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An observational prospective study on the effect of bolus epidural single dose of magnesium as an adjuvant to epidural fentanyl for postoperative analgesia in patients undergoing combined spinal epidural anesthesia.

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ABSTRACT: Introduction: Magnesium(Mg) has been used as an adjuvant to many local anesthetics and has been administered through different routes (iv, i.m, epidural). This was a prospective observational study done in a tertiary care setting. The main objective of this study was to evaluate the efficacy of magnesium as an adjuvant to epidural fentanyl for post-operative pain control in subjects who are undergoing total hip replacement (THR)

Aims and Objectives:1. To evaluate the duration of post-operative analgesia in Mg as an adjuvant to fentanyl.

2. Total duration of analgesia consumed in 24 hours.

Patients and Methods: 50 subjects were selected randomly who were undergoing THR surgery under spinal anesthesia. All subjects received epidural anesthesia with 2 mL of 0.5% hyperbaric bupivacaine intrathecally. Post-operatively, subjects were divided into Group eF [epidural fentanyl group] and Group eFM [epidural magnesium fentanyl group]. Dosage and frequency of Supplementary analgesia (i.v tramadol 50 mg) was recorded and noted down.

Results: The duration of analgesia was significantly longer in Group eFM. The frequency of rescue analgesics in Group eFM was significantly less. VRS was significantly lower in Group e FM.

Conclusion: The administration of magnesium (75 mg) epidurally as an adjuvant prolongs duration of analgesia and significantly decreases post-operative pain in comparison with epidural fentanyl (1µg/kg) alone.

Keywords: analgesia,adjuvant,magnesium, fentanyl

I. INTRODUCTION:

Post-operative pain in THR can be managed by epidurally administering spinal anesthesia[1]. Various adjuvants have been tried and used epidurally to prolong the duration of analgesia[2].

Local anesthetics have a limited duration of action. For denser blocks and faster onset, various adjuvants have been added to local anesthetic solution while minimizing systemic adverse effects along with a reduction in total dose of local anesthetic used[1,2,3].

We designed this prospective observational study to investigate the effects of single bolus dose of magnesium sulfate (75mg) administration as an adjuvant to epidural fentanyl (1µg/kg) on post-operative pain relief and analgesic requirement in patients undergoing total hip replacement surgery.

Aims &Objectives

Primary Aim:

- To evaluate the duration of analgesia of a single bolus of magnesium as an adjuvant to epidural fentanyl for patients of THR surgeries

Secondary Aim:

- Total analgesic consumption in 24 hours in post-operative period.
- Adverse effects of the study drug (if any).

II. MATERIALS AND METHODS:

The study was conducted at the Govt. Bone and Joint Surgery Hospital, an associated hospital of Government Medical College Srinagarin the Department of Anesthesiology and critical care from October 2018 to September 2019. Ethical clearance was provided by hospital ethical committee group and written informed consent was

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taken from all the subjects undergoing THR Surgeries.Fifty subjectswho wereundergoing THR under CSE anesthesia were randomly selected for this study.

INCLUSION CRITERIA:

- Age ≥18 -65 years
- Both genders
- ASA I & II

EXCLUSION CRITERIA

- Age >65 and < 18
- Patients with hepatic, renal, cardiac dysfunction and atrioventricular blocks.
- Pregnant females.
- Patients with known hypersensitivity to local anaesthetics, opioids and magnesium.
- Patients on calcium channel blockers.
- All the known contraindications of centri-neuraxial block.
- Patients with neurological disorders or altered sensorium.
- ASA ≥ III.

PRE ANAESTHETIC-EVALUATION:

Patients selected for total hip replacement were already admitted by the respective orthopedic units. Pre anesthetic evaluation was done 24 hours prior to surgery.Complete history of any present or past medical ailments was taken and noted. Drug therapy, Drug Allergy, previous Anesthetic and surgical interventions were enquired and recorded.A thorough physical examination was carried out.

Motor block was evaluated using modified Bromage scale.

After the surgery, the patients were divided into 2 groups of 25 each; Group Ef and Group eFM. Group eFsubjects received epidural fentanyl (1 µg/kg) in 10 mL isotonic saline, while subjects in Group eFM received epidural magnesium (75 mg) in combination with fentanyl (1 µg/kg) diluted in isotonic saline making a total of 10 mL solution.

