

# Effect of adding dexmedetomidine to 0.75% ropivacaine in peribulbar block for vitreoretinal surgery

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## Abstract

**Background and Aims:** Peribulbar anesthesia is suitable for vitreoretinal (VR) surgery. Dexmedetomidine has been used in peribulbar block (PBB) to improve akinesia and analgesia. We aimed to study the efficacy of adding dexmedetomidine to 0.75% Ropivacaine in PBB for VR surgery. The primary outcome was the requirement of block supplementation and secondary outcome was post-operative analgesic requirement.

**Material and Methods:** 100 adult patients undergoing VR surgery were included in this prospective randomized double-blinded controlled study. The composition of the drug used for PBB in the 3 groups was Group R (8 ml of 0.75% Ropivacaine +0.5 ml normal saline (NS)), Group D25 (8 ml of 0.75% Ropivacaine +25µg Dexmedetomidine) and Group D50 (8 ml of 0.75% Ropivacaine +50 µg Dexmedetomidine).

**Results:** The groups were comparable in terms of patient demographics. The requirement for block supplementation was 16.7% in Group R (5/30), 12.5% in Group D25 (4/32) and 8.8% in group D50 (3/34) ( $P = 0.64$ ). The mean time to first request for post-operative analgesia was  $432 \pm 362$  min in Group R,  $572 \pm 339$  min in Group D25 and  $614 \pm 394$  min for Group D50 ( $P = 0.26$ ). There was significant difference in the heart rate ( $P = 0.047$ ), mean arterial pressure ( $P = 0.012$ ) at 30 min and sedation (RASS) score at 15, 30, 60 ( $P < 0.001$ ) and 120 ( $P = 0.019$ ) min between the D50 and group R. Patients undergoing buckling procedures had significantly shorter time to request for analgesia ( $P = 0.003$ ).

**Conclusion:** Addition of dexmedetomidine does not offer advantage over 0.75% Ropivacaine in PBB for vitrectomy. Its benefit in more painful procedures like scleral buckle needs further validation.

**Keywords:** Dexmedetomidine, peribulbar block, Ropivacaine, vitreoretinal

## Introduction

Peribulbar anesthesia is widely used in ophthalmic anesthesia and is a suitable technique for vitreoretinal (VR) surgery.<sup>[1]</sup> VR surgery is painful due to the traction on the ocular muscles or sclera, increased intra-ocular pressure due to insertion of gas bubble or secondary to encirclement procedures.<sup>[2]</sup> Good akinesia is an essential requisite for VR procedures. Local anesthesia (LA) is preferred to general anesthesia (GA) in view of the better analgesia, earlier rehabilitation and the

presence of systemic conditions like diabetes, hypertension and chronic kidney disease that often co-exist in patients with retinopathy.<sup>[3]</sup> Peribulbar block (PBB) has been found to be an effective and safe alternative to GA in VR surgery. Longer acting local anesthetic agents and adjuvants have been used to improve anesthesia, akinesia and patient satisfaction. Ropivacaine is an S-isomer of Bupivacaine and is associated with lesser cardiotoxicity than Bupivacaine.<sup>[4]</sup> 0.75% Ropivacaine provides satisfactory sensory and motor block for VR surgery. Dexmedetomidine

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is a highly selective alpha 2 agonist with  $\alpha_2: \alpha_1$  activity of 1600:1. It has been used in GA to reduce anesthetic and opioid requirement. Dexmedetomidine has been used effectively as an adjuvant in brachial plexus block, epidural and subarachnoid anesthesia.<sup>[5]</sup>

Dexmedetomidine has been used as adjuvant to PBB in cataract surgery.<sup>[5]</sup> It also reduces intra-ocular pressure. Ropivacaine with hyaluronidase has been used to provide effective analgesia for VR procedures by Ghali *et al.*<sup>[4]</sup> Ours is the first study to examine the efficacy of adding dexmedetomidine to 0.75% Ropivacaine in PBB for VR surgery. The primary outcome was the requirement of supplementation of peribulbar block prior to or during the surgery. The secondary outcome was the post-operative analgesic requirement.

