COMPARATIVE STUDY OF EPIDURAL FENTANYL AND FENTANYL PLUS MAGNESIUM SULPHATE FOR POSTOPERATIVE ANALGESIA

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ABSTRACT

AIMS AND OBJECTIVES

Magnesium has antinociceptive effects in animal and human models of pain. It is found that the addition of Magnesium sulphate 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 sulphate administered postoperatively, along with side effects.

MATERIALS AND METHODS

50 patients undergoing elective lower limb and abdominal surgeries were randomized into one of the two groups with 25 patients in each group. Combined Spinal Epidural Anaesthesia was used for all patients. Spinal anaesthesia with 2.5 cc of 0.5% Hyperbaric Bupivacaine was given. When sensory blockade regressed to L1, patients were given either 50 µg of Fentanyl (diluted to 6cc with normal saline, Group F) or 50 µg of Fentanyl plus 50 mg Magnesium sulphate (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 sulphate with Fentanyl for postoperative Epidural analgesia results in prolongation of Fentanyl analgesia without significant side-effects.

KEYWORDS

Analgesic techniques, Extradural; Pain, Postoperative; Pharmacology, Fentanyl; Pharmacology, Magnesium sulphate.

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INTRODUCTION: Continuous Spinal Epidural (CSE) block combines the rapidity, density and reliability of the subarachnoid block with the flexibility of continuous Epidural block to extend duration of analgesia. The CSE technique has become popular for major orthopedic surgery[1] and in obstetrics.

The role of Epidural anaesthesia and analgesia in reducing the incidence and severity of perioperative physiologic derangements, in addition to relieving pain has been reported in several studies.

Drugs used for Epidural analgesia: Local anaesthetics,[2] Opioids, Local anaesthetic-opioid combinations and other Adjuvants. A variety of adjuvants are used for Epidural infusion to enhance analgesia while minimizing side effects, like Clonidine,[3,4] Epinephrine,[5,6] Ketamine,[7] Sodium bicarbonate, Anticholinesterases, Magnesium etc.

Epidural opioids are proven to be very effective for postoperative analgesia. Because of its greater lipophilic 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[8] administration and the relatively short duration of action makes it the drug of choice for postoperative acute pain. Lipophilic 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.

Magnesium, the non-competitive NMDA antagonist, administered intrathecally, is proved to prolong the duration of spinal opioid analgesia in humans. Co-administration of

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Epidural Magnesium sulphate for postoperative Epidural analgesia has provided a pronounced reduction in patient-controlled Epidural Fentanyl consumption without any side-effects.

On the basis of these evidences, a study was undertaken to compare the effects of Epidural Fentanyl and Fentanyl plus Magnesium sulphate on duration of analgesia, hemodynamic stability and side effects in patients undergoing elective lower limb and abdominal surgeries

METHODOLOGY: The present study was a prospective, randomized, comparative clinical study, was conducted in patients scheduled to undergo elective lower-limb and abdominal surgeries in MNR Medical College and Hospital, Sangareddy. Ethical clearance was obtained from MNR Institutional Ethical committee, Sangareddy. 50 ASA I/II patients scheduled to undergo elective lower limb and abdominal surgeries were selected for the study and randomly allocated into one of the two groups:

Group F (25 patients): To receive Epidural Fentanyl 50 µg (1cc) diluted and made up to 6cc with normal saline.

Group FM (25 patients): To receive Epidural Fentanyl 50 µg (1cc)+ Magnesium sulphate 50mg (4 units in insulin syringe of 50% solution) diluted and made up to 6cc with normal saline.

Preoperatively the following routine investigations were done in all patients.

Blood - Hb%, Blood Grouping & Rh typing, Bleeding time, Clotting time.

RBS, blood urea, serum creatinine.

Urine - albumin, sugar and microscopy.

ECG, X-ray chest, Serum electrolytes if necessary.

Informed/written valid consent was obtained from each patient before starting the study. Every patient was supplied with patient information sheet before taking the consent.

Inclusion Criteria: Patients aged between 35 to 45 years of age of either sex.

Posted for elective lower limb and abdominal surgeries.

ASA grade I/II.

Exclusion Criteria: Patients' refusal: Morbidly obese patients and patients with coagulopathies.

