



Clinical Comparison of Adding Sulfate Magnesium and Dexmedetomidine in Axillary Plexus Block for Prolonging the Duration of Sensory and Motor Block: Study Protocol for a Double-blind Randomized Clinical Trial

Seyed Yousef Shahtaheri¹, Mohammad Tavakoli Rad¹, Bijan Yazdi¹, Mehran Azami², Alireza Kamali¹

¹Department of Anesthesiology and Critical Care, Arak University of Medical Sciences, Arak, Iran

²Department of Orthopedics, Arak University of Medical Sciences, Arak, Iran

Corresponding author: Alireza Kamali, Department of Anesthesiology and Critical Care, Arak University of Medical Sciences, Arak, Iran; Email: alirezakamalimd@gmail.com; Dr.kamali@arakmu.ac.ir; Tel: 00989181622810

Received: 03 June 2019 ♦ **Accepted:** 07 Aug 2019 ♦ **Published:** 31 March 2020

Citation: Shahtaheri SY, Rad MT, Yazdi B, Azami M, Kamali A. Clinical comparison of adding sulfate magnesium and dexmedetomidine in axillary plexus block for prolonging the duration of sensory and motor block: study protocol for a double-blind randomized clinical trial. *Folia Med (Plovdiv)* 2020;62(1):124-32. doi: 10.3897/folmed.62.e49805.

Abstract

Background: The purpose of this study was to compare the effect of magnesium sulfate adjunct to dexmedetomidine on increasing the duration of sensory and motor block in axillary block.

Materials and methods: This study is a double-blind clinical trial. Ninety-nine patients were included in the study. They were undergoing forearm and hand surgery and were referred to Vali-e-Asr Hospital in Arak. The patients were divided into three groups. The first group received lidocaine (1.5%) and dexmedetomidine (0.5 µg/kg). The second group patients were given lidocaine (1.5%) plus magnesium. In the control group, lidocaine (1.5%) was adjusted to 35 cc with normal saline. The final volume was 35 cc in the three groups. Sensory and motor block and pain were measured and data were analyzed using SPSS v. 20. The final volume was 35 cc in the three groups.

Results: The sensory and motor block onset time and the stabilization time of the sensory and motor block in the magnesium sulfate group were lower ($p < 0/001$). Pain in recovery, 2, 4, 6, 12, and 24 hours after surgery was lower in the magnesium sulfate group when compared with the dexmedetomidine group ($p < 0.001$). The lowest dose of opioid was used in the dexmedetomidine group 24 hours after surgery ($p < 0.001$).

Conclusion: The results showed that dexmedetomidine decreases pain. Magnesium sulfate increased the sensory and motor block onset time, and the sensory and motor block stabilization time, but dexmedetomidine increases the motor block duration.

Keywords

axillary block, dexmedetomidine, magnesium sulfate, motor block, sensory block

INTRODUCTION

Axillary network block is applied for anesthesia in the forearm and/or hand surgeries. Epinephrine is commonly used with topical anesthetic agents to induce anesthesia – it has many advantages due to the vasoconstrictive effects. These include increasing the block time and decreasing the maximum plasma level of local anesthetic, and consequently reducing the side effects of these drugs.^{1,2} In addition to creating optimal surgical conditions and faster postoperative patient mobility, it is capable of decreasing the dangers of general anesthesia and reducing the hospital costs, where these dangers in some patients can be associated with adverse effects and even mortality.^{3,4} Injection of anesthetic drugs in the vicinity of the root or trunk of the nerves is the basis of this block.⁵ In order to improve the severity, quality, duration and duration of anesthesia in these blocks, other drugs such as opiates, bicarbonate, adrenaline and dexamethasone with anesthetic drugs have been used.^{6,7} Postoperative pain increases the cost of treatment and the duration of hospital stay. Anesthesiologists have investigated ways to increase the duration of the block using different local anesthetics. Increasing the duration of analgesia makes the patient comfortable after surgery. The possibility of peripheral opioid receptors has led to the use of various drugs in local blocks to increase the duration of analgesia without increasing the side effects.

