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Effect on Post Tonsillectomy Pain Control with IV and Infiltrated Dexamethasone and Infiltrated Bupivacaine: A Randomized Controlled Trial

Amjad Nadeem[1], Mirza Nasheed Baig[2], Nayyer Ayub[3], Farhan Ahmed[4]

[1]Assistant Professor Anaesthesia, Fazaia Medical College, Islamabad
[2]Associate Professor. Fazaia Medical College, Islamabad
[3]Assistant Professor ENT Deptt. Holy Family Hospital, Rawalpindi Medical University
[4]Assistant Professor ENT, HITEC-IMS Taxila

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Address of Correspondent
Dr. Amjad Nadeem
Assistant Professor Anaesthesia,
Fazaia Medical College, Islamabad
drakhattak@hotmail.com

ABSTRACT

Objectives: To evaluate the effect on post tonsillectomy pain control with IV and infiltrated dexamethasone and infiltrated bupivacaine.

Methodology: This randomized controlled trial study was conducted in the department of ENT and neck surgery of Holy Family hospital, Rawalpindi, over a period of one year from May 2019 to May 2020. A total of 140 pediatric patients were selected and were divided into four equal groups randomly by lottery method. Patients in all four groups had endotracheal intubation with general anesthesia. As premedication, all the patients received intravenous midazolam (1mg). Intravenous fentanyl (1.5mg/kg) and propofol (2.5 mg/kg) followed by endotracheal intubation facilitated with atracurium (0.5 mg/kg) were used as general anesthesia in all patients.

Results: There was no significant (p-value >0.05) difference in gender, age of children, postoperative heart rate, postoperative SPO2, and fentanyl consumption. The duration of surgery was significantly (p-value < 0.05) different in all four groups. According to the results, no significant (p-value >0.05) difference was found based on postoperative nausea and vomiting and the requirement of antiemetics. The requirement of analgesics was significantly (p-value <0.05) different among four groups. Minimum number (22.86%) of patients who required the analgesic were in IV dexamethasone group and highest requirement rate (60%) was found in local dexamethasone group followed by bupivacaine (48.57%) group.

Conclusion: Intravenous dexamethasone was found to be more effective for early postoperative pain control and reduction in requirement of analgesics. The use of dexamethasone can be a preferred choice in patients undergoing tonsillectomy.

Keywords: Tonsillectomy, Dexamethasone, Bupivacaine, Pain.

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Introduction

One of the most commonly performed surgical procedures is tonsillectomy around the world. Some complications are associated with tonsillectomy including postoperative pain, nausea and vomiting, bleeding, and infections, causing a significant clinical problem for the patients, their families, and general physicians. Advancement in anesthetic and surgical techniques could not significantly improve these conditions attached to tonsillectomy. Post tonsillectomy, the most common complication is pain and in about 46% of patients, it is controlled very poorly, with the worst condition in the older group of patients. The second most common complication of tonsillectomy is nausea and vomiting occurring in about 30% of the patients.[1,2]

Along with pain, nausea and vomiting some other complications are also common after tonsillectomy like hemorrhage, dehydration, delayed diet, injury of the soft tissue, nasopharyngeal stenosis, and death. Most common among all these complications are post tonsillectomy pain, nausea, and vomiting, which can prolong hospital stay and badly affect the quality of life of the patient. Batter pain management and reduction in nausea and vomiting are well-intentioned objective.[3]

The pain impulses at the entry of the central nervous system, despite general anesthesia create a hyperexcitable state during the surgery. The infiltration of preoperative analgesic drugs or topical administration of local anesthetic agents can have a preventive analgesic effect by blockage of these impulses. The pain after tonsillectomy is caused by muscle spasm due to inflammation and irritation in muscles of pharyngeal structure. Local anesthetic agent through injection or topical administration produce a pharmacologic barrier for sensory pathways prior to surgery and is considered to significantly decrease pain by preventing the access of pain sensory to reach the spinal cord.[4,5]

