

Survival Outcome of Patients with Vulvar Malignancy Treated at a Tertiary Care Cancer Centre: A Cohort Study

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ABSTRACT

Introduction: Vulvar malignancy is a rare gynaecological malignancy and understanding the determinants of vulvar cancer outcomes is essential for improving patient care and guiding future research in this field. The management of vulvar malignancy ranges from wide local excision to radical vulvectomy for early-stage and advanced disease managed by external beam radiotherapy with concurrent chemotherapy.

Aim: To determine the Overall Survival (OS) and Disease-Free Survival (DFS) among patients with vulvar cancer.

Materials and Methods: This was a retrospective cohort study of patients with vulvar malignancy who underwent treatment over a 10-year period (from January 2011 to December 2020) at a tertiary cancer centre in South India, Department of Gynaec Oncology, Malabar Cancer Centre (Postgraduate Institute of Oncology Sciences and Research), Thalassery, Kerala, India. Details such as age, Performance Status (PS), tumour histology, stage, intent of treatment, type of treatment and recurrence were collected from case records. The Kaplan-Meier test was used to estimate OS and DFS.

Results: A total of 29 patients were analysed; the mean age was 67.03 years (ranging from 48 to 93 years). A total of 3

(10.34%) patients were premenopausal and 26 (89.66%) were postmenopausal. A total of 24 (82.8%) cases were squamous cell carcinoma and 3 (10.34%) were adenocarcinoma. A total of 12 (41.4%) patients received curative intent treatment, 13 (44.8%) received palliative intent treatment and 4 (13.79%) received best supportive care. The five-year OS was 28% for all stages, with a median OS of 23.16 months. The five-year OS for curative intent patients was 50%, while for palliative intent patients, it was 15.4%. Out of the nine cases that underwent surgery, 1 (11.1%) had local recurrence, 1 (11.1%) had regional nodal recurrence and one had a distant site recurrence. The estimated five-year DFS was 63.5%.

Conclusion: The present study highlights that early-stage diagnosis and curative intent treatment significantly improve survival outcomes in vulvar cancer. Patients treated with curative intent had a five-year OS of 50% and a DFS of 63.5%, compared to a 15.4% OS in palliative cases. Advanced stage at presentation and older age were associated with poorer prognosis. These findings underscore the need for early detection and individualised, multimodal treatment strategies to optimise outcomes.

Keywords: Inguinal node dissection, Overall survival, Premenopausal

INTRODUCTION

The Global Cancer Observatory (GLOBOCAN) 2022 worldwide estimates indicate 47,342 (0.2% of all sites) new cases and 18,579 (0.2% of all sites) deaths [1]. Vulvar cancer accounts for approximately 5% of female genital cancers [2]. It primarily affects older women and survival outcomes can vary depending on several factors, such as stage at diagnosis, patient age and the type of treatment received.

Vulvar carcinoma can be classified into Human Papillomavirus (HPV)-associated and HPV-independent types. Among vulvar malignancies, squamous cell carcinoma is the most common histology, accounting for 85-90% of tumours, whereas basal cell carcinoma, melanoma, invasive Paget's disease, Bartholin's gland carcinoma and sarcoma are less common. Most cases are unifocal, with the most common sites being the labia majora, followed by the labia minora and clitoris.

The early stage of carcinoma vulva (Stage I and selected Stage II) is managed by wide local excision or radical vulvectomy with unilateral or bilateral inguinofemoral lymphadenectomy. Locally advanced disease is managed by External Beam Radiotherapy (EBRT) and concurrent chemotherapy [3]. Patients with Stage IV B are managed with EBRT for local disease and/or palliative chemotherapy, or in some cases, best supportive care.

Early detection and advancements in surgical and radiation therapies have improved the prognosis for many patients. However, disparities

in healthcare access and individual biological factors continue to influence survival rates. Understanding the determinants of vulvar cancer outcomes is essential for improving patient care and guiding future research in this field. As it is a rare gynaecological malignancy, there is limited data on disease outcomes and long-term survival. The primary objective of the present study was to determine the OS and DFS among patients with vulvar cancer.

MATERIALS AND METHODS

This was a retrospective cohort study in which a total of 29 patients with carcinoma of the vulva were registered at a tertiary care cancer centre in South India, in the Department of Gynaec Oncology, Malabar Cancer Centre (Postgraduate Institute of Oncology Sciences and Research), Thalassery, Kerala, India. The study was conducted from January 2011 to December 2020. The study was approved by the Institutional Review Board (1616/IRB-SRC/13/MCC/07/09/2024/4) with carcinoma of the vulva from January 2011 to December 2020. The date of diagnosis, demographic details, staging, modality of treatment, lymph node metastasis, date of completion of treatment and date of last follow-up were obtained from case files.

