PLACEBO EQUAL TO NALBUPHINE FOR PRURITUS IN PEDIATRICS

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INTRODUCTION

The purpose of this investigation was to evaluate the efficacy of nalbuphine, a partial opioid agonist-antagonist, to treat post-operative opioid-induced pruritus (Pr) in a pediatric population.

METHODS

After approval by the University Research Ethics Boards, the dual centre study planned to recruit 268 subjects, age ≥ 7 , receiving continuous opioid analgesia post-operatively who understood the self-report Colour Analogue Scale (CAS) to score pruritus intensity (PrI). Sample size was estimated to demonstrate a 25% improvement compared to placebo ($\alpha=0.05$ and $1-\beta=0.8$). Subjects who reported PrI score $\geq 5/10$ were randomized to treatment with nalbuphine 50 mcg/kg IV (max 5 mg) or saline placebo. PrI, analgesia (VAS), sedation (5 point score), and side effects of headache, vomiting, and dizziness (yes/no) were recorded at 30 and 60 min. A Pruritus Intensity Difference (PrID) of $\geq 50\%$ was considered a positive outcome. Subjects with PrI score $\geq 5/10$ at 60 min. received nalbuphine 50 mcg/kg IV (max 5 mg).

RESULTS

Of 259 subjects, 212 consented to the study and of these 184 received opioids. The median age was 13 yr (range 7-19) and median weight was 51 kg (range 19.6-134.8). PrI $\geq 5/10$ occurred in 37 (20.1%) subjects. The CAS was well accepted by all subjects. The incidence of Pr was highest in the PCA group (46%), versus continuous opioid infusion (27%) and epidural (27%). Pr occurred over a wide range of opioid doses (9.4-63.2 mcg/kg/hour IV morphine). Epidural hydromorphone resulted in a lower incidence of Pr than intravenous morphine (29.7% vs. 67.6%). PrID of $\geq 50\%$ was achieved in 21 (56.8%) subjects. There was no benefit of nalbuphine (55.6%) compared to saline (57.9%) (Figure 1). No increased sedation or reversal of analgesia was noted. Nalbuphine at 60 min, for PrI ≥ 5 , was given to 8 subjects (13.5%). Of these, 3 received a cumulative dose of 100 mcg/kg IV (max 10 mg) and 3/3 (100%) had a PrID $\geq 50\%$.

DISCUSSION

Saline placebo was as effective as nalbuphine 50 mcg/kg in treating pruritus. The CAS score and PrID proved to be robust instruments for measuring PrI and warrant further investigation with alternate doses, agents or pruritus models.