Patients with vertebral column defects, local sepsis or significant neurological deficits.

ASA grade III/IV/V.

A specially designed proforma was used to collect the data including patients' particulars, indication for surgery, the anaesthetic details, intra-operative monitoring, postoperative follow up, etc.

ANAESTHETIC PROCEDURE: COMBINED SPINAL EPIDURAL TECHNIQUE: After IV access, infusion of Ringer Lactate 10 ml/kg was commenced. Monitors were connected including Pulseoximeter, Non Invasive Blood Pressure and ECG. Basal parameters like blood pressure, pulse rate, SPO2 and respiratory rates were recorded.

Patient was put in lateral or sitting position. Under strict aseptic precautions the back was painted and draped, tips of lumbar spine were palpated and L2-3 or L3-4 space was selected. The skin was infiltrated with about 2 ml of 1% Lignocaine. The Epidural space was identified at L2-L3 or L3-L4 by midline approach using 16 gauge Tuohy's needle by loss of resistance technique. Dural puncture was performed by a needle-through-needle technique with a 25 G spinal needle and 2.5 ml of 0.5% Bupivacaine heavy injected into the intrathecal space. 18 G Epidural catheter is then inserted into the Epidural space. Routine intra-operative monitoring of pulse rate, blood pressure, oxygen saturation and respiratory rate was done for all the patients and the following parameters were noted.

a) Time taken for highest sensory level: It is time taken from giving spinal anaesthesia to maximum height of loss of pinprick sensation.
b) Time for regression to L1: It is time taken for the sensory blockade to regress to L1 after reaching highest sensory level.
c) Duration of surgery: It is time taken from skin incision to completion of surgery.
d) Duration of analgesia: It is the time interval from administration of study drug to the first complaint of pain.

After regression of sensory block (checked by pin prick) to L1, patients in Group F received 50 µg of Fentanyl and Group FM received 50 µg of Fentanyl plus 50 mg

Magnesium sulphate. Patients were monitored for

a) Duration of analgesia (as described above)
b) Haemodynamic changes - PR, NIBP
c) Respiratory rate, SpO2
d) Side effects - nausea, vomiting, pruritus, shivering etc.

After 30 minutes of monitoring in PACU patients were transferred to post-operative ward. Patients' first analgesic requirement time were recorded. Adverse events related to drug and Epidural catheter were observed for 24 hrs.

Results obtained were recorded, compared and analyzed statistically.

Statistical Software: The Statistical software namely SPSS 15.0, Stata 8.0, MedCalc.

9.0.1 and Systat 11.0 were used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs, tables etc.

OBSERVATION AND RESULTS: A comparative randomized study of 50 patients randomly divided into two groups with 25 patients in Group F (Epidural Fentanyl) and 25 patients in Group FM (Fentanyl + Magnesium sulphate) was undertaken to study the efficacy of the drugs in relation to duration of analgesia, and stability pattern of hemodynamics and incidence of adverse affects.

Highest sensory level attained:

Highest sensory Blockade	Group F (n=25)	Group FM (n=25)
T10	0	3 (12.0%)
T8	7 (28.0%)	6 (24.0%)
T6	15 (60.0%)	15 (60.0%)
T5	3 (12.0%)	1 (4.0%)
Inference	Highest sensory blockade is statistically	

Table 1: Comparison of highest sensory level

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

Variables	Group F	Group FM	Significance
Time taken for highest sensory level	13.92±4.50	12.24±3.43	T=1.485; P=0.144
Duration of surgery	99.00±13.31	92.20±15.21	T=1.682; P=0.099

Table 2: Comparison of time taken for highest sensory level and duration of srugery

Time taken for highest sensory level (Min) in Group F and Group FM were comparable. And also duration of surgery (min) in Group F was 99.00±13.31 and in Group FM was 92.20±15.21 with a p=0.099 and they were comparable.

Time for regression of sensory blockade to L1

Variable	Group F	Group FM	Significance
Time for regression to L1(min)	118.80±13.41	119.60±17.85	T=0.179; P=0.859

Table 3: Comparison of time taken for regression of sensory block to L1

Time for regression to L1 (min) in Group F was 118.80±13.41 and in Group FM was 119.60±17.85 with p=0.859 and they were comparable. Once the sensory level regressed to L1, test drug was administered.

