Original Article

Comparison of the Sedative, Hemodynamic, and Anesthetic Effect of Dexmedetomidine, Ketamine, and Etomidate on Cataract Surgery by Phacoemulsification Method: A Randomized Clinical Trial

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Abstract

Purpose: To compare dexmedetomidine, ketamine, and etomidate in the induction of sedation and hemodynamic changes in patients undergoing cataract surgery by phacoemulsification method.

Methods: This was a double-blind clinical trial study carried out on 128 patients. Using the block randomization method, the patients were divided into four equal groups (dexmedetomidine, ketamine, etomidate, and control). Mean arterial pressure, heart rate, and arterial oxygen saturation, Ramsay Sedation Score were recorded every 5 min intraoperatively, in recovery, and 1, 2, 4, and 6 h postoperatively. Moreover, the Aldrete score was measured in recovery time for discharge from the recovery room.

Results: The mean age of participants was found to be 63.16 ± 6.07 years, and there was no statistically significant difference between the groups in terms of age, sex, and body mass index, SpO_2, and heart rate ($P > 0.05$). From 15 min after the start of surgery to 6 h postoperatively, the mean arterial pressure in the dexmedetomidine group was significantly lower than that in the other three groups, including ketamine, etomidate, and control ($P < 0.05$). The mean sedation score (Ramsay) during recovery and 1 h postoperatively was higher in the dexmedetomidine group compared with that in the control group, whereas the recovery time in the dexmedetomidine group was higher than that in the other groups ($P < 0.001$). In addition, the amount of propofol consumption in the two groups of dexmedetomidine and ketamine was significantly less than that in the etomidate and control groups ($P < 0.001$).

Conclusions: According to the results, dexmedetomidine caused better hemodynamic changes with more reduction in blood pressure and heart rate, and patients in the dexmedetomidine group did not require any specific medical treatment. Moreover, higher patient satisfaction and longer recovery duration were observed in the dexmedetomidine group than in the other study groups. As such, it is suggested that dexmedetomidine be used as an adjuvant in cataract surgery for more sedation, analgesia, and optimal intraoperative conditions.

Keywords: Cataract surgery, Dexmedetomidine, Etomidate, Propofol, Sedation

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Introduction

Cataract is the clouding of the lens of the eye, which, along with heart diseases and arthritis, is one of the most common causes of disability in the elderly. In the United States, the prevalence of cataracts in people over 40 years is reported

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to be 20.5 million, whereas in China, it is 23.3% in people over 50 years.[1] Cataracts are responsible for at least 51% of world blindness.[2] Therefore, as one of the most important eye surgeries, cataract surgery is also one of the most common procedures performed on the elderly.[3]

To date, various anesthesia protocols have been proposed for cataract surgery such as general anesthesia, local anesthesia, regional anesthesia, and a combination of these. Recently, due to the development of new technologies in this field such as phacoemulsification cataract surgery, the use of appropriate anesthesia regimens has become one of the challenges facing anesthesiologists.[4]

The most common technique used in phacoemulsification cataract surgery is the use of local anesthesia.[4,5] Providing sedation in the patients while maintaining optimal immunity is the aim of administering anesthetics to patients undergoing cataract surgery.[6] However, since most patients scheduled for cataract surgery are old and have debilitating comorbid conditions, general anesthesia in some patients is associated with major risks such as permanent brain injury.[7]

Several drugs have been used alone or in combination with one another to reduce anxiety and induce sedation in cataract surgery.[8] The present study was conducted in an attempt to introduce the best drug combination with a better sedative effect and the least amount of hemodynamic changes.

Methods

The current study was a randomized, double-blind clinical trial conducted on 128 patients who were selected as candidates for cataract surgery. At first, the purpose of the study was explained to all the participants, and written consent was obtained from them. They ensured that the information of all the studied patients would remain confidential. Furthermore, the protocol of conducting the study was registered in the Research Ethics Committees of Arak University of Medical Sciences under the ethical code number of IR.ARAKMU.REC.1399.339 and approved by the Iranian Registry Clinical Trial center by code IRCT20141209020258N156.

The eligible patients were divided into four equal groups using a random list created by random allocation software and block model. The study population included all patients who were candidates for phacoemulsification cataract surgery. The required sample size for the study was calculated using the results of the study by Yağan *et al*.[9] in 2015 and considering the study power being equal to 80% as well as the confidence interval of 95% in each group equaling 32 patients.

