Darolutamide Real-world Doublet And Triplet Utilization in Metastatic Hormone Sensitive Prostate Cancer (mHSPC): US Community Urology Setting

Poster#MP60-18

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INTRODUCTION

- Darolutamide (DARO) in combination with docetaxel and androgen deprivation therapy (ADT) (triplet therapy [TT]) is FDA approved and an NCCN Guidelines Category 1 preferred treatment for mHSPC.
- There is limited data on real-world utilization and treatment patterns of DARO plus ADT (doublet therapy [DT]) for mHSPC.

OBJECTIVE

The primary objective of this analysis was to describe the clinical profile of those receiving DT.

METHODS

This retrospective descriptive analysis used the largest urology integrated database in the US, PPS Analytics (Specialty Networks) Patient Population Health Management Platform composed of 40 community urology practices. Data acquisition included structured data in electronic medical records and chart abstraction for data in clinical notes. The study included 319 de novo and recurrent mHSPC patients treated with DARO DT or TT between 01/01/2019 and 03/31/2023.

40 Community Urology Practices

192 Patients DARO + ADT Doublet

127 Patients DARO + ADT + Docetaxel Triplet

RESULTS

Of 319 eligible mHSPC patients, 192 (60%) received DT and 127 (40%) received TT. **DT cohort:** Table 1 and Figure 1 present the patient characteristics of those who received doublet therapy (DARO + ADT). **TT cohort:** Table 1 and Figure 2 present the patient characteristics of those who received triplet therapy (DARO + ADT + Docetaxel). Additionally, the number of chemotherapy cycles completed in the TT cohort are presented in Table 2. Comorbid conditions that were present in each patient population is described in Table 3. In addition, 52 total patients (16.3%) had used a novel hormonal agent prior to switching to DT or TT with DARO.

Table 1. Clinical, Patient Demography & Treatment Duration Information

Patient Characteristics N = 319	DARO + ADT (doublet) n = 192 (60%)	DARO + ADT + Docetaxel (triplet) n = 127 (40%)
Median Age (range), years	75.0 (51-89)	66.0 (42-87)
Obese BMI (≥ 30), n (%)	55 (29%)	36 (28%)
Medicare Coverage, n (%)	148 (77%)	67 (53%)
High Gleason Risk Group (≥ 8) at PC Diagnosis, n (%)	81 (42%)	66 (52%)
Mean PSA at Index Date (range), ng/mL	42.3 (0-2061)	92.0 (0-3040)
Used novel hormonal agent prior to switching to DT or TT n (%)	44 (23%)	8 (6%)
Initiated ADT followed by DARO	159 (83%)	55 (43%)
Median Time from PC Diagnosis to Start of Therapy (95% CI), weeks	73 (50, 137)	14 (11, 16)
Median Follow-up (95% CI), weeks	44 (41, 50)	43 (37, 48)
Median Duration of Therapy (95% CI), weeks*	42 (39, 46)	43 (37, 48)

***Additional follow-up may be needed to further evaluate DOT**

Table 2. TT Chemo Cycles Completed

TT Chemo Cycles Completed	Patient Count N = 127
1 to 3 cycles	9 (7%)
4 to 5 cycles	10 (8%)
6 cycles	106 (83%)
7+ cycles	2 (2%)

Table 3. Comorbid Conditions of Interest

Comorbid Conditions N (%)	DARO + ADT (doublet)	DARO + ADT + Docetaxel (triplet)
Hypertension	67 (32%)	36 (28%)
Diabetes	36 (19%)	11 (9%)
Renal Disease	23 (12%)	7 (6%)
Chronic Pulmonary Disease	20 (10%)	7 (6%)
Congestive Heart Failure	20 (10%)	4 (3%)
Peripheral Vascular Disease	18 (9%)	6 (5%)
Cerebrovascular Disease	12 (6%)	5 (4%)
Liver Disease	7 (4%)	6 (5%)
Seizure disorder	1 (1%)	1 (1%)

CONCLUSIONS

Results from this community-representative urology database reveal that DARO DT and TT have been adopted routinely in clinical practice. Furthermore, most patients also possessed unfavorable disease characteristics including high Gleason score and PSA values at diagnosis. These data warrant additional study of treatment patterns in mHSPC as patient characteristics continue to evolve.

LIMITATIONS/DISCUSSION

DOT may be understated since a patient's end date could have been defined as the end of the study period, 03/31/2023.

PLAIN LANGUAGE SUMMARY

- Researchers wanted to learn about how much a drug called darolutamide is used in combination with testosterone lowering alone and in combination with testosterone lowering and chemotherapy in a real-life (not clinical trial) setting.
- Researchers learned that urologists used both darolutamide in combination with testosterone lowering and in combination with testosterone lowering and chemotherapy depending on different patient characteristics.

DARO + ADT (Doublet) Cohort (Fig. 1)

Median Age: 75 years (51-89)
Race:
- African-American: 18%
- White Non-Hispanic: 66%
- Asian: 1.6%
- Other: 14%

42% Gleason Score ≥ 8 At Prostate Cancer Diagnosis

42.3 ng/mL Mean PSA at Index Date

Have Medicare coverage

73 Weeks Median Time from Prostate Cancer Diagnosis to Start of Therapy

42 Weeks Median Duration of Therapy

DARO + ADT + Docetaxel (Triplet) Cohort (Fig. 2)

Median Age: 66 years (42-87)
Race:
- African-American: 17%
- White Non-Hispanic: 63%
- Asian: 1.6%
- Other: 19%

52% Gleason Score ≥ 8 At Prostate Cancer Diagnosis

92.0 ng/mL Mean PSA at Index Date

Have Medicare coverage

14 Weeks Median Time from Prostate Cancer Diagnosis to Start of Therapy

43 Weeks Median Duration of Therapy

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