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Original Research Article

Analgesic efficacy of preoperative single dose intravenous dexamethasone in pediatric tonsillectomies by either sharp snare dissection technique or laser technique: A randomised controlled trial

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ABSTRACT

Background: This study was designed to evaluate the postoperative analgesic efficacy of intravenous dexamethasone, and also to determine the postoperative rescue analgesic consumption, morbidity with respect to surgical technique, quality of oral intake, incidence of postoperative nausea and vomiting (PONV), and discharge from hospital.

Materials and Methods: After ethical committee clearance, a prospective randomized double blind study was planned for one year period on 100 pediatric patients, with5-12 years of age, American Society of Anesthesiologists physical class I and II, undergoing elective tonsillectomy with or without adenoidectomy under general anesthesia were included in the study. Patients were randomly allocated into 4 groups and received the study drug intravenously 10 minutes before induction of anesthesia. Group A undergoing sharp snare dissection tonsillectomy received 0.9% normal saline 50ml, group B sharp snare dissection tonsillectomy received dexamethasone 0.15mg/kg diluted in 0.9% normal saline, group C laser tonsillectomy received 0.9% normal saline 50 ml, group D laser tonsillectomy received dexamethasone 0.15mg/kg diluted in 0.9% normal saline.

Results: We observed statistically significant difference in mean pain scores ($p<0.05$) between dexamethasone group (group B and D) and control group (group A and C) measured by KruskalWallis analysis of Variance test with less pain in dexamethasone group.

Conclusion: Single dose intravenous administration of dexamethasone (0.15mg/kg) resulted in reduction of post-operative pain, need for rescue analgesics, reduced incidence of PONV, early return to normal diet and discharge from the hospital.

1. Introduction

Tonsillectomy is a common surgical procedure performed with or without adenoidectomy that completely removes the tonsil, along with its capsule, by dissecting the peritonsillar space.[1] It is one of the most frequently performed surgical operations in children.[2] Tissue injury induced acute inflammation plays significant role in the genesis of surgical pain and also the incidence of postoperative emesis, which is more frequent in pediatric patients than in adults.[3,4]

Steroids are believed to the reduce tissue damage and postoperative pain by suppressing fibrin deposition, capillary dilatation, edema formation and leukocyte migration.[3,5] Hence dexamethasone and other steroid preparations have been used to minimize tissue injury, edema and related morbidities such as pain, vomiting and poor oral intake.[6]

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Therefore, our study was planned to investigate the analgesic effect and other advantages of single dose 0.15mg/kg intravenous dexamethasone given just before the surgery in pediatric patients undergoing tonsillectomy with or without adenoidectomy by sharp snare dissection or laser technique under general anaesthesia during the first 24 hours of postoperative period. Primary objective of our study was to determine the postoperative analgesic efficacy of intravenous dexamethasone, and secondary objectives were to determine the rescue analgesic requirement and incidence of postoperative nausea and vomiting.

2. Materials and Methods

After the approval of our institutional ethical committee, a prospective randomized, double blinded clinical study was conducted for a period of one year. Written informed consent was taken from patient's parents. One hundred pediatric patients of physical status American Society of Anesthesiologists (ASA) grade I and II, aged 5-12 years undergoing elective tonsillectomy with or without adenoidectomy were included in the study. Where as paediatric patients with coagulopathy, contraindication to steroids, and patients on steroid and antihistaminic, co-morbidities like diabetes mellitus, hypertension, cardiovascular disease, renal disease and gastric disease were excluded from the study.

