Real-World Survival of Patients with Metastatic Castration-Sensitive Prostate Cancer Initiated on Apalutamide or Enzalutamide in an Oncology Database: ROME Study

Mehmet A. Bilen[1], Shawn Du[2], Ibrahim Khilfeh[2], Carmine Rossi[3], Jill Korsiak[3], Alvi Rahman[3], Patrick Lefebvre[2], Dominic Pilon[3], Neal D. Shore[4]

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KEY TAKEAWAY

- In this real-world descriptive analysis of patients with mCSPC, survival rates of patients treated with apalutamide were comparable to those observed in the Phase III TITAN trial (TITAN 24-month survival: 83.3%)[3]

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CONCLUSIONS

- This study found that more patients initiating apalutamide survived by 24 months post-index than those initiating enzalutamide
- These results may be used by clinicians to help inform treatment selection for patients with mCSPC[6]

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BACKGROUND

- Current guidelines recommend the use of androgen receptor signaling inhibitors (ARSIs) in combination with androgen deprivation therapy (ADT) for the treatment of metastatic castration-sensitive prostate cancer (mCSPC)[1]
- ARSIs, including apalutamide and enzalutamide, have demonstrated progression-free and overall survival benefits for patients with mCSPC in the clinical trial setting[2-5], but data evaluating real-world treatment effectiveness remains limited

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OBJECTIVES

- To describe real-world survival among patients with mCSPC who initiated apalutamide or enzalutamide in an oncology setting in the United States (US)

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METHODS (1 of 4)

Data source

- Electronic health record (EHR) data from the Flatiron Metastatic Prostate Cancer (PC) Core Registry were used (study period: 1 January 2013 – 31 May 2023)
- Flatiron Health, Inc. did not participate in data analyses
- Data were de-identified and complied with the patient requirements of the Health Insurance Portability and Accountability Act

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METHODS (2 of 4)

Study design

- A retrospective, longitudinal cohort study of patients with mCSPC initiated on apalutamide or enzalutamide was conducted
- Patients were assigned to mutually exclusive treatment cohorts based on the first oncologist-defined drug episode that included apalutamide or enzalutamide on or after 16 December 2019 (the US Food and Drug Administration approval for enzalutamide in mCSPC), with the start date of the drug episode defined as the index date
- Baseline patient characteristics were evaluated in the 12 months preceding the index date
- The observation period spanned from the index date to the earliest of 24 months post-index, end of clinical activity, or end of data availability
- Concurrent use of ADT, defined as a record for any ADT agent from 180 days prior to the index date to the end of the index ARSI drug episode, was not required for inclusion in the study

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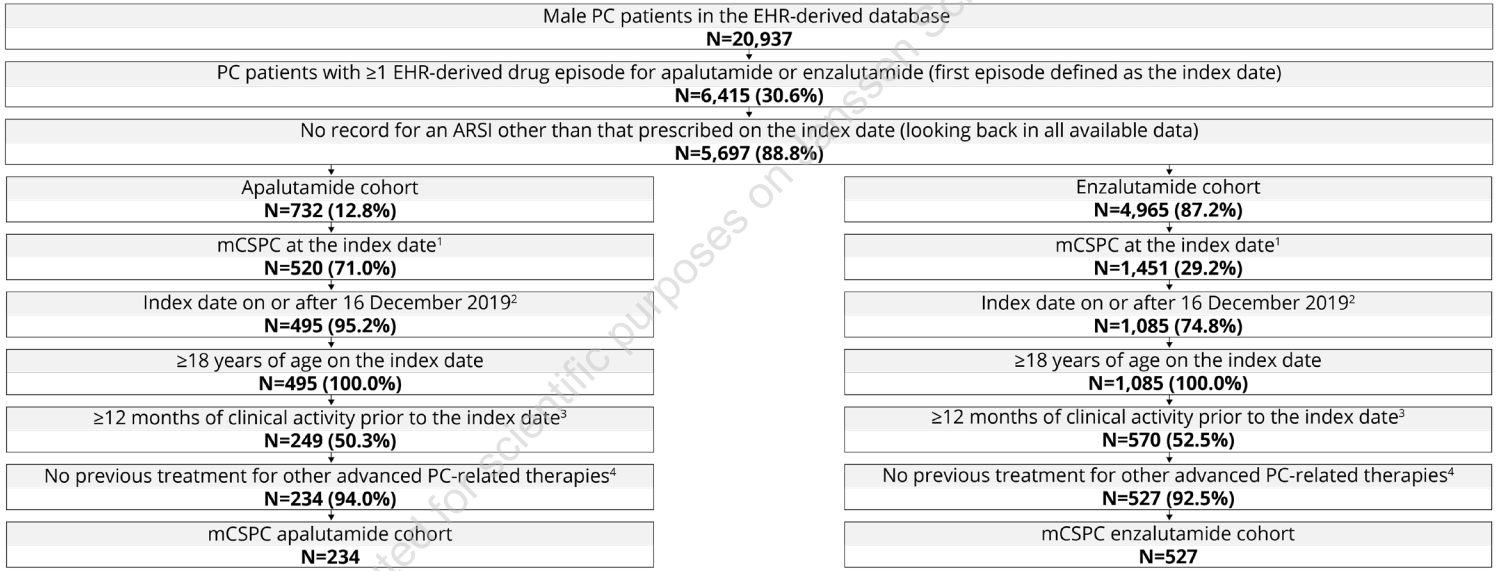
Patient selection criteria

