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

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ABSTRACT

BACKGROUND: Magnesium has antinociceptive effects in animal and human models of pain. It is found that the addition of magnesium to postoperative epidural infusion of fentanyl may decrease the need for fentanyl. We undertook a study to compare the duration of postoperative analgesia after epidural Fentanyl and epidural Fentanyl plus magnesium administered postoperatively, along with side effects.

MATERIALS AND METHODS: 100 patients undergoing elective lower limb surgeries were randomized into one of the two groups with 50 patients in each group. Combined Spinal Epidural Anesthesia was used for all patients. Spinal anesthesia with 2.5 cc of 0.5% hyperbaric bupivacaine was given. When sensory blockade regressed to L1, patients were given either 50µg of Fentanyl (diluted to 6cc with normal saline, Group F) or 50µg of Fentanyl plus 50 mg Magnesium (diluted to 6cc with normal saline, Group FM). Parameters like blood pressure, pulse rate, respiratory rate and oxygen saturation were monitored, and other side effects were noted. Data were analysed by using Student t test and Chi-square/ Fisher Exact tests.

RESULTS: There was significant difference in duration of analgesia between Group F (107 min) and Group FM (143 min). Hemodynamic parameters were stable in both the groups with minimal side effects.

CONCLUSION: Co-administration of magnesium with fentanyl for postoperative epidural analgesia results in prolongation of fentanyl analgesia without significant side-effects.

KEYWORDS : Fentanyl, hyperbaric bupivacaine, magnesium sulphate, Hemodynamic parameters.

INTRODUCTION

Epidural opioids are proven to be very effective for postoperative analgesia. Because of its greater liphophilic nature, *fentanyl* offers some advantages for epidural analgesia. Fentanyl undergoes rapid vascular absorption from the epidural space, and it spreads less rostrally than other commonly used opioids. It may also undergo uptake into epidural fat or diffusion across the dura into the cerebrospinal fluid (CSF). The rapidity of analgesic effect of epidural fentanyl administration and the relatively short duration of action makes it the drug of choice for postoperative acute pain. Liphophilic nature of fentanyl limits its cephalad migration and results in a lower incidence of side-effects such as respiratory depression, urinary retention, nausea, and vomiting (1).

Magnesium, the non-competitive NMDA antagonist, administered intrathecally, is proved to prolong the duration of spinal opioid analgesia in humans (2). Co-administration of epidural magnesium for postoperative epidural analgesia has provided a pronounced reduction in patient-controlled epidural fentanyl consumption without any side-effects (3).

On the basis of these evidences, a study was undertaken to compare the effects of epidural Fentanyl and Fentanyl plus magnesium on duration of analgesia, hemodynamic stability and side effects in patients undergoing elective lower limb orthopedic surgeries.

MATERIALS AND METHODS

The present randomized comparative study was conducted in Department of Anaesthesia, PES Institute of Medical Sciences, Kuppam during January 2016 to April 2017. A total 100 cases of ASA grade I and II undergo elective lower limb orthopedic surgeries were recruited. Cases between age group 35 to 45 years posted for elective lower limb surgeries were included. Cases with vertebral column defects, local sepsis or significant neurological deficits, obese cases and cases with coagulopathies were excluded.

Informed consent was obtained from all the cases and study protocol was approved by institutional ethics committee. Based on the drug administered cases were randomly allocated into two groups i.e. Group F (n=50) administered with epidural fentanyl 50µg (1cc) diluted and made up to 6cc with normal saline and Group FM (n=50) administered with epidural fentanyl 50µg (1cc)+ Magnesium sulphate 50mg (4 units in insulin syringe of 50% solution) diluted and made up to 6cc with normal saline. Preoperatively, routine laboratory investigations was conducted for all the cases.

Spinal anesthesia with 2.5 cc of 0.5% hyperbaric bupivacaine was given. When sensory blockade regressed to L1, patients were given either 50µg of Fentanyl (diluted to 6cc with normal saline, Group F) or 50µg of Fentanyl plus 50 mg Magnesium (diluted to 6cc with normal saline, Group FM). Parameters like blood pressure, pulse rate, respiratory rate and oxygen saturation were monitored, and other side effects were noted. Data were analysed by using Student t test and Chi-square/ Fisher Exact tests.