VAS ≤ 4 means that the patient had adequate pain relief. Rescue analgesia was given when VAS > 4(1mg/kgi.v.tramadol). Subjects first rescue analgesic was noted along with the frequency and total consumption of tramadol.

Post-surgical monitoring included VAS scores on rest, measurement of heart rate, BP,O_2 saturation, and any complication.Pain was regularly assessed and recorded at 0 hr (when patient reached PACU, 2 hour, 4 hour , 6 hour and 24 hour, In addition to the complaint of pain by patient at any time , Sedation was assessed on a 4-point Ramsay scale.

Neurologic complications were noted in all the subjects till 24 h post-operatively. Postoperative monitoring of vital parameters was recorded at 30 min intervals for first hour, then hourly for the next 3 hours and 2hourly for the 8hour period and then every 4hourly for next 12 hours.

Statistical analysis

Statistical software SPSS v 23 and Microsoft Excel were used to carry out the statistical analysis of data. Descriptive statistics of data including percentages and means were reported. Normality of data was tested by Kolmogorov-Smirnov test.

III. OBSERVATION AND RESULTS:

Evaluation of the baseline characteristics of the groups showed that there were no significant differences in age (p >0.05), height (p >0.05) or weight (p >0.05).

Table 1: Demographic parameters (weight, height and age distribution)

Variable	Group	Group	P value
Weight (kg)	eF	eFM	0.900
Sample size	25	25	
Mean ± SD	64.6 ± 8.41	65.2 ± 9.41	
height (cms)			0.547
Mean ± SD	161.52 ± 5.97	160.44 ± 6.61	
Age			0.125
Mean ± SD	48.64 ± 11.77	43.52 ± 11.41	

The weight, height and age distribution in groups eF and eFM were comparable with mean weight in eFand eFM 64.64 kg and 65.2 kg respectively, the mean height in groups eF and eFM as 161.5 cm and 160.4cm respectively and the mean age of 48.64 years in group eF and 43.52 years in eFM.

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Table2:Duration of Surgery

Duration of Surgery (min)	eF	eFM	P value
Mean ± SD	105.6 ± 13.56	109.6 ± 13.22	

The mean duration of surgery in groups eFM was 109.6 ± 13.22 minutes and in group eF was105.6 ± 13.56minutes, hence both groups were comparable with no statistical significance. (p 0.296)

Table 3:Duration of Analgesia

Duration of Analgesia (pain free) in hours	eF	eFM	P Value
Mean ± SD	3.75 ± 1.65	6.31 ± 2.35	0.0001

Duration of analgesia (time from administration of study drug to patient's first complaint of pain) in Group eFM was 6.31±2.35hours (378±141 mins) and in Group eF was 3.75±1.65hours (225±99 mins) with a p 0.0001. It wasstatistically significantly prolonged in Group eFM compared to Group eF. Minimum analgesic duration in group eF was 1.35 hours(81 minutes) and 2.45 hours (147 minutes) in group eFM. Maximum analgesic duration in group eF was 7.15 hours(429 minutes) and group eFM was 12 hours (720 minutes).

Table 4: Total Rescue Analgesic Consumption and Frequency in 24 Hours (Tramadol1 mg/Kg).

frequency of analgesia in 24 hrs	eF	eFM	P Value
Sample size	25	25	<0.0001
Mean ± SD	2.16 ± 0.47	1.12 ± 0.34	
Total Analgesia Consumption (Tramadol 1mg/KG) in 24 hours			<0.0001
Mean ± SD	140.2 ± 30.22	70 ± 18.98	

The mean frequency (No. of doses of rescue analgesia in 24 hours) of rescue analgesia consumption (Tramadol) in group eFM was significantly lower.

Total Tramadol consumption was lower in groupeFM (70 ± 18.98), while as in group eF it was140.2 ± 30.22. (p< 0.0001)

Table 5: VAS score

Time	Group eF	Group eFM	p value
0hr	0±0	0±0	1
2h	1.3±0.6	1.2±0.7	0.411
4h	5.1±0.6	2.3±0.6	0.001
6h	2.1±0.5	4.3±0.5	0.001
8h	3.2 ± 1.2	1.6 ± 0.6	0.001
12h	4.2 ± 0.9	2.7 ± 0.5	0.001
24h	1.4±0.6	1.2±0.6	1

VAS score in group eFM was less when compared to eF group at same time intervals in post-operative period, though there was no statistical difference at 0 and 2hour of post-operative period but was statistically significantly less at 4, 6, 8 and 12 hours of post-operative period(p value, 0.0001).

