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Effect of Oral Melatonin (6 mg) Premedication in Cataract Surgery Under Anaesthetic Eye Block

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Abstract
Background: Cataract surgery, though commonly performed under regional anesthesia, is associated with significant preoperative anxiety and discomfort. Traditional sedatives like benzodiazepines may cause undesirable side effects. Melatonin, a natural neurohormone, has shown promise as a premedication due to its anxiolytic and analgesic properties with minimal adverse effects.
Objective: To evaluate the effect of 6 mg oral melatonin premedication on anxiety levels, analgesia, and intraocular pressure (IOP) in patients undergoing cataract surgery under anesthetic block.
Methods: In this randomized, placebo-controlled trial, 40 patients scheduled for small incision cataract surgery (SICS) under anesthetic block were divided into two groups: Group M (melatonin 6 mg orally) and Group C (placebo), with 20 patients each. State-Trait Anxiety Inventory (STAI) scores, vital signs, and IOP were recorded pre- and postoperatively. Pain was assessed using the Visual Analog Scale (VAS). Statistical analysis was performed on collected data.
Results: Group M showed a significant reduction in postoperative STAI scores at 1 hour (39.5 ± 4.8) and at 24 hours (35.0 ± 4.0) compared to Group C (43.0 ± 5.2 and 41.0 ± 5.1 respectively). Pain scores were also lower in the melatonin group. Hemodynamic parameters and IOP were comparable between groups. No significant adverse effects were reported.
Conclusion: Oral melatonin (6 mg) is an effective premedication for reducing anxiety and improving comfort in cataract surgery under anesthetic block, with a favorable safety profile.
Keywords: Melatonin, cataract surgery, regional anesthesia, anxiety, analgesia, intraocular pressure, STAI, premedication.

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I. Introduction

Cataract surgery is the most commonly performed ophthalmic procedure, often under regional anesthesia. While regional techniques provide good operating conditions and patient cooperation, many patients experience significant preoperative anxiety and intraoperative discomfort. Traditional sedatives like benzodiazepines, although effective, may impair psychomotor function and REM sleep.

Melatonin, an endogenous neurohormone involved in sleep regulation, has anxiolytic, analgesic, and antioxidant properties, with fewer sedative drawbacks. This study investigates the efficacy of 6 mg oral melatonin as a premedicant to reduce anxiety, improve analgesia, and maintain stable intraocular pressure (IOP) in cataract surgery.

II. Methodology

Study Design and Population
This randomized, placebo-controlled clinical study was conducted at Akash Institute of Medical Sciences and Research Center, Bengaluru. After ethical clearance and informed consent, 40 patients scheduled for SICS under anesthetic block were randomized into:
- Group M (Melatonin): Received 6 mg oral melatonin
- Group C (Control): Received placebo

Inclusion Criteria
- Scheduled for elective cataract surgery
- Age as per institutional inclusion norms
- ASA Physical Status I–II

Exclusion Criteria
- History of hypersensitivity to melatonin
- Patients on chronic sedative or antidepressant therapy
- Severe systemic comorbidities

Anesthetic Technique and Monitoring
After baseline STAI scores and vitals were recorded, patients received the study drug or placebo with multivitamins. Patients were monitored for HR, BP, MAP, and SpO_2 every 30 minutes pre- and postoperatively. Surgery was performed under anesthetic block. IOP in the non-operated eye was recorded premedication, preoperatively, and postoperatively.

Outcome Assessments
- Anxiety levels (STAI) at baseline, 1 hour, and 24 hours
- Pain (VAS score) postoperatively
- Hemodynamic parameters
- Intraocular pressure (IOP)
- Adverse effects

Outcome Measures
- Change in STAI anxiety scores
- Pain scores (VAS) postoperatively
- IOP comparison pre- and post-surgery
- Hemodynamic stability
- Safety and adverse events

III. Results

Demographic data (age, gender, weight, comorbidities) and surgery duration were comparable between the two groups (Table 1). Hemodynamic parameters were stable and not significantly different (Table 2).

Anxiety Reduction (STAI Scores)
Melatonin group showed significantly lower STAI scores at 1 hour (39.5 ± 4.8) and 24 hours (35.0 ± 4.0) vs. control (43.0 ± 5.2, 41.0 ± 5.1; $p < 0.05$, Table 3).

