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RESEARCH ARTICLE

A PROSPECTIVE, RANDOMIZED STUDY COMPARING THE ANALGESIC EFFICACY OF SCALP BLOCK WITH 0.25% BUPIVACAINE VS PRE-INCISIONAL LOCAL INFILTRATION WITH 0.25% BUPIVACAINE WITH ADRENALINE (1:400,000) IN PATIENTS UNDERGOING ELECTIVE CRANIOTOMIES

Dr. B. Priyadarshini, Dr. Pushpalatha V., Dr. Madhavi and Dr. N. Santosh Surya Prakash

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ABSTRACT

Background and Aims: Pain is often referred to as the "***fifth vital sign***". Pain management in patients undergoing craniotomies pose a great challenge to the anaesthesiologists. Scalp block forms an important aspect in the multimodal approach to the post-craniotomy pain. The following study compares the analgesic efficacy of Scalp block with traditionally used local wound infiltration technique in providing analgesia to craniotomy patients.

Methods: Performed double blinded, prospective, randomized controlled trial on 60 patients undergoing elective craniotomies divided into 2 groups comparing the analgesic efficacy of Scalp block with 0.25% Bupivacaine vs Pre- incisional wound infiltration with 0.25% Bupivacaine with Adrenaline (1:400,000).

Results: There were significant differences in intra-operative hemodynamics between the two groups. Scalp block resulted in statistically significant reduction in HR,SBP, DBP & MAP. There was increased duration of post-operative analgesia in scalp block group when compared with the local infiltration group. The opioid requirement in the intra-operative period was significantly lesser in scalp block group when compared with the local infiltration group. Requirement of rescue analgesic is significantly lesser during early post-operative period (Upto 8 hours) in the scalp block group when compared with local infiltration group.

Conclusion : Scalp block with 0.25% Bupivacaine is effective and superior to Pre-incisional Local infiltration with 0.25% Bupivacaine with 1:400,000 Adrenaline in attenuating hemodynamic responses, providing increased duration of post-operative analgesia, significant reduction in intra-operative opioids and post-operative rescue analgesic requirements.

INTRODUCTION

Neuroanaesthesia is a speciality where the knowledge and expertise of the anaesthetist may directly influence patient outcome. Evolution of neurosurgical practice is accompanied by new challenges for the anaesthetist with greater focus on functional recovery of neurological status. Post-craniotomy pain has been gaining much attention in neuroanaesthesia recently. It is often compounded by the complex nature of surgery & underlying CNS pathology.

Corresponding Author:- Dr. B. Priyadarshini

Even though craniotomy pain is less severe when compared to other surgical procedures, it has been under treated in the recovery phase for most of the patients[1]. Intracranial structures vary in their sensitivity towards perceiving the painful stimuli. During the intra operative period stimuli like 3-pin insertion, skin incision, dural manipulation, dural and skin closure cause different levels of nociception. Painful stimuli are associated with hemodynamic changes like increase in heart rate and mean arterial pressure.

Scalp block forms an important aspect in the multimodal approach to the post-craniotomy pain. Our study compares the analgesic efficacy of Scalp block with 0.25% Bupivacaine Vs Pre-incisional local infiltration with 0.25% Bupivacaine with Adrenaline (1:400,000) in patients undergoing elective craniotomies.Our primary objective was comparison of intra-operative hemodynamic status, post-operative VAS score and secondary objective was to assess intra-operative opioid requirements & time for first rescue analgesia.

METHODS

After getting the approval of Institutional Ethics Committee (SVSMC/2021-24[012]) and written informed consent, this study was conducted over a period of three years from January 2021 to January 2024 on 60 patients who underwent elective craniotomy in a tertiary care teaching hospital. Patients aged 18-65 years having BMI 18.5- 29.9 kg/m² & of ASA physical status I or II were included in the study. Patients undergoing craniotomy in sitting position, craniotomy for anerysmal clipping, having preoperative opioid dependence, coagulation abnormalities,requiring elective post-operative ventilation were excluded from the study.

Patients were randomized into 2 study groups of 30 each. A pre-anaesthetic check was conducted 1 day prior to surgery to record baseline data. Patients shifted to the operation theatre with intravenous cannula insitu. Standard ASA monitors were connected & vital parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were recorded pre-operatively.A standard induction protocol was followed for all the patients which included premedication with Inj. Midazolam (0.05mg/kg), preoxygenation for 3 minutes, induction with Inj.Fentanyl (2µg/kg), Inj.Thiopentone Sodium (5mg/kg).Neuromuscular blockade was facilitated with Inj.Vecuronium (0.1mg/kg).Anaesthesia was maintained with 30% Oxygen & 70% Nitrous oxide and 1 MAC value of Sevoflurane. Patients were ventilated to maintain normocarbia by setting tidal volume 6-8 ml/kg and respiratory rate 12-20 breaths per minute.

