MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2025.1.104.108

OPEN ACCESS

Key Words
Modified radical vulvectomy, carcinoma vulva, keystone flap, inguinofemoral nodal dissection, complication of nodal dissection

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Received: 25 September 2024
Accepted: 20 November 2024
Published: 13 December 2024

Citation: D. Suresh Kumar, T.D. Bala Murugan, H. Prasanna Srinivasa Rao and G. Varaguna Pandian, 2025. Our Experience in Carcinoma Vulva-Demographic, Clinical, Treatment Trends and Outcomes Among South Indian Population. Res. J. Med. Sci., 19: 104-108, doi: 10.36478/makrjms.2025.1.104.108

Our Experience in Carcinoma Vulva-Demographic, Clinical, Treatment Trends and Outcomes Among South Indian Population

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ABSTRACT
Carcinoma vulva is relatively a rare disease accounting for 1.3% of all gynecological malignancies and 0.3% of all cancers affecting females in India. Predominantly of elderly women with the median age being 67 years and now also common in young females. The purpose of this study is to know the demographic pattern of invasive vulvar cancer, to analyze the surgical options, the postoperative complications, failure pattern and survival following surgical management and to compare our results with other published series. Data was collected from January 2014 to December 2022 in medical record department. A total of 107 patients were included in the age group between 24-85 years were analyzed. Of those 107 patients, 62.9% were below 60 years of age. Thirty-six (33.64%) patients presented with ulcers over external genitalia, 34(31.77%) with pruritus, 23 (21.49%) with pain and 14 (13.08%) with other complaints (like discharge, swelling). During this 8-year period, 44 patients with invasive vulvar carcinoma were treated with surgery. Of 37 patients were locally advanced disease treated by concurrent chemo radiation, 14 patients were metastatic disease treated by palliative intent and best supportive care depends upon Performance status of the patients. outcomes were analyzed. In conclusion, the treatment of vulvar carcinoma should be individualized and involve multidisciplinary collaboration. It is essential to establish a uniform consensus on organ conservation strategies and approaches to reduce morbidity based on findings from these studies.

INTRODUCTION

Carcinoma vulva is relatively a rare disease accounting for 1.3% of all gynecological malignancies[1] and 0.3% of all cancers affecting females in India[2]. Predominantly it is the disease of elderly women with the median age being 67 years, although it is now becoming common in younger age groups[3]. Most patients in developing countries like India present with advanced locoregional disease for various socioeconomic reasons including lack of awareness resulting in poorer outcomes and posing management challenges[4]. There is a striking paucity of literature about carcinoma vulva from developing countries including India. Due to its rarity, large prospective randomized trials that can guide management are few. The purpose of this study is to know the demographic pattern of invasive vulvar cancer, to analyse the surgical options, the postoperative complications, failure pattern and survival following surgical management and to compare our results with other published series.

MATERIALS AND METHODS

Data was collected from January 2014 to December 2022 in medical record department. A total of 107 patients were included in the age group between 24-85 years were analyzed. Preoperative evaluation consisted of clinical examination, routine blood and urine tests, chest radiography and contrast enhanced computed tomography (CECT) of abdomen and pelvis including the groin. Selected patients were additionally evaluated with examination under anaesthesia (EUA), MRI pelvis, cystoscopy and proctoscopy. Histopathological documentation of the primary lesion was done preoperatively. Adjuvant external beam radiotherapy was given if indicated (margin positivity, Involvement of >1 node and presence of extracapsular nodal extension irrespective of the number of nodes) as per multi-disciplinary tumor board (MDT) decision. Locally advanced and unresectable disease patients were treated with External Beam Radiotherapy (EBRT) with concurrent chemotherapy and salvage surgery. Metastatic disease patients treated by Systemic therapy and Best supportive care.

RESULTS AND DISCUSSIONS

Overall, total number of all female cancer diagnosed was11,452 in the year between 2014-2022 in our institute. In this carcinoma vulva was about 0.93%.

