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Research Article

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Evaluating the Effect of Various Doses of Magnesium Sulfate on Quality of Cataract Intra Operative Sedation and Recovery

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Abstract

Background: *The selection of sedative method for cataract surgery which is mostly done for adults is more favored. In this study, we compared various doses of magnesium sulfate for improving the quality of anesthesia and recovery during Cataract surgery.*

Materials and Methods: *In this clinical trial, 150 patients candidate for Cataract surgery were studied in five groups of 30 individuals that 0(group 0), 10(group 10), 20(group 20), 30(group 30) and 40(group 40) mg/kg intravenous Magnesium Sulfate were added to the first to fifth groups at the onset of anesthesia in the common anesthetic method, respectively. The consumption doses of sedatives and narcotics (Midazolam, Fentanyl and Propofol), hemodynamic and respiratory variables during the surgery, and the incidence rate of pain, shivering, nausea and vomiting and the level of surgeon and patients' satisfaction were studied in all groups.*

Results: *1) Demographic, hemodynamic and respiratory variables had no significant difference between the five groups. In the group 30 and 40, the consumption does of Midazolam, Propofol and Fentanyl was considerably less than that in other groups ($P < 0.001$). 2) The highest and lowest levels of satisfaction in patients and physicians were recorded in the group 30 and respectively ($P < 0.001$). 3) None of the patients suffered from postoperative shivering. 4) The incidence of other complications including nausea, vomiting and pain at time of discharging from the operating room had no significant difference between the 5 groups.*

Conclusions: *Using Magnesium Sulfate, especially with the dose of 30 and 40mg/kg caused a significant reduction in need for sedative and narcotic drugs and increased satisfaction in patients and surgeons as well as minimal hemodynamic and respiratory effects during and after cataract surgery.*

Keywords: Cataract, Magnesium Sulfate, Sedation.

Introduction

Cataract surgery is the most common eye surgery all over the world. most patients undergoing this operation are elderly and have underlying diseases and during the surgery, relaxation and immobilization are required which needs adequate anesthesia [1]. Using anesthesia method causes fewer complications is accompanied with more effectiveness and economic justification compared to the general anesthesia. Low dose of Narcotic, Benzodiazepine and Propofol are usually used for anesthesia [2].

In these patients, on one hand, lack of adequate anesthesia and as a result, patients' motion and restlessness can be mentioned as anesthesia complications and on the other hand, much anesthesia, apnea and hemodynamic drop can be mentioned too [3]. Now,

taking narcotic drugs to achieve analgesia is restricted due to the incidence of serious complications in patients undergoing Cataract surgery who are usually elderly individuals. Thus, adding adjunct drugs to the program of anesthetic drugs in this surgery seems useful [3].

Magnesium Sulfate is an electrolyte replacement that is used as anti-seizure, Tocolytic and anti- arrhythmia drug and today, its effect on anesthesia is under study [4]. Based on the conducted studies, it has been determined that in most adults, Magnesium Sulfate can reduce the consumption dose of required anesthetic drugs; and pain, shivering, nausea and vomiting during and after surgery [7-11].

Another problem in Cataract surgery is the incidence of postoperative nausea and vomiting caused more due to the anesthetic drugs [12]. Several studies have also shown that Magnesium Sulfate reduces the incidence rate of postoperative pain and nausea and vomiting these complications [13,14]. Also, Magnesium Sulfate causes shivering in the recovery room by an unknown mechanism [5].

Because Cataract surgery is generally not associated with a lot of pain, and due to the limitation of taking narcotics during surgery, Magnesium can be used. Most papers have evaluated the effect of Magnesium as intrathecal or intravenous processes for reducing postoperative pain and nausea in the recovery room [15-19].

So far, no extensive research has been done on the role of Magnesium in analgesic techniques; accordingly, finding proper doses of Magnesium drug with the best effectiveness and least complications from its injection as an analgesic drugs seems quite essential. Furthermore, given the multiple effects of Magnesium on the cardiovascular and hemodynamic system and also, its role in control of pain and reducing nausea and vomiting and postoperative shivering, the present study is conducted with the aim of determining the effect of various doses of Magnesium Sulfate on Cataract intraoperative sedation and finding its appropriate dose compared to the 0mg group.

