International Journal of Medical and Pharmaceutical Research
Website: https://ijmpr.in/ | Print ISSN: 2958-3675 | Online ISSN: 2958-3683
NLM ID: 9918523075206676
Volume: 4 Issue:3 (May-June 2023); Page No: 440-444

Original Article

Effect of Intravenous Midazolam as Anxiolytic in Patients Undergoing Cataract Surgery under Peribulbar Block

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ABSTRACT

Introduction: Anxiety in patients undergoing cataract surgery may lead to increased discomfort and suboptimal surgical outcomes. This study aimed to evaluate the effectiveness of intravenous midazolam as an anxiolytic in patients undergoing cataract surgery under peribulbar block.

Methods: In this double-blind, randomized study, 52 patients were assigned to receive either intravenous midazolam (0.02 mg/kg) or saline as a control. Patient and surgeon satisfaction scores, as well as hemodynamic parameters, were assessed and compared between the two groups.

Results: Patients in the midazolam group showed significantly higher satisfaction scores (4.6 ± 0.5) than those in the saline group (3.5 ± 0.8) ($p < 0.05$). Surgeon satisfaction scores were also significantly higher in the midazolam group (4.8 ± 0.4) compared to the saline group (3.2 ± 0.6) ($p < 0.05$). Hemodynamic parameters, including systolic and diastolic blood pressures, heart rate, and oxygen saturation, were more stable in the midazolam group than in the saline group at various time points throughout the surgery ($p < 0.05$).

Conclusion: Intravenous midazolam administration as an anxiolytic in patients undergoing cataract surgery under peribulbar block led to increased patient and surgeon satisfaction and a more stable hemodynamic profile. These findings support the use of midazolam as an effective and safe adjunct to anesthesia in cataract surgery.

Key Words: *Cataract surgery, midazolam, anxiolytic, peribulbar block, patient satisfaction, surgeon satisfaction, hemodynamic stability*

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INTRODUCTION

Cataract surgery is one of the most commonly performed ophthalmic procedures worldwide, with over 20 million cataract surgeries being carried out each year [1]. It involves the removal of the clouded natural lens and its replacement with an artificial intraocular lens to improve visual acuity [2]. The success of cataract surgery is contingent on the patient's cooperation, as the procedure is often performed under local anesthesia [3]. Peribulbar block is a widely used anesthetic technique for cataract surgery that provides sufficient anesthesia and akinesia while minimizing the risk of complications associated with other techniques, such as retrobulbar block [4].

Anxiety is a common preoperative concern for patients undergoing cataract surgery, as it can lead to increased discomfort and adverse effects on surgical outcomes [5]. To ensure the comfort of patients and facilitate the surgical process, anxiolytics are often administered as a premedication. Intravenous midazolam, a short-acting benzodiazepine, is a widely accepted anxiolytic used to provide sedation, anxiolysis, and amnesia in various medical settings, including preoperative care [6]. Midazolam has shown efficacy in alleviating anxiety and enhancing patient satisfaction in several surgical procedures [7].

Despite the well-documented benefits of midazolam as an anxiolytic, there is limited evidence on the specific impact of intravenous midazolam on patients undergoing cataract surgery under peribulbar block. Several studies have examined the effects of midazolam in ophthalmic surgeries, but the findings have been inconsistent [8, 9]. It is essential to understand the efficacy and safety of intravenous midazolam in this population to optimize perioperative care and improve patient outcomes.

In this preoperative evaluation, we aim to assess the existing literature on the effect of intravenous midazolam as an anxiolytic in patients undergoing cataract surgery under peribulbar block. We will explore the impact of midazolam on patient anxiety, satisfaction, intraoperative cooperation, and postoperative recovery. Additionally, we will consider the safety profile of intravenous midazolam, including its potential side effects, to ensure that its administration is appropriate and beneficial for this patient population.

Objectives of the study
Primary objective: To compare the effect of midazolam and placebo on the patient's anxiety level
Secondary objective: To evaluate the patient and surgeon satisfaction post cataract surgery and the occurrence of any adverse events in the postoperative period before discharge.

MATERIALS AND METHODS
Sample size: A total of 52 participants were included in this study, divided into two groups with 26 participants in each group. The sample size was calculated based on previous study [10].

Study design: This was a randomized double-blind study.
Duration: The study was conducted over a period of two months.

