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Original Research Article

Assessing intravenous midazolam for conscious sedation during cataract surgery

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ABSTRACT

Background: A large number of geriatric populations above the age of 50 worldwide suffer from cataract. Cataract starts with short-sightedness and gradually worsens resulting in blurring of vision and inability to visualize and distinguish fine details. Surgery is the only available treatment for cataract. Anaesthesia is essential during cataract surgery to minimize pain caused during surgical procedure and to achieve favourable surgical outcome. The current investigation was aimed towards assessing the performance of intravenous midazolam used for conscious sedation during cataract surgery along with peribulbar block.
Methods: Current study is a randomized double blinded study performed for duration of 6 months on 60 patients undergoing cataract surgery at Terna medical college and hospital. Patients were divided in two groups; group M received 0.02 mg/kg midazolam diluted to 5 ml, group N received 5 ml normal saline before cataract surgery. All vital hemodynamic parameters were observed after 5 minutes of sedation, immediately after block administration and after every 15 minutes till the end of the surgery to assess the effect of sedation. Patients and surgeons satisfaction levels were also documented post-surgery.
Results: Patients who were sedated with midazolam prior to cataract surgery along with block exhibited a significant decrease in hemodynamic parameters like SAP, DAP and heart rate which indicated effective sedation. Anxiety level also significantly decreased in the patients who received midazolam. No major adverse or intra-operative events were observed in the patients who received midazolam.
Conclusions: Sedation with midazolam provides haemodynamic conditions favourable for cataract surgery along with high level of patient and surgeon satisfaction.

Keywords: Cataract surgery, Anaesthesia, Midazolam, Hemodynamic parameters, Sedation, Benzodiazepines, Retrobulbar block

INTRODUCTION

Human eye consists of lens which is crystalline in nature and is responsible for vision as it allows the light to pass though it by providing a clear passage and focuses the passed light towards retina to create a sharp and clear image.[1,2] Cataract is a pathological disorder in which the crystalline natural eye lens opacify or becomes cloudy resulting in blurring of specifically capacity of eye to visualize fine details is despaired.[3] Cataracts are painless and except gradual blurring of vision there are no other symptoms of cataract. In cataracts eventually with time colors and contrasts become less clear and night driving, sensitivity to glare of sun or other brighter sources of light develops.[4] Cataract starts with short-sightedness and gradually worsens and if left untreated; in some instances cataract might also result in complete loss of vision rapidly.[5] It is usually observed that cataracts are seen in geriatric patients over the age of 50 years. Published reports revealed that worldwide almost 95 million people are affected by cataract.[4-6] Since cataract is mostly age related disorder there are no specific preventive measures

or medications for the treatment of cataract. The only effective and available treatment of cataract is surgery which is a minute incisional surgery wherein aged cloudy eye lens is replaced with crystal clear artificial lens leading to rapid visual recovery.[7] In extracapsular cataract extraction surgery which is widely used incision is made after retrobulbar block in which local anaesthetic is injected in retrobulbar eye space and lens is removed from its capsule and artificial lens is implanted.[8] Current anaesthetic approaches in cataract surgeries vary from topical to needle technique while eye blocks provide excellent anaesthesia for ophthalmic surgery, many clinicians combine blocks with sedation.[9]

Anaesthesia is essential during cataract surgery not only to ensure patients comfort by numbing or blocking the pain caused during surgical procedure but also to provide a favourable surgical environment to the surgeons which would eventually lead to an optimal outcome.[9,10] An ideal anaesthetic agent would ensure proper sedation with a quick onset and a short duration of action required in ophthalmic procedures.[11] In addition the anaesthetic agent should be non-toxic, economic, should have minimal accumulating capacity and should exhibit no side effects.[10-12] Several drugs such as propofol, benzodiazepines and opioids are used as anaesthetic agents in ophthalmic surgeries.[13] However propofol as anaesthetic agent leads to disorientation and may also cause over sedation, oxygen desaturation and respiratory depression are the short falls of opoids as anaesthetic agents.[14]

Midazolam is a short-acting central nervous system depressant belonging to the class of benzodiazepines.[15] In addition to being hypnotic-sedative, midazolam has anxiolytic, muscle relaxant, anticonvulsant, and amnesic properties.[16] Midazolam was first approved by USFDA in 1985.[16] Midazolam increases the activity of neurotransmitter gamma-aminobutyric acid (GABA) by binding to GABA-A receptors and thereby inducing sedative and hypnotic effects.[17] Although midazolam is one of the most preferred benzodiazepine for inducing anesthetic effect due to its favourable characteristics like quick onset of action, shorter duration of action required in ophthalmic surgical procedures, wider safety margins and high therapeutic index due to profound lipid and water solubility indices; the published reports also reveals about the shortcomings like confusion, in elderly patients caused due to benzodiazepines as anaesthetic agent.[17-19] Thus the current investigation was aimed towards assessing the performance and adverse effects of intravenous midazolam used for conscious sedation during cataract surgery along with retrobulbar block.

