



## The Effects of Sodium Oxybate on Clinical Symptoms and Sleep Patterns in Patients with Fibromyalgia

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**Objective:** Fibromyalgia (FM) is associated with the sleep phenomenon of alpha intrusion, and with low growth hormone secretion. Sodium oxybate (Xyrem) has been shown to increase both slow-wave sleep and growth hormone levels. This double blind, randomized, placebo controlled crossover trial was conducted to evaluate the effects of sodium oxybate on the subjective symptoms of pain, fatigue, and sleep quality and the objective polysomnographic (PSG) sleep variables of alpha intrusion, slowwave (stage 3/4) sleep, and sleep efficiency in patients with FM.

**Methods:** Patients received either 6.0 g/day sodium oxybate or placebo for 1 month, with an intervening 2 week washout period. Efficacy measures included PSG evaluations, tender point index (TPI), and subjective measurements from daily diary entries. Safety measures included clinical laboratory values, vital signs, and adverse events.

**Results:** Twenty-four female patients were included in the study; 18 completed the trial. TPI was decreased from baseline by 8.5, compared with an increase of 0.4 for placebo ( $p = 0.0079$ ). Six of the 7 pain/fatigue scores (overall pain, pain at rest, pain during movement, end of day fatigue, overall fatigue, and morning fatigue) were relieved by 29% to 33% with sodium oxybate, compared with 6% to 10% relief with placebo ( $p < 0.005$ ). Alpha intrusion, sleep latency, and rapid-eye-movement sleep were significantly decreased, while slow-wave (stage 3/4) sleep was significantly increased, compared with placebo ( $p < 0.005$ ). Two of the 5 subjective sleep related variables were significantly different from placebo: morning alertness (improved by 18% with sodium oxybate, compared with 2% for placebo;  $p = 0.0033$ ) and quality of sleep (improved by 33% and 10%, respectively;  $p = 0.0003$ ).

**Conclusion:** Sodium oxybate effectively reduced the symptoms of pain and fatigue in patients with FM, and dramatically reduced the sleep abnormalities (alpha intrusion and decreased slow-wave sleep) associated with the nonrestorative sleep characteristic of this disorder.