Inclusion criteria were as follows: aged 35–85 years, American Society of Anesthesiologist physical status class I and II, candidate for cataract surgery by phacoemulsification method, no mental disorders, no history of chronic use of sedatives, no use of alcohol and drug abuse, no allergies to the study drugs, absence of severe obstructive pulmonary disease and asthma, no history of heart disease, heart block and bradycardia, no systolic blood pressure <90 mmHg, no severe hepatic or renal failure, lack of uncontrolled diabetes, absence of cerebrovascular diseases, and attaining informed consent for the intervention. Exclusion criteria were patient dissatisfaction and the appearance of any complication during sedation, leading to a change in the method of anesthesia or the cancellation of surgery.

Having entered the operating room, the patients underwent standard care and monitoring including noninvasive blood pressure measurement, pulse oximetry, and electrocardiography. Mean arterial pressure, heart rate, and oxygen saturation were measured and recorded at baseline, every 5 min until the end of the operation, at the time of recovery, and 1, 2, and 4 h, postoperatively. Before induction of anesthesia, Ringer solution 5 ml/kg was injected to the patients. Oxygen was administered to the patients through a nasal cannula at a rate of 4 L/min intraoperatively and in recovery. In all three groups, the patients received analgesic and sedative drugs at a definite time (15 min before the operation) in the following manner: fentanyl, 1 μg/kg (Caspian Tamin Pharmaceutical Company – Iran), and midazolam 0.04 mg/kg (midazolex 5 mg/ml ampoule made by Exir Pharmaceutical Company – Iran); and for topical anesthesia, 10 min before the start of surgery, two drops of tetracaine 0.5% (anestocaine 0.5% manufactured by Sina Daru Pharmaceutical Company, Iran) were instilled into the eye which was to be operated on within a 5 min-interval.[10] The four intervention groups received the drugs in the following manner: Group D received dexmedetomidine 0.5 μg/kg intravenously[11] (Medonex ampoule 100 μg/mL made by Exir Company, Iran); Group E received 0.1 mg/kg etomidate[5] (made by Abu Reihan Pharmaceutical Company, Iran); in Group K, 0.5 mg/kg ketamine was administered intravenously[12] (made by Rotexmedica GmbH Arzneimittelwerk, Germany); and Group P received routine treatment with placebo.

For the sake of uniformity, the amount of drug required for the intervention groups was calculated for each patient, and its volume was increased to 10 ml by adding normal saline. The intervention drug-after instilling eye drops into the eye of each patient was administered in each group through slow intravenous injection for 10 min. After that, 25–75 μg/kg/min/IV of propofol (20 mg/ml vial made by Dong Kook Pharm, South Korea) was administered to all the patients as a maintenance dose of intraoperative sedation (to maintain the Ramsay score of 3 throughout the surgery).[13] Next, the surgeries were carried out by one surgeon in all the groups.

In all four groups, patient and surgeon satisfaction with surgery was measured using a Likert scale (7 points) at the end of the operation.[9] Aldrete score was measured in recovery time for discharging from the recovery room. Patients were discharged from recovery if they had an average Aldrete score of 9–10. The time between the end of surgery and the exit from recovery was called the recovery time. In addition, mean arterial pressure, heart rate, arterial oxygen saturation, and Ramsay Sedation Score were recorded every 5 min intraoperatively, in recovery,

and 1, 2, 4, and 6 h, postoperatively. Moreover, mean propofol consumption during surgery was recorded.

The levels of sedation were measured by Ramsay score. The scoring scale varied 1 = patient is restless and agitated; 2 = patient is tranquil, cooperative, orientated, and agitated; 3 = patient is sedated while he/she responds only to commands; 4 = patient responds well to optical and tactile stimulus stimuli; 5 = patient responds to optical and tactile stimuli with laziness and inactivity; 6 = patient does not respond at all.[14,15] The Aldrete score is a tool for measuring the recovery score recorded for patients during the surgical operation and when a score >8 was considered a patient transferability score.[16,17]

Data were analyzed using SPSS software, and the results were presented in the form of graphs and tables. The normality of data was checked by histogram chart and Shapiro–Wilk and Kolmogorov–Smirnov tests. The statistical tests, including one-way analysis of variance (ANOVA), were used to compare the hemodynamic and other quantitative variables among groups. The Chi-square was used to compare the sex proportion among different groups. Repeated measures ANOVA were used to assess the trend of hemodynamic data that was measured for more than 3 times for data analysis in SPSS version 20 (SPSS Inc., Chicago, IL, USA).

