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Authors

Chase, Dana
Shukla, Soham
Moore, Julia
et al.

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BRIEF REPORT

Patient Characteristics Associated with Time to Next Treatment in Patients with Ovarian Cancer Treated with Niraparib: The PRED1CT Real-World Study

Dana M. Chase · Soham Shukla · Julia Moore · Tirza Areli Calderón Boyle · Jonathan Lim · Jessica Perhanidis · Jean A. Hurteau · Jeanne M. Schilder

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ABSTRACT

***Introduction*:** Niraparib first-line maintenance (1LM) therapy has demonstrated clinical benefit for patients with ovarian cancer (OC) in clinical trial and real-world settings, but data on factors associated with real-world patient outcomes remain limited. This analysis identified patient characteristics associated with time to next treatment (TTNT), a proxy for real-world progression-free survival, in patients with OC treated with 1LM niraparib monotherapy.

***Methods*:** This retrospective observational study used a USA nationwide electronic health record-derived deidentified database and included adult patients diagnosed with OC who initiated 1LM niraparib monotherapy after first-line platinum-based chemotherapy. Patients were followed until the earliest occurrence of last clinical activity, death, or end of study period. TTNT was measured from 1LM niraparib initiation to the start of second-line treatment or death. Cox proportional hazards models assessed univariable and multivariable associations between baseline characteristics and TTNT.

***Results*:** Of 7872 patients diagnosed with OC, 526 met the eligibility criteria and were included in this analysis. Median (IQR) duration of follow-up was 14.1 (7.4–23.6) months. In univariable analyses, age, *BRCA*/homologous recombination deficiency (HRD) status, socioeconomic status, stage at initial diagnosis, cytoreductive surgery type, and residual disease status were significantly associated with observed TTNT and were introduced into the multivariable model with other clinically relevant variables. In the multivariable analysis, *BRCA*/HRD status, cytoreductive surgery type, and residual disease status were significantly associated with observed TTNT after covariate adjustment. Conversely, age, Eastern Cooperative Oncology Group performance status, disease stage, niraparib starting

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D. M. Chase (✉)
David Geffen School of Medicine at UCLA,
855 Tiverton Dr, Los Angeles, CA 90024, USA
e-mail: dmchase@mednet.ucla.edu

S. Shukla · J. Moore · T. A. C. Boyle · J. Lim
GSK, Upper Providence, PA, USA

J. Perhanidis · J. A. Hurteau
GSK, Waltham, MA, USA

J. M. Schilder
GSK, Philadelphia, PA, USA

dose status, and first-line bevacizumab use were not associated with observed TTNT.
Conclusion: This real-world, retrospective, observational analysis offers valuable insights on prognostic factors associated with TTNT in patients with OC treated with 1LM niraparib monotherapy after first-line platinum-based chemotherapy. Future studies are needed to examine how additional patient characteristics associated with clinical outcomes may guide treatment decisions and improve outcomes.

Keywords: Electronic health records; First-line; Maintenance therapy; Niraparib; Ovarian cancer; Prognostic factors; Real-world; Time to next treatment

Key Summary Points

Why carry out this study?

Maintenance therapy with a poly(ADP-ribose) polymerase (PARP) inhibitor such as niraparib has been recommended in patients with epithelial ovarian cancer after first-line (1L) platinum-based chemotherapy.

Understanding clinical characteristics associated with outcomes in patients treated with niraparib in a real-world setting remains an unmet need.

What did the study ask?

What clinical characteristics are associated with real-world time to next treatment (TTNT), a proxy for real-world progression-free survival, in patients with ovarian cancer who were treated with 1L maintenance niraparib monotherapy?

What was learned from the study?

Established clinical prognostic factors, such as *BRCA*/homologous recombination deficiency status, type of cytoreductive surgery, and residual disease status were significantly associated with observed TTNT in the adjusted multivariable model.

Other variables assessed in the multivariable model, including age, bevacizumab use in 1L induction setting, niraparib starting dose status, disease stage, and Eastern Cooperative Oncology Group performance status, were not statistically significantly associated with observed TTNT in this patient population.

