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Patient-reported outcomes (PRO) in patients (pts) with BRCA1/2-altered metastatic castration-resistant prostate cancer (mCRPC) receiving niraparib (NIRA) with abiraterone acetate and prednisone (AAP): Results from final analysis of the MAGNITUDE study

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KEY TAKEAWAYS

- In MAGNITUDE, NIRA + AAP maintained baseline HRQoL and showed a trend toward delaying pain progression in patients with *BRCA1/2*-altered mCRPC
- Side effect bother associated with treatment was minimal, further supporting the benefit-risk profile of NIRA + AAP for mCRPC patients with *BRCA1/2* alterations

AAP, abiraterone acetate and prednisone; HRQoL, health-related quality of life; mCRPC, metastatic castration-resistant prostate cancer; NIRA, niraparib; PBO, placebo.

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NAVIGATION

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CONCLUSIONS

- NIRA + AAP showed longer time to pain deterioration, with results consistent across pain scores
- Overall HRQoL was maintained on NIRA + AAP in mCRPC patients with *BRCA1/2* alterations
- Side-effect bother was minimal, and remained stable or improved with NIRA + AAP

AAP, abiraterone acetate and prednisone; HRQoL, health-related quality of life; mCRPC, metastatic castration-resistant prostate cancer; NIRA, niraparib; PBO, placebo.

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INTRODUCTION

- MAGNITUDE, an international phase 3 randomized double-blind study, demonstrated that NIRA + AAP significantly prolonged rPFS compared with PBO + AAP, with the greatest benefit seen in *BRCA1/2*-altered mCRPC patients (median rPFS, 16.6 versus 10.9 months; HR=0.53; 95% CI, 0.36–0.79; P=0.0014)[1]
- In the *BRCA1/2* subgroup, NIRA + AAP also improved time to symptomatic progression (HR=0.56; 95% CI, 0.37–0.85; nominal P=0.0056) and time to cytotoxic chemotherapy (HR=0.60; 95% CI, 0.39–0.92; nominal P=0.0192) compared with PBO + AAP[1]
  - Pre-specified multivariate analysis adjusting for baseline imbalances in key prognostic factors showed a treatment benefit in overall survival in *BRCA1/2* subgroup receiving NIRA + AAP compared with PBO + AAP (HR=0.66; 95% CI, 0.46-0.95; nominal P=0.0237)
- Here, as part of final analysis of MAGNITUDE, we report PRO results (pain, HRQoL, side effect bother) in mCRPC patients with *BRCA1/2* alterations

AAP, abiraterone acetate and prednisone; CI, confidence interval; HR, hazard ratio; HRQoL, health-related quality of life; mCRPC, metastatic castration-resistant prostate cancer; NIRA, niraparib; PBO, placebo; rPFS, radiographic progression-free survival.

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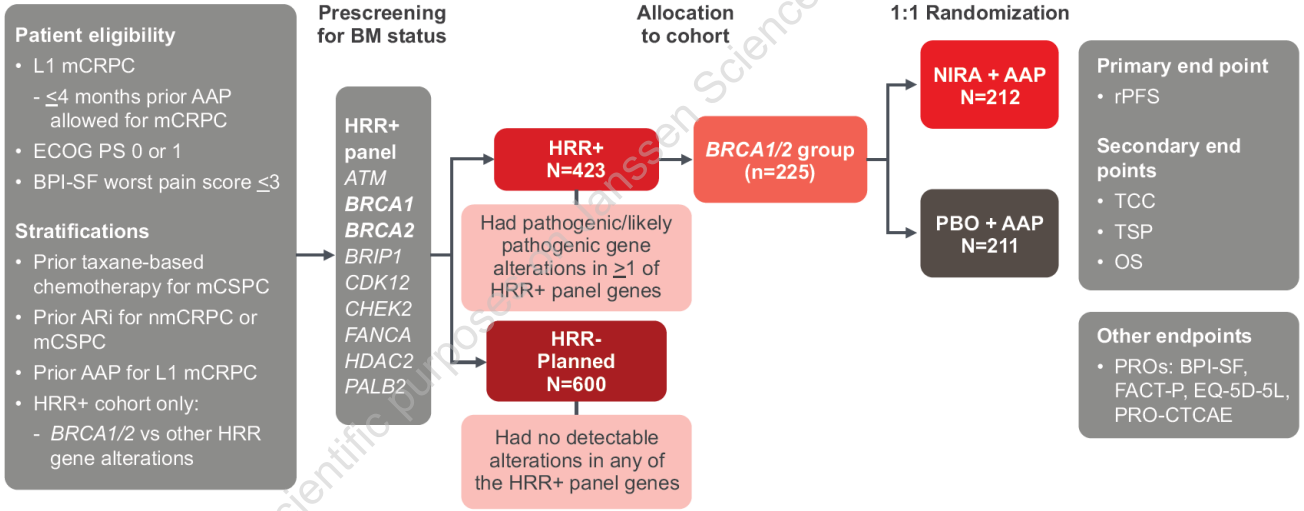
METHODS

