New NCCN Guidelines® for Vulvar Cancer

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NCCN Guidelines Version 1.2016 Panel Members

Vulvar Cancer (Squamous Cell Carcinoma)

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Vulvar Cancer

Objectives:

1) Overview of vulvar carcinoma and FIGO staging.
2) Understand the application of surgery and sentinel lymph node evaluation.
3) Understand the use of radiation and/or chemotherapy in the treatment of vulvar carcinoma.

Vulvar Cancer

2016

5,950 | Cases
1,110 | Deaths

Majority squamous histology (90%)
HPV-dependent & HPV-independent pathways

Carcinoma in Situ (CIS)
small, thick lesions should be excised

Vulvar Cancer

1912 – Radical vulvectomy with bilateral regional lymph nodes was described as the standard approach by Basset. The tenets of en bloc resection was performed only on cadavers.

Dr. S. Way demonstrated improved survival, international adoption of radical surgery.

Little changed until late 1970’s.

Survival predominately dependent on node status.

**Survival**

Negative Lymph Nodes – 70 to 80%
Positive Lymph Nodes – 30 to 40%


Starting in the 1980’s – modifications of treatment to reduce morbidity:

- Groin breakdown
- Leg edema
- Sexual function
- Organ preservation

Goal: Improved quality of life.
Vulvar Cancer

**Modifications**
- Regional Lymph Node Management – unilateral cancers
- Radical Local Excision
- Separate Groin Incision
- Lymphatic Mapping
- Radiation
- Chemotherapy
- Exenteration

Punch Biopsy of Vulva
Vulvar Dystrophy

Paget’s Disease of Vulva
Vulvar Carcinoma in situ

Vulva Carcinoma in situ
Vulvar Cancer

Carcinoma of the Vulva Pre-treatment

Vulvar Cancer
Vulvar Cancer

Recurrent CA Vulva | Status post XRT and now surgery
Radiation Necrosis

Resection w/ removal of pubic bone
Vulvar Cancer
Principles of Vulvar Surgery

- Adequate surgical margin of 1 to 2 cm at primary surgery.
- Lymph node status most important determinant of survival.
- Vulvar midline lesion needs bilateral inguinofemoral groin node evaluation.
- Vulvar lateral lesion (> 2cm from vulva midline) & ipsilateral groin node evaluation.
- Sentinel lymph node biopsy in selected patients.
- Advanced vulvar cancers need individualized therapy approach.
Vulvar Cancer

Carcinoma of the Vulva: Treatment

- Microinvasive defined as <1 mm
- Unilateral carcinoma
  - Limited radical vulvectomy and ipsilateral inguinal femoral node dissection
- Modification of radical vulvectomy
- Sentinel lymph node biopsy
- Lymph node dissection through separate incision
- Postoperative radiation therapy for node positive patients
- Radiation therapy and chemotherapy for inoperable carcinomas
Vulvar Cancer

Sentinel Lymph Node Biopsy (SLNB) Meta-Analysis

- SLNB detection rate of 87% (using radiocolloid and blue dye)
- SLNB – false negative rate was 6.4%
- Recurrence rate:
  - SLNB – 2.8%
  - IFLD – 1.4% (Inguinal Femoral Lymph Node Dissection)

Covens A. Gynecol Oncol 2015;137(2):351-361

Vulvar Cancer

Patient Selection for SLNB

- Unifocal tumor less then 4cm
- Clinically non-suspicious nodes in the groin
- No previous vulvar surgery
- Adequate experience and resources

Covens A. Gynecol Oncol 2015;137(2):351-361
Lymphatic Mapping and Sentinel Node Identification

Carcinoma of Vulva

- Lymphazurin blue dye
- Lymphoscintigraphy

Artist Credit: S.C. McQueen
SYSTEMIC THERAPY

Chemoradiation
• Cisplatin
• 5-FU and cisplatin
• 5-FU and mitomycin-C

Chemotherapy for Advanced, Recurrent/Metastatic Disease
• Cisplatin
• Cisplatin/vinorelbine
• Cisplatin/paclitaxel

