Original Article

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Comparative Study between Dexmedetomidine and Midazolam in Inducing Conscious Sedation in Patients Undergoing Cataract Surgery

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Abstract

Background: Cataract surgery are usually done in elderly patients. Dexmedetomidine is a potent non-opiod sedative and analgesic devoid of respiratory depression. Midazolam is the most commonly used sedative which is commonly associated with respiratory depression specially in elderly patients.

Objectives: To compare the effects of intravenous dexmedetomidine and midazolam on the haemodynamic stability, sedation and intraocular pressure and to study the safety profile of the drug

Methodology: After obtaining permission from institutional ethical committee and patient informed consent, study was conducted at BMCRI from November 2016 to May 2018 in ASA Grade 1 and 2 patients of 40 to 70 year age undergoing cataract surgery. Patients were randomly allocated to two Group D and M of 32 each. Group D received inj. dexmedetomidine 0.25mcg/kg, Group M received inj. midazolam 0.02mg/kg diluted to 10ml over 10 minutes as intravenous injection. Peribulbar block was given with 8-10ml of injection 2% lignocaine with adrenaline with hyaluronidase. Haemodynamic parameters like Heart Rate, Mean Arterial Pressure and SpO2, Intra Ocular Pressure in non-operating eye, Ramsay Sedation Score, Visual Analogue Score and Modified Aldrete Score were recorded.

Results: We concluded that in our study demographic data were comparable. Patients of Dexmedetomidine group had reduction of IOP after drug injection (p=0.001) and at post bulbar block (p=0.002) which is statistically significant compared to Group M patients and also there was statistically significant difference in RSS Score between two groups.

Conclusions: Dexmedetomidine provides same conscious sedation as Midazolam. Dexmedetomidine reduces intraocular pressure and maintains SpO2 when compared to Midazolam in cataract surgery.

Keywords: Cataract surgery; Dexmedetomidine; Midazolam; Intra ocular pressure.

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Introduction

For intraocular procedure such as extraction of cataract it is desirable to achive a normal or reduced IOP.[1] Anaesthesiologist can optimize the conditions for cataract surgery by providing an immobile uncongested field, decreasing IOP and thus minimizing the danger of expulsion of intraocular contents when the eye is opened.[2]

Dexmedetomidine is a selective alpha[2] adrenoreceptor agonist, which provides "conscious sedation" with adequate analgesia, without causing respiratory depression.[3]

It is sedative-hypnotic, anxiolytic and sympatholytic that can attenuate the stress response to surgery (mitigating tachycardia, hypertension) and also decreases IOP during ophthalmic surgery under local anaesthesia. It also allows patients to respond to verbal commands during the sedation. Easy conversion from sleeping to awakening is possible.[4,6,7]

Midazolam is most commonly used benzodiazepine, causes oversedation, respiratory depression, disorientation, confusion and prolonged recovery after long term or high dose use. It has no analgesic component.[6]

Cataract surgery is most commonly done under local anaesthesia with sedation. Several drugs have been used for sedation during this procedure including benzodiazepines, propofol and opiods. However, propofol may cause oversedation and disorientation. Benzodiazepines may result in oversedation, respiratory depression and confusion particularly when administered to elderly patients. Opiods are associated with increased risk of respiratory depression and oxygen desaturation.[6]

The purpose of the current study is tocompare between dexmedetomidine and Midazolam in inducing conscious sedation in Patients undergoing cataract surgery.

Aims and objectives

- To compare the effects of dexmedetomidine and midazolam on the haemodynamic stability, sedation and intraocular pressure.
- To study the safety profile of the above drugs.

Materials and Methods

A total of 64 Inpatients at hospitals attached to Bangalore Medical College and Research Institute, Bangalore, scheduled to undergo cataract surgery under regional anaesthesia. During the period of Nov 2016 – May 2018 will be taken for study, satisfying the inclusion and exclusion criteria

Sample size: With reference to the previous study, a minimum sample size of 42, with 21 per group was calculated based on considering 5% alpha error, 90% power 2 SD in each group of change in haemodynamic parameters and intraocular pressures,and to be sensitive enough to identify difference of 2 mm Hg ofIOP reduction. For better result, a sample size of 64 with 32 in each group has been chosen.

