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Weekly cabazitaxel in "unfit" metastatic castration resistant prostate cancer patients (mCRPC) progressing after docetaxel (D) treatment. CABASEM-SOGUG phase II trial

E.M. Fernandez Parra[1], M. Ochoa[2], D. Castellano[15], L. Munielo[3], M.J. Juan[4], B. Perez Valderrama[5], B. Mellado[6], O. Fernandez Calvo[7], U. Anido[8], M. Domenech[9], S. Hernando[10], J.A. Arranz[11], C. Caballero[12], M. Campayo[6], P. Estevez[5], L. Leon[13], M.A. Climent[14]. [1]*Hospital de Valme, Servicio de Oncología Médica, Sevilla, Spain;* [2]*Hospital Duran i Reynals, Servicio de Oncología Médica, Barcelona, Spain;* [3]*Complejo Hospitalario Universitario de Santiago, Laboratorio de Oncología Traslacional, Santiago de Compostela, Spain;* [4]*Fundación Instituto Valenciano de Oncología, Oncología Médica, Valencia, Spain;* [5]*Hospital Universitario Virgen del Rocío, Servicio de Oncología Médica, Sevilla, Spain;* [6]*Hospital Clinic, Servicio de Oncología Médica, Barcelona, Spain;* [7]*Complejo Hospitalario de Ourense, Servicio de Oncología Médica, Ourense, Spain;* [8]*Hospital Clinico Universitario de Santiago, Servicio de Oncología Médica, Santiago de Compostela, Spain;* [9]*Hospital Althaia de Manresa, Servicio de Oncología Médica, Barcelona, Spain;* [10]*Hospital Universitario Fundación de Alcorcón, Servicio de Oncología Médica, Madrid, Spain;* [11]*Hospital General Universitario Gregorio Marañón, Servicio de Oncología Médica, Madrid, Spain;* [12]*Hospital General Universitario de Valencia, Servicio de Oncología Médica, Valencia, Spain;* [13]*Complexo Hospitalario Universitario de Pontevedra, Servicio de Oncología Médica, Pontevedra, Spain;* [14]*Fundación Instituto Valenciano de Oncologia, Oncología Médica, Valencia, Spain;* [15]*Hospital 12 de Octubre, Madrid, Spain*

Background: Cabazitaxel (C), a novel taxane developed to overcome D resistance, showed an overall survival improvement after D in mCRPC in a three-weekly schedule. Its main toxicity is hematological, especially in unfit patients (Pts). We aimed to evaluate efficacy and safety of weekly C/prednisone (P) schedule in "unfit" mCRPC previously treated with D. Possible relation of CTC counts and its early response with efficacy is analyzed.
Methods: Pts with mCRPC progressing after D treatment with adequate bone marrow, liver and kidney functions were included in this open-label non-comparative trial. Unfit pts defined as ECOG 2, dose reduction due to febrile neutropenia during D treatment or radiation therapy affecting more than 25% of bone marrow reserve. C 10 mg/m^2 was administered on days 1, 8, 15 and 22 of 5-week cycles with P (5 mg b.i.d.). Radiological and PSA response were evaluated according to the PCWG2 criteria and toxicity according NCI-CTC AE.
Results: 70 pts have been enrolled and 1 of them is still on treatment. Median age was 73 y (range 54−85), 71% pts had ECOG 2, 81% had bone, 16% liver and 11% lung metastases. Treatment: 302 cycles (median: 3; range: 1−14); 1116 weekly infusions (median 11; range 1−54). Median dose intensity was 89%. Twenty-two of 59 pts (37.3%) achieve ⩾50% PSA response and 7 (11.9%) ⩾80% PSA response. Radiological response was evaluable in 62 pts. PR was observed in 4 pt (6.5%) and SD in 33 pts (53.2%). Median PSA PFS was 6.7 months and 12 weeks PSA PFS was 78.7%. Median OS was 12.6 months. Most frequent toxicities of all grades and grade 3−4 as % of pts were: anemia (68.6–15.7%), asthenia (60.0–15.7%), thrombocytopenia (15.7−8.6%), diarrhea (35.7−1.4%), nauseas (27.1−1.4%), neutropenia (12.9−4.3%), peripheral neuropathy (8.6−0.0%), and anorexia (25.7−2.9%). Neither grade IV diarrhea nor febrile neutropenia were observed.
Sixteen pts had basal CTC <5 cells/7.5mL (A) and 40 ⩾5 cells/7.5mL (B). Ten pts had early CTC response (conversion from B to A at 4 weeks), 1 CTC progression and 29 did not change CTC group. Results show a favorable association between basal CTC and PFS (median 10.5 (A) vs 4.6 (B) months; p = 0.035). Association between basal CTC and OS (median 14.6 (A) vs 10.9 (B) months; p = 0.088) and CTC early response and OS (median 17.9 (responders) vs 12.7 months (non-responders); p = 0.190) did not reached statistical significance.
Conclusions: Weekly cabazitaxel plus P administered to unfit pts seems as effective as 3-weekly standard treatment but with much lesser toxicity. Basal CTC seems to be related with PFS and OS.
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No conflict of interest.

