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"COMPARISION OF PLAIN BUPIVACAINE WITH BUPIVACAINE PLUS DEXAMETHASONE IN SCALP NERVE BLOCK IN PATIENT UNDERGOING SUPRATENTORIAL CRANIOTOMY UNDER GENERAL ANESTHESIA: A PROSPECTIVE RANDOMISED CLINICAL STUDY".

Anaesthesiology

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ABSTRACT

Background and Aims: This study was carried out to compare the effect of Bupivacaine and Bupivacaine with Dexamethasone when used for scalp block in terms of intraoperative hemodynamic stability and requirement of additional analgesia and anaesthetics intraoperatively. **Methods:** Sample size was calculated from reference study using hemodynamic stability after Scalp incision with Alpha error 0.05, 140 adult patients of either gender ASA-I, II, III scheduled for supratentorial craniotomy were randomized into 2 group. After induction with conventional GA, Group-B received 20 ml of drug (10 ml of 0.5% Bupivacaine +10 ml sterile water) and Group-B+D received 20 ml of drug (10 ml of 0.5% Bupivacaine +2 ml of Dexamethasone +8 ml sterile water). Hemodynamic parameters (HR, MAP, SBP, DBP) were noted baseline, after block and at every 5 minutes till the surgery completed. Intraoperative requirement of additional Fentanyl citrate and postoperative hemodynamic parameters, VAS score and No. of rescue analgesia (Inj.Paracetamol 1gm iv) required in 24hrs were noted. **Results:** There is no significant difference in MAP, Heart rate and fentanyl requirement in both groups intraoperatively. Postoperative analgesia is longer in group B+D (626.85±176.77) than B (329.04±80.09) and requirement of rescue analgesia is more in Group B (2.95±0.52) than Group B+D (1.39±0.73). **Conclusion:** We conclude from our study that both Bupivacaine and Bupivacaine plus Dexamethasone are equally effective in blunting hemodynamic responses and less Fentanyl citrate requirement intraoperatively. But Addition of Dexamethasone with Bupivacaine provide prolonged analgesic effect and less rescue analgesia requirement in the post operative period.

KEYWORDS

Scalp block; Bupivacaine and Dexamethasone; Supratentorial craniotomy.

1. INTRODUCTION

Anaesthesia management of patients undergoing Craniotomy can often be challenging, given the nature of surgery, underlying central nervous system pathology and the desire for postoperative assessment. The brain is enclosed by non-expandable skull with limited reserve to compensate for increase in cerebral blood volume, cerebrospinal fluid and brain tissue, abnormality in any one of these can cause increase in intracranial pressure.[1] During Craniotomies, noxious stimulus such as laryngoscopy, intubation, application of skull pin holder, skin incision and extubation induce intense sympathetic stimulation which causes sudden increase in heart rate, blood pressure and ICP. It can be detrimental for patients with space occupying lesions like tumors, intracranial hematoma, abscess in which intracranial compliance and auto-regulation are compromised. Methods to blunt these noxious stimulus may be by administration of systemic opioids, deepening the level of anaesthesia, Scalp nerve block or local anaesthesia infiltration on incision site.[2] The scalp is densely innervated by C-fibres and the main cause of postoperative pain in patients following Craniotomy is the skin incision and reflection of muscles during the operation rather than brain manipulation and resection. Blockade of nerves that supply the scalp will anaesthetize both superficial and deep layers of the scalp. [Figure 1] Given high dose opioids and anaesthetic agents may result in prolonged emergence and hypotension during periods of low levels of stimuli. Many studies have showed that both SNB and scalp infiltration by local anaesthetics can blunt those hemodynamic responses during craniotomy and might be a better choice for pain relief.[3]

Lignocaine and Bupivacaine are most often used in performing scalp nerve blocks. They are classified as amides based on the nature of their carbonyl-containing linkage group. They exert their clinical effects by blockage of sodium channels, thereby, preventing sodium ion flux across the cell membrane, resulting in reversible interruption of nerve impulses in peripheral nerves.[4] Studies on the use of adjuvants to local anaesthetics to improve the quality and duration of scalp nerve blocks are scant. Corticosteroids are known to cause vasoconstriction on topical application, which is mediated by the occupancy of classic glucocorticoid receptors. According to this theory, steroids bind to intracellular receptors and modulate nuclear transcription. Dexamethasone added to local anaesthetics has been shown to significantly prolong the duration of motor and sensory blockade afforded by interscalene, axillary block. Thus Dexamethasone (preservative free) is added to Bupivacaine in Scalp block to study the intra-operative requirement of Opioids and the duration of Post-operative analgesic effect in Craniotomy patients.

