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Analysis of Clinico-Pathological Profile and Treatment Outcome in Postoperative Patients of Vulvar Carcinoma in a Tertiary Care Centre

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Conflicts of Interest: Nil

Abstract

Aims and objective: To analyze the clinico-pathological data and to correlate outcome of the disease in cancer vulva patients treated by primary surgery.

Material and methods: 65 cases of vulvar cancer patients attending gynaecologic-oncology OPD and treated with primary surgery were analysed over a period of 16 years from 2001 to 2016. **Two cases diagnosed with sarcoma and melanoma was included as a separate entity for analysis.**

Results: In the present study, incidence of vulvar cancer was 3.02% among all gynaecological malignancies with the median age of presentation being 54 years. 95.38%(62/65) of vulvar cancers were squamous cell histology with predominant well differentiated grading (61.29%). **The median tumour size was 3.7 cm.** The incidence of stage-I, -II, -III and –IV diseases were 1.59%, 73.02%, 23.80%, and 1.59% respectively. Radical vulvectomy and lymph node dissection was performed in 98.4%(62/63) and 88.89%(56/63) cases respectively and 49.21% patients received adjuvant treatment. Complications were seen in 53.9%(34/63) cases with wound infection being the most common. **The median follow-up period was 60 months.** Out of 65 **,** 50 patients returned for follow-up. Local or regional recurrence occurred in 32%(16/50) cases. Majority recurred within 2-years of follow-up and in stage-III, margin positive, and cases who did not undergo lymph node dissection. The overall survival of patients with negative and positive lymph node was 42.22 months and 20.004 months respectively. This difference was statistically significant **(P VALUE= 0.021)** .Overall survival with regard to tumour size and adjuvant therapy was not statistically significant.

Conclusion: The study concluded that, in order to improve outcome, radical vulvectomy and lymph node dissection should be the initial treatment for vulvar cancer along with the use of flap to improve body image and prevent wound breakdown. Adjuvant radiotherapy should be considered in margin positive, lymph node positive, or stage-III/IV cases. Age, tumour size, stage, margin and lymph node are the independent prognostic factors. The role of neoadjuvant/definitive concurrent chemoradiation needs further evaluation.

Keywords: Vulvar cancer, radical vulvectomy, lymph node dissection, adjuvant treatment

Introduction

Vulvar cancer (VC) is a relatively rare genital malignancy constituting about 3 to 5% of all gynaecological cancers.[1] It is common in postmenopausal women presenting at 65-70 years of age.[2] However there has been a rise in incidence in younger women in the recent years.[3] According to Woelber et al, the incidence rate is around 2-3 cases/100,000.[3] The rise in incidence of vulvar cancer in recent years is attributed to HPV infection and obesity.[4]

Due to its rarity and lack of much evidence management is a challenging issue for both gynaecologic oncologists and radiation oncologists to plan treatment along with considering psychosexual aspects of the patients. Therefore, proper pre-treatment evaluation is necessary to avoid over- or under-treatment.

Early stage VCs are treated with surgery alone and adjuvant radiotherapy (RT) is tailored in close/positive margins or in nodal metastasis to improve outcome.[5,6] In locally advanced cases, radical vulvectomy (RV) with adjuvant RT or neoadjuvant/definitive chemoradiation are alternative modalities. Lymph node dissection (LND) along with RV is a routine approach for VC. Though preinvasive lesion (VIN), microinvasive carcinoma and FIGO 1A are treated with wide local excision, according to current treatment recommendation FIGO stages 1B onwards require radical vulvectomy along with groin lymph node dissection.[7]

However, data regarding treatment modalities, patterns of failure, prognostic factors and outcomes are not clear till date due to limited and small studies. The present study analysed VCs treated with primary surgery in our department. Data collected from hospital medical records were reviewed and prognostic factors, failure patterns, and survival were analysed.