VULVA-C

CLINICAL STAGE  PATHOLOGIC FINDINGS  PRIMARY TREATMENT

Early Stage:
• T1, Smaller T2  Biopsy

≤1 mm invasion
Wide local resection  Observe

>1 mm invasion

Lateral lesion (≥2 cm from vulvar midline)

Vulvar midline lesion (anterior or posterior)

VULVA-2
CLINICAL STAGE
(Early Stage T1, Smaller T2)

Lateral lesion
(≥2 cm from vulvar midline)
- Radical local resection or modified radical vulvectomy and ipsilateral groin node evaluation
  - Sentinel lymph nodes (SLNs) or ipsilateral groin lymph node (LN) dissection

Vulvar midline lesion
(anterior or posterior)
- Radical local resection or modified radical vulvectomy and bilateral inguinalofemoral groin node evaluation
  - SLNs or bilateral inguinalofemoral groin LN dissection

PRIMARY TREATMENT

- Assessment of primary tumor and nodal surgical pathology
- See Adjuvant Therapy based on Primary Tumor Risk Factors (VULVA-3) and Nodal Status (VULVA-4)

“\textit{The best interest of the patient is the only interest to be considered.}”

William J Mayo, MD
References


- Willis A, Overmair A. A review of complications associated with the surgical treatment of vulvar cancer. Gynecol Oncol 2013;131:467-479


References


Book Chapters

- Greer, BE, Berek JA – Evolution of Primary Treatment of Invasive Squamous Cell Carcinoma of the Vulva. In Gynecology Oncology Treatment Rationale and Techniques | Edited by Greer BE ; Berek JS | New York: Elsevier 1991: 227


New NCCN Guidelines® for Vulvar Cancer

Wui-Jin Koh, MD
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NCCN.org – For Clinicians | NCCN.org/patients – For Patients
NCCN Guidelines for Vulvar Cancer – Underlying principles

- Vulvar cancers are rare tumors
  - Heterogeneous presentation and risk
  - Only 2 randomized treatment trials ‘completed’
  - A handful of important prospective observational studies

- Early stage disease – often cured by resection alone
  - Evolution from ‘Halstedian’ approach to more limited, tailored surgery
  - Sentinel lymph node evaluation
    » GROINSS-VI (van der Zee, JCO 2008; Grootenhuis, Gynecol Oncol 2016)
      - < 3% groin relapse in SLN negative patients (unifocal, < 4 cm)
    » GOG 173 (Levenback, JCO 2012)
      - False negative predictive value 3.7% (tumors 2-6 cm)
      - False negative predictive value 2.0% for tumors < 4 cm
NCCN Guidelines for Vulvar Cancer –
Underlying principles

- Site matters! – primary site vs groins
- Often considered ‘separately’ in treatment planning
  - Metachronous groin failures occur early; rarely curable
  - Local vulvar failures occur later and are often cured with additional surgery (recurrence vs reoccurrence)

  » Stehman, Am J Obstets Gynecol 1996
  » Oonk, Cancer 2003
  » Cormio, Eur J Cancer Care 2010
  » Grootenhuis, Gynecol Oncol 2016
  » Frey, Int J Gynecol Oncol 2016

NCCN Guidelines for Vulvar Cancer –
Underlying principles

- For early stage tumors - adjuvant radiotherapy is an effective treatment modality that significantly decreases recurrence in surgically resected groins with positive LN(s), leading to improvements in RFS and OS
  - Greatest independent predictor of groin relapse is groin node involvement at presentation
  - Radiation to the vulva can lead to significant morbidity

- For locally advanced disease - neoadjuvant radiotherapy (typically with chemotherapy) results in significant clinical and pathologic responses, allowing for reduced-scope/non-exenterative surgery
NCCN Guidelines for Vulvar Cancer – Underlying principles

