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COMPARISON BETWEEN EPIDURAL BUPIVACAINE AND DEXAMETHASONE VERSUS EPIDURAL BUPIVACAINE AND FENTANYL FOR PROLONGATION OF POST OPERATIVE ANALGESIA IN ELECTIVE LOWER LIMB ORTHOPEDICS SURGERY" –AN OBSERVATIONAL STUDY

Anaesthesiology

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ABSTRACT

Background: Different trials have shown that multimodal analgesia through different techniques is associated with superior pain relief. Opioids as epidural adjunct to local anesthetics have been in use for long and α2 agonists are being increasingly used for same. **Material:** After getting Ethical committee approval from our institute, we conducted the study in our hospital in 60 adult male patients aged between 18 – 60 years belonging to ASA Physical status I and II undergoing elective lower limb orthopedic surgeries under epidural anesthesia after obtaining written informed consent. Total 60 patients enrolled in the study were allocated into two groups. Group 1: Patients receiving 11 cc of 0.5 % bupivacaine plus 50 µg (1ml) fentanyl epidurally. Total volume 12 ml. Group 2: Patients receiving 11 cc of 0.5 % bupivacaine plus 4 mg (1 ml) preservative free dexamethasone epidurally. Total volume 12ml. **Results:** In present study, In Group 1, 46.67% were females and 53.3% were males and in Group 2, 50% were females and males respectively. There was no significant difference in demographic profile between two groups. In Group 1, 80% had ASA grade I and 20% had ASA grade II. There was no significant difference in ASA grade between two groups. In the study there was significant difference in mean VAS Score at @3 1/2 Hour, @6 Hour, @ 6 1/2 Hours, @7 Hours, @7 1/2 Hours, @8 Hours, @12 Hours and @24 Hours between 2 groups. There was no significant difference in mean VAS between two groups at other intervals. **Conclusion:** We conclude that epidural administration of bupivacaine +dexamethasone admixture resulted in better postoperative analgesia in terms of lower postoperative pain score, prolonged postoperative analgesia and patient comfort with fewer side effects when compared with the other group of epidural bupivacaine+fentanyl.

KEYWORDS

Epidural Bupivacaine, Dexamethasone, Fentanyl, Elective Lower Limb

INTRODUCTION

International association for study of pain has defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or defined in terms of such damage. The perioperative period is usually associated with a variety of pathophysiologic responses that are initiated or maintained by nociceptive input. Uncontrolled postoperative pain may produce various acute and chronic effects which may be detrimental to the patient. [1]

The perioperative pathophysiological changes that occur during surgery can be attenuated through reduction of transmission of nociceptive input to the central nervous system by providing perioperative analgesia. This also Decreases complications, facilitate recovery during the immediate postoperative period, improves long term recovery, Reduces the length of hospital stay, Improves the quality of life. [2]

Post operative pain management should be planned and tailored to the needs of special population like ambulatory surgical patient, elderly, pediatric, opioid tolerant, obese patients and those with obstructive sleep apnea syndrome. Transmission of nociceptive stimuli from the periphery to the central nervous system results in the neuroendocrine stress response, a combination of local inflammatory substances [3] and systemic mediators of the neuroendocrine response [4]

Suprasegmental reflex response to pain results in increased sympathetic tone, increased catecholamine levels, increased catabolic hormone secretion and decreased secretion of anabolic hormones which results in sodium and water retention, increased levels of blood glucose, free fatty acids, ketone bodies and lactate.

A hypermetabolic state occurs as metabolism and oxygen. The extent of the stress response is influenced by following factors: 1) The type of anesthesia, 2) The degree of surgical trauma.

The stress response may lead to postoperative hypercoagulability. Enhancement of coagulation, inhibition of fibrinolysis, increased platelet reactivity and plasma viscosity may contribute to an increased incidence of postoperative hypercoagulability related events such as deep venous thrombosis, vascular graft failure and myocardial ischemia. [5] The stress response also potentiates postoperative immunosuppression, the extent of which correlates with the severity of surgical injury. Sympathetic activation may increase myocardial oxygen consumption, decrease myocardial oxygen supply through coronary vasoconstriction and attenuation of local metabolic coronary vasodilation. Activation of the sympathetic nervous system also delays return of postoperative gastrointestinal motility, which may develop into paralytic ileus. [6]

Postoperative respiratory function is markedly decreased, especially after upper abdominal and thoracic surgery. Reflex inhibition of phrenic nerve activity is an important component of this decreased postoperative pulmonary function. Patients with poor pain control may breathe less deeply, have an inadequate cough, and more susceptible to the development of postoperative pulmonary complications.

