

Real World Treatment Patterns Among US-Based Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Patients: Results from Syndicated Chart Reviews

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BACKGROUND AND OBJECTIVES

- Prostate cancer (PC) is the second-most commonly occurring cancer in the US.¹
- Up to one third of PC patients develop metastases eventually which is associated with higher mortality.²
- Androgen deprivation therapy (ADT), with luteinizing hormone-releasing hormone (LHRH) agonists/antagonists, has been the cornerstone of systemic treatment for metastatic hormone sensitive prostate cancer (mHSPC) since the 1940s.³
- However, since then, other drug classes including androgen-receptor inhibitors (ARIs) (e.g., bicalutamide, nilutamide, and flutamide), androgen synthesis inhibitor (ASI) (e.g., abiraterone), taxane-based chemotherapy (e.g., docetaxel), and most recently novel androgen-receptor inhibitors (nARIs) (e.g., enzalutamide and apalutamide) have also been approved for mHSPC treatment.
- The National Comprehensive Cancer Network (NCCN) treatment guidelines for mHSPC in the US have evolved in the last 5 years and currently recommend ADT with docetaxel, abiraterone, apalutamide, or enzalutamide as the four standard of care options.⁴
- The objective of this study was to evaluate demographic and clinical characteristics of mHSPC patients in the US, and real-world treatment patterns in light of guidelines.

METHODS

Study Design

- This was a retrospective, real-world data analysis of mHSPC patients using IPSOS Global Oncology Monitor Database (GOMD).
- GOMD is a validated syndicated oncology patient record database composed of physician responses about their patients from periodically-fielded surveys.
- The study included cross-sectional data from January 2018 to June 2020.

Study Population

- Inclusion criteria**
 - Age ≥ 18 years
 - mHSPC disease as determined through a combination of 2 questionnaire fields:
 - 1) Current patient status = “Metastases”
 - 2) Whether patient is considered hormone refractory/castrate resistant = “No”
- Exclusion criteria**
 - Diagnosis of any other primary cancer during the study period

Study Variables

- Patient demographic and clinical characteristics were assessed for all US patients and for the subset of patients on ADT monotherapy .
- Treatment patterns were described as proportions of patients receiving the regimen at time of data capture.

Statistical Analysis

- Descriptive analysis evaluated patient characteristics and treatment patterns.

RESULTS

Sociodemographic and Clinical Characteristics for Entire Cohort

- A total of 3,893 mHSPC patients were included. These patients were predominantly aged 70 years and older (67.4%) and belonged to the White race (62.8%) **(Table 1)**.
- Most patients had metastatic disease within the bone (81.0%) and were well-functioning with ECOG scores 0-1 (84.0%).
- Slightly over half of the patients had higher-grade prostate cancer with Gleason scores 8-10 range (54.2%), and slightly under half had mildly symptomatic to symptomatic bone status (45.9%).
- Hypertension (63.1%), cardiovascular disease (29.9%), and diabetes (25.8%) were the most common comorbid conditions.

mHSPC Treatment Patterns for Entire Cohort

- Among all drug classes, LHRH agonists (82.6%) were most frequently prescribed, followed by ARIs (15.8%), ASI (15.5%), LHRH antagonists (9.2%), and nARIs (7.4%) **(Figure 1)**.
- Among monotherapies, the use of ADT (53.9%) was most frequent followed by docetaxel (2.6%), abiraterone (1.5%), and nARIs (1.5%) as distant second and third **(Figure 2)**.
- The most highly prescribed combination therapies were abiraterone + ADT (13.7%) or ARI + ADT (13.7%).
- The use of other combination therapies including nARI + ADT (5.6%) and docetaxel + ADT (3.3%) was comparatively lower.
- The vast majority of patients (98.4%) received therapy with one or two agents. Only 1.1% of the patients received combination therapy with three agents.

Sociodemographic and Clinical Characteristics for ADT Monotherapy Subgroup

- A total of 2,098 mHSPC patients received ADT monotherapy **(Table 1)**.
- The ADT monotherapy subgroup was the largest within the entire mHSPC sample. Patients in this subgroup were predominantly aged 70 years and older (73.2%) and had insurance coverage under Medicare (74.8%). Most patients had only mildly (38.5%) or asymptomatic (48.9%) bone disease. The top comorbid conditions were hypertension (66.7%), cardiovascular disease (32.4%), and diabetes (26.5%).
- However, despite their dominance within the entire mHSPC sample, ADT monotherapy patients had less lymph node involvement (19.4%), 80.6% were well-functioning with ECOG scores 0-1, and 53.5% had higher grade prostate cancer with Gleason scores 8-10 range.