Duration of analgesia:

Variable	Group F	Group FM	Significance
Duration of Analgesia (min)	107.00±25.82	143.40±39.57	T=3.852; P<0.001**

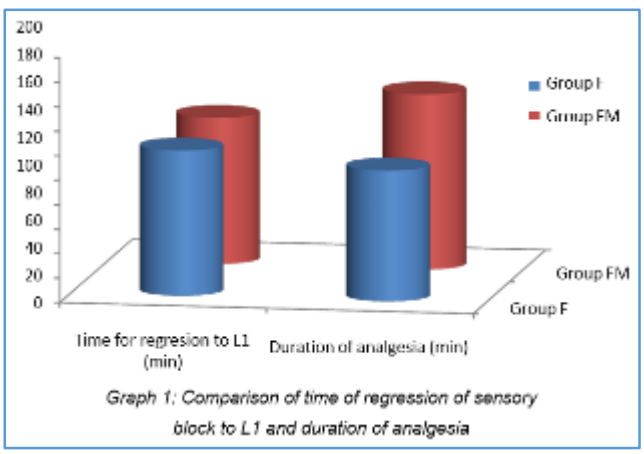
Table 4: Comparison of duration of analgesia

Duration of analgesia (time from administering test drug to patient's first complaint of pain) in Group FM was 143.40±39.57 min and in Group F was 107.00±25.82 min with a p<0.001**. It was significantly prolonged in Group FM compared to Group F. Minimum analgesic duration in Group F was 65 min and 80 min in Group FM. Maximum analgesic duration in Group F was 170 min and Group FM was 215 min.

Time for regression of sensory block to L1 and duration of analgesia:

Variables	Group F	Group FM	Significance
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	T=3.852; P<0.001**

Table 5: Comparison of time for regression to L1 and duration of analgesia



Graph 1: Comparison of time of regression of sensory block to L1 and duration of analgesia

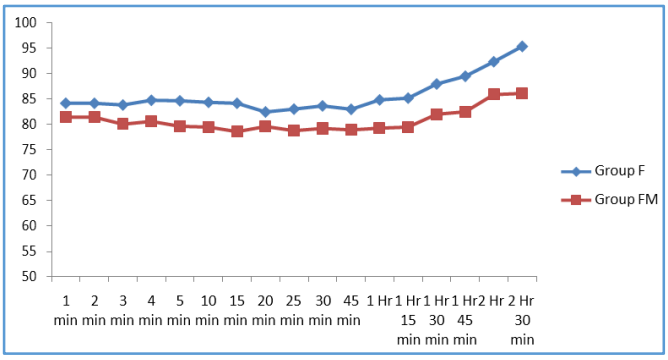
Time taken for regression of sensory level to L1 was comparable in both the groups, but duration of analgesia was significantly prolonged in Group FM compared.

Pulse rate in two groups:

Pulse	Group F	Group FM	Significance
1 minute	84.16±13.45	81.44±12.07	T=0.753;P=0.455
2 minutes	84.16±14.25	81.40±11.56	T=0.752;P=0.456
3 minutes	83.84±13.99	80.04±10.66	T=1.080;P=0.285
4 minutes	84.76±14.12	80.60±9.10	T=1.238;P=0.222
5 minutes	84.64±14.16	79.64±9.05	T=1.488;P=0.143
10 minutes	84.36±14.15	79.48±8.19	T=1.493;P=0.142
15 minutes	84.16±13.31	78.60±8.49	T=1.761;P=0.085
20 minutes	82.44±12.55	79.60±8.89	T=0.924;P=0.360
25 minutes	83.00±12.43	78.76±9.03	T=1.330;P=0.174
30 minutes	83.64±11.93	79.20±8.66	T=1.506;P=0.139
45 minutes	82.96±10.02	78.92±6.56	T=1.686;P=0.098+
1 hr	84.84±9.41	79.24±6.62	T=2.432;p=0.019*
1 hr 15	85.17±10.10	79.48±6.97	T=2.287;P=0.027*
1 hr 30	87.95±9.75	82.00±8.50	T=2.211;P=0.032*

