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[Intervention Review]

Wound drainage following groin dissection for malignant disease in adults

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ABSTRACT

Background

Groin dissection is commonly performed for the treatment of a variety of cancers, including melanoma, and squamous cell carcinoma of the skin, penis or vulva. It is uncertain whether insertion of a drain reduces complication rates, and, if used, the optimum time for drain removal after surgery is also unknown.

Objectives

To assess the current level of evidence to determine whether placement of a drain is beneficial after groin dissection in terms of reducing seroma, haematoma, wound dehiscence and wound infection rates, and to determine the optimal type and duration of drainage following groin dissection if it is shown to be beneficial.

Search methods

In September 2014 we searched the following electronic databases using a pre-designed search strategy: the Cochrane Wounds Group Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*). In November 2013 we searched Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE and EBSCO CINAHL. We did not restrict the search and study selection with respect to language, date of publication or study setting.

Selection criteria

We considered all randomised controlled trials (RCTs) comparing wound drainage with no wound drainage in individuals undergoing groin dissection, where the most superior node excised was Cloquet's node (the most superior inguinal lymph node). No limits were applied to language of publication or trial location. Two review authors independently determined the eligibility of each trial.

Data collection and analysis

Two review authors, working independently, screened studies identified from the search; there were no disagreements.

Main results

We did not identify any RCTs that met the inclusion criteria for the review.

Authors' conclusions

There is a need for high quality RCTs to guide clinical practice in this under-researched area.

PLAIN LANGUAGE SUMMARY

The effects of using drainage tubes after surgical removal of lymph glands from the groin

What are lymph glands?

Lymph glands are part of the body's immune system and swell or enlarge when the body is fighting an infection. They are located in a number of places in the body, including the neck, armpits, and groin.

Why remove lymph glands?

Surgical removal of the lymph glands found in the groin (the inguinal lymph nodes) is an important part of the treatment for several types of cancer, including melanoma and other types of skin cancer, as well as squamous cell cancer of the penis, vulva and the surrounding skin. Sometimes complications, such as wound infection, bruising (haematoma) or a collection of lymph fluid in the area (seroma), can occur after removal of these lymph nodes.

Why insert drainage tubes after surgery?

Surgeons can insert plastic drainage tubes into the area from which the lymph nodes have been removed. These tubes are inserted towards the end of the operation, once the lymph glands have been removed. The aim of the drainage tubes is to drain away any fluid or blood that may collect in the wounds and cause complications. The drains are usually left in place until the amount of fluid draining out of them in a 24-hour period has reduced to a certain volume (typically less than 30 mL to 100 mL), although some surgeons will remove the drains at a particular time point after surgery (this can vary from 1 day to more than 1 week). Patients can remain in hospital while the drain is in place, although many surgeons will let patients leave hospital and have the drain managed on an outpatient basis.

However, it is unclear whether placement of a drainage tube reduces, increases or has no effect on complications following this type of surgery. Furthermore the best timing for removal of drainage tubes is unknown.

The purpose of this review

The aim of this review was to review all randomised clinical trials (RCTs) that have compared what happens to patients who had a drain inserted after removal of the inguinal lymph nodes with patients who did not have a drain. We also looked for RCTs that examined the effect of removing drains at different times. We searched the medical literature up to September 2014 to gather all the available evidence.

What the review discovered

We did not identify any RCTs that compared what happens when you do or do not use drains after surgery for inguinal lymph node removal and therefore we still do not know if drains are beneficial in this context.

