

Original Research Article

RISK FACTORS FOR RECURRENCE IN EPITHELIAL OVARIAN CANCER – INDIAN SETTING

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ABSTRACT

Background: Recurrence following treatment for epithelial ovarian cancer (EOC) remains a major concern in gynec-oncology. The identification of risk factors that attribute to recurrence and also survival is essential to design risk-tailored strategic treatment for each patient. We aim to analyze patients' demographic - histopathological features and to determine the risk factors that are associated with the development of recurrence in Indian setting.

Materials and Methods: This was a retrospective observational study conducted on EOC who underwent curative treatment. Clinical data including relevant history and examination details, tumor marker, stage, complete treatment details, histopathology, follow up data were retrieved. Multiple logistic regression analysis was used to find out the predictive factors of recurrence. Kaplan Meier survival analysis had been used for analyzing disease-free survival and overall survival. A Log-rank test had been used to analyze the difference in survival among different groups

Results: A total of 137 patients were included in the final analysis. Primary cytoreductive surgery was done in 39.4% and the rest 60.4% were treated with neoadjuvant chemotherapy (NACT) and interval cytoreductive surgery (ICS). 41.6% (n=80) had recurrence and the commonest site being intra-abdominal (87.5%). Multivariate analysis identified patients without co-morbidities had 53% less risk of recurrence (HR: 0.47, P-0.01) and FIGO stage associated with risk of recurrence. The 5-year recurrence-free and overall survival were 39% and 75.1% respectively. The higher stage had an increased risk of recurrence in this study and the 5 years RFS of FIGO stage I, II, III, and IV were 83.2%, 60.6%, 22.9%, and 10% respectively (P - 0.0001).

Conclusion: FIGO stage is the single most significant prognostic factor for recurrence and outcome in epithelial ovarian tumors as analyzed by both univariate and multivariate analysis.

Keywords: Ovarian cancer, recurrence free survival, cytoreduction.

INTRODUCTION

Ovarian cancer is the third most common cancer in Indian women with an incidence of 6.7 cases per 100,000 and a mortality rate of 4.8 per 1,00,000 population (GLOBOCAN 2020).^[1] Ovarian cancer is the tenth leading cause of cancer (7.3%) among both males and females and is the third leading cause of cancer (3.26%) among females.^[2] Ninety percent of

ovarian cancers are epithelial in origin which is termed epithelial ovarian cancers (EOC). About 75% of patients with epithelial ovarian cancer present with an advanced stage, due to lack of any satisfactory screening test and disease-specific symptoms in the early stages.^[3] Around 85% of patients diagnosed and treated for ovarian cancer present with recurrence following treatment.^[4]

Various factors are associated with recurrence in epithelial ovarian cancer. Among those factors, the stage of cancer at diagnosis is an important factor that determines the risk of recurrence in ovarian malignancy. Patients with stage I have a ten percent probability of recurrence. Thirty percent of stage II patients have a chance of recurrence. Stage III patients have a seventy to ninety percent chance of recurrence. Stage IV ovarian cancer patients have a ninety to ninety-five percent chance of recurrence. The 5-year relative survival rate for early-stage and late stages are 92% and 29% respectively.^[5] The high mortality in EOC is attributable to many factors, mainly advanced stage at presentation and high propensity to recurrence after treatment for primary cancer. The identification of risk factors that attribute to recurrence and also survival is essential to design risk-tailored strategic treatment for each patient.^[6] In this study, we aim to analyze our patients' demographic - histopathological features and to determine the risk factors (demographic, clinical, radiological, tumor marker, histopathological, and treatment given) that are associated with the development of recurrence in our demographic area which may aid in further research and treatment in our subset of the population in southern India.

MATERIALS AND METHODS

This was a retrospective observational study conducted between January 2020 to August 2021. Approval for the study from the Institutional Review Board (IRB) and the Institutional Ethics Committee (IEC) was obtained before the initiation of study. All patients diagnosed to have EOC and underwent curative treatment between January 2010 to December 2016 were included in the study. Patients with incomplete data in the available case records and patients with outliers with CA125 and those referred after recurrence following complete treatment elsewhere were excluded from the study. Clinical data including relevant history and examination details, tumor marker, stage, complete treatment details, histopathology, follow up and current status of the patients had been collected from case sheets in the medical records division. These patients in their routine follow-up were evaluated as per institutional protocol to detect recurrence. In the event of recurrence, clinical presentation and pattern of recurrence were collected. The follow-up status of the patients were updated either during follow-up visit, or the patients or relatives of concerned patients were contacted telephonically to know the last status of the patient until August 2021. The statistical analyses were conducted using SPSS version 20.1. The data had been expressed in number, percentage, mean, SD, median and interquartile range (IQR). The incidence rate had been calculated for the recurrence. A Chi-

square test had been used to assess the association between each demographic variable and recurrence. In all the analyses, P less than 0.05 had been considered statistically significant. The multiple logistic regression analysis had been used to find out the predictive factors of recurrence. Kaplan Meier survival analysis had been used for analyzing disease-free survival and overall survival. A Log-rank test had been used to analyze the difference in survival among different groups.