## Material and Methods

This prospective double-blinded randomized controlled study was conducted at a tertiary care eye centre in South India after approval of the institutional ethics committee and was registered with the Clinical Trials Registry of India (CTRI/2019/07/020225). 100 ASA I-III adult patients aged greater than 18 years, undergoing vitreoretinal surgery under peribulbar block were included in the study after obtaining a written informed consent. Patients with history of hypersensitivity to the study drugs, significant cardiovascular disease, impaired mental status, refusal to use local anesthetic technique and pregnant women were excluded from the study. All patients underwent routine pre-operative evaluation for vitreoretinal surgery. Details of the anesthetic technique and study protocol were explained to the patients at the preoperative visit. No topical anesthetic or sedative medications were used before or during the block. Details regarding the side, surgery and whether it was a redo procedure were noted.

In the operating room, an intravenous cannula was secured and standard monitors including ECG, pulse oximeter and non-invasive blood pressure were applied. The patients were randomized using a computer-generated random number table into one of the three groups. The composition of the study drug used for peribulbar anesthesia in each of the 3 groups was:- Group R (8 ml of 0.75% Ropivacaine + 300U hyaluronidase + 0.5 ml normal saline), Group D25 (8 ml of 0.75% Ropivacaine + 300U hyaluronidase + 0.25 ml Dexmedetomidine [100µg/ml] + 0.25 ml normal saline) and Group D50 (8 ml of 0.75% Ropivacaine + 300U hyaluronidase + 0.5 ml Dexmedetomidine [100 µg/ml]). The total volume of drug in PBB was 8.5 ml in all the three groups.

The peribulbar block was administered by an anesthesiologist with adequate experience in ophthalmic regional anesthesia. All healthcare personnel including the anesthesiologist and surgeon involved in direct patient care were blinded to the study drug. Peribulbar block was administered using a 24G, 25mm needle using a transcutaneous two injection technique. The first injection was in the inferotemporal quadrant, as far lateral as possible. With the eye in the primary gaze, the needle was advanced parallel to the orbital floor passing the globe equator to a depth controlled by observing the needle/hub junction reaching the plane of the iris and 5ml of the drug administered after negative aspiration. Gentle massage was applied on the eyeball using the middle three fingers. The second injection was given 2mm medial and inferior to the supraorbital notch where the remaining 3.5 ml of drug was deposited at a depth of 15-20 mm. If the eyeball was firm or tense after the first injection, gentle pressure was applied until the eyeball was soft before the second injection. After the second injection the eye was examined every 30 second for onset of corneal anesthesia and akinesia. Corneal anesthesia was assessed by checking the corneal reflex in response to instillation of physiological solution of saline. Onset of motor block was assessed by grading the movement of the eyeball in the four directions: superior, inferior, lateral and medial using a score of 0, 1 or 2 [0 = no movement, 1 = mild movement, 2 = full movement]. A total score  $\leq 1$  was considered adequate for surgery. The time to onset of sensory and motor block were noted. A supplementary block was given in the inferotemporal quadrant with 3 ml of 2% Xylocaine if satisfactory anesthesia or akinesia was not achieved by ten minutes. The supplementation was repeated if the block was incomplete after another 5 minutes.

Intra-operative details including the hemodynamic variables (heart rate, blood pressure, SpO<sub>2</sub>), Richmond agitation sedation scale (RASS) were noted every 15 min for one hour and every 30 minutes thereafter till completion of the surgery. The duration of surgery was noted. Any need for analgesia or akinesia intra-operatively was achieved by administering a Sub Tenon's block with 3 ml of 2% Xylocaine. The patient was excluded from the study if more than two supplementary blocks were needed after the initial peribulbar block. An alternative anesthesia technique was used to complete the case. The patient was encouraged to communicate any pain during the surgery. At the end of the surgery, the surgeon's satisfaction score was obtained using a grading for the efficacy of anesthesia (0- Inadequate anesthesia or akinesia or any other complication necessitating termination of the operative procedure, despite supplementation, 1- Inadequate akinesia and anesthesia, supplementation required, 2- Inadequate akinesia, adequate anesthesia, supplementation required, 3- Inadequate anesthesia, adequate akinesia, supplementation

required, 4- Adequate anesthesia, inadequate akinesia, no supplementation, 5- Adequate anesthesia and akinesia throughout surgery without supplementation).

