Factors influencing quality of life in men with metastatic, castration-resistant prostate cancer treated with abiraterone acetate plus prednisone: a real-world prospective cohort study (IMPACT)

Poster No. 19

S. Feyerabend[1], H. Suttmann[2], J. Gleissner[3], A. Huebner[4], T. Mathes[5], W. Baurecht[6], K. Krützfeldt[7], and H. Sweiti[7]

[1]Studienpraxis Urologie, Nürtingen, Germany; [2]Urologikum Hamburg, Hamburg, Germany; [3] MVZ-DGU - Die GesundheitsUnion GmbH, Wuppertal, Germany; [4]Center for Oncology and Urology, Rostock, Germany; [5]Institut für Forschung in der Operativen Medizin (Universität Witten/Herdecke), Cologne, Germany; [6]acromion GmbH, Frechen, Germany; [7]Janssen-Cilag, Neuss, Germany

BACKGROUND

- **Abiraterone acetate (AA):**
  Abiraterone is an oral androgen biosynthesis inhibitor approved for patients with metastatic castration resistant prostate carcinoma (mCRPC). It has to be taken in combination with prednisone/ prednisolone (P).
- **In randomized controlled trials, AA+P showed**
  - efficacy [1, 2, 3]
  - improvement in quality of life (QoL) [2],
  - mostly mild to moderate adverse drug reactions [4].
- **Real-world data** on factors that may influence QoL in mCRPC patients is **limited**.

METHODS

- **Patient population:** mCRPC, 1) being progressive despite chemotherapy with Docetaxel or 2) being asymptomatic/mildly symptomatic progressive after failure of androgen deprivation
- **Adherence measures:** educational video, diary, dose card, and a telephone reminder service
- **Multivariate analysis of covariance** to assess the influence of study group, prior chemotherapy, age, concomitant medication, Charlson Score, alcohol consumption, cohabitation, school qualification/ vocational training, and self-reported adherence on change in QoL after 3 and 6 months of treatment (analysis of overall patients with FACT-P at baseline))
- **Prostate Cancer-specific Functional Assessment of Cancer Therapy (FACT-P):**
  - 5 categories: physical, social, emotional, functional, additional
  - 39 questions to be answered with 0 to 4
  - Score ranges from 0 (no QoL) to 156 (high QoL)

STUDY DESIGN AND POSTER OBJECTIVE

Multicentric, prospective, cluster-randomized, 2-arm, observational study

780 mCRPC patients:
AA+P treatment

cluster randomization (ratio 1:1)

- **with** adherence measures **Arm A** (n = 390)
- **Arm B** (n = 390) **without** adherence measures

Objective:
Assessment of factors that may influence QoL in men with mCRPC treated with AA+P under real-world conditions

BASELINE CHARACTERISTICS (n = 675)

Age (mean ± SD)	74.7 (7.7)
Living alone, n (%)	89 (13.2%)
High education, n (%)	159 (23.6%)
Alcohol consumption, n (%)	172 (25.5%)
Post-chemotherapy, n (%)	203 (30.1%)
High Morisky Medication Adherence Scale*, n (%)	523 (77.5%)
Charlson Score** 0, n (%)	243 (36.0%)

