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Research Article

Intravenous Ibuprofen Versus Diclofenac Suppository for Perioperative Pain Control in Pediatric Tonsillectomy with or without Adenoidectomy: A Randomized Controlled Trial

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ABSTRACT

Background: This study aimed to compare the combination of intravenous ibuprofen and intravenous paracetamol versus combined diclofenac suppository and intravenous paracetamol for pain control after tonsillectomy or adenotonsillectomy in children.

Methods: This is a randomized controlled study involving 90 children aged between 1 and 7 years, classified as ASA I or II, scheduled to undergo tonsillectomy or adenotonsillectomy between February 2023 and February 2024 at Cairo University Hospitals.

Results: There was a statistically significant difference regarding FLACC score between the two groups (p=0.006) at 10 min after arrival to PACU, while it was not significantly different between the two groups on arrival or discharge from PACU (p=0.054 and 0.208, respectively). There was no statistically significant difference in PPPM between the two groups at 4, 12, and 24 hours postoperative (p=0.718, 0.470, and 0.738, respectively). Regarding the number of patients who received rescue analgesia (pethidine), they were fewer in group A (p=0.031), and the mean dose of pethidine received/kg as rescue analgesia was also significantly lower in group A (p=0.0316). The incidence of postoperative adverse events, i.e., nausea, vomiting, hypotension (low SBP = <70 + 2 (age in years)), bradycardia (less than 60 beats/min), drug allergic reaction, and postoperative bleeding requiring return to the operative room, was zero in the two groups.

Conclusion: The combination of intravenous ibuprofen and intravenous paracetamol was a more effective analgesic regimen than the combined rectal diclofenac and intravenous paracetamol in pediatric patients undergoing tonsillectomy or adenotonsillectomy without increased complications.

Introduction

Postoperative acute pain is unfortunately often underestimated and undertreated in the pediatric population. Opioids are mostly involved in postoperative pain management protocols in children. The side effect profile of opioids, e.g., nausea, vomiting, GIT motility disorders, and respiratory depression, necessitated the need for other alternatives or adjuvants to opioid therapy [1-3].

Paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) are the major players in this field. The opioid-sparing or replacing use of these drugs has been demonstrated following different surgeries in adult as well as pediatric age groups. Such an approach would result in reduced opioid requirements and hence opioid-

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induced side effects, e.g., nausea, vomiting, GIT motility disorders, and respiratory depression [4-5].

Adenotonsillectomy and tonsillectomy are common pediatric procedures during which different NSAID and paracetamol combinations are used for postoperative pain control [6-7].

Other modalities for post-tonsillectomy pain management include steroids, centrally acting non-opioid analgesics, opioids, α-2 receptor agonists, and pregabalin. Ultrasound-guided GPN block will shed new light on multimodal analgesia [8-9].

Diclofenac suppository is one of the standard pain management drugs used alone or in combination in children undergoing tonsillectomy [8-9]. Regarding the risk of postoperative bleeding, a meta-analysis of 36 randomized controlled studies including 1747 children concluded that NSAIDs did not increase the risk of postoperative bleeding [10].

Ibuprofen is a NSAID frequently used in children with an approved safety profile that is comparable to paracetamol. The US Food and Drug Administration (FDA) approved intravenous ibuprofen for use in pain and fever control in 2009 [11-12].

This study aimed to compare IV ibuprofen versus diclofenac suppository for pain control after tonsillectomy or adenotonsillectomy in children.

Methods

This study obtained approval from the Ethics Committee of the Faculty of Medicine, Cairo University, Egypt (Approval code: MD-247-2022, Date: 29-8-2022). Consent was obtained from the patients' guardians.

