Chapter 33
Vulvar Cancer

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PEARLS

- ~5% of all gynecologic malignancies in the United States.
- Anatomy: mons pubis, clitoris, labia majora, labia minora, vaginal vestibule, Bartholin's glands (at posterior labia majora), prepuce over clitoris, posterior fourchette, perineal body.
- Approximately 70% arise in the labia and ~15% arise in the clitoris or perineal body.
- Common presenting symptoms: pruritus, pain, and/or palpable vulvar mass or ulcer.
- Risk factors: HPV, vulvar intraepithelial neoplasia (2–5% progress to vaginal cancer), history of genital warts, multiple sexual partners, history of abnormal Pap smears, immunosuppression, smoking, increasing age, Bowen's disease, Paget's disease, leukoplakia.
- ~80–90% are squamous cell carcinomas. Bartholin's tumors can be adenocarcinomas, adenoid cystic carcinomas, or squamous if they arise in the ductal squamous epithelium. Other histologies: melanoma, sarcoma, basal cell carcinoma, Merkel cell tumors, carcinoid, transitional cell carcinoma, apocrine gland cancer, Paget's disease, and metastatic lesions.

Eric K. Hansen and M. Roach III (eds.), *Handbook of Evidence-Based Radiation Oncology*, https://doi.org/10.1007/978-3-319-62642-0_33

- Melanomas <10% of primary tumors, but are the second most common malignancy of the vulva.
- LN involvement is the most important prognostic factor for survival. 5-yr OS: 86% if limited to vulva, 54% if regional nodes involved, 16% if metastatic disease. ~23% of pts have a local recurrence at 5 years.
- LN spread is to inguinofemoral nodes (superficial and deep). Most superior deep femoral node = Cloquet's node.
- Clitoris can theoretically drain directly to pelvic LN, but rare without inguinofemoral LN involvement.
- Risk of nodal involvement correlates with stage and depth of tumor invasion:
  - IA <1 mm deep <5%, 1–3 mm deep 8–10%, 3–5 mm deep 20%.
  - 5 mm deep or >2 cm size 40%.
  - III 30–80%.
  - IV 80–100%.
- Approximately 20–25% of cN0 pts are pN+.
- Overall incidence of pelvic LN+ is 5%. If inguinal LN+, ~30% risk of pelvic LN+.
- HPV or p16 positivity is associated with better PFS and fewer in-field relapses after RT in vulvar SCC

WORKUP

- H&P with examination under anesthesia (EUA).
- Colposcopy and biopsy of primary and FNA or excisional biopsy of clinically positive inguinal nodes.
- Pap smear of cervix and vagina.
- Cystoscopy, urethroscopy, and/or sigmoidoscopy may be indicated for advanced stages and/or bladder/bowel symptoms.
- CBC, UA, LFT/renal function studies.
- CXR. CT/PET/MRI as needed for evaluating extent of tumor, nodal involvement, and/or for treatment planning.
- Smoking cessation and counseling, if indicated.

STAGING: VULVAR CANCER

Editors' note: All TNM stage and stage groups referred to elsewhere in this chapter reflect the 2010 AJCC staging nomenclature unless otherwise noted as the new system below was published after this chapter was written.

Table 33.1 (AJCC 7TH ED., 2010/FIGO 2008)

Primary tumor (T)		
TNM	FIGO	
Categories	*Stages*	
TX		Primary tumor cannot be assessed
T0		No evidence of primary tumor
Tis*		Carcinoma in situ (preinvasive carcinoma)
T1a	IA	Lesions 2 cm or less in size, confined to the vulva or perineum and with stromal invasion 1.0 mm or less**
T1b	IB	Lesions more than 2 cm in size *or* any size with stromal invasion more than 1.0 mm, confined to the vulva or perineum
T2***	II	Tumor of any size with extension to adjacent perineal structures (lower/distal 1/3 urethra, lower/distal 1/3 vagina, anal involvement)
T3****	IVA	Tumor of any size with extension to any of the following: upper/proximal 2/3 of urethra, upper/proximal 2/3 vagina, bladder mucosa, rectal mucosa, or fixed to pelvic bone

**Note*: FIGO no longer includes stage 0 (Tis)
***Note*: The depth of invasion is defined as the measurement of the tumor from the epithelial–stromal junction of the adjacent most superficial dermal papilla to the deepest point of invasion
***FIGO uses the classification T2/T3. This is defined as T2 in TNM
****FIGO uses the classification T4. This is defined as T3 in TNM