Several studies used various local anesthetics and drugs, where the results are completely different from those reported by them.⁸ Magnesium is the fourth most abundant cation in the body. It has analgesic effects in animals and humans.⁹ These effects regulate the calcium in the cell, so that it is an antagonist of the N-methyl-d-aspartate receptor.¹⁰ Furthermore, calcium plays a key role in the analgesia of topical anesthetic drugs. Calcium permeability is reduced by topical anesthetic drugs. Clinical research has shown that calcium channel blockers can increase the analgesic effect of anesthetics.¹¹

For these reasons, magnesium can increase local anesthetic properties. Magnesium improves the quality of anesthetics and antinociception intravenously and intrathecally.^{12,13} It has been reported in various studies that magnesium is effective in reducing the onset time of the block and in increasing the quality and duration of anesthesia.^{14,15} Dexmedetomidine, a α_2 -adrenergic agonist, is an analgesic, antipyretic and antihypertensive drug.¹⁶ Adding dexmedetomidine to topical anesthetic drugs can be effective during the peripheral nervous block.¹⁷ The axillary block is more commonly used for forearm and/or hand surgeries due to its ease, safety and reliability. Dexmedetomidine is useful as an adjuvant for faster anesthesia and longer anesthesia and can improve hemodynamic changes in forearms and hands.¹⁸ Adding magnesium sulfate without any complications can increase the sensory and motor block.¹⁹

Magnesium sulfate in peripheral blocks improves the duration of anesthesia and the sensory and motor block

without side effects.²⁰ So far, a study has not been conducted to compare the two drugs of dexmedetomidine and magnesium sulfate on the duration of the axillary block. On the other hand, magnesium sulfate is cheaper than dexmedetomidine, therefore it can be more cost-effective when it replaces the latter. Therefore, the aim of this study was to compare the effects of dexmedetomidine and magnesium sulfate on the duration of axillary block.

MATERIALS AND METHODS

This study was a randomized double blind clinical trial. In this study, 99 candidates for forearm and/or hand surgeries who referred to Vali-e-Asr Hospital of Arak were entered into the study after completing the informed consent form.

Inclusion criteria: American society of Anaesthesiologist grading (ASA) I, II, age 18-65 years, both sexes, candidate for forearm and arm surgery with axillary block, forearm and hand fracture, no more than one fracture in the body or surgery, absence of blood coagulation disorders and impaired prothrombin time (PT), partial thromboplastin time (PTT), and international normalized ratio (INR), body mass index (BMI) less than 35, no psychological problems, no history of allergy to used drugs, no previous pregnancy, absence of chronic pain syndrome and absence of neurological disorders.

Exclusion criteria: infection at the site of the block, the block failure.

The patient was transferred to the operating room and the anesthetist's assistant prepared the patient for the axillary block. The block was performed without the specialist knowledge of the materials they contained. First, the patient was placed in supine position. The arm was abducted at a 90° angle to the trunk and the elbow was subjected to a 90° flexion in supination position, followed by placing a pillow under the back of the hand. Then the axillary artery pulse in the axillary region was touched from the most proximal part of the distal area and its location was determined. Afterwards, the axillary region was disinfected with povidone-iodine. In this study, the exact location of the axillary block was determined using a nerve stimulator and a needle block of 5 to 7 (G). After making sure the needle block was in the axillary region, the syringe containing the block solution was attached, and then the solution was injected after negative aspiration for blood. In order to increase the success of the axillary block after the needle insertion, the injection of the drug was done at 3, 9 and 12 hours after receiving nerve stimulation. The patients were randomly divided into three equal groups of receiving either dexmedetomidine, or magnesium sulfate or placebo. The first group received lidocaine (1.5%) and dexmedetomidine (0.5 µg/kg) and diluted in saline to make a volume of 35 ml. In the second group, lidocaine was given (1.5%) plus magnesium sulfate (100 mg) in a volume of 35 ml.¹⁹ In the control group, lidocaine (1.5%) was adjusted to 35 cc with

normal saline. After the blockage, and the arm adduction and arm turned to the patient. After appropriate analgesia, the tourniquet was used. It should be noted that during the operation, the patient was examined for side effects such as bradycardia and reduction of reflexes, hypotension and hypothermia by monitoring and checking reflexes. The protocol was regarded if side effects were observed. But failure cases were identified in each group because they can determine the function and effect of the drug. Pain intensity was measured on the basis of visual analogue scale in recovery 2, 4, 6, 12, and 24 hours after surgery. In this scale, the zero number expresses the lowest value and the 10 represents the highest value.²² In the presence of VAS, more than 4 patients received 0.5 mg/kg pethidine (meperidine) after surgery. The drug was measured 24 hours after surgery in each group.¹³

It is noteworthy that all data were measured by an anesthetist who was unaware of the groupings, and the preparation of the drugs in each group was carried out by an anesthetist, and the specialist assisted an axillary block that was unaware of the medications.

