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Comparison between Magnesium Sulphate and Ketorolac Intravenous Infusion on Characteristics of Spinal Anesthesia

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Abstract

Background: Spinal anesthesia is used widely for many procedures, many adjuvants had been used to prolong duration of sensory and motor block and improve post-operative pain.

Aim of Study: The aim of this study is to compare the effect of magnesium sulphate and ketorolac intravenous infusion on sensory and motor blockage, hemodynamic parameters, duration of analgesia and side effects during spinal anesthesia.

Patients and Methods: Patients were classified randomly into three groups (30 patients each) Group M (Magnesium sulphate Group), Group K (Ketorolac Group), Group C (Control Group). Group M patients received a loading dose of magnesium sulphate 40mg/kg IV over 10min followed by 15mg/kg/h IV infusion, Group K patients received a loading dose of ketorolac (0.4mg/kg) (IV) over 10min followed by 0.8mg/kg/h IV infusion. Group C received 50ml of saline (IV) over 10min followed by saline infusion. After ensuring free flow of cerebrospinal fluid, 3mL of bupivacaine (0.5%) injected Pulse rate, electrocardiography, non-invasive blood pressure and SpO_2 monitored continuously. Measurements: Demographic data (age, weight, BMI, ASA physical status). Hemodynamic (HR, MAP, SpO_2) before giving study drugs, 10min after giving study drugs and after reaching the maximal level of spinal anesthesia and then every 30min till end of surgery. Onset of sensory blockade has been assessed by pinprick method. Onset of motor blockade has been assessed by modified Bromage Scale. Level of sensory and motor blockade has been checked at 3, 5, 10 and 15min after spinal anesthesia and then every 20min throughout the surgery. Time to achieve complete regression from sensory and motor blockade has been noted. All the durations were calculated considering the time of spinal injection as zero time. Post-operatively analgesia has been assessed by the Visual Analog Scale (VAS). The time at which analgesia was first received and total analgesic requirement in 24h was recorded. Patients observed for any adverse effects such as nausea, hypotension.

Results: There were insignificant changes between the three groups in HR and MAP but there was significant decrease in HR and MAP in each group at 10min, maximal level and 30min in comparison with base line.

There were insignificant changes in onset and duration of sensory and motor block in the three studied groups.

The total dose of analgesic consumption (pethidine (mg)) showed significant decrease in Group M in comparison with Group K & Group C with insignificant change between Group K & Group C.

The time of first rescue analgesia showed significant increase in Group M in comparison with Group K & Group C and insignificant changes in Group K in comparison with Group C.

Conclusion: Addition of intravenous magnesium sulphate with spinal anaesthesia provides significant decrease in post-operative analgesic requirements and prolongs the time of the first rescue analgesia as compared to intravenous ketorolac with spinal anaesthesia.

Key Words: *Spinal anesthesia – Magnesium Sulphate – Ketorolac.*

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Introduction

SPINAL anesthesia is used widely for patients undergoing urological procedures, lower abdominal and lower limb surgery. Different adjuvant such as morphine, fentanyl, midazolam and clonidine had been used to prolong spinal anesthesia, providing the possible advantages of the better pain control in the early post-operative period and reduced deep vein thrombosis [1].

Magnesium is the fourth most essential ion in the human body and plays an important role in many cellular functions, such as storage, metabolism, and energy utilization. Magnesium has been reported to produce important analgesic effects including the suppression of neuropathic pain, potentiating of morphine analgesia, and attenuation of morphine tolerance. Although the exact mechanism is not yet fully understood, the analgesic properties of magnesium are believed to stem

from regulation of calcium influx into the cell and antagonism of N-Methyl-D-Aspartate (NMDA) receptors in the central nervous system and inhibition of catecholamine release [2,3].

Ketorolac is a non-steroidal agent with potent analgesic and moderate anti-inflammatory activity, it is used for management of moderate to severe pain. Ketorolac is not associated with respiratory depression, nonspecific COX inhibition may lead to gastric mucosal affection, platelet activity affection and renal insult but these effects are dose and duration dependent [4].

Recently it has been suggested that IV magnesium sulphate and IV ketorlac may affect spinal anesthesia efficiency [5].

Patients and Methods

This prospective, randomized, double-blind comparative study was carried out in Tanta University Hospital from March 2017 to March 2018.