BACKGROUND

Description of the condition

Groin dissection, also known as inguinal lymphadenectomy or inguinal lymph node dissection, is commonly performed as part of

the treatment for some tumours, including melanoma, and squamous cell carcinoma of the skin, penis or vulva, as well as other less common tumours ([Gaarenstroom 2003](#); [Swan 2003](#); [Margulis 2010](#)). It involves removal of all of the lymph nodes in the anatomical area known as the femoral triangle, at the upper inner part of the thigh. When groin dissection is performed because of con-

firmed spread (metastasis) of cancer to a lymph node, the procedure is referred to as a therapeutic lymph node dissection (TLND), and when it is performed because there is a high risk that a cancer might have spread to a lymph node, it is known as a prophylactic lymph node dissection (PLND). Recently the development of sentinel lymph node biopsy (SLNB), a procedure that involves the removal of one or more 'sentinel' lymph nodes (the first node, or group of nodes, to which a cancer will metastasise), has allowed the detection of clinically hidden (occult) micrometastases in the inguinal lymph nodes via a microscope, which could not be detected by examining the patient. In these cases, if the SLNB is positive for metastatic disease, a complete lymph node dissection (CLND) may be performed ([Hakim 2006](#); [Morton 2006](#); [Yeung 2013](#)). According to Hospital Episode Statistics, 688 inguinal lymph node dissections were performed in England in the year 2011 to 2012 ([HSCIC](#)).

Description of the intervention

At the end of the groin dissection, the surgeon usually places one or more drains in the wound ([Ul-Mulk 2012](#)). Commonly, closed suction drains are used, however it is possible that some surgeons may use other drainage systems, such as epidermal vacuum therapy ([Tauber 2013](#)). Surgeons use either a volume-directed indication for removal of the drain(s), for example when drainage is less than 30 ml in 24 hours ([Serpell 2003](#)), or a time-directed indication for removal of the drain(s), for example on the seventh post-operative day irrespective of drain output ([Coblentz 2002](#)).

How the intervention might work

Standard surgical teaching suggests that a drain tube should be placed inside the cavity created by the surgery at the end of the procedure. This will allow any blood or fluid to drain away, thereby preventing the accumulation of blood (haematoma) or serous fluid (seroma) in the cavity and helping to collapse dead space ([Serpell 2003](#)). It is thought that haematoma and seroma rates will be decreased by allowing fluid to drain from the wound. Conversely, complications such as wound infection may be increased by placement of a drain, as it provides bacteria with a potential portal for entry into the subcutaneous space ([Samraj 2007](#); [Carlson 2008](#)).

Why it is important to do this review

It is not clear whether drainage following inguinal lymph node dissection is beneficial. Furthermore, there is uncertainty regarding the correct time to remove drains, and whether to use a time- or volume-directed indication for removal. It is unclear whether insertion of a drain into the groin reduces, or increases, complication rates after this surgery. There have been no previous reviews addressing this question. This systematic review aimed to clarify

this issue and define the quality of evidence supporting current practice.

OBJECTIVES

To assess the current level of evidence to determine whether placement of a drain is beneficial after groin dissection in terms of reducing seroma, haematoma, wound dehiscence and wound infection rates, and to determine the optimal type and duration of drainage following groin dissection if it is shown to be beneficial.

METHODS

Criteria for considering studies for this review

Types of studies

We considered only randomised controlled trials (RCTs) to be eligible for inclusion.

Types of participants

- Patients having groin dissection for metastatic malignant disease, including - but not limited to - malignant melanoma, squamous cell carcinoma of the skin, penis, vulva or anus. The groin dissection could be therapeutic, prophylactic or completion (see [Description of the condition](#)).

- People over 18 years of age; no restriction by gender, no restriction on country of origin.

- The setting for this surgery was hospital inpatient care; adverse events that occurred in the outpatient setting were to be assessed if recorded by the studies.

We excluded trials in which participants underwent more extensive surgery, where dissection included higher lymph node groups including iliac, pelvic and para-aortic nodes. We deemed Cloquet's node (the most superior inguinal node in the proximal groin) to be the superior limit of dissection for eligible studies.

Types of interventions

We decided to include studies reporting the following comparisons (all references below to the use of a surgical drain(s) allude to those inserted into the groin following inguinal lymph node dissection):

- wound drainage compared with no wound drainage;
- one type of wound drain compared with another type of wound drain;
- different timing of drain removal: to include removal according to fixed-time and fixed-volume protocols.