1 hr 45	89.46±8.92	82.48±7.61	T=2.435;P=0.021*
2 hr	92.33±11.75	85.88±6.77	T=1.693;p=0.104
2 hr 30	95.33±12.86	86.10±6.99	T=1.675;p=0.122
3 hr	-	-	-
3 hr 30	-	-	-
4 hr	-	-	-

Table 6: Comparison of pulse rate between two

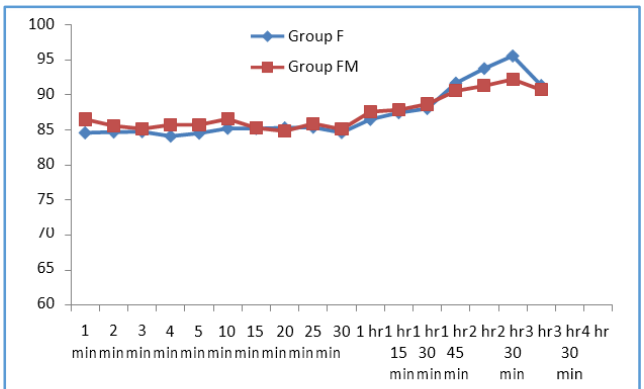


There was a significant increase in the pulse rate from 1 hr 15 min in Group F compared to Group FM, but it was stable in Group FM during the study period.

Mean BP amongst groups:

MAP (mm)	Group F	Group FM	Significance
1 minute	84.56±7.87	86.48±7.68	T=0.873;P=0.387
2 minutes	84.68±7.98	85.55±5.28	T=0.453;P=0.653
3 minutes	84.72±7.42	85.15±5.30	T=;0.234P=0.816
4 minutes	84.09±8.03	85.72±5.49	T=0.836;P=0.407
5 minutes	84.51±7.73	85.72±5.42	T=0.643;P=0.524
10 minutes	85.20±7.41	86.56±5.42	T=0.740;P=0.463
15 minutes	85.17±7.30	85.27±4.57	T=0.054;P=0.957
20 minutes	85.29±7.56	84.81±4.03	T=0.280;P=0.781
25 minutes	85.35±7.56	85.88±5.06	T=0.293;P=0.771
30 minutes	84.61±7.03	85.08±4.51	T=0.279;P=0.781
45 minutes	86.48±5.93	87.58±4.09	T=0.767;P=0.447
1 hr	87.42±6.48	87.84±4.53	T=0.262;P=0.795
1 hr 15 min	88.04±10.51	88.67±4.21	T=0.275;P=0.784
1 hr 30 min	91.65±5.84	90.56±4.77	T=0.683;P=0.498
1 hr 45 min	93.74±7.06	91.28±4.72	T=1.203;P=0.238
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
3 hr	-	-	-
3 hr 30 min	-	-	-
4 hr	-	-	-

Table 7: Comparison of Mean Areterial Pressure



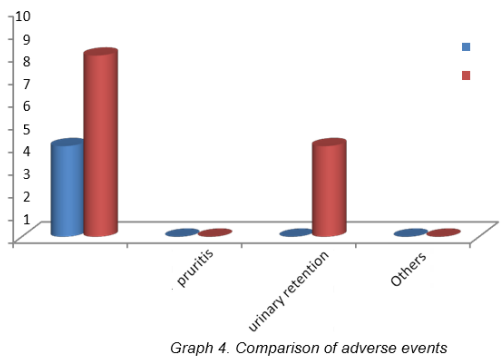
Graph 3: Comparison of MAP

MAP was stable throughout in both the groups and it was comparable.

Adverse events in two groups:

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

Table 8: Comparison of adverse events



Graph 4. Comparison of adverse events

There was no significant difference in incidence of adverse effects like nausea/vomiting, priritis, urinary retention and others in the two groups.

There was no significant difference in incidence of adverse effects like nausea/vomiting, priritis, urinary retention and others in the two groups.

DISCUSSION: 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.

Epidural anaesthesia and analgesia is proven to reduce the incidence and severity of perioperative physiologic derangements, in addition to relieving pain. Adjuvants such as opioids and Magnesium can improve the duration and quality of post operative analgesia.

Epidural Fentanyl, because of its rapidity of onset of analgesia and relatively short duration of action has been drug of choice for acute postoperative pain.

