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***Research Article***

# SINGLE DOSE IV DEXAMETHASONE REDUCES POSTOPERATIVE MORBIDITY FOLLOWING CLEFT PALATE SURGERY

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## ABSTRACT
This prospective randomized double blind study was undertaken to determine the effectiveness of single dose intravenous ( iv) dexamethasone to reduce postoperative morbidity following cleft palate surgery .
100 patients aged 1 to 5years, body weight 5kg to 15kg, ASA I and II were divided into two equal groups. Group A (n=50) received 0.15mg/kg iv dexamethasone and group B (n=50) received normal saline after induction. All the patients in both the groups were induced with halothane and glycopyrrolate 0.004mg/kg. After assessing airway suxamethonium 1.5 mg/kg IV was used for intubation. All of them received intravenous fentanyl 2 ug/kg before incision. Anaesthesia was maintained with $N_2O + O_2$ (2:1) + halothane 0.5% + atracurium 0.5mg/kg. Using Observer Pain Scale, rectal diclofenac 2mg/kg was administered when OPS > 4 or on patient demand. Incidence of nausea, vomiting and local oedema were recorded. Time and quality of first oral intake were also recorded.
Pain score was significantly lower in the group A compared to group B. Requirement of rescue analgesic, incidence of nausea, vomiting and local oedema were less in group A compared to group B.
To conclude, single dose intravenous dexamethasone reduces postoperative morbidity following cleft palate surgery.

***Key Words**: IV Dexamethasone, Post Operative Morbidity, Cleft Palate Surgery*

## INTRODUCTION
Cleft palate surgery continues to be one of the common surgical procedures performed worldwide Michael *et al.,* (2006). Despite advances in anaesthetic and surgical technique post operative morbidity remains a significant clinical problem (White and Nolan (2005). Pain, nausea, vomiting and poor oral intake due to local oedema are the most common morbidities following cleft palate surgery (Less, Pigott 1992). The association of pain and post operative nausea and vomiting is well known (Eaton *et al., 1994;* and White and Nela, 2005). Pain is traditionally controlled with opioid but this increases the risk of post operative nausea and vomiting and may cause respiratory depression (Goddard and Pickup, 1996). To avoid the side effects of opioid, the Non Steroidal Anti Inflammatory Drugs (NSAIDs) are used perioperatively nowadays by different routes (Hodsman *et al.,* 1987) and (Watters *et al.,* 1988; and Brogden *et al.,* 1980). Enteral and rectal route are easy to administer in paediatric patients and has relatively low frequency of side effects (Rainsford and Velo Eds,1985). So rectal diclofenac sodium, a non steroidal anti-inflammatory drug was chosen as postoperative analgesic in our study.
Dexamethasone is known to have anti inflammatory and antiemetic effect (Skjelbred and Lokken 1982). It has been used successfully for chemotherapy induced and postoperative nausea and vomiting following tonsillectomy (Splinter and Roberts, 1996).
The role of iv dexamethasone for relief of pain and postoperative morbidity following cleft palate surgery has not yet been explored. So this study was undertaken to determine the effectiveness of IV dexamethasone to reduce analgesic requirement and post operative morbidity like pain, postoperative nausea vomiting and local oedema following cleft palate surgery.