Table 33.1 (CONTINUED)

Regional lymph nodes (N)		
TNM	*FIGO*	
Categories	*Stages*	
NX		Regional lymph nodes cannot be assessed
N0		No regional lymph node metastasis
N1		One or two regional lymph nodes with the following features
N1a	IIIA	One lymph node metastasis each 5 mm or less
N1b	IIIA	One lymph node metastasis 5 mm or greater
N2	IIIB	Regional lymph node metastasis with the following features
N2a	IIIB	Three or more lymph node metastases each less than 5 mm
N2b	IIIB	Two or more lymph node metastases 5 mm or greater
N2c	IIIC	Lymph node metastasis with extracapsular spread
N3	IVA	Fixed or ulcerated regional lymph node metastasis
Distant metastasis (M)		
TNM	*FIGO*	
Categories	*Stages*	
M0		No distant metastasis
M1	IVB	Distant metastasis (including pelvic lymph node metastasis)

Anatomic stage/prognostic groups

0*: Tis N0 M0
I: T1 N0 M0
IA: T1a N0 M0
IB: T1b N0 M0
II: T2 N0 M0
IIIA: T1, T2 N1a, N1b M0
IIIB: T1, T2 N2a, N2b M0
IIIC: T1, T2 N2c M0
IVA: T1, T2 N3 M0
T3 Any N M0
IVB: Any T Any N M1

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FIGO staging: Pecorelli 2009, Copyright 2009, with permission from Elsevier
*Note: FIGO no longer includes stage 0 (Tis)

Table 33.2 (AJCC 8TH ED., 2017)

Definitions of AJCC TNM

Definition of primary tumor (T)

T category	FIGO stage	T criteria
TX		Primary tumor cannot be assessed
T0		No evidence of primary tumor
T1	I	Tumor confined to the vulva and/or perineum Multifocal lesions should be designated as such. The largest lesion or the lesion with the greatest depth of invasion will be the target lesion identified to address the highest pT stage The depth of invasion is defined as the measurement of the tumor from the epithelial-stromal junction of the adjacent most superficial dermal papilla to the deepest point of invasion
T1a	IA	Lesions 2 cm or less, confined to the vulva and/or perineum, and with stromal invasion of 1.0 mm or less
T1b	IB	Lesions more than 2 cm, or any size with stromal invasion of more than 1.0 mm, confined to the vulva and/or perineum
T2	II	Tumor of any size with extension to adjacent perineal structures (lower/distal third of the urethra, lower/distal third of the vagina, anal involvement)
T3	IVA	Tumor of any size with extension to any of the following—upper/proximal two thirds of the urethra, upper/proximal two thirds of the vagina, bladder mucosa, or rectal mucosa—or fixed to the pelvic bone

VIII

DEFINITION OF REGIONAL LYMPH NODE (N)

N category	FIGO stage	N criteria
NX		Regional lymph nodes cannot be assessed
N0		No regional lymph node metastasis
N0(i+)		Isolated tumor cells in regional lymph node(s) not greater than 0.2 mm
N1	III	Regional lymph node metastasis with one or two lymph node metastases each less than 5 mm, or one lymph node metastasis =5 mm
N1a*	IIIA	One or two lymph node metastases each less than 5 mm
N1b	IIIA	One lymph node metastasis =5 mm
N2		Regional lymph node metastasis with three or more lymph node metastases each less than 5 mm, or two or more lymph node metastases =5 mm, or lymph node(s) with extranodal extension
N2a*	IIIB	Three or more lymph node metastases each less than 5 mm
N2b	IIIB	Two or more lymph node metastases =5 mm
N2c	IIIC	Lymph node(s) with extranodal extension
N3	IVA	Fixed or ulcerated regional lymph node metastasis

*Includes micrometastasis, N1mi, and N2mi

Note: The site, size, and laterality of the lymph node metastases should be recorded

DEFINITION OF DISTANT METASTASIS (M)

M category	FIGO stage	M criteria
M0		No distant metastasis (no pathological M0; use clinical M to complete stage group)
M1	IVB	Distant metastasis (including pelvic lymph node metastasis)

