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# Comparison of efficacy of bupivacaine with Magnesium Sulfate vs. plain bupivacaine as anaesthetic agent in epidural anesthesia in lower limb surgeries and lower abdominal surgeries ( A Randomized controlled Trial)

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**ABSTRACT: Background:** Magnesium (Mg) has been tested as an adjuvant to local anesthetics for prolongation of postoperative epidural and intrathecal analgesia but not with epidural bupivacaine in surgeries in lower limb and lower abdomen.

**Aim of the Study:**
The aim of the study is to compare the efficacy of MgSo4 as an adjuvant to bupivacaine vs plain bupivacaine in surgeries of lower limb and lower abdomen.

**Study Design:**
This study design is a prospective randomized controlled trial.

**Patients and Methods**:
Two groups each with 50 patients undergoing lower limb surgeries and lower adominal surgeries by using lumbar epidural anesthesia. Group A received 15 ml of a mixture of 14 ml bupivacaine 0.5%, 0.5 ml magnesium sulfate 10% (50 mg). Group B received 15 ml of 14 ml levobupivacaine 0.5% and 1ml of normal saline

**Statistical Analysis:**
Chi-square test, unpaired t-test were used

**Results:**The differences among the two groups regarding intraoperative hemodynamics were statistically insignificant (P > 0.05). Significantly shorter onset of sensory and motor block (14.3 [±1.53] and 12.22 [±1.73]) was observed in (bupivacaine+Mg) Group A compared to (plain bupivacaine) Group B (19.66[±1.40] and 19.22[±1.58]) (P = 0.001). Lower visual analog scale (VAS) pain score was observed in Group A from 2nd to 5th hour postoperatively compared to Group B. The time for first analgesic rescue dose was longer in Group A (295.32 [±22.47]) compared to Group B (154.62 [±10.09]) (P = 0.001).

**Conclusions:**Preoperative and intraoperative epidural Mg infusion with bupivacaine resulted in prolonged postoperative analgesia and lower VAS.

**Keywords:** Epidural, bupivacaine, lower abdominal surgeries, lower limb surgeries, magnesium sulfate, pain, VAS

## I. INTRODUCTION

One of the major concern in Anesthesia practice is management of acute pain following surgery. Epidural anesthesia using long-acting local anesthetics is familiar, safe and inexpensive technique, and also it provides postoperative analgesia, yet; the use of different and adjuvants to epidural has become important due to the need of more prolonged postoperative analgesia.[1] Researches are still striving to find the perfect adjuvant with the best satisfying analgesia and with the least side effects, as the currently used adjuvants are associated with side effects such as nausea, vomiting, pruritus,respiratory depression, and urinary retention with morphine,[2] bradycardia, hypotension and sedation with clonidine,[3] and epidural dexamethasone, neurological complications have not been clearly established in most clinical trials.[4] The bupivacaine gives a safer pharmacological profile with less neurological and cardiac adverse effects.[5] Magnesium (Mg) is a naturally occurring cation in the body, the N-methyl-D-aspartate (NMDA) receptor antagonism controls the calcium influx into the cell, which mediates the antinociceptive effect.[6] Very few studies have examined the effect of adding magnesium sulfate (MgSO4) to epidural bupivacaine and it was in different type of format than the present study.

This randomized control study was formulated to assess the effect of preoperative and intraoperative infusion of MgSO4 with bupivacaine

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in epidural anesthesia during lower adominal and lower limb surgeries on postoperative analgesia. The primary outcome variable assessed was the time of first rescue analgesia, and the secondary outcome variables that we assesed are onset of epidural block (sensory and motor),intraoperative hemodynamics and complications such as nausea, vomiting, and visual analog scale (VAS) hourly for the first 5 hours of postoperative period.

## II. METHODOLOGY

After obtaining hospital Ethical Committee approval and obtaining informed written consent from each patient, this prospective randomized study was conducted from Decemer 2018 to the end of Decemer 2019, on 100 patients scheduled for different lower limb and lower abdominal surgeries who were enrolled in the study. Based on a sample study, sample size was calculated according to the difference in the mean value of time to the first need of rescue analgesia between Group A (307.1 ± 16.6) and Group B (155.6 ± 7.95), with an effect size of 0.56. Assuming the $\alpha$ =0.05, power of 80%, so a sample size of 50 patients for each group was minimum required.