INTRODUCTION

Ovarian cancer (OC) presents a substantial burden in the USA, with an estimated 19,680 new cases and 12,740 deaths from OC in 2024 [1]. Most patients present with advanced disease at diagnosis and, as such, prognosis remains poor, with an estimated 5-year survival rate of approximately 50% [1, 2].

For patients diagnosed with advanced OC, standard first-line (1L) treatment includes either primary cytoreductive surgery (PCS) or interval cytoreductive surgery (ICS) and platinum-based chemotherapy with or without bevacizumab [3, 4]. To prolong survival and delay disease progression or recurrence, first-line maintenance (1LM) therapy is recommended for patients who have achieved complete or partial response to 1L therapy [5]. Treatment options for 1LM include bevacizumab or poly(ADP-ribose) polymerase (PARP) inhibitors (PARPi), such as olaparib, rucaparib, niraparib, or a combination of bevacizumab and a PARPi [5].

Niraparib 1LM therapy has demonstrated clinical benefit in both clinical trial and real-world settings. In the phase 3 PRIMA trial, patients with advanced OC who responded to 1L platinum-based chemotherapy demonstrated significantly improved progression-free survival (PFS) with niraparib compared with placebo [6]. After these results, niraparib monotherapy was approved for 1LM treatment of adult patients with advanced epithelial OC who are in a complete or partial response to 1L platinum-based chemotherapy [7]. However, real-world data on patient characteristics associated with outcomes remain limited.

This retrospective observational study aimed to identify variables associated with time to next

treatment (TTNT) in real-world patients treated with niraparib 1LM monotherapy for ovarian cancer.

METHODS

Data Source

This study used data from the nationwide Flatiron Health database. This longitudinal database of deidentified, electronic health record–derived data contains information from approximately 280 cancer clinics representing an estimated 800 sites of largely community-based care across the USA (84.6% of patients included in this study originated from a community oncology practice) [8, 9]. Data include patient-level structured and unstructured data curated via technology-enabled abstraction from physician notes and other unstructured documents [8, 9]. Lines of therapy were oncologist defined and rule based.

Study Population

Female patients diagnosed with OC [including ovarian, fallopian tube, and peritoneal cancer defined as International Classification of Diseases (ICD) codes 183x, 158x (ICD-9), and C56x, C57.0x, C48x (ICD-10)] on or after 1 January 2015, who received 1LM niraparib monotherapy after 1L platinum-based therapy (regimens containing carboplatin, cisplatin, and/or oxaliplatin) were eligible. 1LM niraparib monotherapy must have been initiated during the index period of 1 January 2017, through 1 December 2022 (inclusive). The index date was the start of 1LM niraparib monotherapy. Patients were required to be at least 18 years of age at initial OC diagnosis, have evidence of epithelial (serous, clear cell, mucinous, endometrioid, transitional cell, epithelial not otherwise specified, or unknown) histology, and have at least 2 days of follow-up. Patients were excluded if they had an incomplete medical history (defined as no clinical activity within 90 days after initial diagnosis), missing surgery date if the patient received surgery, or a likely misclassified line of therapy [defined as receipt of PARPi monotherapy (niraparib, olaparib, rucaparib) as 1L induction or second-line treatment]. Patients were followed from the index date until the earliest occurrence of last clinical activity, end of study (28 February 2023), or death.

Study Outcomes and Statistical Analysis

Demographic and clinical characteristics were summarized descriptively and included age at index date, geographic region, race, ethnicity, socioeconomic status (SES), practice type, Eastern Cooperative Oncology Group performance status score, histology at initial OC diagnosis, height and weight, body mass index (BMI), biomarker status [*BRCA* and homologous recombination deficiency (HRD) status], stage at initial diagnosis, platelet count, type of cytoreductive surgery (PCS, ICS, or no surgery), residual disease status, duration of 1L induction therapy, time from end of 1L treatment to start of 1LM niraparib monotherapy, starting dose status, and 1L bevacizumab use. Most characteristics were measured at index date or within the baseline period (see Table S1 in the electronic supplementary material for additional details on variable definitions and measurement windows).

