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Impact of demographic factors on the antidepressant effect: A patient-level data analysis from depression trials submitted to the Pharmaceuticals and Medical Devices Agency in Japan

Tetsuo Nakabayashi, Ayako Hara, Hirofumi Minami



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1 **Abstract**

2 A substantial and variable placebo response can cause unreliable findings in clinical trials
3 designed to demonstrate the efficacy of antidepressants, and the high rate of failed trials
4 represents a major obstacle in the development of new drugs for major depressive disorder
5 (MDD). However, the influence of demographic and symptom factors on the antidepressant
6 effect remains to be established. The purpose of this study was to estimate the magnitude of
7 this influence. A patient-level meta-analysis of data from double-blind, randomized,
8 placebo-controlled trials involving the use of antidepressants for adults with MDD was
9 performed. Data from five confirmatory trials evaluating the efficacy of four antidepressants
10 that were submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) to support
11 new drug applications were pooled ($n = 1,898$). The change in the total score of 17-item
12 Hamilton Depression Rating Scale (HDRS₁₇) was the primary outcome of interest in our
13 analysis. The changes in the total HDRS₁₇ score in both the antidepressant medication group

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