After that, parts were prepared, painted and draped, Group A patients received Scalp Block with 0.25% Bupivacaine and Group B patients received Pre- incisional Infiltration with 0.25% Bupivacaine with 1:400,000 Adrenaline. A Mayfield[TM] head holder was used to stabilize the head during the surgery. At the time of pinning or anytime during procedure, if HR rises more than 10/min or MAP increases by more than 15mmHg over baseline values, attempts will be made to control the HR or MAP by increasing Sevoflurane concentration. If HR or MAP remains higher, then Inj. Fentanyl at dose 0.5µg/kg was given. Mannitol (0.5-1g/Kg IV) was administered to avoid rise in ICP. At the end of surgery, after adequate neuromuscular recovery, patients were reversed with Inj.Glycopyrrolate (0.005mg/kg) and Inj.Neostigmine (0.07mg/kg) and then extubated.

Intraoperative vitals were recorded several times including baseline, after induction, during Scalp block/Local administration, 5 minutes after administration, skull pin insertion, skin incision, pericranial flap dissection, periosteal dissection, bone drilling, dural opening, brain dissection and manipulation, dural closure, bone closure, pericranial closure, skin closure and following extubation.Visual analogue scale (VAS) was explained to all patients. They were instructed to mark the severity of post-operative pain on that scale.The primary outcome of the study was assessmentof intra-operative hemodynamics, post-operativeanalgesia by VAS score.Secondary outcome was to assess intra-operative opioid requirements & time for first rescue analgesia.The VAS scores had been noted post operatively, after extubation, then at half hourly interval for 6 hours and then till 24 hours. Initiation time of rescue analgesia in both the groups was also noted.

Sample size estimation done at 95% confidence level, 90% power at an alpha value of 0.05& beta value of 0.01 was 43, which was rounded of to 60. Descriptive statistics was done for all data and suitable statistical tests of comparison were done. These included the mean and standard deviation (SD) for quantitative variables and category frequency counts for qualitative variables. Next inferential statistical analysis was undertaken. Continuous variables were analysed with the unpaired t-test and categorical variables were analysed with the chi-square test with yates correction. Alpha for significance of all inferences was set at $P < 0.05$. All tests of hypotheses, wherever applicable, were two-

tailed. The data was analysed using SPSS (version 16.0- Copyright-2007) - value of less than 0.05 is taken as significant.

RESULTS

The demographic profiles like age, weight, height, BMI were comparable between the two groups (Table 1).

TABLE 1

DEMOGRAPHIC PROFILE			
Parameters	**Group -A [n=30] (Mean +/- SD)**	**Group-B [n=30] (Mean +/- SD)**	**P value**
Age in Years	41.20 +/- 13.90	41.97 +/- 13.59	0.83
Weight in Kg	55.57+/-6.23	59+/-5.16	0.06
Height in Metres	1.55+/-0.05	1.57+/-0.04	0.15
BMI	23.05+/-1.38	23.95+/-1.29	0.06

ASA Status 1 constituted 50.00% (n=15) of the Group A and 46.67% (n=14) of the Group B. By conventional criteria the association between the techniques and physical status classification is considered to be statistically insignificant since $p > 0.05$.

It has been found that intraoperative HR between the two groups was statistically insignificant following induction, during Scalp block / Local administration, 10 mins following Scalp block/Local administration. Heart rate was statistically significant during 3 pin insertion; pericranial flap,bone, dural dissection; dura, bone, pericranial, skin closure and extubation(Table 2&3).

