

Protocol

Real-world clinical and molecular profile of ovarian cancer patients treated with Olaparib: study protocol and design of the OC-REAL India multicentre ambispective observational study

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ABSTRACT

Background: Globally, ovarian cancer (OC) is the eighth most common cancer among women, accounting for an estimated 3.7% of all cases and 4.7% of cancer-related deaths. Approximately 20-25% of OC cases harbour germline *BRCA1/2* mutations, while homologous recombination deficiency (HRD) has emerged as an important therapeutic biomarker. Poly (ADP-ribose) polymerase (PARP) inhibitors, such as Olaparib, have demonstrated significant clinical benefit as maintenance therapy in patients with *BRCA*-mutated or HRD-positive OC. However, real-world Indian data on the clinical and molecular characteristics of patients receiving Olaparib remain limited. The objective of the study was to evaluate the clinical, molecular, and treatment profile of OC patients receiving Olaparib maintenance therapy.

Methods: This ambispective, cross-sectional, multicentre, non-interventional, real-world evidence study aims to enrol 250 Indian OC patients initiated on Olaparib maintenance therapy. Data will be captured electronically at a baseline visit using an electronic data capture (EDC) system. Variables include demographics, comorbidities, family cancer history, histopathology, surgical and treatment history, *BRCA* mutation and HRD status, CA-125 levels at diagnosis and prior to Olaparib initiation, and details of maintenance therapy.

Conclusions: OC-REAL India study will provide real-world insights into Indian OC patients on Olaparib, including demographics, pathology, and *BRCA*/HRD mutation prevalence. Findings aim to support personalized treatment and improve clinical outcomes. As this is an ongoing study, the results are expected to be published after completion of the study.

Trial registration: The study was registered with the Clinical Trials Registry-India (CTRI; Registration No. CTRI/2025/08/092561)

Keywords: Ovarian cancer, PARP, Olaparib, maintenance therapy, *BRCA*, HRD, Real-world evidence, Targeted therapy

INTRODUCTION

Ovarian cancer (OC) is a malignant disease originating in the ovaries, the paired female reproductive organs

responsible for oocyte production and the secretion of key hormones such as oestrogen and progesterone.¹ The disease develops when ovarian cells undergo uncontrolled proliferation, leading to tumour formation with the

potential to invade surrounding tissues and metastasise to distant sites.² OC represents a heterogeneous group of malignancies, predominantly comprising epithelial tumours, which account for most cases, along with less common germ cell and stromal tumours.¹

Globally, OC ranks as the seventh most diagnosed cancer and the eighth leading cause of cancer-related mortality among women.³ In 2022, approximately 324,398 new cases and 206,839 deaths were reported worldwide, accounting for nearly 2.1% of all cancer-related mortality.⁴ In India, OC remains a significant public health concern, with an estimated 47,333 new cases reported among women in 2022, representing approximately 6.6% of all newly diagnosed cancers in females, according to the International Agency for Research on Cancer (IARC) and GLOBOCAN 2022.^{4,5} Due to its anatomically concealed location and lack of specific early symptoms, OC is frequently diagnosed at an advanced stage, complicating timely diagnosis and effective management.⁶

Delayed clinical presentation increases disease burden and is often associated with extensive peritoneal dissemination, omental involvement, and malignant ascites.⁷⁻⁹ This pattern of spread poses significant challenges to achieving optimal surgical cytoreduction and limits the effectiveness of systemic therapies. Diagnosis and staging of advanced OC require an integrated approach, including clinical evaluation, radiological imaging, serum biomarkers, and histopathological assessment.⁹ Contrast-enhanced computed tomography (CT) and magnetic resonance imaging (MRI) are routinely used to evaluate tumour extent, peritoneal involvement, and lymph node status, while serum cancer antigen-125 (CA-125) serves as a supportive biomarker for assessing disease burden and monitoring treatment response.^{10,11}

Disease extent in OC is classified using the International Federation of Gynaecology and Obstetrics (FIGO) staging system, which remains the global standard for staging and prognostication. FIGO stage III is defined by peritoneal metastasis beyond the pelvis and/or involvement of retroperitoneal lymph nodes, whereas FIGO stage IV indicates distant metastatic spread, including pleural effusion with positive cytology or parenchymal organ involvement.¹² These advanced stages are associated with poorer survival outcomes, highlighting the need of accurate staging in guiding therapeutic planning and clinical decision-making.⁹