## MATERIALS AND METHODS

After approval from the institutional ethical committee and informed written consent, 100 patients, ASA I and II, aged 1to 5 years , body weight 5 to 15kg, undergoing cleft palate surgery under general anaesthesia were divided into two equal groups in a randomized double blind protocol according to computer generated random table. The exclusion criteria included : ASA III and IV, patients with coagulapathy, under treatment with steroids, antiemetic, antihistaminic, aspirin or any NSAIDs. General anaesthesia was administered according to a standard protocol. Induction was done with halothane 2-3% in oxygen. IV line was secured, glycopyrrolate 0.004mg/kg was administered and precordial stethoscope was fixed with tape.Group A (n=50) received 0.15mg/kg of dexamethasone diluted in 5 ml normal saline and group B (n=50) received 5 ml of normal saline IV after induction by one blinded anaesthesiologist. Suxamethonium 1.5 mg/kg iv was given after assessing airway under inhalation anaesthetic and trachea was intubated with proper size RAE tube. All patients received fentanyl intravenously 2ug/kg as analgesic before incision. Anaesthesia was maintained with 0.5% halothane + 66% $N_2O$ in 33% $O_2$ and controlled ventilation using atracurium 0.5 mg /kg first dose and then the dose was reduced to 1/2 or 1/3$^{rd}$ as per requirement. Jackson - Rees modification of Ayre's T piece was used for controlled ventilation. Monitors used were pulse oximetry, NIBP, E.C.G. and $EtCO_2$. Surgical technique was standardized. Intraoperatively all patients received balanced salt solution ( Aerolyte P) infused at the rate of 4 ml/kg/hour for 1st 10 kg, 40ml+ 2ml/kg/hr for next 10 kg, + estimated fluid deficit for period of fasting (50% in 1$^{st}$ hr, 50% in next 2 hrs. with 25% each hour) + 3rd space loss 5ml/kg/hr. Blood loss was average and replaced with 3 times the volume of crystalloid. After surgery, residual neuromuscular block was reversed with injection neostigmin and injection glycopyrrolate. Patients were extubated when they had satisfactory recovery of motor power and were fully awake. The anaesthesiologist who was unaware of the group allocation and the drug administered, monitored all patients in the Post Anaesthesia Care Unit (PACU) for 24 hours. Pain was assessed by Observer Pain Scale. (Which is the most common scale used by nurses in the recovery room in the age group of 1-5 yrs.) or by direct questionnaire to the patients and the parents where applicable.

**Observer Pain Scale (OPS)**

| Item | Score |
|---|---|
| **L**aughing, euphoric | 1 |
| **H**appy, contended | 2 |
| **C**alm or asleep | 3 |
| **M**ild to moderate pain: crying, Grimacing, restlessness; can distract with Toy, food, parental presence | 4 |
| **C**rying, screaming, inconsolable | 5 |

An OPS was assessed at 1,3,6,12,24 hours. When OPS was 4 or if patient feels pain, rectal diclofenac 2mg/kg was administered. Nausea and vomiting if present, was recorded and treated with injection ondansetron (0.1 mg/kg). Presence or absence of local oedema (as visual impression of elongation of uvula and hoarse voice) was noted. At four hours after surgery, plain water was allowed. The quality of oral intake was graded as**:** excellent = on patient's request, good = patient accepts, when offered, fair = patient accepts, when coaxed, poor = patient refuses. (Splinter and Roberts, 1996) If oral intake was delayed, the time and duration between the end of surgery and first acceptance of oral liquid was recorded. Till that time balanced salt solution was infused. At 24 hrs the study was concluded.

Statistical analysis was done. Parametric data were analyzed using unpaired 't' test and non parametric data were analyzed by Mam - Whitney U test or Chi-square analysis, $p < 0.05$ was considered to be significant. The sample size was 50 in each group with type 1($\alpha$ ) error of 5%; type II ($\beta$) error of 20%.

## RESULTS

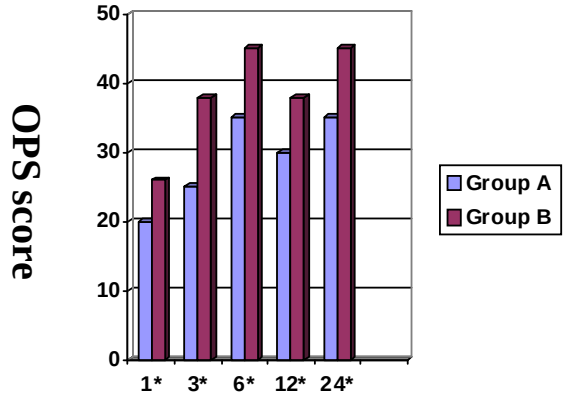
**B**oth the groups were comparable according to age, body weight, sex, duration of surgery and duration of anaesthesia, (Table - 1 ).

