

A Comparison of Hemodynamic Responses and Patient Comfort In Cataract Surgery With And Without Midazolam As Sedation.

Dr. Shashwat Hegde¹, Dr. Sampathila Padmanabha², Dr. Gopal Krishna Bhat³

¹Assistant Professor, Department of anaesthesiology and critical care, Yenepoya medical college, Mangalore, Karnataka, India.

²Professor and Head of department, Department of anaesthesiology and critical care, Yenepoya medical college, Mangalore, Karnataka, India.

Abstract: To investigate if pre-block intravenous sedation using Midazolam minimizes pain, reduces pain recall, and attenuates hemodynamic responses to peribulbar block. A prospective study with intravenous sedation Midazolam 0.02 mg/kg body weight prior to peribulbar block were evaluated for hemodynamic responses and patient comfort in cataract surgery. Intravenous sedation with Midazolam in cataract surgery prior to peribulbar block reduced pain recall and haemodynamic responses to peribulbar block and improved patient satisfaction.

Keywords: Peribulbar block; intravenous Midazolam; cataract surgery; hemodynamic responses; pain, discomfort, pain recall.

I. Introduction:

Cataract surgery is a common operation in elderly patients and is performed under regional anesthesia. Elderly patients usually have associated systemic illness like hypertension, diabetes mellitus and chronic obstructive pulmonary airway disease etc¹. In our hospital cataract surgery is performed under peribulbar block without sedation. The unpleasant memory of operation in many patients is pain associated with needle insertion or discomfort during injection of anaesthetic solution. Routine oral or intravenous sedation is used to minimize the patient discomfort associated with peribulbar block and also to stabilize haemodynamic changes². The ideal sedative amnesic technique should be reliable, safe, should allow early recovery of the patient and there should be minimal post-operative sequel³. During intraocular surgery if there is presence of elevated intraocular pressure before the surgery it is associated with increased risk of surgical complications. It is known that a normal to slightly lower than normal intraocular pressure is usually desirable for such surgeries. To minimize this agent used for intravenous sedation should not increase the intraocular pressure.

II. Materials and Methods:

Primary objective of the study is patients comfort. Secondary objectives were: Haemodynamic responses, pain was assessed during and after surgery using Visual Analogue Scale (VAS). Study was conducted in Yenepoya medical college hospital after obtaining ethical committee clearance. 76 patients were included from either sex, *Inclusion criteria:* Patients with cataract, ASA grade I, II and III, patients in the age group 50- 80 years. *Exclusion criteria:* Patients less than 50 years of age or greater than 80 years, ASA IV and emergency, patient refusal, SpO₂ <90% on room air. A thorough pre-anaesthetic evaluation which included detailed history and general physical examination was done. Based on fulfillment of the above mentioned inclusion and exclusion criteria patients were selected and randomly assigned into either Group M or Group N of 37 patients each. Informed written consent was obtained from these patients. After shifting the patient to the operating table, standard monitors pulse oximetry, noninvasive arterial blood pressure, and electrocardiography was applied. Oxygen was given through nasal prongs. Monitoring included Heart rate, Blood pressure, Oxygen saturation (SpO₂), and pain scores were recorded 1) Just before injection of intravenous Midazolam, 2) After giving 0.02mg/kg bodyweight of Midazolam, 3) During peribulbar block, 4) 10 minutes after the block and then every 10 minutes till the surgery is over. In the second Group N patients the same procedure is followed but without the use of Midazolam.

III. Results:

In our study two Groups containing 37 patients each for cataract surgery under peribulbar block with Group M receiving I.V. Midazolam 0.02mg/kg prior to peribulbar block showed significant difference in hemodynamic parameters with HR, BP both SBP and DBP showed significant difference compared to Group N where patients received no sedation prior to the block.

Heart Rate:

In our study base line heart rate in both the Groups M is 74.351 and Group N is 80.162 both groups showed increased in H.R soon after giving peribulbar block to 88.946 in Group M to 99.108 in Group N there was not much difference in the HR between the 2 groups but after 10 mins there was a fall in HR in the Group M which came down to 75.675 as compared to Group N came down to 89.324. at the end of the procedure that is after 30 mins the mean HR in Group M was 67.784 as compared to 82.270 in Group N the fall might be due to the sedative effect of the midazolam in Group M. In the study done by David H.W. Wong and Pamela M. Merric² compared sedation prior to peribulbar block in cataract surgery using saline Midazolam and alfentanil and found Midazolam was very useful in obtunding the HR following peribulbar block this observation correlate with our study. C.K. Pac-Soo and et al³ also in their study of IV sedation prior to peribulbar block conclude that Midazolam sedation effective in obtunding the HR. J.A. Alhashemi⁴ in his study for IV sedation prior to peribulbar block in cataract compared dexmedetomidine and Midazolam and found dexmedetomidine more useful in obtunding the HR rate compared to Midazolam.

