Poster 82P

Comparative Effectiveness of Nab-Paclitaxel and Paclitaxel in Patients with Platinum-Resistant Ovarian Cancer (COMPASS)

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CONCLUSIONS

- This real-world study of US patients with platinum-resistant ovarian cancer (PROC) showed that nab-paclitaxel had comparable effectiveness and a lower rate of neuropathy compared with paclitaxel monotherapy.
- Nab-paclitaxel is an effective treatment option for patients with PROC and is a valid comparator for clinical trials in PROC.

BACKGROUND

- PROC is defined as ovarian cancer with disease progression within 6 months of the last dose of platinum-based therapy.[1]
- Weekly paclitaxel is an efficacious therapy for patients with PROC, with a median progression-free survival (PFS) of 3.9–5.5 months and an objective response rate of 26–32%.[1–6]
- Nab-paclitaxel is an albumin-bound nanoparticle of paclitaxel and is associated with fewer hypersensitivity reactions and similar or better efficacy than paclitaxel in multiple tumor types.[7–11]
- Clinical trials of nab-paclitaxel monotherapy in PROC have shown a median overall survival (OS) of approximately 12 months.[12–14]
- However, there are no published randomized controlled trials or observational studies that compare the efficacy/effectiveness and safety of nab-paclitaxel with paclitaxel in patients with PROC.

Objective

- To compare the real-world effectiveness and safety of nab-paclitaxel monotherapy with paclitaxel monotherapy in US patients with PROC.

METHODS

Study Design and Data Source

- This was a retrospective cohort study using de-identified patient data acquired from the Flatiron Health Research Database (FHRD), a nationwide electronic health record (EHR)-derived US oncology database (**Figure 1**).[15]

Patient Population

- **Key inclusion criteria:**
  - International Classification of Diseases (ICD) code 9: 183x, 158x; ICD 10: C56x, C57.0x, C48x; ≥2 documented clinical visits, and diagnosis with invasive ovarian, fallopian tube, and/or primary peritoneal cancer.
  - Previously received a platinum-containing line of chemotherapy (carboplatin, cisplatin, or oxaliplatin).
  - Evidence of PROC: a real-world progression event after the start date of platinum + 14 days and <6 months after the last platinum drug episode in any line, or receipt of nab-paclitaxel or paclitaxel following a platinum-containing line of therapy deemed to be PROC by physician review.
  - Treatment with nab-paclitaxel or paclitaxel monotherapy in the PROC setting.
- **Key exclusion criteria:**
  - Mucinous, borderline, or clear cell histology.

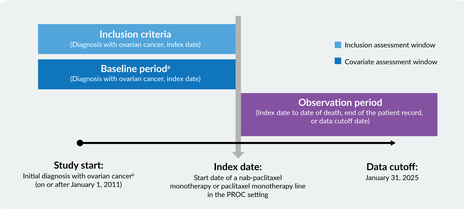
Statistical Analyses

- Descriptive statistics were used to summarize the baseline characteristics and outcomes of the study populations.
- Treatment groups were weighted by the inverse probability of treatment (IPTW), which allows for fairer comparisons by controlling for confounding bias.
- Time-to-event Kaplan–Meier analyses were used to estimate real-world OS and real-world PFS (rwPFS).
  - Log-rank tests were used to compare differences between treatment groups.
  - Cox proportional hazards models were used to determine the association of treatment choice with outcomes, adjusting for covariates.

Study Outcomes

- Real-world effectiveness endpoints included:
  - OS: time from index date to date of death; patients without a date of death were censored at their last confirmed EHR activity date.
  - rwPFS: time from index date to first progression or date of death; patients without an event were censored at the last clinic note date.
- Incidence rate and exposure-adjusted incidence rates of prespecified real-world adverse events (rwAEs).
  - Machine learning was used to extract rwAEs of interest from clinician documentation during treatment with nab-paclitaxel or paclitaxel.

Figure 1. Study Design



[a]Baseline period includes assessment of the following key covariates: ECOG performance status; biomarker testing and status; histology and stage (International Federation of Gynecology and Obstetrics [FIGO] and/or American Joint Committee on Cancer [AJCC] criteria); surgery and residual disease status. *Initial diagnosis with ovarian cancer could occur at any time between January 1, 2011 and the index date.

ECOG, Eastern Cooperative Oncology Group; **PROC**, platinum-resistant ovarian cancer.

RESULTS

Patient Selection

- Among 12,416 patients included in the Ovarian Cancer FHRD, 225 patients met the eligibility criteria and were included in the study (nab-paclitaxel monotherapy, n=67; paclitaxel monotherapy; n=158; **Table 1**). Baseline characteristics are shown in **Tables 2** and **3**.

