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Treatment of osteoarthritis pain with controlled release oxycodone or fixed combination oxycodone plus acetaminophen added to nonsteroidal antiinflammatory drugs: a double blind, randomized, multicenter, placebo controlled trial.

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Abstract

OBJECTIVE:

To compare the efficacy and safety of controlled release oxycodone given every 12 h around the clock with immediate release oxycodone-acetaminophen (APAP) given 4 times daily for osteoarthritis (OA) pain.

METHODS:

Adults (n=167) with moderate to severe OA pain despite regular use of nonsteroidal antiinflammatory drugs (NSAID) entered open label titration for 30 days with immediate release oxycodone qid; 107 qualified for randomization to double blind, parallel group treatment for 30 days with placebo, controlled release oxycodone, or immediate release oxycodone-APAP.

RESULTS:

Following titration with immediate release oxycodone, mean (SE) pain intensity (0, none to 3, severe) decreased from 2.44 (0.04) to 1.38 (0.05) ($p=0.0001$), and quality of sleep (1, very poor; 5, excellent) improved from 2.58 (0.08) to 3.57 (0.07) ($p=0.0001$). Mean dose was about 40 mg/day. Pain intensity and quality of sleep were significantly improved in both active groups compared with the placebo group ($p<0.05$) during the double blind trial. Pain intensity and sleep scores were comparable in both active groups during double blind treatment. Nausea ($p=0.03$) and dry mouth ($p=0.09$) were less common with controlled release oxycodone than immediate release oxycodone-APAP.

CONCLUSION:

Controlled release oxycodone q12h and immediate release oxycodone-APAP qid, added to NSAID, were superior to placebo for reducing OA pain and improving quality of sleep. The active treatments provided comparable pain control and sleep quality. Controlled release oxycodone was associated with a lower incidence of some side effects.

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