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Pre-emptive peritonsillar infiltration of magnesium sulphate and ropivacaine vs. ropivacaine or magnesium alone for relief of post-adenotonsillectomy pain in children

Jiehao Sun [a], Xiuying Wu [b], Xiyue Zhao [a], Feifei Chen [a], Weijian Wang [a,*]

[a] Department of Anesthesiology, 1st Affiliated Hospital, Wenzhou Medical University, Wenzhou, China
[b] Department of Anesthesiology, Shengjing Hospital, China Medical University, Shenyang, China

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ABSTRACT

Objectives: The randomized, double-blinded, placebo-controlled study evaluated the administration of local infiltration of magnesium combined with ropivacaine to reduce pain scores after pediatric adenotonsillectomy.
Methods: Sixty one subjects received 5 ml solution contained 0.25% ropivacaine plus 5 mg/kg magnesium sulphate (Group M + R), 5 ml 0.25% ropivacaine (Group R) or 5 ml solution contained 5 mg/kg magnesium sulphate (Group M). Pain scores in the ward and at home, analgesics received after operation and the adverse effects were recorded.
Results: Compared with group M, patients in group M + R and group R had lower pain scores, less emergence agitation and increased time for first analgesic request. Group M + R had no benefit in reducing pain scores after adenotonsillectomy compared with group R.
Conclusions: Pre-emptive peritonsillar infiltration of magnesium sulphate 5 mg/kg combined with 0.25% ropivacaine couldn't improve analgesia for pediatric adenotonsillectomy compared with 0.25% ropivacaine alone. However, Group M + R had less incidence of emergence agitation. Compared with group M, both of group M + R and group R had better postoperative analgesia.
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1. Introduction

Adenotonsillectomy is one of the most common surgical procedures which is often associated with intraoperative bleeding and postoperative severe pain [1]. Pain after tonsillectomy begins with local tissue damage and does not completely relieve until the broken lesion is covered with mucosa several days later. Not only inflammation but also topical nerve irritation triggers the pain. The tonsillar fossa is well innervated locally by the glossopharyngeal and trigeminal nerves, and highly represented in the cerebral cortex [2]. Inadequate analgesics lead to delayed oral intake, dehydration, greater risk of laryngospasm, and reduced patient satisfaction. Most importantly, inadequate analgesics increase the risk of postoperative hemorrhage from healing surgical wounds and even rehospitalization.

Several measures have been used to reduce pain including: application of fibrin glue [3] prior injections of local anesthetics [4,5], tramadol [6], corticosteroids [7], ketamine [8], prior oral gabapentin [9], acetaminophen [10] and even non-pharmacologic interventions [11] as adjuvant local analgesic compounds. Each method had its own benefits and drawbacks. A systematic review by the Cochrane Library 2000 found the use of perioperative local anesthetic infiltration can't improve postoperative pain [12]. While another Meta-analysis later in 2008 [13] suggested that local anesthetics were most effective to prevent post-tonsillectomy pain. The Meta analysis by author [14] also found local bupivacaine could provide moderate analgesia after post-adenotonsillectomy.

It was reported that NMDA antagonists could prolong analgesic effect of bupivacaine to even a week [15,16], as well as inhibit hyperalgesia [17]. The fundamental theory of pre-emptive analgesia is to impede the establishment of central hyper-sensitization before surgical intervention by analgesic use [18]. We can hypothesize that local infiltration of magnesium sulphate ($MgSO_4$) with ropivacaine

* Corresponding author. Tel.: +86 13676721930.
E-mail address: 16387706@qq.com (W. Wang).

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can also improve patients pain scores and increase satisfaction for pediatric adenotonsillectomy.

2. Materials and methods

The study registered in Chinese Clinical Trial Registry (ChiCTR-TRC-14004919) was approved by the Institutional Research Ethics Committee of the 1st Hospital of Wenzhou Medical University, China (Ethical number: 2014-32). Informed written consent was obtained from all Parents/guardians of the children. The age of patients ranged from 4 to 10 were recruited. Indications for adenotonsillectomy included recurrent tonsillitis and adenotonsillar hypertrophy. The patients excluded from this trial were those who required prophylaxis with antibiotics, who showed evidence of systemic disease that contraindicated participation in the study, who only performed adenoidectomy or whose parents/guardians disagreed with participation in the study.

Pain was determined by CHEOPS (Children's Hospital of East Ontario Pain Scale) in the hospital and PPPM (Parents' Postoperative Pain Measure) scale at home [19]. The child and their parents were educated about the evaluation scales when preoperative anesthetic visit, for the purpose of becoming familiar with the method of evaluation.

All of the patients had a standard anesthetic given by a single consulting anesthetist (A.D.) or a junior member of the team. The patients were randomly divided into 3 groups. Group M + R received 5 ml solution contained 0.25% ropivacaine plus 5 mg/kg $MgSO_4$ ($n = 20$); Group M received 5 ml solution contained 5 mg/kg $MgSO_4$ ($n = 21$); Group R received 5 ml 0.25% ropivacaine ($n = 20$). Due to the vasodilatation effect of $MgSO_4$, we added epinephrine in concentration of 1:200,000 with the test solution in order to provide adequate hemostasis with less toxicity. A randomization code (generated by Microsoft Excel 2003) was used to assign patients to three different groups. The allocation sequence was placed in sealed envelopes for each child, which was opened before each induction of anesthesia.

