ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICINE

DEPARTEMENT OF OBSTETRICS AND GYNECOLOGY

Survival Outcomes of Vulvar Cancer Patients at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia: A retrospective Cohort Study, 2024

Investigator: Binyam Esayas (M.D, Gynecology Oncology Fellow)

Addis Ababa, Ethiopia

November, 2024 G.C.

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A Research Thesis Submitted to Department of Obstetrics and Gynecology, School of Medicine, CHS, Addis Ababa University, in Partial Fulfilment of the Requirements for the Sub-Specialization in Gynecology Oncology.

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Addis Ababa University

College of Health Science, Department of Obstetrics & Gynecology

Research Report Attesting Page

Student Declaration

I declare that this work has not been previously submitted and approved for the award of a degree by this university or any other university. To the best of my knowledge and belief, the dissertation contains no material previously published or written by another person except where due reference is made in the dissertation itself.

Name of student: ……

Signature…… Date……

Supervisors' Declaration

I have undersigned and certify that I have read and at this moment recommend for acceptance to Addis Ababa University dissertation entitled " **Survival Outcomes of Vulvar Cancer Patients at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia: A retrospective Cohort Study, 2024."**

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Abbreviations and Acronyms

AA - Addis Ababa

AAU- Addis Ababa university

AOR - Adjusted Odd Ratio

ART – anti retroviral therapy

ASA – American society of anesthesiologists

BMI – body mass index

BIFLD – bilateral inguinofemoral lymph node dissection

B.Sc. - Bachelor of science

CI - Confidence Interval

DC - Data Collector

DM – diabetes mellitus

DRPC - Departmental Research Postgraduate Committees

Dr. – Doctor

ECOG – Eastern cooperative oncology group

ETH – Ethiopia

EC -Ethiopian calendar

FDA – Food and drug administration

FIGO – The international federation of Gynecologic Oncology

FU – Fluorouracil

G.C. - Gregorian calendar

HTN – hypertension

HIV – human immunodeficiency virus

IHRERC - Institutional Health Research Ethics Review Committee

IOPBT – intraoperative blood transfusion

IRB – institutional review board

IQR - interquartile range

LN – lymph node

LND – lymph node dissection

MD - Medical Doctor

NACT – neoadjuvant chemotherapy

OPD - outpatient department

PI - Principal Investigator

RV – radical vulvectomy

SD – standard deviation

SCC - Squamous cell carcinoma

SPSS - Statistical Package for Social Science

TASH - Tikur Anbessa Specialized Hospital

USA – United states of America

VC – vulvar cancer

VIN – vulvar intraepithelial neoplasm

WHO - World Health Organization

WLE – wide local excision

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Abstract

Background: Vulvar cancer is a rare condition, representing only 4% of gynecological malignancies, with an estimated 26,800 new cases worldwide. According to data from the Addis Ababa City Cancer Registry (AACCR) in 2012, the age-standardized incidence of vulvar cancer was 1.4 cases per 100,000 women annually in Addis Ababa (1,2,3). In Ethiopia, there are few studies that have evaluated the survival outcomes of patients with vulvar cancer.

Objectives: This study aims to present the clinical characteristics, treatment patterns, and survival outcomes of vulvar cancer patients in Ethiopia.

Methods

A retrospective cohort study was conducted, analyzing patient records to gather data on demographics, treatment modalities, and survival outcomes from 2016 to 2022 after obtaining ethical clearance from the institution. Survival probabilities were estimated using the Kaplan–Meier method. Multivariate Cox proportional hazards regression analysis was used to estimate adjusted hazard ratios (HRs) and corresponding 95% confidence intervals (CIs) for prognostic factors.

Result

We identified 81 patient records for the analysis of vulvar cancer. Among these patients, 59.3% were in the age group of 31 to 50 years, with a mean age of 43.9 (SD ± 12.5). The most common presenting symptom was swelling, observed in 76.5% of cases, and the mean tumor diameter exceeded 4 cm in two-thirds of patients. Additionally, 63% of the cases were HIV positive. Among those diagnosed with invasive cancers, 92.8% were classified as squamous cell carcinoma (SCC) by histology, and 40.7% were at stage IV upon clinical staging. Out of the 73 patients who received treatment, two third underwent surgery or received radiotherapy. The overall survival rate was 30.9%, with a median survival time of 34 months (95% CI: 24.2–43.7). The cumulative survival rates at 1, 2, and 5 years were 86.4%, 64.2%, and 27.6%, respectively. A statistically significant correlation was found between the time from diagnosis to treatment and the risk of death, with a hazard ratio of 0.95 (95% CI: 0.91–0.99) and a p-value of 0.037.

