TBC

PROSTATE CANCER REGISTRY

# The Prostate Cancer Registry: Do Patients With Metastatic Castration-Resistant Prostate Cancer (mCRPC) Differ According to Metastatic Status at Diagnosis?


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## BACKGROUND

- The stage at which prostate cancer is diagnosed may influence clinical outcomes in patients, based on the history and progression of the disease and how it is managed.
- In particular, patients who have metastatic disease at diagnosis may differ from patients diagnosed with localized disease who subsequently develop metastases; these differences could have important implications for treatment strategies after castration resistance develops.
- Observational data can provide important perspectives on the optimal management of such patients; however, real-world data in mCRPC are limited.
- The Prostate Cancer Registry, the first international, prospective, observational study of patients with mCRPC, was initiated to examine the characteristics and management of patients with mCRPC in routine clinical practice; previous descriptive analyses of 505 patients indicated enrollment of a real-world patient population.[1,2]

## OBJECTIVES

- Document the characteristics and management of patients with mCRPC in routine clinical practice, independent of treatment used.
- Assess whether the subset of mCRPC patients who had metastatic disease at initial diagnosis differ from those who did not in terms of clinical and disease characteristics in a real-life context.

## METHODS

### Study Design

- Prospective, non-interventional, multicenter registry of > 3000 men with mCRPC (ClinicalTrials.gov identifier: NCT02236637).
- Enrollment was initiated in 2013 and completed in early 2016. Study duration will be 5.5 years with a maximum patient follow-up of 3 years.
- 199 centers in 16 countries across Europe are participating: Austria, Belgium, France, Germany, Israel, Italy, Luxembourg, Poland, Portugal, Russia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the UK. Data from all countries except Israel and Turkey were available for this analysis.
- A range of clinical settings are represented, including oncology and urology specialist clinics, small and large practices, in both public and private health-care systems.

### Eligibility Criteria

- Male aged ≥ 18 years.
- Confirmed diagnosis of adenocarcinoma of the prostate with documented metastatic disease, who may enroll at any time after diagnosis.
- Documented castration resistance defined as disease progression despite testosterone levels < 50 ng/dL and/or androgen deprivation therapy (ADT) and/or orchiectomy. Disease progression is defined by a rise in prostate-specific antigen (PSA) and/or worsening of existing disease/symptoms and/or appearance of new metastases.
- Not currently receiving active treatment for mCRPC (except ADT and/or bone-sparing therapies) or initiating new treatment for mCRPC within the 30 days preceding or following enrollment.
- Signed informed consent/participation agreement, as applicable.

### Data Collection

- Baseline data collected at study entry included:
  - Demographics
  - Disease history, including dates of diagnosis, metastasis and castration resistance, tumor-node-metastasis (TNM) stage, and Gleason score at initial diagnosis
  - Prior prostate cancer treatment, including systemic therapy, radiotherapy, and surgery
  - Clinical characteristics, including comorbidities, concomitant medications, and Eastern Cooperative Oncology Group Performance Status (ECOG PS)
  - Quality of life
  - Medical resource utilization.
- Clinical data collected prospectively at least every 3 months:
  - Systemic and local mCRPC treatment
  - Rationale for treatment choice and reasons for discontinuation
  - Duration and sequencing of treatment
  - Clinical assessments/outcomes, biological parameters, and radiological responses
  - Survival
  - Quality of life
  - Medical resource utilization.
- Data collected include only the data available per patient record; some patient records are not fully complete.
- All clinical data are subject to a validation process to ensure quality control.

### Data Analysis

- This analysis was in patients with ≥ 12 months of follow-up (or less in case of withdrawal, loss to follow-up or death) with available data regarding metastatic (M)-status at time of initial diagnosis.
- Data are descriptive.

## RESULTS

- A total of 1323 consecutive patients, enrolled between June 2013 and October 2014, were analyzed: 549 had distant metastases at initial diagnosis (M1, 41.5%), 526 did not (M0, 39.8%), and 248 were not evaluable (Mx, 18.7%).
- Data for patients with M1- and M0-status are described.

### Patient Characteristics Before Start of Study

- A higher proportion of patients with M1-status at initial diagnosis had a Gleason score of 8-10 at initial diagnosis, and M1 patients also had a shorter time from diagnosis to castration resistance but longer time from first metastatic diagnosis to study entry, compared with M0 patients (Table 1).
  - Time from diagnosis to castration resistance for the M1 patient group is shown in Figure 1; in 50% of patients, this was less than 18 months.
- As expected, M0 patients had received more prior local therapy (radical prostatectomy or prostate radiotherapy) than M1 patients (Table 1).
  - Among M0 patients, a higher proportion had prostate radiotherapy only compared with radical prostatectomy only, both surgery and radiotherapy to the prostate, or no local therapy (Figure 2).

