# A Comparative Evaluation of Dexmedetomidine versus Midazolam-fentanyl for Sedation in Vitreoretinal Surgery under Peribulbar Anaesthesia

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Abstract: <u>Introduction</u>: Midazolam-fentanyl(MDZ:FEN) combination is frequently used for intravenous sedation in ophthalmic surgeries in adults. Dexmedetomidine (DEX), is also indicated for procedural sedation. However, it may cause deeper sedation and patient non-coperation at recommended doses. <u>Aims and objectives</u>: To evaluate the efficacy and safety of low dose of i.v. dexmedetomidine (DEX) (0.25 microgm/kg) versus i.v midazolam-fentanyl (MDZ:FEN) (0.5mg/25microgm) for vitreoretinal surgeries under peribular anesthesia in adults. <u>Materials and methods</u>: In a randomized, double-blind, interventional study, 60 patients(30 each group) aged 20-60 years, scheduled for vitreoretinal surgery under peribulbar block were divided equally to receive either iv MDZ:FEN(0.5mg/25microgm) or iv DEX(0.25 microgm/kg) dose over 10 mins. The vital parameters, ramsay sedation score(RSS), surgeon satisfaction score & effect on respiration were noted. <u>Results</u>: The 'DEX' group patients had stable haemodynamics, level 3 sedation and surgeon satisfaction score of 2–3 (good to excellent operating conditions) with no respiratory depression. The sedation score(RSS) of 3 was achieved at approx 5.3 minutes in MDZ:FEN group as compared to 11.5 minutes in DEX group(p< 0.001). The intraoperative mean blood pressure was significant higher in MDZ:FEN group at 30 to 75 minutes (p<0.001). The post-operative nausea/vomiting was seen in 20 percent patients in MDZ:FEN group(p<0.023) and none in low dose DEX group which was statistically significant. <u>Conclusion</u>: Low dose inj. DEX (0.25microgm/kg) is an effective alternative to inj MDZ:FEN(0.5mg/25microgm) and provides better (level 3)sedation score and stable haemodynamics, surgeon satisfaction and no post-operative nausea/vomitting. Hence both drugs are efficacious but low dose DEX is better than MDZ: FEN in the study.

Keywords: vitreoretinal, ophthalmic, dexmedetomidine, peribulbar-block, monitored anaesthesia care (MAC)

### 1. Introduction

The **procedural sedation** is "a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardio-respiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently."

Vitreoretinal surgery is an ophthalmic surgery which is commonly done under peribulbar anaesthesia seldomly supplemented with intravenous (IV) sedation<sup>[1]</sup>. In peribulbar block, the local anesthetic is deposited above and below the orbit outside the muscle cone in the orbicularis oculi muscle. It blocks cranial nerves III, IV, and VI along with the ciliary nerves and the ciliary ganglion. It doesn't block the optic nerve.

The commonly used drugs for sedation include benzodiazepines (most commonly midazolam) with an opioid (commonly fentanyl), with or without propofol. The midazolam causes faster onset of sedation, less pain on injection, amnesia and improved awakening. The common adverse effects of midazolam include prolonged recovery after long term or highdose use, hypoxaemia, hypotension and respiratory depression when paired with an opioid.

Fentanyl is a synthetic opioid drug. It is used in combination with anesthesia to prevent pain during or postoperative period. It has a quick onset with shorter duration of action. It has very less cardiovascular depressive effects and hypotension rarely with the doses routinely used. It binds with opioid receptors in the CNS and increases the pain threshold, inhibits the ascending pain pathways and thus change the pain reception. In addition to the analgesia, it also suppresses the cough reflex and cause respiratory depression, drowsiness, sedation and post operative nausea and vomiting.