AIM and objective

This study aims at analysing the clinical presentation, prognostic factors, surgical techniques, adjuvant therapy and treatment induced toxicities in vulvar carcinoma patients treated with primary surgery ± adjuvant therapy in accordance with their staging and the treatment outcome.

Materials and methods

65 cases of vulvar carcinoma attending gynaecology oncology OPD and treated with primary surgery were retrospectively analysed from Jan 2001 to Dec 2016. All the cases were admitted in the hospital for treatment. All the data were collected from hospital medical records. Diagnosis and staging was confirmed by clinical and post operative histopathological data.

Inclusion criteria

All the new patients attending gynaecological oncology OPD and undergoing primary surgery were included in the study. Complete clinical and pathological data were collected for analysis.

Pretreatment evaluation: Complete history, general and local examination, complete haematological and biochemical profile, X-ray chest P-A view, ultrasound of abdomen and pelvis, and histopathological study was done in all patients. CT scan was done in few cases where USG was inconclusive.

After pretreatment evaluation, clinicopathological characteristics such as: age, menopausal status, presentation, histopathological type, tumour diameter, FIGO stage, type of treatment, adjuvant therapy, complications, and survival were surveyed, and all patients were clinically staged by using FIGO 2009 staging classification (Hacker 2009)[8]. The cases prior to 2009 were re-staged according to present classification. Different pathological types of VC were recorded (SCC, adenocarcinoma, malignant melanoma, and sarcoma). The

histological grading was recorded as: well differentiated (WD), moderately differentiated (MD), and poorly differentiated (PD).

Surgery was performed in all cases in the form of radical vulvectomy (complete/partial), wide local excision (WLE), and anterior quadrant vulvectomy (AQV) with or without lymph node dissection (LND). LNDs were not performed in cases associated with comorbid conditions and in those patients who refused to give consent after counselling regarding possibility of complications. Primary wound closure was done in 22 cases and the rest required flap repair in the form of lotus petal flap, gracilis and rectus abdominis myocutaneous(RAM) flap. Postoperative histopathological data were recorded such as: lymphovascular invasion (LVI), margin negative /close/positive status, LN positive/negative status, and extracapsular extension .

Radiotherapy was given by external beam radiotherapy and brachytherapy. Patients were followed up at 6-weeks after completion of treatment, every 3 month till 2 year and then every 6 months till 5 year and then annually. Different treatment related acute and late toxicities due to surgery and radiotherapy were recorded. Overall survival was determined with respect to tumour size, lymph node status and adjuvant therapy.

Statistical analysis: Data were recorded on excel chart and analysed by using SPSS version 19 and clinical data were analysed with the help of Chi-square and F test methods. Overall survival (OS) was calculated using the Kaplan–Meier method and prognostic factors were analyzed by multivariate analyses

Results

Patient characteristics(table 1): Majority of the patients were in the age range of 41-60 years with median age of the presentation lies in the fifth decade of life. Labia majora was the most common primary site for the disease, and discharge, pruritus, and ulcer were the most common presentations.

Two cases with diagnosis of sarcoma and malignant melanoma were excluded from analysis.

Majority patients presented with tumour size between 2-5 cm with the median size being 3.7cm, and at stage II and stage III disease. Pretreatment biopsy accuracy was 93.65%. Majority cases were squamous cell carcinoma with well differentiated form being the predominant grade followed by moderately differentiated.

Radical Vulvectomy (98.4%) and LND (88.89%) were performed in most of the cases and 32.14% cases showed lymph node positivity .Primary wound closure was done in 22(35%) cases and in the rest 65%, various flaps like unilateral or bilateral lotus petal flap ,V-Y flap and RAM flap were used. Sartorius transposition to cover the femoral vessels was done in 15 cases. Margin positivity was found in only few patients(4). Nearly half of the patients (49.21%) received adjuvant treatment in terms of RT, and CCRT. Majority of RT/CCRT was given in stage III, or node positive, or margin positive patients.(Table 2)

Out of 63 cases LND was performed in 56 cases. 13 cases did not come for follow-up and were from lymphadenectomy group.

