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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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
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. Postoperative pain is a significant

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**Table 1 - Time to first fluid intake.**

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>2-15 hours</td>
<td>3-24 hours</td>
</tr>
<tr>
<td>Mean</td>
<td>5.4 hours</td>
<td>7 hours</td>
</tr>
<tr>
<td>SD</td>
<td>4.2</td>
<td>4.48</td>
</tr>
</tbody>
</table>

P value < 0.1 (non significant)

**Table 2 - Time to first solid intake.**

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>3-24 hours</td>
<td>12-30 hours</td>
</tr>
<tr>
<td>Mean</td>
<td>9.5 hours</td>
<td>16.50 hours</td>
</tr>
<tr>
<td>SD</td>
<td>5.97</td>
<td>3.97</td>
</tr>
</tbody>
</table>
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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\textsuperscript{6,7} and reduces local edema and erythema after burn injuries in some studies.\textsuperscript{8} Many studies have been carried out to evaluate the effect of diclofenac sodium on pain post tonsillectomy. Colbert et al\textsuperscript{9} compared intravenous tenoxicam with rectal diclofenac sodium and found that both drugs had similar efficacy. Baer et al\textsuperscript{10} 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.

References