AJCC PROGNOSTIC STAGE GROUPS

When T is…	And N is…	And M is…	Then the stage group is…
T1	N0	M0	I
T1a	N0	M0	IA
T1b	N0	M0	IB
T2	N0	M0	II
T1–T2	N1–N2c	M0	III
T1–T2	Nl	M0	IIIA
T1–T2	N2a, N2b	M0	IIIB
T1–T2	N2c	M0	IIIC
T1–T3	N3	M0–M1	IV
T1–T2	N3	M0	IVA
T3	Any N	M0	IVA
Any T	Any N	M1	IVB

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TREATMENT RECOMMENDATIONS

Table 33.3 TREATMENT RECOMMENDATIONS

Stage	Recommended treatment
CIS	Local excision or CO_2 laser
IA	Wide local excision (WLE). Post-op RT (50 Gy) to vulva for + margin, margin<8 mm, LVSI, or depth > 5 mm. [Sample lymph nodes for lesion with >1 mm depth of invasion]
IB/II	WLE with ipsilateral (superficial) LN dissection or sentinel lymph node biopsy for lateralized lesions. Bilateral (superficial) LN dissection for central lesions, lesions>5 mm deep, LVSI, or poorly differentiated lesions. If LN+, add deep inguinal dissection. Post-op RT to vulva for + margin, margin<8 mm, LVSI, or lesions >5 mm deep. Post-op RT to inguinal and pelvic nodes for >1 LN+, or nodal ECE Alternatively, consider pre-op chemo-RT (50 Gy for cN- or 54 Gy for cN+) for lesions close to urethra, clitoris, or rectum because margin may be difficult to obtain. Either elective chemo-RT to groins or planned LN dissection (before or after chemo-RT). If bilateral LN dissection performed initially, pathologic LN findings dictate whether or not RT needed to groins. However, chemo-RT to primary lesion could be delayed. If primary lesion has CR to chemo-RT, consider biopsy, and if negative observation. If <CR or biopsy demonstrates persistent disease, resect with functional preservation if possible, or boost primary to 65–70 Gy or consider radical vulvectomy

Table 33.3 (CONTINUED)

Stage	Recommended treatment
III/IVA	If cN0, perform bilateral LN dissection first followed by chemo-RT to vulva or vulva and inguinal/pelvic nodes (for ECE, >1 LN+) If cN+ fixed or ulcerated, pre-op chemo-RT (45–50 Gy with cisplatin, 5-FU, and/or mitomycin C) provides about 50% CR. Follow with bilateral LN dissection. Surgical salvage for persistent or recurrent disease. If nodal ECE boost to 60 Gy; if gross residual take to 65–70 Gy

STUDIES

INDICATIONS FOR ADJUVANT POST-OP VULVAR RT

- Heaps (Gynecol Oncol 1990): review of surgical-pathologic factors predictive of LR for 135 pts with vulvar CA. Increased LR with + margin, margin <8 mm pathologically or <1 cm clinically, LVSI, and depth > 5 mm.

INDICATIONS FOR PELVIC/INGUINAL RT

- GOG 37 (Homesley, Obstet Gynecol 1986): 114 pts treated with radical vulvectomy and b/l inguinal LND and found to have any inguinal LN+ were randomized to pelvic LN dissection (n = 55) vs. post-op RT (n = 59) with 45–50 Gy to pelvic and b/l inguinal LN (but not to vulva). RT decreased groin recurrence (5% vs. 24%) and improved 2-yr OS (68% vs. 54%). Subset analysis showed benefit only in cN+, pts with >1 pN+ or +LN with ECE. No difference in pelvic recurrence.
- GOG 37 update (Kunos, Obstet Gynecol 2009): 74 mo median survivor f/u. 6-yr OS: 51% post-op RT vs. 41% PLND (p = 0.18). 6-yr cancer-related deaths: 51% post-op RT vs. 29% PLND (SS). >20% ratio of positive ipsilateral LN (# positive LN/# resected) associated with contralateral LN met, relapse, and cancer-related death. Similar late toxicities rates between post-op RT and PLND.

