Original Article

Effect of dexmedetomidine on intraocular pressure as an additive in peribulbar block during glaucoma surgery

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Purpose: The purpose of this study is to assess the effect of dexmedetomidine on intraocular pressure (IOP) as an additive in peribulbar injections in glaucoma surgeries. **Methods:** A prospective, randomized, double-blind, parallel assignment interventional study was conducted for patients undergoing glaucoma surgeries at a tertiary eye care hospital in North India. Patients were randomized to two groups, Dexmed group and Placebo group. In the Dexmed group, dexmedetomidine (0.4 μg/kg body weight) was given as an additive along with peribulbar block. The primary outcome was change in IOP pre- and postperibulbar injections (IOP before the block, and after 5 and 15 min of the block). Secondary outcome measures were onset of block, adverse effects (bradycardia, hypotension, respiratory depression, and level 4 sedation), and surgeon satisfaction. **Results:** A total of 104 patients were randomized, 52 each in the Dexmed group and Placebo group. The percentage decrease in IOP was significantly more in the Dexmed group than in the Placebo group both at 5 and 15 min' post block ($P < 0.05$). At 5 min, the mean percent decrease in IOP in Dexmed group was -10.48, whereas it was 2.85 in the Placebo group. At 15 min, the mean percent decrease in IOP was -22.59 and -9.42 in the Dexmed and Placebo group, respectively. There was no significant difference between the two groups in the onset of block and adverse effects. Surgeon satisfaction was significantly greater in the Dexmed group than the Placebo group ($P < 0.05$). **Conclusion:** Dexmedetomidine lowers IOP significantly in patients undergoing glaucoma surgeries with safe hemodynamic changes and sedative effect.

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Glaucoma filtration surgeries are commonly done under local anesthesia (LA) as the average surgical duration ranges between 20 and 60 min, and a good analgesia is desired to have a controlled surgical environment. Pain during the surgery can cause reflex sympathetic stimulation with a consequent increase in plasma catecholamine resulting in tachycardia, arterial hypertension, arrhythmias, increased intraocular- and intracranial pressure, all of which are detriments to the surgery.[1] The usual volume of LA agent used varies between 5 and 10 mL. Since the average orbital volume is only 30 mL, there is a possibility of an associated rise in intraorbital and intraocular pressure after the peribulbar block.[2]

The study by Donoghue *et al.* showed that the rise in IOP following a block, independent of the injection technique and LA used was greater in patients with glaucoma, and the effect is sustained at 5 min .[3] This may reflect a failure of the normal homeostatic mechanism that compensates for a rise in IOP. In glaucoma patients, transient rises in IOP may be clinically more significant, particularly in the presence of a severely compromised optic nerve. Although regional block provides akinesia and analgesia, appropriate sedation may further aid in lowering pain and anxiety, thereby reducing IOP.

Dexmedetomidine (Dexmed) is an alpha 2 adrenoceptor agonist, which has been shown to promote hemodynamic stability by its central sympatholytic action. It has added analgesic, potent sedative, and IOP lowering properties.[4] Dexmedetomidine causes direct vasoconstriction of the afferent vessels in the ciliary body, thereby reducing the production of aqueous humor (AH), and a consequent decrease in IOP. It also facilitates the drainage of AH by decreasing the sympathetically mediated vasomotor tone in the ocular drainage system.[5,6] Furthermore, its associated hemodynamic response additionally contributes to the IOP lowering effect.[7] Systemically administered α-2 agonists have also demonstrated a neuroprotective effect on retinal ganglion cells against the increase in IOP.[8] Coughing and straining can also cause steep rises in IOP due to the expansion of the veins within the eye; Dexmed by making the patient hemodynamically stable may prevent such an untoward rise in IOP.