Included patients were those who aged between 20 and 60 years old and with American Society of Anesthesiologists (ASA) physical status grade I and II. Exclusion criteria were patient refusal, history of allergic reactions to local anesthetics, coagulopathy, and severe renal, hepatic, respiratory, hepatic, or cardiac disease.

After arrival to the operating room, VAS was explained to the patients. A 16-gauge cannula was inserted after skin and a preload of 500 ml lactated Ringer's solution was infused intravenously. Monitoring was done by five-lead electrocardiography, pulse oximeter, and noninvasive arterial blood pressure was done. Baseline heart rate (HR), mean arterial blood pressure (MAP) and arterial oxygen saturation (SpO2) were noted.

In sitting position Epidural catheter was inserted at the level of L3-L4 intervertebral space, using the loss of resistance and hanging drop technique. Test dose of lidocaine with epinephrine 1:200,000 2-3 ml was given after negative aspiration for cerebrospinal fluid and blood.

Patients then were randomly allotted into two groups the random numbers were kept in a closed envelope:

Group A (n = 50) received 15 ml mixture of 14 ml bupivacaine 0.5% + 0.5 ml MgSO4 10% (50 mg) + 0.5 ml of 0.9 NaCl in epidural catheter at induction.

Group B (n = 50) received a 15 ml mixture of 14 ml bupivacaine 0.5% + 1 ml of 0.9 NaCl in the epidural catheter at induction

Time for the sensory block to reach T10 level was estimated by loss of sensation to pinprick in the mid axillary line, a 22-gauge blunt hypodermic needle was used to stimulate pain at 2 min interval until T10 dermatome was reached. Modified Bromage scale was used to assess time to complete motor block, in which block is graded as follows (i) total, if the patient is unable to move feet and knees, (ii) almost total, if the patient is able to move feet only, (iii) partial, if the patient is just able to move the knees, and (iv) none, if the patient has full extension of feet and knees.If the desired motor or sensory block was not achieved after 15 min from injection of the initial dose , an extra bous of 5 ml of the specific mixture corresponding to each group was infused via epidural catheter insitu.

Patients were excuded in case of failed epidural anesthesia was considered, and patient was excluded if the desired sensory level (T12) or complete motor block was not achieved within 5 min after giving the extra epidural bolus which is given 15 min after the initial dose of epidural anesthesia as mentioned.

lactated Ringer's solution were used to maintain adequate intraoperative fluids. If MAP decreased >20% from the baseline, a bolus dose of 6 mg mephentermine was given and 200 ml lactated Ringer's soution was infused. If heart rate was <50 b.p.m., a bolus dose of 0.6 mg atropine was given.

Intraoperatively, patients MAP, HR, and SpO2 were monitored every 15 min. Onset of motor and sensory block and side effects including respiratory depression, nausea and vomiting were recorded.

Postoperatively, patients were monitored for the following

Postoperatively Pain was measured using VAS (from 0 to 10 where 0 is no pain and 10 is maximum pain) every 1 hour for the first 5 hour

The first analgesic rescue dose is the time from discontinuation of epidural anesthesia till the first use of rescue analgesia in the patient. A satisfactory pain relief is considered when resting VAS is ≤3. If patients had inadequate analgesia supplementary rescue analgesic was used (i.e.,: if VAS ≥4 during hourly measurement or if patient expressed intolerable pain in between VAS measurements periods).

Results are expressed in mean ± standard deviation, median (minimum–maximum), or number in percentage (%). Chi-square test was used for

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Comparing among the categorical data (n [%]). Unpaired t-test was used to compare between different variables in the two groups whenever it was applicable. Statistical analysis is done using EPI INFO version 7.2.4. P value ≤ 0.05 is considered to be cutoff for statistical significance.