Finally, data analysis was performed using SPSS. Comparing quantitative variables including VAS, HR, mean blood pressure (MBP), and SaO₂ and the onset and sta-

bilization of the sensory and motor block among groups conducted the analysis of variance test. When the ANOVA test was significant, the Tukey post hoc test was used to determine the significance level for two by two comparisons. Moreover, assessment of the trend of VAS and other variables was performed by repeated measurement ANOVA.

RESULTS

This double-blind clinical trial was conducted on 99 patients candidates for axillary block and forearm and/or hand surgeries in Vali-e-Asr Hospital in Arak. They were randomly divided into three groups: Group 1 receiving dexmedetomidine, group 2 – receiving magnesium sulfate and group 3 – the placebo group. There was no significant difference in age, sex and body mass index between the three groups ($p>0.05$).

Regarding the results, there was a significant difference between the three groups in terms of the mean blood pressure during surgery ($p<0.05$). At all times, blood pressure in the dexmedetomidine group was lower than those of the other two groups. But in 20 and 25 minutes, a sudden increase in the blood pressure occurred. The magnesium

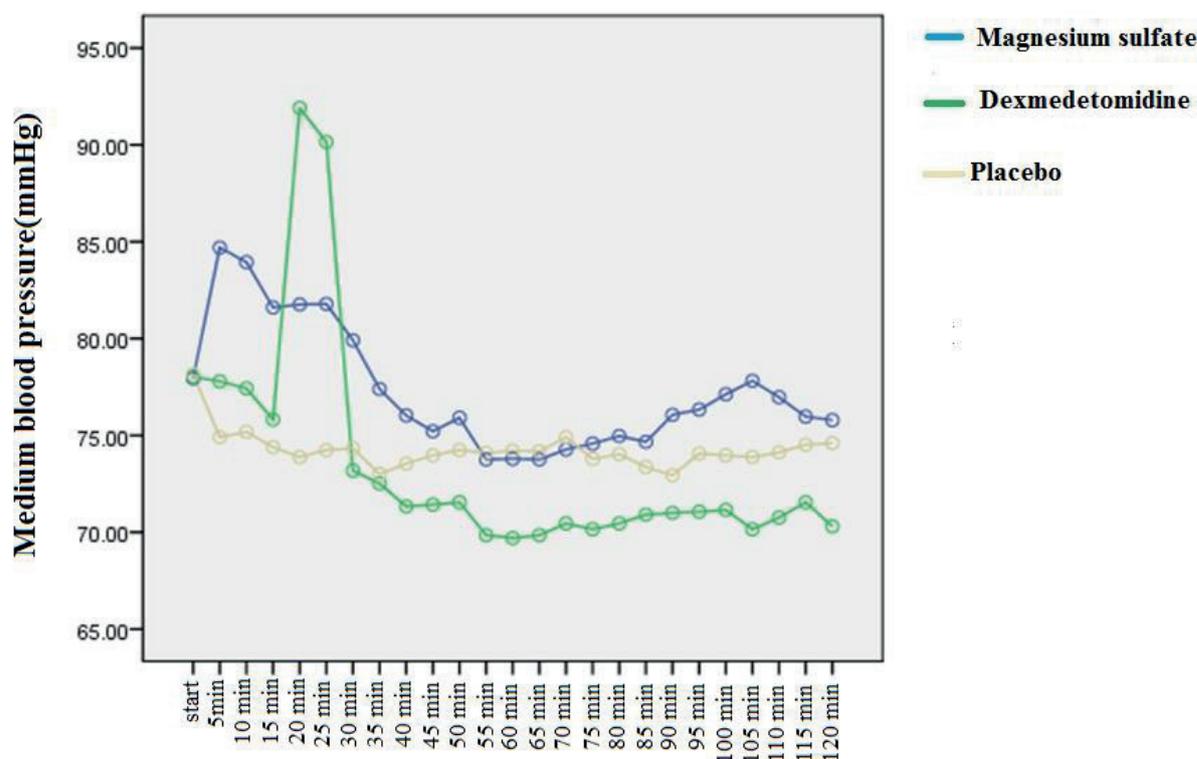


Figure 1. Mean blood pressure in the three study groups (The time the efficiency effect on drugs comparison with the interval of 5 min between groups to 120 min after surgery).

