

Prospective, non-interventional study on the influence of adherence measures on abiraterone therapy of patients with metastatic, castration-resistant prostate carcinoma (IMPACT)

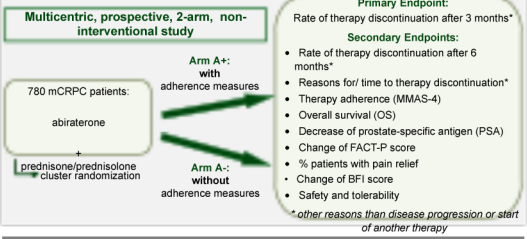
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Abstract: P081 ¹Urologikum Hamburg, Hamburg, Germany; ²Studienpraxis Urologie, Nürtingen, Germany; ³3 MVZ-DGU - Die GesundheitsUnion GmbH, Wuppertal, Germany; ⁴Germany; ⁵Results (2nd interim analysis and additional BFI evaluation)

Introduction
 Abiraterone is an oral androgen biosynthesis inhibitor approved for patients with metastatic castration resistant prostate carcinoma. It has to be taken in combination with prednisone/prednisolone.
 Abiraterone has demonstrated efficacy, including significant improvement in pain relief, fatigue as well as PFS and overall survival [1, 2, 3], with only mild to moderate adverse drug reactions [4].
 Adherence: the extent to which a person's behavior corresponds with agreed recommendations from a health care provider (WHO)
 Problem of oral anti-cancer therapy: adherence steadily decreases over time although it is important for a long term success.

Objective and Study Design

Evaluate the influence of adherence measures on abiraterone therapy of mCRPC patients under routine conditions in comparison to a group without adherence measures.



Methods

- Primary endpoint of the study was the rate of therapy discontinuation due to other reasons than disease progression or start of another therapy
- Adherence measures of Janssen and IFOM: educational video, diary, dose card and a telephone reminder service
- The patient reported adherence was assessed by using the Morisky Medication Adherence Scale (MMAS-4)
- PSA values were evaluated.
- Data on the Functional Assessment of Prostate Cancer Therapy (FACT-P) was assessed.
- Data on the Brief Fatigue Inventory (BFI) questions was assessed as additional evaluation (implemented per Amendment 2, September 2015).
- The minimal important differences (MID) of BFI were calculated for the whole patient population and for pre- and post-chemo patients.
- Correlation between BFI and FACT-P was examined.
- Statistical analysis was done by means of descriptive and exploratory statistical methods.

Results (2nd interim analysis)

The intent-to-treat analysis set of the 2nd interim analysis (cutoff date: 17th June 2015) comprised 277 patients, with 150 patients assigned to arm A+ (54.2%) and 127 patients assigned to arm A- (45.8%).

Rate of therapy discontinuation

Month 3					Month 6						
A+	A-	A+	A-	A+	A+	A-	A+	A-	A+		
ITT		pre-chemo		post-chemo		ITT		pre-chemo		post-chemo	
n=150	n=127	n=108	n=91	n=42	n=36	n=150	n=127	n=108	n=91	n=42	n=36

Adherence measures had no impact on permanent therapy discontinuation.
 Therapy discontinuation rates were low, and comparable for pre- and post-chemo patients.

Morisky Medication Adherence Scale (MMAS-4)

A+	A-	A+	A-	A+	A-
ITT		pre-chemo		post-chemo	
n=150	n=127	n=150	n=127	n=150	n=127

Adherence measures seem to support therapy adherence as reported by patients (PRO).

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Prostate-specific antigen (PSA)

	A+		A-	
	mean (SD)	median	mean (SD)	median
Baseline	204.9 (±312.1)	65.2	232.1 (±518.2)	61.4
Month 3	108.4 (±271.9)	17.5	256.5 (±801.5)	13.0
Month 6	138.0 (±380.0)	17.6	112.1 (±467.5)	8.9

PSA values decreased over time.
 were comparable for both study arms.

Functional Assessment of Prostate Cancer Therapy (FACT-P)

- 5 categories: physical, social, emotional, functional and additional
- FACT-P results were comparable for both study arms
- Overall, FACT-P results slightly improved over time (higher quality of life).

Brief Fatigue Inventory (BFI)

- Additional evaluation
- The BFI patient collective differed from the ITT set and contained 188 patients.
- 3 questions about fatigue intensity and 6 questions about fatigue interference.

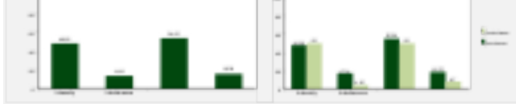
BFI (mean and SD)

	Intensity (n = 85)	Interference (n = 87)	Total (n = 87)
Baseline	3.73 (±2.92)	2.20 (±2.16)	2.40 (±2.07)
Month 3	3.25 (±2.74)	1.96 (±2.08)	2.15 (±1.98)
Difference	-0.48 (-±2.30)	-0.24 (-±1.83)	-0.25 (-±1.69)

Analysis of BFI was not done for the two study arms due to low number of total cases at the time of evaluation.
 Baseline BFI values were not very high

BFI - Minimal Important Difference:

Intensity
 Improvement = Baseline value ≥ 5 points and after 3 months ↓ ≥ 2 points
 Progression = Baseline value present and after 3 months ↑ ≥ 2 points
 Interference
 Improvement = Baseline value ≥ 5 points and after 3 months ↓ ≥ 1.25 points
 Progression = Baseline value present and after 3 months ↑ ≥ 1.25 points



- Fatigue-Intensity/Interference improvement was visible after 3 months
- Pre-chemo patients showed higher progression than post-chemo patients.

Month3: Fatigue (BFI) vs. Quality of Life (FACT-P)

Correlation of BFI and FACT-P: the lower the BFI (fatigue), the higher the FACT-P (quality of life)
 Pearson Correlation: -0.70

Conclusions

- Abiraterone Therapy:**
 - Low therapy discontinuation rates after 3 and 6 months
 - Improvement of PSA values
 - Improvement of quality of life (FACT-P)
 - Improvement of fatigue (BFI, intensity and interference)
 - Improvement of fatigue (BFI) correlates with an improvement of quality of life (FACT-P).
- Adherence measures:**
 - Adherence program seems to have no impact on discontinuation rates
 - Adherence program seems to improve the patient-reported adherence (MMAS-4).

Acknowledgement

Many thanks to all study centers and individuals participating in this study.

References

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