Materials and Methods

In this randomized and double blinded with control group clinical trial, after approval from Medical Research and Ethics Committee of the University and obtaining an informed patient consent, all patients who were candidate for Cataract surgery under topical anesthesia with Tetracaine drop enhanced by sedation and analgesia were included in the study. Other inclusion criteria of patients into the study was as follows: age span below 75 years old and American society of Anesthesiologists(ASA) physical status I-II, no limitation to take Magnesium Sulfate, and lack of sensitivity or addiction to Opioids and or Benzodiazepines or Propofol.

The sample size was determined using the estimation formula of sample size to compare the means and considering the confidence level of 95% (Z1-a/2=1.96), test power of 80% (Z1-b=0.84) and standard deviation of the anesthesia estimated about 1.1 and the minimal significant difference between groups with the rate of at least 0.8 was determined for 30 patients in each.

Before the study began, a random number table was used to generate a randomized schedule specifying the group to which each patient would be assigned upon entry in to the trial. In case of exclusion, the next patient was randomized per schedule. The demographic characteristics of each patient were first asked and recorded in a particular questionnaire. In five groups, 0, 10, 20, 30 and 40mg/kg Magnesium Sulfate were respectively added to patients as bolus at the onset of anesthesia in the common anesthetic method (Midazolam, Fentanyl and Propofol). In all groups Magnesium Sulfate was diluted with sterile normal saline to give 10 ml solutions and the patients in group o received 10cc sterile Normal saline solution instead of. Magnesium Sulfate.

Hemodynamic parameters including systolic, diastolic, and mean arterial blood pressure, heart rate, respiratory rate and arterial oxygen saturation (spo2) of patients just before surgery and at 5^{th}, 10^{th}, 15^{th} and 30^{th} minutes and in the recovery room each 15 minutes to discharging to the ward were recorded by someone who was not aware of the group type of the patients, and consumption dose of anesthetic and narcotic drugs including Midazolam about 25 to 50 mg/kg (milligram per kilogram of patient body weight) every 10 to 15 minutes, Fentanyl about 1-2 microgram/kg every 10 to 15 minutes and finally, if necessary, Propofol about 30 to 60 microgram/kg every two minutes to achieve ramsay sedation score 3 and fixing in this score were measured in each group.

Questions about surgeons (at the end of surgery) and patients' (at the time of discharching from recovery room) satisfaction were asked and recorded using the following- Totally satisfied, satisfied, unsatisfied. Intensity of pain and nausea and vomiting was done with visual analogue scale (VAS, ranges 0-10 cm) and in the case severe pain (VAS> 3), intravenous pethidine with dose of 0.5mg/kg was injected intravenously. When vomiting or marked nausea (VAS>3) was observed, intravenous ondansetron with dose of 0.1mgr/kg was injected.

Also shivering and the length of staying in the recovery room using the Modified Aaldrete Score >9 were evaluated in five groups and recorded in the study questionnaire.

After collecting data, using SPSS software version 22 and Chi-square test, one-way ANOVA, and ANOVA with repetition of consumption and Kruskal -Wallis test, the study data were analyzed.

Results

We performed a double blind, prospective, randomized clinical trial to assess the effect of Various doses of Magnesium Sulfate on quality of cataract intraoperative sedation and recovery. One hundred and fifty patients were studied in five groups. In **(Table 1)**, the distribution of patients' demographic information is given. According to the tests of ANOVA, chi-square and Fisher's exact test, the distribution of demographic variables had no significant difference among five studied groups (P>0.05).