The outcome of the study was TTNT, measured from index date to the start of second-line treatment or death. Patients who did not have an event were censored at the end of follow-up. Median TTNT with 95% confidence intervals (CIs) were estimated with Kaplan–Meier methodology. To assess associations between individual baseline characteristics and TTNT, univariable analyses using Cox proportional hazards models [hazard ratio (HR), 95% CI] were conducted. Multivariable analysis was assessed with a Cox regression model (HR, 95% CI, $p \leq 0.05$), adjusting for covariates. Variables were selected for inclusion in the multivariable analysis using a combination of either a p-value threshold ≤ 0.1 in univariable analyses and/or clinical input regarding the current knowledge of the prognostic value of patient characteristics.

Ethics/Ethical Approval

Permission for authors to access/use the database was provided by Flatiron Health, Inc. This study complied with all applicable patient privacy laws. There was no direct patient contact or primary collection of individual human subject data. The data were de-identified and subject to obligations to prevent re-identification and protect patient confidentiality. Therefore, informed consent and ethics committee or institutional review board approval were not required.

RESULTS

Of 7872 patients diagnosed with OC on or after 1 January 2015, 526 met all eligibility criteria and were included in this analysis (Fig. 1). Most patients were less than 75 years of age (74.3%), white (64.3%), and had stage III/IV disease at initial diagnosis (83.3%; Fig. 2). Median (IQR) follow-up time was 14.1 months (7.4–23.6 months). The observed median TTNT, as measured from start of 1LM niraparib, was 11.2 months (95% CI 9.9–12.4 months).

In univariable analyses of associations with observed TTNT, age, socioeconomic status, stage at diagnosis, *BRCA*/HRD status, type of cytoreductive surgery, and residual disease status were statistically significantly associated with TTNT (Fig. 2). Specific factors associated with shorter observed TTNT included age ≥ 75 years (versus < 75 years); *BRCA* wild type (*BRCA*wt)/homologous recombination deficient (HRd) (versus *BRCA*-mutated), *BRCA*wt/homologous recombination proficient (HRp) or *BRCA*wt/homologous recombination unknown (HRunk) (versus *BRCA*-mutated); receipt of ICS or no surgery (each versus PCS); and having visible residual disease (versus no visible residual disease). Conversely, stage I/II or III (each versus stage IV) disease at initial diagnosis was associated with longer observed TTNT. Characteristics that did not have a statistically significant association with observed TTNT included BMI, race, ethnicity, platelet count, niraparib starting dose status, time to 1LM therapy from end of 1L therapy, duration of 1L therapy, and use of a bevacizumab-containing 1L regimen.

