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RESEARCH ARTICLE
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COMPARISON OF DEXMEDETOMIDINE 0.5MCG/KG IV OR 1MCG/KG IV WITH SALINE AS CONTROL FOR MONITORED ANAESTHESIA CARE IN POSTERIOR SEGMENT OPHTHALMIC SURGERY. A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Conscious sedation is often required during ophthalmic surgeries to ensure patient comfort and cooperation. Dexmedetomidine, an alpha-2 adrenergic agonist, has gained attention for its sedative and analgesic properties. This study investigates the effectiveness and safety of two doses of dexmedetomidine (0.5 µg/kg and 1 µg/kg) compared to a saline placebo in providing sedation for posterior segment ophthalmic surgeries.

Methodology: A double-blind, block-randomized controlled trial was conducted on 75 patients undergoing posterior segment ophthalmic surgeries under local anesthesia. Participants were randomly assigned into three groups (n=25 each) to receive either dexmedetomidine 0.5 µg/kg (Group DL), 1 µg/kg (Group DH), or placebo (Group C) infused over 10 minutes. Sedation, analgesic requirements, hemodynamic parameters, and recovery profiles were assessed. Data were analyzed using STATA 10.1, with ANOVA, Chi-square test, and Games-Howell post hoc analysis applied; $p<0.05$ was considered statistically significant.

Results: Baseline demographic and clinical characteristics were comparable across all groups with no significant differences. Intraoperatively, sedation scores were significantly higher in the DH and DL groups compared to the Control group during the first 60 minutes ($p < 0.0001$). Fewer patients in the DH and DL groups required rescue midazolam and fentanyl, and their mean dosages were significantly lower than in the Control group ($p < 0.0001$). Respiratory parameters remained stable and comparable across groups. Adverse events were mild and not statistically different between groups. Overall, DH and DL groups demonstrated superior sedation and analgesia profiles with minimal side effects.

Conclusion: Both 0.5 µg/kg and 1 µg/kg doses of dexmedetomidine were effective in providing conscious sedation during posterior segment ophthalmic surgeries, with no significant difference in

efficacy. However, the 0.5 µg/kg dose was associated with fewer side effects, indicating a better safety profile. Therefore, a 0.5 µg/kg dose is recommended for monitored anesthesia care in these procedures.

Keywords: Dexmedetomidine, Sedation, Ophthalmologic Surgical Procedures, Anesthesia, Postoperative Care, Alpha-2 Adrenergic Agonists, Perioperative Care, Drug Dosage, Placebos, Adverse Effects.

INTRODUCTION

Anesthetic management for ophthalmic procedures involves several approaches and should be tailored to both the patient and the specific surgical procedure. It is important to consider underlying comorbidities while ensuring patient comfort, cooperation, and safety. Options may include moderate sedation, monitored anesthesia care, or general anesthesia. The use of topical and regional anesthesia as part of the anesthetic plan has significantly enhanced patient care and surgical outcomes [1].

Posterior segment ophthalmic surgeries, such as vitrectomy, often necessitate patient cooperation and minimal eye movement to ensure surgical precision and optimal outcomes. Monitored anesthesia care (MAC) is commonly employed in these procedures to provide sedation while maintaining spontaneous respiration and patient responsiveness [2]. Traditional sedatives like propofol and midazolam, while effective, are associated with risks of respiratory depression and hemodynamic instability, which can be particularly concerning in ophthalmic surgeries where patient immobility and stable physiological parameters are crucial [3]. Dexmedetomidine, a highly selective α_2-adrenergic receptor agonist, has emerged as a promising alternative due to its unique pharmacological profile. It provides sedation that closely resembles natural sleep, offers analgesic properties, and notably lacks significant respiratory depressant effects. These characteristics make it particularly suitable for procedures requiring patient cooperation without compromising respiratory function [4]. some studies have explored the efficacy of dexmedetomidine in ophthalmic surgeries. For instance, its use in retinal surgeries under sub-Tenon's anesthesia has been associated with improved patient and surgeon satisfaction without respiratory complications. Similarly, in cataract surgeries, dexmedetomidine has demonstrated better patient satisfaction and a more stable cardiovascular profile compared to combinations like propofol and alfentanil [5,6].