The use of corticosteroid has been used to prevent and reduce complications after tonsillectomy. Main mechanism behind this pain decline might be anti-inflammatory effect of steroids which can decrease tissue edema, sensitization of pain nerve terminal, and irritation to pharyngeal muscles, which results in postoperative pain relief. Steroid has also been studied as anti-emetic drug as well, but its mechanism of action is not well understood. Theoretically, steroid effect on activation of parasympathetic nerves at operating site to reduce neurotransmitters linked with emetic center of brain stem causing vomiting.[6,7]

Post tonsillectomy pain is usually caused by acute inflammation, nerve irritation and pharyngeal muscle spasm due to tissue injury after tonsillectomy surgery. The main contributors for nausea and vomiting are irritation of gastric mucosa due to swallowed blood and oropharyngeal pain. The edema and fibrosis during the healing can be reduced with infiltration of steroid. The use of steroid can prevent the production of inflammatory cell factors like cytokines in macrophages, monocytes, and lymphocytes. The reduction in the production of these factors can erupts leucocytes, release of lysosomal enzymes and vascular permeability in injury. The use of steroid also prevents the phospholipase enzyme resulting in blockade of pathways for cyclooxygenase & lipoxygenase and production of prostaglandin which results in pain relief.[8,9]

Peritonsillar administration of local anesthetics are very effective in decreasing intraoperative bleeding and postoperative pain, without increasing any chance of side effects.[10] Many local anesthetics are used for this purpose like bupivacaine which has a long-time action as an anesthetic agent. Similarly use of dexamethasone as local infiltration and systemic application has great benefits for postoperative pain control and reduction of nausea and vomiting. No drug is still in routine use for control of postoperative pain and nausea vomiting because it is still not decided and recommended which drug is more effective.[11,12] Therefore, the present study has been planned to evaluate the efficacy of IV and local administration of dexamethasone and local use of bupivacaine for better control of post-tonsillectomy pain, nausea and vomiting in pediatric patients undergoing tonsillectomy.

Methodology

This randomized controlled trial study was conducted after taking approval from the hospital ethical committee. All the children admitted for tonsillectomy in the department of ENT and neck surgery of Holy Family hospital, Rawalpindi, were enrolled for the study. The study period was about one year long from May 2019 to May 2020. Pediatric patients of age from 3 to 12 years of age and both genders were selected for the study sample by taking informed written consent from their guardian. Patients having a bleeding disorder, kidney, liver, lung or cardiac disease, obesity, history of use of steroids or antihistamines with last 24 hours prior to admission or any patient developed any complication after the operation were excluded from the study.

A total sample size of 140 children was selected for the study consisting of 35 children in each group. The sample size was calculated with the help of WHO sample size calculator using a significance level of 95%, Power of test 80%, population standard deviation of 1.75, and mean values of pain after 6 hours in dexamethasone group of 1.7 and bupivacaine group of 2.9. [13]

All the patients were divided into four equal groups randomly by lottery method and sealed envelopes were used for this purpose. Patients in all four groups had endotracheal intubation with general anesthesia. The patients in group I, received IV dexamethasone 0.5 mg/kg (maximum dose of 16mg) with placebo preincision

infiltration. Group II patients received local dexamethasone preincision infiltration (2-4 ml) with saline (0.9% NaCl) and intravenous saline in equivalent volume. Patients in groups III received 0.5% bupivacaine (Marcaine) solution in one tonsillar bed spray through an angulated syringe intraoperatively. Group IV received only normal saline infiltration as control group. As premedication all the patients received intravenous midazolam (1mg). Intravenous fentanyl (1.5 mg/kg) and propofol (2.5 mg/kg) followed by endotracheal intubation facilitated with atracurium (0.5 mg/kg) were used as general anesthesia in all patients. The anesthesia was maintained afterward with fentanyl (1-2 mg/kg), sevoflurane 1-3%, nitrous oxide 70% and oxygen 30%. The sevoflurane concentration was maintained based on blood pressure values within 25% of the pre-induction values. The local anesthetic mixture in total dose of 2-4 ml was applied in both tonsils. The constitution of mixture was based upon 3 ml lidocaine 2% (60 mg), 3 ml bupivacaine 0.5% (15 mg), 3 ml lidocaine 2% with epinephrine 1/200000 (60 mg), 0.5 ml fentanyl 50 µg/ml (25 µg), and 0.3 ml clonidine 150 µg/ml (50 µg). Monopolar electrocautery technique followed by cold dissection according to the hospital practice was used for tonsillectomy. An orogastric tube was used for suction of gastric content prior to extubation in all patients at the end of surgery. All the patients were given intravenous paracetamol (15 mg/kg) about 15 minutes prior to extubation. Extubation was done when patient was fully awake.

