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RANDOMIZED CONTROLLED TRIAL TO COMPARE EFFECTS OF INTRAVENOUS BOLUS VERSUS BOLUS FOLLOWED BY INFUSION OF MAGNESIUM SULPHATE FOR POSTOPERATIVE PAIN FOLLOWING ABDOMINAL HYSTERECTOMY UNDER GENERAL ANAESTHESIA

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ABSTRACT

Introduction: Postoperative pain in abdominal hysterectomy is moderate to severe. Magnesium sulphate has been used as an adjuvant for postoperative pain. Review of literature did not reveal any study showing comparison of magnesium sulphate given either as bolus or bolus followed by infusion. Therefore, this study was planned with primary aim to compare the effects of magnesium sulphate given either as intravenous bolus or bolus followed infusion for post operative pain.

Methods: Randomized, double-blind study was undertaken in Female Patients, 18-60 years of age undergoing open abdominal hysterectomy. GROUP MB (n=20) received magnesium sulphate 50mg/kg bodyweight in 100 ml normal saline solution i.v. as bolus followed by infusion of i.v. normal saline. GROUP MBI (n=20) received magnesium sulphate 50mg/kg in 100ml normal saline solution i.v. as bolus followed by i.v. infusion of magnesium sulphate 10mg/kg/hr. Pain was assessed by Visual Analogue Scale (VAS) score. Between group comparison was done by repeated measure ANOVA followed by Tukey's test.

Results: Postoperative Pain score was less in group MBI as compared to group MB at 2^{nd}, 5^{th}, 9^{th} hours after surgery. At rest of the time points VAS score was comparable in both groups. Duration of analgesia was significantly higher in Group MBI as compared to Group MB.

Conclusions: We recommend that magnesium sulphate 50mg/kg bodyweight in 100ml normal saline solution i.v. as bolus before induction of anaesthesia followed by i.v. infusion of magnesium sulphate 10mg/kg/hr in 50ml/hr saline may provide adequate

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analgesia.

Keywords: Magnesium sulphate; abdominal hysterectomy; pain

1. INTRODUCTION

Total abdominal hysterectomy is one of the most common surgeries performed in gynaecology department.[1] Postoperative pain in abdominal hysterectomy is moderate to severe in intensity.[2] Therefore it is very important to control pain following surgery and anaesthesia. Pain is defined as "an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[3] Many preoperative, intraoperative, and postoperative interventions have been used to reduce postoperative pain. There are a lot of modalities to control postoperative pain like pharmacological agents (opioids, NSAIDS, corticosteroids), regional and neuraxial blocks, local or topical analgesics and non-pharmacological methods. Recently, magnesium sulphate ($MgSO_4$) has been used as an adjuvant to control postoperative pain[4] given either intravenously or intrathecally.

Magnesium, an inorganic ion has been used in many cases like eclampsia, pre-eclampsia, hypokalemia, premature labor, arrythymias, severe asthma etc.[5] Magnesium sulphate has also been found to be useful in blunting cardiovascular response in surgery and anaesthesia.[6] Along with all this, magnesium is known to have anti-inflammatory effect.[7] Magnesium is a non-competitive N-methyl- D-aspartate (NMDA) receptor antagonist and has calcium channel blocking effect. It is found to be safe in different doses; the usual doses of magnesium sulphate is 30-50 mg/kg as bolus dose and 6-20 mg/kg/hour as infusion dose with no significant haemodynamic instability or other side effects like hyporeflexia, respiratory depression and cardiac manifestations.[8]

Magnesium sulphate has been used by many authors either as i.v. bolus followed by continuous infusion or bolus alone. But Review of literature did not reveal any study showing comparison of magnesium sulphate given either as bolus or bolus followed by infusion for postoperative pain.

Therefore, this study was planned with primary aim to compare the effects of magnesium sulphate given either as intravenous bolus or bolus followed infusion for post operative pain in patients undergoing open abdominal hysterectomy under general anaesthesia. Our hypothesis was that patients who will receive magnesium sulphate intravenous bolus followed by infusion will have better postoperative pain score.

