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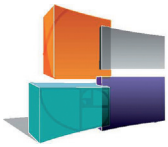

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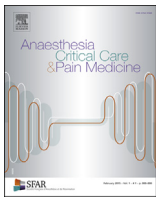

Original Article

A survey of the administration of prednisolone versus ibuprofen analgesic protocols after ambulatory tonsillectomy

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ABSTRACT

Introduction: Postoperative pain, nausea and vomiting are frequent symptoms after tonsillectomy. There have been controversies concerning the advantages and drawbacks of different analgesics in this setting, especially non-steroidal anti-inflammatory drugs, because of potential side effects. We have evaluated the effectiveness and safety of a shift from prednisolone to ibuprofen for postoperative analgesia after tonsillectomy.

Patients and methods: Data from 1231 children scheduled for tonsillectomy over a period of 30 months were analysed. During the first period, children received a combination of paracetamol–prednisolone with codeine as a rescue therapy; in the second period, they received paracetamol and ibuprofen, with tramadol as a rescue therapy. All children received IV dexamethasone at 0.1 mg/kg for antiemetic prophylaxis. The primary end-point was the incidence of severe pain defined as an Objective Pain Scale (OPS) score ≥ 6 at the seventh postoperative day (POD7). Other end-points were postoperative nausea or emesis (PONV), sleep disturbance, oral intake and postoperative haemorrhage and reoperation.

Results: Six hundred and seventy-two and 559 children were included in the prednisolone and ibuprofen groups respectively. OPS scores ≥ 6 were observed in 3.1% of cases (95% confidence interval, 2.3–4.2%) on POD7 for the entire study population. Ibuprofen reduced the incidence of OPS scores ≥ 6 on POD7 (relative risk 0.37, 95% CI: 0.18–0.78; $P = 0.009$), OPS scores in the ambulatory unit ($P < 0.001$) and POD1 ($P < 0.001$), nalbuphine requirements (RR 0.42, 95% CI, 0.34–0.5, $P < 0.0001$), and PONV ($P = 0.01$) compared with prednisolone. Ibuprofen enhanced sleep quality on POD0 ($P < 0.0001$) and POD7 ($P = 0.02$), and oral intake on POD1 ($P < 0.0001$). The incidence of bleeding requiring reoperation was comparable between the two groups (RR 0.8 [95% CI, 0.13–4.78], $p = 0.8$). Predictive factors for an OPS score ≥ 6 at POD7 were OPS score > 4 on the morning and the evening of POD1 (OR 1.24, 95% CI 1.02–1.49, $P = 0.03$ and OR 1.30, 95% CI 1.12–1.55, $P = 0.008$, respectively) and prednisolone use (OR 2.37, 95% CI 1.06–5.31, $P = 0.04$).

Conclusion: The administration of ibuprofen compared to prednisolone improves postoperative comfort in children undergoing ambulatory tonsillectomy without increasing the incidence of side effects.

1. Introduction

Tonsillectomy is a painful procedure requiring an appropriate postoperative analgesic protocol. Opioids are effective in controlling postoperative pain treatment but they are associated with side effects, such as nausea, vomiting and sedation, capable of impairing patient comfort after tonsillectomy. Codeine, which has been commonly used in children scheduled for ambulatory tonsillectomy, has been demonstrated to induce severe side effects, especially in ultra-rapid metabolizers [1,2] and consequently has been contra-indicated in children less than 18 years of age [3]. Non-opioid analgesics are therefore the first line analgesics for postoperative pain management after tonsillectomy.

Oral prednisolone has been combined with paracetamol after tonsillectomy, with controversial results on pain scores [4,5]. Non-steroidal anti-inflammatory drugs (NSAIDs) are highly effective for treating moderate to severe postoperative pain, reducing opioid

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demand and side effects, especially nausea and vomiting [6–8]. A recent meta-analysis documents that NSAIDs improve pain control and decrease opioid requirements in paediatric surgery [8]. Controversy still exists concerning the safety of NSAIDs in children after tonsillectomy. Marret et al. [9] have documented that the use of NSAIDs significantly increases the risk of postoperative bleeding, while others did not find any significant increased risk of reintervention or bleeding [7,10]. One reason for the lack of consensus is the heterogeneity of studies concerning the type of NSAIDs, dosing and duration of treatment. The primary outcome of this retrospective study was to assess pain occurring on the seventh postoperative day after ambulatory tonsillectomy and to determine risk factors for residual severe pain at this time. Secondly, we evaluate the postoperative efficacy and safety of a single NSAID, i.e. ibuprofen, in ambulatory patients scheduled for tonsillectomy, compared with the use of prednisolone in two distinct periods.

