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Primary resistance to abiraterone acetate (AA) after docetaxel treatment in metastatic castration-resistant prostate cancer (mCRPC): A multicenter retrospective analysis.

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Background: AA improves survival in mCRPC patients pre-treated with docetaxel. All patients eventually become resistant at different interval times, but some of them show an early progression and should be considered as primary resistant (PRES). To date, no factors have been identified as predictive of primary resistance. **Methods:** The clinical outcomes of a consecutive series of patients treated with AA after docetaxel failure in 19 Italian Hospitals within a Named Patient Program (NPP) was previously reported (BJU 2014). In the present analysis, we focus on patients who achieved an investigator-assessed PFS \leq 3 months (PRES) and those with PFS \geq 12 months (long term responders, LR). The main aim is to determine clinical characteristics

associated with primary resistance. **Results:** Among the 265 patients enrolled in the NPP, we identified 97 PRES (37%) and 71 LP (27%). Poor performance status, visceral metastases, presence of pain, low baseline haemoglobin level, increased LDH and ALP levels, and short time from diagnosis to AA therapy were significantly associated with early progression (Table).

Conclusions: Several clinical parameters appear to correlate with early progression under AA. Their role as potential predictive factors of resistance deserve further exploration in order to develop alternative treatment strategies.

	PFS ≤ 3 months (PRES)	PFS ≥ 12 months (LR)	p value
Median age (range)	72 (52-88)	74 (56-85)	0.75
Visceral disease location	25 (25.8%)	8 (11.3%)	0.03
Presence of pain	53 (54.6%)	23 (32.4%)	0.005
Performance status	76 (80.9%)	65 (94.2%)	0.019
0-1	18 (19.1%)	4 (5.8%)	
2	3	2	
Unknown			
Median PSA levels (range)	89.1 (0.3->100,00)	37.9 (0.5-1,716)	0.139
Gleason score at diagnosis	31 (36.5%)	24 (39.3%)	0.733
≤7	54 (63.5%)	37 (60.7%)	
≥8	12	10	
Unknown			
Median baseline Hb levels (range)	12 (7-16)	12.6 (9-16)	0.0001
Median baseline ALP levels (range)	117 (14-5,492)	99 (35-1,086)	0.045
Median baseline LHD levels (range)	333 (-2,751)	284 (73-731)	0.001
Median interval from diagnosis to CRPC (months, range)	53 (1-230)	66 (11-179)	0.086
Median interval from diagnosis to AA (months, range)	39 (1-179)	49 (5-179)	0.001

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