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A Prospective Randomised Controlled Study Of The Efficacy Of Pre-Operative Scalp Blocks For Post-Operative Analgesia After Craniotomy

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Abstract:
Background : Postoperative pain after craniotomy is an important clinical concern because it might lead to a number of adverse consequences. Opioids have been the mainstay of analgesic medications, but considering the side effects of opioids, several studies have been conducted to investigate the effect of local anesthetics, especially the scalp block, on postoperative pain. However, the strength of evidence supporting this practice for postoperative pain after craniotomy was unclear and the best occasion of scalp block was also not identified.
Methods:The study was conducted in the department of Anaesthesiology at Cardiothoracic and neurosciences center, Gauhati Medical College & Hospital during the period of July, 2022 to June, 2023. After obtaining institutional ethics committee clearance and written informed consent from the patients and/or their relatives, 120 patients were randomly assigned into two groups of 60 participants each, to receive either scalp block with 0.5% Ropivacaine as a part of multimodal analgesia or standard multimodal analgesia without scalp block after induction of anaesthesia and before surgical incision. Mean arterial pressure (MAP) and HR were recorded at 0, 5, 10, 15, 30 and 60 minutes and then hourly till the end of surgery. Post-operatively, the same parameters were recorded at 1 hour, 2, 4, 6, 8, 12, 16, 20, 24 hours. Post-operative pain, rescue analgesic requirement, nausea & vomiting and any abnormal behaviour were noted. Data obtained from the study was analysed by the statistical package of Windows, the SPSS version 19.0
Results: Patients who received scalp block as part of multimodal analgesia had a better haemodynamic stability in terms of heart rate and MAP compared to patients without scalp block, during the intra-operative period as well as the early post-operative period. Post-operative pain in terms of the Numerical rating scale score and the rescue analgesic requirement was better in the scalp block group. There was no significant adverse effects in either group

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I. INTRODUCTION

Craniotomy is an effective modality for the treatment of several cerebral diseases and injuries, and postoperative pain is an important clinical concern. In almost 86% of patients the pain is of somatic origin, with the involvement of soft tissues and pericranial muscles[1]. Elevated oxygen consumption and catecholamine release caused by postoperative pain lead to brain hyperemia and elevated intracranial pressure, which may predispose them to intracranial hematoma[2,3,4]. Effective pain management and prevention are important to avoid these systemic changes and improve rehabilitation and long-term outcomes[5,6]. Besides, management of early postoperative pain can prevent the development of central sensitization and chronic pain states caused by surgical tissue damage[7,8]. However, pain after a craniotomy is often treated insufficiently, because of the fear that the opioid-induced sedation and miosis will mask neurological pathology. Therefore, several studies have been conducted to investigate the effect of local anesthetics, especially the scalp block, on postoperative pain[9-12].

II. REVIEW OF LITERATURE

Scalp block is a common technique in craniotomy and is widely used to reduce the hemodynamic response and incisional pain during craniotomy procedure[13,14,15]. Analgesia could be achieved by blockade of the following nerves: greater and lesser occipital nerves, the supraorbital and supratrochlear nerves, the zygomaticotemporal nerve, the auriculotemporal nerve, and the greater auricular nerve[16,17,18] . However, the strength of evidence supporting this practice was unclear and the best timing of scalp block was also not

identified. Carella M, Tran G, Bonhomme VL observed that during supratentorial craniotomy, scalp block provided better control of hemodynamics in response to painful events such as pin-fixation and skin-incision. It also provided adequate and prolonged post-operative pain control and decreased intra and post-operative opioid consumption[(3)]. In another study Theerth KA, Sriganesh K, Reddy KR et al demonstrated that Analgesia nociception index (ANI) guided analgesic administration during craniotomy showed lower intra-operative fentanyl consumption in patients receiving scalp block as compared to incision site local anaesthetic infiltration[(4)]. Another study to compare pre-operative scalp block to post-operative scalp block showed no significant difference in post-operative analgesic requirement during the first 24 hours following surgery[(5)].

Therefore, in this study, we aimed to evaluate the efficacy of pre-operative scalp block, as a component of multimodal analgesia, on post-operative analgesia in patients undergoing craniotomy.