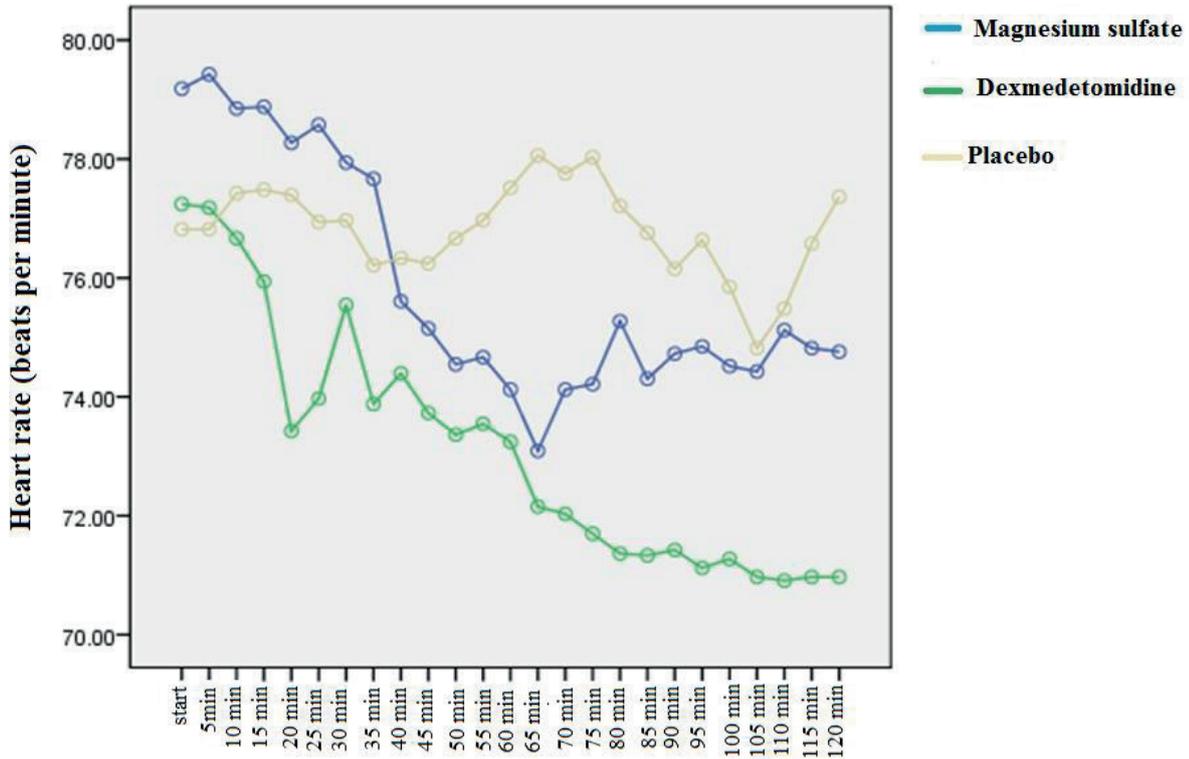


Figure 2. Heart rate in the three study groups (The time the efficiency effect on drugs comparison with the interval of 5 min between groups to 120 min after surgery).