- Chemotherapy in addition to radiation (concurrent) may provide additional therapeutic benefit
  - Especially in advanced, ‘unresectable’ disease
  - May help address systemic risk in patients with multiple positive LNs

GOG 37: N=114 pts (Homesley, Obstet Gynecol 1986)
- Groin LN +, s/p RV and bilateral full (S&D) groin (inguinal-femoral) dissection, randomized to:
  - Bilat pelvic node dissection vs bilat groin/pelvic RT
  - 45-50 Gy @ 1.8-2.0 Gy/fx (Ant/Post photons)
- Study closed at interim analysis – RT advantage
  » Surgical control - 24% groin failure rate
  » XRT - 5% groin failure rate
  » 2 yr Overall Survival: 68% RT vs 54% S (p=.03)
  » 2 yr CSS: 75% RT vs 54% S (p=.004)

“Subset analysis” - Predominant advantage to RT for ≥ 2 LN +, or clinical N2/N3 (suspicious/fixed/ulcerated)
Adjuvant therapy for GN+ vulvar ca

All patients, OS, \( p = 0.03 \)

Homesley, Obstet Gynecol 1986

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Adjuvant therapy for GN+ vulvar ca

All patients, relative survival
\( P = 0.004 \)

Homesley, Obstet Gynecol 1986
Adjuvant therapy for GN+ vulvar ca

Clinical N0/N1 vs N2/N3
(suspicious/fixed/ulcerated)

1 vs ≥ 2 LN+

Homesley, Obstet Gynecol 1986

GOG 37 – long-term outcomes
Median at risk follow up = 74 months
(Kunos, Obstet Gynecol, 2009)

- Hazard Ratio for OS (All-cause Death) = 0.61
  - 95% CI 0.30-1.30 (p=0.18)
  - ‘Favors’ Radiation

Courtesy - Kunos
GOG 37 – long-term outcomes
(Kunos, Obstet Gynecol, 2009)

- Hazard Ratio for Cancer-related Death = 0.44
  - 95% CI 0.19-0.98
  - $P = 0.04$
  - Favors Radiation
  - Benefit manifested via improved groin control:
    S – 24% recur, R – 5% recur

GOG 37 – long-term outcomes
(Kunos, Obstet Gynecol, 2009)

- Persistent groin control and survival benefit favoring RT for
  - $\geq 2$ LN+ : $p < 0.001$
  - N2/N3 (suspicious/fixed/ulcerated): $p = 0.004$
    » Currently ‘re-interpreted’ as Extra-capsular extension (ECE) or “gross” tumor (size threshold?)

- Chronic lymphedema ~ 20%
  - No observable increase with RT (under-evaluated)
  - Associated with DM, cardiovascular disease

Courtesy - Kunos
Adjuvant therapy considerations for 1 groin LN+

- Adj RT for single LN+?
  - GOG 37 was a positive trial for ALL LN+ pts
  - Benefit if less extensive GND? (≤ 12 LNs removed) (Parthasarathy, SEER analysis, Gynecol Oncol 2006)

GOG 37 – long-term outcomes
(Kunos, Obstets Gynecol, 2009)

- Ratio: \( \frac{\text{# positive LNs}}{\text{# resected LNs}} \) > 20%
  - Contralateral LN+: \( P=0.02 \)
  - Pelvic LN+: \( P=0.06 \)
  - Recurrence: \( P=0.03 \)
  - Cancer-related death: \( P=0.02 \)
Adjuvant therapy considerations for 1 groin LN+
GOG 37 – long-term outcomes
(Kunos, Obstets Gynecol, 2009)

Impact of RT on RFS, based on ≤20% vs >20% nodal involvement
Useful clinical decision-making tool

Adjuvant therapy considerations for 1 groin LN+

Size of sentinel-node metastasis and chances of non-sentinel-node involvement and survival in early stage vulvar cancer: results from GROINSS-V, a multicentre observational study

Interpretation: Our data show that the risk of non-sentinel-node metastases increases with size of sentinel-node metastasis. No size cutoff seems to exist below which chances of non-sentinel-node metastases are close to zero. Therefore, all patients with sentinel-node metastases should have additional groin treatment. The prognosis for patients with sentinel-node metastasis larger than 2 mm is poor, and novel treatment regimens should be explored for these patients.

