

A Comparative Evaluation of Dexmedetomidine versus Midazolam-Fentanyl for Sedation in Ocular Surgeries under Peribulbar Anaesthesia in Children

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Abstract: Introduction: The general anaesthesia has been routinely used for children in ocular surgery. Midazolam-fentanyl (MDZ: FEN) combination is frequently used for intravenous sedation in ophthalmic surgeries in adults and adolescents. Dexmedetomidine (DEX), an α_2 adrenoreceptor agonist is also indicated for procedural sedation for ophthalmic use at a loading dose of 0.5 microgm/kg over 10 min. However, it may cause deeper plane of sedation and thus surgeon dissatisfaction due to patient non-cooperation. Aims and objectives: We proposed to evaluate the efficacy and safety of low dose of dexmedetomidine (0.25 microgm/kg) versus midazolam-fentanyl (0.5mg/25microgm) for ocular surgeries under peribulbar anaesthesia in children evaluate. Materials and methods: In a randomized, double-blind, prospective, interventional study, 60 patients (30 each group) aged 10-15 years, scheduled for any ocular surgery under peribulbar block were divided equally to receive either MDZ: FEN (0.5mg/25 microgm) or DEX (0.25 microgm/kg) dose over 10 mins. The vital parameters, effect on respiration, Ramsay sedation score were assessed at regular intervals and surgeon satisfaction score noted at end of the surgery. Results: 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 incidence of nausea and vomiting was lower in DEX group as compared to MDZ: FEN group. Conclusion: Low dose DEX (0.25 microgm/kg) over 10 min is an effective alternative to MDZ: FEN (0.5mg/25 microgm) and provides better (level 3) sedation score and stable haemodynamics, more surgeon satisfaction and no associated post-operative nausea and vomiting as with the use of opioids. All patients were devoid of all known risk and complications associated with general anaesthesia.

Keywords: paediatric eye surgery, ophthalmic, dexmedetomidine, peribulbar-block in children, 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."

The ocular surgery in children is frequently performed under general anaesthesia which has many risk and complications associated with it. The laryngeal spasm, deep anaesthesia, hypotension, tachyarrhythmia, hypoxia etc. to name a few apart from the risk associated with the metabolism of the different anaesthesia drugs and inhalational agents. The current drugs which are commonly used for intravenous sedation under peribulbar block are midazolam with an opioid like fentanyl which can be used in conjunction with or without propofol.

The adverse effect of midazolam with fentanyl is prolonged recovery time, hypoxaemia and respiratory depression. They also have side effects like unpredictable attenuation of stress response to surgery like tachycardia, hypertension and post operative nausea & vomiting.

The α_2 adrenoreceptor agonist, dexmedetomidine provides "conscious sedation" and adequate analgesia with minimum respiratory depression. It is a sedative, hypnotic,

sympatholytic, anxiolytic. It can mitigate stress response to surgery and also decrease intraocular pressure during ocular surgery under peribulbar anaesthesia.^[1]

It is a primary sedative drug and recommended to be used in intensive care and procedural sedation^[2]. It has been recommended at an optional loading dose of 1 microgm/kg dose over 10 minutes followed by maintenance infusion of 0.2-0.7 microgm/kg/h.^{[3][4][5]}

The aim of this study was to compare the efficacy of DEX versus MDZ: FEN group in ocular surgery under peribulbar block in children.

2. Materials and Methods

After the approval of our Institutional ethics committee, a prospective study comprising of 60 paediatric patients (30 each group) in the age range of 10-15 years and American Society of Anaesthesiologist physical (status 1-2) posted for any ocular surgery under local anaesthesia and IV sedation was initiated. The written and informed consent was taken from the patients and guardians. The patients were randomly allocated in one of the two groups during the study period 2019-20.

The patients with baseline heart rate less than 60, systolic blood pressure less than 90mm Hg, any left ventricular dysfunction, valvular heart lesion, any arrhythmias or mental retardation, renal or hepatic impairment were excluded from

the study.

