

Real-World Analysis on Therapeutic Pattern and Economic Burden of Androgen-Receptor Signaling Inhibitors (ARSI) and Taxane-Based Chemotherapy Treated Metastatic Castration-Resistant Prostate Cancer Patients in Italy

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BACKGROUND AND OBJECTIVES

- The treatment of metastatic castration-resistant prostate cancer (mCRPC) has undergone a revolution in the last few years: the fast-growing therapeutic landscape, especially with the advent of new generation hormonal drugs [Sayegh N, et al *JCO Oncol Pract.* 2022;18(1):45-55].
- National guidelines recommend, in addition to ADT, taxane-based chemotherapy, and androgen receptor signalling inhibitors (ARSI), namely abiraterone acetate (with prednisone) and enzalutamide [Linee Guida AIOM 2020 *Carcinoma della Prostata*].
- AIMS:** This real-world analysis investigated the therapeutic patterns and economic burden of mCRPC patients treated with ARSI and taxane-based chemotherapy in Italy.

METHODOLOGY

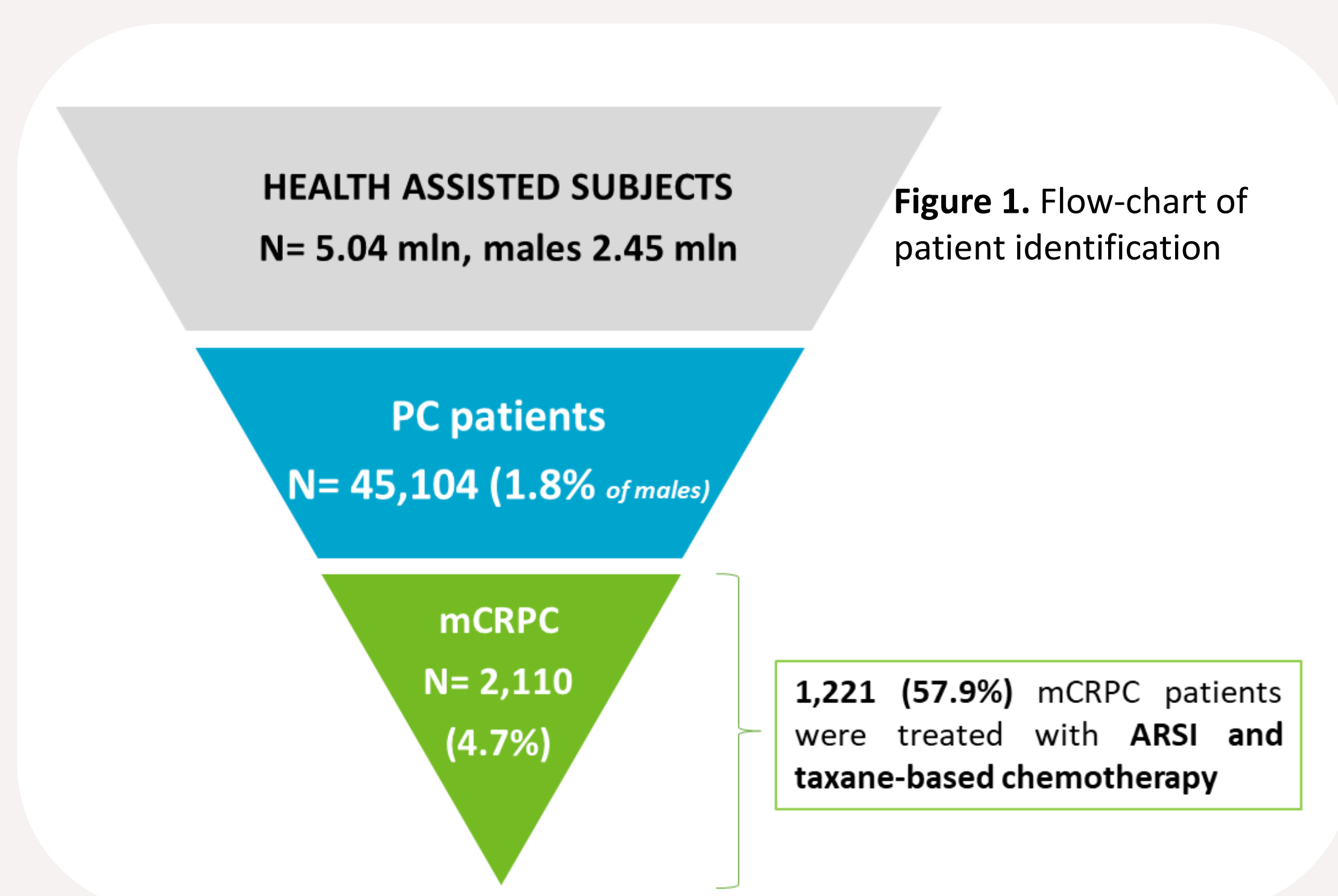


- Italian administrative databases of healthcare entities covering **5 million residents** were retrospectively browsed.
- Across **2010-2021**, PC patients were firstly identified by hospitalization discharge diagnosis ICD-9-CM code 185, or through androgen-deprivation therapy prescription, ATC codes L02AE, L02BB, L02BX, G03HA.
- Among PC patients and during the time-horizon **2015-2020** (inclusion period), **mCRPC were proxied** through treatment with ≥ 1 ARSI [abiraterone (ATC code L02BX03) or enzalutamide (ATC code L02BB04), based on drugs reimbursability criteria for the Italian National Health Service.
- The **index-date** was the date of the first ARSI prescription among the inclusion period.
- The treatment with **taxane-based chemotherapy** [identified and proxied by procedural codes (ICD-9-CM code V58.1, procedures/services codes 99.25, 99.28) and/or the prescription of antineoplastic agents (ATC code L01) including docetaxel (ATC code L01CD02) or cabazitaxel (ATC code L01CD04) were recorded for all patients by considering all available periods, before and after the index-date.

RESULTS

IDENTIFICATION OF STUDY POPULATION

Of **45,104 PC patients** (among 5 million inhabitants), **2,110 on ARSI were identified as mCRPC**: **1,221 had also ≥ 1 record of taxane-based chemotherapy**, 635 (52.0%) before and 586 (48.0%) after ARSI treatment start.



