

Current management of squamous cell vulvar cancer

Neville F Hacker AM MD

**Professor of Gynaecological Oncology
Conjoint, University of New South Wales, Sydney**



J. Obstet. Gynaec. Brit. Cwlth.
Aug. 1966. Vol. 73. pp. 594-598.

THE LATE RESULTS OF EXTENDED RADICAL VULVECTOMY FOR CARCINOMA OF THE VULVA

BY

STANLEY WAY, F.R.C.O.G.

Lecturer in Gynaecological Oncology, The University of Newcastle upon Tyne. Gynaecological Surgeon and Director of the Gynaecological Research Department, Queen Elizabeth Hospital, Gateshead

WITH ASSISTANCE IN FOLLOW-UP

BY

MARGARET HENNIGAN, M.B., Ch.B.(Glasgow), M.R.C.O.G., Registrar
Gynaecological Research Department, Queen Elizabeth Hospital, Gateshead

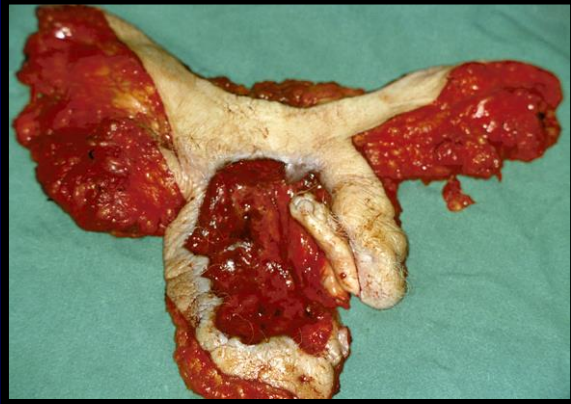
It is now 25 years since one of us performed the first operation in this series, and 18 years since the principles of the operation based on a thorough understanding of the lymphatic anatomy were first published (Way, 1948). Sixty-nine patients were treated before 31st December, 1950, and are

whence she left to visit her "brother" in London. As she would only now be 62 years old she may well survive. Therefore, all 69 patients in the series are eligible for 5 and 10 year follow-up and 67 for 15 years or more. Twenty patients were treated more than 20 years ago.

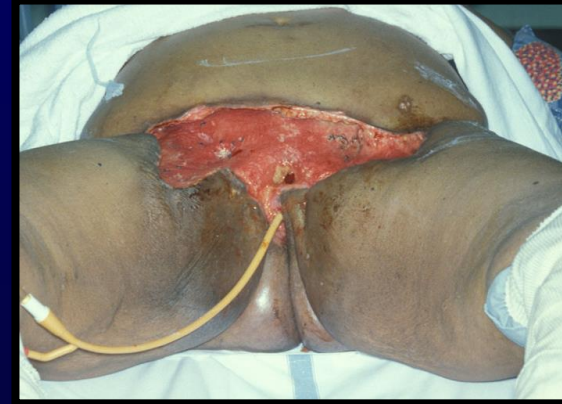


- This paper was published 25 years after Stanley Way performed the first en bloc radical vulvectomy, bilateral groin dissection plus pelvic lymphadenectomy
- His 10-year survival of about 65% represented a paradigm shift from the 20-25% survivals reported for earlier, less radical operations

The Stanley Way Operation



En Bloc radical vulvectomy and bilateral groin LND performed as a UCLA Fellow at the Martin Luther King Jr Hospital, Los Angeles 1979.



The average post-op hospital stay was in excess of 100 days

Psychosexual Adjustment After Vulvar Surgery

BARBARA L. ANDERSEN, PhD, AND NEVILLE F. HACKER, MD

Obstet Gynecol
1983;62:457 - 462

Fifteen patients treated surgically for vulvar cancer from two institutions participated in semistructured interviews and objective assessment to examine postoperative psychologic, social, marital, and sexual adjustment. Descriptive statistics

were used. This strategy enabled the authors to compare these data with those from their previous study of pelvic exenteration patients⁴ and with those of other investigators who have used the measures with

First psychometric analysis of patients having a radical vulvectomy.

Compared to healthy adult women, these patients had:

- Sexual arousal at the 8th percentile, and
- Body image at the 4th percentile

What were the critical modifications to the management of a unifocal vulvar cancer?

- In 1979, Di Saia et al first suggested a “wide local excision” for lesions 1cm or less in diameter with up to 5 mm invasion. He suggested that margins should be at least 3 cm. Several authors pursued this concept for larger unifocal lesions, regardless of diameter or depth of invasion, and in 1984, we coined the term “radical local excision”, implying an operation that was both wide and deep

(Hacker NF et al. Individualisation of treatment for Stage I squamous cell vulvar carcinoma. *Obstet Gynecol* 63: 155-161, 1984)

- Following the paper by Heaps in 1990, and some supporting data, an appropriate margin was generally considered to be 1 cm, which translated to a formalin-fixed margin of about 8 mm

Institution	≤ 8 mm	> 8 mm
UCLA (Heaps et al 1990)	0/91	21/44
UCI (Chan et al 2002)	0/29	13/61
Groningen (De Hulla et al 2002)	0/39	9/40
Total	0/159 (0%)	43/145 (29.7%)

Better clarity on local recurrences in patients with vulvar cancer was provided by the Frenchman, Roman Rouzier in 2002

Local Recurrences in Vulvar Cancer

- Rouzier was the first to describe two types of vulvar recurrence: (a) **primary** site and (b) **remote** site.

- Major risk factor for:

Primary site:

● Margins < 1 cm (p = .002)

Rouzier R et al, *Obstet Gynecol*
2002;100:1159-1167

Remote site:

● Adjacent dermatosis (p < .001)

- In 2009, an analysis of 121 patients from the RHW with cancers confined to the vulva and negative nodes revealed the following:

● Median time to primary site 21 months $P = 0.001$

● Median time to remote site 69 months

Tantipalakorn C et al
Obstet Gynecol
2009;113:895-901

In 1966, Way reported a patient who developed a cancer beside the anus following an earlier operation for a cancer of the clitoris. He stated “.....it can rightly be called a new primary cancer”

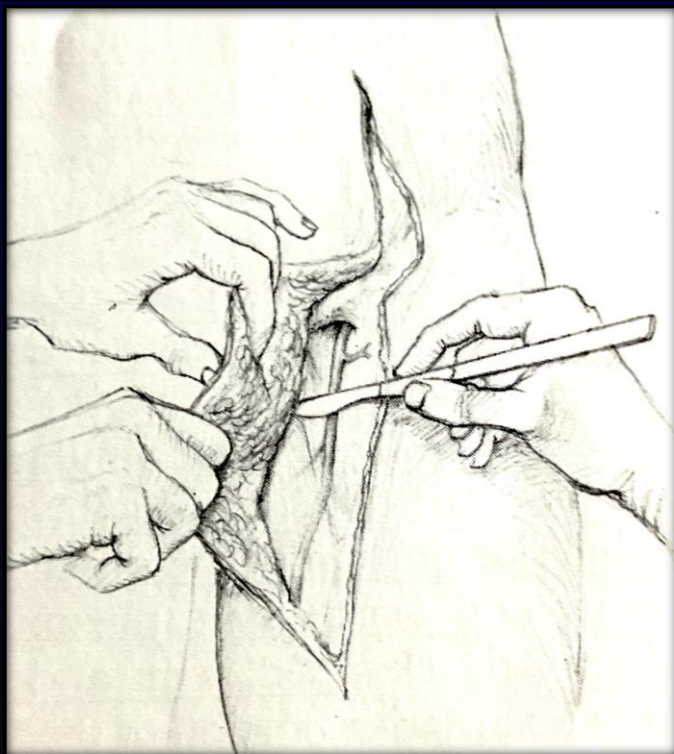
*Remote site recurrences should be regarded as new primary tumors,
and are indicative of the need for lifetime follow-up*

