Comparison of pre-emptive i.v.-tramadol and peritonsillar bupivacaine infiltration for postoperative pain relief after tonsillectomy in children: a prospective double blind randomized controlled trial

L. Ameye ¹, M. Van de Velde MD, PhD, EDRA ^{1,2}, S. Rex MD, PhD^{1,2}, A. Teunkens MD^{1, 2}

¹Department of Anesthesiology, University Hospitals of Leuven, Leuven, Belgium; ² Department of Cardiovascular Sciences, KU Leuven, Leuven, Belgium

Background and goal

Achieving sufficient postoperative analgesia following tonsillectomy in children remains challenging. Conflicting data have been published on the efficacy of local anesthetic infiltration for post-tonsillectomy pain relief.

We hypothesized that peritonsillar infiltration with bupivacaine decreases postoperative pain and reduces the incidence of postoperative nausea and vomiting (PONV) after tonsillectomy in children when compared to intravenous (IV) administration of tramadol.

Endpoints

- **Primary endpoint:** The total amount of patients who received piritramide postoperatively.
- **Secondary endpoints:**
 - The dose of postoperative piritramide administration.
 - The pain scores were registered using the Wong-Baker Faces Pain (WB-FPRS) Rating scale and analgesics were given whenever the given face represented a pain level above patient's pain threshold.
 - Incidence of PONV and oral analgesic requirement during the first 24 hours.
 - Incidence of adverse events and discharge times.

Materials and methods

- **Study design:** Two hundred children, aged between 4 and 10 years and classified as ASA physical status I or II, were included in this prospective, double-blind, randomised controlled trial scheduled for elective adenotonsillectomy in day surgery. Exclusion criteria were allergies against any product used during the whole setting, and lack of parental written informed consent. Patients were randomly allocated to receive either a bolus of 3 mg/kg tramadol IV administered after induction of anesthesia plus an infiltration with 5 ml of saline at the end of surgery or to an IV bolus injection of saline after induction of anesthesia plus an infiltration of the tonsillar loge with bupivacaine 0.25% 5ml at the end of surgery. All patients received paracetamol and ketorolac IV at the start of surgery. The study protocol was approved by the Ethical Committee of the University Hospitals of the KU Leuven, and the Belgian Government (EUDRACT 2011-005467-25). Patients were enrolled between January 2012 and September 2016 after obtaining written parental informed consent.
- **Statistics:** A Fisher’s exact test (two-sided with alpha=5%) was used for the comparison of proportions in the tramadol and bupivacaine group. A Mann-Whitney U test (two-sided with alpha=5%) was used for continuous variables. A linear model for repeated measures was used to compare the evolution over time for the WB-FPRS and hemodynamic parameters.

Results

- Significantly more patients in the infiltration- compared with the tramadol-group required piritramide postoperatively (81% vs 57%; p < .001).
- The total amount of piritramide needed for postoperative analgesia was significantly higher in the infiltration group [median dose (range) 0.7 (0.4,2) vs 1.0 (0.3,3.6), p=0.007] .

- Pain scores were lower in the tramadol group (p<0.001) but this difference decreased over time and disappeared after 45 minutes.
- There were no statistical differences in PONV incidence, need for anti-emetics, oral analgesic consumption, adverse events and discharge times.

Conclusion

Compared with peritonsillar bupivacaine infiltration, pre-emptive tramadol IV decreases the need for postoperative opioids after tonsillectomy in children without increasing side effects.

References

1. Hadden SM, Burke CN, Skotcher S, Voepel-Lewis T. Early outcomes in children after adenotonsillectomy. J Perianesth Nurs. 2011 Apr;26(2):89–95.
2. Sun J, Wu X, Meng Y, Jin L. Bupivacaine versus normal saline for relief of post-adenotonsillectomy pain in children: a meta-analysis. Int J Pediatr Otorhinolaryngol. 2010 Apr;74(4):369–73.