Lancet Oncol 2010
Prophylactic Groin RT (no IFND) in vulvar cancer

- GOG 88 - Clinical N0/N1 vulvar cancer (RV) randomized to groin dissection vs RT
  (Stehman, Int J Radiat Oncol Biol Phys 1992)

  Groin dissection - 5/25 pts with + nodes
  - all received post-op RT
  - no groin recurrence

Groin RT - 5/27 patients failed in-field

Concluded that groin radiation group had significantly decreased survival, PFI, and regional tumor control

Radiation patients received 50 Gy at 3 cm, 50% electrons

Groin RT for vulvar cancer

GOG RT manual (2013) – gog.org
Groin RT for vulvar cancer

T3N0 vulvar cancer

Groin RT for vulvar cancer
Isodose distribution for 50% electrons/50% photons
dosed at 3 cm depth
Prophylactic Groin RT in vulvar cancer

- Very few groin nodes lie within 3 cm of skin
  - (Koh, IJROBP 1993; Eifel, Front Radiat Ther Oncol 1994)

- Clinical palpation of groins is unreliable
  - Subclinical disease ≠ microscopic disease
  - CT-based planning is necessary

- Proper radiation treatment planning allows good groin prophylaxis
  - Petereit, IJROBP 1993
  - Leiserowitz, Gynecol Oncol 1997
  - Katz, IJROBP 2003

GROINSS-VII
(van der Zee)

Unifocal tumor
Opened 2006

- Vulvar cancer T1/T2 < 4cm
- Squamous cell histology
- Depth of invasion >1mm
- Clinical N0

CT/MRI groin(s)
SN biopsy - Blue dye/lymphoscintigraphy (combined technique preferred)

SN – Observation
SN + Radiotherapy (CT-based)
50 Gy to involved groin(s) and low pelvis
Chemo optional

GROnigen International Study on Sentinel nodes in Vulvar cancer – II
SN – Sentinel node
GROINSS-VII/GOG 270

Vulvar cancer
T1/T2 < 4cm
Squamous cell histology
Depth of invasion >1mm
Clinical N0

Re-opened 2011 after interim safety analysis
10/82 SLN+ pts recur
1/46 groins SLN+ ≤ 2mm
9/45 groins SLN+ > 2mm

‘Inadequacy’ of RT to the undissected groin: Potential causes

- Inadequate RT coverage – GOG 88
- Tumor biology
  - Residual tumor volume
  - SLNB-induced changes to the groin microenvironment
    » Tumor hypoxia, accelerated repopulation
- Other reasons?
Scope of RT for GN+ vulvar ca

- **Issues**
  - GOG 37 radiated bilateral groins and pelvis, regardless of nodal laterality
  - Current emphasis on minimizing toxicity and reducing extent of therapy in early stage disease (risk of lymphedema with RT following GND)
  - Adequacy of contralateral groin evaluation

- **Incidence of contralateral (undissected) groin +, when ipsilateral groin is +**
  - ~20% in GOG surgicopathologic study of 277 lateral vulvar cancers, especially if tumor thickness > 5mm (Holmesley, Gynecol Oncol 1993)
  - ~18% in Mayo study of 163 lateral tumors, (tumor size > 2 cm, thickness > 5 mm, or > 2 ipsilat LN+) (Bosquet, Gynecol Oncol 2007)