**Table 1: Demographic data**

| | Group A (n = 50) | Group B (n = 50 ) |
|---|---|---|
| **Age (yrs)** | 2.5 ± 1.5 | 2.3 ± 1.5 |
| **Body Weight (kg)** | 12 ± 2.3 | 12 ± 2.5 |
| **Sex M/F** | 26 / 24 | 25 / 25 |
| **Duration of Surgery (mins)** | 60 ± 10.15 | 60 ± 5.0 |
| **Duration of Anaesthesia (mins)** | 70 ± 9.0 | 70 ± 5.5 |

**G**roup A had significantly lower OPS score than group B at 1,3,6,12,24 hrs postoperatively (Figure 1).

**Figure 1: OPS score in both the groups during postoperative 24 hours**




*p<0.05

**D**uration of analgesia was longer in group A than group B (Table 2).

**Table 2: Duration of analgesia in the both the groups**

| | Group A (n = 50) | Group B (n = 50) |
|---|---|---|
| **Duration of Analgesia ( hour)** | 8 ± 2.0 | 5 ± 1.5* |

** p < 0.05*

**T**able 3 shows dose and number of rescue analgesic between the two groups. Group A showed less requirement of rescue analgesic than group B.

**Table 3: Dose and number of requirement of rescue analgesic between the two groups in 24 hrs**

| Dose and Number of Requirement of Rescue Analgesic | Group A (n = 50) | Group B (n = 50) |
|---|---|---|
| **Rectal Diclofenac (Mg)** | 25 ± 10.02 | 50 ± 10.05** |
| **Number of Patients Requiring Rescue Analgesic** | 20% | 60% * |
| **A) 0 - 6 Hrs** | 0% | 30%* |
| **I) Single Dose** | | |
| **II) Second Dose** | | |
| **B) 6 – 24 Hrs** | 40% | 80% * |
| **I) Single Dose** | 0% | 40%* |
| **II) Second Dose** | | |

**p < 0.05*
***p< 0.001*

**T**able 4 shows incidence of postoperative nausea, vomiting, local oedema, hoarse voice and fluid intake. Group A showed less postoperative complications compared to group B.

**Table 4: Incidence of post operative nausea vomiting, hoarseness and time of first oral intake between two groups**

| | Group A (n = 50) | Group B (n = 50) |
|---|---|---|
| **Incidence Of Nausea & Vomiting** | 8% | 30% ** |
| **Hoarseness** | 0% | 14% * |
| **Time Of First Oral Intake** | 6 hrs | 20 hrs** |
| **Quality Of Oral Intake** | 80% excellent*<br>20% good | 50% excellent*<br>40% good<br>10% fair |

* p < 0.05
** p < 0.001

**DISCUSSION**

Post operative pain is a significant problem following cleft palate surgery in paediatric patients(Fenlon and Somerville 2005). Tissue injury induced acute inflammation, nerve irritation and spasm of exposed pharyngeal muscle is known to play a major role in genesis of post operative pain (Malde *et al.,* 2005; and Michael *et al.,* 2006). Dexamethasone significantly improve the morbidity following cleft palate surgery

and has been shown to reduce the total dose of rescue analgesic in the postoperative period(April *et al.,* 1996 and Senders *et al.,* 1999). Although, narcotic analgesics are the mainstay of pain control, they do not completely control pain and are often discontinued due to their side effects of respiratory depression, nausea, vomiting and constipation etc (Senders *et al.,* 1999). There use in postoperative period is limited. NSAIDs are known to be effective analgesics. The NSAIDs are beneficial as because they avoid the side effects of opioids (Senders *et al.,* 1999). Diclofenac sodium is a nonsteroidal anti-inflammatory drugs with least side effects (Brogden *et al.,* 1980 and Park *et al.,* 2010) . Rectal diclofenac is now available and has been shown to produce good results. Rectal administration of diclofenac carries some advantages. It avoids first pass effect(De Boer *et al.,* 1982). NSAIDS when taken orally may cause dyspepsia, gastric erosions and haemorrhage. The use of suppositories may reduce these side effects although it will not necessarily avoid them, since irritation depends not only on a local action in the stomach but also on the plasma concentration of the drug.