COI DISCLOSURES: Advanced Accelerator Applications (Novartis company) purchased the study report that is the basis for this poster presentation. All authors report no conflicts of interest in this work. The agreement signed by Clicon S.r.l. and Advanced Accelerator Applications does not create any entityship, joint venture or any similar relationship between parties. Clicon S.r.l. is an independent company. Neither Clicon S.r.l. nor any of their representatives are employees of Advanced Accelerator Applications for any purpose.

BASELINE CHARACTERISTICS OF ARSI AND TAXANE-BASED CHEMOTHERAPY-TREATED PATIENTS

Table 1. Baseline demographic and clinical characteristics of patients

ARSI and TAX-treated patients	
N	1,221
Age at index date (inclusion), mean (SD)	73.9 (8.3)
Charlson comorbidity Index, mean (SD)	0.5 (0.7)
- CCI=0 (n, %)	782 (64.0)
- CCI=1 (n, %)	354 (29.0)
- CCI= 2+ (n, %)	85 (7.0)
Patients with at least one record for metastasis	880
Brain metastasis (n, %)	35 (4.0)
Bone metastasis (n, %)	805 (91.5)
Liver metastasis (n, %)	96 (10.9)
Respiratory organs metastasis (n, %)	102 (11.6)
Adrenal gland metastasis (n, %)	5 (0.6)
Peritoneum metastasis (n, %)	21 (2.4)
Lymphnodes metastasis (n, %)	278 (31.6)
Other metastasis (n, %)	58 (6.6)
Follow up, mean (SD)	2.4 (1.6)

In ARSI and taxane-based chemotherapy-treated patients, age averaged **73.9±8.3 years**; The most common metastasis sites were **bones (91.5%) and lymph-nodes (31.6%) (Table 1)**.

METASTASIS: during all available period (characterization and follow-up) it was identified by hospitalization discharge diagnosis ICD-9-CM code 196-198; the following metastatic sites were described: Brain metastasis 198.3x, Bone metastasis 198.5x (and by ATC: M05B08, M05B09)(Degli Esposti et al., GIHTAD (2020) 13-Suppl. 2); Liver metastasis 197.7x, Respiratory organs metastasis 197.0x, 197.1x, 197.2x, 197.3x, Adrenal gland metastasis 198.7x, Peritoneum metastasis 197.6x, Lymphnodes metastasis 196.3x, Other metastasis 197.9x, 198.8x not considered above. CHARLSON COMORBIDITY INDEX (CCI): patients have been characterized based on the Charlson index (comorbidity index), that assigns a score to each concomitant disease (assessed in the 12 months prior index date on drugs treatment and hospitalizations) [Charlson ME et al. A new method of grading prognosis comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987; 40:372-383]