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Abiraterone acetate in metastatic castration-resistant prostate cancer after chemotherapy. A retrospective "Real Life" analysis of activity and safety

M.A. Fabbri[1], E. Cortesi[2], P. Marchetti[3], D. Santini[4], T. Gamucci[5], F. Angelini[6], F. Longo[7], A. Milano[3], M.L. Mancini[2], A. Giuli[7], S. Quadrini[5], I. Sperduti[8], A. Pellegrino[9], R. Ratta[4], F. Primi[1], M.G. Chilelli[1], E.M. Ruggeri[1]. [1]*Ospedale Belcolle, UOC Oncology, Viterbo, Italy;* [2]*Policlinico Umberto I, UOC Oncology B, Rome, Italy;* [3]*Ospedale Sant'Andrea, UOC Oncology, Rome, Italy;* [4]*Campus Biomedico, UOC Oncology, Rome, Italy;* [5]*Ospedale SS Trinità, UOC Oncology, Sora, Italy;* [6]*Regina Apostolorum, UOC Oncology, Albano Laziale, Italy;* [7]*Policlinico Umberto I, UOC Oncology A, Rome, Italy;* [8]*Istituto Regina Elena, Biostatistics Unit, Rome, Italy;* [9]*San Pletro FBF, UOC Oncology, Rome, Italy*

Background: Abiraterone acetate (AA) is a potent, selective androgen (CYP17) biosynthesis inhibitor, which showed to improve overall survival (HR = 0.646) in mCRPC patients progressing after docetaxel. In this retrospective analysis we assessed the safety and efficacy of AA in patients affected with mCRPC progressing after chemotherapy, treated in the normal clinical practice, in several Italian Oncologic Units, after the approval of the drug from the Italian Drug Agency (AIFA).
Material and Methods: We retrospectively reviewed the clinical data of patients affected with mCRCP progressive after chemotherapy who received AA (1000 mg/d) plus prednisone (5 mg/twice daily). Pts were considered eligible if they had received docetaxel as prior chemotherapy. A total of 189 patients were included in the analysis. Main patient characteristics were: median age: 70 years (range 44−89), Gleason score >7: 84%; median PSA at AA start: 35 (range 0.36–2100); duration of prior hormonal therapy <12 vs ⩾12 months: 38 vs 62%; no. of metastatic sites: 1 vs ⩾2: 73 vs 27%; bone only 48%, presence of visceral disease 51%; symptomatic vs non-symptomatic: 53 vs 47%; median number of prior docetaxel courses: 6 (range 1−15); second-line cabazitaxel: 14%. Forty-four percent of patients received bisphosphonates during AA treatment.
Results: AA was well tolerated and no relevant toxicity were observed. After a median follow-up of 8.5 months (range 1−51) the median progression-free survival (PFS) and the median overall survival (OS) were 10 months (95% CI: 7−13) and 26 months (95% CI: 17−35) respectively. No differences in PFS and OS were found based on the response to docetaxel. Patients who received hormonal treatment for ⩾12 months had a statistically significant longer PFS (13 vs 7 months, p = 0.009) and OS (28 vs 17 months, p = 0.03 months). The median decrease in the PSA level >50% was observed in 36% of patients. Patients with only bone metastasis had a PFS of 13 (95% CI: 7.18) and OS 28 months (95% CI:16−40). Twelve patients (6%) presented a scheletal-related event (SRE).
Conclusions: The results achieved in this analysis although retrospective, confirms the activity and safety of AA in these subset of patients.
No conflict of interest.

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Real-world treatment with abiraterone acetate in metastatic castration-resistant prostate cancer (mCRPC) patients in the post-chemotherapy setting in Europe

L. Dearden[1], P. Musingarimi[1], N. Shalet[1], D. Demuth[2], L. Garcia Alvarez[2], A. Muthutantri[2], A. Venerus[2], R. Lasry[2], M. Hankins[2], T. Maher[3]. [1]*Janssen, EMEA HEMAR, High Wycombe, United Kingdom;* [2]*IMS Health, Real World Evidence Solutions, London, United Kingdom;* [3]*Janssen, Medical Affairs, High Wycombe, United Kingdom*

Background: In the COU-AA-301 trial, abiraterone acetate plus low dose prednisone (AA) was found to extend survival in metastatic castrate resistant prostate cancer (mCRPC) patients progressing after docetaxel chemotherapy compared to placebo plus low dose prednisone. However, limited data related to AA treatment and outcomes is available in the real-world. The primary objective of this study was to evaluate treatment duration associated with AA treatment in routine clinical practice in mCRPC patients in the post-chemotherapy setting across four European countries: Belgium, France, Germany and the Netherlands. Other clinical data such as treatment sequencing and survival were assessed to place the treatment duration into context.
Material and Methods: The study was designed as a retrospective chart review. Patients were identified through treating oncologists and urologists registered in the IMS Health Medical Radar physician database. Eligible mCRPC patients were aged ⩾18 years at AA initiation (i.e. baseline), previously treated with docetaxel and naïve to prior AA treatment. Baseline patient characteristics were described using summary statistics. Kaplan–