Dexmedetomidine has emerged as a valuable sedative agent in ophthalmic surgeries due to its unique profile, providing effective sedation and analgesia with minimal respiratory depression. Its ability to maintain patient cooperation and stable intraoperative conditions makes it particularly useful in procedures conducted under monitored anesthesia care. However, in the context of posterior segment ophthalmic surgeries, there is still a lack of clarity regarding the most appropriate dosing strategy. Clinicians often face challenges in selecting between lower and higher doses while trying to achieve optimal sedation without increasing the risk of adverse effects such as bradycardia and hypotension. Although both 0.5 mcg/kg and 1 mcg/kg intravenous doses are commonly used in clinical practice, limited studies have compared their safety and effectiveness specifically in posterior segment surgeries. Recognizing this gap, the present study aims to evaluate and compare these two dosing regimens with a placebo, with the goal of identifying the most effective and safe approach for sedation in patients undergoing posterior segment ophthalmic procedures.

METHODOLOGY

A double-blind, hospital-based, block-randomized controlled trial was conducted by the Department of Anesthesiology at a tertiary care center between December 2020 and October 2022. The study included 75 adult patients undergoing posterior segment ophthalmic surgeries under local anesthesia. Participants were randomly allocated into three groups of 25 each: Group DL received dexmedetomidine 0.5 µg/kg, Group DH received dexmedetomidine 1 µg/kg, and Group C received a placebo (50 mL normal saline), all administered over 10 minutes.

Participants were selected using a convenient sampling technique, including all consecutive patients meeting the eligibility criteria until the sample size was reached. Inclusion criteria were age between 18 and 60 years, ASA physical status I to III, BMI ≤30 kg/m², and expected surgery duration of more than 30 minutes. Patients were excluded if they had difficulty communicating, allergies to study drugs, severe cardiac disease, chronic obstructive pulmonary disease (COPD), suspected liver or kidney dysfunction, or a history of sleep apnea.

Prior to surgery, detailed medical history, physical examination, and relevant investigations were performed, and ASA status was assessed. Written informed consent was obtained from each participant after explaining the procedure and the purpose of the study. Patients were instructed not to move their heads during surgery and to report any discomfort. Sedation was assessed using the Ramsay Sedation Score (RSS), and the total doses of midazolam (mg) required to achieve an RSS of 3 were recorded. The total dose of fentanyl (μg) used to manage intraoperative pain was also noted. Hemodynamic parameters including heart rate, mean arterial pressure, respiratory rate, and oxygen saturation were monitored. Postoperative recovery was evaluated based on the duration of stay in the Post-Anesthesia Care Unit (PACU) and discharge readiness assessed using the Modified Aldrete Score. Data collection was carried out using a multiparameter monitor and syringe pump for drug administration.

Statistical analysis:

Data were coded and analyzed using STATA version 10.1 (2011). Descriptive statistics were used to summarize the data, with mean and standard deviation applied for quantitative variables, and frequency and percentage for qualitative variables. Inferential statistics included tests of significance with a p-value threshold of <0.05 considered statistically significant. ANOVA was used to compare means across the three groups, while pairwise group comparisons were performed using the unpaired t-test with Games-Howell post hoc analysis. The Chi-square test was employed to analyze categorical (non-parametric) data.

Results:

Table-1: Baseline Characteristics of Participants in DH, DL, and Control Groups

Baseline Characteristics		DH (N=25)	DL (N=25)	C (N=25)	p-value
Mean age (years)		49.72 ± 8.06	50.92 ± 7.01	50.16 ± 8.10	0.858
Gender (%)	Female	11 (44%)	11 (44%)	9 (36%)	0.803
	Male	14 (56%)	14 (56%)	16 (64%)	
Mean BMI (Kg/Sq. m)		24.52 ± 3.42	25.28 ± 2.49	25.47 ± 2.46	0.46

The above table 1 showed that the baseline demographic and clinical characteristics of participants across three groups: DH, DL, and Control (C), each consisting of 25 individuals. The groups were comparable in terms of mean age, gender distribution, and body mass index (BMI), with no statistically significant differences observed (all p-values > 0.05). This indicated that the groups were well matched at the start of the study, reducing the risk of baseline bias.

Table-2: Intraoperative Characteristics of Participants in DH, DL, and Control Groups

Intraoperative Characteristics		DH (N=25)	DL (N=25)	C (N=25)	p-value
Mean duration of surgery (Min)		94 ± 15	92.8 ± 14	93.6 ± 13.50	0.955
ASA status	1	18 (72%)	18 (72%)	21 (84%)	0.518
	2	7 (28%)	7 (28%)	4 (16%)	

The above table 2 showed that the mean duration of surgery was similar across all groups, with no significant difference. Most patients were ASA I, and fewer were ASA II. There were no significant differences in ASA status or surgery duration among the DH, DL, and Control groups.

