Section: ENT

Original Research Article

PREOPERATIVE SINGLE DOSE INTRAVENOUS DEXAMETHASONE IN PEDIATRIC TONSILLECTOMIES AND POSTOPERATIVE PAIN: A COMPARATIVE STUDY FROM NORTH INDIA

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Abstract

Background: Pediatric tonsillectomy, a prevalent surgical procedure globally, aims to alleviate conditions like tonsillitis and sleep apnea. However, postoperative pain poses concerns. Glucocorticoids, particularly dexamethasone, with anti-inflammatory properties, have shown pain reduction benefits in adults. This study investigates dexamethasone's efficacy in pain management for pediatric tonsillectomy. **Materials and Methods:** In a 1-year prospective, study conducted at a tertiary care hospital for 1 year for pediatric tonsillectomy cases. Sample size was determined to be 74 participants. Patients were randomly assigned into dexamethasone or control groups, with blinding. Dexamethasone (0.5 mg/kg, max 10 mg) or normal saline was administered preoperatively. The primary outcome, Postoperative Pain Scores, was assessed using the Objective Pain Score (OPS) at 24 hours post-surgery. Data collection was blinded, and statistical analysis utilized SPSS 20.0, with significance set at $p < 0.05$. **Result:** In our study a total of 74 patients were enrolled (37 patients in each group). The mean age in the control group was 9.23 years ± 2.41, and in the dexamethasone group, it was 9.01 years ± 2.73. Furthermore, the objective pain score (OPS) showed a statistically significant difference, with the control group having a higher score (2.65±2.19) compared to the dexamethasone group (1.67±1.46) ($p = 0.026$). Postoperative nausea and vomiting (PONV) demonstrated substantial differences between the groups. In the control group, 43.2% experienced PONV, while only 10.8% had this occurrence in the dexamethasone group ($p = 0.001$). **Conclusion:** In conclusion, this study provides compelling evidence supporting the analgesic efficacy of preoperative single dose intravenous dexamethasone in pediatric tonsillectomies.

INTRODUCTION

Pediatric tonsillectomy is one of the most common surgical procedures performed worldwide. It is typically indicated for recurrent tonsillitis, obstructive sleep apnea, and various upper airway disorders. While tonsillectomy can alleviate these conditions and improve overall quality of life, postoperative pain remains a significant concern, often leading to distress for both patients and caregivers. Therefore, the pursuit of effective pain management strategies is a paramount concern in pediatric tonsillectomy procedures.[1,2]

Over the years, numerous approaches have been explored to mitigate the postoperative pain associated with tonsillectomies. Among these approaches, the utilization of glucocorticoids, particularly dexamethasone, has gained attention due to its anti-inflammatory and immunomodulatory properties. Dexamethasone has been demonstrated to reduce postoperative pain and nausea in various surgical procedures, including tonsillectomies in adults. However, the extent to which its analgesic effects translate to the pediatric population undergoing tonsillectomy, especially considering variations in surgical techniques, remains an area of active investigation.[3,4]

The surgical technique employed during tonsillectomy can significantly influence postoperative pain and recovery. The traditional "sharp snare" dissection technique and the more modern "cautery-assisted" technique are two prevalent methods used by surgeons. The former involves the manual separation of the tonsil tissue from the underlying structures, while the latter employs electrocautery to achieve hemostasis and

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tissue removal simultaneously. Given the potential differences in tissue trauma and wound healing associated with these techniques, the analgesic impact of preoperative dexamethasone might differ.[5,6]

This study aimed to address the knowledge gap concerning the analgesic efficacy of preoperative single-dose intravenous dexamethasone in pediatric tonsillectomy, particularly considering the choice of surgical technique sharp snare dissection or cautery-assisted. By comparing the postoperative pain scores, analgesic requirements, and recovery outcomes of these two surgical methods in the context of dexamethasone administration, this study intends to provide valuable insights into optimizing pain management strategies for pediatric tonsillectomy procedures.

MATERIALS AND METHODS

Study Design

This prospective, randomized, double-blind, placebo-controlled clinical trial was conducted under the Department of ENT in the tertiary care hospital for a period of 1 year between January 2021 and January 2022 among cases planned for pediatric tonsillectomies. Ethical approval was obtained from the Institutional Review Board, and written informed consent was obtained from the legal guardians of all participating pediatric patients.

Sample Size Calculation: The sample size was calculated based on an estimated effect size of 10% derived from previous study and a desired power of 80%.[4] A total of 74 participants were deemed necessary to detect a statistically significant difference in postoperative pain scores between the dexamethasone and control groups.