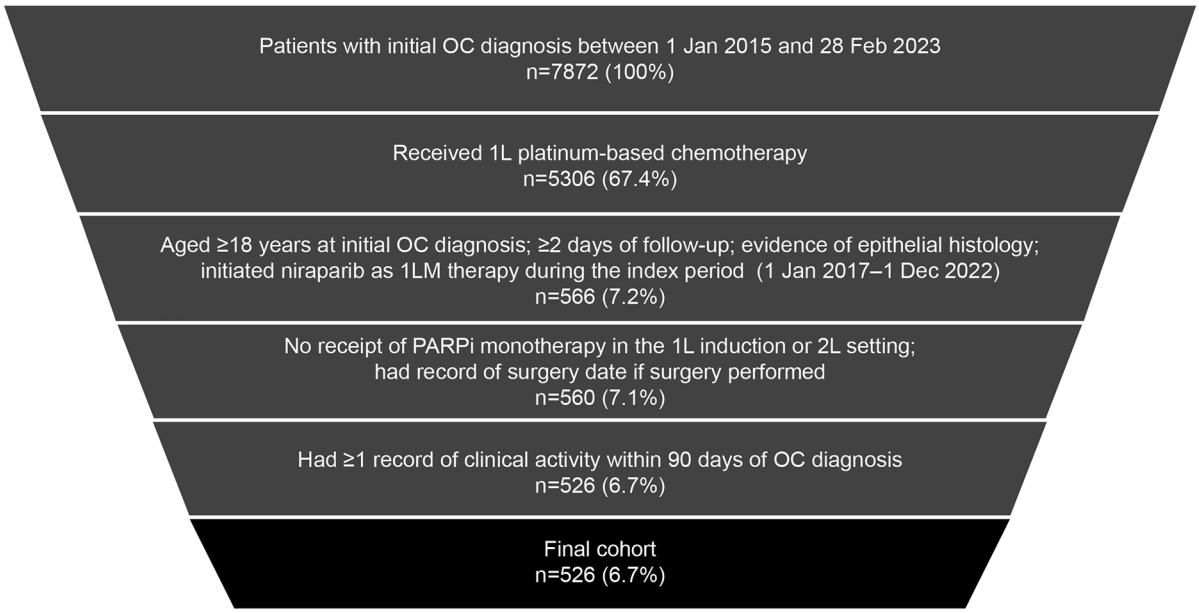

Fig. 1 Study population attrition. *1L* first-line, *1LM* first-line maintenance, *2L* second-line, *OC* ovarian cancer, *PARPi* poly(ADP-ribose) polymerase inhibitor