Conclusion and recommendation

The findings of this study suggest that vulvar cancer remains a significant health concern among middle-aged and HIV positive women. Advanced stage disease during presentation, delays in treatment and 30.9% overall survival indicate challenging prognosis. These findings emphasize the necessity for enhanced awareness, screening, and access to care for vulvar cancer in Ethiopia, particularly among vulnerable populations.

Introduction

Background

Vulvar cancer is an uncommon gynecological malignancy, primarily affecting postmenopausal women, and accounts for only 4% of all gynecological cancers. Squamous cell carcinoma (SCC) of the vulva, the most prevalent subtype, has traditionally been considered a disease of postmenopausal women (1). It is estimated that there were approximately 26,800 new cases worldwide. In 2002, incidence rates for vulvar cancer varied significantly, ranging from less than 0.3 per 100,000 females in Asia to 1.6 per 100,000 females in North America and Europe (2). Most published reports from Africa include relatively small and heterogeneous patient groups. A study conducted in Ghana found that vulvar cancer accounted for 2.1% of all gynecological malignancies. Another study from Nigeria, involving 5,913 gynecological cancer cases, reported that 1.2% were vulvar cancers, with the majority exhibiting squamous cell histology (2). Data from the Addis Ababa City Cancer Registry (AACCR) indicate an age-standardized incidence of 1.4 cases of vulvar cancer per 100,000 women per year in Addis Ababa (3).

A study by Enoro in Addis Ababa at TASH found that approximately 55% of patients were in the 30-50 age group, with a mean age of 43.17 years. Notably, around two-thirds of these patients were HIV positive (4). Another similar study conducted in the same setting revealed that more than half of the participants were aged 30-50 years, with a median age of 39 years, and 83% of this population were HIV positive (3).

The treatment for vulvar cancer primarily depends on histology and staging. Surgical intervention is the predominant approach, particularly for SCC. However, concurrent chemoradiation is an effective alternative, especially for advanced tumors where exenteration may be necessary to achieve adequate surgical margins. Other therapies, such as chemotherapy and immunotherapies, are generally reserved for metastatic or palliative settings or for the treatment of rare histologies, such as melanoma (1,5).

With appropriate management, the prognosis for vulvar cancer is generally favorable, with an overall 5-year survival rate of approximately 70% in operable cases, which correlates with FIGO stage (21).

In a study conducted in the USA, the overall survival rates at 1 and 2 years were reported as 91% and 62%, respectively. A complete response at 3 months was identified as a strong predictor of overall survival (6). A 10-year literature review in India indicated that 48.78% of cases were primarily treated with surgery, 26.83% with radiotherapy, 7.3% with chemotherapy, and 17.07% with combined chemoradiation. Seventy-eight percent of the surgically treated cases showed a mean survival of 5 years (7).

In South Africa, a study by J. L. Butt reported an overall 5-year survival probability of 58.8% across all stages. The survival curves for each stage were 91.2% for stage 1, 82.5% for stage 2, 41.0% for stage 3, and 10.9% for stage 4 (8). A review of hospital-based data on vulvar cancer in Ghana found an 80% and 74% complete clinical response in the primary lesion and lymph nodes, respectively, at 12 weeks post-radiation for 23 patients who completed definitive treatment. The 2- and 5-year overall survival rates for all 30 subjects (70% of whom were stage 4) who completed treatment were 56.7% and 36.7%, respectively (9). A study conducted in Ethiopia reported 1- and 2-year survival rates of 80% and 51%, respectively. Approximately 37% of patients received surgery, 38% received radiotherapy, and 33%

received chemotherapy. Patients with FIGO stage 4 had unfavorable outcomes compared to those with stages 1 to 3 (3).

Statement of the Problem

Vulvar cancer, though accounting for only 4% of gynecological malignancies, represents a significant health issue for women, particularly in regions with limited research and resources. In Ethiopia, the age-standardized incidence rate is notably low at 1.4 cases per 100,000 women annually, yet there is a dearth of comprehensive studies evaluating the clinical characteristics, treatment patterns, and survival outcomes of patients with vulvar cancer. The high prevalence of HIV among patients and the predominance of advanced-stage diagnoses, from the previous study, further complicate treatment and prognosis. Given the rarity of vulvar cancer and the unique demographic and clinical features observed in Ethiopia, there is an urgent need to investigate these aspects to inform clinical practice and improve patient care.

Justification of the Study

This study is justified by the critical gap in knowledge regarding vulvar cancer in Ethiopia, particularly concerning survival outcomes and treatment approaches. By analyzing patient records from 2016 to 2022, this research aims to provide valuable insights into the demographic characteristics, common presenting symptoms, and histological types of vulvar cancer prevalent in the region. The findings will contribute to understanding the impact of patterns of treatment on survival and will highlight the importance of early diagnosis and intervention.

