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THE EFFECTS OF LEVOBUPIVACAINE SCALP BLOCK VERSUS DEXMEDETOMIDINE INFUSION ON HEMODYNAMIC RESPONSE TO SKULL PIN INSERTION IN PATIENTS UNDERGOING ELECTIVE CRANIOTOMY: A RANDOMIZED BLINDED CLINICAL COMPARATIVE STUDY

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ABSTRACT

Background & Aims: The application of skull pin holder elicits an adverse hemodynamic response that can have deleterious effects, which can be attenuated by various drugs. This study was aimed at comparing the effects of levobupivacaine scalp block versus intravenous dexmedetomidine infusion on hemodynamic response to skull pin insertion in patients undergoing elective craniotomy.

Methods: This randomized, prospective, double blind, single hospital study was carried out after Institutional Ethics Committee Clearance. Seventy nine patients aged 18 to 65 years belonging to ASA classes I and II undergoing elective craniotomy surgeries were randomly allocated into 2 groups - Group A (n=39): 20mL of 0.5% levobupivacaine scalp block and Group B (n=40): infusion dexmedetomidine 1mcg/kg over 10 mins followed by 1mcg/kg/hr for 30 minutes after scalp pin insertion. Intraoperative hemodynamics such as Heart rate (HR), Systolic blood pressure (SBP), Diastolic Blood pressure (DBP), Mean arterial pressure (MAP) were recorded at specific intervals. Post operative VAS score were recorded at specific intervals.

Results: The demographic and baseline hemodynamic parameters were comparable. After pinning, the HR, SBP, DBP and MAP were all increased in both the groups which was non significant ($p>0.05$). At later time intervals the parameters decreased and it was found to be lower in scalp block group. Significant differences in HR and SBP at 10 minutes and 15 minutes ($p<0.05$) were seen, while for DBP and MAP it was seen at 10 mins after scalp pin insertion. As observed from post operative VAS score scalp block provided better analgesia than dexmedetomidine infusion.

Conclusion: We conclude that though both scalp block with 0.5% levobupivacaine and dexmedetomidine infusion is effective in attenuating hemodynamic response to scalp pin insertion, scalp block provided superior results.

KEYWORDS :

INTRODUCTION

Skull pin insertion is a fundamental and frequently used manoeuvre for stabilization of the head during craniotomy under general anaesthesia. The head is held by the application of metallic pins, as in Mayfield head holder a step that has been shown to produce severe noxious stimulation. It results in hemodynamic effects such as an abrupt increase in blood pressure and cerebral blood flow.(1)

Different techniques have been used to blunt the deleterious effect with variable success including deepening the level of anaesthesia, premedicating, infiltration with various local anaesthetics etc.(2)

The scalp block is an easy and effective method of blunting the noxious stimuli leading to elevated blood pressure and tachycardia by blocking the nerves.

Dexmedetomidine a selective alpha adrenoreceptor agonist has been shown to attenuate the hemodynamic response to the insertion of pins during neurosurgery.

This study compares the efficacy of levobupivacaine scalp block with that of dexmedetomidine infusion in bringing out which is better in attenuating the hemodynamic responses in skull pin insertion during craniotomy.

AIMS AND OBJECTIVES

1. The aim of this study is to assess and compare the analgesic efficacy of scalp block with 0.5% levobupivacaine versus dexmedetomidine infusion in patients undergoing elective craniotomy based on
A. Intra operative hemodynamic status
B. Post operative VAS score

2. Observation of any side effects or adverse reactions and any other relevant observations.

MATERIALS & METHODOLOGY

This prospective, double blinded, randomized, clinical comparative was conducted under the Department of Anaesthesiology and Critical Care, Gauhati Medical College Hospital, Guwahati with prior permission and approval from the institutional ethical committee and obtaining informed written consent from the participants.

The study was done for a period of 1 year from 1st July 2018 to 30th July 2019 and was conducted in the Neurosurgery operation theatre and respective wards.

Inclusion criteria

- 1 Patients who have given valid consent
- 2 ASA Class 1 and 2
- 3 Age 18-65 years
- 4 Elective surgery
- 5 Pre operative GCS 15

Exclusion criteria

1. ASA Class 3 or more
2. Pre operative GCS <15
3. Pre operative heart rate <45 bpm
4. Pregnancy
5. Known allergic to dexmedetomidine or levobupivacaine
6. Patient refusal
7. Skin conditions precluding the block
8. Emergency surgery

SAMPLE SIZE CALCULATION

Based on previous study(3)

We sought out to find a change in heart rate of 6 beats per minute with a standard deviation of 9.64 from the baseline.

