each paravesical space for all participants. Not an RCT

RCT: randomised controlled trial

DATA AND ANALYSES
Comparison 1. Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term lymphocyst formation: both asymptomatic and symptomatic within 4 weeks after surgery	2	204	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.04, 13.35]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Short-term lymphocyst formation: symptomatic within 4 weeks after surgery	2	237	Risk Ratio (M-H, Fixed, 95% CI)	3.25 [1.26, 8.37]
3 Short-term lymphocyst formation: both asymptomatic and symptomatic at 8 weeks after surgery	2	180	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.30, 1.71]
4 Short-term lymphocyst formation: both asymptomatic and symptomatic at 12 weeks after surgery	1	83	Risk Ratio (M-H, Fixed, 95% CI)	0.13 [0.01, 2.38]
5 Long-term lymphocyst formation: both asymptomatic and symptomatic at 12 months after surgery	1	232	Risk Ratio (M-H, Fixed, 95% CI)	1.48 [0.89, 2.45]
6 Long-term lymphocyst formation: symptomatic at 12 months after surgery	1	232	Risk Ratio (M-H, Fixed, 95% CI)	7.12 [0.89, 56.97]
7 Febrile morbidity	4	571	Risk Ratio (M-H, Fixed, 95% CI)	1.76 [0.87, 3.55]
8 Pelvic infection	4	571	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.11, 1.62]
9 Wound infection	2	334	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.07, 1.18]
10 Wound dehiscence	2	237	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.14, 6.89]
11 Fistula	3	471	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.34, 4.57]
12 Bowel obstruction	2	334	Risk Ratio (M-H, Fixed, 95% CI)	0.2 [0.01, 4.12]
13 Leg oedema	1	137	Risk Ratio (M-H, Fixed, 95% CI)	2.71 [0.75, 9.77]
14 Deep venous thrombosis	2	371	Risk Ratio (M-H, Fixed, 95% CI)	2.02 [0.38, 10.84]
15 Symptomatic ascites	1	137	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.12, 3.92]
16 Blood transfusion	2	237	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.68, 1.21]
17 Duration of surgery (minute)	1	100	Mean Difference (IV, Fixed, 95% CI)	4.20 [-15.35, 23.75]
18 Return of bowel sounds (day)	1	100	Mean Difference (IV, Fixed, 95% CI)	0.14 [-0.11, 0.39]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
19 Hospital stay (day)	2	200	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.34, 0.74]

Analysis 1.1. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 1 Short-term lymphocyst formation: both asymptomatic and symptomatic within 4 weeks after surgery.

Analysis 1.2. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 2 Short-term lymphocyst formation: symptomatic within 4 weeks after surgery.

Analysis 1.3. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 3 Short-term lymphocyst formation: both asymptomatic and symptomatic at 8 weeks after surgery.

Analysis 1.4. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 4 Short-term lymphocyst formation: both asymptomatic and symptomatic at 12 weeks after surgery.

Analysis 1.5. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 5 Long-term lymphocyst formation: both asymptomatic and symptomatic at 12 months after surgery.

Analysis 1.6. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 6 Long-term lymphocyst formation: symptomatic at 12 months after surgery.

Analysis 1.7. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 7 Febrile morbidity.

Analysis 1.8. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 8 Pelvic infection.

Analysis 1.9. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 9 Wound infection.

Analysis 1.10. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 10 Wound dehiscence.

Analysis 1.11. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 11 Fistula.

Analysis 1.12. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 12 Bowel obstruction.

Analysis 1.13. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 13 Leg oedema.

Analysis 1.14. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 14 Deep venous thrombosis.

Analysis 1.15. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 15 Symptomatic ascites.

Analysis 1.16. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 16 Blood transfusion.

Analysis 1.17. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 17 Duration of surgery (minute).

Analysis 1.18. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 18 Return of bowel sounds (day).

Analysis 1.19. Comparison 1 Retroperitoneal drainage versus no drainage after pelvic lymphadenectomy, Outcome 19 Hospital stay (day).

APPENDICES

Appendix 1. CENTRAL search strategy

```
#1 MeSH descriptor Genital Neoplasms, Female explode all trees\\
#2 ((gynae* or gyne* or genital* or pelvi* or ovar* or uter* or fallopian* or vulva* or endometr* or vagina* or cervi*) near/5 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma*))
#3 (#1 OR #2)
#4 MeSH descriptor Lymph Node Excision explode all trees
#5 lymphadenectom*
#6 (lymph* and node* and (excis* or dissect*))
#7 MeSH descriptor Lymphocele, this term only
#8 (lymphocele* or lymphocyst* or (lymph* and cyst*))
#9 (#4 OR #5 OR #6 OR #7)
#10 MeSH descriptor Drainage explode all trees
#11 MeSH descriptor Retroperitoneal Space, this term only
#12 (drain* or retroperitone*)
#13 (#10 OR #11 OR #12)
#14 (#3 AND #9 AND #13)
```

