A Prospective Randomized Study Comparing Ketamine - Propofol vs Midazolam - Propofol sedation in Elective Cataract Surgeries done under Peribulbar Block

Aduru Krishnamurthy[1], A.C. Malarvizhi[2]

ABSTRACT

Introduction: Cataract surgery, a common surgery in elderly population is often considered as a low risk procedure. A well informed, calm, cooperative patient makes the surgery comfortable for them as well as surgeon. Study aims were to compare two sedation methods Ketamine- Propofol vs Midazolam- Propofol in elective cataract surgeries done under peribulbar block.

Material and Methods: 100 patients aged 50-75 years were enrolled in this study. Routine preoperative work up was done. Peribulbar block was given in the eye to be operated which was followed by sedation. Group one recieved sedation with Propofol 0.5mg/kg followed by Ketamine 0.5mg/kg. Group two received sedation with propofol 0.5mg/kg followed by midazolam 0.05 mg /kg. Complications during the procedure and recovery was recorded. Patient sedation was assessed using modified ramsay score and discharge from recovery using modified Alderti score. Five point Likert scale was used to assess patient satisfaction post op.

Results: Group one had much patient satisfaction than group two in cataract surgeries On the contrary, the complications and time of discharge was more in group one than two.

Conclusion: Ketamine/propofol sedation coupled with eye block provided ideal comfortable surgical experience for the patients though the complications and discharge time were more. On the other hand the Propfol/ Midazolam group had lesser complications but more uncomfortable for the patients.

Keywords: Sedation, Cataract, Ketamine, Midazolam, Propofol

INTRODUCTION

Cataract surgery is the most common eye surgery in the elderly.[1] They are quick outpatient procedures with minimal blood loss and postoperative pain. Since the patient group predominantly involves the older population,risk factors are high. For immobility of the eye and profound anaesthesia during eye surgeries various techniques like topical anaesthesia, regional blocks, with or without sedation have been developed.[2] Some discomfort and anxiety are usually associated with many of the regional blocks.[3] Supplementation with intravenous sedation and continuous patient monitoring are frequently preferred,though intravenous sedation also may be associated with increased incidence of medical events.[4] Regional anaesthesia is often preferred over general anaesthesia as it gives significant postoperative analgesia and nausea and vomiting are infrequent.[5,6,7] The patient can return to ambulation faster. General anaesthesia is often reserved for highly uncooperative patients. A combination of midazolam (0.5 to 1 mg), fentanyl (12.5 to 50 µg), and propofol (30 to 50 mg) provides excellent amnesia and sedation for the placement of the blocks.[8,9] For peribulbar block, a 1 : 1 ratio of bupivacaine 0.5% and lidocaine 2% without epinephrine s used.[10] Hyaluronidase is added to speed tissue penetration.[11] The drugs which are commonly used in conscious sedation are propofol, ketamine and midazolam. Propofol is an alkyl phenol and most commonly used intravenous agent.[12,13] Ketamine at a dose of 0.2-0.8mg/kg as a single IV bolus can produce sedation. Ketamine possessing, hypnotic as well as analgesic properties, is also bronchodilator,and when combined with propofol can produce additive sedation.[14,15,16] Midazolam is higly lipid soluble benzodiazepine due to its imidazole ring. Midazolam combined with propofol can accentuate the sedative effects.[17,18]

Study aimed to compare Ketamine -Propofol vs Midazolam-Propofol sedation methods in elective cataract surgeries done under peribulbar block.

MATERIAL AND METHODS

This study was conducted in Department of Anaethesiology Tagore Medical College and Hospital affliated to The Tamilnadu Dr.M.G.R Medical university. After IEC approval, the study was initiated for a period of one year. Informed consent was obtained from all in regional language.

Inclusion criteria: Unilateral cataract surgery,ASA 1-3patients, elective cases, fasting patients, surgeries done under peribulbar block.

Exclusion criteria: ASA > 4,uncooperative patients, surgeries done under other blocks or General anaesthesia. 100 patients aged 50-75 years were enrolled in this study. Routine preoperative work up including complete blood count, renal function test, coagulation profile, ECG, X ray

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chest, Echocardiogram was done in all patients. All patients recieved night sedation with alprazolam 0.5mg at 10pm the day before surgery. Overnight fasting from 10pm was followed in all patients. All the surgeries was performed electively in forenoon session.

