Description of Castration-Resistant Prostate Cancer with Unknown Metastatic Status (CRPC-MX) Population in the Real-world. The AfroDiTa Study.

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INTRODUCTION

- Most patients receiving the backbone treatment for prostate cancer (PC), androgen deprivation therapy (ADT), have an initial PSA response and are classified as hormone-sensitive PC (HSPC). However, they will eventually become non-responsive, a status known as castration-resistant PC (CRPC).
- Accurate diagnosis and classification of PC patients is crucial for their appropriate management, and guidelines recommend regular monitoring of their hormonal and metastatic status, with RADAR supporting PSA testing for CRPC patients every 3 months [1].
- However, the real-world prevalence of the different PC statuses and their management remains poorly documented.
- In the screening phase of the AfroDiTa study, we used an algorithm to classify PC patients according to their hormonal and metastatic status.
- Of 6,169 patients screened, 58.9% were classified as HSPC and 28.8% as CRPC; successful castration was not appropriately monitored in 12.2%.
- Of the 1,778 PC patients classified as CRPC, most had metastasis (M1) (69.8%) and 18.2% had unknown metastatic status (MX), resulting in an overall 5.2% prevalence of castration-resistant PC with unknown metastatic status (CRPC-MX) among ADT-treated patients in the Spanish real-world setting[2].

OBJECTIVES

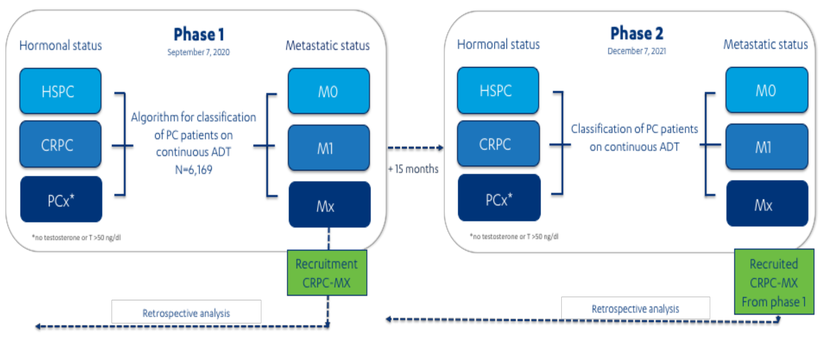
- To describe retrospectively the management of CRPC-MX patients during the 15 months prior to their entry in the study.
- To assess the real-world prevalence of CRPC-MX patients.
- To describe the clinical and demographic characteristics of CRPC-MX patients since prostate cancer diagnosis.

METHODS

Study Design

- AfroDiTa is a retrospective, multicenter, real-world study including adult patients with CRPC-MX who had received continuous androgen deprivation therapy (ADT) for ≥6 months before their inclusion in the study in 46 Spanish hospitals.
- In the screening phase of the AfroDiTa study, PC patients on ADT were classified according to hormonal and metastatic status, using an algorithm designed *ad hoc* based on clinical guidelines.
- In Phase 1 (this presentation), 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 analysed.
- A diagram of the study design is shown in **Figure 1**.

Figure 1. Diagram of the AfroDiTa study design

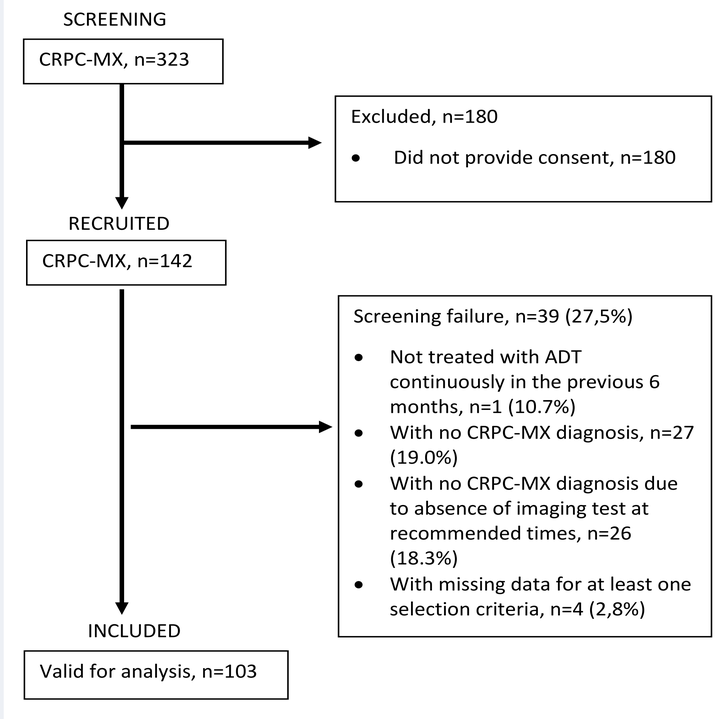


RESULTS

Characteristics of CRPC-MX patients at diagnosis

- Of 323 CRPC-MX patients identified during the screening phase[1], 103 were included (**Figure 2**).