In our institute, all patients undergoing VR surgery are given an eye patch that is opened only the next morning. Hence, only analgesia was studied in the post-operative period. The pain relief was scored using a verbal numerical rating scale (NRS) of 0-10 with 0 representing “no pain” and 10 representing “worst pain”. The pain score was recorded at 1h, 2h, 6h and 24 h post op. The time to first request for analgesia and total analgesic requirement in 24 hours was noted. The end point of the study was at 24 hours.

### Statistics

The sample size was calculated assuming that the addition of Dexmedetomidine to Ropivacaine would increase the success rate of the PBB from 75% to 99%, accepting a 2-tailed  $\alpha$ - error of 0.05 and power of 80%.<sup>[4]</sup> This required at least 30 patients in each group. The statistical software SPSS 22.0, and R environment ver. 3.2.2 were used for the analysis of the data. Results on continuous measurements are presented as mean  $\pm$  SD, if parametric and in median (interquartile range), if the distribution is non-Gaussian. Results on categorical measurements are presented in number (%). Chi-square/Fisher Exact test was used to find the significance of study parameters on categorical scale between two or more groups, non-parametric setting and for qualitative data analysis. Analysis of variance (ANOVA) was used to find the significance of normally distributed continuous data between the three groups. Continuous data with non-parametric distribution was analyzed using Kruskal Wallis test.  $P < 0.05$  was considered significant.

### Results

100 patients were recruited in this study of which data collected from 96 patients was analyzed. Two patients

were excluded as the eyeball became tense after injection of only 6 ml of study drug with total akinesia and surgical anesthesia. One patient was excluded as he required more than two block supplementations. Another patient was excluded as the surgery was done after induction of general anesthesia due to a language barrier. There was no difference in the demographic characteristics and surgical details of the patients between the three groups. [Table 1]. 5/30 (16.7%) patients in Group R, 4/32 (12.5%) patients in Group D25 and 3/34 (8.8%) patients in group D50 required a supplementation of peribulbar block. There was no statistical difference between the groups in the requirement for LA supplementation ( $P = 0.64$ ). Six patients, 2 in Group R, 3 in Group D25 and 1 patient in Group D50 were given a pre-operative repeat block. Of the six patients who required a Sub tenon's block intraoperatively, two had inadequate akinesia, two experienced pain and two patients had inadequate akinesia and anesthesia. The block characteristics and efficacy are detailed in Table 2. The median time to onset of corneal anesthesia and akinesia was shorter in the dexmedetomidine containing groups but was not statistically significant. The post-operative analgesic requirement, including time to first request for analgesia and total analgesic consumption in the first 24 hours, was comparable in the three groups. Patients who underwent scleral buckling called for their first pain relief measure (363 min) significantly earlier than those undergoing simple vitrectomy (674 min) ( $P = 0.003$ ) though no statistical difference was found between the groups ( $P = 0.128$ ) [Figure 1 and Table 3]. There was no significant difference between the three groups in patients ( $P = 0.36$ ) not asking for any pain relief in the first 24 hours. The heart rate and mean arterial pressure at baseline, 15, 30, 60, 120 minutes are shown in Figures 2 and 3. There was a significant difference in the heart rate ( $P = 0.047$ ) and MAP ( $P = 0.012$ ) at 30 minutes after administration of the PBB. On applying *post hoc* Tukey test, it was seen that there was a significant decrease in the heart rate and MAP at 30 minutes in the D50