What modification was critical to improve the morbidity of the groin dissection

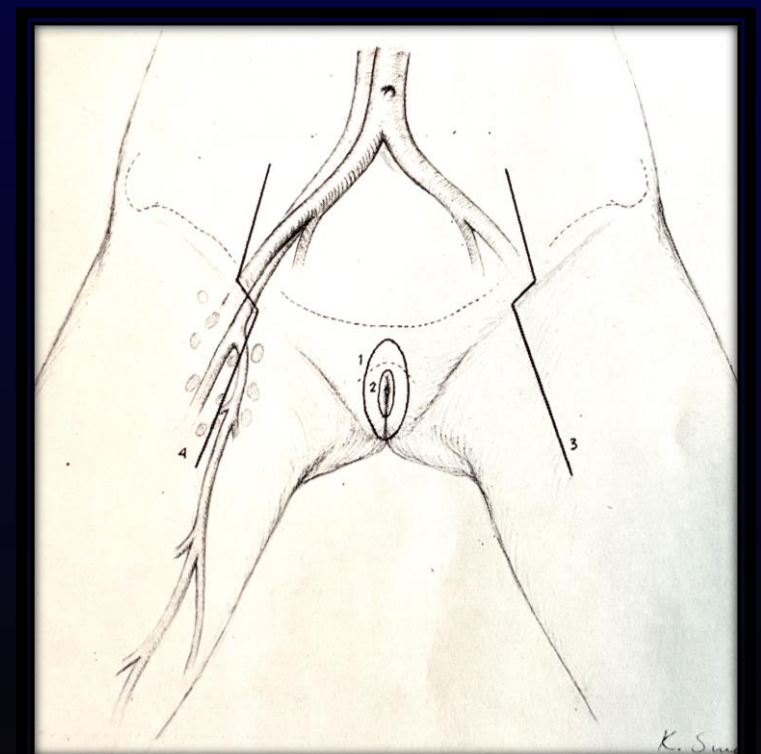
THE SURGICAL TREATMENT OF INVASIVE CARCINOMA OF THE VULVA

Surg Gynecol Obstet
1965;121:1243

RALPH L. BYRON, JR., M.D., F.A.C.S., DANIEL R. MISHELL, JR., M.D., and
ROBERT H. YONEMOTO, M.D., F.A.C.S., Duarte, California



- Ralph Byron recommended a separate vertical incision for the groin dissection while continuing with the radical vulvectomy



Current Management of Squamous Vulvar Cancer

- *Management of early primary cancers, including surgical margins*
- Management of lymph nodes in early vulvar cancer
- Management of lymph nodes in late vulvar cancer
- Management of the advanced primary cancers



**Current management requires individualization of treatment for both the primary lesion
and the lymph nodes**

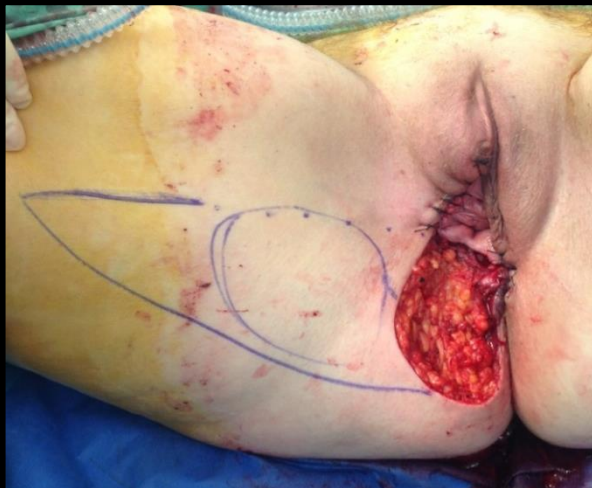
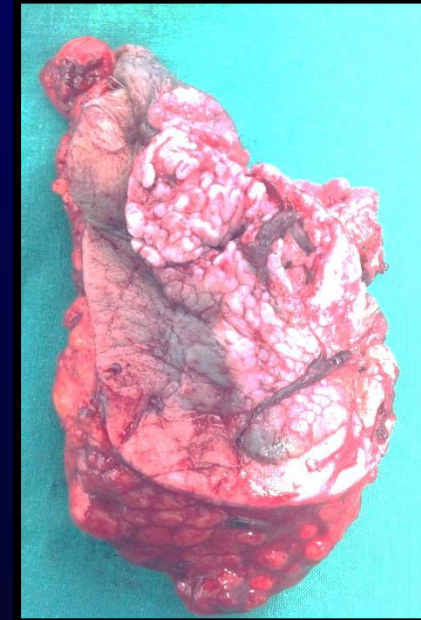
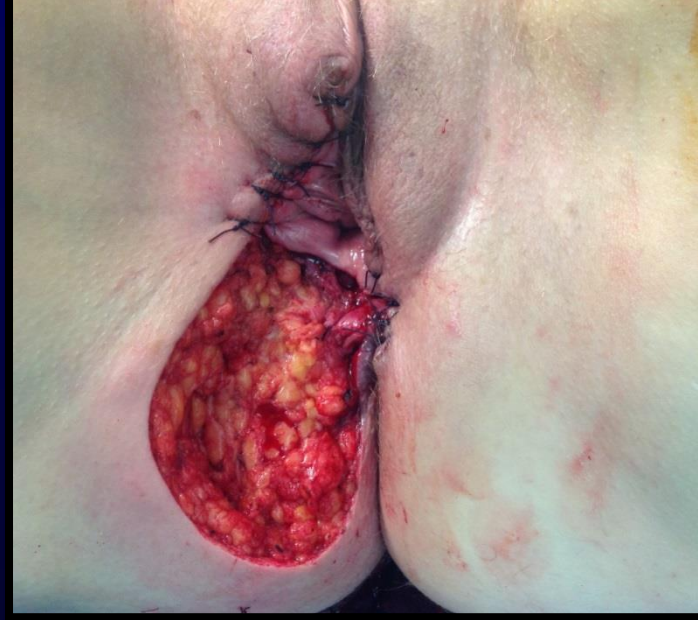
**Small primary cancer
Remainder of vulva is normal**



**Radical local excision
with primary closure**



Large primary cancer
Remainder of vulva is normal
Radical local excision and VY flap to close the defect



**Invasive cancer anteriorly
VIN posteriorly**

Radical Anterior Vulvectomy and Skinning Posterior Vulvectomy



Multifocal Invasive Vulvar Cancer, VIN, and Lichen Sclerosus



- Radical vulvectomy
- Histology showed 4 separate foci of invasive cancer, 2 of them invasive to at least 5mm

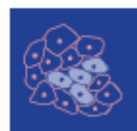
What is a safe surgical margin for a radical local excision?

- Since 2010, several authors have suggested that the histological margin was not predictive of local recurrence and have questioned the need for surgical margins of 1 cm
- Groenen et al. (2010) recommended removing “no more than sufficient surrounding tissue”
- Woelber et al. (2011) recommended that the main goal should be to achieve “complete tumour resection, irrespective of tumour-free margins”
- Nooij et al. (2016) suggested that “tumour positive margins” were the only risk factor.

None of these studies subdivided the recurrences into those at the primary site and those at a remote site.

- In a review of the literature, te Grootenhuis et al. (2018) concluded that the division into primary and remote site recurrences was “arbitrary and not reproducible”. They concluded that there was “no lower limit (apart from involved margins), below which further treatment should be recommended.”

In view of all this controversy, we wrote an article for a special issue of Cancers , after reviewing our experience at the Royal Hospital for Women over almost 30 years



cancers



Review

Conservative Management of Vulvar Cancer—Where Should We Draw the Line?

Neville F. Hacker ^{1,*}  and Ellen L. Barlow ²

¹ School of Women's and Children's Health, Faculty of Medicine & Health, University of New South Wales, Sydney 2052, Australia

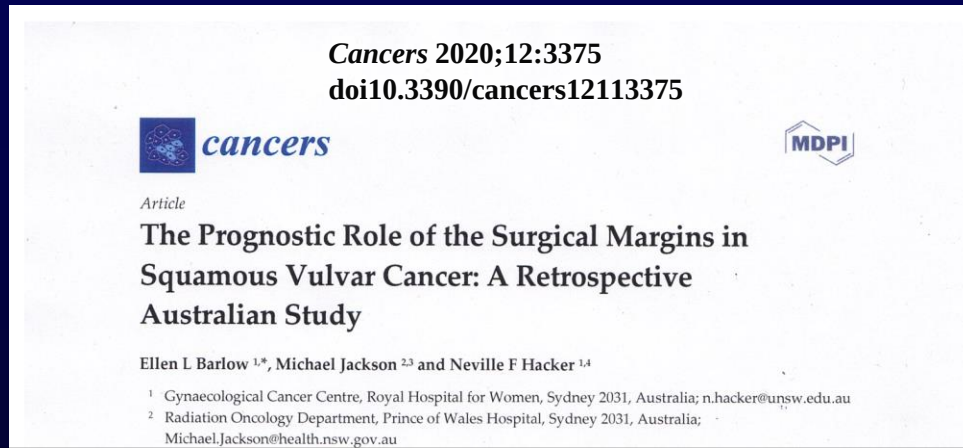
² Gynaecological Cancer Research Group, School of Women' and Children's Health, Faculty of Medicine & Health, University of New South Wales, Sydney 2052, Australia; ellen.barlow@unsw.edu.au

* Correspondence: n.hacker@unsw.edu.au

Cancers 2024,16,2991
doi.org/10.3390/cancers16172991

What is a safe surgical margin for a radical local incision?

