A randomized, double-blind, placebo-controlled phase 3 study of the relative efficacy and tolerability of tapentadol IR and oxycodone IR for acute pain

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Abstract

To evaluate the relative efficacy and tolerability of tapentadol immediate release (IR) and oxycodone IR for management of moderate to severe pain following orthopedic surgery (bunionectomy).
Randomized patients (N = 901) received oral tapentadol IR 50 or 75 mg, oxycodone HCl IR 10 mg, or placebo every 4-6 h over a 72-h period following surgery. Acetaminophen (< or =2 g) was allowed in the first 12 h after the first dose of study drug. In the primary analysis, tapentadol IR (50 and 75 mg) was evaluated for efficacy superior to placebo and non-inferior to oxycodone HCl IR 10 mg (using sum of pain intensity difference [SPID] over 48 h), and tolerability superior to oxycodone IR (using incidence of treatment-emergent adverse events [TEAEs] of nausea and/or vomiting).
Statistically significantly higher mean SPID(48) values were observed with tapentadol IR (50 and 75 mg) and oxycodone HCl IR 10 mg than placebo (all $p < 0.001$). The efficacy of tapentadol IR 50 mg and 75 mg was non-inferior to oxycodone HCl IR 10 mg. The incidence of TEAEs of nausea and/or vomiting was statistically significantly lower with tapentadol IR 50 mg versus oxycodone IR 10 mg (35 vs. 59%; $p < 0.001$). No statistically significant difference in the incidence of nausea and/or vomiting was observed between tapentadol IR 75 mg and oxycodone IR 10 mg (51 vs. 59%; $p = 0.057$). A possible limitation of this study was that the intense dose and patient monitoring may not represent real-world situations and may result in higher incidences of TEAEs than expected in a practice setting; this bias would be similar for all treatment groups.
Clinically meaningful and statistically significant improvements were observed with tapentadol IR 50 mg and 75 mg compared with placebo for the relief of moderate-to-severe acute pain after orthopedic surgery. Tapentadol IR 50 mg and 75 mg were non-inferior to oxycodone HCl IR 10 mg for the treatment of acute pain based on the primary efficacy endpoint of SPID(48) and the pre-specified margin of 48 points. The incidence of nausea and/or vomiting was statistically significantly lower for tapentadol IR 50 mg and numerically lower for tapentadol IR 75 mg than for oxycodone HCl IR 10 mg.

"...sic options exist, acute pain is often undermanaged, and many patients continue to experience pain[5,6,7]. Opioids are commonly used to manage moderate to severe acute pain [6,8]. ..."

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