

Original Research Article


Study of Dexmedetomidine as intramuscular premedication in outpatient cataract surgery: A placebo – controlled study

D. Srinivasa Naik¹, K. Ravi Kumar¹, Surendra Babu², R. Pandu Naik^{3*}

¹Assistant Professor, ²Post graduate, ³Associate Professor

Department of Anesthesiology, Sarojini Devi Eye Hospital and Osmania Medical College, Hyderabad, India

*Corresponding author email: ramavathpandu9@gmail.com

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Abstract

Aim: To evaluate the effects of Dexmedetomidine to reduce the intra ocular pressure and sedation in day care cataract surgeries.

Materials and methods: This study was conducted in 50 patients of either sex, belonging to 40 – 60 years of age, ASA grade I and II admitted for cataract surgeries. Patients were randomized into two groups of 25 each. Group D received 1 mcg/mg of Dexmedetomidine as IM route, Group P received placebo as IM and intra ocular pressure changes, hemodynamic parameters, sedation levels and SPO₂, anxiolysis and pain were monitored.

Results: There was a statistically significant difference in group D before and after premedication in terms of intra ocular pressure reduction. This was not seen in placebo group. Systolic blood pressure, diastolic blood pressure and heart rate in the study was a statistically difference in group D before and after premedication. There was no statistically significant difference in group P before and after premedication. There was a statistically significant difference (P<0.05) between the group D and group P in terms of sedation. Oxygen saturation observed in group D and group P at intervals of 0, 10, 20, 30, 40, 50, 60 min showed no statistical significance (P>0.05). There was a statistically significant

difference ($P < 0.05$) between the group D and group P in terms of pain relief and anxiety after premedication.

Conclusion: Results suggested that Dexmedetomidine produces sedation and a reduction of intra-ocular pressure with minimal hemodynamic side effects when given intramuscularly as premedication before cataract surgery under regional anesthesia.

Key words

Dexmedetomidine, Cataract surgeries, Intra-ocular pressure.

Introduction

Anesthesia is an important pre requisite of any surgery. It is also equally important in ophthalmic surgery. General anaesthesia requires a longer time and causes more post operative discomfort. It is preferred for patients who cannot cooperate fully with surgeon for reasons like mental retardation, senility and deafness. With the advent of safer local anesthetics and the desire to mobilize the patient in early post operative period, local anesthesia has become more popular in ophthalmic surgery [1]. Adding the sedation to local anaesthesia is most comfort for both patients and surgeon. Most of the cataract surgeries are being done as day care. So along with local anaesthesia, sedation is gaining popular. Additional advantages with sedation are hemodynamic stability and reduction in the patient discomfort. In olden days, many sedative agents like Benzodiazepines, opioids [2] and alpha-agonists like clonidine are present, but recently Dexmedetomidine, a second generation alpha-agonist is being used in sedation.

Alpha-agonists have an analgesic, sedative and anxiolytic properties [3]. These agents have fewer side effects like respiratory depression, gastro intestinal disturbances and deep sedation. Another advantage is easy arousable sedation and hemodynamic stability. Dexmedetomidine is a highly selective alpha 2 – adrenoreceptor agonist [3] that has an alpha 2 to alpha 1 selectivity ratio of 1600:1, therefore, it is eight times greater than that of clonidine. It provides better quality of anaesthesia during local anaesthesia procedures. It is also used as a pre medication agent, adjuvant to local anesthetics and intravenous regional anesthesia (IVRA) [4].

Along with its properties Dexmedetomidine has unique property of reducing intra ocular pressure [5]. It is most useful in ophthalmic surgeries. The major requirements for ophthalmic surgeries under regional anesthesia include immobility and uncongested operative field, normal intra ocular pressure (IOP), analgesia of the globe and conjunctiva, good cooperation between the patient and the surgical team and cardiovascular stability. Akinesia and analgesia of the globe can be achieved with a regional block⁶ but appropriate pre medication may improve the operative conditions by reducing the intra ocular pressure, attenuating the hypertensive response produced by anxiety and the injection of local anesthetic. Light sedation may also be beneficial, but over sedation is not advised as day care surgery demands rapid recovery and return to street fitness.

Hence, we have undertaken this study to evaluate the effects of Dexmedetomidine to reduce the intra ocular pressure and sedation in day care cataract surgeries.