The heart rate in two groups was comparable both in pre op and post op period. There was no significant rise or fall in heart after administering study drug (Fig. 1).

The trend in SBP remained stable and was comparable in both groups after study drug was administered. There was no significant change in SBP in the study period (Fig. 2).

The trend in DBP remained stable and was comparable in both groups after study drug was administered. There was no statistically significant variation in DBP at any point of time during study period (Fig. 3).

The mean saturation in groups eF and eFM was comparable at every point of time in

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study period. This variable was statistically insignificant throughout the study period.

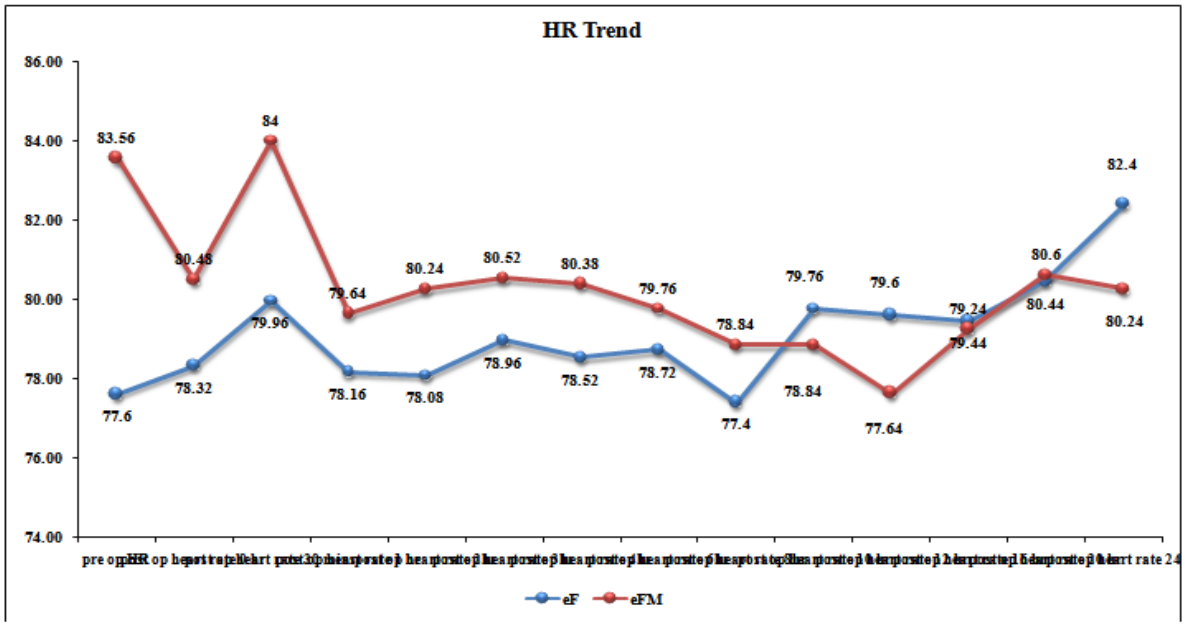

Fig.1: Trend in HR in both groups during study period