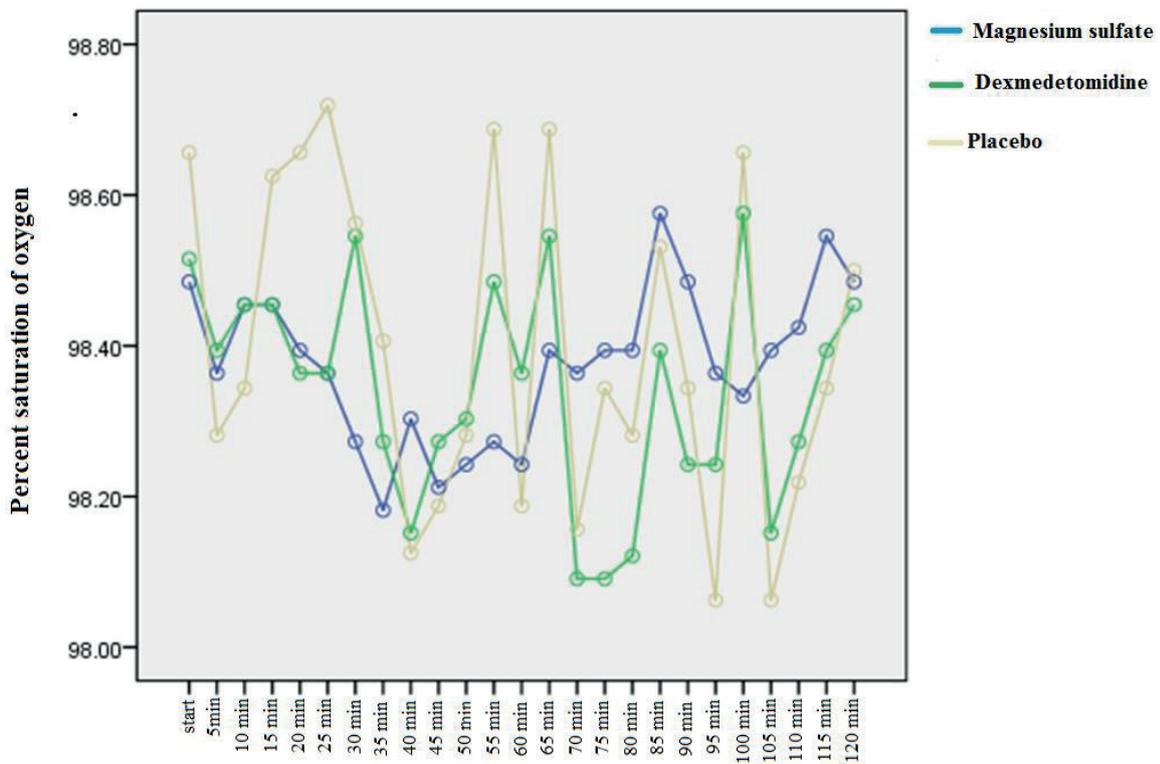


Figure 3. Oxygen saturation in the three study groups (The time the efficiency effect on drugs comparison with the interval of 5 min between groups to 120 min after surgery).

Table 1. Comparison of mean and standard deviation of sensory block in the three study groups

Group	Magnesium sulfate	Dexmedmotidine	Placebo	<i>p</i> -value*	Between groups**
Sensory block	Mean±SD	Mean±SD	Mean±SD		
Sensory block start time (min)	2.23±3.93	1.07±4.90	1.16±6.12	<0.001	M with D and P
Sensory block stabilization time (min)	2.67±9.48	1.51±11.30	2.07±14.60	<0.001	M with D and P

*ANOVA TEST; **based on Tukey post hoc test; M: magnesium sulfate; D: dexmedmotidine; P: placebo

Table 2. Comparison of mean and standard deviation of motor block in the three study groups

Group	Magnesium sulfate	Dexmedmotidine	Placebo	<i>p</i> value*	Between groups**
Motor block	Mean±SD	Mean±SD	Mean±SD		
Motor block start time (min)	1.82±3.42	1.39±4.00	1.80±6.06	<0.001	M with D and P
Motor block stabilization time (min)	2.86±8.18	1.57±9.69	2.39±13.87	<0.001	M with D and P

*ANOVA TEST; **based on Tukey post hoc test; M: magnesium sulfate; D: dexmedmotidine; P: placebo

Table 3. Mean and standard deviation of bromage score in the three study groups

Group	Magnesium sulfate	Dexmedmotidine	Placebo	<i>p</i> -value*	Between groups**
Bromage	Mean±SD	Mean±SD	Mean±SD		
In the first 5 minutes	0.639±0.969	0.618±0.848	0.452±0.272	<0.001	M with D and P
In the first 10 minutes	0.816±2.33	0.809±2.03	0.505±1.45	<0.001	M with D and P
In the first 15 minutes	0.488±2.63	0.501±2.87	0.662±2.42	0.285	

*ANOVA test; **based on Tukey *post hoc* test; M: magnesium sulfate; D: dexmedmotidine; P: placebo

Table 4. Mean and standard deviation of motor block duration in the three study groups

Group	Magnesium sulfate	Dexmedmotidine	Placebo	<i>p</i> -value*	Between groups**
Motor block	Mean±SD	Mean±SD	Mean±SD		
Time to get bromage 0 or 1 (off) (min)	207.00±19.64	322.14±20.30	148.22±22.52	<0.001	D with M and P

*ANOVA TEST; **based on Tukey post hoc test; M: magnesium sulfate; D: dexmedmotidine; P: placebo

Table 5. Comparison of mean and standard deviations of pain score in the three study groups