Material and methods

A placebo control study of Dexmedetomidine intra muscular premedication agent in day care cataract surgery at Sarojini Devi Eye Hospital, Hyderabad was done. Present study was conducted during 2013 to 2015 in Fifty (50) patients undergoing cataract surgery under local anesthesia.

Inclusion criteria

Patients of either sex between 40 – 60 years of age. ASA Grade I or II with Normal un-operated eye.

Exclusion criteria

Patients' age below 40 years and above 60 years, Single eye patients, Patients having hypertension, active ocular infection and high myopias, history of convulsions or epilepsy, Glaucoma patients and also patients who refuse to participate in study.

After approval of institutional ethics committee, 50 consenting patients fulfilling the inclusion criteria were considered for our study. A pre-anesthetic check up was done for all patients, which included a detailed history, general physical and systemic examination. Ophthalmologic examination was done by the ophthalmologist. Basic investigations including a baseline ECG, HIV, Hbs Ag were done. Patients were kept nil per oral overnight. Patients were randomized into two groups of 25 each.

Group D: Received 1 mcg/mg of Dexmedetomidine as IM route

Group P: Received placebo as IM route.

Technique

Patient was placed in supine position and blood pressure, heart rate, sedation levels and SPO₂ were checked. Non operative eye was selected because of the risk of infection in operating eye. After that schiotz tonometer properly sterilized was used to measure intra ocular pressure. IOP was recorded. Antibiotic drops were installed in eye.

Then study drug was given in left deltoid region as intra muscular route. SpO₂ was measured every 10 min up to one hour. After 45 minutes, intraocular pressure (IOP), blood pressure (BP), and heart rate (HR) were rerecorded. Sedation levels were assessed by Ramsay sedation score. Peribulbar block was given to operated eye. Anxiolysis and pain was assessed by VAS. Sedation levels were assessed by Ramsay sedation score. Anxiolysis and pain was assessed by VAS during the time of peribulbar block.

The collected data was analyzed using chi-square test, independent student test and p<0.05 was considered significant. The statistical software

namely SPSS 18, were used for the analysis of the data and Microsoft word and excel had been used.

Results

It was a placebo control study of Dexmedetomidine given intra muscular as a premedication agent in day care cataract surgery conducted for a period of 2 years in Fifty (50) patients undergoing cataract surgery under local anesthesia.

The minimum age in group D and group P were 40 years. The maximum age in group D and group P were 60 years. The mean age in group D was 52.36 ± 6.24 years, group P was 51.64 ± 6.48 years. There was no significant difference in the age of patients between the groups. There was no significant difference in the sex distribution of the patient between the groups (P>0.05) as per **Table - 1**.

There was a statistically significant difference in group D before and after premedication. There was a no statistically significant difference (0.4987) in group P before and after pre medication as per **Figure - 1**.

Systolic blood pressure, diastolic blood pressure and heart rate in the study was a statistically difference in group D before and after premedication. There was no statistically significant difference in group P (P Value 0.5718) before and after premedication as per **Table - 2**.

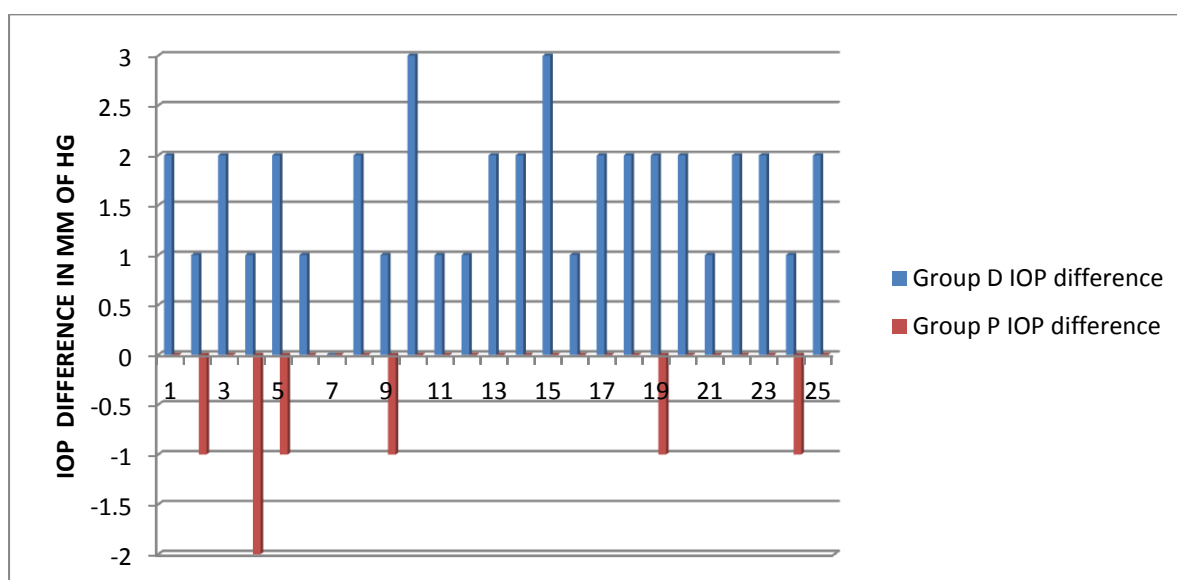
There was a statistically significant difference (P<0.05) between the group D and group P in terms of sedation. Oxygen saturation observed in group D and group P at intervals of 0, 10, 20, 30, 40, 50, 60 min showed no statistical significance (P> 0.05) as per **Figure - 2**.