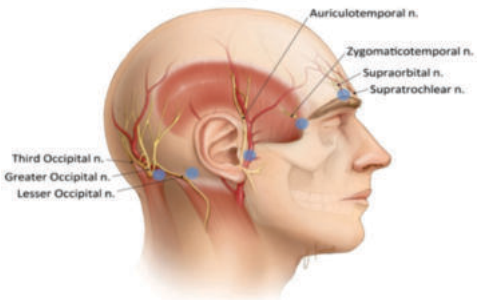


Figure 1 : Anatomy of Scalp nerves

2. METHODOLOGY

After taking permission from *Scientific and Ethical Research Committee* of Government Medical college and SSG Hospital, Vadodara, a double blinded randomized controlled trial was carried out.

Inclusion Criteria:

- Age Group – 18-70years of either gender.
- ASA – I/II/III.
- Mallampatti Grade- I / II /III
- Patients diagnosed with intracranial space-occupying lesions scheduled for elective supratentorial cranial surgeries and Craniotomy surgeries.
- Pre-operative GCS 15/15
- Patient able to give written & informed consent.
- Patient able to understand VAS regarding assessment of pain.

Exclusion Criteria:

- Patient not willing for procedure.
- Patients having uncontrolled Diabetes, Hypertension, Liver and Kidney disorders.
- Pregnant patients.
- Hypersensitivity to any local anesthetic drug or drugs used in this study.
- Patients with significant h/o drug or alcohol abuse, psychiatric illness.
- Patients with scalp infection.
- BMI ≥ 30

Sample size was estimated as follows:
As per primary reference, the difference in Heart rate between Group B (Using Bupivacaine) and Group R (Using Ropivacaine) after 60 secs of Scalp block is Mean -77 with SD 7.23 in Group B , and Mean -79 with SD 7.1 in Group R. Two sided Confidence interval, α-error of 0.05: 95%,Power of the study (beta error of 0.2) : 80%.The sample size was 140 (70 in each group of the study).

On a visit before one day, a full system assessment was performed as part of the pre-anesthetic checkup, and all patients underwent standard laboratory tests.

The procedure was described to every patient, and their written informed consent was obtained. Standard protocol for Nil per Oral guideline was followed. After bringing the patient inside operation theatre, intravenous line was secured, monitor was attached, and baseline vital parameters were recorded. All patients were preme dicated with Inj. Glycopyrrolate 5mcg/kg, Inj. Fentanyl 1mcg/kg and Inj. Ondansetron 0.1 mg/kg IV 5 minutes before induction.

Grouping Of Patients:
The study population was randomly allocated to two groups using the *sealed envelope method.*

Group B -Patients were given general anaesthesia and Scalp Block given bilaterally. Drug used:- 0.5% Bupivacaine 10ml + Sterile water 10ml = 20ml (10ml on each side)

Group B+D- Patients were given general anaesthesia and Scalp Block given bilaterally.Drug used:- 0.5% Bupivacaine 10ml + 8mg of Dexamethasone (preservative free) 2ml + Sterile water 8ml = 20ml (10ml on each side)