2. MATERIAL AND METHODS

This Randomized double blinded study was conducted from November 2018 to April 2020 in the Department of Anaesthesiology, Critical Care & Pain Medicine and Department of Obstetrics and Gynaecology after getting approval from the Institutional Ethical Committee-Human research (IEC-HR). The drug for infusion was prepared by an independent

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anaesthesiologist who was not participating in the study and nature of drug and group was unknown to the observer and patient.

Patients were informed about the study in detail then informed consent was taken from each patient willing to participate in the study. Patients having following criteria were included in the study. Female aged between 18-60 years with ASA I & II scheduled for abdominal hysterectomy under general anaesthesia were included in the study. Patients with History of cardiovascular diseases, compromised renal/ hepatic/ neuronal functions, endocrine disease or Patient on any drug affecting cardiovascular parameters e.g. calcium channel blockers, beta blockers, magnesium sulphate etc. were excluded.

Considering the variability of bolus as 4.518[9] and 0.621[10] for bolus with infusion, to estimate a mean difference of 15 units in VAS score at alpha= 5% and power= 90%, a sample of 10 subjects in each group was required. Taking 10% as drop out, we proposed to consider a sample of 20 cases in each group.

Female patients fulfilling the above-mentioned selection criteria were selected randomly on the day of operation. They were allocated to one of the following two groups by computer generated randomization charts. GROUP MB (n=20): Patients of this group received magnesium sulphate 50mg/kg bodyweight in 100 ml normal saline solution i.v. as bolus over a period of 15 minutes before induction of anaesthesia followed by infusion of i.v. normal saline infusion 50ml/hr intraoperatively till completion of surgery. GROUP MBI (n=20): Patients of this group received magnesium sulphate 50mg/kg bodyweight in 100ml normal saline solution i.v. as bolus over a period of 15 minutes before induction of anaesthesia followed by i.v. infusion of magnesium sulphate 10mg/kg/hr in 50ml/hr normal saline intraoperatively till completion of surgery. On arrival to the operating table, monitoring of all patients for continuous electrocardiograph (ECG), heart rate (HR), noninvasive blood pressure (NIBP) (Systolic, diastolic and mean BP) and arterial oxygen saturation (SpO2) were started and their baseline preoperative values were recorded. Same monitoring was continued throughout the procedure. IV crystalloids solution were started after securing an IV access on the forearm of the patient. Induction of anaesthesia was done by injection morphine 0.1mg/kg body weight IV and injection propofol 1-2.5mg/kg body weight IV followed by injection vecuronium bromide 0.1 mg/kg body weight IV. Intermittent positive pressure ventilation (IPPV) was given with face mask through Bain's circuit using O2, N2O (1:1) and isoflurane (0.5-1%) till complete muscle relaxation was achieved, confirmed by train of four monitoring. The trachea was intubated using an oral cuffed endotracheal tube of appropriate size. Anaesthesia was maintained by using a mixture of O2 + N2O (1:2) and isoflurane (0.5-2%) through close circuit. The ventilatory parameters for IPPV were adjusted to maintain EtCO2 between 35-40mmHg. Top up doses of vecuronium bromide were given as per requirement under neuromuscular monitoring by Train of Four (TOF). I.V. fluid was given as per requirement. 15 minutes before the reversal of anaesthesia inj. Ondansetron 4mg i.v. was given. At the end of surgery residual neuromuscular blockade was reversed by injection neostigmine 0.05mg/kg and injection glycopyrrolate 0.01mg/kg I.V. and was confirmed by TOF monitoring. Trachea was extubated after adequate recovery. If, during surgery any patient showed an increase in systolic BP (SBP) by more than 20% of the pre operative

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baseline value, it was controlled by increasing the concentration of isoflurane upto a maximum value of 2%. If any patient showed hypotension i.e. decrease in SBP by more than 20% of the pre operative value or SBP <90mmhg, it was initially managed by giving fast IV fluids and decreasing the concentration of isoflurane accordingly. In the event of bradycardia (HR<60/min), injection atropine 0.3mg IV was given, repeat dose was used if required. Haemodynamic parameters like Heart rate (HR), Mean arterial pressure (MAP) and saturation pressure of oxygen (SpO2) were recorded at pre medication and during medication at 5 min, 10 min and 15 min, pre induction, just after induction of anaesthesia, after intubation at 1, 3, and 5 minutes and every 5 min thereafter till end of surgery. End tidal carbon dioxide (EtCO2) was monitored and recorded after tracheal intubation every 5 minutes till the end of surgery.