- Since 1987, we have consistently aimed for a surgical margin of 1 cm in all patients with a unifocal vulvar cancer at the RHW in Sydney, and information on all primary cancer sites was recorded.



Summary

This paper demonstrated that:

- (i) the division of vulvar recurrences into those at the primary and those at a remote site is real and reproducible
- (ii) surgical margins should remain at 1 cm to decrease primary site recurrences
- (iii) margins ≤ 5 mm should be treated by re-excision or radiation therapy

- Number of patients 345
- Median follow-up 93 mos
- Positive nodes 102 (30%)
- 5-year DSS 86%
- Vulvar recurrence 78 (23%)

Primary site 33 (42%)

Remote site 45 (58%)

- Vulvar recurrence with margins ≤ 8 mm:

Primary site 26/27 (96%)

- Vulvar recurrence with margins > 8 mm

Remote site 44/51 (86%) ($p < 0.001$)

If margins were ≤ 5 mm, re-excision/ radiation therapy reduced the rate of recurrence from 40% to 4% ($p < 0.003$)

Management of Squamous Vulvar Cancer

- Management of early primary cancers, including surgical margins
- *Management of lymph nodes in early vulvar cancer*
- Management of lymph nodes in late vulvar cancer
- Management of the advanced primary cancers

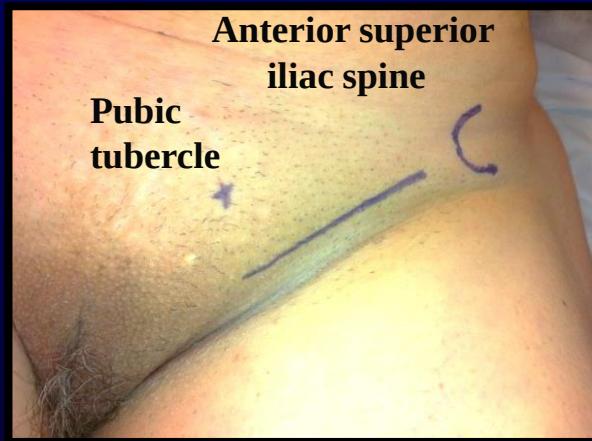
Mis-management of the lymph nodes usually results in the death of the patient



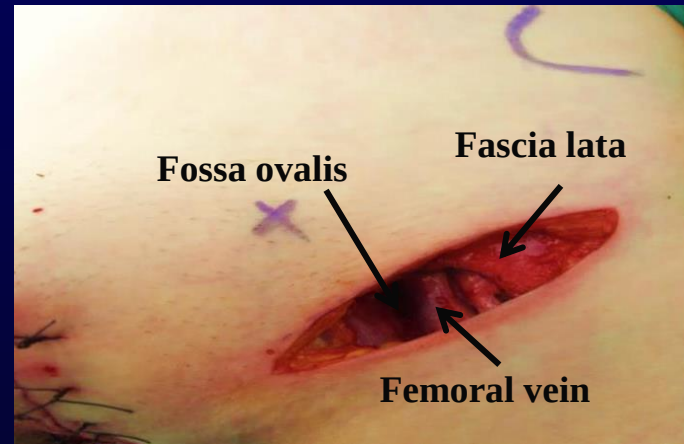
Radical Vulvectomy and Bilateral Inguinal Lymphadenectomy Through Separate Groin Incisions

NEVILLE F. HACKER, MD, RONALD S. LEUCHTER, MD,
JONATHAN S. BEREK, MD, THOMAS W. CASTALDO, MD,

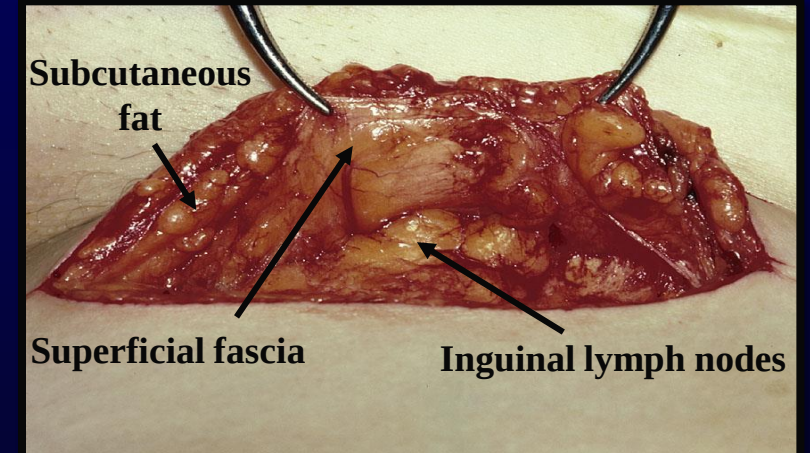
Obstet Gynecol 1981;58:574



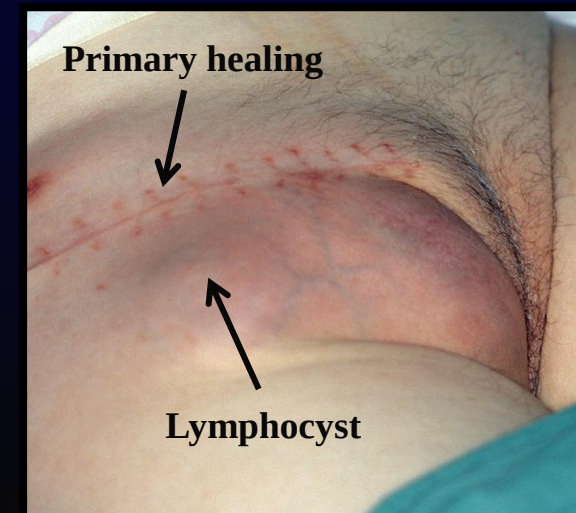
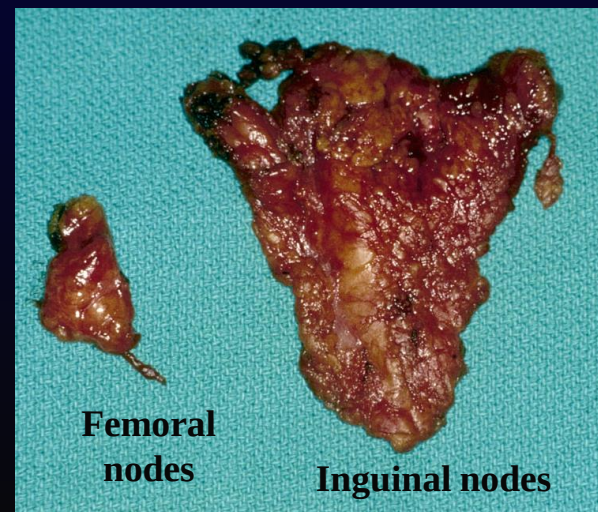
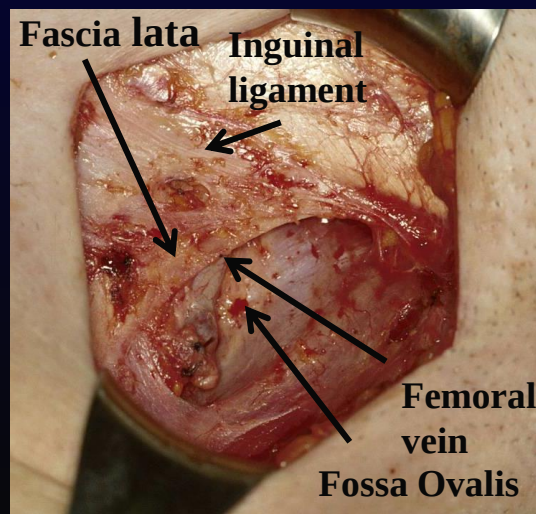
Incision 1 cm above and parallel to groin crease



Incision overlies the fossa ovalis



Preservation of subcutaneous fat to ensure primary healing



Management of patients with proven lymph node metastases

Lymph node status

Adjuvant therapy

1 metastases with no
extracapsular spread



No radiation to groins
or pelvis

≥ 2 metastases
Extracapsular spread



Bilateral groin and pelvic
radiation, with or
without chemotherapy

Subcutaneous metastases
after unilateral groin and
pelvic radiation



van der Velden J et al
Gynecol Oncol. 2021;160:128-133.