Effective single Epidural dose for Fentanyl is found to be 50- 100 µg, with rapid onset of analgesia in 5-10 min and shorter duration of action (2-4 hr).

Bilir, et al[9] in their study had used 50 mg of bolus Epidural Magnesium followed by continuous Epidural infusion of 100mg (24ml) for 24 hr (1ml/hr) post-operatively, along with Epidural Fentanyl infusion for patient controlled Epidural analgesia.

Arcioni, et al[10] in their study had started the patient on Epidural infusion of 100 mg/hr of Magnesium sulphate (2%-5 ml/hr) through Epidural elastometric pump. Infusion was started after giving spinal anaesthesia and was disconnected after 36hr of continuous infusion. Patients received postoperative analgesia through PCA pump loaded with morphine hydrochloride.

Based on the above studies, we fixed the dose of Epidural Fentanyl 50 µg bolus. We preferred to use a smaller dose of Epidural Magnesium bolus of 50 mg, that would not cause any side effects. And we undertook a study in 50 ASA I/ II patients posted for elective lower limb surgeries with 25 patients in each group, Group F (Fentanyl) and Group FM (Fentanyl+ Magnesium).

The demographic criteria were noted and various study parameters such as duration of surgery, duration of analgesia, hemodynamics and side effects were noted and compared among the two groups.

Age and gender distribution: In the present study both groups were comparable with respect to age (Group F 39.92 yr, Group FM 40.6 yr, p=0.583) and gender (both groups having 18 males and 7 females, p=1) distribution.

Study Parameters: 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.

Duration of analgesia: Since the duration of surgery and time to regression of sensory block to L1 was similar and comparable in both the groups statistically, the time between regression to L1, when test drug was given, and patients' first complaint of pain more correctly represents duration of analgesia due to test drugs with minimal bias associated with spinal block and duration of surgery.

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 25 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.

Noxious stimulation leads to the release of neurotransmitters, which bind to various subclasses of excitatory amino acid receptors, including NMDA[10,11] receptors. NMDA receptor signaling may be important in determining the duration of acute pain. Therefore, NMDA receptor antagonists may play a role in the prevention and treatment of post-injury pain. Magnesium blocks calcium influx and noncompetitively antagonizes NMDA receptor channels.[12] Mg can have an effect on pain when used alone, but it has also been shown that it can reveal the analgesic properties of opioids.[13] In this way the coadministration of Magnesium with Fentanyl may prolong Fentanyl analgesia.

In study conducted by Bilir, et al, where they used Fentanyl PCEA in Group F and Fentanyl PCEA with 50 mg bolus Mg and continuous Mg infusion Epidurally in Group FM, time to first analgesic requirement (comparable to duration of analgesia in our study) was slightly longer in Group FM (51.6 min) compared to Group F (37.1 min). Compared with patients in Group F, patients in Group FM received smaller doses of Epidurally infused Fentanyl at all time points after 30 min. There was 25% reduction in Fentanyl consumption in Group FM at the end of 24 hr compared to Group F. Thus, addition of Mg allowed lesser requirement of Fentanyl in the post operative period due to its NMDA receptor antagonist action and potentiation of opioid. analgesic effects. This is comparable to the results of the present study wherein adding Mg (50 mg) to Fentanyl (50 µg) Epidurally as a single dose markedly increased duration of Fentanyl analgesia in group FM compared to group F.

In the study conducted by R. Arcioni et al, using Epidural Mg infusion and morphine for postoperative analgesia, postoperative morphine requirements assessed for 36 hrs were less in Epidural Magnesium group (24.0 mg) compared to control group (38.96 mg). Mean morphine requirement was reduced by 38%. This was attributed to NMDA receptor antagonism of Mg and pain modulation and its potentiation of opioid analgesia. Similar potentiation of Fentanyl analgesia is seen with Epidurally administered Mg as a single dose in the present study.

Hemodynamic Changes: There was significant increase in pulse rate in Group F compared to Group FM from 1 hour 15 minutes.

The Mean Arterial Blood Pressure between the two groups were comparable throughout the study period, and they were stable.

