Real-World Treatment Patterns in Patients with *BRCA*1/2-Positive Metastatic Castration-Resistant Prostate Cancer Initiating First-Line Therapy

Mehmet A. Bilen[1], Ibrahim Khilfeh[2], Kevin H. Li[2], Carmine Rossi[3], Erik Muser[2], Laura Morrison[3], Annalise Hilts[3], Lilian Diaz[3], Patrick Lefebvre[3], Dominic Pilon[3], Daniel J. George[4]

[1]Emory University School of Medicine, Atlanta, GA, USA; [2]Janssen Pharmaceuticals, Horsham, PA, USA; [3]Analysis Group, Inc., Montréal, QC, Canada; [4]Duke University Cancer Center, Durham, NC, USA

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KEY TAKEAWAY

In this real-world study, ADT monotherapy, enzalutamide, olaparib, abiraterone acetate, and docetaxel were the most used medications in 1L for patients with *BRCA*-positive mCRPC

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CONCLUSIONS

- Most patients who received ADT monotherapy in 1L died, while most patients receiving an advanced treatment, notably chemotherapy, progressed quickly to 2L suggesting an unmet treatment need for patients with *BRCA*-positive mCRPC
- For patients with *BRCA*-positive mCRPC, PARP inhibitor use was most prevalent in 1L, among whom most used abiraterone acetate or an androgen receptor inhibitor immediately prior as well as chemotherapy in 2L

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BACKGROUND

- Among patients with prostate cancer (PC), many with advanced metastatic disease develop resistance to androgen deprivation therapy (ADT), resulting in metastatic castration-resistant prostate cancer (mCRPC)[1-3]
- Molecular heterogeneity is a notable challenge in the treatment of mCRPC; patients who harbor alterations in homologous recombination repair (HRR) genes, particularly *BRCA1* or *BRCA2* (hereafter "*BRCA*-positive") have poorer disease prognosis[4,5]
- New targeted medications such as poly ADP-ribose polymerase (PARP) inhibitors have been proven to be effective in the treatment of *BRCA*-positive mCRPC[6,7]
- Despite these advances, real-world data on medication use and treatment patterns among patients with *BRCA*-positive mCRPC initiating first-line (1L) therapy in the United States (US) is lacking

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OBJECTIVE

- This study aimed to describe real-world treatment patterns and outcomes among treated patients with *BRCA*-positive mCRPC in a US clinical practice setting

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METHODS (1 of 4)

Data source

- Electronic medical record (EMR) data from the Flatiron-Foundation Medicine, Inc. (FMI) Metastatic PC Clinico-Genomic Database (CGDB) were used (study period: 1 January 2011 to 30 June 2022)
- Data were de-identified and Health Insurance Portability and Accountability Act (HIPAA) compliant
- Flatiron Health, Inc. and FMI did not participate in data analyses

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METHODS (2 of 4)

Study design

- A retrospective longitudinal cohort study design was used
- Patients with mCRPC treated in 1L were selected among those initiating an oncologist-defined advanced line of therapy (LOT; i.e., androgen receptor signaling inhibitors, chemotherapies, estrogens, immunotherapies, PARP inhibitors, and radiopharmaceuticals) on or after 1 January 2019, or who were treated with ADT monotherapy at the time of mCRPC diagnosis
  - For patients with an advanced LOT in 1L, the index date was defined as the start date of the first LOT on or after the date of mCRPC diagnosis
  - For patients with ADT monotherapy in 1L, the index date was defined as the date of mCRPC diagnosis, with all patients having overlapping span of ADT use on the index date
- Baseline patient characteristics were evaluated in the 12 months preceding the index date
- Treatment sequences were assessed during the observation period which spanned from the index date until the end of clinical activity or data availability (i.e., 30 June 2022)
- Patients treated with an oncologist-defined advanced LOT were classified as *BRCA*-positive based on testing results observed prior to or on the index date
- Patients treated with ADT monotherapy were classified as *BRCA*-positive based on testing results observed at any time (i.e., prior to or after the index date)