Inclusion Criteria:

1. Patients aged 40-70 yrs of either sex.
2. Patients posted for cataract surgery under regional anaesthesia.
3. Patients with ASA (American society of Anaesthesiologists) Grade 1 & 2.

Exclusion criteria:

1. Patients with baseline heart rate less than 60 per minute.
2. Patient with COPD,chronic renal failure and hepatic dysfunction.
3. Patients with glaucoma

Methodology

After obtaining clearance and approval from Institutional Ethical Committee, patients who were posted for cataract surgery under regional anaesthesia, fulfilling inclusion and exclusion criteria who give informed written consent will be included in the study.

Patients were randomly allocated using a computer generated number to one of the two groups: Dexmedetomidine group (Group D) and Midazolam group (Group M) (n = 32each).

Group D - received injection Dexmedetomidine 0.25µgm/kg diluted in 10ml NS, slow IV over 10 minutes.

Group M -received injection Midazolam 0.02mg/kg diluted in 10ml NS, slow IV over10 minutes.

Preoperative evaluation of all patientswas done, which includes medical history, physical examination and laboratory tests like CBC, RFT, LFT, ECG. The patient will be premedicated with tablet alprazolam 0.5mg the night before surgery. In the pre-operative room, patient will be put on standard monitors like non-invasive blood pressure,pulse oximetry and electrocardiogram. All basal parameters were recorded including IOP

in non-operating eye by using schiotz tonometer.

In Group D, patients were received 0.25 µg/kg of dexmedetomidine diluted in 10ml of NS over 10 minutes as IV injection. In Group M, patients were received 0.02 mg/kg of midazolam diluted in 10 ml of NS over 10 minutes as slow IV injection. Under aseptic precations in supine postion, peribulbar block was given with injlignoadrenaline(8-10 ml) with hyaluronidase10 minutes after the injection of drug and all vital parameters were recorded including IOP in non-operating eye using schiotz tonometer.

Level of sedation is assessed by Ramsay Sedation Score and level of analgesia by Visual Analogue Scale. Modified Alderet Score is used to assess the readiness for discharge post-operetively.HR, MAP, SpO_2, RSS and VAS score were recorded pre-operatively every 5th minute till 30th minute. Post-operatively HR, MAP, SpO_2, RSS, VAS and MAS score were recorded. Adverse effects like hypotension, bradycardia and decrease in saturation(desaturation) were recorded.

We defined

Hypotension: as 20-30% decrease in MAP and treated with fluid bolus followed byinjmephentramine.

Bradycardia: as heart rate <60 beats per minute and is treated with inj atropine.

Decrease in saturation (Desaturation): as SpO_2<90% and is treated with administration of oxygen.

Statistical Analysis

Statistical analysis will be performed as follows: Student t test to compare the nominal data between the groups, Chi-square test to compare categorical data between the groups.P<0.05 will be significant. All the analysis will be done using SSPS 16 version.

Results and Analysis

Age and sex distribution

The mean age for Group D was 58.53±7.34years and for Group M was 59.44±6.72years. The p value is 0.6 which is not significant.46.9% female and 53.1% male patients were there in Group D and 50% of female and 50% male were there in Group M with p=0.6 which is not significant.On comparison of age and sex distribution was similar in both groups which is statistically not significant. Therefore age and sex distribution was comparable in both groups.

Table 1: Age Distribution.

	Group D		Group M	
	Mean	SD	Mean	SD
Age	58.53	7.34	59.44	6.72

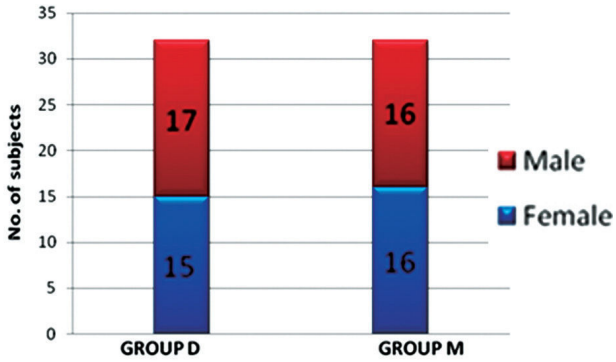

Fig. 1: Gender Distribution of Patients Studied.

