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A COMPARISION BETWEEN BILATERAL INFRAORBITAL/ PALATINE NERVE BLOCK USING LEVOBUPIVACAINE AND DEXMEDETOMIDINE WITH PARACETAMOL PER RECTAL SUPPOSITORIES FOR POST OPERATIVE PAIN IN PEDIATRIC LIP AND ORAL SURGERIES.

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ABSTRACT

INTRODUCTION: AIM: Comparative assessment of post-operative pain relief after administration of bilateral infraorbital /palatine nerve block with per rectal paracetamol suppositories in paediatric lip and oral surgeries was done. **METHOD:** A randomized double blind controlled trial was conducted on 60 ASA I and ASA II pediatric patients of age group 3 month to 5 years undergoing lip and oral surgeries. Patients were randomly allocated in two groups of 30 each. Group A: Patients were given bilateral infraorbital/palatine nerve block using levobupivacaine 0.25% with dexmedetomidine 1µg/ml. Group B: Patients were given per rectal paracetamol suppositories 15mg/kg. Degree of intraoperative pain was assessed using heart rate, blood pressure, and SPO2. Degree of post-operative pain relief was evaluated using FLACC score. Duration of postoperative analgesia, Need of rescue analgesia and any complications secondary to block were observed. **STATISTICAL ANALYSIS**: Student t test unpaired is was used in the study for comparison between the groups for statistical analysis. **RESULTS:** During intraoperative period the vitals remained more stable in group A than in group B the difference being statistically significant (p value <0.001) till the end of surgery. Group A had less FLACC scoring as compared to group B in postoperative period with longer duration as compared to group b. p value <0.001. **CONCLUSION:** Infraorbital/palatine nerve block using levobupivacaine with dexmedetomidine is more effective in pain relief in both intraoperative as well as post-operative period as compared to per rectal paracetamol suppositories.

KEYWORD: paracetamol suppositories,infraorbital palatine nerve block,cleft lip, cleft palate, flacc.

INTRODUCTION

Cleft lip and palate are the commonest craniofacial abnormalities.[1] It requires surgical intervention at a very early stage of infancy. Surgical correction of this defect involves considerable amount of tissue dissection and mobilisation and hence is associated with appreciable postoperative pain. Pain may also trigger complex biochemical and physiological stress responses and cause impairments in pulmonary, cardiovascular, neuro-endocrinal, gastrointestinal, immunological and metabolic functions.[2] In addition in cleft lip repair, pain relief is important to prevent the agitated child from handling the delicate surgical site repeatedly postoperatively.[3]

Postoperative pain is expected but nonetheless undesirable 'by-product' of all surgical procedures. In adequate pain control may result in increased morbidity or mortality. The common mode of analgesic pharmacotherapy available to treat pain following cleft lip and palate surgery includes opioids and non-opioids like paracetamol and NSAID's. After surgical correction of cleft palate (palatoplasty), patients are more prone to develop postoperative respiratory difficulty due to narrowed airway, increased secretion, pain, and sedation caused by opioid analgesics.

Infraorbital nerve block are being increasingly used as alternative to opioids and non opioids for pain relief. They are commonly used in conjunction with general anaesthesia as they also provide good preemptive analgesia. They are becoming increasingly popular with the accumulating evidence of advantages such as smooth intraoperative course, decreased requirement of general anaesthetic drugs, decreased stress response. In addition they are easy to perform and safe. Paracetamol is a relatively safe analgesic in children.[4] In this study we are comparing the role of infraorbital nerve block and palatine nerve block for intraoperative as well as post operative pain in pediatric cleft lip and palate surgeries as compared to the pain relief by paracetamol rectal suppositiories for the same surgeries in same age group.

MATERIAL AND METHODS

After obtaining institutional ethical committee clearance, the study was undertaken on 60 children, between 4 months to 6 years of age of either sex belonging to ASA class I scheduled for elective unilateral cleft lip and palate repair under general anaesthesia in in

L.L.R. Hospital G.S.V.M. Medical College Kanpur U.P. and Leelamani hospital India. This study was conducted during the period of January 2014 to August 2015 in L.L.R. Hospital G.S.V.M. Medical College Kanpur U.P. and Leelamani hospital India.