FIGURE 1: Study design

- Patients with mCRPC and HRR gene alterations were randomized 1:1 to receive, orally, either NIRA + AAP or PBO + AAP daily in 28-day cycles
- PRO assessments included BPI-SF and FACT-P
- TTD in pain (BPI-SF worst, BPI-SF average, BPI-SF pain interference, and FACT-P PRS) were compared between treatment arms using proportional hazards regression models
- Changes from baseline in HRQoL (FACT-P total, scale of 0-156) were compared using repeated measures analysis
- Patient-reported tolerability was assessed in both arms as a single item from FACT-P (GP5, side effect bother)



AAP, abiraterone acetate and prednisone; ARi, androgen receptor inhibitor; BM, biomarker; BPI-SF, Brief Pain Inventory-Short Form; ECOG PS, Eastern Cooperative Oncology Group Performance Status; FACT-P, Functional Assessment of Cancer Therapy-Prostate; HRR, homologous recombination repair; mCRPC, metastatic castration-resistant prostate cancer; NIRA, niraparib; OS, overall survival; PBO, placebo; PRO-CTCAE, Patient-reported Outcome(s) Common Terminology Criteria for Adverse Events; PRS, pain-related scale; rPFS, radiographic progression-free survival; TCC, time-to-initiation of cytotoxic chemotherapy; TSP, time-to-symptomatic progression; TTD, time-to-deterioration.

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RESULTS

TABLE 1: PRO baseline scores in patients with *BRCA1/2*-altered mCRPC

- PRO compliance for BPI-SF and FACT-P was >85% in 225 patients with BRCA1/2-altered mCRPC across all treatment visits and assessments
- At baseline, patients reported relatively low pain and positive HRQoL
- Baseline mean pain and HRQoL scores were similar across NIRA + AAP and PBO + AAP treatment groups

	NIRA + AAP mean (SD)	PBO + AAP mean (SD)	Possible score range	Higher score indicates...
BPI-SF worst pain (item 3)	1.09 (1.57)	1.35 (1.98)	0-10	Greater pain intensity
BPI-SF average pain	0.83 (1.21)	1.04 (1.42)	0-10	Greater pain intensity
BPI-SF pain interference	0.77 (1.45)	0.87 (1.44)	0-10	More pain interference
FACT-P Total	116.33 (18.42)	114.77 (18.97)	0-156	Better HRQoL
FACT-P PRS	12.7 (3.65)	12.96 (3.42)	0-16	Less pain

AAP, abiraterone acetate and prednisone; BPI-SF, Brief Pain Inventory Short Form; FACT-P, Functional Assessment of Cancer Therapy-Prostate; HRQoL, health-related quality of life; NIRA, niraparib; PBO, placebo; PRO, patient-reported outcome; PRS, pain-related scale; SD, standard deviation.

