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Original Research Article

Assessment of clinical epidemiology, treatment patterns, and survival outcomes in epithelial ovarian cancer: a retrospective analysis from a tertiary cancer centre in North India

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ABSTRACT

Background: Ovarian cancer stands as the daunting third most prevalent cancer among females. The aim of this study is to assess the clinical epidemiology, treatment patterns (including end-of-life care), and survival outcomes among patients diagnosed with epithelial ovarian cancer.
Methods: This retrospective analysis encompassed all patients diagnosed with epithelial ovarian cancer and enrolled at the tertiary cancer center, IGMC Shimla in Himachal Pradesh. The study included patients registered between January 2014 and December 2018, spanning all age groups.
Results: During the aforementioned period, ovarian cancer accounted for 18.7% of gynaecological cancers among females out of which epithelial ovarian cancer accounted for 14.8% of the cases. The median age of patients diagnosed with epithelial ovarian cancer (EOC) was 54.5 years. Most patients hailed from Shimla, followed by Mandi and Kullu districts, among the twelve districts in the state of Himachal Pradesh. The majority of patients were diagnosed at advanced stages FIGO III and IV, comprising a total of 77.1%. Chief complaints included abdominal pain, followed by abdominal distention, heaviness, or bloating. The median duration of follow-up was 27 months (with a standard deviation of ±9.175). The median overall survival (OS) for stage I, II, III, and IV was 92.59 months, 87 months, 82.17 months, and 52.5 months, respectively, and these differences were statistically significant.
Conclusions: Ovarian cancer patients are often diagnosed in advanced stages III and IV, primarily due to late diagnosis and the presence of vague symptoms. Achieving optimal cytoreduction significantly improves overall survival. Therefore, it's crucial to raise awareness among general physicians in rural healthcare settings and the public about the symptoms of ovarian cancer to facilitate early detection. Additionally, there's a notable deficiency in end-of-life discussions and palliative care management, which should be accessible to every patient.

Keywords: Epithelial ovarian cancer, Cytoreduction surgery, Survival outcomes in ovarian cancer, Advanced OC

INTRODUCTION

Ovarian cancer amounts to 3rd most common cancer among females in India. It is also 9th most common cause of cancer deaths as per GLBOCAN India 2020 data as well as National Cancer registry.[1] Owing to lack of warning symptoms most of the patients are diagnosed in later advanced stages and have bad prognosis. Ovarian cancer undergoes a chronic course with continuum of recurrence episodes with gap of symptom-free periods.

Current standard of care is surgery and platinum-based chemotherapy which form the backbone of the ovarian cancer treatment. The goal of the surgery is to adequately stage the disease in early stage i.e., staging laparotomy and "optimal cytoreduction" in advanced stage which translates to debulk the tumor to an optimal residual level

as possible.[2] As the advancement and evolution of newer biological agents and targeted treatment approach is being explored it undoubtedly brings hope of turning this dreaded disease into a manageable chronic disease. Many recently approved trials have paved its way to new therapeutic approaches like the inclusion of anti-angiogenic therapies, PARP inhibiters, and checkpoint inhibitors.[3-5] The quality of cancer care in Indian scenario varies due to logistics and resource constraints. This study represents the patterns of care in past 5 years in our tertiary cancer centre in North India along with continuous evolution in management due to better availability of resources.

METHODS

This study was a retrospective analysis of the all the patients of epithelial ovarian cancer enrolled at tertiary cancer centre, IGMC Shimla in Himachal Pradesh. All the patients registered from January 2014 to December 2018 with epithelial ovarian cancers were included in the study across all age groups. Data were retrieved from record files of the tertiary cancer centre.

Data related to patients' demography, clinical status, modes of diagnosis like ca 125 levels, radiological investigations - ultrasonography (USG), computed tomography (CT), positron emission tomography (PET) scan, surgical detail and follow-up was abstracted. Specific data related to palliative care was also noted such discussion about prognosis of the disease, hospital/casualty admissions at terminal stage, aggressive treatment at end of life, palliative procedures, and usage of morphine. Patients with incomplete data, germ cell tumors/sex cord stromal tumors of ovary and those who were registered but opted for further treatment at another centre were excluded.

