Ovarian Cancer Retrospective European (O'CaRE) Observational Study to Assess Burden of Disease and Time to Next Treatment in Real-World Clinical Practice: Results from the United Kingdom

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Background

- In 2020 there were an estimated 313,959 new cases of ovarian cancer and 207,252 deaths from ovarian cancer worldwide[1]
- Until recently, the standard of care for first-line (1L) treatment of epithelial ovarian cancer was a combination of surgery and chemotherapy, with or without inclusion of antiangiogenic therapy[2,3]
- Use of poly(adenosine diphosphate [ADP]–ribose) polymerase (PARP) inhibitors as maintenance therapy has become more common following demonstrations of their efficacy across patient populations and treatment lines in clinical trials[4]
- Real-world studies investigating how patients with ovarian cancer are treated in clinical practice are lacking

Conclusions

- Median time to next treatment (TTNT) decreased with each progressive line of therapy, and outcomes generally worsened with each line of treatment
- Potential limitations of this analysis include its retrospective design, the small number of patients in several of the subgroups, and limitations associated with electronic case report data, which can be subject to incomplete data entry and coding errors
- Overall, these findings demonstrate an unmet need in patients with ovarian cancer as there was significant morbidity and mortality and most patients require multiple lines of therapy
- With the recent changes to the treatment landscape, additional analyses will be needed to investigate the overall use and efficacy of maintenance therapies, including PARP inhibitors, in patients with advanced ovarian cancer treated in clinical practice

Poster #745P

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Objectives

- The retrospective O'CaRE study assessed real-world burden of disease, treatment patterns, and outcomes in patients with ovarian cancer through analysis of healthcare data across 5 European countries
- Interim results are reported herein for the UK cohort

Methods

- O'CaRE is a multicenter, retrospective, noninterventional study conducted using medical records from patients aged ≥18 years diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer from January 1, 2014, to December 31, 2015. Patients who received PARP inhibitor treatment as an investigational medicine were ineligible
- Patients were followed for a maximum of 4 years after the index date or until death or loss to follow-up, whichever occurred first; the index date was defined as the date of initial diagnosis
- Kaplan-Meier methodology was used to estimate TTNT1 (time from last recorded 1L treatment dose to start of 2L treatment), TTNT2 (time from end of 2L to start of 3L treatment), TTNT3 (time from end of 3L to start of 4L treatment), progression-free survival (PFS; time from end of 1L treatment to beginning of 2L treatment, documentation of progression, or patient death, whichever occurred first), and overall survival (OS; time from end of 1L treatment to patient death)
- For TTNT, PFS, and OS analyses, patients lost to follow-up or reaching the end of the observation period were censored at their last contact date/end of observation period; patients who died were censored at their date of death

Results

- This interim analysis of the UK cohort included a total of 166 patients
- Median patient age at index date was 65 years, and more than 65% of patients had stage III or IV disease at diagnosis (Table 1)

Treatments

- For 1L treatment, 50.0% of patients received a combination of surgery (primary debulking surgery or interval debulking surgery) + chemotherapy, with an additional 15.1% of patients receiving surgery + chemotherapy + antiangiogenic therapy (Table 2)
- 25.9% of patients received chemotherapy alone for 1L treatment

Results *(cont'd)*

Table 1. Patient Characteristics at Index Date

	Overall population (N=166)
Demographic characteristics	
Age, median (IQR), years	65 (54–73)
Weight, median (IQR), kg	67.8 (59.0–79.9)
Disease characteristics	
Location of initial cancer diagnosis, n (%)	
Ovary	137 (82.5)
Primary peritoneal	24 (14.5)
Fallopian tube	5 (3.0)
Histological grading, n (%)	
Low grade[a]	10 (6.0)
High grade[b]	142 (85.5)
Missing	14 (8.4)
FIGO staging at diagnosis, n (%)	
I	21 (12.7)
II	17 (10.2)
III	84 (50.6)
IV	26 (15.7)
Missing	18 (10.8)
BRCA mutation status, n (%)	
*BRCA*wt	35 (21.1)
*BRCA*m	7 (4.2)
Unknown or missing	124 (74.7)
ECOG score at index date, n (%)	
0	51 (30.7)
1	32 (19.3)
2–3	6 (3.6)
Missing	77 (46.4)

[a]Included numerical grade 1 and descriptive category Low; [b]Included numerical grades 2–4 and descriptive category High. *BRCAm*, *BRCA* mutated; *BRCAwt*, *BRCA* wild type; ECOG, Eastern Cooperative Oncology Group; IQR, interquartile range.