Out of 50 follow-up cases, 33(67.35%) cases were living with no evidence of disease and 16 cases (32.65%) recurred. Out of 16 recurrent cases 3 cases died due to the disease. Relapse or recurrent time after treatment ranged from 3 months to 5 years **with the median time to relapse being 15 months.** Majority cases (87.5%, 14/16) recurred within 2-years of follow-up.

11 cases recurred in the lymphadenectomy group : 4 out of 13 LN positive cases (all the 13 cases were taking RT: 1 case from stage-II; 2 cases from stage-III and 1 case from stage stage-IV) and 7 out of 30 LN negative cases (3 cases from stage-II: 1/4 cases taking RT and 2/20 cases

not taking RT; 4 cases from stage-III: (4/5 cases taking RT and 0/1 cases not taking RT). 5 cases recurred in the nonlymphadenectomy group. (all were from stage-II: 4/5 cases taking RT and 1/1 case not taking RT).

Out of 4 margin positive cases, one case did not come for follow up and remaining 3 cases developed recurrence. One stage-II case where LND was performed, but margin and LN positive developed distant metastasis (lung) in spite of ajuvant therapy.

In our study, femoral artery blowout occurred in 1 patient which was managed with saphenous vein grafting. Injury to femoral nerve occurred in 1 patient. Wound infection was the most common acute toxicity due to surgery and dermatitis as the most common acute toxicity due to RT and lymphedema being the most common late complication (table 3).

Overall survival of patients with negative lymph node was 42.22 months (95% CI: 30.06- 57.34) whereas for patients with positive lymph node status was 20.004 months (95% CI: 10.039- 29.96). This difference was statistically significant (P VALUE= 0.021) (figure 1).

5-year OS of patients with different tumour size was not statistically significant (p value=0.433)(figure 2). 5-year OS in patients who received adjuvant treatment and those who did not receive was statistically significant (p value=0.043)(figure 3). 5-year OS for patients with stage II or less and stage III or more was not significant (p-value=0.165) (figure-4).

Discussion

VC accounts for 3-5% of all gynaecological malignancies. A study showed that the incidence of VC was 2.89% among all gynaecological malignancies [9] quite similar to ours i.e 3.02%.According to Imoto et al.[10], Sharma et al.[11], and Thakur et al.[9], the median age of presentation in VC was 68-years, 63-years, and 58-years respectively. In our study the median age of presentation was 54 years. Majority of the cases (74%) in our study occurred in postmenopausal women and according to Thakur et al, [9] it was 58.82% Majority occur in postmenopausal age group with median age being 65-70 years.

Majority cases occur in the genital skin surface ; itching, pain, and excrescence being the early symptoms .Pruritus, discharge and ulcer were the common presentations in our study accounting for 49.23%, 27.70%, and 24.61% respectively. The study by Thakur et al.[9] showed that genital tumours and genital itching were the common symptoms accounting for 70.59% and 56.47% respectively .

A study showed that 72.94% cases presented with lesion at lateral site of labia, whereas, 27.06% cases were found with lesion over medial part of labia or midline structures like clitoris and perineum.[10] Majority (73.02%; 46/63) patients in the present study had tumour size between 2-5cm supporting the literature (Thakur et al.: 69.41% cases within 2-5cm; Imoto et al.: median tumour size was 33 mm).[9,10]

The pretreatment biopsy accuracy was 93.65%(58/62) in our study supported by Thakur et al where it was 93.58% (73/78).[9] Squamous cell carcinoma(SCC) is the most common type of histology among all VCs constituting around 90% of the cases and well differentiated histologic grading is the predominant form. Majority patients were SCC (95.38% 62/65) in our study and well differentiation (61.29% 38/62) is the predominant histologic grading which was supported by Thakur et al (SCC: 84.71% 72/85, well differentiated grading: 79.17% 57/72) and Sharma et al (well differentiated grading: 31/60).[9,11]

Majority of the patients in our study were diagnosed at stage-II which was supported by Thakur et al[9] (41/85). Whereas, according to Imoto et al.[10], Sharma et al.[11], most were in stage-I (45%), and stage-III (31/60) respectively .