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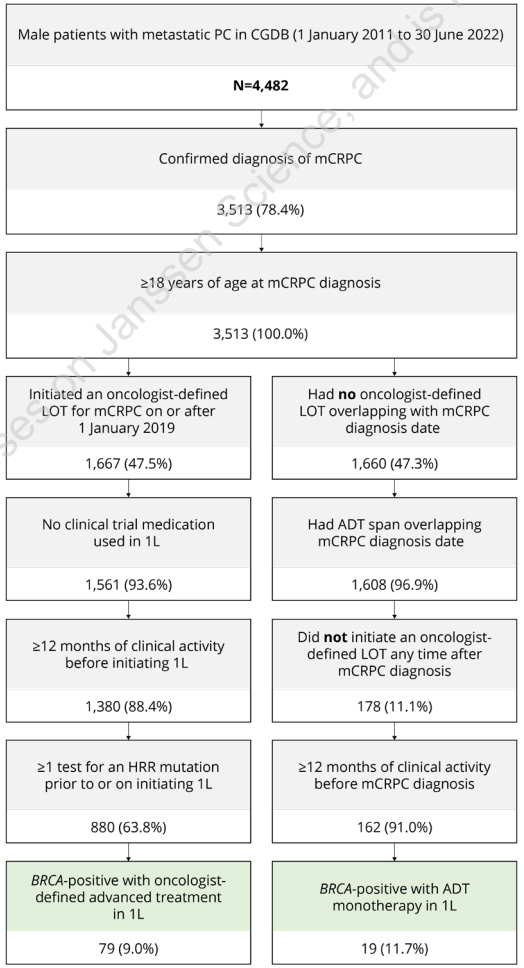
Patient selection criteria

FIGURE 1: Selection of the 1L mCRPC study population

- The inclusion and exclusion criteria used to select patients with mCRPC initiating 1L therapy are shown in **Figure 1**



1L: first-line; ADT: androgen deprivation therapy; CGDB: Clinico-Genomic Database; HRR: homologous recombination repair; LOT: line of therapy; mCRPC: metastatic castration-resistant prostate cancer; PC: prostate cancer.

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METHODS (4 of 4)

Study outcomes

- Treatment sequences from 1L to third-line (3L), if observed, were assessed
  - Reasons for censoring (i.e., initiation of a clinical trial drug, death, loss to follow-up, and end of data availability) before starting a subsequent LOT were also assessed
- For the subgroup of patients treated with an oncologist-defined advanced LOT in 1L, time-to-next treatment (TTNT) was defined as the time from 1L initiation (index date) to the start of second-line (2L) therapy, including the use of a clinical trial drug

Statistical analysis

- Kaplan-Meier (KM) analysis was used to assess the proportion of patients initiating a subsequent LOT up to 12-months post-index
- TTNT analysis was censored at the earliest of i) end of clinical activity (including death), or ii) the end of data availability

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Baseline characteristics

TABLE 1: Baseline demographic and clinical characteristics

- Overall, 98 *BRCA*-positive patients with mCRPC initiating 1L were analyzed, of which 79 were treated with an advanced LOT in 1L and 19 were treated with ADT monotherapy (**Figure 1**)
- Among the ADT monotherapy subgroup, a greater proportion of Black patients (26.3%) and a lower proportion of patients treated in a community-based practice (57.9%) were observed than in the advanced LOT subgroup (**Table 1**)
- In addition, a greater proportion of patients using ADT monotherapy were diagnosed in the localized setting (68.4%) and had Gleason score ≤7 (31.6%)