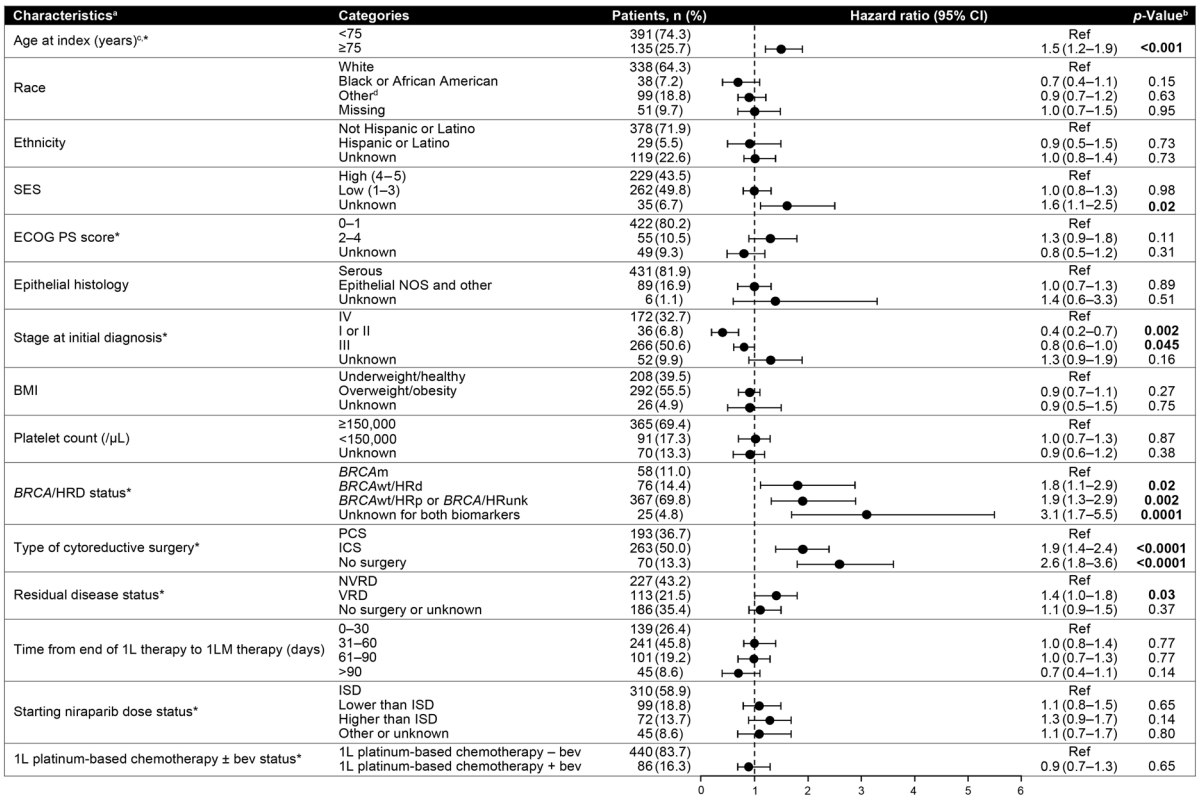

Fig. 2 Univariable analyses estimating the association of patient characteristics and time to next treatment (TTNT). Categories selected for inclusion in the multivariable model are denoted with an asterisk. [a]Statistically significant hazard ratio values > 1 indicate association with shorter TTNT than the reference category. Statistically significant values < 1 indicate association with longer TTNT than the reference category. [b]*p*-values ≤ 0.1 are denoted by bold text. [c]Patients with a birth year of 1938 or earlier may have an adjusted birth year in the database because of patient de-identification requirements. [d]Other includes Asian and Hispanic/Latino patients because of small sample sizes. *1L* first-line, *1LM* first-line maintenance, *bev* bevacizumab, *BMI* body mass index, BRCA*m BRCA* mutated, BRCA*wt BRCA* wild-type, *CI* confidence interval, *ECOG PS* Eastern Cooperative Oncology Group performance status, *HRD* homologous recombination deficiency, *HRd* homologous recombination deficient, *HRp* homologous recombination proficient, *ICS* interval cytoreductive surgery, *ISD* individualized starting dose, *NOS* not otherwise specified, *NVRD* no visible residual disease, *PCS* primary cytoreductive surgery, *Ref* reference group, *SES* socioeconomic status, *VRD* visible residual disease

In the multivariable analysis, *BRCA*/HRD status, type of cytoreductive surgery, and residual disease status were statistically significantly associated with TTNT after adjusting for other patient characteristics (Fig. 3). Specifically, *BRCA*wt/HRd status relative to *BRCA*-mutated status [HR, 2.0 (95% CI 1.2–3.2)], *BRCA*wt with either HRp or HRunk relative to *BRCA* -mutated status [2.0 (1.3–3.0)], receiving ICS [1.8 (1.3–2.4)] or no surgery [2.7 (1.7–4.3)] relative to PCS, and having visible residual disease [1.5 (1.1–2.1)] relative to no visible residual disease were associated with shorter observed TTNT. Age, Eastern Cooperative Oncology Group performance status, disease stage, niraparib starting dose status, and first-line bevacizumab use were not associated with observed TTNT.

DISCUSSION

In this real-world, retrospective, observational study, we assessed factors associated with