Participants: The study enrolled pediatric patients aged 3 to 12 years, scheduled for elective tonsillectomy due to recurrent tonsillitis or obstructive sleep apnea. Patients with known allergies to dexamethasone or contraindications for its use were excluded from the study. A total of 74 eligible patients were enrolled in the trial.

Randomization and Blinding: Patients were randomized into two groups using computer-generated random numbers: the dexamethasone group and the control group. Allocation concealment was achieved through sealed opaque envelopes, and both patients and the clinical team were blinded to the intervention. Dexamethasone (0.5 mg/kg, maximum 10 mg) or control (normal saline) was prepared in identical syringes by the pharmacy department.

Intervention: Approximately 30 minutes prior to surgery, patients in the dexamethasone group received preoperative single dose intravenous dexamethasone, while patients in the control group received an equivalent volume of normal saline. The intervention was administered by a nurse who was not involved in the subsequent data collection.

Surgical Technique: The tonsillectomy procedures were conducted under general anesthesia using endotracheal intubation. All tonsillectomies were performed by experienced otolaryngologists using a scalpel and snare technique. Hemostasis was achieved using electrocautery, and the surgical technique followed standard protocols for pediatric tonsillectomy.

Outcome Measures

Postoperative Pain Scores was the primary outcome. A validated numeric rating scale Objective Pain Score (OPS) was used for assessing severity of pain at 24 hours post-surgery (Minimum score 0 and maximum score 10).[6]

Secondary Outcomes: Analgesic Requirements: The total amount of rescue analgesics (e.g., acetaminophen, ibuprofen) consumed during the first 24 hours post-surgery. Time to First Analgesic Request: The time interval between completion of surgery and the first request for rescue analgesics. Incidence of Postoperative Nausea and Vomiting: The occurrence and severity of postoperative nausea and vomiting were assessed using a categorical scale.

Data Collection and Analysis: Baseline patient characteristics, surgical details, and anesthesia information were recorded for each participant. The data on primary and secondary outcomes were collected by trained personnel who were blinded to the intervention. All statistical analyses were conducted using SPSS 20.0. Statistical analysis was performed using appropriate tests, including independent t-tests, and chi-square tests, to compare outcomes between the dexamethasone and placebo groups. A significance level of $p < 0.05$ was considered statistically significant.

Ethical Considerations: The study adhered to ethical guidelines, including the Declaration of Helsinki and relevant regulatory requirements. Patient confidentiality was maintained, and any adverse events were promptly reported and managed.

RESULTS

In our study a total of 74 patients were enrolled (37 patients in each group). The mean age in the control group was 9.23 years ± 2.41, and in the dexamethasone group, it was 9.01 years ± 2.73. The p-value was 0.714, indicating no statistically significant difference in age between the groups. In the control group, 21 participants (56.8%) were male, while 19 participants (51.4%) were male in the dexamethasone group. In the control group, 30 participants (81.1%) underwent tonsillectomy, compared to 28 participants (75.7%) in the dexamethasone group. The mean duration of surgery in the control group was 23.15 minutes ± 6.21, and in the dexamethasone group, it was 21.45 minutes ± 5.43. The p-value was 0.214, indicating no significant difference in the duration of surgery between the groups. Statistical analysis revealed that both the groups were comparable in terms of gender, weight,

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tonsil size grade, and procedure type ($p > 0.05$) [Table 1].

In [Table 2] regarding crying response, the control group had 10.8% of participants crying without responding to tender loving care, while the dexamethasone group showed only 2.7% exhibiting this response ($p = 0.020$). For movement, 27.0% of the control group displayed restlessness compared to 8.1% in the dexamethasone group ($p = 0.032$). In terms of agitation, 8.1% of the control group exhibited hysterical behavior, in contrast to 2.7% in the dexamethasone group ($p = 0.039$). Pain verbalization results indicated that 48.6% of the control group could localize pain, compared to 32.4% in the dexamethasone group ($p = 0.050$). Blood pressure assessment demonstrated that 43.2% of the control group had blood pressure ≤10% of preoperative levels, while this was seen in 67.6% of the dexamethasone group ($p = 0.035$). Furthermore, the objective pain score (OPS) showed a statistically significant difference, with the control group having a higher score (2.65±2.19) compared to the dexamethasone group (1.67±1.46) ($p = 0.026$).