	By 1L therapy subgroup		
	Overall 1L *BRCA*-positive treated cohort N=98	Advanced LOT n=79	ADT monotherapy n=19
Age, years, mean ± SD [median]	**72 ± 9 [74]**	**73 ± 8 [74]**	**70 ± 10 [69]**
Race, n (%)			
White	57 (58.2)	47 (59.5)	10 (52.6)
Black	15 (15.3)	10 (12.7)	5 (26.3)
Asian	3 (3.1)	2 (2.5)	1 (5.3)
Other	14 (14.3)	13 (16.5)	1 (5.3)
Unknown	9 (9.2)	7 (8.9)	2 (10.5)
Insurance plan type, n (%)			
Medicare	54 (55.1)	45 (57.0)	9 (47.4)
Commercial	27 (27.6)	23 (29.1)	4 (21.1)
Dual coverage	4 (4.1)	3 (3.8)	1 (5.3)
Medicaid	1 (1.0)	1 (1.3)	0 (0.0)
Unknown	12 (12.2)	7 (8.9)	5 (26.3)
Practice type, n (%)			
Community only	68 (69.4)	57 (72.2)	11 (57.9)
Academic only	21 (21.4)	13 (16.5)	8 (42.1)
Academic and community	9 (9.2)	9 (11.4)	0 (0.0)
Disease stage at initial PC diagnosis, n (%)			
Localized PC	58 (59.2)	45 (57.0)	13 (68.4)
mCSPC	40 (40.8)	34 (43.0)	6 (31.6)
Prior evidence of ADT use[1], n (%)	**97 (99.0)**	**78 (98.7)**	**19 (100.0)**
Time from mCRPC diagnosis to initiation of advanced LOT[2], days, mean ± SD [median]	-	**225 ± 446 [42]**	-
Year of mCRPC diagnosis, n (%)			
2017 or prior	12 (12.2)	6 (7.6)	6 (31.6)
2018	10 (10.2)	7 (8.9)	3 (15.8)
2019	25 (25.5)	21 (26.6)	4 (21.1)
2020	21 (21.4)	19 (24.1)	2 (10.5)
2021	22 (22.4)	19 (24.1)	3 (15.8)
2022	8 (8.2)	7 (8.9)	1 (5.3)
Type of mutation[3], n (%)			
Germline	21 (21.4)	19 (24.1)	2 (10.5)
Somatic	18 (18.3)	14 (17.7)	4 (21.1)
Unknown	44 (44.9)	36 (45.6)	8 (42.1)
Missing	40 (40.8)	32 (40.5)	8 (42.1)
Most recent ECOG performance score, n (%)			
0	29 (29.6)	27 (34.2)	2 (10.5)
1	32 (32.7)	29 (36.7)	3 (15.8)
2	4 (4.1)	4 (5.1)	0 (0.0)
Not available	33 (33.7)	19 (24.1)	14 (73.7)
Gleason score at initial PC diagnosis, n (%)			
≤6	5 (5.1)	3 (3.8)	2 (10.5)
7	11 (11.2)	7 (8.9)	4 (21.1)
8	23 (23.5)	16 (20.3)	7 (36.8)
9	27 (27.6)	24 (30.4)	3 (15.8)
10	13 (13.3)	13 (16.5)	0 (0.0)
Not available	19 (19.4)	16 (20.3)	3 (15.8)
Pre-index treatment use[4], n (%)			
First-generation anti-androgens	57 (58.2)	44 (55.7)	13 (68.4)
Abiraterone acetate	50 (51.0)	47 (59.5)	3 (15.8)
Localized PC therapy	49 (50.0)	37 (46.8)	12 (63.2)
Next-generation androgen receptor inhibitors	49 (50.0)	46 (58.2)	3 (15.8)
Bone antiresorptive therapy	27 (27.6)	25 (31.6)	2 (10.5)
Chemotherapy	14 (14.3)	14 (17.7)	0 (0.0)

1L: first-line; ADT: androgen deprivation therapy; ECOG: Eastern Cooperative Oncology Group; HRR: homologous recombination repair; LOT: line of therapy; mCSPC: metastatic castration-sensitive prostate cancer; mCRPC: metastatic castration-resistant prostate cancer; PC: prostate cancer.

Notes:

1. Prior evidence of ADT use was defined as any ADT at any time prior to (and excluding) the index date.
2. Time from mCRPC diagnosis to advanced LOT and year of advanced LOT initiation were only reported among patients with an oncologist-defined LOT.
3. Mutation types were not mutually exclusive as patients could have multiple mutations tests or ≥2 different mutations.
4. Treatments received were reported any time in the period of clinical activity prior to the index date.

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Treatment sequences

- Treatment sequences for *BRCA*-positive patients are shown in **Figure 2**
  - Among those treated with an advanced LOT in 1L, 43.0% (n=34) did not initiate 2L, of which 35.3% were lost to follow-up, 29.4% died, 29.4% were censored at the end of data, and 5.9% initiated a clinical trial drug
  - Among patients treated with ADT monotherapy, 52.6% died, 26.3% were lost to follow-up, and 21.1% were censored at the end of data
- Among those who initiated 2L (n=45), the most used therapies were docetaxel (22.2%), olaparib (20.0%), abiraterone acetate (13.3%), and enzalutamide (11.1%)
- In patients receiving 2L, 51.1% (n=23) did not initiate 3L, of which 34.8% died, 34.8% were lost to follow-up, 26.1% were censored at the end of data, and 4.3% initiated a clinical trial drug
- Among patients who used an androgen receptor inhibitor (i.e., apalutamide, enzalutamide, or darolutamide; n=23) immediately prior to 1L mCRPC, most initiated abiraterone acetate in 1L mCRPC (26.1%; **Figure 3**)
- Among patients who used abiraterone acetate (n=23) immediately prior to 1L mCRPC, most initiated olaparib in 1L mCRPC (34.8%)