After confirming fasting status IV access was obtained using 20G intracath. Routine monitors like ECG,NIBP, Pulse Oximetry was connected. Oxygen was delivered by nasal cannula at 4l/minute. Glycoprolate 0.2mg IV was given to all patients. The patient, they were divided into groups randomly. Peribulbar block was given in eye to be operated and was followed by sedation. Group one received sedation with Propofol 0.5mg/kg followed by ketamine 0.5mg/kg. Group two received sedation with propofol 0.5mg/kg followed by midazolam 0.05 mg /kg. Patient sedation was assessed using modified Ramsay scale after 5 minutes of sedation (table-1). For cataract surgeries RSS score > 3 was considered as adequate sedation.[19,20] Surgery was initiated and most of the surgeries got over within 30 minutes. If patients were not adequately sedated RSS <2, incremental doses of propofol was given as boluses IV in both the groups and the average propofol dose in mg/kg was calculated in each group.

Level of response	Ramsay sedation scale
1	Patient is anxious and agitated or restless, or both
2	Patient is co-operative, oriented, and tranquil
3	Patient responds to commands only
4	Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
5	Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6	Patient response exhibits no response

Table-1: Modified Ramsay Sedation scale

Variables	Demographic data	
	Group A (N=49)	Group B (N=49)
Age (years) mean±SD	64.1±21	65.2±15
Sex (M/F) mean±SD	22/27	24/25
Weight(KG) mean±SD	57±14	59±17
Height(CM)) mean±SD	155±5	156±6
ASA status 1	22	18
2	18	20
3	9	11

Table-2: Comparison of Demographic data

Intra operatively, heart rate, blood pressure, saturation was monitored regularly at every 5 minute intervals. Intra operative complications like bradycardia. tachycardia, hypertension, fall in saturation was taken as significant if >20% of base line value and was considered as minor complications. Cardiac arrest, apnoea and laryngospasm was considered as major complications.All complications were noted and intervened immediately. The completion of procedure without major complication was considered as success rate of sedation.

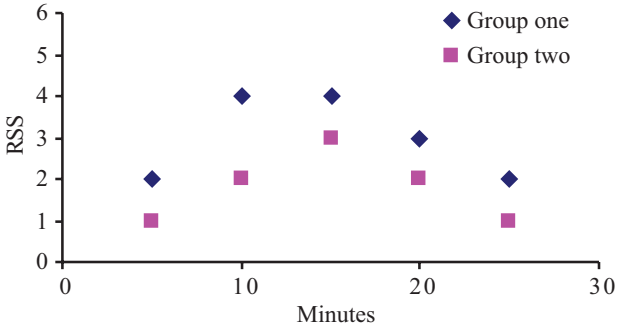
After the procedure, patients were then shifted to recovery from the operative room.The modified Alderti score which is determined by scoring from 0 to 10 according to patients activity, saturation, consciousness, respiration and circulation[21,22] was used for discharge from recovery. Patients with a score of >9 was shifted to ward from recovery. The time between end of surgery to shifting to ward (recovery time) was noted. Complications during recovery like nausea, vomiting, dizziness, headache, delirium was recorded. After the patients were shifted to ward, a blinded resident assessed the patient's satisfaction of surgery using five point Likert scale[23] after an hour.

STATISTICAL ANALYSIS

The results were tabulated and statistical analysis was done. All qualitative data was expressed as means ± SD and compared using student's paired t test. All Categorical data was expressed as % and compared with Pearson's chi squared test (x^2 test). A *P* value of < 0.05 was considered statistically significant.

RESULTS

Out of 100 patients included in this study 2 patients were excluded because they were not fasting. The rest of the 98 patients who have consented for the study were evaluated. There was no statistically significant difference in age,



Graph-1: Comparison of Sedation Scores

Parameters		Group One (N=49)	Group Two (N=49)	P Value
Average profopol dose (MG/KG)	Mean±SD	0.7±0.145	0.83±.149	0.0510
Duration of surgery (MIN)	Mean±SD	25±3	26±2.5	0.0762
Adequate sedation score (RSS >2)	N%	49(100%)	39(79.59%)	0.0012
Recovery time (MIN)	Mean±SD	35.08±22	25.22±18	0.170
Complications during procedure	N%	15(30.6%)	6(10.20%)	0.0473
Complications recovery	N%	10(20.40%)	2 (4.08%)	0.0275
Average likert scale	Mean±SD	2.33±1.18	3.53±0.83	0.0255

Table-3: Evaluation of patients during and after procedure

weight, height and sex between both groups (table-2). The physical status grading was also similar in both the groups. The ASA status in group A and B were as follows ASA 1 (22,18), ASA 2 (18, 20), ASA 3 (9,11) which was insignificant.