**Table 1. Patient Characteristics Before Study Entry**

| M-status at initial diagnosis | M0 n = 526 | M1 n = 549 |
|---|---|---|
| At initial diagnosis | | |
| Gleason score 8-10, n (%) | 218 (44.6) | 331 (66.5) |
| Prior to study entry | | |
| Years from diagnosis to CRPC, median (range) | 5.4 (0-20) | 1.5 (0-16) |
| Years from first M diagnosis to study entry, median (range) | 1.3 (0-15) | 2.0 (0-13) |
| Radical prostatectomy, n (%) | 204 (38.8) | 31 (5.6) |
| Prostate radiotherapy, n (%) | 300 (57.0) | 49 (8.9) |

**Figure 1. Time From Initial Diagnosis to Castration Resistance in M1 Patients**

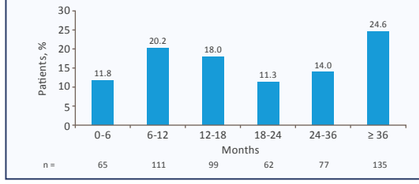
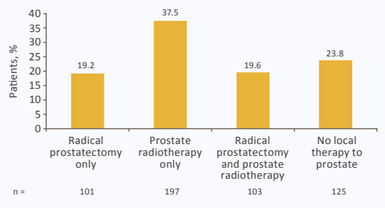



**Figure 2. History of Local Therapy to the Prostate in M0 Patients**




### Patient Characteristics at Study Entry (mCRPC)

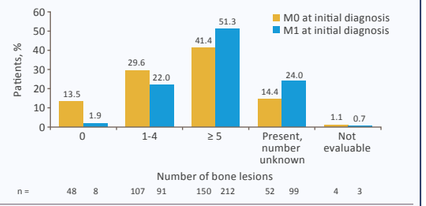
- Compared with M0 patients at initial diagnosis, initial M1 patients were slightly younger, with a lower proportion aged ≥ 75 years at study entry (Table 2).
- M1 patients had slightly worse ECOG PS than M0 patients, with higher proportions with scores of 2 or ≥ 3 (Table 2).
- PSA and alkaline phosphatase levels were higher in the M1 than the M0 group (Table 2).
- At study entry, a higher proportion of patients in the M1 group had ≥ 5 bone metastases (lesions) compared with the M0 group (51.4% vs 41.4%; Figure 3); analgesic use was also higher among M1 patients (Figure 4).

**Table 2. Patient and Disease Characteristics at Study Entry (mCRPC)**

| M-status at initial diagnosis | M0 n = 526 | M1 n = 549 |
|---|---|---|
| Age, years, mean (SD) | 73.6 (7.2) | 70.6 (8.6) |
| ≥ 75 years, n (%) | 241 (45.8) | 187 (34.1) |
| ECOG PS, n (%)[a] | | |
| 0-1 | 436 (87.2) | 426 (83.4) |
| 2 | 51 (10.2) | 71 (13.9) |
| ≥ 3 | 13 (2.6) | 14 (2.7) |
| Biological parameters, median (range) | | |
| Prostate-specific antigen, ng/mL | n = 507<br>45.9 (0-5910) | n = 530<br>61.7 (0-10710) |
| Lactic acid dehydrogenase, U/L | n = 234<br>273.0 (3-3232) | n = 190<br>273.0 (5-2890) |
| Hemoglobin, g/dL | n = 469<br>12.5 (7-17) | n = 480<br>12.5 (7-16) |
| Alkaline phosphatase, U/L | n = 393<br>97.8 (2-2825) | n = 407<br>126.0 (1-3110) |
| Serum testosterone, ng/dL | n = 376<br>0.30 (0.0-58.0) | n = 406<br>0.31 (0.0-51.0) |

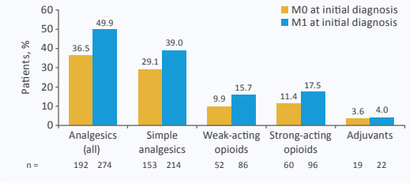
SD, standard deviation.
[a]Some patients not evaluable.

**Figure 3. Number of Bone Lesions at Study Entry (mCRPC)**




Data are % patients with a record of bone lesion assessment at study entry: M0, n = 362; M1, n = 413.

**Figure 4. Analgesic Use at Study Entry**




M0, n = 526; M1, n = 549.

### First Treatments for mCRPC on Study

- A total of 458 (87.1%) M0 and 453 (82.5%) M1 patients initiated 1 or more new treatments for mCRPC. The first documented treatment received on study was:
  - M0 group, n (%): abiraterone 182 (39.7); enzalutamide 84 (18.3); docetaxel 146 (31.9); cabazitaxel 46 (10.0).
  - M1 group, n (%): abiraterone 182 (40.1); enzalutamide 53 (11.7); docetaxel 173 (38.1); cabazitaxel 45 (9.9).

## CONCLUSIONS

- In this real-life cohort of 1323 mCRPC patients, approximately half presented with metastatic disease at initial diagnosis of prostate cancer.
- A higher percentage of patients with M1-status at diagnosis presented with aggressive and extended disease at mCRPC stage.
- M-status at initial diagnosis may be a clinical indicator of future treatment and prognosis in mCRPC, and follow-up of these patients over the course of the study will clarify how these differences and subsequent treatment may affect clinical outcomes.

## REFERENCES


1. Chowdhury S, et al. Poster presented at the 18th ECCO - 40th ESMO European Cancer Congress, 25-29 September 2015, Vienna, Austria. P039.
2. Chowdhury S, et al. Poster presented at the ISPOR 18th Annual European Congress 7-11 November 2015, Milan, Italy. PCN296.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