Table 2: ASA Grade distribution of patients in both the groups.

	GROUP D Column N		GROUP M Column N	
	Count	%	Count	%
Grade 1	17	53.1	22	68.8
Grade 2	15	46.9	10	31.3

In Group D, ASA Grade 1 patients were 53.1% and ASA Grade 2 were 46.9%. In Group M ASA Grade 1were 68.8% and ASA Grade 2 were 31.3% with the p value of 0.2

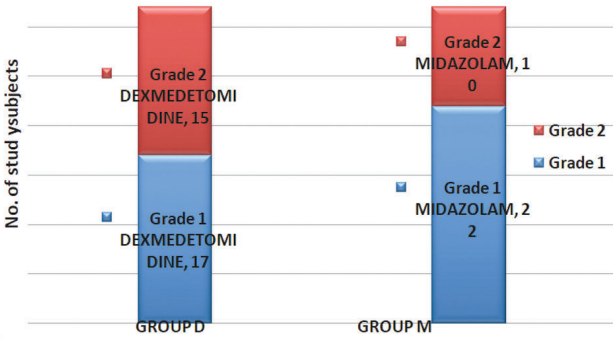

Fig. 2: ASA Grade Distribution.

Table 3: BMI distribution of patients studied.

	GROUP D		GROUP M		
	Mean	SD	Mean	SD	p
BMI	23.63	1.37	23.87	2.00	0.6
Weight	60.59	5.11	61.75	6.52	0.4
Height	160.09	4.75	160.75	4.66	0.6

BMI for Group D was 23.63±1.37 and for Group M was 23.87±2.00 with p value of 0.6 which is not significant.

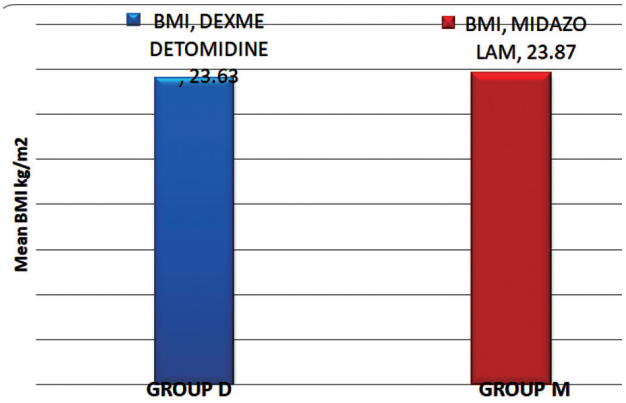

Fig. 3: BMI distribution between 2 groups.

Table 4: Duration of surgery in both the groups.

	Group D		Group M	
	Mean	SD	Mean	SD
Duration of surgery in minutes	26.66	2.32	27.31	1.62

p=0.2

The mean duration for surgery for Group D was 26.66±2.32 minutes and for Group M was 27.31±1.62 minutes with the p value of 0.2 which is not clinically and statistically significant.

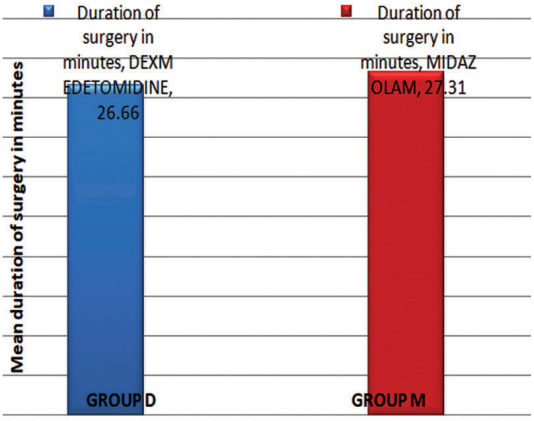

Fig. 4: Duration of surgery between two groups.

