Comparing The Efficacy of Ibuprofen alone with Ibuprofen and Paracetamol in Combination in Relieving Post Tonsillectomy Pain in Children: A Prospective Comparative Study

Saqib Aziz, Noshad Ali, Muhammad Ilyas, Saba Rehman, Saeed Khan*, Deepak Rai

1Fellow Head and Neck Surgical Oncology, Shaukat Khanum Hospital, Lahore.
2Postgraduate Trainee, Department of ENT, Jinnah Postgraduate Medical Centre Karachi.
3Associate Professor, Department of ENT, PGMI/AMC/LGH Lahore
4Medical Officer, Paeds Department, RMI Peshawar.
5Assistant Professor, Department of ENT & Head and Neck, Hayatabad Medical Complex/PGMC, Peshawar
6Post Graduate Trainee, FCPS, Department of ENT, JPMC Karachi

*Corresponding Author: Saeed Khan; Assistant Professor; Email: azhar.khan78@yahoo.com

Conflict of Interest: None.

ABSTRACT

Background: Tonsillectomy is a frequent surgical intervention for recurrent tonsillitis in both adults and children, employing predominantly the cold steel method. Pain management post-surgery primarily involves NSAIDs and opioids, with varying degrees of effectiveness and side effects.

Objective: The study aimed to evaluate the pain relief efficacy of combining ibuprofen with paracetamol compared to the use of ibuprofen alone in children post-tonsillectomy.

Methods: Following ethical approval, 278 children with recurrent sore throat and quinsy were enrolled in an inpatient study at the Department of ENT, A unit of Hayatabad Medical Complex, Peshawar, from May 06 to August 30, 2023. This analytic cross-sectional study utilized a comparative prospective data collection approach and non-probability convenience sampling. Participants included 142 boys and 136 girls, aged 6 to 12 years.

Results: Of the total 278 children, 142 (51.1%) were male and 136 (48.9%) female. Ibuprofen alone was prescribed to 136 children, while 134 received a combination of ibuprofen and paracetamol. Among those treated with the combination therapy, 65 (23.4%) reported no pain (VAS scores 1-3). In contrast, those receiving ibuprofen alone reported moderate pain (VAS scores 4-7) as follows: 2.2% (N=6), 11.2% (N=31), 19.4% (N=54), and 9.4% (N=26); and severe pain (VAS scores 8-10) was reported by 6.5% (N=18) and 0.4% (N=1).

Conclusion: The combination of ibuprofen and paracetamol is significantly more effective in managing post-tonsillectomy pain in children compared to ibuprofen alone.

Keywords: Children, Ibuprofen, Paracetamol, Post-tonsillectomy pain, Tonsillectomy, VAS scale.

INTRODUCTION

Recurrent tonsillitis constitutes a significant indication for the performance of tonsillectomy in both adults and children, although the presence of tonsils alone does not necessitate this surgical intervention (1). Annually, over half a million tonsillectomies are conducted in the United States, positioning it as the second most common pediatric surgical procedure (3). Among the various techniques available for tonsillectomy, cold steel dissection remains the most prevalent (4). Postoperative pain is a universal symptom following this surgery, and while acetaminophen, opioids, and nonsteroidal anti-inflammatory drugs (NSAIDs) have been recognized as effective analgesics, opioids are often associated with adverse effects such as drowsiness, respiratory distress, nausea, vomiting, itching, and constipation.

NSAIDs offer an efficacious alternative with a reduced propensity for such side effects, significantly diminishing the requirement for opioids (7,8,9). Recent meta-analyses have corroborated the utility of NSAIDs in managing postoperative pain and minimizing opioid dependency after pediatric surgical procedures (9). However, the application of NSAIDs in the post-tonsillectomy period is marred...
by controversy due to potential risks of impaired platelet function and subsequent bleeding (5,6). Despite these concerns, the safety profile of NSAIDs remains debated; while some studies, like that of Marret et al., have highlighted an increased risk of postoperative bleeding, others have not observed such complications (8,10).

It has been observed that the perception of pain varies with age, with adolescents and adults reporting higher levels of discomfort post-tonsillectomy compared to children under 12 years of age (11). This study endeavors to assess the efficacy of intravenous ibuprofen alone versus a combination of ibuprofen and paracetamol in alleviating post-tonsillectomy pain in a tertiary care setting. Given the diverse array of antibiotics available for pain management, this investigation aims to delineate the most effective treatment modality, thereby facilitating prolonged pain relief.