III. AIMS AND OBJECTIVES

To study the efficacy of regional scalp block with 0.5% Ropivacaine as a component of multimodal analgesia in patients undergoing craniotomy

IV. MATERIALS & METHODS:

Study site: the study was conducted in the Department of Anaesthesiology, Cardiothoracic and Neurosciences center, Gauhati Medical College & hospital, Guwahati, Assam

Duration: July 2022 to June 2023

Sample size calculation: For the sample size calculation, we defined a relevant difference of25% in the change in MAP in the control and study groups. Using a two tailed alpha value (0.05) and a beta value (0.1) 45 observations per group were found to be sufficient to detect a significant difference (>20% from baseline). To make up for any data loss due to dropouts we included 60 patients in each group

Study design: prospective, randomized, controlled and double blinded

Group allocation: 120 adult patients scheduled to undergo craniotomy for intracranial space occupying lesions were recruited for the study. They were randomised by a computer generated program into two groups of 60 participants each. Group 1 received scalp block with 0.5% ropivacaine in addition to standard MMA after induction of anaesthesia. Group 2 received standard MMA without scalp block

Inclusion criteria:

-ASA I and II patients

-Age group 18-65 years

Exclusion criteria:

-not consenting for participation in the study

-known allergy to local anaesthetics

-patients whose pre-operative GCS <12

-known personality disorder

-patients who were expected to require post-operative mechanical ventilation

-chronic alcohol or opioid intake

ANAESTHESIA TECHNIQUE—patients were advised fasting for 6 hours prior to surgery. Standard anaesthesia technique for induction was followed. Inj. glycopyrrolate 0.2mg i.v.and Inj.fentanyl citrate 2 µg/kg body weight i.v. were given 5 minutes before induction.Induction of anaesthesia was done with inj propofol 2 mg/kg. Rocuronium bromide 1mg/kg body weight was used to facilitate endotracheal intubation and the trachea was intubated with an appropriate size endotracheal tube when the train of four(TOF) count was < 2. Bilateral air entry was checked and intermittent positive pressure ventilation(IPPV) started with volume-control mode and tidal volume(TV) of 6-8ml/kg maintaining $EtCO_2$ between 30-40 mm of Hg.

Landmark based scalp block was administerd with 0.5% Ropivacaine 1-2 ml in each nerve in the study group 15 minutes prior to the pin-fixation or skin incision. Then the surgical site was cleaned and draped and the surgery started. Just before skin incision the surgeon infiltrated the skin with 2% lignocaine + adrenaline.

The scalp block was administered by the principal investigator and another investigator, who was allowed to enter the OT after the start of surgery, would record the observations. Standard multimodal analgesia with inj ketorolac 30 mg iv infusion and paracetamol 1 g infusion was administered in addition to inj fentanyl in all patients.

Anaesthesia was maintained with oxygen, air and sevoflurane with a MAC between 0.7-1. Top-up doses of the relaxant were administered as and when required, on the basis of neuromuscular monitoring.

The MAP and HR were recorded at 0, 5, 10, 15, 30 and 60 minutes and then hourly till the end of surgery. Post-operatively, the same parameters were recorded at 1 hour, 2, 4, 6, 8, 12, 16, 20, 24 hours.

Postoperative analgesic requirement was assessed by Numerical rating Scale (NRS).Fentanyl 0.5 µg/kg was administered as rescue analgesic when NRS was more than 3. Depending on the pain severity, Inj.

diclofenac sodium 75 mg as i.v. infusion or paracetamol 1 g infusion was administered additionally, if needed. Any postoperative adverse effect, like nausea, vomiting, any abnormal movement or abnormal behaviour was recorded. Patients experiencing nausea or vomiting received Inj. Ondansetron 4 mg i.v. as a rescue anti-emetic.

STATISTICAL ANALYSIS

The data generated after the assessment of the subjects in the two groups were tabulated and analysed statistically using the statistical package for the social science system version SPSS 19.0. Continuous variables are expressed as mean ± SD(standard deviation), and categorical variables are presented as absolute numbers and percentages. The comparison of normally distributed continuous variables between the groups was performed using student's T test. Nominal categorical data between the groups was compared using Chi-square test or Fisher's exact test as appropriate. $P < 0.05$ was considered statistically significant.