Preanaesthetic evaluation was done a day prior to surgery and were kept nil by mouth for solid food upto 6 hours and for clear fluids upto 2 hours prior to surgery. Patients were premedicated with trichlophos 0.5-1gm orally 30-45 minutes (mins) before shifting to operation theatre. Randomisation was done using computer generated random number table. Patient and the anesthesia provider were blinded in the study. Drug solution was prepared by the anaesthesiologist not involved in the study. In the preoperative room, patients in respective groups according to sealed envelope technique will receive either 50 ml 0.9% normal saline or 0.15mg/kg dexamethasone diluted to 50ml using 0.9% normal saline respectively over 10 minutes by an second anesthesiologist not involved in the study. Each group consists of 25 patients (Table 1). Patients were shifted in the operating room and standard monitors like electrocardiogram (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SPO2) were connected. Baseline readings were recorded. All patients were premedicated with injection midazolam 0.05 mg/kg and inj. pentazocine 0.3 mg/kg intravenously (IV). Induction was done using intravenous Thiopentone 5mg/kg and after adequate bag and mask ventilation muscle relaxant intravenous succinylcholine 2 mg/kg was given, then patients were intubated with appropriate sized endotracheal tube. Intermediately acting muscle relaxant intravenous vecuronium 0.1mg/kg was given. Anaesthesia was maintained with sevoflurane, 60% Nitrous Oxide in oxygen and controlled ventilation using injection vecuronium 0.1 mg/kg IV. Intravenous fluid was given according to the body weight of the patient and surgical blood loss. Intra-operatively electrocardiogram (ECG), end-tidal carbon-dioxide ($EtCO_2$), non-invasive blood pressure (NIBP), pulse oximetry (SPO_2), respiratory rate (RR) and pulse rate (PR) were monitored. At the end of procedure, neuromuscular blockade was reversed with injection neostigmine 0.05mg/kg and glycopyrrolate 0.02 mg/kg IV. Patient was extubated after the return of spontaneous respiration with tidal volume greater than 5ml/kg, purposeful movement, eye opening and facial grimace.

CHEOPS (Children's Hospital of Eastern Ontario Pain Scale) scale was used for assessing postoperative pain lasting for 24hours (hrs) in patients aged below 7 years, and visual analogue scale (VAS) was used in patients above7 years of age. The CHEOPS is a behavioral scale for evaluating postoperative pain in young children. The CHEOPS scale includes cry, facial expression, child verbal, torso, touch and legs for assessing severity of pain.[7] Minimum score 4 and maximum score 13.

The VAS score is assessed by asking the patient to point out the position on the line between the faces to indicate the level of pain. And it's the spectrum of facial expression of pain in which far left end of the spectrum indicates 'No pain' and the far right end indicates 'Worst pain ever'.[8]

Recordings were done every half hourly for first 2 hour (hr), hourly for next 4 hrs and then at 6, 10, 14 and 24 hours. Rescue analgesia was administered with paracetamol 10mg/kg orally on demand by patients or when visual analogue scale score (VAS score)>4(>7 years) or when CHEOPS scale >4 (<7 years).

Patients were allowed to take oral fluids after 4 hrs of surgery and acceptance of oral fluids recorded. Quality of oral intake was graded as follows, Score 4 = excellent i.e. patient requests food, score 3=good i.e. patient accepts it, when offered, score 2 = fair i.e. patient accepts it, score 1= poor i.e. patient refuses. Nausea and vomiting were recorded at 6, 10, 14 and 24hrs. All postoperative observations and scores were assessed by the same anesthesiologist who was unaware of the patient group assignment and disclosed at the end of 24 hours. Patient discharge from the hospital was also recorded.[9]

2.1. Statistical analysis

Sample size (n = 100) estimation was done by using open episoft were version 2.3.1. At 95% confidence level and 80% power of the study, As observed by Malde AD,[10] the pain free subjects in control group at 6-24hrs was 40% and dexamethasone group was 91%. The sample size estimated to find this difference was 17 to 25 in each group. The statistical analysis was determined by t- test and ANOVA test for parametric data and chi-square test for non-

parametric data. Differences were considered significant if p value < 0.05.

Table 1: Group distribution

Groups	
Group A	Undergoing sharp snare dissection tonsillectomy received 0.9% normal saline 50 ml IV.
Group B	Undergoing sharp snare dissection tonsillectomy received dexamethasone 0.15mg/kg diluted in 0.9% normal saline 50 ml IV.
Group C	Undergoing laser tonsillectomy received 0.9% normal saline 50 ml IV.
Group D	Undergoing laser tonsillectomy received dexamethasone 0.15mg/kg diluted in 0.9% normal saline IV.