After approval from Institutional Ethics Committee (approval code number 53244), an informed written consent was taken from each patient. Every patient received an explanation to the purpose of the study and a secret code number to ensure privacy to participants and confidentiality of data. Research results were only used for scientific purposes. Any unexpected risk appears during the course of the research was cleared to the participants and Ethical Committee on time and proper measures was taken to overcome or minimize these risks. Ninety patients aged between 18 and 60 years, ASA I & II, scheduled for lower abdominal, urological and lower limb surgeries were enrolled into the present study.

Patient refusal, patients with known hypersensitivity or contraindications to local anesthetic or study drugs, patients with history of sleep apnea, obesity (BMI >30), myopathy or neuromuscular disease, patients with second or third degree heart block, patients with hepatic and renal dysfunction, psychiatric illness and any contraindication to spinal anesthesia were excluded from the study.

Patients were classified randomly into three groups (30 patients each) Group M (Magnesium sulphate Group), Group K (Ketorolac Group), Group C (Control Group), pre-operative assessment was done to all patients and they were preloaded with injection of Ringer lactate (10ml/kg). On arrival to operation room, patients medicated with study drugs. Group M patients received a loading dose of magnesium sulphate 40mg/kg IV over 10min followed by 15mg/kg/h IV infusion, Group K patients received a loading dose of ketorolac (0.4mg/kg) (IV) over 10min followed by 0.8 mg/kg/h IV infusion. Group C received 50ml of saline (IV) over 10min followed by saline infusion. Lumbar puncture performed at the level of L3-L4/L4-L5 space with 23/25-gauge spinal needle. After ensuring free flow of cerebrospinal fluid, 3mL of bupivacaine (0.5%) injected Pulse rate, electrocardiography, non-invasive blood pressure and SpO_2 monitored continuously. Oxygen delivered by an oxygen mask (5L/min) to all patients throughout procedure.

Measurements: Demographic data (age, weight, BMI, ASA physical status). Hemodynamic (HR, MAP, SpO_2) before giving study drugs, 10min after giving study drugs and after reaching the maximal level of spinal anesthesia and then every 30min till end of surgery. Onset of sensory blockade has been assessed by pinprick method. Onset of motor blockade has been assessed by modified Bromage Scale. Level of sensory and motor blockade has been checked at 3, 5, 10 and 15min after spinal anesthesia and then every 20min throughout the surgery. Time to achieve complete regression from sensory and motor blockade has been noted. All the durations were calculated considering the time of spinal injection as zero time. Postoperatively analgesia has been assessed by the Visual Analog Scale (VAS). The time at which analgesia was first received and total analgesic requirement in 24h was recorded. Patients observed for any adverse effects such as nausea, hypotension.

Results

There was no statistical significant difference between study groups as regards to demographic data (age, sex, BMI, ASA physical status) (Table 1).

There was insignificant changes between the three groups in HR and MAP but there was significant decrease in HR and MAP in each group at 10min, maximal level and 30min in comparison with base line (Tables 2,3).

There were insignificant changes in onset and duration of sensory and motor block in the three studied groups (Table 4).

The total dose of analgesic consumption [pethidine(mg)] showed significant decrease in Group

M in comparison with Group K & Group C with insignificant change between Group K & Group C.

The time of first rescue analgesia showed significant increase in Group M in comparison with Group K & Group C and insignificant changes in Group K in comparison with Group C (Table 4).

There was insignificant difference in bradycardia, hypotention and nusea & vomiting in study groups.

Table (1): Demographic data of the three studied groups.

	Group M	Group K	Group C	Test	*p*-value
Age (years):					
Range	20-48	20-58	19-57	F:	0.804
Mean ± SD	33.60±7.11	34.97±9.44	34.70±8.74	0.219	
Sex:					
Male (%)	19 (63.3%)	17 (56.7%)	17 (56.7%)	χ^2:	0.832
Female (%)	11 (36.7%)	13 (43.3%)	13 (43.3%)	0.367	
BMI (kg/m^2):					
Range	18-24.5	18.2-25	18-25	F:	0.872
Mean ± SD	21.04±1.85	21.09±1.95	21.30±2.23	0.137	
ASA:					
I (%)	17 (56.7%)	16 (53.3%)	15 (50%)	χ^2:	0.875
II (%)	13 (43.3%)	14 (40.7%)	15 (50%)	0.268	

Table (2): Onset of motor and sensory block (min) time of motor and sensory block (min) total dose of analgesic requirements [mg (pethidine)] and time of first rescue analgesia (hr.) in the three studied groups.

