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Comparison of dexmedetomidine & midazolam as intramuscular sedation in cataract surgeries under peribulbar block

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Abstract

Background: Cataract has been documented to be the most significant cause of blindness, vision less than 20/200 in better eye on presentation is defined as blindness (1). Cataract surgery is mostly performed under regional anaesthesia with monitored anaesthesia care and sedation (2). Although akinesia and analgesia can be achieved with a regional block, appropriate sedation may lower anxiety of patient, reduce pain on injection during procedure of block, maintain hemodynamic stability, lower intraocular pressure and improve patient comfort (3,4).

Aim: To compare Dexmedetomidine and Midazolam as intramuscular sedation in cataract surgeries under peribulbar block

Objective: To study & compare the effects of intramuscular Dexmedetomidine and Midazolam with respect to-i) Degree of sedation ii) Degree of analgesia iii) Effect on blood pressure, heart rate, respiratory function iv) Effects on intraocular pressure v) Side Effects if any-hypotension, bradycardia, respiratory depression

Method: 120 patients aged 18-80 years, ASA grade 1, 2 undergoing elective cataract surgeries were selected randomly into three group-

Group D—l Received intramuscular Inj. Dexmedetomidine 1 µg/kg,

Group M— Received intramuscular Inj. Midazolam 20 µg/kg

Group C— Control group. Received intramuscular Inj. Normal saline 1.5 ml

The drug was injected into gluteus muscle 45 min before peribulbar block.

Results: Sedation & analgesia in dexmedetomidine group was comparable with midazolam. Mean arterial pressure (MAP), Heart rate (HR) & discomfort were non

significantly lower in Group D compared with Group M. But IOP was significantly decreased by dexmedetomidine.

Conclusions: Intramuscular dexmedetomidine (1μg/kg) given 45 minutes before peribulbar block provided better sedation and more reduction in intraocular pressure as compared to intramuscular midazolam (20μg/kg), and both drugs were without serious cardiovascular and respiratory side effects.

Keywords: Intramuscular Dexmetedomidine, midazolam, cataract surgery, peribulbar block

Introduction

Cataract is the most significant cause of preventable blindness & surgery is the mainstay of treatment of cataract (1). Anesthesia for cataract surgery today aims at creating a comfortable environment for the patient and the surgeon during surgery and a quick recovery of function without inherent added risks.

Anaesthesia for ophthalmic surgical procedures should provide an immobile, clear operative field, low-to-normal intraocular pressure, cardiovascular stability and good co-operation between the patient and the surgeon (3). Although, akinesia and analgesia can be achieved with regional block, appropriate premedication may improve the operative condition by reducing the intraocular pressure, attenuating the hypertensive response produced by anxiety or injection of local anaesthetic for institution of block and provide patient comfort (4).

Midazolam has been a popular drug for sedation (5). The alpha 2 agonist dexmedetomidine has generated an interest again in the anesthesiology due to its property of providing conscious sedation, analgesia and cardiac stability (6,7). Hence this study was planned to compare dexmedetomidine and midazolam as intramuscular sedation in patients undergoing cataract surgery under peribulbar blockade.

Methods

After approval of college ethics committee and informed written consent,120 adult patients of both sex enrolled in this study. Sample size was calculated by using EPI info software. Minimum sample size was calculated 40 in each group. We included ASA grade I & II patients whose ages were between 18-80 years posted for elective surgeries and willing to participate. Patients having pregnancy, advanced liver/ kidney disease, pseudophakia in other eye, Glaucoma, H/o allergy to any medication, patient on beta blocker and patient not willing to participate in study were excluded.

Intervention Allocation

The Patients were Randomised into Three Groups of 40 Patients each using Minitab software

Group D: Patients in this group received intramuscular inj. Dexmedetomidine 1μg/kg, volume was made up to 1.5 ml by dilution with normal saline.

Group M: Patients in this group received intramuscular inj. Midazolam 20μg/kg, volume was made up to 1.5 ml by dilution with normal saline.

Group C: Patients in this Control group received intramuscular Normal saline 1.5 ml.