Table 5: Baseline HR, MAP, SpO_2, IOP distribution in both the groups.

	Group D		Group M		
	Mean	SD	Mean	SD	P
Base HR	86.00	11.25	81.97	9.88	0.2
Base MAP	92.00	9.61	89.41	7.20	0.2
Base SPO_2	97.75	1.67	97.94	1.74	0.6
Base IOP	16.63	2.20	16.28	1.99	0.5

There was no statistically significant difference in baseline HR, MAP, SpO_2, IOP between both the groups.Mean baseline HR in Group D was 86±11.25 and in Group M was 81.97±9.88 with p value of 0.2 which is not significant.

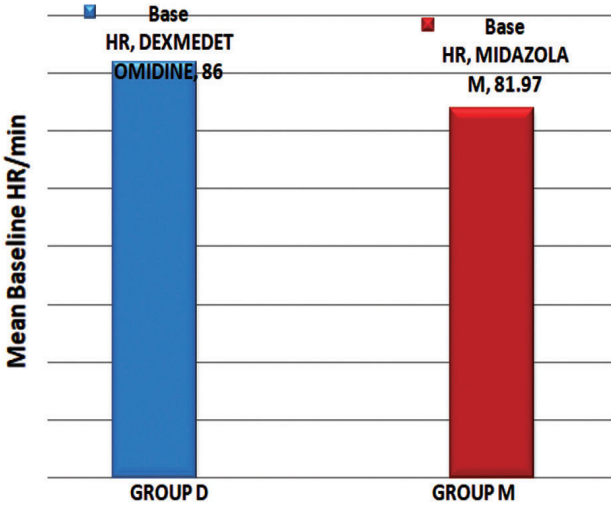

Fig. 5: Comparison of heart rate, Mean arterial pressure, Spo_2 and IOP in both groups.

Table 6: Comparison of HR in both the groups.

	Group D		Group M		
	Mean	SD	Mean	SD	P
Baseline	86.00	11.25	81.97	9.88	.133
Post drug injection	81.94	9.67	81.19	9.04	.750
Post bulbar block	80.03	8.79	80.53	9.09	.824
Intra-op 5thmin	77.97	9.61	80.38	8.99	.305
Intra-op 10th min	76.66	8.91	80.28	9.14	.113
Intra-op 15th min	75.78	8.87	80.38	8.80	.042
Intra-op 20th min	76.91	9.19	80.44	8.86	.172
Intra-op 25th min	77.16	9.05	80.31	9.05	.069
Intra-op 30th min	75.56	8.75	79.90	8.92	.060
Post-op 5th min	76.09	8.49	80.19	8.59	.160
Post-op 10th min	77.38	8.64	80.44	8.60	.107
Post-op 15thmin	77.00	8.44	80.53	8.85	.133

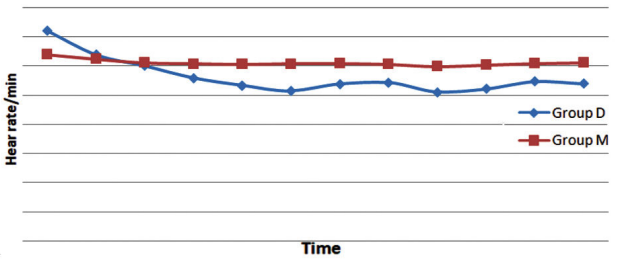

Fig. 6: Comparison of HR in both the groups.

Group D patients had decrease in heart rate when compared to Group M patients at intra-operative 5th minute to post-operative 15th minute.

Table 7: Comparison of MAP in both the groups.