TREATMENT PATTERNS ARSI AND TAXANE-BASED CHEMOTHERAPY-TREATED PATIENTS

In **ARSI and taxane-based chemotherapy-treated patients**, **52% started with taxane-based chemotherapy, 16% with Enzalutamide and 32% with Abiraterone**. The therapeutic pattern involving taxane-based chemotherapy and **only one ARSI was identified in 67% of patients**. Moreover, **33% of patients progressed to a second ARSI during the follow-up**. The most frequent patterns reporting the combination of medications are reported in **Figure 2**. In red are highlighted the most frequent patterns involving **taxane-based chemotherapy and two ARSI (Figure 2)**.

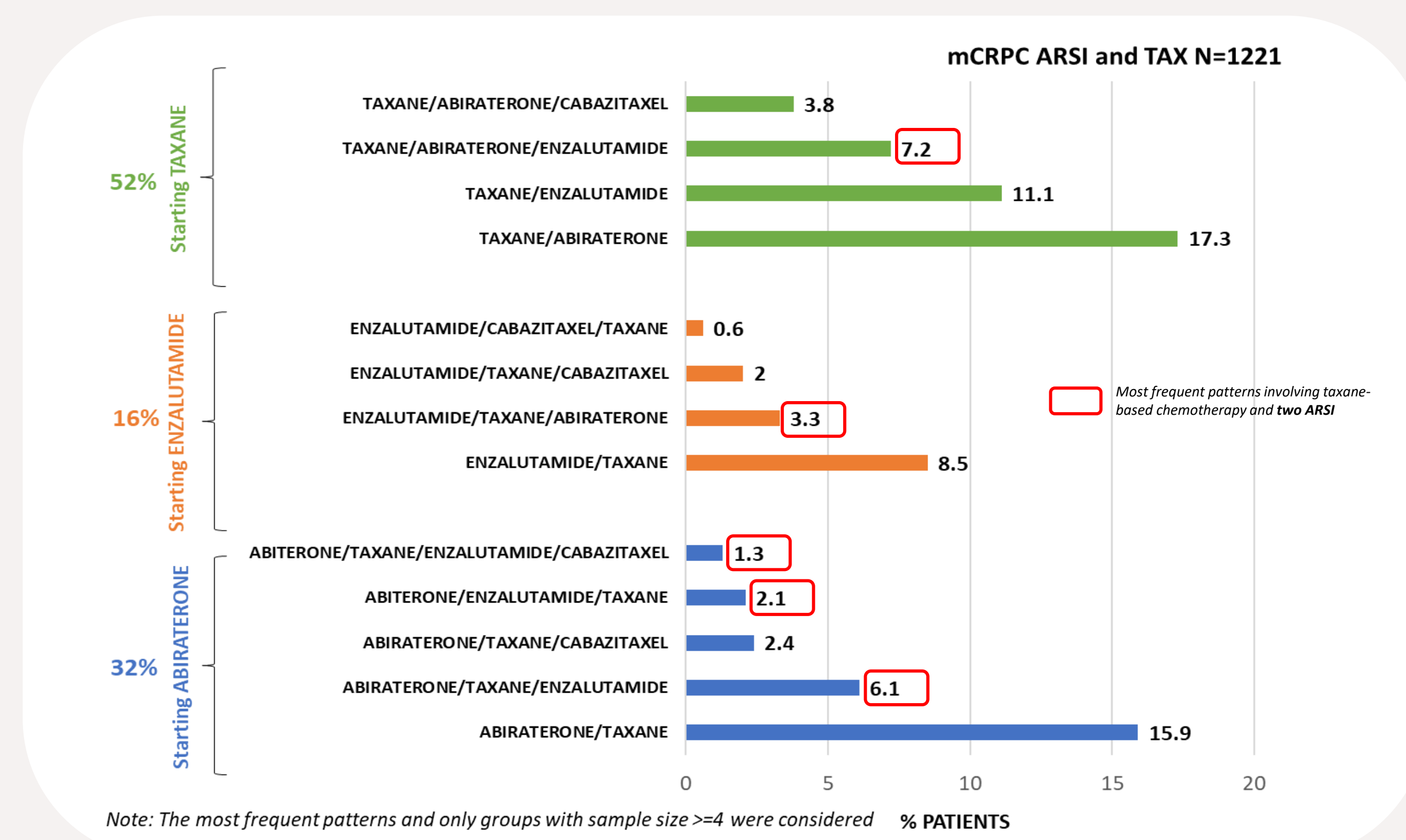


Figure 2. Most frequent treatment pattern (non-repeated pattern) among patients evaluated among all available period

