

# To Compare the Mean Pain Score after giving Dexamethasone versus Placebo following Tonsillectomy in Children with Recurrent Acute Tonsillitis

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## ABSTRACT

**Background:** Pain is one of the most important hurdles for patient rehabilitation following tonsillectomy. Insufficient analgesia leads to poor oral ingestion, which causes lethargy, late recovery and wellbeing. Dexamethasone is a glucocorticoid which is mostly used to reduce the pain and difficulties after tonsillectomy.

**Aim:** To compare mean pain score after administering dexamethasone vs. placebo following tonsillectomy among children with recurrent acute tonsillitis.

**Study design:** Randomized controlled trial.

**Setting:** Department of ENT-I, Services Hospital, Lahore.

**Duration of study:** The duration of study was six month i.e. from 15.07.2015 to 14.01.2016.

**Methods:** Total 100 patients were included and divided into two groups (50 patients in each group). Group-A patients were given dexamethasone 0.1mg/kg while patients of Group-B treated with placebo (normal saline).

**Results:** Patients age range was between 4 to 17 years. In group-A patients the mean age was  $10.48 \pm 4.14$  years and in group-B patients the mean age was  $9.92 \pm 3.93$  years. Result shows that 30(60%) patients in group-A and 38 (76.0%) patients in group-B were males while in Group-A 20(40%) patients and in Group-B 12(24%) patients were female. The comparison showed that postoperative mean pain score was  $2.86 \pm 1.05$  in group-A and  $4.08 \pm 1.04$  in group-B. Difference between both groups was found statistically significant as the p value was  $< 0.001$ . Stratification in relation to gender and age was performed.

**Conclusion:** Study concluded that dexamethasone single intravenous injection at anesthesia induction decreased the frequency of early and late pain acuteness after twelve hour of surgical procedure. A 0.1mg/kg dose of dexamethasone seemed to be as effective.

**Keywords:** Dexamethasone, Tonsillectomy, Placebo, Postoperative pain.

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## INTRODUCTION

Tonsillectomy is most frequently performed surgical procedure in Otorhinolaryngology departments in both children and adults<sup>1</sup>. Among upto 57% patients, recurrent tonsillitis is a sign for tonsillectomy<sup>2</sup>. In USA, over 530,000 tonsillectomies are carried out per year among children aged less than twelve years with recent rates of 1.46 & 0.53 per 1000 children for adeno-tonsillectomy and tonsillectomy, respectively. Among children, tonsillectomy is usually related to moderate to acute local pain with/without referred otalgia for 7 to 20 days. Mostly the post-tonsillectomy pains is the outcome of muscle spasm due to irritation, edema and inflammation of pharyngeal musculature<sup>3</sup>.

Tonsillectomy is linked with medical problems that comprise hospitalization, anesthesia risks and throat pain. Other than pain, there are also several morbidities caused by tonsillectomy are nausea, vomiting, bleeding and insufficient oral intake<sup>4</sup>. Among children, recovery period mostly requires one week while adults remain symptomatic for two weeks. Odynophagia could be harsh enough and can limit the oral intake that occasionally patients can get dehydrated needing readmission for additional management<sup>5</sup>.

Post-tonsillectomy pain occurs due to numerous factors; this is more severe during first 3 postoperative days and can continue till day 10<sup>2</sup>. There are several

techniques in the literature to manage this pain. A study carried out by Buland and coworkers (2012) divided patients in two groups. One groups was managed through dexamethasone while other was placebo group. Study demonstrated that after twelve hours, the pain was 0-3 (mild) among 80 percent patients who were administered dexamethasone and among 46 percent patients who were not administered dexamethasone<sup>3</sup>. Dexamethasone postoperative usage to manage post-tonsillectomy pain was examined in a study carried out in Pakistan by Hashmi and teammates (2012) which demonstrated that the group who was given dexamethasone, the pain score after twelve hours was less  $3.87 \pm 0.62$  among patients when compared with patients not administered dexamethasone  $4.66 \pm 0.94$ <sup>5</sup>. In a study Herman and associates (2012) highlighted that significant pain (VAS >3) incidence did not vary in both dexamethasone and placebo groups<sup>6</sup>.

The study undertaken by Herman and associates (2012) assessed the intravenous dexamethasone effect on the reduction of pain after 12 hours of tonsillectomy under the general anesthesia among children measured through visual analog scale (VAS). Study demonstrated that there was no change in the pain score of dexamethasone group when compared with placebo group. However, local studied demonstrated variations. In local studies, even dexamethasone effect is controversial because Buland and coworkers (2012) demonstrated mild pain while Hashmi and teammates (2012) indicated moderate pain score. The results of present study will assist in selecting

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dexamethasone as a best treatment option if study outcomes support dexamethasone.

The objective of study was To compare mean pain score after administering dexamethasone vs. placebo following tonsillectomy among children with recurrent acute tonsillitis.

## MATERIAL AND METHODS

It was randomized controlled trial carried out at Services Hospital Lahore at Department of ENT-I of Services Hospital, Lahore. The duration of study was six month i.e. from 15.07.2015 to 14.01.2016. The sample size of the study was 100 cases (50 cases in each group) calculated with 95 percent confidence level, 80 percent power of test, taking anticipated mean  $\pm$  SD of the mean pain score in both groups namely  $3.87 \pm 0.62^{[5]}$  among patients of dexamethasone group and  $4.66 \pm 0.94^{[5]}$  among patients of placebo group following tonsillectomy for recurrent acute tonsillitis. Non-probability consecutive sampling technique was used. Patients aged 4-17 years, both gender and clinically diagnosed cases of recurrent acute tonsillitis during past one month were included. Patients having history of Quinsy (Muffled Voice, Trismus and fever above  $99 \pm F$  Odynophagia), bleeding disorders (APTT<33, INR <1.0 and PT<13) and concomitant adenoidectomy.