FIGURE 1: Patient identification flowchart



ARSI: androgen receptor signaling inhibitor; EHR: electronic health record; FDA: Food and Drug Administration; PC: prostate cancer; PSA: prostate specific antigen; mCSPC: metastatic castration-sensitive prostate cancer.

Notes:

1. mCSPC status was based on evidence of metastatic disease, identified through chart confirmation, in the absence of castration resistance. Castration resistance was identified using an algorithm incorporating i) physician-reported castration resistance in medical chart, ii) observed rising PSA value of ≥2 ng/mL while on hormone therapy and ≥1 higher subsequent PSA value within three months of the first elevated PSA test, or iii) physician documented rising PSA on hormone therapy plus a change in treatment.
2. The FDA approved apalutamide as a treatment for mCSPC on 17 September 2019 and enzalutamide as a treatment for mCSPC on 16 December 2019; only patients with an index date on or after the latter of the two FDA approval dates (16 December 2019) were included.
3. Clinical activity was defined as the period from the first to last record in the database. Patients with no observation period after the index date were excluded.
4. Other advanced PC-related therapies included chemotherapy, immunotherapy, estrogens, radiopharmaceuticals, and poly ADP-ribose polymerase inhibitors.

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METHODS (4 of 4)

Study outcomes

- Real-world survival was evaluated as the time from the index date to patients' date of death
  - Mortality from any cause was captured from structured and unstructured (e.g., clinician notes) EHR sources, and through linkages to the Social Security Death Index and obituary data
  - Mortality information in the EHR-derived database was presented as the month and year of death; thus, by default, patients' date of death was set as the first day of the month of death
  - For patients with clinical activity during the month of death, their date of death was set as their end of clinical activity for that month

Statistical analyses

- Kaplan-Meier (KM) analysis was used to describe the proportion of patients surviving up to 24 months post-index using an intention-to-treat approach
- An unadjusted Cox proportional hazards model was used to evaluate the association between index treatment and real-world survival

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Baseline characteristics

TABLE 1: Baseline demographic and clinical characteristics

- There were 234 apalutamide (mean age: 73.2 years; 59.8% White, 13.7% Black) and 527 enzalutamide (mean age: 73.9 years; 55.2% White, 13.1% Black) patients included in this study (**Table 1**)
- The majority of patients were treated in community-based practices (apalutamide: 70.5%; enzalutamide: 79.7%)
- The median time between metastasis and index treatment initiation was 2.3 months in the apalutamide cohort and 2.8 months in the enzalutamide cohort
- Most patients had prior use of ADT before initiation of apalutamide (84.2%) or enzalutamide (85.2%)

	Apalutamide N=234	Enzalutamide N=527
Age, years, mean ± SD [median]	**73.2 ± 7.4 [73.0]**	**73.9 ± 8.1 [74.0]**
Race, n (%)		
White	140 (59.8)	291 (55.2)
Black	32 (13.7)	69 (13.1)
Asian	4 (1.7)	7 (1.3)
Other	23 (9.8)	82 (15.6)
Unknown	35 (15.0)	78 (14.8)
Insurance type, n (%)		
Commercial	60 (25.6)	142 (26.9)
Medicare	9 (3.8)	15 (2.8)
Other	17 (7.3)	46 (8.7)
Unknown	148 (63.2)	324 (61.5)
Practice setting, n (%)		
Community	165 (70.5)	420 (79.7)
Academic	58 (24.8)	93 (17.6)
Both	11 (4.7)	14 (2.7)
Index year, n (%)		
2019	2 (0.9)	4 (0.8)
2020	48 (20.5)	158 (30.0)
2021	64 (27.4)	162 (30.7)
2022	87 (37.2)	155 (29.4)
2023	33 (14.1)	48 (9.1)
Time between metastasis and index date, median [Q1, Q3]	**2.3 [1.1, 9.0]**	**2.8 [1.2, 13.3]**
***De novo* PC,[1] n (%)**	**57 (24.4)**	**147 (27.9)**
Prior use of ADT,[2] n (%)	**197 (84.2)**	**449 (85.2)**
≥12 months between ADT initiation and index date	108 (54.8)	253 (56.3)
Gleason score at initial PC diagnosis, n (%)	**198 (84.6)**	**395 (75.0)**
≤6	14 (7.1)	37 (9.4)
7	82 (41.4)	129 (32.7)
8	31 (15.7)	84 (21.3)
9	66 (33.3)	123 (31.1)
10	5 (2.5)	22 (5.6)
Most recent ECOG score,[3] n (%)	**145 (62.0)**	**360 (68.3)**
0	87 (60.0)	170 (47.2)
1	47 (32.4)	146 (40.6)
2	8 (5.5)	40 (11.1)
3	2 (1.4)	4 (1.1)
4	1 (0.7)	0 (0.0)
PC-related medication use,[4] n (%)		
First-generation anti-androgens	86 (36.8)	149 (28.3)
Bone antiresorptive therapy	35 (15.0)	107 (20.3)
Localized PC therapy,[5] n (%)	**109 (46.6)**	**261 (49.5)**
Radical prostatectomy	73 (31.2)	170 (32.3)
Radiation therapy[6]	72 (30.8)	149 (28.3)