In group one (PK n=49), 15 patient had intra operative complications which included hemodyamic instability which included bradycardia, tachycardia, hypertension and drop in saturation (>20% variability from baseline). Out of 15, three patient had bradycardia inspite of premedication with IV glycopyrolate. This was treated symptomatically. 5 patients had blood pressure measurements of DBP > 98mmof hg. In these patients increments of IV Propofol was given as bolus to decrease the blood pressure. Four patients developed tachycardia which didn't require any intervention. Three patients had saturation drop up to 95% with nasal cannula. None of the patients saturation dropped below that (graph-1). Hence average propofol dose used in this group along with ketamine is 0.7±0.145mg/kg. In group two, four patients developed hemodynamic changes. One patient had tachycardia due to anxiety which settled with additional dose of 20mg IV Propofol. Three patients had DBP> 95mm of hg with responded to Propofol boluses IV. Saturation was well maintained in all patients except two were it dropped to 95%. Complications during the procedure was significant between the groups (*P* value 0.047).

Most of patients in group one had RSS of 3 and 4 and none of the patients were deeply sedated (>5). 25 patients had RSS of 4, 15 had RSS of 3, 9 had RSS of 2. In group two, 20 patients had RSS of 3, 12 patients had RSS of 2 and 17 patients had RSS of 1. All these 17 patients required additional propofol incremental dose IV to deepen sedation. Hence the average propofol dose in group 2 is 0.83±0.149 mg/kg which was insignificant between the groups. The average duration of surgery between the groups was similar.

Complications in recovery was statistically significant between both the groups. (*P* value 0.0275). Five patients had vomiting in spite of propofol being used, two had headache, one had dizziness, and two had delirium. All these patients were monitored closely in recovery all settled spontaneously. In group two, only two patients had vomiting and none reported headache, dizziness or delirium. The saturation was maintained >95% in both groups. The average discharge time from recovery using modified alderti score was 35.08±0.22 minutes in group one and 25.22±18 minutes in group two which was insignificant.Patient satisfaction was assessed using five point Likert scale which was 2.33±1.18 in group one and 3.53±0.83 in group two which was significant (*P* value 0.025) (table-3).

DISCUSSION

Sedation for the patients undergoing cataract surgical procedures during local/regional anesthesia balances both goals of patient comfort with safety and an optimal outcome. According to Hug "the required doses of analgesic an sedative hypnotic drugs are proportional to the intensity of noxious stimulation".[24] Therefore, the type of surgical procedure and the local anesthetic technique used as well as patients' co morbidities will determine the sedation techniques to be used. With the increased use of topical anesthesia for cataract surgeries the need for traditional injection eye blocks (i.e., peribulbar and retrobulbar blocks) has decreased. Since these blocks can be uncomfortable to patients when compared to topical anesthesia the role of sedation becomes crucial.[25,26] In our centre we routinely use peribulbar block for all cataract surgerie hence we attempted to compare two sedation methods, and which was comfortable for the patients during the procedure.

With the increased prevalence of cataract extraction by phaco emulsification has led to decreased use of injection eye blocks and more use of topical anesthesia or in combination. The type of block used, alters the sedation requirements due to patient or surgical difficulties.[27] Patients undergoing cataract surgery under topical anesthesia have been found to have more intra operative and postoperative discomfort than those given a sub-Tenon block.[28] The retrobulbar and peribulbar blocks result in equivalent levels of pain control, which are superior to that of topical anesthesia. It has been reported that additional sedation or analgesia was required intra operatively more often in patients having topical anesthesia versus retrobulbar block.[29,30] The use of injection blocks was associated with lower systolic blood pressures, even in hypertensive patients, as compared with topical anesthesia.[30]

Similarly the surgeons have reported better surgical conditions in patients during retrobulbar or peribulbar blocks as compared with topical anesthesia.[31] There was strong evidence that globe akinesia is equivalent in retrobulbar and peribulbar techniques. They found weak evidence that the pain on injection retrobulbar blocks > peribulbar blocks > sub-Tenon block.[32] As far as intraoperative pain is concerned, they found strong evidence that retrobulbar blocks result in far less surgical pain than topical anesthesia, moderate evidence that peribulbar blocks result in less pain than topical anesthesia, and weak evidence that sub-Tenon block patients experience less pain than those who have topical anesthesia.[33] When 98 patients under went bilateral cataract surgery 1 week apart with differing anesthesia techniques for each eye, topical versus peribulbar/retrobulbar block, 70 patients preferred peribulbar/retrobulbar, 10 patients preferred topical (all had topical anesthesia for the first eye), and 18 patients indicated no preference.[34] Hence due to the above mentioned reasons, we chose to do this study in surgeries done only under peribulbar block.