Results

The present study was conducted on 128 patients including four groups of 32 patients in the hospital, who were similar in terms of gender. It was found that 50% (64 patients) of participants were female, and 50% (64 patients) were male. ANOVA [Table 1] showed that there was no statistically significant difference between the four groups in terms of age and body mass index ($P > 0.05$).

Comparison of the mean blood pressure [Table 2] of patients in the four study groups showed that there was no statistically significant difference between the study groups up to 10 min after the start of surgery ($P > 0.05$). However, from 15 min after the start of surgery to 6 h postoperatively, a statistically significant difference was observed between the study groups. *Post hoc* ANOVA to compare groups in pairs showed that the mean blood pressure of the dexmedetomidine group was statistically different from that in the other three groups, with the mean blood pressure in the dexmedetomidine group being significantly lower than that in the other three groups, namely ketamine, etomidate, and control ($P < 0.05$). However, the mean blood pressure in the other three groups including ketamine, etomidate, and control did not show a statistically significant difference ($P > 0.05$). Figure 1 shows the trend of patients' blood pressure, showing that the blood pressure trend in the dexmedetomidine group was statistically different from that in the other three groups ($P = 0.035$).

Comparison of mean heart rate [Table 3] of patients in the all study groups showed that there was no statistically significant difference in the mean heart rate intraoperatively and postoperatively and up to 6 h after operation ($P > 0.05$). Figure 2 shows the heart rate trend of patients at different times after the start of surgery in the four study groups.

Figure 3 presents the comparison of the mean SpO_2 of patients in the study groups. The trend of SpO_2 in patients at different

Table 1: Comparison of the mean age and body mass index of patients in the study groups at different postoperative times

Variable	Dexmedetomidine	Etomidate	Ketamine	Control	*P**
			Mean±SD		
Age	63.16±6.17	63.13±6.00	63.22±6.79	63.16±6.52	0.99
BMI	24.38±2.64	24.31±2.86	24.31±2.73	24.34±2.82	0.99

*Based on one-way analysis of variance, BMI: Body mass index, SD: Standard deviation

Table 2: Comparison of mean blood pressure in the study groups at different postoperative times

Blood pressure	Dexmedetomidine	Etomidate	Ketamine	Control	*P**
			Mean±SD		
Before the start of operation	93.16±5.45	93.19±4.75	93.16±4.81	93.13±3.88	0.999
5 min after operation	91.56±5.23	93.03±4.58	93.31±4.78	93.03±3.78	0.427
10 min after operation	90.75±4.81	92.94±4.48	93.44±4.81	92.94±3.85	0.083
15 min after operation	90.34±4.73	92.84±4.50	93.53±4.81	92.81±3.81	0.028
20 min after operation	89.88±4.38	92.75±4.48	93.69±4.69	92.69±3.81	0.004
25 min after operation	89.69±4.21	92.69±4.48	93.69±4.69	92.88±3.76	0.002
30 min after operation	90.28±4.09	92.97±4.51	93.66±3.65	93.09±3.66	0.009
Min 5 in recovery	90.69±3.69	93.13±4.51	93.91±3.51	93.38±3.43	0.010
2 h after operation	91.51±3.28	93.25±4.05	94.31±3.80	93.72±3.11	0.014
4 h after operation	92.47±2.46	93.66±3.51	94.78±3.14	94.06±2.60	0.019
6 h after operation	92.97±1.96	94.19±3.07	94.84±3.14	94.28±2.57	0.048

*Based on one-way analysis of variance, SD: Standard deviation

Table 3: Comparison of mean heart rate in the study groups at different postoperative times

