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EPIDURAL FENTANYL AND FENTANYL PLUS MAGNESIUM FOR POST-OPERATIVE ANALGESIA: A COMPARATIVE STUDY

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ABSTRACT **Aim:** To compare and study duration of analgesia, haemodynamic stability and side effects, if any. **Introduction:** CSE block combines the rapidity, density, and reliability of the subarachnoid block with the flexibility of continuous epidural block to extend duration of analgesia. Epidural opioids are proven to be very effective for postoperative analgesia. **Materials And Methods:** A prospective, study was undertaken in patients posted for elective lower limb surgeries. 50 patients age 35-45 years with ASA class I and II were randomly grouped into two groups. Group I – were given epidural fentanyl. Group II– were given epidural fentanyl with magnesium. **Results:** Group II patients had prolonged duration of fentanyl analgesia without any significant side effects. **Discussion:** The addition of magnesium 50mg to epidural fentanyl 50µg prolongs the duration thus provides better analgesia and reduces the requirements of rescue analgesics. **Conclusion:** Addition of magnesium sulfate (50 mg) to epidural fentanyl (50 µg) for elective lower limb orthopedic surgeries has prolonged the duration of fentanyl analgesia without any significant side effects.

KEYWORDS : CSE, magnesium, fentanyl, post-operative analgesia

INTRODUCTION

- The term "acute pain" refers to the typical physiological reaction to a negative chemical, thermal, or mechanical stimulation.[1]
- The continuous spinal epidural (CSE) block technique is widely employed in major orthopedic surgery and obstetrics.[2]
- To extend the duration of analgesia, it combines the rapidity, density, and dependability of subarachnoid block with the flexibility of continuous epidural block.

Drugs Used For Epidural Analgesia:

1. Local anaesthetics[3]
2. Opioids[4]
3. Local anaesthetic – opioid combinations[5]
4. Other Adjuvants[6]:

When using epidural infusion, a number of adjuvants are employed to maximize analgesia and reduce adverse effects, such as Clonidine[7,8], Epinephrine[9,10], Ketamine[11], Sodium bicarbonate[12], Anticholinesterases[11], Magnesium[13,14].

- Postoperative analgesia has been shown to respond very well to epidural opioids.
- Fentanyl is more lipophilic than other frequently used opioids, which allows it to absorb from the epidural space quickly and spread less rostrally in the body.[15]
- It also results in a lower incidence of side-effects such as respiratory depression, urinary retention, nausea, and vomiting.[15]
- With regard to its quick analgesic effect and brief duration of action, epidural fentanyl is the preferred medication for treating acute pain following surgery.[15]
- It has been demonstrated that intrathecally given magnesium, a non-competitive NMDA antagonist, prolongs the duration of spinal opioid analgesia in humans.[16].
- Patient-controlled epidural fentanyl consumption has significantly decreased with the co-administration of epidural magnesium for postoperative epidural analgesia, and there have been no negative side effects.[14].
- Based on these data, a study comparing the effects of epidural fentanyl and fentanyl with magnesium on side effects, hemodynamic stability, and analgesia duration was conducted on patients undergoing elective lower limb orthopedic surgery.

AIMS AND OBJECTIVES

In order to evaluate and compare the effectiveness of epidural fentanyl and the combination of epidural fentanyl and magnesium given after lower limb surgery with regard to:

1. Duration of analgesia
2. Hemodynamic stability and
3. Side effects, if any

MATERIALS & METHODS

Study Design: A prospective randomized comparative clinical study.

Method Of Data Collection: The data will be collected in the pre-tested proforma consisting of age, sex, and weight meeting the objectives of the study.

Study Population: Patients with ASA I & II, aged 35-45 years posted for lower limb orthopaedic surgeries.

Sample Size: 50 patients in the department of anaesthesiology at Santhiram Medical College and General Hospital,Nandyal for a duration of 6 months.

Sampling Criteria:

Inclusion Criteria

1. Patients who gave written and informed consent.
2. Patients aged between 35-45years of age posted for elective lower limb surgeries
3. ASA grade I & II

Exclusion Criteria

1. Patient who did not give written and informed consent.
2. Individuals with morbid obesity.
3. People suffering from coagulopathy.
4. People with abnormalities of the spinal column
5. Severe neurological deficiencies or local sepsis.