Table 1: Year-2014-2022 CA Vulva Cases Year Wise Statistics

Year	All Female Cancers	CA Vulva	%
2014	1246	15	1.20
2015	1111	11	0.99
2016	1155	12	1.04
2017	1046	14	1.34
2018	1277	10	0.78
2019	1322	8	0.61
2020	1291	16	1.24
2021	1493	8	0.54
2022	1511	13	0.86
Total	11452	107	0.93

The mean and median ages of the patients were 52.5 and 55 years, respectively (range: 24-85 years). Of those 107 patients, 62.9% were below 60 years of age. Thirty-six (33.64%) patients presented with ulcers over external genitalia, 34(31.77%) with pruritus, 23 (21.49%) with pain and 14 (13.08%) with other complaints (like discharge, swelling). Labia majora was the predominant site of disease in 80%, labia minora in 14.3% and clitoris in 5.7%. Demographic survey reflects rural population of Tamil Nadu have higher incidence than urban district population. Most common histopathological finding of all vulval carcinoma in our institute was moderately differentiated squamous cell carcinoma. About 39% stage III, 29% stage II, 19% stage I and 14% stage IV were treated in the hospital.

Table 2: Most Common Histopathological Finding of All Vulval Carcinoma in Our Institute was Moderately Differentiated Squamous Cell Carcinoma

Stage	Percentage
I	19% 20/(107)
II	29% (31/107)
III	39% (41/107)
IV	14% (15/107)

During this 8-year period, 44 patients with invasive vulvar carcinoma were treated with surgery. Of 37 patients were locally advanced disease treated by concurrent chemo radiation, 14 patients were metastatic disease treated by palliative intent and best supportive care depends upon Performance status of the patients. 12 patients were lost follow up during treatment and evaluation. 5 patients of locally advanced disease were completed concurrent chemoradiation and underwent salvage surgery.

Table 3: Surgical Procedures

Surgery for primary tumour	Number of patients	Node dissection	
		Unilateral	Bilateral
Modified Radical vulvectomy	44	11	33

Of 44 patients were treated by modified radical vulvectomy, the most common histology pattern was moderately differentiated squamous cell carcinoma 84% (n=37) followed by well differentiated squamous cell carcinoma 9% (n=4) and poorly differentiated carcinoma 6% (n=3). All had pathological R0 resections except 3 (2 positive margins, 1 close margin). Of 44 patients, 33 patients were underwent bilateral nodal dissection, 11 patients were underwent unilateral nodal dissection. 59.1% (26/44) were found to be node positive and 40.9% (18/44) node negative. A total of 4 patients had extra capsular nodal spread (ECS), of which 3 died and 1 defaulted follow-up. Three of the node negatives and 4 of the node positives patients, totally 7 patients developed local recurrence disease at nodal site and primary vulval site respectively. Primary vulval site recurrences were treated by wide local excision and flap cover local reconstruction. Nodal recurrence managed by nodal dissection and concurrent chemo radiation and adjuvant chemo therapy. In our series, the median node retrieval was 8 which is above the recommended number of 6 nodes.

Table 4: Postoperative Complications

Complication	Frequency	Percentage%
Seroma	32/44	72%
Flap necrosis	24/44	54%
Wound infection	8/44	18%

We had no perioperative (30-day) mortality. Postoperative complications were mainly due to nodal dissection. Seroma was the most common complication requiring repeated aspirations in 72% (32/44). Skin flap necrosis 54% (24/44) with wound gaping was the troublesome complication following nodal dissection. It was salvaged with the debridement of the necrosed part followed by secondary suturing in some cases, split skin graft in few cases. A total of 5 patients required flap reconstruction of wound (one for post vulvectomy area, four for inguinal wound), of which 2 had flap necrosis. The majority of patients developed Grade 1 and Grade 2 lower limb lymphedema following nodal dissection but not to the extent of producing significant symptoms and were treated conservatively for symptoms relief. Twenty eight patients were candidates for adjuvant radiotherapy, of which 5 declined therapy. Of those 5 defaulters, 2 patients with nodal positivity remained disease-free for 16 and 22 months, respectively. One patient with margin positivity and negative nodes was disease-free at 17 months. One patient with extra capsular nodal disease, developed regional recurrence at 7 months and the other patient retro viral positivity who underwent radical local excision remained disease-free till last follow-up (17 months).