The parameters of pain were assessed and recorded after surgery, every hour for six hours, then every 3 hours for next 12 hours and at the end of 24th hour. Pain assessment was done by Visual Analogue Scale (VAS) score. If any patient had VAS Score ≥3 rescue analgesia was given in the form of inj. Diclofenac sodium 1 mg/kg body weight IV and time was noted. Period of analgesia was recorded. If pain was not relieved by inj. Diclofenac sodium, inj. Morphine 3mg i.v. was administered and time was noted. Any adverse effect like hypotension, bradycardia, nausea, vomiting, shivering or any other effect reported by the patient was recorded. The primary outcome was to compare postoperative pain score in two groups. And secondary outcome included Comparison of post operative requirement of rescue analgesic in two groups.

Statistical analysis

Between group comparison and within group comparison was done by repeated measure ANOVA followed by Tukey's test if data found normal. Otherwise between group comparison and within group comparison were done by Mann Whitney Ü test and Friedman test respectively. P value <0.05 was considered as significant.

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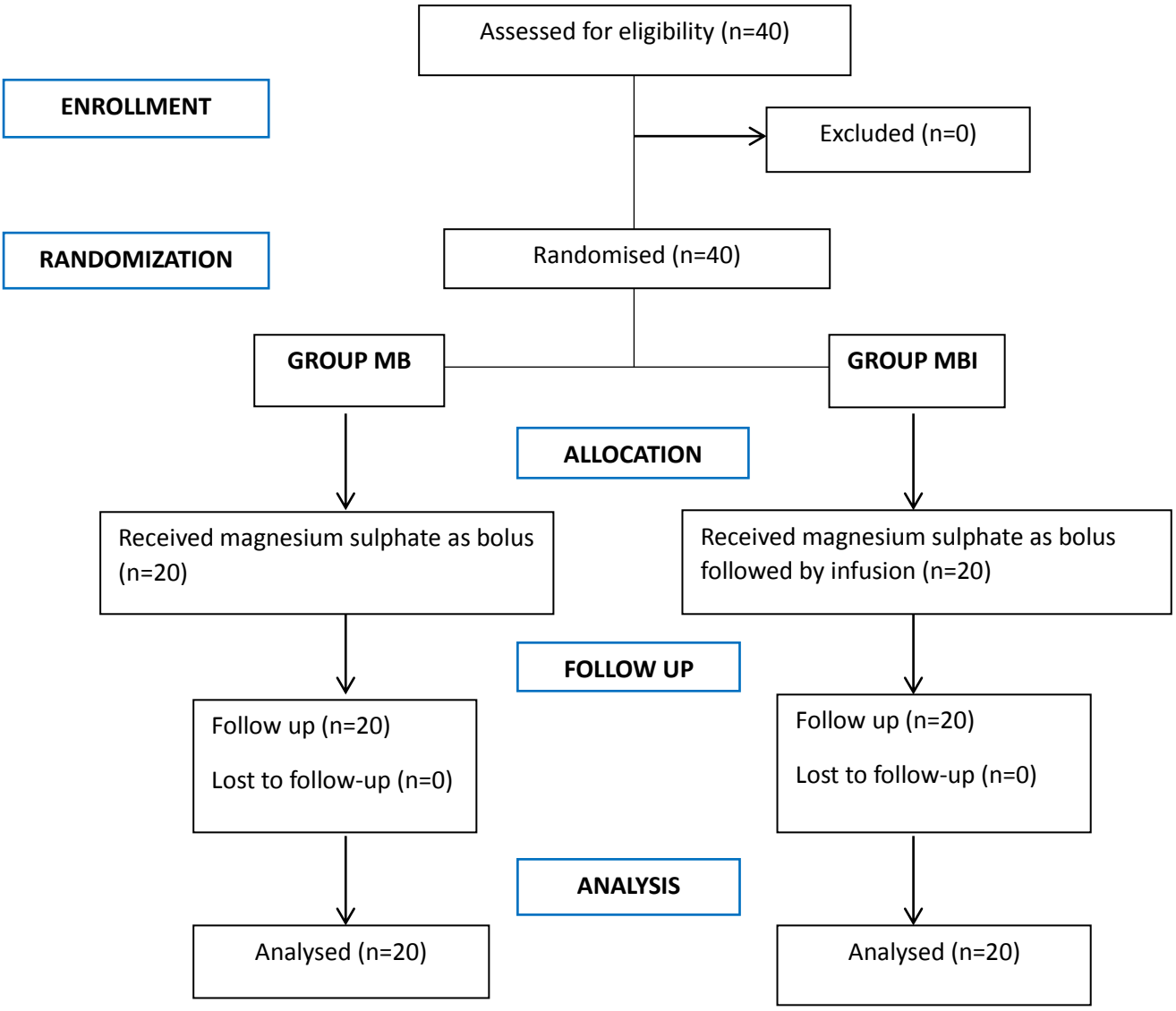

