



Single-Dose Intraoperative Methadone for Pain Management in Pediatric Tonsillectomy: A Randomized Double Blind Clinical Trial



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INTRODUCTION

- Background:** There is no consensus on the optimal management of pediatric perioperative tonsillectomy pain.^{1,2} Methadone, a long-duration opioid, may provide extended analgesia that may better match the anticipated duration of pain.³
- Study Aims:** Determine an initial analgesic and well-tolerated dose of intraoperative methadone in children undergoing tonsillectomy.
- Hypothesis:** Single-dose methadone would result in less 7-day postoperative opioid use compared with as-needed short-duration opioids in pediatric tonsillectomy.

METHODS

- Design:** Double-blind, randomized trial in children (3-17 years) undergoing extracapsular tonsillectomy
- Intervention:** Single-dose intravenous methadone (0.1 mg/kg then 0.15 mg/kg age-ideal body weight, in a dose escalation paradigm) versus as-needed fentanyl controls (2:1 ratio, 20 patients per group)
- Measurements:** Opioid use, pain scores, adverse events, and side effects (in-hospital and 7 days post-op)
- Primary outcome:** Total 7-day opioid use (OME/kg).
- Secondary outcomes:** Opioid use in the Post-Anesthesia Care Unit (PACU) and daily pain scores.
- Data analysis:** Chi-squared, Fisher's exact test, and the Kruskal-Wallis rank sum test. Pairwise comparisons performed using Dunn's Kruskal-Wallis test, adjusting for multiple testing using Bonferroni correction.

RESULTS

Characteristic	Control N = 20	Methadone (0.1mg/kg) N = 20	Methadone (0.15mg/kg) N = 20
Age (year)	4.0 [3.0, 6.3]	4.5 [4.0, 6.3]	4.5 [3.8, 7.0]
Male	13 (65%)	6 (30%)	11 (55%)
Actual Weight (kg)	19.7 [16.0, 33.1]	19.1 [17.1, 23.6]	19.4 [14.5, 37.6]
Age-ideal body weight (kg)	18.0 [15.4, 22.8]	18.3 [17, 22.8]	18.0 [16.5, 23.6]
Race			
White	11 (55%)	18 (90%)	12 (60%)
Black	3 (15%)	1 (5%)	6 (30%)
Other	6 (30%)	1 (5%)	2 (10%)
Ethnicity			
Non-Hispanic	18 (90%)	17 (85%)	17 (85%)
Hispanic	2 (10%)	3 (15%)	3 (15%)
ASA Physical Status	2 [1, 2]	2 [2, 2]	2 [2, 2]
Outpatient Status	18 (90%)	19 (95%)	17 (85%)