## III. RESULTS

One hundred and three (103) patients were enrolled in the study; three patients were excluded due to failure of epidural block. Type of the performed surgeries were hernias (n = 38), appendicitis (n = 29), bipolar hemiarthroplasty (n = 17), total knee replacement (13), and total hip replacement (3).

**Demographic data**

All patients were analogous regarding demographic data including age, sex, weight, and ASA classification [Table 1].

**Table 1** Demographic data

| | Group A | Group B |
|---|---|---|
| AGE | 35.94+/- 10.22 | 37.42+/- 11.54 |
| Gender(F/M) | 20/30 | 20/30 |
| weight | 76.41+/- 7.6 | 83.33+/- 8.9 |

Intraoperative hemodynamics such as
HR and MAP were measured intraoperatively every 15 min, and they were comparable with P > 0.05 {[Table2 and 3, Figures1 and and2]}.

**Table 2**

| Time | Mean arterial blood pressure | |
|---|---|---|
| | Group A | Group B |
| 0 | 98 | 96 |
| 15 | 83 | 92 |
| 30 | 88 | 96 |
| 45 | 89 | 94 |
| 60 | 88 | 93 |
| 75 | 90 | 93 |
| 90 | 92 | 92 |
| 105 | 91 | 92 |

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**Figure 1**

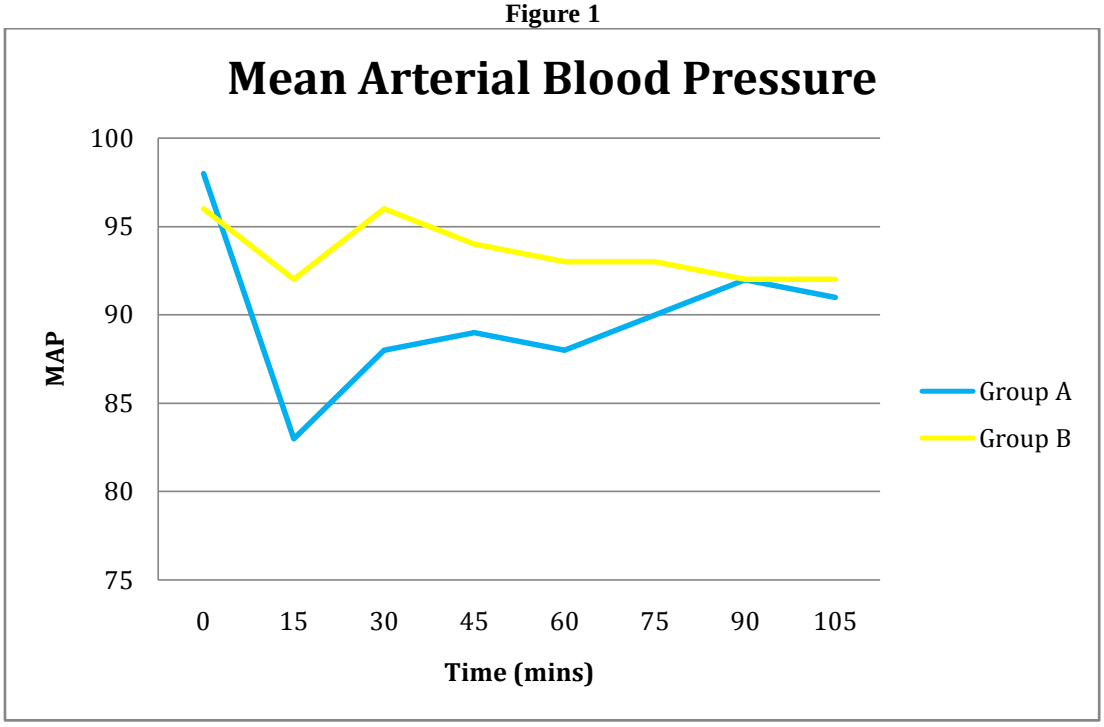


**Table 3** Mean value of the heart rate in the two study groups

| | Mean Heart Rate | |
|---|---|---|
| Time | Group A | Group B |
| 0 | 74 | 74 |
| 15 | 77 | 80 |
| 30 | 81 | 82 |
| 45 | 82 | 83 |
| 60 | 83 | 85 |
| 75 | 83 | 86 |
| 90 | 81 | 85 |
| 105 | 82 | 84 |