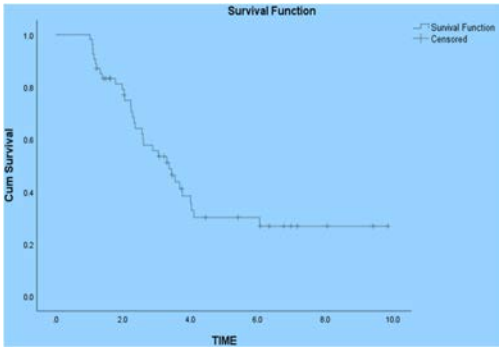

Fig 1: Kaplan-Meier Curve-Disease-Free Survival for All Cases

The median period of 5 year follow up of all patients in our institute, the estimated 5 year overall survival was 38.5%. In comparison with various studies worldwide

Source Study	Country	5-Year Survival
SEER (Surveillance, Epidemiology and End Results) Database	United States	Localized: 86%, Regional: 54%, Distant: 16%
De Hullu, J.A., et al. (2019) "Vulvar Cancer Incidence and Survival in the Netherlands"	Netherlands	Overall:70% (early-stage higher)
Mahner, S., et al. (2015) "Vulvar Cancer in a Large German Cohort"	Germany	Early-stage: 75%, Advanced: 30%
Office for National Statistics (ONS), 2020 "Cancer Survival in England"	United Kingdom	Stage I: >80%, Overall: 60-70%
AIHW (Australian Institute of Health and Welfare) Report, 2019	Australia	Overall: 74%, Stage I: >80%
Sharma et al. (Journal of Cancer Research and Therapeutics. (2010))	India	Early Stage – >80% Overall -41%

Carcinoma vulva is a rare cancer, mainly affecting elderly women. Our patients were younger when compared to other published series.

Table 5: Mean and Median Age of the Patients in Different Series

Study	Study period	Total no of patients	Mean age in years	Median age in years	Age range in years
Bafna *et al.*	1996-2000	37	54.7	60	24-80
Le *et al.*	1980-2004	58	-	71.3	28.3-90.9
Sharma *et al.*	1998-2005	60	-	63	24-92
Hampl *et al.*	1998-2007	102	57	-	18-93
Eke *et al.*	1998-2009	11	61.2	-	54-79
Soliman *et al.*	2002-2009	32	-	56.5	23-86
Present series	2004-2013	34	52.5	55	23-73