Demographic information including age, weight, and gender, along with intraoperative and post-operative finding were noted. Postoperative nausea and vomiting after 24 hours, and pain based on VAS score of 10 points, 0 indicating no pain and 10 indicating worst possible pain, were recorded on a predesigned Performa after 6, 12, 24 hours, days 2, 3 and 5. Fentanyl consumption, duration of surgery, surgical technique, amount of fentanyl administered, heart rate (HR), mean arterial pressure (MAP) and oxygen concentration (SPO_2) were also recorded.

All the collected data was entered and analyzed through SPSS v. 25. Qualitative data was presented in the form of mean and standard deviation and qualitative data as frequencies with percentages. One Way ANOVA test was applied to compare means of all four groups and Chi-square test was applied to compare qualitative variables among the groups. P-value ≤ 0.05 was considered significant.

Results

In this randomized control trial study, a total of 140 children were selected and divided into four equal groups. Each group consisted of 35 patients. The distribution of demographic information showed that there was no significant (p-value > 0.05) difference in demographic characteristics like gender and age of children of all four groups. Similarly, no significant (p-value > 0.05) difference was found in postoperative heart rate, postoperative SPO_2, and fentanyl consumption. The duration of surgery was significantly (p-value < 0.05) different in all four groups and analysis showed that Group I, IV dexamethasone group had significantly less mean operative time as compared to other groups. The highest mean operative time was found in local dexamethasone group in comparison to other three groups as elaborated in table I.

Table I: Demographic and Postoperative Characteristics of the patients (n=140)

Characteristics	Study Groups				P-value
	Group I	Group II	Group III	Group IV	
Age of the patient					
Mean ± SD	24.8 ± 5.6	27.9 ± 6.1	26.5 ± 5.9	28.3 ± 6.2	0.064
Gender of the patient					
Male	20 (57.14%)	22 (62.86%)	21 (60%)	19 (54.28%)	0.899
Female	15 (42.86%)	13 (37.14%)	14 (40%)	16 (45.71%)	
Post-Operative HR					
Mean ± SD	102.56 ± 13.22	104.5 ± 14.59	103.75 ± 12.89	104.35 ± 13.23	0.93
Post-operative SPO_2					
Mean ± SD	98.85 ± 1.25	99.20 ± 0.94	98.76 ± 0.89	99.10 ± 1.05	0.525
Fentanyl Consumption					
Mean ± SD	42.25 ± 19.25	43.35 ± 17.95	46.70 ± 18.35	45.85 ± 18.76	0.724
Duration of Surgery					
Mean ± SD	28.75 ± 8.24	38.85 ± 7.85	32.73 ± 8.15	33.65 ± 7.95	0.000

Group I = IV Dexamethasone group, Group II = Local Dexamethasone group
Group III = Bupivacaine group, Group IV = Control group

According to the results no significant (p-value > 0.05) difference was found based on postoperative nausea and vomiting and requirement of antiemetics. The requirement of analgesics was significantly (p-value < 0.05) different among four groups. Minimum number of patients who required the analgesic were in IV dexamethasone group and only 22.86% patient in this group required analgesic postoperatively. Highest requirement rate was found in local dexamethasone group in which 60% of the patients required additional analgesics, followed by bupivacaine (48.57%) and control (31.43%) groups as shown in table II.