The study was prepared by an anesthesiologist who did not participate in collection data and anaesthetist giving drug & conducting cases as well as anesthesiologist caring for the patient in post-anaesthesia care unit were blinded to the drug given.

After securing Intravenous line with 20 G cannula, baseline heart rate, blood pressure (systolic, diastolic and mean), respiratory rate& $ETCO_2$ and intraocular pressure were recorded. Intraocular pressure was measured in the non-operative eye by Schiotz Tonometer. Then the study

drug was injected into gluteus muscle. Vitals were recorded at 15, 30 and 45 min after that.

In operation theatre Peribulbar block was given by ophthalmologist with 5 ml of 2% lignocaine with adrenaline (1:200000) + 5 ml of 0.5 % bupivacaine and hyluronidase (1500IU). Surgery was done by qualified ophthalmologist with at least 3 years of experience. Oxygen at 2 L/min was supplemented under drapes. Post block, patient was monitored every 5 minutes till the end of surgery for heart rate, blood pressure, respiratory rate, $ETCO_2$ and sedation score. On an average all surgeries were completed within 30 - 35 minutes.

Postoperatively patients were monitored in post anesthesia care unit (PACU) for same vitals along with pain score, sedation score at 15 & 30 minutes in PACU. Patient was assessed for recovery score at 30 min. & discharged if recovery score > 8. Patients were asked whether they had any discomfort intraoperatively. Postoperatively after 6 hours, patient was again assessed for vitals in their respective ward.

All adverse events including but not limited to bradycardia (Heart rate < 45 bpm), hypotension (Drop of 20% in baseline mean arterial pressure), respiratory depression (Respiratory rate < 8 breaths/min, oxygen saturation < 94% and $ETCO_2$> 45 mmHg) were recorded.

Intraoperatively, drugs inj. Atropine 0.6mg IV for bradycardia, inj. Mephenteramine 3 mg increments for hypotension and Inj. Fentanyl 10 µg top ups for additional analgesia were given if required (VAS>4). If respiratory rate < 8, then it was planned to stimulate the patient to arouse him.

Statistical Analysis

After resolution of all issues, the database was analyzed by SPSS 17.0 version and Graph Pad Prism 5.0. Statistical analysis was done by using descriptive and inferential statistics using one way Anova test, student t test, z test, multiple comparison Tukey test.

Results

In general, dexmedetomidine was well tolerated and no serious side effects were observed in the present study. The groups did not differ significantly with regard to age, sex, ASA classification and vital parameters.

Table 1: Patient Demographic & Baseline Characteristics.

Age (Yrs.)	**Normal Saline**	**Dexmedetomidine**	**Midazolam**	**p-Value**
	64.75(6.24) [53-78]	64.55(6.13) [52-76]	64.25(7.29) [51-78]	0.943 NS, p>0.05
Gender(M/F)	25/15	26/14	24/16	0.89 NS, p>0.05
Grades				
ASA				
I	24(60%)	24(60%)	25(62.5%)	0.88
0032 II	16(40%)	16(40%)	15(37.5%)	NS, p>0.05
Values				
Premedication Values				
HR (beat/min)	69.40(11.97)	76.05(13.31)	73.87(11)	0.058 S, p>0.05
MAP (mmHg)	87.43(8.36)	92.04(11.42)	88.32(9.66)	0.091 NS, p>0.05
ETCO2(hmm Hg)	34.87(2.20)	33.80(2.57)	33.57(2.79)	0.064 NS, p>0.05
RR (breaths/min)	13.82(1.53)	14.10(2.10)	14.67(2.31)	0.082 NS, p>0.05
IOP (mmHg)	13.73(2.49)	15.17(1.88)	13.89(2.33)	0.009 S, p<0.05

