COMPARATIVE EVALUATION OF BILATERAL INFRAORBITAL NERVE BLOCK USING ROPIVACAINE VERSUS BUPIVACAINE FOR POST-OPERATIVE ANALGESIA IN CHILDREN UNDER GOING CHEILOPLASTY

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ABSTRACT: This prospective, randomized, double blind study was conducted on 60 patients in the age group of 3 months to 3 years, undergoing cheiloplasty in the Department of Plastic & Microsurgery at Christian Medical College and Hospital, Ludhiana from April 1, 2010 to August 30, 2012 to compare the efficacy of Ropivacaine to Bupivacaine used in infra - orbital nerve block for post-operative analgesia. The patients were divided into two groups of 30 patients each. Group I received general anesthesia + bilateral infraorbital block with 2 ml of 0.2% Ropivacaine (1ml on each side), while Group II received general anesthesia + bilateral infraorbital block with 2ml of 0.2% Bupivacaine(1ml on each side), approximately half an hour prior to extubation. Post-operatively patients were assessed at 0, ½, 1, 2, 4, 6, 8, and 24 hours for analgesia by Hanallah's ten point score, heart-rate and E.C.G. changes. Time for first rescue analgesia was noted. The results were compared and student's 't' test and chi-square test were applied to see the level of significance. A significantly lower pain scores were observed in Ropivacaine group (p< 0.05). Significantly better behavioral parameters were observed in Ropivacaine group.

KEYWORDS: Infra-orbital block, Bupivacaine, Ropivacaine, Cheiloplasty.

INTRODUCTION: Cleft lip repair is a common surgery in infants. As such children with cleft lip tend to have a compromised airway due to associated congenital anomalies like Pierre Robin syndrome, Treacher Collins syndrome etc. After surgical correction of cleft lip, they are more prone to develop post-operative respiratory difficulty due to narrowed airway, increased secretion, pain and sedation caused by opioids.^{1, 2} Hence, regional block, using local anesthetics, becomes a good option in this surgery.

The supremacy of bilateral infraorital block using bupivacaine over intravenous fentanyl as well as over peri-incisional infiltration in has been shown by previous studies.^{3, 4}

Ropivacaine was developed after Bupivacaine was noted to be associated with significant number of cardiac arrests. Ropivacaine has been used for peripheral block in children for surgical pain.

Though the use of Ropivacaine in regional blocks in facial surgeries has been well established, studies are still needed to establish its supremacy over Bupivacaine in cleft lip surgeries.^{5,6} The aim of this study was to compare Ropivacaine & Bupivacaine in infra-orbital block for post-operative pain control in children undergoing cleft lip surgery.

MATERIALS & METHODS: This study was a prospective, randomized, double blind study conducted on 60 patients of ASA Grade I or II in the age group of 3 months to 3 years, undergoing cheiloplasty in the Department of Plastic & Microsurgery at Christian Medical College and Hospital, Ludhiana.

PREOPERATIVE EVALUATION: All patients included in the study underwent a pre-anesthetic checkup including assessment of age, weight, hemoglobin, upper respiratory infections and congenital cardiac anomalies. Written informed consent was obtained from the parents during the preoperative visit. The children were kept nil per oral for both solids and liquids 4 Hrs. before the surgery.

EXCLUSION CRITERIA:

- 1. Bleeding disorders
- 2. Infection in the region of infraorbital foramen
- 3. Congenital heart disease
- 4. Prior hypersensitivity to amide group of Local Anaesthetics
- 5. Hepatic Disease
- 6. History of convulsive disorders

PREMEDICATION: All patients were pre-medicated with 0.5 mg/kg of syrup Midazolam, half an hour before taking them inside the OT.

ANAESTHESIA TECHNIQUE: The vitals of the children included in the study were noted and monitors i.e. E.C.G. electrodes and saturation probe were connected. Anesthesia was induced by inhalational agents using oxygen, nitrous oxide and sevoflurane, followed by IV cannulation. Endotracheal intubation using uncuffed endotracheal tube of appropriate size was performed using succinyl choline (2mg/kg) and anesthesia maintained with oxygen (30%), nitrous oxide (70%) and sevoflurane. Muscle relaxation was facilitated by Inj. Atracurium (0.5 mg/kg initial dose and 0.1 mg/kg maintenance dose).

Ventilation was controlled using Mapleson F circuit. A temperature probe was introduced after inducing the patient. Inj. Fentanyl (1mcg/kg) was given before the first incision for intraoperative pain control. Intra-operative fluids were given according to 'Holliday and Segar formula'. The patients were monitored intraoperatively for heart rate, arterial oxygen saturation and temperature.