Intended $\alpha=0.05$ and power=80%

A sample size of 98 was calculated (including potential drop-outs)

PLAN OF STUDY

In this randomized, prospective, double blind, single hospital study ninety eight (98) patients aged 18 to 65 years undergoing elective craniotomy surgery were enrolled. 12 patients were excluded as they did not meet the inclusion criteria and 7 patients refused to participate. This study was conducted on 79 patients undergoing elective craniotomy surgeries. Study population was divided into two groups (Group A and Group B) using computer generated online block randomizer.

- Group A- 20mL of 0.5% Levobupivacaine Scalp block and Normal Saline infusion calculated on the basis of weight.

- Group B- Dexmedetomidine infusion 1mcg/kg over time period of 10 minutes before induction of anaesthesia, followed by a maintenance of 1mcg/kg/hr from the time of intubation till 30 minutes after skull pin application. Also received 20ml of normal saline as scalp block.

Procedure:

Pre anaesthetic assessment and laboratory investigations were done few days prior to the procedure. Pre operative fasting was done as per protocol.

The infusion that is either dexmedetomidine or normal saline was started 10 minutes prior to intubation. A standard induction protocol was followed for all patients that is Injection Propofol(2mg/kg) i.v, Injection Fentanyl (1mcg/kg) i.v, and Injection Rocuronium (0.5mg/kg) .All medications were diluted with sterile 0.9% saline .Airway secured with appropriate sized endotracheal tube. Inhalational anaestheticsevoflurane was administered with 1 % fixed dial settings and maintained on spontaneous respiration with 70% nitrous oxide in 30% oxygen. Patient's ventilation was controlled to maintain a target value of end tidal carbon dioxide of 30 to 38 mm Hg.Under all aseptic and antiseptic precautions, scalp block was given. Scalp pin insertion was started 5 minutes after scalp block. Hemodynamic parameters were noted at the specific intervals.

At the end of surgery, patient was reversed with Inj.Glycopyrrolate (0.005mg/kg) and Inj.Neostigmine (0.05mg/kg). The patients were extubated when awake or able to protect his airway. The time from discontinuation of sevoflurane and extubation was noted in both the groups. Rescue Analgesia : Injection Ketorolac 0.5mg / kg intravenously when VAS>4.

PARAMETERS NOTED

- Intraoperative hemodynamics- heart rate , systolic blood pressure, diastolic blood pressure,mean blood pressure.
- Measured at intervals- at baseline, at induction ,during skull pin insertion,at 1,2,4,10,15,30 minutes after skull pin insertion.
- Visual Analogue Scale (VAS) score post operatively at just after extubation, at 1,2 ,3,4,6,8 and 12 hours after extubation.
- Adverse effects.

RESULTS

All data were analysed using appropriate statistical methods. Tests employed were t-test, chi- square test, Mann Whitney test as applicable. The software used was IBM SPSS version 21.0 and Microsoft Excel to generate graphs and tables.

P value :

P> 0.05 considered non significant

P< 0.05 considered significant

DEMOGRAPHIC CHARACTERISTICS

The demographic data is shown in Table 1. 79 patients were enrolled in the study of which 39 patients belonged to the Group A (Levobupivacaine) and 40 patients belonged to group B(Dexmedetomidine). The demographic data were comparable.

Table 1. Demographic parameters.

		Group A	Group B	P- Value
No of Patients		39	40	
Sex	Male	21	21	0.904
	Female	18	19	
Age	Mean ± SD	40.615 ±11.27	38.0 ±11.07	0.763
Weight	Mean ± SD	55.19 ±12.19	53.68 ±11.79	0.942
ASA	Class 1	27	24	0.391
	Class 2	12	16	
Duration of Surgery		122.41 ± 22.64	120.65 ± 29.43	0.766

Baseline values which were recorded were comparable between the two groups.

At the time of induction and scalp pin insertion ,mean heart rate increased in comparison to baseline in both the groups. However in both the groups ,Group A and Group B , the increase was not statistically significant (p value >0.05). In both the groups maximum increase in heart rate occurred during the insertion of the scalp pin with 3.14% increase in Group A and 4.01% increase in Group B. In the

intergroup comparison shown in the table ,the increase in mean heart rate in both the groups compared at induction and during scalp pin insertion is not statistically significant (p value >0.05)

At 1 minute and 2 minutes after scalp pin insertion ,mean heart rate increased from baseline in both the groups. both of which were not significant (p value >0.05).

Intergroup comparison of mean heart rate between group A and Group B shows statistical significance at 10 minutes after scalp pin (p value=0.014) and at 15 mins after scalp pin (p value=0.004). At 4 mins and at 30 minutes mean heart between the two groups is found to be not statistically significant (p value >0.05).