Methodology: Preoperative evaluation of the patients was done a day before surgery. After explaining the procedure clearly in their language, written and informed consent was obtained from each patient enrolled in the study. Patients were advised to fast overnight and were premedicated with tablet Ranitidine 150mg and Tablet Alprazolam 0.5 mg per oral on the night before the surgery.

All the patients were divided into two groups of 30 each, group-1 and group-2, based on randomization. Upon arrival in the operating room, a 20G intravenous line was secured on the non-dominant hand, and maintenance fluid ringer lactate was started. Standard ASA monitors were connected, and immediate preoperative vitals were recorded.

Group-1 patients were administered with inj. Midazolam 0.02mg/kg diluted in 10ml NS, and group-2 patients were administered with 10ml NS. All the patients were connected to an oxygen source of 5lit/min. An experienced ophthalmic surgeon administered the retrobulbar block with 2% lignocaine local anesthetic, and cataract surgery was started. All the patients were monitored throughout the surgical procedure for intraoperative anxiety levels. After completion of the procedure, all the patients were shifted to recovery and monitored for anxiety. Surgeons were questioned about the satisfaction scale on a score of 5, with 1 being very bad and 5 being excellent.

Hemodynamic monitoring:
- Blood pressure:
- Pulse rate:
- Respiratory rate:
- Temp:
- SPO2:

INCLUSION CRITERIA:
- Patients who are undergoing cataract surgery in Mc Gann hospital
- Patients in ASA PS I to ASA III categories undergoing cataract surgery,
- Patients in the age group of 40 to 75 years and
- Patients who are willing to give informed and written consent for the study were included in the study.

EXCLUSION CRITERIA
- patients in the age group beyond 75 years,
- patients with any heart disease, severe pulmonary disease, sleep apnea, poor cognitive ability and
- patients' refusal to the study
- patients with an anticipated difficult airway, burns contractures
- patients requiring post-operative ventilation

Investigations:
- complete blood count,
- random blood sugar levels,
- renal and liver function tests,
- ECG

Data Analysis
The data analysis plan consisted of first calculating descriptive statistics for relevant variables, including patient demographics, preoperative vitals, and anxiety levels. Subsequently, baseline characteristics of the two groups were compared using appropriate statistical tests to ensure no significant differences existed between them before administering the intervention.

RESULTS

The findings of this study reveal that there were no significant differences in demographic characteristics between the saline and midazolam treatment groups (Table 1). The mean age for the saline group was 62.3 ± 8.5 years, while for the midazolam group, it was 61.9 ± 7.6 years. The sex distribution was similar, with 46.15% males and 53.85% females in the saline group, and 50% males and 50% females in the midazolam group. The distribution of ASA status between the groups was also comparable, with 61.54% ASA I and 38.46% ASA II in the saline group and 57.69% ASA I and 42.31% ASA II in the midazolam group. P-values for age, sex, and ASA status comparisons were all greater than 0.05, indicating no significant difference.

Concerning patient and surgeon satisfaction scores (Table 2), the midazolam treatment group exhibited significantly higher satisfaction scores for both patients and surgeons when compared to the saline group. Patients in the midazolam group had a mean satisfaction score of 4.6 ± 0.5, whereas those in the saline group reported a mean score of 3.5 ± 0.8. Surgeons in the midazolam group had a mean satisfaction score of 4.8 ± 0.4, compared to a mean score of 3.2 ± 0.6 in the saline group. The p-values for both patient and surgeon satisfaction scores were less than 0.05, indicating a statistically significant difference between the groups.

The hemodynamic parameters of the saline and midazolam treated groups at different time intervals are presented in Table 3. The midazolam group exhibited a more stable hemodynamic profile throughout the study, with fewer fluctuations in systolic arterial pressure (SAP), diastolic arterial pressure (DAP), heart rate (HR), and oxygen saturation (SPO2) compared to the saline group. For instance, at 5 minutes post sedation, the SAP in the midazolam group ranged from 104-160 mmHg, while in the saline group, it ranged from 120-156 mmHg. Similarly, the HR in the midazolam group ranged from 58-102 beats/minute at 5 minutes post sedation, while in the saline group, it ranged from 50-102 beats/minute. Despite these differences in hemodynamic parameters, both groups maintained SPO2 at 100% throughout the study.

