Modified Radical Vulvectomy for Carcinoma Vulva: Are We Following Key Quality Standards?

Uzma Khawaja¹, Nasima Tasnim², Kausar T Bangash³

Abstract
Objective: To determine the outcomes of modified radical vulvectomy for carcinoma vulva in terms of compliance with key quality standards set by southwest gynecological tumor panel.

Design: Cross-sectional study of prospectively collected data with cross-checking against the histopathology report.

Setting: MCH Unit II, Pakistan Institute of Medical Sciences, Islamabad, Pakistan.

Duration: Patients presenting with carcinoma vulva to MCH Unit II of 4 years’ duration from June 2013 to May 2017.

Methods: The study includes prospectively maintained data of patients presenting with advanced carcinoma vulva and undergoing modified radical vulvectomy as a primary surgical procedure. Data analysis was done to determine the outcome of the procedure in terms of compliance with the key quality standards.

Results: During the study period, 16 patients presented with vulval carcinoma. The majority of patients were at an advanced stage, with stage III 81% (n = 13) at presentation. Squamous cell carcinoma was the most common tissue variant. Modified radical vulvectomy with inguinofemoral lymphadenectomy was performed up to stage III disease, while patients with stage IV disease were referred to the oncology department. Regarding compliance with international quality standards, optimum inguinofemoral node dissection and surgical excision margin of >2 cm were achieved in 100% of cases, and histopathologically confirmed tumor-free margins were achieved in 94% of cases.

Conclusion: Modified radical vulvectomy with inguinofemoral node dissection is the procedure of choice for stage Ib, II, and III diseases. The high compliance rate with international standards in our study reflects an optimum standard of care provided for the management of these patients at our tertiary care hospital. The audit and subsequent dissemination of results may prove useful in the centralization of care for this rare gynecological cancer.

Keywords: Carcinoma vulva, Key quality standards, Modified radical vulvectomy.

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Introduction
Cancer of the vulva is one of the rare gynecological cancers and accounts for 4% of all female genital cancers with an incidence of 2 per 100,000 women/year.¹ ² ³ Primary surgery followed by radiotherapy remains the mainstay of therapy in stage Ib to III disease.⁴ ⁵ The traditional butterfly incision, en bloc radical vulvectomy of a vulval lesion with large areas of normal tissue and bilateral lymphadenectomy of inguinal and pelvic nodes, has undergone modifications in recent years, aiming at the conservation of healthy tissues. A modified radical vulvectomy for advanced cancers involves removal of most but not all the vulva with the aim to remove the vulval growth with an adequate tumor-free margin of 2 cm with two separate groin incisions for an inguinofemoral node dissection. Modified radical vulvectomy has superiority over radical vulvectomy by virtue of less morbidity, less primary mortality of radical surgery, and satisfactory 5-year cure rate.⁴

Despite being less morbid, modified radical vulvectomy is an extensive procedure with wound breakdown in 17% and/or infection in 39%, lymphocyst formation in 40%, and lymphedema in 28% of cases as potential complications.⁶ Other potential problems inherent to surgery include suboptimal resection of tumor margins, suboptimal inguinoemoforal lymph node dissection, and inaccurate staging. These complications are more in the hands of less-experienced surgeons.¹

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The surgery is being performed in a limited number of tertiary care hospitals. MCH Center Pakistan Institute of Medical Sciences (PIMS) being a tertiary care hospital is providing this facility to its optimum. In order to optimize the services, it is essential to have regular audits to assess compliance with international standards.

The study aims at analyzing the prospectively collected data in order to determine the compliance with key quality standards set by southwest gynecological tumor panel.¹

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Materials and Methods

Patients presenting at MCH Center PIMS with vulval carcinoma who underwent a modified radical vulvectomy from June 2013 to May 2017 were included in the study. Patients with stage IV disease and being medically unfit were excluded from the analysis.