Inguinal lymph node metastasis was reported with a frequency of 6-50% cases.[11] The present study showed that 32.14% of cases had lymph node positivity postoperatively. Both the presence and number of inguinal LN metastasis has the greatest impact on the prognosis of VC followed by other prognostic factors such as: age, tumour diameter, histologic grading, depth of invasion, tumour thickness, lymphovascular space invasion, margin status, and extranodal extension.[3,12,13]

The presentation of vulvar cancer (VC) and its appropriate management has changed to a great extent over the years. Earlier, most of the patients presented with advanced disease and were treated primarily with local excision or wide en-bloc resection with butterfly incision which resulted in less 5-year overall survival (OS) and very high incidences of wound breakdown. The introduction of radical vulvectomy (RV) by 3-incision technique with flap closure and separate incision for inguinal node dissection has resulted in improved survival. Both traditional and perforator flaps must be included as first line option for reconstruction. Lotus flap, traditional V-Y flap and perforator based V-Y flaps are the best option for defects limited to the vulvoperineal area. VRAM flap, DIEP flap, ALT flap, or SCIP flap are the most useful options when groin or mons pubis defects are associated with vulvoperineal resection.[14]

Published data shows that large primary tumour, deep invasion, LVI, LN metastases, and close/positive surgical margins are the risk factors for recurrence (Heaps et al., Binder et al., Burger et al., and Woelber et al.)[15,16,17,3]. The relation of margin status with recurrence of the disease is not clear till date. According to Black et al., the recurrence rate was significantly higher (70% vs 30%) in pathologically positive margins.[18] According to Viswanathan et al., in cases with ≤5mm surgical margin local recurrence rate is high, but adjuvant RT (≥56 Gy dose) may decrease the risk of local recurrence.[19] According to Chan et al., margin clearance of ≥8mm leads to better loco-regional control.[20] In our study all the margin positive cases developed recurrence (100%), whereas, 28.57% (14/49) margin negative cases developed recurrence of the disease, demonstrating pathologically positive margin to be a strong prognostic factor for recurrence of the disease.

Adjuvant RT in locally advanced cases after RV improves loco-regional control in comparison to surgery alone (Perez et al.).[21] According to Katz et al., RT only or RT plus LND is effective in preventing inguinal LN recurrence in vulvar SCC.[22] Adjuvant groin and pelvic RT should be given in cases with ≥ 2 positive LNs, extracapsular extension, or in those with inadequate lymphnode dissection (Homesley et al.).[23] The role of adding concurrent CT to RT in adjuvant setting is not clear till date.

Lymphnode dissection may lead to sacrifice of the great saphenous vein and may be a cause of delayed healing leading to lymphatic retention cyst, lower extremity edema, incontinence, and sexual dysfunction affecting quality of life.[9] There are chances of wound infection, cellulitis and formation of lymphatic cyst from the area of operated wound leading to delayed healing and swelling of the area. In the present study, we found wound infection/delayed wound healing, wound dehiscence, skin toxicity, vaginal ulceration as surgery or radiotherapy induced acute complications, whereas, lymphocyst, lymphedema, vaginal stenosis as the treatment induced late complications. Wound infection (34.92%) is the most common complication due to surgery supported by Thakur et al where it was reported to be 37.66% of the major complications.[9] 25.81% patients developed RT-induced grade-III skin toxicities, but none had treatment induced mortality.