Additionally, the study's focus on a cohort with a significant proportion of co-morbidities like HIV-positive patients and offers a unique opportunity to explore the interactions between vulvar cancer and co-morbidities that may affect treatment outcomes. Establishing a clearer picture of survival probabilities and prognostic factors will not only aid in the development of targeted treatment protocols but also serve as a foundation for future research initiatives. Ultimately, this study aims to enhance the management of vulvar cancer in Ethiopia, leading to improved patient outcomes and contributing to the broader understanding of this rare malignancy within low-resource settings.

Objectives

General objectives

To assess the overall survival of vulvar cancer patients treated at Tikur Anbessa Specialized Hospital (TASH) from January 2016 to December 2022

Specific Objectives

1. To evaluate the demographics of vulvar cancer patients treated at TASH during the study period
2. To assess the tumor characteristics of vulvar cancer patients treated at TASH during the study period
3. To examine the treatment patterns for vulvar cancer patients treated at TASH during the study period
4. To identify predictors of survival in vulvar cancer patients treated at TASH during the study period.

Methodology

Study Design: This study was a retrospective cohort study.

Study Area and Period: The research was conducted at Tikur Anbessa Specialized Hospital (TASH), a teaching university hospital located in the capital city of Ethiopia. TASH encompasses various departments and specialized units, including gynecology oncology and clinical oncology. The study was performed over a period of 6 years, from January 2016 to December 2022.

Study Population: All patients diagnosed with primary vulvar cancer who were managed at the gynecology oncology unit and the clinical oncology unit (radiation and medical oncology) at TASH during the study period were included.

Inclusion and Exclusion Criteria: All patients with histologically confirmed primary vulvar cancer were included in the study. Patients with secondary vulvar carcinoma were excluded.

Data Collection Tools and Procedures: Data, including demographic information and clinical profiles were extracted from the patients' hospital record using a structured data collection index for statistical description and analysis. Residents, who were trained conducted the data collection. The principal investigator ensured the completeness of the data at each step. The data were then cleaned, coded, and entered into SPSS for analysis.

Operational Definitions: An "event" is defined as the occurrence of death during the study period or the last recorded visit for patients lost to follow-up.

Statistical Analysis: Data, including demographic information and clinical profiles were extracted from the patients' hospital record using a structured data collection index for statistical description and analysis.

Descriptive statistics were generated using SPSS, presenting findings in the form of rates, and proportions. Univariate analysis was conducted to evaluate the effects of independent variables. Kaplan-Meier survival curve was employed to estimate survival rates, and the hazard ratios (HR) along with 95%% CI were calculated using a multivariate COX proportional hazard regression model to identify predictors of survival.

Ethical Consideration: As this study involved a retrospective chart review, a waiver of informed consent was requested and granted by the Department Research and Publication Committee (DRPC). This waiver allowed for the use of existing patient records without direct patient interaction, minimizing risk to participants. All data were handled with strict confidentiality to protect patient privacy, and the study adhered to ethical guidelines for research involving human subjects

Results

Sociodemographic characteristics of the study participants

Ninety-two cards from vulvar cancer patients were retrieved for analysis. Among these patients, 81 had biopsy proven invasive vulvar cancer, and 11 had preinvasive disease.

Among these patients, 59.3% were in the 31-50 year age group, with a mean age of 43.9±12.5 years; 58%resided in Addis Ababa, and nearly half were either widowed or divorced.

Table 1. The sociodemographic characteristics of the vulvar cancer patient, from 2016-2022 (n=81)

Variable		Frequency	Percent
Age in years			
	<20	0	0%
	20-30	10	12.5%
	31-40	29	35.8%
	41-50	19	23.5%
	51-60	14	17.3%
	>60	9	11.1%
Religion			
	Muslim	7	8.6%
	Orthodox	31	38.3%
	Protestant	3	3.7%
	Unknown	40	49.4%
Residence			
	Addis Ababa (capital city)	47	58.0%
	Amhara	6	7.4%
	Oromia	4	4.9%
	Others	24	29.6%
Marital status			
	Married	37	45.7%
	Widowed	31	38.3%
	Divorced	7	8.6%
	Single	2	2.5%
	Unknown	4	4.9%

Clinical characteristics of vulvar cancer patients

As shown in Table 2, almost all patients had an eastern Cooperative Oncology Group (ECOG) performance status of 1. Patients often present with more than one symptom, but the most common presenting symptom is vulvar swelling in 73.9% of the patients. The mean (SD) duration of symptoms was 23.16 (±28.9) months. In 59.3% of the patients, the mean diameter of the tumor was > 4 cm. Fifty-

one (63%) patients were HIV positive. Among HIV-positive patients, 32 patients had CD4 counts recorded on the chart. Among these patients, approximately 90% had a CD4 count >200.