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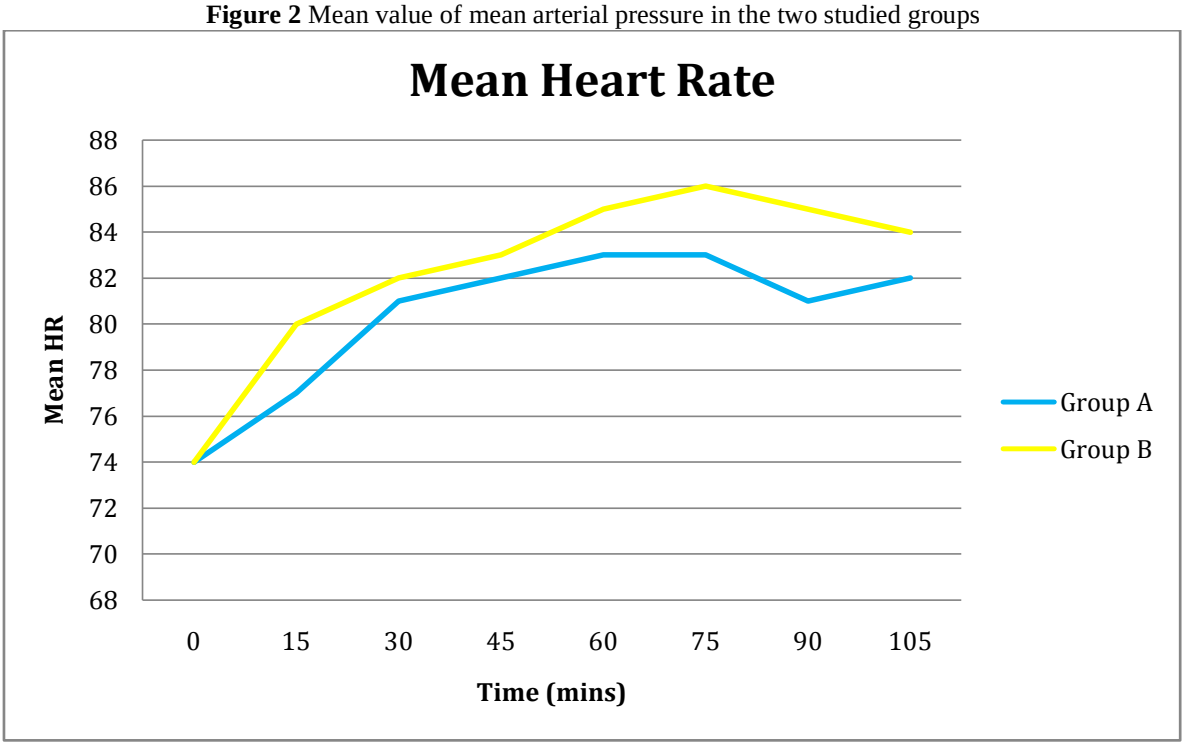
**Figure 2** Mean value of mean arterial pressure in the two studied groups




Onset of epidural block

Onset of a complete motor block was statistically shorter in the A group compared to B group (P = 0.001). And time to reach complete sensory block at level of T10 was statistically shorter in the A group compared to B group (P = 0.001) [Table 4].

**Table 4** Onset of motor and sensory block in Minutes

| Block Character | Group A | Group B | P value |
|---|---|---|---|
| onset of motor block (min) | 15.20+/-1.42 | 20.26+/- 1.44) | 0.001* |
| onset of sensory block at T10 (min) | 13.32+/-1.56 | 19.86+/- 1.42 | 0.001* |

Data expressed as mean+/-SD. * P≤ 0.05. SD= Standard Deviation

**Incidence of complications**

The difference was not showing statistical significance between two groups regarding complication such as respiratory depression, nausea, vomiting (P = 1.00). Three patients in Group A and 5 patients in Group B experienced nausea. Respiratory depression and vomiting did not happen in both the groups.