Dexmedetomidine (DEX) is an alpha2-adrenergic receptor agonist. It provides, analgesia, sedation, anxiolysis, hypnosis and sympatholysis<sup>[2],[3],[4]</sup>. It provides minimal respiratory depression. The patients respond and follow verbal commands but fall asleep when not stimulated<sup>[10].</sup> It also act as analgesic like ketamine, but not up to the same degree.<sup>[5]</sup> The cardiovascular effects are minimal like mild bradycardia and a decrease in systemic vascular resistance. It is approximately 1600 times more selective for the alpha2 receptors as compared to alpha1 receptors and therefore has minimal side effects. It is a sedative – hypnotic, anxiolytic and sympatholytic that can attenuate the stress response to surgery (mitigating tachycardia, hypertension) and also decrease intraocular pressure (IOP) during ophthalmic surgery under local anaesthesia.<sup>[6],[7],[8]</sup> It is recommended at an initial loading dose of 1µg/kg slowly over 10 min, followed by maintenance infusion of  $0.2-0.7 \mu g/kg/h$ .

In our randomized, double-blind, prospective, interventional study, we compared the efficacy of low dose dexmedetomidine  $(0.25\mu g/kg)$  with midazolam-fentanyl (MDZ:FEN) in terms of patient comfort and haemodynamic response in vitreoretinal surgery under peribulbar block<sup>[1]</sup>

### 2. Materials and Methods

Patients undergoing vitreoretinal surgery under peribulbar anaesthesia by the department of Anaesthesiology in

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Ophthalmology Operation Theatre, S.M.S. Medical College and Attached Group of Hospitals, Jaipur. The permission was taken from Institutional Ethics committee vide letter no 119/MC/EC/2018, concerned Head of the Department of ophthalmology, Clinical trials registry-India (C.T.R.I./2019/ 11/021892) & informed consent was obtained from the patient and relatives after complete explanation about the study protocol and procedure to the patients.

Sample size was calculated to be a minimum of 23 subjects in each of the two groups at alpha error 0.05 and study power 90% to detect expected difference of 10 beats per minute in mean heart rate at 30 minutes between two groups and SD of 10 beats per minute. Hence for study purpose sample size was increased and rounded off to 30 subjects in each group. This sample size was also adequate to cover all other study variables.

Sixty eligible cases were randomly allocated in two study groups A and B. In this study the randomization was done by sealed envelope method. A total of 60 envelope (30 per group) were made, each envelope mentioning a particular study group. One of my colleagues was asked to pick up an envelope from the box. Patient was allocated to the group mentioned on the envelope. Study drug was prepared by my colleage and was administered blindly by me to the patient.

The anesthetist who gave anesthesia was different from the anesthetist who observed the study variables. Patients were told that an anesthetic agent was given to them but details were not given.

**Study groups**: The study was conducted in following two group of patients. Each group consisted of 30 patients(n= 30 per group).

<u>Group</u> <u>A</u>: Dexemedetomidine (DEX)group patients received  $0.25\mu$ g/kg body weight of dexmedetomidine over 10 minutes.

**<u>Group B</u>**: Midazolam:Fentanyl (MDZ:FEN) group patients received iv. midazolam 0.5mg with fentanyl 25µg over 10 minutes.

Both the above preparation were made to a volume of 20 ml with saline. Peribulbar block with 8 ml of local anaesthetic comprising 3 ml of 0.5% bupivacaine, 5 ml of 2% lignocaine and hyaluronidase was given after 10 min of starting test drugs and surgery was started after achieving adequate block. The vital parameters like HR, SBP and DBP, RR, SpO2 were noted every 5 min for the first 15 min (5, 10, 15), every 15 min until the end of surgery and every 30 min for 4 h in the post-operative ward ,while level of sedation (RSS: 1–6) was noted just before the start and at the end of surgery and for 4h in the post operative period. Inj. Diclofenac aqua i.v. 1 ml was given as rescue analgesia.

The selected patients were of age 20-60 years, weight 40-80 kg, patients of both gender- male & female, ASA grade 1 and 2, undergoing vitreoretinal surgeries with duration upto 1-2 hrs and anxious patients who were not permitting surgery under peribulbar block.

The, patient not willing to give consent, mentally sick patient, patients with baseline heart rate (HR) <60/min, patients with history of allergy or hypersensitivity to any drug and patient already on analgesics, transquillizers, phenothiazine, CNS depressant drugs or sedative drugs were excluded from the study.