Molecular characterisation has emerged as a critical component of advanced OC evaluation.¹³ High-grade serous ovarian carcinoma (HGSOC), the most common subtype in advanced disease, is frequently associated with defects in DNA damage repair pathways. Among these, germline or somatic mutations in breast cancer gene 1 (*BRCA1*) and breast cancer gene 2 (*BRCA2*) disrupt homologous recombination repair and promote genomic instability.¹⁴ An Indian multicentre study involving 239 patients reported pathogenic germline mutations in *BRCA1*

and *BRCA2* in 15.5% and 5.9% of patients, respectively, with 15.1% having a family history of ovarian or breast cancer.¹⁵ These findings highlight the importance of routine germline *BRCA* testing in patients with OC, particularly those with a relevant family history. Beyond *BRCA* mutations, HRD encompasses alterations in multiple genes involved in DNA repair pathways, further contributing to disease progression.¹⁶ These molecular alterations influence tumour biology and have direct therapeutic relevance by increasing tumour sensitivity to DNA damage-targeted therapies.¹⁷ The integration of clinical features, FIGO stage, histopathological findings, and molecular profiling is now fundamental to the management of OC. Assessment of *BRCA* mutations and HRD status provides valuable prognostic and predictive information and plays a crucial role in guiding the use of targeted therapies, particularly poly (ADP-ribose) polymerase (PARP) inhibitors.¹⁸ Tumours harboring *BRCA1/BRCA2* mutations, as well as those exhibiting HRD, demonstrate increased sensitivity to DNA repair-targeted therapies. This biologically driven approach has shifted therapeutic strategies from cytotoxic chemotherapy toward precision-based therapies tailored to underlying molecular alterations.¹⁹ PARP inhibitors represent a major therapeutic advancement in the management of OC with *BRCA* mutations or HRD. These agents inhibit DNA repair, leading to the accumulation of DNA damage that is selectively toxic to tumour cells with impaired homologous recombination repair. Olaparib, a first-in-class PARP inhibitor, induces synthetic lethality in *BRCA*-mutated and HRD-positive tumours by targeting this pathway.^{20,21} Clinical trial data have demonstrated that maintenance therapy with Olaparib significantly prolongs progression-free survival in patients with newly diagnosed or recurrent advanced OC, particularly in those with *BRCA* mutations or HRD-positive disease. These findings have established Olaparib as a standard maintenance therapy in appropriately selected populations and underscore the importance of molecular testing at diagnosis.²²

The recent availability of generic Olaparib in India has improved cost accessibility, enabling broader real-world use. However, existing Indian studies remain limited by small sample sizes and insufficient data on family history and *BRCA* mutation prevalence.¹⁵ Additionally, genetic testing for *BRCA* mutations and HRD status is not routinely performed across many centres, leading to under-recognition of mutation-driven OC. This lack of population-specific evidence and limited biomarker testing underscores the need for systematic evaluation in Indian patients.

Accordingly, the OC-REAL India (OC: Real-world evidence and oncologist experience in India) study has been designed to address these evidence gaps by generating real-world data on patient demographics, clinicopathological characteristics, and mutation prevalence. These insights intend to aid clinical decision-making and, in the context of increased accessibility to generic Olaparib, may facilitate broader patient inclusion

and real-world evaluation of familial and molecular characteristics of OC in the Indian setting.



Figure 1: Schematic flow chart of the study.

METHODS

General study details

OC-REAL India is an ambispective (incorporating both retrospective and prospective data collection), cross-sectional, multicentre, observational real-world study designed to evaluate the clinical and molecular characteristics of OC patients initiated on Olaparib. The study will be conducted across approximately 50 oncology centres in India. Eligible patients include those who are treatment-naïve to Olaparib or have been initiated on Olaparib within ≤ 3 months prior to enrolment, receiving it as maintenance therapy in routine clinical practice. All enrolled patients will be evaluated at a baseline visit. Data collection includes demographic characteristics, disease profile, molecular status, and treatment history.

Ethical considerations

This study will be conducted in compliance with the approved protocol, the principles of the Declaration of Helsinki, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice (ICH-GCP), and regulatory requirements in India. The study protocol was approved by the Ethicare Ethics Committee (IEC) vide reference number EEC/AMPL/2025/002 on 09 July 2025. The study

has been registered with the CTRI under registration number CTRI/2025/08/092561. Following informed consent, eligible participants will be enrolled, and baseline data will be recorded. Dissemination of study findings will occur through publication in a peer-reviewed journal and presentation at national and international conferences. Results will also be shared with investigators and institutions. The aggregated study findings will be made publicly available to inform clinical practice.