	Range	Mean ± SD	F.Test	*p*-value	
Onset of sensory block (min):					
Group M	2-4.5	3.37±0.74	0.256	0.775	
Group K	2-4.5	3.40±0.77			
Group C	2-5	3.50±0.74			
Onset of motor block (min):					
Group M	3-6	4.37±0.83	0.117	0.890	
Group K	3-5.5	4.32±0.61			
Group C	3-6	4.42±0.93			
Duration of motor block (min):					
Group M	74-92	81.43±4.88	1.712	0.187	
Group K	69-88	78.80±6.17			
Group C	70-90	80.87±6.25			
Duration of sensory block (min):					
Group M	123-150	135.97±7.72	1.778	0.175	
Group K	120-150	133.73±9.06			
Group C	120-140	132.17±6.56			
Total analgesic requirement (mg):					
Group M	40-120	71.67±18.30	13.638	0.001 *	p_1 0.002*
Group K	75-160	95.50±29.87			p_2 0.001*
Group C	70-165	110.67±36.38			p_3 0.052
Time of first rescue analgesia (hr):					
Group M	2-5	3.37±0.71	33.418	0.001 *	p_1 0.001*
Group K	1-4	2.70±0.70			p_2 0.001*
Group C	1-3	1.88±0.70			p_3 0.061

p 1: Group M & Group K.
p2: Group M & Group C.
p3: Group K & Group C.

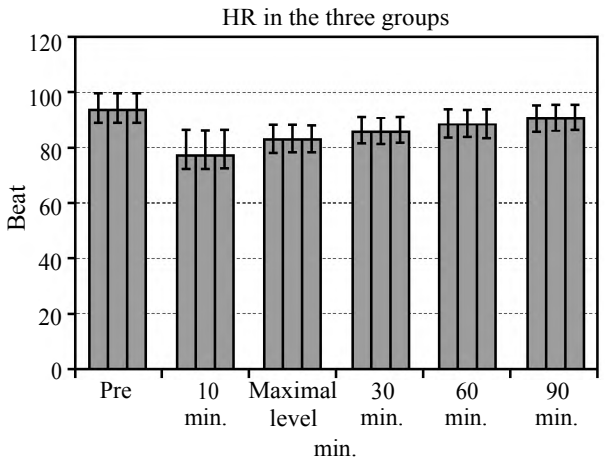

Fig. (1): Comparison between heart rate (beat/min) changes in the three studied groups.

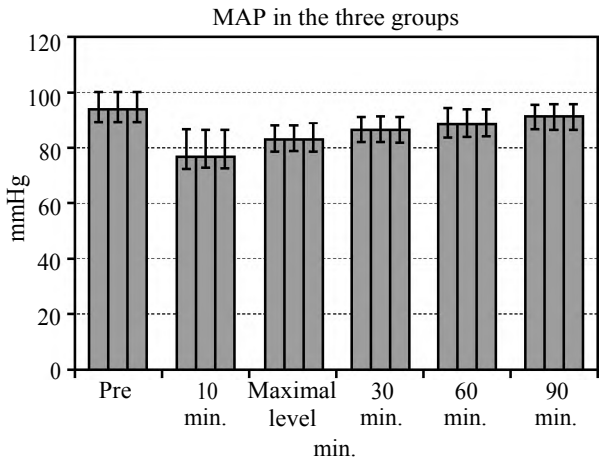

Fig. (2): Mean Arterial blood Pressure (MAP) changes in the three studied groups.

Discussion

Various systemic and Intrathecal adjuvants are combined with LAs in order to potentiate the spinal block and prolong analgesia [6]. They allow reduction of the LA dose [7], thus enables faster recovery of motor function and voiding, with elimination of side effects associated with larger doses and consequently a faster discharge [8].

As regard demographic data and patient characteristics, there was no significant difference between the three studied groups.

Concerning hemodynamic changes after giving study drugs, mean arterial blood pressure & HR showed significant decrease at 10min, maximal level of spinal anesthesia and 30min after induction of spinal anaesthesia and insignificant changes at 60min, 90min in the three study groups with insignificant changes between the three study groups, so no effect of magnesium sulphate or ketorolac on hemodynamics was encountered.