There was a statistically significant difference (P<0.05) between the group D and group P in terms of anxiety and pain relief after premedication as per **Figure - 3**.

Table - 1: Demographic distribution in both groups.

Age (Years)	Group D		Group P	
	No	%	No	%
40-45	5	20	6	24
46-50	5	20	5	20
51-55	6	24	6	24
56-60	9	36	8	32
Total	25	100	25	100
P Value	0.69 Not significant			
Gender				
Male	16	64	16	64
Female	9	36	9	36
Total	25	100	25	100
P Value	1.00 Not significant			

Figure - 1: Intra-ocular pressure difference.



Discussion

Dexmedetomidine is a potent alpha-2 adrenoreceptor agonist with eight time higher affinity and selectivity for the alpha-2 adrenoreceptor than clonidine and much fewer alpha-1 effects. This is responsible for the hypnotic and analgesic effects of such drugs without the unwanted vascular effects because of the activation of alpha-1 receptors. Dexmedetomidine is suitable for sedation and analgesia during the entire perioperative period as a premedication, an anesthetic adjuvant for

general and regional anaesthesia, and as a post operative analgesic.

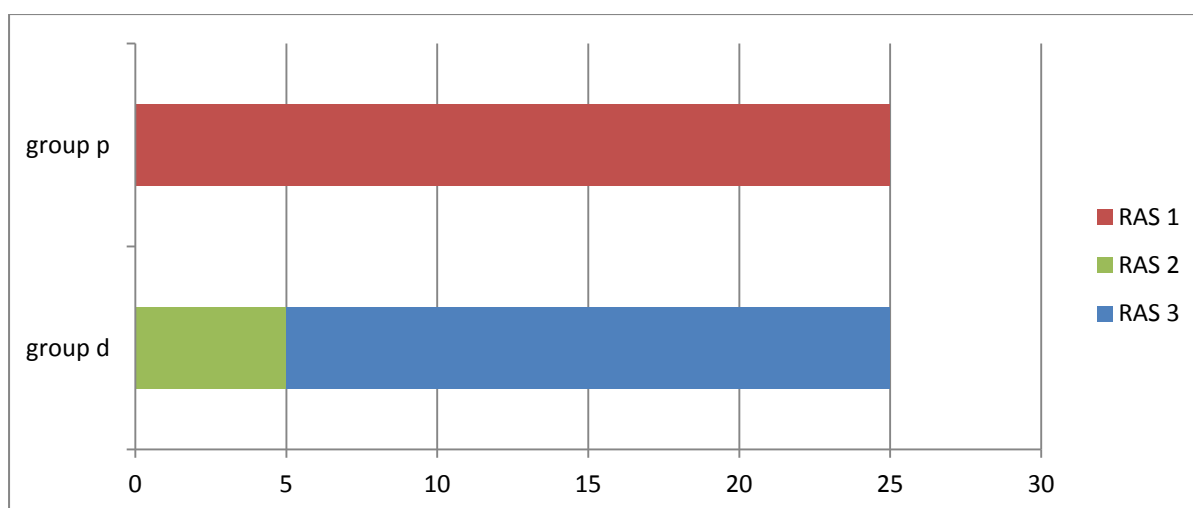
In the study by P S Ghodki, Shalini P Sardesat [7], Dexmedetomidine premedication in cataract surgery under topical anesthesia to assess patient and surgeon satisfaction, conducted prospective randomized study on 60 patients (30 (Dexmedetomidine) and 30 (placebo)) in two groups, group D received Dexmedetomidine premedication 1 mcg/kg over 10 min intravenous route and group C received saline at the same rate. Dexmedetomidine decreased the intra