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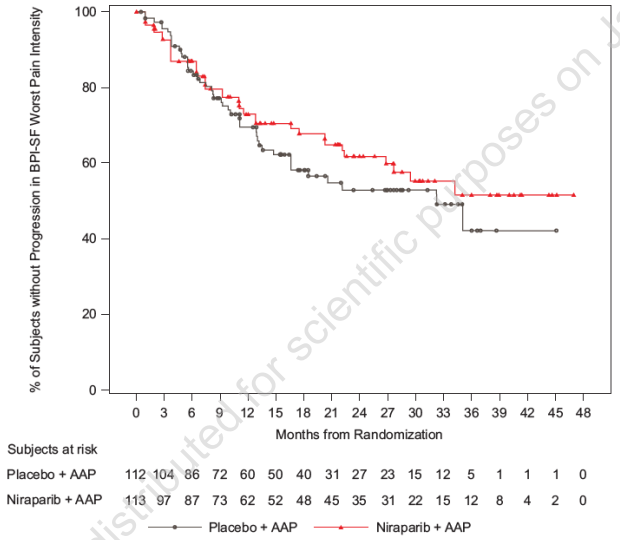
RESULTS

FIGURE 2A. Summary of TTD (BPI-SF worst pain/average pain)

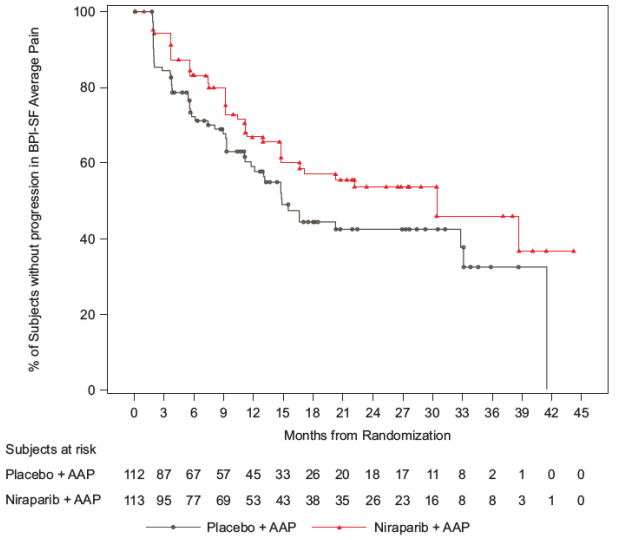
- Median TTD in BPI-SF worst pain and BPI-SF worst pain/average pain were numerically longer for NIRA + AAP vs. PBO + AAP

	Deterioration threshold	HR (95% CI)[a]
BPI-SF worst pain	2-point increase at 2 consecutive visits	0.809 (0.524,1.249)
BPI-SF average pain	≥half standard deviation of baseline	0.690 (0.458,1.039)

BPI-SF Worst Pain



BPI-SF Average Pain



[a]Hazard ratio is from stratified proportional hazards model. Hazard ratio <1 favors niraparib + AAP treatment

AAP, abiraterone acetate and prednisone; BPI-SF, Brief Pain Inventory Short Form; CI, confidence interval; HR, hazard ratio; NIRA, niraparib; PBO, placebo; TTD, time-to-deterioration.

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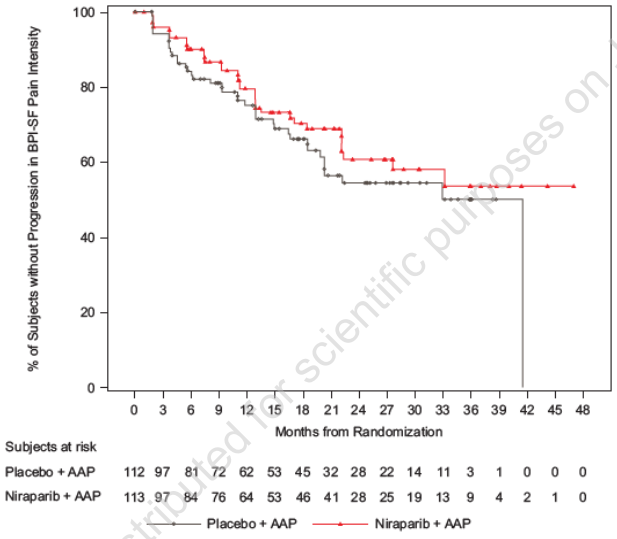
RESULTS