Table-3: Comparison of Mean Scores Across Time Intervals in DH, DL, and Control Groups

Intervals	DH (N=25)	DL (N=25)	C (N=25)	p-value
0 min	4.00 ± 0.00	4.00 ± 0.00	1.52 ± 0.77	< 0.0001
10 min	4.00 ± 0.00	4.00 ± 0.00	1.44 ± 0.65	< 0.0001
20 min	4.00 ± 0.00	4.00 ± 0.00	2.04 ± 0.45	< 0.0001
30 min	4.00 ± 0.00	3.96 ± 0.20	2.60 ± 0.50	< 0.0001
40 min	3.80 ± 0.41	3.80 ± 0.41	2.96 ± 0.20	< 0.0001
50 min	3.40 ± 0.50	3.40 ± 0.50	2.92 ± 0.28	< 0.0001
60 min	2.92 ± 0.28	3.00 ± 0.00	2.92 ± 0.28	0.357
70 min	2.91 ± 0.29	3.00 ± 0.00	2.45 ± 0.51	0.037
80 min	2.91 ± 0.29	2.96 ± 0.21	2.63 ± 0.49	0.048
90 min	2.76 ± 0.44	2.72 ± 0.46	2.39 ± 0.50	0.032
100 min	3.00 ± 0.00	3.00 ± 0.00	2.33 ± 0.49	< 0.0001
110 min	2.60 ± 0.55	2.80 ± 0.45	2.25 ± 0.50	0.028
120 min	3.00 ± 0.00	3.00 ± 0.00	2	NA

The above table 3 showed that the mean scores across different time intervals for the DH, DL, and Control groups. Both DH and DL groups consistently maintained higher scores compared to the Control group, especially during the initial 60 minutes, with statistically significant differences ($p < 0.0001$).

After 60 minutes, scores in all groups gradually declined, though DH and DL remained higher overall. From 70 minutes onward, some differences between groups remained statistically significant, indicating sustained effectiveness in the DH and DL groups compared to the Control.

Table-4: Incidence of Events Across Time Intervals in DH, DL, and Control Groups

Intervals	DH (N=25)	DL (N=25)	C (N=25)	p-value
0 min	0 (0%)	0 (0%)	0 (0%)	NA
10 min	0 (0%)	0 (0%)	0 (0%)	NA
20 min	0 (0%)	0 (0%)	0 (0%)	NA
30 min	0 (0%)	0 (0%)	0 (0%)	NA
40 min	0 (0%)	0 (0%)	0 (0%)	NA
50 min	0 (0%)	0 (0%)	0 (0%)	NA
60 min	0 (0%)	0 (0%)	4 (16%)	< 0.0001
70 min	0 (0%)	0 (0%)	10 (40%)	
80 min	0 (0%)	0 (0%)	6 (24%)	
90 min	5 (20%)	5 (20%)	5 (20%)	
100 min	0 (0%)	0 (0%)	3 (12%)	
110 min	2 (8%)	1 (4%)	3 (12%)	
120 min	0 (0%)	0 (0%)	0 (0%)	NA

The above table 4 showed that the incidence of events across time intervals in the DH, DL, and Control groups. No events were observed in any group up to 50 minutes. From 60 minutes onward, events appeared primarily in the Control group, with a significant difference noted at 60 minutes ($p < 0.0001$).

At 90 minutes, all groups reported equal incidence (20%). Sporadic occurrences were noted afterward in all groups, but the Control group consistently showed higher incidence earlier.

Table- 5: Comparison of Respiratory Parameters Across Groups at Different Time Intervals

Comparison of Respiratory Parameters	Intervals	DH (N=25)	DL (N=25)	C (N=25)	p-value
Respiratory rate	0 min	14.68 ± 0.75	14.68 ± 0.75	14.24 ± 1.39	0.213
	30 min	14.72 ± 0.98	14.96 ± 1.02	14.56 ± 0.82	0.759
	60 min	14	-	14	NA
Oxygen saturation	0 min	99.76 ± 0.44	99.76 ± 0.44	99.04 ± 2.28	0.106
	30 min	99.40 ± 0.71	99.20 ± 0.82	98.64 ± 2.71	0.26
	60 min	100	-	98	NA

The above **table 5** showed that compared respiratory parameters—respiratory rate and oxygen saturation—at different time intervals among the DH, DL, and Control groups. Respiratory rates remained stable and comparable across all groups, with no statistically significant differences at 0 and 30 minutes ($p = 0.213$ and 0.759, respectively). Similarly, oxygen saturation was consistently high across all groups, with no significant differences observed ($p > 0.05$). At 60 minutes, data were incomplete for the DL group, but the available values indicated stable respiratory function overall.