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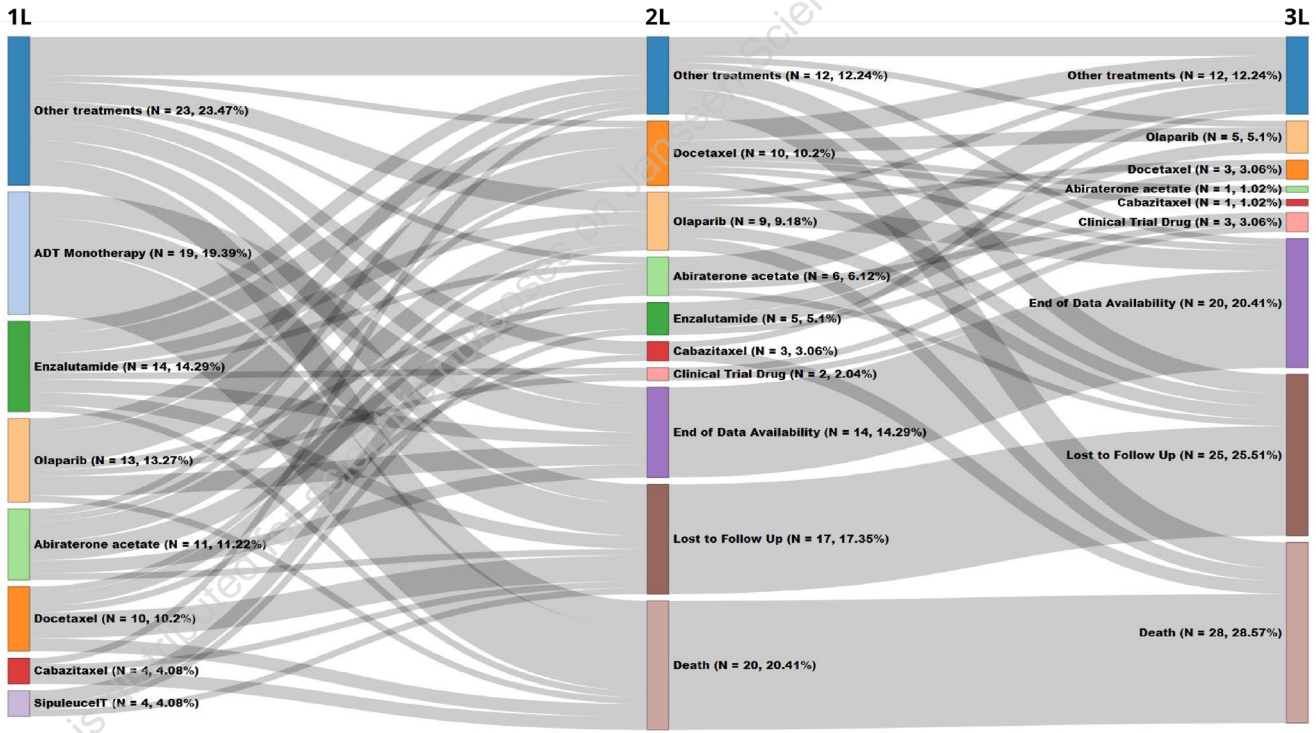
FIGURE 2: Treatment sequences among patients with *BRCA*-positive mCRPC initiating 1L therapy[1]



1L: first-line; 2L: second-line; 3L: third-line; ADT: androgen deprivation therapy; mCRPC: metastatic castration-resistant prostate cancer.

Note:

1. Other treatments were defined as treatments that were not among the top 7 most frequently used treatments. These include the following treatments, used either as monotherapy or in combination therapy: apalutamide, carboplatin, pembrolizumab, atezolizumab, etoposide, cyclophsophamide, darolutamide, doxorubicin, radium-223, fluorouracil, leucovorin, oxaliplatin, niraparib, and rucaparib.

