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[Intervention Review]

Surgical interventions for early squamous cell carcinoma of the vulva

Jacobus van der Velden¹

¹Department of Obstetrics and Gynaecology, Academic Medical Centre, Amsterdam, Netherlands

Contact: Jacobus van der Velden, Department of Obstetrics and Gynaecology, Academic Medical Centre, PO Box 22660, Meibergdreef 9, Amsterdam, 1105 AZ, Netherlands. j.vandervelden@amc.uva.nl.

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ABSTRACT

Background

Radical surgery has been standard treatment for patients with early vulvar cancer since the mid 1900s. Survival figures are excellent, but complication rates are high. Since 1980, surgery has become more individualised in order to decrease complications in patients with limited disease.

Objectives

To compare the effectiveness and safety of individualised treatment with that of standard extensive surgery.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2007, Issue 4), MEDLINE (1966 to April 2007) and EMBASE (to April 2007). We also searched our own publication archives, based on prospective handsearching of six leading relevant journals from December 1986. Reference lists of identified studies, gynaecological cancer handbooks and conference abstracts were also scanned.

Selection criteria

Randomized controlled trials (RCTs), case controlled and observational studies on the effectiveness of surgery (local surgery and regional lymph node dissection) on patients with cT1N0M0 squamous cell carcinoma of the vulva.

Outcome measures were overall, disease-specific, disease-free survival (DFS), treatment complications, quality of life (QoL).

Data collection and analysis

Three review authors (AA, JVD, MS) independently assessed study quality and extracted data.

Main results

From three studies, we concluded there was no difference in the incidence of:

1. local recurrent vulvar cancer between radical local excision and radical vulvectomy, or
2. groin recurrence between ipsilateral groin node dissection and bilateral groin node dissection in patients with a well lateralised tumour.

Furthermore, superficial groin node dissection is not as safe as full femoro-inguinal lymph node dissection. The triple incision technique is a safe procedure provided tumour free margins are greater than 8 mm and the slight increase in recurrences does not outweigh the reduction in complications.

Authors' conclusions

The available evidence regarding surgery for early vulvar cancer is generally poor. From the studies of sufficient quality we concluded that radical local excision is a safe alternative to radical vulvectomy for patients with early vulva carcinoma.

Contralateral groin node dissection can be omitted in patients with a lateralized tumour, and the triple incision technique is as safe as an en bloc dissection. However, omission of femoral lymph node dissection results in a higher incidence of groin recurrences.

Further good quality studies are required, though conducting RCTs on vulvar cancer treatment may not be realistic due to the rarity of the disease. However, observational studies of higher quality could provide us with more reliable evidence.

PLAIN LANGUAGE SUMMARY**Less extensive surgery for vulvar cancer appears safe and limits mutilation**

Vulvar cancer is rare, affecting mainly older women. Until the 1980s, affected women underwent extensive, mutilating surgery. Groin nodes on both sides as well as all vulvar tissue were removed. Recently surgeons have carried out a smaller operation, leaving as much vulvar tissue as possible behind. No randomized controlled trials (RCTs) have been conducted on the safety of this reduced surgery, but from the available evidence it appears to be safe to perform this smaller operation in most patients.

BACKGROUND

Vulvar cancer is a disease of elderly women with a mean age at diagnosis of approximately 70. The incidence in industrialized countries is two per 100,000 per year (Platz 1995). In developing countries the (age adjusted) incidence is 50% lower. According to population-based studies, about 75% of vulvar malignancies are squamous cell carcinomas (Platz 1995; Van der Velden 1996). The tumour metastasizes primarily to the inguinal lymph nodes (Morley 1976). Current standard treatment for patients with early squamous cell carcinoma of the vulva (cT1-2N0M0 tumours) is primary surgery, followed by radiotherapy if indicated (Hacker 1994). Surgery consists of a radical excision of the tumour and a bilateral inguinal lymph node dissection. This treatment policy results in excellent survival figures, but also in high complication rates. Wound healing problems are observed in a large proportion of patients, and in the long term psychosexual complications and lymphoedema are frequently seen. Because of high complication rates, a more individualized approach has been developed in recent years (Hacker 1994). Currently, patients with small tumours undergo less extensive surgery. The aim is to reduce complications without compromising survival. This individualization of treatment is based on case-control studies, studies with historic controls and observational studies. Only two RCTs, both addressing the role of radiotherapy in vulvar cancer treatment, have been published (Homesley 1986; Stehman 1992b).