NODAL EVALUATION AND MANAGEMENT

- GOG 88 (Stehman, IJROBP 1992): 121 pts with IB–III cN0 treated with radical vulvectomy randomized to b/l inguinal RT (50 Gy to D3, without pelvic RT) vs. b/l radical LN dissection. If pLN+, then received RT (50 Gy) to b/l groin and pelvis. Interim analysis of only 58 pts demonstrated improved 2-yr OS (90% vs. 70%) with surgery and decreased inguinal recurrences.
  - Criticisms: RT addressed only inguinal nodes, whereas surgery included pelvic LN dissection if inguinal LN+; arms biased since no CT used for staging; poor technique of RT (prescribed to D3, all inguinal recurrences received < prescribed dose); 50 Gy should sterilize microscopic disease as evidenced by University of Wisconsin retrospective review with good technique (Petereit, *IJROBP*1993).
- Kirby (Gynecol Oncol 2005): retrospective review of 65 pts with stage I/II vulvar cancer treated with vulvectomy and superficial inguinal lymphadenectomy (SupIL). Pts with pathologically negative SupIL had 4.6% recurrence rate in the inguinal region and 16.9% recurrence on the vulva. 5-yr DFS and OS were 66% and 97%, respectively.
- Van der Zee (JCO 2008): observational study looking at 623 groins in 403 pts. 259 pts with unifocal vulvar disease and negative sentinel node (SN). 3-yr groin recurrence rate was 2.3% and OS 97%. Short-term and long-term morbidity was decreased with sentinel node removal vs. sentinel node removal + inguino-femoral lymphadenectomy. Basis for GOG 173.
- GOG 173 (Levenbach, JCO 2012): 452 pts with SCC vulva, depth of invasion at least 1 mm, tumor limited to the vulva, primary tumor size 2–6 cm, no inguinal LN on exam, had SLNB followed by lymphadenectomy. SLN identified in 92% of pts, of which 32% were positive, but 8% false-negative SLN rate (positive LN found with complete dissection). For pts with tumors <4 cm, if SLN negative, the risk of a false-negative SLN is <3%.

CHEMO-RT

- GOG 101 (Moore, IJROBP 1998): phase II trial of 41 pts with unresectable T3 or T4, any LN status treated with pre-op chemo-RT with 1.7 Gy b.i.d. d1–4, 1.7 Gy qd d5–12 to 23.8 Gy with cisplatin on d1 and 5-FU on d1–4 → 2 week break → repeat to total dose 47.6 Gy. For cN0, RT was to vulvar area only and for cN+ included inguinal and pelvic LN. Surgery 4–8 wks after chemo-RT. Pre-op chemo-RT had 47% cCR and 55% 4-yr OS (expect 20–50%). 54% had gross residual disease, but only 3% were unresectable.
- GOG 101 (Montana, IJROBP 2000): 46 pts with advanced disease in the inguino-femoral nodes (stage IVA) N2/N3 received a split course of RT (47.6 Gy) to the primary and LN with concurrent cisplatin/5-FU followed by surgery. 95% were deemed resectable after chemo-RT. LC of primary and lymph nodes was 76% and 97%, respectively.
- Landrum (Gynecol Oncol 2008): 63 pts with stage III/IV disease treated with primary surgery vs. primary chemo-RT (weekly cis or 2 cycles of cisplatin plus 5-FU with RT). Primary chemo-RT pts were younger (61 vs. 72 yo), had fewer nodal metastasis (54% vs. 83%), and larger tumors (6 vs. 3.5 cm). No difference in OS, PFS, or recurrence rates between surgery and chemo-RT groups.
- GOG 205 (Moore, Gynecol Oncol 2012): phase II, 58 pts, unresectable T3 or T4, any N. RT (1.8 × 32 daily fx = 57.6 Gy) with weekly cisplatin (no 5-FU) followed by resection of residual disease. cCR in 37 pts (64%), of which 29 had pCR (50% of total).

IMRT

- Beriwal (IJROBP, 2006): retrospective study, 15 pts treated with IMRT; 7 pts with pre-op chemo-RT (cis + 5FU) and 8 pts with post-op RT. Median dose: 46 Gy in the pre-op, 50.4 Gy post-op groups. Mean volume > 30 Gy was reduced with IMRT vs. 3D CRT: small bowel (44% vs. 71%); rectum (45% vs. 87%); bladder (62% vs. 88%). Grade 3 small-bowel toxicity in 1 pt. At median f/u 12 mos, 5 pts (71%) had cCR and 3 pts (42.8%) had pCR in pre-op group. In the adjuvant group, 2 pts had recurrences in the treatment field. No late Grade 3 toxicities.

