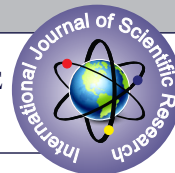


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COMPARISON OF ANALGESIC EFFECTS OF MAGNESIUM SULPHATE VERSUS FENTANYL AS AN ADJUVANT TO INTRATHECAL 0.5% HYPERBARIC BUPIVACAINE FOR ABDOMINAL HYSTERECTOMY: A RANDOMIZED DOUBLE BLIND, INTERVENTIONAL STUDY



Anaesthesiology

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ABSTRACT

Background: Spinal anaesthesia is the most commonly used technique for infraumbilical surgeries and it has some disadvantages, such as a short duration of motor blockade and post-operative analgesia. This study is designed to compare the analgesic effect of intrathecal fentanyl versus magnesium sulphate with hyperbaric bupivacaine duration of analgesia, onset and duration of sensory and motor block, sedation and to evaluate the side effects, if any.

Aim: To assess and compare the analgesic effect of intrathecal magnesium sulphate versus fentanyl as an adjuvant to intrathecal 0.5% hyperbaric bupivacaine in abdominal hysterectomy.

Method: This study was conducted in 60 patients of both sexes of ASA physical status I and II scheduled for abdominal hysterectomy. Patients were randomly divided into two groups and were given the drugs intrathecally as per group distribution; Group A received 3.5 ml of 0.5% hyperbaric bupivacaine + 0.5 ml of (25 mcg) of fentanyl intrathecally. Group B received 3.5 ml of 0.5% hyperbaric bupivacaine + 0.5ml (100mg) of magnesium sulphate intrathecally.

Result: Time of onset of sensory and motor blockade was delayed in Group B compared with Group A, and this was statistically significant. A statistically significant longer duration of analgesia was observed in Group B compared with the group A. The recovery of motor blockade was found also delayed in group B as compared to group A, which was statistically significant. The hemodynamic parameters were comparable in the perioperative period ($P > 0.05$).

Conclusion: Magnesium sulphate as adjuvant to intrathecal bupivacaine is better option than fentanyl with intrathecal bupivacaine, as it provides longer duration of analgesia, better haemodynamic stability and with less side effects.

KEYWORDS

Bupivacaine (0.5%), Magnesium Sulphate, Fentanyl, Spinal Anaesthesia, Abdominal hysterectomy.

INTRODUCTION

Spinal anesthesia also called spinal block or sub-arachnoid block (SAB) is a form of regional anaesthesia involving injecting the local anaesthetic into sub-arachnoid space. It is a preferred means anaesthesia for obstetrics and gynecological surgery as it has several advantages. It is economic, simple to perform, reduced risk of pulmonary aspiration, produces rapid onset of anaesthesia, complete muscle relaxation and requires less drug doses.⁽⁶⁾

Total abdominal hysterectomy requires traction of peritoneum and gut handling resulting in visceral pain which is poorly localized. This type of pain requires more intense block so higher doses of hyperbaric bupivacaine is required. Increasing the dose of local anaesthetic increases the risk of higher block. To provide good operation condition with better patient acceptance, addition of an opioid to local anaesthetic allows a reduction in dosage of local anaesthetic prolonged post operative analgesia improves intraoperative analgesia and provides post operative pain relief for longer duration (7).

Intrathecal magnesium has been found to prolong the duration of analgesia in various surgical procedures like lower limb surgeries and as adjuncts to general anesthesia for pain management. Magnesium blocks calcium influx and noncompetitively antagonizes N-methyl-D-aspartate receptor channels leading to analgesia and can cause side effects of nausea, vomiting, and hypotension at higher doses.⁽⁸⁾

The actions of fentanyl and congeners are similar to those of other -receptor agonists. Fentanyl is a popular anaesthetic because of its relatively short time to peak analgesic effect, rapid termination of effect after small bolus doses, and cardiovascular safety.⁽¹⁰⁾

This study is designed to compare the analgesic effect of intrathecal fentanyl versus magnesium sulphate with hyperbaric bupivacaine duration of analgesia, onset and duration of sensory and motor block, sedation and to evaluate the side effects, if any.

METHODOLOGY

This was a hospital based prospective interventional randomized double blind controlled study. Study was approved by the research and review board of our medical college. Due permission from the

institutional ethical committee was taken and informed written consent from all the patients undergoing study was also obtained before the study.

All patients underwent thorough pre anaesthetic check-up and were fasted for at least 6 hours before the procedure. After taking written informed consent, patients were randomly allocated to one of the two groups using sealed enveloped method. All routine monitors were attached and preoperative baseline readings of NIBP, PR and saturation were noted. After securing an IV access using 18G intravenous cannula all patients irrespective of the group were preloaded with Ringer's Lactate 15ml/kg over 10mins. Under all aseptic precautions spinal anaesthesia was performed in the operating room at the $L_3 - L_4$ interspace, with the patient in the sitting position using 25G Quincke spinal needle.