A written informed consent was obtained for both kinds of procedures from parents/guardians to assign them specific procedure and utilizing their information for research. Detailed history from each patient was obtained including demographic data namely name, address, age and gender. By lottery technique, patients were divided in two equivalent groups. Patients of Group-A were given dexamethasone 0.1mg/kg while patients of Group-B treated with placebo (normal saline). By same surgeon, tonsillectomies were performed under the general anesthesia with dexamethasone I/v injection in Group-A while normal saline I/v infection was administered in Group-B patients. After twelve hours of procedure, pain was noted through face pain scale.

The collected data was analyzed through SPSS version 20.0. Quantitative data were age and post-operative pain score. These variables were presented as Mean $\pm$ SD. Qualitative variable was gender and presented as frequencies and percentages. Comparison of the postoperative pain score between both groups was carried out by t-test. Data was stratified for age, gender to deal with effect modifier. Post-stratification t-test was applied. P value  $\leq$  0.05 was considered significant.

## RESULTS

During study one hundred patients (50 patients in each group) were included and the duration of study was six months. Group-A patients received dexamethasone 0.1 mg/kg and Group-B patients were given placebo (normal saline). Patients' age range was between 4 to 17 years. In group-A patients the mean age was  $10.48 \pm 4.14$  years and in group-B patients the mean age was  $9.92 \pm 3.93$  years. Result shows that 30(60%) patients in group-A and 38(76%) patients in group-B were males while in Group-A 20 (40%) patients and in Group-B 12(24%) patients were female.

The comparison showed that postoperative mean pain score was  $2.86 \pm 1.05$  in group-A and  $4.08 \pm 1.04$  in group-B. Difference between both groups was found statistically significant as the p value was <0.001

## DISCUSSION

Short-term pre-, intra- and post-operative dosages of steroid are routinely utilized by several surgeons, particularly during head and neck surgeries, to decrease vomiting, swelling and to protect function. In available literature, no accepted agreement is found regarding this practice. Dexamethasone is a glucocorticoid which is mostly used to reduce the pain and difficulties after tonsillectomy. All probable opinions coexist in publications about dexamethasone, starting from statement that it has "no significant effect on postoperative pain amount" and ending with opposite opinion<sup>[115]</sup>. Partly, this dispute is based upon dissimilar timings of medicine administrating (pre-, intra- and post-operative).

An additional weak point could be pain testing. Use of VAS (Visual Analogue Scale) or the image type is in fact the single way to obtain particular qualitative information from patients himself. Hence, subjective experience (pain) is checked through subjective technique (VAS pain score self-reported). Previously, it has been described that visual analogue scale, being based upon self-perception is not able to offer a valid and reliable data to practitioner

Numerous researches have assessed dexamethasone effects on pain after the pediatric tonsillectomy but these studies included small number of respondents and not utilized standardized anesthetic methods as well as rescue treatment procedures.

Also, the outcomes of some studies that assessed the impact of single intravenous corticosteroid administration were contradictory, in that a few researches demonstrated a helpful effect, while the others studies did not.

However, the dexamethasone anti-inflammatory effects are well recognized, their effects on the postoperative pain continue to debate.

In a recent study, effect on pain was observed just after twelve hours of surgery. Based upon dexamethasone pharmacokinetic profile, it is anticipated that anti-inflammatory effects of dexamethasone will occur after several hours of its administration. Hence, this is not shocking that dexamethasone effect on the postoperative pain was seen only after twelve hours. Also, this could explain that why some researches did not succeed to assess considerable pain reduction after dexamethasone use in immediate postoperative phase.

During present research, mean pain score was considerably lesser among patients of dexamethasone group as compared to placebo group (P-value <0.001).

The dexamethasone best dosage is a matter of debate as well. Gunter and colleague and Kim and partners compared the doses of dexamethasone ranging from 0.0625 to 1.0mg/kg during pediatric tonsillectomy. Authors did not see dosage dependent effect on pain incidence.

A research was undertaken by Carr and associates in which the effects of postoperative dexamethasone single I/v dose was evaluated on pain among patients who underwent tonsillectomy. VAS was used to assess pain for

ten days. The second group was given placebo. No significant difference was found between both groups while dexamethasone group had less pain during initial various days. A single dosage was not related to harmful effects, thus risk-benefit ratio could be beneficial regarding this practice. In another research, the effectiveness of steroid was observed in decreasing postoperative difficulties in relation to pain, hemorrhage, emesis, weight loss and halitosis among patients experiencing tonsillectomy.<sup>[128]</sup>

The postoperative administration of dexamethasone enhanced pain score, decreased analgesic needs, allowed patients early oral liquid intake and enhanced postoperative ingestion and oral intake quality. These results could be due to dexamethasone anti-inflammatory effect, which can decrease local pain and edema. These outcomes are comparable to patients getting steroid for severe pharyngitis where symptoms recovery is mostly caused by pain release secondary to steroids anti-inflammatory action.

A study conducted by Carr and associates<sup>[128]</sup> concluded that no evidence were found that dexamethasone single dose decreases pain after surgical procedure. Stewart and colleagues<sup>[25]</sup> also stated that administration of dexamethasone in this regime decreased postoperative pain and analgesic needs after adult tonsillectomy<sup>[25]</sup>.

## CONCLUSION

Study concluded that dexamethasone single intravenous injection at anesthesia induction decreased the frequency of early and late pain acuteness after twelve hour of surgical procedure. A 0.1mg/kg dose of dexamethasone seemed to be as effective.

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