Effects of dexamethasone resulted in the improvement of nausea, diet intake, trismus and pain(Tom *et al.,* 1996 and Park *et al.,* 2010). By inhibiting phospholipase enzyme, corticosteroids block both the cyclooxygenase and lipooxygenase pathway and thus prostaglandin production, thereby leading to pain relief (Tom *et al.,* 1996). NSAIDs also prevents COX I-2 and provide relief of pain (Carr *et al.,*). When diclofenac was used with dexamethasone the analgesia was prolonged as seen is group A who showed a low OPS score and less requirement of rescue analgesic in the post operative period.

Post operative nausea and vomiting is multifactorial (Nuki, 1990) Though exact mechanism by which certicosterioids act as antiemetic is not known, probably it increases the β endorphin level in the central nervous system and thus causes the feeling of wellbeing, it has been proved that dexamethasone prevents nausea and vomiting in the post operative period following tonsillectomy(Catlin and Grimes, 1991).

In our study we have seen less incidence of nausea and vomiting along with excellent pain control in dexamethasone group (group A). Moreover, single dose dexamethasone is devoid of side effects like gastritis and adrenal suppression (Papangelou, 1972).We selected 0.15mg/kg mg dose of iv dexamethasone as the universal dose. Dose range in paediatric group varies from 0.15mg/kg to 1mg/kg (Vosdoganis and Baines, 1999). We have therefore used the lowest dose. We found significantly better quality of oral intake with dexamethasone, perhaps by decreasing pain and inflammation – possibly due to its additive effect with NSAIDs. The study of Steward *et al.,* showed patients who received dexamethasone had earlier onset time of fluid intake than others. Elhakim *et al.,* studied the effect of dexamethasone on recovery from tonsillectomy in children. Few required rescue analgesic, time to first rescue analgesic was longer and stime to first oral intake was shorter in dexamethasone group (Steward *et al.,* 2001 and Senders *et al.,* 1999). This is also supported by other workers(Ethakim *et al.,* 2003).

In our study the patients in group A had taken plain water at 4 hours onwards due to reduced pain and inflammation caused by additive effect of diclofenac and dexamethasone. No patient complained of hoarseness or laryngeal oedema in this group.

So we can conclude that a single iv dose of dexamethasone prolongs analgesia, reduces opioid requirement, produces less incidence of PONV and allows early oral intake thus reducing morbidity in the postoperative period.

## REFERENCES

**April MM, Callan ND and Nowak DM (1996)** . The effect of intravenous dexamethasone in pediatric adenotonsillectomy. *Archive of Otolaryngol Head Neck Surgery* **122** 117-122.

**Bolton CM, Myles PS and Nolan T *(2006).*** Prophylaxis of postoperative vomiting in children undergoing tonsillectomy: a systematic review and meta - analysis. *British Journal of Anaesthesia* **97**(5) 593–604.

**Brogden RN, Hell RC, Parkers GE and Speight TM (1980).** Diclofenac sodium: a review of its pharmacological properties and therapeutic use in rheumatic diseases and pain of varying origin. *Drugs* **20** 24-8.

