PND102

Correlation Analysis of the Change in SF-36 With Change in Patient-Identified Most Bothersome Symptom and Monthly Migraine Days in Patients With Chronic Migraine: Results of the PROMISE-2 Study

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KEY POINTS

- Efficacy with migraine preventive treatment is primarily established through measuring MMDs over time; however, MBS has been shown to be an important influence on patients' perception of improved disease status.
- Changes in MMDs and MBS each correlated with improvements in SF-36 domains after 12 weeks of treatment with eptinezumab or placebo.

CONCLUSIONS

- In patients with CM, the combined changes in MMDs and changes in patient-identified MBS explained approximately 9–14% of the variability in SF-36 domain scores (bodily pain, physical role functioning, and social functioning), with MMDs and MBS each contributing individually.
- These results support MBS as an important influence on HRQOL, providing further evidence that patient-identified MBS can provide an important treatment approach for improved outcomes.

Background

- In PROMISE-2, Patient Global Impression of Change responses—a measure of patient satisfaction—were more closely correlated with changes in patient-identified most bothersome symptom (MBS; r=0.83) than with changes in monthly migraine days (MMDs; r=0.51).[1]
  - The analysis suggested that improvements in patient-identified MBS are highly correlated with patients' perception of an improved disease status in patients with chronic migraine (CM).
- PROMISE-2 also measured health-related quality of life (HRQOL) using the Short-Form Health Survey (SF-36; v2.0), which found that the domains most impacted at baseline were bodily pain, physical role functioning, and social functioning.[2]
  - Treatment with eptinezumab provided clinically meaningful improvements in each domain as early as Week 4 and through 24 weeks of treatment.
- It is not known whether changes in HRQOL are more closely associated with changes in MBS or MMDs.

Objective

- To evaluate the relationship between changes in the most impacted SF-36 domains and changes in patient-identified MBS and MMDs among patients with CM