Sentinel node biopsy for cancers <4 cm diameter

VOLUME 26 • NUMBER 6 • FEBRUARY 20 2008

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Sentinel Node Dissection Is Safe in the Treatment of Early-Stage Vulvar Cancer

Ate G.J. Van der Zee, Maaïke H. Oonk, Joanne A. De Hullu, Anca C. Ansink, Ignace Vergote, René H. Verheijen, Angelo Maggioni, Katja N. Gaarenstroom, Peter J. Baldwin, Eleonore B. Van Dorst, Jacobus Van der Velden, Ralph H. Hermans, Hans van der Putten, Pierre Drouin, Achim Schneider, and Wim J. Sluiter

From the University Medical Center Groningen, University of Groningen, Groningen; Radboud University Nijmegen Medical Center, Nijmegen; Erasmus Medical Center, Rotterdam; VU University Medical Center; Academic Medical Center, Amsterdam; Leiden University Medical Center, Leiden; University Medical Center Utrecht, Utrecht; Maastricht University Medical Center, Maastricht; Catharina Hospital, Eindhoven, the Netherlands; University Hospitals Leuven, Leuven, Belgium; European Cancer Institute, Milan, Italy; Addenbrooke's Hospital, Cambridge, United Kingdom; Hôpital Notre Dame-Centre Hospitalier de l'Université de Montréal, Montréal, Québec, Canada; and Charité-Universitätsmedizin Berlin, Berlin, Germany.

Submitted August 20, 2007; accepted October 4, 2007.

Presented at the 11th Biennial Meeting of the International Gynecologic Cancer Society, October 14-18, 2006, Santa Monica, CA, and the Society of Gynecologic Oncologists 37th Annual Meet-

ABSTRACT

Purpose

To investigate the safety and clinical utility of the sentinel node procedure in early-stage vulvar cancer patients.

Patients and Methods

A multicenter observational study on sentinel node detection using radioactive tracer and blue dye was performed in patients with T1/2 (< 4 cm) squamous cell cancer of the vulva. When the sentinel node was found to be negative at pathologic ultrastaging, inguinofemoral lymphadenectomy was omitted, and the patient was observed with follow-up for 2 years at intervals of every 2 months. Stopping rules were defined for the occurrence of groin recurrences.

Results

From March 2000 until June 2006, a sentinel node procedure was performed in 623 groins of 403 assessable patients. In 259 patients with unifocal vulvar disease and a negative sentinel node (median follow-up time, 35 months), six groin recurrences were diagnosed (2.3%; 95% CI, 0.6% to 5%), and 3-year survival rate was 97% (95% CI, 91% to 99%). Short-term morbidity was decreased in patients after sentinel node dissection only when compared with patients with a positive sentinel node who underwent inguinofemoral lymphadenectomy (wound breakdown in groin: 11.7% v 34.0%, respectively; $P < .0001$; and cellulitis: 4.5% v 21.3%, respectively; $P < .0001$). Long-term morbidity also was less frequently observed after removal of only the sentinel node compared with sentinel node removal and inguinofemoral lymphadenectomy (recurrent erysipelas: 0.4% v 16.2%, respectively; $P < .0001$; and lymphedema of the legs: 1.9% v 25.2%, respectively; $P < .0001$).

Patients with cancers ≤ 4 cm diameter 403
False negative rate 2.3%

Death from Recurrence in an Undissected Groin

Author	Recurrence	DOD
Rutledge (1970)	4	3
Magrina (1979)	4	3
Hoffman (1983)	4	4
Hacker (1984)	3	3
Monaghan (1984)	4	4
Lingard (1992)	7	7
Burke (1995)	4	3
Case reports	10	8
Davy (2006)	11	10
te Grootenhuys (2016)	7	7
Klapdor (2017)	2	2
TOTAL	60	54 (90%)

The issue is not about morbidity (lymphedema) – it is about risk

The question that should be asked is: “What risk is the patient, properly informed, prepared to take?”



Women's Preference for Sentinel Node Biopsy

Farrell R et al *Int J Gynecol Cancer*
2014;24:813-19.

60% risk of
lymphedema
with an IFLND



1:100 risk of dying
from cancer with
a SNB

● Patients with early vulvar cancer	60
● No risk at all	32 (53%)
● 1: 1,000,000 risk	6 (10%)
● 1: 200 to 1: 1000	10 (17%)
● 1: 2 to 1: 100	9 (15%)
● Undecided	3 (5%)



Mary Li, the wife of Li Cunxin, Mao's Last Dancer, and recently retired Director of the Queensland Ballet Company in Brisbane.

Mary Li underwent this management last year to save her ballet career and I have her permission to tell her story

Q Weekend
June 29-30, 2024

A major improvement on sentinel node biopsy alone was the use of ultrasonic surveillance of the groin for those patients who had a negative sentinel node



DOI: 10.1111/1471-0528.15341
www.bjog.org

Gynaecological oncology

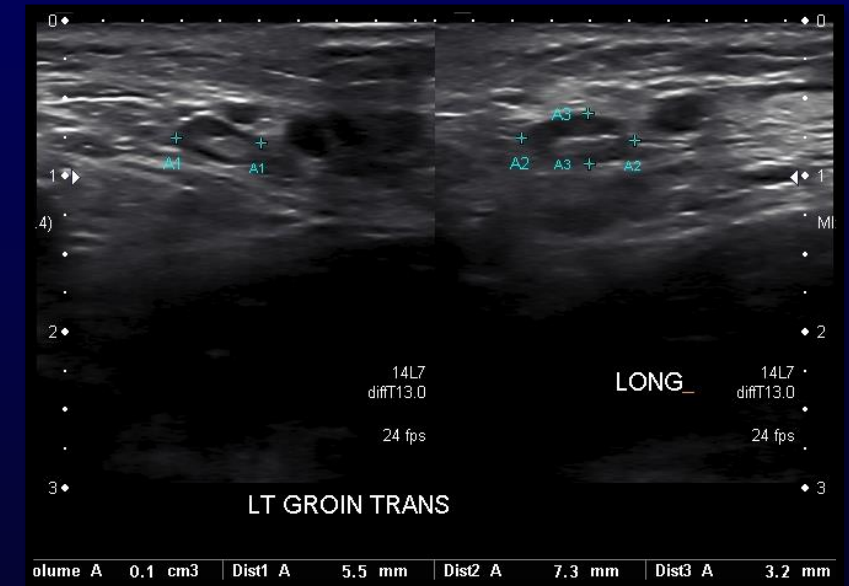
The efficacy of ultrasound in the follow up after a negative sentinel lymph node in women with vulvar cancer: a prospective single-centre study

AW Pouwer,^a RDM Mus,^b J IntHout,^c AGJ van der Zee,^d J Bulten,^e LFAG Massuger,^a JA de Hullu^a

^a Department of Obstetrics and Gynaecology, Radboud University Medical Center, Nijmegen, the Netherlands ^b Department of Radiology, Radboud University Medical Center, Nijmegen, the Netherlands ^c Department of Health Evidence, Radboud Institute for Health Sciences, Radboud University Medical Center, Nijmegen, the Netherlands ^d Department of Obstetrics and Gynaecology, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands ^e Department of Pathology, Radboud University Medical Centre, Nijmegen, the Netherlands

Correspondence: AW Pouwer, Department of Obstetrics and Gynaecology (791), Radboud University Medical Center, PO Box 9101, 6500 HB Nijmegen, the Netherlands. Email Anne-Floor.W.Pouwer@Radboudumc.nl

