

INTRODUCTION

HRQoL is a relevant endpoint in trials in advanced prostate cancer. An association between HRQoL and OS has been reported. The Functional Assessment of Cancer Therapy- Prostate (FACT-P) is a validated HRQoL PRO in mCRPC.

We aimed to:

- a. Evaluate the impact of pain on baseline FACT-P scores and time to FACT-P progression
- b. Compare the prognostic ability of the different FACT-P subscales
- c. Evaluate the association the time to FACT-P progression in the different Armstrong prognostic groups
- d. Evaluate the prognostic impact of changes in FACT-P scores after 3 cycles of treatment

METHODS:

We evaluated the association between FACT-P and OS in the COU-301 and COU-302 trials (abiraterone vs placebo in mCRPC pts). FACT-P scores, sub-scores (physical (PWB), emotional (EWB), functional (FWB), social (SWB) well-being, prostate cancer subscale (PCS)) FACT-G and the Trial Outcome Index (TOI) were calculated. A decrease in 3 (PWB, EWB, SWB, FWB, PCS), 9 (FACT-G, TOI) or 10 (FACT-Total) points after 3 cycles was considered clinically relevant. Presence of pain at baseline was defined as a score ≥ 2 in the BPI-SF item 3 (“Worst pain in the last 24 hours”) Armstrong prognostic risk groups were calculated in the COU-AA-302 dataset. The association between FACT-P and OS was evaluated with Kaplan-Meier, Cox-regression models and c-indices. The association of baseline FACT-P scores and presence of pain was evaluated with univariate linear regression models.

RESULTS:

2,177 pts (COU-301: 1,121 /COU-302: 1,056) had valid baseline (BL) FACT-P scores. Mean BL scores were 106.6 (COU-301) and 122.3 (COU-302). Baseline total FACT-P scores were associated with OS in both COU-AA-301 ($p < 0.001$) and COU-302 ($p < 0.001$), independent of treatment. All FACT-P sub-scale scores except SWB were significantly associated with OS. A decrease in FACTP scores was associated with decreased OS in COU-301 (19.6 vs 14.2m; HR: 1.8; $p < 0.001$) and COU-302 (34.4 vs 27.7m; HR: 1.3; $p = 0.009$) datasets. Median time to FACT-P total score deterioration was 11 months (95%CI: 10.3-11.4) in the pooled dataset, 11.2 months (95%CI: 10.2-13.8) in COU-AA-301 and 11 months (95%CI: 8.5 -11.3) in the COU-AA-302 datasets. 1189 pts (52%) had pain at baseline (BPI-SF ≥ 2). The presence of pain was associated with worse baseline FACT-p total and sub-scale scores in both the COU-AA-301 and COU-AA-302 datasets. Time to FACT-P progression was significantly shorter in patients with pain at baseline in the COU-AA-302 dataset (10.3 vs 8.3; HR: 1.6; $p = 0.007$), but not in the pooled (HR: 1.1; $p = 0.1$), or in the COU-AA-301 (0.96; $p = 0.69$) datasets. In the COU-AA-302 dataset, median time to FACT-P total score deterioration was 14 months (95%CI: 11.1-16.6) for low , 8.3 months (95%CI: 6.5-10.3) for intermediate and 3.8 months (95%CI: 2.5-10.4) for high risk patients (HR: 0.63; $p < 0.001$).

CONCLUSIONS

Baseline FACTP total score and subscales (except SWB) are significantly associated with outcome. Patients with favorable prognostic features have longer time to QoL deterioration.

Early declines in HRQoL can be observed after 2 cycles of treatment and are associated with worse outcome.

Prospective evaluation of the significance of changes in HRQoL is needed.