ocular pressure and the difference was statistically high significant ($p < 0.0001$). A randomized controlled clinical trial conducted by H Ayoglu, et al. [8], on 40 patients. They observed after the Dexmedetomidine loading dose, intra ocular pressure was significantly (12.3(1.0) mm of hg) decreased, compared with pre operative value (16.1(0.8)) mm of hg ($p < 0.005$).

Table - 2: Blood pressure and Heart rate changes in the study.

	Group D		Group P	
	Mean	SD	Mean	SD
Systolic blood pressure				
Before premedication	130	11.18	127.6	16.41
After premedication	110.4	10.59	130	13.22
P Value	0.0001		0.5718	
Diastolic blood pressure				
Before premedication	80.8	7.023	77.6	10.11
After premedication	69.6	7.89	79.2	8.124
P Value	0.0001		0.5718	
Heart rate				
Before premedication	85.44	8.82	90.88	11.09
After premedication	78.36	7.26	93.96	11.73
P Value	0.0033		0.3344	

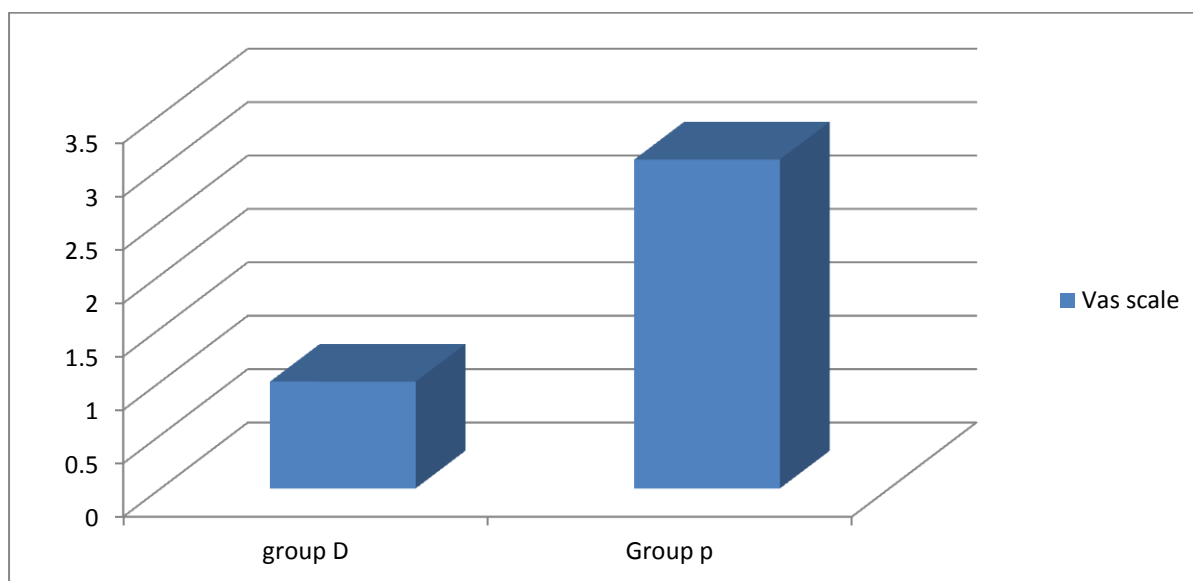
Figure - 2: Sedation score.



Virkkila M, et al. [9], conducted study of Dexmedetomidine agent for day case cataract surgery which was a comparative study of Dexmedetomidine, midazolam and placebo in 90 patients undergoing day care cataract surgery under regional anesthesia. The trial drug was injected into the deltoid muscle 45 min before the periocular block. They concluded

Dexmedetomidine 1 mcg/kg decreased IOP before, during and after surgery. The maximum reduction in mean (SD) IOP occurred in the Dexmedetomidine group just before discharge from hospital 17.7 (2.8) mm of hg to 11.5 (2.9) mm of hg ($P < 0.001$) compared with midazolam and placebo. In contrast midazolam did not differ from saline placebo.