TABLE 2

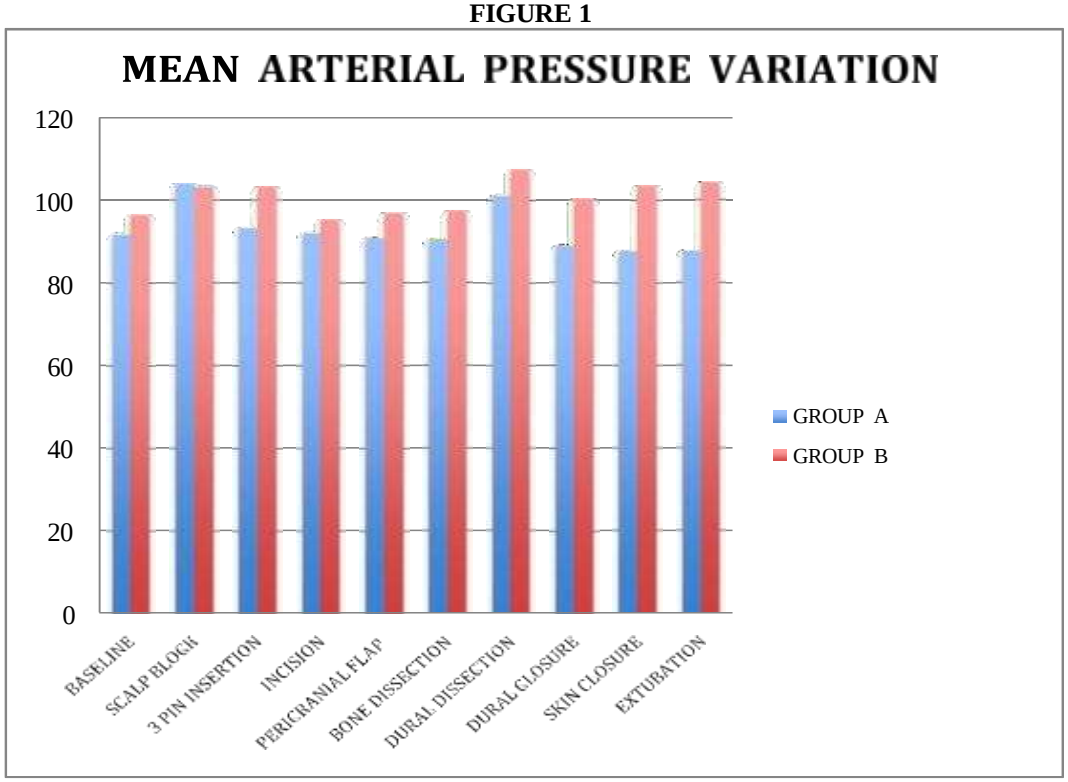
Heart Rate	**EVENT**	**BASELINE**	**INDUCTION**	**SCALPBLOCK**	**10MINAFTER SCALP**	**3PININSERTION**	**INCISION**	**PERICRANIALFLAP#1**	**PERICRANIALFLAP#2**	**PERICRANIALFLAP#3**
TIME				0 min	10 min	25 min	40 min	55 min	70 min	85 min
SCALP	**Mean**	85.73	88.73	96.30	88.27	87.50	85.40	84.43	83.47	82.17
	SD	9.23	6.57	7.40	6.22	5.60	5.56	4.17	5.29	5.18
LOCAL	**Mean**	84.85	88.19	94.77	89.12	93.88	88.69	96.35	90.96	90.27
	SD	9.30	7.16	6.56	6.05	6.69	5.71	6.19	5.81	5.09
PVALUE		0.72	0.77	0.42	0.60	.002	0.06	.002	0.003	0.002

TABLE 3

	EVENT	BONEDISSECTION	DURAL DISSECTIO	BRAINWORK #1	BRAINWORK #2	DURALCLOSURE	BONECLOSURE	PERICRANIA LCLOSURE	SKINCLOSURE	EXTUBATION
TIME		100 min	115 min	130 min	150 min	165 min	180 min	195 min	210 min	220 Min
SCALP	Mea n	82.70	90.10	82.70	82.97	80.93	80.07	78.90	78.83	77.77
	SD	5.59	4.99	5.64	5.15	4.88	4.71	5.47	4.79	4.29
LOCAL	Mea n	90.27	97.50	89.19	89.58	92.38	93.08	993.73	94.19	94.85
	SD	4.96	5.37	4.49	3.91	3.14	3.72	3.95	4.52	3.83
P VALUE		0.002	0.001	0.002	0.003	0.002	0.002	0.001	0.003	0.002

SBP, DBP & MAP(Figure 1) between the two groups were statistically insignificant with p value of >0.05 following induction, during Scalp block / Local administration, 10 mins following Scalp block/Local administration. SBP,DBP & MAP were statistically significant with p value of <0.05 during 3 pin incertion; pericranial flap,bone, dural dissection; dura, bone, pericranial, skin closure and extubation.

FIGURE 1



Scalp block resulted in a significant reduction in Visual Analog Score (VAS) levels compared to Local infiltration as far as first 6 hours of early post-operative period. After that there were no statistically significant differences in VAS scores between the two groups (Figure 2).

