Evaluating treatment patterns and outcomes of patients with platinum-resistant ovarian cancer: results of a real-world cohort in the United States

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Introduction

- Platinum-resistant high-grade ovarian, primary peritoneal, and fallopian tube cancers (PROC) are among the most aggressive and recurrent forms of gynecologic malignancies.
- Current treatment options for patients with PROC are limited, with low response rates (chemotherapy-based regimens), short median progression free survival (PFS)[1] and overall survival (OS) of < 1 year[1].
- Raludotatug deruxtecan (R-DXd; DS-6000a) is a potential first-in-class CDH6-targeting anti-body drug conjugate (ADC) that is currently under investigation. The ongoing REJOICE-Ovarian-01 clinical study aims to evaluate the clinical efficacy and safety of R-DXd in PROC patients who have progressed on standard-of-care therapies.
- As new therapies are developed or approved, contemporaneous real-world data are needed to characterize the unmet clinical needs, treatment landscape, and outcomes among patients with PROC in the United States (US).

Objectives

In a real-world PROC cohort:

- Evaluate real-world clinical outcomes (overall survival (rwOS), progression-free survival (rwPFS), time-to-next-treatment (rwTTNT), response rate (rwRR))
- Describe index line of therapy (LOT) treatments
- Describe socio-demographic and clinical characteristics
- Assess biomarker testing patterns and status

Methods

Design

- Non-interventional, retrospective, observational study using US-based advanced ovarian cancer data from Flatiron Health, a longitudinal, electronic health record-derived database, comprised of de-identified patient-level data[2]
- **Study population:**
  - Women aged ≥18 years diagnosed with advanced (stage III/IV) ovarian, fallopian tube, and/or primary peritoneal cancer on or after 01 May 2020
  - Received first line (1L) platinum-based chemotherapy (PBC)
  - Received a 2L treatment
  - Met criteria for PROC between 2L and 4L
  - Had ≥3 months of potential follow-up from index LOT start date to data cut-off of 28 Feb 2025
- **PROC definition:**
  - 2L: platinum-free interval (PFI) between 90-180 days and subsequent LOT includes a qualifying therapy
  - 3L or 4L: PFI ≤180 days and subsequent LOT includes a qualifying therapy
  - Qualifying therapies included any of the following drugs as monotherapy or in combination with one another: doxorubicin, doxorubicin pegylated liposomal, paclitaxel, paclitaxel protein-bound, topotecan, gemcitabine, cyclophosphamide, docetaxel, etoposide, gemcitabine, ifosfamide, irinotecan, ixabepilone, melphalan, pemetrexed, vinorelbine, bevacizumab, or mirvetuximab soravtansine-gynx
- **Two indexing approaches:**
  - Randomly-selected index LOT: among patients with multiple treatment lines meeting PROC eligibility criteria, a random treatment line was selected as the index LOT
  - First-eligible index LOT: utilized the earliest eligible treatment line meeting PROC criteria as the index LOT

Analyses

- Descriptive statistics to report demographics, clinical characteristics, index LOT treatments, and clinical outcomes.
- Kaplan-Meier methods to estimate real-world time-to-event outcomes.

Results

Demographics and clinical characteristics

- 106 women with PROC were included: median age of 70 years, primarily White (72%) and non-Hispanic (71%), with an ECOG performance score of 0-1 (63%), and treated at community practices (75%; **Table 1**).
- Most were diagnosed between 2020-2022 (82%), with serous histology (78%), and stage III disease at the time of diagnosis (53%).
- Majority of patients were tested for (**Table 2**):
  - BRCA mutation (97%), with 7% of tests showing a mutation
  - HRD (59%), with 30% of tests positive
  - FRα (59%), with 30% of tests showing high expression (percent staining ≥75% and stain intensity 2+)
- GIS status was largely unknown (21% of patients were tested).