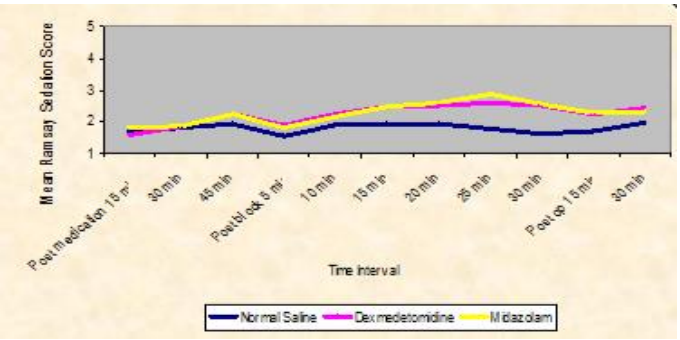
Sedation, Discomfort and Analgesia

Dexmedetomidine and midazolam both provide more sedation when compared with control group. But there was no significant difference in ram say sedation score between dexmedetomidine and midazolam group. The maximum Ramsay sedation score in dexmedetomidine group is 3 and in midazolam group is 4. Ramsay sedation score of 4 indicates oversedation.

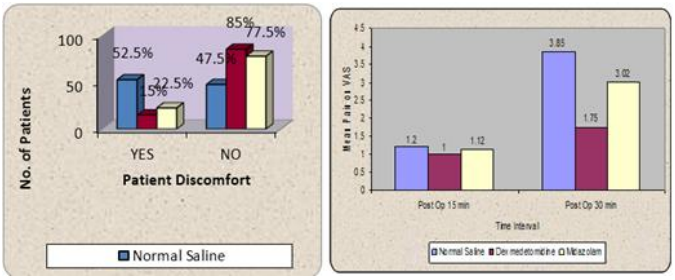
Also when comparing discomfort to patient between groups during perioperative period, it was found that there was no difference between dexmedetomidine and midazolam.

We compared the pain perception postoperatively by visual analogue score (VAS). Postoperatively after 15 min, there were no statistically significant differences among the groups. But after 30 min, mean VAS in midazolam group is 3.02 and in dexmedetomidine group is 1.75. This difference is statistically significant ($p<0.05$).

Graph 1: Showing Ramsay Sedation Scores between Three Group.



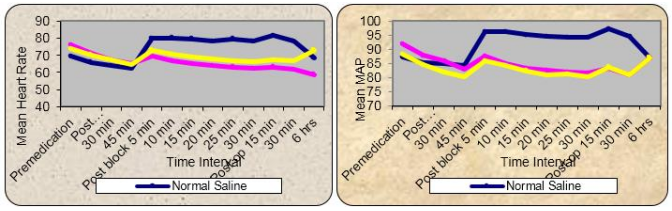
Graph 2: Showing Comparison of Patient´s Discomfort & VAS.



Heart Rate and Blood Pressure

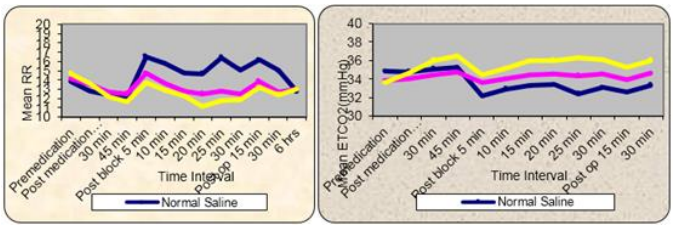
Dexmedetomidine induced a moderate decrease in heart rate and blood pressure. But In pairwise comparison with midazolam, the difference was not statistically different ($p>0.05$) during whole perioperative period. In comparison to placebo group by ANOVA test with dexmedetomidine & midazolam, the differences were statistically significant ($p<0.05$). One patient in dexmedetomidine group received atropine because of bradycardia (heart rate<45beats/min)

Graph 3: Showing Comparison of HR & MAP between three Groups.