Approximately half an hour before extubation, group I patients received bilateral infraorbital block with 0.2% Ropivacaine and Group II patients received the same with 0.2% Bupivacaine. The drug to be administered was drawn by a separate anesthetist, not involved in the study.

At the end of the surgery, muscle relaxation was reversed by Inj. Atropine $0.02\ mg/kg$ and Inj. Neostigmine $0.05\ mg/kg$ IV.

POST OPERATIVE PAIN ASSESSMENT: Pain assessment was done at 0, ½, 1, 2, 4, 6, 8 and 24 hours. Zero hour was taken from the time the patient was extubated. Parents/attendants were asked regarding the pain and the information obtained was incorporated into the assessment. Pain was assessed using Hanallah's pain assessment score.

Besides this, Heart rate and E.C.G. were also noted at same time intervals.

RESCUE ANALGESIA: Patients with unsatisfactory pain relief (score>7 twice during 5 minutes period) were given Inj. Paracetamol (10mg/kg). The time for 1st rescue analgesia was noted.

STATISTICAL ANALYSIS: In order to test the significance of mean difference between the two groups, unpaired t-test and chi-square tests were used. A p value of less than 0.05 was taken as statistically significant.

RESULTS: Total 60 patients were included in this study. The mean age of patients in Ropivacaine group was 10.89+/-9.27 months and that in Bupivacaine group was 8.93+/-7.49 months. The mean weight of patients in Ropivacaine group was 6.88 +/- 2.67 Kgs while in Bupivacaine group was 6.31 +/- 2.31 Kgs.

Statistically significant lower mean pain score was observed in Ropivacaine group compared to Bupivacaine group at 0 hour (i.e. immediate post-operative period) The mean pain score at 0 Hrs. in Ropivacaine group was 0.07+/-0.385 and in Bupivacaine group was 0.72+/-1.25 (P= 0.012).

• There was statistically significant difference in the behavioral profiles of the two groups with children in Ropivacaine group showing better results. The number of children who cried were significantly less in Ropivacaine group compared to Bupivacaine group at 0 hour (2 vs. 8, p=0.014), ½ hour (16 vs. 24, p=0.044) and 2 hours (7 vs. 15, p=0.050). The number of children showing agitation were significantly less in Ropivacaine group compared to Bupivacaine group at 4 hours (0 vs. 5, p=0.034).

The mean time to 1^{st} rescue analgesia in ropivacaine group (5.36+/-2.438 hours) was comparable to bupivacaine group (4.50+/-2.565 hours). (p=0.192)

Post-operative heart rates and systolic blood pressure recordings were comparable in two groups.

DISCUSSION: In this study, 60 patients in age group of 3 months to 3 years participated. The mean age in Ropivacaine group was 10.8333 +/- 9.27051 months, while that in bupivacaine group was 8.9375 +/- 7.49704 months. In study done by Jindal et al, mean age of the patients receiving infraorbital nerve block with bupivacaine was 8.48 +/- 7.11 months, 7 which was comparable to our study.

The mean weight in ropivacaine group was 6.8857 +/- 2.67398kgs. The mean weight in bupivacaine group was 6.3125 +/- 2.62589 kgs.

In study done by Jindal et al, mean weight was $6.67 \text{ kgs} +/-1.63^7$. This too was comparable to our study.

The average pain score was significantly lower in ropivacaine group than bupivacaine group.

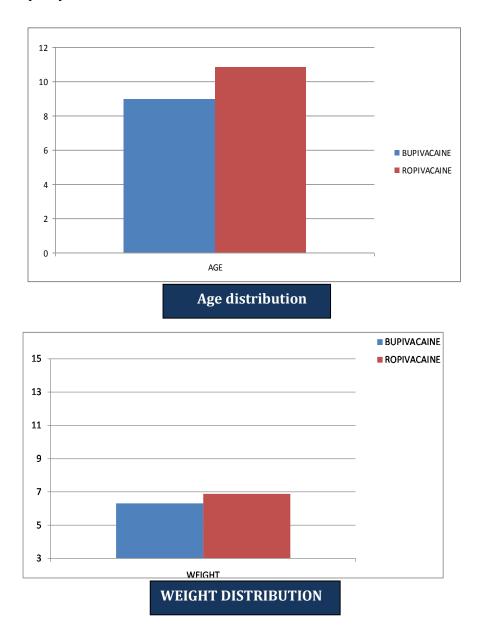
Unal et al compared 0.2% ropivacaine and 0.25% bupivacaine used as pertonsillar infiltration for post-operative pain in children undergoing tonsillectomy found lower VAS in bupivacaine group. This contrast from our study is probably due to a higher concentration of bupivacaine (0.25%) used as compared to 0.2% used in ours⁸. Fibla et al compared analgesic quality of 0.5% bupivacaine and 0.2% ropivacaine used in paravertebral block for post-operative analgesia and found lower mean VAS value in bupivacaine group. This discrepancy from our study can be explained by administration of a higher dose of bupivacaine (75mg) compared to ropivacaine (40mg) in contrast to our study in which equal doses of the two drugs(4mg) were used.⁹