Systolic blood pressure and diastolic blood pressure:

In our study the base line mean systolic blood pressure mean systolic BP in Group M was 137.865 and Group N was 139.027 but during peribulbar block there was increase in systolic blood pressure was seen Group M 142.649 and Group N 146 not much of a difference between the 2 groups the mean diastolic blood pressure baseline for Group M was 86 and Group N was 88.324 which increased during peribulbar block to 91.892 in Group M and 94.865 in Group N. The next 10 mins there was slight reduction in SBP of Group M to 136.48 and DBP 84.054 and in Group N the SBP 140.189 and DBP was 88.514. but significant difference is seen in the SBP at the end of the surgery at the end of 30 mins the SBP of Group M was 125.919 and Group N it was 135.243 on the other hand DBP showed not much of difference. At the end of 30 mins DBP in Group M was 81.081 and in Group N it was 85.649. David H.W. Wong and Pamela M. Merric¹ This study demonstrates that in elderly patients, iv Midazolam-alfentanil combination attenuated haemodynamic responses. Midazolam reduced systolic BP. This study supports my study observation that midazolam reduces systolic BP. C.K. Pac-Soo² this study demonstrates only Midazolam prevented and increase in arterial pressure. In non sedated patents the systolic and diastolic pressure increased there was also increase in heart rate respectively. J.A. Alhashemi⁴ study also states the Midazolam is useful in reduction in systemic blood pressure.

Pain scores:

In our study we found most of the patients belonging to Group M were uncomfortable during the time of peribulbar block application and some time in between procedure they wake up suddenly from sleep and found it uncomfortable with the drape over their face. About 16 patients (43.2%) in the Group M belong to grade 4 (uncomfortable) about 29% of the patients of Group M were grade 5. And another 24.3% (9 patients) were grade 3 of VAS. While in Group N patients were in Grade 5 (59.5%) 22 patients they had a near dreadful experience during peribulbar anaesthetic block. Another 15 people of the group (40.5%) were in grade 6. In the above mentioned studies have not used VAS in their studies.

Level of anxiety and postoperative patient satisfaction:

The term sedation used in the study does not refer to degree of drowsiness but rather describes a state of anxiolysis when the patient feels very relaxed, they can become very drowsy but verbal communication is very much retained. In our study the level of anxiety was graded into 3 grades and it was found that about 97.3% that is 36 patients who received I.V. Midazolam prior to the block where in grade 1 (normal or no anxious) and 91% about 34 patients in the Group N where grade 2 (anxious) till the procedure ended. Post operatively patient satisfaction after cataract surgery was also determined by interviewing the patients first post-operative day. Most of the patients 94.6% about 35 patients who received inj Midazolam prior to the block were satisfied as the fear of surgery and the peribulbar block was reduced due to the sedation provided by Midazolam. While about 73% that is about 27 patients there was no postoperative satisfaction. A very high rate of significance with p value <0.01 was found in terms of patient satisfaction following cataract surgery.

Fiona E. McHardy et al (2002)⁵ conducted a study to determine the ideal sedative regimen for intraocular surgery under peribulbar block. The addition of alfentanil and propofol to Midazolam was evaluated they concluded that systolic blood pressure in patients who received alfentanil was 6% lower than that patient who had not at the time of insertion of peribulbar block pain scores of the patient who had been given alfentanil were lower during postoperative period than those who had not the addition of alfentanil to Midazolam was advantageous in producing sedation for insertion intraocular block. Celiker V et al (2007)⁶ : compared Midazolam, propofol and fentanyl in terms of sedation during cataract surgery. Hemodynamic parameters, sedation levels, postoperative satisfaction and side effects were investigated, They concluded the

combination of Midazolam propofol and fentanyl should be preferred to other study as the sedation levels is suitable for cataract extraction with high postoperative patient satisfaction and without any side effects.

IV. Conclusion:

Following conclusions can be drawn from this study:

- IV sedation in cataract surgery prior to peribulbar block is a common practice in most of the centers.
- There is a significant difference between the two Groups in study with respect to hemodynamic stability seen adequately in Group M although initially while giving peribulbar block there was a rise seen in base line BP, HR. But as the surgery proceeded it was seen that Group M patients who received iv Midazolam had profound hemodynamic stability as compared with Group N who did not receive iv midazolam. Midazolam was able to obtund any increase in HR or systemic blood pressure.
- Due to perioperative adequate sedation there was good patient co-operation with adequate anxiolysis, the patents were very much relaxed and not too drowsy with adequate verbal commands and airway reflexes very well maintained.
- Post operatively when the patients who received IV Midazolam were interviewed about their experience during the surgery majority number of patients in Group M had a satisfactory intra-operative event.