After completion of surgery, surgeon satisfaction score was assessed by asking set number of questions about:

- a) Patient co-operation(score 1),
- b) Deeper level of sedation (score 1),
- c) Any patient movement during the surgery (score 1).

The total score generated will be grades as:-Excellent (score 3), Good(2), Fair(1), Poor(0)

The poor operating conditions included deeper level of sedation (RSS 4), snoring, sudden involuntary movement of the head, respiratory depression causing raised IOP which may make the surgery difficult.

Anaesthetist Satisfaction Score: Depending on various parameters like the patient heart rate, blood pressure, respiratory rate, SPO<sub>2</sub>, Ramsay sedation score, Pain on visual analogue scale (VAS) and side effects of the drug used, the anaesthetic satisfaction score will be calculated. Each of the parameter will be given a weightage score of one. If any deviation out of the targeted range happen then the parameter will be awarded zero.

Ramsay sedation score of Level 3 sedation was targeted in the intraoperative period. Vital parameters HR, SBP and DBP, RR, SpO2 were noted every 5 min for the first 15 min (5, 10, 15), every 15 min until the end of surgery and every 30 min for 4 h in the post-operative ward while level of sedation (RSS: 1-6) was noted just before the start and at the end of surgery and for 4h in the post operative. Bradycardia was defined as fall in heart rate below 60 beats per minute and was treated with incremental doses of atropine 0.4 to 0.6 mg i.v. Other adverse effects(if any) just after iv drug or in peri-operative period were noted and treated accordingly. Hypotension was defined as fall in mean arterial pressure greater than 20% from the baseline value and was treated by incremental doses of i.v..mephentermine.

The Software used for statistical analysis was Epi info version 7.2.1.0. Nominal/categorical variables were summarized as frequency and percentage and were analyzed using Chi square test/Fischer's Exact test as applicable. Continuous variables were summarized as mean and standard deviation and were analyzed using student t test and ordinal variables like anaesthetist satisfaction score and surgeon satisfaction score were analyzed using Mann Whitney test. A p value < 0.05 was taken as statistically significant.

# 3. Results

The demographic data of the two groups in terms of age, height, weight and gender were comparably the same. The haemodynamics, respiratory status and sedation score(intra-

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operative) and surgeon satisfaction score of the two groups were comparably the same.

The 'DEX' group patients had lower intra-operative diastolic blood pressure at 30 minutes to 75 minutes (p<0.001) and lower mean blood pressure as compared to MDZ: FEN group from 30 to 75 minutes(p<0.004). However, due to low dose of DEX used, no active intervention was required. The MDZ:FEN group had slightly lower heart rate during intra-operative period but it was statistically not significant.

Post-operatively heart rate was significantly lower in MDZ: FEN group at 60 minutes to 240 minutes(P<0.05) as compared to DEX group. The diastolic blood pressure was higher in MDZ:FEN group as compared to DEX group at 0, 30, 60 min in the post-operative period which was significant (p<0.05).

The sedation score (RSS) of 3 was achieved at approx 5.3 minutes in MDZ:FEN group as compared to 11.5 minutes in DEX group(p< 0.001).The anaesthetist satisfaction score was comparatively slightly better in DEX group but it was not statistically significant (p= 0.268). The poor operating conditions was not reported in either of the two groups.

The post-operative nausea/vomiting<sup>2</sup> was seen in 20 percent patients in MDZ:FEN group and none in low dose DEX group which was statistically significant(p=0.024).

 Table 1: Comparison of mean Duration of Surgery (min) of

study groups						
Groups	N	Mean	Std. Deviation			
Group A	30	74.8	16.9			
Group B	30	72	10.7			





Figure 1: Comparison of mean Duration of Surgery (min) of study groups

Above table 1 and fig. 1 reveals the mean duration of surgery among study groups. The mean duration of surgery in subjects of group A (74.8 min) was higher than the subjects of group B which had 72 min of mean duration of surgery. This difference in mean duration of surgery analysed using t-test among the two study groups was not statistically significant. (p=0.441).