Magnesium causes a dose-dependent negative inotropic effect, and in humans haemodynamic studies have shown that it has a peripheral (predominantly arteriolar) vasodilatory effect. After rapid infusion of 3 or 4g of magnesium sulphate, systolic arterial pressure decreased in relation to decreased systemic vascular resistance [9] in the present study, considering the negative intropic effect of Mg, prehydration with 10ml/kg of lactated Ringer's solution was performed and the Mg bolus dose was infused over 10min, which is probably why no significant hypotension was encountered after administering the Mg bolus dose and no significant inter-group haemodynamic differences were observed during the surgery.

Ketorolac has analgesic properties through direct anti-inflammatory effects. Moreover, ketorolac neither causes respiratory depression, nor other side-effects such as vomiting, itching, and hemodynamic instability, but it has some gastrointestinal and antiplatelet effects [10].

In agreement with our results Kumar M et al., 2013 [11]. Studied the effect of intravenous magnesium sulphate on post-operative pain following spinal anesthesia. Patients were given either $MgSO_4$ 50mg/kg in 10mL within 10min, followed by an infusion of $MgSO_4$ 10mg/kg/hr. IV in 4mL (MG group) for 12hrs. or normal saline in same volume and rate for 12hrs. After initiating the infusion, spinal anesthesia was given. they reported that hemodynamic variability did not differ from the control group.

Also, Shah P.N 2016 [12]. In their study they assessed the hemodynamic effects of intravenous magnesium sulfate and rescue analgesia requirement with spinal anesthesia patients received either 250mg of intravenous magnesium sulfate followed by an infusion of 500mg magnesium sulfate (25mg/mL) at the rate of 20mL/hour; or the same volume of normal saline (control group) as bolus and infusion they were in line with our results as they noticed insignificant fall of MAP & HR. In this study the doses was lower than our study but in both studies no effect on MAP and HR was observed.

In contrast to our study Sebastian S.K et al., 2015 [13] in their study on perioperative Magnesium sulphate infusion with spinal anaesthesia. 'M' Group for magnesium and 'S' group for placebo. 'M' Group was infused with 500ml normal saline containing Magnesium sulphate at a dose of 8mg/kg/hr. till

the end of the surgery. The placebo Group 'S' also received same amount of normal saline till the end of surgery. There was increase in hypotension in M Group 36.7% compared to placebo.

In addition Albrecht E et al., 2013 **[5]** in their study Peri-operative intravenous administration of magnesium sulphate and postoperative pain: A meta-analysis. Twenty-five trials comparing magnesium with placebo were identified. They found that bradycardia was more common in magnesium group.

In ketorolac group, our results were in agreement with those of Khezri M.B et al., 2018 **[14]**. In their study on one hundred and fifty patients who were scheduled for elective cesarean section under spinal anesthesia were randomly allocated to one of three study groups to receive intravenous ketorolac (Group K), meperidine (Group M) or normal saline (Group P). They found that there was hemodynamic stability as these drugs can prevent high blood pressure and tachycardia by decreasing anxiety, fear and pain.

To the best of our knowledge we didn't find any study suggested that ketorolac infusion affect MAP & HR.

As regards the onset, duration and level of sensory and motor block, our results showed no significant difference between the three groups.

As regard Group M our results were in agreement with Kumar M et al., 2013 **[11]** found that magnesium infusion with spinal anaesthesia has no effect on onset, duration and level of sensory and motor block between studied groups.

Also, Hwang J.Y et al., 2010 **[15]** in their study I.V. infusion of magnesium sulphate during spinal anaesthesia improves post-operative analgesia they foud no effect of magnesium on the level of bupivacaine induced sensory block or the duration of spinal analgesia.

In contrast to our study Shah P.N et al., 2016 **[12]** found that intravenous magnesium sulfate prolongs the duration of sensory and motor blockade of spinal anesthesia.

As regard Group K we didn't find significant effect of ketorolac infusion on onset, duration and level of sensory and motor block. To the best of our knowledge this is the first study on the effect of ketorolac infusion on characteristics of spinal anaesthesia.

As regarding total analgesic requirement and time of first rescue analgesia Group M had delayed 1st analgesic requirement and had the least total consumption of rescue analgesia compared to Group K and Group C and there were no diffrence between Group K compared to Group C.

As regard Group M our results were in agreement with Shah P.N. et al., 2016 **[12]** who concluded that the use of intravenous Mg with spinal anesthesia delayed and decreased the need of rescue analgesics after spinal anesthesia.

Also Albrecht E et al., 2013 **[5]** found that perioperative magnesium can provide a clinically important reduction in opioid consumption.

