A Dose-finding Study of Sufentanil Sublingual Microtablets for the Management of Postoperative Bunionectomy Pain

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Introduction: Sufentanil sublingual microtablets (SSMs) at a dose of 15 µg per tablet have been studied for postoperative patient-controlled analgesia with a 20-minute lockout via a bedside handheld system over 2 days to 3 days of use. For more short-term (<24 hours) management of acute moderate-to-severe pain, such as in the ambulatory surgical setting, a single, higher-strength SSM dose administered via a health care provider would be of benefit as it would require less frequent administration and avoid the setup of a drug delivery system.

Materials and Methods: This study was a two-center, randomized, double-blind, placebo-controlled trial for 12 hours in patients 18 years to 80 years of age who were undergoing bunionectomy alone or with hammertoe repair. Patients were randomly assigned at a 2:2:1 ratio to treatment with SSM 20 µg, SSM 30 µg, or placebo. The primary endpoint was time-weighted summed pain intensity difference to baseline over 12 hours (SPID12). Patients had to have a pain intensity score of 4 or higher just before initial microtablet dosing. Additional doses were administered when requested by the patient, with a minimum redosing interval of 1 hour.

Results: One hundred patients were randomized and received study drug. The SSM 30 µg was superior in the treatment of post bunionectomy surgical pain compared with placebo as demonstrated by the SPID12 score (6.53 vs. -7.12, respectively; p = 0.003) as well as all other secondary efficacy end points. The SSM 20-µg dosage strength was not superior to placebo for primary or secondary efficacy measures. Adverse events were similar among the three groups with the exception of nausea, vomiting, and somnolence, which demonstrated a dose-dependent increase in occurrence.

Conclusions: Efficacy and tolerability results from this study suggest that sufentanil 30mcg tablets dispensed sublingually via single-dose applicator may offer a viable alternative to IM or IV dosing in an ambulatory surgery population.