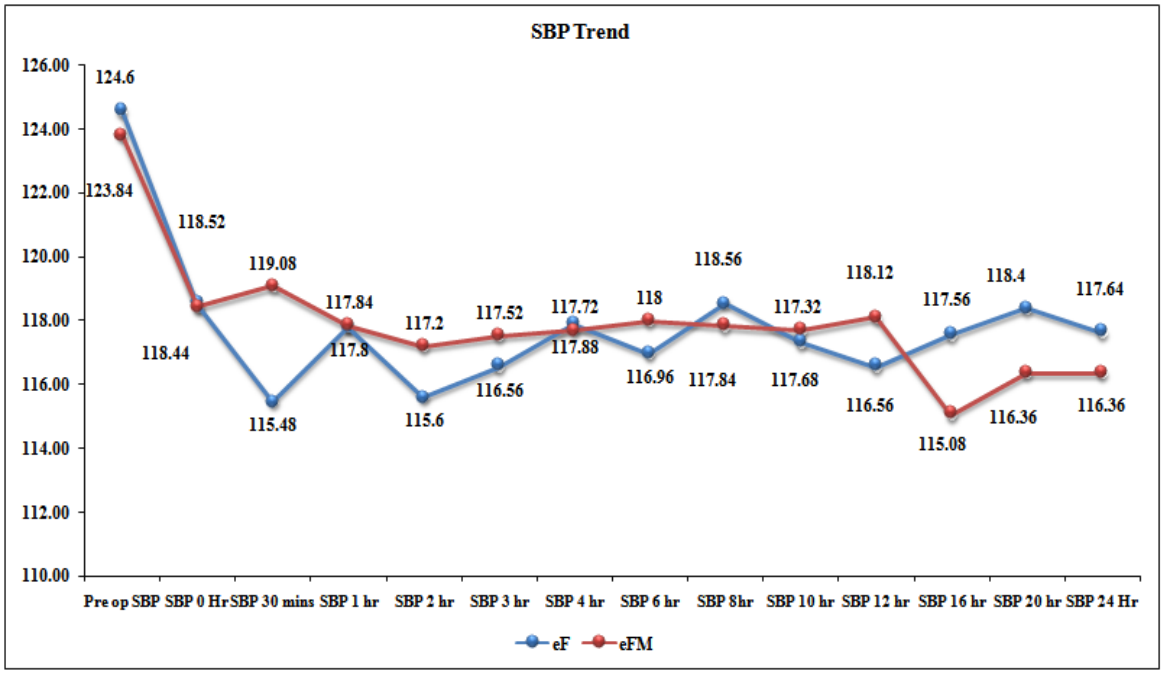

Fig.2: Trend in SBP in both groups during study period

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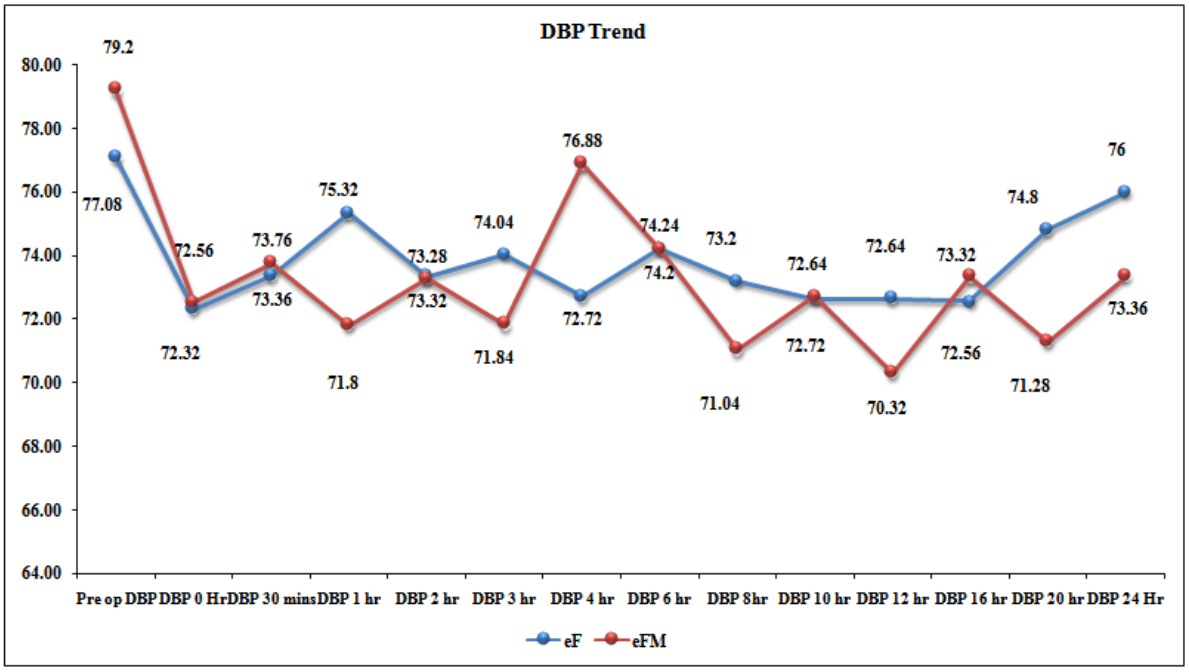

Fig.3: Trend in DBP in both groups during study period.

IV. DISCUSSION:

DURATION OF ANALGESIA & VAS SCORE:

In our study we found that the epidurally administered adjuvant magnesium increases the duration of analgesia in post-operative period [Group eFM 6.31±2.35 hour (378±141 mins) vs 3.75±1.65 hour (225±99 mins) in group eF with p 0.0001] thereby duration upto the first rescue analgesia is increased, consequently we found that the VAS score was low in eFM group as compared to eF group, when compared at same hours of post-operative period. The observations and results of our study weresimilar to many other studies.