The most important developments in the surgical treatment of early vulvar cancer are:

- Radical vulvectomy replaced by a radical local excision of the tumour
- En bloc dissection replaced by the so-called triple incision technique
- Omission of contralateral lymph node dissection in patients with laterally localized and small tumours
- Inguinal and femoral lymph node dissection replaced by inguinal lymph node dissection.

Our aim in this review is to determine whether there is clear evidence that the changes in surgical treatment strategy as mentioned above are safe and effective.

OBJECTIVES

The objectives of this review were to determine whether the effectiveness and safety of modified (individualized) treatment is comparable with that of more extensive surgery. The main outcomes of interest were survival, recurrence and complication rates.

The following issues were addressed in this review:

1. Is a radical local excision as effective as radical vulvectomy?
2. Is the triple incision technique as effective as en bloc dissection?
3. Is an ipsilateral node dissection only as effective as a bilateral node dissection in patients with a lateral tumour?
4. Is an inguinal node dissection as effective as an inguinal and femoral node dissection?

METHODS

Criteria for considering studies for this review

Types of studies

Studies regarding patients with histologically proven cT1-2N0M0 squamous cell carcinoma of the vulva were considered for this review. Only studies on the effectiveness of treatment were incorporated.

It was anticipated that only a very small number of RCT's have been conducted on vulvar cancer treatment. Therefore, observational studies, case-control studies and studies with historic controls were also considered for incorporation in this review.

Types of participants

Patients with early squamous cell carcinoma of the vulva were included, i.e. patients with cT1-2N0M0 tumours:

- T1: tumour confined to the vulva, maximum diameter two cm.
- T2: tumour confined to the vulva, diameter larger than two cm.
- N0: no clinically suspicious lymph nodes
- M0: no clinical suspicion of distant metastases

Types of interventions

- Radical vulvectomy is defined as: excision of the complete vulvar skin and subcutaneous tissue.
- A radical local excision is defined as: an excision of the tumour with a margin of one cm, horizontally as well as vertically.
- Inguinal and femoral lymphadenectomy is defined as: removal of all lymph node bearing fatty tissue between the inguinal ligament, the sartorius muscle and the adductor longus muscle, and dissection of the femoral lymph nodes located in the fossa ovalis medial to the femoral vein.
- Inguinal lymphadenectomy is defined as: removal of all lymph node bearing fatty tissue between the inguinal ligament, the sartorius muscle, the adductor longus muscle above the level of the fascia lata.
- Pelvic lymph node dissection is defined as: removal of the lymph node bearing tissue along the distal part of the external iliac artery and vein, and along the obturator nerve.

The following surgical procedures were studied:

- Radical vulvectomy with bilateral en bloc dissection of (femoral and) inguinal lymph nodes
- Radical vulvectomy with bilateral en bloc dissection of (femoral and) inguinal and pelvic lymph nodes
- Radical vulvectomy with bilateral (femoral and) inguinal lymph node dissection through separate groin incisions
- Radical vulvectomy with bilateral (femoral and) inguinal and pelvic lymph node dissection through separate groin incisions
- Radical local excision with bilateral (femoral and) inguinal lymph node dissection through separate groin incisions
- Radical local excision with bilateral (femoral and) inguinal and pelvic lymph node dissection through separate groin incisions
- Radical local excision with unilateral (femoral and) inguinal lymph node dissection
- Radical local excision with omission of node dissection.

Types of outcome measures

- Overall, disease specific survival and DFS.
- Complications of treatment: wound healing, lymphoedema, psychosexual problems
- QoL issues

Search methods for identification of studies

Electronic searches

The following electronic databases were searched:

Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2007, Issue 4)
 MEDLINE (Silver Platter 1966 to April 2007)
 EMBASE (1980 to April 2007)
 PDQ (searched for ongoing trials April 2007)

The highly sensitive search strategy (HSSS) for RCTs as described in the Cochrane Handbook for Reviewers (Higgins 2008) was not used because the authors felt they were unlikely to find many RCTs

The search strategies used for each of the trial databases may be viewed in the additional tables:

[Table 1 - CENTRAL](#)

[Table 2 - MEDLINE](#)

[Table 3 - EMBASE](#)

We searched both free text terms and headings. MeSH headings were exploded.