Statistical analysis

Data was retrieved from the hospital records and keyed into Microsoft excel spreadsheet and analysed in the form of charts, tables, and percentages. Statistical analysis was done using IBM statistical package for the social sciences (SPSS) Statistics for Windows from IBM Corp (released 2020, Version 27.0. Armonk, NY). Overall Survival was estimated from the time of diagnosis to the time of progression or death. Patients not experiencing any event were censored at the time of last follow-up.

RESULTS

In these five years 11,470 patients were registered in our centre out of which 6165 were males and 5305 were females.

Among females there were 1527 (28.7%) patients of gynaecological cancers which comprises of cancers of cervix, ovary, vagina, vulva and uterus. Out of those gynaecological cancers 286 patients (18.7%) of ca ovary were registered in this time frame. Of those 35 patients with incomplete data, 25 patients of GCT/sex cord stromal tumor and those who defaulted after registration (hence received no treatment at our centre) were excluded. Hence 226 patients of epithelial ovarian cancer (EOC) were included in the study (Figure 1).

Among twelve districts in state of Himachal Pradesh, majority of the patients were from Shimla followed by Mandi and Kullu district. Figure 2 shows the demographic profile of the patients.

Clinical profile is tabulated in Table 1. The median age of the patient reporting with epithelial ovarian cancer was 54.5 years (range 23 to 83 years). Most of the patients were multiparous and presented with the performance status of ECOG 2. Baseline C125 levels were increased in 87.6% of the patients. Most of the patients belonged to advanced stage FIGO III and IV (total 77.1%).

Abdominal pain was the chief complaint followed by abdominal distention, heaviness, or bloating. Few patients presented with palpable mass or lump as the presenting complaint.

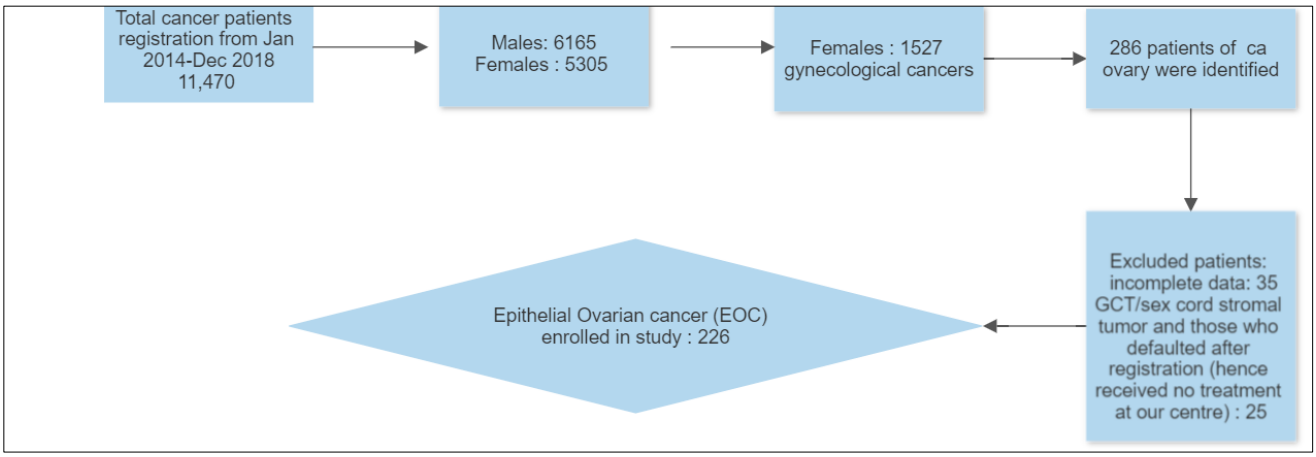

Figure 1: Selection of the study population.

