Real-World Comparative Effectiveness of Nab-Paclitaxel and Standard-of-Care Chemotherapies in Patients With Platinum-Resistant Ovarian Cancer (COMPASS 2.0)

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Poster 161P

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CONCLUSIONS

- This study assessed the real-world effectiveness and safety of nab-paclitaxel compared with the standard-of-care (SOC) therapies pegylated liposomal doxorubicin (PLD), topotecan, and gemcitabine in patients with platinum-resistant ovarian cancer (PROC)
- Nab-paclitaxel demonstrated favorable or similar real-world progression-free survival (rwPFS), overall survival (OS), and real-world adverse events (rwAEs) across unadjusted and adjusted analyses compared with PLD, topotecan, and gemcitabine
- Nab-paclitaxel is an effective PROC treatment option and a valid comparator for clinical trials

BACKGROUND

- PROC is defined as ovarian cancer with disease progression within 6 months of the last dose of platinum-based therapy[1]
- SOC therapies for PROC include paclitaxel, PLD, topotecan, and gemcitabine, as well as chemotherapy plus bevacizumab[2]
  - These SOC monotherapies exhibit broadly similar median PFS (2–5.7 months), objective response rate (ORR; 0–39.5%), and median OS (7.2–16.2 months) in clinical trials and retrospective analyses[3–15]
- Nab-paclitaxel is an albumin-bound nanoparticle of paclitaxel that is an efficacious therapy for patients with PROC, with a median PFS of 3.8–5.5 months, ORR of 23–35.8%, and median OS of 11.5–17.4 months[16–19]
  - Nab-paclitaxel is associated with fewer hypersensitivity reactions than paclitaxel[20]
- In a retrospective real-world study (COMPASS) of patients with PROC, nab-paclitaxel exhibited comparable effectiveness and lower incidence rates of prespecified rwAEs compared with paclitaxel[21]
- To our knowledge, this is the first study to assess the efficacy/effectiveness or safety of nab-paclitaxel vs PLD, topotecan, or gemcitabine in patients with PROC

Objective

- To compare the real-world effectiveness and safety of nab-paclitaxel vs PLD, topotecan, or gemcitabine in US patients with PROC

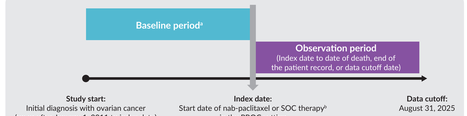
METHODS

- Methods used in this analysis were consistent with those reported in the previously published retrospective analysis evaluating nab-paclitaxel and paclitaxel monotherapies (COMPASS)[21]

Study Design and Data Source

- Retrospective cohort study using de-identified patient data from the Flatiron Health Research Database (FHRD), a US nationwide electronic health record (EHR)-derived oncology database (**Figure 1**)

Figure 1. Study Design



[a]Baseline period included assessment of key covariates. [b]PLD, topotecan, or gemcitabine.
PLD, pegylated liposomal doxorubicin; PROC, platinum-resistant ovarian cancer; SOC, standard of care.

METHODS Cont'd

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 non-maintenance platinum-containing line of therapy (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 platinum-containing line
  - Treatment with nab-paclitaxel, PLD, topotecan, or gemcitabine as a first-line (1L) or second-line (2L) therapy in the PROC setting
- **Key exclusion criteria**: mucinous, borderline, or clear cell histology

Study Outcomes

- rwPFS: time from index date (**Figure 1**) to first progression or date of death; patients without an event were censored at the last clinic note date
- OS: time from index date to date of death; patients without a date of death were censored at their last confirmed EHR activity date

Statistical Analysis

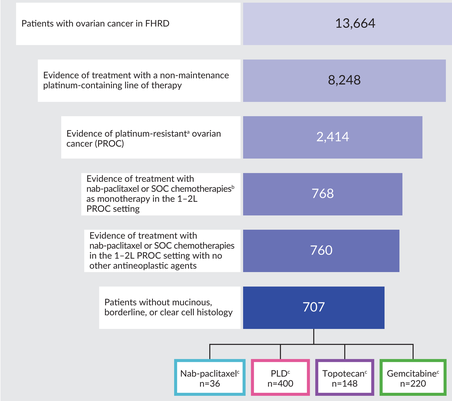
- Descriptive statistics to summarize baseline characteristics and outcomes
- Inverse probability of treatment weighting (IPTW) adjustment was used in treatment comparisons to minimize confounding bias due to the non-randomized nature of this study
- Log-rank tests to compare differences between treatment groups in rwPFS and OS
  - Cox proportional hazards models to determine the association of treatment choice with outcomes, adjusting for covariates

RESULTS

Patient Selection and Baseline Characteristics

- Of the 13,664 patients in the Ovarian Cancer FHRD, 707 patients met the eligibility criteria and were included in the study (**Figure 2**)
- Baseline patient demographic and clinical characteristics are shown in **Table 1**