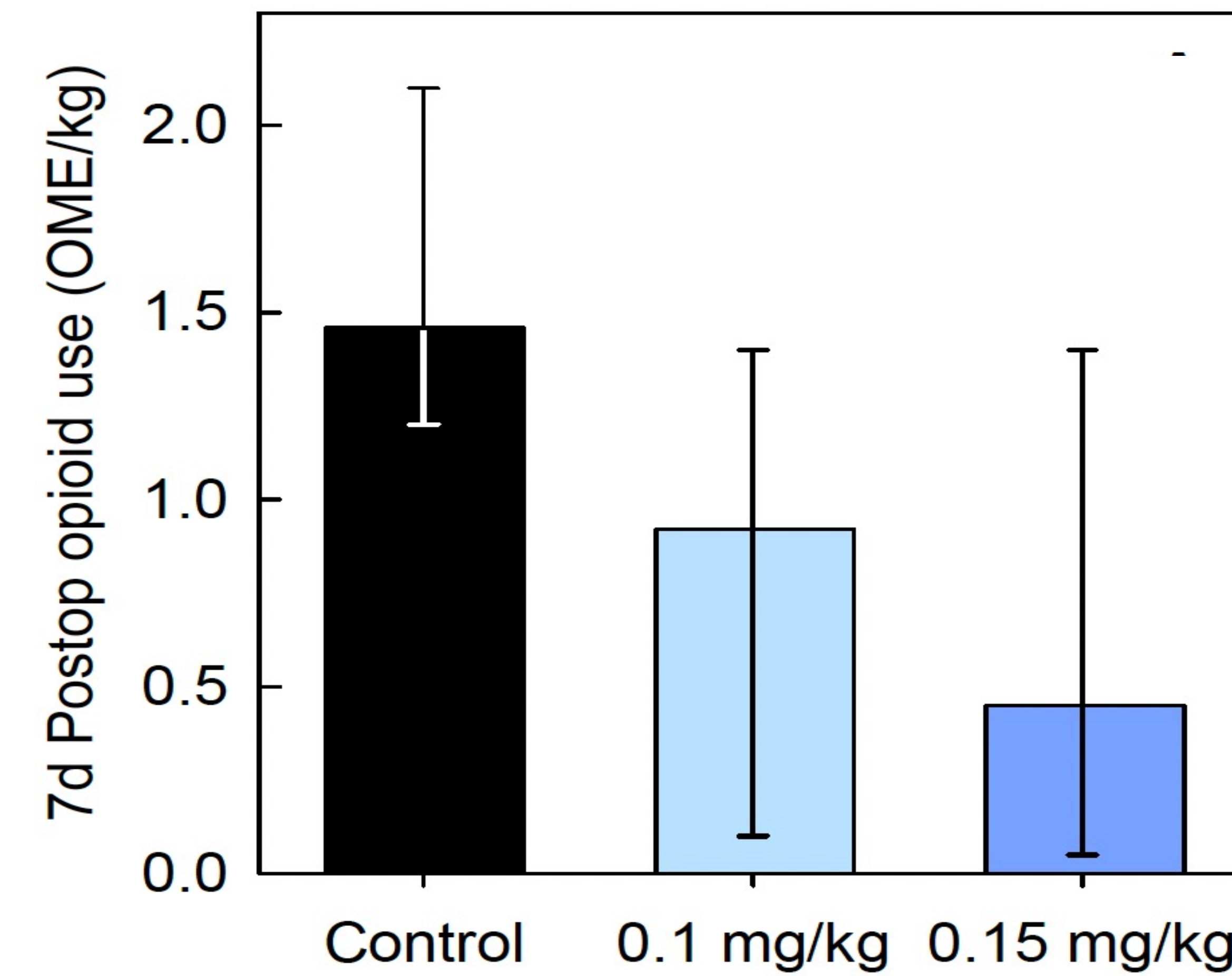


Figure 1. Total 7-day Opioid Use
Methadone 0.1 mg/kg vs control, p = 0.045, Methadone 0.15 mg/kg vs control, p = 0.023. Results are median (IQR), N=20/group.