EVALUATION OF HEALTHCARE RESOURCE CONSUMPTION AND DIRECT COSTS

In **ARSI and taxane-based chemotherapy-treated alive patients**, the average healthcare resource consumptions/patient at 1-year follow-up were: **13.0±6.1 drug prescriptions, 24.7±13.8 specialist services and 0.7±1.3 hospitalizations**. These consumptions generated a total healthcare direct cost of **35,522€/patient**, prominently burdened by all-drug expenses (30,192€) (**Figure 3**).

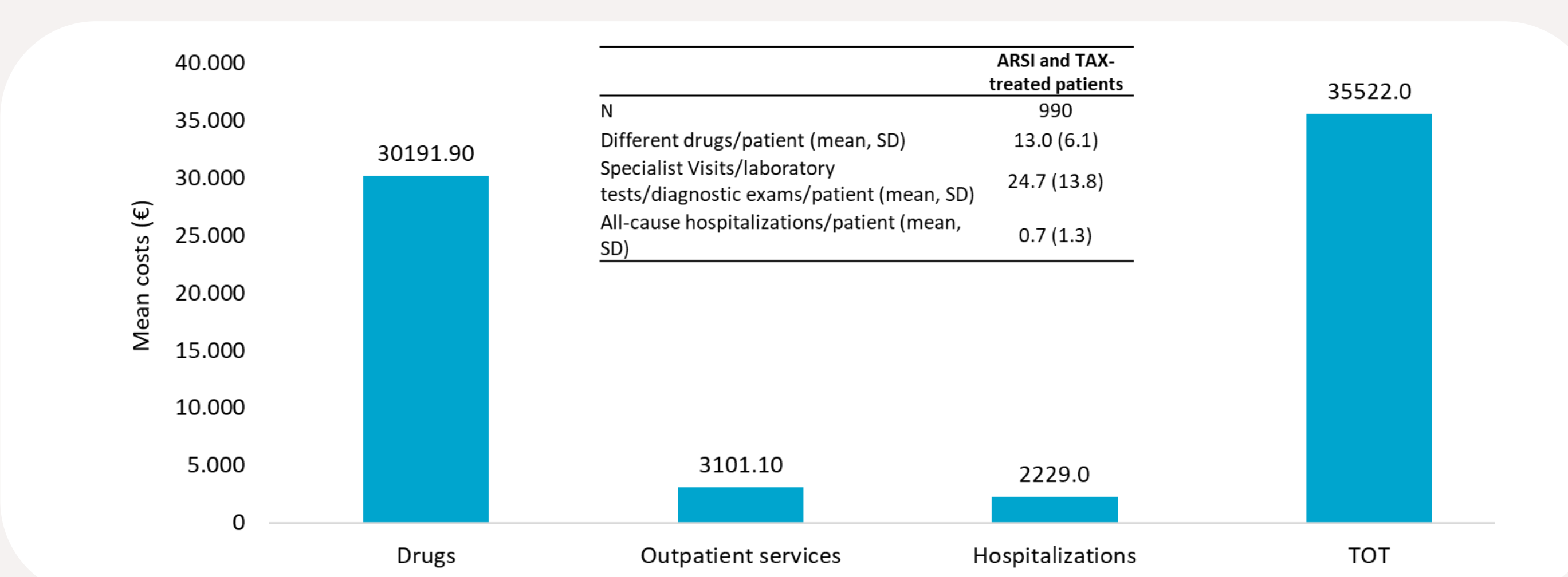


Figure 3 Healthcare resource consumptions and related direct costs estimated during the first year of follow-up

CONCLUSIONS

This analysis reported the therapeutic pattern and the economic impact of mCRPC in an Italian clinical practice setting. Among patients requiring ARSI and taxane-based chemotherapy, about 67% received one ARSI and 33% received a second ARSI during the follow-up (with 9.7% of patients being treated consecutively with 2 different ARSI). These data suggested a possible unmet therapeutic need for patients' management, also in consideration of the recent recommendation by scientific community on possible cross-resistance issues with sequential ARSI treatment. Moreover, the evaluation of economic burden taking into consideration patient' clinical outcomes, should be add to these evidence.