Figure 2. Flow chart of study patients



RESULTS (continued)

- Median age at PC diagnosis was 75.4 years (**Table 1**).
- Median PSA at PC diagnosis was 19.0 ng/mL (**Table 1**).
- Most patients had high risk or locally advanced PC (**Table 1**).

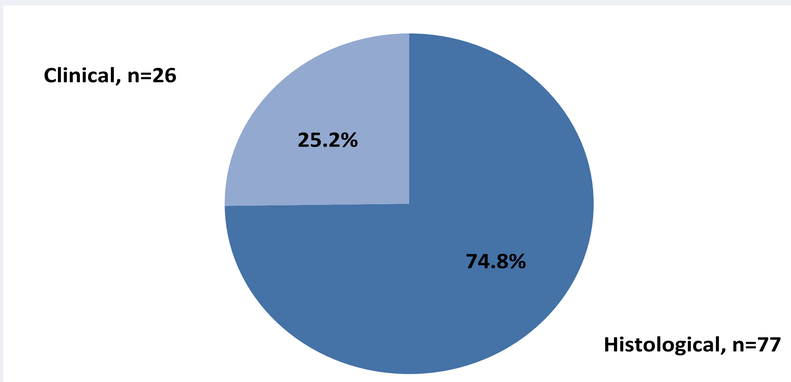
Table 1. Characteristics of study patients at initial diagnosis, N=103

Age at diagnosis (years), median (IQR) n=103	75.4 (67.8-80.4)
D'Amico risk, *n (%)* n=70	
Low	10 (14.3)
Intermediate	18 (25.7)
High	36 (51.4)
Locally advanced	6 (8.6)
PSA at diagnosis (ng/mL), *median (IQR)*	19.0 (10.6-46.6)

PSA: Prostate Specific Antigen. IQR: interquartile range

- 25% of included CRPC-MX patients lacked histological diagnosis. This finding is consistent with other publications in Spain[3] (**Figure 3**).

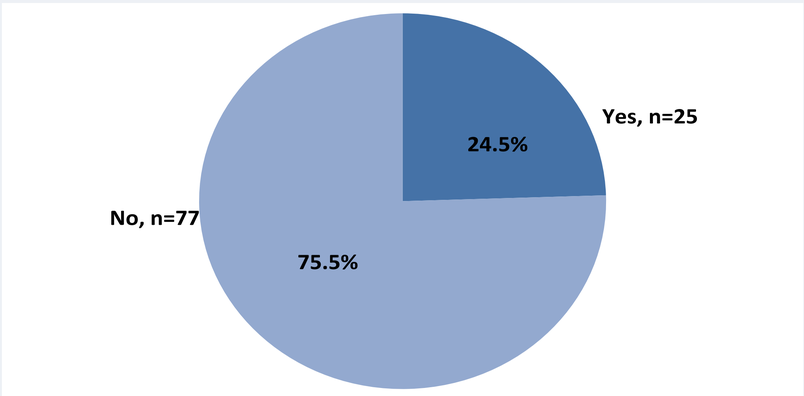
Figure 3. Histological diagnosis, N=103



Clinical management at initial diagnosis

- Most patients (n= 77, 75.5%) did not receive treatment with curative intent (**Figure 4**).

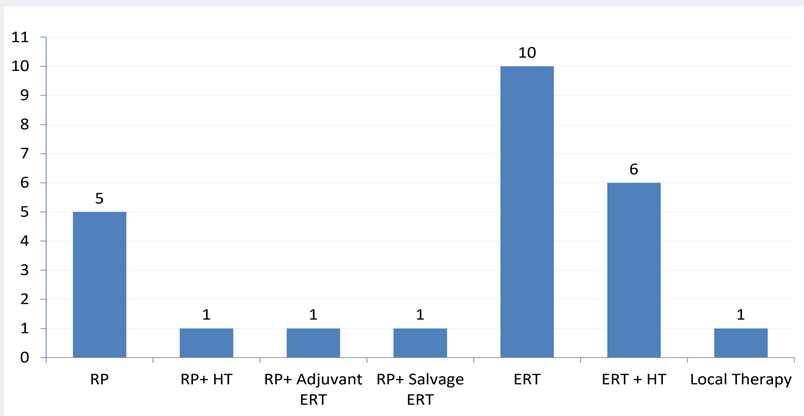
Figure 4. Treatment with curative intent at initial diagnosis, N=102*



*one patient had missing data

- The most frequent curative treatment was Radiotherapy (n=10, 40%) followed by Radiotherapy + Hormonal Therapy (n=6, 24%) and Radical Prostatectomy (n=5, 20%) (**Figure 5**).