Heart rate	Dexmedetomidine	Etomidate	Ketamine	Control	*P**
	Mean±SD				
Before the start of surgery	90.88±7.20	90.91±6.44	90.78±7.05	90.91±5.87	0.999
5 min after operation	89.53±6.85	90.72±6.38	91.06±6.79	90.66±5.68	0.796
10 min after operation	89.13±6.49	90.63±6.31	91.22±6.56	90.53±5.55	0.587
15 min after operation	88.91±6.20	90.53±6.27	91.34±6.53	90.44±4.49	0.454
20 min after operation	89.34±5.95	90.69±6.12	91.19±6.39	90.63±5.33	0.645
25 min after operation	89.72±5.72	91.00±5.77	91.22±6.20	90.91±5.21	0.723
30 min after operation	90.16±5.50	91.41±5.46	91.38±6.15	91.31±4.90	0.764
Recovery	90.75±5.00	91.88±4.78	92.09±5.36	92.84±3.52	0.361
2 h after operation	91.31±4.54	92.44±4.35	92.41±5.24	93.16±3.24	0.416
4 h after operation	91.47±4.36	92.91±3.70	92.75±4.93	93.78±2.64	0.147
6 h after operation	92.13±3.89	93.34±3.43	93.22±4.53	93.97±2.60	0.250

*Based on one-way analysis of variance, SD: Standard deviation

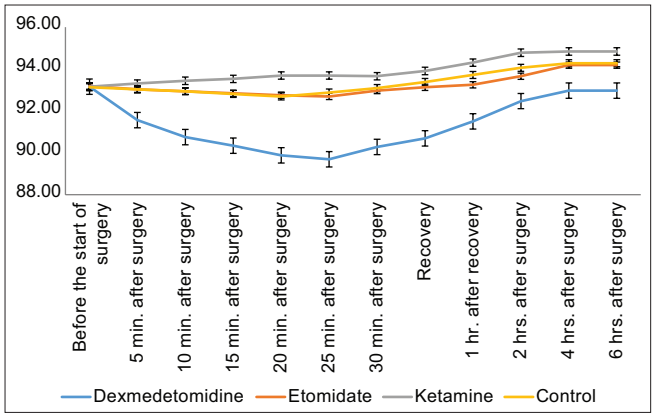

Figure 1: Comparison of the trend of patients' blood pressure at different times postoperatively in the study groups

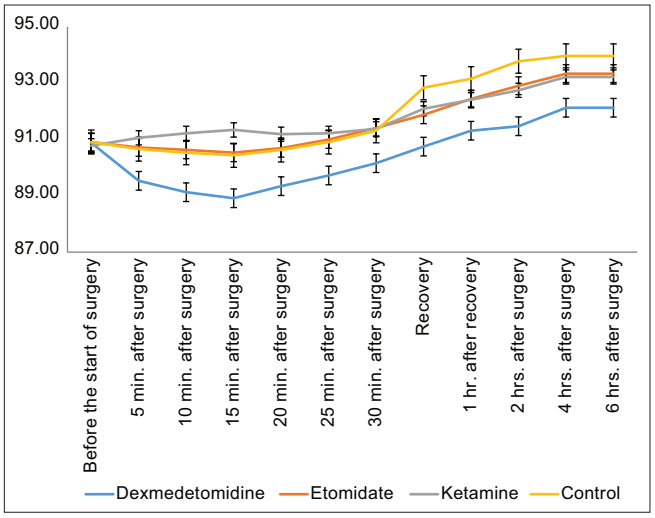

Figure 2: Comparison of the trend of patients' mean heart rate at different times postoperatively in the study groups

times after the start of surgery indicates that there did not exist a statistically significant difference in SpO_2 among the study groups ($P > 0.05$).

Figure 4 shows the comparison of the mean sedation scores of patients in the four study groups, in which there was no statistically significant difference between the study groups at different times ($P > 0.05$), except at recovery time ($P = 0.005$) and 1 h after operation ($P < 0.001$). However, based on Tukey's follow-up test, it was found that during recovery and 1 h after the operation, the mean sedation score of patients in the dexmedetomidine group was significantly higher than that in the control group (placebo). However, no statistically significant difference was found to exist between the other groups ($P > 0.05$).