Fig 1: Consort flow diagram

3. RESULTS

The study consisted of 40 female patients scheduled for elective abdominal hysterectomy under general anaesthesia aged between 18-60 years and belonging to ASA class 1 and 2. Patients were divided into two equal groups by computer-generated randomization charts as shown in consort flow diagram (Fig 1).

There was no statistically significant difference in the age of the patients in the two groups (Table 1) .

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Mean height of patients was 155.30 ± 5.08 cm and 154.80 ± 4.32 cm in group MB and MBI respectively. All cases recruited into both groups were women. All above parameters of patients were statistically comparable between two groups. (p>0.05).

The mean ± SD of intraoperative heart rate (HR) is shown in table 2. Before bolus, 1 min and 3 min time points in both the groups, HR were statistically significantly different in two groups. The mean ± SD at before bolus was 88.85±7.15 in group MB and 95.30±12.29 in group MBI, at 1 min was 86.30±8.15 in group MB and 94.70 ±13.59 in group MBI, at 3 mins was 79.10±9.25 in group MB and 87.70±10.7 in group MBI, with p values of 0.049, 0.022, 0.009 respectively. However, at all other points of time, difference between the groups for intraoperative HR was not significant. The Overall p value for difference in heart rate of both the groups was 0.571. (Table 2)

As shown in table 3, The MAP was statistically significant at pre-induction and 120 mins. The MAP at pre- induction in groups MB and MBI was 82.4±6.92 and 88.25±7.42 respectively, with p- value of 0. 013.The MAP at 120 mins was 92.8±7.61 in group MB and 87.26±8.45 in group MBI with p-value of 0.038 without clinical significance. On comparison, trends of MAP were statistically comparable between the two groups with an overall p-value of 0.699.

The data in table 4 indicates that the mean pain was different between the two groups at some time points. The mean ± SD of VAS score at 0 min, 2, 5, and 9 hours after the surgery in group MB and group MBI was 1.45 ± 1.46 and 0.55 ± 0.75 (p=0.019), 3 ± 1.71 and 1± 0.72 (p=0.001), 1.6 ± 0.75 and 2.5± 1.31 (p=0.011), 3.6 ± 1.5 and 2.1 ±1.07 (p=0.001) respectively. Pain reported by group MBI was significantly less at 0 min, 2, 5, and 9 hours after the surgery in comparison with group MB.

The mean duration of analgesia was significantly higher in Group MBI as compared to Group MB as shown in table 5. The mean of number of Diclofenac injections required was 2.90 ± 0.31 and 2.30 ± 0.66 in group MB and MBI respectively with a significant difference, p-value 0.001. The mean of total dose of rescue analgesic (Diclofenac) required in 24 hours in group MB was lower (161.50 ± 21.54 mg) as compared to Group MBI (122.45 ± 37.33 mg) with a significant difference between two groups (p-value = 0.001). In group MB, 6 (30%) out of 20 patients and in group MBI, 4 (20%) out of 20 patients required additional analgesic morphine 3mg as rescue analgesic but there was no statistically significant difference between the two groups (P>0.05)

All forty patients were sedated but easily arousable on verbal command in early postoperative period (upto 2 hours). None of the patients in both groups showed any other side effects (Table 6).

