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Original Research Article

Effect of pre-operative rectal diclofenac suppository on post operative analgesic requirement in cleft lip palate repair

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Abstract: Respiratory depression, sedation, nausea and vomiting are common problems associated with the use of opioid analgesics during surgeries. Diclofenac, a non-steroidal anti-inflammatory drug (NSAID) can be an effective and safe option. The Aims and objectives in the present study was done to assess the efficacy and safety of rectal diclofenac, used in cleft palate repair for post-operative analgesia. The Materials and methods in a prospective randomized double blind study were done including 60 children's posted for cleft lip and palate repair. The patients were divided into Group A (did not receive any suppository) and Group B (received diclofenac suppository at 1mg/kg dose before induction and intubation). Pain assessment was done using Modification of Objective pain scale. In Results the Mean age in Group A and Group B was 27.13±17.18 and 33.60±20.71 months respectively. In group A, 80% children require rescue analgesia as compared to Group B (26.66%). There was a significant reduction in pain score at 90 minutes and at 2 hours in Group B as compared to Group A ($p<0.05$). In Conclusion the Administration of rectal diclofenac can be an alternative in reducing postoperative pain.
Keywords: rectal diclofenac, postoperative pain, cleft lip palate repair.

INTRODUCTION

It is not easy to detect the cause of pain in children's. Crying or restlessness of child may be due to pain or other reasons like hunger or fear. Associated pain is known to cause damage to cardiovascular, pulmonary, and gastrointestinal functions in children [1].

The reported incidence of cleft lip/palate is around one in 897 live births per, which is one of the most common birth related defect. Cleft lip/palate always requires surgical treatment during early stages of life.[2] Opioids were the drug of choice initially for post- operative pain but because of higher chances of side effects like nausea, vomiting and respiratory depression, NSAIDs are now becoming the drug of choice [2].

Reports have proved the effectiveness of diclofenac sodium when given pre-operatively in children's in the form of rectal suppository [3]. In present study we evaluated the efficacy of pre-operative rectal diclofenac sodium suppository for the alleviating the post-operative pain.

MATERIALS AND METHODS

A prospective randomized double blind study was done including 60 children's posted for cleft lip and palate repair. Ethical Committee approval was obtained before starting the study. Children aged between 9 months to 5 years having ASA physical status I or II were included in the study. Patients with ASA physical status III and IV, having prolonged bleeding time and clotting time, history suggestive of liver and kidney disease, allergy to aspirin or related drugs and history of asthma were excluded from the study.

All children were kept NPO for at least 4 hours prior to surgery and randomly divided using envelope method into Group A (did not receive any suppository) and Group B (received diclofenac suppository at 1mg/kg dose). Baseline hemodynamic variables were recorded. Continuous monitoring of pulse rate (PR), arterial oxygen saturation (SpO2), temperature, end tidal CO2 (EtCO2) and blood pressure (BP) was done.

As premedication, glycopyrolate (0.005mg/kg), ondansetron (0.01mg/kg) and midazolam (0.02mg/kg) were given by intra venous route. Anesthesia was induced using either ketamine (1-2

mg/kg) or suxamethonium (2mg/kg) via intra venous route. Intubation with an or tracheal tube and throat packing was also done.

Rectal diclofenac suppository (1 mg/kg) was inserted in lateral position following induction and intubation in Group B children's. Maintenance was done with 50% O2 + 50% N2O, IV fentanyl (1 µgm/kg) and IV atracurium (0.5 mg/kg) using closed circuit. In reversal IV glycopyrrolate 0.01 mg/kg or IV neostigmine (0.05 mg/kg) was given.

PR, SpO2 and BP was recorded every 15 min for the first 90 min, than every hour up to 6 hours post-operative. Pain assessment was done using Modification of Objective pain scale. Intravenous paracetamol was given as rescue analgesic if pain score was more than 3.

Pain scoring (Modification of Objective pain scale) was done as crying (0 - No crying; 1- Crying but responds to Tender loving care (TLC); 2 - Crying not responding to TLC), movement (0 - None, 1 - Restlessness, 2 - Thrashing) and agitation (0 - Asleep/calm, 1 - Mild, 2 - Hysterical) [4].