Types of outcome measures

Primary outcomes

- Wound complications by final follow-up (as defined by study authors; including any or all of: dehiscence (wound breakdown), haematoma, seroma).
- Wound infection, as defined by the Centers for Disease Control and Prevention (CDC) criteria (Horan 1992): that is, infection occurring within 30 days after groin dissection and the patient had at least one of the following:
  - purulent drainage from the superficial incision;
  - micro-organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial incision;
  - superficial incision that is deliberately opened by a surgeon and is culture-positive, or not cultured and the patient had at least one of the following signs or symptoms: pain or tenderness; localised swelling; redness; or heat;
  - diagnosis of a superficial incisional surgical site infection by the surgeon or attending physician.

Secondary outcomes

- Length of hospital stay.
- Volume of fluid drained.
- Number of aspirations.
- Drain reinsertion.
- Lymphoedema.
- Quality of life outcomes including patient-reported outcome measures, e.g. pain scores (using a validated scale).
- Adverse events (in any setting).

Search methods for identification of studies

Electronic searches

We searched the following electronic databases to identify reports of relevant RCTs:

- The Cochrane Wounds Group Specialised Register (4 September 2014);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2014, Issue 8);
- Ovid MEDLINE (1946 to October Week 5 2013);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations 6 November 2013);
- Ovid Embase (1974 to 2013 November 06)
- EBSCO CINAHL (1982 to 07 November 2013).

We used the following search strategy in the Cochrane Central Register of Controlled Trials (CENTRAL):

```
#1 MeSH descriptor: [Lymph Node Excision] explode all trees 1033
#2 MeSH descriptor: [Lymph Nodes] explode all trees and with
qualifiers: [Surgery - SU] 76
#3 ("inguinal lymph node dissection" or "inguinal lymphadenec-
tomy" or (groin next dissect*) or (groin next surg*)):ti,ab,kw 38
#4 {or #1-#3}
#5 MeSH descriptor: [Drainage] explode all trees 1986
#6 MeSH descriptor: [Suction] explode all trees 733
#7 drain*:ti,ab,kw 4040
#8 #5 or #6 or #7 4641
#9 #4 and #8 133
```

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in [Appendix 1](#), [Appendix 2](#) and [Appendix 3](#) respectively. We adapted this strategy to search Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2011). We combined the EMBASE search with the Ovid EMBASE filter developed by the UK Cochrane Centre (Lefebvre 2011). We combined the CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2011). We did not restrict trials with respect to language, date of publication or trial setting.

We searched the following clinical trials registries:

- ClinicalTrials.gov (<http://www.clinicaltrials.gov/>) (13 April 2014);
- WHO International Clinical Trials Registry Platform (<http://apps.who.int/trialsearch/Default.aspx>) (13 April 2014);
- EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu/>) (13 April 2014).

Searching other resources

Two review authors (DT, HS) checked the reference lists of included trials independently for additional eligible trials.

Data collection and analysis

Selection of studies

Two review authors (DT, HS) independently determined the eligibility of each trial identified by analysing the titles and abstracts of all citations found through the search strategy previously described. We retrieved a full-text copy of each citation that reported a potentially eligible trial, and for records where eligibility could not be determined by the title and abstract alone. Working independently, the two review authors applied the eligibility criteria; any discrepancies were resolved by consensus discussion with the third review author (DF). Where necessary, we sought additional

information from the principal investigator of the trial concerned. We justified any exclusion of a potentially eligible trial from the review in the final report.

Data extraction and management

We did not identify any trials that could be included in the review. However, in future, if suitable trials are published, the plan is that two review authors (DT, HS) independently will extract data for each included trial using a pre-designed data extraction form to extract the following data:

- details of the trial (first author, year of publication, journal, publication status, period and country of trial, sources of funding, trial design, sample size);
- patient characteristics (age, sex, type of disease, stage of disease, type of surgery and prior treatment status);
- quality of the trial;
- details of the surgery (PLND, TLND or CLND, number of nodes removed);
- details of the intervention;
- clinical variables related to patient well-being;
- duration of follow-up; and
- outcomes.