Table-6: Use and Dosage of Rescue Medications in DH, DL, and Control Groups

Use and Dosage of Rescue Medications	DH (N=25)	DL (N=25)	C (N=25)	p-value
Requiring rescue midazolam	8(32%)	11(44%)	25(100%)	< 0.0001
mean rescue midazolam dose	1± 0.40	1.18 ± 0.00	3.16 ± 0.19	< 0.0001
Requiring rescue fentanyl	10(40%)	11(44%)	20(80%)	0.007
Mean rescue fentanyl dose	1.1± 0.30	1.27 ± 0.40	3± 0.70	< 0.0001

The above table 6 showed that significantly more patients in the Control group required rescue midazolam and fentanyl compared to the DH and DL groups ($p < 0.0001$). The Control group also received higher mean doses of both drugs. These results indicated that the DH and DL groups had more effective baseline sedation and analgesia.

Table 7. Comparison of Intra-operative Ramsay Sedation Score

Intervals (min)	DH (N=25)	DL (N=25)	C (N=25)	p-value
0	4.00 ± 0.00	4.00 ± 0.00	1.52 ± 0.77	< 0.0001
10	4.00 ± 0.00	4.00 ± 0.00	1.44 ± 0.65	< 0.0001
20	4.00 ± 0.00	4.00 ± 0.00	2.04 ± 0.45	< 0.0001
30	4.00 ± 0.00	3.96 ± 0.20	2.60 ± 0.50	< 0.0001
40	3.80 ± 0.41	3.80 ± 0.41	2.96 ± 0.20	< 0.0001
50	3.40 ± 0.50	3.40 ± 0.50	2.92 ± 0.28	< 0.0001
60	2.92 ± 0.28	3.00 ± 0.00	2.92 ± 0.28	0.357
70	2.91 ± 0.29	3.00 ± 0.00	2.45 ± 0.51	0.037
80	2.91 ± 0.29	2.96 ± 0.21	2.63 ± 0.49	0.048
90	2.76 ± 0.44	2.72 ± 0.46	2.39 ± 0.50	0.032
100	3.00 ± 0.00	3.00 ± 0.00	2.33 ± 0.49	< 0.0001
110	2.60 ± 0.55	2.80 ± 0.45	2.25 ± 0.50	0.028
120	3.00 ± 0.00	3.00 ± 0.00	2.00	NA

Table 7 depict the comparison of intra-operative Ramsay sedation score of the groups. At all the time intervals, except 60 mins, the mean RSS differed significantly between the groups (all p-values <0.05). Post-hoc analysis revealed that the mean RSS was significantly less in the C group than both DH and DL groups. However, DH and DL groups did not differ significantly in mean RSS (all p-values > 0.05).

Table-8: Incidence of Adverse Events in DH, DL, and Control Groups

Incidence of Adverse Events	DH (N=25)	DL (N=25)	C (N=25)	p-value
Nausea	3 (12%)	5 (20%)	6 (24%)	0.541
Vomiting	2 (8%)	2 (8%)	4 (16%)	0.571
Bradycardia	4 (16%)	3 (12%)	0 (0%)	0.728
Tachycardia	0 (0%)	0 (0%)	2 (8%)	
Hypertension	0 (0%)	0 (0%)	1 (4%)	
Hypotension	4 (15%)	3 (12%)	1 (4%)	
RD	0 (0%)	0 (0%)	2 (8%)	

The above Table 8 showed that the incidence of adverse events in the DH, DL, and Control groups. Nausea, vomiting, and hypotension were the most commonly reported events, with slightly higher rates in the Control group. Bradycardia occurred only in the DH and DL groups, while tachycardia, hypertension, and respiratory depression (RD) were reported only in the Control group. No statistically significant differences were observed between the groups ($p > 0.05$).