The analysis of the data showed that pain score based on visual analogue scale (VAS) showed a highly significant (p-value < 0.001) difference among all four groups at 6^{th}, 12^{th}, 24^{th}, hour, day 3, and day 5 follow up times. At 6th hour IV dexamethasone group patients had minimum (3.6 ± 1.0) mean pain score as compared to other three groups. Highest mean pain score (6.8 ± 2.2) at 6th hour was noted in control group, followed by bupivacaine group (4.9 ± 1.8), and local dexamethasone (4.5 ± 1.1) group. After 12 hour of surgery the lowest mean pain score was observed in (3.4 ± 1.2), IV dexamethasone group and local dexa group (3.4 ± 1.3). Highest mean pain score was noted in control group (5.9 ± 1.9) followed by bupivacaine group (4.3 ± 1.6) at 12th hour.

After 24 hours lowest mean pain score was observed in IV dexamethasone group (2.6 ± 0.9) and local dexamethasone group (2.8 ± 1.1). Highest pain based on mean pain score was noted in control group (5.5 ± 1.3) followed by bupivacaine group (4.3 ± 1.6). Same trend of pain score was noted at day 3, at which minimum pain score was in IV dexamethasone group (1.8 ± 0.7) and local dexamethasone group (2.2 ± 0.9), with highest pain in control group having mean pain score of (4.3 ± 1.2). After 5th day of surgery, the trend of pain changed, and it was noted that minimum mean pain score at 5th day was observed in bupivacaine group (0.5 ± 0.6) and control group (0.5 ± 0.9). Highest mean pain score was noted in IV dexa group (0.8 ± 0.6) followed by local dexamethasone group (0.7 ± 0.5) as elaborated in table III.

Discussion

Tonsillectomy is a commonly performed surgical procedure throughout the world. Although it is a simple procedure but has a significant morbidity associated with it. Most common complications connected to tonsillectomy are pain, nausea, vomiting, bleeding, poor oral intake, and dehydration. The inflammation and irritation of pharyngeal muscles due to surgery cause muscle spasm which is the main cause of post

Table II: Distribution of Postoperative Nausea/vomiting, and requirement of antiemetic and analgesics (n=140)

Characteristics	Study Groups				P-value
	Group I	Group II	Group III	Group IV	
Post-operative Nausea and Vomiting					
Yes	8 (22.85%)	12 (34.29%)	12 (34.29%)	9 (25.71%)	0.624
No	27 (77.14%)	23 (65.71%)	23 (65.71%)	26 (74.29%)	
Antiemetic Required					
Yes	10 (28.57%)	13 (37.14%)	12 (34.29%)	11 (31.43%)	0.885
No	25 (71.43%)	22 (62.86%)	23 (65.71%)	24 (68.57%)	
Analgesic Required					
Yes	8 (22.86%)	21 (60%)	17 (48.57%)	11 (31.43%)	0.007
No	27 (77.14%)	14 (40 %)	18 (51.43%)	24 (68.57%)	

Table III: Comparison of postoperative pain at different time points (n=140)

Study Groups				P-Value
Group I	Group II	Group III	Group IV	
Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
VAS score at 6th hour				
3.6 ± 1.0	4.5 ± 1.1	4.9 ± 1.8	6.8 ± 2.2	0.000
VAS score at 12th hour				
3.4 ± 1.2	3.4 ± 1.3	4.3 ± 1.6	5.9 ± 1.9	0.000
VAS score at 24th hour				
2.6 ± 0.9	2.8 ± 1.1	4.1 ± 1.2	5.5 ± 1.3	0.000
VAS score at day 3				
1.8 ± 0.7	2.2 ± 0.9	3.6 ± 1.1	4.3 ± 1.2	0.000
VAS score at day 5				
0.8 ± 0.6	0.7 ± 0.5	0.5 ± 0.6	0.5 ± 0.9	0.000

tonsillectomy pain. Different modalities are in practice to control postoperative pain like intravenous opioids, local anesthetic agents, non-steroidal anti-inflammatory drugs (NSAIDS), use of steroids locally or intravenously and nerve blocks. Perioperative opioids are most commonly used method for pain control, but it has some common complications linked with its use especially nausea, vomiting, pruritis and respiratory depression.[14] The use of non-steroidal anti-inflammatory drugs is also common as postoperative analgesia. Both routes intramuscular and intravenous are employed for administration of NSAIDS. Although the use of NSAIDS is easy but these are not used preferably because of their side effects like poor analgesia and anti-platelet activity which can result in enhanced chances of bleeding in some patients.[15]