This was a prospective randomized controlled study involving 90 children aged between 1 and 7 years classified as American Society of Anesthesiologists physical status I or II scheduled to undergo tonsillectomy or adenotonsillectomy in the period between February 2023 and February 2024 at Cairo University Hospitals. Patients with a past history of cardiopulmonary, kidney, or liver dysfunction; asthma; GIT bleeding; coagulation disorders; or allergy to either NSAIDs or paracetamol were excluded from the study. A computer-generated sequence was used for randomization before induction of anesthesia, and the closed envelope method was used for randomization to one of the study groups. Group A: (n=45) patients received intravenous paracetamol 15 mg/kg and intravenous ibuprofen 10 mg/kg, and Group B: (n=45) patients received intravenous paracetamol 15 mg/kg and diclofenac suppository 1-2 mg/kg. Patients were premedicated with ketamine 3 mg/kg + midazolam 0.25 mg/kg + atropine 20 mcg/kg by IM route before induction of anesthesia in their rooms. After arrival to the OR, anesthesia was induced using a face mask with 100% oxygen and 6% sevoflurane. Propofol and atracurium were administered, followed by endotracheal intubation with an appropriately sized cuffed endotracheal tube. Anesthesia was maintained with 1-1.5% isoflurane, and ventilation was adjusted to deliver a tidal volume of 8 ml/kg. Dexamethasone was administered as an adjunct for postoperative pain relief and antiemesis. Ibuprofen was diluted to a concentration of ≤4 mg/mL in normal saline and administered intravenously as a 10 mg/kg infusion of 30 minutes duration in patients randomized to group A. In patients randomized to group B, diclofenac suppository (1-2 mg/kg) was administered after endotracheal intubation. Paracetamol was administered by IV route as a 15 mg/kg infusion over 15 minutes for both groups after endotracheal intubation. After tonsillectomy and proper hemostasis, inhalational anesthesia was discontinued, and reversal of muscle relaxant was done using neostigmine (0.05 mg/kg). Extubation was done after recovery of conscious level and recovery of motor power. Patients were then transferred to the post-anesthesia care unit (PACU), where vital signs were recorded every 10 minutes. If a child exhibited separation anxiety, a parent was permitted to stay with the child during the stay in PACU. Ondansetron was administered when a patient exhibited retching, vomiting, or nausea. The FLACC score was used to assess the severity of postoperative pain by an assessor who was blinded to the intervention done for analgesia. If the FLACC score was ≥4, 1 mg/kg pethidine was administered as a rescue analgesic up to a maximum dose of 2 mg/kg. Parents were instructed on using the parents' postoperative pain measure (PPPM) scores before discharge from the PACU. Parents were directed to give their child 10 mg/kg ibuprofen syrup for a PPPM score ≥6 or when a child exhibited any discomfort. A follow-up call was made by a designated independent researcher at 4, 12, and 24 hours after the operation, where parents reported their child's pain score and the requirement for additional analgesic doses. The primary outcome was the FLACC pain score at 10 minutes after arrival to PACU. Secondary outcomes were the FLACC pain score on arrival to PACU, the FLACC pain score on discharge from PACU, the number of children who received rescue pethidine in the PACU, the dose of pethidine received as a rescue analgesia in the PACU, the incidence of postoperative adverse events [nausea, vomiting, hypotension (low SBP = <70 + 2(age in years)), bradycardia less than 60 beats/min, drug allergic reaction, postoperative bleeding requiring return to the operative room], and the PPPM in the first 24 hours scores at 4, 12, and 24 hours after the operation.

Sample size

Sample size was calculated using G-power software. The mean FLACC score in a group that used rectal diclofenac was 4.68+- 0.74 in a previous study [13]. If the use of IV ibuprofen decreased the pain score by at least 10% and considering that an alpha error of 0.05 was

significant and the power of the study was more than 80%, the minimum required number was 82 patients (41 in each group). We increased the number to 45 in each group to compensate for dropouts.

Statistical analysis

Statistical Package for Social Science (SPSS) software, version 15 for Microsoft Windows (SPSS Inc., Chicago, IL, USA), was used for data analysis. Categorical data was presented as frequency and was analyzed by the chi-square test. Continuous data was checked for normality using the Shapiro-Wilk test and was presented as mean ± standard deviation or median (interquartile range) as appropriate. Continuous data was analyzed using the unpaired t-test or Mann-Whitney test according to the normality of the data. Repeated measures were analyzed using the analysis of variance for repeated measures. A p-value less than 0.05 was considered statistically significant.

Results

We screened a total of 90 patients for eligibility, all of whom met the inclusion criteria. Consequently, 90 patients were randomized into two equal groups of 45 each (Figure 1).

There was no significant difference between groups A and B regarding gender (p=0.527), age (p=0.098), weight (p=0.092), and type of operation (p=0.809) (Table 1).

The FLACC score at 10 minutes after arrival to PACU (the primary outcome measure) was 3.82±1.87 in group A and 4.93±1.91 in group B (p=0.006). While it was not significantly different between the two groups on arrival or discharge from PACU (p=0.054 and 0.208, respectively) (Table 2).

There was no statistically significant difference in PPPM between the two groups at 4, 12, and 24 hours postoperative (p=0.718, 0.470, and 0.738, respectively) (Table 3). Regarding the number of patients who received rescue analgesia (pethidine), they were fewer in group A (p=0.031) (Figure 2). And the mean dose of pethidine received/kg as rescue analgesia was also significantly lower in group A (p=0.0316) (Table 4).

The incidence of postoperative adverse events, i.e., nausea, vomiting, hypotension (low SBP = <70 + 2(age in years)), bradycardia (less than 60 beats/min), drug allergic reaction, and postoperative bleeding requiring return to the operative room, was zero in the two groups, A and B.