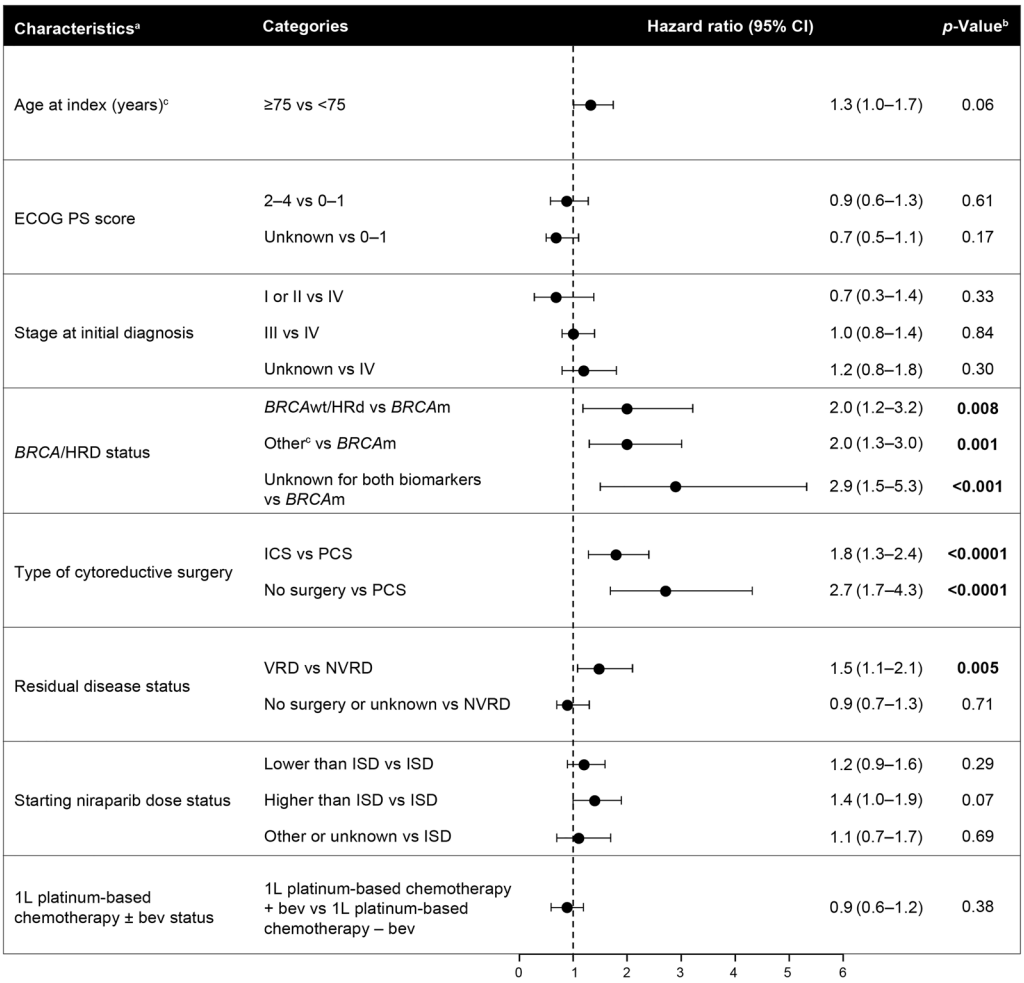

Fig. 3 Final multivariable model of baseline characteristics associated with time to next treatment (TTNT). [a]Hazard ratio values > 1 indicate association with shorter TTNT than the reference category. Values < 1 indicate association with longer TTNT. [b]*p*-values ≤ 0.05 are denoted by bold text. [c]Patients with a birth year of 1938 or earlier may have an adjusted birth year in the database because of patient de-identification requirements. [d]Other was defined as HRp or *BRCA*wt with either HRp or HRunk status. *1L* first-line, *bev* bevacizumab, BRCA*m* *BRCA* mutated, BRCA *wt* *BRCA* wild-type, *CI* confidence interval, *ECOG PS* Eastern Cooperative Oncology Group performance status, *HRD* homologous recombination deficiency, *HRd* homologous recombination–deficient, *HRp* homologous recombination–proficient, *ICS* interval cytoreductive surgery, *ISD* individualized starting dose, *NVRD* no visible residual disease, *PCS* primary cytoreductive surgery, *unk* unknown, *VRD* visible residual disease, *wt* wild type

TTNT in patients with OC who received 1LM niraparib monotherapy after 1L platinum-based chemotherapy. In univariable analyses, age ≥ 75 years; *BRCA*wt/HRd, *BRCA*wt/HRp, or *BRCA*wt/HRunk status; receipt of ICS; no surgery; and visible residual disease were statistically significantly associated with shorter observed TTNT, whereas stage I/II or stage III disease at diagnosis were associated with longer observed TTNT. Conversely, BMI, race and ethnicity, platelet count, niraparib starting dose status, time to 1LM therapy from end of 1L therapy, duration of 1L therapy, and use of a bevacizumab-containing 1L regimen were not statistically significantly associated with observed TTNT in this population. After adjustment, *BRCA*wt/HRd, other *BRCA*/HRD status, or unknown *BRCA*/HRD status, receipt

of ICS, no surgery, and having visible residual disease were associated with shorter observed TTNT in the multivariable model.

The purpose of TTNT is to function as a proxy for PFS in the real-world setting. In the phase 3 PRIMA trial, median PFS was 13.8 months (95% CI 11.3–14.2 months) in the overall cohort, 19.6 months (95% CI 13.6 to not estimable) in the HRd/*BRCA*wt subgroup, and 8.1 months (95% CI 5.7–9.4) in the HRp subgroup [6]. These values are consistent with the observed TTNT in the current study of a primarily *BRCA*wt and/or HRp population and supports the continued use of TTNT as a proxy for real-world PFS.

The observed median TTNT in this study was also consistent with that of another real-world analysis. In that study, patients diagnosed with stage III/IV OC who received any type of 1LM, including bevacizumab, a PARPi, paclitaxel, or gemcitabine in the maintenance setting after 1L treatment, had a median TTNT of 13.3 months (95% CI 11.7–15.8 months) [10]. Although these values are numerically larger than the observed 11.2-month median TTNT in this analysis, in that study, TTNT was estimated from the end of 1L treatment, whereas in this analysis, TTNT was measured from the date of 1LM niraparib initiation. Notably, the time from end of 1L therapy to initiation of 1LM therapy was more than 30 days for most patients in this analysis. Therefore, numeric differences in observed TTNT may be due to how TTNT was measured rather than significant differences in patient outcomes.