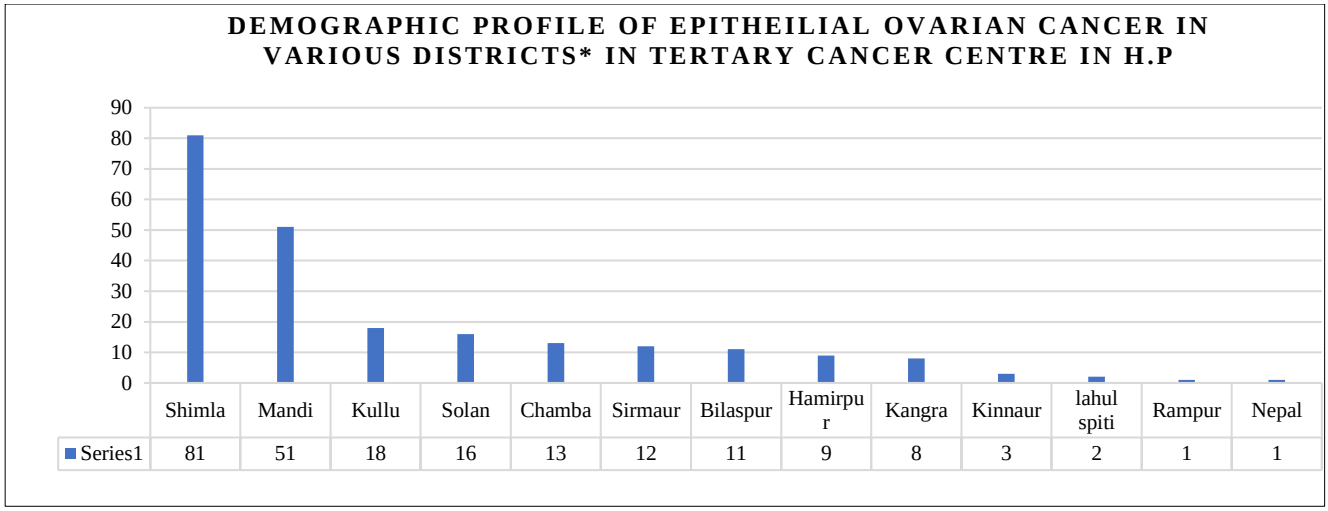

Figure 2: Demographic profile of ovarian cancer load at tertiary cancer centre from various districts of Himachal Pradesh.