The third review author (DF) will resolve any discrepancies regarding data extraction, in order to reach consensus. In the presence of multiple reports on a included trial, we will assemble the most complete data-set feasible for the trial.

Assessment of risk of bias in included studies

We did not identify any trials that could be included in the review. However, in future, if suitable trials are published, two review authors (DT, HS) independently will assess each trial for risk of bias using the Cochrane Collaboration's 'Risk of bias' tool (Higgins 2011). Selection bias, performance bias, detection bias, attrition bias and reporting bias will be considered for each individual trial. Where there are unclear risks of bias due to inadequate descriptions within the trial report, we will attempt to contact the trial authors in order to clarify the risk. All efforts made to obtain additional information will be reported in the review. Any discrepancies will be resolved by consensus discussion with the third review author (DF).

Measures of treatment effect

We did not identify any trials that could be included in the review. However, in future, if suitable trials are published, we will analyse dichotomous variables (wound complications, wound infection, drain re-insertion, lymphoedema) as risk ratios (RR) with 95% confidence intervals (CI). We will analyse continuous variables (length of stay, volume of fluid drained, number of aspirations, total aspirate volume, total volume of drainage, patient-reported

outcome measures) as mean differences. Where different scales are used to assess continuous outcomes, we will analyse using standardised mean difference (SMD).

Unit of analysis issues

We did not identify any trials that could be included in the review. However, in future, if suitable trials are published, we will use the clinically relevant time points reported in each trial to calculate complication rates. Wound infection, as defined by the CDC criteria, has to occur within 30 days of the procedure, therefore this time point will be used as a cut-off for this outcome measure (see above). Where cluster-randomised trial designs are encountered, including, for example, randomisation by surgeon, or by operating list, we will analyse on the basis of allocation, using summary values for each cluster.

If bilateral groin dissections are performed with separate randomisation of each groin, we plan to analyse the results on a 'per groin' rather than a 'per participant' basis, as the outcomes of the two sides are likely to be independent, except for patient-reported outcome measures, which will not be analysed in these participants, as the effects of the two interventions are not separable. We also plan to conduct a sensitivity analysis on a 'per participant' basis to determine if there is an effect of bilateral groin dissections in the same patient.

Dealing with missing data

We did not identify any trials that could be included in the review. However, in future, if the results of an RCT are published, but information on the outcome of interest is not reported, we will contact the trial authors for the missing information. Where continuous data are not presented as mean and standard deviations we contact the trial authors for the information in this format. All efforts made to obtain additional information will be reported in the completed review. Where possible, we intend to analyse by intention-to-treat (Hollis 1999). If participants are allocated to one intervention, but after randomisation underwent a different intervention, they will be analysed according to their randomisation allocation. If the results for dichotomous variables are not reported in some participants, we will base our analysis on both a worst possible outcome (for example, wound infection occurred in all non-reported cases), and a best possible outcome (for example, wound infection did not occur in all non-reported cases). Where participants are excluded from the analysis without good cause, we will conduct a sensitivity analysis to determine any effect of attrition bias.

Assessment of heterogeneity

We did not identify any trials that could be included in the review. However, in future, if suitable trials are published, we will explore heterogeneity using the χ^2 test with significance set at

P value 0.10, and measure the quantity of heterogeneity using the I^2 statistic (Higgins 2002).

Thresholds for the interpretation of the I^2 statistic can be misleading. A rough guide to the interpretation used is as follows:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

When interpreting the I^2 statistic, we will take factors such as clinical and methodological heterogeneity, along with whether the heterogeneity is in the magnitude of effect or in the direction of effect, into account, particularly where ranges overlap.

