A COMPARISON OF THE EFFECT OF ORAL PARACETAMOL AND CLONIDINE ON PEDIATRIC PREOPERATIVE ANXIETY IN ADENOTONSILLECTOMY

S Abbas Hosseini Jahromi, S Massumeh Hosseini Valami, N Naseh

ABSTRACT
Objective: To see the effect of oral paracetamol and clonidine on pediatric preoperative anxiety in adenotonsillectomy.
Methodology: The participants of this double blind clinical trial study consisted of 120 children. Their age range was between 3-12 years. They were in ASA class I of anesthesia and were chosen for elective adenotonsillectomy in Qods hospital in Qazvin, Iran. The patients were randomly divided in three equal groups. One group received paracetamol 20 mg/kg, another group received 4mcg/kg clonidine orally 60-90 minutes before operation and the third group received placebo. As the first step, in order to do the statistical analysis, intensity of preoperative anxiety had been evaluated by Modified-Yale Preoperative Anxiety Scale (m-Yale PAS) and data were transformed to the SPSS software. Then different statistical procedures like Chi-square, One way Anova and Tukey test were performed.
Results: There was no significant difference (statistical) of age, weight and sex among three groups. Mean score of anxiety was significantly lower in paracetamol and clonidine’s groups than placebo’s group, but there was no significant statistical difference between paracetamol and clonidine’s groups in decreasing preoperative anxiety score.
Conclusions: Oral paracetamol like oral clonidine decreases preoperative anxiety score. Thus one can use paracetamol instead of clonidine.

KEY WORDS: Paracetamol, Clonidine, Preoperative anxiety.

INTRODUCTION

Preoperative anxiety is an important problem because it produces undesired effects on postoperative outcome and it interacts with anesthesia. Anxiety specially generates significant side effects in pediatric patients though controlling it is very remarkable. Adenotonsillectomy is one of the most common surgeries in pediatric age groups and preoperative anxiety can be considered a major problem in these patients.

Preoperative anxiety not only changes doses of drugs which need for induction, maintenance of anesthesia, recovery from anesthesia,
sedation and analgesia, but also it affects psychological conditions of children and their parents.

Preoperative anxiety leads to tension, fight, anger and apprehension in children. They show them differently in postoperative period. Postoperative anxiety can produce inharmonious behavior such as nocturia, problem in eating and disturbed sleep. Stress and anxiety activate Hypothalamous-Hypophysis-Adrenal axis and increase glucocorticoid level. They also change the function of immune system and make the body more prone to infection.

Stress releases hormones such as cortisol, catecholamines and cytokinin. These hormones increase negative nitrogen balance and catabolism and ultimately delay wound repair and weaken immune system postoperatively. Due to restricted energy reserve in children and their large glucose requirement, they are sensitive to the response of a surgery.

Now a days in Iran a few children receive preoperative medication before operation. Thus they are more prone to anxiety and its side effects. In order to prevent these problems, we decided to compare paracetamol, which is a safe drug in routine and usual therapeutic dose, useful for analgesia and decreasing temperature in febrile children with clonidine which has confirmed anti-anxyolitic effect.

If anti-anxiety effect of paracetamol is proven, one can use it as preoperative medication in pediatric age group.

METHODOLOGY

This study was performed after taking permission of institution’s human subjects committee, and getting informed consent of the parents of the participants. In this double blind clinical trial, 120 children with age range of 3-12 years and in class I of Anesthesia had been scheduled for adenotonsillectomy. Those with positive history of common cold during previous five weeks and patients with positive history of fever, convulsion, drug allergy, asthma and consumers of anticonvulsive drugs, sedatives and antihistamines had been exited from the study. The first step was to randomly assign the patients to three groups according to their colored card.

In the first group, paracetamol 20mg/kg, in the second group clonidine 4mcg/kg and in the third one 5 ml placebo were administered orally 60-90 minutes before operation. In all patients severity of anxiety had been assessed with modified Yale preoperative anxiety score (m-Yale PAS) in operative room before intravenous catheterization.

