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Original Contribution

Tramadol wound infiltration is not different from intravenous tramadol in children: a randomized controlled trial[☆]



Ana Laura Albertoni Giraldes MD (Anesthetist)^a, Angela Maria Sousa MD, PhD (Chief)^{b,*}, Alexandre Slullitel MD, MSc (Anesthetist)^c, Gabriel Magalhães Nunes Guimarães MD (Anesthetist)^b, Melina Geneviève Mary Egan Santos MD (Anesthetist)^d, Renata Evangelista Pinto MD (Anesthetist)^d, Hazem Adel Ashmawi MD, PhD (Anesthetist)^e, Rioko Kimiko Sakata MD, PhD (Assistant Professor)^a

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Abstract

Study Objective: The purpose of this trial was to assess if tramadol wound infiltration is superior to intravenous (IV) tramadol after minor surgical procedures in children because tramadol seems to have local anesthetic-like effect.

Design: Randomized double-blind controlled trial.

Setting: Postanesthesia care unit.

Patients: Forty children, American Society of Anesthesiologists physical status I or II, scheduled to elective inguinal hernia repair.

Interventions: Children were randomly distributed in 1 of 2 groups: IV tramadol (group 1) or subcutaneous infiltration with tramadol (group 2). At the end of the surgery, group 1 received 2 mg/kg tramadol (3 mL) by IV route and 3-mL saline into the surgical wound; group 2 received 2 mg/kg tramadol (3 mL) into the surgical wound and 3-mL saline by IV route.

Measurements: In the postanesthesia care unit, patients were evaluated for pain intensity, nausea and vomiting, time to first rescue medication, and total rescue morphine and dipyrone consumption.

Main Results: Pain scores measured during the postanesthesia recovery time were similar between groups. Time to first rescue medication was shorter, but not statistically significant in the IV group. The total dose of rescue morphine and dipyrone was also similar between groups.

^aDepartment of Anesthesia, Surgery Division, Pediatric Anesthesia Unit, Federal University of São Paulo, São Paulo, Brazil

^bPain Management Service, Cancer Institute of the State of Sao Paulo, São Paulo, Brazil

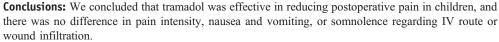
^cDepartment of Anesthesia and Pain Management, Santa Paula Hospital, São Paulo, Brazil

^dDepartment of Anesthesia, University Hospital, University of São Paulo, São Paulo, Brazil

^eDepartment of Anesthesia, Hospital das Clinicas from the University of São Paulo, São Paulo, Brazil

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^{*} Corresponding author at: Angela Maria Sousa, Department of Anesthesia, Hospital das Clinicas from the University of Sao Paulo. Av. Dr Enéas de Carvalho Aguiar, 255 - 8th floor - PAMB - Cerqueira César - CEP 05403-000, Brazil. Tel.: +551126616680; fax: +551138850997. E-mail address: angela.sousa0309@gmail.com (A.M. Sousa).



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1. Introduction

It is well recognized that optimal postoperative pain management is essential for children and that analgesia should be started even before the surgery. Standardized approaches for postoperative nausea and vomiting and pain control are both important factors to be optimized in outpatient children undergoing minor surgical procedures. Preventive multimodal analgesia, which comprises a combination of different drugs and regional anesthesia techniques, can offer the advantage of high-quality pain relief [1] and reduced amount of opioid consumption in the perioperative period [2]. Local anesthetics administered either by neuraxial techniques, peripheral nerve blocks, or local infiltration are adopted as adjuvants to general anesthesia and are associated to excellent pain control, rapid recovery from anesthesia, and fewer opioid side effects [3].

Tramadol has been demonstrated to have local analgesic effect in previous studies in adults [4,5] and children [6-9]. Besides being a weak synthetic opioid, tramadol inhibits the reuptake of monoaminergic neurotransmitters (5-hydroxytryptamine and noradrenaline) and has a local anesthetic—like action on peripheral nerves [10] similar to lidocaine 1% [11]. The addition of tramadol to local anesthetics in peripheral nerve block prolongs the duration of the analgesia [12,13] and has an analgesic effect similar to levobupivacaine when injected subcutaneously [4].

The objective of this study was to evaluate if wound infiltration with tramadol confers additional beneficial results in terms of postoperative pain control of children submitted to minor pediatric surgeries.

2. Subjects and methods

After approval by institutional ethics committees for Analysis of Research Projects of Darcy Vargas Children's Hospital and São Paulo Hospital of the Federal University of São Paulo and written informed parental consent had been obtained, children were scheduled to undergo unilateral inguinal hernia repair.

This prospective double-blind randomized clinical trial consecutively recruited 40 American Society of Anesthesiologists (ASA) physical status I or II children, aged between 3 and 12 years, undergoing elective unilateral inguinal hernia repair. Exclusion criteria were parental refusal, preoperative pain, previous analgesic ingestion in the 48-hour period

before surgery, known or suspected allergic reaction to any of the drugs studied, or previous history of coagulopathy.

Children were then randomized (random number generator) preoperatively using sealed envelopes to receive 1 of the 2 treatments: a dose of 2 mg/kg of tramadol in a total 3-mL volume syringe either by intravenous (IV) route (group 1) or by wound infiltration (group 2). The initial tramadol concentration was 50 mg/mL, and it was further diluted to a maximum 3-mL saline solution, so final concentration varied according to patient's weight. An independent nurse not involved in the study prepared both administered solutions. At the time of skin suture, according to the allocation group, 1 of these 2 different solutions was blindly made available for the anesthesiologist to be administered by IV route, whereas the other was equally provided to the surgical team to perform wound infiltration.

Children were given 0.5 mg/kg oral midazolam 30 minutes before anesthesia induction, which consisted in 4% to 5% end-tidal sevoflurane concentration in 100% oxygen. Standard monitoring consisted of electrocardiogram, pulse oximetry, capnography, and noninvasive continuous blood pressure measurement. Once an adequate depth of anesthesia had been achieved, an IV access was secured. A laryngeal mask airway was used to manage the airways. Before incision, ilioinguinal-iliohypogastric nerve blockade (IINB) was performed according to classical anatomical landmarks. The anterior superior iliac spine was palpated, and a point 1.0 to 1.5 cm cephalad and toward the midline was located. A 22-gauge short beveled needle was passed through the external and internal oblique muscles, and 2.0 to 2.5 mL of local anesthetic was deposited in a fan-like fashion cephalad toward the umbilicus, medially, and caudad toward the groin. As the needle was advanced through the external and internal oblique muscles, a pop was elicited providing a guide of proper needle placement. Just before removal from the skin, another 0.5 to 1.0 mL of local anesthetic was injected subcutaneously to block the iliohypogastric nerve. So, a total of 3 mL of 1% lidocaine solution was injected into these 2 layers. Anesthesia was maintained with 50% oxygen/air mixture and sevoflurane (2.5%-3%) with spontaneous breathing throughout the procedure. After incision, IV fentanyl (0.5 µg/kg) was administered if blood pressure or heart rate had more than 30% increase compared to preoperative values. If necessary, assisted ventilation was provided according to end-tidal carbon dioxide measurements. If a second fentanyl rescue dose was considered necessary, the ilioinguinal nerve block has judged insufficient, and the patient was excluded from

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