*ml- milliliter, †IV – intravenous

3. Results

Demographic data concerning patients age (p - 0.1302), sex (p - 0.6872), weight (p – 0.5521), type of procedure either sharp snare adenotonsillectomy / tonsillectomy (p-1.0000) or laser adenotonsillectomy / tonsillectomy (p - 0.7001) were comparable in all four study groups (Table 2). Mean duration of surgery in laser tonsillectomy group C (41.52min) and D (43.12min) was more than sharp snare dissection group A (25.72min) and B (20.12 min) with p value - 0.00001. (Table 2)

The mean VAS score in group A at 2hrs, 4hrs, 6hrs, 10hrs, 14hrs and 24hrs is 4.24, 6.47, 5.65, 5.29, 4.47 and 3.88 respectively and in group B at 2hrs, 4hrs, 6hrs, 10hrs, 14hrs, and 24hrs is 2.11, 1.16, 0.42, 2.63, 4.0, and 2.74 respectively. Mean VAS score in group C at 2hrs, 4hrs, 6hrs, 10hrs,14hrs, and 24hrs is 7.23,6.15,5.38, 5.54,4.77, and 3.69 respectively and in group D at 2hrs, 4hrs, 6hrs,10hrs, 14hrs, and 24hrs is 5.11,6.56,6.11,5.44,4.78, and 4.21 respectively.(Table 3)

The mean CHEOPS score in group A at 2hrs, 4hrs, 6hrs, 10hrs, 14hrs, and 24hrs is 5.25,7.00,6.50,6.13,5.75, and 4.75 respectively and in group B at 2hrs, 4hrs, 6hrs, 10hrs, 14hrs, and 24hrs is 4.00, 4.20,4.80,4.00,4.00, and 5.20 respectively. Mean CHEOPS score in group C at 2hrs, 4hrs, 6hrs, 10hrs, 14hrs, and 24hrs is 6.17, 6.33,5.75, 5.25, 4.92 and 4.67 respectively and in group D at 2hrs, 4hrs, 6hrs,10hrs, 14hrs, and 24hrs is 4.14,5.43,6.43,6.29,5.57, and 4.57 respectively. (Table 4)

The mean time for rescue analgesic requirement in all four groups had a statistically significant difference among each other with the p value of 0.00001. (Table 5) The percentage of patients requiring rescue analgesics in dexamethasone group i.e. group B was 52% and group D 100% as compare to the control group i.e. group A 100% and group C 100%. Therefore, 48% of patients in group B not required rescue analgesic postoperatively. (Figure 1)

Statistically significant difference seen between control groups (A and C) and dexamethasone groups (B and D) with the p value of 0.0217 with respect to vomiting postoperatively. (Figure 2)

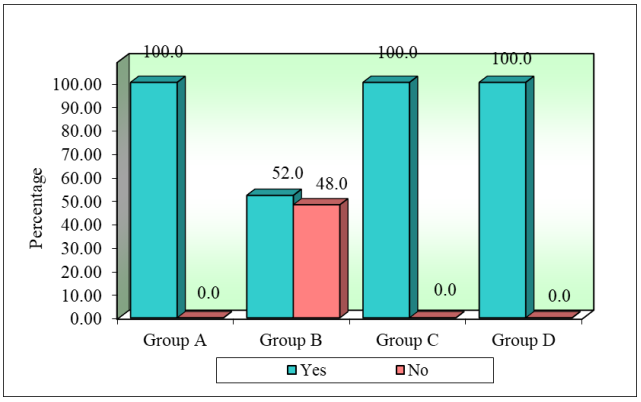

Fig. 1: Comparison of four groups with respect to rescue analgesic consumption postoperatively over 24 hrs period