FIGURE 2B. Summary of TTD (BPI-SF pain interference, FACT-P PRS)

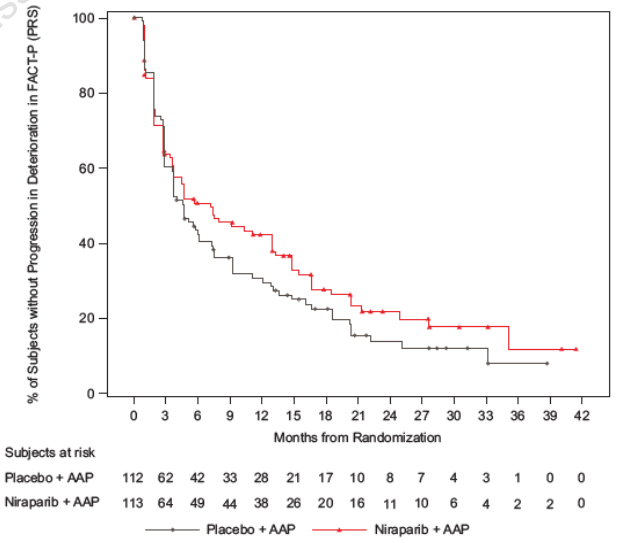
- Median TTD in BPI-SF pain interference and FACT-P PRS were numerically longer for NIRA + AAP vs. PBO + AAP

	Deterioration threshold	HR (95% CI)[a]
BPI-SF pain interference	≥30% increase from baseline	0.771 (0.481,1.234)
FACT-P PRS	≥2-point decrease	0.819 (0.595,1.127)

BPI-SF Pain Interference



FACT-P PRS



[a]Hazard ratio is from stratified proportional hazards model. Hazard ratio <1 favors niraparib + AAP treatment

AAP, abiraterone acetate and prednisone; BPI-SF, Brief Pain Inventory Short Form; CI, confidence interval; FACT-P, Functional Assessment of Cancer Therapy-Prostate; HR, hazard ratio; NIRA, niraparib; PBO, placebo; PRS, pain-related scale; TTD, time-to-deterioration.

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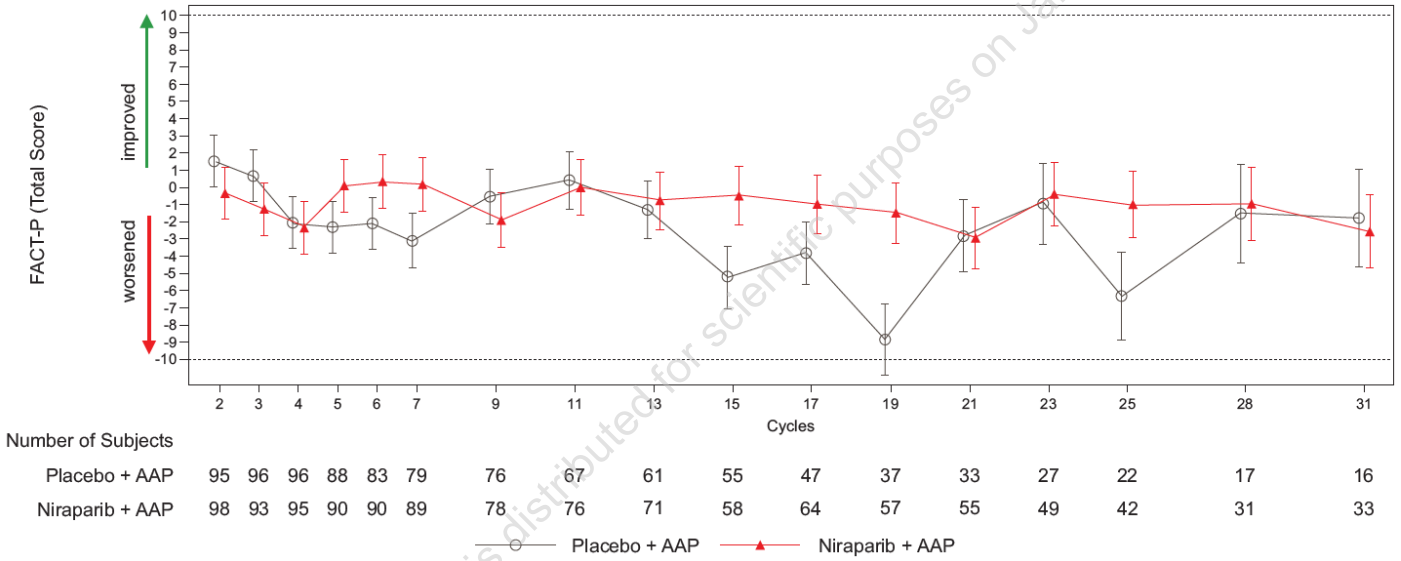
FIGURE 3. Change from baseline in FACT-P Total Score