Figure 5. Curative treatment combinations, N=25



ERT: radiotherapy; HT: hormonal therapy; RP: radical prostatectomy

CRPC diagnosis

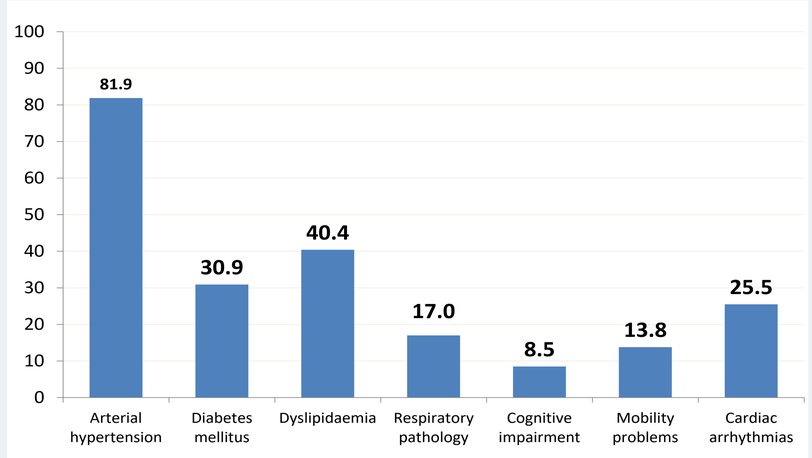
- Median PSA at CRPC diagnosis was 5 ng/mL.
- 32.4% and 12.7% of patients received 1 and ≥2 secondary hormonal manipulations after failure in responding to ADT.

RESULTS (continued)

Characteristics at study inclusion

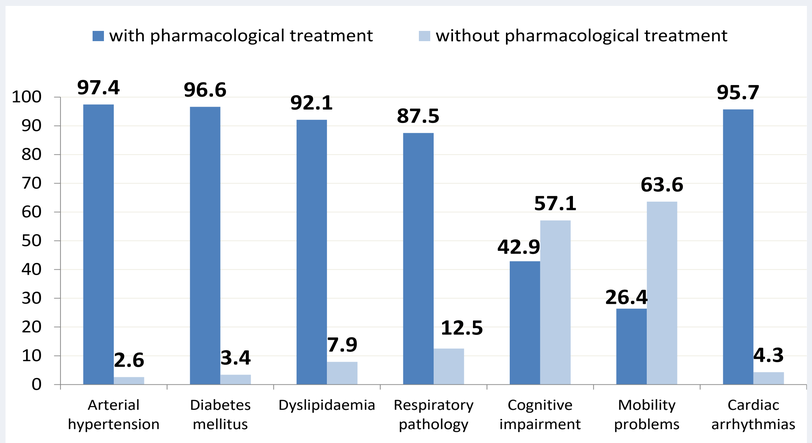
- At study inclusion, mean (SD) age was 84.7 (7.4) years.
- ECOG was 0 (31.6%), 1 (51.9%), and ≥2 (16.5%).
- The median time from initial PC diagnosis to inclusion was 9.3 years.
- Most patients (91.3%) had comorbidities, the most frequent being arterial hypertension (n=77, 81.9%), dyslipidemia (n=38, 40.4%), and diabetes mellitus (n=29, 30.9%) (**Figure 6**).

Figure 6. Main comorbidities (%)



- Most of the patients with comorbidities were under medication treatment for these comorbidities (**Figure 7**).

Figure 7. Pharmacological treatment of main comorbidities (%)



Clinical management in the previous 15 months

- In the 15 months before inclusion, almost 75% of CRPC-MX patients had less than 4 visits to any health center, which is in contrast with RADAR guidelines, which recommends PSA monitoring for CRPC patients every 3 months.[1]
- In the 15 months before inclusion, 65 (63.1%) of patients had no imaging tests.

CONCLUSIONS

- In the Spanish real-world setting, CRPC-MX patients tended to be old and comorbid.
- Most CRPC-MX patients received non-curative treatment despite ECOG being ≤1 in 83.5% of this population. Of note, ADT treatment seems to be initiated in a proportion of patients without a histological diagnosis or appropriate imaging tests.
- The proportion of PC patients without histological diagnosis are consistent with other publications in Spain[3].
- RADAR guidelines[1] for visits and imaging tests were not followed in more than 50% of cases.
- Despite the limitations inherent to retrospective analyses and to data reported from clinical records, this study highlights an urgent need for improving the management of a subset of PC patients with advanced disease.

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DISCLOSURES

AG-P, AQ-G, and JMdT are Janssen-Cilag employees.

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