Since the risk of surgical complications is higher in a glaucoma patient, especially if IOP is uncontrolled, any maneuver that stabilizes the patient hemodynamically, along

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with good control of IOP, would assist in alleviating the adverse surgical conditions. To the best of our knowledge, there are very few studies to date that have examined the effect of dexmedetomidine on IOP in patients undergoing glaucoma surgeries. So, the study aimed to find out the effect of dexmedetomidine on IOP after being used as an additive in peribulbar injections during glaucoma surgery.

Methods

It is a prospective, randomized, double-blind, parallel assignment interventional study conducted in a tertiary eye care hospital in North India. The study was approved by the institutional research board and was done following the Declaration of Helsinki. After obtaining written informed consent, consecutive glaucoma patients aged 18–80 years of both sexes undergoing trabeculectomy or phaco-trabeculectomy with American Society of Anaesthesiology (ASA) physical status I or II patients were included in the study.[9] Exclusion criteria included known allergy to the medications including the study drug, patients with any corneal abnormality, significant cardiovascular disease (second [Mobitz II type] or third-degree heart block), congestive heart failure, chronic heart failure (New York Heart Association III–IV), symptomatic coronary artery disease, uncontrolled hypertension, ASA grade more than III, body mass index >35, uncontrolled diabetes mellitus, chronic clonidine therapy, hepatic and renal impairment, ongoing drug or alcohol abuse, coagulopathy, pregnancy, patients on antipsychotics and antiepileptics, mentally challenged patients/dementia/deafness/difficult to communicate/cannot lie supine, chronic obstructive lung disease, INR more than 1.7 or with significant coagulopathy.

Patients were randomly assigned using a computer-generated list into two groups, the Dexmed group (Group 1) and the Placebo group (Group 2). A single certified person who was blinded was designated for giving the block in all patients. The total amount of block given was the same in all patients (10 mL). In the Dexmed group, peribulbar block was given using 10 mL of a mixture of local anesthetics with dexmedetomidine. The mixture was composed of 4.5 mL of (0.5% bupivacaine admixed with 150 IU of hyaluronidase) + 4.5 ml of 2% lignocaine +1 mL of dexmedetomidine (0.4 µg/kg body weight, mixed with distilled water). In the Placebo group, the mixture was composed of 4.5 mL of (0.5% bupivacaine admixed with 150 IU of hyaluronidase) + 4.5 ml of 2% lignocaine + 1 mL of normal saline. Gentle intermittent ocular massage was given by the hand for 2 min to all patients in a similar way. IOP was recorded at three time points with a Perkin's tonometer after instillation of fluorescein dye: (1) just before giving the block, (2) 5 min after block after the digital massage of 2 min, and (3) 15 min after block, just before cleaning and draping. All healthcare personnel providing direct patient care were masked to the "study drug" injected. Preanesthetic evaluation and fasting status of 4 h was ensured. No premedication (sedative drugs) was given. Oxygen 2–3 L/min was supplemented through a nasal cannula, and an IV line was placed. Preoperatively, baseline vital parameters, i.e., heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), respiratory rate (RR), and peripheral oxygen saturation (SpO2) were noted.