Table 1: Distribution of demographic variables in 5 groups

Variable	Group Level	0mg	10 mg	20 mg	30 mg	40 mg	P-value
Age (year)	Mean	9±63.1	11.8±61.5	8±60.4	10.5±61.4	6.7±65.7	0.23
Sex	Male (N)	16(53.3)	16(53.3)	14(46.7)	16(53.3)	24(80)	0.08
	Female (N)	14(46.7)	14(46.7)	16(53.3)	14(46.7)	6(20)	
ASA	I	16(53.3)	16(53.3)	14(46.7)	14(46.7)	14(46.7)	0.96
	II	14(46.7)	14(46.7)	16(53.3)	16(53.3)	16(53.3)	
Weight	Kg	8.3±72.9	71±9.5	71.7± 8.8	72.3±8.5	72.3±9.3	0.93
Smoking	Yes	2(6.7)	4(13.3)	6(20)	2(6.7)	8(26.7)	0.12
	No	28(93.3)	26(86.7)	24(80)	28(93.3)	22(27.3)	
Drug abuse	Yes	2(6.7)	2(6.7)	4(13.3)	0(0)	8(26.7)	0.09
	No	28(93.3)	28(93.3)	26(86.7)	30(100)	22(73.3)	

In diagrams 1-6, the mean hemodynamic parameters of patients in the five groups have been shown at 5, 10 and 15 minutes during surgery and 15 and 30 after surgery. According to ANOVA with repeated observations, the mean hemodynamic parameters had no significant difference in the five mentioned groups (P>0.05); While the mean systolic blood pressure has had more drops in the group 0 at the 5th minute and also, heart rate in groups 20, 30 and 40 was higher than the other groups at the 5th minute.

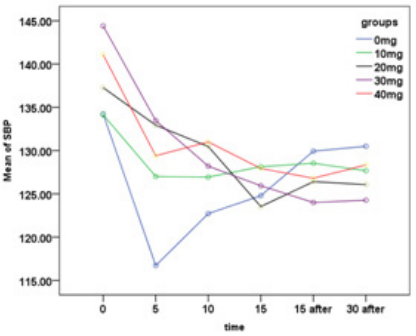

Diagram 1: The mean and standard deviation of systolic blood pressure at 5, 10 and 15 minutes during surgery and 15 and 30 after surgery in five groups (P=0.72)

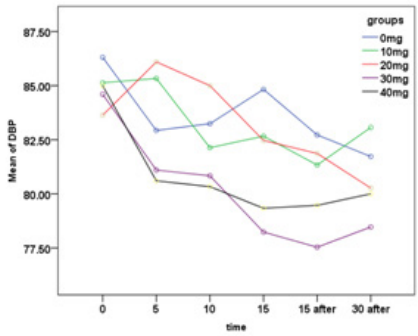

Diagram 2: The mean and standard deviation of diastolic blood pressure at 5, 10 and 15 minutes during surgery and 15 and 30 after surgery in five groups (P=0.1)

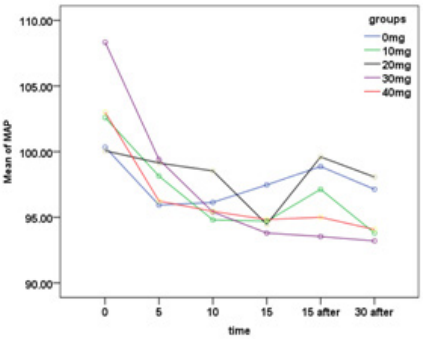

Diagram 3: The mean and standard deviation of arterial blood pressure at 5, 10 and 15 minutes during surgery and 15 and 30 after surgery in five groups (P=0.95)

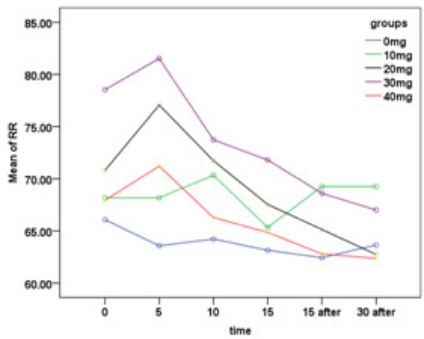

Diagram 4: The mean and standard deviation of heart rate at 5, 10 and 15 minutes during surgery and 15 and 30 after surgery in five groups (P=0.07)

