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Oxycodone/Naloxone an ADF Option for Chronic Low Back Pain

Fran Lowry | May 08, 2014

TAMPA, Florida — A novel extended-release formulation of oxycodone and naloxone in a fixed 2:1 ratio (OXN, Purdue Pharma) may be useful as an abuse-deterrent formulation (ADF) option in the treatment of opioid-experienced patients with chronic low back pain.

"Chronic low back pain is a huge public health problem," Jerry A. Green, MD, from Purdue Pharma, LP, Stamford, Connecticut, told *Medscape Medical News*. "Many patients receive opioids but still do not obtain pain relief."

"Naloxone is a potent mu-opioid receptor antagonist and adds to the abuse-deterrent properties of oxycodone," he said. "We wanted to test OXN, which is currently available in 29 countries outside the [United States], and is under development here, for its ability to relieve moderate to severe pain in patients with chronic low back pain who have been exposed to opioids."

Dr. Green presented the results from a randomized, double-blind, placebo-controlled trial comparing this formulation with placebo here at the American Pain Society (APS) 33rd Annual Scientific Meeting. The study was funded by Purdue Pharma.

Chronic Back Pain

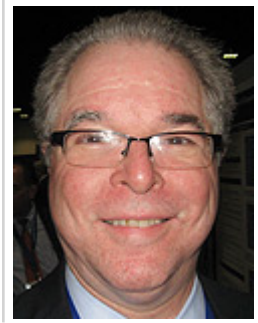
Before randomization, 1095 patients with uncontrolled chronic low back pain receiving opioid therapy who had baseline scores of 5 or greater were entered into an open-label titration period where they were exposed to escalating doses of OXN (10, 20, 30, or 40 mg of oxycodone twice daily and 5, 10, 15, or 20 mg of naloxone).

Patients who showed benefit in terms of analgesic efficacy and tolerability were then randomly assigned to receive placebo (n = 302) or OXN (n = 298) for 12 weeks.

The primary efficacy endpoint was the "average pain over the last 24 hours" score, and secondary efficacy variables were the Sleep Disturbance subscale of the Medical Outcomes Study (MOS) Sleep Scale and the Patient Global Impression of Change (PGIC).

Demographic and baseline characteristics were similar between the treatment groups.

At week 12, patients randomly assigned to OXN had a clinically and statistically greater improvement in the average pain score over the last 24 hours scores compared with patients randomly assigned to placebo (treatment difference [standard error], 0.45 [0.163]; *P* = .0055).



MOS Sleep Disturbance subscale scores also improved for patients assigned to OXN (36.4 for placebo vs 31.1 for OXN), for a between-group difference of 5.3 (95% confidence interval, 0.9 - 9.8; *P* = .0191).

Similarly, at week 12 more patients receiving OXN chose "very much improved" or "much improved" on the PGIC scale compared with patients receiving placebo (55.6% vs 39.9%; *P* = .0002).

The adverse event profile was what one would expect with opioid analgesics, Dr. Green

said.

Dr. Jerry A. Green

Table. Adverse Events With OXN vs Placebo

Adverse Event	Placebo (n = 302), n (%)	OXN (n = 298), n (%)
Nausea	14 (4.6)	25 (8.4)
Vomiting	6 (2.0)	14 (4.7)
Headache	9 (3.0)	10 (3.4)
Upper respiratory tract infection	12 (4.0)	10 (3.4)
Constipation	3 (1.0)	9 (3.0)
Diarrhea	15 (5.0)	5 (1.7)

"We Need Options"

"I think the study by Green et al is a very interesting study because it uses a novel fixed-dose combination of oxycodone and naloxone extended release and shows analgesic efficacy in a highly prevalent chronic pain population like chronic low back pain, with a statistically significant and durable effect," said Joseph V. Pergolizzi Jr, from Johns Hopkins University School of Medicine, Baltimore, Maryland, asked by *Medscape Medical News* to comment on the study.

Dr. Joseph V. Pergolizzi

"We need to have options — there is no one golden bullet that works in 100% of our patients," Dr. Pergolizzi, who was not part of the study, said.

"Also, this represents one more example of an abuse-deterrent formulation that appears to have reasonable safety and efficacy in a chronic pain population."

This study was funded by Purdue Pharma. Dr. Green is an employee of the company. Dr. Pergolizzi has reported financial relationship with Inspirion Delivery Technologies.

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