Table 1. Demographic and clinical characteristics: randomly-selected^ index LOT

Demographic or Clinical Features; Overall (N = 106)			
Age (yrs) at index date		**Histology at advanced diagnosis, n (%)**	
Median (Q1, Q3)	70.0 (61.0, 76.0)	Clear cell	≤5
Min, Max	47.0, 85.0	Endometrioid	≤5
Age group at index date, n (%)		Epithelial NOS	16 (15.1%)
41-54	8 (7.5%)	Serous	83 (78.3%)
55-64	31 (29.2%)	Unknown	≤5
65-74	31 (29.2%)	**Stage at advanced diagnosis, n (%)**	
≥ 75	36 (34.0%)	III	56 (52.8%)
Race, n (%)		IV	50 (47.2%)
Black or African American	8 (7.5%)	**Year of advanced diagnosis, n (%)**	
White	76 (71.7%)	2020	23 (21.7%)
Other Race	9 (8.5%)	2021	38 (35.8%)
Unknown	13 (12.3%)	2022	26 (24.5%)
Ethnicity, n (%)		2023	≤20
Hispanic or Latino	9 (8.5%)	2024	≤5
Not Hispanic or Latino	75 (70.8%)	**ECOG at index date, n (%)**	
Unknown	22 (20.8%)	0	26 (24.5%)
BMI, kg/m² at index date, n (%)		1	40 (37.7%)
Median (Q1, Q3)	25.1 (22.0, 29.2)	2	11 (10.4%)
Min, Max	15.9, 53.3	3	≤5
Geographic region, n (%)		4	≤5
Midwest	7 (6.6%)	Missing	25 (23.6%)
Northeast	9 (8.5%)	**Liver function at index date, n (%)**	
South	47 (44.3%)	Mildly impaired	15 (14.2%)
West	12 (11.3%)	Normal	76 (71.7%)
Unknown	31 (29.2%)	Missing	15 (14.2%)
Practice type, n (%)		**Renal function at index date, n (%)**	
Academic	20 (18.9%)	Severely impaired	≤5
Community	79 (74.5%)	Moderately impaired	33 (31.1%)
Both	7 (6.6%)	Mildly impaired	41 (38.7%)
Socioeconomic status at index date, n (%)		Normal	23 (21.7%)
1 (Lowest)	11 (10.4%)	Unknown	≤10
2	12 (11.3%)	**LOT at randomly-selected index, n (%)**	
3	20 (18.9%)	2L	40 (37.7%)
4	23 (21.7%)	3L	46 (43.4%)
5 (Highest)	28 (26.4%)	4L	20 (18.9%)
Unknown	12 (11.3%)		

^No appreciable differences observed between randomly-selected index LOT and first-eligible index LOT analytic approaches

Table 2. Biomarker testing status: randomly-selected^ index LOT

Biomarker Status*† Overall (N = 106)			
BRCA tested, n (%)		**FRα tested, n (%)**	
Yes	103 (97.2%)	Yes	62 (58.5%)
Any mutation	7 (6.8%)	Positive (any expression)	32 (51.6%)
No mutation	92 (89.3%)	High expression ††	18 (29.0%)
Other	≤5	Negative	30 (48.4%)
Unknown	≤5	Result unknown	≤5
HRD tested, n (%)		**GIS tested, n (%)**	
Yes	63 (59.4%)	Yes	22 (20.8%)
Positive	19 (30.2%)	Positive	≤5
Negative	42 (66.7%)	Negative	15 (68.2%)
Result unknown	≤5	Result unknown	≤5

*Biomarker status within ever before index date to +30 days of index date
† Presence of biomarker testing is on the *patient* level. N and percent specific results are on the *test* level; a patient may have more than 1 test result. N unique tests is larger than N patients.
†† High FRα expression defined as percent staining ≥75% and stain intensity 2+
^No appreciable differences observed between randomly-selected index and first-eligible index analytic approaches

Index LOT treatments

- LOT number distribution:
  - Randomly-selected index LOT: 38% of index LOTs in 2L, 43% - 3L, 19% - 4L.
  - First eligible index LOT: 50% of index LOTs in 2L, 44% - 3L, and 6% - 4L.
- Main index treatments were similar in both approaches (**Table 3**):
  - Non-platinum chemotherapy monotherapy (43% and 41%)
  - Non-platinum chemotherapy monotherapy + bevacizumab (32% and 39%)
  - Mirvetuximab soravtansine-gynx (13% and 13%).
- Across index LOT number in both approaches:
  - Non-platinum chemotherapy monotherapy was the most common therapy in 3L, with the addition of bevacizumab most commonly in 2L.
  - Mirvetuximab soravtansine-gynx was most often used in 3L.

Table 3. Real-world index LOT treatments of PROC patients

Randomly-Selected Index LOT	Overall (N=106)	2L (N=40)	3L (N=46)	4L (N=20)
Non-platinum chemotherapy monotherapy	45 (42.5%)	15 (37.5%)	21 (45.7%)	9 (45.0%)
Doxorubicin	28 (62.2%)	12 (80.0%)	14 (66.7%)	≤5
Non-platinum chemotherapy + bevacizumab	34 (32.1%)	19 (47.5%)	14 (30.4%)	≤5
Doxorubicin + bevacizumab	26 (76.5%)	15 (78.9%)	10 (71.4%)	≤5
Non-platinum chemotherapy combination therapy(+/- bevacizumab or PARPi)	≤5	≤5	0 (0%)	0 (0%)
Mirvetuximab soravtansine-gynx	14 (13.2%)	≤5	≤10	≤5
Other	≤15	≤5	≤5	≤10
First-Eligible Index LOT	**Overall (N=106)**	**2L (N=53)**	**3L (N=47)**	**4L (N=6)**
Non-platinum chemotherapy monotherapy	43 (40.6%)	19 (35.8%)	20 (42.6%)	≤5
Doxorubicin	30 (69.8%)	13 (68.4%)	15 (75.0%)	≤5
Non-platinum chemotherapy + bevacizumab	41 (38.7%)	25 (47.2%)	16 (34.0%)	0 (0%)
Doxorubicin + bevacizumab	28 (68.3%)	17 (68.0%)	11 (68.8%)	0 (0%)
Non-platinum chemotherapy combination therapy (+/- bevacizumab or PARPi)	≤5	≤5	0 (0%)	0 (0%)
Mirvetuximab soravtansine-gynx	14 (13.2%)	≤5	9 (19.1%)	≤5
Other	≤10	≤5	2 (4.3%)	0 (0%)