Participants

The planned total sample size for the study is 250 patients.

Inclusion criteria

The study population will include adult female patients aged ≥ 18 years diagnosed with ovarian, primary peritoneal, or fallopian tube cancer who have been prescribed Olaparib either as treatment-naïve therapy or initiated within ≤ 3 months prior to enrolment. Patients with available molecular testing results for *BRCA* mutation and HRD status who are willing to provide written informed consent will be eligible for inclusion in the study.

Exclusion criteria

Patients who fail to provide signed informed consent (during the retrospective enrolment), those with medical conditions that may interfere with safe study completion as determined by investigator, individuals participating in another clinical trial, or those with incomplete or unavailable molecular testing results will be excluded.

Participants will be selected from patients visiting the outpatient department/clinic who are willing and able to comply with all study requirements and fulfil the predefined eligibility criteria, including the inclusion and exclusion criteria specified in the protocol.

Study objectives

Primary objective

Primary objective was to evaluate the baseline demographic including molecular characteristics of OC, patient initiated on Olaparib.

Secondary objective

Secondary objective was to assess the co-relation of *BRCA* and HRD mutation status with clinicopathologic characteristics.

Study methodology

Eligible participants will be identified during routine visits at participating centres. After confirmation of eligibility based on the inclusion criteria, written informed consent will be obtained. Each participant will then be assigned a

unique identification number to ensure confidentiality and de-identification of medical records across all study documentation. Baseline demographic, clinical, histopathological, and molecular data will subsequently be recorded.

Primary endpoints

Clinical profile of OC patients initiated on Olaparib, including demographics such as age, height, body mass index (BMI), body surface area (BSA), geographical location (state), education, and occupation.

Disease comorbidities include the presence of hypertension, diabetes mellitus, coronary artery disease, autoimmune disorders, renal impairment, obesity, depression, anxiety, asthma, and COPD.

Molecular characteristics in *BRCA1/2* mutations (germline and/or somatic), which impair homologous recombination repair and predict sensitivity to PARP inhibitors.

Baseline tumour marker levels, such as serum CA-125 concentration measured at the time of OC diagnosis and prior to initiation of Olaparib therapy.

Documentation of Olaparib as a therapy (dose, frequency), used alone/in combination with bevacizumab therapy.

Secondary endpoints

Correlation of *BRCA* and HRD mutations with clinicopathologic properties, such as lifestyle and medical history, marital status, menstrual (age at menarche/menopause, infertility), and reproductive history, along with hormonal use (oral contraceptives, HRT) and gynaecological surgical procedures (performed before cancer diagnosis).

Assessment of family history of cancer, including documentation of breast, ovarian, prostate, pancreatic, or other cancers in first- or second-degree relatives. Family history is an important clinical indicator of an increased likelihood of *BRCA* mutations and may provide a supportive context for HRD status.

Disease characteristics are defined through histological subtypes (serous, mucinous, endometrioid, clear cell), tumour grade, stage at diagnosis (FIGO classification), and disease status (newly diagnosed or recurrent- platinum sensitive).

Prior treatment history of surgery and chemotherapy will be documented to inform therapeutic strategies. Type of cytoreductive surgery (upfront or interval debulking residual classification R0-R2) and chemotherapy details such as neoadjuvant/adjuvant regimens, number of cycles, platinum-free interval, and response (complete, partial, stable, or progressive disease) will be captured.

ECOG performance scale (0-4), which measures functional status, score 0: fully active with no restrictions, score 1: restricted in physically strenuous activity but ambulatory, score 2: ambulatory, capable of self-care but unable to work, score 4: completely disabled, no self-care, confined to bed/chair.

The exposure of interest in this study is initiation of Olaparib therapy in OC patients with known *BRCA* and/or HRD mutation status. Eligible participants include previously treated or newly diagnosed patients with ovarian, primary peritoneal, or fallopian tube cancer who are either naïve to Olaparib or had initiated Olaparib within the previous 3 months. Molecular exposure variables include *BRCA1/BRCA2* mutation status and HRD status.

Potential confounders include age, comorbidities, prior lines of treatment, disease stage, histopathologic subtype, family history, concomitant medications, ECOG performance status, and previous chemotherapy exposure, all of which may influence both mutation status and clinical characteristics. These variables will be systematically collected to allow descriptive and exploratory assessment of their relationship with *BRCA* and HRD status.