Our results are similar to study by Deeepaksharma and colleagues[4] (2018) who demonstrated that 50mg of epidural Magnesium added to 50 mcg of epidural Fentanyl, in total hip replacement surgeries, significantly increases the average time (398 ± 69.55 mins) to rescue analgesia as compared to epidural fentanyl alone (264.83±38.03 mins)[4]. They also demonstrated the low VAS scores in the post-operative period in magnesium group[4]. The results of this study are similar with our study where the duration of analgesia in eFM group was similar(378±141 mins) with low VAS scalein post-operative period.

Like-wise our results are similar to the results of study by M. santhisree[5].The longer duration of analgesia(378±141 mins) in eFM group v (225 ± 99 mins in eF group) in our study can be attributed to higher dose of fentanyl used (1ug/kg). Our results also matches with the study of Sonali bainwait[6],

The results of our study coincided with the study by Sun et al[7]who compared the postcesarean analgesic profileof four different epidural solutions administered in the perioperative period[7]. All patients received 0.1% bupivacaine 10mL with one of the following: morphine 1.5 mg, magnesium 500 mg, morphine 1.5 mg and magnesium 500 mg, or placebo. Patients who received all three drugs (bupivacaine, magnesium, and morphine) had significantly lower postoperative pain scores at rest and with movement, an increased time to first analgesic request, and increased satisfaction at 24 hours after surgery compared with women who received only two drugs[7].

Prolongation of duration of analgesia by adding epidural magnesium to fentanyl has also been demonstrated in a study on labouranalgesia byBuvanendran A, McCarthy RJ[8].

In terms of VAS score our results are also highly consistent with the studies by Bilir[9](2007) and Arcioni[10] where it was concluded that administration of epidural magnesium in hip surgeries resulted in lower VAS scores[10].

The greater duration of post-operative analgesia and lower VAS score in our study at the same hours in post-operative period when compared to many of other studies can be explained by the fact that both the magnesium and fentanyl were used in higher doses.

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Post Operative Analgesic Consumption:

In our study the addition of epidural Magnesium to Epidural Fentanyl significantly decreased the totalrescue analgesic consumption in post-operative period.IV Tramadol (1mg/kg) was used as the rescue analgesia and its consumption and frequency of dosing was seen significantly decreased in eFM group. In eFM group, the mean frequency of rescue analgesia was 1.12±0.34 in 24 hours, significantly lower than eF group, where it was 2.16±0.47. The total rescueanalgesic consumption was significantly lower in eFM group (70±18.98) as compared to eF group (140.2±30.22).(p 0.0001). Hence the frequency of rescue analgesia requirement was lower in Group eFM in the 24-h study period.

Our results matched with results of study by M. Santhisree[5]who concluded that after the administration of single bolus epidural dose of magnesium sulfate (75 mg) with fentanyl(50µg) decreases the frequency of rescue analgesic (intravenous tramadol 50mg) required in 24hrs postoperative period in Group FM (2.3±0.5) was significantly less than in Group F (4.3±0.5) (p=0.001)

Our results are also consistent with results of study by Arcioni[10]andReem Abdel RaoufElsharkawy[11.]

The results of our study are comparable with study by Bilir and colleagues,who reported reduction in postoperative fentanyl consumption after adding epidural magnesium to epidural fentanyl[9].

Similar to our study, the results of study by M. Santhisree[5]concluded thatthe frequency of rescue analgesic in Groupmagnesium was statistically significantly less than in Group fentanyl.

ADVERSE EFFECTS:

The concern of neuromuscular blockade and neurological problems afteri.v magnesium[12,13,14]has been mentioned in the literature but no such side effects were seen in our study .

No patient complained of pruritis or any skin irritation. However only patient in eFM group had one episode of vomiting.Similar to our observations, Studies by shiva[12], sarika[13], Ramadan shabana[14], farouk[15] didn't observed any adverse effects of epidural magnesium in any of the patients.

LIMITATIONS:

1. We didn't check the dose response relationship of magnesium for post-operative pain.
2. Small sample size
3. Response of movement on pain was not assessed

V. CONCLUSION:

Epidural magnesium (75 mg) as an adjuvant prolongs duration of analgesia and significantly decreases post-operative pain in comparison with epidural fentanyl (1µg/kg) alone.

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