Induction of anesthesia was performed by fentanyl (2 μg/kg), propofol (2 mg/kg), and rocuronium (0.6 mg/kg). Thereafter, all patients were intubated. Standard monitoring which included electrocardiography (ECG), noninvasive blood pressure (NIBP), pulse oximetry (SpO_2), end tidal CO_2 and sevoflurane concentrations was used in the operating room. Ventilation was manually assessed to maintain the end-tidal CO2 between 30 and 40 mmHg Anesthesia was maintained with sevoflurane (MAC = 1–1.5) adjusted to maintain heart rate and blood pressure values within 20% of baseline values.

Adenotonsillectomy was performed by cold dissection technique, without utilization of electrocauterization, and hemostasis was achieved by compression with moist gauze swab. Just prior to tonsillectomy, the surgeons infiltrated the study medications superficially into the peritonsillar fossa at the lower pole, upper pole, anterior pillar, posterior pillar and subcapsular plane (2 ml/tonsil) using a straight 23-G needle. The depth of the infiltration was superficial as 3 mm of needle was injected. During adenotonsillectomies or tonsillectomies, none of the patients received additional analgesics. The time of hemostasis after the removal of tonsils was recorded.

After extubation, the patients were transferred to the post-anesthetic care unit (PACU) where an anesthetist or a nurse who was unaware of the study drug observed the patients. Postoperative pain scores using CHEOPS were recorded on 20th minute and 1st hour during the stay of the PACU. CHEOPS scores at 4th, 8th, 24th hour, the second and third day post-operatively were attained by the nurse in the ward. The scores in the ward were assessed by two registered nurses trained how to assess pain using the CHEOPs before the study. They were asked of the severity of throat pain when swallowing at the 1st day postoperatively. The way to evaluate swallowing pain was drinking 100 ml of water. We only observed patients for 3 days before discharging from our hospital. The parents assessed the pain scores using PPPM in the 7th day after operation at home. The trial was undertaken in a double blinded manner. Neither the parents/children, nor the assessing nurses were aware of the technique used. Subjects with postoperative CHEOPS values of 5 and over were given 1 mg/kg tramadol hydrochloride IV for rescue analgesia, and subjects with pain in the ward after removal of the IV catheter received tramadol tablet (25 mg) by the oral route.

Adverse events, such as laryngospasm, breathing difficulties, bleeding, nausea and vomiting, otalgia, and hypotension were recorded. Severity of laryngospasm was evaluated based on a four-point scale: 0: lack of laryngospasm; 1: inhalation stridor; 2: complete obstruction of vocal cords; 3: cyanosis.

Data are expressed as mean ± SD or number of patients. Normal distribution of data was checked by the Kolmogorov–Smirnov test. CHEOPS scores and PPPM score were analyzed using the ANOVA test (in case of normal distribution) or Kruskal–Wallis test (in case of non-normal distribution). All possible multiple comparisons, the Bonferroni Correction was applied for controlling Type I error. Thus, $p < 0.017$ was considered statistically significant. The time to first use of postoperative analgesia was compared among groups using Kaplan–Meier survival analysis and the log-rank test. Categorical data were assessed by the χ^2 test or Fisher's exact test as appropriate. Statistical significance was assumed for $p < 0.05$.

The postoperative CHEOPS score on 4th hour was considered the primary endpoint, and was used to estimate the sample size. It was calculated that sample size of 20 patients in each group with a power of 80% when the alpha error was taken as 0.05, and beta error was taken as 0.20 can detect a 20% difference between group M + R with group M and group R. To account for drop-outs, we recruited 22 patients to each group. Sample size estimates were done using PASS software (PASS 2008, Kaysville, UT, USA). Statistical analyses were done using SPSS 17.0 software (SPSS Inc., Chicago, IL, USA).

3. Results

Sixty one patients completed the study (Fig. 1). Patient characteristics and duration of surgery were comparable among the four groups (Table 1).

Postoperative pain scores were summarized in (Fig. 2). The incidence of swallowing pain was significantly less in group M + R ($p = 0.015$) and group R ($p = 0.037$) compared with group M, respectively. Total number of analgesic interventions were significantly less in group M + R ($p = 0.008$) and group R ($p = 0.003$) compared with group M, respectively. There was no difference between Group M + R and Group R in the swallowing pain and the analgesic interventions. There was also no difference among the three groups in the PPPM on 7th day at home.

As shown in the Kaplan–Meier analysis (Fig. 3), Group M had a significantly shorter time to first analgesic request than Group M + R ($p = 0.012$) or Group R ($p = 0.033$). Group M + R had no statistical difference compared with Group R ($p = 0.664$).

Adverse effects were listed in Table 2. The incidence of laryngospasm in group M and group M + R was less than group R ($p = 0.042$).

4. Discussion

In the postoperative period, the main cause of morbidity is oropharyngeal pain. In fact, children have significant pain within the first day after surgery. It was proposed that more than 80% of children needed pain medication at home after day-case adenoidectomies

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