2. Patients and methods

The current survey was part of an audit of clinical practice performed in our institution since 2006, and approved since the initiation of the audit by the supervisory authorities (*Haute Autorité de santé*, Paris, December 2006, improvement in the quality of care in ambulatory surgery by creating a health care network between hospital and general physicians). We studied a cohort of ASA I–II children aged less than 13 years who underwent ambulatory tonsillectomy performed for sleep disordered breathing or recurrent tonsillitis from April 2011 to September 2013. Parents or legal surrogates provided a written informed consent to be included in the survey and for data analysis. Data were retrieved from electronic medical records, written postoperative questionnaires (see below for details) completed by parents and the corresponding general practitioner (GP). The retrospective analysis was performed after verifying that the names and any references made to each patient and parents were de-identified to render the analysis anonymous, in accordance with the instructions from the supervisory authority. Procedures included only ambulatory patients, and children with cardiac disease, neuromuscular disorders, orofacial deformities, recent pulmonary infections, obesity ($>$ 95th percentiles of the BMI) or severe apnoea syndrome were excluded as being non-valid criteria for ambulatory surgery. Children with a documented allergy to ibuprofen and/or instable asthma and/or any acute viral infection were also excluded. Parents were instructed on how to manage pain control during the anaesthetic preoperative consultation and analgesic treatment was clearly detailed at this stage. The survey was then divided in two periods during the retrospective analysis from April 2011 to September 2012, and from October 2012 to September 2013. The anaesthetic, surgical, and the acute pain unit institutional teams modified the protocol in September 2012 after careful deliberation, with a shift from codeine to tramadol for rescue analgesia at home, following warnings published in the literature [1,2], and to respond to the discomfort frequently raised by parents whose children took oral prednisolone. Data were analysed every month by the acute pain service associated with the physicians and surgeons in charge of ambulatory surgery.

2.1. Intraoperative management and analgesia in ambulatory units

Tonsillectomy was performed during the morning in all cases. Oral intake of clear fluid was allowed until 2 h before surgery, and solid intakes were stopped 6 h before surgery. Premedication was provided by oral midazolam at 0.3 mg/kg (maximum 5 mg) 30 minutes before surgery, and was associated with ibuprofen at 10 mg/kg in the second period. All the surgical procedures were performed under general anaesthesia with tracheal intubation. Surgical dissection was performed either by conventional electrodissection or with harmonic scalpels at the discretion of the three surgeons involved from the start of the study. No partial tonsillectomy was performed. In children less than 6 years of age, anaesthesia was induced with sevoflurane at 6–8% in air–O_2 50%/50% followed, after establishment of an intravenous (IV) access, by propofol 2–3 mg/kg with sufentanil 0.3 μg/kg. Children $>$ 6 years of age had intravenous induction with propofol at 3 mg/kg and sufentanil at 0.3 μg/kg. All children were given modified Ringer Lactate containing 1 g/100 mL glucose when under 7 years of age or conventional Ringer Lactate with the same modality: 20 mL/kg during the first hour, then 4–6 mL/kg/h until oral feeding. Anaesthesia was maintained with sevoflurane at 2–3% in 50% O_2–air to keep mean arterial pressure within 20% of baseline values, and controlled ventilation adapted to achieve an $ETCO_2$ between 35 and 40 mmHg. All the children received a single IV dose of dexamethasone at 0.15 mg/kg after tracheal intubation for prevention of postoperative nausea and vomiting (PONV). Normothermia was maintained using a forced air warmer before induction until discharge from the post-anaesthesia care unit (PACU). During surgery, no additional opioid was administered and all patients received one IV (10 mg/mL) with paracetamol at 15 mg/kg and ketamine at 0.3 mg/kg. They were extubated at the end of the surgical procedure in the operative room and transferred to the PACU. Children systematically received 2 L/min supplemental O_2 and V nalbuphine at 0.2 mg/kg was administered when the Objective Pain Scale (OPS, [11]) score was $\geq$ 4 during swallowing, and repeated only once in the ward if necessary according to the OPS score. Nausea and/or vomiting were treated with IV ondansetron at 0.1 mg/kg. In the ambulatory unit, all the children received an oral dose of paracetamol at 0.15 mg/kg six hours after the first IV dose. In the first part of the study, children were given prednisolone at 0.5 mg/kg, upon the resumption of oral feeding in the ambulatory surgical unit. In the second part of the study, ibuprofen at 10 mg/kg was given simultaneously. Discharge criteria were an OPS score $\leq$ 3 with no vomiting for 2 hours after oral intake, spontaneous voiding and no bleeding. No antibiotics were given during and after surgery and no local infiltration was performed during surgery.

2.2. Postoperative analgesia at home

Before October 2012, postoperative analgesia was achieved with a systematic combination of oral paracetamol at 15 mg/kg/6 h and prednisolone at 0.5 mg/g/d for 7 days. Codeine at 1 mg/kg/6 h was used as a rescue therapy when the OPS score was $\geq$ 4 during this period. From October 2012 to September 2013, the postoperative protocol included the same dose of paracetamol for 7 days associated with oral ibuprofen at 10 mg/kg/8 h for 4 days, and an oral suspension of tramadol at 1 mg/kg/8 h$^{/}$(100 mg/mL) was used as a rescue therapy when the OPS score was $\geq$ 4.

2.3. Measurements

The data included demographics, duration of surgery, anaesthetic induction, surgical procedure (electrodissection or harmonic scalpel), pain, oral food intake, sleep quality and postoperative complications including postoperative haemorrhage, transfusion, readmission, and reoperation. Pain was assessed using the Objective Pain Scale validated [11] in infants and children and including five physical criteria, each ranging from 0 to 2 (best to worst). The OPS score was modified (Table 1) for postoperative evaluation at home by changing blood pressure assessment by observation of posture (0: no special posture; 1: flexing legs and