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P035

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

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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 routinary clinical practice, in several Italian Oncologic Units, after the approval of the drug from the Italian Drug Agency (AIFA).

Methods

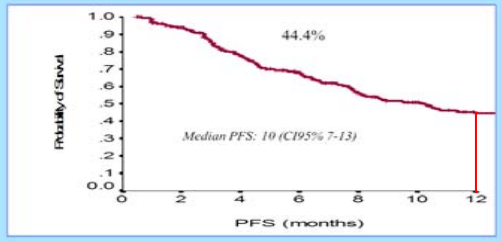
We retrospectively reviewed the clinical data of patients affected with mCRCP progressive after chemotherapy who received AA (1000 mg/d) plus prednisone (5 mg/twice daily). Pts were considered eligible if they had received prior docetaxel. A total of 189 patients were included in the analysis. Main patient 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%, bone and 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.

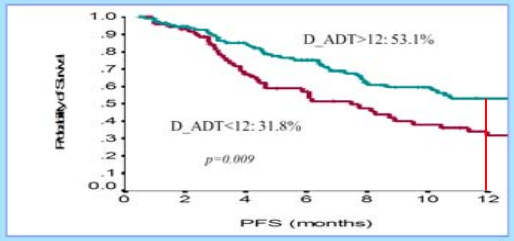
Table 1 Characteristics of patients

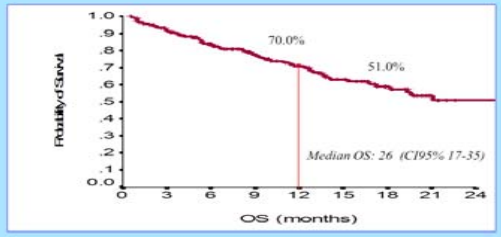
Number of patients	N=189
Median age	70 (range 44-89)
Gleason score ≥ 7	84%
mPSA at AA start	35 (range 0,36-2100)
Duration of prior hormonal therapy < 12 months ≥12 months	 38% 62%
No. of metastatic sites <2 ≥3	 73% 27%
Sites of metastatic disease : Bone only Bone and visceral disease	 48% 51%
Symptomatic No Symptomatic	53% 47%
Median number of prior docetaxel courses	6 (range 1-15)
Second_line Cabazitaxel	14%

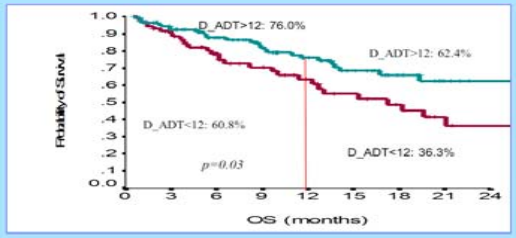
Results

AA was well tolerated and no relevant toxicity was 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).









Conclusion

The results achieved in this analysis although retrospective, confirms the activity and safety of AA in these subset of patients.