	Group D		Group M		
	Mean	SD	Mean	SD	P
Baseline	92.00	9.61	89.41	7.20	.226
Post drug injection	87.81	8.21	86.41	5.91	.435
Post bulbar block	86.16	6.91	87.03	8.20	.646
Intra-op 5thmin	86.56	9.79	87.38	6.11	.692
Intra-op 10th min	86.53	7.86	88.25	6.04	.330
Intra-op 15th min	85.94	8.06	86.88	5.54	.590
Intra-op 20th min	86.13	8.48	85.75	4.91	.829
Intra-op 25th min	85.30	6.42	86.91	4.91	.271
Intra-op 30th min	85.15	5.63	86.30	4.79	.408
Post-op 5th min	86.16	5.75	86.78	4.34	.625
Post-op 10th min	85.72	6.11	85.97	5.10	.860
Post-op 15thmin	86.50	6.37	85.88	4.44	.650

Group D patients had lower MAP when compared to Group M patients at post bulbar block to post-operative 15th minute which is not significant.

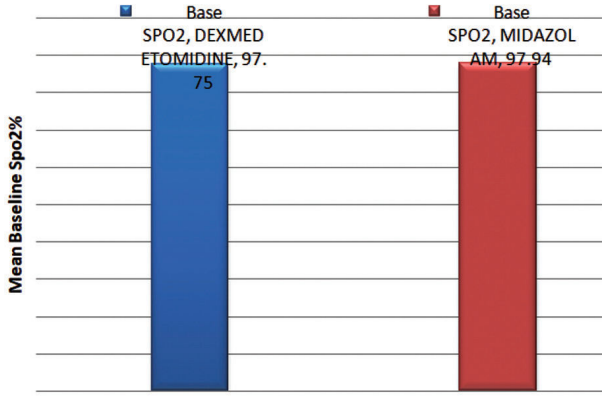

Fig. 7: Comparison of MAP between two groups.

Table 8: Comparison of SpO_2 in both the groups.

	Group D		Group M		
	Mean	SD	Mean	SD	p
Baseline	97.75	1.67	97.94	1.74	0.7
Post drug injection	97.78	1.68	96.09	2.66	0.003
Post bulbar block	97.78	1.60	95.72	2.87	0.001
Intra-op 5thmin	97.78	1.58	94.81	2.55	<0.0001
Intra-op 10th min	97.69	1.65	94.66	2.15	<0.0001
Intra-op 15th min	97.81	1.64	94.38	1.58	<0.0001
Intra-op 20th min	97.63	1.72	94.69	1.97	<0.0001
Intra-op 25th min	97.68	1.78	94.81	1.89	<0.0001
Intra-op 30th min	97.74	1.53	94.40	1.87	<0.0001
Post-op 5th min	97.87	1.60	94.78	2.61	<0.0001
Post-op 10th min	97.78	1.58	95.00	1.81	<0.0001
Post-op 15thmin	97.84	1.59	95.03	1.69	<0.0001

The mean SpO_2 in Group M was lower when compared to mean SpO2 in Group D at all the time which is statistically significant.

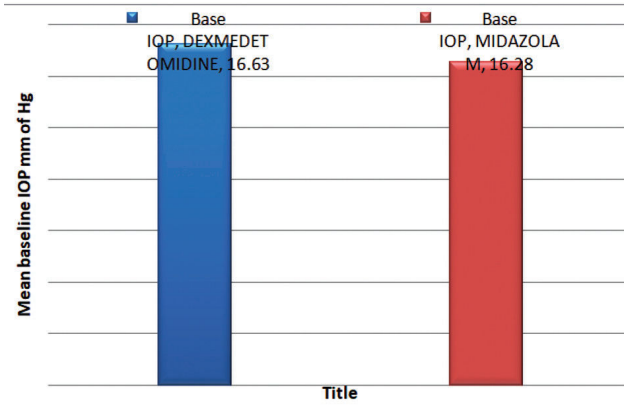

Fig. 8: Comparison of Spo_2 in both the groups.

Table 9: Comparison of IOP in both the groups.