Pre-oxygenation was performed for 3 minutes with 100% O2 with closed circuit. Induction with Inj. Propofol 2mg/kg IV,followed by Vecuronium bromide 0.1mg/kg IV. Patient lungs was manually ventilated for 3mins with 100% oxygen before orotracheal intubation. Direct laryngoscopy performed after 3mins, by appropriate sized Macintosh blade and tracheal intubation performed within 15 seconds using appropriate sized cuffed flexometallic tube. Intra-operatively, Patients lung were mechanically ventilated with Tidal volume 6-8 ml/kg and respiratory rate 14-16/min to maintain end tidal PC02 35-40mmHg. Anaesthesia was maintained with Oxygen, Air and Desflurane on controlled ventilation. Muscle relaxant was given as intermittently with 1/4th of bolus dose of Vecuronium Bromide. All the vital parameters monitored intraoperatively and noted on every 30 mins which includes Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean Arterial Pressure (MAP), Heart rate (HR), Peripheral oxygen saturation (SPO2) and $EtCO_2$.Intraoperatively fluid and blood loss were replaced accordingly with IV fluids, blood and blood products. Supplemental dose of Inj.Fentanyl citrate 0.5mcg/kg iv was given if intraoperative rise in heart rate and Mean Arterial Pressure >20% from the baseline value. After all aseptic and antiseptic precaution, Scalp block was performed using 24-$1_{1/2}$ needle. The nerves blocked are Supraorbital nerve, Supratrochlear nerve, Zygomaticotemporal nerve, Auriculotemporal nerve, Greater Occipital nerve and Lesser Occipital nerve.[Table 1]

Table 1 : Anatomical landmarks of infiltration of Scalp nerves and Volume of drug

SENSORY INNERVATIONS OF THE SCALP	ANATOMICAL LANDMARKS OF INFILTRATION	VOLUME OF DRUG (LA)
SUPRAORBITAL NERVE	Supraorbital notch (approx. midpoint of the superior border of the orbit)	1 ml
SUPRATROCHLEAR NERVE	Superiomedial angle of the orbit	1 ml
AURICULOTEMPORAL NERVE	Between the tragus of ear and pulsation of the superficial temporal artery (1-1.5cm anterior to tragus)	2 ml
ZYGOMATICOTEMPORAL NERVE	Supraorbital margin to the posterior part of the zygomatic arch	2 ml
GREATER OCCIPITAL NERVE	Approx. halfway between the occipital protuberance and the mastoid process and medial to the occipital artery	2 ml
LESSER OCCIPITAL NERVE	2.5cm lateral to the Greater occipital nerve and towards the mastoid process	2 ml

Following parameters were studied:
1. Vital parameters:
Heart rate, Mean arterial pressure, SpO_2, $EtCO_2$ were noted at baseline, after GA, after Scalp block, after Pin insertion, after Scalp incision, at interval of 2 minute, 5 minutes, 10 minutes, 20 minutes, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 150 minutes and 180 minutes.

2. Requirement of Inj. Fentanyl citrate:
Supplemental dose of Inj. Fentanyl citrate 0.5mcg/kg IV was given if intraoperative rise heart rate and Mean Arterial Pressure > 20% from the baseline value.

Post-operatively, patient was extubated with reversal of residual neuromuscular block once patient met the criteria of extubation which includes Spontaneous breathing with adequate tidal volume generation, normothermia, no active bleeding, haemodynamically stable, and reversed with Inj. Neostigmine - 50 mcg/kg iv and Inj. Glycopyrrolate - 10 mcg/kg iv. Postoperative pain assessment was done using VAS (Visual analogue Score). Postoperative vitals and VAS score were noted till 24hrs after surgery. Inj. Paracetamol (30mg/kg) IV was used for rescue analgesia if VAS ≥4.

3. Total Duration of analgesia:
Time from injection of drug to the time for first demand of rescue analgesia (VAS score>=4)

4.Total requirement of rescue analgesia in 24 hours post operatively
Mean and Standard deviation values were taken out. Statistical analysis of the data for the various parameters was done using student's 't' test for all continuous variables and chi-square test was used for qualitative (nonparametric) data using MedCalc software. P value was used to determine the significance of a statistical study. The P value < 0.05 was considered as significant and p value <0.01 was considered as highly significant.

3. RESULTS
All 140 patients included in the study were analysed. The demographic - age, gender, ASA and Duration of Surgery - parameters were comparable between both the groups [Table 2]. There was no statistically significant intergroup variation observed in hemodynamic parameters – Heart rate, Mean arterial pressure, SpO2, EtCO2 (P > 0.05). The total dose of intraoperative requirement of Inj.Fentanyl citrate was comparable in both the groups [Table 3].The total duration of analgesia is longer in Group B+D (626.85±176.77) than Group B (329.04±80.09) [Table 3] [Figure 2] which is highly significant. The number of rescue analgesia required in postoperative period is higher in Group B (2.95±0.52) than Group B+D (1.39±0.73) [Table 3] [Figure 3].