In our study, [Table 3]. shows that for oral intake, statistically significant differences were observed between the groups. In the control group, 13.5% of participants refused oral intake compared to 2.7% in the dexamethasone group. Moreover, 32.4% of the control group accepted liquid intake only when forced, while 13.5% exhibited this response in the dexamethasone group. Additionally, 37.8% of the control group demanded oral intake compared to 59.5% in the dexamethasone group ($p = 0.047$). The mean duration of First Oral Intake was significantly shorter in the dexamethasone group (3.17±1.48 hours) compared to the control group (5.22±4.76 hours) ($p = 0.014$). Regarding rescue analgesics, 91.9% of the control group required them, in contrast to 62.2% in the dexamethasone group ($p = 0.002$). The mean rescue analgesic time was significantly longer in the dexamethasone group (13.29±4.37 hours) compared to the control group (4.41±1.67 hours) ($p < 0.0001$). Postoperative nausea and vomiting (PONV) demonstrated substantial differences between the groups. In the control group, 43.2% experienced PONV, while only 10.8% had this occurrence in the dexamethasone group ($p = 0.001$). Additionally, the occurrence of nausea was 24.3% in the control group and 8.1% in the dexamethasone group ($p = 0.058$). Vomiting was observed in 18.9% of the control group, while only 2.7% had this response in the dexamethasone group ($p = 0.024$).

Table 1: Baseline characteristics of the patients in the both groups.

Variables	Frequency	%	Frequency	%	P value
	Control		Dexamethasone		
Age (in years)	9.23±2.41		9.01±2.73		0.714
Gender					
Male (n=40)	21	56.8	19	51.4	0.640
Female (34)	16	43.2	18	48.6	
Weight (in Kg)	19.22±6.74		18.98±6.27		0.874
Tonsil size grade					
I (n=3)	2	5.4	1	2.7	0.923
II (n=31)	15	40.5	16	43.2	
III (n=27)	13	35.1	14	37.8	
IV (n=13)	7	18.9	6	16.2	
Procedure					
Tonsillectomy (n=58)	30	81.1	28	75.7	0.572
Adenotonsillectomy (n=16)	7	18.9	9	24.3	
Duration of surgery (in minutes)	23.15±6.21		21.45±5.43		0.214

Table 2: Pain score distribution among patients in the both groups.

Variables	Frequency	%	Frequency	%	P value
	Control		Dexamethasone		
Crying					
Crying and does not respond to TLC	4	10.8	1	2.7	0.020
Crying but respond to TLC	13	35.1	5	13.5	
Not crying	20	54.1	31	83.8	
Movement					
Restless	10	27.0	3	8.1	0.032
None	27	73.0	34	91.9	
Agitation					
Hysterical	3	8.1	1	2.7	0.039
Mild	13	35.1	5	13.5	
Asleep/calm	21	56.8	31	83.8	
Pain verbalization					
Localizes pain	18	48.6	12	32.4	0.050
Cannot localize pain	6	16.2	2	5.4	
Asleep/no pain verbalization	13	35.1	23	62.2	
Blood pressure					
≤10% of preoperative	16	43.2	25	67.6	0.035
>10% of preoperative	21	56.8	12	32.4	

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Objective pain score	2.65±2.19	1.67±1.46	0.026

TLC: tender love and care

Table 3: Clinical outcome of the patients in both groups.

Variables	Frequency	%	Frequency	%	P value
	Control		Dexamethasone		
Oral intake (liquid)					
Refuses	5	13.5	1	2.7	0.047
Accepts when forced	12	32.4	5	13.5	
Accepts when asked	6	16.2	9	24.3	
Demands	14	37.8	22	59.5	
Mean duration of FOI (in hours)	5.22±4.76		3.17±1.48		0.014
Blood pressure					
Systolic (in mmHg)	84.76±39.13		80.39±37.18		0.045
Diastolic (in mmHg)	48.60±22.86		46.72±24.05		0.037
Rescue analgesic					
Yes	34	91.9	23	62.2	0.002
No	3	8.1	14	37.8	
Mean RAT (in hours)	4.41±1.67		13.29±4.37		< 0.0001
PONV	16	43.2	4	10.8	0.001
Nausea	9	24.3	3	8.1	0.058
Vomiting	7	18.9	1	2.7	0.024

FOI: First Oral (Liquid) Intake RAT: Rescue Analgesic time, PONV: Postoperative Nausea and Vomiting

DISCUSSION

The present study aimed to investigate the analgesic efficacy of preoperative single dose intravenous dexamethasone in the context of pediatric tonsillectomies. The findings revealed valuable insights into the impact of dexamethasone administration on various pain-related responses, physiological parameters, and postoperative outcomes in this patient population.