Overall Survival(OS) was significantly inferior for pathologically node positive patients than node negative patients (p-value=0.042).[11] A study by Imoto et al. showed that 5-year OS for inguinal LN metastasis positive and negative cases were 51.9% and 85.4% respectively which was statistically significant (p-value of 0.0161).[10] A study by Mahner et al showed that 3-year PFS and OS rates for node positive patients versus node negative patients were statistically significant with p-value <.001.[24] In the present study, OS of patients with negative lymph node was 42.22 months whereas for patients with positive lymph node status was 20.004 months. This difference was statistically significant (p value= 0.021) supporting Sharma et al, Imoto et al, and Mahner et al.[11,10,24]

According to Sharma et al, the 5-year OS was 41% for all the stages and there was no significant difference in survival of patients age >65 years versus older patients and among histopathological grading.[11] However, 5-year OS of patients with different tumour size was not statistically significant (p value=0.433) supporting Imoto et al (p-value=0.0791).[10] 5-year OS for stage-2 or less and stage-3 or more was not statistically significant (p value=0.165), whereas, it was significant for Imoto et al (p-value=0.0093).[10] Five-year OS in patients who received adjuvant treatment compared to those who didn't receive was statistically significant (p value=0.043) in the present study.

Conclusion

In the recent times VC is increasing in younger age groups. Symptoms with vulvar itching, genital warts, genital ulcerations, genital discharge or bleeding should be promptly investigated to rule out and diagnose early stage vulvar cancer in order to improve outcome of the disease in terms of disease free survival and overall survival. As wound infection is the most common postoperative complication causing a delay in starting adjuvant therapy, use of appropriate flap is necessary. It is also important that the operated wound area should undergo dry dressing and adequate vacuum drainage to avoid hematoma and lymphocyst formation in order to prevent infection and prompt healing. Due to low follow-up rates, the co-relation of various prognostic factors with outcome of the disease is not very conclusive and and requires continuation of the study for a significant outcome data. The role of concurrent chemoradiation needs to be evaluated.

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Patient characteristics	Present study (n=65)	Sharma et al. 2010 (n=60)	Thakur et al. 2013 (n=85)	Imoto et al. 2016(n=40)
Incidence	3.02%	NA	2.89%(85/3391)	
Age in years Range Median	26-75 54	24-92 63	24-88 58	37-90 68
Primary sites (n=65) Clitoris Labia Majora Both Mons	 11(16.92%) 40(61.54%) 13(20%) 1(1.54%)	NA	72.94% (lateral side of labia) 27.06% (medial or midline of clitoris & peritoneum)	NA
Tumour size (n=63) <2 cm 2-5 cm >5 cm	 08(12.70%) 46(73.02%) 09(14.28%)	NA	16(18.82%) 59(69.41%) 10(11.77%)	NA
Pretreatment biopsy Done +ve -ve	 63 59(93.65%) 04(6.34%)	NA	78 73(93.58%) 05(06.42%)	NA
Type SCC Melanoma Adenocarcinoma Sarcoma Others	 62(95.38%) 1(1.54%) 1(1.54%) 1(1.54%) 0	Carcinoma (100%)	 72(84.71%) 5(5.88%) 0 0 8	40(100%)
HP grading of SCC WD MD PD Unknown	 38(61.29%) 22(35.48%) 02(3.23%) 0	 31 13 14 2	 57(79.17%) 11(15.28%) 4(5.56%) 0	NA
Stages (n=63) I II III IV	 1(1.59%) 46(73.02%) 15(23.80%) 1(1.59%)	 2 17 31 9	 30 41 13 1	 18(45%) 4(10%) 15(37.5%) 3(7.5%)

Table-1: The patient characteristics in comparison to recent literature.

NA = not applicable, D = discharge. P = pruritus, U = ulcer, M = mass, SCC = squamous cell carcinoma, WD = well differentiated, MD = moderately differentiated, and PD = poorly differentiated.