Assessment of reporting biases

We did not identify any trials that could be included in the review. However, in future, if suitable trials are published, we will compare the reported outcomes with those stated in the methods of the trials, and also those listed in the protocols in clinical trials registries as both primary and secondary outcomes. Where sufficient trials are identified (a minimum of 10), we will assess for publication bias by creating a funnel plot using software within Review Manager 5.3, using visual inspection to detect publication bias.

Data synthesis

We did not identify any trials that could be included in the review. However, in future, if suitable trials are published, we will present a narrative overview of any included trials. Where appropriate, we will present meta-analyses of outcome data using RevMan 5.3 (RevMan 2014). The decision to pool data in a meta-analysis will depend on the availability of outcome data and the assessment of between-trial heterogeneity. Where trials measure the same underlying effect we plan to use a fixed-effects model, and where this is not the case we plan to use a random-effects model - if sufficient studies are identified to inform the distribution of effects (i.e. more than five trials). However, we do not intend to pool data where heterogeneity is very high (I^2 values of 75% or above).

For dichotomous outcomes we plan to present the summary estimate as a risk ratio (RR) with 95% confidence intervals (CI). Where continuous outcomes are measured in the same way across trials, we will present a mean difference (MD) with 95% CI. Where trials measure the same outcome using different methods we will present a standardised mean difference (SMD).

Subgroup analysis and investigation of heterogeneity

If suitable trials are published in future, we will consider the following variables for subgroup analyses.

- Effects of CLND or PLND versus TLND. These subgroups may behave differently, as those patients undergoing a TLND have macroscopic cancer in the lymph node basin,

which, theoretically, may require a larger volume of tissue to be removed and create a larger dead space, thereby increasing the potential drainage after inguinal lymph node dissection. By contrast, some authors have suggested that, when compared to TLND, CLND has an increased risk of wound infection owing to two procedures having been performed in the same anatomical location in rapid succession (de Vries 2006).

- Type of cancer, for example melanoma versus vulval cancer, versus anal cancer, versus penile cancer.
- Type of drain used, for example closed suction drainage versus gravity drainage.

Ability to conduct such analyses will also depend on whether the required information is recorded in the trial publications. If data are not included, we plan to contact trial authors to obtain the data.

Sensitivity analysis

If suitable trials are published in future, we plan to undertake a sensitivity analysis that includes, and then excludes, trials at high risk of bias, repeating this analysis to include trials at unclear risk of bias as well. We acknowledge that there is no accepted definition of what constitutes a trial at high risk of bias, therefore, we intended to assess the severity of any biases for each outcome. We intended to assess risk of bias using the Cochrane Collaboration 'Risk of bias' tool (Higgins 2011).

Presentation of results

If suitable trials are published in future, we will present the main results of the review in 'Summary of findings' tables, which provide key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on the main outcomes, as recommended by the Cochrane Collaboration (Schünemann 2011a). We will include the following main outcomes in the 'Summary of findings' tables.

- Wound complications (dehiscence, haematoma, seroma).
- Wound infection.

The 'Summary of findings' table will include an overall grading of the evidence related to each of the main outcomes, using the GRADE approach (Schünemann 2011b).

RESULTS

Description of studies

Results of the search

A total of 308 unique records were retrieved following removal of duplicate records. There were no ongoing trials identified from the WHO ICTRP, EU clinical trials register or ClinicalTrials.gov. Sixteen potentially eligible studies were identified for abstract screening. Of these, eight records were considered to be potentially relevant and retrieved for full text review, but none of these eight studies met our predefined inclusion criteria.

Included studies

No RCTs were identified that compared patients undergoing inguinal lymph node dissection with or without drains inserted into the inguinal region.

Excluded studies

Eight studies were excluded from the review. Four trials were excluded because they studied pelvic drainage following hysterectomy and pelvic lymphadenectomy, with no inguinal lymph node dissection (Lopes 1995; Patsner 1995; Franchi 1997; Franchi 2007). Two trials looked at pelvic drainage following extended pelvic lymphadenectomy for urological conditions, where the extent of dissection was superior to Cloquet's node, with no inguinal node dissection (Danuser 2013; Ozdemir 2013). One trial looked at para-aortic drainage following para-aortic lymphadenectomy for gynaecological cancer, with no inguinal lymph node dissection (Morice 2001). One study looked at vascular groin dissections, where no lymph nodes were removed (Youssef 2005).