In m-Yale PAS, anxiety was assessed based on their activities, (1-4) emotional expression, (1-4) Vocalization, (1-6) state of arousal (1-4) and interaction with family members. The minimum of score is five (minimum anxiety) and the maximum is 22 which means severe anxiety.

After determining the intensity of anxiety, venous catheterization had been done. Children received drug for premedication, induction and maintenance of anesthesia in equal condition.

All data was transferred to the SPSS-10 software and analyzed statistically with Chi-square test and Turkey after test. P-Value less than 0.05 was considered meaningful.

RESULTS

The mean age in control group was 7.48±2.9, in clonidine group was 7.3±2.69 and in paracetamol group was 6.9±2.7 years (P-Value>0.05), which did not show significant statistical difference among three groups. About 45% of control group, 52% of clonidine and 42% of patients in paracetamol group were male, so there was not any significant statistical gender difference among three groups. (P-Value= 0.64)

The mean of weight in control group was 24.15±7.6 kg, in clonidine group was 23.98±8.2 kg and in paracetamol group was 22.58±7.7 kg. Therefore there was not significant statistical difference according to their weight. (P-Value >0.05)

The mean of the anxiety score in control group was 12.43±4, in paracetamol group was 6.13±2.4 and in clonidine group was 6.08±1.
As regards Turkey after test, difference of anxiety score between control-paracetamol group and control clonidine group make sense and seems completely reasonable (P-Value=0.001) but there was not significant statistical difference between paracetamol and clonidine group. (P-Value=0.99). (Table-I)

DISCUSSION

Children are more vulnerable to stress of surgery due to presence of restricted energy supply, larger brain mass and their excessive requirement to glucose.9 It is determined that more than 60% of children who had an operation, encountered negative behavioral changes in 2 weeks after that time.1,10

The most important factors which determine postoperative outcome are incisional pain, nausea and vomiting, preoperative anxiety and discomfort from intravenous injection.11 There is an agreement among anesthesiologist about treatment of preoperative anxiety. Anti-anxiety effect of clonidine has been documented previously5-7,12 but anxiolytic effect of paracetamol was not studied.

In this study there was no significant statistical difference among three groups in regarding their age, sex and weight thus three groups were cohort with each other. This study determined that anxiety score was lower in paracetamol and clonidine group than control one but there was not significant statistical difference between clonidine and paracetamol group. This means that paracetomol and clonidine can equally decrease preoperative anxiety in the children. Thus we can use paracetamol instead of clonidine.

There is some data to suggest that paracetamol may have analgesic activity on cannabinoid receptors in the CNS and that this activity is mediated through a metabolite (N-arachidonyphenolamine).13 This metabolite may have an antianxiolytic activity through the same receptors but this has not yet been described.

Analgesic effect of paracetamol is due to inhibition of cox-3.14 Paracetamol also increases serotonin bioavailability and its analgesic effect can be blocked by tropisetron.15 As a result it may produce anti-anxiety effect by this way but it is not proven.

As such further research focusing on the effects of paracetamol on mood and anxiety is needed. If anti-anaxylitic effect of paracetamol are established one, we can use it for sedation.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean’s difference</th>
<th>Standard deviation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control-paracetamol</td>
<td>6.30</td>
<td>0.659</td>
<td>0.001</td>
</tr>
<tr>
<td>Control-clonidine</td>
<td>6.34</td>
<td>0.667</td>
<td>0.001</td>
</tr>
<tr>
<td>Paracetamol-clonidine</td>
<td>0.046</td>
<td>0.668</td>
<td>0.99</td>
</tr>
</tbody>
</table>

Fig1: Mean of anxiety score (on the basis of m-YPAS) in control, paracetamol and clonidine group.

Table-I: Comparison of difference in mean anxiety score (on the basis of m-YPAS) between control, paracetamol and clonidine group.
Paediatric preoperative anxiety

of children before undertaking different procedures.

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REFERENCES