RESULTS

Table 1: Age wise and gender wise distribution of patients.

Age and gender	Group F	Group FM	Significance
Number of patients	50	50	
Age in years	39.92±4.23	40.6±4.46	t=0.553;p=0.583
Male	36 (72.0%)	36 (72.0%)	$\chi 2$=0.000;P=1.000
Female	14(28.0%)	14(28.0%)	

Table 2: Comparison of type of cases.

Age and gender	Group F	Group FM
Fracture femur	18 (36%)	22 (44%)
Fracture patella	10 (20%)	8 (16%)
Fracture both bone leg or tibia	18 (36%)	14 (28%)
Split skin graft of leg	4 (8%)	6 (12%)

Table 3: Comparison of highest sensory level.

Highest sensory blockade	Group F	Group FM
T10	0	6(12.0%)
T9	14(28.0%)	12(24.0%)
T6	30(60.0%)	30(60.0%)
T5	6(12.0%)	2(4.0%)
Inference	Highest sensory blockade is statistically similar between two groups with P=0.324	

Time taken for attainment of highest sensory level and duration of surgery

Comparison of time taken for regression of sensory block to L1
Comparison of duration of analgesia

Comparison of time for regression to L1 and duration of analgesia

Variables	Group F	Group FM	Significance
Time taken for highest sensory level (min)	13.92±4.50	12.24±3.43	T=1.485;p=0.144
Duration of surgery(min)	99.00±13.31	92.20±15.21	T=1.682;p=0.099
Time for Regression to L1 (min)	118.80±13.41	119.60±17.85	T=0.179;p=0.859
Duration of analgesia (min)	107.00±25.82	143.40±39.57	143.40±39.57

Figure 1. Comparison of pulse rate between groups.

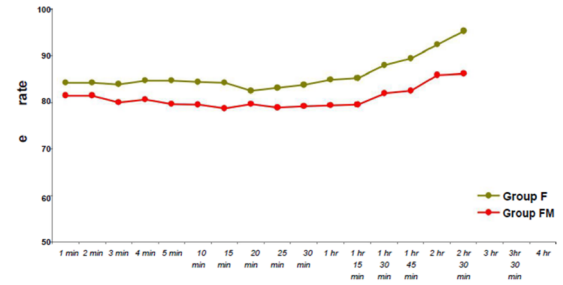


Figure 2. Comparison of SBP between study groups.

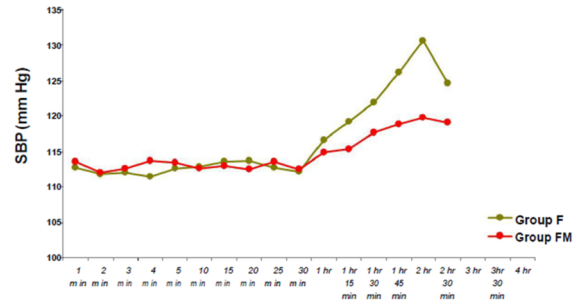


Figure 3. Comparison of DBP between study groups.

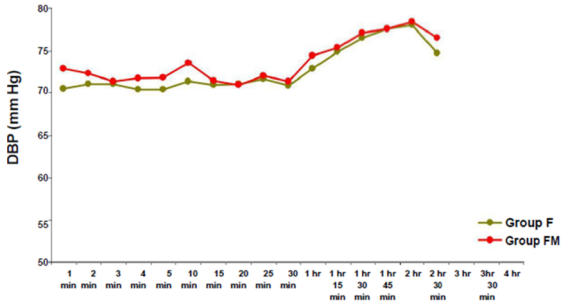


Figure 4. Comparison of MAP between study groups.