 Table 2: Comparison of Intra op Heart rate (bpm) among

 study groups

study groups						
Time	Group A	Group B	P value			
0 min	$77.8 \pm 7.3$	$76.4 \pm 6$	0.432			
5 min	$73.9 \pm 7.3$	$71.8 \pm 5.7$	0.212			
10 min	$71 \pm 8.2$	$68.6\ \pm 5.6$	0.196			
15 min	$69.2 \pm 7.3$	$68.8 \pm 5.5$	0.780			
30 min	$67.1 \pm 6.2$	64.7 ± 5	0.105			
45 min	$68.8 \pm 6.3$	$66.6 \pm 5.5$	0.164			
60 min	69.8 ± 5.9	66.8 ± 5.1	0.051			
75 min	70.1 ± 6.1	68.5 ± 6.1	0.432			



Figure 2: Comparison of Intra op Heart rate among study groups

Above table 2 and fig. 2 shows the trend of intra op Heart rate among study groups analysed using t-test which was not significant(p>0.05).



Figure 3: Comparison of Intra op SBP among study groups

Above table 3 shows the intraoperative trend of systolic blood pressure (SBP).



Figure 4: Comparison of Intra op DBP among study groups

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Above fig. 4 shows the trend of intraoperative diastolic blood pressure (DBP)

 
 Table 5: Comparison of Intra op MAP (mmHg) among study groups

	,		
Time	Group A	Group B	P value
0 min	$99.3 \pm 8.2$	$99.4 \pm 7.1$	0.973
5 min	$95.6\pm7.7$	$94.5\pm6.9$	0.561
10 min	$92.3\pm8.3$	$91.4\pm6.8$	0.648
15 min	$90.4 \pm 8.3$	$90.9\pm7$	0.828
30 min	$86.6 \pm 7.3$	$94.1 \pm 6.7$	<0.001 (S)
45 min	$88.4\pm7.2$	$94.6\pm6.8$	0.001 (S)
60 min	$89.4\pm7$	$94.9\pm7.4$	0.005 (S)
75 min	89.2 ± 8.2	$96.8 \pm 7$	0.004 (S)



Figure 5: Comparison of Intra op MAP among study groups

Above table 5 and fig. 5 shows the trend of Mean arterial pressure among study groups and analysed using t-test which was significant from 30 to 75 minutes.

 Table 6: Comparison of Intra op Sedation Score among

 study groups

study groups						
Time	Group A	Group B	P value			
0 min	$1 \pm 0$	$1 \pm 0$	-			
5 min	$2 \pm 0.2$	3 ± 0	<0.001 (S)			
10 min	$2.9\ \pm 0.4$	3 ± 0	0.321			
At start of Sx	$3 \pm 0$	$3 \pm 0$	-			
End of Sx	$3 \pm 0$	$3 \pm 0$	-			



Figure 6: Comparison of Intra op Sedation Score among study groups

Above table 6 and fig. 6 shows the comparison of intra op sedation score among study groups analysed using Mann whitney test which was significant difference at 5 minutes (p < 0.001).

 Table 7: Comparison of mean highest level of sedation

 score of study groups

secre of study groups						
Groups	N	Mean	Std. Deviation			
Group A	30	3	0			
Group B	30	3	0			



Figure 7: Mean Highest Sedation score (RSS)

Above table 7 and fig. 7 shows the mean highest level of sedation score achieved which was similar in both the study groups.

 Table 8: Comparison of mean Time to achieve highest level

 of sedation (min)

Groups	Ν	Mean	Std. Deviation
Group A	30	11.5	2.2
Group B	30	5.3	0.5
		0.0	1 0.001

t-test = 15.334; at 58 degree of freedom; p < 0.001 (S)



Figure 8: Comparison of mean Time to achieve Highest level of sedation (mins)

Above table 8 and fig. 8 shows the mean time to achieve highest level of sedation among study groups analysed using t-test which was significant ( p < 0.001).

 Table 9: Comparison of mean depth of sedation(RSS)

among study groups						
Groups	Std. Deviation					
Group A	30	3	0			
Group B	30	3	0			



Figure 9: Comparison of mean depth of sedation among study groups

Above table 9 and fig. 9 shows comparison of mean depth of sedation among study groups analysed using t-test. The

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mean depth of sedation was RSS score 3 in both the groups. The highest level of sedation achieved was 3 and no patient experienced excessive sedation score.