*One patient was a migrant from Nepal

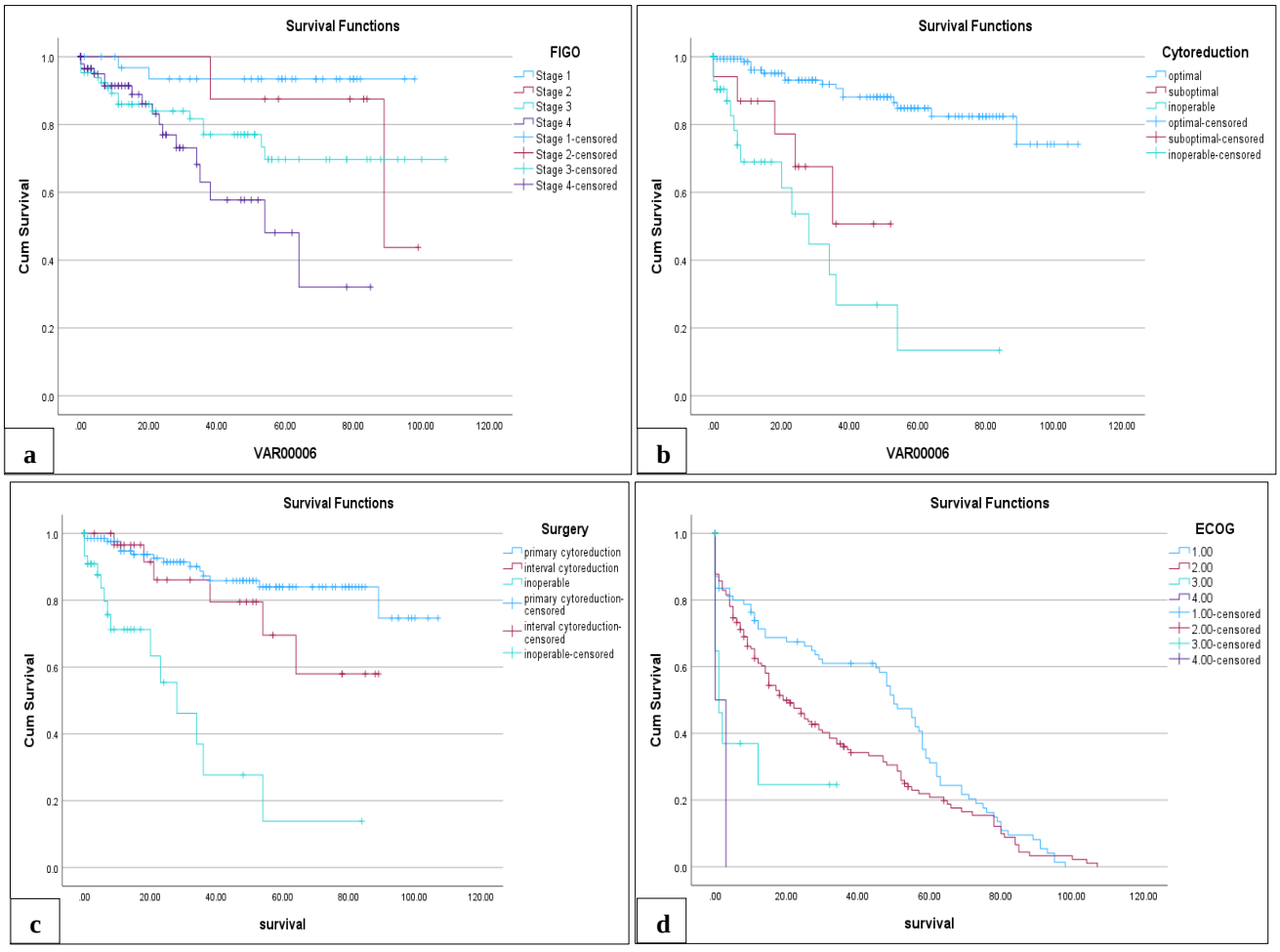

Figure 3: (a) Kaplan-Meier plot of OS (months) in relation to stage; (b) Kaplan-Meier plot depicting OS (months) in relation to extent of surgery; (c) Kaplan-Meier plot depicting OS (months) in relation to primary, interval cytoreduction, and patients deemed inoperable; and (d) Kaplan-Meier plot depicting OS (months) in relation to ECOG status.

OS: Overall survival

Table 1: Clinical profile (n=226).

Patient's characteristics	Frequency
Age (years) (SD)	
Mean	53.8 (±12.35)
Median	54.5 (±12.35)
Range	23-83
Parity no. (%)	
Nulliparous	18 (7.8)
Uniparous	12 (5.2)
Multiparous	196 (84.8)
Performance status (ECOG) no. (%)	
1	72 (31.2)
2	135 (58.4)
3	17 (7.4)
4	2 (0.9)
CA125 levels no. (%)	
<35	22 (9.7)
35-100	18 (8.0)
100-1000	86 (38.1)
1000-2000	32 (14.2)
>2000	62 (27.4)
unknown	6 (2.7)
FIGO stage no. (%)	
Stage 1	37(16)
Stage 2	8 (3.5)
Stage 3	84 (36.4)
Stage 4	94 (40.7)
Stage unknown	8 (3.5)
Chief complaints no. (%)	
Abdominal pain	133 (58.8)
Abdominal heaviness/distension/ bloating	93 (41.11)
Abdominal mass/lump	11 (4.8)
GI disturbances	9 (3.98)
Menstrual disturbances	7 (3.09)
GU disturbances	4 (1.7)
Neck swellings	3 (1.3)
Respiratory symptoms	2 (0.88)
Infertility	1 (0.44)
Institute for surgery (N=167)	
Tertiary centre/medical college	140 (83.8)
Peripheral hospital	14 (8.38)
Private hospital	13 (7.78)

Overall, the medical colleges or tertiary care centres constituted the main centres where surgery was performed (n=140, 83.8%) followed by peripheral (n=14, 8.3% or private hospitals (n=13, 7.78%).