ADT: androgen deprivation therapy; ECOG: Eastern Cooperative Oncology Group; mCSPC: metastatic castrate-sensitive prostate cancer; PC: prostate cancer; Q1: first quartile; Q3: third quartile; SD: standard deviation.

Notes:

1. De novo PC defined as ≤180 days between first observed PC diagnosis and metastasis, in patients without prior radical prostatectomy or radiation therapy.
2. Prior use of ADT medication was assessed any time prior to the index date.
3. ECOG scores were assessed any time prior to and including the index date. The ECOG status recorded closest to the index date was reported.
4. Advanced PC medication use was assessed during the 12-month baseline period and on the index date.
5. Localized PC therapy included radical prostatectomy, radiation therapy, cryotherapy and high intensity focused ultrasound, and was assessed any time prior to and including the index date.
6. Included radiation therapy to the prostate, brachytherapy (internal radiation therapy) and radioactive seeds.

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Treatment patterns

- Apalutamide median time on-treatment was 10.9 months over a median observation period of 13.3 months, while enzalutamide median time on-treatment was 11.1 months over a median 14.8-month observation period (**Table 2**)
- Few apalutamide (11.5%) or enzalutamide (12.5%) patients initiated treatment with any other ARSI during the observation period
- Approximately 16% of patients in both cohorts used another advanced PC-related medication during the observation period

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TABLE 2: Treatment patterns in the observation period

Treatment patterns	Apalutamide N=234	Enzalutamide N=527
Duration of follow-up,[1] months, mean ± SD [median]	15.4 ± 10.9 [13.3]	16.7 ± 11.0 [14.8]
Duration of treatment,[2] months, mean ± SD [median]	13.0 ± 10.2 [10.9]	13.8 ± 10.5 [11.1]
Started treatment with any other ARSI post-index,[3] n (%)	27 (11.5)	66 (12.5)
Started treatment with any advanced PC medication post-index,[4] n (%)	37 (15.8)	84 (15.9)
Chemotherapies	32 (13.7)	64 (12.1)
Immunotherapies	5 (2.1)	17 (3.2)
Radiotherapy	3 (1.3)	7 (1.3)
PARP inhibitors	5 (2.1)	8 (1.5)

ARSI: androgen receptor signaling inhibitor; PARP: poly ADP-ribose polymerase; PC: prostate cancer; SD: standard deviation.
Notes:
1. Defined as the time from the index date to the earliest of end of clinical activity (including death) or the end of data availability.
2. Defined as the time from the index date to the earliest of treatment discontinuation, end of clinical activity (including death) or the end of data availability.
3. Included apalutamide, enzalutamide, abiraterone acetate, or darolutamide.
4. Categories are not mutually exclusive; patients could start more than one advanced PC medication during the observation period.

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Real-world survival

- Unadjusted real-world survival rates obtained from KM analyses were as follows (**Figure 2**):
  - By 12 months: 91.5% (apalutamide), 90.4% (enzalutamide)
  - By 18 months: 87.9% (apalutamide), 80.3% (enzalutamide)
  - By 24 months: 85.4% (apalutamide), 73.9% (enzalutamide)
- By 24 months post-index, apalutamide patients had a 41% lower mortality rate relative to patients initiated on enzalutamide (unadjusted hazard ratio = 0.59, 95% confidence interval [CI]: 0.37, 0.95; p=0.030)
- In the Phase III trials, 24-month overall survival rates were 83.3% for patients treated with apalutamide in TITAN[3] and 86.0% for patients treated with enzalutamide in ARCHES[5]