 Table 10: Comparison of mean duration of sedation (min)

	among study groups					
	Groups	Ν	Mean	Std. Deviation		
	Group A	30	117	5.3		
	Group B	30	114.7	2.9		
_	2.056 at 59 degree of freedoms $n = 0.011(0)$					

t test = 2.056; at 58 degree of freedom; p = 0.044 (S)

Above table 10 shows comparison of mean duration of sedation(RSS 3) in min among study groups which was analysed using t-test which was significant (p value 0.044).

 Table 11: Comparison of mean Duration of analgesia (min)

 among study groups

	Groups	Ν	Mean	Std. Deviation		
	Group A	30	152.1	4.9		
	Group B	30	148.1	2.5		
t tes	t test = $3.938$ ; at 58 degree of freedom; p < $0.001$ (S)					

Above table 11 and shows comparison of mean duration of analgesia (min) among study group which was analysed

using t-test which was significant.

 Table 12: Frequency of side effects among study groups

Side affects	Group A		Group B		D voluo
Side effects	Ν	%	Ν	%	r value
Nausea / vomiting	0	0	6	20	0.024 (S)
Bradycardia	0	0	0	0	-
hypotension	0	0	0	0	-

Above table 12 shows shows comparison of frequency of side effects among study groups which was analysed using Fischer exact test. The side effects like nausea/vomiting was not seen in dexmedetomidine group while it was seen among six patients in midazolam-fentanyl group in the post-operative period (p value 0.024) which was significant.The bradycardia requiring any active intervention was not reported in any of the two study groups.The significant hypotension requiring any intervention was not seen in any of the above two study group.

# 4. Discussion

The present study was conducted in the department of Anaesthesiology, SMS Medical College and attached group of hospitals, Jaipur with due permission from the Ethics Committee , the research review board and Clinical Trials Registry-India (C.T.R.I.). Sixty patients of either sex belonging to age group of 20-60 years, weighing 40-80 kg with ASA grade 1 and 2 were scheduled to undergo vitreoretinal surgery under peribulbar block under sedation was given either dexmedetomidine (n=30) or midazolamfentanyl (n=30).

The present study was done to compare dexmedetomidine and midazolam-fentanyl with intra-operative haemodynamic changes, respiratory rate, oxygen saturation, ramsay sedation score, surgeon satisfaction score, anaesthetist satisfaction score and any undesirable side effects in vitreoretinal surgeries under peribulbar block. During vitreoretinal ocular surgeries in adults, moderate sedation is a useful adjunct to the local anaesthetic (peribulbar ) block as it improves the patient comfort, removes anxiety and provides stable haemodynamics during the intra-operative period .The low dose DEX intravenously can be a preferred mode of sedation for better control of intra-operative hypertension. The over sedated patients may stop obeying verbal commands, and thus non-cooperation during the surgery results in poor surgeon satisfaction score. The over sedation can also cause hypoventilation, hypercapnia and airway obstruction, restlessness and unexpected or unwanted movements during the intraoperative period. So, the judicious titrated dosage of the study drug helped us in achieving the targeted sedation and patient co-operation.

**In our study**, there was no difference in the mean age, height, weight, sex and ASA grade 1 & 2 in both the groups. Both groups were comparable without any statistical significance. In our study, the use of low dose DEX achieved better control of intra-operative hypertension. Though the intra op heart rate was lower in MDZ:FEN group as compared to DEX group but there was no statistical difference seen. In our study, the lower mean blood pressure was observed in DEX group as compared to MDZ:FEN group from 30 to 75 minutes (p<0.004).

**Ramaswamy(2016)**<sup>[1]</sup> **et al** also observed similar low mean intra-operative blood pressure in DEX group as compared to MDZ:FEN group from 30 to 150 minutes.(p<0.001).

