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Abstract: The magnitude of placebo response and its predictors in fibromyalgia syndrome (FMS) and painful peripheral diabetic neuropathy (DPN) had not been studied. We performed a systematic review by searching MEDLINE, CENTRAL, SCOPUS, and the databases of the U.S. National Institutes of Health and the Pharmaceutical Research and Manufacturers of America until July 2010. We included randomised controlled trials of any pharmacological therapy compared with pharmacological placebo in patients with FMS and painful DPN. Pain values were converted to a 0 to 100 scale. We computed the pooled weighted mean difference (WMD) between pain baseline and end of treatment scores in placebo and active drug groups using a random effects model. A total of 72 studies (9827 patients) in FMS and of 70 studies in DPN (10,297 patients) were included. The pooled WMD in the FMS-placebo group was 7.69 (95% confidence interval [CI] 6.10 to 9.29) and 17.11 (95% CI 16.41 to 17.90) in painful DPN. The pooled WMD in the FMS-active drug group was 13.96 (95% CI 11.93 to 15.99) and in painful DPN was 22.54 (95% CI 20.49 to 24.58). The correlation between WMD in the placebo and active drug group in FMS was r=0.69 and painful DPN r=0.47. Placebo accounted for 45% of the response in the drug groups in FMS and for 62% in painful DPN. The
placebo response was higher in painful DPN than in FMS (P<.001). The placebo response was not associated with age, sex, and race, but with year of study initiation, pain baseline, and effect size in active drug groups in both diseases.