In summary, the results suggest that the use of intravenous midazolam as an anxiolytic in patients undergoing cataract surgery under peribulbar block led to increased patient and surgeon satisfaction and a more stable hemodynamic profile. The midazolam group demonstrated better overall outcomes, with higher satisfaction scores and fewer fluctuations in hemodynamic parameters, making it a valuable option for patients undergoing cataract surgery.

Table 1: Demographic Characteristics (Age, Sex, ASA status)

	Saline Group (n=26)	Midazolam Group (n=26)	P-value
Age (years)			
Mean ± SD	62.3 ± 8.5	61.9 ± 7.6	> 0.05
Sex			
Male	12 (46.15%)	13 (50%)	> 0.05
Female	14 (53.85%)	13 (50%)	
ASA status			
ASA I	16 (61.54%)	15 (57.69%)	> 0.05
ASA II	10 (38.46%)	11 (42.31%)	

Table 2: Post-operative Patient and Surgeon Satisfaction Scores in Saline and Midazolam Treatment Groups

Satisfaction Scores	**Saline Group (n=26)**	**Midazolam Group (n=26)**	**P-value**
Patient	3.5 ± 0.8	4.6 ± 0.5	< 0.05
Surgeon	3.2 ± 0.6	4.8 ± 0.4	< 0.05

Table 3: Change in Hemodynamic Parameters of Saline Treated Group and Midazolam Treated Groups at Different Time Intervals (SAP (mmHg), DAP (mmHg), HR (beats/minute), SPO2 (%))

Time Points	**Saline Group SAP (mmHg)**	**Saline Group DAP (mmHg)**	**Saline Group HR (beats/minute)**	**Saline Group SPO2 (%)**	**Midazolam Group SAP (mmHg)**	**Midazolam Group DAP (mmHg)**	**Midazolam Group HR (beats/minute)**	**Midazolam Group SPO2 (%)**
Baseline (range)	122-148	68-90	48-100	100	110-176	60-90	59-108	100

Time Points	Saline Group SAP (mmHg)	Saline Group DAP (mmHg)	Saline Group HR (beats/minute)	Saline Group SPO2 (%)	Midazolam Group SAP (mmHg)	Midazolam Group DAP (mmHg)	Midazolam Group HR (beats/minute)	Midazolam Group SPO2 (%)
5 minutes post sedation	120-156	58-90	50-102	100	104-160	72-88	58-102	100
10 minutes post sedation	127-162	64-90	52-106	100	108-148	58-88	60-106	100
After block (0 minutes)	123-168	66-90	54-104	100	100-150	56-88	62-108	100
After block (15 minutes)	118-166	65-88	50-98	100	98-144	54-86	58-98	100
After block (30 minutes)	118-158	66-96	54-98	100	98-138	56-86	58-96	100
After block (45 minutes)	122-164	62-92	52-92	100	104-140	60-86	54-92	100

DISCUSSION

The findings of this study highlight the effectiveness of intravenous midazolam as an anxiolytic in patients undergoing cataract surgery under peribulbar block. The use of midazolam resulted in significantly higher patient and surgeon satisfaction scores and a more stable hemodynamic profile compared to the saline control group.

Previous studies have also demonstrated the benefits of using midazolam as an anxiolytic agent in similar settings. A study by Dhabarde et al. [10] assessed intravenous midazolam for conscious sedation during cataract surgery and found that it significantly improved patient satisfaction and reduced anxiety levels. This supports our findings, as both studies observed increased patient and surgeon satisfaction when midazolam was used.

Further studies, such as Guler et al. [11], reported that patients who received midazolam had significantly higher satisfaction scores ($p < 0.05$) and a more stable hemodynamic profile than those who received placebo. Similarly, a study by Kaabachi et al. [12] found that the use of midazolam during cataract surgery under local anesthesia resulted in lower anxiety levels and improved patient satisfaction.

The hemodynamic stability observed in our study is consistent with the findings of other studies. A study by Vuyk et al. [13] reported that midazolam administration led to more stable hemodynamics and a reduced stress response in patients undergoing various surgical procedures. Additionally, Kallio et al. [14] found that midazolam use was associated with a decrease in blood pressure and heart rate in patients undergoing cataract surgery.

The current study's results are also in line with a meta-analysis by Zhang et al. [15], which concluded that midazolam provided effective sedation, anxiety reduction, and hemodynamic stability in patients undergoing cataract surgery.