**Carr MM, Williams JG and Carmichael L (1999).** Effect of steroids on post tonsillectomy pain in adults. *Archive of Otolaryngology Head Neck Surgery* **125** 1361-4.
**Catlin FI and Grimes WJ (1991).** The effects of steroid therapy on recovery from tonsillectomy in children. *Archive of Otolaryngology Head Neck Surgery* **117** 649-52.
**De Boer AG, Moolenaar F, De Leede LGJ and Breimer DD (1982).** Rectal drug administration: Clinical pharmacokinetic considerations. *Clinical Pharmacokinetics* **7** 285-311.
**Elhakim *et al.*, (2003).** Dexamethasone reduces postoperative vomiting and pain after pediatric tonsillectomy. *Canadian Journal of Anaesthesia* **50** 392-397.
**Eaton AC, Marsh JL and Pilgram TK (1994).** Does reduced hospital stay affect morbidity and mortality rate following cleft lip and palate repair in infancy? *Plastic Reconstructive Surgery* **94** 911-915.
**Fenlon S and Somerville N (2005 June).** Anaesthesia for cleft lip and palate surgery. *Continuing Education in Anaesthesia Critical Care and Pain* **5**(3) 76-79.
**Goddard JM and Pickup SE (1996).** Postoperative pain in children Anaesthesia **51** 588-591.
**Hodsman NBA, Bums J, Blyth A, Kenny GNC, McArdle CS and Rotman H (1987).** The morphine sparing effects of diclofenac sodium following abdominal surgery. *Anaesthesia* **42** 1005-1008.
**Less VC and Pigott RW (1992).** Early postoperative complication in primary cleft lip and palate surgery: how soon may we discharge patients from hospital? *British Journal of Plastic Surgery* **45** 232-234.
**Malde AD, Sonawane VS and Jagtap SR (2005).** Effect of dexamethasone on post tonsillectomy morbidities. *Indian Journal of Anaesthesia* **49**(3) 202-207.
**Michael CB, Alejandro CJ, Eric MK and Douglas RM (2006).** Short stay cleft palate surgery with intraoperative Dexamethasone and Marcaine. *Plastic Surgery* **57**(3) 245-247.
**Nuki G(1990).** Pain control and the use of non-steroidal analgesic anti-inflammatory drugs. British Medical Bulletin **46** 262-278.
**Park SY, Kim SH,Lee Ae, Cho SH, Chee WS and Jin HC *et al.*, (2010).** Prophylactic effect dexamethasone ------ perioperative sore throat. *Korean Journal of Anaesthesiology* **58**(1) 15-19.
**Papangelou L(1972)** : Steroid therapy in tonsillectomy. Laryngoscope **82** 297-302.
**Rainsford KD and Velo GP (Eds) (1985).** Side-Effects of Anti-Inflammatory Drugs. Lancaster: MTP Press Limited 55-72.
**Skjelbred P and Lokken P (1982).** Post operative pain and inflammatory reaction reduced by injection of a corticosteroid. *European Journal of Clinical Pharmacology* **89** 117-20.
**Splinter WM and Roberts DJ (1996).** Dexamethasone decrease vomiting in children after tonsillectomy. *Anesthesia Analgesia* **83** 913-6.
**Steward DL, Welge JA and Myer CM (2001).** Do steroids reduce morbidity of tonsillectomy? Metaanalysis of randomized trial. *Laryngoscope* **111**(10) 1712-1718.
**Steward DL, Welge JA and Myer CM (2003).** Steroids for improving recovery following tonsillectomy in children. Cochrane Database Systemic Review CD003997.
**Senders CW, Di Maro SM, Brodie HA *et al.*, (1999).** The efficacy of perioperative steroid therapy in pediatric primary palatoplasty. *Cleft palate Craniofacial Journal* **36** 340-344.
**Tom LW, Templeton JJ, Thompson ME *et al.*, (1996).** Dexamethasone in adenotonsillectomy. *International Journal of Pediatrics* **37** 115-120.
**Vosdoganis F and Baines DB (1999).** The effect of single dose IV dexamethasone in tonsillectomy in children. *Anaesthesia and Intensive Care* **27** 489-492.
**White CM and Nolan AJ (2005).** An evaluation of pain and postoperative nausea and vomiting following introduction of guidelines for tonsillectomy. *Pediatric Anesthesia* **15**(8) 683-688.
**Watters CH, Patterson CC, Mathews HML and Campbell W (1988).** Diclofenac sodium for post – tonsillectomy pain in children. *Anaesthesia* **43** 641-643.