

EP16.73 Long-term Pain and Adherence Observational Study for Endometriosis Treatment (LAVENDER): An Interim Analysis

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Introduction

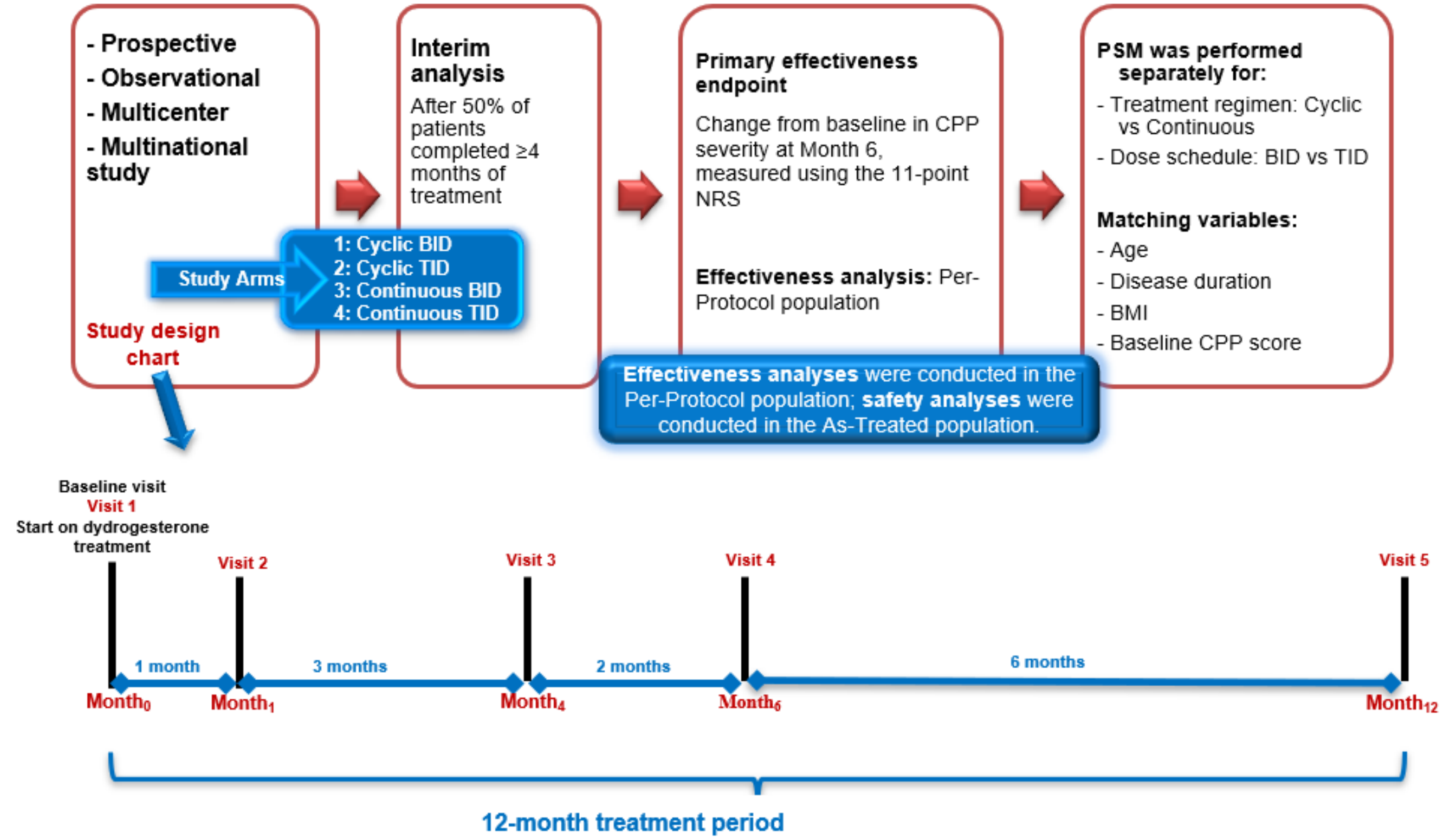
Endometriosis-associated chronic pelvic pain (CPP) substantially impairs quality of life. Although dydrogesterone (DYD) is commonly used for endometriosis management, real-world evidence on its long-term effectiveness and safety remains limited.

