

Real-World Safety and Efficacy Outcomes with Abiraterone Acetate Plus Prednisone or Prednisolone as the First- or Second-Line Treatment for Metastatic Castration-Resistant Prostate Cancer: Data from the Prostate Cancer Registry

Anders Bjartell · Nicolaas Lumen · Pablo Maroto · Thomas Paiss · Francisco Gomez Veiga · Alison Birtle · Gero Kramer · Ewa Kalinka · Dominique Spaëth · Susan Feyerabend · Vsevolod Matveev · Florence Lefresne · Martin Lukac · Robert Wapenaar · Luis Costa · Simon Chowdhury

Corresponding author:

Anders Bjartell MD PhD FEBU
Professor in Urology, Dept of Translational Medicine, Medical Faculty, Lund University
Senior Consultant, Dept of Urology, Skåne University Hospital
Jan Waldenströms gata 5, SE 205 02 Malmö, Sweden
E-mail: anders.bjartell@med.lu.se

Supplementary figure

Fig. S1 Study flow.

mCRPC, metastatic castration-resistant prostate cancer.

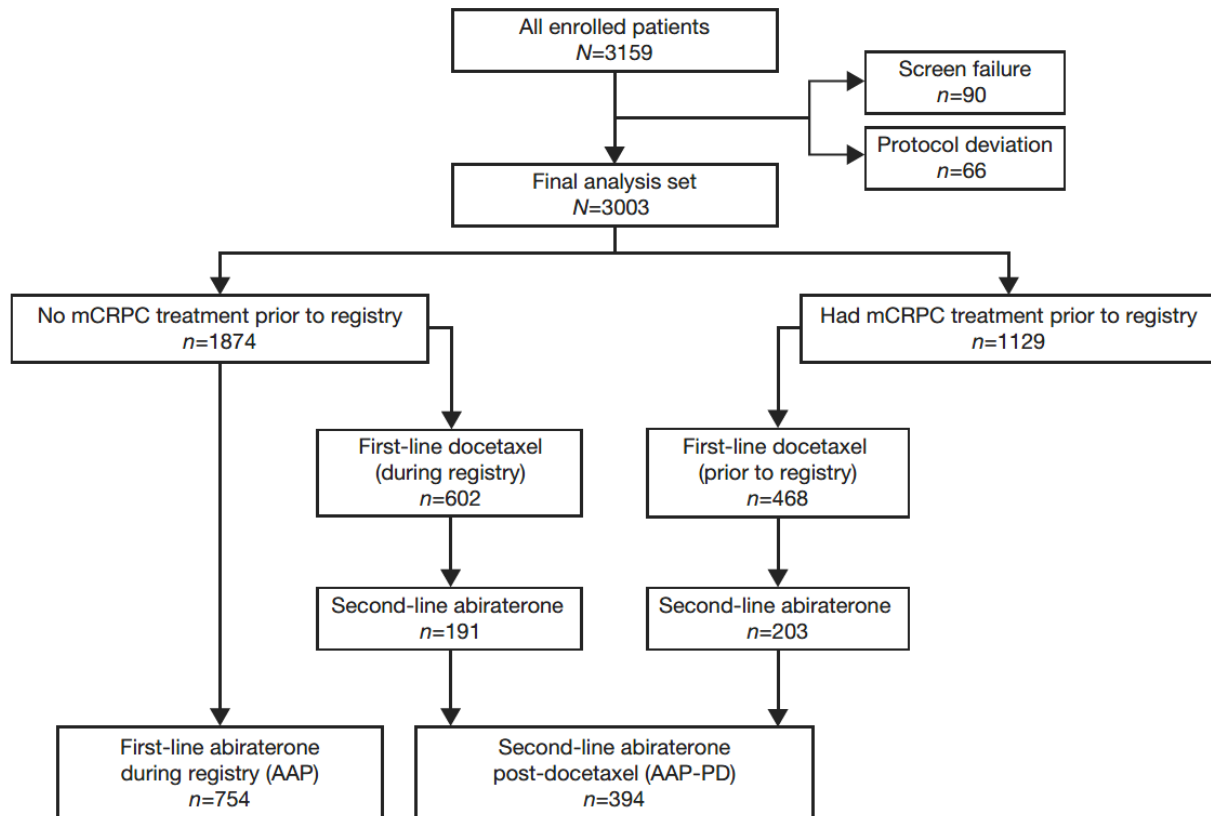


Table S1 Treatment-emergent adverse events of special interest

	AAP		AAP-PD	
	All patients (N=754)	Patients with CV comorbidities (n=504)	All patients (N=394)	Patients with CV comorbidities (n=234)
Number of patients with at least one TEAE, n (%)	487 (64.6)	338 (67.1)	222 (56.3)	132 (56.4)
<i>Preferred term, n (%)</i>				
Vascular disorders	69 (9.2)	42 (8.3)	26 (6.6)	18 (7.7)
Hypertension	24 (3.2)	12 (2.4)	5 (1.3)	3 (1.3)
Hot flush	20 (2.7)	14 (2.8)	9 (2.3)	4 (1.7)
Hypotension	6 (0.8)	3 (0.6)	2 (0.5)	1 (0.4)
Intermittent claudication	-	-	2 (0.5)	2 (0.9)
Hematoma	5 (0.7)	3 (0.6)	-	-
Lymphoedema	5 (0.7)	1 (0.2)	1 (0.3)	1 (0.4)
Deep vein thrombosis	2 (0.3)	2 (0.4)	1 (0.3)	1 (0.4)
Hypertensive crisis	2 (0.3)	-	-	-
Orthostatic hypotension	2 (0.3)	2 (0.4)	1 (0.3)	1 (0.4)
Peripheral arterial occlusive disease	-	-	1 (0.3)	1 (0.4)
Peripheral artery stenosis	-	-	1 (0.3)	-