References:

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Sex distribution

			GROUP		Total
			With midazolam	Without Midazolam	
SEX	Male	Count	12	24	36
		%	32.4%	64.9%	48.6%
	Female	Count	25	13	38
		%	67.6%	35.1%	51.4%
Total		Count	37	37	74
		%	100.0%	100.0%	100.0%

a. $\chi^2=7.789$ $p=0.005$ hs

Table1 shows the sex didtribution in both the Groups under study. about 34% of males were in Group M as comparison to 67.6% in the same Group. While in Group N about 64% are male as compared to 15%

SBP

GROUP		N	Mean	Std. Dev iation	t
SBPBASE	With midazolam	37	137.865	7.587	.711 p=0.479 ns
	Without Mdazolam	37	139.027	6.423	
INJSBP	With midazolam	37	132.514	7.404	
	Without Mdazolam	0	.	.	
PBSBP	With midazolam	37	142.649	4.900	2.710 p=0.008 hs
	Without Mdazolam	37	146.000	5.706	
SBP10	With midazolam	37	136.486	8.068	2.622 p=0.011 sig
	Without Mdazolam	37	140.189	2.952	
SBP20	With midazolam	37	132.405	10.550	1.396 p=0.167 ns
	Without Mdazolam	37	135.135	5.488	
SBP30	With midazolam	37	125.919	11.109	4.543 p<.001 v hs
	Without Mdazolam	37	135.243	5.698	

Table 2Comparison of Perioperative systolic blood pressure in both Groups. It shows high significance with P value = 0.008 post block for patients with Group M who received I.V. Midazolam compared to Group N. even significant results were found in next 10 mins among Group M as compared to Group N.

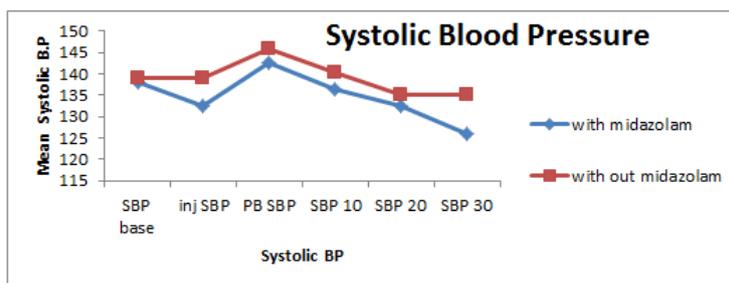


Figure 1 Systolic blood pressure graph.

DBP

	GROUP	N	Mean	Std. Deviation	t
DBPBASE	With midazolam	37	86.000	6.377	1.602
	Without Mdazolam	37	88.324	6.101	
INJDBP	With midazolam	37	82.189	4.345	2.517
	Without Mdazolam	37	91.892	4.760	
PBDP	With midazolam	37	91.892	4.760	2.517
	Without Mdazolam	37	94.865	5.381	
DBP10	With midazolam	37	84.054	5.972	3.477
	Without Mdazolam	37	88.514	5.020	
DBP20	With midazolam	37	82.811	5.802	1.838
	Without Mdazolam	37	85.189	5.322	
DBP30	With midazolam	37	81.081	4.728	3.757
	Without Mdazolam	37	85.649	5.687	

Table 3 Comparison of perioperative diastolic blood pressure in both the groups and very high statistical significance with respect to diastolic blood pressure is seen in patients of Group M compared to Group N.

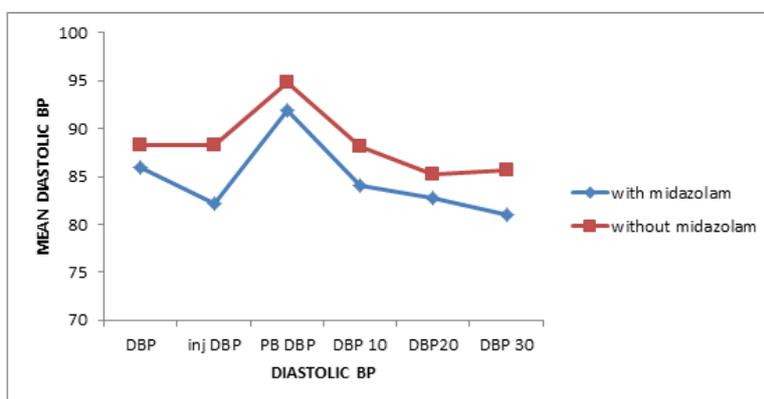


Figure 2 Diastolic blood pressure graph.