OPERATIONAL DEFINITIONS

Recurrence of epithelial ovarian cancer in this study was defined as confirmation of recurrence with imaging in epithelial ovarian cancer patients treated with curative intent and completed treatment. Response assessment after neoadjuvant chemotherapy was assessed using Response Evaluation Criteria in Solid Tumours (RECIST) 1.1 criteria. Optimal cytoreduction was defined as no macroscopic residual disease after cytoreductive surgery either as primary or interval cytoreductive surgery. Sub optimal cytoreduction was defined as the presence of any macroscopic disease after cytoreductive surgery either as primary or interval surgery. Disease free survival was defined as the length of time from completion of primary treatment to time the patient survives without any signs or symptoms of epithelial ovarian cancer recurrence or last date of follow-up. Overall survival was defined as the length of time from the date of diagnosis of primary ovarian cancer or registration to that time a patient diagnosed with epithelial ovarian cancer is alive or last date of follow-up. Multi organ resection was defined as the simultaneous resection of additional visceral organs of the abdomen in addition to standard cytoreductive surgery as described for ovarian cancers.

RESULTS

In this study, the data of 154 epithelial ovarian cancer patients who underwent curative treatment were analysed. Out of these 154 patients, 17 patients with outlier variables for CA 125 values were excluded and hence 137 patients were included in the final analysis. The last status of the patients were followed up and updated till August 2021. The median follow-up period of our study was 66 months. The mean age of patients at diagnosis was 50.6 years, ranging from 21 to 74 years. Among the study population age distribution, up to 50 years (49.6%) and above 50 years (50.4%) were almost equal. Co-morbidities were seen in 35 % of the patients. The baseline ECOG performance status of the study population with ECOG <2 and 2 were 83.9% and 16.1% respectively. The majority of our study population had a body mass index of less than 30(88.3%).

Table 1: Treatment characteristics of patients with epithelial ovarian cancer (N=137)

TREATMENT CHARACTERISTICS	No. of Patients	PERCENTAGE (%)
COMPLETENESS OF CYTOREDUCTION		
Optimal	133	97.1
Suboptimal	4	2.9
MULTI-ORGAN RESECTION		
Yes	27	19.7
No	110	80.3
DETAILS OF ORGAN RESECTED		
Colon	19	13.9
Rectum	4	2.9
Others	4	2.9
None	110	80.3
RESPONSE TO CHEMOTHERAPY		
Complete	7	5.1
Partial	70	51.1
Unknown	5	3.6
Not applicable	54	39.4
LYMPH NODE POSITIVITY		
Present	30	21.9
Absent	75	54.7
Unknown	22	16.1
Not applicable	10	7.3
DURATION BETWEEN SURGERY AND CHEMOTHERAPY		
≤ 5 weeks	96	70.1
> 5 weeks	19	13.9
Not applicable	22	16.1

The median CA 125 at diagnosis was 485 units/ml and 50.4% of patients had less than the median value. Serous carcinoma was found to be the most common histology subtype (55.5%) in our study; FIGO Stage III was the commonest stage (51.8%). Ascites were present in 56.9% of the patients (n=78) and among those, 46.1% were positive for malignant cytology. Primary cytoreductive surgery was done in 39.4% of the patients and the remaining 60.4% were treated with neoadjuvant chemotherapy (NACT) and interval cytoreductive surgery (ICS). The

cytoreduction was optimal in 97.1% of patients (Table 1). Multi visceral resection was necessary for 19.7% of patients. The commonest organs resected were the colon and rectum (13.9% and 2.9%). Tumour response to chemotherapy assessed by RECIST 1.1 criteria was complete in 5.1% and partial in 51.1%. Among patients who underwent lymph node dissection, the lymph node positivity rate was 21.9%. After surgery, 70.1% of patients underwent adjuvant chemotherapy within 5 weeks.

