HSD10

Real-World Characteristics and Treatment Patterns of Patients Treated with Talazoparib + Enzalutamide for Metastatic Castration-Resistant Prostate Cancer in the US Community Oncology Setting

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Objective

To examine the real-world patient characteristics, HRRm testing and treatment patterns of T+E for mCRPC in the US community oncology setting.

Conclusions

This study provides early evidence describing real-world patient characteristics and use of T+E for mCRPC in the community oncology setting.

The most common HRRm were BRCA2, CDK12 and ATM and most patients had high-volume disease and prior treatment with ARPi.

This study will inform future real-world effectiveness analyses of T+E for mCRPC with HRRm and complement clinical trial data with subgroups that were previously underrepresented.

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References: 1. Heiss BL, et al. *J Clin Oncol*. 2024;42(15):1851-1860. **2.** The US Oncology Network. https://usoncology.com/our-company/. Accessed April 13, 2026. **3.** Agarwal N, et al. *Future Oncol*. 2023;20(9):493-505.

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Background

- Talazoparib plus enzalutamide (T+E) was FDA-approved in June 2023 as treatment for metastatic castration-resistant prostate cancer (mCRPC) harboring alterations in the homologous recombination repair pathway (HRRm).[1]
- There is limited data characterizing real world treatment patterns of T+E, including HRRm testing, and treatment sequencing.

Materials and Methods

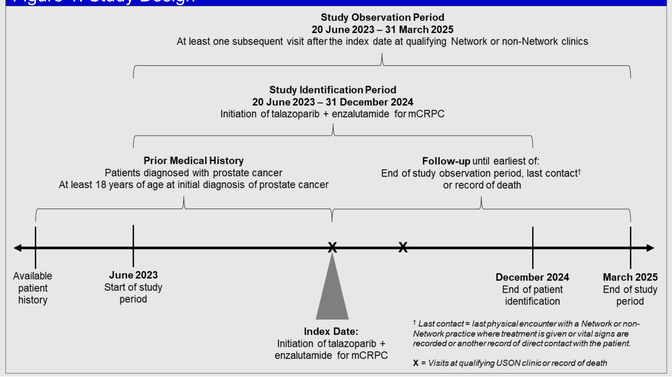
STUDY DESIGN

- This was a retrospective observational cohort study of patients initiating T+E for mCRPC (index) between 6/20/2023 – 12/31/2024 in The US Oncology Network or non-Network practices. (**Figure 1**).

DATA SOURCES

- Data were sourced from structured fields of The US Oncology Network's iKnowMed (iKM) electronic health record (EHR) supplemented with chart abstraction.
- The US Oncology Network includes over 3,200 providers in over 700 sites of care across the US, and ~50 non-Network clinics have adopted the iKM EHR and participate in real-world research activities with Ontada.[2]

Figure 1. Study Design



VARIABLE DEFINITIONS

- Baseline characteristics within 60 days pre-index, HRRm results and prostate cancer treatment history through the end of follow-up (3/31/2025) were described overall and stratified by receipt of prior androgen receptor pathway inhibitor(s) (ARPi) and/or prior docetaxel.
- Somatic and/or germline testing results for a multigene panel of 12 genes directly or indirectly involved in HRR (ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, RAD51C) were recorded from all available records.
- High volume disease was defined as ≥4 bone metastases, ≥1 bone metastases outside of the pelvis and vertebral column, or visceral metastases, and/or explicit documentation within the charts.[3]

Results

PATIENT CHARACTERISTICS

- Overall, 52 patients were included with median (IQR) age of 73 (65-80) years and median (IQR) 8 (5-12) months follow-up (**Table 1**).
- Among patients with available data at baseline, the median (IQR) PSA was 11.9 (4.8-53.4) ng/mL, most patients had ECOG 0-1 (89% of n=36), Gleason ≥8 (79% of n=34) and had high-volume disease (77% of n=52), and there were 10 (23% of n=44) patients with Black or African American race (**Table 1**).
- High-volume disease was documented in 37 (84% of n=44) patients with prior ARPi (**Table 1**).