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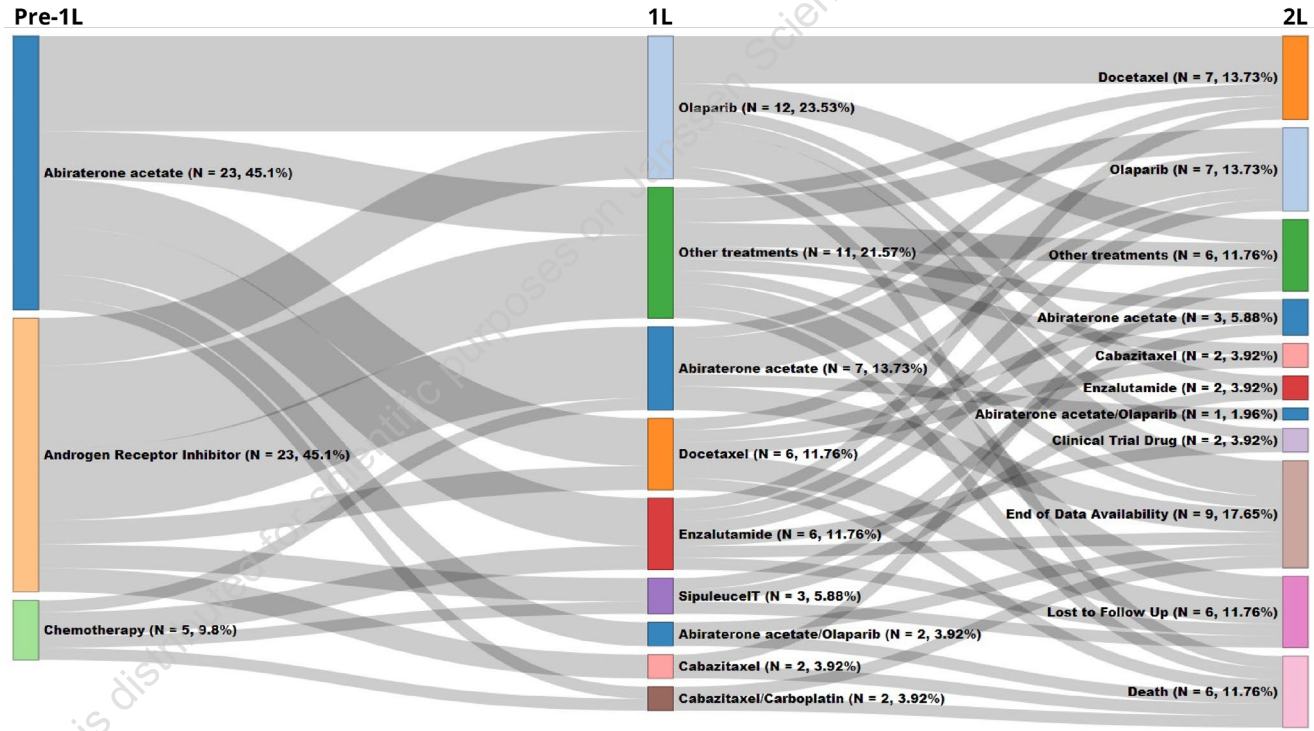
FIGURE 3: Treatment sequences among *BRCA*-positive patients by immediate prior treatment before mCRPC[1,2]



1L: first-line; 2L: second-line; mCRPC: metastatic castration-resistant prostate cancer.

Notes:

1. Treatment sequences were reported among patients with use of abiraterone acetate, androgen receptor inhibitor (i.e., apalutamide, darolutamide, enzalutamide), or chemotherapy immediately prior to the 1L start date.
2. "Other treatments" were defined as those that were used by less than 2 patients in 1L, or not used in 1L, and include: apalutamide/sipuleucel-T, niraparib, enzalutamide/sipuleucel-T, abiraterone acetate/olaparib/sipuleucel-T, carboplatin, fluorouracil/leucovorin/oxaliplatin, abiraterone acetate/sipuleucel-T, apalutamide, carboplatin/etoposide, pembrolizumab, enzalutamide/radium-223, paclitaxel, olaparib/radium-223, fluorouracil/leucovorin/oxaliplatin/trastuzumab, topotecan, carboplatin/docetaxel.