Traditionally various techniques and drugs have been adopted for postoperative analgesia. These include regional techniques like epidural analgesia with local anesthetics alone or opioid alone or combination of both, peripheral blocks, NSAIDS, parenteral opioids, non-epidural analgesia like intrapleural analgesia, paravertebral block, intra articular analgesia etc.[6,7]

Epidural opioids and steroid have been used successfully for long time for chronic pain syndrome. The safety of epidural opioid and steroids is well established. Based on the above evidences and concepts in this study we used fentanyl and dexamethasone epidurally to study the effects on acute postoperative pain.

MATERIAL AND METHOD

After getting Ethical committee approval from our institute, we conducted the study in our hospital in 60 adult male patients aged between 18 – 60 years belonging to ASA Physical status I and II undergoing elective lower limb orthopedic surgeries under epidural anesthesia after obtaining written informed consent. Patients were allocated into one of the two groups (30 patients per group) by lotting method.

Inclusion Criteria:

- Adult patients aged 18 – 60 years
- ASA physical status I and II
- For elective lower limb orthopedic surgeries
- Written informed consent

Exclusion Criteria:
- Patient unwilling for the procedure
- Patients suffering from fever, drug allergy, thyroid disease, coagulation disorders and neuromuscular diseases.
- Emergency procedures under spinal anesthesia
- Patients with known hypersensitivity to local anesthetic
- Patients requiring supplementation with general anesthesia
- Patient with local site infection.
- Patient with uncontrolled diabetes, respiratory disease, cardiovascular disease, liver and renal disease.

Total 60 patients enrolled in the study were allocated into two groups.
- Group 1: Patients receiving 11 cc of 0.5 % bupivacaine plus 50 µg (1ml) fentanyl epidurally. Total volume 12 ml.
- Group 2: Patients receiving 11 cc of 0.5 % bupivacaine plus 4 mg(1 ml) preservative free dexamethasone epidurally. Total volume 12ml.

Detailed Procedure

All patients received a total volume of 12 ml of study drug. The level of blockade was then noted. In the pre anesthetic visit, study plan was explained in detail to all the patients. Written informed consent obtained after explaining the study in their own language patient was prepared for the surgery with fasting period of 8 hours. Antacid prophylaxis was given with inj. Pantoprazole 40 mg IV 2 hours before surgery. Baseline vital parameters were recorded in the patient waiting room.

In the operating room patient was connected to five lead ECG, Non Invasive Blood Pressure, Pulse Oximeter and baseline parameters were recorded. An intravenous line was established with 18 G intracath and preloaded with 15 ml / kg of ringer lactate. After the administration of study medication, the onset of analgesia and the level achieved was noted at 5 min interval till 20 mins. Surgery was allowed to proceed when the level of blockade was T8.

Throughout the intraoperative period vitals like heart rate, systolic and diastolic blood pressure, mean arterial pressure, oxygen saturation and respiratory rate were monitored. At the end of surgery in two groups (~100 to 120 mins) the level of sensory blockade was assessed and then epidural catheter was removed.

The patient was shifted to recovery room and observed and vitals were recorded and shifted to Post Anesthesia Care Unit(PACU) In the PACU, pain score was observed at 30 min, 60 min, 90 min, 120,150,180 min, & then every ½ hourly intervals up to 8hrs were observed in ward on a 10cm Visual analogue scale (no pain at 0 cm end and „worst pain ever at 10cm end) and for occurrence of side effects like nausea, vomiting, pruritus, respiratory depression, sedation and changes in hemodynamic variables.

The time since injection of drug into epidural space to the time required to obtain sensory blockade up to T8 (loss of pin prick to 22-gauge needle) was noted as onset of analgesia. The time between the onset of analgesia and return to baseline VAS of 5 was noted as the duration of analgesia.

When the VAS score was more than 5 or when the patients complained of pain. Rescue analgesia was given with Inj. Diclofenac 75mg was given intramuscularly and epidural catheter was removed. The patients were followed for a period of 24 hours in PACU for any occurrence of nausea, vomiting, sedation, pruritus, respiratory depression (RR<10/min), and parameters like duration of analgesia, hemodynamic variables etc. were noted.

Visual Analogue Scale

A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of value and cannot easily be directly measured (example - the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain).From the patient's perspective this spectrum appears continuous and their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. Operationally a VAS is usually a horizontal line, 10cm / 100 mm in length. The patient marks on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in centimeters/millimeters from the left hand end of the line to the point that the patient.

Statistical Analysis:

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square test was used as test of significance for qualitative data.