From the results of the searches, relevant articles were identified and scanned by three review authors (AA, JV and MS).

Searching other resources

The reference lists of the relevant papers found were searched for further studies and the authors of all relevant trials were contacted to give information relating to their participation in any hitherto unpublished trials. Papers in all languages were sought.

In December 1986, the first author started a prospective handsearch of publications on the treatment of vulvar cancer of the following journals:

- American Journal of Obstetrics and Gynecology
- British Journal of Obstetrics and Gynaecology
- Cancer
- Gynecologic Oncology, and Obstetrics and Gynecology.

In addition, the International Journal of Gynecologic Cancer has been handsearched from the first issue (1991). Reference lists of books on gynaecological cancer (Berek 1994; Burghardt 1993) were also searched, as well as abstracts from conferences on gynaecological cancer.

Publications that met the set criteria were selected.

Data collection and analysis

Selection of studies

Selection of studies was carried out by three review author (AA, JV, MS). No effort was made to blind the review authors to names of

authors, institutions, journals etcetera. The reason for this was that all the both review authors were too familiar with the literature on vulvar cancer treatment and would have recognized most studies even when they were blinded.

As it was known to the review authors that only a small number of RCTs have been published, other types of studies were incorporated in this review, i.e. prospective observational studies, case-control studies and studies with historic controls.

First selection criteria were the following

1. The study deals with cT1-2N0M0 squamous cell carcinoma of the vulva patients.
2. The topic of the study is effectiveness of surgical treatment. One or more of the above mentioned issues is addressed.
3. In RCTs, treatment is uniform within a treatment arm
4. In case-control and historic control studies, treatment is uniform within each group
5. In observational studies, treatment is uniform in the entire group.

We identified twelve studies that appeared to meet these first selection criteria (Arvas 2005; Ayhan 1988; Burger 1996; Burke 1995; DiSaia 1979; Farias-Eisner 1994; Grimshaw 1993; Hacker 1981; Heaps 1990; Helm 1992; Hoffman 1992; de Hullu 2002; Siller 1995; Stehman 1992 (a)).

Data extraction and management

After this first selection, studies were assessed with the aid of three critical review form. One for RCT's, one for case control studies and studies with historic controls, and one for observational studies (Table 4; Table 5; Table 6). The critical review forms were filled out independently by both authors. Differences were resolved by discussion.

Not a single study met all the criteria that were set out in the critical review forms. However, excluding all studies from further analysis would result in no systematic review at all. Therefore it was decided to include studies that met at least the following criteria:

- all participants had clinical T1-2N0M0 vulvar cancer, or it was possible to analyse these participants separately
- surgical interventions were described adequately
- for studies with (non-randomized) controls, interventions should be the same in each group, apart from the experimental intervention

Eleven studies were excluded from further analysis for the following reasons:

- impossibility to analyse the patients with early vulvar cancer separately (Burger 1996; Grimshaw 1993; Hacker 1981; Heaps 1990; Helm 1992; Siller 1995)
- treatment not uniform (Andrews 1994; Arvas 2005; Ayhan 1988; Farias-Eisner 1994)
- treatment groups did not receive the same treatment apart from the experimental intervention (Hoffman 1992;

RESULTS

Description of studies

Applying the selection criteria as described above, three studies were eligible for further analysis. All were observational studies (Burke 1995; de Hullu 2002; DiSaia 1979).

Risk of bias in included studies

The quality of the three included studies was fair. Problems that remained after the selection process as described above were:

The definition of interventions

In all studies, the surgical interventions were described in sufficient detail. However, in none of them details regarding radiotherapy interventions were addressed.

Complications: incidence and definition of grade

An adequate description of common complications (wound complications, voiding problems, cellulitis, lymphoedema) was not stated in one study (DiSaia 1979). The grade of complications was not defined in any study. In only one study, sexual problems were (briefly) addressed (DiSaia 1979).