Phlebitis	2 (0.3)	1 (0.2)	1 (0.3)	-
Thrombophlebitis	-	-	1 (0.3)	-
Aortic stenosis	1 (0.1)	1 (0.2)	-	-
Capillary fragility	1 (0.1)	1 (0.2)	-	-
Circulatory collapse	1 (0.1)	1 (0.2)	-	-
Flushing	1 (0.1)	1 (0.2)	-	-
Pallor	1 (0.1)	1 (0.2)	-	-
Peripheral coldness	1 (0.1)	1 (0.2)	-	-
Subclavian vein thrombosis	1 (0.1)	-	-	-
Superior vena cava stenosis	1 (0.1)	-	-	-
Thrombosis	1 (0.1)	-	2 (0.5)	2 (0.9)
Aortic aneurism	-	-	1 (0.3)	1 (0.4)

Arterial disorder	-	-	1 (0.3)	1 (0.4)
Capillary leak syndrome	-	-	1 (0.3)	1 (0.4)
Varicose vein	1 (0.1)	-	-	-
Vasculitis	1 (0.1)	-	-	-
Venous thrombosis	1 (0.1)	-	-	-
Cardiac disorders	55 (7.3)	39 (7.7)	16 (4.1)	9 (3.8)
Cardiac failure	12 (1.6)	11 (2.2)	4 (1.0)	3 (1.3)
Atrial fibrillation	11 (1.5)	8 (1.6)	3 (0.8)	3 (1.3)
Myocardial infarction	7 (0.9)	6 (1.2)	2 (0.5)	2 (0.9)
Angina pectoris	6 (0.8)	5 (1.0)	1 (0.3)	-
Myocardial ischemia	3 (0.4)	1 (0.2)	-	-
Cardiac failure congestive	2 (0.3)	2 (0.4)	1 (0.3)	-
Palpitations	2 (0.3)	-	-	-
Tachycardia	2 (0.3)	-	1 (0.3)	-
Acute coronary syndrome	1 (0.1)	-	-	-
Acute myocardial infarction	1 (0.1)	1 (0.2)	1 (0.3)	1 (0.4)
Angina unstable	1 (0.1)	1 (0.2)	1 (0.3)	-
Aortic valve sclerosis	-	-	1 (0.3)	-
Aortic valve stenosis	1 (0.1)	1 (0.2)	1 (0.3)	-
Arrhythmia	1 (0.1)	-	1 (0.3)	1 (0.4)
Atrioventricular block first degree	-	-	1 (0.3)	-
Atrial flutter	1 (0.1)	-	-	-
Bradycardia	1 (0.1)	1 (0.2)	-	-
Cardiac arrest	1 (0.1)	-	-	-
Cardiac disorder	1 (0.1)	-	-	-
Cardiac failure chronic	1 (0.1)	1 (0.2)	-	-
Cardiopulmonary failure	1 (0.1)	1 (0.2)	-	-
Cardiotoxicity	1 (0.1)	1 (0.2)	-	-
Coronary artery disease	1 (0.1)	-	-	-
Coronary artery stenosis	1 (0.1)	1 (0.2)	-	-
Left ventricular failure	1 (0.1)	1 (0.2)	-	-
Supraventricular tachycardia	1 (0.1)	1 (0.2)	-	-
Metabolism and nutrition disorders	59 (7.8)	42 (8.3)	19 (4.8)	11 (4.7)