The pre-anaesthetic evaluation and fasting of 5 hrs was assured. The pre-operatively vital parameters like heart rate, respiratory rate, systolic blood pressure, diastolic blood pressure, peripheral oxygen saturation and conscious level were noted before administration of the drug. The intraoperative monitoring included electrocardiogram, non-invasive blood pressure, SpO₂, respiratory rate, and Ramsay sedation scale.

MDZ-FEN group patients received IV midazolam (0.5mg) with fentanyl 25 microgm/kg over 10 minutes. 'DEX' group patients received DEX 0.25 microgm/kg IV over 10 minutes through syringe infusion pump. All preparations were made to a volume of 20 ml with saline. The chit in the box method was followed for randomization. The drug combinations were prepared by an anaesthesiologist not involved in monitoring and follow up.

The peribulbar block was given after 10 minutes of starting IV sedation (on completion of loading dose). It was given with about 5 to 8ml of local anaesthetic comprising of 2% lignocaine, 0.5% bupivacaine and hyaluronidase. The surgery was started after achieving adequate block. The vital parameters like HR, SBP, DBP, RR, SpO₂ and level of sedation (RSS: 1-6) were noted every 5 minutes for the first 15 minutes, every 15 minutes until the surgery ends and every 30 minutes for 4 hour in the post operative period. The level 3 sedation was targeted in the intraoperative period.

The adverse effects like hypotension, bradycardia, respiratory depression, level 4 sedation were noted at regular intervals and treated. After completion of surgery, surgeon satisfaction score was assessed and noted as – Excellent (score 3), Good (2), Fair (1) and Poor (0). The poor operating conditions for the surgeon were snoring, sudden involuntary movement of head, deeper sedation (RSS 4), respiratory depression causing increased IOP. The nausea and vomiting in the postoperative period was treated with IV ondansetron. The post operative pain was treated with IV diclofenac 75mg. The patients were discharged when the criteria for discharge was satisfied.

The sample size of 30 in each group was sufficient to highlight the significant effect on the outcome of study and its an ongoing study in our college. The categorical/nominal data was expressed as number and percentage was analysed using Chi square test. Quantitative data was expressed as mean and standard deviation and was analysed using t-test. Ordinal data was expressed as median and range and was analysed using Mann Whitney test. All statistical analysis was done with appropriate statistical software. P value less than 0.05 was taken as statistically significant.

3. Results

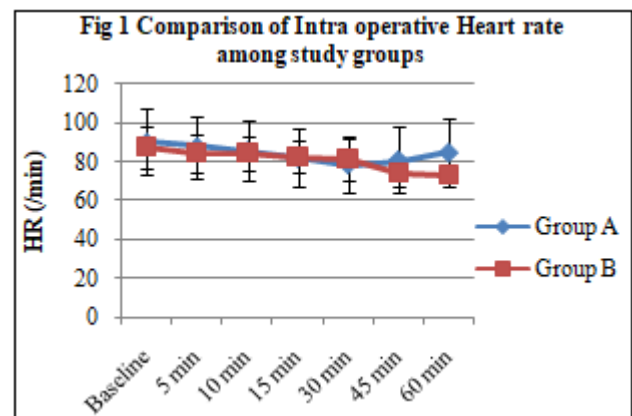
The demographic data of the two groups were comparable. The DEX group patients had lower DBP than MDZ: FEN group at various minute intervals 30, 45, 60. The poor operating conditions were not reported in either of the two groups. The MDZ: FEN group had significantly higher incidence of nausea (P= 0.001) and vomiting (P= 0.002) as

compared to DEX group which had nil post operative nausea and vomiting.

Table 1: Comparison of Intra operative Heart rate among study groups

Time	Group A	Group B	P value
Baseline	90.1 ± 16.9	87.4 ± 11.3	0.548
5 min	87.8 ± 16.0	84.5 ± 10.1	0.440
10 min	85.7 ± 15.4	84.5 ± 8.8	0.764
15 min	82 ± 15	82.5 ± 8.1	0.897
30 min	78.5 ± 14.4	81.3 ± 10.4	0.478
45 min	80.9 ± 16.9	74.3 ± 6.5	0.209
60 min	84.8 ± 17.6	73.3 ± 4.3	0.109

Above table 1 shows the trend of intra op Heart rate among study groups analysed using t-test which was not significant (p>0.05).