Table-2: Treatment and outcome

Surgical procedures (n=63)		
WLE	1(1.6%)	
Partial RV	43(68.2%)	
-AQV	1	
-HV	14	
Complete RV	19(30.15%)	
LND (n=56)		
Node +ve	18(32.14%)	
Node-ve	38(67.86%)	
Margin status (n=63)		
Positive	4(6.35%)	
Negative	59(93.65%)	
Wound closure(n=63)		
Primary	22(35%)	
U/L Lotus petal flap(LPF)	12	
B/L LPF	19	
Sartorius transposition	7	65%
V-Y flap	2	
RAM Flap	1	
Adjuvant therapy		
Not taken	32(50.79%)	
RT	28(44.45%)	
Concurrent CCRT	3(4.76%)	
Follow-up (n=63)		
Came	50(79.37%)	
Not came	13(20.63%)	
Recurrence (n=16)		
Local	10(62.50%)	
Lymph node	2(12.50%)	
Loco-regional	3(18.75%)	
Loco-regional + DM	1(6.25%)	

RV = radical vulvectomy, AQV = anterior quadrant vulvectomy,HV=Hemi vulvectomy, WLE = wide local excision,U/L=unilateral,B/L=bilateral,RAM=rectus abdominis myocutaneous, LVI = lymphovascular invasion, LND = lymph node dissection, RT = radiotherapy, CCRT = chemoradiotherapy, and DM = distant metastasis.

Table-3: Treatment complications

Types of treatment	Immediate				Delayed		
Surgery (n=63)	WI	UI	Swelling	WD	L-cyst	L-dema	VS
	22	1	1	8	2	7	1
	34.92%	1.59%	1.59%	12.67%			
RT/CCRT (n=31)	Dermitits			Ulceration	WC		
	Gr-I	-II	-III	4	3		
	17	08	06				
	54.84%	25.81%	19.35%				

WI = wound infection, VI = vascular injury, ITFN = Injury to femoral nerve, UI = urinary incontinence, WD = wound dehiscence, L-cyst = lymphocyst, L-dema = lymphedema, VS = vaginal stenosis, Gr = grade, and WC = wound complication

Figure 1: Survival Analysis of lymph node status

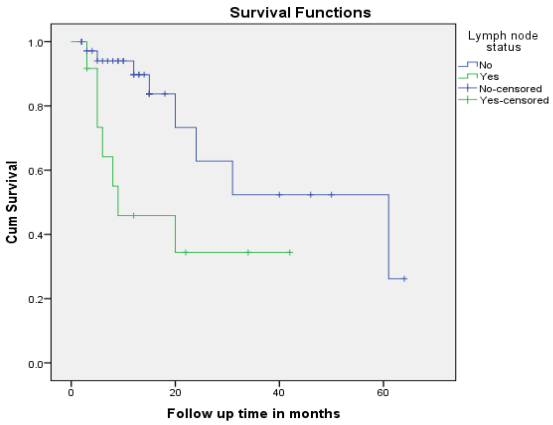

Figure 2-Survival analysis of tumour size.

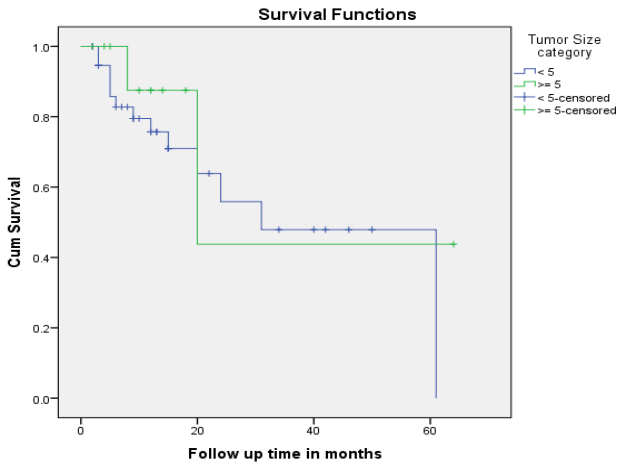

Figure 3-Survival analysis in patients receiving adjuvant treatment.