

Comparative study of diclofenac sodium and paracetamol for treatment of pain after adenotonsillectomy in children

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ABSTRACT

Objectives: To compare the analgesic efficacy of diclofenac sodium and paracetamol on post adenotonsillectomy postoperative pain and oral intake.

Methods: Between January 1999 and July 2000, 80 children aged 3-14 years, underwent tonsillectomy and adenoidectomy for either recurrent tonsillitis or adenotonsillar hypertrophy in Prince Zeid Ben Al-Hussein Hospital and Prince Rashid Ben Al-Hussein Hospital. Forty-one children received diclofenac sodium suppositories (1-3mg/kg) postoperatively, whereas 39 children received only paracetamol syrup (10-15 mg/kg) in 4 divided doses. All children were observed for postoperative pain, oral intake, vomiting, temperature and complications.

Results: Children who received diclofenac sodium had significantly less pain, less elevation of temperature, more oral intake, and started drinking significantly sooner than the paracetamol group. Two children in the diclofenac group experienced nausea and vomiting compared to 12

children in the paracetamol group in the first day. The time to first solid intake was significantly earlier in the diclofenac sodium group ($p < 0.0001$). With regard to complications, one patient in each group developed secondary hemorrhage, one child developed otitis media in the 2nd group. Each group had one readmission, and 2 children from the paracetamol group had an emergency department visit for pain and dehydration.

Conclusion: Diclofenac sodium has a significant effect on decreasing the pain associated with swallowing postoperatively and on the general condition of the patient. Improved oral intake resulted in a lower incidence of nausea and vomiting and allowed safer and earlier hospital discharge.

Keywords: Paracetamol, diclofenac sodium, postoperative pain, tonsillectomy, complications, bleeding.

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Adenotonsillectomy is one of the most frequent Ear, Nose and Throat (ENT) operations performed in children. Electrocautery dissection tonsillectomy has been shown to reduce operation time and virtually eliminate immediate postoperative hemorrhage,¹ but it may increase pain and decrease oral intake causing later complications.² Nonsteroidal anti-inflammatory drugs (NSAIDs) are effective in the treatment of postoperative pain, but side effects may hinder their use in some patients in

the preoperative period.³ Diclofenac is a NSAID with pronounced anti-rheumatic, anti-inflammatory, analgesic and anti-pyretic properties. Diclofenac inhibits prostaglandin synthesis, which play a major role in the causation of inflammation, pain and fever.⁴ Paracetamol produces analgesia and anti-pyresis by a mechanism similar to that of salicylate, which involves inhibition of prostaglandin synthesis. The purpose of this study was to compare the analgesic efficacy of diclofenac sodium and

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paracetamol administered postoperatively on post-adenotonsillectomy pain, oral intake and general condition of the patients.

Methods. Between January 1999 and July 2000, 80 Jordanian children aged 3-14 years underwent adenotonsillectomy at Prince Zeid Ben Al-Hussein Hospital and Prince Rashid Ben Al-Hassan Hospital. Patients with renal disease, gastrointestinal disease, chronic pain states or daily intake of NSAIDs were excluded. Informed consent was obtained from all families. All patients were admitted one day prior to surgery after showing normal results for their routine investigations. The patients were divided into 2 groups: first group (41) patients received diclofenac sodium (1-3mg/kg) in 2 divided doses, first dose at the end of surgery before the patient woke-up from anesthesia, with the 2nd dose 8 hours postoperatively. The second group (39) patients received paracetamol syrup (10-15mg/kg) in 4 divided doses. Inhalation anesthesia with halothane was used and supplemented with intravenous fentanyl 200-400mg and endotracheal tube inserted. Adenotonsillectomy was carried out by shaving and curette for adenoidectomy and electrocautery dissection for tonsillectomy. Homeostasis was secured by bipolar cautery. Ligature was not used in this study for homeostasis. All patients underwent extubation in the operating room then transferred to the recovery room, vital signs were assessed, and after appropriate care in the recovery room the children were transferred to the inpatient floor. During this interval any instance of crying, vomiting or agitation was recorded. The children were assessed 6, 10 and 24 hours after surgery to see whether they required pain medication. Time of first oral intake and quantity was recorded, temperature, nausea and vomiting was also recorded. All children were on crystalline penicillin injection or Erythromycin from the time of admission, and they were discharged on oral antibiotics for 7 days.