Moreover, Hwang J.Y et al., 2010 **[15]** found that magnesium sulphate given i.v. during spinal anaesthesia reduced post-operative pain and analgesic consumption without complications.

In contrast to our study, Ko et al., 2001 **[16]** reported that administering magnesium in patients undergoing abdominal hysterectomy 50mg/kg in the pre-operative period and 15mg/kg/h intraoperatively and 6h after the operation had no effects on post-operative pain.

Also Tramer M.R et al., 2007 **[17]**, in their study on patients undergoing ambulatory ilioinguinal hernia repair or varicose vein operations supplemented with other analgesic adjuvants, pretreatment with IV magnesium sulfate 4g has no impact on post-operative pain and analgesic consumption.

As regard Group K our results were in agreement with Beatriz et al., 2017 **[18]**, in their study No preemptive analgesic effect of pre-operative ketorolac administration following total abdominal hysterectomy: A randomized study. Patients in the ketorolac group received 30mg of IV ketorolac 30min before surgical incision, while the control group received normal saline. There was no difference in pain intensity between the two groups the time to first rescue analgesia and the total analgesic consumption were similar.

Our results were in disagreement with Khezri M.B et al., 2018 **[14]**. They found that preemptive prescription of a single dose of intravenous ketorolac can effectively reduce severity of post-operative pain and prolong the time of first rescue analgesia.

Regarding side effects in our study, there were insignificant difference among three groups.

In agreement with our results Kumar M et al., 2013 **[11]** found that the incidence of bradycardia, hypotension, nausea and vomiting was insignificant in patients received IV magnesium sulphate.

Also Shah P.N 2016 **[12]** found that incidence of bradycardia, hypotension, nausea and vomiting in patients received IV magnesium sulphate was insignificant.

In contrast to our results Sebastian S.K et al., 2015 **[13]** found that hypotension was significantly increased in patient received IV magnesium sulphate.

Also Albrecht E et al., 2013 **[5]** found that bradycardia was significantly increased with IV magnesium sulphate.

As regard Ketorlac Nistal N.B et al., 2018 **[14]** found that the incidence of bradycardia, hypotension, nausea and vomiting was insignificant in patients received IV, ketorolac.

Conclusion:

Addition of intravenous magnesium sulphate with spinal anaesthesia provides significant decrease in post-operative analgesic requirements and prolongs the time of the first rescue analgesia as compared to intravenous ketorolac with spinal anaesthesia.

Based on this study we recommend administration of IV bolus (40mg/kg) and infusion (15mg/kg/hr) of magnesium sulphate with spinal anaesthesia, it is safe to use; it improves post-operative analgesia and reduces analgesic requirement without having any effect on onset and recovery from spinal anesthesia.

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مقارنة تآثير سلفات المغنسيوم وكيتورلاك عن طريق التسريب الوريدى على إنسداد الإحساس والحركة والمعاملات الفسيولوجية ومدة التسكين والآثار الجانبية آثناء التحدير النصفى

المقدمة: يعد التخدير النصفى من آكثر الطرق شيوعاً. حيث يعتبر التخدير النصفى داخل الآم العنكبوتية من آفضل الوسائل لتسكين آلام ما بعد الجراحة يتم إعطاء إضافات للتخدير النصفى لتحسين سرعة البدء ومدة التسكين والتقليل من جرعة المخدر وبالتالى القضاء على بعض الآثار الجانبية المرتبطة بالجرعات الكبيرة.

وقد إستخدمت كل من كبريتات المغنسيوم عن طريق الحقن فى الوريد، الميدازولام، الكيتامينو مضادات الإلتهاب غير الستيروتيدية لهذا الغرض.

الهدف من البحث: الهدف من هذه الدراسة مقارنة تآثير سلفات المغنسيوم وكيتورلاك عن طريق التسريب الوريدى على إنسداد الإحساس والحركة والمعاملات الفسيولوجية ومدة التسكين والآثار الجانبية آثناء التحدير النصفى.

المرضى وطرق البحث: تم إجراء هذه الدراسة على ٩٠ مريضاً من الجنسين طبقاً لتصنيف الجمعية الآمريكية لآطباء التخدير مجهزين لعمل جراحات آسفل البطن والآطراف السفلية والمسالة البولية.