Table 1. mHSPC Patient Characteristics (Overall and by ADT Monotherapy Subgroup)

Variables		Overall (N = 3,893)	ADT Monotherapy (N = 2,098)
Age Group	70 and older	67.4%	73.2%
Race	Asian	2.4%	1.9%
	Black	24.3%	24.6%
	Hispanic/ Latino	9.3%	10.0%
	Native American	0.8%	0.9%
	White	62.8%	62.2%
	Other	0.4%	0.4%
Metastatic Site	Bone	81.0%	80.7%
	Lymph	27.1%	19.4%
	Other ^a	7.1%	7.8%
	Lung	4.5%	3.0%
	Liver	2.2%	1.3%
	Brain	0.3%	0.2%
ECOG Score Category	0-1	84.0%	80.6%
	2-3	15.5%	19.1%
	3+	0.1%	0.0%
	Missing	0.4%	0.3%
Gleason Score Category	8-10	54.2%	53.5%
	7	26.4%	31.6%
	2-6	8.4%	6.6%
	Unknown	7.6%	5.8%
	Missing	3.4%	2.5%
Bone Symptom Status	Asymptomatic	47.9%	48.9%
	Mildly symptomatic	34.6%	38.5%
	Symptomatic	11.3%	6.4%
	Missing	6.2%	6.2%
Top Comorbid Conditions	Hypertension	63.1%	66.7%
	Cardiovascular disease	29.9%	32.4%
	Diabetes	25.8%	26.5%
	Pulmonary disorder	13.0%	14.4%
	Renal dysfunction	9.3%	9.7%
Primary Payor	Medicare	68.7%	74.8%
	Other ^b	31.3%	25.2%
ECOG: Eastern Cooperative Oncology Group; "Unknown" is a default category in the data which indicates physician does not have information for a variable; "Missing" is a category created during analysis if no values were entered for a variable; ^a Other metastatic sites include peritoneum and other sites; ^b Other primary payors include employee insurance, government, HMO, indemnity, Medicaid, PPO, no payment, patient/self, residents' insurance, rural co-op, VA/Military, other, and unknown			

Figure 1. Guideline-Relevant mHSPC Drug Classes (% Utilization)

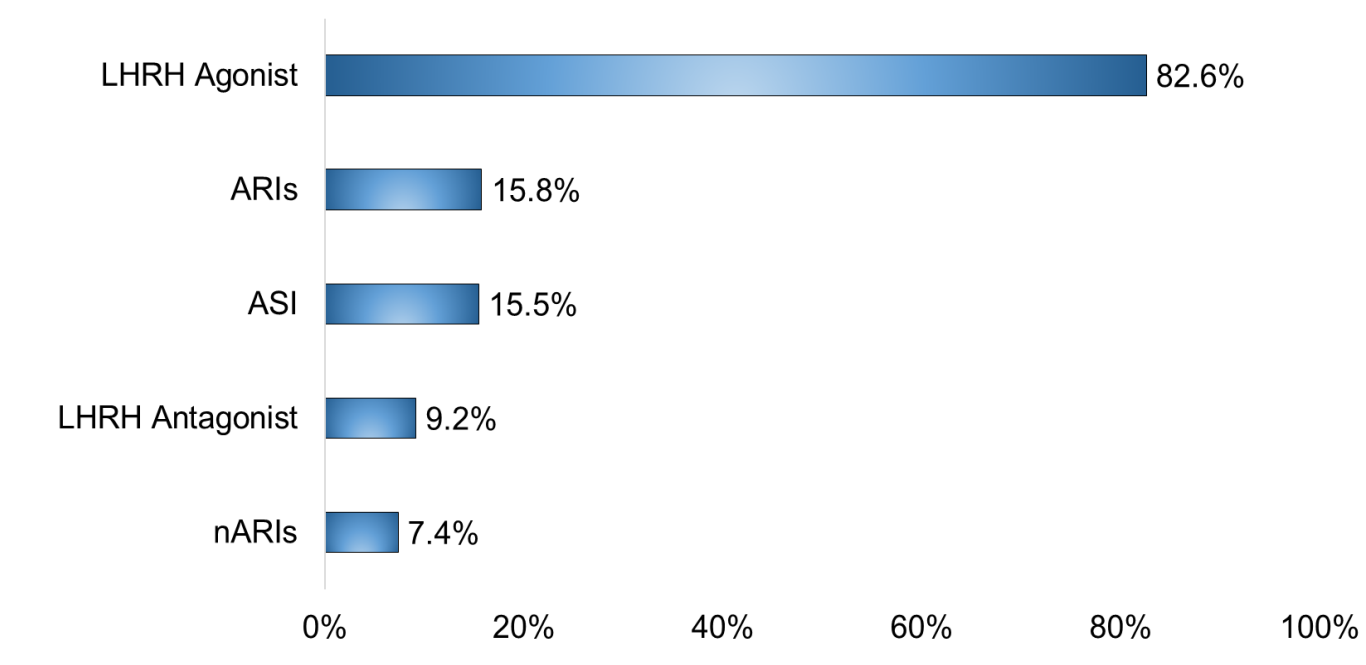
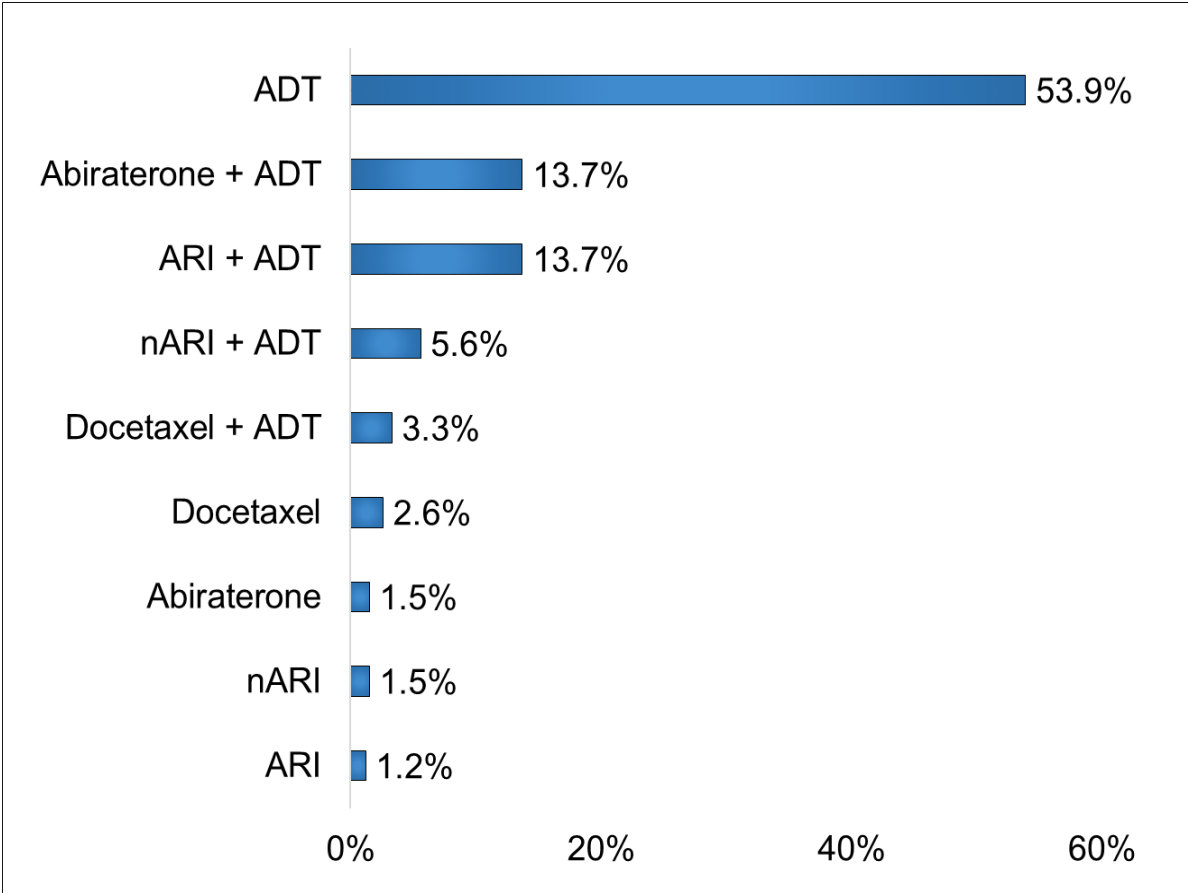