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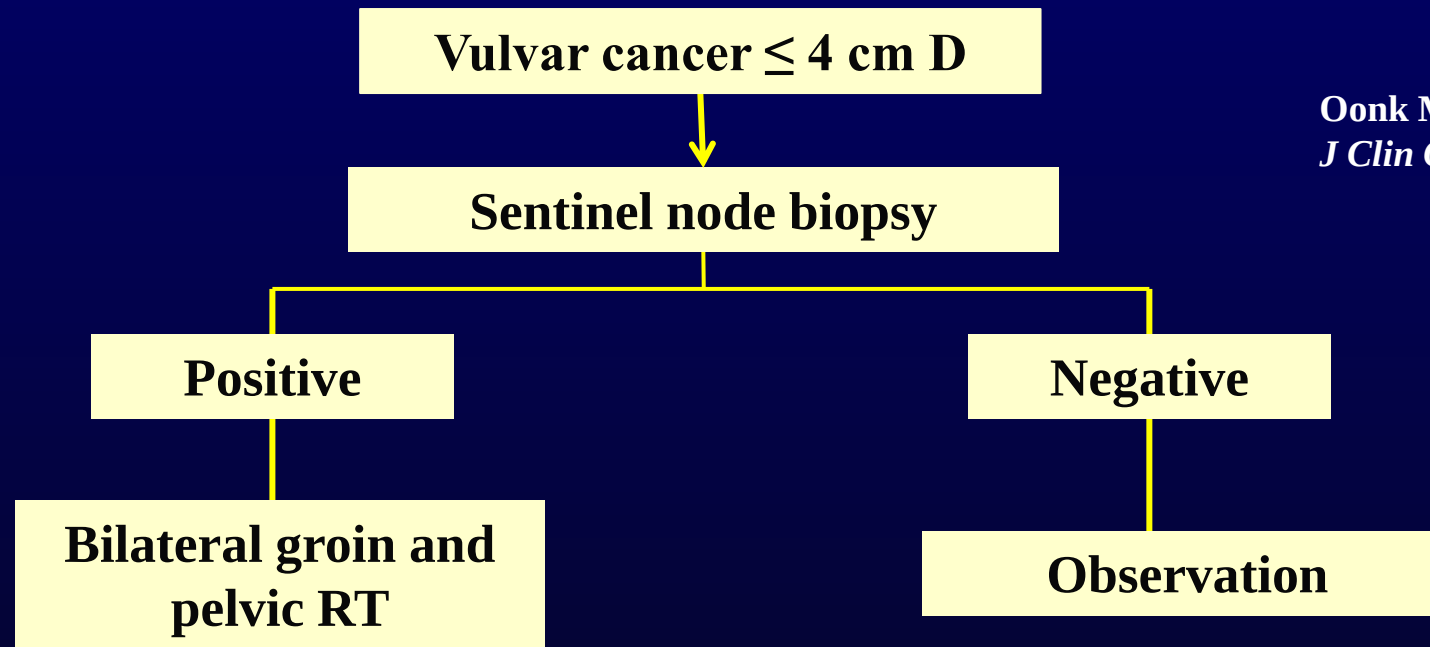


- 79 patients were followed every 3 months for 24 months.
- Two false-negatives (2.5%) were detected, but both were cured after I-F LND and post-operative radiation

I now believe that sentinel node biopsy and serial ultrasonic surveillance of the groin(s) for patients with negative sentinel nodes should be considered the standard of care

How to treat patients with a positive sentinel node was investigated in the GROINS SS-V II Trial

Oonk MHM et al
J Clin Oncol 2021;39: 3623-32



Groin Recurrence after radiation 12.2% (10 of 82)

Interim analysis
in 2010

Nodal micro metastases ≤ 2mm 2.2 %

Nodal macro metastases > 2mm 20 %

Study was then modified to require full groin dissection for metastases > 2mm

Final results

- For 160 patients with SN micrometastases, the groin recurrence rate at 2 years was 1.6%
- For 162 patients with SN macrometastases, groin recurrence rate was 22% after RT and 6.9% with IFL (p = 0.01)
- **GROINSS-V-III started recruitment in 2021.** It is investigating whether chemoradiation and increasing the radiation dose from 50 to 56 Gy can further improve survival

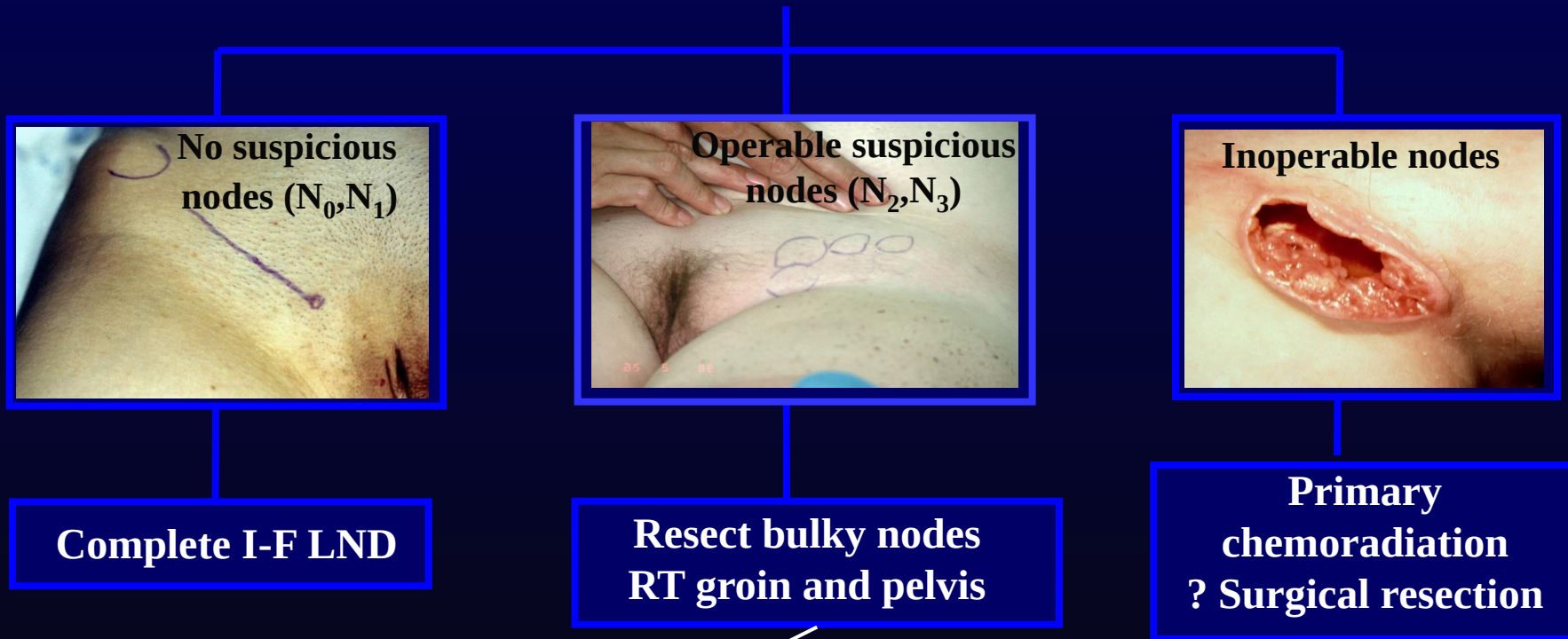
Management of Squamous Vulvar Cancer

- Some epidemiological data about invasive vulvar cancer
- Management of early primary cancers, including surgical margins
- Management of lymph nodes in early vulvar cancer
- *Management of lymph nodes in late vulvar cancer*
- Management of the advanced primary cancers



Management of Lymph Nodes in Advanced Vulvar Cancer

CT Scan of groins, pelvis and abdomen or PET/CT

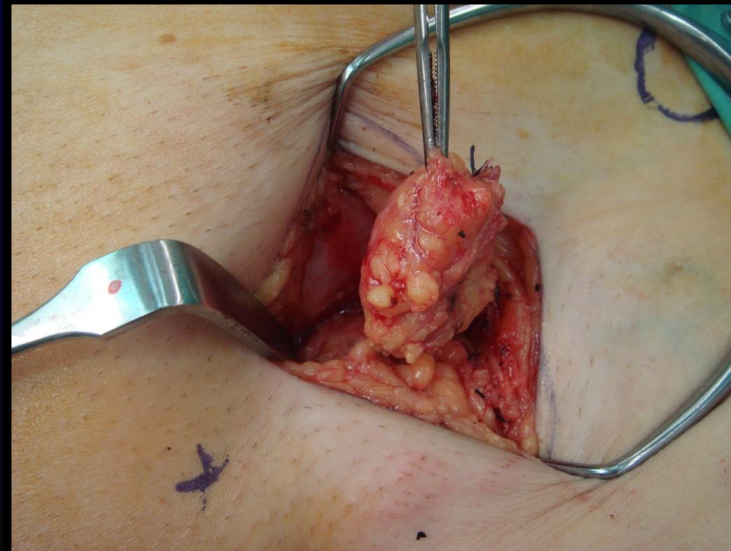


The objective with operable cases should be to decrease
LLL without compromising survival