Continuous data was represented as mean and standard deviation. Independent t test was used as test of significance to identify the mean difference between two quantitative variables. p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

RESULTS

Total 60 patients enrolled in the study were allocated into two groups.
- Group 1: Patients receiving 11 cc of 0.5 % bupivacaine plus 50 µg (1ml) fentanyl epidurally. Total volume 12 ml.
- Group 2: Patients receiving 11 cc of 0.5 % bupivacaine plus 4 mg(1 ml) preservative free dexamethasone epidurally. Total volume 12ml.
- In present study, In Group 1, 46.67% were females and 53.3% were males and in Group 2, 50% were females and males respectively. The mean age of subjects in Group 1 was 49.63 ± 11.07 years and in Group 2 was 50.00 ± 12.18 years. The demographic data like age, sex, were comparable to each other in all the two group. There was no significant difference in demographic profile between two groups.
- In Group 1, 80% had ASA grade I and 20% had ASA grade II. In Group 2, 90% had ASA Grade I and 10% had ASA grade II. There was no significant difference in ASA grade between two groups.
- Mean basal heart rate in Group 1 was 81.87 ± 8.52 bpm and in Group 2 was 83.47 ± 7.74 bpm. There was no significant difference in basal heart rate between two groups.
- Mean SBP in Group 1 was 118.67 ± 8.19 mm hg and in Group 2 was 117.00 ± 7.02 mm hg. There was no significant difference in SBP between two groups.
- Mean DBP in Group 1 was 74.33 ± 7.28 mmhg and in Group 2 was 75.33 ± 5.71 mmhg. There was no significant difference in DBP between two groups.
- Mean SpO2 in Group 1 was 98.53 ± 0.51 mmhg and in Group 2 was 98.87 ± 0.57 mmhg. There was no significant difference in SpO2 between two groups.
- Mean Onset of Analgesia in Group 1 was 331.00 ± 85.39 seconds and in Group 2 was 393.00 ± 88.21. There was significant difference in onset of analgesia between two groups
- Mean Peak onset in Group 1 was 501.00 ± 81.17 seconds and in Group 2 was 548.0 ± 99.01. There was significant difference in mean Peak onset between two groups.
- In Group 1, Level achieved was T10 in 63.33% and T8 in 36.67%. In Group 2, level achieved was T10 in 63.33% and T8 in 36.67%. There was no significant difference in Level achieved between 2 groups.
- In both Group 1 and Group 2, 60% had Bromage Scale I and 40% had Bromage Scale II. There was no significant difference in Bromage Scale between 2 groups.
- In Group 1, Post op sensory level was T10 in 6.67% and T12 in 93.33% and in Group 2, Post op sensory level was T10 in 10% and T12 in 90%. There was no significant difference in post op sensory level between two groups.
- In the study there was significant difference in mean VAS Score at @3 1/2 Hour, @6 Hour, @ 6 1/2 Hours, @7 Hours, @7 1/2 Hours, @8 Hours, @12 Hours and @24 Hours between 2 groups. There was no significant difference in mean VAS between two groups at other intervals.
- Mean Duration of analgesia in Group 1 was 335.17 ± 33.95 min and in Group 2 was 382.43 ± 39.25. There was significant difference in Duration of analgesia between two groups.
- In Group 1, 6.67% had Bradycardia, 13.33% had Hypotension, 26.67% had Nausea & vomiting and 16.67% had Pruritus. In Group 2, 0% had Bradycardia, 26.67% had Hypotension, 3.33% had Nausea & vomiting and 0.00% had Pruritus. There was no significant difference in Bradycardia, Hypotension b/w 2 groups. There was significant difference in Side Effects between two groups.

	Group				p value
	Group 1		Group 2		
	Mean	SD	Mean	SD	
Onset of Analgesia	331.00	85.39	393.00	88.21	0.008*

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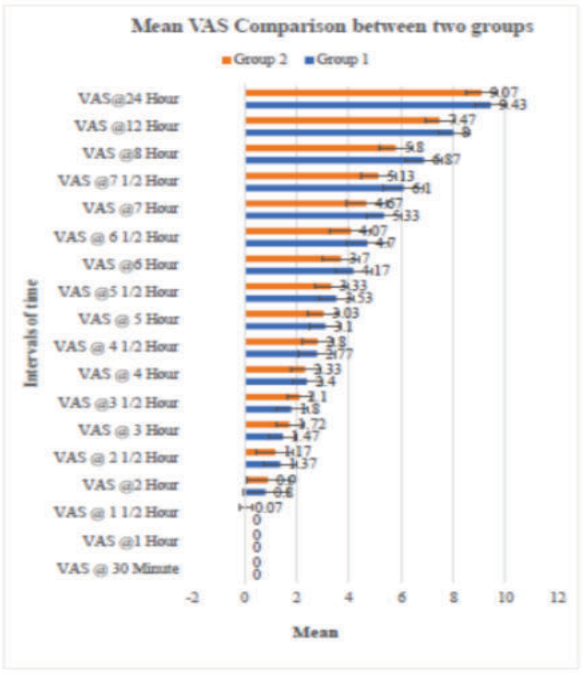