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Time-to-next treatment

- Among patients initiating an advanced LOT in 1L, the median TTNT (i.e., 2L) was 6.2 months (**Figure 4**)
- At 12 months, rates of 2L initiation were greater among patients who used an androgen receptor inhibitor immediately prior to 1L mCRPC

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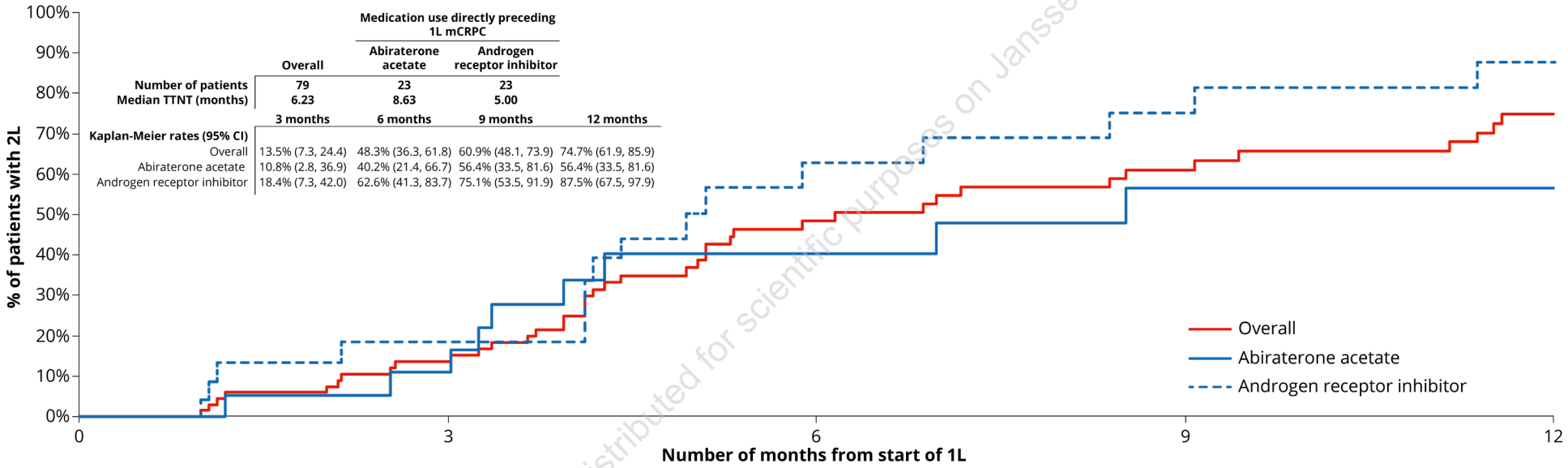
FIGURE 4: Time-to-next-treatment among patients initiating advanced LOT in 1L by immediate prior treatment before mCRPC[1,2,3]

	Overall	Medication use directly preceding 1L mCRPC: Abiraterone acetate	Medication use directly preceding 1L mCRPC: Androgen receptor inhibitor
Number of patients	79	23	23
Median TTNT (months)	6.23	8.63	5.00
	3 months	6 months	9 months	12 months
Kaplan-Meier rates (95% CI)				
Overall	13.5% (7.3, 24.4)	48.3% (36.3, 61.8)	60.9% (48.1, 73.9)	74.7% (61.9, 85.9)
Abiraterone acetate	10.8% (2.8, 36.9)	40.2% (21.4, 66.7)	56.4% (33.5, 81.6)	56.4% (33.5, 81.6)
Androgen receptor inhibitor	18.4% (7.3, 42.0)	62.6% (41.3, 83.7)	75.1% (53.5, 91.9)	87.5% (67.5, 97.9)



1L: first-line; 2L: second-line; CI: confidence interval; LOT: line of therapy; mCRPC: metastatic castration-resistant prostate cancer; TTNT: time-to-next-treatment.

Notes:

1. Patients with prior use of androgen receptor inhibitors included apalutamide, enzalutamide, or darolutamide.
2. TTNT was defined as the time from 1L start date to 2L start date (including clinical trial medications), if observed.
3. TTNT was censored at the earliest of i) the end of clinical activity (including death), or ii) the end of data availability.

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Real-World Treatment Patterns in Patients with *BRCA*1/2-Positive Metastatic Castration-Resistant Prostate Cancer Initiating First-Line Therapy

Mehmet A. Bilen, Ibrahim Khilfeh, Kevin H. Li, Carmine Rossi, Erik Muser, Laura Morrison, Annalise Hilts, Lilian Diaz, Patrick Lefebvre, Dominic Pilon, Daniel J. George

LIMITATIONS

The EMR database used for this study may contain inaccuracies or omissions (e.g., diagnosis dates, treatment start dates), but these are expected to be random and affect all patients equally. Diagnoses or medical services obtained outside of the Flatiron oncology network will not be captured. The patients captured in the Flatiron database may not be representative of patients with mCRPC in the US in general, thus limiting the generalizability of the study.

Presented at American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU); January 25-27, 2024; San Francisco, CA and online.

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