Inclusion criteria

1. Age between 4 months – 6 years.
2. ASA class I.
3. Children undergoing surgery for complete unilateral cleft lip.

Exclusion criteria

1. Sensitivity to local anaesthetics.
2. Bleeding diathesis.

A thorough pre-anaesthetic evaluation was performed by taking history and clinical examination. In all the children, weight, heart rate, respiratory rate and clinical signs if any were recorded. Investigations like haemoglobin %, urine for albumin, sugar and microscopy were done. Investigations like blood sugar, electrocardiograph (ECG), blood urea, serum creatinine and chest x-ray were performed if required.

After explaining the anaesthetic procedure, written informed consent for participation in the study was obtained. The 60 patients were randomly allocated into two groups (group I and group P).

Group I received pre-operatively, bilateral infraorbital /palatine nerve block with inj.levobupivacaine 0.25% and dexmedetomidine 1mcg/ml
Group P received pre-operatively paracetamol rectal suppositories 15mg/kg.
Children were premedicated with inj. glycopyrrolate 0.005 mgkg-1 IM ,inj.fentanyl 2mcg/kg fifteen minutes before induction. Once the child was sedated, the child was shifted to operation theatre and was placed on a warming mattress to prevent hypothermia. The child was pre-oxygenated with 100% O2 for 3 minutes. During the mean time, intravenous access was secured using appropriate 22G/24G cannula and intravenous fluid isolyte P was started. Pulse oximetry and electrocardiogram monitors were attached.

The child was induced with inj,propofol 2.5 mg/kg iv and intubation was facilitated with inj. suxamethonium 2 mgkg-1 IV after confirming the feasibility and adequacy of ventilation. Patient was intubated with an orotracheal RAE (Ring, Adair and Elwyn) south polar tube of

an appropriate size under direct laryngoscopy. The tube was secured after confirming bilateral equal and clear air entry. An oropharyngeal pack was inserted after positioning the patient for surgery. Patient received infraorbital nerve block after induction.

Anaesthesia was maintained with N2O: O2 (50:50), inj. midazolam 0.05 mgkg-1 IV, inj. fentanyl 1µgkg-1 IV, inj. vecuronium 0.1 mgkg-1 IV and incremental dose of 0.02 mgkg-1 as and when required.

Depending on the group to which the patient belongs, the patient either received bilateral infraorbital nerve block (1 ml on each side) or paracetamol rectal suppositories. In group I, infraorbital nerve block was given transcutaneously at a point on an imaginary line connecting the pupil and angle of the mouth which was bisected by the perpendicular dropped from the alae nasi.

In group P, the patient was given paracetamol rectal suppositories according to the dose Maintenance IV fluid required was calculated as per Holiday-Segar's formula of 4:2:1. Parameters like, heart rate, blood pressure, respiratory rate and oxygen saturation were noted down as baseline, every 10 minutes intraoperatively and thereafter every 2 hours for one day postoperatively. Duration of surgery and intra-operative complications if any (hypothermia, bleeding) were noted. At the end of the surgery, muscle relaxation was reversed with inj. glycopyrrolate 0.01 mgkg-1 and inj. neostigmine 0.05 mgkg-1 after adequate attempts were confirmed. The child was extubated after through suctioning. The degree of postoperative pain relief was evaluated using FLACC score.

If the child was in pain (FLACC score > 4), rectal paracetamol suppositories (15 mgkg-1) was administered as rescue analgesic. It was repeated if needed. Pain score and the time to first supplementation of rescue analgesic were noted. The child was followed up for 24 hours at frequent intervals (2, 4, 8, 12, and 24).

STATISTICAL ANALYSIS

The duration of postoperative analgesia in group I was (24 ± 0) hours. In comparison, the duration of postoperative analgesia in group P was (8.93 ± 0). The difference in the duration of postoperative pain was statistically significant.

RESULTS

All patients completed the prospective study. The statistical analysis of the demographic data was done using unpaired student 't' test. There were no significant differences between the groups regarding age, sex, weight. Table (1).