**Table 1: Demographic Characteristics of The Patients and Surgical Details**

	Group R (n=30)	Group D25 (n=32)	Group D50 (n=34)	P
Age (years) (Mean $\pm$ SD)	54.00 $\pm$ 10.49	53.78 $\pm$ 14.44	56.65 $\pm$ 17.05	0.67
Gender (M/F)	24/6	25/7	26/8	0.94
Weight (kg) (Mean $\pm$ SD)	71.40 $\pm$ 16.67	68.62 $\pm$ 14.75	68.88 $\pm$ 12.29	0.76
ASA grade (I/II/III)	3/27/0	4/28/0	4/30/0	1.0
Redo surgery (Y/N)	4/26	8/24	3/31	0.18
Side (RE/LE)	15/15	16/16	16/18	0.96
Surgery				
Vitrectomy + oil/gas insertion	12	20	9	
Cataract + vitrectomy	10	8	13	0.05
Buckling procedures (including sclera buckle $\pm$ vitrectomy $\pm$ cataract)	8	4	12	
Duration of surgery (min)	85.00 $\pm$ 38.21	68.75 $\pm$ 33.36	82.21 $\pm$ 39.87	0.18

Mean $\pm$ SD

group compared to the R group. There was no difference in oxygen saturation (SpO<sub>2</sub>) between the three groups. None of the patients required intraoperative oxygen supplementation, atropine or pressor support. Patients in the D50 group were significantly more sedated and had lower RASS scores than the control group R at 15, 30 and 60 minutes ( $P < 0.001$ ) and at 120 minutes (0.019). The RASS score at baseline was similar in the groups. There was no difference in the surgeon satisfaction score between the three groups ( $P = 0.29$ ). There was no significant difference in the NRS between the three groups at 1, 2, 6 and 24 hours. ( $P > 0.05$ ).

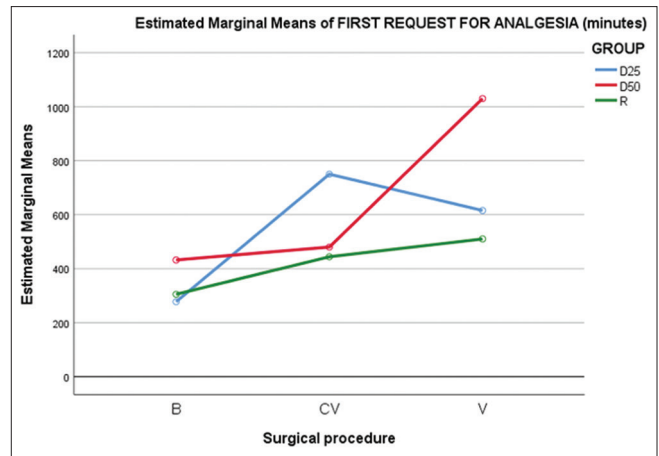
## Discussion

The usefulness of any adjuvant in peribulbar block may be assessed based on the quality of block, post-operative pain relief and its effects due to systemic absorption. Peribulbar dexmedetomidine has been shown to be a beneficial adjunct in both cataract and VR surgery.<sup>[5-9]</sup> VR procedures are lengthier and more painful than cataract surgery. Our study is unique in being the first one to evaluate the effect of the  $\alpha_2$  agonist dexmedetomidine with a potent local anesthetic, 0.75% ropivacaine, in VR surgery.