Several measures will be incorporated to minimize bias. Selection bias will be reduced by enrolling consecutive eligible patients across 50 geographically distributed centers in India, thereby improving representativeness of real-world clinical practice. Information bias will be minimized through use of predefined eligibility criteria, standardized case report form (CRFs), and uniform baseline assessments. As this is a non-interventional observational study, treatment decisions remain independent of study participation, thereby reducing intervention-related bias. Furthermore, molecular and clinicopathologic data will be collected from routine clinical records and diagnostic reports to improve accuracy and reduce recall bias. Although residual confounding inherent to observational studies cannot be completely excluded, comprehensive collection of demographic and clinical variables is intended to support robust descriptive analyses and interpretation of findings.

Statistics

The design and analysis of this real-world evidence study have limited prior reference material, which limits the precision of the sample size calculation. However, published epidemiological studies estimate the prevalence of pathogenic variants in *BRCA1/BRCA2* at approximately 17%, with variability across populations and testing methods.

Based on this prevalence rate, the primary outcome of the study is the clinical and molecular profile of OC patients already initiated on Olaparib or those who will be starting on Olaparib treatment, which informed the sample size estimation.¹⁵

Using an estimated *BRCA* mutation prevalence of 17%, a sample size of 225 participants was calculated to provide an 80% probability (power) of detecting associations between *BRCA* mutation, HRD status, and clinicopathologic characteristics at a 95% confidence level, with a marginal error of 0.05. Considering an expected attrition rate of 10% due to loss or incomplete data, the final sample size required for the study was set at 250 participants.²³

Sample size estimation was conducted using standard statistical methods for proportion-based analyses, incorporating results from mutation prevalence, confidence interval, and expected variability in clinical characteristics. An interim analysis will be conducted after the enrolment of the first 100 participants to assess data completeness and review the planned sample size. Final analyses will be performed on the full cohort of 250 participants receiving Olaparib therapy.

Data will be entered into a secure, validated EDC system equipped with built-in range and logic checks to ensure accuracy. Automated data queries will be generated for missing, inconsistent, or out-of-range values and subsequently resolved by site investigators. Regular data reviews will be conducted to monitor ongoing data quality, thereby ensuring the integrity and reliability of the study dataset.

Data will be summarized using descriptive statistics. Continuous variables will be expressed as mean±standard deviation (SD) if normally distributed, or median with interquartile range (IQR), if normality assumptions are not met. Categorical variables will be presented as frequencies and percentages. Associations between categorical variables (e.g., *BRCA* mutation/HRD status and clinicopathological features) will be analysed using Chi-square or Fisher's test, as appropriate. Comparisons of continuous variables across mutation subgroups will be performed using an independent-samples t-test or a Mann-Whitney U test, based on the data distribution. Correlation analysis will be performed to explore relationships between *BRCA* mutation and HRD status, as well as clinicopathologic characteristics such as historical subtype, platinum response, ECOG performance status, and family history.

Potential confounding variables, including age, comorbidities, histopathological subtype, prior treatment history, ECOG performance status, and family history, will be systematically collected and considered during interpretation of associations between molecular status and clinical characteristics. Since this is a non-interventional observational study, residual confounding cannot be completely excluded; however, comprehensive baseline data collection is intended to minimize its impact.

Missing data will not be formally imputed. Analyses will be performed using available data for each variable and endpoint. The extent of missing data, if any, will be

described in the final analysis. Interim analysis will be conducted after enrolment of 100 patients, and final analysis will be performed after completion of enrolment of all 250 patients.

All statistical tests will be two-sided, with significance set at $p < 0.05$. All statistical summaries and analyses will be performed using IBM SPSS Statistics for Windows, Version 21 (Armonk, NY: IBH Corp.).

DISCUSSION

OC is influenced by a complex interplay of demographic, clinical, and reproductive factors, including age at diagnosis, tumour biomarker levels, menstrual and reproductive history, and underlying molecular alterations, such as *BRCA* mutation and HRD status. In real-world clinical practice, these parameters collectively affect the disease presentation and progression.

Age is a well-established determinant in the epidemiology of OC, with studies demonstrating that the age-specific incidence rate (ASIR) increases with advancing age.²⁴ A cross-sectional study by Sindiani et al reported a mean age of 54.5 years (range 27-74 years) among 59 patients with primary epithelial OC. Similarly, Kheiri et al evaluated 127 OC cases, reported a mean age at presentation was 52.3 years (SD: 14.210 years), and a mean age at menarche was 13.59 (SD: 2.706 years).^{25,26} Similarly, a retrospective study by Vedpathak and Nayak involving 50 patients with OC reported that 52% (n=26) were in the age group of 20-40 years.²⁷ Together, these findings highlight age-related variations in the clinical presentation of OC and underscore differences in disease patterns observed within the Indian population.