DISCUSSION

In the present study, baseline demographic and clinical parameters, including mean age, gender distribution, and BMI, were comparable across the high-dose dexmedetomidine (DH), low-dose dexmedetomidine (DL), and control groups. No statistically significant differences were noted in age ($p = 0.858$), gender ($p = 0.803$), or BMI ($p = 0.46$), suggesting adequate baseline matching. These findings align with the study by **Rupwate KR et al. [7] (2020)**, where no significant differences were observed in demographic variables between the groups. Their mean age and weight values were closely matched, and both groups had identical gender distribution (60% males, 40% females; $p = 1.000$), supporting the reliability of randomization and group allocation in both studies.

Regarding intraoperative characteristics, the mean duration of surgery was similar across the DH (94 ± 15 min), DL (92.8 ± 14 min), and control (93.6 ± 13.5 min) groups ($p = 0.955$), comparable to the findings of **Rupwate KR et al.**,[7] (2020) who reported durations of 89.5 ± 13.35 min and 89.0 ± 16.21 min in Group D and Group M, respectively ($p = 0.896$). Additionally, ASA physical status was comparable across groups in our study ($p = 0.518$), in agreement with **Rupwate KR et al.,** who also found no significant difference in ASA classification between groups ($p = 0.717$). These consistencies reinforce the methodological soundness of the present trial [7].

In terms of sensory block quality and duration, our study found that both DH and DL groups consistently achieved higher sensory block scores compared to the control group, especially from 0 to 50 minutes, where both maintained a complete block (~score 4), with high statistical significance ($p < 0.0001$). These differences became less pronounced beyond 60 minutes. This superior and sustained block with dexmedetomidine is corroborated by **Pereira EM et al. [8] (2024)**, who also demonstrated that dexmedetomidine significantly prolonged sensory and motor block durations and delayed the time to first analgesic request when added to local anesthesia. These results support the efficacy of dexmedetomidine in enhancing regional anesthesia quality.

Respiratory parameters such as respiratory rate and oxygen saturation remained stable and comparable among DH, DL, and control groups at all measured intervals. No significant respiratory depression was observed. This aligns with the findings of **Muttu S et al.**,[9](2005) who reported stable respiratory and hemodynamic parameters with dexmedetomidine use. **Candiotti KA et al. [10] (2010)** also found no significant change in heart rate and mean arterial pressure, although they reported respiratory depression in both DEX groups ($p = 0.018$). Conversely, **Ramaswamy SS et al. [11] (2016)** observed a higher incidence of bradycardia and hypotension at a DEX loading dose of 0.5 µg/kg, indicating that dose adjustments may influence cardiovascular side effects. In our study, both high and low doses maintained stable hemodynamics, suggesting that the dosages used were within safe limits.

Intra-operative sedation, as measured by the Ramsay Sedation Score (RSS), was consistently higher in the DH and DL groups than in the control group. From 0 to 50 minutes, RSS in DH and DL remained around 4.0, indicating deep sedation with responsiveness, while the control group had significantly lower scores ($p < 0.0001$). Sedation scores tapered slightly from 60 to 120 minutes, but dexmedetomidine groups still maintained significantly higher sedation levels. These findings are consistent with **Pegu J et al. [12] (2021)**, who observed higher RSS in the dexmedetomidine group (mean 1.93 vs. 1.65 in the placebo group), suggesting better sedation and patient cooperation due to dexmedetomidine's central actions. **Gelil et al. [13] (2014)** also noted improved sedation when dexmedetomidine was used as an adjuvant, supporting our observations.

However, **Chawla B et al. [14] (2024)** raised concerns about dexmedetomidine-induced intraoperative floppy iris syndrome (IFIS) during cataract surgery, even at low doses (0.2 µg/kg infusion). Though our study did not assess IFIS specifically, this observation underscores the need for caution when using dexmedetomidine in ophthalmic procedures.

LIMITATION

- Bispectral index could have given more precise data for sedation but it could not be done due to cost constraints.
- Intraocular pressure was not measured at any point during this study.

CONCLUSION

We conclude that both doses of dexmedetomidine (0.5 µg/kg and 1 µg/kg) were effective in providing conscious sedation during posterior segment ophthalmic surgeries when compared to saline placebo. There was no statistically significant difference between the two doses in terms of mean blood pressure, pulse rate, or Ramsay Sedation Score, indicating similar efficacy. However, the incidence of side effects such as bradycardia and hypotension was slightly higher in the 1 µg/kg group (16%) compared to the 0.5 µg/kg group (12%), suggesting that the lower dose is associated with a better safety profile. Therefore, we recommend using a 0.5 µg/kg loading dose of dexmedetomidine for monitored anesthesia care in posterior segment ophthalmic procedures.

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