Group	Magnesium sulfate	Dexmedmotidine	Placebo	<i>p</i> -value*	Between groups**
Pain	Mean±SD	Mean±SD	Mean±SD		
Recovery	0.645±0.333	0.585±0.303	1.097±1.272	<0.001	D with P M with P
2 hours later	0.927±1.21	0.712±0.515	0.853±2.33	<0.001	D with M and P
4 hours later	1.08±1.78	0.883±1.03	0.507±3.515	<0.001	D with M and P
6 hours later	0.899±3.060	0.983±1.697	0.636±4.303	<0.001	D with M and P
12 hours later	0.826±4.606	1.020±2.333	0.501±4.757	<0.001	D with M and P
24 hours later	0.936±5.424	0.969±3.242	0.902±5.575	<0.001	D with M and P

*ANOVA TEST; **based on Tukey post hoc test; M: magnesium sulfate; D: dexmedmotidine; P: placebo

Table 6. Comparison of mean and standard deviations of drug consumption in the three study groups

Variable	Group Mean±SD	Magnesium sulfate Mean±SD	Dexmedmotidine Mean±SD	Placebo Mean±SD	p-value*	Between groups**
Pethidine (mg)		2.70±60.50	1.81±40.70	2.25±110.80	<0.001	D with M and P

*ANOVA TEST; **based on Tukey post hoc test; M: magnesium sulfate; D: dexmedetomidine; P: placebo

sulfate group had higher blood pressure than those of the placebo and dexmedetomidine groups. The lowest blood pressure was in the dexmedetomidine group and the highest – in the magnesium sulfate group (Fig. 1). At 20 and 25 minutes the blood pressure got higher only in the dexmedetomidine group.

However, the overall gradient of the graph was similar for the groups of magnesium sulfate and dexmedetomidine, which indicates a similar reduction ratio. It seems that the decrease in blood pressure and the transient increase in blood pressure occurring at 20 and 25 minutes were due to the accumulation of perivascular medications in the axillary pod and the systemic absorption of dexmedetomidine. This vascular uptake is likely to result in systemic effects of dexmedetomidine, which is associated with a relative reduction in blood pressure and its transient increase is consistent with these effects.

As a result, dexmedetomidine was found to reduce blood pressure in comparison to magnesium sulfate and the blood pressure in the control group. It is worth noting that in this case the reduction in blood pressure does not include a drug complication according to the average patient base, and none of the groups showed an acute complication (Fig. 1).

Based on the results presented herein, there was a significant difference between the three groups in terms of heart rate during surgery at minutes 20, 25, and 65, 100, 110 to 120 ($p<0.05$). There was no significant difference in the heart rate between the groups at 20, 30, 65, and 105 minutes ($p>0.05$). At all times, the heart rate in the dexmedetomidine group was lower than that in the other two groups. The magnesium sulfate group also had a lower heart rate than that in the placebo group. As shown in Fig. 2, the patients in the dexmedetomidine group had a lower mean heart rate. Due to vascular accumulation in axillary pods, vascular drug absorption of dexmedetomidine occurred, which caused a decrease in the heart rate in comparison with the magnesium sulfate and control groups. It is worth noting that in this case, heart rate reduction does not include a medication complication due to the average patient base. None of the groups indicated that patients with drug-related complications needed management (Fig 2).

There was no significant difference between the three groups in terms of oxygen saturation ($p>0.05$) (Fig. 3).

The onset and stabilization of the sensory block were significantly different in the three groups ($p<0.001$). In the groups of dexmedetomidine and magnesium sulfate, the onset and stabilization of the sensory block was found to be lower than that of the placebo group. In addition, the onset

and stabilization of the sensory block in the magnesium sulfate group was smaller than in the other two groups (Table 1).

There was a significant difference between the onset and stabilization of the motor block in the three groups ($p<0.001$). In groups 1 and 2, the onset and stabilization of the motor block was less than that of the placebo group. The onset and stabilization time of the motor block in the magnesium sulfate group was lower compared to the other two groups (Table 2).

Bromage score was significantly different in the first 5 to 10 minutes among the three groups ($p<0.001$). In the magnesium sulfate group, Bromage score was more than that in the other two groups in the first 5 to 10 minutes. The Bromage score showed no significant difference between the three groups during the first 15 minutes ($p>0.05$) (Table 3).

The duration of motor block was significantly different in the three groups ($p<0.001$). The duration of obtaining Bromage score 0 or 1 (off) at the minute was longer in the dexmedetomidine group as compared to the magnesium sulfate group. The dexmedetomidine and magnesium sulfate groups had a longer block time than the placebo group (Table 4).

As indicated in Table 5, pain had a significant difference between the three groups at all times ($p<0.001$). The pain in the dexmedetomidine group was lower compared to the magnesium sulfate and placebo group. Furthermore, the pain in the dexmedetomidine and magnesium sulfate groups was found to be lower when comparing with placebo group (Table 5). Based on the data presented in Table 6, the amount of opioids consumed 24 hours after surgery was significantly different in the three groups ($p<0.001$). In the dexmedetomidine group, the lowest drug was used within 24 hours after surgery (Table 6).