Effects of interventions

We used two observational studies (Burke 1995; DiSaia 1979) to answer questions 1, 3 and 4 and one study (de Hullu 2002) was used to answer question 2 as stated in the objectives.

1. Is radical local excision as effective as radical vulvectomy?

From Table 7, it is obvious that despite lack of details on radiotherapy interventions and complications, radical local excision appears to be a safe alternative to radical vulvectomy, as the recurrence rate is low. None of the patients with a local recurrence died of vulvar cancer.

2. Is the triple incision technique as effective as en bloc dissection?

After the first selection, we had identified five studies to answer this question. However, after using the critical review form, only one of these five studies was selected. In the study by Hacker (Hacker 1981), 14 patients had 'old' FIGO stage III disease. It was not possible to analyse the other 86 separately. In the study of Helm (Helm 1992), the only study with matched controls, a similar problem was present. In addition the treatment was not uniform in the experimental arm. In 'general', a superficial groin node dissection was performed, but in 'some cases' (no numbers stated), femoral nodes were dissected as well. In the study by Grimshaw (Grimshaw 1993), 10 out of 100 patients had no squamous cell carcinoma, but a tumour of another cell type. In the study of Farias-Eisner (Farias-Eisner 1994) the interventions were not uniform.

The study by de Hullu (de Hullu 2002) showed that recurrences in either groin or skin bridge were more frequent after wide local excision and inguinofemoral lymphadenectomy through separate incisions (13.2% versus 21.5% within two years). All recurrences had developed in patients with at least one tumour free margin less than 8 mm. In this study QoL and treatment morbidity were not registered; this should be weighed against the increase in recurrence rate. Provided that tumour free margins of greater

than 8mm are considered the separate incision technique is safe as the combined incidence of skin bridge and groin recurrences still remains very low and does not outweigh the reduction in complications as shown in Table 8.

3. Is an ipsilateral groin node dissection only as effective as a bilateral groin node dissection in patients with a lateral tumour?

Only one study (Burke 1995) that may answer this question was selected. From Table 9, it is obvious that recurrent disease in a previously undissected groin is a relatively rare event after an ipsilateral groin node dissection in a patient with a lateral tumour. This occurred in only one patient, and she was salvaged by groin dissection and radiotherapy.

4. Is a superficial groin node dissection as effective as a femoro-inguinal groin node dissection?

It is shown in Table 10 that groin recurrences did not occur in the (highly selected) patients studied by DiSaia (DiSaia 1979), but did occur in the patients studied by Burke (Burke 1995). All three groin recurrences occurred in previously tumour negative groins.

DISCUSSION

Summary of main results

The main problem when trying to conduct a systematic review on vulvar cancer treatment is the lack of studies with sufficient quality. As we are dealing with a rare disease, it is not realistic to expect that a large number of RCTs been done. However, the conduction of observational studies of good quality should be feasible. The current systematic review taught us that even a good quality observational study is a rare feature.

Quality of the evidence

Main methodological problems in the identified studies were:

1. The definition of the type of participants. In 1988, FIGO staging for vulvar cancer patients was changed from a clinical into a surgical /pathological staging system. Thus, according to the new staging system, the FIGO stage cannot be established until after surgical treatment. As a consequence, it is not possible to define a preoperatively uniform patient group in terms of FIGO staging. Unfortunately, the use of the clinical Tumour-Nodes-Metastasis (TNM) system is not widespread. Many clinicians still tend to use the old (clinical) FIGO staging for preoperative assessment. As a result, considerable confusion exists regarding the definition of patient groups. Comparison of interventions is virtually impossible when the type of participants is ill-defined. Another problem is to define which tumours are lateral, and which ones are medial/median.
2. The definition of interventions. In only a limited number of studies, surgical interventions are defined adequately. In particular, there is a considerable problem with the definition of the lymph node dissection. Levenback (Levenback 1996) developed a questionnaire regarding the surgical interventions in vulvar cancer patients. This questionnaire was distributed among 50 gynecologic oncologists in the USA, 44 of whom were board-certified. Even among this group of selected, well trained gynecologic oncologists, there was poor agreement regarding the definition of superficial inguinal and femoro-inguinal groin

node dissection. We expect that the lack of agreement regarding the definition of interventions will not be better among other gynaecologic oncologists. For radiotherapy interventions, the situation is even worse, as they are seldom addressed at all in studies with a surgeon as the first author.