Postoperative data

There difference concerning VAS score was statistically significant between two groups, as it was significantly lower in GroupA compared to Group B during the 2nd and 3rd hour postoperatively. VAS was not noted in the study after the 3rd hour in B group and after the 5th hour in A group, as top up dose of epidural tramadol was given to alleviate pain [Table 5 and Figure 3].

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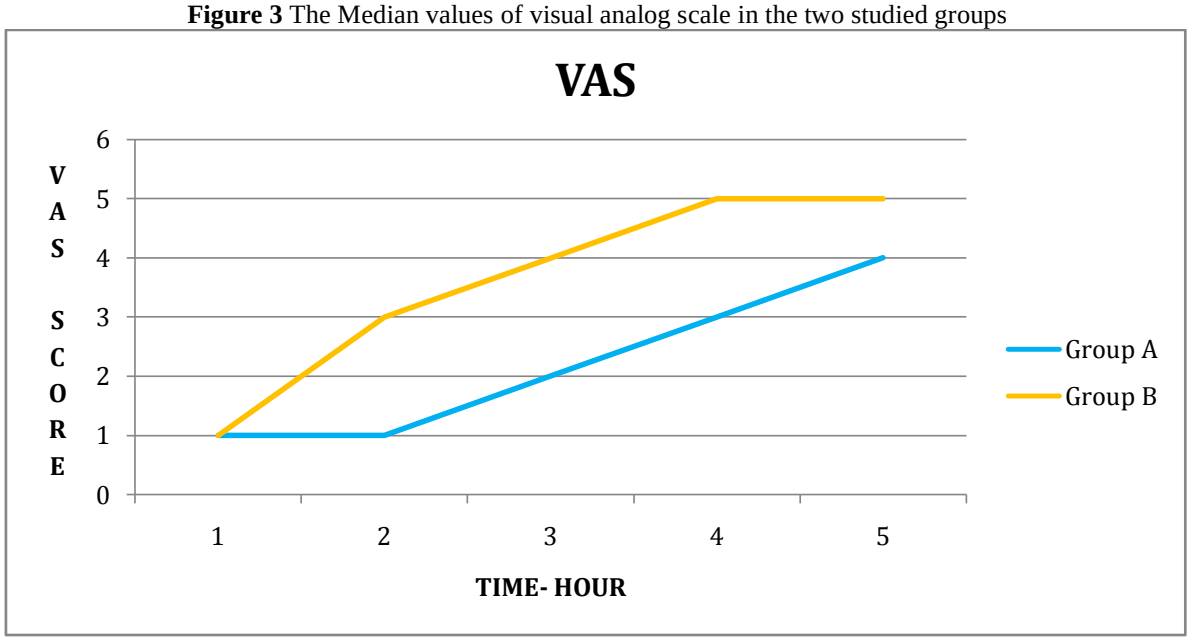
**Table 5** Intergroup comparison between median values of postoperative visual analog scale in the two studied groups

| VAS | Group | |
|---|---|---|
| Hour | Group A | Group B |
| 1 | 1.0 (1.0-1.0) | 1.0 (1.0-1.0) |
| 2 | 1.0 (1.0- 2.0)* | 3.0 (2.0-4.0)* |
| 3 | 2.0 (2.0-3.0)* | 4.0 (3.0-5.0)* |
| 4 | 3.0 (2.0-4.0)* | 5.0 (4.0-6.0)* |
| 5 | 4.0 (3.0-4.0)* | 5.0 (4.0-6.0)* |

Data Expressed as a Median (Min-Max), *P≤ 0.05

**Figure 3** The Median values of visual analog scale in the two studied groups




First rescue analgesic dose

The time for first dose analgesic rescue was significantly longer in the A group compared to the B group, P = 0.001 [Table 6].