Our results revealed that there was no significant difference in the duration of surgery in the three groups ($p>0.05$). On the other hand, no significant differences were found between the failure in the three groups ($p>0.05$).

DISCUSSION

The organs block regional anesthesia is one of the most important and efficient methods to induce analgesia and anesthesia when performing surgical operations or control the patient's pain after surgery.²³ This block causes favorable conditions during surgery as well as faster postoperative patient mobility; on the other hand, it is capable of reducing the risks of general anesthesia, which can lead to

undesirable side effects in some patients.⁴ In this regard, a medication with the desired effects such as increasing the time of the effect of anesthetic drugs, increasing the amount of block and accelerating the onset of efficacy has great value in anesthetic medicine. Therefore, the aim of this study was to compare the effect of adding magnesium sulfate and dexmedetomidine on increasing the duration of axillary block sensory and motor block.

This double-blind clinical trial was performed on 99 persons with forearm and hand surgery, candidate for axillary Block at Vali-e-Asr Hospital. They were randomly divided into three groups. The results of the current study demonstrated a significant difference between the three groups in terms of the average blood pressure during surgery. At all times, heart rate in the dexmedetomidine group was lower when comparing other two groups and the magnesium sulfate group had a lower heart rate than placebo. In this study, no significant difference between the three groups in terms of oxygen saturation.

The onset and stabilization of the sensory and motor block were found to be significantly different in the three groups; therefore, in both groups of dexmedetomidine and magnesium sulfate, the onset and endurance of the sensory and motor block was determined to be lower as compared to placebo group, while this amount was lower in magnesium sulfate than the other two groups. The results demonstrated that Bromage score (in the first 5 and 10 minutes), duration of motor block and pain at all times in the three groups were statistically significant. Furthermore, there was a significant difference in the amount of opioid consumed 24 hours after surgery in the three groups, which was the lowest drug in 24 hours after surgery in the dexmedetomidine group.

The results of other similar studies were consistent and, in some findings, were inconsistent with the results of the present study. For example, Zaman et al., in 2017, conducted a study to investigate the effect of dexmedetomidine to lidocaine on the onset and duration of axillary block. They reported that adding dexmedetomidine to lidocaine in an axillary block was not capable of changing the onset of the sensory and motor block, while the sensory and motor block duration and analgesia was found to be increased.²⁴

The results of Zaman et al. (2017) are consistent with our findings on the duration of block and analgesia. However, in our study, the initiation of sensory and motor block in the magnesium sulfate group was less than that of the dexmedetomidine group, and the dexmedetomidine group was less than placebo. The cause may be related to the use of lidocaine where 1.5% was used in this study, but in the study of Zaman and colleagues, lidocaine 1% has been applied and, the number of samples was less than our study. In another study, Li and colleagues conducted a study to add magnesium sulfate as an adjuvant for local anesthesia and to facilitate environmental blocks under the form of a meta-analysis.

The results depicted that magnesium sulfate in blocks increased the duration of anesthesia ($p < 0.001$) and increased duration of sensory and motor block ($p < 0.001$).

They stated that magnesium sulfate could be used in block, to increase the duration of pain and the block of sensory and motor activity.²⁰

The results of our study showed that dexmedetomidine increased the duration of anesthesia. However, magnesium sulfate has a better effect on the placebo group, suggesting that the findings of our study are consistent with the study of Li et al.

On the other hand, significant differences were observed in the duration of the sensory block in the dexmedetomidine group ($p < 0.001$). The duration of motor block was also higher in the dexmedetomidine group and there was a significant difference between the two groups. In addition, hemodynamic changes were statistically significant. The group receiving dexmedetomidine was in better condition and no side effects were observed. Adding dexmedetomidine to ropivacaine causes quicker onset of anesthesia, longer duration of analgesia, where can be used for forearm and/or hand surgery.¹⁸ In another study, Kaygusuz et al. (2012) conducted a study aimed at effects of dexmedetomidine in combination with ropivacaine for an axillary brachial plexus block. They reported that dexmedetomidine shortened sensory block onset time and increase the duration of the sensory and motor block and time to first analgesic use.²⁵ The results of the study were similar to the present study because they used 0.5% ropivacaine and 1.5% lidocaine was also used in our study.

