602P-Prevalence of Castration-Resistant Prostate Cancer (CRPC) of Unknown Metastatic Status in the Real-World Setting: The AfroDiTa Study

Miguel Rodrigo-Aliaga[1], José L. Álvarez-Ossorio[2], Andrés Rodríguez-Alonso[3], Ángela García-Porrero[4], Alba Quesada-García[4], Jacobo Muñoz del Toro[4], Alfredo Rodríguez-Antolín[5]

[1] University General Hospital of Castellón. Castellón, Spain; [2] Puerta del Mar University Hospital. Cádiz, Spain; [3] Complejo Hospitalario Universitario de Ferrol. Ferrol, Spain; [4] Medical Affairs Department, Janssen-Cilag. Madrid, Spain; [5] University Hospital 12 de Octubre. Madrid, Spain.

INTRODUCTION

- Most patients receiving androgen deprivation therapy (ADT), the backbone treatment for PC, have an initial PSA response and are classified as hormone-sensitive PC (HSPC). However, they will eventually progress to become non-responsive, a status known as castration-resistant PC (CRPC).
- PC patients are classified according to their metastatic status in metastatic (M1) and non-metastatic (M0).
- Accurate diagnosis of prostate cancer (PC) patients is crucial for their appropriate management, and guidelines recommend regular monitoring of their hormone and metastatic status.[1,2]
- However, the real-world prevalence of the different PC statuses remains poorly documented.

OBJECTIVES

- To describe the non-pharmacological clinical management of castration-resistant PC patients with unknown metastatic status (CRPC-MX) during 15 months.
- The first phase of this study aimed to assess the real-world prevalence of CRPC-MX patients.

METHODS

Study Design:

- AFRODITA is a retrospective, multicenter, real-world study including adult patients with CRPC who had received continuous ADT for ≥6 months before their inclusion in the study in 46 Spanish hospitals.
- In phase 1, PC patients on ADT were classified according to hormonal and metastatic statuses, using an algorithm designed *ad hoc* based on clinical guidelines. In addition, the subgroup of CRPC-MX patients was evaluated retrospectively.
- In phase 2, 15 months after the start of the study, all patients on ADT at that date will be reviewed and classified again according to hormonal and metastatic status. Evolution of patients initially classified as CRPC-MX will also be analyzed.
- A diagram of the study design is shown in Figure 1.

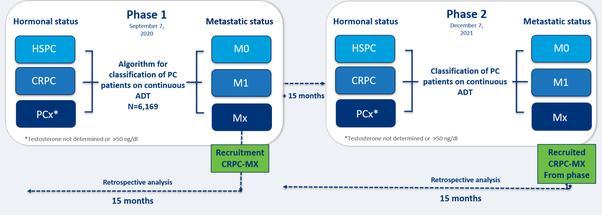

Figure 1. Diagram of the AfroDiTa study design

RESULTS

- A total of 6,169 PC patients were included.
- Most PC patients were classified as HSPC (58.9%). Testosterone was either not determined or above >50 ng/dL in 12.3 % of patients, indicating that successful castration was not appropriately monitored. The classification of patients according to their hormonal status is shown in Figure 2.

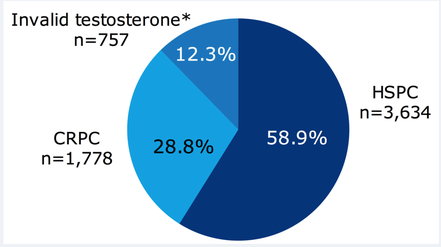

Figure 2. Classification of PC patients according to their hormonal status.
***Not determined or >50 ng/dL**

- Most of the 3,634 PC patients classified as HSPC had unknown metastatic (MX) status. The classification of HSPC patients according to their metastatic status is shown in Figure 3.

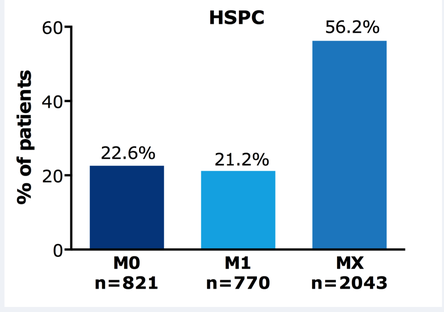

Figure 3. Classification of HSPC patients according to their metastatic status

RESULTS (continued)

- Most of the 1,778 PC patients classified as CRPC had metastasis (69.8%) and 18.2% had unknown metastatic status (CRPC-MX). The classification of CRPC patients according to their metastatic status is shown in Figure 4.