Table 2A: Univariate analysis on demographic and baseline prognostic factors for recurrence in epithelial ovarian cancer (n=137)

Cancer (n=157)

CHARACTERISTICS	RECURRENCE	P-value
AGE, years		
≤ 50	44.5	0.114
> 50	33.7	
COMORBIDITIES		
Present	54.5	0.017
Absent	30.1	
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS		
<2	88	0.117
2	31.8	
BODY MASS INDEX		
< 30	38.8	0.44
≥ 30	50	
CA 125, units/ml		
≤ 485	48.9	0.005
> 485	28.4	
HISTOLOGY		
Serous Carcinoma	34.7	0.418
Clear Cell Carcinoma	50	
Endometrioid Adenocarcinoma	66.7	
Mucinous Carcinoma	67.5	
Poorly Differentiated Carcinoma	20	
Adenocarcinoma, NOS	20	
Others	45.8	
FIGO Stage		
I	83.2	0.0001
II	60.6	
III	22.9	

IV	10	
ASCITES		
Present	31	0.037
Absent	49.8	

In the analyzed study population, 41.6% (n=80) had recurrence. The commonest site of recurrence was intra-abdominal (87.5%). The other sites were the lung, pleural cavity, lymph nodes, and brain. The nodal recurrences were seen in the retroperitoneum, mediastinum, inguinal region, and neck. The treatment for recurrent EOCs was palliative mostly and treated with chemotherapy. Among patients with recurrence, 8% (n=7) underwent secondary cytoreduction and among them 57% (n=4) of the procedures were optimal.

In univariate analysis, absence of co-morbidities (P - 0.017), CA 125 level above 485 IU/ml at diagnosis (P - 0.005), higher stage (P - 0.0001), presence of ascites (P - 0.037), absence of multi organ resection (P - 0.042), presence of colorectal resection (P - 0.005), decreased response to chemotherapy (P - 0.0001), node positivity (P - 0.016) was associated with increased risk of recurrence which was statistically significant. [Table no 2A and 2B]

Table 2B: Univariate analysis on treatment factors for recurrence in epithelial ovarian cancer (n=137)

CHARACTERISTICS		RECURRENCE
ASCITIC FLUID CYTOLOGY FOR MALIGNANCY		
Positive	32.9	0.526
Negative	32.1	
Not done	45.4	
COMPLETENESS OF CYTOREDUCTION		
Optimal	40.2	0.015
Suboptimal	0	
MULTI-ORGAN RESECTION		
Yes	27.5	0.042
No	41.8	
DETAILS OF ORGAN RESECTED		
Colon	22.2	0.005
Rectum	33.3	
None	43.7	
RESPONSE TO CHEMOTHERAPY		
Complete	35.7	0.001
Partial	13.9	
LYMPH NODE POSITIVITY		
Present	21.5	0.016
Absent	45.3	
Unknown	35.6	
Not applicable	41.4	
DURATION BETWEEN SURGERY AND CHEMOTHERAPY		
≤5 weeks	33.7	0.124
>5 weeks	40.3	
Not applicable	65.2	

Multivariate analysis identified two factors independently predictive of tumour recurrence, co-morbidities and FIGO stage. Patients without co-morbidities had 53% less risk of recurrence compared to those with co-morbidities (HR - 0.47, 95% CI 0.26

- 0.84, (P-0.01). FIGO stage was significantly associated with risk of recurrence (stage I: HR -0.15, 95% CI 0.04 - 0.56, p - 0.004, stage II: HR - 0.19, 95% CI 0.05 - 0.67, p - 0.01, stage III: HR - 0.68, 95% CI 0.32 - 1.43, P - 0.30, stage IV: HR - 1).

Table 3: Multivariate analysis on prognostic factors for recurrence in epithelial ovarian cancer (n=137)

CHARACTERISTICS	RECURRENCE		
	HR	95% CI	P
COMORBIDITIES			
Present	1		
Absent	0.47	0.26 to 0.84	0.01
CA125			
≤ 485	0.96	0.56 to 1.72	0.96
> 485	1		
FIGO STAGE			
I	0.15	0.04 to 0.56	0.004
II	0.19	0.05 to 0.67	0.01
III	0.68	0.32 to 1.43	0.3
IV	1		
ASCITES			
Present	0.57	0.31 to 1.05	0.08
Absent	1		

COMPLETENESS OF CYTOREDUCTION			
Optimal	0.44	0.15 to 1.29	0.13
Suboptimal	1		
MULTI-ORGAN RESECTION			
Yes	0.45	0.05 to 4.07	0.48
No	1		
DETAILS OF ORGAN RESECTED			
None	0.74	0.10 to 5.44	0.78
Colon	4.39	0.87 to 22.12	0.07
Rectum	0.59	0.08 to 4.26	0.6
Others	1		
RESPONSE TO CHEMOTHERAPY			
Not applicable	2.18	0.35 to 13.68	0.41
Complete	5.22	0.64 to 42.37	0.12
Partial	6.47	1.12 to 37.48	0.04
None	0	0 to 2.50	0.97
Unknown	1		
LYMPH NODE POSITIVITY			
Present	1.52	0.68 to 3.42	0.3
Absent	1.52	0.70 to 3.32	0.29
Unknown	1		