**Table 6**

| Time for 1st analgesic requirement | | Group | |
|---|---|---|---|
| | Group A | Group B | P value |
| TIME | 296.94+/-20.04 | 150.16+/-10.8 | 0.001 |

Time for first anlgesic rescue dose (minutes)

## IV. DISCUSSION

The current study showed that adding of 50 mg MgSO4 to epidural bupivacaine is associated with shortening of the time to reach sensory and motor block, prolongation of both postoperative analgesic effect, and time for the first epidural analgesic dose without any hemodynamic complications.

Regardless the route of administration whether intravenous, intrathecal, or epidural, the

actual site of action of Mg is probably at the NMDA receptors in spinal cord. Magnesium inhibits the central sensitization from peripheral painful stimulus regulated by NMDA receptors by its NMDA receptor antagonism effect.[7] This effect is firstly based on physiological calcium antagonism, via voltage-dependent regulation of calcium influx into the cell.[8]

In previous trials, MgSO4 has proven to be an effective adjuvant when added to bupivacaine in epidural anesthesia during different surgeries such as orthopedic surgeries and cesarean section ,[9,10,11] or when it is added to bupivacaine in spinal anesthesia in major orthopedic surgeries.[12] To our best knowledge, there are very little studies that evaluated the effect of adding MgSO4 to epidural bupivacaine on postoperative analgesia.

Arcioni et al.[10] found that addition of spinal anesthesia with combined subarachnoid and epidural MgSO4 in patients undergoing orthopedic surgery significantly lowered postoperative analgesic required by the patients after major orthopedic surgeries without much affecting hemodynamics.

Kandil et al.[11] studied the use of epidural MgSO4 to decrease requirements of narcotics in orthopedic surgery. They declared that adding magnesium to epidural bupivacaine is associated

with significant improvement in VAS and significant reduction in the number of patients demanding early postoperative analgesia as well as total fentanyl utilisation.

Hasanein et al.[12] studied the action of single dose of 50 mg epidural Magnesium as an adjuvant to 50 µg fentanyl and bupivacaine 0.125% for labor analgesia. It was associated with quicker onset, prolonged duration of action, and lowered the occurence of breakthrough pain with no side effects on fetus and mother assessed by cord blood acid-base status,fetal HR tracings and Apgar score.

On sixty patients going through hip replacement surgeries using combined spinal–epidural anesthesia, Banwait et al.[13] studied the postoperative analgesic effect provided by single dose 75 mg MgSO4 added to the epidural fentanyl 1 µg/kg at the conclusion of the surgery compared to the epidural fentanyl 1 µg/kg alone. They found that it was associated with prolonged analgesia and lesser need of rescue analgesic requirements than which is witnessed with epidural fentanyl alone.

Though the outcomes of these studies are in correlance with the current study such as epidural MgSO4 provides prolonged postoperative analgesia without much side effects, the main differences between them and the current study are, using a single dose bolus of epidural MgSO4 either pre-operatively or postoperative and the variety of surgery which are different from that included in the present study which included visceral traction and laparotomy most of the enrolled patients.

Evaluating the postoperative analgesic effect of epidural Mg on the same type of surgeries included in the present study was conducted by Gupta et al.[14] on sixty patients undergoing total abdominal hysterectomy, but they used postoperatively a single dose of 50 mg/ml of epidural MgSO4 with 9 ml of 0.125% bupivacaine, and they conclude the study that Mg has provided prolonged time of postoperative analgesia and decreased postoperative utilisation of fentanyl without any complications.

In correlance with the present study, Farouk[15] evaluated the deterrent analgesic effect of MgSO4 when adjoined to a multimodal patient-controlled epidural analgesia (PCEA) on ninety patients sted for abdominal hysterectomy under GA, who were assigned into one of the three groups. (1) Pre-MgSO$ group received a bolus of epidural Mg 50 mg prior to induction of anesthesia, then infused 10 mg/h till the conclusion of surgery. (2) Post-Mg group received epidural normal saline during the same time periods as pre-Mg group and bolus epidural Mg 50 mg at the conclusion of surgery. (3) Control group received epidural normal saline during all the three periods.During immediate postoperative period and continued for three days, patients in the two Mg groups received PCEA with bupivacaine 0.08%,fentanyl 1 µg/ml and Mg 1 mg/ml, and patients in control group received PCEA with bupivacaine 0.08% and fentanyl 1 µg/ml. Lower pain scores and analgesic consumption were recorded lower in the pre-Mg group comparing to the post-Mg and control groups, and in post-Mg group there was no side effects detected compared to the control group.