Aim and objectives

Primary aim of the present study was to determine the effect of midazolam and placebo (normal saline) on the hemodynamic parameters during cataract surgery. Objectives of the current investigation were to assess and compare the effect of midazolam with placebo with reference to patient and surgeon satisfaction post cataract surgery and to determine the patient anxiety level and occurrence of any adverse events in the post-operative period before discharge.

METHODS

Study design, location and duration

Current study was a randomized double blinded study performed at Terna medical college and hospital, Nerul, Navi Mumbai for duration of six months.

Sample size

Current study was performed on total 60 patients undergoing cataract surgery. Patients were randomly divided in to two groups with 30 patients in each group.

Inclusion criteria

Patients falling in ASA I to ASA III categories undergoing cataract surgery, patients in the age group of 30 to 75 years and patients who gave their consent for the study were included in the study.

Exclusion criteria

Exclusion criteria for the current study were; patients in the age group beyond 75 years, patients with heart disease, severe pulmonary disease, sleep apnea, poor cognitive ability and patients who refused to give their consent to participate in the study.

Procedure

After receiving written informed consent from the 60 participating patients who were scheduled to undergo cataract surgery, they were divided in two equal groups consisting of 30 participants each. All the patients belonged to (American society of anaesthesiologists) ASA I to ASA III categories and were in an age group range of 30 to 75 years. Group allocation was done randomly using computer based random numbering technique. Group M received 0.02 mg/kg midazolam diluted to 5 ml and group N received 5 ml normal saline. After preoperative anaesthesia checkup and routine investigations patients were scheduled for cataract surgery. Patients characteristics like age, weight, gender and ASA status were documented prior to surgery. On the day of surgery IV cannulation was done in the pre-operative area and then the patients were shifted to operation theatre. Multipara monitor was attached and vital baseline parameters including heart rate (HR), blood pressure in terms of systolic arterial pressure (SAP) and diastolic arterial pressure (DAP) and oxygen saturation (SPO_2) were recorded. All the patients received oxygen through nasal cannula at the rate of 2 litres/minute. Drugs were administered to patients by anaesthesiologist who was not

involved in the study 10 minutes prior to block administration. Retrobulbar block was given by ophthalmic surgeon unaware of the identity of groups. Ten minutes post-surgery, surgeon's satisfaction was recorded. The surgeon's satisfaction was recorded to be good if the patient responded appropriately to his request and did not move unexpectedly during the procedure. Patient and surgeon satisfaction was recorded at the end of the surgery as per the five degree scale (Table 1).

Table 1: Scale for patient and surgeon satisfaction.

Score	Inference
1	Very bad
2	Bad
3	Moderate
4	Good
5	Very good

Patients were then shifted to PACU and were observed for an hour for anxiety experienced by the patients. The anxiety levels of patients were assessed by linear visual analogue scale (VAS) from 0 to 10; 0 for feeling normal and 10 for extreme anxiety. Along with anxiety levels of patients; occurrence of any adverse events like bradycardia, trachycardia, hypertension, hypotension, respiratory depression, nausea and vomiting were recorded in PACU before patient's discharge. All parameters and observations were recorded by same anaesthesiologist who is not involved in the study.

Statistical analysis

Unpaired student t test and Chi square test were used for data analysis, $p<0.05$ was considered as statistically significant.

RESULTS

It was observed through the current study findings that maximum patients coming for cataract surgery where in the age group of 56 to 65 years followed by 66 to 75 years of age group (Figure 1). The age range of patients who turned up for cataract surgery in the current investigation was from 39 years (minimum) to 75 years (maximum).

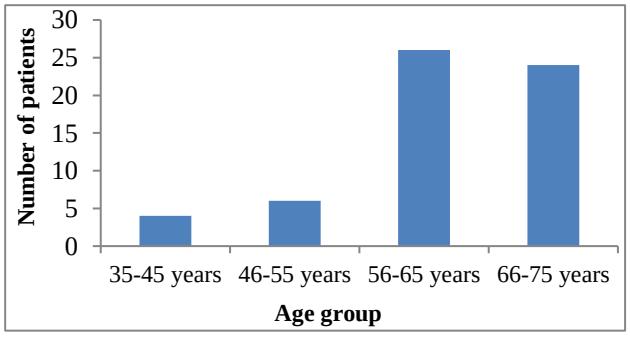

Figure 1: Distribution of study participants on the basis of age.

