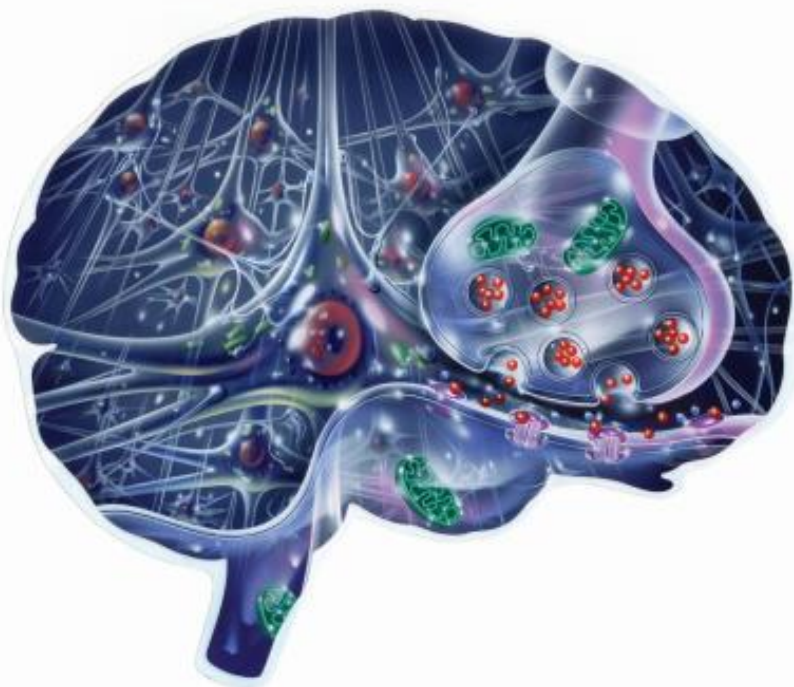


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EFFICACY AND SAFETY OF AGOMELATINE (25–50 MG/DAY) VERSUS ESCITALOPRAM (10–20 MG/ DAY) IN SEVERE GENERALIZED ANXIETY DISORDER

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Background: Generalized anxiety disorder (GAD) is a prevalent psychiatric disorder associated with significant disability and morbidity. Evidence on the efficacy and tolerability of agomelatine in GAD is accumulating (NB agomelatine is not approved for the treatment of GAD).

Objectives: To assess 12-week efficacy and safety of agomelatine at 25–50 mg versus escitalopram 10–20 mg in non-depressed outpatients with severe GAD.

Methods: A phase 3, randomized, double-blind, 12-week, comparative study. Patients were randomized to receive either agomelatine 25–50 mg ($n = 261$) or escitalopram 10–20 mg ($n = 262$). Primary outcome measure was change in Hamilton Anxiety (HAM-A) total score at week 12. Secondary measures included treatment response (HAM-A total decrease $\geq 50\%$ from baseline) and change in the Toronto Hospital Alertness Test (THAT) total score.

Findings: Decreases on mean HAM-A total score were observed in both the agomelatine and escitalopram groups at week 12 (-16.0 ± 9.1 and -16.9 ± 8.4 , respectively) in the full analysis set.

Response rates at week 12 (using the last observation carried forward approach) were 61% in agomelatine and 65% in escitalopram groups. Patients' alertness improved over 12 weeks in both treatment groups.

Fewer patients on agomelatine reported at least one emergent adverse event (AE) than those receiving escitalopram (46.9% versus 58.8%, respectively). Most frequently reported AEs in the agomelatine group were headache and nausea. Transaminase increases (alanine *aminotransferase* (ALT) and/or aspartate transaminase (AST) >3 upper limits of normal) were reported in two patients on agomelatine and four patients on escitalopram. All transaminase levels normalized after treatment cessation.

Conclusions: Both agomelatine and escitalopram reduced anxiety symptoms in patients with severe GAD. Agomelatine was better tolerated.