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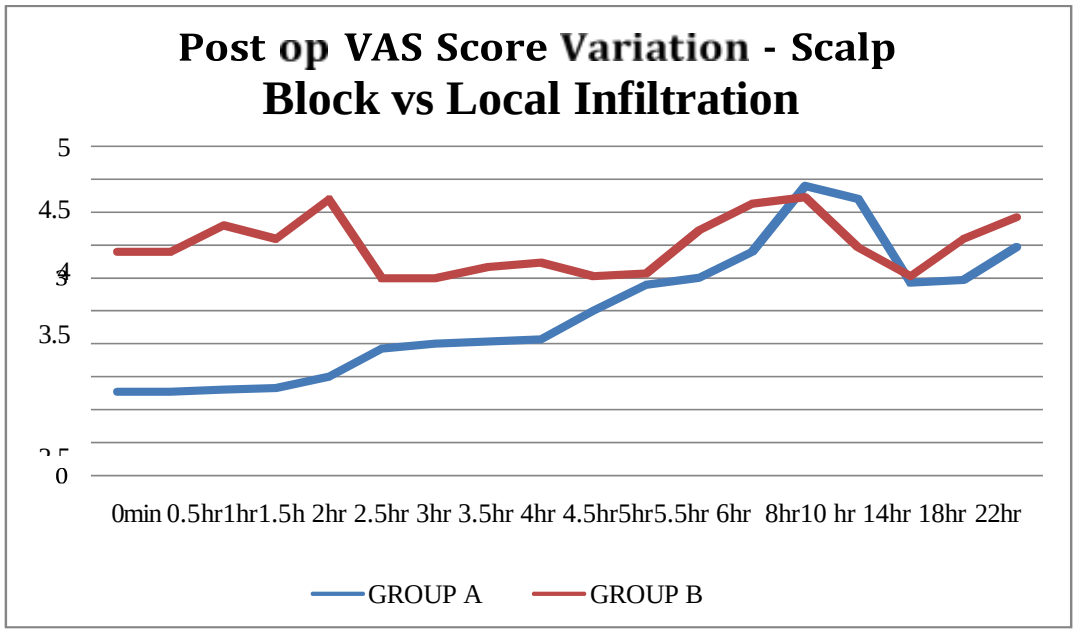
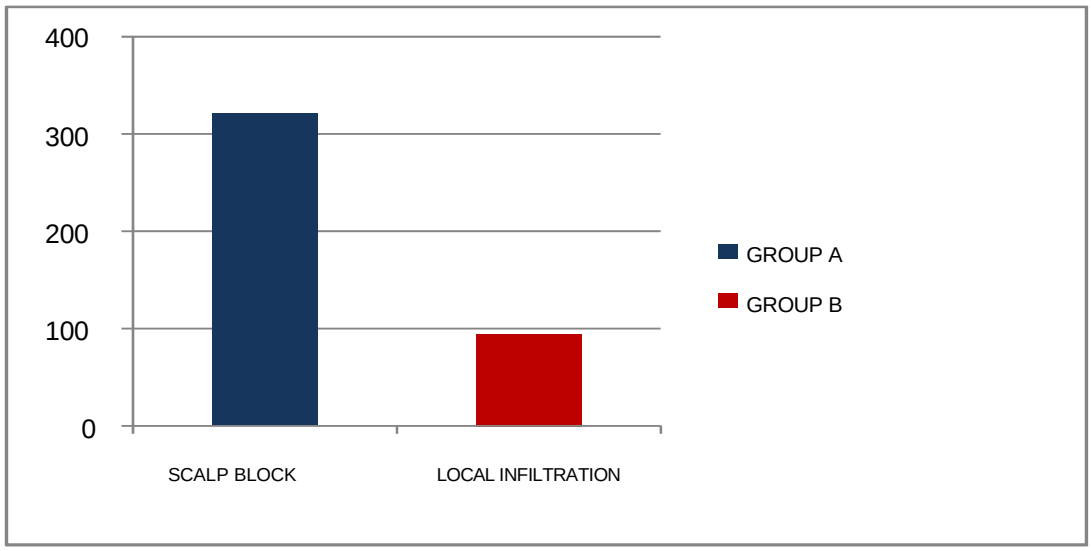
FIGURE 2



The anaesthesia protocol was standardized between the two groups with Inj. Fentanyl 2µg/kg as a pre-emptive analgesic. After that, variation in intra-operative hemodynamics was manipulated with increase in sevoflurane concentration. If no satisfactory response is obtained, then Inj. Fentanyl at the dose of 0.2µg/kg was given IV. It has been found that mean Fentanyl requirement was 142.67 µg/kg in the Group A and 188.67 µg/kg in Group B. Hence, Scalp block has statistically significant reduction in intra- operative opioid requirement since the P-value is <0.05.