The objective of this study is to rigorously compare the effectiveness of ibuprofen alone to that of a combined regimen of ibuprofen and paracetamol in the management of postoperative pain following tonsillectomy in children. Through this comparative analysis, we aim to identify an optimal analgesic strategy that not only ensures substantial pain relief but also minimizes potential adverse effects, thereby contributing to the improvement of pediatric postoperative care.

MATERIAL AND METHODS
Following the approval of the Hospital Ethical Committee, a study was conducted on an inpatient basis from May 6, 2023, to August 30, 2023, at the Department of Otorhinolaryngology- A unit of Hayatabad Medical Complex in Peshawar. This research was designed as an analytic cross-sectional study, employing a comparative prospective data collection methodology alongside a non-probability convenience sampling technique. The study encompassed two hundred and seventy-eight children, presenting with recurrent sore throat (experiencing at least 6-7 episodes per year for more than one year) and recurrent quinsy. Among the participants, 142 were boys, and 136 were girls, with their ages ranging from 6 to 12 years.

Children diagnosed with blood dyscrasias, upper and lower respiratory tract, and cardiopulmonary diseases were excluded to ensure the study's integrity. Prior to the surgical procedure, routine preoperative investigations, including Full Blood Count (FBC), coagulation profile, and virology tests, were meticulously conducted. Hemostasis was achieved using silk-1, and all participants received postoperative analgesics. The cohort was dichotomized, with fifty percent administered a single analgesic and the remainder receiving a combination of analgesics.

The administration of ibuprofen was calibrated based on weight, with doses ranging from 4 to 10 mg/kg/dose given orally in syrup form every 6-8 hours. Similarly, the dosage of paracetamol was set at 10-15 mg per kilogram of the child's weight, also administered in syrup form once every 6 hours. The intensity of pain experienced postoperatively was quantified using a Visual Analog Scale (VAS; 0-100 mm), which comprised a 100 mm horizontal line demarcated by two endpoints indicating 'no pain' and 'the worst pain possible.' A physician instructed each child to mark a point on the line corresponding to their perceived pain intensity. The VAS was scored by measuring the distance from the 'no pain' endpoint to the mark made by the child. Comprehensive information and guidance on utilizing the VAS were provided to each child upon hospital admission.

To determine the requisite sample size, a calculation was performed using Raosoft, which indicated a need for 278 participants. This calculation was based on a confidence level of 95%, a margin of error of 5%, a total population size of 2000, and an expected response distribution of 70%.

Statistical analyses were executed using the SPSS windows program, version 26 (SPSS Institute, Inc., Chicago, IL, USA). Descriptive statistics were calculated for the demographic characteristics of the study population and are presented as means (with standard deviations [SD]), medians with ranges, or as absolute and relative frequencies. For the comparative analysis between the two groups within the study population, the Mann-Whitney U test was employed. A P-value of less than 0.05, at a 95% confidence limit, was considered statistically significant.

RESULTS
Table 1 illustrates the gender distribution of the 278 children who participated in the study. Out of the total participants, 142 were male, accounting for 51.1% of the study population, while 136 were female, representing 48.9%. This table provides an overview of the demographic composition of the study group.
Table 1: Gender Distribution of Study Participants

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>142</td>
<td>51.1</td>
</tr>
<tr>
<td>Female</td>
<td>136</td>
<td>48.9</td>
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<tr>
<td>Total</td>
<td>278</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 2 Use of pain killer

<table>
<thead>
<tr>
<th>Painkiller</th>
<th>Cases</th>
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<th></th>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Valid</td>
<td>Missing</td>
<td>Percent</td>
<td>Percent</td>
<td>N</td>
<td>Percent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>136</td>
<td>3</td>
<td>97.8%</td>
<td>2.2%</td>
<td>139</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td>paracetamol and ibuprofen</td>
<td>134</td>
<td>5</td>
<td>96.4%</td>
<td>3.6%</td>
<td>139</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