**In our study** we required only one time loading dose to get RSS 3 and excellent surgeon satisfaction score (as we didn't arouse the patient repeatedly who was sedated).Though **Ramaswamy et al** observed similar RSS score of 3 but they aroused the patient intra-operatively to measure the RSS, as a result, the requirement for the drug was slightly more as compared to our study. The surgeon satisfaction score of 3 was seen in both the study groups in our study which is similar to the study conducted by **Ramaswamy et al**.

The low dose DEX group achieved and maintained target level of sedation easily. It corresponds with study of **Candiotti KA(2010)**<sup>[9]</sup> **et al.** They used dex 1 microgm/kg (group A), dex 0.5 microgm/kg(group B) and placebo saline (group C) in three sub-group of patients in the study.The dexmedetomidine group reqired less opioids and maintained target level of sedation(RSS 4) easily without any significant drop in heart rate, oxygen saturation.In our study we targeted level 3 sedation according to RSS score and hence our requirement for the drug was still less of just 0.25 microgm/kg of dexmedetomidine. The target sedation of RSS 3 was achieved easily in our study since we used lower dose of DEX as compared to study conducted by Candiotti et al.

**AM abdelhamid**(**2016**)<sup>[16]</sup> **et al** conducted a study by comparing iv dexmedetomidine with dexmedetomidine as adjuvant to peribulbar block in cataract surgery and concluded that IV dexmedetomidine in cataract surgery produces intra-operative sedation with hemodynamic stability with minimal side effects. Our study concludes similar results and no episode of bradycardia or hypotension

was seen due to one time low dose DEX (0.25 microgm/kg) used in our study.

The MDZ:FEN group had slightly longer duration of level 2 sedation as compared to DEX group in the postoperative period which didn't require any active intervention. The surgeon satisfaction was equally comparable .With low dose of study drugs, the anaesthetist satisfaction score was slightly better in DEX group as compared to MDZ:FEN though it was not statistically significant. Our study is in line with study conducted by **Ramaswamy(2016)<sup>1</sup> et al.** 

The study conducted by **Sethi**  $P(2014)^{[13]}$  et al for comparing dexmedetomidine versus midazolam for conscious sedation in endoscopic retrograde cholangiopancreatography concluded the superiority of dexmedetomidine over midazolam in conscious sedation and our study also observes superior alternative to midazolamfentanyl combination which is in favour with our study.

**P. Gupta** (2014)<sup>[12]</sup> **et al** in a study conducted on Dexmedetomidine ameliorates monitored anaesthesia care concluded that the requirement of additional analgesic is not there when iv dexmedetomidine is given in monitored anaesthesia care. The midazolam needs to be given with opioids like fentanyl and side effect of opioids like nausea and vomiting are present. We used low dose dexmedetomidine (0.25microgm/kg) which was sufficient to achieve target level of sedation and patient comfort with no side effects. This is in line with our study.

The dexmedetomidine is a superior alternative to midazolam and when a study conducted on guided BIS score (target > 85) by **Apan A** (2009)<sup>[17]</sup> et al , the dexmedetomidine (0.25microgm/kg/hr) slightly decreased the heart rate more as compared to midazolam (25microgm/kg/hr) infusion though it was not statistically significant, which correlates with our study.

In a study conducted by **Alhashemi JA** (2006)<sup>[18]</sup> et al on outpatient cataract surgery, a loading dose of 1 microgm/kg followed by 0.1 to 0.7 microgm/kg of dexmedetomidine was used which caused more hypotension and more suppression of heart rate, delayed recovery and deeper sedation(RSS>4) making dexmedetomidine an unsuitable drug for cataract surgery patients under peribulbar block and this study is in contradiction to our study that's why we used low dose DEX and concluded our low dose was superior to midazolamfentanyl combination. The low dose DEX given over 10 minutes was well tolerated by the patient haemodynamically and had excellent surgeon satisfaction score. It was a good alternative over midazolam-fentanyl combinations and we succeeded in stable haemodynamics.

The dexmedetomidine has an alpha agonist property so it doesn't required any additional analgesic drug like opioids in our study that we use with midazolam. This correlated with the study conducted by **Mansour**  $A(2012)^{[11]}$  et al for use of dexmedetomidine as analgesic in painful posterior segment surgery.