Significant increase in the pulse rate 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 50mg Magnesium administered Epidurally along with Fentanyl has no significant cardiorespiratory adverse effects.

Bilir, et al.[9] in the study of Epidural Magnesium and Fentanyl for postoperative pain, found that SBP, DBP, MAP, pulse rate and oxygen saturations remained stable, and there was no significant difference between the groups. Epidural Mg had no adverse effects on cardiorespiratory systems.

No significant differences were found in cardio-respiratory variables like SBP, DBP, MAP, heart rate, respiratory rate or SPO2 between the groups in study, of Epidural Mg to reduce postoperative analgesic requirements, conducted by R. Arcioni, et al,[10] Magnesium maintained hemodynamic stability.

In the above mentioned studies (Bilir, et al, and Arcioni, et al.) the hemodynamic parameters were stable and comparable between the groups for the obvious reasons that one of the studies had used PCA (using morphine) and the other PCEA (using Fentanyl) for postoperative analgesia. Similarly in the present study, during the duration of analgesia, hemodynamic parameters were stable and comparable in the two groups. Thus we conclude that 50 mg of Epidurally administered Mg has no adverse effects on hemodynamics.

Adverse Effects: 1 patient (4%) in Group F and 2 patients (8%) in Group FM experienced nausea / vomiting which was not statistically significant. 1 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.

Neither there were differences in the incidence of these side effects between the groups in the above mentioned studies (Bilir, et al, and Arcioni et al.), nor were any additional adverse events.Many authors have studied the role of Mg for postoperative analgesia.

Buvanendran, et al[14] demonstrated in pregnant women that, if Mg 50 mg and Fentanyl 25 µg were given intrathecally, the median duration of analgesia was significantly prolonged compared with plain intrathecal Fentanyl. Similarly, in another study by Ozalevli, et al[15] it is reported that the addition of intrathecal Magnesium 50 mg to spinal anaesthesia prolongs the period of anaesthesia without additional side-effects. Bilir, et al, showed that Epidural administration of Magnesium reduced postoperative Epidural Fentanyl consumption in comparison with the saline group. Arcioni, et al, also showed that Epidural Magnesium supplementation of spinal anaesthesia has reduced postoperative morphine requirements.

Wolf C. J. and Thompson S. W.[12] showed the induction and maintenance of central sensitization is dependant on methyl-D-aspartic acid receptor activation: implications for the treatment of post-injury pain and hypersensitivity states.

The present study had certain limitations. Study group was relatively small. Preoperative serum Mg levels were not assessed in our patients which may affect pharmacodynamics of Mg. Since postoperative analgesia was the primary study parameter assessed and motor blockade was not assessed, no conclusions could be drawn about Mg induced changes in motor blockade as dose used was small and no muscle relaxants were used. Since the distribution of the type of lower limb surgeries were uniform in both the groups (F and FM), the possibility of bias is minimized.

Thus in the present clinical study Epidurally administered Mg is shown to prolong the duration of Fentanyl analgesia without significant side effects, and also a good safety profile of Epidurally administered Mg in humans.

SUMMARY AND CONCLUSION: In our study, we have compared the efficacy of Epidural Fentanyl 50 µg and Epidural Fentanyl 50 µg plus Magnesium sulphate 50 mg with respect to duration of analgesia, hemodynamic stability and side effects in the postoperative period.

Study population consisted of 50 ASA I/ II patients posted for elective lower limb and abdominal surgeries and randomly divided into two groups, Group F (Epidural Fentanyl 50 µg diluted to 6 ml with normal saline) and Group FM (Epidural Fentanyl 50 µg + Magnesium sulphate 50 mg diluted to 6 ml with normal saline). Age, sex, duration of surgery, highest level of sensory blockade, time taken for highest sensory blockade, time for regression of sensory blockade to L1 were comparable in the two groups. But duration of analgesia was significantly prolonged in Group FM compared to Group F. Adverse effects in the two groups were also comparable. We found that coadministration of Magnesium Sulphate to Epidural Fentanyl for postoperative analgesia prolonged duration of Fentanyl analgesia without any side effects.

It has been concluded from our study that addition of Magnesium Sulphate to Fentanyl in Epidural analgesia prolonged the duration of analgesia and decreased the dose of Epidural Fentanyl requirement.

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