Bulky nodes removed from right and left groins

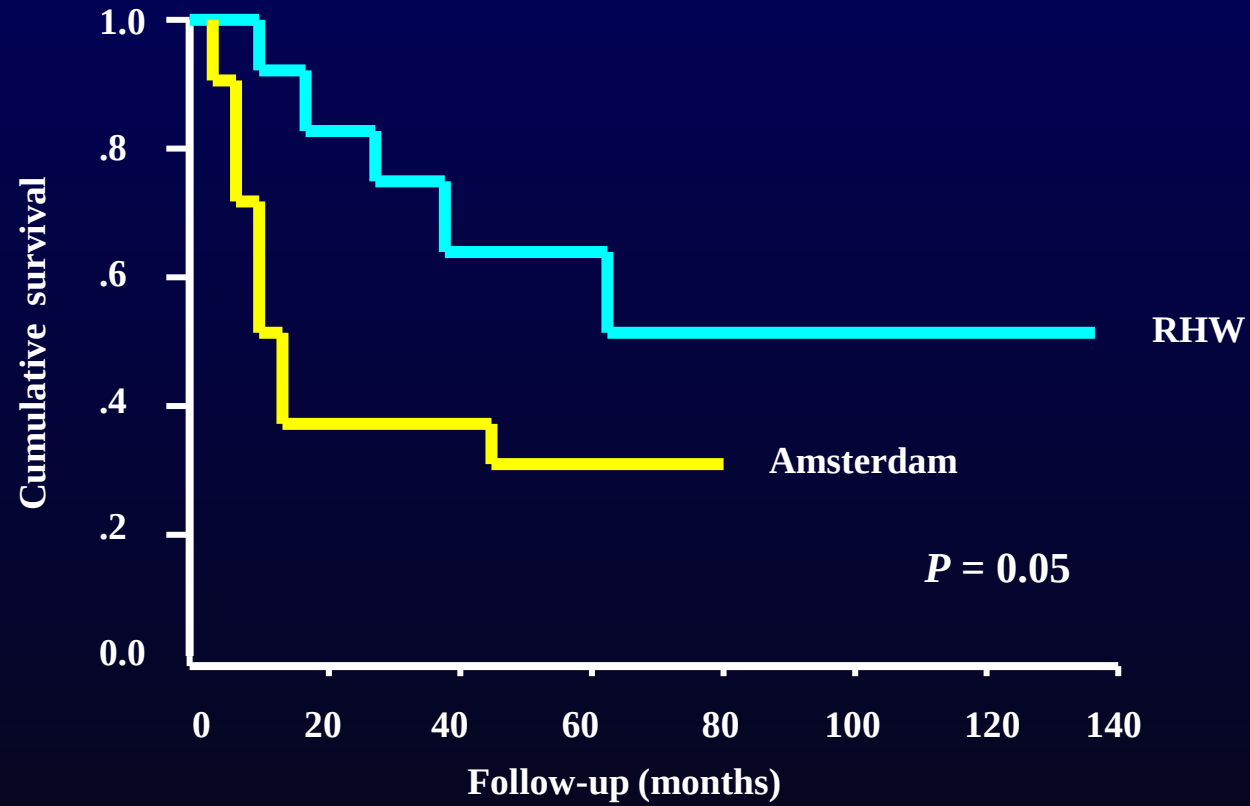


- Non-enlarged are left in-situ for treatment with post-op radiation
- This will decrease the incidence of lymphedema

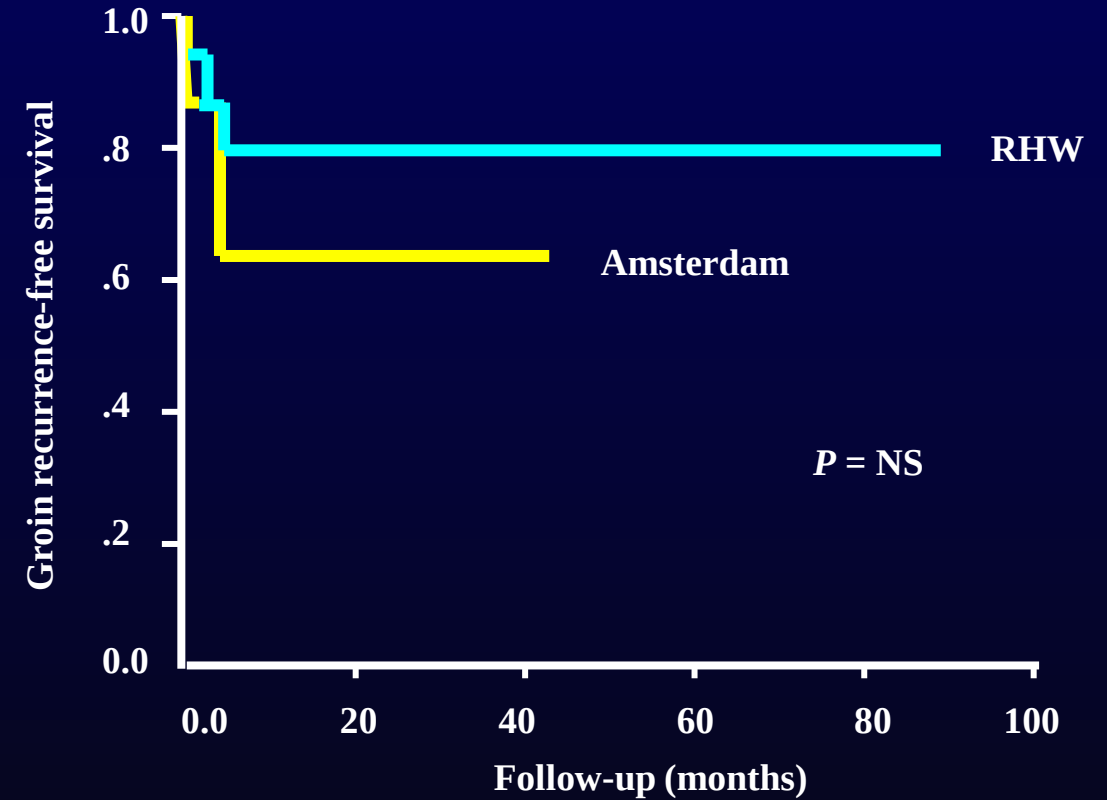


Debulking of groin lymph nodes

Disease-specific Survival



Groin recurrence-free survival

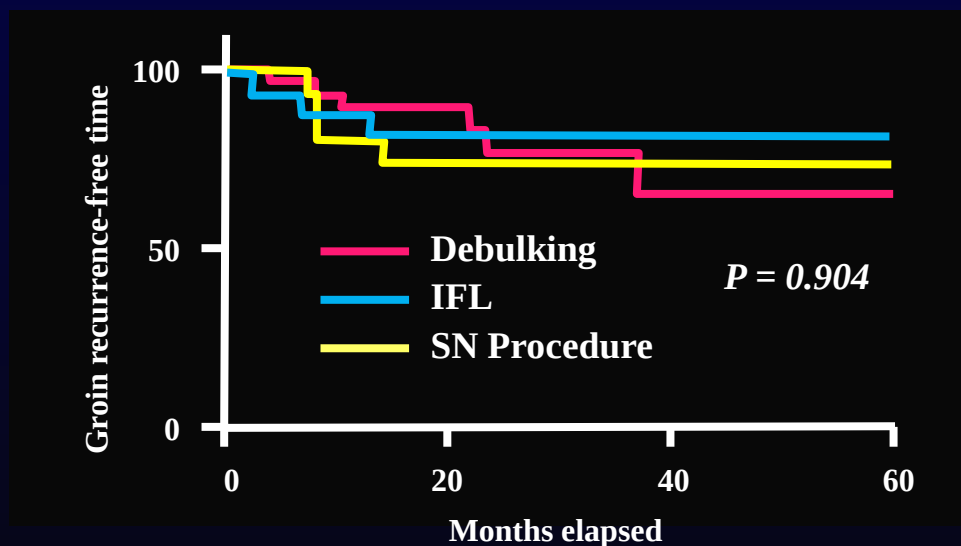


— Nodal debulking N = 17
— Groin dissection N = 23

Groin surgery vs risk of recurrence in patients with lymph node positive vulvar cancer

- Number of patients 68
- Sentinel node biopsy 12
- I-F lymphadenectomy 23
- Nodal debulking 33

Adjuvant radiation was given to 82% of patients



Nooij LS (Leiden),
Gynecol Oncol,
2015; 139: 458-464.

Patients having nodal debulking had significantly fewer lymphocysts ($p = 0.032$) and less lymphedema ($p = 0.002$) than patients having I-F LND.

Article

Selective Removal of Only Clinically Suspicious Positive Lymph Nodes Instead of a Complete Inguino-Femoral Lymph Node Dissection in Squamous Cell Carcinoma of the Vulva

Guus Fons ¹, Nikki B. Thuijs ², Ming Tjong ¹, Lukas J. A. Stalpers ³ and Jacobus van der Velden ^{1,*}

¹ Department of Gynecologic Oncology, Amsterdam UMC, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands; g.fons@amsterdamumc.nl (G.F.); m.tjong@amsterdamumc.nl (M.T.)