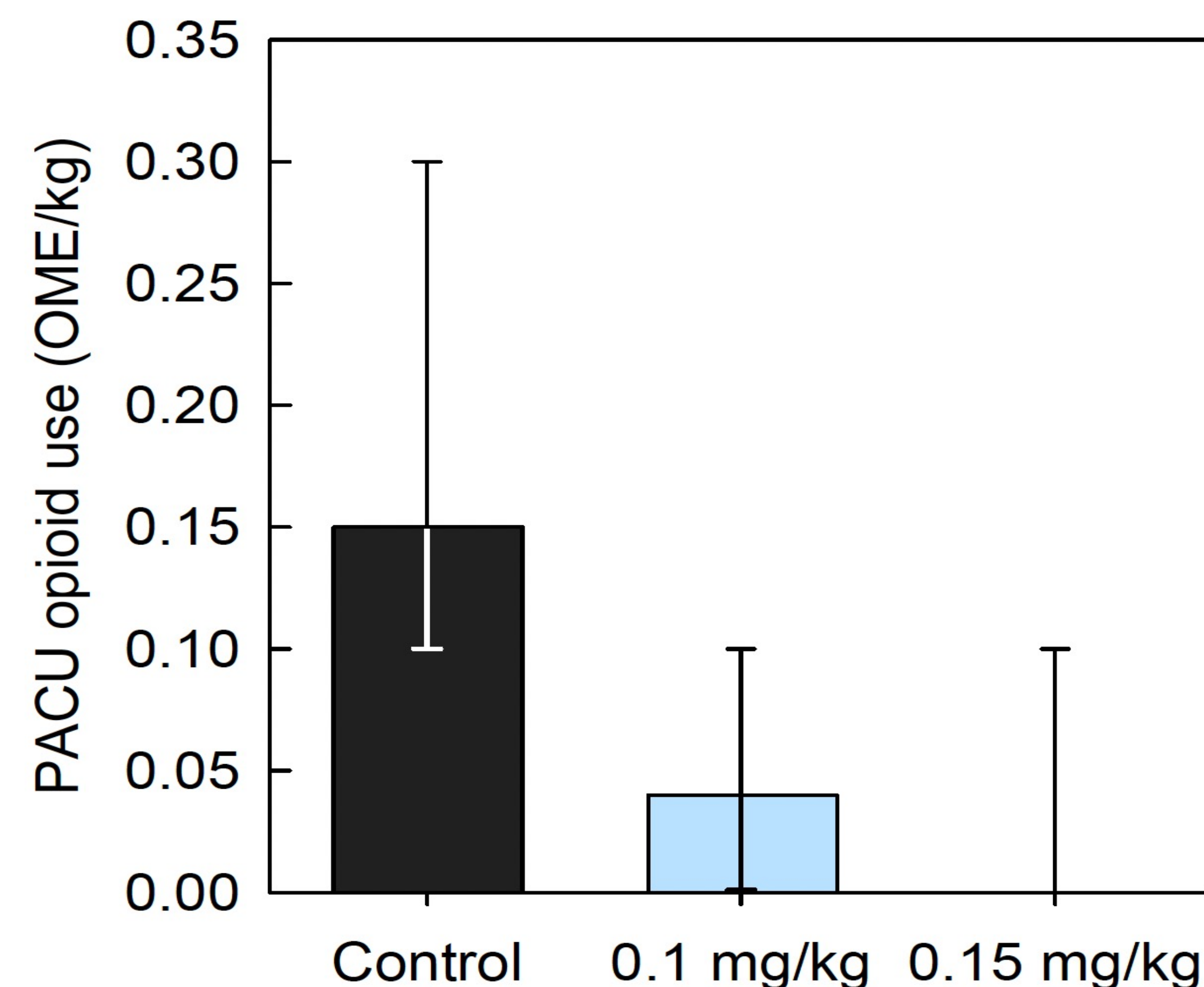


Figure 2. PACU Opioid Use
Methadone 0.1 mg/kg vs control, p = 0.061, Methadone 0.15 mg/kg vs control, p = 0.021. Results are median (IQR), N=20/group.