Table 2. The clinical characteristics of the study participants from 2016- 2022 (n=81)

Variable	Frequency	Percent
ECOG function status		
Zero	1	1.2%
One	78	96.4%
Two	2	2.3%
Presenting symptoms		
Vulvar itching	14	17.3%
Vulvar swelling	62	76.5%
Discharge	2	2.5%
Inguinal swelling	2	2.5%
Difficulty of urination	1	1.2%
Duration of symptom in month		
<=6	21	25.9%
7-12	32	39.5%
13-24	10	12.3%
>24	18	22.2%
Size of tumor		
<2 cm	1	1.2%
2-4 cm	32	39.5%
>4 cm	48	59.3%
HIV		
Negative	30	37%
Positive	51	63%

Diagnosis related characteristics of vulvar cancer

Almost 95% of the study participants were diagnosed via punch biopsy, and almost 93% were diagnosed via as SCC via histopathological examination.

Table 3. Diagnosis related characteristics of vulvar cancer patients, from 2016-2022 (n=81)

Variable	Frequency	Percent
Types of biopsies		
Punch	77	95.1%
Wedge	4	4.9%
Types of malignant		
SCC	75	92.8%
Adenocarcinoma	2	2.4%
Embryonal rhabdomyosarcoma	1	1.2%
Melanoma	1	1.2%
Verrucous carcinoma	1	1.2%
Vulvar sarcoma	1	1.2%

Vulvar cancer staging via FIGO classification

All of the patients had documented clinical stage on the chart. Sixteen (19.7%)of these patients had stage 1 disease, 11 (13.6%) had stage 2 disease, 21 (25.9%) had stage 3 disease and 33 (40.7%) had stage 4 disease. This shows that almost two thirds of the patients were in the advanced stage.

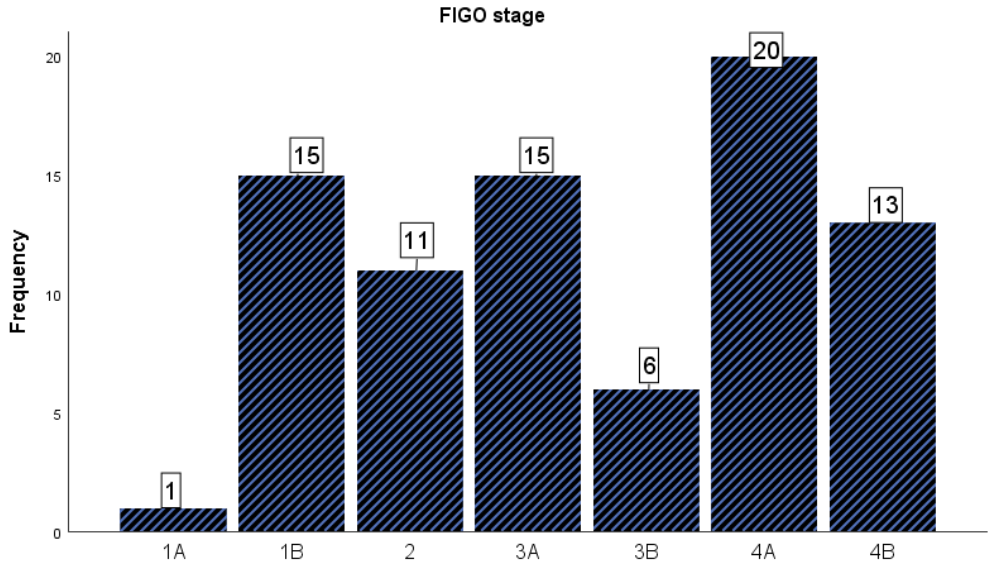


Figure 1 : Stage of vulvar cancer according to FIGO classification

Treatment related characteristics of the patient

Among the patients diagnosed with invasive vulvar cancer after histopathological evaluation, 90% (73 out of 81) received treatment. The mean time elapsed from pathological diagnosis to treatment was 7.4 months (± 9.3 months).

Two-thirds of the patients received either surgical treatment or radiotherapy, while the remaining patients received chemotherapy, the majority of whom were treated with palliative intent. Among those who underwent surgery, 79.3% had radical vulvectomy with bilateral inguino-femoral lymphadenectomy.