LAVENDER was designed to evaluate DYD in routine clinical practice across the Middle East, Turkey, Africa, and Pakistan.

Aim

To evaluate the effectiveness and safety of DYD in reducing endometriosis-associated CPP and to compare outcomes by treatment regimen and dosing schedule.

Study Design / Methods



Patient Disposition

	As-treated population n = 193		Per-protocol population n = 151
	Treatment Regimens Cyclic: n = 85 Continuous: n = 66		Dose Schedule BID: n = 137 TID: n = 14

Results

Baseline demographic characteristics (Per-Protocol Population, N=151)

In the Per-Protocol population (N=151), baseline characteristics were generally comparable across treatment groups. The mean (SD) age was 32.4 (6.65) years, and mean BMI was 25.63 (4.94) kg/m². Most patients had Stage II endometriosis (35.1%), and 94.7% reported painful menstruation at baseline. Additional characteristics are shown in Figure 1.

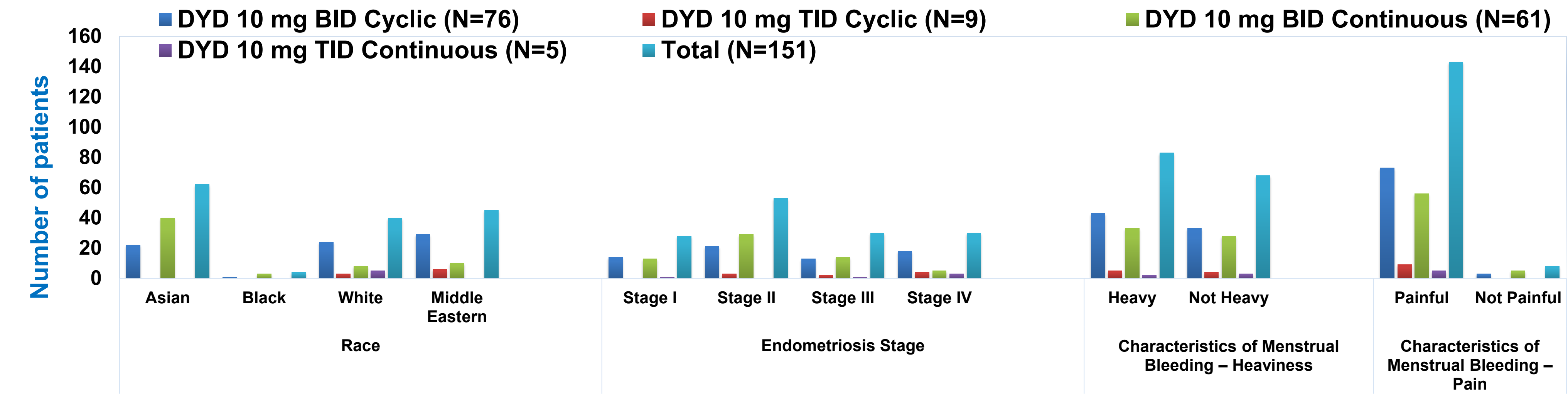


Figure 1: Baseline Demographic and Clinical Characteristics (Per-Protocol Population)

Chronic pelvic pain (CPP)

Figure 2 shows sustained reductions in CPP severity, measured by the 11-point NRS, across DYD treatment groups from baseline through follow-up.

After PSM, cyclic DYD showed significantly greater CPP reduction than continuous treatment at Month 6 (4.3 vs 2.1-point reduction; p=0.0007), while no significant differences were observed between BID and TID dosing schedules.