The results of one-way ANOVA presented in Table 4 showed that there was a statistically significant difference between the four groups in terms of mean recovery time (Aldrete ≥9), amount of propofol consumption, and patient satisfaction score ($P < 0.001$). However, there was no statistically significant difference between the four groups in terms of surgery duration and surgeon's satisfaction score ($P > 0.05$). Tukey's *post hoc* analysis also showed that the recovery time (Aldrete ≥9) in the dexmedetomidine group was significantly higher than that in the other groups ($P < 0.001$). However, no statistically significant difference was found to exist between the three groups of ketamine, etomidate, and control ($P > 0.05$). In addition, *post hoc* test showed that the amount of propofol consumption in the two groups of dexmedetomidine and ketamine was significantly less than that in the etomidate and control groups ($P < 0.001$). Furthermore, patients' satisfaction score in dexmedetomidine and control groups was significantly higher than that in ketamine and etomidate groups ($P < 0.001$).

Discussion

The results of the current study showed that there was no statistically significant difference between groups in terms of age, sex, and body mass index and that the randomization of the study groups was sufficient. The comparison of patients' mean blood pressure from 15 min after the start of the operation to 6 h postoperatively was statistically significant,

Table 4: Comparison of mean of surgery duration, recovery time (Aldrete ≥9), amount of propofol consumption, patient satisfaction score, and surgeon satisfaction score in the study groups at different postoperative times

	Dexmedetomidine	Etomidate	Ketamine	Control	*P**
	Mean±SD				
Duration of operation	21.88±1.38	21.94±1.29	21.94±1.29	21.94±1.32	0.997
Recovery time (Aldrete ≥9)	35.13±3.73	26.16±4.14	25.50±3.67	24.47±3.71	>0.001
Amount of propofol consumption (mg)	40.16±4.48	45.38±4.41	40.19±4.23	51.38±4.99	>0.001
Patient satisfaction score	6.19±0.38	5.53±0.76	5.47±0.80	6.16±0.37	>0.001
Surgeon satisfaction score	6.0±0.00	6.0±0.00	6.0±0.00	6.0±0.00	1.00

*Based on one-way analysis of variance, SD: Standard deviation

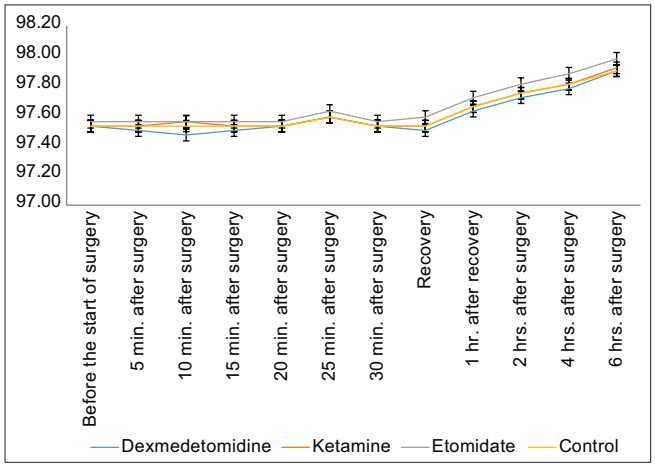

Figure 3: Comparison of the trend of patients' mean SpO_2 at different times postoperatively in the study groups

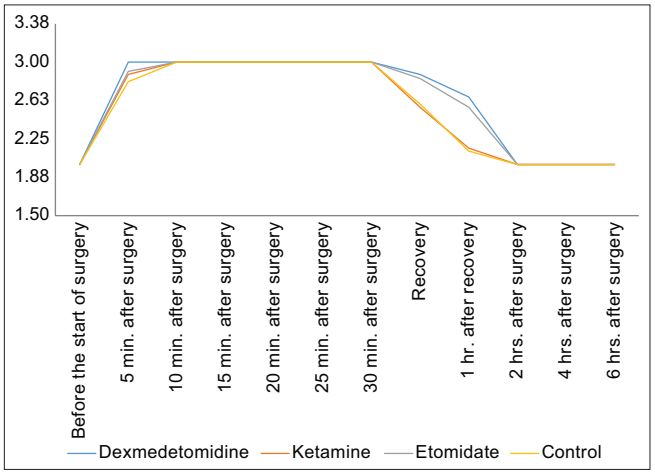

Figure 4: Comparison of the trend of patients' mean sedation (Ramsay) score at different times postoperatively in the study groups