Figure 2. Patient Flow



[a]The eligible time frame for real-world progression events to evaluate presence of platinum resistance was the start date of the platinum-containing line + 14 days (exclusive) up to 6 months after the last platinum episode within the line of therapy. If a patient initiated a line subsequent to the platinum-containing line earlier than 6 months from the last platinum dose, then the upper bound of the eligible time frame was truncated to the start date of the subsequent line + 14 days (inclusive).
[b]PLD, topotecan, or gemcitabine.
[c]n values are not unique patients; patients may have received more than one type of therapy and therefore could be included in more than one treatment group.
1–2L, first or second line; FHRD, Flatiron Health Research Database; PLD, pegylated liposomal doxorubicin; PROC, platinum-resistant ovarian cancer; SOC, standard of care.

RESULTS Cont'd

Table 1. Baseline Demographic and Clinical Characteristics

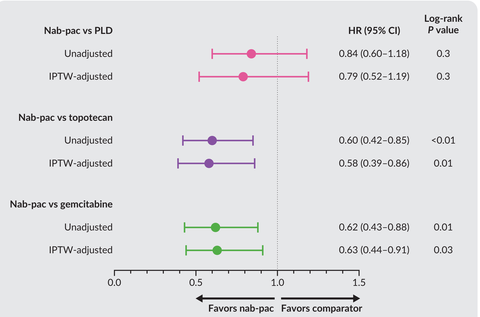
Characteristic	Nab-paclitaxel (n=36)	PLD (n=400)	Topotecan (n=148)	Gemcitabine (n=220)
Age at index date, years				
Median (IQR)	70.0 (60.5–76.5)	69.0 (60.0–76.5)	68.0 (60.0–75.0)	70.5 (61.0–78.0)
Race				
White	28 (77.8)	294 (73.5)	106 (71.6)	162 (73.6)
Black/African American	2 (5.6)	27 (6.8)	11 (7.4)	15 (6.8)
Asian	1 (2.8)	8 (2.0)	3 (2.0)	7 (3.2)
Other/Unknown	5 (13.9)	71 (17.8)	28 (18.9)	36 (16.4)
Ethnicity				
Hispanic or Latino	1 (2.8)	26 (6.5)	10 (6.8)	8 (3.6)
Not Hispanic or Latino	24 (66.7)	316 (79.0)	121 (81.8)	186 (84.5)
Unknown	11 (30.6)	58 (14.5)	17 (11.5)	26 (11.8)
Practice type				
Academic	3 (8.3)	78 (19.5)	23 (15.5)	58 (26.4)
Community	32 (88.9)	302 (75.5)	118 (79.7)	149 (67.7)
Both	1 (2.8)	20 (5.0)	7 (4.7)	13 (5.9)
SES index				
1 (lowest SES)	2 (5.6)	39 (9.8)	19 (12.8)	29 (13.2)
2–4	21 (58.3)	244 (61.0)	83 (56.1)	122 (55.5)
5 (highest SES)	9 (25.0)	86 (21.5)	30 (20.3)	55 (25.0)
Unknown	4 (11.1)	31 (7.8)	16 (10.8)	14 (6.4)
Insurance status				
Commercial health plan	23 (63.9)	278 (69.5)	105 (70.9)	144 (65.5)
Medicare	6 (16.7)	42 (10.5)	17 (11.5)	33 (15.0)
Uninsured/insurance not documented	6 (16.7)	54 (13.5)	15 (10.1)	29 (13.2)
Other[a]	1 (2.8)	26 (6.5)	11 (7.4)	14 (6.4)
Stage at diagnosis				
I	0 (0)	7 (1.8)	5 (3.4)	3 (1.4)
II	0 (0)	14 (3.5)	6 (4.1)	8 (3.6)
III	17 (47.2)	196 (49.0)	80 (54.1)	107 (48.6)
IV	12 (33.3)	120 (30.0)	46 (31.1)	70 (31.8)
Unknown	7 (19.4)	63 (15.8)	11 (7.4)	32 (14.5)
Histology				
Serous	28 (77.8)	319 (79.8)	126 (85.1)	167 (75.9)
Endometrioid	1 (2.8)	10 (2.5)	6 (4.1)	10 (4.5)
Epithelial, not otherwise specified	6 (16.7)	67 (16.8)	13 (8.8)	42 (19.1)
Unknown/not documented	1 (2.8)	4 (1.0)	3 (2.0)	1 (0.5)
ECOG performance status at index date				
0–1	20 (55.6)	256 (64.0)	94 (63.5)	125 (56.8)
≥2	5 (13.9)	64 (16.0)	26 (17.6)	49 (22.3)
Unknown	11 (30.6)	80 (20.0)	28 (18.9)	46 (20.9)
Lines of therapy in PROC setting at index				
1	16 (44.4)	294 (73.5)	76 (51.4)	103 (46.8)
2	20 (55.6)	106 (26.5)	72 (48.6)	117 (53.2)