Statistical Analysis

- The demographic data were analyzed using either Student's t-test (or) chi-square test.
- Quantitative data was analyzed by student's t test and qualitative data was analyzed by chi-square test.
- All values were expressed as mean + (or) – standard deviation.
- $P < 0.05$ was considered statistically significant.

METHODOLOGY

A randomized single-blinded study was taken up among 80 patients aged between 35-45 years undergoing lower limb surgeries in the department of anaesthesiology at Santhiram medical college and general hospital for a duration of 6 months. An informed, bilingual and written consent was obtained from all the patients.

All the patients underwent pre anesthetic check-up.

- The procedure of the technique and the development of paraesthesia were explained to the patient to ensure good co-operation.
- All the patients were asked to fast for at least six hours before the surgery.
- In the surgery room, we monitored for patient's electrocardiograph

(ECG), heart rate, oxygen saturation (SpO2) and blood pressure.
- Baseline vital parameters were also assessed. Premedication with Alprazolam 0.5mg is given one night before surgery.
- After shifting the patient to the operation theatre (OT), monitors were connected, and IV line was secured.
- Patient in lateral or sitting position, back was draped,18G epidural catheter is inserted and lumbar puncture done with 25G spinal needle.
- Sub arachnoid block achieved.
- Following block regression, patients meeting the inclusion and exclusion criteria were split into two groups of twenty-five patients each at random.

Group I – To receive epidural fentanyl 50 µg (1ml) diluted and made up to 10ml with normal saline.

Group II – To receive epidural fentanyl 50 µg (1ml) + Magnesium sulphate 50mg diluted and made up to 10ml with normal saline.

- Patients are monitored for,
- Duration of analgesia
- haemodynamic changes – HR, NIBP
- respiratory rate, SpO2
- Side effects – nausea, vomiting, pruritus, shivering etc.

RESULTS

Table- I: Comparison Of Duration Of Analgesia

Variable	Group I	Group II	Significance
Duration of analgesia (min)	107.00 ± 25.82	143.40 ± 39.57	T=3.852;p<0.001**

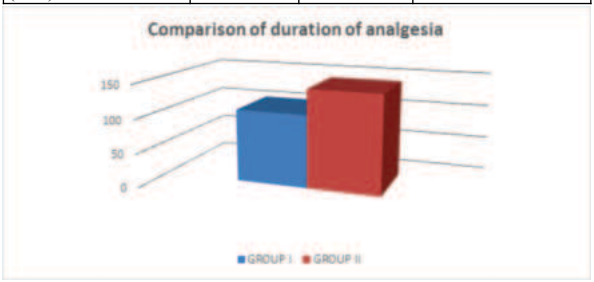

Figure 1

Group II experienced a considerably longer duration of analgesia in comparison to Group I.

65 minutes was the minimum analgesic duration in group I, and 80 minutes in group II.

Group I's and Group II's maximum analgesic durations were 170 and 215 minutes, respectively.

Table – II: Comparison Of Heart Rate Between Two Groups

Pulse rate	Group I	Group II	Significance
1 minute	84.16±13.45	81.44±12.07	T=0.753;p=0.455
5 minute	84.64±14.16	79.64±9.05	t=1.488;p=0.143
15 minute	84.16±13.31	78.60±8.49	t=1.761;p=0.085
30 minute	83.64±11.93	79.20±8.66	t=1.506;p=0.139
1 hr	84.84±9.41	79.24±6.62	t=2.432;p=0.019*
1 hr 30 min	87.95±9.75	82.00±8.50	t=2.211;p=0.032*
2 hr	92.33±11.75	85.88±6.77	t=1.693;p=0.104
2 hr 30 min	95.33±12.86	86.10±6.99	t=1.675;p=0.122

The heart rate in Group II was steady during the trial period, while it increased significantly in Group I after one hour

Table-III: Comparison Of Mean Arterial Pressure

MAP (mm Hg)	Group I	Group II	Significance
1 minute	84.56±7.87	86.48±7.68	T=0.873;p=0.387
5 minute	84.51±7.73	85.72±5.42	T=0.643;p=0.524
15 minute	85.17±7.3	85.27±4.57	T=0.054;p=0.957
30 minute	84.61±7.03	85.08±4.51	T=0.279;p=0.781
1 hr	87.42±6.48	87.84±4.53	T=0.262;p=0.795
1 hr 30 min	91.65±5.84	90.56±4.77	T=0.683;p=0.498
2 hr	95.55±9.42	92.19±5.36	T=1.111;p=0.278
2 hr 30 min	91.33±3.71	90.70±5.72	T=0.178;p=0.862

MAP was comparable and remained constant in both groups.