Decreased appetite	16 (2.1)	10 (2.0)	8 (2.0)	7 (3.0)
Hypokalemia	16 (2.1)	12 (2.4)	3 (0.8)	2 (0.9)
Hyperglycemia	11 (1.5)	8 (1.6)	1 (0.3)	-
Hypocalcemia	10 (1.3)	6 (1.2)	-	-
Hyperkalemia	5 (0.7)	3 (0.6)	-	-
Diabetes mellitus	4 (0.5)	3 (0.6)	-	-
Hypertriglyceridemia	3 (0.4)	2 (0.4)	-	-
Hyponatremia	3 (0.4)	3 (0.6)	-	-
Dehydration	2 (0.3)	2 (0.4)	1 (0.3)	1 (0.4)
Folate deficiency	-	-	1 (0.3)	-
Hypoalbuminemia	2 (0.3)	-	1 (0.3)	1 (0.4)
Hypomagnesemia	-	-	2 (0.5)	1 (0.4)
Cachexia	1 (0.1)	-	1 (0.3)	1 (0.4)
Diabetes mellitus inadequate control	1 (0.1)	2 (0.4)	1 (0.3)	-
Diabetic metabolic decompensation	1 (0.1)	1 (0.2)	1 (0.3)	-
Dyslipidemia	1 (0.1)	1 (0.2)	1 (0.3)	-
Hypercalcemia	1 (0.1)	1 (0.2)	1 (0.3)	-
Hypoproteinemia	1 (0.1)	1 (0.2)	-	-
Increased appetite	1 (0.1)	1 (0.2)	-	-
Vitamin B12 deficiency	1 (0.1)	1 (0.2)	-	-
Vitamin D deficiency	1 (0.1)	1 (0.2)	1 (0.3)	-

AAP abiraterone acetate plus prednisone/prednisolone; *AAP-PD* AAP after docetaxel; *CV* cardiovascular; *TEAE* treatment-emergent adverse event.

Table S2 Treatment-emergent serious adverse events with occurrence in > 1% of patients who received AAP

	AAP
Number of patients exposed	1490
Number of patients with at least one TESAE, <i>n</i> (%)	496 (33.3)
<i>System-organ class/preferred term, n (%)</i>	
General disorders and administration site conditions	177 (11.9)
Disease progression	55 (3.7)
General physical health deterioration	53 (3.6)
Death	28 (1.9)
Vascular disorders	19 (1.3)
Infections and infestations	106 (7.1)
Urinary tract infection	24 (1.6)
Pneumonia	22 (1.5)
Renal and urinary disorders	63 (4.2)
Hematuria	25 (1.7)
Cardiac disorders	58 (3.9)
Cardiac failure	15 (1.0)
Musculoskeletal and connective tissue disorders	48 (3.2)
Back pain	16 (1.1)
Gastrointestinal disorders	47 (3.2)
Injury, poisoning and procedural complications	37 (2.5)
Respiratory, thoracic and mediastinal disorders	37 (2.5)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	36 (2.4)
Nervous system disorders	36 (2.4)
Blood and lymphatic system disorders	33 (2.2)
Anemia	26 (1.7)

AAP abiraterone acetate plus prednisone/prednisolone, TESAE treatment-emergent serious adverse event.