The comparison between both the groups Intraoperatively as well as postoperatvely are shown in table[2,3,4]. the comparison was made between heart rate, respiratory rate and post operatively pain scoring using FLACC Score,duration of analgesia and complication.[Table 5,6]

1. The bilateral infraorbital nerve block or b/l palatine nerve block given with 0.25% levobupivacaine with dexmedetomidine provides more prolonged analgesia (Mean 24 ± 0 hrs) than paracetamol (Mean 8.93±3.53 hrs) for complete / incomplete cleft lip/cleft palate repair.
2. The efficacy of analgesia was more in nerve block group than in that of paracetamol. As evident by FLACC Score which has mean 2.16 at 8 hours in nerve block group as compared to mean of 4.83 in paracetamol group at the same time where we supplemented rescue analgesia to the patient.
3. The nerve block group has more stable heart rate with a mean of 127.8 as compared to paracetamol group which has mean of 138.73 at the same time that is on 8 hours where we needed to supplement rescue analgesia.
4. 4 The nerve block group has more stable respiratory rate with a mean of 29.35 as compared to paracetamol group which has mean of 33.7 at the same time that is on 8 hours where we needed to supplement rescue analgesia.
5. The complication like hematoma formation and bleeding was higher in infraorbital nerve block group as compared to paracetamol suppository.

Table 1: Demographic variable

Age	Block	Paracetamol	T	P	Inference
Mean	2.78	2.78	1.90	>0.05	NS
SD	0.87	1.14			
Weight					
Mean	12.62	12.37	0.55	>0.05	NS
SD	0.87	1.14			

Table 2: Heart rate in different groups

Heart rate	Block	Paracetamol	T	P	Inference
10 minute			-3.63	<.001	HS
Mean	106.64	114.4			
SD	7.26	9.17			
20 minute					
Mean	110.51	115.13	-2.24	<.05	S
SD	6.48	9.28			
30 minute					
Mean	109.64	117.1	-4.05	<.001	HS
SD	6.54	7.67			
40 minute					
Mean	107.54	121.93	-8.43	<.001	HS
SD	6.53	6.68			
	Block	**Paracetamol**	**T**	**P**	**Inference**
2 hours			-10.22	<.001	HS
Mean	110.51	125.66			
SD	6.48	4.48			
4 hours					
Mean	115.61	133.8	-14.2	<.001	HS
SD	5.08	4.78			
8 hours					
Mean	127.8	138.73	-11.9	<.001	HS
SD	3.97	3.07			
12 hours					
Mean	130.0	139.93	-10.49	<.001	HS
SD	4.23	2.89			
Mean	131.09	138.73	-8.8	<.001	HS
SD	3.63	3.07			
24 hours					
Mean	132.38	140.16	-10.61	<.001	HS
SD	3.51	1.95			

Table 3: Respiratory rate in different groups

Respiratory rate	Block	Paracetamol	T	P	Inference
10 minute			1.79	>0.05	NS
Mean	26.51	25.96			
SD	0.99	1.35			
20 minute					
Mean	26.51	25.96	1.79	>0.05	NS
SD	0.99	1.35			
30 minute					
Mean	26.51	25.96	1.79	>0.05	NS
SD	0.99	1.35			
40 minute					

Mean	28.48	27.23	3.10	<0.01	MS
SD	0.99	1.97			
	Block	**Paracetamol**	**T**	**P**	**Inference**
2 hours					
Mean	26.51	26.56	-0.16	>0.05	NS
SD	0.99	0.33			
4 hours					
Mean	27.87	29.09	-6.09	<0.001	HS
SD	1.05	1.49			
8 hours					
Mean	29.35	33.7	-18.42	<0.001	HS
SD	0.68	1.1			
12 hours					
Mean	29.35	35.2	-33.5	<0.001	HS
SD	0.47	0.83			
18 hours					
Mean	29.35	36.86	-23.4	<0.001	HS
SD	0.68	1.62			
24 hours					
Mean	29.61	38.9	-19.6	<0.001	HS
SD	.047	2.54			