	Group				p value
	Group 1		Group 2		
	Mean	SD	Mean	SD	
Duration of analgesia	335.17	33.95	382.43	39.25	< 0.001*

DISCUSSION

An observational study was done by involving 60 patients under ASA I and II to Compare the Epidural Bupivacaine and Dexamethasone Versus Epidural Bupivacaine and Fentanyl for prolongation of post operative analgesia in elective lower limb orthopedics surgery. Based on the observations and results obtained in our study involving 30 patients in each group are discussed in detail by comparing with the available evidences in the literature. The analgesic efficacy of epidurally administered 0.5% bupivacaine + 50 µg fentanyl (Group 1) and 0.5% bupivacaine + 4 mg dexamethasone (Group 2) was studied.
All the demographic variables like age, sex, were comparable to each other. There is no statistically significant difference between the parameters. The two-segment time regression was comparable between all the two groups.

The onset of analgesia was earlier in the fentanyl and local anesthesia group when compared to the dexamethasone and local anesthesia group. This finding correlates with the study done by Manpreet Kaur et al[8] in 2008 who studied the effect of 2.5 ml of 0.5% bupivacaine in spinal anesthesia and 1.5 ml 0f 0.5% bupivacaine along with opioids like 25 mcg butorphanol and 1.5 ml of epidural 1.5 ml of 0.5 % bupivacaine 10 mcg sufentanil in spinal anesthesia. In his study he concluded that opioids resulted in early onset of action, low post operative VAS score and analgesic requirements and prolonged analgesic duration similar to our study which showed Fentanyl adjuvant with local anesthesia leads to early onset of action compared to the Dexamethasone and local anesthetic .

The onset of analgesia was earlier in the group 1 receiving fentanyl (331 seconds) than compared with group 2 receiving dexamethasone (393 seconds). This correlates with study of Youn Yi Joun et al., [9] in 2011 compared outcomes of epidural 0.25% ropivacaine with fentanyl 50 mcg and epidural 0.25% ropivacaine with dexamethasone 5 mg in patients undergoing radical subtotal gastrectomy as a randomized controlled study concluded that epidural fentanyl resulted in early onset of action, Epidural Dexamethasone shows less VAS scores and less rescue analgesic requirements than opioid group.

The results of our study correlate with study done by Khafagy et al., [10] in (2010). studied the effect of epidural dexamethasone in patients undergoing lower abdomen surgeries. In his study Group 1patients received 10cc of 0.25 % bupivacaine alone and Group 2 patients received 10cc of 0.25 % bupivacaine and fentanyl 50 mcg epidurally and Group 3 patients received 10cc of 0.25%bupivacaine with 4 mg dexamethasone. he concluded that epidural dexamethasone resulted in low post operative pain score and analgesic requirements and prolonged analgesic duration and correlate with our study.

Shrestha et al.,[11] in 2007compared addition of dexamethasone (8 mg) or tramadol (2 mg/ kg) to bupivacaine in brachial plexus block, and the duration of postoperative analgesia was substantially more in the dexamethasone group than in tramadol group (1028 and 453 min), This results confirms the results of our study that bupivacaine and dexamethasone gives more duration of analgesia compared to bupivacaine and fentanyl.

There was statistically significant difference in the incidence of nausea, vomiting, and pruritus in group 1 patients receiving fentanyl compared with group 2 patients receiving dexamethasone .This correlated with the study done by Bisgaard et al[12] in 2003 who conducted a double blind study in 88 patients were randomized into iv dexamethasone 8 mg and placebo 90 mins before laparoscopic cholecystectomy, concluded that less incidence of nausea, pruritus, overall pain following IV administration of dexamethasone 8 mg. This results corelates with our study drug of dexamethasone has less side effects.

CONCLUSION

We conclude that epidural administration of bupivacaine +dexamethasone admixture resulted in better postoperative analgesia in terms of lower postoperative pain score, prolonged postoperative analgesia and patient comfort with fewer side effects when compared with the other group of epidural bupivacaine+fentanyl.

We also conclude that this epidural dexamethasone resulted in prolonged postoperative analgesia compared to epidural fentanyl without any side effects like nausea, vomiting, pruritus, sedation except hypotension in few patients.

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