The primary outcome was a change in IOP pre- and postperibulbar injections (IOP before the block, and 5 and 15 min after the block). Secondary outcomes were the onset of block, adverse events, and surgeon satisfaction. The onset of the block was defined as time started from the injection of LA till ocular movement grade of <1. Ocular movement[10] was evaluated at 30 s interval in all four directions using a three-point scale: 0: complete akinesia, 1: limited movement, and 2: normal movement. Block supplementation, if given, was noted. Total surgery time was noted. Complete anesthesia in terms of analgesia and akinesia was ensured at the beginning of the surgery in all patients. All surgeries were performed by fellowship-trained experienced glaucoma surgeons of more than 7 years. Intraoperative monitoring included ECG (electrocardiogram), noninvasive blood pressure, pulse oximetry, RR every 10 min during surgery. Sedation level[11] was assessed with a modified Ramsay sedation scale at every 10 min during, and at the end of surgery. It was graded as: (1) anxious and agitated or restless or both; (2) cooperative, oriented, and tranquil; (3) responds to commands only; (4) brisk response to a light glabellar tap or loud auditory stimulus; and (5) no response to a light glabellar tap or loud auditory stimulus. Adverse effects [bradycardia (HR < 20% of baseline), hypotension (MAP < 20% of baseline), respiratory depression (RR < 10/min), and level 4 sedation], if any, were noted and treated. Surgeon satisfaction was evaluated after surgery using a five-point Likert scale: Completely satisfied: Patient with painless, quiet, and ideal surgical conditions; Satisfied: Patient with some painful expression, slight anxiety, and good surgical conditions; Slightly dissatisfied: Patient with moderate pain, anxiety, and adequate surgical conditions; Dissatisfied: Patient with severe pain, anxiety, and suboptimal surgical conditions; and Very dissatisfied: Patient with severe pain, restless, and inadequate surgical conditions.

Statistical analysis: descriptive and inferential statistical analysis has been carried out using computer software SPSS trial version 23 and primer. Qualitative data were expressed as mean and percentages, and quantitative data as mean, median, or standard deviation. The difference in proportion was analyzed using the Chi-square test. The difference in means among the groups was analyzed using the Student's t-test. The significance level for tests was determined as 95% ($P < 0.05$). To detect a difference of 20% between the two groups at an alpha error of 0.05, and achieve 90% power of the study, the sample required was 45 in each group. We took 10% extra subjects.

Results

A total of 104 patients were randomized, 52 patients each in the Dexmed group and the Placebo group. The demographic profile of patients, including age, gender, diagnosis, and type of glaucoma surgery were comparable in both the groups ($P > 0.05$) [Table 1]. ASA grade, the onset of anesthesia, and duration of surgery were not found to be significantly different in either group. Preoperatively, IOP, and all the hemodynamic parameters, including HR, SBP, DBP MAP, and RR were similar in both groups ($p > 0.05$). The mean age in years was 59.5 and 58.7 in the Dexmed and Placebo groups, respectively. Out of 104 patients, 93 had primary glaucoma and 11 had secondary glaucoma. The percentage decrease in IOP was significantly more in the Dexmed group than in the Placebo group, both at 5 and 15 min postblock ($P < 0.05$). At 5 min, the mean percent decrease in IOP in the Dexmed group was -10.48, whereas there was an increase of 2.85 in the Placebo group. At 15 min, the mean percent decrease in IOP was -22.59 and -9.42 in the Dexmed and Placebo groups, respectively [Table 2]. There was no significant difference

between the two groups regarding the onset of the block and adverse effects. None of the patients in this study cohort required supplemental block. However, surgeon satisfaction was significantly greater in the Dexmed group than the Control group ($P < 0.05$). A higher number of surgeons in the Dexmed group were completely satisfied compared to the Placebo group (45 vs 13) [Table 3]. Mean SBP, Mean DBP, and MAP measured at every 10 min were found to be significantly reduced throughout the procedure in the Dexmed group compared to the Placebo group ($P < 0.05$) [Table 4]. However, there was no significant difference in HR and RR between the two groups. Ramsay scale was also found to be significantly reduced in the Dexmed group ($p < 0.05$) till 50 min of surgery, but none of the patients were in grade 4 sedation. There were no adverse effects noted due to the anesthesia in both the Placebo group and the Dexmed group.