In this present study very young children were not included and patients of 5 to 18 years were enrolled for better reliability of pain response on the basis of visual analogue scale (VAS). Some other studies have also used similar age group like El Daly A et al, also enrolled patient of this age group.[16]

The use of dexamethasone and its efficacy in post tonsillectomy pain has been indicated by previous studies, which have shown a significant reduction in morbidity after tonsillectomy. Significant reduction in incidence of early and late postoperative nausea, vomiting and pain scores were noted after tonsillectomy with a single dose of dexamethasone. The anti-emetic mechanisms of dexamethasone are not well known yet, although its anti-emetic property is well established.[17]

According to the results of this present study no significant (p-value > 0.05) difference was found based on postoperative nausea and vomiting and the requirement of antiemetics. The requirement of analgesics was significantly (p-value < 0.05) different among four groups. The minimum number of patients who required the analgesic were in IV dexamethasone group and the highest requirement rate was found in local dexamethasone group in which 60% of the patients required additional analgesics. The results of present study are not in agreement with many other studies in which the effect of dexamethasone on PONV following pediatric tonsillectomy was studied. Majority of the studies showed that the use of dexamethasone reduces the rate of vomiting postoperatively in children after tonsillectomy as compared to placebo group.[18]

Better results in terms of reduction in postoperative nausea and vomiting have been observed with intravenous administration of dexamethasone.[19] Although the mechanism through which dexamethasone exert its anti-emetic effect is still unknown; yet the antiemetic effect is widely accepted and supported by many studies.[20]

The analysis of the data showed that pain score based on visual analogue scale (VAS) showed a highly significant (p-value < 0.001) difference among all four groups at 6^{th}, 12^{th}, 24^{th}, hour, day 3, and day 5 follow up times. At 6^{th} hour IV dexamethasone group patients had minimum (3.6 ± 1.0) mean pain score as compared to other three groups. The lowest mean pain score was observed in IV dexamethasone group at 6^{th} hour (3.4 ± 1.2), 12 hours (2.6 ± 0.9), 24^{th} hour (2.8 ± 1.1) and at day 3 (1.8 ± 0.7). After 5th day of surgery, the trend of pain changed, and it was noted that minimum mean pain score was observed in bupivacaine group (0.5 ± 0.6). The results agree to some previous studies.[10,21]

The use of dexamethasone systemically and local infiltration, both reduce postoperative pain scores and requirement and consumption of analgesics after tonsillectomy. Similarly, the use of dexamethasone by any route has proved to be efficient for treatment of postoperative nausea and vomiting. However, the outcomes of local infiltration in comparison to systemic administration of dexamethasone have not been studied well especially in children. There are few shortcomings associated with single systemic injection of dexamethasone like wide distribution and short acting time which makes it impact less optimal than required. The infiltration of dexamethasone is more effective in terms of reduced pain scores postoperatively, decreased average consumption of postoperative analgesia, shortened the time to oral intake, and decreased the incidence of postoperative nausea and vomiting.[22]

Conclusion

Intravenous dexamethasone, infiltrated dexamethasone, and infiltrated bupivacaine were all effective on postoperative pain in comparison to control group. In all these groups intravenous dexamethasone was found to be more effective for early postoperative pain control and reduction in the requirement of analgesics. The use of dexamethasone can be a preferred choice in patients undergoing tonsillectomy because of its being inexpensive, safe, and easily applicable. These results can be further verified and confirmed in similar larger trials.

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