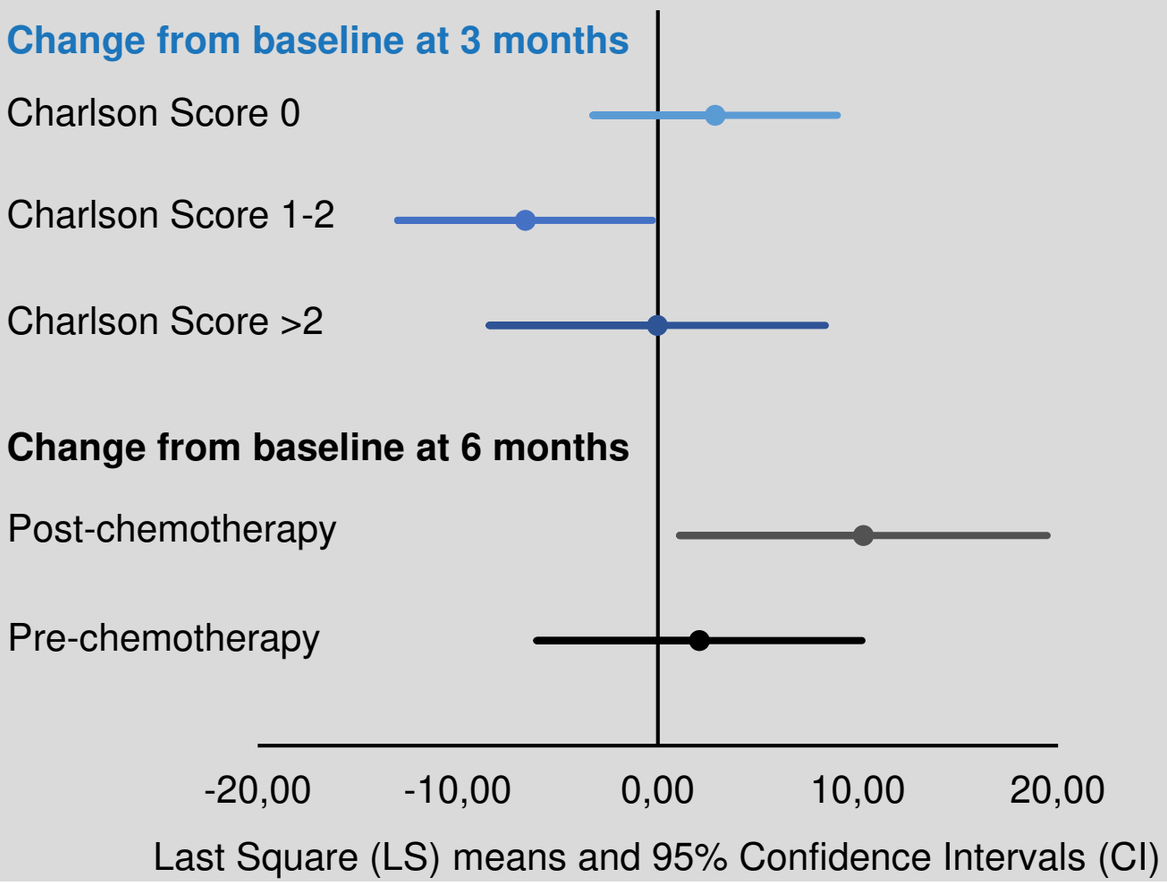
***MMAS-4:** questionnaire to assess patient-reported adherence; ****Charlson Score:** predicts the mortality for a patient with comorbidities (in total 22 conditions)

n: number of patients, SD: standard deviation

RESULTS: FACT-P TOTAL SCORE

- The mean change from baseline (MCB) of the FACT-P total score showed a slight increase in QoL after 3 months (n=428, MCB=3.5±16.8) and 6 months (n=339, MCB=3.6 ± 20.0).

Multivariate analysis of covariance of change from baseline at specified time:



Comparison	N	Diff. betw. LS means	95% CI	p-value
Charlson Score 0 vs. 1-2	68, 70	9.50	(3.65, 15.35)	0.0016
Charlson Score 0 vs. >2	68, 29	2.90	(-4.65, 10.45)	0.4493
Charlson Score 1-2 vs. >2	70, 29	-6.60	(-13.83, 0.64)	0.0735
Post- vs. Pre-chemotherapy	36, 92	8.20	(0.82, 15.58)	0.0297

- At 3 months, change from baseline in QoL was higher in patients without comorbidities.
- At 6 months, change from baseline in QoL was higher for patients who had not received prior chemotherapy.
- For the remaining factors (see methods), statistical uncertainty was high, and the effect was weak.

CONCLUSION

- **In the first six months of treatment, QoL is stable in men with mCRPC treated with AA+P.**
- **This finding is concordant with RCTs showing that treatment with AA+P significantly delayed QoL deterioration.**
- **No prior chemotherapy and the absence of comorbidities appear to have a positive impact on the stability of QoL.**

[1] DeBono et al. N Engl J Med 2011; 364(21): 1995-2005.
[2] Ryan et al. Lancet Oncol 2015, 16 (2): 152-160.
[3] Fizazi et al., Lancet Oncol 2012, 13(10): 983-992.
[4] Fizazi et al. European Urology 2016, 70(3): 438-444.

*Permission to use the MMAS scales is required. Reproduction and distribution is protected by US copyright laws. A license agreement to use the scale is available from: Donald E. Morisky, ScD, ScM, MSPH, Professor, MMAS Research, LLC, 2020 Glencoe Ave, Venice, CA 90291-4007, dmorisky@gmail.com.

Many thanks to all study centers and individuals participating in this study! * The study was sponsored by Janssen-Cilag GmbH, Germany.