Inclusion criteria: Patients with carcinoma of the vulva who underwent treatment at this centre from January 2011 to December 2020 were included. Diagnosis was confirmed through biopsy.

Exclusion criteria: Patient with missing data and those with second malignancies were excluded.

Study Procedure

Data were collected regarding age, Performance Status (PS), tumour histology, stage, intent of treatment, type of treatment and recurrence.

Surgical management included wide excision, radical vulvectomy and hemivulvectomy, with or without inguinofemoral node dissections. In the case of wide excision, the primary tumour was resected with a minimum margin of 1 cm. In radical vulvectomy, the skin, subcutaneous tissue, labia majora, labia minora and clitoris were removed en bloc with the tumour. Inguinofemoral block dissection, either unilateral or bilateral, was performed through transverse incisions below the inguinal ligament. Sartorius transposition was done in all cases.

Adjuvant external beam radiotherapy was administered at a dose of 50 Gy in 2 Gy per fraction, once weekly for five days a week over five weeks, if indicated based on the multispecialty board's decision. After completion of treatment, patients were followed-up every three months for the first two years, every six months for the next three years and annually thereafter. At each follow-up visit, a complete physical examination was conducted. DFS was calculated in months from the date of completion of treatment to the date of first recurrence. Overall Survival (OS) was calculated in months from the date of completion of treatment to the date of death, whether due to the disease or any other cause.

STATISTICAL ANALYSIS

Categorical variables were expressed as percentages and continuous variables as mean±Standard Deviation (SD) or median {Interquartile Range (IQR)}. Univariate analysis for categorical variables was conducted using the Chi-square test. The Kaplan-Meier test was used to estimate OS. A p-value of less than 0.05 was considered statistically significant. Data were analysed using Statistical Package for Social Sciences (SPSS) 29.0 software.

RESULTS

A total of 29 patients were analysed. The mean age of women presenting with vulvar malignancy was 67.03 years (range 34-93 years). Of the total, 3 (10%) patients were premenopausal and 26 (90%) were postmenopausal. Most of the study population was multiparous, with 22 (75.9%) patients. A total of 1 (3.4%) patient had a prior history of Vulvar Intraepithelial Neoplasia (VIN) and 2 (6.8%) patients had a history of Cervical Intraepithelial Neoplasia (CIN) [Table/Fig-1]. A total of 1 patient (3.4%) had a history of smoking. A total of 4 (13.8%) patients were unmarried and 9 (31%) patients were married before the age of 18 years. The most common presentation was a lump in the vulva, reported by 18 (64.5%) patients, followed by itching in 9 (32.5%). The most common site of malignancy was the labia majora, affecting 23 (80.5%) patients, followed by the clitoris.

Patient characteristics		n (%)
Histology	Squamous cell carcinoma	24 (82.8)
	Adenocarcinoma	3 (10.3)
	Malignant melanoma	1 (3.4)
	Basal cell carcinoma	1 (3.4)
Menopausal	Pre-menopausal	3 (10.3)
	Post-menopausal	26 (89.7)
PS	1	15 (51.7)
	2	8 (27.6)
	3	17.2 (17.2)
	4	3.4 (3.4)
Parity	Nulli	7 (24.1)
	Multi	22 (75.9)

[Table/Fig-1]: Patient characteristics and histology in patients with vulvar carcinoma treated at tertiary care cancer centre (n=29).

The most common histology was squamous cell carcinoma in 24 (82.8%) cases, followed by adenocarcinoma in 3 (10.3%). There was 1 (3.4%) case of malignant melanoma and 1 (3.4%) case of basal cell carcinoma. A total of 9 (31%) patients were classified as FIGO Stage I, VI (20.7%) were Stage II, 8 (27.5%) were Stage III and 6 (20.7%) were Stage IV [Table/Fig-2]. A total of 6 (20.7%) patients had metastasis at the time of diagnosis. Two patients had liver metastasis, one had lung metastasis and three patients had metastasis to the left supraclavicular node. A total of 10 (34.5%) patients had inguinal node metastasis at diagnosis.

Variables		n (%)
FIGO stage	I	9 (31)
	II	6 (20.7)
	III	8 (27.5)
	IV	6 (20.7)
Nodal metastasis	Yes	10 (34.5)
	No	19 (65.5)

[Table/Fig-2]: FIGO stage and nodal metastasis in vulvar carcinoma in tertiary care centre.

FIGO: International federation of gynaecology and obstetrics

A total of 12 (41.4%) patients underwent curative intent treatment, 13 (44.8%) patients underwent palliative intent treatment and four patients received best supportive care for pain management, nasogastric feeding and urinary catheterisation [Table/Fig-3]. Among the curative intent treatments, 7 patients (24.1%) underwent surgery alone, one patient received surgery and radiotherapy, three patients received chemoradiation and one patient underwent surgery and chemoradiation. Among surgically treated patients, one underwent posterior pelvic exenteration and bilateral inguinal node dissection [Table/Fig-4].

