

Does Melatonin Affect Sleep Disturbance and Functional Outcomes in Orthopaedic Trauma Patients? A Prospective, Randomized Controlled Trial

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Purpose: Trauma patients have a high incidence of sleep disturbance that is associated with chronic pain and delayed recovery. Surgical patients are often prescribed sleep aids while inpatients, but not routinely on discharge, so these patients may be undertreated. Melatonin is a sleep-promoting hormone whose natural production is altered following surgery. Exogenous melatonin promotes stable sleep cycles without the sedative or delirium side effects of standard opioids or hypnotics. We hypothesized that taking melatonin would improve sleep quality and functional outcomes of orthopaedic trauma patients after surgery.

Methods: We conducted a double-blinded, prospective, randomized controlled trial on all operative adult orthopaedic trauma patients. Exclusion criteria included head trauma, cognitive impairment, or previously diagnosed sleep disturbance. Patients were enrolled at the 2-week postoperative visit and randomized to either glucose tablets (placebo) or 5-mg melatonin tabs. Patients took the medication daily for 4 weeks. All patients received sleep hygiene education. Primary outcome measures were Pittsburgh Sleep Quality Index (PSQI), Visual Analog Scale (VAS), and Short Form 12 (SF-12) surveys completed at 2 and 6-week clinic visits.

Results: 30 patients were enrolled (18 placebo and 12 melatonin). The groups were similar in age, sex, and fracture type. The melatonin group had a higher average ISS, but this was not significant ($P = 0.106$). Average VAS, PSQI, and SF-12 scores improved between visits in both groups, but there was no significant difference in the amount of improvement between groups.

Conclusion: Early results show that surgical patients have sleep and functional deficits in the postoperative period that improve over time. In our limited sample, patients taking melatonin versus a placebo control showed no significant difference in improvement. A larger sample size is needed to appropriately power this question.