The Sample size was calculated 30 patients in each group at 95% confidence and 80% power to verify the expected difference of $27 \pm (23.3)$ minutes (as per seed article) total duration of analgesia in both groups. This study was conducted in following two groups of patients. Each group consist of 30 patients ($n = 30/\text{group}$).

Group A received intrathecal 0.5% hyperbaric bupivacaine 3.5 ml + 25µg fentanyl (total volume 4 ml) and group B received intrathecal 0.5% hyperbaric bupivacaine 3.5 ml + magnesium sulphate 100mg (0.5 ml) {total volume 4ml} [1gm (2ml) magnesium sulphate diluted by adding 3 ml 0.9 % normal saline so the concentration would be 200mg/ml].

Patient was placed in supine position with a 15° head down tilt immediately after spinal injection. An indwelling urinary catheter was inserted before the start of the operation. Intra-operative fluid management was done according to the blood loss and hemodynamic parameters. Intraoperative, vitals will be recorded at 2 mins interval for first 20 mins from the time of injection of spinal solution and there after every 10 mins for the complete period of surgery.

Intra-operative sensory loss assessment was done by pin prick test at every 2 minutes till highest level was achieved after spinal injection, at the end of surgery and in recovery room until 2 segment regression.

Motor blockage was assessed by Modified Bromage Scale (MBS). Blood pressure was monitored non-invasively every 5 minutes throughout surgery and heart rate with ECG and oxyhemoglobin saturation was monitored continuously during surgery. A decrease in mean arterial pressure greater than 15% below the baseline value was treated by incremental doses of inj. mephenteramine 6mg intravenously. Decrease in heart rate below 50 beats/min was treated with incremental doses of atropine 0.6mg intravenously.

Postoperatively, the pain was assessed by using visual analog pain scale (VAS) between 0 and 10 (0 = no pain, 10 = most severe pain). It was assessed at every 30 min. postoperatively.

All Statistical analysis was done using theepi info version 7.2.1.0 statistical software. The Categorical variables were summarized as percentage and were analyzed using Chi square test. Continuous variables were summarized as mean and standard deviation and were analyzed by student's t-test.

RESULTS

In this study satisfactory surgical anaesthesia was attained in all the cases. The demographic and baseline hemodynamic parameters were comparable in all the groups ($p > 0.05$) (Table 1).

Table1: Demographic Data And Baseline Hemodynamic Variables Age And Weight Expressed As (mean + Sd)

	GROUP A	GROUP B
Age (yrs.)	46.93±8	44.30±3.22
Height(cm)	163.0 ± 4.40	162.93± 3.10
Weight (kg)	60.83±2.05	61.10±2.70
ASA grade (I,II)	83.3,16.7	83.3,16.7

The mean time of onset of sensory block in group A was 3.57 ± 0.73 and in group B 3.93 ± 0.37 minutes. Mean time of onset of sensory block was earlier in group A as compared to (group B and statistically significant.

The mean time onset of motor block in group A was 4.77 ± 0.77 minutes and in group B was 5.80 ± 0.71 minutes. The mean time of onset of motor block was earlier in group A as compared to group B, was statistically significant.

Duration of sensory block was 221.67 ± 20.52 minutes in group A while in group B was 263.67 ± 27.73 in minutes. Duration of sensory block was prolonged in magnesium sulphate group as compared to fentanyl and statistically significant.

Duration of motor block was 196.33 ± 21.25 minutes in group A while in group B 241 ± 27.46 in minutes. There was statistically significant difference in duration of motor block as p value = 0.001.

We observed that VAS score was significantly higher in group A as compared to group B for 270 mins post operatively.

The mean duration of analgesia i.e. time from intrathecal injection to patients demand for analgesic was 3.69 ± 0.35 in hrs in group A while 4.39 ± 0.47 in hrs in group B. It was significant $p = 0.001$ (S).

In group A 10% patients had hypotension and bradycardia while in group B 6.67% patients had hypotension and bradycardia. Difference in incidence of hypotension and bradycardia was statistically significant. ($p = 0.026$)

Table 2: Block (Sensory & motor) and Analgesia. Values are (Mean + SD)

	GROUP A	GROUP B
Onset of sensory block (min)	3.57 ± 0.73	3.93 ± 0.37
Onset of motor block (min)	4.77 ± 0.77	5.80 ± 0.71
Total duration of analgesia (hrs)	3.69 ± 0.35	4.39 ± 0.47
Duration of sensory block (min)	221.67 ± 20.52	263.67 ± 27.73
Duration of motor block (min)	196.33 ± 21.25	241 ± 27.46

Rescue analgesic was given for VAS Score ≥ 3 . None of the patients experienced pain in group A and group B up to 30 minutes postoperatively. Difference in mean VAS score was higher in group A as compared to group B at 60min., 90min., 120 min, 150min, 180min, 210min, 240min, 270 min. and 300 min. as P value < 0.001 which was statistically significant.