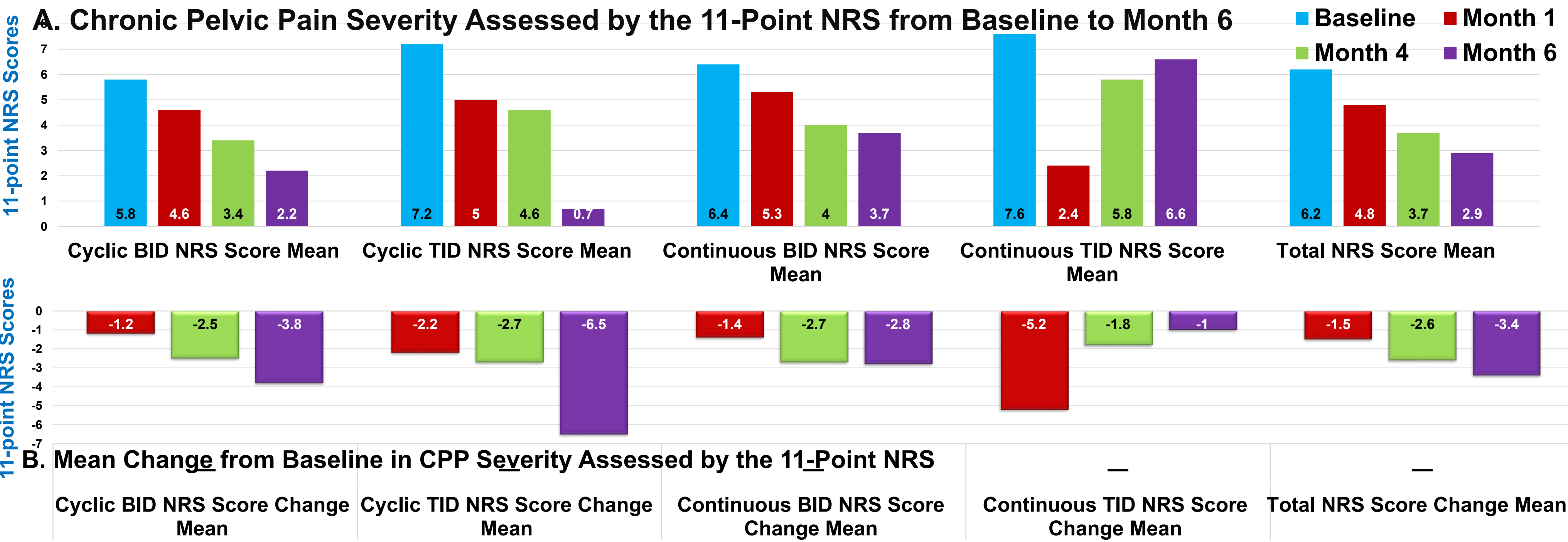


Figure 2: CPP Severity Assessed by the 11-Point Numerical Rating Scale (Per-Protocol Population)

SF-36 Quality of Life Domains

Figure 3 shows improvements across SF-36 QoL domains by Month 6 in the Per-Protocol population. The greatest improvements were observed in role limitations due to physical health, role limitations due to emotional problems, health change, and pain domains.

