Original Article

Comparison of Efficacy of Scalp Infiltration of Bupivacaine Plus Dexmedetomidine and Bupivacaine Alone as Preemptive Analgesia to Blunt Hemodynamic Response to Craniotomy. Efficacy of dexmedetomidine and bupivacaine scalp infiltration

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Abstract

Background: Increase in heart rate and blood pressure are the prominent hemodynamic changes seen in response to various noxious stimuli in neurosurgical procedures. In patients with intracranial pathologies hypertension and tachycardia can result in raised intracranial pressure causing morbidity. The aim is to compare the effect of scalp infiltration of bupivacaine alone and bupivacaine plus dexmedetomidine to attenuate hemodynamic response to noxious stimuli during craniotomy under general anaesthesia. **Material and Methods:** Bupivacaine (n = 30) or bupivacaine with dexmedetomidine (n = 30) scalp infiltration was administered to sixty patients undergoing neurosurgeries in a prospective randomization study. Heart rate (HR) and mean arterial pressure (MAP) were recorded at baseline, after pin insertion, scalp incision, during duramater opening and closure, during skin closure, on admission to the post anesthesia care room (PACU) and 2 h after arrival in the PACU. **Results:** In PACU mean arterial pressure in group 1 was significantly more when compared to mean arterial blood pressure in group 2 (p= 0.04) and its baseline blood pressure. (p= 0.01) HR and MAP did not differ significantly across the groups at any of the other predetermined time periods or when compared to their baseline MAPs. **Conclusion:** Addition of dexmedetomidine with bupivacaine in local scalp infiltration offered no additional benefit in attenuating hemodynamic response to various sharp noxious stimuli in neurosurgical procedures However dexmedetomidine prolonged the analgesic effect of bupivacaine.

Keywords: General anaesthesia, Bupivacaine, Noxious stimuli.

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Introduction

Intraoperative and postoperative hemodynamic stability is essential for neurosurgeries. Increases in intracranial pressure (icp), blood pressure, and heart rate are prevented. Because periosteal nerve endings are stimulated during pin insertion and scalp incision, there is an abrupt rise in heart rate and mean arterial blood pressure.[1] This increases risk of cerebral venous hemorrhage, increase in brain edema, risk of premature rupture of a cerebral aneurysm and sudden increase in intracranial pressure.[2] Acute and persistent postoperative craniotomy pain when not treated properly can lead to chronic pain.[3] Pain intensity is difficult to diagnose and quantify in these patients due to their inability to express and they might have altered sensorium postoperatively.[4] So pain relief is important for neurosurgical procedures to reduce hospital stay, mortality and morbidity in these patients.

Usually multimodal analgesia is used including non-steroidal drugs (NSAIDS), paracetamol and opioids to reduce intraoperative and postoperative pain. But there is risk of masking of signs of early neurological problems due to sedation and miosis caused by opioids. Other side effects of opioids include nausea, vomiting and respiratory depression. Respiratory depression can lead to hypercarbia thus increasing intracranial pressure in these patients. NSAIDS have a risk of bleeding after craniotomy and paracetamol alone is not effective.[5] Hence management of pain relief should be optimum with less use of opioids and NSAIDS.[6]

Scalp infiltration and scalp block are the regional anaesthesia techniques which are used in neurosurgical patients to provide adequate pain relief. These have lower complications and also allow assessment of neurological examination in these patients.[7] Bupivacaine is a potent local anesthetic used in regional,

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epidural, spinal anaesthesia and local infilteration. It is usually offered in three concentrations 0.25%, 0.5%, 0.75%. Local anaesthetic agents act by increasing the threshold of action potential thus blocking the generation of action potential in nerve cells.[8]

Only few studies heve been conducted in the past to evaluate the effect of scalp infilteration on postcraniotomy pain. We hypothetised that addition of dexmedetomidine to bupivacaine will lead to better hemodynamic parameters (heart rate and mean arterial blood pressure) as compared to bupivacaine alone in local scalp infilteraion in neurosurgical procedures. In order to examine the effects of bupivacaine with and without dexmedetomidine in local scalp infiltration to reduce hemodynamic response to different intraoperative painful stimuli, a prospective double blind randomized clinical experiment was carried out (pin insertion, skin incision, duramater opening and closure, skin closure) and on post-operative hemodynamic parameters in patients undergoing neurosurgeries.

Materials and Methods

This is a prospective, double blind, randomized control trial that was conducted in the tertiary care centre from April 2023 to August 2025 after approval from the Institutional Ethics Committee (BREC/22/078). Study was registered in Clinical Trials Registry of India (CTRI/2023/03/050630). Written and informed consent was taken from the patients.