The number and total dose of rescue analgesics required was noted along with observation for any bleeding excess than usual was also noted. The quantitative data was analyzed using IBM SPSS- ver.20 software and expressed as mean± standard deviation (SD) and difference compared using one-factor analysis of variance. The qualitative data was compared with chi-square analysis. P<0.05 was considered significant.

RESULTS

In present study, the mean age in Group A and Group B was 27.13±17.18 and 33.60±20.71 months respectively. Mean weight in Group A and Group B was 9.72±2.67 and 10.31±3.07 kgs respectively. Male to female ratio in Group A and Group B was 1:1 and 2: 1 respectively.

Analysis of requirement of rescue analgesia revealed that in Group A, 24 (80%) patients required rescue analgesia whereas in Group B, 8 (26.66%) patients required rescue analgesia. In Group A, 4 (16.66%) patients required second dose of rescue analgesia.

Table 1: Distribution of pain score between both the groups

Time	Group A	Group B	P Value
0 min	0.2±0.41	0.5±0.78	NS
30 min	1.23±1.01	1.67±1.54	NS
60 min	1.17±1.23	1.33±1.12	NS
90 min	1.17±0.99	2.57±1.79	0.003
2 hrs	1.37±1.35	2.43±1.52	0.006
3 hrs	0.77±0.94	1.43±1.33	NS
4 hrs	0.53±0.68	0.77±0.68	NS
5 hrs	0.73±0.98	0.79±0.82	NS
6 hrs	0.43±0.68	0.37±0.56	NS

Data is expressed as mean±SD, NS; not significant

DISCUSSION

Need of analgesia to a child during minor surgeries can be achieved by NSAIDs, as they are considered to be the best alternatives and can be tailored to suit the need of a child? NSAIDs are also well accepted for the management of post-operative pain as determined by different parameters like decrease in pain score and opioid sparing effect [5, 6]. NSAIDs like diclofenac are mainly administered pre-operatively because of its pharmacodynamic and pharmacokinetic properties in order to achieve the analgesia at expected time [3].

Rectal diclofenac is reported to be convenient and safe approach leading to complete absorption of drug.[7] Rectal administration also favors sustained release of drug, hence provide quick onset and longer duration of analgesia. Diclofenac is also reported to be safe in children who are more than 6 months old [7,8].

Advantage of rectal administration is that it gets absorbed within 60 min of time and T_{max} is achieved just after 50 minutes of insertion, hence equal to the analgesic effect of any oral preparation [3]. In present study, there was a significant reduction in pain score at 90 minutes and at 2 hours in Group B as compared to Group A (p<0.05). This can be due to the analgesic effect of diclofenac.

Also there was no significant decrease in pain score at 3, 4, 5, and 6 hours in Group B as compared to Group A, the possible reason for this may be due to that most of the children (up to 50%) in group A received rescue analgesia after 4 hour post –operatively. Due to that all children receiving rescue analgesia were pain free hence did not have pain after 3 hours.

In present study it was evident from the pain score of children that diclofenac (1 mg/kg) administered rectally was effective from 30 min after operation and effect was sustained till 6th hour. The possible reason for late onset of diclofenac action was due to the residual effect of IV fentanyl (1 μgm/kg) given as intra-operative analgesic [3]. Adarsh et al have performed a study of cleft palate repair on 60 children to compare the effect of diclofenac with conventional treatment and found no significant reduction in pain score for the first 30 minutes [3]. Almost similar findings were reported by present study.

Adarsh *et al.;* had also found significant reduction in pain score at 60 and 90 mins in diclofenac treated group [3]. In present study number of children receiving rescue analgesia was also reduced in Group B. Whereas in Group A 13.33% patients needed rescue analgesia twice. Similar observations were made by Adarsh *et al.;* [3].

Agrawal K in his review also reported that rectal suppository of diclofenac was effective in providing postoperative analgesia [9]. Babu *et al.;* studied different surgical methods of cleft lip and cleft palate and advocated the use of diclofenac for post-operative analgesia [10]. The present study had limitations too; there was less number of children to compare the results. A large randomized trial is required to confirm the findings of present study.

CONCLUSION

Rectal diclofenac sodium is suited for a pre-emptive approach and proved to be an efficient drug as part of balanced analgesia and helps to reduce the consumption of opioids in the post-operative period.

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