The Hong Kong Society for Colposcopy and Cervical Pathology Clinical Pathological Conference:

VAIN and VIN

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Case 1
Case History

* F/54, Para 3
* Menopaused for 2 years
* Pap smear (24/4/2014): low grade squamous intraepithelial lesions

* Colposcopy: pinpoint cervix, squamo-columnar junction not seen, mild acetowhite at 3-6 o'clock of upper vagina, no punctation or mosaicism, no iodine uptake at vagina till 1cm from cervix
Colposcopy
Case History

- Vaginal biopsy, right side: VAIN II and HPV effect
  Vaginal biopsy, left side: VAIN I and HPV effect

- Discussed extended hysterectomy + bilateral salpingoophorectomy
  Option of monitoring told, with chance of progression of disease

- Opt for observation, plan follow up 6 months later
Case 1

Right: VAIN II
Left: VAIN I
HPV effect in background
P16 staining – block positive on high grade VAIN
Left vaginal biopsy: VIN I and HPV effect
Case 2
Case History

* F/52, Para 2
* First presented in 2011 with postmenopausal bleeding

* **Physical examination:** 3cm cervical tumor and induration of vaginal mucosa at the vaginal fornices

* **Colposcopy:** 3cm cervical tumor with atypical vessels involving bilateral fornices and anterior vagina, acetowhite lesion down to anterior one third of vagina
Case History
Cervical and anterior vaginal biopsy: squamous cell carcinoma

Radical hysterectomy, bilateral salpingoophorectomy and pelvic lymph node in November 2011

Pathology: squamous cell carcinoma of cervix and VAIN III at vaginal cuff with clear margins

Adjuvant whole pelvis irradiation and cisplatin
Case History

* Vault smear August 2012: negative for intraepithelial lesion or malignancy

* Vault smear February 2013: high grade squamous intraepithelial neoplasia (HSIL)

* Colposcopy: 2cm long vagina with iodine stain negative and acetowhite lesion at right vaginal vault

* Vaginal biopsy: VAIN III
Case History

- Vaginectomy in May 2013
- Pathology showed VAIN III, clear resection margins
Vault smear Nov 2013: HSIL

Colposcopy: 1cm vagina with dense acetowhite, mosaic pattern and punctuation over posterior vagina and lower distal urethra

Cystoscopy: normal, urethral length 2cm
Case History

* Vaginal biopsy showed VAIN III
* Complete vaginectomy and distal urethra resection in August 2014
* Pathology: VAIN III with no invasion
Case 2
2011: SCC cervix

• Vaginal cuff margin: VAIN II

• (SCC cervix: 0.8 cm invasion, 3.5 cm span, right and left pelvic LN+)
Cervix
Cervix: SCC
Cervix: SCC, stromal invasion
Vaginal cuff margin: high grade dysplasia
Case 2: HSIL

2013 Vault smear 1
HSIL

2013 Vault smear 2
2014
Vaginectomy: VAIN III
2014: Vaginectomy: VAIN III
2014: Vaginectomy: VAIN III
Case 2

• 2011: ca cervix, vagina involved, margin: moderate dysplasia (VAIN II)

• 2012, 2013 : Vault smears ASCH; HSIL.

• 2013: vaginal biopsy: VAIN III; vaginal excision: VAIN III with minimal clearance: 1 mm.

• 2014: vaginal biopsy: VAIN III.

• 2014: vaginectomy: VAIN III, mucosal margins involved at 4, 10 o’clocks.
VAIN
VAIN

* Incidence 0.2 to 0.3 per 100,000 women
* Mean age 35 years old

Risk factors
* Smoking, low social economic status, history of abnormal Pap smear, genital warts, early hysterectomy