Inclusion criteria: Patients of any sex aged 18 to 70 years, belonging to American Society of Anesthesiologists (ASA) physical status I, II & III, scheduled to undergo craniotomy for tumor, aneurysm, tuberculoma, to remove epileptic focus and who were able to understand the study protocol were included in the study.

Exclusion criteria: The patients who had history of hypertension, diabetes mellitus and cardiovascular disease, allergy to local anaesthetic drugs or dexmedetomidine and who refused to participate were excluded from the study.

Sample size: By using the formula for calculating sample size when comparing two groups with quantitative data as the end point: x

$$n=\frac{2SD^2(Z_{\frac{\alpha}{2}}+Z_{\beta})^2}{d^2}$$

Where n= sample size for each group

SD= Standard deviation

$Z\alpha/2 = Z0.05/2 = Z0.025 = 1.96$ (From Z table) at type 1 error of 5%.

$Z\beta = Z0.20 = 0.84$ (From Z table) at 80% power.

d= effect size= difference between mean values.

From study done by Biswas et al [9] y, mean values of pre-incisional SAP in two groups were 127.0 mmhg and 116.0 mmhg. So, d= (127.0-116.0) = 11.0 Putting all these values we got n= 26. Considering 10% attrition rate and rounding off, final sample size was 30. So, 30 patients were enrolled in each group of the study.

A total of 60 patients who were scheduled to undergo neurosurgeries were recruited and randomized in two equal groups with 30 patients in each group. Sequentially Numbered Opaque Sealed Envelopes (SNOSE) were used to disguise allocation, and a computer-generated random allocation sequence was used for randomization. This study was double-blind, in which both the anaesthesiologist and patients were blinded with the study groups. The study drug solution was prepared by anaesthesia technician who did not participate in data collection and analysis.

All the patients were given general anesthesia using standard protocol. All patients were monitored intraoperatively using standard parameters such as electrocardiogram (ECG), invasive Blood Pressure (IBP) and oxygen saturation (SpO2). Group 1 received scalp infiltration, using 2mg/kg of 0.25% bupivacaine before skin incision and pin insertion. Group 2 received scalp infiltration using 2mg/kg of 0.25% bupivacaine plus 1µg/kg of dexmedetomidine before skin incision and pin insertion. At baseline, following pin insertion, scalp incision, dural opening and closure, skin closure, admission to the post anesthesia care unit (PACU), and two hours after arrival in the PACU, heart rate (HR) and mean arterial pressure (MAP) were measured. Any side effects related to drugs such as bradycardia (>20% decrease from baseline), hypotension (> 20% decrease from baseline), arrhythmias etc. were noted intraoperatively and were treated according to standard protocol.

Statistical Analysis: The information was entered into a Microsoft Excel spreadsheet after being coded. IBM SPSS Statistics Version 25 for Windows (SPSS Inc., IBM Corporation, NY, USA) was used for the analysis. Standard deviations, averages, and percentages were all calculated using descriptive statistics. Prior to statistical analysis, the Kolmogorov Simonov test was used to ensure that the data were normal. The Wilcoxon signed-rank test and the Mann–Whitney U-test were used to compare two independent observations in quantitative data. The chi square test was used for qualitative data comparison of all clinical indicators. Level of significance was set at P≤0.05.

Results

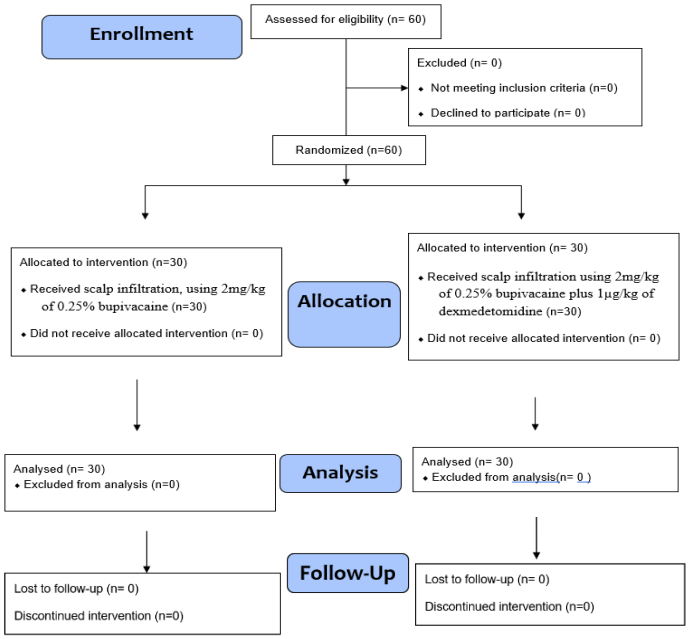

Figure 1: Consort Flow Diagram for the Study.

