Real-World Overall Survival in Second-Line Maintenance Niraparib Monotherapy vs Active Surveillance in Patients With Recurrent Ovarian Cancer

**Background**

- Ovarian cancer (OC) is one of the leading causes of gynecological cancer-related deaths worldwide.
- Patients with advanced disease often require and require multiple lines of chemotherapy.
- Second-line (2L) treatments typically include platinum-based regimens for patients with platinum-sensitive disease; however, survival tends to decrease with each subsequent line of therapy.
- Niraparib is an oral poly (adenosine diphosphate (ADP)-ribose) polymerase (PARP) 1/2 inhibitor that has demonstrated improved progression-free survival (PFS) in the 2L maintenance (2Lm) setting in patients with recurrent OC in the NOVA trial, while maintaining a consistent safety profile.
- NOVA (NCT01473742) was a randomized, double-blind, placebo-controlled Phase 3 trial assessing the efficacy of maintenance niraparib for patients with platinum-sensitive recurrent OC. PFS was the primary endpoint and overall survival (OS) was a secondary endpoint.

**Aim**

The aim of this real-world study was to compare OS in breast cancer gene mutation type (BRCA) patients with recurrent OC who initiated 2Lm monotherapy or were under active surveillance (AS) to complement NOVA trial results.

**Methods**

- This analysis used the US nationwide Flatiron Health database of electronic health records to record longitudinal data. The database contains patient-level structured and unstructured data, linked to technology-enabled electronic patient records.
- The study included patients diagnosed with OC including peritoneal and fallopian tube cancers during the study period (9 January 2011 to 31 May 2022) from approximately 260 cancer centers with >500 active cases.
- The index date was defined as the end of 2L non-maintenance therapy.

**Results**

Overall, 179 and 707 BRCA/OC patients received niraparib 2Lm or were under AS, respectively (Table 1).

<table>
<thead>
<tr>
<th>Selection criteria, n (%)</th>
<th>2Lm</th>
<th>AS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients diagnosed with OC from 1 Jan 2011 to 31 May 2022</td>
<td>18,304 (100)</td>
<td>21,894 (100)</td>
</tr>
<tr>
<td>had an initial diagnosis prior to 31 May 2021</td>
<td>9840 (53.7)</td>
<td>14,749 (67.6)</td>
</tr>
<tr>
<td>with evidence of epithelial histology</td>
<td>9140 (50.1)</td>
<td>14,420 (64.5)</td>
</tr>
<tr>
<td>received 2L prior lines of therapy</td>
<td>2105 (11.5)</td>
<td>403 (1.8)</td>
</tr>
<tr>
<td>were ≥18 years at the index date and did not initiate any type of 1L during a predefined window of time, including only patients with ≥6 months of non-maintenance niraparib maintenance</td>
<td>1570 (8.6)</td>
<td>206 (0.9)</td>
</tr>
<tr>
<td>had an index date between 1 Jan 2017 and 31 May 2022</td>
<td>1273 (6.9)</td>
<td>19 (0.1)</td>
</tr>
<tr>
<td>had 30 days of clinical activity within 60 days of initial index date</td>
<td>1173 (6.3)</td>
<td>265 (1.2)</td>
</tr>
</tbody>
</table>

**Conclusions**

- The real-world study included an older and more diverse patient population that typically included in randomized controlled trials.
- Consistent with the results of the NOVA trial, the median OS in niraparib 2Lm cohort was 5.7 months greater than the AS cohort.

- The real-world study provides informative data on OS outcomes in patients with BRCA/OC receiving niraparib 2Lm versus AS from the Flatiron Health database.
- Homogenous reimbursement defintion testing in the real world is limited and presented evidence for BRCA1/2-positive subgroup. In addition, data distinguishing between AS and other non-AS were not available; therefore, conclusions can only be made for patients who were started on AS.

**Target trial exclusion criteria**

- BRCA-Cancer Screening: Patients with ≥18 years at the index date and did not initiate any type of 1L during a predefined window of time.

**Acknowledgments**

The study was funded by GSK (2019). Medical writing support was provided by Cheyney TM, RDC, and Dorothy Leung, MSc. Flatiron Health, Inc. provided insurance data and clinic-level data. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

**References**


**Disclosure**

- No proprietary or commercial interests that pose a conflict of interest.

**Author email address:** Kathale@ouhsc.edu

**Presented at**

- European Society for Medical Oncology (ESMO) Gynecological Cancers Annual Congress, Barcelona, Spain, February 23–24, 2023

**Figure 1. Study design**

- Patients from 227 academic medical centers in the US were included in the study. Patients were classified into 3 groups: 1) patients who started on 1L treatment with a chemotherapy agent (C); 2) patients who started on 1L treatment with an immunotherapy agent (I); and 3) patients who did not start on 1L treatment (N).

- The median OS in niraparib 2Lm cohort was 5.7 months greater than the AS cohort.

- The real-world study provides informative data on OS outcomes in patients with BRCA/OC receiving niraparib 2Lm versus AS from the Flatiron Health database.

- Homogenous reimbursement defintion testing in the real world is limited and presented evidence for BRCA1/2-positive subgroup. In addition, data distinguishing between AS and other non-AS were not available; therefore, conclusions can only be made for patients who were started on AS.

- The real-world study included an older and more diverse patient population that typically included in randomized controlled trials.

- Consistent with the results of the NOVA trial, the median OS in niraparib 2Lm cohort was 5.7 months greater than the AS cohort.

- The real-world study provides informative data on OS outcomes in patients with BRCA/OC receiving niraparib 2Lm versus AS from the Flatiron Health database.

- Homogenous reimbursement defintion testing in the real world is limited and presented evidence for BRCA1/2-positive subgroup. In addition, data distinguishing between AS and other non-AS were not available; therefore, conclusions can only be made for patients who were started on AS.

- The real-world study included an older and more diverse patient population that typically included in randomized controlled trials.

- Consistent with the results of the NOVA trial, the median OS in niraparib 2Lm cohort was 5.7 months greater than the AS cohort.