Out of 226 patients of EOC 167 patients got operated on and underwent either primary cytoreduction or interval cytoreduction. In three patients' surgery was deferred in view of gross in unresectable disease. 59 patients were inoperable who received palliative chemotherapy. Table 2 shows treatment details of the patients.

Table 2: Treatment details of the patients (n=226).

Rx history	Frequency (%)
Operable	167 (73.89)
Inoperable	59 (26.1)
Operable	**N=167**
Primary cytoreduction	134 (80.2)
Interval cytoreduction	33 (19.7)
Surgery deferred due to gross unresectable disease (on table)	3*
Operable	**N=167**
Optimal debulking	153 (91.6)
Suboptimal debulking	17 (10.1)
Chemotherapy NACT received	**N=226**
Yes	46
No	180
Lines of chemotherapy	**N=226**
1st line	123 (54.4)
2nd line	29 (12.8)
3rd line	19 (8.4)
>4 lines	20 (8.8)
Unknown	35 (15.4)
Platinum free interval	**N=226**
Platinum-sensitive	101 (44.6)
Platinum-resistant	38 (16.8)
Platinum-refractory	7 (3.09)
Unknown/defaulted	80 (35.3)
Palliative radiation	**N=226**
Yes	22 (9.7)
No	204 (90.2)
Sites of palliative RT	**N=26**
Pelvic mass	14
Brain	7
Cutaneous mets	2
Bone	1
Supraclavicular LAP	1
Paraaortic LAP	1

*Surgery deferred due to gross unresectable disease

A total of 46 patients receives neo adjuvant chemotherapy. Most common regimen was Paclitaxel and carboplatin 4-6 cycles. Majority of the patients (n=123,54.4%) received first line chemotherapy. Among those patients who received chemotherapy platinum sensitivity was established in 101 patients, 38 were platinum resistant and 7 were platinum refractory. 12.8% (29) patients received second line chemotherapy.

Various regimens were single agent liposomal doxorubicin (LD), platinum doublets like LD along with cisplatin or carboplatin, single agent gemcitabine, gemcitabine along with cisplatin or carboplatin, CAP regimen (cisplatin doxorubicin and cyclophosphamide), topotecan and addition of bevacizumab in few patients.

Oral chemotherapeutic agents such as capecitabine, tegafur and uracil were also tried in few patients based

upon performance status or based on their willingness to avoid intravenous chemotherapy. 8.4% (19) patients received third line chemotherapy, 8.8% patients received fourth and more lines of chemotherapy. In 35 patients' status for chemotherapy administration was unknown. Only one patient received PARP inhibiter Olaparib as part of the treatment. Other regimens apart from mentioned above were oral etoposide/cyclophosphamide, oral chlorambucil. Tamoxifen was also used in a few patients.

A total of 125 (55.0%) patients had residual disease at their last visit and 76 (33.4%) patients were disease free on last visit. In few patients (11.4%) the disease status was unknown. Three patients had synchronous ca vagina, cholangiocarcinoma, and ca gall bladder.

A total of 24 (10.5%) patients received palliative radiation out of which 14 received radiation in pelvic mass followed by whole brain RT in seven patients who developed brain metastasis. Rest of the sites were bone, painful cutaneous mass at chest wall and supraclavicular lymph nodal mass.

Prognosis and nature of disease discussion was done with 39 (17.1%) patients in the last month of their visit/death.