Patients receiving a combination of painkillers (Ibuprofen with Paracetamol) N=13 (4.7%), N=56 (20.1%), N=65 (23.4%) complained of No pain labelled 1,2 and 3, Respectively. While patients receiving a single painkiller (Ibuprofen alone) N=6 (2.2%), N=31 (11.2%), N=54 (19.4%), N=26 (9.4%) complained of Moderate pain labelled 4,5,6,7 and N=18 (6.5%), N=1 (0.4%) Severe pain labelled 8,9,10, Respectively. There was a statistical significant difference between pain control in two groups (Mann Whitney U test p <0.05)

Table 3 Frequency of pain

<table>
<thead>
<tr>
<th>Valid</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
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</thead>
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<tr>
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<td>20.1</td>
<td>20.7</td>
<td>25.6</td>
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<tr>
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<td>65</td>
<td>23.4</td>
<td>24.1</td>
<td>49.6</td>
</tr>
<tr>
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<td>2.2</td>
<td>2.2</td>
<td>51.9</td>
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<tr>
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<td>11.5</td>
<td>63.3</td>
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<tr>
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<td>9.4</td>
<td>9.6</td>
<td>93.0</td>
</tr>
<tr>
<td>severe_pain_8</td>
<td>18</td>
<td>6.5</td>
<td>6.7</td>
<td>99.6</td>
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<tr>
<td>severe_pain_9</td>
<td>1</td>
<td>.4</td>
<td>.4</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>270</td>
<td>97.1</td>
<td>100.0</td>
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</tr>
<tr>
<td>Missing</td>
<td>System</td>
<td>8</td>
<td>2.9</td>
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<td>Total</td>
<td>278</td>
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</table>

**DISCUSSION**

Tonsillectomy, a prevalent surgical intervention in the pediatric population, plays a critical role in the management of recurrent sore throat and quinsy. This study aimed to assess the comparative efficacy of ibuprofen alone versus a combination of ibuprofen and paracetamol in managing postoperative pain, utilizing the Visual Analog Scale (VAS) for pain measurement. The selection of VAS was grounded in its well-documented reliability and validity for pain self-assessment in children aged seven years and above (12,13,14), providing a robust framework for our analysis.

Our findings demonstrated that patients who received a combination of analgesics experienced significantly improved pain control compared to those administered ibuprofen alone. This observation is congruent with prior research conducted by N. Aldamluji, affirming the benefits of multimodal pain management strategies. Further, the study's outcomes align with the findings of Tolsa HK, which highlighted the efficacy of specific antibiotics in the control of mild to moderate pain (15,16), albeit our focus was on analgesic rather than antibiotic therapy. Notably, the endorsement of NSAIDs as the first-line treatment by some Swedish and French guidelines (17,18) reinforces the relevance of our study within the broader context of postoperative pain management protocols.
The strength of this research lies in its direct comparison of two prevalent analgesic regimens, offering valuable insights into optimal pain management strategies post-tonsillectomy. The utilization of VAS as a measurement tool further enhances the study's credibility, providing a quantifiable measure of pain that is both reliable and valid for the pediatric age group concerned.

However, the study's scope is limited by its single-center design, which may restrict the generalizability of the findings. The involvement of multiple centers could potentially yield more comprehensive insights, reflecting a broader spectrum of patient responses and operational practices. Such expansion would not only affirm the current findings but also provide a more nuanced understanding of the efficacy of combined analgesic therapy across diverse clinical settings.

Our research substantiates the superior efficacy of combined ibuprofen and paracetamol therapy over ibuprofen alone in managing post-tonsillectomy pain in children. These findings suggest a potential shift towards multimodal analgesic strategies in clinical practice, although further studies encompassing multiple centers are warranted to validate these conclusions across varied populations and clinical environments.

**CONCLUSION**

In conclusion, this study has demonstrated that the combination of ibuprofen and paracetamol provides superior pain management following tonsillectomy when compared to ibuprofen alone. The findings suggest that incorporating a dual analgesic regimen could enhance patient comfort and recovery outcomes post-surgery.

The implications of this research highlight the importance of adopting a multimodal approach to pain management in post-tonsillectomy care for children. Healthcare providers are encouraged to consider the benefits of combined analgesic therapy in clinical practice to improve the overall quality of postoperative care and patient satisfaction.

**REFERENCES**