Original Article

A prospective randomized double-blinded study of dexmedetomidine versus propofol infusion for orbital surgeries

Bipasha Mukherjee, Varsha Backiavathy, R. Sujatha[1]

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Abstract:

PURPOSE: Orbital surgeries are traditionally taken up under general anesthesia. Local anesthesia combined with moderate sedation can also be considered as an alternative option. This study was performed to compare the safety and efficacy of dexmedetomidine and propofol infusion for orbital surgeries under local anesthesia.

METHODS: Twenty patients undergoing orbital surgery by a single surgeon were enrolled in this prospective randomized study. Selected patients were randomly administered dexmedetomidine (Group D) or propofol (Group P). Hemodynamic and respiratory effects, sedation levels, recovery profile, analgesic properties, and satisfaction levels of the patients and the surgeon were assessed.

RESULTS: There was a significant decrease in mean arterial pressures following drug administration compared to initial measurements in both the groups. However, a statistically significant decrease in heart rate was observed only in Group P. The sedation score at the end of loading dose was 3.3 ± 0.82 in Group D and 2.5 ± 0.52 in Group P and this difference was also statistically significant (*P* value-0.027). The surgeon's satisfaction score was 6.5 ± 0.71 in Group D and 5.6 ± 1.07 in Group P (*P* value – 0.045). There were no statistically significant differences observed in patients' satisfaction, pain, and anxiety scores in either group. No major hemodynamic changes or complications were noted in either of the groups.

CONCLUSION: Dexmedetomidine, in comparison to propofol, provides better sedation levels with good hemodynamic stability. It also offers better surgeon satisfaction, thus providing a useful alternative for general anesthesia in selective patients undergoing orbital surgery.

Keywords:

Dexmedetomidine, local anesthesia, orbital surgery, propofol, sedation

Introduction

As a rule, orbital surgeries are done under general anesthesia. However, many of these procedures can be performed under local anesthesia when combined with moderate sedation. The advantages are that it shortens the time duration spent inside the operation theater and in the hospital and it avoids the risks and other complications of general anesthesia. There are few reports of orbital surgeries being done under local anesthesia.[1]

Propofol and dexmedetomidine are two short-acting sedatives which are used for procedural sedation. In the field of ophthalmology, the use of dexmedetomidine and propofol is well-documented in cataract and vitreoretinal surgeries.[2-4] Propofol (2, 6-diisopropylphenol) has a dose-related sedative effect, a nondose-related anxiolytic effect, fast onset of action, and a quick recovery profile.[5] Dexmedetomidine (alpha-2 adrenergic agonist) has been used increasingly as a new armamentarium to provide sedative/hypnotic, anxiolytic, and sympatholytic effects. The added advantage of dexmedetomidine over propofol is that it has an analgesic effect and it causes sedation without any respiratory depression.[6,7] Comparative studies between propofol and dexmedetomidine in vitreoretinal surgery have shown dexmedetomidine to be a valuable adjuvant.[2] The authors concluded

Department and Institution, Orbit, Oculoplasty, Aesthetic and Reconstructive Services, [1]Department of Anesthesia, Sankara Nethralaya, Medical Research Foundation, Chennai

Address for correspondence:
Dr. Bipasha Mukherjee, Orbit, Oculoplasty, Aesthetic and Reconstructive Services, Sankara Nethralaya, Medical Research Foundation, 18, College Road, Chennai - 600 006, Tamil Nadu, India.
E-mail: drbpm@snmail.org

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that dexmedetomidine was associated with equivalent hemodynamic effects, adequate respiratory function, better analgesic properties, similar surgeon's satisfaction, and higher patient's satisfaction as compared to propofol at similar sedation levels.