A total of 78 (34.3%) patients visited ER or underwent hospital admission for distressing symptoms in last one month before their last visit in the hospital. Distressing signs and symptoms included ascites, subacute intestinal obstruction, intestinal obstruction, pleural effusion, pain abdomen, decreased intake, thromboembolism, pancytopenia, febrile neutropenia, thrombocytopenia, and anaemia.

For relief of these symptoms some patients underwent minor palliative procedures like ascitic tap, pleural tap or blood transfusions for build-up. Palliative surgical procedures like palliative loop colostomy (n=6) were mainly performed for intestinal obstruction.

A total of 27 (11.8%) patients were given morphine for pain relief as a part of pain relief in end-of-life care. Dosage was adjusted as per requirement and details were entered in the morphine register maintained by the department.

The median duration of follow-up was 27 months (standard deviation ±9.175). Median OS for stage I, II, III, and IV was 92.59 months, 87 months, 82.17 months and 52.5 months respectively and was statistically significant (Figure 3a).

Primary cytoreduction had significantly improved OS compared with those who underwent Interval cytoreduction or those who were deemed inoperable (92.184 months [95% CI, 85.215 to 99.153] versus 69.223 [95% CI, 56.272 to 82.175] versus 32.796 months (CI 19.622 to 45.970) with highly significant p value <0.001.

Optimal cytoreduction was associated with better mean survival (92.68 months, 95% CI 86.20 to 99.172) as compared to suboptimal (36.82 months 95% CI 26.535 to 47.118) or inoperable (31.9 months 95% CI 18.81 to 44.99) patients with highly significant p value <0.001. ECOG status was also a significant factor in survival with significant p value (Figure 3b-d).

DISCUSSION

This study presents a retrospective analysis of patients who underwent treatment for ovarian cancer (OC) at a prominent cancer centre in North India from January 2014 to December 2018. This analysis stands as the inaugural comprehensive report from Himachal Pradesh, offering a detailed assessment of treatment patterns and outcomes among these patients. Among the total cohort of 11,470 registered cancer patients during the years 2014 to 2018, ovarian cancer accounted for 2.49% of the overall cancer cases. Notably, a comparable burden of 2.94% was observed in a retrospective study conducted by Meena et al focusing on a single institute's experience in North India, spanning a nine-year period from 2010 to 2018. In our centre OC constituted 18.7% of the total gynaecological cancers in 5-year period between 2014-2018.

In the same region, a recent prospective study conducted at a tertiary care center's department of obstetrics and gynaecology by Ravindran et al spanning from June 2019 to May 2020, revealed that ovarian cancer (OC) constituted 20.7% of the gynaecological cancer cases.[6] This statistic positioned OC as the second most prevalent gynaecological malignancy, following cervical cancer which comprised the majority at 58.1%. This data indicates a slight rise in incidence within our state. Additionally, in a study conducted by Puri et al the proportion of ovarian malignancy cases accounted for 26% of all gynaecological malignancies during a four-year period.[7]

Epithelial ovarian cancers (EOC) comprised 79.01% of the total ovarian cancer cases, with serous histology emerging as the predominant subtype within this study. Puri et al study reported epithelial ovarian cancer as 44% of the total histology. Mondal et al study indicated it to be 60.9% of all cases.[8] A separate single-institutional study conducted in North India found that epithelial OCs constituted a substantial 88.4% of all ovarian cancers. Similarly, epithelial cancers constituted 84.4% (n=406) of all ovarian malignancy cases in a study by Maheshwari et al.[9]

The majority of patients were reported from Shimla district, followed by Mandi and Kullu districts. A noticeable trend in case numbers was observed, with an increase from 45 patients in 2014 to 56 patients in 2018. However, there was a slight dip in case numbers in 2016. Murthy et al reported a mean annual percent increase of ovarian cancer in India, varying between 0.7% to 2.4% across different age groups.[10] This upward trend might signify heightened exposure to ovarian cancer risk factors,

or alternatively, improved diagnostics and increased awareness facilitated by enhanced healthcare facilities.