3. Studies with uniform interventions are extremely rare. This makes comparison of different types of treatment difficult.
4. Follow up problems were encountered as not all patients are accounted for at the end of follow up, and duration of follow up was often obscure.
5. The main goal of individualized (i.e. in many cases less radical) treatment is the reduction of perioperative and long term complications. However, from the available evidence, it is not clear whether complication rates have decreased. This is due to the lack of data on incidence of complications and the lack of clear definitions of grade of complications.

AUTHORS' CONCLUSIONS

Implications for practice

Good quality studies of surgical treatment for vulvar cancer are rare. We identified only two observational (and no other type) studies that just met the minimum criteria as set by the Cochrane Collaboration ([Higgins 2008](#)).

Despite the methodological problems, we feel that we can draw some conclusions from the available evidence that may have implications for practice.

1. For patients with T1-2 tumours, radical local vulvar excision is a safe treatment option.
2. In early vulvar cancer the incidence of skin bridge recurrence after treatment with the triple incision technique is low, probably no more than one per cent provided a tumour free margin of greater than 8 mm. Therefore, it appears to be safe to replace en bloc

dissection by the triple incision technique in cT1-2N0M0 vulvar cancers.

3. From the limited evidence available, it appears that ipsilateral groin node dissection is safe in patients with a lateral cT1N0M0 tumour.
4. Omission of femoral lymph node dissection is unsafe. Even in a population with a very favourable prognosis, 3 in 76 (four per cent) groin recurrences were observed in previously operated groins.

Implications for research

Because vulvar cancer is a rare disease with a good prognosis in early stages, it will be difficult to conduct RCTs sufficient numbers. However, observational studies can also help to increase the amount of evidence. Until now, the majority of published observational studies do not meet the minimum criteria set by the Cochrane Collaboration ([Higgins 2008](#)). Thus, there is considerable room for improvement.

Future observational studies on the effectiveness of surgical treatment of early vulvar cancer should at least meet the following criteria:

- Clear definitions of type of participants and type of interventions
- Uniform interventions
- Clearly stated follow up time
- Clearly accounted follow up status for all participants
- Definition of type, incidence and grade of complications.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Burke 1995

Methods	observational study
Participants	n=76; cT1-2N0M0
Interventions	radical local excision 2cm margin, inguinal node dissection, +/- radiotherapy
Outcomes	actuarial survival at 28 months: 83%; cancer related death in 5%; 12% local recurrence, but no death due to local recurrence
Notes	complications insufficiently addressed

de Hullu 2002

Methods	observational study
Participants	n=253 cT1-2N0M0
Interventions	wide local excision with inguinal node separate incision
Outcomes	disease free survival 83%; groin/skin bridge recurrence 6,3%
Notes	complications insufficiently addressed

DiSaia 1979

Methods	observational study
Participants	n=18; cT1N0M0, tumour <1 cm
Interventions	radical local excision 3 cm margin, inguinal node dissection, +/- radiotherapy
Outcomes	100% survival at 32 (7-74) months; no local recurrence
Notes	complications insufficiently addressed

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Andrews 1994	Treatment not uniform
Arvas 2005	Treatment not uniform
Ayhan 1988	Treatment not uniform
Burger 1996	Not possible to analyse patients with early vulvar cancer separately
Farias-Eisner 1994	Treatment not uniform
Grimshaw 1993	Not possible to analyse patients with early vulvar cancer separately
Hacker 1981	Not possible to analyse patients with early vulvar cancer separately
Heaps 1990	Not possible to analyse patients with early vulvar cancer separately
Helm 1992	Not possible to analyse patients with early vulvar cancer separately
Hoffman 1992	Treatment groups did not receive same treatment apart from experimental intervention
Siller 1995	Impossibility to analyse the patients with early vulvar cancer separately
Stehman 1992a	Treatment groups did not receive same treatment apart from experimental intervention