The median recurrence-free survival was 30.3 months (figure 1). The 5-year recurrence-free survival was 39%. The 5-year overall survival was 75.1%(figure 2). Mean overall survival was 100.4 months (95% CI: 91.35 - 109.41). The 5-year recurrence-free survival (RFS) was 54.5% and 30.1% in patients with and without co-morbidities respectively (P - 0.017). CA-125 level above 485 IU/ml at diagnosis had a high risk of recurrence with 5 years RFS of 28.4% (P - 0.005). The higher stage had an increased risk of recurrence in this study and the 5 years RFS of FIGO stage I, II, III, and IV were 83.2%, 60.6%, 22.9%, and 10% respectively (P - 0.0001). Patients with ascites at presentation had an increased risk of recurrence with 5 years RFS of 31% compared to those with no ascites whose 5 years RFS were 49.8% (P - 0.037). Patients who underwent optimal cytoreductive surgery had significantly better 5year RFS of 40.2% than sub-optimally operated patients (P - 0.015). The risk of recurrence was higher among patients who underwent multi-organ resection with 5 year RFS of 27.5% than those with no history of multi-organ resection in cytoreductive surgery [5 years RFS - 41.8%, (P - 0.042)]. Neo-adjuvant chemotherapy-treated patients with the complete response as per RECIST 1.1 criteria had better RFS than partial and non-responders (P - 0.0001). Lymph node-positive patients confirmed histologically had less than 5 years of RFS (21.5%) compared to node-negative patients (45.3%) which was statistically significant(P-0.016).

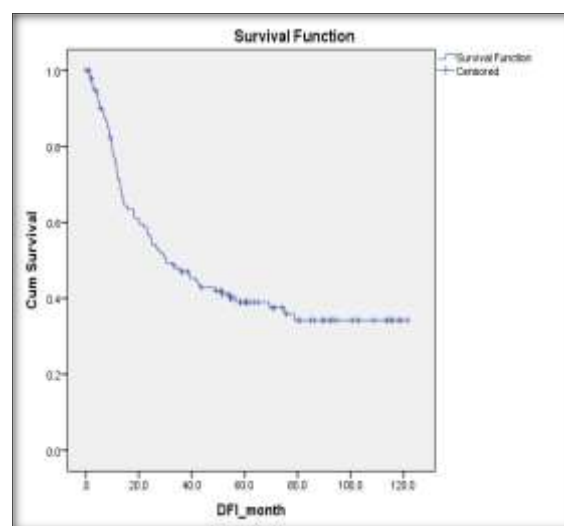


Figure 1: Kaplan-Meier estimated recurrence-free survival in epithelial ovarian cancer

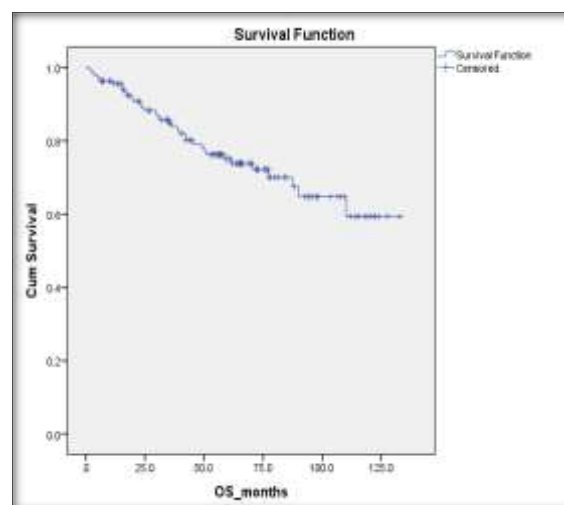


Figure 2: Kaplan-Meier estimated overall-free survival in epithelial ovarian cancer

DISCUSSION

Co-morbidities and FIGO stage were the two significant prognostic factors for recurrence in multivariate analysis in patients diagnosed stage I to IV epithelial ovarian cancer patients treated with curative intent.