Identification of factors that are prognostic of positive outcomes could inform patient selection and improve response to maintenance therapy. Indeed, previous reports and other available evidence have identified several factors that are associated with longer TTNT. One analysis of patient electronic health records data from 2011–2018 investigating risk factors for progression after 1L platinum-based chemotherapy found that patients with stage IV disease or those who underwent ICS had shorter observed TTNT than those with stage III disease or those who underwent PCS [11]. A more recent report found that high-risk factors, including stage IV disease, not undergoing surgery or receiving neoadjuvant therapy plus ICS, visible residual disease after surgery, and *BRCA*wt disease or unknown *BRCA* status, were all associated with shorter TTNT than that for patients without any high-risk factors. These findings were regardless of whether the patient underwent maintenance therapy or active surveillance [10]. Consistent with these previous studies, this study provides supportive data that *BRCA*wt/HRd, other, or unknown *BRCA*/HRD status; receiving interval cytoreductive or no surgery; and having visible residual disease were associated with shorter observed TTNT for patients receiving niraparib 1LM monotherapy in this real-world population.

Interestingly, some factors shown to be statistically significant in previous analyses, such as race and SES [12–15], were not identified as prognostic in this study. Data on race and ethnicity are not required in electronic medical records and may not be accurately reflected in this study population. Furthermore, SES was measured at an area level for this analysis, complicating the assessment of its association with individual-level outcomes. Notably, neither the use of bevacizumab in 1L induction treatment nor the dose of niraparib were associated with TTNT after adjusting for other variables, although the latter typically affects other outcomes such as tolerability [16].

As with all studies, the findings presented here should be considered within the context of potential limitations. As a retrospective, observational study, this was not a predictive analysis and could not assess causality; future investigations should evaluate potential mechanisms by which these factors contribute to 1LM effectiveness, including niraparib effectiveness. TTNT was selected as an outcome given the available data, but future studies may consider assessing factors prognostic of real-world PFS. For ease of interpretability, the prognostic variables were modeled as categorical variables, but this reduced statistical power. In addition, the database that was used contains information primarily from USA patients cared for in community-based practices, so these findings may not be generalizable to the overall OC population. Lastly, as with any retrospective database study, the database used in this investigation is subject to missing data and possible errors, and data regarding any care

or treatment received outside of this network were not available.

Opportunities for future research include evaluating which factors predict niraparib treatment benefit and if results are similar for other PARPis. Additionally, the association of patient characteristics with other outcome measures such as OS and real-world PFS should be assessed. However, such analyses would be contingent on the availability of these variables in real-world datasets with sufficient follow-up time (for OS).

CONCLUSIONS

This real-world, retrospective, observational analysis offers valuable insights on prognostic factors associated with TTNT in patients with OC treated with 1LM niraparib monotherapy after 1L platinum-based chemotherapy. Future studies are needed to examine how additional patient factors associated with clinical outcomes may guide treatment decisions and improve outcomes.

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Data Availability. The data that support the findings of this study were originated by and are the property of Flatiron Health, Inc., which has restrictions prohibiting the authors from making the data set publicly available. Requests for data sharing by license or by permission for the specific purpose of replicating results in this manuscript can be submitted to PublicationsDataAccess@flatiron.com.

Declarations

Conflict of Interest. Dana Chase reports consultant fees from AstraZeneca and GSK and honoraria from AstraZeneca, GSK, Immunogen, and Seagen/Genmab. Soham Shukla, Julia Moore, Tirza Areli Calderón Boyle, Jonathan Lim, Jean A. Hurteau, and Jeanne M. Schilder are employees of GSK and may hold stock/shares in GSK. Jessica Perhanidis is an employee of GSK and reports stock/shareholder at GSK and Boston Scientific.

Ethical Approval. Permission for authors to access/use the database was provided by Flatiron Health, Inc. This study complied with all applicable patient privacy laws. There was no direct patient contact or primary collection of individual human subject data. The data were de-identified and subject to obligations to prevent re-identification and protect patient confidentiality. Therefore, informed consent and ethics committee or institutional review board approval were not required.

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