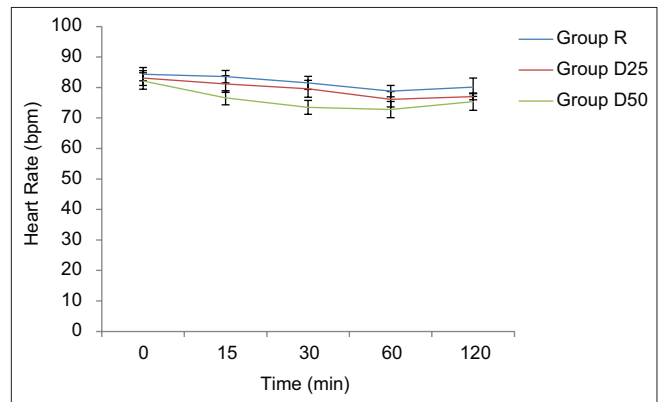
We found that the addition of dexmedetomidine did not significantly shorten the time to onset of surgical anesthesia. Other studies have also shown a similar effect regardless of the local anesthetic combination.<sup>[8,10,11]</sup> Authors like Channabasappa *et al.*,<sup>[5]</sup> and Abdelhamid *et al.*,<sup>[6]</sup> found dexmedetomidine to reduce the time to onset of corneal anesthesia and globe akinesia. They added dexmedetomidine to a PBB mixture of Lidocaine/Bupivacaine and Lidocaine/Bupivacaine/hyaluronidase respectively.

The proposed mechanism of dexmedetomidine is direct action on the peripheral nerve to potentiate local anesthetic effect. Central analgesia, vasoconstriction, and anti-inflammatory properties do not fully explain the efficacy of dexmedetomidine in peripheral nerve blockades.<sup>[12-14]</sup> In peribulbar block, the drug is deposited extraconally and needs to diffuse through the muscle cone to reach its site of action. This may explain the absence of utility of dexmedetomidine in decreasing the time to onset of surgical anesthesia.<sup>[15]</sup> Bharti *et al.*,<sup>[16]</sup> reported no reduction in onset time when Clonidine, an  $\alpha_2$  agonist was used as an adjuvant in PBB.

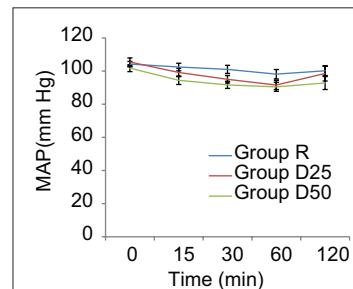
0.75% Ropivacaine has been shown to require greater PBB supplementation than a 1:1 mixture of Lidocaine and Bupivacaine, or 0.75% Levobupivacaine.<sup>[3,4,8]</sup> The block success rate after ten minutes, in our control group was 83.7%, which is higher than that reported by Ghali *et al.*,<sup>[4]</sup> (75%) who also used 0.75% Ropivacaine with hyaluronidase. Our results



**Figure 1:** Comparison of first request for analgesia between groups and the type of surgery .V= Vitrectomy; CV= Cataract + vitrectomy; B= Buckling procedures (including scleral buckle ± vitrectomy ± cataract)



**Figure 2:** Heart rate



**Figure 3:** Mean arterial pressure

show that the number of patients requiring an additional block was lower in the D25 and D50 groups but was not statistically significant. El Shmaa *et al.*,<sup>[17]</sup> noted a significant decrease in the need for additional injections when dexmedetomidine was added to PBB (Lidocaine/0.5% Levobupivacaine/hyaluronidase). Their control group had block success rate of 60%.

The time to first request for post-operative analgesia in the control group (432 min) is similar to Ghali *et al.*, (393 min).<sup>[4]</sup> Patients in the D25 and D50 groups did have longer pain free period post-operatively but not statistically significant. Also, the total analgesic consumption on the first post-operative

**Table 2: Block Characteristics and Efficacy of Analgesia**

	Group R (n=30)	Group D25 (n=32)	Group D50 (n=34)	P
Onset of corneal anesthesia (sec)	60 (30,60)	37.5 (30,76.3)	47.5 (30,77.5)	0.76
Onset of globe akinesia (sec)	105 (30,323)	82.5 (30,218)	67.5 (34.8,308)	0.97
No request for analgesia in first 24h (n/%)	10 (33.33%)	13 (40.63%)	13 (38.24%)	0.36
Paracetamol in 24h (mg)	871±376	909±402	849±414	0.89
Diclofenac in 24h (mg)	96.4±36.6	75±0	83.3±25	0.44