Current study findings revealed that majority of the participating patients undergoing cataract surgery possessed body weight in the range of 55 to 64 kg, followed by 45 to 54 kg (Figure 2). Amongst the patients participating in current study investigation minimum bodyweight was found to be 38 kg and maximum body weight was found to be 68 kg. It was also observed through the gender based distribution study in the current investigations that male patients who underwent cataract surgery outnumbered the female patients (Figure 3). The American society of anaesthesiologists (ASA) status based distribution studies of all the participating patients in current investigation revealed that almost half of the participating patients exhibited ASA class I (normal and healthy) whereas remaining one half of the patients exhibited ASA class II (patients with mild systemic disease) (Figure 4). The patients who exhibited ASA class II suffered from complications like hypertension (HT) or diabetes mellitus (DM) or both of them.

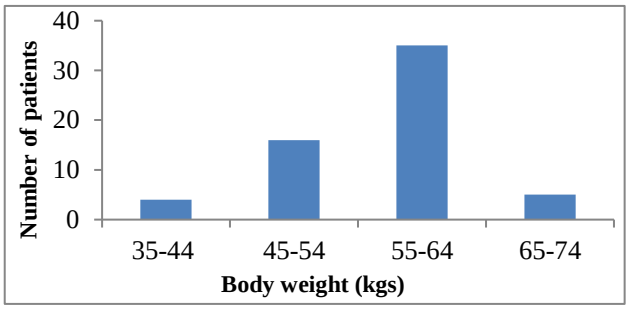

Figure 2: Distribution of study participants on the basis of body weight.

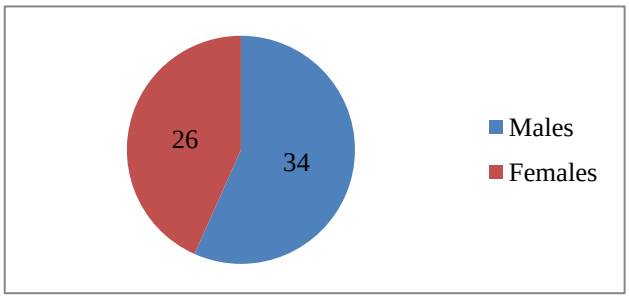

Figure 3: Distribution of study participants on the basis of gender.

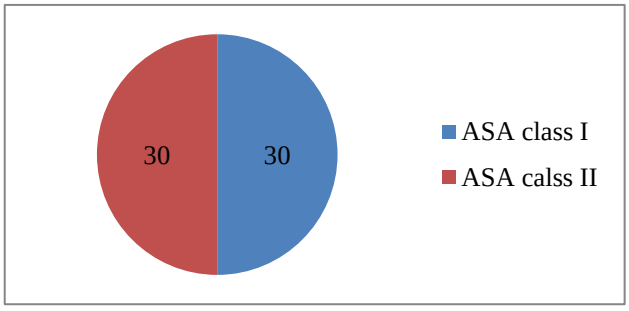

Figure 4: Distribution of study participants on the basis of ASA status.

Since the primary objective of the current study was to assess the effectiveness of midazolam as an effective sedative to be used during cataract surgery along with block, so in context to the stated objective; current investigational studies revealed that both surgeons; performing the cataract surgery and patients; undergoing cataract surgery were highly satisfied with the use of midazolam as an effective sedative during surgery, It was depicted from the study findings that there was a significant difference in both surgeon and patient satisfaction level between midazolam treatment group and saline treatment group (Table 2) (Figure 5).

The majority of surgeons (70%) gave a satisfaction score of 5 (very good satisfaction level) for the cataract surgery done on patients previously sedated using midazolam, in comparison to the cataract surgery performed on patients who received only normal saline for which the surgeons gave a satisfaction score ranging from 2 to 4 (bad to moderately good). Current study investigations also revealed that patients who underwent cataract surgery where highly satisfied with the surgery when they were sedated with midazolam in comparison to the patients who were received normal saline before surgery. Majority of the patients (76.66%) gave a satisfaction score of 5 when they received midazolam whereas the patient's satisfaction score ranged from 2 to 3 when they received normal saline before surgery.