Survival

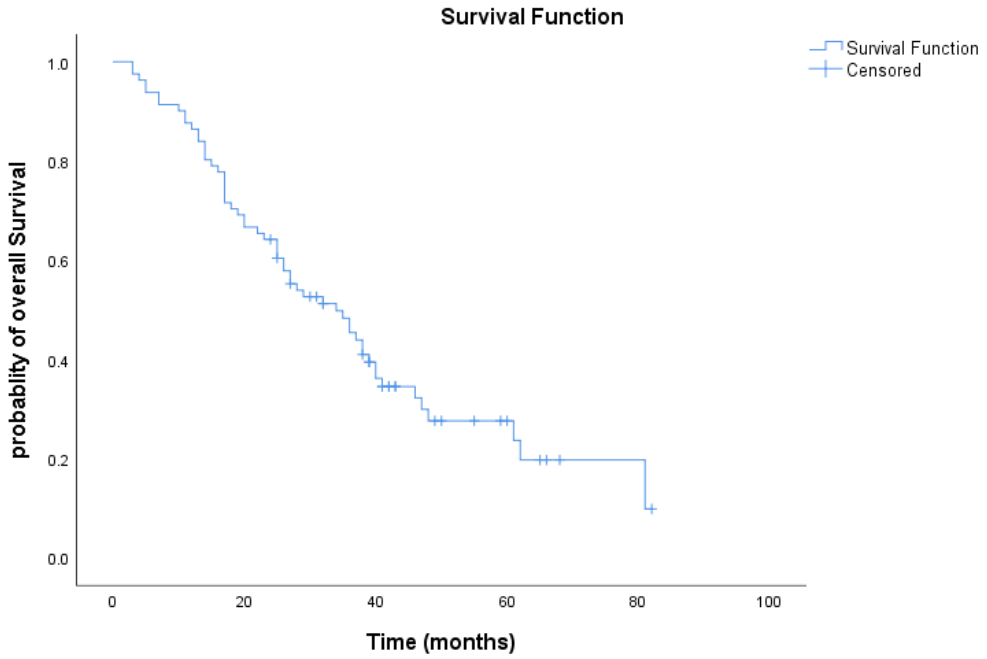
Among the 81 patients diagnosed with vulvar cancer via biopsy, the overall survival rate was 30.9%, with a median survival time of 34 months (95% CI: 24.2–43.7). The cumulative survival rates at 1, 2, and 5 years were 86.4%, 64.2%, and 27.6%, respectively.

Univariate analysis revealed a significant correlation between disease stage and the type of treatment received with overall survival. Patients with stages I, II, III, and IV vulvar cancer had overall survival rates of 68.8%, 45.5%, 9.5%, and 20.2%, respectively (figure 3).

Compared to those treated with chemotherapy or radiotherapy for palliative intent, vulvar cancer patients who underwent surgery or received curative intent radiotherapy had a higher overall survival

rate of 48.5% (figure 4). In contrast, those receiving chemotherapy or palliative radiotherapy had an overall survival rate of only 17.5%.

Furthermore, a statistically significant correlation was found between the time elapsed from diagnosis to treatment and the risk of death, as determined by multivariate Cox regression analysis. The hazard ratio (HR) indicated that the risk of death increased with a HR of 0.95 (95% CI: 0.91–0.99), with a p-value of 0.037.



Time (months)	0	12	24	36	48	60
No. at risk	81	70	51	31	12	7
No. deaths	0	11	29	43	53	53

Figure 2 : Cumulative overall survival probability of the total cohort of Vulvar cancer patients.