Clinical Features of 121 Patients with Vaginal Intraepithelial Neoplasia (VAIN)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>VAIN I</td>
<td>40</td>
<td>33%</td>
</tr>
<tr>
<td>VAIN II</td>
<td>55</td>
<td>46%</td>
</tr>
<tr>
<td>VAIN III</td>
<td>26</td>
<td>21%</td>
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<table>
<thead>
<tr>
<th>Location</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Upper third</td>
<td>94</td>
<td>78%</td>
</tr>
<tr>
<td>Middle third</td>
<td>5</td>
<td>4%</td>
</tr>
<tr>
<td>Lower third</td>
<td>5</td>
<td>4%</td>
</tr>
<tr>
<td>Upper/middle thirds</td>
<td>4</td>
<td>3%</td>
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<tr>
<td>Upper/middle/lower thirds</td>
<td>1</td>
<td>1%</td>
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<tr>
<td>Indeterminate</td>
<td>12</td>
<td>10%</td>
</tr>
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<table>
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<tr>
<th>Focality</th>
<th>Count</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Unifocal</td>
<td>43</td>
<td>39%</td>
</tr>
<tr>
<td>Multifocal</td>
<td>67</td>
<td>61%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical intraepithelial neoplasia (concomitant or antecedent)</td>
<td>60</td>
<td>65%</td>
</tr>
<tr>
<td>Vulvar intraepithelial neoplasia (concomitant or antecedent)</td>
<td>12</td>
<td>10%</td>
</tr>
</tbody>
</table>

Dodge JA et al 2001
Retrospective study of 23 untreated VAIN

* At least 3 years follow up
* Progress to invasive cancer: 9%
* VAIN persist: 13%
* VAIN regress: 78%

Markku A et al 1991
Table 2. Normalization, Persistence, Progression, and Recurrence Rates by Grade of Dysplasia in the Natural History Group and the Treatment Group

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>VAIN 1</th>
<th>VAIN 2 or VAIN 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Natural history group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normalization</td>
<td>74</td>
<td>60</td>
<td>14</td>
</tr>
<tr>
<td>Persistence</td>
<td>7 (9)</td>
<td>6 (10)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Progression</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Recurrence</td>
<td>3 (4)</td>
<td>3 (5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Treatment group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normalization</td>
<td>53</td>
<td>15</td>
<td>38</td>
</tr>
<tr>
<td>Persistence</td>
<td>4 (8)</td>
<td>2 (13)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Progression</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Recurrence</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

VAIN, vaginal intraepithelial neoplasia.
Data are n or n (%).
* P=.99.
† P=.57.
VAIN

Retrospective study, 100 VAIN II/III, 32 VAIN I

* Progression of VAIN II/III to invasive cancer: 8%
* No VAIN I progress to invasive cancer
VAIN – Signs and Symptoms

- Asymptomatic: 94%
- Recurrent vaginal discharge: 2%
- Abnormal vaginal bleeding: 3%

- Present with abnormal cytology: 76%
- Present with vaginal warts: 22%

VAIN – Diagnosis

* Diagnosis by colposcopy directed vaginal biopsy

* Acetowhite epithelium: 84%
* Absence of iodine uptake: 81%
* Punctuation: 14%
* Mosaicism 2%

VAIN – Treatment

* **Conservative**

* **Medical**: topical imiquimod, 5-fluorouracil, tricholoroacetic acid

* **Surgical**: laser ablation/ excision, vaginectomy

* **Brachytherapy**

Factors affecting choice of treatment:

* Age
* Comorbidities
* Number and location of lesions
* Length of vagina
* Sexual activity
* Grade of VAIN
* Previous treatment, previous radiotherapy
* Physician experience
* Patient preference
VAIN – Treatment

Vaginectomy

* **Cure rate**: 80% (24 VAIN II/III cases)
* **Advantage**: Assess possibility of invasive cancer and resection margins (occult invasion in 13%)
* **Disadvantage**: bladder or rectal injury, loss of coital function, vesicovaginal fistula, rectovaginal fistula

* More successful than laser treatment in hysterectomized group (79% versus 54% success rate)

Laser ablation

- **Cures rate**: 68% (28 VAIN II/III cases)
- **Advantage**: minimal blood loss, suitable for multifocal lesions, sexual function can be retained
- **Disadvantage**: no histology, invasive cancer may be missed

- Not desirable for VAIN at vaginal vault
- VAIN III in vaginal vault treated with laser ablation associated with higher risk of recurrence (OR 2.07)

Intravaginal 50% tricholoroacetic acid
* Successful in 53% (17 VAIN II/ III), 100% (11 VAIN I cases)
  (At least 1 year follow up)

5-fluorouracil cream
* Successful in 46%
  (11 VAIN II/ III cases, 0.2-19 years follow up)

VAIN – Treatment

Brachytherapy

* Considered in highly selected patients such as poor surgical candidate with extensive VAIN

* Local control rate: 93%
  (28 VAIN III cases, mean follow up 41m)