Various drugs have been tried and used for conscious sedation in cataract surgeries. Commonly used drugs are Propofol, Midazolam, Ketamine, Fentanyl and Dexmetedomidine. Habib et al, reported in his study that single bolus dose of propofol before peribulbar block reduced recall without major side effects or without airway support.[13] Propofol at a dose of 0.5mg/kg can produce sedation as well has a antiemetic effect also. Ketamine is a complete anesthestic, and at a dose of 0.2-0.8mg/kg as a single IV bolus can produce sedation.[14] Ketamine as a bronchodilator,and when

combined with propofol can produce adequate sedation.[15] Midazolam is higly lipid soluble benzodiazepine due to its imidazole ring.It is a short acting drug used for sedation, anxiolysis, amnesia.A dose of 0.02mg/kg as a single IV bolus dose was used as sedation in roup two. Midazolam combined with propofol can accentuate the sedative effect.[14] Since propofol is in common use, we evaluated the dose of propofol needed to produce aqequate sedation scores (RSS >2), in combination with ketamine in group one and midazolam in group two.

Sedation analgesia for eye blocks, is not without complications. According to the American of Anesthesiologists Closed Claim database, patient movement during ophthalmologic surgery was the second most common cause of eye injury associated with anesthesia, all of which resulted in blindness.[35,36] Three quarters of patients injured during sedation received a combination of two or more drugs.[17]

Among a large cataract surgery population (n _19,250) in a study of nine eye centers, only 26% of surgeries were accomplished with topical anesthesia, and the remainder with injection blocks.[38] The use of short-acting hypnotics during injection blocks increased the incidence of adverse events when used solely (1.4%) or when combined with opioids (1.75%), sedatives (2.65%), or both (4.04%).[39] The Agency for Healthcare Research and Quality evidence report found only weak evidence that sedation improved anxiety control, pain relief, or patient satisfaction.[40] There was insufficient evidence that any class of sedative agent was associated with improved outcome over other agents. The authors remarked that surgeon specific factors such as duration of surgery might greatly influence the outcomes. changes in the surgical techniques, the need for anesthesia care for eye surgery is increasingly being questioned.

In a retrospective review of 270 cataract operations monitored by registered nurses at Consultations were required more frequently for patients with American Society of Anesthesiologists physical status III (16%) as compared with American Society of Anesthesiologistsphysical status II (3.3%). The most common reasons for consultations were electrocardiogram interpretation (10cases) and help with intravenous catheter placement (5cases).[41,42]

Perhaps the utilization of anesthesia care during ophthalmologic surgery can be justified solely by the improvement of patient and surgeon satisfaction. In a study conducted by Friedman et al, the patients were given theoretical choices of eye anesthesia (topical *vs.* block) and types of sedation (intravenous vs oral) with estimations of expected pain, side effects, and recovery time. Patients chose the combination of oral sedation and injection block over topical anesthesia and intravenous sedation, although this regimen is used infrequently in most practices.[31]

The Agency for Healthcare Research and Quality's extensive review of the literature discovered a high level of patient satisfaction with anesthesia care regardless of sedation strategy or the local anesthesia technique.[40]

This study had many limitations, as sedation scores was compared only in surgeries done under peribulbar block. Patients literacy played an important factor which was not included. Patients who have already undergone cataract surgery previously without sedation, using a different block technique may have affected the results. Surgeon's feedback would have helped us but not included.

CONCLUSION

Newer surgical procedures and the increasing popularity of topical anesthesia have altered the need for the anesthesist, presence for cataract surgeries.In this study, Ketamine/ propofol sedation coupled with eye block provided ideal comfortable surgical experience for the patients though the complications during surgery, recovery, longer discharge time was observed. On the other hand the Propfol/ Midazolam group had more recall, which was uncomfortable for the patients though complications were less.

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