ADDITIONAL TABLES
Table 1. CENTRAL Search Strategy

1 vulv*
2 surg*
3 dissect*

Table 1. CENTRAL Search Strategy *(Continued)*

4 (#2 or #3)
 5 (#1 and #4)
 6 (neoplas* near malig*)
 7 cancer*
 8 carcino*
 9 (tumor* near malig*)
 10 (tumour* near malig*)
 11 (neoplas* near cancer*)
 12 (tumor* near cancer*)
 13 (tumour* near cancer*)
 14 (#6 or #7 or #8 or #9 or #10 or #11 or #12 or #13)
 15 (#5 and #14)
 16 VULVAR NEOPLASMS [su] explode all trees (MeSH)
 17 (#15 and #16)

Table 2. MEDLINE Search Strategy

1 vulv*
 2 surg*
 3 dissect*
 4 #2 or #3
 5 #1 and #4
 6 neoplas* near malig*
 7 cancer*
 8 carcino*
 9 tumo?r near malig*
 10 neoplas* near cancer*
 11 tumo?r near cancer*
 12 #6 or #7 or #8 or #9 or #10 or #11
 13 #5 and #12
 14 #13 and (TG = "HUMAN")
 15 #14 and (PT = "CLINICAL-TRIAL")
 16 explode "Vulvar-Neoplasms"/ all subheadings
 17 explode "Gynecologic-Surgical-Procedures"/ all subheadings
 18 #15 and #16 and #17

Table 3. EMBASE Search Strategy

1 vulv*
 2 surg*
 3 dissect*
 4 #2 or #3
 5 #1 and #4
 6 neoplas* near malig*
 7 cancer*
 8 carcino*
 9 tumo?r near malig*

Table 3. EMBASE Search Strategy (Continued)

- 10 neoplas* near cancer*
 11 tumo?r near cancer*
 12 #6 or #7 or #8 or #9 or #10 or #11
 13 #5 and #12
 14 #13 and (TG = "HUMAN")
 15 #14 and (PT = "CLINICAL-TRIAL")
 16 explode "Vulvar-Neoplasms"/ all subheadings
 17 explode "Gynecologic-Surgical-Procedures"/ all subheadings
 18 #15 and #16 and #17

Table 4. Critical review form (randomised studies)

No.	Data extraction	Yes/No
1.	Did study population meet our criteria? or: is it possible to analyse patients that meet our criteria separately?	
2.	Was assignment of patients to treatment randomized?	
3.	Were patients analysed in the groups to which they were randomized?	
4.	Were the groups similar at the start of the trial?	
5.	Aside from the experimental intervention, were the groups treated equally?	
6.	Were all patients who entered the trial accounted for at its conclusion?	
7.	How long was follow up?	
8.	Were interventions defined adequately?	
9.	How precise was the estimate of the treatment effect? -disease free survival -complications	
10.	Were all clinically important outcomes considered? -disease free survival -complications	

Table 5. Critical review form (studies with non-randomised controls)

No.	Data extraction	Yes/No
1.	Did study population meet our criteria? or: is it possible to analyse patients	

Table 5. Critical review form (studies with non-randomised controls) *(Continued)*
 that meet our criteria separately?

2.	Were patients analysed in the groups to which they were assigned?
3.	Were the groups similar before treatment?
4.	Aside from the experimental intervention, were the groups treated equally?
5.	Were all patients accounted for at the end of follow up?
6.	How long was follow up?
7.	Were interventions defined adequately?

Table 6. Critical review form (observational studies)

No.	Data extraction	Yes/No
1.	Did study population meet our criteria? or: is it possible to analyse patients that meet our criteria separately?	
2.	Were all observed patients accounted for at the end of follow up?	
3.	How long was follow up?	
4.	Were interventions defined adequately?	
5.	How precise was the estimate of the treatment effect? -disease free survival -complications	
6.	Were all clinically important outcomes considered? -disease free survival -complications	

Table 7. Radical local excision versus radical vulvectomy

Trial characteristic	DiSaia 1979	Burke 1995
Type of study	observational	observational
Number of cases	18	76
Type of participants	cT1N0M0, tumour <1 cm	cT1-2N0M0
End of follow up	all accounted for	all accounted for

Table 7. Radical local excision versus radical vulvectomy (Continued)