Figure 2. mHSPC Therapeutic Regimens (% Utilization)



ADT: Androgen deprivation therapy; ARI: Androgen receptor inhibitor; nARI: Novel androgen receptor inhibitor

DISCUSSION

- NCCN guidelines recommend treatment via combination therapy of ADT plus abiraterone, or docetaxel, or nARIs such as enzalutamide or apalutamide, for mHSPC treatment.³
- Study results show that ADT monotherapy was the most frequently prescribed treatment for mHSPC in the US despite high rates of bone metastases and competing comorbidities. Use of guideline-recommended combination therapies was relatively low within the study period. These findings highlight the discrepancy between guideline recommendations and real-world practice especially in the yet low use of newer agents.
- Our findings are consistent with previous literature which reports low real-world utilization of guideline-recommended combination therapies for mHSPC patients.⁵⁻⁹
- The relative recency of nARI approvals in the US (2019) may have contributed to the low utilization found in this study.
- Further studies are needed to understand the reasons for underutilization of guideline-recommended therapies as well as the impact of patient disease and comorbidity features on treatment selection for mHSPC.

STUDY LIMITATIONS

- In the GOMD, mHSPC diagnosis relies on physician adjudication, with chance of interpersonal variability when applying diagnostic criteria.
- Recall bias in survey responses may have contributed to underestimates of treatments used.
- GOMD data is cross-sectional and so only supports descriptive analysis, not conclusions of causation.

CONCLUSIONS

- Despite clear evidence that docetaxel, abiraterone, enzalutamide, apalutamide, and now darolutamide have shown overall survival benefit versus ADT, and are incorporated into guidelines, two-thirds of patients in the US receive either ADT alone or ADT in combination with ARI. The use of preferred regimens in NCCN guidelines is low.
- Our study findings underscore the gap between newer guideline-recommended therapies and real-world treatment patterns for mHSPC and highlights the need for further integration of recommended therapies in mHSPC treatment.

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DISCLOSURE

Authors Partridge J, Chen SL, Appukuttan S, and Jhaveri J are employees of Bayer Pharmaceuticals.