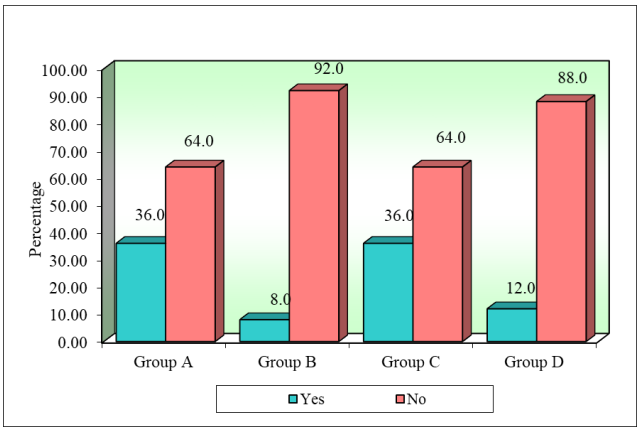

Fig. 2: Comparison of four groups (A,B,C,D) with respect to nausea and vomiting for 24 hrs postoperatively

4. Discussion

In our study the mean pain scores (VAS and CHEOPS) in dexamethasone groups (group B and D) was lower than placebo group (group A and C) which is statistically significant. And the mean time for rescue analgesic requirement in dexamethasone group (groups B and D) was more as compared to placebo group(group A and C) which is statistically significant. Similar results were found in study conducted by Malde AD[10] et al which showed reduced requirement of rescue analgesic in dexamethasone group compared to placebo in first six hours.

A study conducted by Kann MN[11] et al in children receiving single dose intravenous dexamethasone before tonsillectomy showed significantly reduced early post-

Table 2: Comparison of four groups with respect to demographic data, procedure and duration of surgery

Variables	Group A (n-25)	Group B (n-25)	Group C (n-25)	Group D (n-25)	P- Value
Age (years)	8.68±2.66	9.72± 2.39	7.96±2.34	8.96±3.03	0.1302
Weight (kg)	18.32±5.55	19.72±6.82	17.20±5.10	18.76±7.21	0.5521
Gender (male/female)	13/12	13/12	16/9	16/9	0.6872
Duration of surgery (mins)	25.72±5.23	20.12±5.40	41.52±8.14	43.12±6.91	0.00001
Type of procedure (adenotonsillectomy/tonsillectomy)	5/20	5/20	3/22	5/20	1.0000

* kg – kilogram, †mins – minutes

Table 3: Comparison of four groups (A, B, C, D) with respect to VAS scores at 2hrs, 4hrs, 6hrs, 10hrs, 14hrs and 24hrs by Kruskal Wallis ANOVA

Group	2 hrs		4hrs		6 hrs		10 hrs		14 hrs		24 hrs	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group A	4.24	2.44	6.47	1.81	5.65	1.90	5.29	1.40	4.47	1.50	3.88	1.65
Group B	2.11	0.81	1.16	1.21	0.42	0.84	2.63	2.31	4.00	2.31	2.74	1.79
Group C	7.23	1.01	6.15	0.55	5.38	1.50	5.54	1.20	4.77	1.01	3.69	0.75
Group D	5.11	1.71	6.56	1.65	6.11	1.08	5.44	0.92	4.78	1.22	4.11	1.08
H-value	43.7920		44.8500		47.3260		24.2170		3.3980		9.2580	
P-value	0.00001*		0.00001*		0.00001*		0.00001*		0.3340		0.0260*	

*p<0.05

Table 4: Comparison of four groups (A, B, C, D) with respect to CHEOPS scores at 2hrs, 4hrs, 6hrs, 10hrs, 14hrs and 24hrs by Kruskal Wallis ANOVA

Group	2 hrs		4hrs		6 hrs		10 hrs		14 hrs		24 hrs	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Group A	5.25	1.49	7.00	1.07	6.50	1.41	6.13	1.55	5.75	1.67	4.75	1.49
Group B	4.00	0.00	4.20	0.45	4.80	1.10	4.00	0.00	4.00	0.00	5.20	1.79
Group C	6.17	1.47	6.33	0.65	5.75	1.22	5.25	1.29	4.92	1.00	4.67	1.30
Group D	4.14	0.38	5.43	1.81	6.43	0.53	6.29	0.76	5.57	0.53	4.57	0.79
H-value	16.4200		12.9030		5.7180		9.6230		7.4410		0.4230	
P-value	0.0010*		0.0050*		0.1260		0.0220*		0.0590		0.9350	