Results. Data from 80 patients was analyzed, 41 patients in the first group and 39 patients in the 2nd group. Objective measurement showed 6 patients (15%) in the paracetamol group, while only 1 patient (2.5%) in the diclofenac sodium group had a temperature higher than 38°C 6 hours postoperatively. Nausea and vomiting episodes up to 10 hours postoperatively were recorded in 1 patient in the first group (2.5%) and in 12 patients (31%) in the paracetamol group, and it was significantly lower (P value = 0.05) in children who received diclofenac sodium. The extreme values test showed that oral intake was significantly higher (p value = 0.02) in children who received diclofenac sodium (595ml in the first group versus 390ml in the 2nd group). Earache was experienced by 10 patients (26%) in the paracetamol group as compared to 2 patients (5%) in

Table 1 - Time to first fluid intake.

	Group 1	Group 2
Range	2-15 hours	3-24 hours
Mean	5.4 hours	7 hours
Standard deviation	4.2	4.48
P value < 0.1 (non significant)		

Table 2 - Time to first solid intake.

	Group 1	Group 2
Range	3-24 hours	12-30 hours
Mean	9.5 hours	16.50 hours
Standard deviation	5.97	3.97

the diclofenac group in the first 24 hour postoperative period. The number of patients who had no oral intake 6 hours postoperatively was 3 patients (7%) in the diclofenac sodium group as compared to 15 patients (38%) in the paracetamol group. After 24 hours all patients in the diclofenac sodium group had oral intake (active swallowing) while 5 patients (13%) in the 2nd group had no oral intake. The time to first oral fluid and solid intake was recorded as shown in (Table 1 and 2). The time to first oral fluid intake was earlier in the first group but statistically non-significant ($p < 0.1$) while the time to first solid intake was significantly earlier ($p < 0.001$). The time to first solid intake was used as a crude parameter for postoperative pain, which was shorter in the first group (diclofenac sodium group).

With regard to complications post tonsillectomy, there were no episodes of primary hemorrhage (first 24 hours) in both groups, one child in each group developed secondary hemorrhage. A patient in the paracetamol group was admitted on the 7th day for observation and intravenous fluid without further surgical treatment, the other 14 year old patient in the diclofenac sodium group required suctioning of the clot and mouth gargle with hydrogen peroxide (3%) and admission for observation and antibiotic therapy. One child in the paracetamol group developed otitis media on the 5th day postoperatively. One case in each group had readmission to hospital. Two cases in the 2nd group had to visit the emergency department for pain and dehydration.

Discussion. Adenotonsillectomy is the most common surgical procedure in the specialty of otolaryngology.⁵ Postoperative pain is a significant

problem that continues to be untreated in the pediatric population, which leads to the inability to tolerate oral fluids and unplanned hospitalization. Prostaglandins contribute to pain and inflammation after tissue injury and the antinociceptive action of NSAIDs is attributed usually to peripheral inhibition of prostaglandin synthesis. It has been demonstrated that topical application of NSAIDs modifies the inflammatory response of ultraviolet irradiation^{6,7} and reduces local edema and erythema after burn injuries in some studies.⁸ Many studies have been carried out to evaluate the effect of diclofenac sodium on pain post tonsillectomy. Colbert et al⁹ compared intravenous tenoxicam with rectal diclofenac sodium and found that both drugs had similar efficacy. Baer et al¹⁰ compared the effects of rectally administered diclofenac sodium (12.5ml) with paracetamol and concluded that diclofenac for pain relief after adenoidectomy is safe and effective. In our study, we found that diclofenac sodium given (1-3mg/kg) in 2 divided doses after adenotonsillectomy increases liquid and solid intake in the first 24 hours, decreases pain and resulted in earlier discharge from hospital. Only one case of secondary hemorrhage occurred in each group.

We conclude that administration of diclofenac sodium increases safety, decreases pain, results in a lower incidence of nausea and vomiting and increases oral intake and is helpful for the children and their parents.

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