Discussion

Glaucoma eyes are complex eyes with a faulty auto regulation. Likewise, surgeries in these eyes are complex and longer in duration than a cataract surgery. To achieve an uneventful intra- and postoperative outcome, a hemodynamically stable patient with a well-controlled IOP is necessary during the surgery. Dexmedetomidine is a potent alpha 2 adrenoceptor agonist that provides dose-dependent sedation, analgesia, sympatholysis, and anxiolysis without significant respiratory depression. It was found to significantly reduce IOP when used intravenously, and along with the subtenons injection during cataract surgery. However, its effect on IOP reduction was not studied in glaucoma patients till the initiation of this study. This randomized control trial was thus conducted to study the effect of dexmedetomidine on IOP when added with a peribulbar block in patients undergoing glaucoma surgery. It was observed in this study that Dexmed causes significant IOP reduction at a dose of 0.4 μg/kg body weight along with conscious sedation, better patient cooperation, and higher surgeon satisfaction.

Peribulbar and retrobulbar injections have the potential to cause IOP elevation, which is accentuated in glaucoma patients. The IOP rise in addition to volume injection depends on the speed of injection, interindividual variation in orbital volume and compliance, the resistance of the orbital septum to orbital volume increase, and vascular effects.[3] One study reported that the IOP changes at 1 and 5 min were significantly higher in the glaucoma patients, and the maximum increase in IOP was noted to be 25 mmHg at 1 min, and 23 mm Hg at 5 min.[3] External ocular compression after a block has been found to lower IOP in various studies.[12,13] In this study, gentle intermittent ocular compression was given by hand for 2 min to all patients in a similar way as constant compression can compromise optic nerve blood flow.

Table 1: Demographic data

Variables	Dexmed		Placebo		Total	*P*
	Number	%	Number	%		
Age	59.58	11.31	58.75	13.47		0.73
Gender						
Female	25	48.08	23	44.23	48	0.84
Male	27	51.92	29	55.77	56	
Type of Glaucoma						
Primary	46	88.46	47	89.03	93	0.58
Secondary	6	11.54	5	9.62	11	
Gonioscopy						
Open	27	41.5	35	56.4	62	0.28
Closed	24	57.6	18	42.8	42	
Surgery						
Phacotrabeculectomy	37	71.15	40	76.92	77	0.63
Trabeculectomy	15	28.85	12	23.07	27	

Table 2: IOP changes pre- and postperibulbar injections

Group	Dexmed				Placebo				*P*
	n	Mean	SD	Median	*n*	Mean	SD	Median	
IOP Preblock	52	22.56	9.59	21.00	52	20.56	7.09	18.50	0.229
IOP at 5 min Postblock	52	19.69	7.50	18.00	52	20.85	6.81	20.00	0.413
IOP difference in 5 min	52	-3.06	4.57	-2.00	52	0.06	4.91	-1.00	0.001
% decrease 5 min	52	-10.48	19.20	-12.50	52	2.85	25.59	-6.10	0.003
IOP at 15 min Postblock	52	16.63	6.54	15.00	52	18.15	5.87	18.00	0.215
Difference in IOP at 15 min	52	-5.92	5.75	-4.50	52	-2.40	4.12	-2.00	0.001
% decrease at 15 min	52	-22.59	20.82	-24.25	52	-9.42	19.13	-12.50	0.001

IOP – Intraocular pressure

Table 3: Surgeon satisfaction

Satisfaction	Dexmed		Placebo		Total	*P*
Completely satisfied	45	86.54%	13	25%	58	<0.001
Dissatisfied	0	0%	1	1.92%	1	1.0
Moderately satisfied	3	5.77%	5	9.62%	8	0.713
Satisfied	3	5.77%	31	59.62%	34	<0.001
Slightly dissatisfied	1	1.92%	2	3.85%	3	1.0