Orbital surgeries are different from cataract and vitreoretinal surgeries, as the orbital tissues have dense vascular and nerve supply, and dissection of these tissues is more painful when compared to intraocular procedures. However, selective patients can undergo orbital surgeries under local anesthesia with sedation.[1]

Since there are no published studies, we compared the safety and efficacy of dexmedetomidine sedation with those of propofol in patients undergoing orbital surgery. The efficacy was evaluated by assessing the pain and anxiety felt during the surgery. Intraoperative and postoperative hemodynamic and respiratory stability evaluated the safety of the drug administered. The outcome measures include hemodynamic stability, respiratory effects, sedation levels, pain score, anxiety score, and satisfaction scores of the patient as well as the surgeon. This study is the first of its kind to assess the perception of pain during injection of local anesthesia in orbital surgeries.

Methods

This is a prospective, randomized, double-blinded study, the sample size being 10 cases in each group between the periods from May 2015 to December 2016. The sample size was calculated by considering the level of significance at 5% and the power of the test ($1 - \beta$) to 80%. With a medium effect size[4] and using the correlational formula, the minimum required sample size using G*Power 3 was calculated to be 10 for each group. Using a simple computer-generated random sampling technique, the patients were randomly assigned to either of the two groups [Flowchart 1]. The institutional review board and ethics committee approval was obtained. The tenets of the Declaration of Helsinki were followed.

Patients with American Society of Anesthesiologists physical status I and II and aged 25–75 years requiring external dacryocystorhinostomy and orbital interventions without bone removal were included in the study. All the patients underwent preanesthetic physical evaluation. Patient's anxiety level was measured by a blinded investigator using the Amsterdam Preoperative Anxiety and Information Scale (APAIS). The anxiety scale of APAIS consists of four items and each item is rated on a 5-point Likert scale, with the end poles being "not at all" (1) and "extremely" (5).[8] The answers were added up to form a total anxiety score for each patient. Anxiety was categorized as moderate when the total score ranged from 11 to 15 and severe when the total score ranged 16–20 [Table1].

Patients with a history of previous orbital surgery, uncontrolled diabetes or hypertension, severe cardiac disease, renal failure, hepatic disease, pregnancy, concurrent use of vasodilators/ negative ionotropes, and allergy to dexmedetomidine/propofol/ local anesthesia; those who are anxious (APAIS score >16); and those with a history of anxiety-related disorders were excluded from the study.

Selected patients were offered the option of undergoing surgery under local anesthesia and the choice to convert to general anesthesia in case of intraoperative difficulty or discomfort.

Informed consent was obtained from all patients who satisfied the inclusion criteria.

The outcome measures assessed were hemodynamic stability, respiratory effects, sedation levels at the end of loading dose, analgesia score (pain perceived during local infiltration and surgery), and anxiety score and satisfaction score of the patient, as well as the surgeon. The patients were clearly explained about visual analog scale (VAS) to evaluate the pain and anxiety perceived by them during the injection – 0 representing no pain and 10 representing the most severe pain [Figure 1].

Ten patients each were randomly assigned to either of the two groups Flowchart 1:

- Group D: Patients receiving dexmedetomidine infusion
- Group P: Patients receiving propofol infusion.

All patients were advised nil per oral for 6 h prior to surgery. Injection ondansetron 4 mg was given through intravenous (IV) route in the operation theater prior to the start of the infusion. Oxygen (4 L) was administered through a nasal cannula. IV propofol or dexmedetomidine was infused by a non-blinded anesthesiologist. Dexmedetomidine (Precedex, 200 μg/2 mL; Abbott, USA) was diluted with 0.9% normal saline to a concentration of 4 μg/mL in 50 ml syringe. Group D received 1 μg/kg of dexmedetomidine over 10 min as a loading dose using an infusion pump, followed by dexmedetomidine infusion 0.2–0.6 μg/kg/h. In Group P, a loading dose of propofol 0.5 mg/kg was infused over 10 min, followed by a maintenance dose of 0.5–2 mg/kg/h. Infusion doses of test drugs were titrated to have the patient sleeping without any airway obstruction. To maintain the uniformity of the technique, the regional block was administered and the surgery was performed by the same blinded orbital surgeon in all the patients.