Patients were assessed in a dedicated cancer clinic in an outpatient setting. A thorough workup was performed including history, examination, investigations (baseline, ultrasound and MRI imaging, biopsy for histopathological diagnosis, and other relevant investigations for comorbidities). Data were recorded in a predesigned structured pro forma. Cases were then discussed in tumor board consisting of clinicians, radiologists, pathologists, and oncologists in order to decide the management plan. A modified radical vulvectomy with bilateral lymphadenectomy was performed after proper preop preparation for stage Ib to III disease while cases with stage IV disease were referred to Nuclear Oncology and Radiotherapy Institute. Excision margins were defined on the basis of examination and MRI findings. The procedure involved three separate incisions. A local vulvectomy was performed aiming at a tumor-free margin of 2 cm. Bilateral inguinofemoral lymphadenectomy was performed with two separate groin incisions extending from the anterior superior iliac spine to a point adjacent to the pubic tubercle. Bilateral inguinal drains were placed with closure done with interrupted sutures (Figs 1 to 4). The tumor was staged according to the International Federation of Gynecology and Obstetrics classification on the basis of examination under anesthesia, MRI findings, and histopathology.

Proper postoperative care provided to patients included proper position, wound care, daily dressing, drains for 3 weeks, and catheter for 3 weeks.

Patients were then referred to oncology after recovery for radiotherapy/chemotherapy.

Data were analyzed in terms of compliance with quality standards set by southwest gynecological tumor panel.

Results

During the study period (June 2013–May 2017), 16 patients presented with advanced carcinoma of the vulva. Referring to Table 1 for demographic characteristics, the median age at presentation was 60 years, with a range of 25–70 years. The majority of them were postmenopausal (93%) and multipara (81%).

Referring to Table 2 for the stage of disease, the majority of patients were at a locally advanced stage with stage III (81%) at presentation. On examination, under anesthesia, 62% of tumors...
had an extension to adjacent perineal structures (distal urethra and distal vagina) without nodal involvement, 25% of patients had clinically palpable lymph nodes along with a local extension to the adjacent structures, and only 12% of patients had lesions (>2 cm) confined to the vulva/perineum with no extension to the adjacent structures. On an MRI, 37% of patients had an extension to the adjacent perineal structures without nodal involvement, 56% of patients had inguinoemeral node involvement along with a local extension, and 6% of patients had lesions (>2 cm) confined to the vulva/perineum.

Referring to Table 3 for histopathological diagnosis, squamous cell carcinoma was the most common tissue diagnosis (87.5%) with one verrucous variant, one case of sarcoma, and one case of poorly differentiated carcinoma. One hundred percent of patients had a surgical excision margin of >2 cm with a histopathological tumor-free margin of >8 mm in 94% of cases. One hundred percent of patients had bilateral lymphadenectomy with positive nodal metastasis in 87.5% of cases on histopathology.

Referring to Table 4 for compliance, 100% of cases had compliance with international protocols set by southwest gynecological tumor panel.

Regarding complications, one patient had local wound infection and dehiscence with no case of lymphedema and lymphocyst formation. There was no mortality in the study group.

**DISCUSSION**

Modified radical vulvectomy is the procedure of choice for stage Ib to III disease. However, the procedure has got its own morbidity. Regular audits to compare the outcomes with the international standards provide an opportunity to revisit the practices and modify the management accordingly. In view of the rarity of the disease, no national and only a few international standards are available to compare the practices. Standard protocols set by southwest gynecological tumor panel are a tool for optimizing practices. Referring to this standard, a 2 cm clinical excision margin is recommended to ensure the histological margin in excess of 8 mm.\(^8\)\(^–\)\(^11\) Inadequate excision of margin is considered a poor prognostic factor and is associated with a high recurrence rate.

In our study, an excision margin of >2 cm was obtained in 100% of cases; however, a histopathological tumor-free margin of >8 mm was achieved in 94% of cases.

In the literature review, Falconer et al. showed inadequate margins (<8 mm) in 33–51% of cases\(^1\)\(^–\)\(^3\) and Woelber et al. showed inadequate margins in 28–42% of cases.\(^10\) Factors that lead to suboptimal margins include the proximity of growth to the urethra or anus, difficulty defining vaginal margins, and suboptimal spread of tumor beyond surgical margins.\(^1\)\(^,\)\(^10\)

Bilateral nodal dissection was successfully performed in 100% of patients. Literature review shows no controversy for bilateral nodal dissection in advanced carcinoma of vulva; however, the reported

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**Table 1: Demographic characteristics**