*p<0.05

Table 5: Comparison of four groups (A, B, C, D) with respect to rescue Analgesics post op timing in first 24 hrs by one way ANOVA

Group	Mean	Std.Dev.
Group A	3.52	1.33
Group B	11.54	3.07
Group C	2.08	0.40
Group D	4.00	2.00
F-value	89.9603	
P-value	0.00001*	

*p<0.05

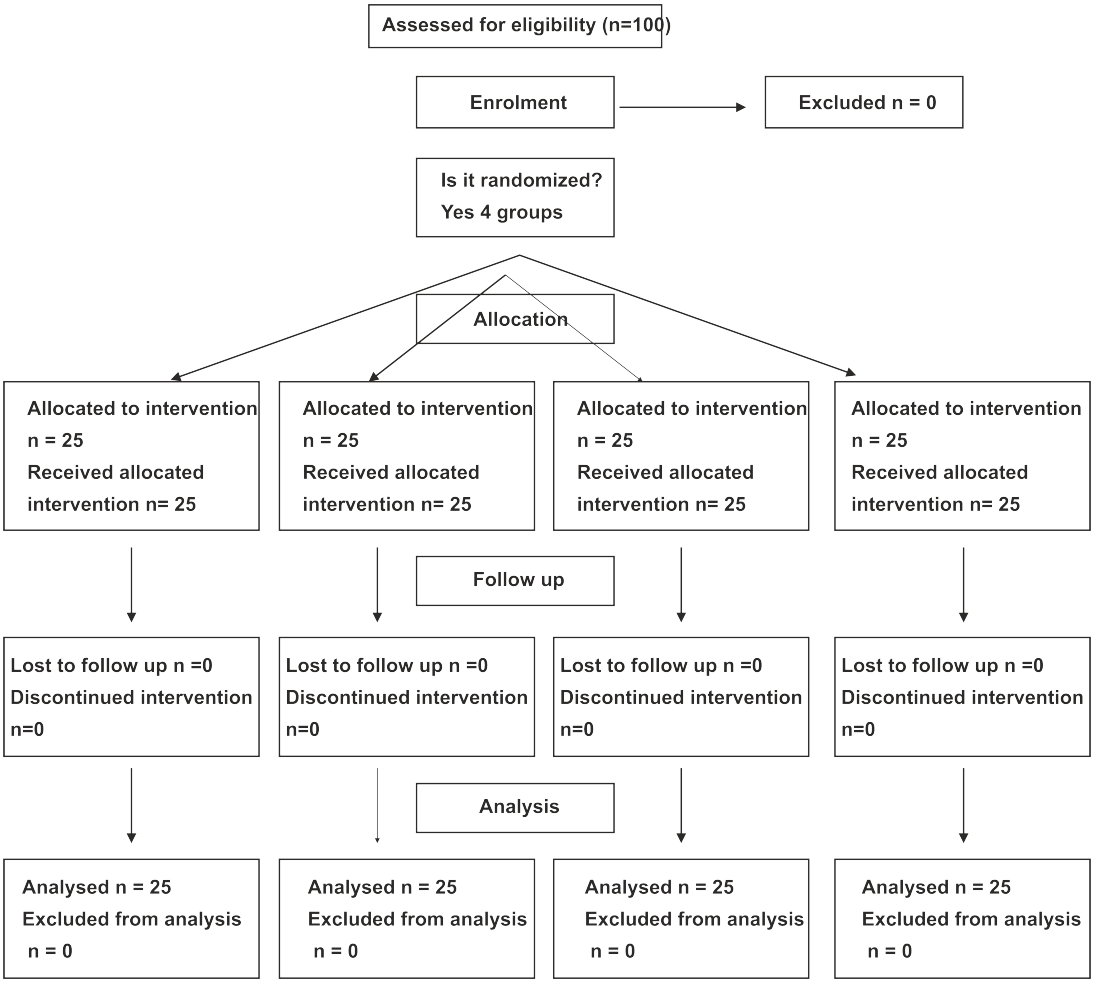

Diagram 1: Consort diagram of the study

tonsillectomy pain with sharp snare dissection tonsillectomy without any significant side effects which is similar to our study findings.