The surgeon, the patient, and the person recording the hemodynamic data were masked to the composition of the anesthetic solution by a drape anchored over the infusion system. Since propofol has a distinctive milky opaque color, the arm with the infusion cannula was curtained off from the surgical field.

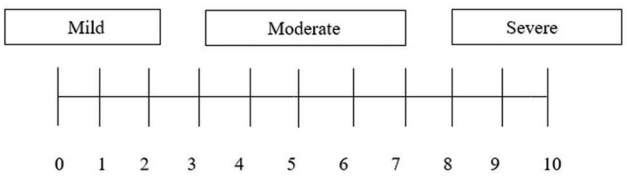


Figure 1: Visual Analog Scale (VAS)

The vital parameters were monitored continuously and the level of sedation (Ramsay Sedation Score[9]) was noted prior to the infusion [Table 2]. The level of sedation was assessed again 10 min following the infusion (i.e., end of loading dose). The local anesthetic injection was administered when the sedation level was at Ramsay sedation score 3. Appropriate deep regional nerve block and superficial block at the site of incision were administered. A mixture of 4 ml of 2% lignocaine with adrenaline (1:100,000) and 4 ml of 0.5% bupivacaine was used in all cases. Immediately after the injection, the VAS was shown to the subject to mark the pain perceived by them during the injection. Patients were encouraged to communicate with the surgeon regarding pain during the surgery and if required rescue analgesia with injection fentanyl 0.5 mg/kg was given and repeated after 30 min if VAS score was four or more.

Heart rate, respiratory rate, blood pressure, and partial pressure of oxygen saturation were monitored throughout the surgery. Any episode of bradycardia (heart rate <20% of baseline), hypotension (mean arterial pressures [MAP] <20% of baseline), postoperative nausea, and vomiting was noted. During the procedure, if the respiratory rate dropped below 10, SpO_2 <92%, heart rate <45, or MAP <50 mm/Hg, infusion dose was reduced. The infusion was stopped approximately 10 min before the end of surgery. Arousal time, quality of recovery, and adverse events were recorded.

All patients were observed in the postanesthetic care unit until the Aldrete was ≥9. After surgery, both surgeon and patient, blinded to the group, graded the level of satisfaction on a 7-point Likert–like verbal rating scale [Figure 2]. The patient's perception of pain and anxiety was again assessed using VAS.

At the end of the study, the data were subjected to statistical analysis using SPSS version 14.0 for Windows (BM SPSS Statistics 14.0, Chicago, Illinois, USA). Numerical variables are reported as means, standard deviation, and medians. A paired *t*-test was used to compare the mean difference between the pre- and postblood pressure and pulse rate in propofol and dexmedetomidine groups. Nonparametric tests were used since the sample size is small and violation of normality assumption. Mann–Whitney *U*-test was used to test the median difference between the propofol and dexmedetomidine groups. $P < 0.05$ is considered statistically significant.

Results

The demographic and clinical parameters were not significantly different between the two groups. In Group D, seven patients were male, the mean (standard deviation) age was 42 years. In Group P, six patients were male, mean age was 42 years. The mean surgical time was 45 min in Group D and 53.5 min in Group P. All surgeries were uneventful without any intraoperative complications [Table 3].

There was a statistically significant decrease in MAPs following drug administration compared to initial measurements in both the groups [Table 4]. However, there was a statistically significant decrease in heart rate only in Group P [Table 5].

The sedation score at the end of loading dose was 3.3 ± 0.82 in Group D and 2.5 ± 0.52 in Group P and this difference was statistically significant (*P* value-0.027). The intraoperative pain and anxiety scores were low in both the groups with no statistically significant difference between them [Table 6].