Heart rate

	GROUP	N	Mean	Std. Deviation	t
Baseline haemodynamics	With midazolam	37	74.351	7.896	3.032
	Without Mdazolam	37	80.162	8.578	
Injection Midazolam	With midazolam	37	69.135	6.338	
	Without Mdazolam	0	.	.	
Peribulbar block	With midazolam	37	88.946	6.502	7.208
	Without Mdazolam	37	99.108	5.592	
10 mins	With midazolam	37	75.676	7.138	9.350
	Without Mdazolam	37	89.324	5.281	
20 mins	With midazolam	37	71.054	6.196	13.567
	Without Mdazolam	37	88.027	4.419	
30 mins	With midazolam	37	67.784	6.042	12.994
	Without Mdazolam	37	82.270	3.079	

Table 4: Comparison of perioperative heart rate in both Groups with very high statistical significance for the Group M who received I.V. Midazolam as compared to Group N. with post block P value< 0.01 and similar result seen after 10,20 and 30 minutes.

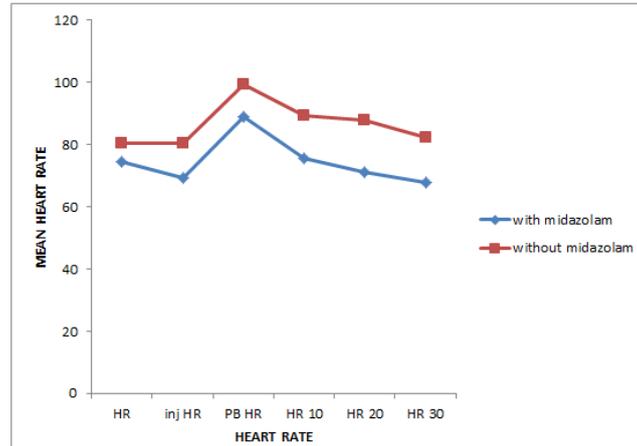


Figure 3 Perioperative Heart rate graph.

Group Statistics

	GROUP	N	Mean	Std. Deviation	t
AGE	With midazolam	37	62.027	3.926	3.418
	Without Mdazolam	37	65.432	4.616	
VAS	With midazolam	37	4.000	.816	8.940
	Without Mdazolam	37	5.405	.498	
PATIENT SATISFACTION	With midazolam	37	.054	.229	8.135
	Without Mdazolam	37	.730	.450	

Table 5 Visual analogue score and patient satisfaction.

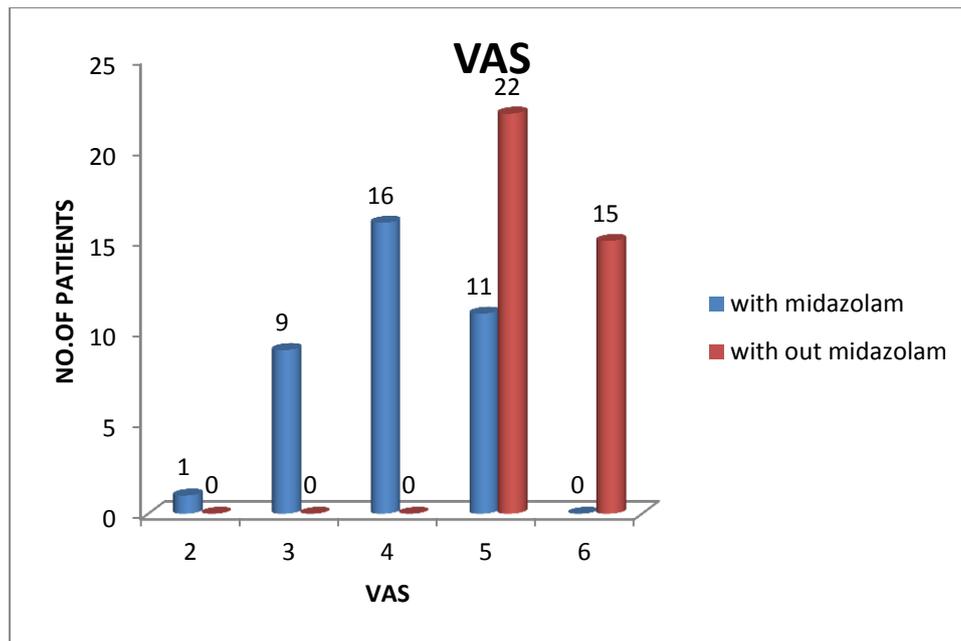


Figure 4 Comparison of VAS between two groups.