Table – IV: Comparison Of Oxygen Saturation

SPO2 (%)	Group I	Group II	Significance
1 minute	98.88±0.78	98.72±0.61	Z=0.797;p=0.426
5 minute	98.76±0.83	98.68±0.69	Z=0.274;p=0.784
15 minute	98.96±0.68	98.76±0.52	Z=1.081;p=0.280
30 minute	98.96±0.61	98.80±0.58	Z=0.936;p=0.349
1 hr	99.08±0.57	98.96±0.45	Z=0.833;p=0.405
1 hr 30 min	99.04±0.67	98.95±0.46	Z=0.530;p=0.596
2 hr	99.17±0.41	99.00±0.33	Z=1.015;p=0.310
2 hr 30 min	98.67±0.58	99.00±0.00	Z=1.626;p=0.068+

There was no significant variation in oxygen saturation in both the groups after administering test drugs. It was stable and comparable.

Table V: Adverse Events In Two Groups

Adverse events	Group I (n=25)	Group II (n=25)	Significance
Nausea/ Vomiting	1(4.0%)	2(8.0%)	NS
Pruritis	0	0	NS
Urinary retention	00	1(4.0%)	NS
Others	0	0	NS

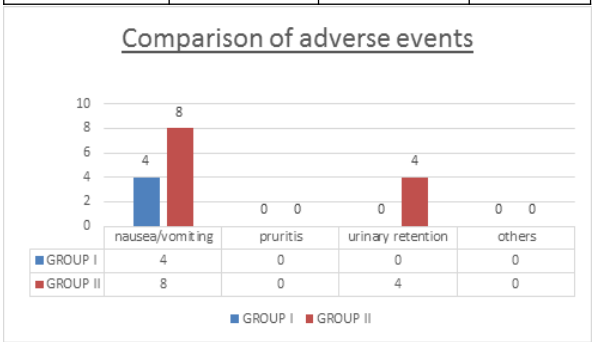

Figure 2

Incidence of side events such as nausea/vomiting, pruritus, urine retention, and others did not significantly differ between the two groups

DISCUSSION

- Ineffective treatment of postoperative pain can result in chronic postsurgical discomfort.[6]
- It has been demonstrated that epidural anesthesia and analgesia not only relieve pain but also lessen the frequency and severity of perioperative physiologic disturbances.
- Adjuvants like magnesium and other opioids can prolong and enhance post-operative analgesia
- Since epidural fentanyl produces analgesia quickly and has a short half-life, it has been the medication of choice for treating immediate postoperative pain.[15]
- An effective single epidural dose of 50–100 µg of fentanyl has been reported to have a quick onset of analgesia (5–10 min) and a shorter half-life (2-4 hrs).
- In order to provide patient-controlled epidural analgesia, Bilir et al.[14] employed a 50 mg bolus epidural magnesium infusion, followed by a continuous 100 mg (24 ml) epidural infusion for 24 hours (1 ml/hr) postoperatively.
- This concluded that there was lesser requirement of fentanyl in group II compared to group I at the end of 24hr.
- In Arcioni et al.[13]'s trial, the patient received an epidural infusion of magnesium sulphate (2%–5 ml/hr) at a rate of 100 mg/hr using an epidural elastometric pump. After administering spinal anesthetic, the infusion was started, and it was stopped after 36 hours of nonstop infusion.
- Patients used a PCA pump supplied with morphine hydrochloride for postoperative analgesia.
- In both the above given studies, the haemodynamic variables are stable.

CONCLUSION

When it came to the maximum level of sensory blockade reached, the amount of time it took to reach the highest level of sensory blockade, and the amount of time it took for the sensory blockade to regress, the outcomes of our study comparing epidural fentanyl with epidural

fentanyl + magnesium for postoperative analgesia were similar,

However, for elective lower limb orthopedic procedures, adding magnesium sulfate (50 mg) to epidural fentanyl (50 µg) has extended the duration of fentanyl analgesia without causing any appreciable side effects.

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