Intent of treatment	n (%)
Curative	12 (41.4)
Palliative	13 (44.8)
Best supportive care	4 (13.8)

[Table/Fig-3]: Intent of treatment in vulvar carcinoma in tertiary care centre.

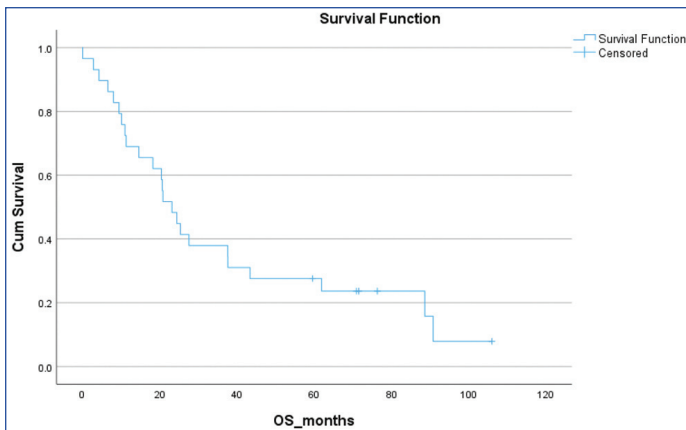
Type of surgery	No.
Wide excision	3
Radical wide excision+I/L IFND	1
Radical wide excision+B/L IFND	2
Radical Vulvectomy+B/L IFND	1
Hemivulvectomy+B/L IFND	1
Posterior pelvic exenteration+B/L IFND	1

[Table/Fig-4]: Type of surgery in vulvar carcinoma in tertiary care centre.

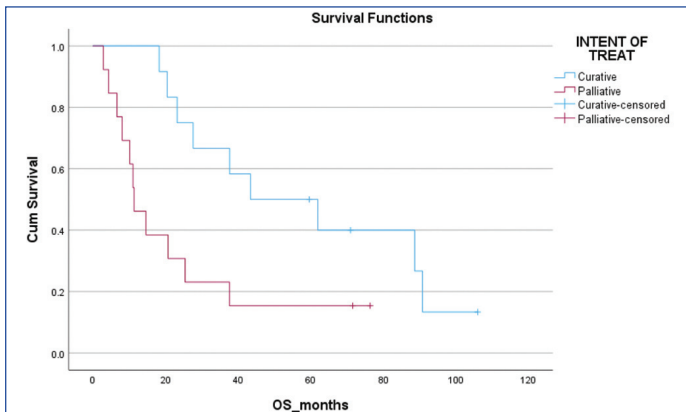
I/L: Ipsilateral; B/L: Bilateral; IFND: Inguinofemoral node dissection

Among palliative care patients, 11 received palliative radiotherapy and two patients received palliative chemotherapy. One palliative intent patient underwent a palliative stoma. The five-year overall survival was 28% for all stages and the median OS was 23.16 months (95% CI 16.54-29.78) as shown in [Table/Fig-5]. The five-year overall survival for curative intent patients was 50%, while for palliative intent patients, it was 15.4% as displayed in [Table/Fig-6]. The estimated five-year DFS was 63.5%, as shown in [Table/Fig-7]. The median follow-up period was 76 months. One-year OS was 69%, two-year OS was 48% and five-year OS was 28%. The median OS among curative intent patients was 43 months, while among palliative patients, it was 11 months, which was statistically significant with a p-value of 0.016.

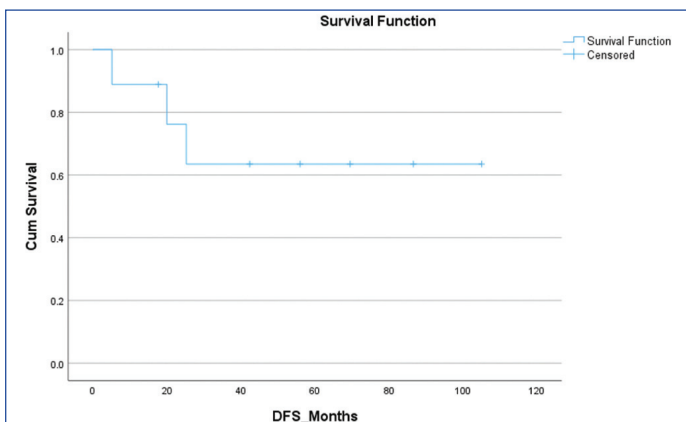
The mean DFS among surgically treated patients was 73 months (95% CI 44-102). One-year DFS was 88.9%, two-year DFS was 76.2% and five-year DFS was 64%. FIGO stage-wise, the five-year OS was 44.4% in Stage I, 33.3% in Stage II, 25% in Stage III and 16.7% in Stage IV.