Figure - 3: Visual Analog Score (VAS).



Dexmedetomidine as intra muscular premedication in outpatient cataract surgery with placebo controlled dose ranging study was conducted by Virkkila M, et al. [10]. They studied the effects of Dexmedetomidine a new alpha agonist on intra ocular pressure in 35 (ASA Status 1 and 2) patients undergoing day care cataract surgery under periocular anesthesia. Five different doses of Dexmedetomidine (0.25, 0.5, 0.75, 1.0 and 1.5 mcg/kg) were used in this double blind randomized placebo controlled study. They conclude 1 mcg/kg dose of Dexmedetomidine produced a 32% reduction of IOP (P=0.002).

Yang Sun, et al. [11] studied low dose intra muscular Dexmedetomidine as premedication – A randomized controlled trial. They studied ASA grade I adult patients undergoing suspension laryngoscopic surgery were randomized to receive intra muscular Dexmedetomidine (1 mg/kg) or midazolam (0.02 mg/kg) 30 min, Prior to anesthesia induction. They noticed both drugs have hemodynamic effects but Dexmedetomidine group had very better results. The mean arterial pressure responses after extubation were attenuated in the Dexmedetomidine group compared to midazolam group. No hypotension was noted in any patients.

Dexmedetomidine causes increased hypotension in older adults when used for cataract surgery compared to propofol. This study conducted by Irwin Gratz, et al. [12], they evaluated the hemodynamic effects suitability and safety of Dexmedetomidine compared with propofol in older adults having outpatient cataract surgery under monitored anaesthesia care. The prospective single blind, randomized study was conducted using 47 patients ≥ 55 years old undergoing cataract surgery. The two patient groups received either IV Dexmedetomidine 1 mcg/kg over 10 min, followed by maintenance IV infusion 0.2-0.7 mg/kg/hr (Dexmedetomidine N=24) (or) propofol infused between 25-120 mg/kg/min (PRO group N=23). Patients arterial pressures at base line were 104.7 (2.6) and 107.5 (2.7) mm of hg in Dexmedetomidine and propofol groups respectively (P=0.45). At discharge the pressures were 78.1 (2.5) and 98.1 (2.6) mm of hg in Dexmedetomidine and propofol groups respectively (P<0.05).

Remifentanyl (or) Dexmedetomidine for monitored anesthesia care during cataract surgery under topical anesthesia by Jue Hee Park and Jae Young Kwon [13].

The aim of study was to compare Dexmedetomidine with remifentanyl during

cataract surgery in patients under topical anaesthesia. 80 ASA Grade 1-3 patients (age 60-80 years) who were scheduled for elective cataract surgery under topical anesthesia were enrolled in this study. Patients group D received 0.5mcg/kg over 10 min followed by 0.2 mcg/kg/hr infusion. Group R patients received target controlled infusion to reach 1ng/ml target effect site concentration. Significantly lower systolic blood pressure and mean arterial blood pressure were noticed in group D, compared with those in group R.

Hyo-seak Na, IN Aesous, et al. [14] studied Dexmedetomidine is effective for monitored anesthesia care in outpatients undergoing cataract surgery. They studied on 31 eligible patients were randomly divided into two groups, Dexmedetomidine was administered in group D at 0.6 mcg/kg/hr and propofol, alfentanil was infused concomitantly in group P at a rate of 2 mg/kg/hr and 20 mcg/kg/hr respectively. In this study they noticed hypotension 8 cases (25.8%) in group P and 1 case (3.2%) in group D ($P<0.05$). They conclude Dexmedetomidine is useful in monitored anesthesia care in cataract surgery.

H. Ayoglu, et al. [8], they noticed with Dexmedetomidine sedation systolic blood pressure lower from 30 min after administration ($P<0.05$). Virkkila [9] noticed Dexmedetomidine IM useful in reducing systolic blood pressure after administration of 45 min.