The surgeon's satisfaction score was 6.5 ± 0.71 in Group D and 5.6 ± 1.07 in Group P, the difference being again statistically significant (*P* value – 0.045). Rescue analgesia during the intraoperative period was administered in three patients in Group P and one patient in Group D. There were no statistically significant differences observed in patients' satisfaction and pain scores during local anesthesia [Table 6]. No untoward effects were noted in any of the groups.

Discussion

Conventionally, orbital surgeries are performed under general anesthesia, but the removal of well-defined anterior orbital tumors and external dacryocytorhinostomy can be performed under local anesthesia. Local anesthesia is always preferable to general anesthesia whenever possible, as it leads to a better safety profile and shorter hospital stay and incurs less expenditure. Propofol and dexmedetomidine are short-acting sedatives. When titrated to the desired effects by infusion, these prove superior to conventional sedation with intermittent bolus doses of benzodiazepines. Propofol has stood the test of time as an agent for sedation in the intensive care unit and for

1	2	3	4	5	6	7
Extremely dissatisfied	Dissatisfied	Somewhat dissatisfied	Undecided	Somewhat satisfied	Satisfied	Extremely satisfied

Figure 2: 7-point Likert–like verbal rating scale

Table 1: Amsterdam preoperative anxiety and information scale

1. I am worried about the anesthetic
2. The anesthetic is on mind continually
3. I am worried about the procedure
4. The procedure is on mind continually

The measure of agreement with these statements should be graded on a 5 point Likert scale from 1=not at all to 5=extremely. The score is the sum of all four questions

Table 2: Ramsay sedation score

Score	State
1	Awake, agitated, and restless patient
2	Cooperative, oriented, and calm patient
3	Patient responding to only commands
4	Patient sleeping and responding rapidly to glabellar tap
5	Patient sleeping and responding slowly to stimuli
6	Patient not responding to painful stimulus

Table 3: Demographic data, operative procedures, and operative time

	Dexmedetomidine group (n=10)	Propofol group (n=10)
Age (median)	42 (range: 20-62 years)	42 (range: 23-68 years)
Gender (male:female)	7:3	6:4
Operative procedure	External dacryocystorhinostomy: 5 Excisional orbital biopsy (dermoid): 1 Incisional biopsy (lacrimal gland mass): 1 Optic nerve sheath fenestration: 3	External dacryocystorhinostomy: 4 Evisceration + implant: 3 Orbital implant removal: 1 Incisional biopsy: 2 Sebaceous gland carcinoma: 1 Intraconal mass (lymphoma): 1
Operative time	45 min (range: 20-75 min)	53.5 min (range: 40-70 min)

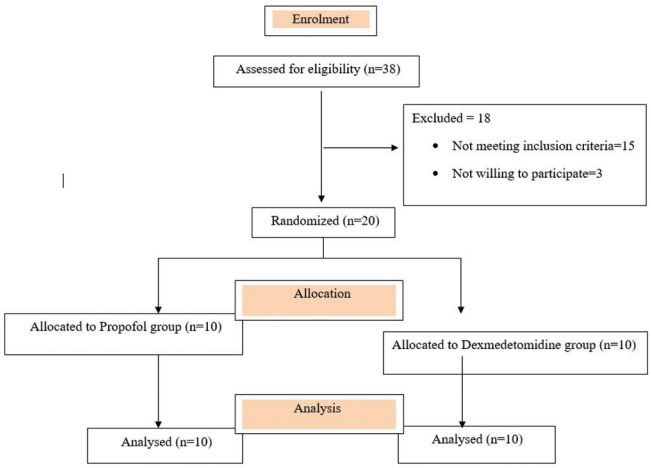
Table 4: Mean arterial pressures following drug administration

Mean arterial BP (mmHg)	Preloading dose	Postloading dose	*P*
Propofol	101.67±13.13	90.8±9.43	0.003
Dexmedetomidine	103.33±20.1	89.93±10.25	0.031

BP=Blood pressure

Table 5: Pulse rate following drug administration

Pulse rate (/min)	Preloading dose	Postloading dose	*P*
Propofol	90±16.14	81±13.51	0.018
Dexmedetomidine	79.9±14.67	75.44±14.21	0.205