[a]Includes Medicaid, other government program, patient assistance program, worker's compensation, other payer (type unknown), and self-pay.
Data are n (%) unless otherwise indicated.
ECOG, Eastern Cooperative Oncology Group; IQR, interquartile range; PLD, pegylated liposomal doxorubicin; PROC, platinum-resistant ovarian cancer; SES, Socioeconomic Status.

rwPFS

- Both the unadjusted and IPTW-adjusted hazard ratios (HRs) consistently favored nab-paclitaxel over topotecan and gemcitabine (**Figure 3**)
- The unadjusted and IPTW-adjusted HRs were comparable for nab-paclitaxel vs PLD

Figure 3. HR for Unadjusted and IPTW-Adjusted rwPFS

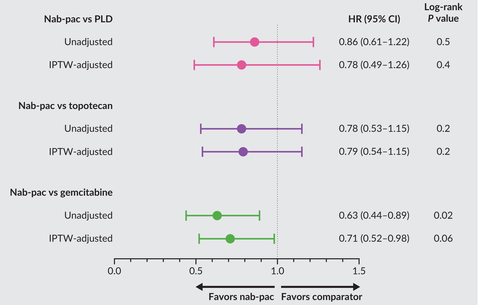


The covariates for the IPTW-adjusted analysis were selected if *P* was <0.1 and missingness was <25%. They included ethnicity for all comparators, number of prior lines in the PROC setting for PLD, year of index date for topotecan, and practice type for gemcitabine.
CI, confidence interval; HR, hazard ratio; IPTW, inverse probability of treatment weighting; Nab-pac, nab-paclitaxel; PLD, pegylated liposomal doxorubicin; rwPFS, real-world progression-free survival.

OS

- The IPTW-adjusted HR for nab-paclitaxel vs gemcitabine numerically favored nab-paclitaxel, and in the unadjusted analysis, nab-paclitaxel significantly improved OS compared with gemcitabine (**Figure 4**)
- The unadjusted and IPTW-adjusted HRs were comparable for nab-paclitaxel vs PLD and vs topotecan

Figure 4. HR for Unadjusted and IPTW-Adjusted OS



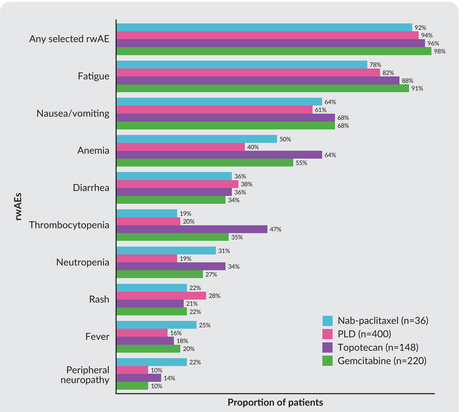
IPTW adjustment performed using the same covariates as for rwPFS.
CI, confidence interval; HR, hazard ratio; IPTW, inverse probability of treatment weighting; Nab-pac, nab-paclitaxel; OS, overall survival; PLD, pegylated liposomal doxorubicin; rwPFS, real-world progression-free survival.

- The Kolmogorov-like "supremum" test for proportional hazards assumptions confirmed that the assumption was not violated for either rwPFS or OS

rwAEs

- Several rwAEs were observed at a higher rate with comparator therapies than with nab-paclitaxel: rash was higher with PLD; fatigue, thrombocytopenia, and anemia were higher with topotecan and with gemcitabine (**Figure 5**)
- Peripheral neuropathy and fever were seen at higher rates with nab-paclitaxel compared with the comparator therapies

Figure 5. rwAEs[a] of Incidence ≥20% in Any Treatment Group



[a]Prespecified rwAEs for this study were anemia, diarrhea, fatigue, febrile neutropenia, fever, hand/foot syndrome, infusion-related reaction, leukopenia, nausea/vomiting, neutropenia, peripheral edema, peripheral neuropathy, rash, stomatitis, and thrombocytopenia.
PLD, pegylated liposomal doxorubicin; 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 SOC therapies in PROC
- Nab-paclitaxel was associated with numerically and, in some comparisons, significantly longer rwPFS and OS vs PLD, topotecan, and gemcitabine across unadjusted and IPTW-adjusted analyses. However, EHR missingness and limited data may lead to residual confounding
- The incidence rates of prespecified rwAEs were similar to or lower for nab-paclitaxel than for PLD, topotecan, and gemcitabine; however, the nab-paclitaxel group was smaller than the comparator groups, which limits interpretation

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