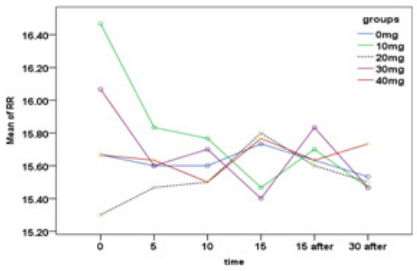

Diagram 5: The mean and standard deviation of respiratory rate at 5, 10 and 15 minutes during surgery and 15 and 30 after surgery in five groups (P=0.12)

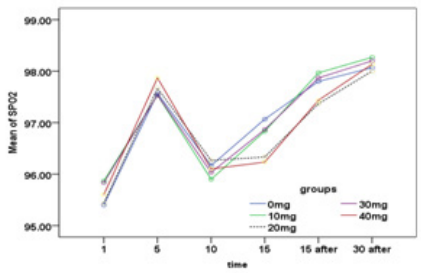

Diagram 6: The mean and standard deviation of Spo2 at 5, 10 and 15 minutes during surgery and 15 and 30 after surgery in five groups (P=0.47)

According to **(Table 2)**, the amount of taking Midazolam, Propofol and Fentanyl in the groups 30 and 40 was significantly lower than that in other groups (P<0.001).On the other hand, the consumption dose of the above-mentioned drugs was significantly more in group 0 (P<0.001).The highest and lowest level of patients' and physicians' satisfaction was in the group 30 and 0, respectively (P<0.001). In terms of the incidence of postoperative complications, none of the patients experienced postoperative shivering. 2 case (6.7%) in group 0, 3 cases (10%) in group 10 and 1 case (3.3%) in group 20 suffered from postoperative significant nausea and vomiting and Ondansetron using while in the other two groups, no significant nausea and vomiting and Ondansetron using was observed and the difference among five groups was not significant (p = 0.31). Also, 1 case (3.3%) in group 0, 2 cases (6.7%) in group 10, 2 cases (6.7%) in group 20, 1 case (3.3%) in group 30, and 1 case (3.3%) in group 40 had postoperative mild pain (VAS less than 3) and difference among the five groups was not significant (P=0.99).

The mean length of staying in the recovery room has also been shown in **(Table 2)**. According to ANOVA, no significant difference was observed among the 5 groups in this regard (p = 0.76).

Table 2: Drug use, satisfaction and postoperative complications in the five studied groups

Variable		0mg	10 mg	20 mg	30 mg	40 mg	P-value
Midazolam(mg)		2±0	1.97±0.13	2±0.01	1.33±0.48	1.6±0.5	<0.001
Propofol(mg)		75.3±27	47±30.7	64±36.5	29.3±36.3	21.3±32.8	<0.001
Fentanyl(µgr)		116.7±51.4	113.3±29.2	106.7±17.3	80±24.9	93.3±17.3	<0.001
Patient's satisfaction	Totally Satisfied (Nr-%)	3(10)	2(6.7)	2(6.7)	8(26.7)	12(40)	18(60)
	Satisfied (Nr-%)	23(76.6)	26(86.7)	25(83.3)	22(73.3)	18(60)	
	Unsatisfied (Nr-%)	4(13.33)	2(6.7)	3(10)	0(0)	0(0)	
Doctor's satisfaction	Totally Satisfied (Nr-%)	2(6.7)	2(6.7)	2(6.7)	8(26.7)	12(40)	0.001
	Satisfied (Nr-%)	22(73.4)	26(86.6)	20(66.7)	22(73.4)	14(53.3)	
	Unsatisfied (Nr-%)	6(20)	2(6.7)	8(26.7)	0(0)	2(6.7)	
Shivering (Nr-%)		0(0)	0(0)	0(0)	0(0)	0(0)	1
Nausea &Vomiting (Nr-%)		2(6.7)	3(10)	1(3.3)	0(0)	0(0)	0.31
Post-operative pain (Nr-%)		1(3.3)	2(6.7)	2(6.7)	1(3.3)	1(3.3)	0.99
Use of Ondansetron (Nr-%)		2(6.7)	3(10)	1(3.3)	0(0)	0(0)	0.31
Duration of stay in recovery(min.)		35.2±97.7	32.1±91.7	32.5±91	36.2±99	34.11±90	0.76