Risk of bias in included studies

We identified no trials eligible for inclusion, therefore we cannot comment on risk of bias.

Effects of interventions

We could not determine the effect of wound drainage following groin dissection for malignant disease in adults because we did not identify any eligible trials for inclusion in the review.

DISCUSSION

Summary of main results

No eligible trials were identified for inclusion in this review, therefore it has not been possible to generate any results at this time concerning the effect of drain insertion on complications following lymphadenectomy limited to Cloquet's node as the superior limit of dissection.

Overall completeness and applicability of evidence

We identified no RCTs that were eligible for inclusion in this review, therefore the evidence regarding wound drainage following groin dissection for malignant disease is incomplete. Quasi RCTs were not eligible for inclusion in the review and whilst we could have made a decision (post hoc) to widen the inclusion criteria to include quasi RCTs we did not do this. In the event we did not identify through the search process any quasi RCTs which would have met the inclusion criteria for this review.

Quality of the evidence

As we identified no eligible trials to include in the review.

Potential biases in the review process

The potential for bias in the review process is low. Our literature search was conducted by the Cochrane Wounds Group, working to accepted standards; and included five electronic databases and three clinical trial registries. We applied no language limits to the search and are confident there was no risk of bias in the search strategy. Two review authors (DRT and HS), working independently and according to defined inclusion/exclusion criteria, were responsible for trial selection. We cannot exclude the possibility of publication bias due to non-publication of trials, for example because papers were rejected by journal editors, or because results were non-significant. However, because we have identified no randomised trials investigating this area, we believe journals would be likely to publish results of trials in this area, had they been conducted.

Agreements and disagreements with other studies or reviews

We have not identified any other published reviews which address this question.

AUTHORS' CONCLUSIONS

Implications for practice

At present the impact of wound drainage following groin dissection for malignant disease in adults remains unclear and clinicians have minimal evidence on which to base their decision making regarding the role of wound drainage following groin dissection.

Implications for research

This review has identified an urgent and pressing need for high quality randomised trials comparing groin drain insertion with no drain in patients following inguinal lymph node dissection for all causes of pathology. At present there is no evidence from randomised controlled trials available to guide clinical decision making for the benefit of patients in this important area. Trials have been conducted to investigate the impact of drain insertion for pelvic lymph node dissection for both gynaecological and oncological surgeries, therefore, it is reasonable to suppose that a trial