Menstrual and reproductive history is another critical determinant of OC. Women who experience early menarche (below age 12) and late menopause (after age 52) are likely to have a greater number of ovulatory cycles, which is associated with a 30-40% higher risk of OC.²⁸ A study by Vedpathak and Nayak observed that 32% (n=16) of patients were in the perimenopausal age group, and 14% (n=7) of patients were in the postmenopausal age group.²⁷ The million women study observed that nulliparous women had a 24% higher risk of OC relative to women with one child, including a 50% higher risk of endometrioid tumours and a 70% higher risk of clear cell tumours.²⁸ These figures highlight the importance of menstrual and reproductive history in shaping ovarian risk profiles and emphasize the need to evaluate these factors in the Indian population, where age at menarche, menopause, and parity patterns may differ. Beyond menstrual and reproductive health, lifestyle and comorbidities also play a significant role in disease progression. Chronic conditions such as diabetes mellitus, hypertension, and heart disease are prevalent in OC patients.²⁹ Vedpathak and Nayak also reported that hypertension was the most prevalent comorbidity, followed by diabetes.²⁷ These chronic disorders not only

affect disease course but also influence the treatment tolerance, surgical outcomes, and long-term survival of OC patients. Lifestyle factors such as tobacco use, smoking, and alcohol consumption add complexity and influence the therapeutic responses. Wang et al analyzed 519 women with OC and reported the adverse impact of tobacco smoking on disease progression. The risk was even higher in women consuming ≥ 15 cigarettes a day.³⁰ These findings suggest that active tobacco consumption increases the symptom burden and may potentially alter therapeutic response.

The clinical presentation of OC is often non-specific, contributing to delayed diagnosis and advanced-stage detection. Abdominal pain and distension are the most commonly observed symptoms across multiple studies. Sindiani et al reported lower abdominal pain in 50.1% of OC patients, and distension was observed in 32.2% of patients.²⁵ Garg et al found abdominal distension in 73% and pain in 52%.³¹ Similarly, Yogambal et al reported abdominal pain in 66.9% and abdominal mass in 28.1% of OC patients.³² Additionally, a study conducted by Kamal et al reported an abdominal mass in 81% of OC patients.³³ These presentations underscore the need for systematic documentation to better understand symptom burden. Histopathological evaluation also varied; Hossain et al found serous tumours to be most prevalent (82.7%), followed by mucinous (10.7%), endometrioid (5.3%), and clear cell tumours (1.3%).³⁴ Prognostic variables such as FIGO stage have been emphasized in previous studies. Due to delayed diagnosis and the absence of effective screening techniques, over 70% of OC cases are diagnosed at advanced stages (FIGO III-IV).³⁵ Taken together, these data highlight the heterogeneity in clinical presentation and histology, as well as the prognostic importance of FIGO stage.

At the molecular level, germline and somatic *BRCA1/2* mutations, together with HRD, define the distinct biological subsets of OC. HRD acts as a central axis of genomic instability and therapeutic relevance. Women who inherit germline pathogenic variants in the *BRCA1* or *BRCA2* genes have a higher risk of developing OC than the general population. For *BRCA1* carriers, the lifetime risk is estimated at 45%-50%, while for *BRCA2* variant carriers it is 17%-21%.³⁶ No significant variation in the age at diagnosis of OC was observed according to the type of common *BRCA* mutation.³⁷ Family history further stratifies risk, with mutations detected in 19% of women reporting a first-degree relative with breast or OC, compared with only 6.5% in women without affected relatives. Among *BRCA1* mutation carriers, penetrance estimates highlight the substantial clinical burden, with a cumulative lifetime OC risk of approximately 36% by age 80.¹⁵ These results highlight the importance of age-specific incidence and family history in identifying women at elevated risk, while also emphasizing the distinct temporal and familial patterns associated with *BRCA1* and *BRCA2* mutations.