Table 1. Demographic and Clinical Characteristics

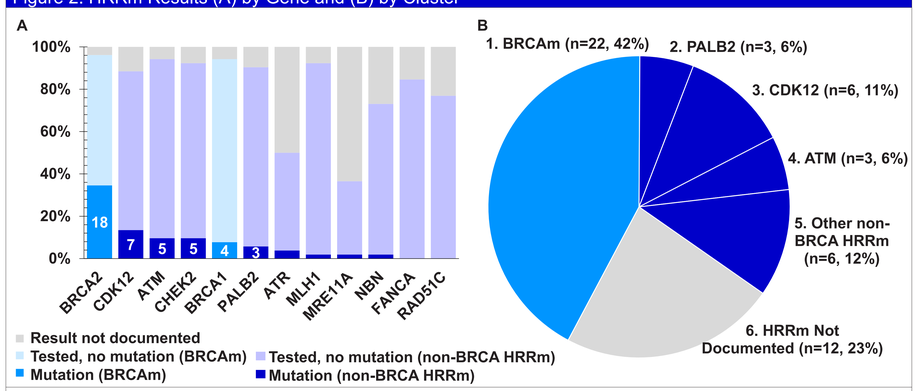
Variable	Total N=52	Prior ARPi and prior docetaxel (N = 28)	Prior ARPi, no prior docetaxel (N = 16)	No prior ARPi[a] (N = 8)
Median (IQR) age at Index	72.5 (65.0-80.3)	71.0 (65.8, 76.2)	80.0 (66.5, 86.3)	74.5 (64.0-80.3)
Race, n (%)				
White	27 (52%)	12 (43%)	10 (62.5%)	5 (63%)
Black or African American	10 (19%)	6 (21%)	<3	<3
Other Race	7 (13%)	4 (14%)	3 (18.8%)	<3
Not documented	8 (15%)	6 (21%)	<3	<3
Ethnicity, n (%)				
Hispanic or Latino	4 (8%)	3 (11%)	<3	<3
Not Hispanic or Latino	40 (77%)	20 (71%)	13 (81.2%)	7 (88%)
Not documented	8 (15%)	5 (18%)	<3	<3
Practice Region, n (%)				
West	23 (44%)	12 (43%)	7 (43.8%)	4 (50%)
Midwest	14 (27%)	8 (29%)	4 (25.0%)	<3
South	14 (27%)	7 (25%)	5 (31.2%)	<3
Northeast	<3	<3	<3	<3
Practice Rurality, n (%)				
Urban	46 (88%)	27 (96%)	13 (81.2%)	6 (75%)
Rural	6 (12%)	<3	3 (18.8%)	<3
Disease Stage at Initial Diagnosis (if available), or at Oncologist Referral, n (%)				
Stage II-III	5 (10%)	3 (11%)	<3	<3
Stage IVA	8 (15%)	6 (21%)	<3	<3
Stage IVB or IV NOS	24 (46%)	12 (43%)	10 (62.5%)	<3
Not documented	14 (27%)	7 (25%)	4 (25.0%)	3 (38%)
High-Volume Disease at Index, n (%)	40 (77%)	24 (86%)	13 (81.2%)	3 (38%)
Gleason Score at Baseline, n (%)				
N with available data	34	21	10	3
<8	7 (21%)	3 (14%)	3 (30.0%)	<3
≥8	27 (80%)	18 (86%)	7 (70.0%)	<3
ECOG Performance Status within 60 Days Prior to Index, n (%)				
N with available data	36	23	9	4
0	8 (22%)	3 (13%)	4 (44.4%)	<3
1	24 (67%)	18 (78%)	3 (33.3%)	3 (75%)
2	4 (11%)	<3	<3	<3
Median (IQR) PSA at Baseline, ng/mL	11.9 (4.8, 53.8)	12.5 (5.0-34.1)	14.6 (4.3-83.2)	7.6 (6.1-31.8)

[a]Includes patients with prior docetaxel but no prior ARPi, neither docetaxel/ARPi, or no prior systemic therapy.

HRRm TESTING & RESULTS

- Documentation of HRRm testing was available in 50 (96.2%) patients, including testing for both BRCA and non-BRCA genes in 49 (94.2%) patients.
- Both germline and somatic HRRm testing was observed in 33 (63.5%) patients, whereas 17 (32.7%) patients only had documentation of somatic HRRm testing.
- HRRm were documented in 40 (77%) patients and the most common HRRm were BRCA2 (n=18), CDK12 (n=7), ATM and CHEK2 (n=5, each) (**Figure 2**).

Figure 2. HRRm Results (A) by Gene and (B) by Cluster



Note: Patients may have ≥1 mutation in Figure 2A but are assigned to one cluster in Figure 2B based on the order presented.

TREATMENT PATTERNS

- Prior to T+E, 44 (85%) patients had prior treatment with ARPi, of which 28 (54%) patients had received ARPi+docetaxel.
  - Of the 44 patients with prior ARPi, 75% (n=33) initiated ARPi in the metastatic or non-metastatic CSPC setting, whereas 25% (n=11) initiated ARPi in the mCRPC setting.
- The median (IQR) time from provider documentation of mCRPC to initiation of T+E was 10.1 (4.5-35.0) months among patients with prior ARPi and docetaxel, 3.3 (0.6-8.3) months in patients with prior ARPi only, and 1.6 (0.8-4.0) months in patients without prior ARPi.
- T+E was initiated as the 1st, 2nd, and 3rd or later regimen for mCRPC in 30 (57%), 8 (15%) and 14 (27%) patients, respectively.

Limitations

- Given the relatively recent approval of T+E, the available sample size and follow-up durations were limited.
- Some variables of interest were not complete which may have introduced misclassification bias.
- Treatment regimens were assigned based on orders rather than confirmed receipt and/or adherence.

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