Pain Scores
VAS scores were lower in the melatonin group, though not numerically specified.

IOP
No significant differences in intraoperative IOP between groups.

Adverse Effects
Minimal in both groups. Melatonin was well-tolerated.

Table 1 – Demographic Comparison

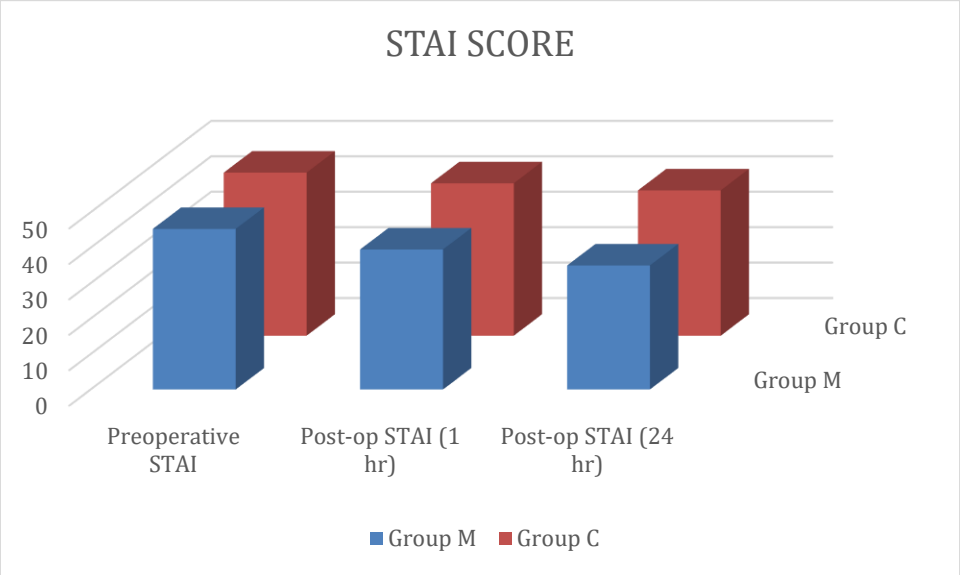
Parameter	**Group M (n=30)**	**Group C (n=30)**	**p-value**
Age (years)	68.5 ± 7.3	69.1 ± 6.9	0.65
Gender (M:F)	04:06	05:05	0.85
Weight (kg)	70.2 ± 10.1	69.8 ± 9.7	0.78
Comorbidities	30% (Diabetes)	28% (Diabetes)	0.87

Table 2 – Hemodynamic Parameters

Parameter	**Group M**	**Group C**	**p-value**
Baseline HR	75.5 ± 2.0	75.7 ± 2.1	0.82
Post-op HR	72 ± 6	73 ± 7	0.65
Systolic BP (mmHg)	120 ± 10	121 ± 12	0.68
Diastolic BP (mmHg)	75 ± 8	76 ± 9	0.71

Table 3 – STAI Score Comparison

Time Point	Group M	Group C	p-value
Preoperative STAI	45.3 ± 5.5	46.0 ± 5.8	0.63
Post-op STAI (1 hr)	39.5 ± 4.8	43.0 ± 5.2	0.02
Post-op STAI (24 hr)	35.0 ± 4.0	41.0 ± 5.1	0.01



IV. Discussion

Melatonin, as demonstrated in this study, provides effective anxiolysis and analgesia in cataract surgery. Compared to traditional agents like benzodiazepines, melatonin has a safer profile with minimal sedation and no significant effect on hemodynamic parameters. These findings align with prior research by Yousaf et al., Khezri et al., Naguib et al., and Sane et al., supporting melatonin's role in perioperative care.

The absence of significant changes in IOP and hemodynamics suggests that melatonin can be safely used without compromising ocular physiology or systemic stability. Moreover, its oral administration improves patient compliance and feasibility in outpatient settings.

Limitations

- Small sample size
- Single-center study
- IOP values not statistically significant
- Pain scores not comprehensively detailed

V. Conclusion

Oral melatonin (6 mg) is an effective, safe, and well-tolerated premedication for cataract surgery under anesthetic block. It significantly reduces anxiety, improves pain perception, and ensures hemodynamic stability, enhancing the perioperative experience without adverse effects.

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