Blanchard et al 2011
VAIN - Recurrence

Vaginal Intraepithelial Neoplasia Recurrence According to the Method of Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of recurrences/total number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-Fluorouracil</td>
<td>13/22 (59.1%)</td>
</tr>
<tr>
<td>Laser</td>
<td>16/42 (38.1%)</td>
</tr>
<tr>
<td>Partial vaginectomy</td>
<td>0/13 (0%)</td>
</tr>
</tbody>
</table>

*Note. P = 0.001. Table includes patients (n = 77) who received treatment for VAIN and were followed up for 7 or more months and had at least one posttreatment Papanicolaou smear.*

Another study recurrence following vaginectomy: 17% (23 VAIN III)
## Risk Factors for VAIN Recurrence among 92 Patients Followed Up for ≥7 Months

<table>
<thead>
<tr>
<th>Factor</th>
<th>Number of recurrence/total number (%)</th>
<th>Odds ratio</th>
<th>95% confidence interval</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;35</td>
<td>16/54 (30%)</td>
<td>0.7</td>
<td>(0.3, 1.8)</td>
<td>0.50</td>
</tr>
<tr>
<td>≥35</td>
<td>14/38 (37%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAIN type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>8/17 (47%)</td>
<td>2.1</td>
<td>(0.7, 6.2)</td>
<td>0.16</td>
</tr>
<tr>
<td>I or II</td>
<td>22/75 (29%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAIN location</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper one-third</td>
<td>22/70 (31%)</td>
<td>0.8</td>
<td>(0.3, 2.2)</td>
<td>0.67</td>
</tr>
<tr>
<td>All other</td>
<td>8/22 (36%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAIN focality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multifocal</td>
<td>21/47 (45%)</td>
<td>3.3</td>
<td>(1.3, 9.0)</td>
<td>0.02</td>
</tr>
<tr>
<td>Unifocal</td>
<td>7/36 (19%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laser or 5-FU</td>
<td>29/64 (45%)</td>
<td>22.4</td>
<td>(1.3, 393.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vaginectomy</td>
<td>0/13 (0)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dodge JA et al 2001
Followed up with colposcopy and cytology

No evidence to support optimal interval and duration of follow up

6 monthly to annual follow up

Late progression to invasive cancer has been reported (up to 14 years)

Long term followed up

Case 3
Case History – May 2009

* F/86
* First presented in May 2009 for itchy left vulval mass for 2 months

* Physical examination: pinkish discoloration at both vulva, 4 cm x 3 cm raised erythematous plaque-like lesion at left vulva
Case History
Case History

- Vulval biopsy: VIN III
- Left simple vulvectomy done on 20/7/09
- Pathology: very extensive VIN III, medial margin involved, no stromal invasion
Case History – Jan 2011

* Colposcopy: 1.5 cm raised lesion at posterior part of right labia majora, dense acetowhite changes with punctuation

* Vulval biopsy: VIN II, no invasion
Case History

* Wide local excision done 19/9/2011

* Pathology: right and left vulval skin: VIN III, resection margins involved
* Moderate acetowhite lesion over upper vulval region, dense acetowhite lesion over left para-urethral region

* Left para-urethral biopsy, right vulva biopsy: VIN III, no stromal invasion

* 5% Imiquimod application twice weekly for 8 weeks
Follow up in Jan 2013, August 2013

* Colposcopy: dense acetowhite at periurethral region & upper vulva
* Para-urethral, left vulval biopsy: VIN III, no stromal invasion
* Patient refuse surgery
* Advised to observe lesion and report if any suspicious changes
* Colposcopy: dense acetowhite at periurethral region & upper vulva
Case History – June 2014

* Right vulval biopsy: At least VIN III, invasion cannot be excluded
  Left vulval biopsy: VIN II

* Refuse surgery, plan follow up 6 months
Case 3

Vulva: High grade squamous intraepithelial lesion
2009: Left vulva, simple vulvectomy
2011: wide local excision
2011 WLE, HSIL (VIN III)
• 2009: left vulva, simple vulvectomy: VIN 3, extensive, no stromal or lymphovascular invasion. Medial margin +.
• 2011: WLE: VIN III, margin +.
• 2012: right and left peri-urethral biopsies — VIN III.
  2013: Left vulva and periurithral biopsies: VIN III
  2014: Right vulval biopsy: at lest VIN III, invasion cannot be excluded. Left: VIN II.