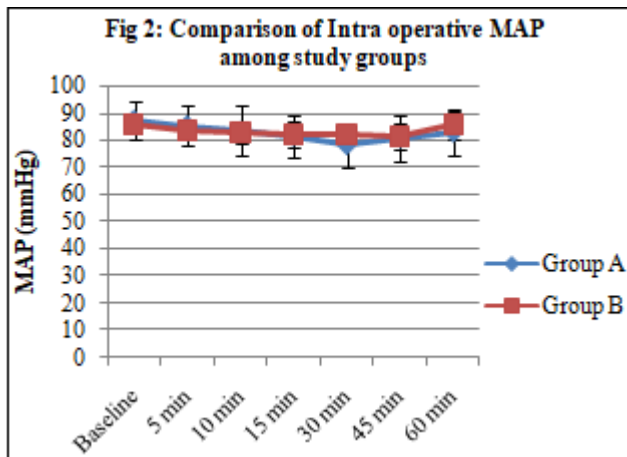


Above fig. 1 shows the trend of intra op Heart rate among study groups analysed using t-test which was not significant (p>0.05).

Table 2: Comparison of Intra operative MAP among study groups

Time	Group A	Group B	P value
Baseline	87.4 ± 7	85.8 ± 3.6	0.417
5 min	85.4 ± 7.6	83.8 ± 3.8	0.419
10 min	83.4 ± 9.1	82.7 ± 4.2	0.772
15 min	81.4 ± 8.1	82.2 ± 4.5	0.718
30 min	78.2 ± 8.2	82.2 ± 3.2	0.052
45 min	80.7 ± 8.4	81.5 ± 4.6	0.743
60 min	82.9 ± 8.5	85.7 ± 5.1	0.445

Above table 2 shows the trend of Mean arterial pressure among study groups and analysed using t-test which was not significant.

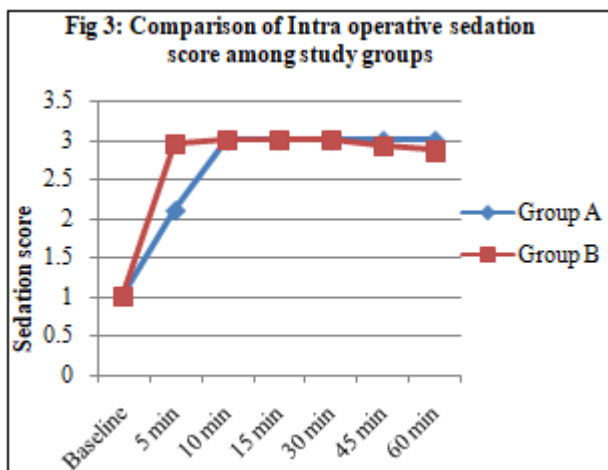


Above fig. 2 shows the trend of Mean arterial pressure among study groups and analysed using t-test which was not significant.

Table 3: Comparison of Intra operative sedation score among study groups

Time	Group A	Group B	P value
Baseline	1 ± 0	1 ± 0	-
5 min	2.10 ± 0.31	2.95 ± 0.22	<0.001
10 min	3 ± 0	3 ± 0	-
15 min	3 ± 0	3 ± 0	-
30 min	3 ± 0	3 ± 0	-
45 min	3 ± 0	2.92 ± 0.28	0.291
60 min	3 ± 0	2.86 ± 0.38	0.220

Above table 3 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).



Above fig. 3 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 5: Frequency of postoperative complications among study groups

Side effect	Group A	Group B	P value
Nausea / vomiting	0	3 (15%)	0.236

Above table 5 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

3 patients in midazolam-fentanyl group in the post-operative period.