Labia majora was the most common site of disease in our series (80%) followed by labia minora (14.3%) and clitoris (5.7%). Hampl[3] in their series of 224 patients reported that the tumour localization changed significantly from the labia to the area between the clitoris and the urethra (38.4%) [Stella Decker 2008]. Given the small number in our series, such a shift in location could not be commented on. Most of our surgeries were radical vulvectomies and most had some form of lymph node surgery. After the landmark study by Hacker[4] the traditional radical block resection of the vulva and inguinofemoral nodes through single incision underwent a drastic change in favour of separate vulvar and groin incisions which achieved similar cure rates with less morbidity[4] an 8-year period. Studying the relationship between surgical margins and local recurrence, Heaps[11] reported no failures in 91 patients whose closest tumour margins were 8mm or more in the fixed specimen[11]. However, in a study by Groenen[12] the local recurrence rate did not differ between patients in whom the margin was <8mm or 8mm and above. We follow the practice of giving at least 1 cm gross margin. In a series by Le *et al.* the total number of nodes harvested during surgery was proved to be an independent predictor of both progression-free and overall survivals. They propose to define optimal inguinal nodal dissection using a cut-off value of at least 10 nodes in total for bilateral IFBD [H]. In our series the median nodal yield for unilateral and bilateral inguino femoral block dissection were 8 and 17, which indicates optimal dissection. The major morbidity of vulvar cancer surgery follows lymphadenectomy. Recently, a number of investigators explored the use of intraoperative lymphatic mapping to identify sentinel node that would predict the presence or absence of regional metastases[9]. Participants in a 2008 expert panel at an International Sentinel Node Society Meeting concluded that sentinel node biopsy "is a reasonable alternative to complete inguinal lymphadenectomy when performed by a skilled multi-disciplinary team in well selected patients"[13]. We are yet to practice sentinel node biopsy in vulvar cancer.

Fig 2: Radical Vulvectomy with Keystone Flap Cover

In our series 44.4% (14/31) of the patients developed skin flap necrosis and in other Indian series 88.4% had considerable groin wound dehiscence following lymphadenectomy. Comparing saphenous vein sparing to saphenous vein ligation during inguinal lymphadenectomy, Zhang[14] reported significant decrease in the development of short-term lower extremity lymphedema and phlebitis but not seroma and acute cellulitis in the saphenous vein spared group[14]. However Soliman[15] conclude that "wound complications after inguinofemoral lymphadenectomy are very high, with no single pre, intra, or postoperative factor that could be incriminated and saphenous vein sparing provided no significant difference in decreasing local complications"[15]. In our institution we do not practice saphenous vein sparing as routine. Judson[16] reported that Sartorius muscle transposition was not beneficial based on a randomized controlled trial[16]. However, we routinely practice this technique because, in situations where inguinal wound gaping occurs due to skin flap necrosis this will prevent exposure of major vessels. In our study, almost >63% were diagnosed with FIGO Stage II/III disease, supporting previous reports of clinical and behavioral barriers that lead to delays in diagnosis according to Canavan TP, Cohen D *et al.* and Homesley[10] studies. [Harlen[5] Canavan[6] Homesley[7]. In our series, 5 (9.25%) patients defaulted follow-up. However, poor follow-up in Indian females due to several factors like long traveling distance, poor socioeconomic status and elderly age is not unusual[8]. Older women are less likely to conduct home self-examinations of the vulva and often fail to seek treatment for vulval symptoms for longer period of delay and health system facilities in rural population also have been reported to contribute to the delay in diagnosis by providing treatment before obtaining a biopsy or consider referral[8]. Therefore, it is important that women understand the need for continued gynecologic examinations and the importance of timely evaluations of vulvar lesions. Majority of patient in our hospital underwent modified radical vulvectomy and lymphadectomy leads to long term complication include chronic leg edema, genital prolapse and urinary stress incontinence for 6 or more weeks after surgery which similar to the study conducted at the University of Mainz, Germany, more than half of the patients treated from 1973-2002[9]. Limitation of the study is number of patient analysed is less than the previous other studies, sentinel lymph nodal biopsy not done and do not have data on quality of life measurements.

CONCLUSION

In conclusion, the treatment of vulvar carcinoma should be individualized and involve multidisciplinary collaboration. Our study identified stage and nodal positivity as significant prognostic factors. We observed that most patients were from rural areas and presented with advanced disease, likely due to low awareness and limited screening in these populations. Increasing awareness and implementing earlier screening could help identify cases sooner and improve treatment outcomes. Given the scarcity of data, particularly from India and other developing countries, we emphasize the need for more multi centric studies to address this issue, considering the low prevalence. It is essential to establish a uniform consensus on organ conservation strategies and approaches to reduce morbidity based on findings from these studies.

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