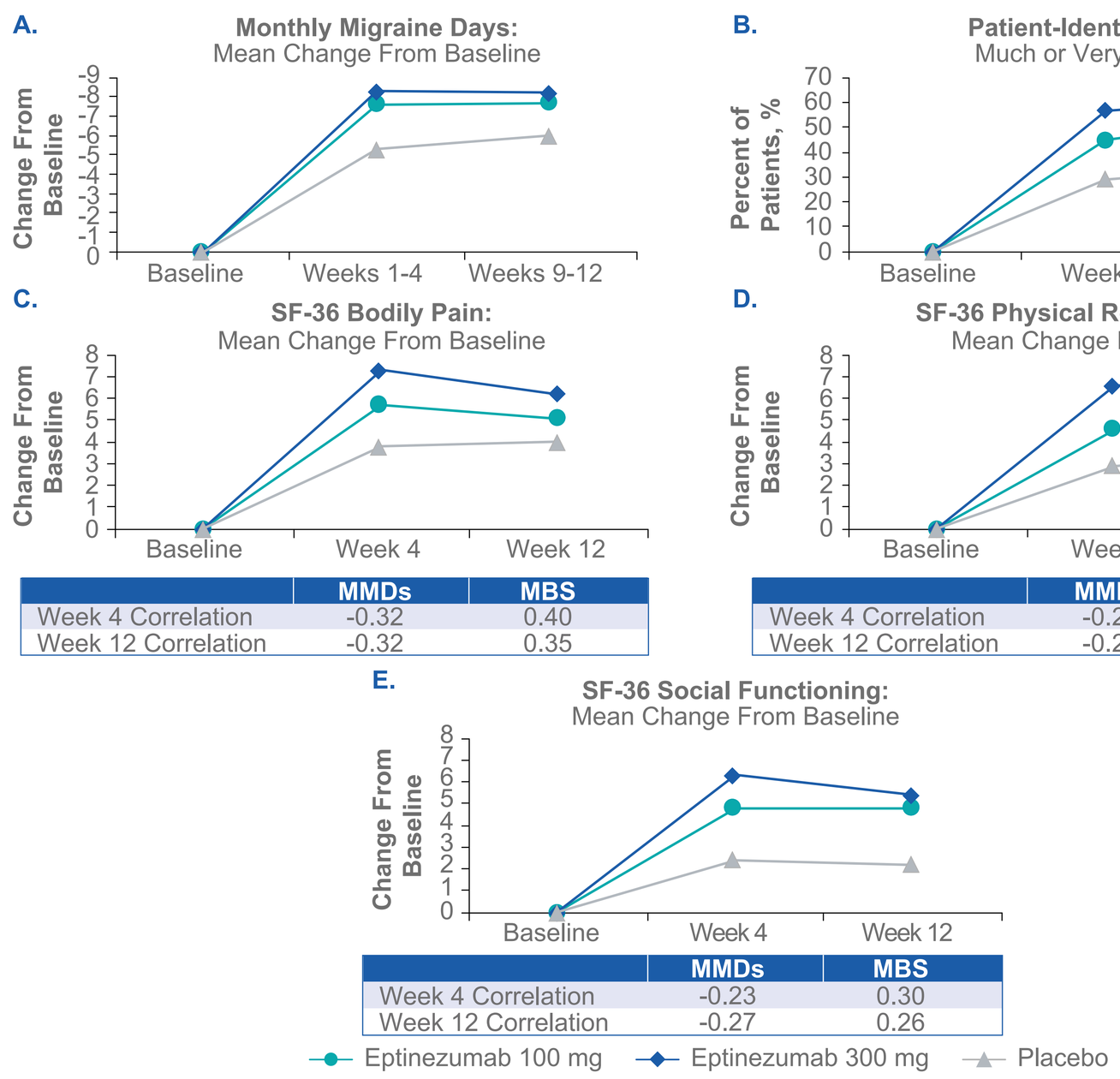
Methods

- PROMISE-2 (NCT02974153) was a double-blind, randomized, placebo-controlled trial evaluating eptinezumab for the preventive treatment of migraine in patients with CM.[3]
  - MMDs: captured via daily eDiary
  - Patient-identified MBS: verbally described by patients without limitation (global assessment) at screening; rated at Weeks 4 and 12 using a 7-point scale from "very much improved" to "very much worse"[4]
  - SF-36: survey given at baseline and at Weeks 4 and 12 **(Table 1)**[5]
- Spearman correlations and R^2 (ie, correlation squared) values from linear models were used.

Results

- At Week 4, changes in SF-36 bodily pain scores were moderately correlated with changes in MBS and weakly correlated with changes in MMDs; correlations at Week 12 were similar for both endpoints **(Figure 1C)**.
- Similarly, changes in SF-36 physical role functioning scores were more highly correlated with changes in MBS than changes in MMDs at Week 4, with comparable correlation values at Week 12 **(Figure 1D)**.
- Correlations between SF-36 social functioning scores and MBS or MMDs were weakly correlated at both the Week 4 and Week 12 time points **(Figure 1E)**.
- The regression analyses for the influence of changes in MMDs and MBS on changes in SF-36 domain scores at Week 12 demonstrated that both MMDs and MBS contribute individually to SF-36 across domains **(Figure 2)**.
  - Together (dark gray), changes in MBS (gold) and changes in MMDs (orange) explained 8.9% to 14.4% of the variability in changes from baseline across SF-36 domains (white circles), with the combined R^2 greater than the individual R^2 for each domain.