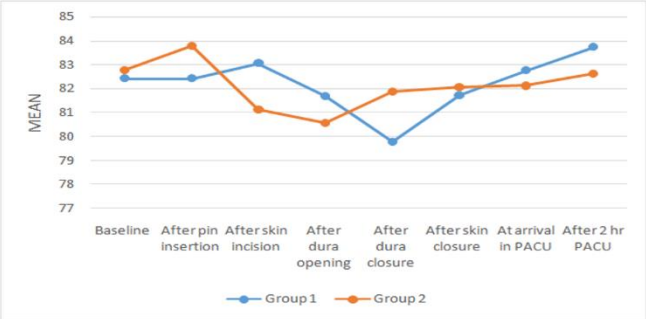

Figure 2: Graph showing comparison of groups according to heart rate

Total 60 patients were enrolled in the study with 30 patients in each group (n = 30). No exclusions were reported. [Figure 1] Both groups had comparable demographic profile with respect to age, weight, height, gender and ASA status [Table 1].

Pair wise comparison revealed no significant difference (p ≥0.05) in heart rate (HR) between the groups at predefined intervals (pin insertion, skin incision, duramater opening and closure, skin closure, at transfer in PACU and at 2 hours in PACU). [Table 2] There was no statistically significant difference in heart rate of both groups at above defined intervals when compared to their baseline HR.

In PACU mean arterial pressure in group 1 was significantly more than group 2 (p= 0.04). [Table 3] Also when mean arterial pressure in PACU of group 1 was compared to its baseline blood pressure, statistically significant difference (p= 0.01) was found. There was no discernible change in MAP across the groups at any of the other predetermined time periods or when compared to their baseline MAPs.

In the dexmedetomidine group (group 2) two patients had bradycardia, one had hypotension out of 30 patients. In group 1 only one patient had hypotension, and none had bradycardia. Other side effects related to study drugs were not observed.

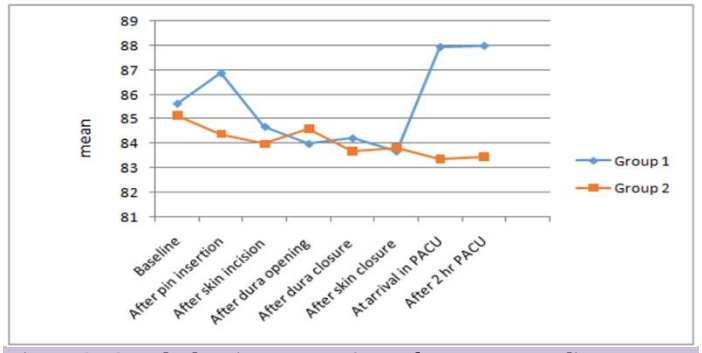

Figure 3: Graph showing comparison of groups according to mean arterial blood pressure.

Table 1: Comparison of groups according to demographics

	Group 1	Group 2	P value
Age	41.90±13.555	46.37±11.470	0.17
Height	166.87±7.930	167.47±8.792	0.78
Weight	65.67±10.303	64.93±10.738	0.78
Gender (female/male)	14/16	13/17	0.79
ASA (I/II)	20/10	18/12	0.59

Table 2: Comparison of groups according to heart rate.

		Mean	Std. Deviation	P value
Baseline	Group 1	82.43	15.967	0.92
	Group 2	82.80	15.103	
After pin insertion	Group 1	82.43	13.688	0.69
	Group 2	83.80	12.759	
After skin incision	Group 1	83.07	14.069	0.58
	Group 2	81.13	13.198	
After dura opening	Group 1	81.70	13.168	0.73
	Group 2	80.57	12.094	
After dura closure	Group 1	79.80	13.443	0.57
	Group 2	81.87	14.522	
After skin closure	Group 1	81.73	13.316	0.92
	Group 2	82.07	13.125	
At arrival in PACU	Group 1	82.77	12.714	0.85
	Group 2	82.13	14.755	
After 2 hr PACU	Group 1	83.73	13.794	0.76
	Group 2	82.63	14.185	

Table 3: Comparison of groups according to mean arterial blood pressure

		Mean	Std. Deviation	P value
Group 1	Baseline	85.63	9.178	0.84
Group 2		85.17	9.454	
Group 1	After pin insertion	86.87	9.497	0.29
Group 2		84.40	8.677	
Group 1	After skin incision	84.70	9.798	0.77
Group 2		84.00	9.337	
Group 1	After dura opening	84.60	9.644	0.69
Group 2		83.60	9.747	