Age exhibits a notable association with ovarian cancer incidence. In our investigation, approximately half of the patients fell within the 40 to 60-year age bracket, with a calculated mean age of 53.8 years and a median age of 54.5 years. Puri et al study revealed a mean age at diagnosis of 52.1±8.96 years (median=52). The patient cohort in Meena et al study displayed a median age of 50 years, spanning an age range of 18 to 85 years. Basu et al documented a mean age of 48.8±11.2 years. Li's epidemiologic risk prediction model indicated a median age of 52.4 years for EOC across diverse countries.[11] In a retrospective-prospective study encompassing 50 patients, Dhiman et al found that the majority (46%) of advanced ovarian cancer cases were in the 51 to 60-year age group, followed by patients aged over 60 years (34%).[12]

Inci and Rasch et al conducted a prospective study known as the RISC-GYN trial.[13] Their findings highlighted that patient characteristics, particularly an Eastern cooperative oncology group performance status (ECOG PS) greater than 1 and obesity (BMI >25 kg/m^2), hold significant predictive value for severe postoperative complications. They additionally emphasized that, in future risk prediction, surgeons should focus on performance status instead of merely aggregating co-morbidities. ECOG PS and BMI warrant heightened consideration in clinical decision-making, treatment strategizing, and patient counselling. In our own study, most patients (58.4%, n=135) presented with an ECOG performance status of category 2. In a study by Meena et al, it was reported that most patients fell within an ECOG PS of ≤1.

Meena et al observed that abdominal distension and gastrointestinal disturbances stood out as the most frequent symptoms. Their findings indicated that symptom duration exceeded 4 months in 53.8% of patients, followed by a duration of 2 to 4 months in 31.8% of patients. Similarly, Dhiman et al noted the most consistent clinical finding as the presence of ascites, which manifested in 92% (46) of patients, while being absent in 8% (4) of patients.

Arora et al from Saint Vincent Hospital also noted that ovarian cancer's presentation involves a combination of symptoms, including abdominal fullness, bloating, nausea, abdominal distention, early satiety, fatigue, alterations in bowel movements, urinary symptoms, back pain, dyspareunia, and weight loss.[14] In our study, abdominal pain, discomfort, heaviness, the presence of a lump/mass, and distension emerged as the most common presenting complaints, exceeding 95% prevalence. Interestingly, ascites was evident in approximately 80% of patients at some point during their journey, be it upfront, during treatment, or follow-up. However, positive cytology was confirmed in only about one-third of the patients. Notably, one patient presented with the rare complaint of primary infertility, leading to a diagnostic pathway that ultimately revealed ovarian malignancy.

Bilateral ovarian involvement (57.5%) exceeded unilateral cases in our study. Micci and Haugom et al presented a series of 32 bilateral ovarian carcinoma cases, employing karyotyping and high-resolution comparative genomic hybridization (CGH).[15] Their analysis revealed that contralateral ovarian spread occurred in bilateral ovarian cancer instances and constituted a late event in the tumors clonal evolution. In the study by Mondal et al metastatic tumors were observed to affect both ovaries in 72% of cases, while 49.5% of malignant serous tumors were bilateral. A Jharkhand-based study indicated that among 27 mucinous tumors, only 18.5% were bilateral, whereas out of 25 serous tumors, 52% displayed bilateral involvement.[16]

In Puri et al report, 24% of patients were diagnosed at stage III and 20% at stage IV. A study from a tertiary care hospital in Jharkhand highlighted that the majority of patients (66.6%) were diagnosed at stage III and IV combined. In a decade-long study spanning from January 2001 to December 2010, Mondal et al found that most malignant tumors presented as stage III (60%) or stage II (20%) disease. Meena et al reported that 76% of patients presented with an advanced stage of disease (stage III-IV). In our center, stage III (36.4%) and IV (40.7%) combined comprised the majority (around 77.1%) of ovarian cancer cases, aligning with findings from other Indian studies. This prevalence could stem from factors like delayed referrals by primary care physicians, the absence of proper screening tests, and the presence of chronic and vague symptoms such as abdominal pain and bloating, which mimic other common ailments.