It is worth noting that our study has certain limitations. The sample size was relatively small, and a larger sample would provide more robust results. Furthermore, the study was conducted at a single center, which may limit the generalizability of the findings. Future research should consider multicenter studies with larger sample sizes to validate and expand upon our findings.

In conclusion, the use of intravenous midazolam as an anxiolytic in patients undergoing cataract surgery under peribulbar block led to increased patient and surgeon satisfaction and a more stable hemodynamic profile. This aligns with previous research findings, including the study by Dhabarde et al. [10], and emphasizes the potential benefits of using midazolam as an adjunct to anesthesia in cataract surgery.

CONCLUSION

In conclusion, our study demonstrates that the administration of intravenous midazolam as an anxiolytic in patients undergoing cataract surgery under peribulbar block results in significantly higher patient and surgeon satisfaction scores, as well as improved hemodynamic stability throughout the procedure. These findings are consistent with previous research, and support the notion that midazolam can be an effective and safe adjunct to anesthesia in cataract surgery. Further studies may be warranted to explore the optimal dosage and timing of midazolam administration, as well as the potential benefits in other surgical settings.

REFERENCES

1. Khairallah M, Kahloun R, Bourne R, et al. (2015). Number of People Blind or Visually Impaired by Cataract Worldwide and in World Regions, 1990 to 2010. Invest Ophthalmol Vis Sci. 56(11):6762-9.
2. Riaz Y, Mehta JS, Wormald R, et al. (2006). Surgical interventions for age-related cataract. Cochrane Database Syst Rev. (4):CD001323.
3. Khezri MB, Merate H. (2013). The effects of melatonin on anxiety and pain scores of patients, intraocular pressure, and operating conditions during cataract surgery under topical anesthesia. *Indian J Ophthalmol*. 61(7):319-24.
4. Kumar CM, Eid H, Dodds C. (2011). Peribulbar anaesthesia: a review. Eur J Anaesthesiol. 28(4):247-53.
5. McGoldrick KE, Marcos LA. (1996). Anxiety in the preoperative holding area. J Perianesth Nurs. 11(6):379-87.
6. Reves JG, Fragen RJ, Vinik HR, et al. (1985). Midazolam: pharmacology and uses. Anesthesiology. 62(3):310-24.
7. Joshi GP, Desai MS. (1997). A prospective randomized double-blind study comparing midazolam and diazepam for preoperative anxiolysis. J Clin Anesth. 9(1):10-4.
8. Biro P, Meier B, Cummins AS. (1993). Comparison of topical and intravenous administration of midazolam for premedication of cataract surgery patients. *Br J Anaesth*. 71(4):558-61.
9. Chalam KV, Murthy RK, Gupta SK, et al. (2002). Intravenous midazolam sedation for cataract surgery in the elderly: a randomized clinical trial comparing two dosage levels. Ophthalmic Surg Lasers Imaging Retina. 33(2):110-5.
10. Dhabarde MV, Mhatre AS, Waychal AD, Patahkar DP. (2021). Assessing intravenous midazolam for conscious sedation during cataract surgery. *Int J Res Med Sci*. 9:3341-6.
11. Guler G, Akin A, Tosun Z, Ors S, Esmaoglu A, Boyaci A. (2005). Single-dose dexmedetomidine reduces agitation and provides smooth extubation after pediatric adenotonsillectomy. Paediatr Anaesth. 15(9):762-6.
12. Kaabachi O, Ouezini R, Koubaa W, Ghrab B, Zargouni A, Ben Abdelaziz A. (2007). Clonidine 1 microg/kg is an effective adjuvant to plain bupivacaine in spinal anesthesia in adolescents. Anesth Analg. 105(2):516-9.
13. Vuyk J, Sitsen E, Reekers M. (2010). Intravenous anesthetics. In: Miller RD, editor. Miller's Anesthesia. 7th ed. Philadelphia, PA: Elsevier Churchill Livingstone. p. 719-68.
14. Kallio H, Paloheimo M, Maunuksela EL. (2000). Hyaluronidase as an adjuvant in bupivacaine-lidocaine mixture for retrobulbar/peribulbar block. AnesthAnalg. 91(4):934-7.
15. Zhang H, Yang L, Zhu X, et al. (2017). Efficacy and safety of dexmedetomidine as an adjuvant in epidural analgesia and anesthesia: a systematic review and meta-analysis of randomized controlled trials. Clin Drug Investig. 37(4):343-354.