so the mean blood pressure in the dexmedetomidine group was significantly lower than that in the other three groups, namely ketamine, etomidate, and control. Similar results showed in several studies, which demonstrate the superiority of dexmedetomidine over other drugs. In the study by Yağan *et al*. comparing dexmedetomidine and ketofol-ketamine, dexmedetomidine was found to reduce heart rate.[9] Furthermore, Fekrat and Jerineshin concluded that compared to midazolam-fentanyl, dexmedetomidine improved respiratory changes in patients undergoing cataract surgery under local anesthesia and that dexmedetomidine was an effective alternative to the midazolam-fentanyl combination while providing a reliable level of sedation and hemodynamic stability.[18] Ghali *et al*. compared dexmedetomidine and propofol for sedation in patients undergoing vitreoretinal surgery and found that the level of sedation, discharge from recovery, and patient and surgeon satisfaction in the dexmedetomidine group was similar to those in the propofol group and that dexmedetomidine could be a suitable alternative to propofol in vitreoretinal surgery.[12] Therefore, it can be concluded that dexmedetomidine is a safe and appropriate choice for induction of sedation in cataract surgery. In the study by Aghadavoudi *et al*., it was found that in the etomidate group, the mean percentage of oxygen saturation in recovery was higher than that in the ketamine group.[13] Dexmedetomidine is a new-generation highly selective α2-adrenergic receptor agonist that is used in some studies due to sedative and analgesic sparing effects, reduced delirium and agitation, perioperative sympatholysis, and cardiovascular stabilizing effects.[10-12,15,19,20]

In the present study, in the dexmedetomidine group, the mean level of analgesia during recovery and 1 h postoperatively was significantly higher than that in the control group (placebo). However, there was no statistically significant difference between ketamine and etomidate groups. In the study by Adinehmehr *et al*., similar results were obtained, and the recovery time in the etomidate group was found to be shorter than that in midazolam and propofol groups.[5] In another study by Sanatkar on comparing the effectiveness of two drug combinations of midazolam-ketamine (ketamine group) and midazolam-fentanyl (fentanyl group), it was observed that a drop in blood pressure to <120.79 was equal to 13% in the ketamine group and 86.4% in the fentanyl group.[21] In addition, in a study by Krishnamurthy and Malarvizhi, it was found that the combination of ketamine and propofol with retrobulbar block for cataract surgery – compared to midazolam-propofol – is very useful for both the patient and the surgeon, although it has more complications and longer recovery duration.[22]

In the current study, the recovery time (Aldrete ≥9) in the dexmedetomidine group was significantly longer than that

in the other groups, but there was no statistically significant difference between the three groups of ketamine, etomidate, and control. Yağan *et al*. compared dexmedetomidine and ketofol-ketamine and found that dexmedetomidine increased the Aldrete score to 9 and above compared with ketofol, but there was no difference in sedation or pain level between the two groups.[11] Similarly, Aghadavoudi *et al*. in a study on the two groups of etomidate-fentanyl (E/F) and ketamine-midazolam-fentanyl (K/M/F) showed that the mean intraoperative systolic and diastolic blood pressure was higher in K/M/F group. However, the mean recovery time in the E/F group was shorter than that in the other group. In general, the use of etomidate and fentanyl is as effective as midazolam, ketamine, and fentanyl in cataract surgery by phacoemulsification method with less cardiac and respiratory complications and recovery time.[13]

The heart rate and blood pressure were lower in the dexmedetomidine group while the amount of propofol consumption in the two groups of dexmedetomidine and etomidate was significantly less than that in the ketamine and control groups. In addition, patients' satisfaction score in dexmedetomidine and control groups was significantly higher than that in ketamine and etomidate groups. Since dexmedetomidine is an alpha-2 adrenergic agonists, with analgesic, sedative, and antihypertensive properties,[23] adding it to local anesthetics can be effective in surgery.[20,24]

However, some limitations of this study were the small sample size and impossible follow-up due to the limited amount of time at postintervention.

According to the results of this study, the amount of intraoperative propofol consumption in the dexmedetomidine group was less than that in the other groups. However, compared to other groups, dexmedetomidine caused better hemodynamic changes with more reduction in blood pressure. Moreover, the patients in the dexmedetomidine group did not require any specific medical treatment, and higher patient satisfaction and longer recovery duration were observed in the dexmedetomidine group than in the other study groups. As such, it is suggested that dexmedetomidine be used as an adjuvant in cataract surgery for more sedation, analgesia, and optimal intraoperative conditions.

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Conflicts of interest

There are no conflicts of interest.

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