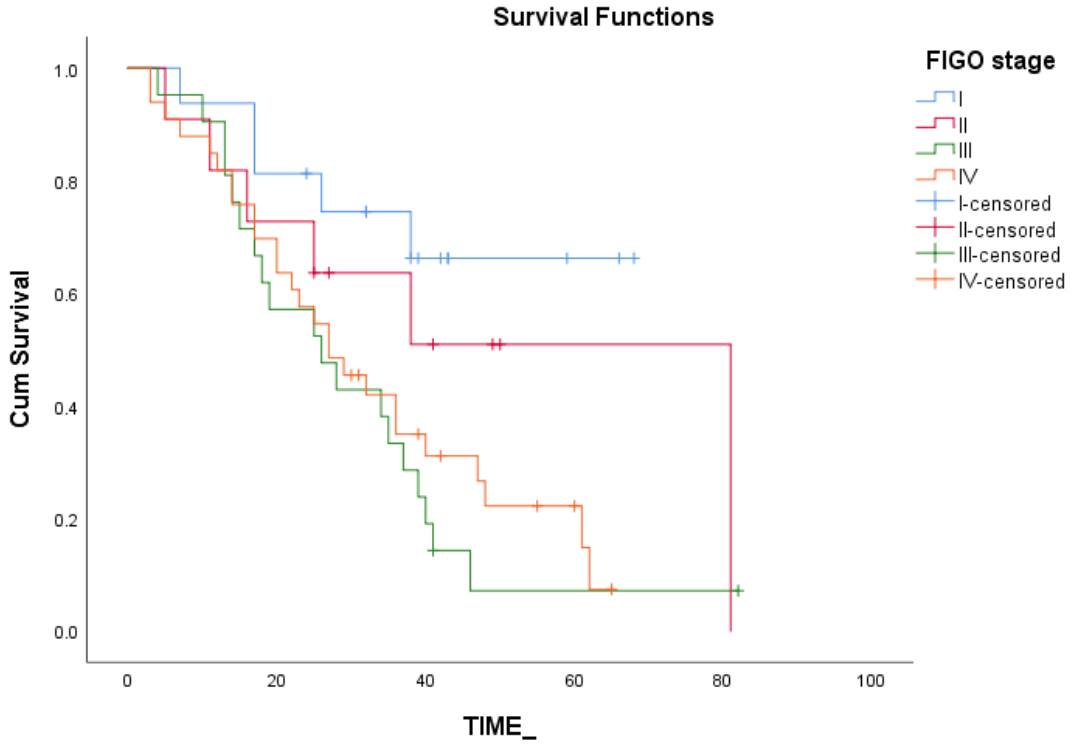


Figure 3 : Kaplan-Meier curve of patient survival according to FIGO staging

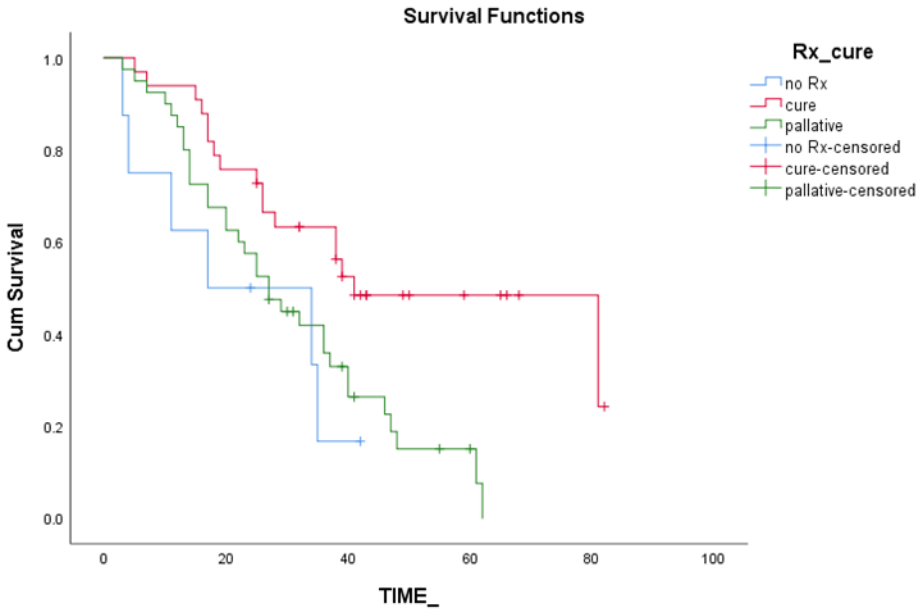


Figure 4 : Kaplan-Meier curve of patient survival according to type of treatment given

Table 4: predictors of survival

Variables	P value	HR	95.0% CI for HR Lower	Upper
Age : continuous	0.550	0.990	0.960	1.022
Time elapsed between diagnosis to treatment : continuous	0.037	0.955	0.915	0.997
FIGO stage :ref : stage 1				
Stage 1*	0.327			
Stage 2	0.466	0.684	0.247	1.898
Stage 3	0.196	0.563	0.236	1.344
Stage 4	0.181	1.570	0.811	3.039
HIV: ref ; negative	0.181	1.775	0.766	4.112
LNs status : ref : positive	0.065	0.259	0.062	1.085
Tumer size in cm : continuous	0.453	1.043	0.934	1.165
Type of Treatment given : ref : no treatment				
No treatment *	0.450			
Surgery	0.490	0.731	0.300	1.782
Radiotherapy	0.217	0.513	0.178	1.481
Chemotherapy	0.324	0.697	0.341	1.428
Radiotherapy& chemotherapy	0.795	0.901	0.413	1.969
Surgery & radiotherapy	0.262	0.649	0.305	1.382
Surgery, chemotherapy& radiotherapy	0.268	2.267	0.533	9.642
ECOG performance status : continuous	0.090	0.137	4.791	0.609

Discussion

Vulvar cancer predominantly affects older women. In Western Europe, the average age of patients is over 70 years (10). In contrast, studies from some African countries, such as Ghana, report a median age of 56.3 years (9). In our study, 58.3% of participants were aged 31 to 50 years, with a mean age of 43.9 years (SD ± 12.5). This discrepancy may be attributed to the low life expectancy and the significant proportion of patients who are HIV positive, making them more susceptible to early-onset vulvar cancer (11). The etiology may also resemble that of cervical cancer, leading to earlier disease presentation.

Approximately 58% of the cases originated from the Addis Ababa area. This could be due to misidentification during hospital registration, as many patients' relatives are from Addis Ababa. Additionally, during the study period, Addis Ababa was the only facility offering radiotherapy services and gynecologic oncologists.

More than three-fourths of the patients presented with vulvar swelling, followed by vulvar itching. In most literature, a long history of vulvar itching is a common presenting symptom. The difference in our study may be due to patients presenting at later stages of vulvar cancer, despite having symptomatic follow-ups for HIV. Itching could have been perceived as a minor symptom, while swelling may indicate a more serious condition.