- Beriwal (IJROBP, 2013): retrospective study, 42 pts, stage I-IVA treated twice-daily IMRT and with 5-FU/cisplatin during the first and last weeks of treatment or weekly cisplatin with daily RT. Median dose 46.4 Gy. 33 pts (78.6%) had resection of vulva, 13 of which had inguinal LND. pCR in 48.5%, of which 15 had no recurrence within a median time of 26.5 mos. 17 pts had partial CR, 8 of which (47.1%) developed recurrence in the vulvar surgical site within a median follow-up of 8 mos. No grade 3 chronic GI/GU toxicities.

MIDLINE BLOCK

- Dusenberry (IJROBP 1994): 27 pts with stage III/IV disease with pLN+ treated with post-op RT with a midline block. 48% central recurrence rate with the use of the midline block. Authors recommended including tumor bed (no midline block) post-op RT for pts with LN+.

RADIATION TECHNIQUES

SIMULATION AND FIELD DESIGN

- Simulate supine, frog-leg position with custom immobilization.
- Wire vulva, anus, scars. Simulate with and without bolus or use virtual bolus in planning. If rectum distended >3.5 cm, repeat simulation after further bowel prep.
- Traditional borders: superior = L5/S1 or mid SI if clinically no involved pelvic LN (L4/5 if pelvic LN+); inferior = flash vulva and 3 cm inferior to bottom of ischium; lateral = 2 cm beyond pelvic brim and greater trochanter (anterior superior iliac spine) to include inguinal LN.
- Bolus vulva +/- groin(s) prn. Confirm dose received under bolus with TLDs early in treatment course.
- CT plan depth of groin nodes. May need to boost groins with en face electrons.
- MRI may identify satellite lesions, muscle invasion, and/or dermal involvement not easily identified on CT.

- Follow consensus recommendations for contouring vulva and regional nodes (Gaffney, IJROBP 2016). Consider IMRT to reduce dose to normal structures.
  - GTV = gross disease on exam, CT, MRI.
  - Primary CTV:
    - Always include at least 1 cm margin on GTV and entire vulva.
    - If GTV invades vagina, include 3 cm CTV margin on GTV or entire vaginal canal.
    - If GTV invades anus, bladder, or rectum, include 2 cm CTV margin on anorectum or bladder.
    - If GTV invades urethral meatus, include 2 cm CTV margin.
    - If GTV invades mid or proximal urethra, include entire urethra and bladder neck in CTV.
    - If GTV invades clitoris, include 2 cm CTV margin.
    - If post-op, negative margins, include entire operative bed. If close/+ margin, add 2 cm margin.
  - LN CTV:
    - In general, include entire nodal bed plus echelon above grossly involved LN. If groin node grossly involved, include contralateral groin in CTV too.
    - For lesions involving only vulva or vulva and distal vagina, include bilateral inguino-femoral, obturator, internal and external iliac LN.
    - If proximal half of posterior vagina involved, also include presacral S1–S3 nodes.
    - If anus/anal canal involved, include bilateral inguino-femoral, obturator, internal and external iliac, perirectal, and presacral nodes.
  - PTV = CTV + 0.7–1 cm depending on body habitus, stability.

DOSE PRESCRIPTIONS

- 1.8 Gy/fx.
- Post-op: 45-50.4 Gy to vulva tumor bed and regional LN. Boost primary up to 60–70 Gy for close or involved margins. Boost nodal extracapsular extension to 54–60 Gy.

- Definitive: primary and involved nodes 60–70 Gy; 45–50.4 Gy for elective nodes.
  - Boost may require brachytherapy.

DOSE LIMITATIONS

- Small bowel <45–55 Gy, prefer V40 Gy to V45 Gy <30%
- Femoral heads <45 Gy, prefer V30 Gy <50%, V40 Gy < 35%, V44 Gy <5%
- Bladder <60 Gy, prefer V45 Gy to V50 Gy <35%
- Rectum <60 Gy, prefer V45 Gy <60%
- Lower vagina <75–80 Gy

COMPLICATIONS

- Acute: epilation of pubic hair, hyperpigmentation, skin reaction, moist desquamation, diarrhea, cystitis.
- Late: atrophy of skin and telangiectasia, shortening and narrowing of vagina, vaginal dryness. Femoral neck fracture <5%, associated with osteoporosis and smoking.

FOLLOW-UP

- H&P q3–6 mo × 2 yrs, every 6–12 mo × 3–5 yrs, then annually based on risk of disease recurrence.

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