In a previous study by Dhiman et al among stage IV patients, the most frequent site of metastasis was the pleura, observed in 18% (n=9) of cases. The liver accounted for 6% (n=3) of metastases, while other extra-abdominal sites were seen in 4% (n=2) of patients. Contrasting these findings, our study identified the liver as the primary site of metastasis in our stage IV cohort, representing 44.6% (n=42) of cases. The second most common site was malignant pleural effusion, constituting 28.7% (n=27) of the patients in our study.

In Meena et al study, the baseline serum cancer antigen-125 (CA125) level was elevated in 79.8% of patients. Similarly, in our study, elevated CA125 levels were observed in 87.6% of patients. Among these cases, 41.5% exhibited CA125 levels exceeding 1000 units/ml, and 27.4% had levels surpassing 2000 units/ml. Only 9.73% of patients demonstrated normal CA125 levels below 35 units/ml. Dhiman et al focused exclusively on advanced-stage ovarian cancers, reporting that CA125 levels at presentation were elevated in all 50 (100%) patients. Specifically, 6% of patients had levels less than or equal to 100 units/ml, 44% exhibited levels ranging from 100 to 1000 units/ml, 38% had levels between 1001 and 5000 units/ml, and 12% showed levels exceeding 5000 units/ml.

In a cohort study by Funston et al involving over 50,000 women who underwent CA125 testing in English general practice, it was revealed that among those with a CA125 level at or above the conventional cutoff of 35 U/ml, 10.1% were diagnosed with ovarian cancer, and 12.3% were diagnosed with a different type of cancer.[17] Interestingly, this study indicated that almost one-third of women aged ≥50 years with a CA125 level ≥35 U/ml were ultimately diagnosed with some form of cancer.

Complete resection of the macroscopic disease is one of the most important independent prognostic factors in advanced OC and as the majority of the patients reach to us in advanced stage advanced ovarian cancer surgery (AOCS) aims to achieve maximal cytoreduction to increase survival, and even provide a definitive cure in some cases.[18] While cytoreductive surgery (CRS) is recognized as an effective approach for managing advanced-stage EOC, it's important to acknowledge that CRS is a multifaceted treatment that can significantly influence a patient's post-surgery quality of life (QoL). Research pertaining to QoL in women who underwent CRS with the inclusion of bevacizumab or hyperthermic intraperitoneal chemotherapy (HIPEC) demonstrated that the surgical intervention did not have a detrimental effect on their QoL.[19]

Boer et al in their study highlighted that a higher QoL was seen in patients who had surgery with the use of the Plasma Jet device at 12 months postoperatively. The Plasma Jet is a thermal plasma energy device. An electrical current is discharged across the device elements inside, where argon gas is heated to generate plasma. The Plasma Jet emits a high-energy jet of argon plasma for direct tissue effects and is able to cut or vaporize small tumor foci.[20]

Access to advanced systemic treatments like bevacizumab and PARP inhibitors in ovarian cancer is restricted to urban areas due to high costs. Resource constraints limit their usage, with just one of our patients receiving PARP inhibitors. Absence of tailored national guidelines leads oncologists to rely on international standards, possibly mismatched to India's genetic and socioeconomic landscape. Nonetheless, efforts like the National Cancer Grid propose guidelines adapted for local conditions, aiming to integrate these advancements gradually. Despite challenges, there's a gradual absorption of newer treatments into clinical practice, signalling a potential shift towards more equitable cancer care in India.

CONCLUSION

Our patient cohort reflects national trends, demonstrating late presentation and unfavourable outcomes typical of ovarian cancer. Diagnosis often occurs in advanced stages III and IV, attributed to delayed recognition and vague symptoms. Optimal cytoreduction markedly improves survival rates, emphasizing the critical need for heightened awareness among rural physicians and the public to facilitate early detection. Additionally, addressing the deficit in end-of-life discussions and palliative care is vital, ensuring comprehensive support for all patients.

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