Dexmedetomidine for monitored anesthesia care during cataract surgery under topical anesthesia, studied by Jue Hee Park and Jai Young Kwon [13], they concluded patients receiving 0.5 mcg/kg over 10 min followed by 0.2 mg/kg/hr infusion decreases the diastolic blood pressure. A J. Alhashemi [15], they done double – blind study compared the use of Dexmedetomidine and midazolam in patients undergoing cataract surgery. They noticed mean arterial pressure in group D and group M is 65 (2) mm of Hg versus 72 (2) mm of Hg. Virkkila M, et al. [9], studied Dexmedetomidine with comparison with

midazolam and placebo. They concluded Dexmedetomidine induced moderate decrease in blood pressure ($P<0.001$ compared with placebo).

Yang Sun, et al. [11], low dose intra muscular Dexmedetomidine as premedication, they studied on heart rate effects in intubation and extubation. The result was heart rate response followed tracheal intubation and extubation was attenuated in the Dexmedetomidine group compared to the midazolam group. Irwin Gratz, et al. [12] studied patients heart rate at base line were 74.8 (3.0) for Dexmedetomidine group and 73.2(2.8) beats per minute for the propofol group. At the time of surgery the mean heart rate for the Dexmedetomidine group was 61.5 (2.2) beats per min versus 69.1 (2.3) bats per min was propofol group ($P<0.05$). They concluded Dexmedetomidine decreases the heart rate significantly. Hyo Seak Na, et al. [14] noticed significant decrease in heart rate in Dexmedetomidine group. One case (3.2%) bradycardia occurred in Dexmedetomidine group.

H. Ayoglu, H.A. Hunkaya, et al. [8], studied 40 patients either Dexmedetomidine sedation (Group D) or no sedation (Group C). In Group D intra operative mean heart rate was found to be lower up to 50 min ($P<0.05$). One dose of atropine was needed in 5 patients in Group D, but the administrative of the study drug was not stopped after the atropine treatment.

A J Alhashemi [15] done double blind study compared the use of Dexmedetomidine and midazolam in patients undergoing cataract surgery. In this study group D and group M mean heart rate is 65(2) versus 72(2) beats per min respectively ($P<0.05$). Virkkila M [9], studied on Dexmedetomidine, midazolam and placebo group in cataract surgeries. They noticed statistically significant reduced heart rate in their study ($P<0.001$ compared with placebo).

Jue-Hee Park and Jae-young Kwon [13] studied comparison between Remifentanyl and

Dexmedetomidine in cataract surgery. They noticed no significant statistical difference in SPO₂ was observed between the two groups. Hyo-Seak Na, et al. [14] studied Dexmedetomidine and propofol with alfentanil groups in monitored anaesthesia care in outpatients undergoing cataract surgery. They noticed no statistical significant between two groups in relation to SPO₂ levels.

In the study of PS. Ghodki, et al. [7], Dexmedetomidine versus placebo as a premedication in day care cataract surgery were concluded group D had better sedation than group P. There was a significant increase in sedation assessed by the Ramsay sedation score at all times in group D received Dexmedetomidine (P<0.0001). H. Ayoglu, et al. [8] studied Dexmedetomidine sedation during cataract surgery under regional anaesthesia. They use Ramsay sedation score to notice the sedation during surgery. Intra operative RSS were higher in Group D after the loading dose of Dexmedetomidine (P<0.05).

A J Alhashemi [15] done double blind study compared between Dexmedetomidine and midazolam in patients undergoing cataract surgery. Group D patients had slightly higher satisfaction with sedation (P<0.05) but delayed readiness for discharge was noticed.

Virkkila M, et al. [10] also studied Dexmedetomidine effects on sedation during outpatient cataract surgeries as premedication agent. They noticed significant sedation levels present in Dexmedetomidine group. Yang Sun, Chaolei Liu, et al. [11], studied low dose intramuscular Dexmedetomidine as premedication. They observed anxiety by pre induction and they concluded Dexmedetomidine effectively reduce anxiety in significant number of patients. H. Ayoglu, et al. [8], studied Dexmedetomidine sedation during cataract surgery under regional anaesthesia. They also examined analgesia during the time of local anesthesia injection and concluded significant analgesia present in Dexmedetomidine group.

Conclusion

Dexmedetomidine produces sedation and reduction of intra-ocular pressure with minimal hemodynamic side effects when given intramuscularly as premedication before cataract surgery under regional anaesthesia. It is suitable for sedation and analgesia during the entire perioperative period as a premedication, an anesthetic adjuvant for general and regional anaesthesia, and as a post operative analgesic.

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