Table 4: Intraoperative hemodynamic parameters Pre- and Postblock

	Dexmed			Placebo			*P*
	No	Mean	SD	No	Mean	SD	
SBP							
Preblock	52	139.23	16.80	52	140.65	17.17	0.67
@10 min	52	124.37	17.85	52	143.71	20.85	<0.001
@20 min	52	120.17	16.50	52	140.83	21.34	<0.001
@30 min	47	119.70	16.72	45	143.87	19.80	<0.001
@40 min	25	121.92	14.61	18	146.61	20.36	<0.001
@50 min	13	120.00	12.58	10	148.80	22.00	0.001
@60 min	6	121.33	12.52	5	149.40	20.76	0.021
DBP							
Preblock	52	80.73	7.32	52	82.46	7.67	0.242
@10 min	52	73.56	9.58	52	81.92	9.52	<0.001
@20 min	52	71.08	9.58	52	80.40	9.77	<0.001
@30 min	47	69.55	9.28	45	81.42	10.93	<0.001
@40 min	25	69.16	7.22	18	81.44	11.62	<0.001
@50 min	13	70.31	7.79	10	80.70	13.69	0.032
@60 min	6	73.17	8.70	5	77.60	8.99	0.429
MAP							
Preblock	52	94.42	12.48	52	98.60	9.39	0.057
@10 min	52	87.83	12.18	52	99.42	13.80	<0.001
@20 min	52	84.44	12.17	52	98.37	12.82	<0.001
@30 min	47	83.53	11.29	45	99.87	14.66	<0.001
@40 min	25	85.44	10.35	18	102.50	16.82	<0.001
@50 min	13	86.08	10.04	10	102.60	16.18	0.007
@60 min	6	85.50	10.82	5	98.80	16.08	0.136

SBP - Systolic blood pressure, DBP - Diastolic blood pressure, MAP - Mean arterial pressure, SD - Standard deviation

When Dexmed was used as a premedication in patients undergoing cataract surgery under topical anesthesia in a dose of 1 mcg/kg over 10 min, it was found to significantly decrease IOP from mean 17.10 ± 1.92 mmHg to postoperative 13.81 ± 1.63 mmHg.[14] It was also found to reduce IOP significantly when used in subtenon block during cataract surgery in a dose of 0.5 µg/kg.[15] Likewise, in our study at 15 min, the mean percent decrease in IOP was -22.59 and -9.42 in the Dexmed and Placebo group, respectively. We used a dose of 0.4 µg/kg body weight in all patients and found this dose to cause significant and safe IOP reduction without any adverse event.

The degree of IOP change was also compared between the two groups. At 5 min, there was a higher number of patients with an IOP reduction of more than 9 mmHg in the Dexmed group ($N = 11$) compared to the Control group ($N = 4$) ($P < 0.09$).

Table 5: Degree of IOP change at 15 min

	Dexmed		Placebo		Total	*P*
	No	%	No	%		
Decrease in IOP						
<3 mmHg	6	11.54	10	19.23	16	0.41
3-6 mmHg	14	26.92	14	26.92	28	0.82
6-9 mmHg	6	11.54	8	15.38	14	0.77
>9 mmHg	17	32.69	3	5.77	20	0.001
No change	3	5.77	4	7.69	7	1.00
Increase in IOP						
<3 mmHg I	4	7.69	10	19.23	14	0.15
3-6 mmHg I	2	3.85	3	5.77	5	1.00
<3 mmHg	7	13.46	8	15.38	15	1.00
3-6 mmHg	3	5.77	7	13.46	10	0.31
>6 mmHg	1	1.92	10	13.46	8	0.01

IOP – Intraocular pressure

However, a more important parameter to consider here is the IOP increase of more than 6 mmHg that occurred significantly more in the Control group ($N = 10$) than in the Dexmed group (N = 1) ($P = 0.01$). This shows that Dexmed can have a positive effect in blunting the initial IOP rise caused by the volumetric expansion of orbital tissues immediately after peribulbar block. At 15 min, there were 17 patients with IOP reduction of more than nine in the Dexmed group and only three patients in the Control group ($P < 0.001$), indicating that the level of IOP reduction was much more in the Dexmed group [Table 5]. This can prove to be extremely useful to the surgeon since lower IOP, especially while performing crucial steps during trabeculectomy surgery, can present a more safe and comfortable environment to the surgeon.