	Group D		Group M		
	Mean	SD	Mean	SD	P value
Base IOP	16.63	2.20	16.28	1.99	0.5
post drug injection IOP	14.40	2.25	16.24	2.03	0.001
Post bulbar block IOP	12.58	2.12	14.26	2.01	0.002
		0.0001		0.0001	0.002

Mean IOP in Group D is 14.40±2.25mmof Hg at post drug injection and is 12.58±2.12mm of Hg at post bulbar block which is lower when compared to mean IOP in Group M at post drug injection and post bulbar block with statistically and clinically significant p value of 0.002.

Table 10: Comparison of RSS Score in both the groups.

	Group D		Group M		
	Mean	SD	Mean	SD	p
Post drug injection	2.56	.50	2.47	.51	.461
Post bulbar block	2.84	.37	2.72	.52	.273
Intra-op 5thmin	2.91	.30	2.81	.47	.344
Intra-op 10th min	2.94	.25	3.03	.59	.413
Intra-op 15th min	2.97	.18	3.13	.55	.133
Intra-op 20th min	2.97	.18	3.28	0.52	.002
Intra-op 25th min	2.94	.25	3.22	.55	.011
Intra-op 30th min	2.81	.40	3.20	.55	.004
Post-op 5th min	2.78	.42	3.09	.59	.017
Post-op 10th min	2.66	.48	3.03	.59	.007
Post-op 15thmin	2.47	.51	3.03	.54	.000

RSS score in Group D is lower than Group M at intra-operative 15th minute to post-operative 15th.

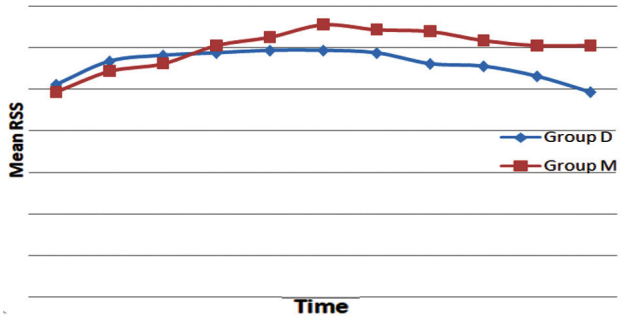

Fig. 9: Comparison of RSS score between two groups.

Table 11: Comparison of VAS score in both the groups.

	Group D		Group M	
	Mean	SD	Mean	SD
Post drug injection	.00	.00	.00	.00
Post bulbar block	.00	.00	.00	.00
Intra-op 5thmin	.00	.00	.00	.00
Intra-op 10th min	.00	.00	.00	.00
Intra-op 15th min	.00	.00	.00	.00
Intra-op 20th min	.00	.00	.00	.00
Intra-op 25th min	.00	.00	.00	.00
Intra-op 30th min	.00	.00	.00	.00
Post-op 5th min	.00	.00	.00	.00
Post-op 10th min	.00	.00	.00	.00
Post-op 15th min	.06	.25	.19	.40

VAS Score was comparable between both the groups

Table 12: Comparison of MAS Score in both the groups.

	Group D		Group M		
	Mean	SD	Mean	SD	P
Post-op 5th min MAS	9.22	.42	9.06	.44	0.15
Post-op 10th min MAS	9.34	.48	9.13	.42	0.06
Post-op 15th min MAS	9.50	.51	9.06	.44	<0.0001

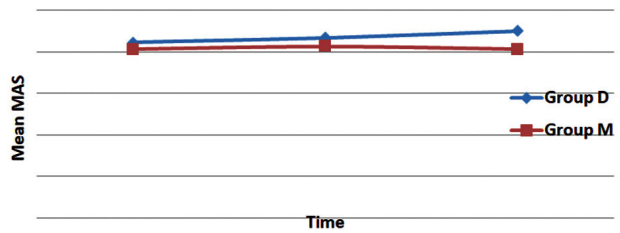

Fig. 10: Comparison of MAS Score in both the groups.

Mean MAS score in Group D is 9.22±0.42 at post-operative 5th minute with p value of 0.15, 9.34±0.48 at post-operative 10th minute with p value of 0.06, and 9.50±0.51 at post-operative 15th minute with p value of <0.0001. This p value was statistically significant, but not clinically as all the patients had MAS Score of 9-10.