V. RESULTS AND OBSERVATIONS:

120 patients were included in our study with 60 patients in each group. In group 1, 32 patients (53.3%) were male and 28 (46.7%) female, whereas in group 2, 34 (56.7%) patients were male and 26 (43.3%) female. The mean age of the patients in group 1 was 46.7 ± 10.14 years whereas, in group 2 it was 49.2 ± 11.657 years.

TABLE 1

Heart rate (beats per minute)	**Group 1**	**(n=60)**	**Group 2**	**(n=60)**	**P Value**
	Mean ± SD	**Range**	**Mean ± SD**	**Range**	
Baseline	82.98 ± 16.779	54 – 108	80.64 ± 11.754	56 – 98	0.378
0 min (at incision)	87.76 ± 20.906	54 – 130	84.66 ± 9.510	60 – 92	0.295
5 mins	94.12 ± 16.758	66 – 128	97.70 ± 11.285	62 – 105	0.183
10 mins	88.38 ± 16.484	68 – 130	87.86 ± 14.060	56 - 96	0.856
15 mins	79.78 ± 18.835	54 – 116	80.20 ± 10.474	52 – 85	0.880
30 mins	77.70 ± 16.737	51 – 100	76.14 ± 7.791	52 – 84	0.509
60 mins	78.90 ± 14.241	60 – 108	76.44 ± 9.128	52 – 82	0.226
2 hours	79.94 ± 16.303	52 – 116	77.94 ± 10.334	50 – 84	0.418
End of surgery	94.18 ± 13.018	67 – 118	96.76 ± 10.599	75 – 112	0.235
1sthr post-op	75.48 ± 9.671	52 – 88	88.40 ± 7.489	70 – 99	<0.001
2ndhr post-op	73.86 ± 6.138	58 – 84	84.26 ± 5.394	64 – 85	<0.001
4th hr post-op	73.16 ± 7.611	60 – 84	91.80 ± 6.289	60 – 103	<0.001
6th hr post-op	70.22 ± 6.355	62 – 85	95.12 ± 9.442	65 – 114	<0.001
8th hr post-op	89.54 ± 8.877	68 – 106	93.32 ± 7.112	61 – 108	0.0116
12thhr post-op	92.76 ± 12.342	54 – 118	92.11 ± 8.761	64 – 105	0.746
16thhr post-op	96.13 ± 9.543	65 – 112	95.67 ± 10.712	60 – 110	0.792
20thhr post-op	94.77 ± 10.132	62 – 115	96.16 ± 12.398	57 – 112	0.503
24thhr post-op	96.14 ± 6.091	71 – 106	94.25 ± 9.645	62 – 108	0.197

Table 1 shows that the heart rate in the two groups were comparable throughout the intraoperative period. In the post-operative period,the heart rate was significantly higher in Group 2 in the first 8 hours.

TABLE 2

MAP (mm Hg)	**Group 1**	**(n=60)**	**Group 2**	**(n=60)**	**P Value**
	Mean ± SD	**Range**	**Mean ± SD**	**Range**	
Baseline	112.96 ± 11.779	97 – 125	109.14 ± 11.754	92 – 118	0.077
0 min (at incision)	106.35 ± 10.906	82 – 111	108.69 ± 9.510	79 – 115	0.208
5 mins	97.12 ± 16.758	83 – 105	101.72 ± 11.285	82 – 109	0.080
10 mins	95.27 ± 16.484	82 – 108	102.26 ± 14.060	88 – 132	0.0138
15 mins	94.72 ± 18.835	79 – 113	104.20 ± 10.474	81 – 125	0.0009
30 mins	98.73 ± 16.737	88 – 114	108.16 ± 7.791	75 – 119	0.0001

60 mins	91.95 ± 14.241	72 – 107	101.44 ± 9.128	79 – 113	<0.0001
2 hours	94.94 ± 16.303	70– 112	103.34 ± 10.334	72 – 119	0.0009
End of surgery	96.88 ± 13.018	82 – 115	115.76 ± 10.599	81 – 125	<0.0001
1st hr post-op	104.48 ± 9.671	85 – 116	102.42 ± 7.489	90 – 114	0.1983
2nd hr post-op	86.86 ± 6.138	71 – 95	101.21 ± 5.394	92 – 108	<0.0001
4th hr post-op	83.16 ± 7.611	65 – 99	98.80 ± 6.289	82 – 115	<0.0001
6th hr post-op	95.24 ±8.454	77 –108	97.11 ± 9.134	80 – 109	0.2557
8th hr post-op	87.58 ± 11.023	73 – 112	96.32 ± 7.664	79 – 106	<0.0001
12th hr post-op	92.76 ± 13.976	74 – 121	94.17 ± 8.178	81 – 116	0.498
16th hr post-op	111.15 ± 9.122	82 – 125	113.37 ± 6.115	88 – 126	0.061
20th hr post-op	109.77 ± 8.112	85 – 118	111.16 ± 5.422	92 – 121	0.074
24th hr post-op	98.14 ± 6.871	82 – 109	99.22 ± 6.166	85 – 107	0.376

