

Pilot Randomized Controlled Trial of Melatonin versus Low-Dose Quetiapine for Insomnia in Generalized Anxiety Disorder

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Background

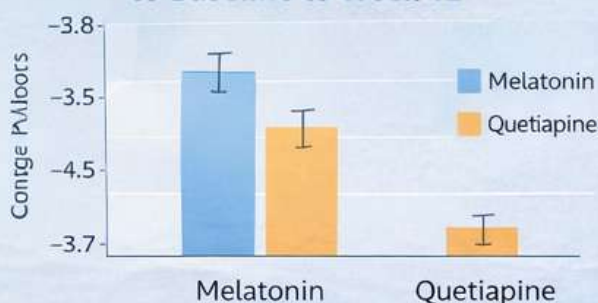
Insomnia is a persistent clinical condition in patients with generalized anxiety disorder, often resistant to standard anxiolytic interventions.

Currently, comparative preliminary data evaluating melatonin and low-dose quetiapine for sleep disturbances in this population are limited, necessitating further investigation to establish evidence-based treatment approaches.

Methods

- Baseline PSQI values were comparable between groups: melatonin 12.5 ± 2.4 versus quetiapine 12.3 ± 2.4 ($p = 0.78$). At the 12-week assessment, PSQI scores improved to 6.7 ± 2.5 in the melatonin group and 7.7 ± 2.0 in the quetiapine group (mean reduction in PSQI from baseline was 5.6 ± 2.0 points in the melatonin group compared with 4.6 ± 1.1 points in the quetiapine group. This treatment effect favored melatonin, (95% CI -0.31 to 2.7 ; $p = 0.11$).

Change in PSQI from Baseline to Baseline to Week 12



- Incidence of daytime somnolence (10% vs. 0; $p = 0.09$).

No serious adverse events documented in either treatment group.

Methods

- A single-center, double-blind, parallel-group pilot randomized trial with 20 adults meeting diagnostic criteria for generalized anxiety disorder with clinically significant sleep disturbance.
- Participants were randomly assigned in a 1:1 ratio to receive either melatonin-only or quetiapine 25 mg nightly ($n = 10$) for 12 weeks.
- The primary outcome measure was change in Pittsburgh Sleep Quality Index (PSQI) scores from baseline to week 12.
- Secondary outcomes included assessment of daytime somnolence and treatment-related adverse events requiring discontinuation.



No serious adverse events documented in either treatment group.

Conclusion

- Both melatonin and low-dose quetiapine demonstrated clinically meaningful improvements in sleep quality over the 12-week treatment period, with melatonin showing a modest numerical advantage that did not reach statistical significance. Larger, more powered clinical trials are needed to appropriately detect clinically important differences between interventions.