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TABLE 1: DEMOGRAPHIC PROFILE

Parameters	**Group MB (n = 20) Mean±SD**	**Group MBI (n = 20) Mean±SD**	**p - value**
Age (years)	42.50±10.28	42.00±10.27	0.879
Body Weight (kg)	55.75±4.92	53.60±6.89	0.263
Height (cm)	155.30±5.08	154.80±4.32	0.739
Sex ratio Male:Female	0:20	0:20	-

$p<0.05$ significant

TABLE 2: INTRAOPERATIVE HEART RATE

Intraoperative Heart Rate (bpm)	**Group MB (n = 20) Mean±SD**	**Group MBI (n = 20) Mean±SD**	**p – value**
Before Bolus	88.85±7.15	95.30±12.29	0.049
5 min DB	88.90±9.14	94.15 ±13.18	0.151
10 min DB	86.70±8.06	91.30±11.85	0.159
15 min DB	86.25±9.81	89.00±9.54	0.374
Pre-Induction	85.15±11.61	88.15±10.37	0.394
Pre-Intubation	77.40±10.18	79.35±8.26	0.510
Post-Intubation	92.65±9.69	99.60±13.54	0.069
1 min	86.30±8.15	94.70±13.59	0.022
3 min	79.10±9.25	87.70±10.7	0.009
5 min	76.80±7.99	82.60±12.19	0.083
10 min	76.25±5.57	79.25±8.97	0.211
15 min	75.65±6.26	77.50±8.53	0.439
20 min	75.90±7.74	75.95±7.27	0.983
25 min	77.25±10.67	76.15±6.17	0.692
30 min	77.85±12.93	76.00±6.51	0.571
35 min	79.40±15.01	78.35±8.7	0.788
40 min	81.10±14.81	79.40±10.85	0.681
45 min	82.25±13.53	81.05±9.59	0.748
50 min	83.60±12.8	81.40±10.3	0.553
55 min	83.55±11.5	82.10±9	0.659
60 min	82.60±10.42	84.60±9.12	0.522
65 min	83.95±10.25	83.75±8.3	0.946
70 min	81.10±9.77	81.80±7.81	0.803
75 min	80.55±7.65	81.60±7.14	0.656
80 min	82.60±8.29	86.15±12.2	0.288

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85 min	84.70±9.35	87.70±11.79	0.378
90 min	85.90±7.95	86 00±9.15	0.970
95 min	87.20±9.04	85.80±10.49	0.653
100 min	88.15±11.34	85.75±6.85	0.422
105 min	88.40±13.08	83.85±6.88	0.176
110 min	86.70±11.07	83.21±6.45	0.240
115 min	85.20±8.61	83.31±5.95	0.434
120 min	86.30±8.16	83.47±6.76	0.247
Within Groups Comparison (p-value)	<0.001	Within Groups Comparison (p-value)	<0.001
Overall p-value = 0.571			

TABLE 3: INTRAOPERATIVE MEAN BLOOD PRESSURE

Intraoperative Mean Arterial Pressure (mm Hg)	**Group MB (n = 20) Mean±SD**	**Group MBI (n = 20) Mean±SD**	**p – value**
Before Bolus	92.5±7.48	93.45±5.86	0.657
5 min DB	89.1±7.51	93.4±7.51	0.078
10 min DB	87.45±6.13	90.35±7.63	0.193
15 min DB	86.6±7.58	88.55±6.91	0.400
Pre-Induction	82.4±6.92	88.25±7.42	0.013
Pre-Intubation	67.1±7.98	70.75±7.18	0.136
Post-Intubation	91±9.91	90.65±10.17	0.912
1 min	84.2±6.48	86.85±7.48	0.238
3 min	80.6±9.01	84.75±7.18	0.115
5 min	79.05±10.86	81.8±6.22	0.331
10 min	78.1±6.71	77.7±5.89	0.842
15 min	78.95±6.05	78.05±5.35	0.621
20 min	81.95±9.81	78.6±7.13	0.224
25 min	81.1±10	77.6±6.66	0.200
30 min	79.75±11.48	80.9±8.65	0.722
35 min	81.2±10.8	79.9±7.7	0.663
40 min	82.45±10.14	82.6±10.88	0.964
45 min	85.3±9.15	81.3±10.39	0.204
50 min	88.6±10.24	82.65±8.46	0.052
55 min	85.65±11.46	82.05±9.31	0.282
60 min	87.4±7.31	85.5±9.62	0.486
65 min	87.15±10.63	85.75±8.94	0.655
70 min	86.55±9.98	85.2±9.13	0.658
75 min	83.6±7.94	85.60±7.95	0.405

