Prospective evaluation of the response to prednisone-dexamethasone switch in castration-resistant prostate cancer patients treated with abiraterone pre- and post-docetaxel.

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Background: Abiraterone acetate (AA) administered with prednisone (P) to reduce mineralocorticoid-related adverse events improves survival in CRPC with a favourable tolerance profile. However, in the phase I/II of AA without steroids, dexamethasone 0,5mg/day was added after biochemical progression reaching a 25% of PSA decline. Lorente et al (BJC, 2014) showed durable biochemical responses in 40% of cases treated with AA and steroid switch in the post-docetaxel setting. We hypothesize that P to D switch in patients with biochemical progression to AA+P would lead to secondary responses also in the pre-docetaxel setting. **Methods:** Change of P 5mg/12h to D 0.5mg/24h was prospectively tested in clinically stable CRPC with biochemical progression (> 25% PSA rise over nadir, confirmed in a second determination) and/or limited radiological progression (< 3 new bone/lymphatic metastasis, non-bulky), after ³12 weeks of AA+P. PSA was monitored q4wks. CT- & bone-scans were performed every 12-16 weeks. Biochemical and radiological responses were evaluated by PSAWG2 and RECIST criteria. Survival outcomes were calculated using Kaplan-Meier method. **Results:** 18 patients were included (11 pre- & 7 post-docetaxel). Median age 72 (60-85); visceral, bone and/or lymph metastasis were present in 17%, 83% and 50% of patients. Median PSA at AA+P and AA+D commencement was 81 ng/ml and 100ng/ml, respectively. Biochemical response was observed in 83% of patients: 56% with a PSA decrease ≥ 30%, and 28% with PSA decrease ≥ 50%. Median biochemical progression-free survival (bPFS) with AA+P was 5.7 months (CI95% 2.9-9.1) and 3.8m (CI95% 1.4-6.5) in the pre- and post-docetaxel setting, respectively. Median bPFS with AA+D was 5.4m (1.2-8.8) and 2.5 (CI95% 1.1-2.9) in the pre- and post-docetaxel settings. Two radiological partial responses were observed with AA+D. **Conclusions:** Clinically stable patients with

limited disease progression after AA+P may benefit from steroid switch in both the pre- and post-docetaxel settings.