Respiratory rate, End tidal carbon dioxide and peripheral saturation- When compared during perioperative period, shows statistically no significant difference among dexmedetomidine and midazolam group, There was no case of respiratory depression and desaturation**.**

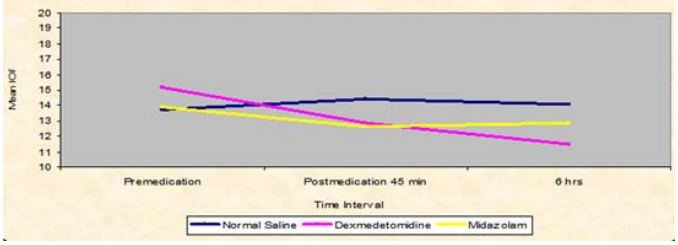
Graph 4: Showing Comparison of Respiratory rates & ETCO2 between Three Group.



Intraocular Pressure (IOP)

Dexmedetomidine cause significant fall in intraocular pressure when compared with midazolam. Dexmedetomidine cause maximum of 23% fall in IOP whereas midazolam cause only 9% fall from baseline IOP.

Graph 5



Aldrete Score

Recovery of patients was compared by Aldrete score. And we found no statistically significant difference among three groups.

Discussion

In accordance with studies conducted by Virk Kila (16) and colleagues, J. A. AL Hashem we also found that dexmedetomidine and midazolam were effective in providing adequate intraoperative sedation, But group dexmetedonine patients were more satisfied with their sedation than those in group midazolam. 4 patients in midazolam group were over sedated and responded with brisk response to the stimuli which might endanger surgical condition. 0n the other hand, although some patients in dexmedetomidine group fell asleep during operation, they were cooperative and surgical conditions were not endangered. This suggests that alpha 2 agonists may have a distinct sedative effect compared with other sedative premedicant like benzodiazepine. Our view is that after dexmedetomidine even heavily sedated patients are easily arousable and cooperative.

Any discomfort experienced by patient was sought by asking the question, “Did you have any discomfort during surgery?” at the time of discharge from PACU. We found that discomfort experienced by patients in group dexmedetomidine was not statistically different from group midazolam. This is in accordance with study of W Lio, G Ma, QG Suet al. [23] who evaluated the efficacy & patient tolerance of dexmedetomidine compared with midazolam for sedation in patients undergoing flexible bronchoscopy.

The analgesic effects of dexmedetomidine are complex. Locus ceruleus is the site of origin of descending medullospinal noradrenergic pathway, known to be important modulator of nociceptive neurotransmission. Stimulation of α_2 adrenoceptor in this area terminates pain signals leading to analgesia. Also, the alpha2-adrenoceptors located at the nerve endings have a possible role in the analgesic mechanisms of alpha2-agonists by preventing NE release. [14]

Due to these analgesic properties, VAS in patients of dexmedetomidine group was significantly lower than midazolam group, This difference in VAS mainly observed 30 min, postoperatively. Ayoglu et al. [4] demonstrated dexmedetomidine decreases pain caused due to needle prick while giving peribulbar block. This may be due to the analgesic property of dexmedetomidine. M. Erzurum’s, B.

Aydin, B. Ustaet al. [6] in their study of Patient comfort & surgeon satisfaction during cataract surgery using topical anaesthesia with or without dexmedetomidine sedation, stated that dexmedetomidine has analgesic property along with sedation also. Ashraf Ghali, Abdul Kader, Mahfouz et al. [21] observed that patients receiving dexmedetomidine during vitroretinal surgery have lower VAS scores for pain.

In our study though there was no significant differences in heart rate and mean arterial blood pressure between patients of both groups but the lower values were observed in dexmedetomidine group. This can be explained by decreased sympathetic outflow and circulating levels of catecholamines.

Similar hemodynamic changes have been observed by J.A. AL Hashemi [17]. He concluded that patients in

dexmedetomidine group had lower heart rate & MAP than patients in midazolam group ($p < 0.05$) undergoing cataract surgery. C. W. Cheung, C.L.A. Ying, W.K. Chiu et al. [18] also found similar results. He compared dexmedetomidine and midazolam for intravenous sedation during third molar surgery and found that heart rate & MAP were lower in dexmedetomidine group.