Table 2: Demographic data

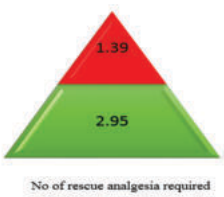
Parameters	Group B	Group B+D
Age (years)	38.01±12.70	40.60±13.39
Gender M:F	50:20	51:19
Duration of Surgery (mins)	174.42±36.22	173.57±37.49
ASA grading ASA I:II:III	6:26:38	5:23:42

Table 3: Comparison of Intraoperative and Postoperative variables

Parameters	Group B	Group B+D	P-value
Total dose of Fentanyl (mcg)	74.35±9.81	73.71±16.43	P>0.05 [Not significant]
Total duration of Analgesia (mins)	329.04±80.09	626.85±176.77	P<0.000 [Highly Significant]
No of Rescue analgesia	2.95±0.52	1.39±0.73	P<0.0001 [Highly Significant]

Figure 2 : Total duration of analgesia

Figure 3 : No of rescue analgesia required



GROUP B & GROUP B+D

4. DISCUSSION

Anaesthesia for neurosurgical procedures requires a sound knowledge of cerebral and spinal cord anatomy, blood supply and metabolism, effects of anaesthetic agents on intracranial pressure and cerebral blood flow as well as awareness of modern neuroradiology and neurophysiological monitoring techniques pertinent to management of specific cases. Neurosurgical procedures range from burr hole drilling for evacuation of extradural hematomas to more intricate surgeries involving excision of supra and infratentorial mass lesions, clipping of cerebral aneurysms, resection of arteriovenous malformations, awake craniotomy for epilepsy surgery, management of head injury patients, interventional neuroradiology and robotic surgery.Tumors involving the central nervous system, though uncommon, are not a rare entity in clinical practice. More than 80% of brain tumors in adults are supratentorial, the commonest being gliomas (36%), meningiomas (32.1%) and pituitary adenomas (8.4%). Anaesthetic management of supratentorial brain tumors requires an understanding of the pathophysiology of local or generalized rising intracranial pressure, regulation and maintenance of cerebral perfusion and how to avoid secondary systemic insults to the brain. These secondary insults to the already injured brain may be local or systemic: local insults include further rise of intracranial pressure, tearing of cerebral vessels by midline shift, epilepsy and vasospasm; systemic insults include hypercapnia, hypoxemia, hypotension or hypertension, hypo- or hyperosmolality, hypo or hyperglycemia and hyperthermia .[5]

The cornerstone of neuroanaesthesia is the prudent manipulation of the intracranial pressure-volume relationship. The main normal intracranial components of the brain (tissue, blood and cerebrospinal fluid) are contained in an unyielding skull. The primary goal of neuroanaesthesia is to avoid intracranial compartment volume increase, especially for cerebral blood volume, by judicious choice of anaesthetic agents and their optimal dosages, maintaining mean arterial pressure to preserve cerebral autoregulation and optimizing partial pressure of carbon dioxide in the blood. Close hemodynamic monitoring warrants placement of an invasive arterial line for beat-to-beat monitoring of blood pressure; risk of bleeding and venous air embolism, need to infuse vasoactive drugs and evidence of cardiovascular compromise indicate the need for central venous catheter placement; in addition to pulse oximetry, electrocardiogram and end tidal carbon dioxide, the need for special monitoring is decided on a case-to-case basis : neuromuscular monitoring should be used if muscle relaxants are given during the surgery, electroenc ephalography(EEG) monitoring can inform the anaesthesiologist about cerebral ischemia and depth of anaesthesia; monitoring of evoked potentials is helpful in observing intactness of specific central nervous system pathways during surgical manipulation.[6]

Anaesthetic aims during maintenance of anaesthesia during supratentorial surgery are:

I) Control of brain tension via control of cerebral blood flow and cerebral metabolic rate (chemical brain retractor concept). Components of this concept encompass the following:
- Mild hyperosmolality (use 0.9% saline) as baseline infusion; give 20% mannitol 0.25 – 1 gm/kg before bone flap removal.
- Intravenous anaesthetic agent (propofol) to provide adequate depth of anaesthesia
- Mild hyperventilation
- Mild controlled hypotension: mean arterial blood pressure of 50-65mmHg to decrease cerebral blood volume and intracranial pressure
- Normovolemia
- Head up positioning, no compression of jugular veins
- Minimal positive end-expiratory pressure
- Avoid bucking on ventilator by using adequate muscle relaxants

ii) Awakening from neurosurgery mandates maintenance of stable arterial blood pressure (and thus, cerebral blood flow and intracranial pressure), stable oxygenation and carbon dioxide tension and normothermia as well as avoidance of coughing and raised airway pressure.

Postoperative Pain Management in Supratentorial Craniotomies: Modalities and Challenges in postoperative neurosurgical patients presents a unique challenge: on one hand, inadequate analgesia may cause agitation, hypertension and vomiting, which increase the risk of intracranial bleed; on the other hand, narcotic analgesics may cause respiratory depression and hypercapnia, which result in cerebral vasodilatation and increased intracranial pressure. Pain experienced by patients after craniotomy seems to be of somatic origin, most likely involving the scalp, pericranial muscles and soft tissue, and from manipulation of duramater.[15] De Benedittis et al (1996) undertook a pilot study to assess prevalence of pain in postoperative craniotomy patients and quoted a figure of 60% for moderate to severe pain. Among craniotomies, supratentorial surgeries are considered to be less painful than infratentorial procedures.[7]

Geze et al (2009) conducted study on 45 ASA I or II patients. The effect of scalp block and local infiltration on Hemodynamic and stress response to skull pin placement for craniotomy. They were randomly allocated into three groups of 15 person in each group (Group C) Control Group, (Group S) Scalp block and (Group L) local infiltration. When HR and MBP were compared between groups, the increase in HR was also significant for groups L and C when compared with group S during head pinning and 1st 2nd and 3rd minute after pinning ($P<0.05$). The increase in MBP was also significant in groups L and C when compared with group S during head pinning and 1st and 2nd minute after pinning ($P<0.05$). This increase in MBP was higher in group C for the 1st and 2nd minute after pin inserting when compared with group L ($P<0.05$) and group S ($P<0.01$). The Plasma cortisol increased in Group C at the 5th minute compared with baseline between the two other groups. He demonstrated that Hemodynamic stability was better maintained using scalp nerve block during initial surgery and that neuroendocrine response decreased significantly after skull pin holder application.[8] Thus in our study Scalp block was given in neurosurgery patients to access the haemodynamic stability, postoperative analgesia and also studied the intraoperative requirement of systemic opioids.

Singh et al (2012) conducted a Comparative study on effects of Ropivacaine scalp block versus Dexmedetomidine infusion on Hemodynamic response to skull pin insertion of Neurosurgical patients, 64 patients subjected to elective craniotomy randomized in Group D(Dexmedetomidine) given bolus 1mcg/kg IV infusion over 10mts before induction, maintenance 1mcg/kg /h from induction till 5 mins after pinning . Group S (scalp block) bilateral Ropivacaine scalp block with 30 ml of 0.5% Ropivacaine 15ml each side given. Intra-group analysis revealed that decrease in heart rate with respect to baseline was significant S group as compared to D group; decline in SBP as compared to baseline in both groups were statistically significant in both groups, decrease DBP significant in S Group and not significant in D Group, MAP in S Group remain consistently lower by about 10% as compared to baseline with strong statistical significance. In this study scalp blockade with 0.5% Ropivacaine is very effective to bolus dose of Dexmedetomidine (1mcg/kg) followed by (1mcg/kg) in attenuation skull pin responses.[9] This study supported our study only in a case bupivacaine is used instead of Ropivacaine as local anaesthetic agent.