Table 1- Demographic data of patients.

	Group A	Group B	P value
Age	5.31±1.53	4.73±1.68	0.098
Weight	20.13±4.03	18.62±3.49	0.092
Gender			
Male	20(44.4%)	23(51.1%)	0.527
Female	25(55.6%)	22(48.9%)	
Operation			
Tonsillectomy	11(24.4%)	12(26.7%)	0.809
Adenotonsillectomy	34(75.6%)	33(73.3%)	

Values are presented as mean±SD or number(percentage)

Table 2- FLACC pain score between studied groups.

	Group A	Group B	P value
FLACC score on arrival to PACU	0.27±0.72	0.58±1.01	0.054
FLACC pain score at 10 min in PACU	3.82±1.87	4.93±1.91	0.006*
FLACC pain score on discharge from PACU	1.00±1.43	1.47±1.62	0.208

*Significant

Table 3- PPPM score between studied groups.

	Group A	Group B	P value
PPPM score after 4 HR	4.33±2.15	4.42±2.04	0.718
PPPM score after 12 HR	5.80±1.34	6.11±1.90	0.470
PPPM score after 24 HR	7.04±2.22	6.84±2.14	0.738

Table 4- Dose of pethidine received in two groups.

	Group A	Group B	P value
Pethidine (mg)	0.29±0.46	0.51±0.51	0.0316*

Values are presented as mean±SD; *Significant

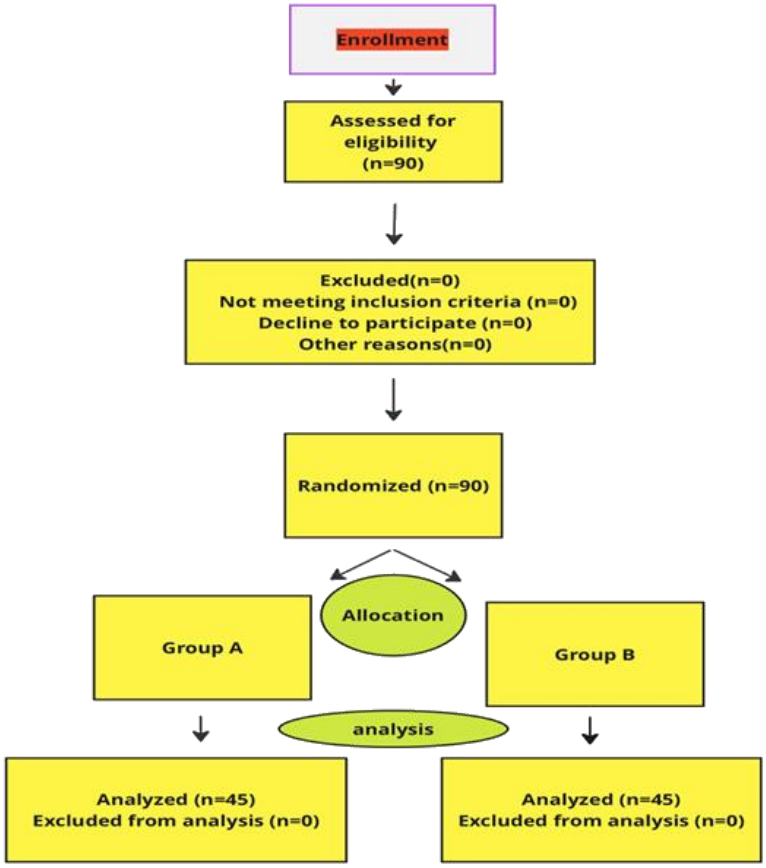

Figure 1- Consort flow chart of study participants.