of drain insertion for inguinal dissection would be feasible, and ethical given the current state of balance of clinicians (Coblentz 2002; Serpell 2003; Ul-Mulk 2012).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Danuser 2013	Extent of dissection superior to Cloquet's node; obturator, external iliac and hypogastric nodes excised in extended pelvic lymphadenectomy, no inguinal lymph node dissection Danuser studied 331 consecutive patients undergoing extended pelvic lymph node dissection to include obturator, external iliac and hypogastric lymph nodes, following radical prostatectomy. Their patient groups were divided into three series: the first series (132 participants) underwent open radical prostatectomy with two 'easy flow' drains placed in the right and left obturator fossae, with randomisation by coin toss just after surgery into two groups: Group 1 (66 participants) had shortening of the drains on post-operative days three and five, with drain removal at day seven. Group 2 (66 participants) had their drains removed on post-operative day one. Drain removal was delayed across both groups, if required, until drainage volume was less than 100 mL over 24 hours. The next 73 consecutive patients (Group 3) underwent open radical prostatectomy with no drain inserted. The final 126 consecutive patients (Group 4) were treated with robot-assisted radical prostatectomy, with no drain inserted. Seroma (asymptomatic and symptomatic) occurred in 6% of Group 1, 12% of Group 2, 10% of Group 3 and 3% of Group 4. Significant differences were reported between Groups 2 and 4 (P value 0.02). There were no wound complications noted in any of the groups, however, drain insertion necessitated two to five days longer in hospital, although the authors did note that "drain management, care and removal could also be carried out on an outpatient basis"
Franchi 1997	Pelvic drainage following hysterectomy and dissection of common external iliac and obturator nodes, no inguinal lymph node dissection
Franchi 2007	Pelvic drainage following hysterectomy and pelvic lymph node dissection, no inguinal lymph node dissection Franchi studied 234 patients following radical hysterectomy and pelvic lymph node dissection with 117 patients randomised (no details given on randomisation methods) to insertion of two suction drains, placed in the retroperitoneal fossa via a vaginal or abdominal route. Drains were removed when drainage volume was less than 50 mL over 24 hours. There was no difference in incidence of asymptomatic or symptomatic seroma between the two trial arms and no difference for other post-operative complications
Lopes 1995	Pelvic drainage following hysterectomy and external iliac, internal iliac and obturator node dissection, no inguinal lymph node dissection Lopes studied 100 consecutive patients following radical hysterectomy and bilateral pelvic lymph node dissection of the external iliac, internal iliac and obturator nodes. Fifty-one patients were randomised, using numbered envelopes, to insertion of a suction drain into each pelvic sidewall. Drains were removed when drainage volume was less than 100 mL over 24 hours. The incidence of seroma in the drained group that was revealed by clinical examination (5.9%) and ultrasound (15.6%) did not differ significantly from the undrained group for both clinical examination (6.1%) and ultrasound (17.4%), leading the authors to conclude that there "appears to be no advantage to the routine use of pelvic suction drainage following radical hysterectomy and pelvic lymphadenectomy"
Morice 2001	Pelvic and para-aortic lymphadenectomy, no inguinal node dissection
Ozdemir 2013	Extent of dissection superior to Cloquet's node; extended pelvic lymphadenectomy, no inguinal node dissection Ozdemir studied 58 patients with bladder carcinoma, treated surgically with radical cystectomy, extended bilateral pelvic lymph node dissection and orthotopic bladder pouch substitution. Patients underwent pseudo-randomisation by coin-tossing, with 22/58 given a pelvic drain, which was removed when the drainage was less than 100 mL over

(Continued)

	24 hours. There were no statistically significant differences observed between groups for length of hospital stay, or early or late postoperative complications, including wound infection, haematoma and seroma
Patsner 1995	Not an RCT; pelvic drainage following hysterectomy and pelvic lymphadenectomy, no inguinal lymph node dissection Patsner studied 120 consecutive patients with invasive cervical cancer who underwent radical abdominal hysterectomy and bilateral pelvic lymph node dissection, with removal of common iliac and pelvic lymph nodes. The first 60 patients had bilateral Jackson-Pratt closed suction drains placed in the retroperitoneal spaces, and the next 60 patients had no drains inserted. No difference in rates of post-operative infection or seroma were reported between groups (no statistical analysis presented)
Youssef 2005	Groin dissection for vascular reconstruction, no lymph nodes excised

Abbreviation

RCT; randomised controlled trial

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Ovid MEDLINE search strategy

```
1 exp Lymph Node Excision/ (35104)
2 exp Lymph Nodes/su [Surgery] (3223)
3 (inguinal lymph node dissection or inguinal lymphadenectomy or groin dissect* or groin surg*).tw. (820)
4 or/1-3 (36691)
5 exp Drainage/ (44541)
6 exp Suction/ (10324)
7 drain*.tw. (87070)
8 or/5-7 (111510)
9 4 and 8 (2095)
10 randomized controlled trial.pt. (389483)
11 controlled clinical trial.pt. (89863)
12 randomi?ed.ab. (349033)
13 placebo.ab. (156696)
14 clinical trials as topic.sh. (175353)
15 randomly.ab. (199204)
16 trial.ti. (124282)
17 or/10-16 (915623)
18 (animals not (humans and animals)).sh. (3966240)
19 17 not 18 (844415)
20 9 and 19 (235)
```