Median (IQR); Mean±SD

**Table 3: Mean Time to First Request for Analgesia in Minutes. The Number of Cases Requesting for Analgesia is Indicated Within Parentheses**

Surgery	Group			Overall Mean
	R (20)	D25 (n=19)	D50 (n=21)	
V	510 (9)	615.45 (11)	1030 (6)	674* (26)
CV (n=14)	444 (5)	750 (4)	480 (5)	544 (14)
B (n=20)	305 (6)	277.45 (4)	432 (10)	363*(20)
Overall mean	432 (20)	572 (19)	614 (21)	

V=Vitrectomy; CV=Cataract+vitrectomy; B=Buckling procedures (including scleral buckle±vitrectomy±cataract). \*P=0.003

day was similar across the three groups. In contrast, others like Kabarity Reem *et al.*,<sup>[9]</sup> and Hafez *et al.*,<sup>[8]</sup> reported prolonged post-operative analgesia with dexmedetomidine in PBB. Both used an LA combination of 0.5% bupivacaine and lidocaine. Hence, the absolute amount of long-acting LA administered was lesser than in our study. Khalil *et al.*,<sup>[18]</sup> found lower post-operative pain scores in the first 6 hours and lesser analgesic consumption when dexmedetomidine was added to PBB. The scleral buckling procedures were associated with earlier demand for pain relief. A larger study using dexmedetomidine as an adjuvant in this subgroup is required to make any conclusive interpretation.

The sedative and hemodynamic effects due to systemic absorption of dexmedetomidine were evident in the D50 group. The HR and BP decreased at 30 minutes when compared to the R group. Comparable hemodynamic variability without instability has also been reported by OzairyHala *et al.*,<sup>[11]</sup> Hafez *et al.*,<sup>[8]</sup> and Gujral *et al.*<sup>[10]</sup>

Several authors have observed greater sedation with the use of dexmedetomidine as an adjuvant in PBB. Hafez *et al.*,<sup>[8]</sup> reported higher Ramsay scores starting from 15 minutes and extending up to 60 minutes, similar to our results. This systemic side effect may prove useful in providing a calm and unagitated patient contributing to superior surgeon satisfaction as described by Gujral *et al.*<sup>[10]</sup> This may also contribute to better intra-operative patient comfort. Nevertheless, deep sedation in VR surgery may prove counter-productive due to magnified respiratory excursion and sudden jerking movement while waking up.<sup>[19]</sup> In fact, Ramaswamy *et al.*, reported dissatisfaction with higher doses of intravenously administered dexmedetomidine.<sup>[20]</sup>

Dexmedetomidine has been used in different doses from 15 µg to 50 µg in PBB. Its efficacy in improving the block quality depends upon the LA used, addition of hyaluronidase and the type of ophthalmic surgery. It may not prove to be an effective additive with long-acting LA or for short duration surgery. A more detailed study of its use in the scleral buckling procedures may reveal its effectiveness in them. Sedation is a significant effect with dexmedetomidine is administered intravenously or at higher doses in PBB. Hafez *et al.*,<sup>[8]</sup> opined that 25 µg is the most suitable dose to use in PBB.

The limitations of this study are that duration of akinesia was not studied. Also, the surgeon satisfaction was assessed only on the basis of eye anesthesia. Patient factors, like having a calm patient, were not included in this score though sedation was assessed independently.

## Conclusion

The addition of dexmedetomidine does not offer any extraordinary advantage to a potent LA like 0.75% ropivacaine in vitrectomy. Its benefit in more painful procedures like scleral buckle need further evaluation. The effects due to systemic absorption of dexmedetomidine are evident from fifteen minutes after peribulbar administration but do not require any intervention.

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## Key Messages

The addition of dexmedetomidine does not offer any extraordinary advantage to 0.75% ropivacaine in vitrectomy. Its benefit in more painful procedures like scleral buckle need further evaluation. The effects due to systemic absorption of dexmedetomidine are evident from fifteen minutes after peribulbar administration but do not require any intervention.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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