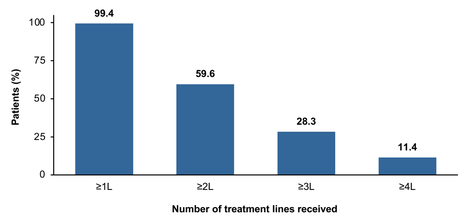
Table 2. 1L Treatment

	Overall population (N=166)
PDS + chemotherapy, n (%)	
PDS + chemotherapy	51 (30.7)
PDS + chemotherapy + antiangiogenic therapy	10 (6.0)
IDS + chemotherapy, n (%)	
IDS + chemotherapy	32 (19.3)
IDS + chemotherapy + antiangiogenic therapy	14 (8.4)
Other, n (%)	
Chemotherapy alone	43 (25.9)
Chemotherapy + antiangiogenic therapy	8 (4.8)
PDS alone[a]	6 (3.6)
PDS + chemotherapy + antiangiogenic therapy + secondary debulking surgery	1 (0.6)
No intervention	1 (0.6)

[a]Included PDS only and laparotomy/total abdominal hysterectomy.
1L, first-line; IDS, interval debulking surgery; PDS, primary debulking surgery.

- During follow-up, 99.4%, 59.6%, 28.3%, and 11.4% of patients received ≥1, 2, 3, or 4 lines of therapy, respectively (Figure 1)
- Overall, 3% (n=5) of patients received PARP inhibitor maintenance therapy during follow-up; of note, patients who received PARP inhibitor treatment as an investigational medicine were ineligible

Figure 1. Number of Treatment Lines Received During Follow-up

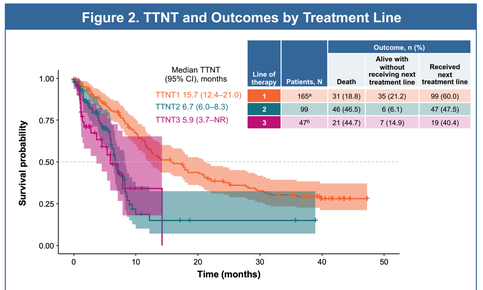


1L, first-line; 2L, second-line; 3L, third-line; 4L, fourth-line.

Outcomes

- In the overall study population, 33.7% of patients experienced a complete response, and 31.3% of patients experienced a partial response following initiation of 1L treatment
- Median TTNT decreased with each progressive line of therapy; calculated median TTNT1, 2, and 3 were 15.7, 6.7, and 5.9 months, respectively (Figure 2)

Figure 2. TTNT and Outcomes by Treatment Line

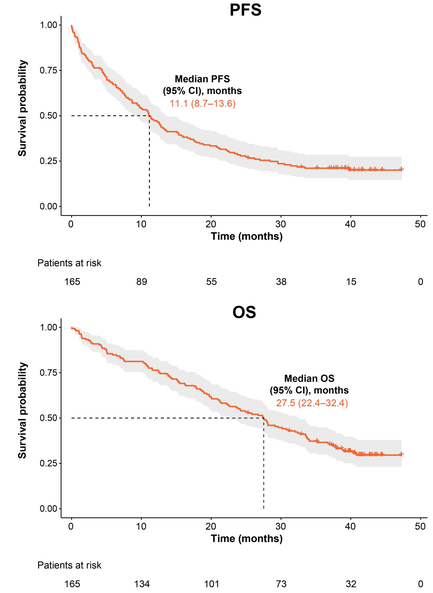


Line of therapy	Patients, N	Outcome, n (%)		
		Death	Alive with without receiving next treatment line	Received next treatment line
1	165[a]	31 (18.8)	35 (21.2)	99 (60.0)
2	99	46 (46.5)	6 (6.1)	47 (47.5)
3	47[b]	21 (44.7)	7 (14.9)	19 (40.4)

[a]One patient died and did not receive 1L treatment and was therefore excluded from analysis; [b]One patient had 3L treatment ongoing and was therefore not included in the TTNT3 analysis.
1L, first-line; NR, not reached; TTNT1, time to next treatment 1; TTNT2, time to next treatment 2; TTNT3, time to next treatment 3.

- Median PFS was 11.1 months (95% CI, 8.7–13.6 months; Figure 3A)
  - Throughout the observation period, 79.5% of patients had progression
- Median OS was 27.5 months (95% CI, 22.4–32.4 months; Figure 3B)
  - Throughout the observation period, 31.3% of patients were alive, 41.6% had died of cancer-related causes, 25.3% had died of unspecified causes, and 1.8% died of causes unrelated to cancer

Figure 3. PFS and OS



OS, overall survival; PFS, progression-free survival.

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Conflicts of Interest

Dr. McGrane reports honoraria for advisory boards of Bristol Myers Squibb, Ferring, GlaxoSmithKline, Ipsen, Merck, and Roche; for speaking events at educational meetings from Astellas, Bayer, Bristol Myers Squibb, GlaxoSmithKline, Ipsen, Pfizer, and Roche; travel grants for conferences from Astellas, Bristol Myers Squibb, and GlaxoSmithKline. **Dr. Shaw** reports funding for travel by GlaxoSmithKline. **Dr. Anand** received honoraria from Tesaro/GlaxoSmithKline for advisory boards meetings; and for speaking at educational events by AstraZeneca, Clovis Oncology, and Tesaro/GlaxoSmithKline. **Dr. Madhuri** has nothing to disclose. **Dr. Krell** has acted in an advisory capacity to GlaxoSmithKline at advisory boards. **Dr. Saunders** is an employee of Open Health, which is being funded for their work in this project by GlaxoSmithKline. **Drs. Hawkes, Schilder, York, and Astrom** are employees of GlaxoSmithKline.

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