Appendix 2. Ovid EMBASE search strategy

```
1 exp lymph node dissection/ (24381)
2 (inguinal lymph node dissection or inguinal lymphadenectomy or groin dissect* or groin surg*).tw. (1138)
3 or/1-2 (25185)
4 exp wound drain/ (22)
5 exp wound drainage/ (18256)
6 exp suction drainage/ (1498)
7 exp suction/ (7418)
8 drain*.tw. (120180)
9 or/4-8 (136598)
10 3 and 9 (1253)
11 Randomized controlled trials/ (41034)
12 Single-Blind Method/ (18481)
13 Double-Blind Method/ (120993)
14 Crossover Procedure/ (38901)
15 (random$ or factorial$ or crossover$ or cross over$ or cross-over$ or placebo$ or assign$ or allocat$ or volunteer$).ti.ab. (1314112)
16 (doubl$ adj blind$).ti.ab. (148081)
17 (singl$ adj blind$).ti.ab. (14330)
18 or/11-17 (1377870)
```

19 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/ (20651671)
 20 human/ or human cell/ (15032995)
 21 and/19-20 (14986339)
 22 19 not 21 (5665332)
 23 18 not 22 (1189119)
 24 10 and 23 (143)

Appendix 3. EBSCO CINAHL search strategy

S23 S10 AND S22
 S22 S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21
 S21 MH "Quantitative Studies"
 S20 TI placebo* or AB placebo*
 S19 MH "Placebos"
 S18 TI random* allocat* or AB random* allocat*
 S17 MH "Random Assignment"
 S16 TI randomi?ed control* trial* or AB randomi?ed control* trial*
 S15 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)
 S14 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)
 S13 TI clinic* N1 trial* or AB clinic* N1 trial*
 S12 PT Clinical trial
 S11 MH "Clinical Trials+"
 S10 S5 AND S9
 S9 S6 OR S7 OR S8
 S8 TI drain* OR AB drain*
 S7 (MH "Suction+")
 S6 (MH "Drainage+")
 S5 S1 OR S2 OR S3 OR S4
 S4 TI (groin dissect* or groin surg*) OR AB (groin dissect* or groin surg*)
 S3 TI (inguinal lymph node dissection or inguinal lymphadenectomy) OR AB (inguinal lymph node dissection or inguinal lymphadenectomy)
 S2 (MH "Lymph Nodes/SU")
 S1 (MH "Lymph Node Excision+")

CONTRIBUTIONS OF AUTHORS

David Thomson: conceived, designed and co-ordinated the review. Searched identified titles, abstracts and full papers and assessed for eligibility. Wrote and edited the review. Advised on the review and approved the final version prior to submission.

Hazim Sadideen: conceived and designed the review. Searched identified titles, abstracts and full papers and assessed for eligibility. Wrote and edited the review. Advised on the review and approved the final version prior to submission.

Dominic Furniss: conceived and designed the review. Wrote and edited the review. Advised on the review and approved the final version prior to submission. Is the guarantor of the review.

Contributions of editorial base

Kurinchi Gurusamy: edited the protocol; advised on methodology, interpretation and protocol content. Approved the final protocol prior to submission.

Nicky Cullum: Approved the final review prior to submission.

Sally Bell-Syer: co-ordinated the editorial process. Advised on methodology, interpretation and content. Edited the protocol and review.

Amanda Briant: ran the searches and edited the search methods section.

DECLARATIONS OF INTEREST

David R Thomson - none known

Hazim Sadideen - none known

Dominic Furniss - none known

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Internal sources

- No sources of support supplied

External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are no differences between the protocol and the full review.

INDEX TERMS

Medical Subject Headings (MeSH)

*Lymph Node Excision; Drainage [*methods]; Groin; Neoplasms [*surgery]

MeSH check words

Adult; Humans