Age did not have a significant influence on recurrence and survival in our study and was similar to the published results earlier.^[7] In multivariate analysis patients without comorbidities had 53% less risk of recurrence compared to those with comorbidities. ECOG performance status did not have an impact on recurrence and death in our study. This is in contrast to most of the previous studies where they described the poor performance status were associated with decreased recurrence or PFS and OS.^[8-11]

Body mass index(BMI) did not have significant relation on recurrence-free survival in our study (5 year RFS: BMI < 30 - 38.8%, BMI ≥ 30 - 50%, p - 0.177) and it was similar to a retrospective study report by Karina E Hew et al who showed obesity does not have a significant effect on the period of recurrence in primary epithelial ovarian cancer.

CA 125 levels > 485 IU/ml had an increased probability of recurrence. The adoption of 485 IU/ml as the cut-off for the CA 125 level using stratification was based on the average CA 125 values among the collected data. The current analysis did not show a significant association between histology types and recurrence possibly due to inter-observer variability in the pathological review of epithelial ovarian cancers.^[12,13]

In our study, the stage was one of the significant predictive factors for recurrence, with advanced-stage patients having a higher risk of recurrence compared to early-stage cancer patients. The presence of ascites was a negative prognostic factor and had statistically significant decreased recurrence-free survival. Chan K et al also reported that patients with ascites had decreased recurrence than patients without ascites (p - 0.05). More than one-third of newly diagnosed ovarian cancer patients have ascites at initial presentation. The presence of ascites corresponds to peritoneal spread and indicates a poor prognosis. The presence of ascites is a major source of morbidity to ovarian cancer patients both during initial presentation and at recurrence.^[12]

Patients with optimal cytoreductive surgery had decreased risk of recurrence compared to suboptimal cytoreduction in this study. Previous studies by Winter et al also had similar results but they showed better progression-free and overall survival with microscopic, and up to 1 cm of residual disease.^[14] Also Bristow et al in their meta-analysis showed a 5.5% increase in median overall survival with each 10 % increase in tumor resection.^[15]

Multi-organ resection in initial cytoreductive surgery was a negative prognostic factor of recurrence in this study. The common organ removed in our study was

colon and rectum similar to Vagliasindi et al in their study reported large bowel.^[16] The other organs resected were small bowel and upper abdominal procedures such as full-thickness diaphragmatic excision, diaphragmatic stripping, splenectomy, distal pancreatectomy, liver resection, and cholecystectomy. Disease recurrence was seen in 29.7% of patients.^[16]

A complete response to chemotherapy had significantly decreased RFS than partial or no response. Santoro A et al reported that chemotherapy response score was a significant prognostic value for PFS and OS. They compared the tumor response in omental and adnexal samples. Partial tumor response in omental tissues was associated with a poor outcome in comparison to partial response in adnexal specimens.^[17]

Histopathologically confirmed lymph node metastasis confirmed an increased risk of recurrence compared to lymph node-negative patients. Among neoadjuvant chemotherapy-treated patients, Noori K et al reported RFS of 15.7 and 26.8 month lymph node-positive and lymph node-negative patients respectively.^[18] Microscopic nodal metastases in early ovarian cancer are approximately 13% to 20%, the rate increases to more than 50% in patients with advanced ovarian cancer. The 5-year overall survival was 75.1%. Mean overall survival was 100.4 months. Though pathologically positive lymph nodes had a negative impact on recurrence in this study, the importance of node dissection in epithelial ovarian cancer on survival needs to be redefined by further studies. The major limitations of this study are its retrospective design that depends on effective documentation of patient history. Other limitations are small sample size and single-center study, and thus, the findings may not be generalized to other geographical locations. The patient's genetic characteristics such as BRCA gene mutations, which are a cardinal aspect of personalized medicine in the present era, are not part of this study.^[19] Based on online database searches, this may probably be the first study in the Indian population studying the prognostic factors recurrence in epithelial ovarian cancer and hence shall guide in planning future prospective studies in epithelial ovarian cancer. The knowledge from this study shall form the basis to counsel patients with ovarian cancer during their primary treatment and explain the importance of aggressive follow-up and surveillance based on the presence of adverse prognostic factors.^[19] However, robust high-quality prospective studies shall be carried out to provide additional insight into this information, which may be translated into clinical practice for the benefit of patients.

CONCLUSION

In this study, comorbidities, pre-treatment CA 125 level, FIGO stage, ascites, multiorgan resection, tumor response to chemotherapy, and lymph node

status are significant prognostic factors for recurrence in epithelial ovarian cancer. Among these factors, the FIGO stage is the single most significant prognostic factor for recurrence and outcome in epithelial ovarian tumors as analyzed by both univariate and multivariate analysis. This study result also reinforces the importance of surgical staging and optimal cytoreduction in ovarian malignancy, which enables the prognostication of the disease in terms of recurrence and survival.

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