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80 min	82.95±8.24	84.65±7.63	0.502
85 min	85.15±8.14	87.05±7.4	0.445
90 min	86.15±7.39	89.1±8.23	0.240
95 min	85.8±9.41	89.7±5.62	0.120
100 min	87.65±8.93	88.4±7.15	0.771
105 min	84.75±9.56	87.65±4.3	0.224
110 min	88.6±8.26	85.94±5.52	0.248
115 min	89.6±7.35	86.57±7.98	0.226
120 min	92.8±7.61	87.26±8.45	0.038
Within Groups Comparison (p-value)	<0.001	Within Groups Comparison (p-value)	<0.001
Overall p-value = 0.699			

TABLE 4: POSTOPERATIVE PAIN SCORE

VAS	**Group MB (n = 20) Mean±SD**	**Group MBI (n = 20) Mean±SD**	**p – value**
0 min	1.45±1.46	0.55±0.75	0.019
1 Hr	2.05±1.73	1.05±1.9	0.090
2 Hr	3±1.71	1±0.72	0.001
3 Hr	2.75±1.44	1.95±1.43	0.086
4 Hr	2.35±1.03	2.3±1.34	0.895
5 Hr	1.6±0.75	2.5±1.31	0.011
6 Hr	1.95±0.82	2.75±1.33	0.028
9 Hr	3.6±1.5	2.1±1.07	0.001
12 Hr	2.15±0.93	1.8±1	0.260
15 Hr	1.65±0.48	1.65±0.58	1.000
18 Hr	2.65±0.67	2.95±1.14	0.318
24 Hr	1.4±0.5	1.1±0.64	0.107
Overall p- value = 0.002			

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TABLE 5: DURATION OF ANALGESIA AND RESCUE ANALGESIA

Parameters	Group MB (n = 20) Mean±SD	Group MBI (n = 20) Mean±SD	p - value
Duration of analgesia (min)	129.00±83.22	273.00±110.93	0.001
Number of Diclofenac injections required	2.90±0.31	2.30±0.66	0.001
Total Dose of Diclofenac (mg) required	161.50±21.54	122.45±37.33	0.001
Total Dose of Morphine (mg)	0.9±1.41	0.6±1.23	0.478
No. of patients required Morphine (%) as additional analgesic	6(30%)	4(20%)	0.465

TABLE 6: SIDE EFFECTS

Complication Present	Group MB (n = 20)	Group MBI (n = 20)	p – value
Sedation	20	20	-
PONV	0	0	-
Bradycardia	0	0	-
Hypotension	0	0	-
DTR Depression	0	0	-

4. DISCUSSION

Postoperative pain after total abdominal hysterectomy is moderate to severe in intensity.[2] Due to side effects of opioids, anaesthesiologists use non-opioids medications to control postoperative pain.[11]

The present study was designed as randomized double blinded trial to compare the effects of intravenous bolus versus bolus followed by infusion of magnesium sulphate for postoperative pain after abdominal hysterectomy under general anaesthesia.

In the present study, intraoperative haemodynamic parameters like Heart rate, mean arterial pressure were recorded at various time intervals. Statistical analysis showed that these parameters were comparable at most of the time points. In a study done by Kiran et al on single dose of intravenous magnesium sulphate for prevention of postoperative pain after inguinal surgery, they found that comparison of haemodynamic paremeters during intraoperative period between magnesium group and control group at different time intervals was statistically insignificant.[12]

In our study, significantly less VAS score was seen just at the end of surgery, 2nd, 5th, and 9th hours after the surgery (p value <0.05) in group MBI.