Table 1. Patient Flow

Criteria	Nab-paclitaxel monotherapy, n	Paclitaxel monotherapy, n
Patients included in the February 2025 Ovarian Cancer FHRD	12,416	
Evidence of treatment with a platinum-containing line of therapy	7,675	
Evidence of PROC[a,b]	2,382	
Evidence of treatment with nab-paclitaxel or paclitaxel as mono- or combination therapy in PROC setting	141	648
Evidence of treatment with nab-paclitaxel or paclitaxel as monotherapy in PROC setting	70	164
Excluding patients with mucinous, borderline, or clear cell histology	67	158

[a]If a patient had multiple platinum-containing lines meeting the above criteria, the first platinum-containing line was chosen to define the time point at which the patient was considered platinum-resistant.
[b]Evidence of PROC: a real-world progression event after the start date of platinum + 14 days and <6 months after the last platinum drug episode in any platinum-containing line, or receipt of nab-paclitaxel or paclitaxel following a platinum-containing line of therapy deemed to be PROC by physician review.

FHRD, Flatiron Health Research Database; **PROC**, platinum-resistant ovarian cancer.

Baseline Demographic and Clinical Characteristics

Table 2. Baseline Demographic Characteristics

Characteristic	Nab-paclitaxel monotherapy (n=67)	Paclitaxel monotherapy (n=158)
Age at index date, years		
Median (IQR)	67 (59, 75)	69 (61, 75)
Race, n (%)		
White	48 (71.6)	124 (78.5)
Black/African American	5 (7.5)	11 (7.0)
Asian	2 (3.0)	0 (0)
Other/unknown	12 (17.9)	23 (14.6)
Ethnicity, n (%)		
Hispanic or Latino	5 (7.5)	6 (3.8)
Not Hispanic or Latino	48 (71.6)	135 (85.4)
Unknown	14 (20.9)	17 (10.8)
Practice type, n (%)		
Academic	9 (13.4)	59 (37.3)
Community	55 (82.1)	92 (58.2)
Both	3 (4.5)	7 (4.4)
Insurance status, n (%)		
Commercial health plan	47 (70.1)	106 (67.1)
Medicare	7 (10.4)	26 (16.5)
Uninsured/insurance not documented	10 (14.9)	15 (9.5)
Other	3 (4.5)	11 (7.0)

IQR, interquartile range; **SD**, standard deviation.

Table 3. Baseline Clinical Characteristics

Characteristic, n (%)	Nab-paclitaxel monotherapy (n=67)	Paclitaxel monotherapy (n=158)
Stage at diagnosis[a]		
I	0	3 (2)
II	2 (3)	9 (6)
III	30 (45)	89 (56)
IV	25 (37)	38 (24)
Unknown	10 (15)	19 (12)
Histology		
Serous	55 (82)	132 (84)
Non-serous		
Transitional cell	0	1 (1)
Endometrioid	2 (3)	4 (3)
Epithelial, not otherwise specified	9 (13)	17 (11)
Unknown/not documented	1 (2)	4 (3)
Baseline ECOG performance status		
0	15 (22)	36 (23)
1	22 (33)	63 (40)
≥2	10 (15)	38 (24)
Unknown	20 (30)	21 (13)
Lines of therapy prior to index		
1	7 (10)	19 (12)
2	14 (21)	36 (23)
3	13 (19)	40 (25)
≥4	33 (49)	63 (40)

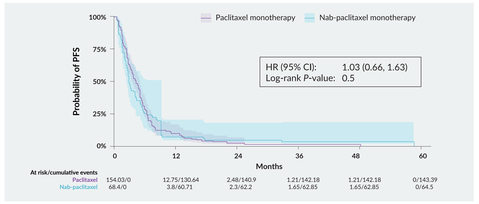
[a]Stage based on FIGO and/or AJCC criteria.

ECOG, Eastern Cooperative Oncology Group.

rwPFS

- Unadjusted and IPTW-adjusted rwPFS were comparable for nab-paclitaxel and paclitaxel monotherapy (**Figure 2**).
  - Unadjusted hazard ratio (HR), 1.11; 95% confidence interval (CI), 0.82, 1.49; log-rank *P*-value, 0.5.
- A sensitivity analysis using doubly-robust IPTW showed consistent results (HR, 1.06; 95% CI, 0.73, 1.56; log-rank *P*-value, 0.83).
- All progression events were based on clinician notes; 78% were also supported by radiographic evidence, and <20% by tumor marker evidence (e.g. CA-125).