However, unlike our study result, a recently published study comparing the IOP lowering efficacy of dexmedetomidine in patients undergoing glaucoma surgery after being added to a peribulbar block did not find any statistical difference between the various groups in pre- and postinjection, and after the surgery.[16] This study randomized 98 eyes to three groups, 35 eyes with dexmedetomidine 50 µg, 33 eyes with dexmedetomidine 25 µg, and 30 eyes in Control group (C). The preinjection IOP was 27.71 ± 2.52, 27.25 ± 3.53, and 26.2 ± 3.57 mmHg in groups D50, D25, and C, respectively, which increased to 29.71 ± 1.69, 30.25 ± 2.36, and 29.4 ± 3.75 in groups D50, D25, and C, respectively, postinjection. This study group however did not specify the time of IOP measurement after the injection. So, further studies are required to confirm the IOP lowering effects of Dexmed in glaucoma patients.

As regards the hemodynamic parameters, SBP, DBP, and MAP were found to be significantly lower in the Dexmed group compared to the Placebo group in our study with no significant changes in HR and RR, and none of the patients needed any treatment for either hypotension or low MAP. The result again highlights the efficacy of Dexmed in stabilizing the patient hemodynamically. Our findings corroborate with results of Abdelhamid AM *et al.* who on comparing intravenous (1 µg/kg over 10 min; followed by 0.4 µg/kg/h IV infusion) and peribulbar routes of Dexmed administration (50 µg) in patients undergoing cataract surgery found that HR did not significantly change with peribulbar injection,[1] but on systemic administration, patients had significant fall in HR. Both groups

also had a significant reduction in IOP compared to the Control group before and after the block.[1] Pal *et al.* also found no significant change in HR with an intravenous dose of 0.4 μg/kg over 10 min .[17] Hence, the dose and route of administration are important determinants when injecting Dexmed. Systemic route and higher dose can increase the risk of adverse events.

RR also did not show any significant change in pre- and post-Dexmed injection. This is because the mechanism of action of Dexmed, unlike other sedatives, is by hyperpolarization of noradrenergic neurons in locus ceruleus. This is similar to natural sleep phenomena in the human body and, in a way, is responsible for maintaining respiratory function.[4]

The onset of anesthesia was not found to be significantly different in each of the groups. We used hyaluronidase in both the groups, which might have had some effect even in the Placebo group leading to a not so significant difference between the two. The mean Ramsay score was 1.93 in the Dexmed group and 1.65 in the Placebo group signifying a more cooperative, oriented, and tranquil patient in the former. This is because it efficiently suppresses nociceptive signal transmission in the spinal cord when it joins to pre- and postsynaptic receptors causing sedation, analgesia, and adequate quality anesthesia. Gelil *et al.* also showed improvement of sedation on the addition of Dexmed to LA in their study.[18]

The risk of surgical complications like posterior capsular rent and suprachoroidal hemorrhage is higher with a high intraoperative IOP. However, none of our patients underwent any dreaded complications, both intraoperatively and postoperatively. The surgeon comfort was significantly higher in the Dexmed group, as seen in our study.

We had a few limitations to our study. Ocular compression was given in all the patients for 2 min, which could lower the IOP additionally and confounded the IOP lowering effect of the medication used. We tried to maintain homogeneity by giving the massage to all patients in a similar way thus minimizing the bias. Second, we did not study the persistence of the effect of anesthesia after the surgery. It will be interesting to know whether patients with Dexmed injection are more comfortable and stable in the postoperative period.

Conclusion

We conclude that dexmedetomidine can be safely used in ASA I/II patients as an additive in the peribulbar block as it provides hemodynamic stability with IOP lowering that is required during a complex procedure such as trabeculectomy, which necessitates a tranquil patient and stable IOP for the entire duration. However, more studies are required to further assess the safety and efficacy of dexmedetomidine in patients undergoing glaucoma surgery.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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