Discussion

Patients of Group D received injection 0.25µg/kg dexmedetomidine diluted in 10ml of NS over 10 minutes and patients of Group M received injection 0.02mg/kg midazolam diluted in 10ml of NS over 10minutes. HR, MAP, SpO_2, IOP in non-operating eye were recorded. Peribulbar block was given with injection ligno-adrenaline and hyaluronidase. HR, MAP, SpO_2 and IOP in non-operating eye were recorded. HR, MAP, SpO_2, RSS and VAS score were recorded intra-operatively every fifth minute. Post-operatively, HR, MAP, SpO_2, RSS, VAS and MAS score were recorded every fifth minutes till fifteenth minute. Incidence of bradycardia, hypotension and decrease in SpO_2 were recorded.

Hypothesis made before starting the study

We hypothesized that dexmedetomidine compared to midazolam provides good sedation, reduces IOP, provides hemodynamic stability and can be used safely in patients undergoing cataract surgery.

Demographic Data

Demographic data comparing the age, gender, weight, height, BMI, ASA grade and duration of surgery [Table 1,2,3 and Figure 1,2,3] were comparable between both the groups and did not show any significant statistical difference.

In our study we observed a decrease in heart rate [Table 6 and Figure 6] in Group D when compared to Group M at intra-operative 5th minute to post-operative 15th minute but was not statistically significant and did not require any intervention. This was in accordance with the study done by J AAlhashemi et al[6] in 2006. They also observed decrease in heart in patients receiving dexmedetomidine but did not require any interventions.

In our study we observed that MAP[Table 7 and Figure 7] was comparable between both the groups. The study conducted by Hyo-Seok Na et al[7] in 2011, patients receiving dexmedetomidine had decrease in systolic blood pressure when compared to those patients receiving propofol alfentanyl combination. In this study patient of group D had received 0.6µg/kg/hr infusion, but in our study patients of Group D had received inj dexmedetomidine 0.2µg/kg diluted in 10ml NS over 10minute as single injection.

In our study we observed that there was a statically significant (p=<0.0001) reduction in SPO_2[Table 8 and Figure 8] in Group M when compared to Group D all the time, but it is not clinically significant as most of them have maintained SpO_2>90%. 4 patients of Group M had decrease in SpO_2 and required administration of oxygen via nasal prongs. This is in accordance with the study conducted by J AAllhashemi et al[6] in 2006 and Hoda H et al9 in 2016.

In our study we observed that patients of Group D had reduction of IOP [Table 9] at post drug injection (p=0.001) and at post bulbar block (p=0.002) which is statistically significant compared to Group M patients. This is in accordance with the study conducted by H Ayoglu et al[7] in 2007. They also observed significant reduction in IOP in patients receiving dexmedetomidine.

In our study we observed statistically significant difference in RSS Score[Table 10 and Figure 9] between Group D and Group M at intra-operative 20th, 25th and 30th minute, but it was not clinically significant as the RSS score is between 2 to 3, which indicates moderate (conscious) sedation. This was in accordance with the study conducted by DevangiA Parikh et al[8] in 2013.

VAS score [Table 11] was comparable between both the groups in our study, which was against the study conducted by Hoda H et al[9] in 2016.

In our study MAS score [Table 12 and Figure 10] post-operatively at the 5th and 10th minute was comparable between both the groups, but at 15th minute (p=<0.0001) there was a statistically significant difference between both the groups, and was not clinically significant, as both the groups patients had MAS score of 9, which indicated the readiness for discharge. This was in accordance with the study conducted by Hoda H et al[9] in 2016.

Conclusion

In conclusion, our study demonstrates that dexmedetomidine provides same conscious sedation as midazolam. Dexmedetomidine reduces intraocular pressure and maintains SpO_2 when compared to midazolam in cataract surgery.

Limitation

Sample size was small and single centre study and there is lack of correlation between causes of acute kidney injury and severity of hypomagnesemia

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