In a study conducted by **Ko K-H** (2015)<sup>[15]</sup> et alon effective dose of dexmedetomidine for adequate sedation in elderly

patients under spinal anaesthesia, was determined out of the five groups using loading dose of 0.1, 0.3, 0.5, 0.7 and 1.0  $\mu$ g/kg, respectively. The ED<sub>50</sub> and ED<sub>95</sub> of dexmedetomidine for adequate sedation were 0.29  $\mu$ g/kg and 0.86  $\mu$ g/kg. The target level of sedation was  $RSS \ge 3$ . The dose greater than 0.5 µg/kg resulted in haemodynamic instability. This is in line with our study where we used the dose of 0.25  $\mu$ g/kg and our target sedation score was RSS 3. We didn't over sedate the patient which would otherwise decrease the surgeon satisfaction score due to patient non co-operation. Also we didn't arouse the patient in between to measure RSS and hence our requirement for the drug was less than the study conducted by Ko K-H (2015)<sup>[15]</sup> et al. The slight over sedation of patient may cause involuntary movements which is not accepted in delicate vitreoretinal surgery. We used the lowest possible dose and the patient co-operation was maintained with low side effects and haemodynamic stability.

In our study, the post-operative nausea/vomiting was seen in 20 percent patients (p 0.024) in MDZ:FEN group and none in low dose DEX group which was statistically significant. The PONV may cause high intra ocular pressure which may be detrimental in ophthalmic surgery. It corresponds to the study conducted by **Ramaswamy**<sup>[1]</sup> et al. The study conducted by **Liang X(2015)**<sup>[14]</sup> et al also showed that dexmedetomidine is efficient in controlling post operative nausea and vomiting (PONV).

### 5. Summary

The study was conducted in Department of Anesthesiology; S.M.S. Medical College, Jaipur. **The heart rate** decreased in both the groups intra-operatively. There was no statistical difference in heart rate during intraoperative period. **The systolic blood pressure** decreased more in DEX group as compared to midaz-fentanyl(MDZ:FEN) group though it was not statistically significant. **The surgeon satisfaction score** of excellent (3) was obtained in both the groups. **The anaesthetist satisfaction score** was comparable in both the study groups. **The RSS score** of 3 was maintained in both the groups and our requirement for the drug was lower as we didn't arouse the patient to measure RSS intra-operatively.

The diastolic blood pressure was significantly lower in DEX group as compared to midaz-fentanyl group from 30 to 75 minutes during the intra-operative period. The mean blood pressure was significantly lower in DEX group as compared to midaz-fentanyl group from 30 to 75 minutes during the intra-operative period. The Ramsay sedation score of 3 was achieved at 11.5 minutes in DEX group as compared to 5.3 minutes in midazolam-fentanyl group. The post op diastolic bp was less in DEX group as compared to MDZ:FEN group at 0, 30 and 60 minutes which was significant however, no active intervention was required to treat hypotension due to low dose DEX used in our study. The post-operative nausea and vomitting was seen in 20% of the patients in midazolam-fentanyl group due to opioids. None of the patient in DEX group reported to have nausea or vomiting. Thus we conclude that DEX is an effective alternative to MDZ:FEN for conscious sedation in vitreoretinal surgery along with peribulbar block.

#### 6. Conclusion

The low dose DEX (0.25 µg/kg) used in our study is an effective alternative to MDZ:FEN (0.5mg/25 µg) in combination with the peribulbar block, and provided better sedation score (level 3), stable haemodynamics and excellant surgeon and anaesthetist .Because of the low dose used, we did not experienced bradycardia, hypotension in any of our patients in the study group. DEX was not associated with post-operative nausea and vomiting as with the use of MDZ:FEN and no respiratory depression was noticed in the intra and post-operative period. The patients felt well and there was neither snoring due to deep sleep nor the patient was uncooperative due to anxiety to interfere with the surgery. The satisfaction score of surgeon was excellent with the low dose. There was no significant change in haemodynamics. Hence in my opinion though both the drugs are efficacious but DEX is better than MDZ:FEN.

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