Limitations

- Patients diagnosed at early stages whose disease later advanced were not included.
- Patients rechallenged with platinum or uncommon, non-standard-of-care therapies after meeting the PROC definition, were not included.
- Limited ability to assess uptake of FRα testing and mirvetuximab soravtansine-gynx, which was approved in November 2022, half-way through the study period.

Outcomes

- Using the randomly selected approach (**Figures 1a, 2a, Table 4**) the median rwOS was 7.1 months (95% CI: 5.4-11.5) and median rwPFS – 3.6 months (95% CI: 2.5-4.5).
- Using the first-eligible index line, rwPFS and rwTTNT estimates did not appreciably differ, but median rwOS appeared longer at 10.0 months (95% CI: 7.1-12.7).
- In the first-eligible index LOT, the rwRR was 20.2% (**Table 4**).

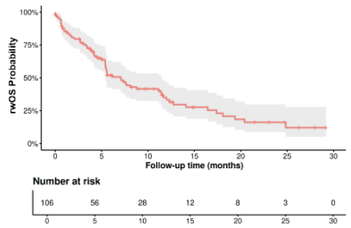

Figure 1a. Kaplan-Meier curve and estimates for rwOS using the randomly-selected index LOT for PROC patients

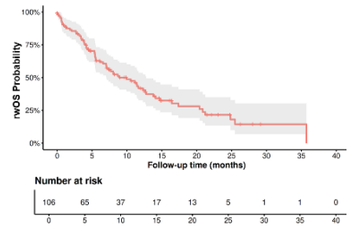

Figure 1b. Kaplan-Meier curve and estimates for rwOS using the first-eligible index LOT for PROC patients

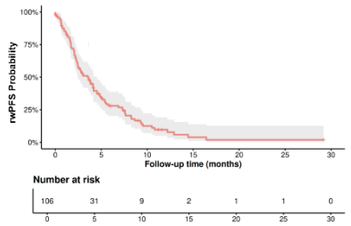

Figure 2a. Kaplan-Meier curve and estimates for rwPFS using the randomly-selected index LOT for PROC patients

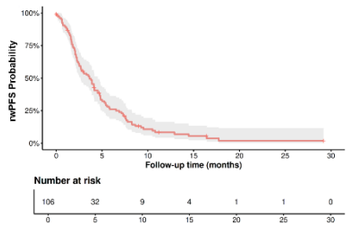

Figure 2b. Kaplan-Meier curve and estimates for rwPFS using the first-eligible index LOT for PROC patients

Table 4. Real-world outcomes of PROC patients

Outcome Parameter	Randomly-Selected Index LOT (N=106)	First-Eligible Index LOT (N=106)
rwPFS, median (95%CI), months	3.6 (2.5, 4.5)	3.6 (2.7, 4.5)
rwTTNT, median (95%CI), months	4.1 (3.4, 5.4)	4.2 (3.8, 5.6)
rwOS, median (95%CI), months	7.1 (5.4, 11.5)	10.0 (7.1, 12.7)
rwRR, %	N/A	20.2%*
* For patients with at least 1 known response assessment (n=79)		

Conclusions

- Real-world PROC cohorts are heterogeneous, including patients with poor functional status and organ function, who may be at increased risk of suboptimal outcomes.
- Biomarker testing uptake is high; nearly all PROC patients were tested BRCA and over half were tested for FRα and HRD.
- Outcomes across both analytic index LOT approaches were poor, reflected by short rwPFS, rwOS, and rwTTNT.
- Despite an evolving therapeutic landscape, a high unmet need persists at both the earliest time a patient may be identified as PROC, and throughout their real-world treatment journey.

References
1. Davis A, Tinker AV, Friedlander M. Platinum resistant ovarian cancer: what is it, who to treat and how to measure benefit? Gynecol Oncol 2014; 3:624-31
2. Flatiron Database Characterization Guide. https://flatiron.com/database-characterization

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Disclosures
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