آسباب الإستبعاد من الدراسة:

- تم إستبعاد المرضى الذين لديهم موانع التخدير النصفى.
- وتم تقسيم المرضى إلى ثلاث مجموعات كل مجموعة من ٣٠ مريض.

مجموعة M (سلفات المغنسيوم):

بعد الوصول إلى غرفة العمليات المجموعة الآولى سوف يتم حقن جرعة من سلفات المغنسيوم ٤٠ملجم لكل كجم فى مدة قدرها ١٠ دقائق تتبع بجرعة ١٥مجم/كجم فى الساعة عن طريق التنقيط الوريدى.

مجموعة K (كيتورلاك):

المجموعة الثانية سوف يتم حقن جرعة من الكيتورلاك بمعدل ٠.٤ملجم لكل كجم فى مدة قدرها ١٠ دقائق تتبع بجرعة ٠.٨مجم/كجم فى الساعة عن طريق التنقيط الوريدى.

مجموعة C (محلول ملح):

والمجموعة الثالثة سوف يتم حقن ٥٠مل من محلول ملح فى مدة ١٠ دقائق تتبع بمحلول ملح عن طريق التنقيط الوريدى.

متابعة القياسات الحيوية آثناء العملية: تم متابعة ضغط الدم والنبض ورسم القلب، كما تم متابعة حدوث آى نوبات من القئ آو الرعشة.

القياسات التى تم تسجيلها:

١- البيانات الديمغرافية (العمر، الوزن، مؤشر كتلة الجسم، تصنيف الجمعية الآمريكية للتخدير للحالة الجسمانية).

٢- متوسط ضغط الدم ومعدل النبض ونسبة آكسجين الدم قبل إعطاء عقاقير الدراسة وبعد ١٠ دقائق من إعطائها وبعد ذلك كل ٣٠ دقيقة حتى نهاية العملية الجراحية.

٣- بداية تآثر الإحساس.

٤- بداية تآثر الخواص الحركية.

٥- درجة تأثر الخواص الحسية والحركية سيتم فحصها بعد ١٥، ١٠، ٥، ٣ دقيقة من إعطاء التخدير النصفى وبعد ذلك كل ٢٠ دقيقة خلال العملية الجراحية وسوف يتم تسجيل الوقت الذى يحدث عنده إنحسار كامل للإنسداد الحسى والحركى.

٦- سوف تحسب جميع المدد بإعتبار وقت حقن العمود الفقرى كالساعة صفر.

٧- بعد إنتهاء العملية سيتم تقييم التسكين بمقياس الآلم البصرى ومجموع الإحتياجات من المسكن فى ٢٤ ساعة وسيتم تسجيل الوقت الذى بدأ فيه الإحتياج إلى مسكن بعد الجراحة.

النتائج: وقد أظهرت نتائج الدراسة وجود تغيرات ليست ذات قيمة بين المجموعات الثلاثة فى معدل النبض ومتوسط ضغط الدم لكنه تم ملاحظة حدوث إنخفاض فى معدل النبض ومتوسط ضغط الدم فى كل مجموعة على حده فى الدقيقة العاشره وعند الوصول للمعدل الآقصى من التخدير النصفى وعند الدقيقة الثلاثون.

وقد كانت هناك تغييرات ليست ذات قيمة فى درجة تآثر الخواص الحسية والحركية بين الثلاث مجموعات.

ولكن لوحظ أن المجموعة M لم تحتاج إلى جرعة كبيرة من الآدوية المسكنة بعد الجراحة مقارنة بالمجموعتين K و C كما أن الوقت اللازم لإعطاء الجرعة الآولى من الآدوية المسكنة كان أطول فى المجموعة M مقارنة بالمجموعتين K و C.

الخلاصة: إضافة سلفات المغنسيوم عن طريق التنقيط الوريدى لحالات التخدير النصفى يزيد من مدة تسكين الآلم ما بعد الجراحة ويقلل من جرعة الآدوية المسكنة ما بعد الجراحة مقارنة بعقار الكيتورلاك عن طريق التنقيط الوريدى. وبالإعتماد على نتائج هذه الدراسة ننصح بإضافة سلفات المغنسيوم بجرعة ٤٠ملجم لكل كجم تتبع ب ١٥ملجم لكل كجم عن طريق التنقيط الوريدى مع حالات التخدير النصفى حيث أنها آمنه فى الإستخدام وتساعد على تقليل آلام ما بعد الجراحة بدون التأثير على الخواص الحسية والحركية للتخدير النصفى.