- **Management of the pelvis**
  - 28% of patients with GN+ had pelvic LN+ on GOG 37 PND arm (Holmesley, Obstet Gynecol 1986)
  - Mayo analysis – 14/108 (13%) of GN+ had pelvic LN+, increasing to 40% if > 2 GN+ (Bosquet, Gynecol Oncol 2007)
Vulvar cancer T1/T2 < 4cm
Squamous cell histology
Depth of invasion >1mm
Clinical N0

- **SN**
  - **SN -**
  - **SN +**
    - ≤ 2mm: **Observation**
    - > 2mm:
      - **Radiotherapy (CT-based)**
        - 50 Gy to involved groin(s) and low pelvis
        - Chemo optional
      - **Full lymphadenectomy**
      - **Radiotherapy**
        - 50-56 Gy to involved groin(s) and low pelvis
        - Chemo optional

**Clinical considerations for coverage:**
- Size of primary tumor
- Location of primary tumor
- # ipsilateral groin nodes+

**4 field**

**IMRT**
Adjuvant RT for vulvar ca - Primary site?

- Predictors of vulvar relapse (Heaps, Gyn Oncol 1990)
  - Tumor-free margin < 8mm (48% LF)
    » de Hullu, Cancer 2002; Chan, Gynecol Oncol 2007
    » Viswanathan, Gynecol Oncol 2013 – used 5 mm margin cutoff
  - Tumor thickness, depth of invasion > 10mm
  - ‘Spray’ pattern histology
  - Vascular space invasion

- Toxicity of RT to vulvar tissues
- Majority of vulvar relapses salvageable

Adjuvant RT for vulvar ca - Primary site?

- RT to primary site improves LC substantially in patient with close or positive surgical margins
  Faul, IJROBP 1997; Viswanathan Gynecol Oncol 2013

- “My practice pattern” – adjuvant primary site RT
  - If patient is not candidate for further surgery
    » + margin(s)
    » ≥ 3 ‘Heaps factors’, or 2 factors and LN+
Adjuvant therapy for groin node + vulvar ca
Concurrent chemotherapy?

- No phase III data

- **GOG 37** (Holmesley, Obstets Gynecol 1986)
  - Groin node +, superior RT arm
    » 2 year survival rate = 68%
  - Pelvic LN+
    » 2 yr survival rate = 23%

- Extrapolated data of enhanced response rates and distant control with chemoRT in LN+ cancers (cervix, rectal)

- Elderly with medical comorbidities

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**GOG 37 – long-term outcomes**
(Kunos, Obstets Gynecol, 2009)

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Pelvic Node Resection</th>
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<tbody>
<tr>
<td>Distant</td>
<td>Distant</td>
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<tr>
<td>9</td>
<td>8</td>
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<td>3</td>
<td>13</td>
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<td>7</td>
<td>6</td>
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3 concurrent local & distant relapses counted separately

Courtesy - Kunos

Systemic Risk – implications for therapy?
Impact of adjuvant chemotherapy with radiation for node-positive vulvar cancer: A National Cancer Data Base (NCDB) analysis


Conclusion: In a large population-based analysis, adjuvant chemotherapy resulted in a significant reduction in mortality risk for node-positive vulvar cancer patients who received adjuvant radiotherapy.

Vulvar Cancer (Squamous Cell Carcinoma)

PRIMARY TUMOR RISK FACTORS

- Negative margins
- Positive margin(s) for invasive disease

ADJUVANT THERAPY TO THE PRIMARY SITE

- Negative margins for invasive disease: Observe or Adjuvant RT based on other risk factors
- Positive margins for invasive disease: Adjuvant RT
- Unresectable: See Surveillance (VULVA-8)

VULVA-3
Vulvar cancer – locally advanced
T4N2
Vulvar cancer – locally advanced T4N2

GOG 101 - Preop CRT for local-regionally advanced vulvar ca
(Moore 98, Montana 2000, IJROBP)