The results of this study and similar studies show the positive effects of magnesium sulfate and dexmedetomidine on improving the condition of the sensory and motor block in a variety of aspects, where side effects are negligible.

Although the current study is the only investigation comparing the antinociceptive effect of both drugs mentioned. The effects of dexmedetomidine on postoperative analgesia and an increase in block time were significantly better, but certainly in each selection for block the availability and cost of the drug should also be taken into account. For magnesium sulfate, there is such an advantage now. Meanwhile, this drug helps to quickly complete the block.

The main limitations of our study were its retrospective design and the relatively small number of cases that were available for study because only 99 patients had inclusion criteria.

CONCLUSION

The results of the present study indicate that the onset and stabilization of the sensory and motor block in the magnesium sulfate group was lower than in the other two groups, while the duration of motor and sensory block was found to be higher in the dexmedetomidine group. The duration of analgesia was further determined in the dexmedetomidine group, and the opioid level was lower in the second 24-hour period in the dexmedetomidine as compared to other two groups.

ACKNOWLEDGMENTS

Authors are grateful for the guidance of the Clinical Research Council of Vali-e-Asr Hospital and the support of the deputy of the Arak Medical University

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Arak University of Medical Sciences. This study was approved by ethic code of IR.ARAKMU.REC.1395.429. In addition, the registration code at the Iranian Center for Clinical Trials is IRCT2017041920258N38

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Клиническое сравнение добавления сульфата магния и дексмететомидина при блоке подмышечного сплетения для увеличения продолжительности сенсорного и моторного блока: протокол исследования для двойного слепого рандомизированного клинического испытания

Сейед Юсеф Шахтахери¹, Мохамад Тавакола Рад¹, Бийджан Язда¹, Мехран Азами², Алиреза Камала¹

¹ Кафедра анестезиологии и интенсивного ухода, Университет медицинских наук - Арак, Арак, Иран

² Кафедра ортопедии, Университет медицинских наук - Арак, Арак, Иран

Адрес для корреспонденции: Алиреза Камала, Кафедра анестезиологии и интенсивного ухода, Университет медицинских наук Арак Арак, Иран; Email: alirezakamalimd@gmail.com; Dr.kamali@arakmu.ac.ir; Тел: 00989181622810

Дата получения: 03 июня 2019 ♦ **Дата приемки:** 07 августа 2019 ♦ **Дата публикации:** 31 марта 2020

Образец цитирования: Shahtaheri SY, Rad MT, Yazdi B, Azami M, Kamali A. Clinical comparison of adding sulfate magnesium and dexmedetomidine in axillary plexus block for prolonging the duration of sensory and motor block: study protocol for a double-blind randomized clinical trial. Folia Med (Plovdiv) 2020;62(1):124-32. doi: 10.3897/folmed.62.e49805.

Абстракт

Введение: Целью данного исследования было сравнение добавления сульфата магния к дексмететомидину для увеличения продолжительности сенсорного и моторного блока при подмышечном блоке.

Материалы и методы: Это двойное слепое клиническое исследование. Девяносто девять пациентов были включены в исследование. Они перенесли операцию на предплечье и руке и были направлены в больницу Вали-э-Аср в Араке. Пациенты были разделены на три группы. Первой группе вводили лидокаин (1,5%) и дексмететомидин (0,5 µg/kg). Вторую группу лечили лидокаином (1,5%) и магнием. В контрольной группе лидокаин (1,5%) растворяли в 35 см³ физиологического раствора. Окончательный объём составил 35 см³ во всех трёх группах. Сенсорный и моторный блок и боль были измерены, и данные были проанализированы с использованием SPSS v. 20. Окончательный объём составил 35 см³ во всех трёх группах.

Результаты: Время проявления сенсорного и моторного блока в группе приёмом сульфата магния было ниже ($p < 0,001$). Боль при восстановлении через 2, 4, 6, 12 и 24 часа после операции была ниже в группе с приёмом сульфата магния по сравнению с группой с приёмом дексмететомидина ($p < 0,001$). Самая низкая доза опиоида была использована в группе, получавшей дексмететомидин, через 24 часа после операции ($p < 0,001$).

Выводы: Результаты показали, что дексмететомидин уменьшал боль. Сульфат магния увеличивал время проявления сенсорного и моторного блока и время стабилизации сенсорного и моторного блока, но дексмететомидин увеличивал продолжительность моторного блока.

Ключевые слова

подмышечный блок, сенсорный блок, моторный блок, дексмететомидин, сульфат магния.