Seyhan et al conducted a study on three different doses of magnesium on anaesthetic requirements and postoperative pain relief in gynaecological surgery. Based on the results, magnesium 40mg/kg bolus with 10mg/kg/hr iv infusion reduced postoperative pain and

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opioid analgesics consumption significantly. Along with this, intraoperative propofol and neuromuscular blocking agent's requirement was also reduced.[13] Similar study was done by Khafagy et al with different dose of magnesium and observed that magnesium 50 mg/kg bolus followed by 8 mg/kg/hr infusion significantly reduced intraoperative propofol and vecuronium and postoperative fentanyl consumption. Doubling magnesium infusion rate to 16mg/kg/hr added minimal benefits and delayed recovery.[14]

A similar study was done by Ryu et al, in patients who underwent gynaecological surgery using magnesium sulphate 50 mg/kg i.v. as a bolus and then 15 mg/kg/ h i.v. by continuous infusion and control group received same amount of normal saline. The postoperative VAS scores at rest and on movement were significantly less in magnesium group with p value <0.05 as compared to normal saline group.[5]

On comparison of duration of analgesia, in a study by Kumar et al, first rescue analgesia was required after 334 +/- 202 min in MG group and after 233 +/- 141 min in NS group with significant difference ($p < 0.05$).[15]

These studies and present study showed that magnesium bolus dose in preoperative period followed by magnesium infusion during surgery reduced pain in postoperative period and provided longer duration of analgesia.

In the present study, the mean number of Diclofenac injections and mean Diclofenac dosage (mg) was significantly lower in Group MBI as compared to Group MB. Similarly, Kiran et al observed in their study in 2011 that Requirement of rescue analgesia during first 4 hrs and at 8 hrs and 16 hrs was less in group which received magnesium sulphate 50mg/kg in 250ml isotonic saline than in control group($P<0.05$).[12] Similar study was done in 2015 by Taheri et al in patients undergoing total abdominal hysterectomy under general anaesthesia. Postoperative pain score and Pethidine requirement was significantly lower in magnesium group at 6, 12, and 24 hours after TAH.[16] Levaux et al conducted a study and concluded that Cumulative piritramide consumption was significantly higher in non-magnesium group than in group Mg at 6, 12 and 24 hour.[17]

Moreover , Bhatia and colleagues conducted a study , It was found that patients in the magnesium and normal saline groups had similar morphine requirement during the first 24 hours postoperatively ($p = 0.07$).[18] which is in collaboration to our study.Similar study was done by Marinova et al with different magnesium dosages but result was same as postoperative pain and total analgesic requirement of morphine was significantly lower ($P < 0.05$) in magnesium group compared to control group.[19] Moreover, kumar et al[15] also showed similar results in their study.In contrast to present study, Ghaffaripour et al didn't find reduction in opioid consumption and pain severity following bolus followed by iv infusion of magnesium sulfate in patients undergoing laminectomy in the first 24 hours postoperatively. The differences were statistically insignificant in terms of postoperative morphine consumption and VAS score with p value of 0.23 and 0.52 respectively in Mg and control groups of their study.[20]

In the present study, all patients who received magnesium sulphate showed sedation in postoperative period. Similar results were observed by Kiran et al in their study using

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magnesium sulphate and found that patients in group who received magnesium were more sedated as compared to control group (sedation score 1.86 vs. 1.40) (P=0.000).[12]

STRENGHTS OF OUR STUDY

This is the only study to compare the effects of magnesium sulphate given either as intravenous bolus or bolus followed infusion for post operative pain in patients undergoing open abdominal hysterectomy under general anaesthesia.

LIMITATIONS OF OUR STUDY

Serum magnesium concentration of the patients was not estimated, although no patient developed any feature of hypermagnesemia.

5. CONCLUSION

It was concluded that magnesium sulphate given 50 mg/kg iv bolus followed by 10mg/kg/hr intraoperative infusion provided prolonged duration of analgesia, low VAS score for pain, reduction in requirement of analgesics dose and number of injections with mild and manageable adverse effects as compared to magnesium 50 mg/kg bolus only in the patients of abdominal hysterectomy.

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Conflict of Interest: NIL

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