Table 2 : Intergroup Comparison Of Mean Heart Rate Between Group A And Group B

	Mean Heart Rate ± SD (bpm)		
TIME	Group -A	Group -B	p- value
Baseline	79.82 ± 9.19	80.25 ± 8.41	0.829
Induction	81.41 ± 8.73	82.65 ± 9.05	0.529
At Scalp pin insertion	82.33 ± 9.12	83.47 ± 8.08	0.566
1 min after scalp pin insertion	82.33 ± 7.50	83.22 ± 8.41	0.620
2 mins after scalp pin insertion	81.49 ± 9.05	83.13 ± 8.85	0.419
4 mins after scalp pin insertion	78.59 ± 8.48	82.72 ± 10.40	0.056
10 mins after scalp pin insertion	77.64 ± 8.49	82.15 ± 7.51	0.014
15 mins after scalp pin insertion	75.23 ± 7.96	80.48 ± 8.02	0.004
30 mins after scalp pin insertion	75.90 ± 7.40	77.30 ± 7.31	0.399

Similar trends were seen in the other hemodynamic parameters- SBP, DBP and MAP. At the time of induction (following dexmedetomidine infusion) and scalp pin insertion (following scalp block),each of mean systolic blood pressure, mean diastolic blood pressure and mean of mean arterial pressure increased but these increase was not statistically significant in both the groups (p >0.05)

Intergroup comparison of mean systolic blood pressure between group A and Group B shows no statistical significance at 4 minutes after scalp pin (p value >0.05) and at 30 minutes after scalp pin insertion (p value >0.05). At 10 minutes (p value=0.042) and 15 mins (p value=0.030) after scalp pin insertion mean systolic blood pressure between the two groups is found to be statistically significant (p value >0.05).

Intergroup comparison of mean diastolic blood pressure between group A and Group B shows no statistical significance at 4 minutes after scalp pin (p value >0.05), at 15 minutes after scalp pin insertion (p value >0.05) and at 30 mins after scalp pin insertion (p value >0.05). At 10 minutes mins (p value= 0.031) after scalp pin insertion mean diastolic blood pressure between the two groups is found to be statistically significant (p value >0.05).

Intergroup comparison of mean MAP between group A and Group B shows no statistical significance at 4 minutes after scalp pin (p value >0.05) and at 15 minutes after scalp pin insertion (p value >0.05) and at 30 minutes (p value >0.05). However at 10 mins (p value= 0.014) after scalp pin insertion mean MAP between the two groups is found to be statistically significant (p value >0.05).

No significant adverse effects were seen in both the groups.

Table 3. visual Analogue Scale

TIME	GROUP A	GROUP B	P VALUE
0 hour	1.28 ± 0.83	1.83 ± 1.03	0.010
1 hour	1.51 ± 0.82	2.0 ± 0.82	0.010
2 hour	1.89 ± 0.91	2.41 ± 0.86	0.010
3 hour	2.16 ± 0.87	2.72 ± 0.66	0.002
4 hour	3.04 ± 0.76	2.80 ± 0.57	0.085
6 hour	2.58 ± 0.75	2.85 ± 0.64	0.082
8 hour	2.81 ± 0.81	2.93 ± 0.69	0.509
12 hour	3.12 ± 0.58	3.28 ± 0.45	0.163

It is seen that Levobupivacaine Scalp Block resulted in a significant reduction in Visual Analog Score level compared to Dexmedetomidine infusion during the first 3 hours of post operative period.

Table 4: Duration Of Post Operative Analgesia

GROUP	Mean Duration of Analgesia (mins)	Standard Deviation
Levobupivacaine Scalp Block (A)	308	49.18
Dexmedetomidine Infusion (B)	263	48.08
P value	0.0001	

DISCUSSION

All the patients were anaesthetized using the same standard general anaesthesia technique and except the trial drugs there was no difference between the groups with respect to anaesthetic agents or other drugs. The same anaesthesiologist intubated all the patients.

Hypoxia and hypercarbia were avoided in all the cases. The tidal volume was kept constant (8ml/kg) and respiratory rate in a range of 14-16/min to keep the EtCO₂ within 30-38 mmHg, similar to the study of *Marco Ghignone et al (1988)*(4) Alveolar ventilation was assumed to be comparable in all the patients at any point of time. Mean EtCO₂ in group-A was 33.05 ± 2.64 to 34.10 ± 2.70 and in group B, it was 33.37 ± 3.09 to 34.92 ± 2.37. Hence, mean EtCO₂ was comparable (p > 0.05) in both the groups throughout the observation period.