² Department of Pathology, Amsterdam UMC, University of Amsterdam, Meibergdreef 9, 1081 HV Amsterdam, The Netherlands; n.thuijs@amsterdamumc.nl

³ Department of Radiotherapy, Amsterdam UMC, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands; l.stalpers@amsterdamumc.nl

* Correspondence: j.vandervelden@amsterdamumc.nl; Tel.: +31-205669111

Simple Summary: When there is evidence for the spread of a vulvar tumor to the regional lymph nodes in the groins, local resection of the primary tumor and complete removal of these regional lymph nodes, which is frequently followed by radiotherapy, is recommended. This treatment results in significant side effects. Alternative treatment methods with fewer side effects are therefore being explored. In this study, 40 patients with evidence for spread of the tumor to the lymph nodes, resulting in large (bulky) nodes, were treated with removal of the enlarged lymph nodes only, followed by radiotherapy, leaving behind the nodes that looked normal. The survival of this group was compared with a similar group of 37 patients treated with the removal of all nodes in the groin(s). Although in both groups the survival rate was poor (5 years survival: 29.4% vs. 23.8%), there was no difference between the groups. Therefore, we recommend removing only bulky nodes in cases where there is a proven spread of the tumor in these nodes.

Citation: Fons, G.; Thuijs, N.B.; Tjong, M.; Stalpers, L.; van der Velden, J. Selective Removal of Only Clinically Suspicious Positive Lymph Nodes Instead of a Complete Inguino-Femoral Lymph Node Dissection in Squamous Cell Carcinoma of the Vulva. *Cancers* **2023**, *15*, 3844. <https://doi.org/10.3390/cancers15113844>

Abstract: Background. The oncological safety of only removing bulky, positive groin lymph nodes followed by radiotherapy without performing a complete inguino-femoral node dissection (IFL) in

Variable

Nodal Debulking
(N = 40)

I-F LND
(N =37)

Median age (yrs)

74

77

Med Tumor diameter (mm)

48

46

Diameter largest node (mm)

29

21

Extranodal spread

63%

68%

Nodal metastases >15mm

85%

78%

Conclusion

The selective removal of suspicious inguinal nodes yields similar oncological outcomes compared with patients matched for important prognostic variables and treated with a complete IFL when both are followed by radiotherapy

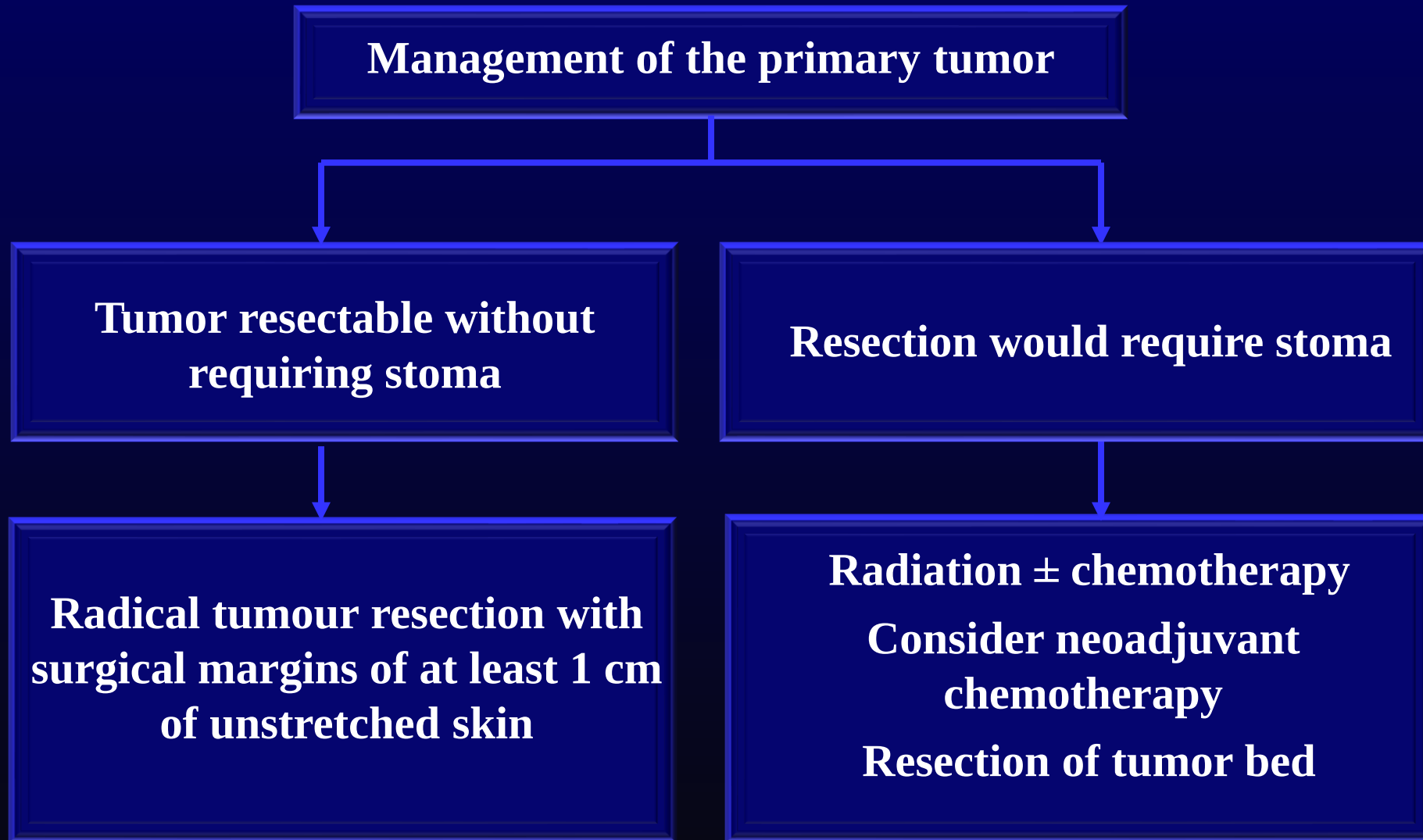
- Data from the Gynaecologic Oncology Department at Amsterdam UMC 1985 -2020
- After 2007, nodal debulking replaced complete I-F LND

Management of Squamous Vulvar Cancer

- Management of early primary cancers, including surgical margins
- Management of lymph nodes in early vulvar cancer
- Management of lymph nodes in late vulvar cancer
- *Management of the advanced primary cancers*



Management of Locally Advanced Primary Tumor

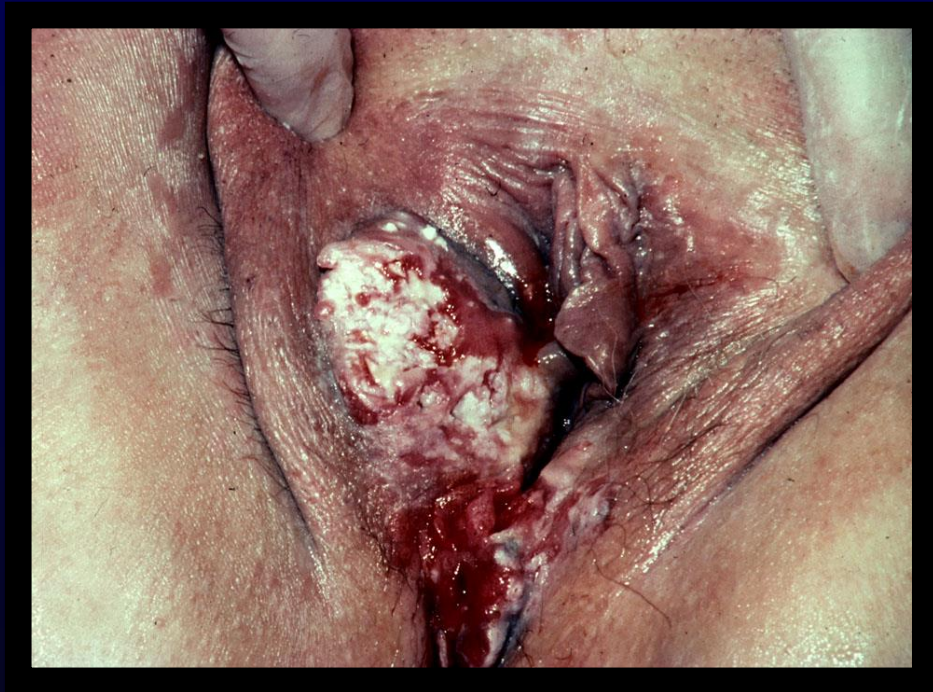


- Large primary tumor involving the distal vagina, close to urethra, but well clear of anus
- No palpably enlarged groin nodes