<table>
<thead>
<tr>
<th>Week</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<tbody>
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<td>5FU</td>
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<td>Cisplatin</td>
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<tr>
<td>RT</td>
<td>X X X X X</td>
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<td>X X X X</td>
<td>X X X X</td>
<td>X X X X</td>
<td>X X X X</td>
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<tr>
<td>RT - 47.6 Gy in 28 fx</td>
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RT - 47.6 Gy in 28 fx
GOG 101 - Preop CRT for locally regionally advanced vulvar ca

- **Primary tumors** (Moore, IJROBP 98)
  - 71 evaluable patients (non primary RV candidates)
  - 2 unresectable, 1 exent, 2 colostomies
  - All others underwent resection of tumor bed (or bx’s if cCR)
  - 34 cCR (48%), 22 pCR (31%)
  - 55% A/NED, median 50 m f/u

- **Groin nodes** (Montana, IJROBP 2000)
  - 38/40 (95%) of groins rendered resectable
  - 41% pCR
  - 12 pts A/NED, median 78 m f/u

Locally advanced vulvar cancer – GOG 205
(Moore, Gynecol Oncol 2012)

- Evaluated primary tumor only (successor to GOG 101)
  - Increase RT dose to GTV to 57.6 Gy
  - Weekly CDDP @ 40 mg/m2/wk x 6-7 cycles (no 5FU)
  - Eliminate elective break
  - All patients undergo initial bilateral GND unless unresectable
    - groin node RT is then tailored to groin pathology findings (GOG bias)
  - Endpoint analysis: 45% pCR (20% relative improvement over 31% pCR in GOG 101)
  - 58 evaluable patients (non primary RV candidates)
**Locally advanced vulvar cancer**

**GOG 101 vs 205** *(Moore, Gyn Oncol 2012)*

<table>
<thead>
<tr>
<th></th>
<th>GOG 101</th>
<th>GOG 205</th>
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<tr>
<td>Evaluable</td>
<td>71</td>
<td>58</td>
</tr>
<tr>
<td>CCR</td>
<td>34 (48%)</td>
<td>37 (64%)</td>
</tr>
<tr>
<td>PCR</td>
<td>22 (31%)</td>
<td>29 (50%)</td>
</tr>
<tr>
<td>PCR/CCR</td>
<td>22/34 (65%)</td>
<td>29/37 (78%)</td>
</tr>
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**GOG 279 - successor trial to GOG 205: locally advanced vulvar cancer**

- Cisplatin/gemcitabine/RT phase II study
  - Increase GTV dose to 64 Gy
  - IMRT incorporated to reduce toxicities
- Primary endpoint goal – pCR ≥ 65%
  - If pCR sufficiently high, especially in cCR cases, do all patients need post-chemoRT surgery?
Vulvar cancer – locally advanced

IMRT for locally advanced vulvar cancer

- Beriwal, Gynecol Oncol 2008
  - ~ 45 Gy pre-op, with 2 cycles 5FU/CDDP
  - Surgical resection 6-8 wks later
  - N=18 pts
  - cCR – 13/18 (72%)
  - pCR – 9/14 (64%)
  - No Gr ≥3 acute nor late toxicities
Vulvar cancer – locally advanced

BUT... Generous RT coverage is needed
- Not analogous to early vulvar cancer with ‘skin-bridge’ preservation, ‘triple incisions’
- May have significant altered/obstructed lymphatics
Locally advanced vulvar cancer

- Initial ChemoRT to primary, groins, and pelvis
  - Concurrent weekly cisplatin (30-40 mg/m²/wk)
  - 45 Gy to at-risk, microscopic CTV
  - 57.6 – 60 Gy to GTV (primary and nodes)
    » Careful use of IMRT (generous volumes)
  - Re-image and reevaluate at 6-8 weeks
    » Resect/biopsy primary tumor site
    » Limited groin resection of imageable residual
  - In clearly node+ cases, I favor up-front chemoRT to avoid delay of primary therapy, groin wound breakdown prior to RT, etc.