Pinosky et al (1996) conducted a study in Medical university of South Carolina on 21 patients (11 patients in Bupivacaine group and 10 patients in control group) the effects of Bupivacaine scalp block on hemodynamic response to craniotomy. Among them significant increase in hemodynamic variables occurred during head pinning in control group. SAP increased by 40+ 6 mm Hg and DAP by 30+ 5mmHg from baseline during pinning in patients in control group and increase MAP (32+6mm Hg) and HR (22+3 bpm), increase Isoflurane requirement at pinning over baseline values were also observed in control groups. This Study demonstrates the scalp block using 0.5% Bupivacaine blunts the stress response to head pinning.[10]

Can et al (2017) studied Effects of scalp block with Bupivacaine vs Levobupivacaine response to head pinning and comparative efficacies in postoperative analgesia. 90 patients were randomly divided into three groups. Group B received 20ml of 0.5% Bupivacaine, Group L received 20ml of 0.5% Levobupivacaine, Group C received placebo. Scalp block performed 5mts before head pinning. The HR and MAP in Group B and L significantly lower than Group C at T6 ($P<0.01$ and $P<0.05$). The VAS score of conscious patient in Group C were significantly higher than those of conscious patients in Group B and Group L at 2 hours postoperatively ($P<0.05$). Scalp block preserves the Hemodynamic profile by blunting the sympathetic responses to intraoperative stimulation and decreasing the severity of pain in early postoperative period. The clinical effects of Bupivacaine and Levobupivacaine were similar in post-operative analgesic effects.[11]

The use of Dexamethasone as an adjuvant to anaesthetics can be

considered under two headings : adjuvant to general anaesthetics and adjuvant to regional blocks. It has no analgesic effect when given along with general anaesthesia via intravenous route. However, with regional blocks with local anaesthetics it prolongs the duration of analgesia.

Kopacz et al (2003) showed that dexamethasone in a biodegradable microcapsule form with bupivacaine prolonged the duration of intercostal nerve blockade in healthy human volunteers.[12] Dexamethasone was used as an adjuvant in a double-blinded prospective randomized control study by Movafegh et al (2006), 48 in sixty patients undergoing forearm and hand surgery under axillary block. They were divided into two groups: one group received 1.5% lignocaine with 2 ml of saline and the other received 1.5% lignocaine and 2 ml (8 mg) of dexamethasone in the axillary block. There was no significant difference in the onset of sensory and motor blockade in both groups. However, the duration of sensory and motor blockade was significantly prolonged in the dexamethasone group.[13]

Zhao et al (2021) studied the effect of Dexamethasone as a adjuvant to pre-emptive incision site infiltration analgesia in pediatric craniotomy patients. Eight children were randomly assigned to either Ropivacaine plus Dexamethasone group who received pre-emptive incision site infiltration with 0.2% Ropivacaine plus 0.025% Dexamethasone or Ropivacaine group who received 0.2% Ropivacaine alone. Ropivacaine with Dexamethasone has reduced pain score of 2.0 when compared to Ropivacaine group postoperatively. The time of first rescue analgesia demand was 24hrs in Ropivacaine with Dexamethasone and 8.5hrs in Ropivacaine alone. This study concluded that addition of Dexamethasone to Ropivacaine for preoperative incision site infiltration has better postoperative analgesic effect than Ropivacaine alone in pediatric craniotomy patients.[14]

In our study, we compared Plain Bupivacaine and Bupivacaine plus dexamethasone in scalp nerve block, the intraoperative requirement of opioids were comparable in both the groups. The analgesic effect was prolonged when given with adjuvant (Dexamethasone) and the requirement of rescue analgesia was also reduced postoperatively.

5. CONCLUSION

From our study, we have concluded that Scalp nerve block effectively blunts the haemodynamic response to noxious stimulus during craniotomy surgeries. Hence intraoperative requirement of anaesthetics and opioids is reduced.Both Plain Bupivacaine and Bupivacaine with Dexamethasone are equally effective in blunting hemodynamic responses and less Fentanyl requirement intraoperatively. But addition of Dexamethasone with Bupivacaine provide prolonged analgesic effect and less rescue analgesic requirement in postoperative period.

6. Financial Support And Sponsorship

None.

7. Conflicts Of Interest

None.

Clinical Trial Registration Number: REF/2022/03/041500

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