Investigation of hemodynamic parameters in current study in both the patients groups who underwent cataract surgery and who received either midazolam or normal saline prior to surgery revealed that the patients who were sedated with midazolam prior to cataract surgery exhibited a significant decrease in parameters like SAP (p=0.030), DAP (p=0.047) and heart rate (p=0.049), these in turn revealed that there was an effective sedation induced in the mentioned group of patients who received midazolam (Table 3). Whereas it was observed that in patients who received only normal saline prior to cataract surgery there was no significant reduction in any of the hemodynamic parameters). SPO_2 value was observed to remain unchanged in patients of both the groups at any time point before or after surgery.

Current study investigation revealed that anxiety level significantly decreased in the patients who received midazolam in comparison to patients who were only on normal saline. It was observed that anxiety score of all 30 patients who received midazolam was 0; whereas the anxiety score of maximum patients (53.33) who received normal saline was observed to be 2 followed by anxiety score 3 (30%) (Table 4). Current study investigations revealed that there were no major adverse events observed in the patients of either of the groups. Whereas intra-operative events like anxiety, pain, body parts movement, crying of patients and not properly following surgeons instructions were observed in 11 (36.6%) patients who received only saline prior to surgery. Only mildly intense intra-operative events like snoring, pain while giving block and position complain of patient were observed in 5 (6%) of patients who received midazolam prior to surgery.

Table 2: Post-operative patient and surgeon satisfaction scores in saline and midazolam treatment groups.

Score	Surgeon satisfaction		P value	Patient satisfaction		P value
	Saline treatment group; N (%)	Midazolam treatment group; N (%)		Saline treatment group; N (%)	Midazolam treatment group; N (%)	
1	0 (0)	0 (0)	0.03277 (significant difference)	0 (0)	0 (0)	0.02324 (significant difference)
2	3 (10)	0 (0)		11 (36.66)	0 (0)	
3	14 (46.66)	2 (6.66)		16 (53.33)	0 (0)	
4	13 (43.33)	7 (23.33)		3 (10)	7 (23.33)	
5	0 (0)	21 (70)		0 (0)	23 (76.66)	

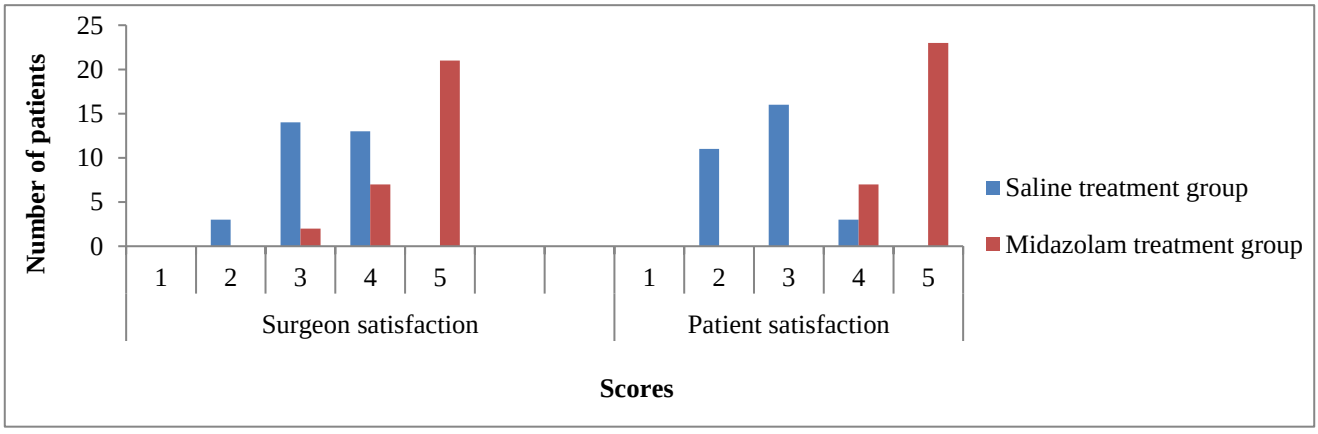

Figure 5: Post-operative patient and surgeon satisfaction scores in saline and midazolam treatment groups.

Table 3: Change in hemodynamic parameters of saline treated group and midazolam treated groups at different time interval.