- Radical resection of primary lesion, including resection of distal 1 cm of urethra; gracilis myocutaneous graft to repair the defect.
- Bilateral inguinal-femoral lymphadenectomy
- One positive node (<5 mm). No RT

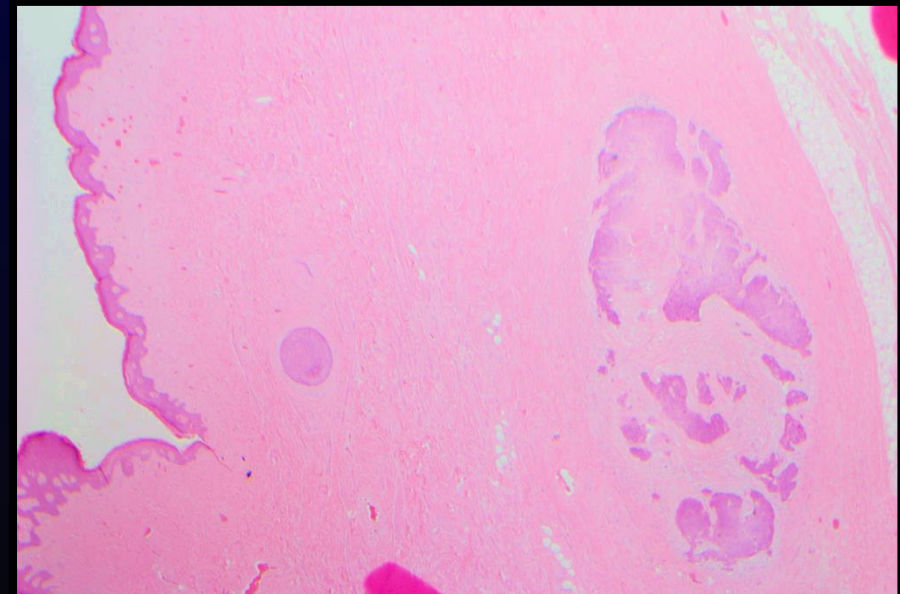
- Large T3 cancer involving anus.
- Resection would necessitate colostomy



Microscopic residual disease



Same patient post external radiation



Tumour bed resected 6 weeks post-radiation

Improved survival with definitive chemoradiation compared to definitive radiation alone in squamous cell carcinoma of the vulva: A review of the National Cancer Database

Yuan James Rao ^{a,1}, Re-I China^{a,1}, Caressa Hui ^a, David G. Mutch ^b, Matthew A. Powell ^b, Julie K. Schwarz ^a,

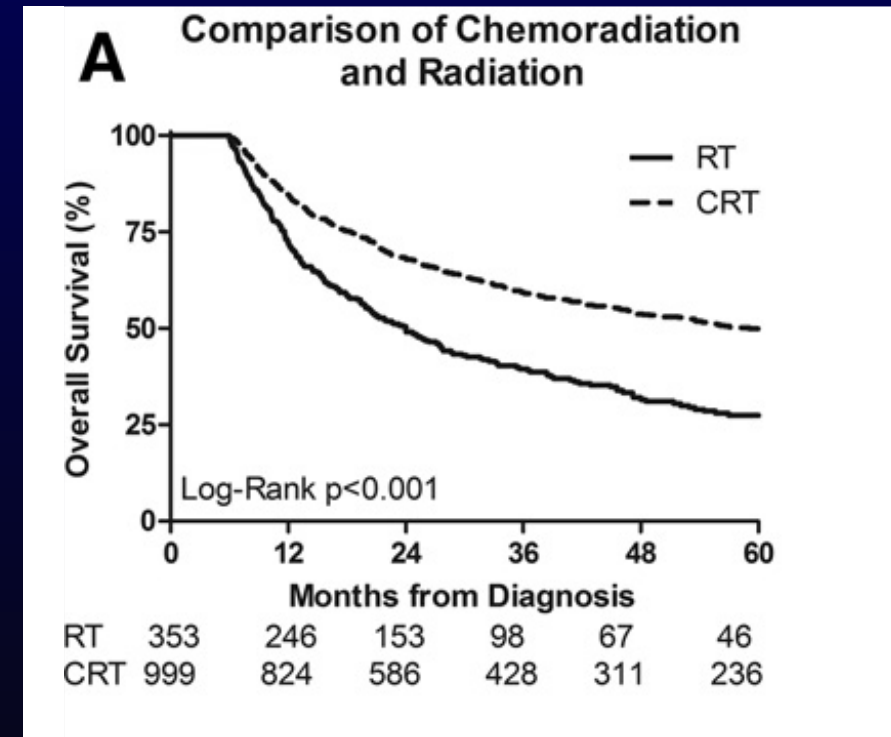
Perry W. Grigsby ^a, Stephanie Markovina ^{a,*}

^a Department of Radiation Oncology, Washington University School of Medicine, 660 S. Euclid Ave., St. Louis, MO 63110, United States

^b Division of Gynecologic Oncology, Washington University School of Medicine, 660 S. Euclid Ave, St. Louis, MO 63110, United States

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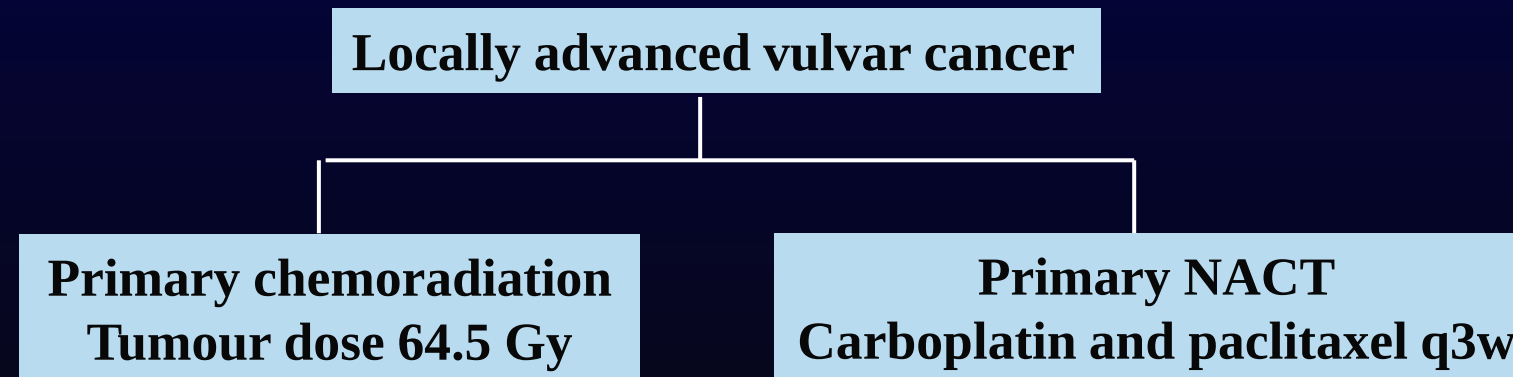


- These data were based on 1352 patients identified from the National Database between 2003 and 2014.
- Patients receiving chemo RT were younger ($p < 0.001$) and had more advanced disease ($p < 0.001$)
- Median radiation dose was 5940 cGy (4000-7920 cGy)
- An earlier Cochran Review had shown no advantage to the addition of chemotherapy

Is there a role for neoadjuvant chemotherapy in patients with advanced vulvar cancer?



This is a multicentre, prospective phase II randomised trial



- Patients with pelvic node metastases are not eligible
- Estimated sample size is 98
- Complete accrual expected in 2028, with presentation of results in 2030

Conclusions Regarding Vulvar Cancer Management

- **Surgery for vulvar cancer should be centralized and individualized**
- **Radical local excision with 1 cm margins is appropriate for unifocal T1 and T2 lesions**
- **Margins less than 5 mm should be treated by re-excision or radiation**
- **Patients with ≥ 2 positive nodes or with extranodal spread should be treated with bilateral groin and pelvic radiation**
- **Bulky positive nodes should be resected without removing normal sized nodes prior to bilateral groin and pelvic radiation**
- **If resection of advanced cancer would necessitate a stoma, primary radiation therapy, or neoadjuvant chemotherapy on a trial, should be used**
- **For unifocal cancers ≤ 4 cm, sentinel node biopsy should be performed, and patients with negative sentinel nodes should be followed with second monthly groin ultrasound for at least 12 months**
- **Patients with positive sentinel nodes ≤ 2 mm diameter should be treated with bilateral groin and pelvic radiation**
- **Patients with positive sentinel nodes >2 mm should have at least removal of the positives node(s) before bilateral groin and pelvic radiation**

THANK YOU FOR YOUR ATTENTION