Table 2 shows that the Mean arterial pressure was significantly lower in Group 1 patients from 15 mins into the intraoperative period till the end of surgery. In the post-operative period, Group 1 shows a lower MAP till the first 8 hours, except the 1st hour and the 6th hour.

TABLE 3

NRS score	GROUP 1	GROUP 2	p-VALUE
1st hr post-op	1.21 ± 0.15/10	2.34 ± 0.33/10	<0.0001
2nd hr post-op	1.13 ± 0.04/10	2.23 ± 0.05/10	<0.0001
4th hr post-op	1.56 ± 0.24/10	4.09 ± 0.32/10	<0.0001
6th hr post-op	2.06 ± 0.02/10	2.55 ± 0.04/10	<0.0001
8th hr post-op	4.11 ± 0.07/10	4.14 ± 0.07/10	0.021
12th hr post-op	2.63 ± 0.55 /10	2.97 ± 0.43/10	0.0003
16th hr post-op	3.36 ± 0.37/10	3.56 ± 0.43/10	0.0076
20th hr post-op	4.72 ± 0.12/10	4.76 ± 0.14/10	0.095
24th hr post-op	4.32 ± 0.04/10	4.33 ± 0.03/10	0.124

Table 3 shows that the NRS score in patients of Group 1 was significantly lower in the first 16 hours postoperatively.

TABLE 4

			Group			
			Group 1	Group 2	Total	P value
ONV	None	Count	53	51	104	0.564
		% within Group	88.33%	85.0%	86.67%	
	Nausea/ vomiting	Count	7	9	16	
		% within Group	11.67%	15.0%	13.33%	
otal		Count	60	60	120	
		% within Group	100.0%	100.0%	100.0%	

Table 4 shows that the incidence of PONV was 11.67% in group 1 while in group 2 it was 15.0%. The p-value of 0.564 indicates that it is not statistically significant.

The average duration of surgery in group 1 was 158.80 ± 18.39 minutes and in group 2 was 154.90 ± 16.83 minutes. The values in both the groups are comparable (p = 0.271).

The mean fentanyl consumption used as rescue analgesic between the two groups. In group 1 the median time to first request of rescue analgesic was 5 hours 36 mins, and the cumulative fentanyl requirement was 65.7 micrograms in 24 hours. In group 2, the median time to first request for rescue analgesic was 2 hours 23 minutes and the cumulative fentanyl requirement was 125.3 micrograms in 24 hours.

In group I the mean requirement of additional analgesics (NSAIDS and/or paracetamol) over and above fentanyl was 1.2 doses in 24 hours, while in group 2 the requirement was 2.7 doses. The difference in both the groups is statistically significant.

VI. DISCUSSION:

Anesthetic management of patients undergoing craniotomy can often be challenging because of the complexity of surgery, the underlying central nervous system pathology, and the need for early postoperative neurological assessment. There is no consensus on the best anesthetic agents for use in neurosurgery. Combining a regional anesthetic with a general anesthetic may offer advantages for most patients. Blocking noxious input to the abundant sensory nerve supply of the scalp would blunt the hemodynamic response to pain associated with head pin application and the incision. Infiltration of the incision site with local anesthetic agents before craniotomy incision is an accepted practice by many neurosurgeons, but this local anesthetic effect is short lived. A ''scalp block'' involves regional anesthesia to the nerves that innervate the scalp, providing analgesia for a considerable period of time extending into the postoperative period. Combining regional and general anesthesia has the potential for decreasing intraoperative general anesthetic requirements and attenuating hemodynamic responses to pain.