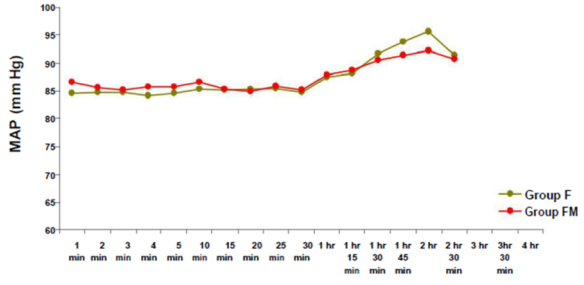


Figure 5. Comparison of oxygen saturation between study groups.

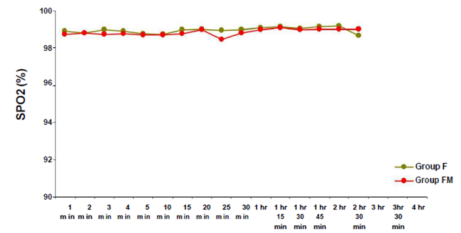
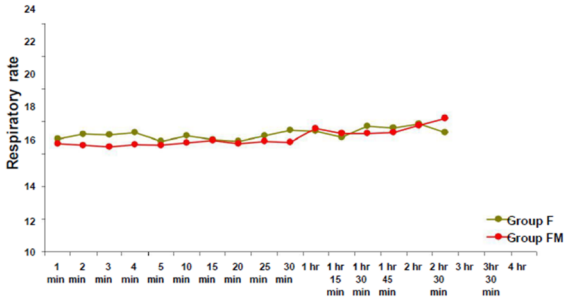


Figure 6. Comparison of respiratory rate between study groups.



DISCUSSION

Postoperative pain may produce a range of detrimental effects and if not treated effectively may lead on to chronic postsurgical pain (13). Combined Spinal Epidural block, as it combines the rapidity, density, and reliability of the subarachnoid block with the flexibility of continuous epidural block to extend duration of analgesia, is used for the study purpose (4).

Highest level of sensory blockade achieved in both the groups was comparable (T6 in 60% of the patients) and statistically similar (p=0.324). Time taken for highest sensory level was comparable in both the groups. Duration of surgery was also comparable in both the groups. Time taken for regression of sensory blockade to L1 (Group F 118.80 min, Group FM 119.60 min, p=0.859) was comparable in both the groups. Test drug was administered at this point of time in all the patients.

In the present study, there was significant prolongation of duration of analgesia in Group FM (143.40 mins) compared to Group F (107.0 mins) with p<0.001. Out of 50 patients in Group F, maximum duration of analgesia was 170 min and minimum was 65 min with a Mean of 107.0 ± 25.82. In Group FM maximum duration of analgesia was 215 min and minimum was 80 min with a Mean of 143.4 ± 39.57.

There was significant increase in pulse rate in Group F compared to Group FM from 1 hour 15 minutes. Similarly there was significant increase in SBP in Group F compared to Group FM from 1 hr 30 minutes. These parameters remained stable in Group FM. The DBP and MAP between the two groups were comparable throughout the study period, and they were stable. Significant increase in the pulse rate and SBP in Group F compared to Group FM in our study from 1 hour 15 minutes could be attributed to onset of patients' pain (coinciding with the wear off of the analgesic effect : mean duration of analgesia in Group F was 107 min, with minimum analgesic duration of 65 min ± SD25.8). Oxygen saturation and respiratory rates remained stable, and there was no significant difference between the groups. Thus we infer that Mg 50 mg administered epidurally along with fentanyl has no significant cardiorespiratory adverse effects.

2 patient (4%) in Group F and 4 patients (8%) in Group FM experienced nausea/ vomiting which was not statistically significant. 2 patient (4%) in Group FM experienced urinary retention and was not statistically significant. There was no incidence of pruritus or any other adverse effects in both the groups.

CONCLUSION

In our study comparing epidural fentanyl and epidural fentanyl plus magnesium for postoperative analgesia, the results were comparable with respect to highest sensory blockade attained, time taken for highest sensory blockade and time to regression of sensory blockade to L1. But addition of magnesium sulfate (50 mg) to epidural fentanyl (50µg) for elective lower limb orthopedic surgeries has prolonged the duration of fentanyl analgesia without any significant side effects.

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