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. Sixty paediatric patients of either sex belonging to age group of 10-15 years, weighing 20-50 kg with ASA grade 1 and 2 were scheduled to undergo any ocular surgery under peribulbar block under sedation was given either dexmedetomidine (n=30) or midazolam-fentanyl (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, and any undesirable side effects in ocular surgeries under peribulbar block.

In ocular surgeries in children in the age group of 10 to 15 years, 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 intraoperative period^{[10][11]}, thus, removing the need of general anaesthesia in children in the target age group. The low dose DEX intravenously can be a preferred mode of sedation for better control of intra-operative haemodynamics^[12] as compared to routinely used midazolam-fentanyl combination.

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.

Haemodynamics:

In our study, the use of low dose DEX achieved better control of intra-operative haemodynamics as compared to MDZ: FEN group. The intra operative 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 60 minutes which was significant (p<0.004). **Ramaswamy (2016)^[1] 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). The alpha₂ adrenoreceptor agonist attenuates the sympathetic response and thus gives better haemodynamic control^{[6][7][8]}. The magnitude of decrease in heart rate and blood pressure is proportional to the dose of dexmedetomidine and in our study, the low dose did not require any active intervention. The MDZ: FEN group also had comparable results and we were able to avoid the need of general anaesthesia in both the study groups. **In our study** the respiratory rate was slightly lower in MDZ: FEN group but the intervention was not required due to low dose of midazolam and fentanyl used in our study. The incidence of respiratory depression was almost nil in DEX group. In a study conducted by **Ko K-H (2015)^[15] et al** 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

µg/kg, respectively. The ED₅₀ and ED₉₅ of dexmedetomidine for adequate sedation were 0.29 µg/kg and 0.86 µg/kg. The target level of sedation was RSS ≥ 3. The dose greater than 0.5 µg/kg resulted in haemodynamic instability. This is in line with our study where we already used the lowest possible dose of the study groups.

Sedation:

In our study we used the low dose of 0.25 µg/kg and our target sedation score was RSS 3. We didn't over sedate the patient and neither arouse the patient in between to measure RSS and hence our requirement for the drug was less than required in the study conducted by **Ko K-H (2015)**^[15] **et al.** The slight over sedation of patient may cause an involuntary movement which is not accepted in delicate ocular surgery. We used the lowest possible dose and the patient co-operation was maintained with least side effects and better haemodynamic stability. The children who are over sedated may stop obeying verbal commands and cause communication break. The over sedation may also cause hypoventilation, hypercapnia, restlessness, airway obstruction and unwanted movements during the intraoperative period. So, the judicious titrated dosage of the study drugs helped us in achieving the targeted sedation and patient co-operation.

The low dose DEX group achieved and maintained target level of sedation easily in study conducted by **Candiotti KA (2010)**^[9] **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 required 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 lower target sedation of RSS 3 was achieved easily in our study as compared to study conducted by Candiotti et al since we didn't arouse the patient in between to assess the RSS score.

AM abdelhamid (2016)^[16] **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 onetime low dose DEX (0.25 microgm/kg) used in our study.

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 midazolam-fentanyl combination which is in favour with our study.

P. Gupta (2014)^[12] **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)**^[17] **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)**^[18] **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 midazolam-fentanyl 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.

Surgeon satisfaction score:

In our study, the patient co-operation was maintained throughout the surgery. 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.**

Post-operative Adverse effects:

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**^[11] **et al.** The study conducted by **Liang X (2015)**^[14] **et al** also showed that dexmedetomidine is efficient in controlling post operative nausea and vomiting (PONV). The MDZ: FEN group patients had higher incidence of nausea and vomiting in the post operative period causing increased intraocular pressure which is not good in ocular surgeries. The DEX is also helpful in the prevention of nausea and vomiting due to direct antiemetic property of alpha₂ adrenoceptor agonist^[9]. The results are similar to the study conducted by **Ramaswamy et al.**

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 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 60 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 60 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-operative nausea and vomiting** 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 excellent surgeon satisfaction score. 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 our opinion though both the drugs are efficacious but DEX is better than MDZ: FEN.

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