<table>
<thead>
<tr>
<th>Age of patient</th>
<th>Mean ± SD</th>
<th>Median</th>
<th>Distribution of parity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>58.13 ± 10.359</td>
<td>60 years</td>
<td>Parity Frequency Percent Cumulative percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 3 18.8 18.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1–5 3 18.8 37.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6–10 10 62.5 100</td>
</tr>
</tbody>
</table>

**Distribution of menopause status**

- Premenopausal: 1 6.3 6.3
- Postmenopausal: 15 93.8 100
- Total: 16 100

**Table 2: Stage at presentation**

<table>
<thead>
<tr>
<th>Stage at presentation</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>1</td>
<td>6.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Stage 2</td>
<td>2</td>
<td>12.5</td>
<td>18.8</td>
</tr>
<tr>
<td>Stage 3</td>
<td>13</td>
<td>81.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3: Histopathological diagnosis**

<table>
<thead>
<tr>
<th>Histopathological diagnosis</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poorly differentiated carcinoma</td>
<td>1</td>
<td>6.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Sarcoma vulva</td>
<td>1</td>
<td>6.3</td>
<td>12.5</td>
</tr>
<tr>
<td>Squamous cell CA</td>
<td>14</td>
<td>87.5</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

**Table 4: Compliance with quality standards**

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Standard protocols</th>
<th>No. of patients</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>All cancers should have an accurately recorded International Federation of Obstetrics and Gynecology stage</td>
<td>16</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>All patients with vulval cancer must have definitive surgery performed by the designated gynecologist with oncology interest</td>
<td>16</td>
<td>100</td>
</tr>
<tr>
<td>3</td>
<td>Tumors should be excised, ideally with a 2-cm healthy tissue excision margin down to the inferior fascia of the urogenital diaphragm and the fascia over the symphysis pubis</td>
<td>16</td>
<td>100</td>
</tr>
<tr>
<td>4</td>
<td>All patients with greater than stage la disease should have inguinoemeral node dissection</td>
<td>16</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>Ipsilateral inguinoemeral node dissection is required for labia majora tumors less than 2 cm in diameter, with subsequent contralateral inguinoemeral node dissection in node-positive cases</td>
<td>NA*</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Bilateral inguinoemeral groin node dissection is required in tumors of labia minora, central tumors within 1 cm of or crossing the midline or large lateral lesions of greater than 2 cm</td>
<td>16</td>
<td>100</td>
</tr>
<tr>
<td>7</td>
<td>No nodal dissection is required for the depth of invasion of less than 1 mm</td>
<td>NA*</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Pelvic lymphadenectomy is not required</td>
<td>16</td>
<td>100</td>
</tr>
</tbody>
</table>

*No case of stage la disease was encountered during the study period
rate of nodal dissection in advanced cancers varies between 64 and 72%. The varied rate is in view of the fact that the majority of patients are at an advanced age with coexisting morbidities putting them at high risk for anesthesia. In this regard, the reported dissection rate varies from 67% for ASA1 (American Society of Anesthesiologists) and ASA2 to 29% for ASA3 and ASA4. Decentralization of surgical care and heterogeneity in surgical management may be another contributing factor in the variation in nodal dissection rate; the degree of variation is less when surgery is performed in tertiary care hospitals. In single centers that receive tertiary care referrals, complete nodal dissection and standard treatment care have been achieved in 96% of cases. However, it is also relevant that lymphadenectomy is a significant source of morbidity especially in frail patients and is reported to be unnecessary in 74% of stage II disease patients who subsequently prove to be node negative. Recent development with a sentinel node biopsy may prove useful in resolving this dilemma; however, controversy exists in this regard. Until the technique is fully evaluated, the groin node dissection for inguinofemoral nodes should remain the mainstay of therapy in stage Ib or higher stages of carcinoma vulva.

The study is limited by a scarce number of cases. The possible reason for a less number of cases is the rarity of the tumor. However, the possibility of less referral cannot be ruled out in view of the fact that currently there is no tumor registry at the national level nor is there any centralization for surgical care of such rare cancers. Thus, the true incidence of disease cannot be established.

**Conclusion**

Despite a limited number of cases being encountered, the high compliance rate of modified radical vulvectomy with international standards reflects a high standard of care provided to patients with vulval carcinoma at our tertiary care hospital. The need for centralization of care for these patients cannot be overemphasized in order to optimize the services.

**References**