[Table/Fig-5]: Overall Survival (OS) of patients with carcinoma vulva at tertiary cancer centre.



[Table/Fig-6]: Comparison of survival among curative and palliative intent patients with carcinoma vulva.



[Table/Fig-7]: Disease-Free Survival (DFS) among surgically treated patients with carcinoma vulva.

A total of 5 (17.2%) patients who received curative intent treatment experienced relapse. Among the nine patients who underwent surgery, 3 (33.3%) patients had recurrence. One had local recurrence, one had inguinal nodal recurrence and one had paraaortic nodal recurrence. After recurrence, four patients received palliative intent treatment and one patient received best supportive care.

DISCUSSION

The present retrospective study provides valuable insights into the survival outcomes of patients with vulvar carcinoma treated at a tertiary care centre in India. Despite the small cohort, the findings resonate with global trends and emphasise the critical role of early diagnosis, choice of treatment modalities and demographic factors like age in determining outcomes.

Stage at Diagnosis and Survival Outcomes

Consistent with existing literature, the present study confirms that the stage at diagnosis is a primary determinant of survival. Patients

diagnosed in early stages (FIGO I and II) had significantly higher five-year overall survival (OS) compared to those diagnosed at advanced stages (FIGO III and IV), with stage-wise survival rates declining progressively: 44.4% for Stage I, 33.3% for Stage II, 25% for Stage III and 16.7% for Stage IV. These findings are aligned with the 2021 FIGO staging report, which cited five-year OS rates ranging from 86.3% in Stage IA to 18.3% in Stage IVB [4].

Present observations are also consistent with Meelapki P et al., who reported a clear decline in survival across stages in their study of 145 patients with squamous cell carcinoma of the vulva. Their five-year OS ranged from 66.7% in Stage IA to 11.4% in Stage IVB [5]. Conversely, patients diagnosed at advanced stages face more aggressive disease progression and often require more extensive surgery, radiation therapy and chemotherapy, which may reduce survival outcomes [6]. These results highlight the importance of early detection and timely treatment, particularly in low-resource settings where diagnostic delays are common.

Impact of Age on Prognosis

The mean age in the present study was 67 years, with 90% of patients being postmenopausal, underscoring the predominance of this malignancy in older women. Age at diagnosis is a well-recognised prognostic factor, with older patients often presenting with more advanced disease and receiving less aggressive treatment due to co-morbidities or poor PS [7]. Kumar S et al., found that older patients in the US were less likely to undergo definitive surgery compared to younger women, which could explain their poorer outcomes [7]. This emphasises the need for age-adapted treatment protocols that balance efficacy and tolerability, especially in elderly patients.

Multimodal treatment- particularly surgery combined with radiotherapy- remains the cornerstone for managing early and locally advanced vulvar cancers. Studies by Gaarenstroom KN et al., and Heaps JM et al., have demonstrated improved outcomes with combined treatments, particularly in reducing local recurrence and enhancing survival [8,9]. However, morbidity associated with radical surgeries, such as bilateral inguofemoral lymphadenectomy, remains a concern, underscoring the need for less invasive strategies and improved patient selection.

Treatment modality significantly influenced prognosis. Patients treated with curative intent had a five-year OS of 50%, compared to 15.4% among those treated with palliative intent. Among surgically treated patients, the estimated five-year DFS was 64%, with a median DFS of 73 months. These findings are comparable to those of Jeevarajan S et al., who reported a five-year DFS of 65.4% in their cohort of patients treated surgically for vulvar carcinoma [10].

Role of HPV and Biological Subtypes

Although the present study lacked HPV status data, it is important to recognise the emerging role of HPV-associated Vulvar Squamous Cell Carcinoma (VSCC) as a distinct clinical entity. HPV-positive tumours are generally associated with better prognosis and younger patient age compared to HPV-negative tumours, which are more aggressive and typically occur in older women [11,12]. A study by Rasmussen CL et al., further affirmed that HPV-negative vulvar cancers have significantly worse survival outcomes than their HPV-positive counterparts [13]. Future prospective studies should include HPV typing to better understand its prognostic implications and explore targeted therapeutic strategies.

Limitation(s)

The retrospective nature of the present study, small sample size and lack of HPV and quality of life data are limitations that restrict generalisability. However, the trends observed align with national and global literature and provide a foundation for larger multicentric prospective studies.

CONCLUSION(S)

The present study highlights that early-stage diagnosis and curative intent treatment significantly improve survival outcomes in vulvar cancer. Patients treated with curative intent had a five-year OS of 50% and a DFS of 63.5%, compared to a 15.4% OS in palliative cases. Advanced stage at presentation and older age were associated with poorer prognosis. These findings underscore the need for early detection and individualised, multimodal treatment strategies to optimise outcomes.

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