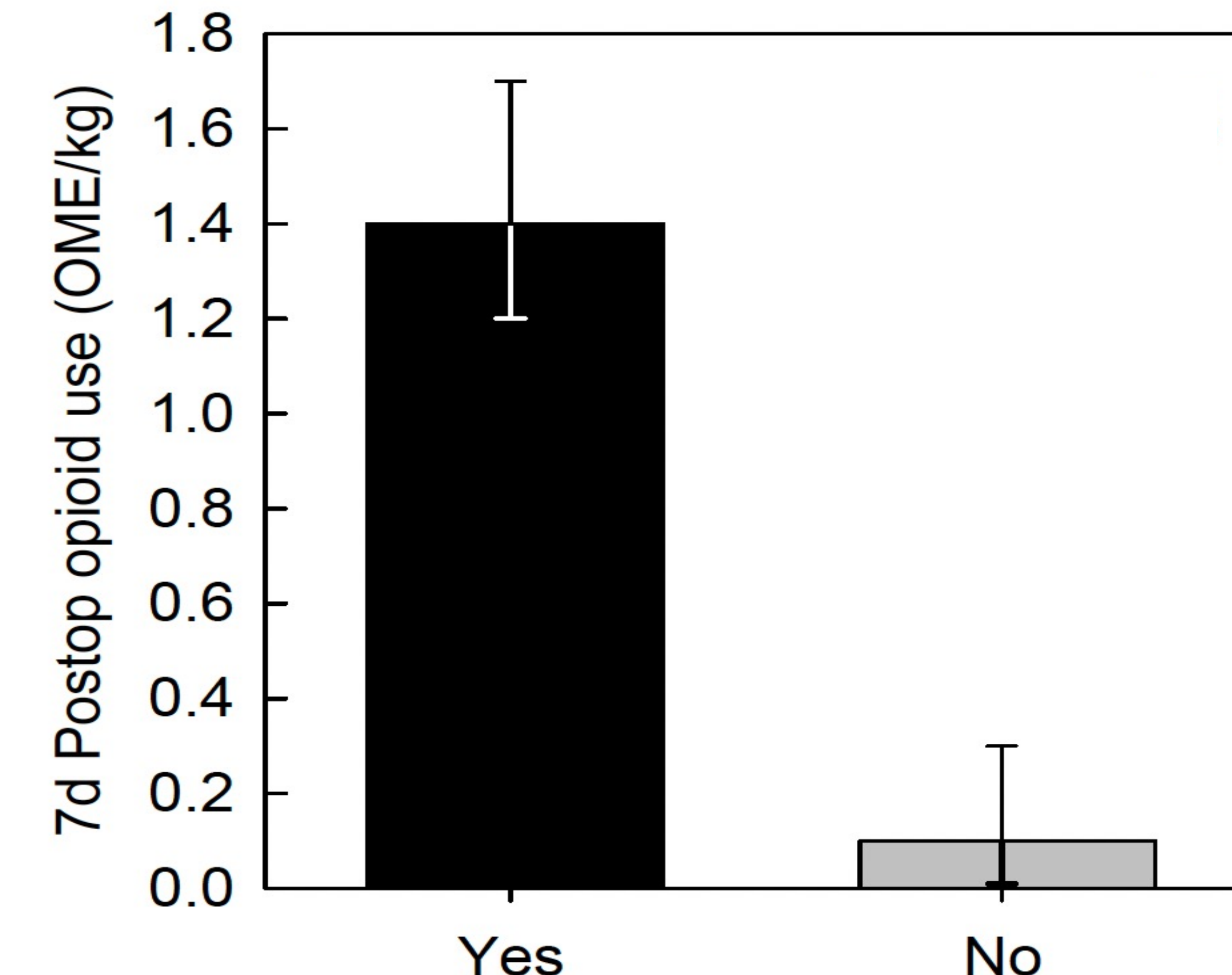


Figure 3: Total opioid use stratified by need for PACU opioid
p < 0.001. PACU opioid (N=36/60) vs. no PACU opioid (N=24/60), Results are median (IQR).

DISCUSSION

- Methadone 0.15 mg/kg resulted in less rescue opioids needed in PACU, post-PACU, and total 7-day opioid use.
- No difference in daily pain scores or acute pain score trajectories between groups
- No difference in postop opioid related side effects between groups
- No major adverse events (respiratory distress, need for naloxone, unexpected hospital or PICU admission)
- PACU LOS was less in both methadone groups compared to controls
- Across treatment groups, adolescents used higher postop opioid than younger groups
- Need for rescue opioid in PACU was associated with higher total 7-day opioid use

CONCLUSIONS

- In this small study, a single dose of methadone 0.15 mg/kg age-ideal body weight was opioid sparing in our sample of children undergoing tonsillectomy
- These initial data can be used to inform a larger trial to support the use of methadone analgesia for pediatric tonsillectomy

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