Fifty-nine percent of patients had a tumor diameter greater than 4 cm, and in two-thirds of cases, both labia were involved. This is indicative of late-stage disease, often resulting in inoperable cases or inadequate surgical resection. Similar findings were reported in a study conducted in this hospital in 2017 (4).

Among the evaluated patients, nearly 93% were diagnosed with squamous cell carcinoma (SCC). This percentage is higher than that reported in Dutch studies, where a lower incidence of SCC was observed (12). This higher prevalence in our study may be attributed to the younger, HIV-positive population, as HPV-associated SCC of the vulva is common.

Regarding clinical staging, 16 patients (19.7%) had stage I disease, 11 (13.6%) had stage II, 21 (25.9%) had stage III, and 33 (40.7%) had stage IV disease. This finding aligns with studies conducted in this hospital and in Ghana and Botswana, which also reported a predominance of locally advanced vulvar cancer (3, 4, 13, 14). In contrast, studies from the USA and Sweden indicated that approximately 62% and 52.3% of patients, respectively, were diagnosed with FIGO stage I disease (15, 16). This discrepancy may stem from inadequate screening, even though many patients were followed up at HIV clinics and had limited access to tertiary care.

Radical surgical excision and sentinel lymph node (SLN) biopsy are the preferred primary treatment modalities for localized vulvar cancer, with adjuvant treatment based on surgical findings. In our study, 90.1% of patients received treatment after biopsy diagnosis, with 35.8% undergoing surgery. Among those who had surgery, 79.3% underwent radical vulvectomy with bilateral inguino-femoral lymphadenectomy.

The overall survival rate in our cohort was 30.9%, with a median survival of 34 months (95% CI: 24.2–43.7). The cumulative survival rates at 1, 2, and 5 years were 86.4%, 64.2%, and 27.6%, respectively. The

1-year survival rate is comparable to that of vulvar cancer patients in the USA (91%) (6) and higher than the 81% reported in a study from England (17). However, the 2-year survival rate in our study was higher than that reported in Ghana and Botswana (13, 14). A similar study in the same setting conducted years ago reported a 51% 2-year survival rate, likely reflecting improved access to early treatment and better surgical and oncological care over the years (3).

In comparison, 5-year survival rates for vulvar cancer patients in India, South Africa, and Croatia were reported at 78%, 58.8%, and 72.9%, respectively (7, 8, 19). A German study reported a 5-year survival rate of 87.5% for patients under 50 years, which is higher than our findings (18). This difference can be attributed to earlier diagnosis and treatment in those studies, as well as better access to care.

A statistically significant correlation was identified between the time elapsed from diagnosis to treatment and the risk of death. The hazard ratio indicated a risk increase with an HR of 0.95 (95% CI: 0.91–0.99), and the mean time from pathological diagnosis to treatment was 7.4 months (± 9.3). There are no existing studies that evaluate the relationship between the time from diagnosis to treatment and survival. A systematic review by Dorothy et al. highlighted the scarcity of infrastructure, equipment, medication, and human resources in sub-Saharan Africa as reasons for delays in receiving quality cancer care (20).

Limitations of the Study

This study was conducted at a single center, which may limit the generalizability of the findings. However, the inclusion of all patients in the analysis helps to mitigate this limitation.

Conclusion and recommendation

Conclusion

The analysis of vulvar cancer patients revealed significant insights into the demographics, clinical characteristics, and survival outcomes in this population. The high prevalence of squamous cell carcinoma and the considerable proportion of patients presenting with advanced-stage disease highlight the need for improved early detection and treatment strategies. The median survival of 34 months and the overall survival rate of 30.9% indicate a challenging prognosis, particularly in patients with delays in treatment. Additionally, the significant correlation between the time from diagnosis to treatment and the risk of death underscores the importance of timely intervention. These findings emphasize the necessity for enhanced awareness, screening, and access to care for vulvar cancer in Ethiopia, particularly among vulnerable populations.

Recommendations

1. **Increase Awareness and Education**: Implement community outreach programs to raise awareness about vulvar cancer, its symptoms, and the importance of early detection, especially targeting women in the 31-50 age group.

2. **Enhance Screening Programs**: Establish regular screening (history and physical examination) initiatives in healthcare facilities to facilitate early diagnosis, particularly for high-risk populations, including those living with HIV.

3. **Improve Access to Care**: Strengthen referral systems and increase access to specialized gynecological services, including radiotherapy, to ensure timely treatment for vulvar cancer patients.

4. **Research and Data Collection**: Encourage further research to explore the factors influencing survival outcomes in vulvar cancer patients, and establish a national cancer registry to monitor incidence and outcomes effectively.