It can be observed that comparison of the effects of the two studied drugs on intraoperative haemodynamic parameters in the present study is justified, as the demographic data and other patient variables and baseline haemodynamic parameters were all comparable and type of surgery, anaesthetic procedure and anaesthetic agents, equipments used were same between the two groups. Also, any confounding factors like patients with GCS < 15, emergency surgeries, patients with extremes of age (age < 18 yrs, age > 65 yrs) were excluded from the study. The two groups differed only with respect to the study drugs used.

In a retrospective study by *Pardey Bracho*(5) et.al., patients who received scalp block with levobupivacaine prior to skull pin placement and incision were compared with controls in terms of hemodynamic stability and anaesthesia/analgesia requirements. The Scalp nerve block resulted in good intraoperative hemodynamic stability and reductions in the required doses of anaesthetics and opioids.

Banu O. Can(6) et al. compared two drugs as scalp block-levobupivacaine and bupivacaine on haemodynamic response to head pinning and found out that both levobupivacaine and bupivacaine were similar as far as preservation of hemodynamic profile was concerned.

Geze et al.(2009) compared the effects of scalp block and local infiltration on attenuating the hemodynamic response with regard to skull pin placement. Responses monitored were HR, SBP, DBP, Serum cortisol, and ACTH before and after skull pin placement. They found out that the above mentioned variables were significantly lower in scalp block group. They therefore came to a conclusion that scalp block was effective in attenuating hemodynamic response and stress response to skull pin placement.(7)

Uyar et al. showed that a single bolus dose of dexmedetomidine before induction of anaesthesia attenuated the hemodynamic and neuroendocrine response to skull pin insertion as compared to that of placebo.(8)

Tanskanen et al (2006) in his study concluded that with dexmedetomidine there was a decreased response to noxious stimuli, intubation and extubation, thus yielding greater hemodynamic stability compared with placebo.(9)

Many other studies validate the role of dexmedetomidine in obtunding the hemodynamic responses to head pinning.

After analysis of the results it was found that Scalp Block resulted in a significant reduction in Visual Analogue Score levels compared to the Dexmedetomidine infusion till the 6 hours of post operative period. The results are supported by the following studies as follows:

Bala et al. assessed the efficacy of scalp block with 0.5% Bupivacaine in Craniotomy patients on post operative pain relief. They concluded that scalp block with 0.5% Bupivacaine significantly reduce the severity

of pain in patients undergoing craniotomy.(10)

Nyugen et al. evaluated 30 patients who were randomized to receive a scalp block with either ropivacaine or normal saline. Over a 48 hour post operative period, the pain scores were lower after ropivacaine infiltration. The time to first rescue analgesic administration and the need for rescue drugs differed between the two groups.(11)

Ayoub et al. evaluated the efficacy of transitional analgesia with either a scalp nerve block or morphine after remifentanyl-based anaesthesia in 50 patients undergoing craniotomy. They reported that the quality of transitional analgesia and postoperative hemodynamics obtained by scalp block were similar to those obtained by morphine. However morphine administration was associated with a higher incidence of nausea and vomiting.(12)

Hwang et al. tested the efficacy of levobupivacaine scalp blocks on patient recovery in a study. The post operative pain scores and pain-controlled analgesia consumption were lower, and the time from recovery to the first use of patient-controlled analgesia and rescue analgesics were longer in the levobupivacaine group than the control group.(13)

Banu O. Can et al. in their study comparing the effects of scalp block with levobupivacaine versus bupivacaine on post operative VAS score in patients undergoing head pinning found out that VAS scores at 2 hours were different significantly among the group receiving 0.5% bupivacaine, 0.5% levobupivacaine and those receiving placebo as normal saline.(6)

The VAS scores of the conscious patients in the placebo group were significantly higher than the patients receiving levobupivacaine or bupivacaine scalp block. It was concluded that both levobupivacaine and dexmedetomidine infusion resulted in better post operative analgesia than placebo.

4 patients experienced nausea and 1 incidence of dry mouth in group A, while 1 patient experienced nausea, 6 patients had intraoperative hypotension and 4 patients experienced dry mouth in group B.

CONCLUSION

0.5% Levobupivacaine scalp block and Dexmedetomidine infusion given at a dose of 1mcg/kg over 10 minutes followed by continuous infusion of 1mcg/kg/hr for 30 minutes after skull pin insertion, both drugs effectively blunted the hemodynamic response to skull pin insertion intraoperatively.

Levobupivacaine scalp block in comparison to dexmedetomidine provides better hemodynamic stability and post operative analgesia. Both drugs didn't lead to any significant side effects.

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