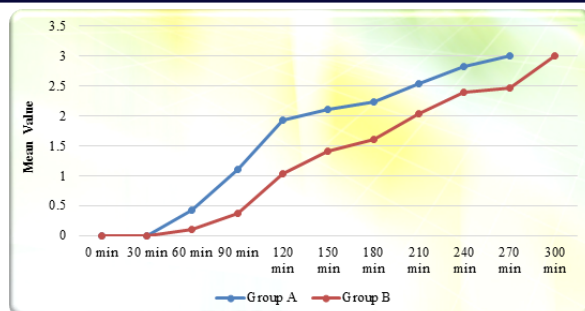


Figure 1. Comparison Of Post-operative Pain Vas Between Group-a And Group-b

DISCUSSION

Spinal anaesthesia is the most commonly used technique for abdominal hysterectomy surgeries, as it is cost effective and easy to administer. However, postoperative pain control is a major problem, because spinal anaesthesia using only local anaesthetics drugs is associated with relatively short duration of action and thus early rescue analgesic is needed in the postoperative period. Various drugs such as clonidine, midazolam, fentanyl and others have been studied for prolongation of the effect of spinal anaesthesia and duration of analgesia.⁽⁶⁾

Fentanyl is a highly selective μ receptor agonist, which is mainly responsible for its analgesic properties. Analgesia is produced principally through interaction with μ receptors at supraspinal sites. Fentanyl also binds to κ receptors causing spinal analgesia, sedation and anesthesia.

Magnesium blocks calcium influx and noncompetitively antagonizes N-methyl-D-aspartate receptor channels leading to analgesia and can cause side effects of nausea, vomiting, and hypotension at higher doses.

With above background present study was conducted to compare postoperative analgesic effect of intrathecal magnesium sulphate and fentanyl with hyperbaric bupivacaine (0.5%) in patients under going total abdominal hysterectomy under spinal anaesthesia.

There was no significant difference between the two groups in terms of demographic data and duration of surgery.

The mean time of onset of sensory block in group A was 3.57 ± 0.73 and in group B 3.93 ± 0.37 minutes. Mean time of onset of sensory block was earlier in group A as compared to group B. This was statistically significant as p value was 0.016. Nath Mirdu P et al (2012)⁸ also found that mean onset of sensory block was earlier in fentanyl as compared to magnesium sulphate.

The mean time onset of motor block in group A was 4.77 ± 0.77 minutes and in group B was 5.80 ± 0.71 minutes. The mean time of onset of motor block was earlier in group A as compared to group B. It was statistically significant as p value = 0.001

Nath Mirdu P et al (2012)⁸ also found that time taken for achieving motor block was earlier in fentanyl group as compared to magnesium sulphate group.

Duration of sensory block was 221.67 ± 20.52 minutes in group A while in group B the mean duration of sensory block was 263.67 ± 27.73 in minutes. There was statistically significant difference in duration of sensory block as p value = < 0.001 .

Khalili G et al (2011)¹¹ also reported that intrathecal magnesium sulphate significantly prolongs the mean duration of sensory block compared to intra thecal fentanyl.

Duration of motor block was 196.33 ± 21.25 minutes in group A while in group B the mean duration of motor block was 241 ± 27.46 in minutes. There was statistically significant difference in duration of motor block as p value = 0.001.

Nath Mirdu P et al (2012)⁸ also reported that the magnesium sulphate

significantly prolonged the mean duration of motor block as compared to fentanyl group

Difference in mean. VAS score was significantly higher in group A as compared to group B at 60,90, 120, 150, 180, 210, 240, 270 and 300 minutes postoperatively. as P value <0.001 which was statistically significant

We observed that VAS score was significantly higher in group A as compared to group B for 270 mins post operatively.

Previous studies conducted by Nath Mirdu P et al (2012)⁸, Khezri MB, Yaghobi S, Hajikhani M, et al (2012)⁽¹⁰⁾ they also found that vas score was significantly less in magnesium sulphate group as compared to fentanyl group

The mean duration of analgesia was 3.69 ± 0.35 in hrs in group A while 4.39 ± 0.47 in hrs in group B. It was significant $p=0.001$ (S). The duration of analgesia was longer in magnesium sulphate group as compared to fentanyl group. Studies conducted by Nath Mirdu P et al (2012)⁸, Khezri MB, et al (2012)¹⁰ they also found that duration of analgesia was prolonged in magnesium sulphate group as compared to fentanyl group.

In group A 10% patients had hypotension and bradycardia while in group B 6.67% patients had hypotension and bradycardia. Difference in incidence of hypotension and bradycardia was statistically significant. ($p=0.026$)

Our findings are in concordance with findings of Nath Mirdu P et al (2012)⁸. They also had similar incidence of side effects in perioperative period.

CONCLUSION

Magnesium sulphate as an adjuvant to intrathecal bupivacaine is better option than fentanyl with intrathecal bupivacaine, as it provides longer duration of sensory block, prolongs the period of analgesia, better haemodynamic stability and with less side effects.

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