P085 Rash in patients treated with apalutamide in different prostate cancer settings. A real world study

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Introduction & Objectives: Apalutamide is an oral androgen receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. Currently, its approved indications are for non metastatic castration resistant prostate cancer (NM-CRPC) (clinical trial SPARTAN) and metastatic hormone-sensitive prostate cancer (M-HSPC) (clinical trial TITAN). Rash is a common adverse event of this drug. Characteristically, it is an itchy maculo-papular rash. The overall incidence of skin rash in the apalutamide groupin SPARTAN was 23.8% (5.2% grade≥3) and in TITAN 6.5% (2.7% grade ≥3). The rash can be treated with antihistamines, topical or systemic corticosteroids, with/without apalutamide dose interruptions/reductions.

Materials & Methods: 38 patients treated with Apalutamide were analyzed. 11 of them were NM-CRPC and 27 M-HSPC. We analyzed the PSA response to Apalutamide and Rash toxicity.

Results: Patients and prostate cancer features can be seen in table 1.

	NM-CRPC	M-HSPC
Age (X, SD)	75.08 (8.37)	71.99 (6.64)
PSA before apalutamide (Me, IQR)	3.71 (6.48)	7.61 (22.91)
PSA nadir with apalutamide (Me, IQR)	0.22 (0.87)	0.06 (0.31)
Time with apalutamide (X, SD)	10.44 (6.43)	6.81(4.26)
Progression to APA	0 (0%)	1 (3,7%)

X=average; SD=standard deviation
Me=median;IQR=interquartilic range.

Rash risk with apalutamide and its impact on prostate cancer treatment is summarized in table 2.

	NM-CRPC	mHSPC	P value
Nº patients with rash	1 (9.1%)	10 (37%)	0.085

high grade rash (>=3). Nº (%)	0 (0%)	4 (14.8%)	0.177
Median time from apalutamide onset to rash (Me, IQR)	6.33	3.59 (60.86)	0.53
Dose reduction due to Rash. Nº (%)	0 (0%)	3 (11.11%)	0.25
Suspension due to rash. Nº (%)	0 (0%)	3 (11.11%)	0.25

1 patient with NM-CRPC (9.1%) developed rash whereas 10 patients with HSPC (37%) developed rash; p value approached statistically signification (p=0.085). No association between rash and PSA response to apalutamide was found: Median PSA nadir with apalutamide in patients who developed rash was 0.02 (IQR 0.88) whereas in patients that did not develop this complication it was 0.145 (IQR 0.38) (p=0.24). Median PSA difference after apalutamide in patients who developed rash was 8 (IQR 24.67) whereas in patients that did not develop this complication it was 4.72 (IQR 24.67) (p= 0.72).

Conclusions: Our experience shows that rash was more frequent and more severe in patients with M-HSPC, compared to NM-CRPC. However, in the SPARTAN study more rash was described compared to TITAN study, although the proportion of high grade was higher in the TITAN study.