Discussion

According to the results obtained from our study, patients who did not receive Magnesium Sulfate or received its low concentration, received relatively high doses of Midazolam, Fentanyl and Propofol; while by increasing the concentration of Magnesium Sulfate, the rate of Propofol and opioid intake was reduced. Other conducted studies have also shown that using Magnesium Sulfate as premedication can reduce complications and severity of postoperative pain. In a study by Gupta et al, the effect of infusing Magnesium Sulfate on postoperative pain and requiring postoperative opioid was studied in the surgery under general anesthesia in which need for opioid for pain relief in the group receiving Magnesium Sulfate was significantly lower than that in 0mg group [7]. Also, in the study conducted by Steinlechner et al, the use of Magnesium Sulfate as premedication in patients undergoing cardiac surgery has been associated with reducing postoperative pain and complications [8]. In an study by Seyhan et al, various doses of Magnesium Sulfate was used in gynecological surgery where the dose of using opioid and pain intensity in 0mg group was more than that in patients receiving Magnesium Sulfate [9]. In the study by Tauzin et al, the effect of different doses of Magnesium Sulfate on postoperative pain and complications in patients undergoing abdominal surgery was

also evaluated in which patients receiving higher dose of Magnesium Sulfate had less postoperative pain intensity and need for opioid was fewer in them [11].

Based on the results of our study, all patients receiving 30mg and 40mg of Magnesium Sulfate were satisfied with the applied method. Also, in the group receiving 30mg and 40mg of Magnesium Sulfate, a more number of surgeons were satisfied with the applied method and dissatisfactory cases were related to patients in 0mg group and patients with low dose of Magnesium Sulfate.

Our data showed that hemodynamic parameters such as blood pressure, heart rate, respiratory rate and arterial blood oxygen saturation were not significantly different between the five groups during the study period (P> 0.05). In addition, no case of hemodynamic instability and respiratory difficulty were seen in the five groups. However, the mean systolic blood pressure had more drop at 5 minutes in group 0. Although it was no significant, it could be due to more consumption of anesthetic and narcotic drugs. At 5 minutes, mild increase in heart rate in groups20, 30 and 40 was higher than that in other groups. In group 10, there was no change and in group 0, it reduced. This could be due to the direct effect of Magnesium Sulfate on Vagus nerve ability on heart; however, through reducing sympathetic ability, the indirect effect of anesthetic and narcotic drugs causes to drop in heart rate and systolic and diastolic blood pressure at the onset of the effect and patient's expectation for the surgery [6].This effect can be important in patients; especially those who cannot tolerate changes in Bradycardia or that increasing hear rate is dangerous for them.

On the other hand, postoperative complications such as shivering were not observed in any of the studied groups and pain in the observed cases was mild and on nausea, no significant difference was also seen. Also, on the length of stay in recovery room, no significant difference was observed in the studied groups. So far various studies have been conducted on the effects of Magnesium Sulfate on reducing postoperative complications that most studies have concluded a significant reduction in postoperative complications in the group receiving Magnesium Sulfate [7-11]. Also, Magnesium Sulfate causes to reduce shivering in recovery through an unknown mechanism [5].Therefore, given the results obtained from the study and comparison with other studies, the overall conclusion is that using Magnesium Sulfate, especially with a dose of 30mg and 40mg is associated with a significant decrease in need for anesthetic and narcotic drugs, increase patients' and surgeons' satisfaction and at least hemodynamic and respiratory effects on patients. Therefore, using the above-mentioned doses of Magnesium Sulfate is recommended in anesthesia of Cataract surgeries.

The limitation of our study was the small sample size and the fact that we followed patients with age span below 75 years old and ASA physical status I-II, only till discharging from the recovery room; however, the findings seem particularly in spite of this. Also we suggest altering the study design and further investigation.

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