The scalp is the soft tissue which covers the cranial vault excluding the facial bones. It is made of 5 layers and has a generous vascular and sensory nervous supply. Blocking these nerves can provide effective anaesthesia of the scalp. The trigeminal and spinal nerves from the superficial cervical plexus provide sensory innervation through 6 different nerves on each side of the scalp. The ophthalmic, maxillary, and mandibular branches of the trigeminal nerve supply the anterior scalp, whereas the greater and lesser occipital nerves supply the posterior scalp behind.

In neurosurgery, supplementing general anaesthesia with a scalp block can blunt painful response to pin application and scalp incision, and can reduce opioid requirements, promoting early emergence for neurological assessment. Modern advances in neurosurgery, especially awake craniotomy, have brought a resurgence in the use of this block.

Several studies have shown that after craniotomy, the majority of patients experience pain inspite of standard analgesic usage. Quiney N, Cooper R, Stoneham M et al[(19)] have reported severe or moderate pain (poorly controlled with codeine alone) in the first 24 hours after craniotomy in the majority of 53 patients studied. De Benedittis G, Lorenzetti A, Migliore M et al[(20)] studied 37 patients after neurosurgery, and found that two-third of the patients experienced moderate tosevere pain in the first 48 hours after surgery. In their study, the pain was predominantly superficial in 86% of patients, suggesting somatic rather than visceral origin, with possible involvement of pericranial muscles and soft tissues. Scalp infiltration with local anesthetic has been studied as a way of decreasing postoperative pain. In a randomized double-blind study, Bloomfield EL, Schubert A, Secic M, et al[(21)] infiltrated the scalp with 0.25% bupivacaine or saline coupled with epinephrine both before incision and after scalp closure. Although their study was limited to 1 hour in the immediate postoperative period, it showed that wound infiltration with local anesthetics decreases pain scores on admission to the postanesthesia care unit for up to 1 hour. Another prospective doubleblind randomized and placebo-controlled trial showed that 0.25% bupivacaine preincision scalp infiltration did not have any significant effect on postcraniotomy pain and analgesic requirement, although it did delay the requirement of the first analgesic dose.[(22)]

Nguyen A, Girard F, Boudreault D et al[(23)] performed a prospective double-blinded randomized study in 30 patients receiving a block with 0.75% ropivacaine or saline. The ''scalp block'' involved blockade of the supraorbital, supratrochlear, auriculotemporal, great auricular, and greater and lesser occipital nerves as described by Pinosky et al[(24)] after skin closure and before awakening. Pain was assessed starting at 4 and up to 48 hours postoperatively. The average pain scores in the ropivacaine group was significantly lower when compared with the saline group for up to 24 hours, and the analgesic effect seemed to persist for at least 48 hours postoperatively. In our study, we observed that the patients receiving pre-incision scalp block with 0.5% Ropivacaine, as part of multimodal analgesia, provided significantly better analgesia upto 6-8 hours post-operatively.

In their study Bala I, Gupta B, Bhardwaj N et al[(25)] found that bupivacaine injection with epinephrine was effective in decreasing postoperative pain. They reported that 60% of patients receiving saline injection experienced moderate to severe pain some time during the first 12 postoperative hours in comparison to 25% patients who received bupivacaine scalp block. In addition, the median pain scores were significantly lower up to 6 hours postoperatively in patients who had received bupivacaine nerve blockade. The duration of pain relief in this study corresponded with the expected duration of action of bupivacaine with epinephrine. Our study shows that the post-operative analgesic effect was prominent within the first 6 to 8 hours.

A recent prospective randomized controlled double-blinded study by Ayoub C, Girard F, Boudreault D et al[(26)] has suggested that the postoperative analgesia offered by morphine and scalp blocks are equivalent, although the incidence of nausea and vomiting was slightly more frequent in the morphine group.

VII. SUMMARY:

Patients who received scalp block as part of multimodal analgesia had a better haemodynamic stability in terms of heart rate and MAP compared to patients without scalp block, during the intra-operative period as

well as the post-operative period. Post-operative pain in terms of the Numerical rating scale score and the rescue analgesic requirement was better in the scalp block group. There was no significant adverse effects in either group.

VIII. CONCLUSION:

Scalp block with local anaesthetics is a very useful component of multimodal analgesia in patients undergoing craniotomy with better haemodynamic control in the intraoperative and early post-operative period with better post-operative analgesia, without any significant adverse effects.

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