The mean duration of post-operative analgesia in Group A was 320.34 minutes with SD of 30.81.Whereas, the mean duration of analgesia in Group B was found to be 94.67 minutes with SD of 22.25. Hence, there is statistically significant increase in duration of post operative analgesia in Group A when compared to Group B since P-value is <0.05(Figure 3).

FIGURE 3



It has been found that only 6.67% (n=2) in the Group A required rescue analgesic in the first 6 hours. On the other hand, 73.33% in the Group B required rescue analgesic within the first 6 hours. After 6 hours, there is no much difference in the requirement of rescue analgesics between the two groups. There is statistically significant increase in mean time for 1st dose of Inj. Paracetamol in Group A compared to Group B and total number of rescue analgesics required in Group A is less compared to Group B.

DISCUSSION

In our study, it has been found that Scalp block with 0.25% Bupivacaine was associated with stable intraoperative hemodynamics during skull pinning when compared with the Local infiltration. These results are correlating with the studies mentioned as follows: Pinosky, Mark et al[2] conducted a study to assess the effect of Scalp block with 0.25% bupivacaine on hemodynamic responses like SBP, DBP,MAP during 5 mins after induction, during pinning and 3 mins after pinning. They have observed that scalp block with 0.25% Bupivacaine blunts the hemodynamic response to skull pinning. There were no additional requirements of opioids or end tidal Isoflurane in scalp block group. Rubial M et al[3], compared the efficiency of scalp block on attenuating the hemodynamic response with regard to skull pin placement. They have observed that hemodynamic responses were higher in group that has received opioids than in group that has received scalp block with local anaesthetic agents. They also found that hemodynamic response in scalp block group was comparatively lesser than that of local infiltration group.

In present study the Scalp block resulted in a significant reduction in intra-operative HR, SBP, DBP & MAP values compared to Local infiltration during pericranial flap dissection, dural incision, bone dissection as well as during dural, bone and skin closure. Lawan Tuchida et al[4], conducted study to find out the efficacy of Scalp block with 0.25% Bupivacaine on intra-operative hemodynamics comparing with scalp block with 0.9% Saline. They concluded that Scalp block with 0.25% Bupivacaine reduces rise in HR & MAP in response to noxious stimulation.

Bala et al[5] concluded that Scalp block using 0.5% Bupivacaine significantly reduces the severity of pain in patients undergoing craniotomy. Further, it has been found that Local infiltration group requires 1µg/kg of Inj. Fentanyl higher than that of Scalp Block group. Lawan Tuchida et al[4] had found that Scalp block group requires less intraoperative Inj.Fentanyl when compared with the control group, there is statistically significant increase in duration of post operative analgesia in Scalp block group when compared to the Local infiltration group. In our study it has been found that, Scalp block resulted in a significant increase in mean time required for first dose of Inj. Paracetamol compared to local infiltration .Biswas et al[6] had found that Scalp block with 0.25% Bupivacaine delayed the need of rescue analgesic till 480 mins when compared with 30 mins in placebo group. They concluded that Bupivacaine delayed the requirement of the first dose of the rescue analgesic in their study.

In our study total number of rescue analgesics required in scalp block group is then infiltration group. Postoperative drowsiness, postoperative complications like nausea and vomiting, were increased in patients who were given local infiltration corroborating with the increase in Inj.Fentanyl requirements in Local infiltration group.

Our results are in accordance with Hansen et al[7] who conducted a systemic review on post craniotomy pain relief. Four treatment modalities and a total of 519 patients & nine RCTS were compared. They concluded that Scalp block with local anaesthetic agents produces pain relief for about 6 hours of immediate post operative period and the incidence of nausea and vomiting is much lesser when compared with other groups.

CONCLUSION

In conclusion, Scalp block with 0.25% Bupivacaine is effective and superior to Pre-incisional local infiltration with 0.25% Bupivacaine with 1:400,000 Adrenaline in attenuating hemodynamic responses to noxious stimuli. Scalp block also provides increased duration of post-operative analgesia when compared with local infiltration. Scalp block also results in significant reduction in intra-operative opioids and post-operative rescue analgesic requirements.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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