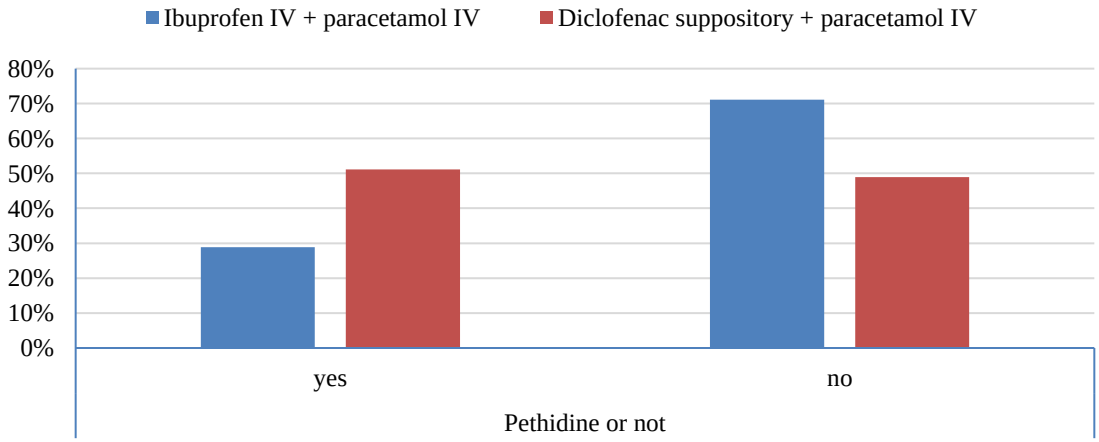

Figure 2- Number of the patients who received rescue analgesia between two groups.

Discussion

In the present study, the combination of IV ibuprofen and IV paracetamol was found to be superior to the combination of IV paracetamol and rectal diclofenac in providing postoperative analgesia for children undergoing tonsillectomy or adenotonsillectomy. We believe that IV ibuprofen demonstrated superior efficacy, particularly at 10 minutes after recovery, due to its faster onset of action via the intravenous route compared to other administration methods. In general, IV medications are preferred in the perioperative period due to their rapid

and reliable effects. The regional audit of six National Health Service (NHS) hospitals in the south of the United Kingdom reported that IV NSAIDs were the preferred route for anti-inflammatory analgesia in the perioperative setting, primarily because of their reliability and speed of onset [13].

Our findings align with those of Cui et al. [14], who conducted a randomized, double-blind, placebo-controlled study involving 95 pediatric patients undergoing tonsillectomy. They compared IV ibuprofen to placebo and found that fewer children in the ibuprofen group required rescue analgesia. Additionally, there were no significant differences in supplementary fentanyl doses, surgical blood loss, or postoperative bleeding between the two groups. However, our study differs in that we assessed postoperative pain using the FLACC and PPPM scales, which provide a more precise evaluation, and our study population consisted of younger children.

Similarly, our results are in agreement with the study by Moss et al. [15], a multicenter, randomized, double-blind, placebo-controlled trial that included 161 pediatric patients undergoing tonsillectomy. They compared a single preoperative dose of 10 mg/kg IV ibuprofen to a placebo for postoperative pain management. Increased pain was treated with IV fentanyl (0.5 μg/kg) when the visual analog scale (VAS) exceeded 30 mm. Their primary endpoint was the total postoperative fentanyl consumption for rescue analgesia. They observed a significant reduction in postoperative rescue analgesia in the ibuprofen group. However, Moss et al. reported a decrease in the number and the amount of rescue analgesic doses, rather than in the number of patients who required postoperative analgesia.

Furthermore, Abdelbaser et al. [16] conducted a study on 68 pediatric patients who underwent open cardiac surgery via a median sternotomy incision. They compared IV ibuprofen to placebo (0.9% saline) and found that the mean total fentanyl consumption in the first 24 hours post-extubation, as well as the median postoperative modified objective pain score, was significantly lower in the ibuprofen group. Additionally, there were no significant increases in postoperative complications such as bleeding, epigastric pain, or vomiting.

In contrast to our findings, Lee et al. [17] conducted a retrospective study of 163 adult patients undergoing laparoscopic cholecystectomy, comparing the analgesic effects of preoperative IV ibuprofen versus IV ketorolac. They found that postoperative pain scores recorded immediately in the recovery room were significantly higher in the ibuprofen group compared to the ketorolac group. Additionally, a greater number of patients in the ibuprofen group required immediate postoperative analgesics. The discrepancy between their findings and ours may be due to differences in study design; while they compared two IV-administered NSAIDs, our study compared IV ibuprofen to rectal diclofenac.

To the best of our knowledge, our study is the first to compare IV ibuprofen with another NSAID administered via a different route (rectal diclofenac) in this type of surgery. Importantly, we did not observe any complications in either study group. While concerns have been raised regarding increased postoperative bleeding following tonsillectomy with NSAID use, current evidence does not support this. A meta-analysis of 36 randomized controlled trials, including 1,747 children, concluded that NSAIDs do not increase the risk of postoperative bleeding [10,18].

This study had some limitations. The study's age range was restricted, which limited its scope. A larger sample size with precise age stratification could have provided a clearer understanding of the effects of IV ibuprofen and contributed to a more accurate analgesic regimen for children.

Conclusion

In conclusion, the combination of IV ibuprofen and intravenous paracetamol was a more effective analgesic regimen than the combined rectal diclofenac and IV paracetamol in pediatric patients undergoing tonsillectomy or adenotonsillectomy without increased complications.

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