Flowchart 1: Consort diagram

procedural sedation. It is known for its faster onset of action and quick recovery profile. Dexmedetomidine has been approved by the Food and Drug Administration for sedation during surgical procedures in 2008. This highly selective alpha-2 adrenergic receptor agonist provides sedation without respiratory depression along with conferring analgesia.[10] Dexmedetomidine has been safely used to sedate patients during various endoscopy procedures, awake craniotomy, awake carotid endarterectomy, and shockwave lithotripsy.[7,11] Superficial infiltration along with deep regional blocks of the zygomaticotemporal, zygomaticofacial, infraorbital, and supraorbital nerves provides adequate analgesia for anterior orbital surgeries and nasolacrimal procedures.[12]

This study was to compare the safety and efficacy of dexmedetomidine with propofol infusion for orbital surgeries done under local anesthesia. It revealed a statistically significant decrease in MAPs with the infusion of these drugs at the end of the loading dose in concordance with other studies [Table 4].[2,3,13] With respect to heart rate, a statistically significant decrease was noted only in Group P (P = 0.018).This could be attributed to the preoperative tachycardia noted in three patients in the propofol group which fell significantly after the titration of propofol. In our study, the dexmedetomidine group had statistically significant better sedation levels at the end of the loading dose. As respiratory depression is one of the dreaded complications of propofol, the loading dose of propofol in our study was kept less compared to most similar studies.[2] With the intraoperative infusion rate of both the drugs titrated to Ramsay sedation score 3, both the groups maintained adequate respiration and were hemodynamically stable throughout the surgery.

The intraoperative pain and anxiety scores were low in both the groups, with the patients in Group D having lesser scores (P = 0.395). Supplementary analgesia with IV fentanyl 30 µg was administered for three cases in Group P and one case in Group D, proving the additional analgesic effect of dexmedetomidine. However, there were no significant differences in the pain scores during the administration of local anesthesia between the groups.

Both the groups showed good surgeon and patient satisfaction scores [Table 6]. The surgeon satisfaction score was significantly better for Group D, probably because less number of patients in this group complained of pain and was more cooperative. Better surgeon satisfaction can also be attributed to the relatively bloodless field in the intraoperative period. The postoperative recovery was also smooth. Similar studies with propofol and dexmedetomidine for vitreoretinal and cataract surgeries found no difference in the patient and surgeon satisfaction scores between the two drugs.[2,3] Propofol is slightly cheaper than dexmedetomidine by around INR 780 (12 USD). However, dexmedetomidine has the edge over propofol with a better safety profile, additional analgesic effect, and better surgeon satisfaction. The smaller sample size is the only drawback of this study.

Table 6: Sedation scores, pain scores during the local administration and operative period, and satisfaction scores of the surgeon and patient

	Propofol	Dexmed	*P*
Sedation score after loading dose	2.5±0.53	3.3±0.82	0.027
Time to achieve Ramsay sedation score 3 after loading dose	9.6±5.76 min	10.3±4.16 min	0.672
Pain score during LA	2.6±2.01	3±1.32	0.395
Pain score during surgery	2.9±2.88	1.7±1.49	0.411
Anxiety score	1.9±2.42	1.3±1.06	0.969
Rescue analgesia	3 patients	1 patient	
Surgeon satisfaction score	5.6±1.07	6.5±0.71	0.045
Patient satisfaction score	5.8±1.55	6.4±0.7	0.416

LA=Local anesthesia

Conclusion

Dexmedetomidine, with good hemodynamic stability and reliability in achieving the required level of sedation, is somewhat better than propofol as it has additional analgesic property. Local anesthesia with dexmedetomidine infusion should be considered an acceptable alternative for general anesthesia to orbital surgery in selected patients.

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Conflicts of interest

There are no conflicts of interest.

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