5. **Training for Healthcare Providers**: Provide ongoing training for healthcare providers on the diagnosis and management of vulvar cancer to improve patient outcomes and treatment protocols.

By addressing these recommendations, it is possible to mitigate the burden of vulvar cancer in Ethiopia and improve patient care, ultimately enhancing survival outcomes for this vulnerable population.

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Availability of data and materials

The data that support the findings of this study are available upon request from the corresponding author.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no conflicts of interest.

Author contributors

Principal investigators and Authors were entirely responsible for the study design, conduct, and data analysis.

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Appendices

Questionnaire

Baseline Information

Age MRN

1 Age at the diagnosis of vulvar cancer
2 Date of diagnosis of vulvar cancer
3 HIV Status Positive ☐ Negative ☐
On ART Yes ☐ CD4 at diagnosis How long on ART
No ☐ VL at diagnosis

Sociodémographies

4 Religion **6** Ethnicity
5 Residence **7** Marital Status at Time of Diagnosis

Clnincal presentaion

7 ECOG functional status 0 1 2 3 4 5
8 Presenting symptom

A	Vulvar itching	☐	D	Bleeding	☐
B	Vulvar swelling	☐	E	Change in color	☐
C	Discharge	☐	F	Sore	☐
G	Other specify				

9 Duration of Symptoms
10 Date of Diagnosis
11 Site involved
11 Tumor size (largest diameter)

Labium majus, left	☐	Lower urethral	☐
Labium majus, right	☐	Lower vaginal	☐
Labium minus, left	☐	Anal	☐
Labium minus, right	☐	Upper urethral or vaginal	☐
Central	☐	Bladder or rectal mucosa	☐
Clitoral	☐	No visible tumor	☐
Can't be determined	☐		

Biopsy

12 Procedure Punch biopsy ☐ Wedge biopsy ☐
13 Laterality Left ☐ Right ☐ Midline ☐ Not known ☐
14 Histological type and Differentiation
15 Lymphovascular invasion and Perineurial (intraneural) invasion Present ☐ Not identified ☐
16 Vulvar preinvasive lesion status type and site
17 Paget disease Present ☐ Not identified ☐ Uncertain ☐

18	**Procedure**	Local excision ☐	Partial vulvectomy, right	☐
		Left wide local excision ☐	Partial vulvectomy, anterior	☐
		Right wide local excision ☐	Partial vulvectomy, posterior	☐

Partial vulvectomy, left ☐ Total vulvectomy ☐

Pathology

19 Lymph nodes Present ☐ Absent ☐

Only applicable if 'Lymph nodes, Present' is selected, answer Q

20 Lymph nodes, present Inguinofemoral nodes, left ☐

Inguinofemoral nodes, right ☐

21 Macroscopic site, size, length, width and thickness

If tumor visible Q

22 Nearest macroscopic margin ,distance

23 Histological type and differentiation

24 Microscopic, horizontal dimension, depth of invasion and tumor thickness

25 Lymphovascular invasion and perineural invasion Present ☐ Not identified ☐ Uncertain ☒

26 Extension to margin , margin involved distance to closest margin and closest margin

27 Vulvar preinvasive lesion status type and site

28 Paget disease site and margin involved

29 Non-neoplastic epithelial disease Lichen sclerosus ☐ Lichen planus ☐ Squamous hyperplasia ☐

if 'Lymph nodes, present' includes 'Sentinel lymph nodes'. Q

30 LN status, sites involved, Number retrieved…. Number positive from each sites

31 Extranodal extension yes ☐ No ☐

32 Histological evidence of distant metastasis Present ☐ Not identified ☐

33 Provisional FIGO stage

Treatment

34 Treatment given Yes ☐ No ☐

35 What treatment did you receive first? surgery Chemo Radiotherapy combination

If surgery

36 Date of surgery

37 Type of surgery

38 Lyphadnectomy type and site

If radiotherapy

39 Date of First Radiation

40 Date of Last Radiation

41 Dose of Radiation (Gy)

42 Cycles of Radiation

43 Time between the cycles

44 Finish Radiation: yes ☐ No ☐

If no, why not?

45 Type of Radiation

46 Time lapse between date of pathological diagnosis and date of first attendance

47 Time lapse between date of first attendance and commencement of radiotherapy treatment

48 Radiation sequence with surgery yes ☐ No ☐

49 Radiation sequence with chemotherapy yes ☐ No ☐

If chemotherapy

50	Type of chemo given	NACT ☐		ADJ ☐		Palliative ☐
51	Medication given					
52	Date of first Chemotherapy					
53	Number cycles of chemo					
54	Date of last chemotherapy					
55	Treatment stopped	yes	☐	No	☐	
56	Reason why it is stopped?					
57	Comorbidity					
58	Previous treatment of other disease					

Clinical response (follow up)

59	Status at the last follow up	Alive	☐	Died	☐
60	Date of last follow up visit				