Post tonsillectomy pain is mainly due to tissue injury induced acute inflammation, nerve irritation and spasm of exposed pharyngeal muscle. Corticosteroids decrease the inflammation by inhibiting the early phase of inflammation and also inhibits phospholipase pathway, thus reducing prostaglandin synthesis and thereby reducing the intensity of pain.[4]Many studies like Khani et al,[2] Yasmin et al,[4] Aasboe et al[12] have shown the efficacy of corticosteroids in tonsillectomy for alleviating the post operative pain.

The percentage of patients requiring rescue analgesic in group B is less as compared to all other groups (Figure 2) which is similar to study conducted by Obasikeneet al,[13] which showed more pain in laser technique compared to conventional and ultrasonic scalpel technique. This was in contrast to the Malaysian study by Ishlah et al,[14] where the total post-operative pain was not significantly different between the two groups. Reason might be the operating surgeons who would have been well versed with conventional dissection method than laser technique, which was contributing to the prolonged surgical duration and early postoperative pain with in laser technique.

Pain and irritation of gastric mucosa by swallowed blood are two main contributors of high incidence of post-operative nausea and vomiting (PONV) after tonsillectomy.[4] The mechanism of dexamethasone induced antiemesis is not fully understood, but central inhibition of prostaglandin synthesis and decrease in 5-HT turnover in the central nervous system (CNS) or changes in the permeability of blood cerebrospinal fluid (CSF) barrier to serum proteins may be involved.[4] Clinically significant anti-inflammatory effects of dexamethasone in humans has been reported predominantly in dental or ear, nose and throat procedures (adenoidectomy and tonsillectomy).[15] Dexamethasone is a highly potent glucocorticoid and has long half-life of 36-72 hours. Single intravenous dose of steroids is devoid of side effects like gastritis, delayed healing in surgical patient, adrenal suppression etc.[2,4,15]

In our study the incidence of postoperative nausea vomiting is lesser in dexamethasone group (group B and D) as compared to placebo group when we used the dose of 0.15mg/kg which is similar to study conducted by Hermans et al,[16] where they proved that the dose of 0.15 mg/kg dexamethasone was equally as effective as 0.5 mg/kg in preventing postoperative nausea and vomiting. A study conducted by Splinter et al[17] evaluated the effect of preoperative dexamethasone in tonsillectomy surgery and concluded that dexamethasone 150 μg/kg, reduced the overall incidence of vomiting p<0.001. Aouad et al[18] assessed the effect of intravenous dexamethasone in adenotonsillectomy procedure, and found that the overall incidence of vomiting was significantly less in the dexamethasone group as compared with the Saline group (23% and 19% (p< 0.05).

The decreased incidence of pain and postoperative nausea vomiting with the use of preoperative single dose intravenous dexamethasone has results in early oral fluid intake, avoiding the hazards of prolonged intravenous fluid supplementation and confinement to bed with an intravenous line.

One of the limitations of our study is that we have not monitored the MACage and compared, which would have given better insights on the depth of anaesthesia.

5. Conclusion

Single dose intravenous dexamethasone (0.15mg/kg) administration preoperatively in patients undergoing tonsillectomy with or without adenoidectomy showed reduction of post-operative pain, the need for rescue analgesics, and reduced incidence of post operative nausea and vomiting which resulted in early return to normal diet with better quality of food intake and early hospital discharge in both sharp snare dissection technique and laser technique in comparison with control group.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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