Group 1	After dura closure	84.23	7.445	0.8
Group 2		83.70	8.766	
Group 1	After skin closure	83.70	8.510	0.95
Group 2		83.83	8.918	
Group 1	At arrival in PACU	87.93	9.255	0.04 (S)
Group 2		83.37	8.054	
Group 1	After 2 hr PACU	87.98	9.242	0.04(S)
Group 2		83.47	7.417	

Discussion

In our investigation, we discovered that when dexmedetomidine is added to scalp infiltration to lessen hemodynamic response to skull pin insertion, skin incision, duramater incision, and skin and duramater closure, it offers no extra benefit over bupivacaine. However, mean arterial pressure was significantly lower in dexmedetomidine group in PACU when compared with baseline as well as on pair wise comparison. It might be due to prolonged analgesic effect provided by dexmedetomidine. In neurosurgical procedures, we generally encounter acute sympathetic activity in response to pin insertion. So skin is infilterated with local anaesthetic drugs such as bupivacaine, levobupivacaine, ropivacaine etc. to blunt this hemodynamic response.

Adjuvants are often added to prolong the anaesthetic effect of bupivacaine and to reduce its dose. Dexmedetomidine has been used as an adjuvant to prolong and increase the analgesic effect of local anaesthetic successfully.[10] Dexmedetomidine is a highly selective alpha 2 adrenergic receptor agonist. It works by obstructing the cation current that is induced by hyperpolarization (Ib current). Ib current restores the nerve to its typical resting potential. Thus, blocking of Ib current leads to prolong hyperpolarisation of the nerve. This effect of dexmedetomidine is more in C – fibres (pain) than A alpha fibres (motor). Scalp is richly innervated by C fibres. This effect of dexmedetomidine explains the prolongation of analgesia when used as adjuvant to local anaesthetic drugs.[11]

Several pharmacological agents have been tried by researchers in local scalp infiltration to attenuate the hemodynamic response to skull pin insertion with variable success. Local anaesthetic (LA) drugs used in skull infiltration target major sensory innervations to scalp. In 1998, a randomized clinical trial by Bloomfield et al concluded that that scalp infiltration with 0.25% bupivacaine with epinephrine attenuates intraoperative hemodynamic responses and reduces postoperative pain in adult patients undergoing craniotomy. These results were similar to the current study.[12]

Sahana et al observed that the addition of dexmedetomidine to 0.5% ropivacaine offered no more advantageous scalp block than ropivacaine alone in terms of lowering the hemodynamic reaction to the insertion of a skull pin during neurosurgery. They observed that both heart rate and mean arterial blood pressure showed no difference between the groups.[13]

To reduce the harmful effects of hemodynamic response to skull pin insertion, potent narcotics and deep levels of anaesthesia have been proposed by various researchers. Addition of alpha 2 agonists to local anaesthetic drugs like bupivacaine, levobuivacaine and ropivacaine through intrathecal, epidural route or in peripheral nerve blocks have been used by several investigators in the past.[7,13,14] They demonstrated the improved sensory efficacy of local anaesthetic drugs.

Kondavagilu SR et al conducted a study to compare two intravenous doses of dexmedetomidine (0.5µg/ml and 1µg/ml) to compare attenuation of heart rate in between the groups. They found no variation in hemodynamic measures during the intraoperative period between the two dosages of dexmedetomidine.[15] Mohamaddi et al (2009) conducted a randomized clinical study to evaluate the effect of scalp infiltration with bupivacaine on early hemodynamic responses during craniotomy. Similar to our study, they observed that bupivacaine infiltration resulted in more stable hemodynamics (heart rate and mean arterial blood pressure) during early stimulation after craniotomy.[16]

Result of the current study was negative in contrast to study done previously.[7] Dexmedetomidine is a weak analgesic and the active control (bupivacaine) infilterated in both the study groups, which was responsible for the negative result of this study. General anaesthesia with adequate depth and multimodal analgesia was used in both groups which might also be responsible. It has been well established that, the duration of analgesia is prolonged by addition of dexmedetomidine to local anaesthetic agents during peripheral nerve blocks. This explains the substantial variation in the two groups' mean arterial pressure in PACU (dexmedetomidine group had lower blood pressure). On comparison to baseline mean arterial blood pressure, significant difference in was noted.

Major limitation of our study was that we used multimodal analgesia and variable anaesthesia levels in different patients which might have resulted in the negative result of this study. Also it was a single centre study thus limiting external validity.

Conclusion

This study demonstrated that addition of dexmedetomidine with bupivacaine in local scalp infiltration provided no additional benefit in attenuating hemodynamic response to various sharp noxious stimuli like skull pin insertion, skin and duramater incision and their closure. However dexmedetomidine prolonged the analgesic effect of bupivacaine so postoperative mean arterial blood pressure was more stable in dexmedetomidine group.

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Conflicts of interest

There are no conflicts of interest.

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