Length of follow up	32 (7-74) months	median 38 months
Intervention	radical local excision 3cm margin inguinal node dissection +/- radiotherapy	radical local excision 2cm margin inguinal node dissection +/- radiotherapy
Defined adequately	yes for surgery, no for radiotherapy	yes for surgery, no for radiotherapy
Complications addressed	only orgasm +/-	yes apart from sexuality
% complications	no loss of orgasm	19% perioperative 30% late
Grade of complication defined	no	no
Local recurrence	none	9 (12%) no death due to local recurrence
Disease free survival	100% at 32 (7-74 months)	actuarial survival at 38 months: 83% (in 5% vulvar cancer related death)

Table 8. Triple incision technique versus en bloc dissection

trial characteristic	de Hullu 2002
type of study	observational
number of cases	253
Type of participants	T1-2 NOM0
End of follow up	all accounted for
Length of follow up	median 110 months
Intervention	Wide local excision margin 1 cm, inguinal node dissection
Defined adequately	Yes for surgery, yes for radiotherapy
Complications adressed	No
Local recurrence	9 (11,4%)
Groin / skin bridge recurrence	5 (6,3%)
Disease free survival	83%

Table 9. Groin node dissection: Ipsilateral versus bilateral for lateral tumours

Trial characteristic	Burke 1995
Type of study	observational
Number of cases	51
Type of participants	cT1-2N0M0
End of follow up	all accounted for
Length of follow up	median 38 months
Intervention	radical local excision 2 cm margin inguinal node dissection +/- radiotherapy
Defined adequately	yes for surgery no for radiotherapy
Complications addressed complications addressed	yes apart from sexuality
% complications	19% perioperative 30% late
Grade of complication defined	no
Disease free survival	actuarial survival at 38 months: 83% (in 5% vulvar cancer related death)

Table 10. Groin node dissection: superficial versus femoro-inguinal

Trial characteristic	DiSaia 1979	Burke 1995
Type of study	observational	observational
Number of cases	18	76
Type of participants	cT1N0M0, tumour <1 cm	cT1-2N0M0
End of follow up	all accounted for	all accounted for
Length of follow up	32 (7-74) months	median 38 months

Table 10. Groin node dissection: superficial versus femoro-inguinal (Continued)

Intervention	radical local excision, 3 cm margin, inguinal node dissection, +/- radiotherapy	radical local excision, 2 cm margin, inguinal node dissection, +/- radiotherapy
Defined adequately	yes for surgery, no for radiotherapy	yes for surgery, no for radiotherapy
Complications addressed	only orgasm +/-	yes apart from sexuality
% complications	no loss of orgasm	19% perioperative 30% late
Grade of complication defined	no	no
Groin recurrence	0	3 (4%)
Disease free survival	100% at 32 (7-74 months)	actuarial survival at 38 months: 83% (in 5% vulvar cancer related death)

WHAT'S NEW

Date	Event	Description
3 July 2014	Review declared as stable	This review is now stable as the intervention is standard practice. An area of development is sentinel node assessment and a review on this topic is now available: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010409.pub2/abstract .

HISTORY

Protocol first published: Issue 1, 1998

Review first published: Issue 2, 2000

Date	Event	Description
14 April 2008	Amended	Converted to new review format.
9 March 2008	New citation required and minor changes	The slight increase in recurrences after using the triple incision technique does not outweigh the reduction in complications.
1 April 2007	New search has been performed	The literature searches as described in the search strategy section were updated on April 2007. One new relevant study was found.

CONTRIBUTIONS OF AUTHORS

AA - originated review question, carried out the literature search and made the first selection of studies, made definitive selection of studies, did data extraction and wrote the review.

JV - made definitive selection of studies, did data extraction and commented several drafts of review.

MC - edited all previous versions of the review.

MS- updated the review this latest version of the review; carried out the literature search and made a selection of studies.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- NHS R & D programme, UK.

External sources

- No sources of support supplied

NOTES

This review is now stable as the intervention is standard practice. An area of development is sentinel node assessment and a review on this topic is now available: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010409.pub2/abstract>.

INDEX TERMS

Medical Subject Headings (MeSH)

Carcinoma, Squamous Cell [*surgery]; Vulvar Neoplasms [*surgery]

MeSH check words

Female; Humans