Figure 2. IPTW-Adjusted rwPFS



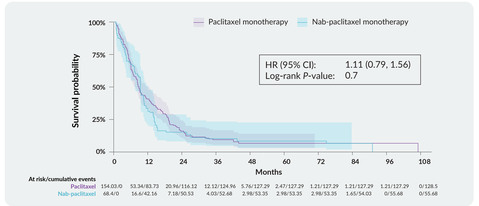
Covariates were selected if the *P*-value was <0.1 and missingness <25% and included baseline ECOG performance status, practice type, ethnicity, and time from platinum resistance to index date. In the sensitivity analysis using doubly-robust IPTW, ECOG (the only variable not balanced after IPTW) was included as a covariate in a multivariable Cox proportional hazards model.

CI, confidence interval; **HR**, hazard ratio; **IPTW**, inverse probability of treatment weighting; **rwPFS**, real-world progression-free survival.

OS

- Unadjusted and IPTW-adjusted OS were comparable for nab-paclitaxel and paclitaxel monotherapy (**Figure 3**).
  - Unadjusted HR, 0.95; 95% CI, 0.69, 1.3; log-rank *P*-value, 0.7.
- A sensitivity analysis using doubly-robust IPTW showed consistent results (HR, 1.07; 95% CI, 0.75, 1.51; log-rank *P*-value, 0.28).

Figure 3. IPTW-Adjusted OS



IPTW adjustment performed using the same covariates as for rwPFS.

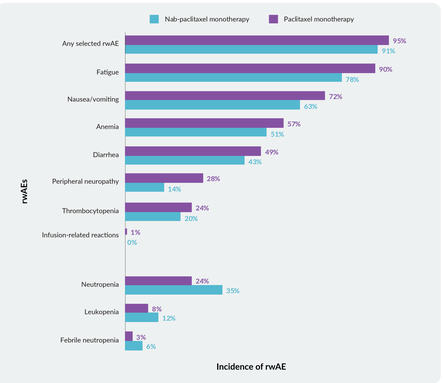
CI, confidence interval; **HR**, hazard ratio; **IPTW**, inverse probability of treatment weighting; **OS**, overall survival.

- The Kolmogorov-like test for proportional hazards assumptions confirmed that the assumption was not violated for either endpoint (rwPFS or OS).

Prespecified rwAEs

- Incidence rates of prespecified rwAEs were lower with nab-paclitaxel than paclitaxel, with the exception of neutropenia, leukopenia, and febrile neutropenia (**Figure 4**).
- The observed trends in the incidence of prespecified rwAEs persisted when adjusted for exposure (data not shown).
- Peripheral neuropathy was reported twice as frequently with paclitaxel than with nab-paclitaxel (28% vs 14%).

Figure 4. Overall Incidence of Prespecified rwAEs



Two patients treated with paclitaxel monotherapy and two patients treated with nab-paclitaxel monotherapy were excluded due to changes in taxane therapy.

rwAE, real-world adverse event.

DISCUSSION

- To our knowledge, this is the first study assessing the real-world effectiveness and safety of nab-paclitaxel vs paclitaxel in patients with PROC.
- rwPFS and OS were comparable for nab-paclitaxel and paclitaxel monotherapy across unadjusted and multiple adjusted analyses. However, EHR missingness and limited data may lead to residual confounding.
- The incidence rates of prespecified rwAEs were lower with nab-paclitaxel than paclitaxel, with the exception of neutropenia, leukopenia, and febrile neutropenia. Notably, peripheral neuropathy was reported twice as frequently with paclitaxel as with nab-paclitaxel. Lack of rwAE resolution data may overestimate event rates.

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Disclosures

Mark Shahin: disclosures in My ESMO. Robert Coleman: disclosures in My ESMO. Raina Mathur: current employment with Flatiron Health, which is an independent subsidiary of the Roche Group, and stock ownership in the Roche Group. Anju Parthan: disclosures in My ESMO. Prakirthi Yerram: current employment with Flatiron Health, which is an independent subsidiary of the Roche Group, and stock ownership in the Roche Group. Amanda Kesner-Hays: disclosures in My ESMO. Rachel Myers: current employment with Flatiron Health, which is an independent subsidiary of the Roche Group, and stock ownership in the Roche Group. Iulia Cristina Tudor: employee and stock ownership, Corcept Therapeutics, Incorporated. Darin Dobler: disclosures in My ESMO. Adrian M. Jubb: disclosures in My ESMO.

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