The molecular landscape of HRD extends beyond conventional *BRCA1/BRCA2* mutations, reflecting a broader spectrum of genomic instability in OC.³⁸ Ren et al reported that biallelic alterations in *BRCA1/BRCA2*, along with chromosome-specific loss of heterozygosity (LOH), play a major role in the development of HRD across Asian cancer cohorts.³⁹ Fiegl et al further demonstrated that *BRCA1* promoter methylation represents an important epigenetic mechanism contributing to HRD in high-grade serous ovarian carcinoma (HGSOC).⁴⁰ Moreover, studies by Zhao et al and Wei et al showed that RNA methylation pathways, particularly N6-methyladenosine (m6A) modification, influence homologous recombination-related gene regulation and thereby contribute to HRD in OC.^{41,42} Murai and Pommier also described the therapeutic relevance of PARP inhibitors such as Olaparib, which exert antitumor effects through PARP1/2 trapping and catalytic inhibition, while HRD-associated molecular signatures may help identify a wider population of patients likely to benefit from these therapies.⁴²

Beyond family history, *BRCA* mutation, and HRD status, functional markers such as CA-125 have proven valuable in monitoring disease activity and therapeutic response. Serum CA-125 levels are increased in 50% of type-I OC and 92% of advanced-stage tumours, which are mostly type-II OC.⁴³ These findings of mutation status and biomarker responsiveness emphasize the importance of integrating molecular testing with clinical monitoring.

Clinical trials have consistently demonstrated superior antitumor activity and prolonged progression-free survival in patients with *BRCA* mutations, establishing PARP inhibition, particularly with agents such as Olaparib, as a biomarker-driven therapy in OC.^{44,45} In alignment with the ICMR guidelines, which recommend multimodal management including optimal cytoreductive surgery, platinum-based chemotherapy, and maintenance strategies for patients achieving a response, PARP inhibitors such as Olaparib have emerged as an important maintenance option.⁴⁶ The availability of generic Olaparib has improved treatment accessibility for patients in India. However, prior Indian studies were limited by insufficient data on family history and *BRCA* mutation prevalence, underscoring the need for large-scale evaluation.¹⁵ The OC-REAL India study has therefore been designed to address these gaps by comprehensively assessing demographic characteristics, clinicopathological features, and their correlation with mutation status, while reinforcing the clinical relevance of *BRCA*/HRD testing in OC patients. Together, a guideline-based multimodal approach, systematic genetic testing, CA-125 monitoring, and cost-effective targeted therapy with generic Olaparib provide a strategic framework for personalized management that may improve outcomes for women with mutation-driven OC.

Strengths

The OC-REAL India study is a multicentre real-world investigation evaluating OC patients receiving Olaparib in

India. Its strengths lie in the systematic evaluation of both clinical and molecular characteristics of OC patients within routine practice settings, ensuring relevance to everyday clinical care. The multi-centre design, with planned enrolment of approximately 250 patients across 50 geographically distributed sites, enhances the generalizability of findings and captures regional diversity. The integration of biomarker stratification, including *BRCA* mutation and HRD status, provides clinically significant insights to guide personalized strategies. In addition, the study's comprehensive data capture, including family history, reproductive factors, and treatment patterns, offers a detailed profile of patients, thereby enriching the understanding of heterogeneity in OC management in the Indian context.

Limitations

The cross-sectional observational design limits the study to capturing clinical characteristics at a single time point, and the reliance on a single baseline visit without longitudinal follow-up precludes the assessment of long-term outcomes. Potential selection bias may also arise, as enrolment is restricted to patients prescribed Olaparib in routine clinical practice. Additionally, dependence on available molecular testing results may introduce further bias if testing patterns vary across centres. Given the ambispective nature of the study, the retrospective component may also be subject to recall bias or incomplete documentation for certain variables. Overall, the study design underscores the need for long-term prospective studies to better understand treatment effects within the Indian population.

CONCLUSION

The OC-REAL India study addresses a critical evidence gap by generating robust real-world evidence on the clinical and molecular profiles of Indian OC patients who are already initiated on Olaparib (within ≤ 3 months of enrolment or scheduled for initiation). Through its cross-sectional, multicentre design, the study systematically captures demographic details, histopathological features, treatment patterns, and biomarker status (*BRCA* mutation and HRD status), thereby generating a comprehensive profile of OC patients across multiple centres. These findings are expected to enhance understanding of the true heterogeneity of patients encountered in routine practice, given the limited availability of large-scale studies in India.

The findings are expected to highlight the pivotal role of timely diagnosis and comprehensive genetic testing in accurately identifying patients most likely to benefit from PARP inhibitor-based maintenance therapy. Collectively, the findings from OC-REAL India are expected to support informed clinical decision-making, personalized management strategies and precision oncology approaches for OC in the Indian healthcare setting.

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