HPV (koilocytosis) in background.
2014: right vulval biopsy
At least VIN III: stromal invasion?
At least VIN III: stromal invasion not excluded
• VIN III, usual type
• HPV related (Koilocytosis +)
• Small tumor nests/buds, anastomosing—suspicous of invasive squamous cell carcinoma.
VIN

* Incidence 1.2 to 2.1 per 100,000 women
* Mean age 46 years old
* Incidence is on the rise, mean age decreasing
* Associated with immunocompromised (4.3%), smoking (67%), human papillomavirus (92%)

VIN

* Premalignant lesion, 9% of 88 untreated patients progress in 12 to 96 months to invasive vulvar carcinoma

* VIN III progression to invasive vulvar carcinoma: 6.5%

* Occult carcinoma in 3.2-22% of VIN II/III

* Spontaneous regression of VIN II/III: 1.2 to 12%, most related to pregnancy

VIN

* Multifocal in 51%, unifocal in 49%

* Most commonly affected sites: labia majora, labia minora, posterior fourchette

van de Nieuwenhof HP et al 2008, ACOG 2011, McNally OM et al 2002
VIN - Classification

International Society for the Study of Vulvovaginal Disease 2004 classification:

* VIN apply to high grade squamous lesions (former VIN 2 and VIN 3)
* VIN 1 no longer use
VIN - Classification

2 types of VIN

* Usual (90%)
  Associated with HPV, younger patients

* Differentiated type (6%)
  Associated with vulvar dermatologic conditions such as lichen sclerosis, older patients

VIN – Signs and Symptoms

* Pruritus (in 60%, most common symptom)
* Asymptomatic (22%)
* Pain
* Dysuria
* Lesions mostly elevated, can be flat
* Color from white to gray, red to brown to black

van de Nieuwenhof HP et al 2008, ACOG 2011, McNally OM et al 2002
VIN – Signs and Symptoms

* Ulcerated, eroded or roughened surface suggest invasion

* Examine with colposcopy after applying 3-5% acetic acid for several minutes, examine whole genital tract
  - Acetowhite lesion
  - Abnormal vessels (mosaicism, punctuation)
* Diagnosis by histology
VIN - Treatment

Aim

* Exclude invasive disease
* Relieve symptoms
* Eradicate HPV infection
* Minimize distortion of adjacent tissues
* Reduce risk of progression to invasive disease
* Sustain remission

Todd RW et al 2005
VIN - Treatment

* Wide local excision preferred initial intervention
* Aim margin 0.5 to 1 cm

* No difference in recurrence between local excision and vulvectomy

ACOG 2011, van Seters M et al 2005
Laser vaporization if cancer not suspected, ablate to 2mm depth
Cure rate lower than excisional technique

Retrospective study, VIN
- 14 laser vaporization, 38 laser excision
- 87% cured by excision
- 75% cured by vaporization

Sideri M et al 1999
VIN - Treatment

* Medical management lower success rate
* Can be considered for recurrent disease, multifocal disease, ruled out cancer
RCT: imiquimod versus placebo

* Imiquimod cream twice weekly for 16 weeks
* Imiquimod group 26 cases, placebo 26 cases

* Reduction in size >25% at 20 weeks:
  - imiquimod 81%, placebo 0%
* HPV cleared from lesion:
  - imiquimod 58%, placebo 8%

van Seters M et al 2008
RCT: imiquimod versus placebo

* At 1 year, 35% complete response (elimination), 46% partial response (reduction in size 26 to 75%) in imiquimod group

* Progress to invasive disease (12 months follow up): Imiquimod 1 case, placebo 2 cases

van Seters M et al 2008
### Table 2. Side Effects.