Figure 1. Changes in MMDs, MBS, and SF-36 Domain Scores Over 12 Weeks



	MMDs	MBS
Week 4 Correlation	-0.32	0.40
Week 12 Correlation	-0.32	0.35

	MMDs	MBS
Week 4 Correlation	-0.29	0.39
Week 12 Correlation	-0.29	0.33

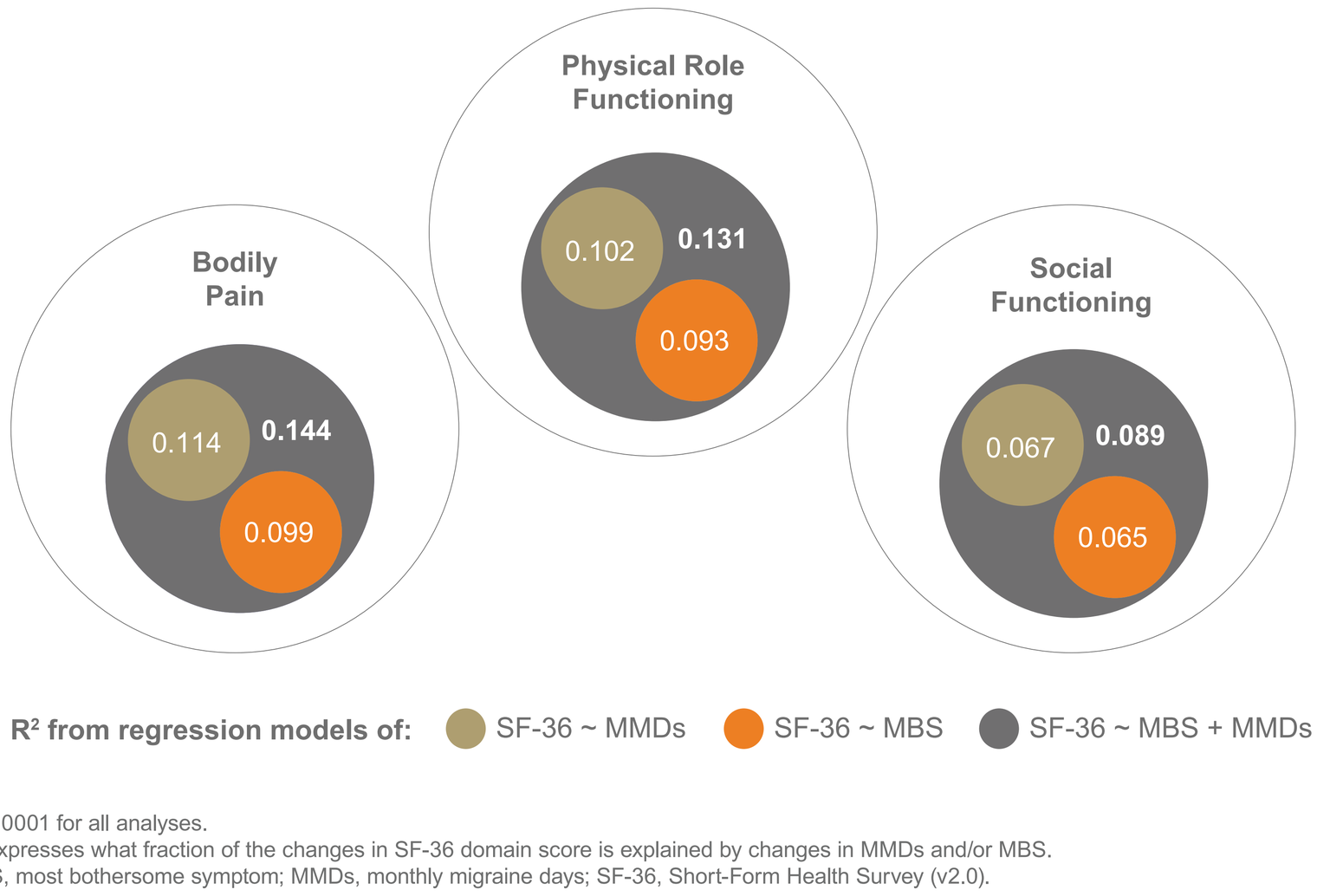
	MMDs	MBS
Week 4 Correlation	-0.23	0.30
Week 12 Correlation	-0.27	0.26

Spearman correlations.
MBS, most bothersome symptom; MMDs, monthly migraine days; SF-36, Short-Form Health Survey (v2.0).

Table 1. Descriptions of Included SF-36 Domain Scores[5]

	Definition of Lowest Possible Score	Definition of Highest Possible Score
Bodily pain	Very severe and extremely limiting pain	No pain or limitations due to pain
Physical role functioning	Problems with work or other daily activities as a result of physical health	No problems with work or other daily activities
Social functioning	Extreme and frequent interference with normal social activities due to physical and emotional problems	Performs normal social activities without interference due to physical or emotional problems

Figure 2. Venn Diagram Representation of Regression Analyses of SF-36 Domains, MMDs, and MBS



P<0.0001 for all analyses.
R^2 expresses what fraction of the changes in SF-36 domain score is explained by changes in MMDs and/or MBS.
MBS, most bothersome symptom; MMDs, monthly migraine days; SF-36, Short-Form Health Survey (v2.0).

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