Pain-Related Responses and Analgesic Efficacy:

Studies by April et al., Ohlms et al., Kaan et al., Catlin et al., and Elhakim et al., have found that dexamethasone effectively reduced post tonsillectomy pain.[7-11] But Ishlah et al., did not found such difference.[12] In our study, the objective pain score (OPS) showed a statistically significant difference, with the control group having a higher score (2.65±2.19) compared to the dexamethasone group (1.67±1.46) (p = 0.026). The dexamethasone group demonstrated significantly fewer instances of crying that did not respond to tender loving care, restlessness, and hysterical agitation, compared to the control group. These findings suggest that dexamethasone administration might contribute to a more tranquil postoperative experience for pediatric tonsillectomy patients, potentially indicating an analgesic effect beyond pain relief. Moreover, the differences in pain verbalization and blood pressure within the dexamethasone group further underscore the potential benefits of dexamethasone in enhancing pain management and overall patient comfort. In our study we used Dexamethasone with dose as 0.5 mg/kg (maximum 10 mg). In the studies by Wang et al., Gunter et al., and Kim et al., they did not observe a dose dependent effect on the incidence pain.[13-15]

Physiological Parameters and Recovery

In our study, the mean duration of First Oral Intake was significantly shorter in the dexamethasone group (3.17±1.48 hours) compared to the control group (5.22±4.76 hours) (p = 0.014). This observation could signify a more rapid return to normal oral intake, potentially contributing to improved patient satisfaction and reduced postoperative recovery period. Anderson et al., Rundle et al., Ong et al., Papangelou et al., and Malde et al., also observed similar finding.[16-20] Furthermore, the reduction in systolic and diastolic blood pressure in the dexamethasone group highlights the potential for dexamethasone to attenuate the stress response associated with surgery, potentially contributing to a smoother recovery process. Studies by Czarnetzki et al., Brigger et al., and Steward et al., showed that administration of dexamethasone was not associated with significant side-effects in children undergoing tonsillectomy.[21-23]

Analgesic Requirements and Postoperative Nausea and Vomiting

In our study, regarding rescue analgesics, 91.9% of the control group required them, in contrast to 62.2% in the dexamethasone group (p = 0.002). The mean rescue analgesic time was significantly longer in the dexamethasone group (13.29±4.37 hours) compared to the control group (4.41±1.67 hours) (p < 0.0001). The dexamethasone group exhibited significantly lower rates of rescue analgesic use and delayed time to first rescue analgesic request. This suggests that preoperative dexamethasone administration may contribute to an extended duration of analgesic effect, reducing the need for additional pain management interventions in the immediate postoperative period. In the control group, 43.2% experienced PONV, while only 10.8% had this occurrence in the dexamethasone group (p = 0.001). Studies by Henzi et al., Eberhart et al., Karaman et al., Splinter et al., Pappas et al., Elhakim et al., and Aouad et al., also observed the significantly lower rates of PONV, nausea, and vomiting.[11,24-29]

Clinical Implications and Future Directions

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The results of this study have important clinical implications for pediatric tonsillectomy procedures. Preoperative single dose intravenous dexamethasone appears to offer significant benefits in terms of pain control, physiological stabilization, reduced analgesic requirements, and mitigation of postoperative nausea and vomiting. These findings suggest that dexamethasone may serve as a valuable adjunct to pain management strategies in pediatric tonsillectomy, potentially leading to enhanced patient satisfaction and improved recovery outcomes.

Future research could delve further into the optimal dosing regimen and duration of dexamethasone administration, as well as potential long-term effects on postoperative recovery and patient well-being. Additionally, investigating the mechanisms through which dexamethasone exerts its analgesic and antiemetic effects could provide deeper insights into its therapeutic potential in this surgical context.

Limitations

It is important to acknowledge certain limitations of the current study. The sample size, while sufficient to detect significant differences, might limit the generalizability of the findings. Furthermore, the study did not explore the potential adverse effects or long-term outcomes associated with dexamethasone administration in this population. Finally, the study focused on short-term outcomes, leaving room for investigations into the sustained effects of dexamethasone beyond the immediate postoperative period.

CONCLUSION

In conclusion, this study provides compelling evidence supporting the analgesic efficacy of preoperative single dose intravenous dexamethasone in pediatric tonsillectomies. The observed reductions in pain-related responses, improved physiological stabilization, diminished analgesic requirements, and decreased incidence of postoperative nausea and vomiting highlight the potential of dexamethasone as an adjunctive tool for optimizing postoperative pain management and recovery outcomes in this patient population.

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