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Imiquimod (N=26)</th>
<th>Placebo (N=26)</th>
<th>P Value*</th>
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<tbody>
<tr>
<td>Reported by the patient:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vulvar pain or pruritus</td>
<td>24</td>
<td>7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Headache</td>
<td>7</td>
<td>5</td>
<td>0.52</td>
</tr>
<tr>
<td>Apathy</td>
<td>5</td>
<td>0</td>
<td>0.03</td>
</tr>
<tr>
<td>Weariness</td>
<td>8</td>
<td>4</td>
<td>0.20</td>
</tr>
<tr>
<td>Muscular ache</td>
<td>3</td>
<td>1</td>
<td>0.35</td>
</tr>
<tr>
<td>Flulike symptoms</td>
<td>5</td>
<td>3</td>
<td>0.47</td>
</tr>
<tr>
<td>Other side effects:‡</td>
<td>4</td>
<td>4</td>
<td>1.00</td>
</tr>
<tr>
<td>No side effects</td>
<td>1</td>
<td>13</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Reported by the investigator:

<table>
<thead>
<tr>
<th>Erythema</th>
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</thead>
<tbody>
<tr>
<td>Mild-to-moderate</td>
<td>14</td>
<td>2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Severe</td>
<td>6</td>
<td>0</td>
<td>0.02</td>
</tr>
<tr>
<td>Erosion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild-to-moderate</td>
<td>17</td>
<td>5</td>
<td>0.001</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
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<tr>
<td>Vesiculation</td>
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<td>0.06</td>
</tr>
<tr>
<td>Edema</td>
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<td>&lt;0.001</td>
</tr>
<tr>
<td>Ulceration</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
</tbody>
</table>

van Seters M et al 2008
* Cidofovir cream and 5-fluorouracil varying efficacy, more adverse effects, fallen out of favour

* Other treatment: photodynamic therapy, corticosteroid, retinoids, interferon alfa: either limited data or poor results

Todd RW et al 2005
Systemic review with 3322 VIN III cases

- Vulvectomy: 19% recurrence
- Local excision: 22% recurrence
- Laser vaporization: 23% recurrence

Van Seters M et al 2005
**Table 1. Comparison of Vulvar Intraepithelial Neoplasia III Patients With and Without Recurrent Disease**

<table>
<thead>
<tr>
<th></th>
<th>Recurrence</th>
<th>No recurrence</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>22</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>Average age (y)</td>
<td>42</td>
<td>47</td>
<td>.23</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>18 (82%)</td>
<td>33 (89%)</td>
<td>.60</td>
</tr>
<tr>
<td>Black</td>
<td>4 (18%)</td>
<td>3 (8%)</td>
<td>.25</td>
</tr>
<tr>
<td>Other</td>
<td>1 (3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobacco use</td>
<td>17 (77%)</td>
<td>29 (78%)</td>
<td>.90</td>
</tr>
<tr>
<td>Cervical dysplasia</td>
<td>14 (64%)</td>
<td>19 (51%)</td>
<td>.36</td>
</tr>
<tr>
<td><strong>Genital warts</strong></td>
<td>13 (59%)</td>
<td>11 (30%)</td>
<td>.03</td>
</tr>
<tr>
<td>Cervical dysplasia or genital warts</td>
<td>18 (82%)</td>
<td>22 (59%)</td>
<td>.07</td>
</tr>
<tr>
<td><strong>Multifocal lesions</strong></td>
<td>13 (59%)</td>
<td>11 (30%)</td>
<td>.03</td>
</tr>
<tr>
<td>Positive margins</td>
<td>18 (82%)</td>
<td>21 (57%)</td>
<td>.05</td>
</tr>
<tr>
<td><strong>Negative margins</strong></td>
<td>3 (14%)</td>
<td>15 (41%)</td>
<td>.03</td>
</tr>
<tr>
<td>Unknown margins</td>
<td>1 (5%)</td>
<td>1 (3%)</td>
<td>.71</td>
</tr>
<tr>
<td>Vulvar cancer</td>
<td>6 (27%)</td>
<td>9 (24%)</td>
<td>.80</td>
</tr>
</tbody>
</table>
VIN – Follow up

- Regular vulvar self examination
- Long term follow up 6 to 12 months initial year then annually
Premalignant lesion, 9% progress to invasive cancer
Low rate of spontaneous regression 1.2 to 12%
Wide local excision initial intervention
Laser vaporization lower cure rate
Medical treatment lower cure rate, most investigated → imiquimod cream
Long term follow up
- Progression of VAIN II/III to invasive cancer: 8%
- 80% may regress
- Vaginectomy higher success rate than laser vaporization or medical treatment (5-fluorouracil cream, 50% tricholoroacetic acid)
- Laser not desirable for VAIN at vaginal vault
- Brachytherapy for highly selected cases
- Long term follow up
THANK YOU!
Reference