Appendix 2. MEDLINE search strategy

MEDLINE Ovid

```
1 exp Genital Neoplasms, Female/
2 ((gynae* or gyne* or genital* or pelvi* or ovar* or uter* or fallopian* or vulva* or endometr* or vagina* or cervi*) adj5 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma*)).mp.
3 1 or 2
4 exp Lymph Node Excision/
5 lymphadenectom*.mp.
6 (lymph* and node* and (excis* or dissect*)).mp.
7 Lymphocele/
8 (lymphocele* or lymphocyst* or (lymph* and cyst*)).mp.
9 4 or 5 or 6 or 7 or 8
10 *Drainage/
11 Retroperitoneal Space/
12 (drain* or retroperitone*).mp.
13 10 or 11 or 12
14 3 and 9 and 13
15 randomized controlled trial.pt.
16 controlled clinical trial.pt.
17 randomized.ab.
18 placebo.ab.
19 clinical trials as topic.sh.
20 randomly.ab.
21 trial.ti.
22 15 or 16 or 17 or 18 or 19 or 20 or 21
23 14 and 22
```

key:

mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier

pt=publication type

ab=abstract

ti=title

sh=subject heading

Appendix 3. Embase search strategy

Embase Ovid

```
1 exp female genital tract tumor/
```


2 ((gynae* or gyne* or genital* or pelvi* or ovar* or uter* or fallopian* or vulva* or endometr* or vagina* or cervi*) adj5 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma*)).mp.

3 1 or 2

4 exp lymphadenectomy/

5 lymphadenectom*.mp.

6 (lymph* and node* and (excis* or dissect*)).mp.

7 lymphocele/

8 (lymphocele* or lymphocyst* or (lymph* and cyst*)).mp.

9 4 or 5 or 6 or 7 or 8

10 exp surgical drainage/

11 retroperitoneum/

12 (drain* or retroperitone*).mp.

13 10 or 11 or 12

14 3 and 9 and 13

15 crossover procedure/

16 double-blind procedure/

17 randomized controlled trial/

18 single-blind procedure/

19 random*.mp.

20 factorial*.mp.

21 (crossover* or cross over* or cross-over*).mp.

22 placebo*.mp.

23 (double* adj blind*).mp.

24 (singl* adj blind*).mp.

25 assign*.mp.

26 allocat*.mp.

27 volunteer*.mp.

28 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27

29 14 and 28

key:

[mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

Appendix 4. Specific criteria for allocation concealment rating

Clearly yes: rate A

- Some form of centralised randomisation scheme, such as having to provide participant details by phone to receive treatment group allocation
- A scheme controlled by a pharmacy or nutritional unit
- An onsite computer system, given that allocations are in a locked, unreadable file that can be accessed only after inputting participant details
- Assignment envelopes, provided that they are sequentially numbered, sealed, and opaque
- Other combinations that appear to provide assurance of adequate concealment

Unclear: rate B

- Assignment envelopes, without description of adequate safeguards
- Use of a 'list' or 'table'
- Flip of a coin
- A trial in which the description suggests adequate concealment, but other features are suspicious - e.g. markedly unequal controls and trial groups
- Stated random, but unable to obtain further details

Clearly no: rate C

- Alternation
- Case record numbers, dates of birth, day of the week, or any other such approach
- Any allocation procedure transparent before assignment, such as an open list of random numbers

WHAT'S NEW

Date	Event	Description
24 January 2019	Amended	No potentially relevant new studies identified during the most recent search (22 Mar, 2017). The conclusions of this Cochrane review are therefore still considered to be up to date for this topic. A scoping search of the literature will be reviewed in 2022.

HISTORY

Protocol first published: Issue 4, 2008

Review first published: Issue 1, 2010

Date	Event	Description
28 June 2017	New citation required but conclusions have not changed	We identified no additional studies for inclusion.
30 April 2014	New search has been performed	The review was updated. The top-up literature search was performed on 10 January 2014.
30 April 2014	New citation required but conclusions have not changed	No new studies met the inclusion criteria, therefore further analysis was unnecessary and the conclusion remains the same.

CONTRIBUTIONS OF AUTHORS

Kittipat Charoenkwan: took the lead in writing the review, selected trials for inclusion, extracted data, and performed statistical analysis and interpretation of data.

Chumnan Kietpeerakool: selected trials for inclusion, extracted data, performed statistical analysis and interpretation of data, and commented on drafts of the review.

DECLARATIONS OF INTEREST

Kittipat Charoenkwan is a coauthor of the article 'A prospective randomised study comparing retroperitoneal drainage with no drainage and no peritonization following radical hysterectomy and pelvic lymphadenectomy for invasive cervical cancer', published in the *Journal of Obstetrics and Gynaecology Research* 2002;28(3):149-53.

Chumnan Kierpeerakool: None known

SOURCES OF SUPPORT

Internal sources

- Department of Obstetrics and Gynaecology, Faculty of Medicine, Chiang Mai University, Thailand.
- Department of Obstetric and Gynaecology, Faculty of Medicine, Khon Kaen University, Thailand.

External sources

- None, Other.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Searching other resources

In this update review, we added sources for ongoing trials, including the WHO International Clinical Trials Registry Platform (WHO ICTRP) (www.who.int/ictcp/en/) and ClinicalTrials.gov (www.clinicaltrials.gov), and sources of unpublished studies and grey literature including GreyNet.org (www.greynet.org), the Ohio College Library Center (OCLC) WorldCat dissertations and theses (www.oclc.org/support/services/firstsearch/documentation/dbdetails/details/WorldCatDissertations.en.html) and index to theses (ProQuest Dissertations & Theses: UK & Ireland). We also added the lists of conferences used for searching abstracts and proceedings.

INDEX TERMS

Medical Subject Headings (MeSH)

Drainage [*methods]; Genital Neoplasms, Female [*surgery]; Lymph Node Excision [*adverse effects]; Lymphocele [etiology] [*prevention & control]; Pelvis; Randomized Controlled Trials as Topic; Retroperitoneal Space; Suction [methods]

MeSH check words

Female; Humans