Table 4: FLACC Score in different groups

FLACC Score		**2 hr**	**4 hr**	**8 hr**	**12 hr**	**18 hr**	**24hr**
Paracetamol	Mean	0.4 ± .48	3.8 ± 0.83	4.83 ± 1.06	5.53 ± 0.49	5.60 ± 0.48	6.0 ± 0.73
Block	Mean	00	0.74 ±0.65	2.16 ±0.71	3.22 ±0.41	2.16 ±0.71	3.67 ±0.58
P value		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 5: Duration of analgesia

GROUP	**DURATION OF ANALGESIA IN HR (MEAN ±SD)**
GROUP I	24 ± 0
GROUP P	8.93 ± 3.53

Table 6: Complications encountered

Complications	**GROUP I**	**GROUP P**
BLEEDING	01	00
BRONCHOSPASM	01	01
HAEMATOMA FORMATION	01	00
OTHERS	00	00

DISCUSSION

Pain is perhaps the most feared symptom of any disease, which a man is always trying to alleviate and conquer since ages. The international association for study of pain defines it as

an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

There is no longer any debate whether infants and children have the capacity to feel pain[5] or that the experience of pain by a child can have negative short and long term consequences. In fact, there is increasing evidence of biologic and behavioural consequences of improperly treated pain. Cleft lip palate is one of the most common congenital anomaly requiring surgical intervention at a very early stage of infancy. Surgical correction of this defect involves considerable amount of tissue dissection and mobilisation and hence is associated with appreciable postoperative pain.

The use of regional anaesthetic techniques in infants and children has become increasingly accepted as standard of care during the final decades of the twentieth century. In the late 1980s and early 1990s, studies suggested infraorbital nerve block as the local analgesic technique of choice for repair of cleft lip, as it avoided the potential risk of respiratory depression that may occur when opioid analgesics are used.[6] Regional anaesthetic techniques can reduce the overall intra operative requirement of both inhaled[7] and intravenous anaesthetic agents and allow a more rapid return to the preoperative state while providing effective postoperative pain relief with minimal sedation.

We conducted this study to evaluate the efficacy and duration of postoperative analgesia of preoperative bilateral infraorbital nerve/palatine nerve block using levobupivacaine and dexmedetomidine with that of paracetamol rectal suppositories for cleft lip/palate surgeries. Infraorbital nerve block is an established technique for repair of upper lip lacerations in adults.[8]

In our study, the demographic data were comparable for age, weight. The duration of surgery was also comparable in between the two groups Using FLACC score. Which has been validated in infants and children,[9] we used a FLACC pain score of more than 4, as the criteria for supplementing rescue analgesia. The duration of postoperative analgesia in group I was (24 ± 0) hours. In comparison, the duration of postoperative analgesia in group P was (8.93 ± 0). The difference in the duration of postoperative pain was statistically significant.
When compared with the studies conducted by other authors with different concentrations and volumes of inj.bupivacaine with inj.adrenaline (1:200,000).[10,11.12] The durations were more than that observed by them, using inj. bupivacaine 0.5% (1 to1.5 ml on each side) with

inj.adrenaline (1:200,000) had postoperative analgesia for a mean 19.4 ± 5.06 hours with infraorbtinal nerve block.

The increase in duration Of post-operative analgesia in our study validate the use of adjuvant dexmedetomidine with levobupivacaine which is responsible for increase in the duration of effect. We used rescue analgesia i.e rectal paracetamol (15mg/kg) once the FLACC score was more than 4 In infraorbital group the FLACC was more than 4 at 24 hours only in two patients as compared to paracetamol group where FLACC becomes more than 2 after about 8.93±3.53The complications encountered due to infraorbital nerve block was bleeding at the site of injection and haematoma formation while in paracetamol group bronchospasm was encountered.

Based on the result of the present study, we recommend the use of preoperative bilateral infraorbital nerve block over paracetamol for cleft lip/cleft palate repair to provide good postoperative analgesia lasting up to 24 hours.

CONCLUSION

The bilateral infraorbital nerve block or bilateral palatine nerve block given with 0.25% levobupivacaine with dexmedetomidine provides more prolonged and efficacious analgesia than paracetamol for complete / incomplete cleft lip/cleft palate repair.

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