Kogler et al.[16] randomly alloted seventy patients undergoing thoracic surgery in general anesthesia into two groups; Group 1, patients received 10 mg 0.5% levobupivacaine, 0.2 µg/kg sufentanil, and 50 mg 10% Mg through epidural catheter (Th 4-Th 6) 15 min before induction of general anesthesia, then continuous epidural infusion of 10% Mg given at a dose of 10 mg/h was started following induction. Then patients were administered a continuous epidural infusion of sufentanil 1 µg/ml, levobupivacaine 1 mg/ml, and 10% Mg 1 mg/ml for 48 h postoperatively. Group 2 patients were preoperatively injected with 10 mg of 0.5% levobupivacaine and 0.2 µg/kg of sufentanil through epidural catheter (T4-T6) preoperatively, then same volume of epidural 0.9% NaCl, and then

continuous epidural infusion of sufentanil 1 µg/ml and levobupivacaine 1 mg/ml for 48 h postoperatively. at the same time frame as Group 1.

In agreement with the current study, they concluded that the preoperative use of epidural Mg followed infusion resulted in better postoperative analgesia and reduced analgesic consumption with a lesser incidence of postoperative nausea,vomiting and shivering. Main differences in the Kogler et al. study were difference in action site, i.e., thoracic epidural, different anesthesia technique, i.e., General Anesthesia, they used two adjuvants to epidural levobupivacaine, i.e.,MgSO4 and sufentanil and finally they continued use of epidural analgesia postoperatively.

Radwan et al. a similar study was recently done.[17] which included 66 elderly patients going through laminectomy and lumbar discectomy surgery under General Anesthesia. Preoperatively, patients were allotted into three different groups; Group A got 14 ml levobupivacaine 0.5% + 1 ml saline, Group B got 14 ml levobupivacaine 0.5% + 50 mg MgSO4, and Group C got 14 ml levobupivacaine 0.5% + 50 µg fentanyl. Then, post induction of GA, continuous epidural infusion in a rate of 5 ml/h was infused as follow: Group A got levobupivacaine 0.125%, Group B got levobupivacaine 0.125% + 2 mg/ml MgSO4, and Group C got levobupivacaine 0.125% + 4 µg/ml fentanyl. Mg and fentanyl groups were hemodynamically comparable.onset of Motor and Sensory block was significantly quicker in Mg group when compared to the other 2 groups. MgSO4 and fentanyl groups were comparable in regards to postoperative analgesia as they had a longer duration of analgesia than that of the control group with a lesser number of participants requiring either the first or second rescue analgesic dose. The main differences between the present study and Radwan et al. study are the types of surgeries i.e without visceral traction and with smaller skin incision, type of population who are above 65 years of age, sample size was smaller, type of anesthetic technique was combined epidural and general anesthesia, and additional dose of 1.5 µg/kg fentanyl was injected intravenously during induction of general anesthesia in all the groups, and finally the use of levobupivacaine, 0.125% which is a low conventration dose, during epidural infusion intraoperatively.

## V. LIMITATIONS AND RECOMMENDATIONS

Difference in types of surgeries may lead to alterations in the analgesic duration. This can be preveted in future studies by enrolling patients scheduled for similar surgical procedure. Moreover, different doses of epidural MgSO4 must be examined in ucoming studies.

## VI. CONCLUSIONS

We have concluded that using MgSO4 as adjuvant to bupivacaine in epidual anesthesia before and during orthopaedic and lower abdominal surgeries was associated with faster onset of action of the epidural block and an increased potency of the block, and it has a more prolonged duration of postoperative analgesia.
No significant side effects were observed during the study in the form of nausea, vomiting, and respiratory depression.

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**Conflicts of interest**
There are no conflicts of interest.

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