- Patients in the BRCA1/2 subgroup receiving NIRA + AAP maintained HRQoL, whereas those receiving PBO + AAP had poorer overall HRQoL in some later cycles
  - Differences were less than the established clinically meaningful change threshold



AAP, abiraterone acetate plus prednisone; FACT-P, Functional Assessment Cancer Therapy-Prostate; HRQoL, health-related quality of life; NIRA, niraparib; PBO, placebo.
Note: Truncation is applied for all subsequent visits at the first visit where 90% or more of the subjects are missing for each PRO measure and from either arm. This truncation cycle is applied across both treatment arms. LSMEANS are derived based on the mixed effects model with baseline, visit, treatment, visit by treatment interaction as fixed effects and individual subjects as random effect. Vertical bars represent standard error estimates. The dotted horizontal lines represent clinically meaningful change score thresholds for individual patients.

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FIGURE 4. Distribution of response for side-effect bother (FACT-P GP5)

- FACT-P item GP5 in the BRCA1/2 subgroup showed side-effect bother was rated "not at all" or "a little bit" by 87% of NIRA + AAP and 92% of PBO + AAP patients averaged across treatment cycles

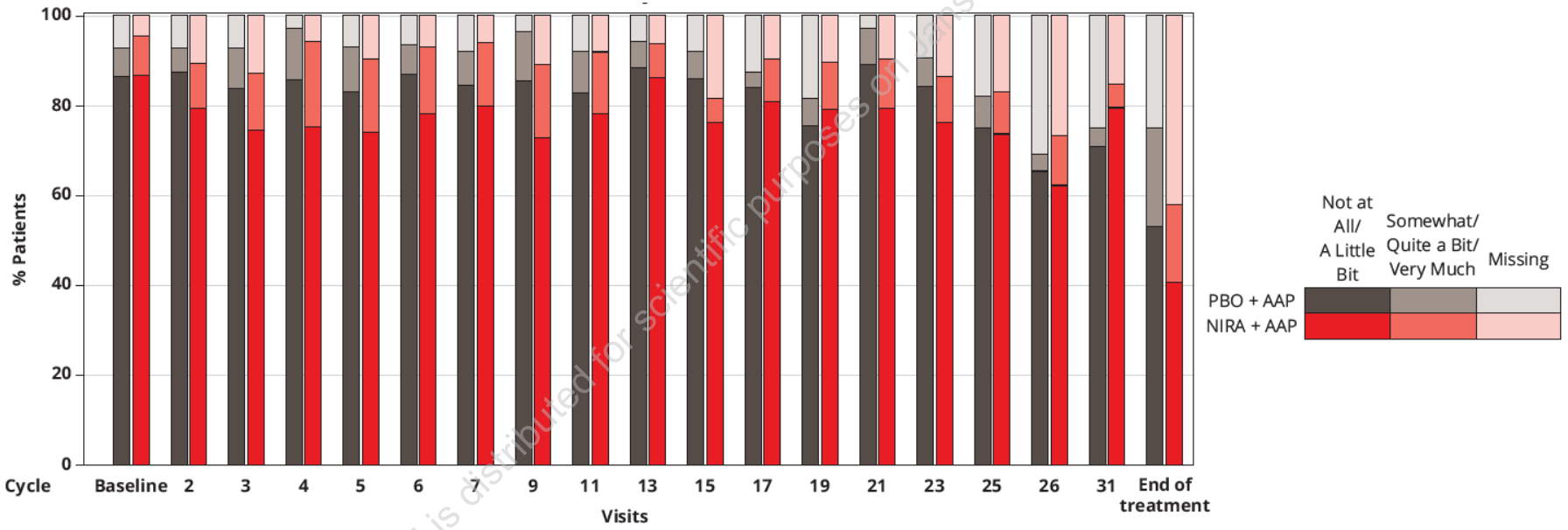

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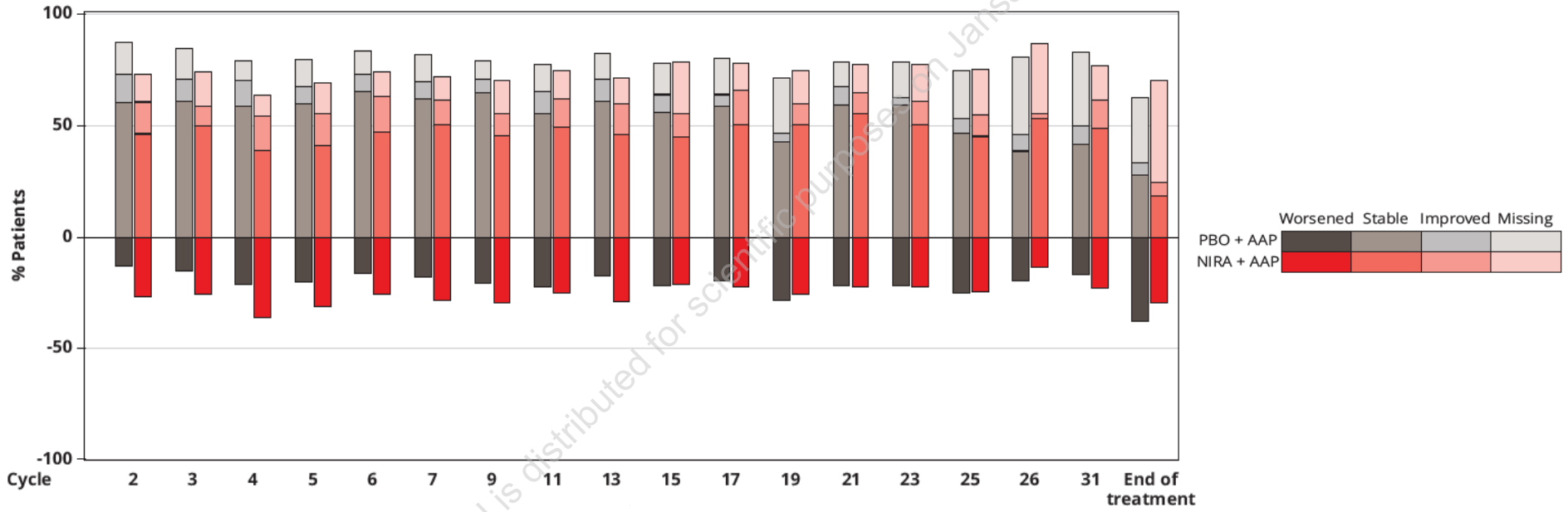
FIGURE 5. Change in response from baseline for side effect bother (FACT-P GP5)

- In both treatment groups, a greater proportion of patients reported that side effect bother remained 'stable' or 'improved' rather than 'worsened' during treatment



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DISCLOSURES:

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NAVIGATION

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CONCLUSIONS
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TTD summary
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FIGURE 5
Side-effect bother (change)
APPENDIX