Time points	Saline treated group				Midazolam treated group			
	SAP (mmHg)	DAP (mmHg)	HR (beats/ minute)	SPO_2 (%)	SAP (mmHg)	DAP (mmHg)	HR (beats/ minute)	SPO_2 (%)
Baseline (range)	120-150	70-92	50-102	100	108-178	62-92	61-110	100
5 minutes post sedation (range)	122-158	60-92	52-104	100	102-162	74-90	60-104	100
10 minutes post sedation (range)	125-160	66-92	54-104	100	106-150	60-90	62-104	100
After block (0 minutes) (range)	125-170	68-92	56-102	100	102-152	58-90	64-106	100
After block (15 minutes) (range)	120-164	67-90	52-100	100	100-146	56-88	60-100	100
After block (30 minutes) (range)	120-160	68-94	56-100	100	100-140	58-88	60-98	100
After block (45 minutes) (range)	120-162	64-94	54-94	100	106-142	62-88	56-94	100

Table 4: Post operative anxiety score of patients of saline and midazolam treatment groups.

Anxiety score	Groups		P value
	Saline treatment group; N (%)	Midazolam treatment group; N (%)	
0	0 (0)	30 (100)	0.0087
1	4 (13.33)	0 (0)	
2	16 (53.33)	0 (0)	
3	9 (30)	0 (0)	
4	1 (3.33)	0 (0)	

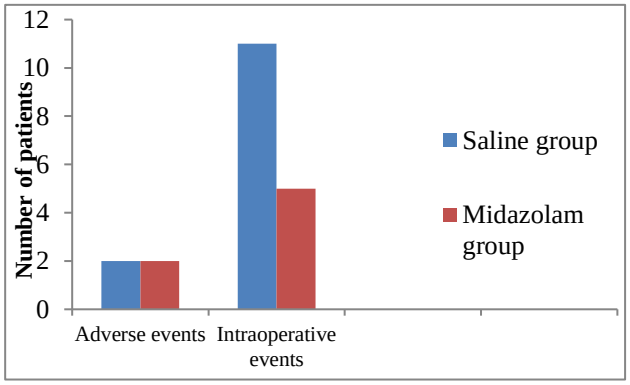

Figure 6: Distribution of study participants of saline and midazolam treatment groups on the basis of observed adverse or intra-operative events.

DISCUSSION

Most of the patients coming for cataract surgery belong to the geriatric age group. In the current study majority of the cataract surgery patients belong to the age group 55 to 64 years of age group; this was in accordance to the report published by Gollogly et al.[20] Current study finding also revealed that there was not much correlation between body weight of the patient and cataract but revealed that male patients undergoing cataract surgery outnumbered female patients; this observation was in accordance to the study report published by Song et al.[21]

The anxiety levels of patients undergoing cataract surgery are often observed to be high which in turn not only affects haemodynamic parameters like SAP, DAP and HR of patients; but may also lead to restlessness of patients resulting into movement of patients during surgery which can be a substantial disturbing factor for the surgeon. In a study conducted and published by Cok et al in 2008 it was reported that midazolam alone may produce optimal block conditions for the patients which was satisfactory during the cataract surgical procedure.[22] Cok et al also reported that heart rate values significantly reduced after the block in both the groups who received the treatment of midazolam alone or midazolam in combination with fentanyl.[22]

The findings of Cok et al were in close agreement to current study findings which reveal the decrease in hemodynamic parameters like HR, SAP and DAP among patients who received midazolam.

Cok et al also reported that sedation score and alertness significantly decreased in patients of both the groups after the block.[22] Habib et al in 2004 reported midazolam as commonly used benzodiazepine for sedation and amnesia.[23] Katz et al in 2000 studied and reported that amnesic effect of midazolam might affect assessment of pain and help the patients to forget the unpleasant feelings associated with surgery.[24] The current study findings which was an extension of study established and observed in the previously published reports.

The current study finding not only reports the effect of midazolam on hemodynamic parameters and sedation but it also addresses the assessment of level of patient and surgeon satisfaction during cataract surgery. The inference of the current study findings is that the satisfaction levels of patients who underwent cataract surgery and surgeons who performed cataract surgery after receiving midazolam after block was higher than the satisfaction levels of patients who did not receive midazolam or the surgeons operating on patients who were not given midazolam. These current study findings closely resemble the study findings published by Cok et al, Kost et al and Alhashemi et al.[25,26]

Limitations

Limitation of the current study was the relative small sample size of the study population, which was not adequate to make concrete recommendations.

CONCLUSION

It was concluded from current study findings that sedation with midazolam along with reterobulbar block provides hemodynamic conditions favourable for cataract surgery. Sedation with midazolam also increases the satisfaction levels of both surgeons and patients performing or undergoing cataract surgery. Midazolam reduces anxiety levels of patients without exhibiting any significant side effects in post-operative phase.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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