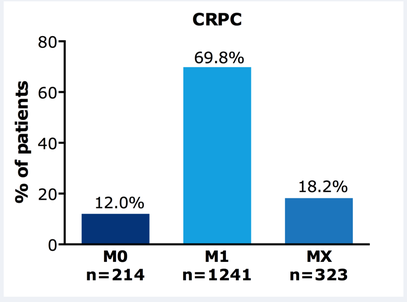

Figure 4. Classification of CRPC patients according to their metastatic status

- Most of the 757 PC patients with unknown hormonal status had unknown metastatic status (MX) (73.4%). The classification of PC patients with unknown hormonal status according to their metastatic status is shown in Figure 5.

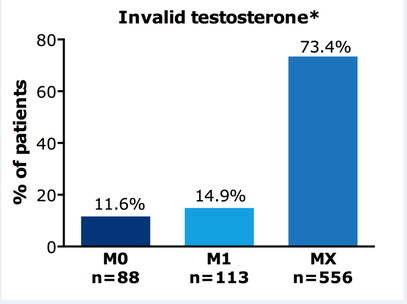

Figure 5. Classification of patients with unknown hormonal status according to their metastatic status.
***Not determined or >50 ng/dL**

- The overall prevalence of CRPC-MX among ADT-treated patients in the Spanish real-world setting was 5.2%.
- The metastatic status was unknown in 47.3% of PC patients. The classification of all PC patients according to hormonal and metastatic statuses is summarized in Table 1.

RESULTS (continued)

Table 1. Classification of prostate cancer patients receiving androgen deprivation therapy according to hormonal and metastatic statuses, N=6,169

	n	%
Valid testosterone[a]	**5,412**	**87.7**
HSPC-M0	821	13.3
HSPC-M1	770	12.5
HSPC-MX	2,043	33.1
CRPC-M0	214	3.5
CRPC-M1	1,241	20.1
CRPC-MX	**323**	**5.2**
Invalid testosterone[b]	**757**	**12.3**
M0	88	1.4
M1	113	1.8
MX	556	9.0

HSPC, hormone-sensitive prostate cancer; CRPC, castration-resistant prostate cancer; M0, non-metastatic; M1, metastatic; MX; unknown metastatic status.
[a]below castration levels (i.e., <50 ng/dL)
[b]above castration levels (i.e., >50 ng/dL) or not determined

CONCLUSIONS

- The prevalence of CRPC-MX observed in this large patient series is similar to previously reported studies[3,4].
- In ADT-treated PC patients in the real-world setting:
  - Successful castration is not appropriately monitored in a subset of PC patients
  - Metastatic status is unknown in almost half of PC patients
  - Almost 1 of every 10 patients have unknown hormone and metastatic statuses
- Suboptimal adherence to clinical guidelines recommendations for the characterization and follow-up of PC patients[1,2] leads to inaccurate diagnosis and may preclude patients' access to appropriate treatments.

REFERENCES

[1]E. D. Crawford et al. 2019. Journal of Urology 201 (4): 682–92.
[2]N. Mottet, et al. 2020. "EAU - EANM - ESTRO - ESUR - SIOG Guidelines on Prostate Cancer."
[3]A. Sánchez, et al. 2017. LXXXII Congreso Nacional de Urología, Sevilla, Spain.
[4]V.J. Valencia-Guadalajara, et al. 2020 Arch. Esp. Urol. 73 (6): 499-508

ACKNOWLEDGEMENTS

The authors would like to acknowledge all the participating sites and investigators. The authors acknowledge the contributions of BioClever (Spain) (CRO), and the medical writing assistance of Sara Cervantes (i2e3, Spain). This study was sponsored by Janssen-Cilag Spain.

DISCLOSURES

MR received a research grant from Janssen, advisor fees from Janssen, Ipsen, Astellas, Bayer and Pfizer, and speaker fees from Janssen and Astellas. AG-P, AQ-G, and JMdT are Janssen-Cilag employees.

CORRESPONDENCE

Miguel Rodrigo Aliaga• Department of Urology, University General Hospital of Castellón, Castellón, Spain.• E-mail: m-rodriao@hotmail.com

Poster presented at ESMO Congress • September 2021