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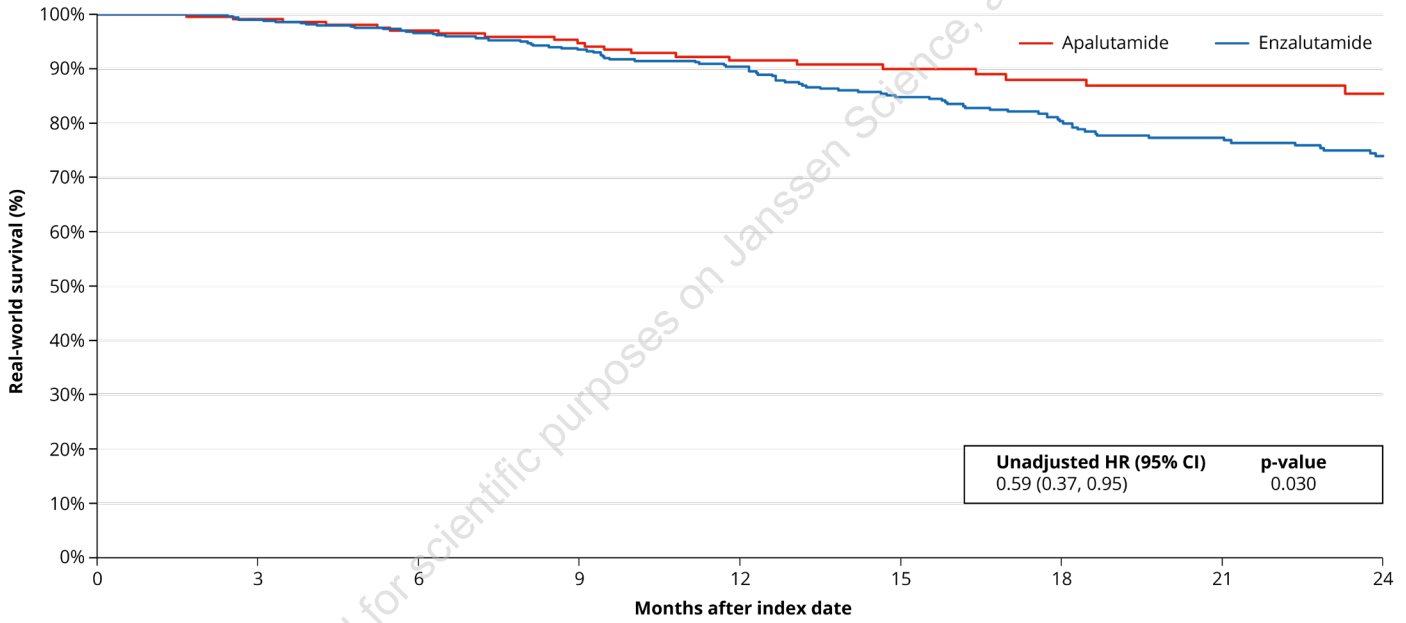
FIGURE 2: Kaplan-Meier rates for real-world survival



	3 months	6 months	9 months	12 months	15 months	18 months	24 months
At risk, n (%)							
Apalutamide	205 (87.6)	178 (76.1)	158 (67.5)	130 (55.6)	103 (44.0)	82 (35.0)	54 (23.1)
Enzalutamide	482 (91.5)	423 (80.3)	374 (71.0)	318 (60.3)	263 (49.9)	220 (41.8)	140 (26.6)
Kaplan-Meier rates, %							
Apalutamide	99.1%	97.0%	94.7%	91.5%	89.9%	87.9%	85.4%
Enzalutamide	99.0%	96.6%	93.5%	90.4%	84.8%	80.3%	73.9%

CI: confidence interval; HR: hazard ratio.

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LIMITATIONS

- This study relied upon EHR data that may contain inaccuracies or omissions (e.g., diagnosis dates, treatment start dates) and does not capture any diagnoses, medical services, or prescription fills obtained outside of the oncology network.
- This study was descriptive in nature, and differences in characteristics between apalutamide and enzalutamide patients were not accounted for.
- Information on chart-confirmed site of metastatic disease, an important predictor of survival, was not available and not accounted for in analysis.
- The database represents the community and academic oncology perspective and may not be representative of the entire population of patients with mCSPC in the US, which may limit the generalizability of results.

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DISCLOSURES:

M. A. Bilen is an employee of Winship Cancer Institute and has received consulting fees from Janssen Pharmaceuticals. C. Rossi, J. Korsiak, A. Rahman, P. Lefebvre, and D. Pilon are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Janssen Pharmaceuticals. S. Du and I. Khilfeh are employees of Janssen Pharmaceuticals and stockholders of Johnson and Johnson. N. D. Shore is an employee of the Carolina Urologic Research Center and Genesis Care and has received consulting fees from Janssen Pharmaceuticals.

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