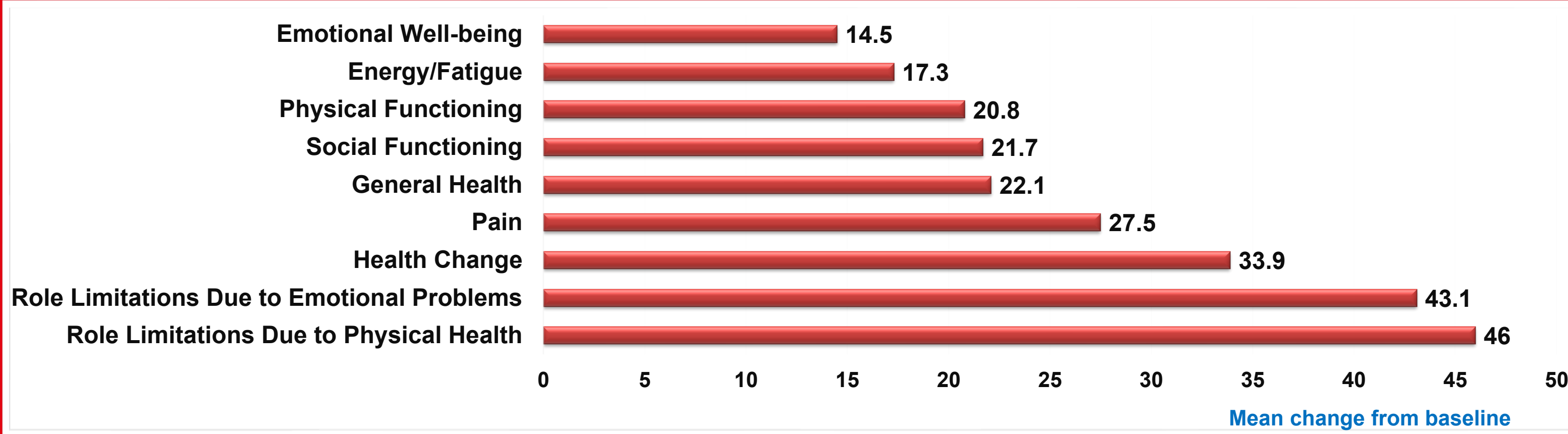


Figure 3: Mean Change from Baseline in SF-36 Domain Scores at Month 6 (Per-Protocol Population, Total Study Group)

Pain-Related Outcomes

As shown in Figures 4 and 5, following propensity score matching, cyclic DYD was associated with significantly greater improvements in pain-related outcomes at Month 6 compared with continuous treatment. Dysmenorrhea severity, assessed using the 11-point NRS, showed a greater reduction with cyclic treatment (mean change: -4.6 vs -3.2; p=0.0129; Figure 4). In addition, cyclic treatment was associated with a significantly greater reduction in analgesic-use days per menstrual cycle (-3.8 vs +0.1 days; p=0.0314; Figure 5), further supporting the pain-related benefit of the cyclic regimen..

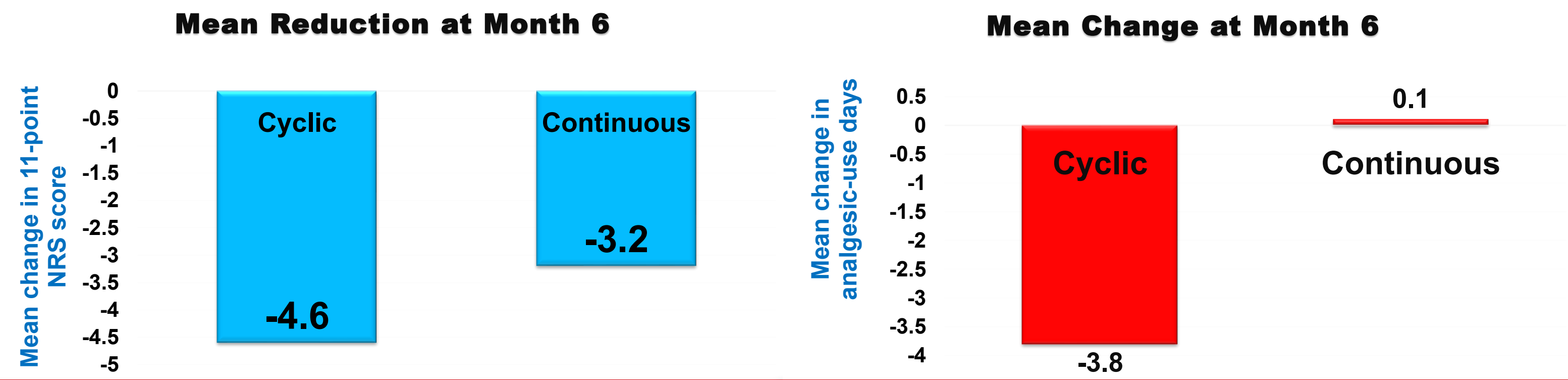


Figure 4: Change in Dysmenorrhea Severity at Month 6 (Per-Protocol Population)

Figure 5: Change in Analgesic Use at Month 6 Following PSM (Per-Protocol Population)

Conclusion

- ❑ DYD demonstrated a clinically meaningful reduction in endometriosis-associated chronic pelvic pain (CPP), as measured by the 11-point Numerical Rating Scale (NRS).
- ❑ The treatment effect was observed as early as Month 1 and sustained through Month 6, with significantly greater pain reduction at Month 6 among patients receiving cyclic treatment compared with continuous treatment following propensity score matching.
- ❑ Given the limited number of patients receiving TID dosing, no significant differences were observed between BID and TID dosing schedules after matching.

Acknowledgement

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