Amongst the behavioral parameters, crying and agitation were more in bupivacaine group than ropivacaine group.

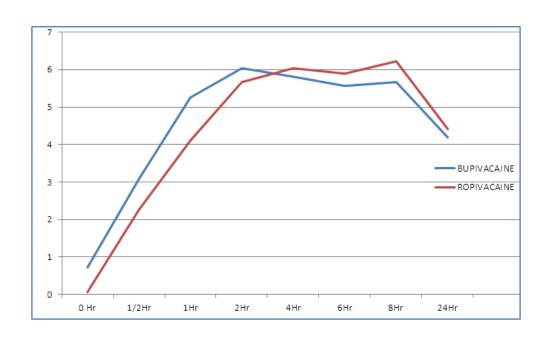
In the study by Jindal et al, patients receiving bupivacaine alone had poorer behavioral profile compared to those receiving bupivacaine with clonidine.⁷

Whereas comparing ropivacaine to ropivacaine with clonidine, Laha et al did not find any such difference. 10

In conclusion, the present study showed that Ropivacaine is a better alternative to bupivacaine for administration of infra-orbital nerve block for post-operative analgesia in children undergoing cheiloplasty.



PAIN SCORE		BUPIVACA	AINE			P value			
	N	MEAN+/-SD	MIN	MAX	N	MEAN+/-SD	MIN	MAX	
0 Hr.	40	0.72+/-1.25	0	4	40	0.07+/385	0	2	0.012
½ Hr.	40	3.09+/-1.653	0	5	40	2.26+/-2.011	0	5	0.125
1Hr	40	5.25+/-1.295	1	8	40	4.11+/-1.948	0	6	0.052
2Hr	40	6.03+/-1.656	2	9	40	5.67+/-1.144	3	8	0.346
4Hr	40	5.81+/965	4	8	40	6.04+/-1.160	5	9	0.687
6Hr	40	5.56+/-1.366	1	8	40	5.89+/934	4	8	0.265
8Hr	40	5.66+/-2.309	0	10	40	6.22+/-1.695	1	9	0.436
24Hr	40	4.19+/-2.162	0	8	40	4.41+/-1.526	0	6	0.993
				PAIN	SCOF	RE			



	0 HOUR 1		1/2	½ HOUR 1 HO			HOU	OUR 2 H			HOURS		4 HOURS			6 HOURS			8 HOURS			24 HOURS		
Score	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2
No. of Patients of Ropivacaine Group	28	2	0	14	16	0	4	24	2	1	22	7	0	19	11	0	20	10	1	13	16	3	25	2
No. of Patients of Bupivacaine Group	22	8	0	6	24	0	1	27	2	0	15	15	1	16	13	1	22	7	5	6	19	6	23	1
P value	0	.014		0.044			0.219			0.050			0.488			0.555			0.108			0.585		

	0 HOUR ½ HOUR		1 HOUR			2 HOURS			4 HOURS			6 HOURS			8 HOURS			24 HOURS						
Score	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2
No. of																								
Patients of	29	1	0	10	11	_	10	10	1	1	20	0	26	4	0	1	20	0	3	22	_	,	24	2
Ropivacaine	29	1	U	19	11	0	10	19	1	1	29	0	26	4	U	1	29	U	3	23	4	4	24	2
Group																								
No. of																								
Patients of	27	3	0	15	15	0	2	26	2	0	25	5	29	1	0	1	28	1	_	24	2	5	25	_
Bupivacaine	27	3	U	15	15	U		26		U	25	5	29	1	U	1	28	1	4	24		5	25	0
Group																								
P value	0	.116		(0.265 0			0.087	•	0.034			0.331			0.153			0.593			0.516		
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