After the intramuscular administration of the drugs, at 15, 30, 45 mins, there was a decreasing trend in respiratory rate and an increasing trend in $ETCO_2$ as compared to the baseline values, but the difference was statistically insignificant among groups. Respiratory rate increased significantly after institution of peribulbar block in all groups. This increased respiratory rate at 5 min post block could due to pain while instilling peribulbar block. When the respiratory rates at 5, 10, 15, 20, 25 and 30 mins were compared with the respiratory rate at 45 mins after medication (just before peribulbar block), it was seen that the difference in group D became statistically non-significant ($p=0.45$) at 15 min; in group M the difference became statistically non-significant at 20 min. This means that the respiratory rate in group D settled earlier. The $ETCO_2$ increased after the intramuscular administration of the drugs and the difference in increase of the values of $ETCO_2$ became significant between groups D and M at 30 mins after administration of drug, the difference continued to be significant at 45 mins with the higher values seen in group M. After the peribulbar block at 5 mins, the $ETCO_2$ decreased in all groups corresponding to the increase in respiratory rate seen in the groups. When the $ETCO_2$ at 5, 10, 15, 20, 25 and 30 mins were compared with the $ETCO_2$ at 45 mins after medication (just before peribulbar block), it was seen that the difference in group D became statistically non-significant ($p=0.45$) at 20 min; in group M the difference became statistically non-significant at 25 min; while it continued to be significantly decreased in the control group (corresponding to the increased respiratory rate) till the end of surgery. Between the study groups, the patients receiving dexmedetomidine showed higher respiratory rates and lower $ETCO_2$ than the patients receiving midazolam. Also the increase in respiratory rates and corresponding fall in $ETCO_2$ post block approached pre block values earlier in group D as compared to group M.

The respiratory rates in any patient did not fall below 10 breaths/minute and the $ETCO_2$ did not increase beyond 39 mm Hg. None of the patients had to be aroused in order to stimulate his/her respiration. Low flow oxygen supplementation has been recommended for all the patients undergoing ophthalmic surgery under local anaesthesia [27]. Our patients received 2l/min oxygen via nasal cannula, none of the patients showed a decline in SpO_2 values. Keith A. Candiotti, Sergio D. Bergese, Paula M. Bokeschet al. [7] concluded in his study of monitored anaesthesia care with dexmedetomidine that at the doses studied (0.5 and 1 microgram/kg) as bolus followed by infusion of 0.2 to 1 microgm/kg/hour, patients receiving dexmedetomidine had a lower incidence of clinically relevant respiratory depression than placebo group who received midazolam 0.5mg bolus for sedation and 25 µg fentanyl for pain as rescue medication. Ashraf Ghali, Abdul Kader, Mahfouz et al. [21] compared dexmedetomidine and propofol in patients undergoing vitroretinal surgery & Ashraf Darwish, Rehab Sami, Mona Raafat et al. [22] compared dexmedetomidine and propofol in patients undergoing anterior ophthalmic surgery& both stated that respiratory rate values of dexmedetomidine were higher than propofol whereas CO_2 expired was similar in both

groups. These results are in accordance with our study results.

We used Aldrete score to quantify recovery score for discharge. We assessed patients postoperatively at 30 min in PACU & discharged patients if Aldrete score was >8. We found all patients all study groups were fit to be discharged at 30 minutes. There is statistically non-significant difference among three groups for Aldrete score (p=0.15).

An important finding in this study was no delayed recovery in all groups. Similar results were found by H Ayoglu [4] who investigated the efficacy of dexmedetomidine during cataract surgery under regional anaesthesia.

In this study, we observed the advantageous effect of Dexmetedomidine in reducing intraocular pressure. Similar results were found M. Virk Kila, Ali-melkkila, J. Kanto et al. [10] in his study of Dexmetedomidine as intramuscular premedication for day case cataract surgeries stated that dexmedetomidine 1 µg/kg decreased IOP.

Conclusions

Thus we conclude that intramuscular dexmedetomidine (1µg/kg) given 45 mins before peribulbar block provided better sedation and more reduction in IOP as compared to intramuscular midazolam (20µg/kg), and both drugs were without serious cardiovascular and respiratory side effects.

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