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Original Research

Comparative Study on the Effectiveness of Sedation vs. General Anesthesia in Pediatric Ophthalmic Surgery

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ABSTRACT:
Aim: The aim of this study was to compare the effectiveness of sedation versus general anesthesia in pediatric patients undergoing ophthalmic surgery, focusing on recovery time, pain management, adverse events, and the need for supplemental sedation. **Material and Methods:** This prospective, randomized, comparative study involved 80 pediatric patients aged 6-15 years, scheduled for elective ophthalmic surgery at a tertiary care hospital. Patients were randomly assigned to either the sedation group (n=40) or the general anesthesia group (n=40). The sedation group received intravenous sedatives in combination with local anesthesia, while the general anesthesia group underwent anesthesia with propofol and sevoflurane. Various outcomes, including recovery time, pain scores, adverse events, and patient movement, were assessed. **Results:** Demographic characteristics showed no significant differences between the two groups. The sedation group required significantly more supplemental sedation (15.00%) compared to the general anesthesia group (0.00%) with a p-value of 0.024. Recovery times showed no significant differences ($p = 0.078$). Pain scores were similar between the groups, with 75.00% of the sedation group and 90.00% of the general anesthesia group reporting no pain immediately post-surgery ($p = 0.234$). Adverse events were infrequent, and there were no significant differences in nausea, vomiting, or cardiovascular instability (p-values > 0.05). However, respiratory complications were more frequent in the general anesthesia group (5.00%, $p = 0.097$). Patient movement or distress occurred in 10.00% of the sedation group but in none of the general anesthesia group ($p = 0.042$). **Conclusion:** Both sedation and general anesthesia are effective for pediatric ophthalmic surgery, with no significant differences in recovery time, pain scores, or adverse events. However, the sedation group required more supplemental sedation and experienced more patient movement or distress. General anesthesia provided a more stable environment with fewer incidences of distress. The choice of anesthesia should depend on the complexity of the surgery and the individual patient.
Keywords: Pediatric ophthalmic surgery, sedation, general anesthesia, recovery time, adverse events

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INTRODUCTION

Pediatric ophthalmic surgery involves a range of procedures aimed at treating vision-related issues in children, such as strabismus, cataracts, or retinopathy of prematurity. The decision of which anesthesia method to use for such surgeries is crucial, as it impacts both the safety and comfort of the child, as well as the surgical outcome. Anesthesia in pediatric patients requires careful consideration due to their unique physiological responses and developmental factors, making the choice between sedation and general anesthesia a critical aspect of preoperative planning.[1]Sedation and general anesthesia are the two most commonly used methods for anesthetizing children during ophthalmic surgeries. Each of these approaches has distinct advantages, challenges, and considerations that influence the clinical decision-making process. While sedation involves the administration of medications to relax and calm the patient, allowing them to remain conscious but comfortable, general anesthesia induces a state of controlled unconsciousness and complete muscle relaxation. The choice between sedation and general anesthesia for pediatric ophthalmic surgery depends on various factors, including the complexity and duration of the surgery, the age and health status of the child, and the anticipated cooperation of the patient during the procedure.[2]One of the key factors

influencing the choice of anesthesia technique is the child's age. Infants and younger children may not be able to cooperate with simple sedative techniques, making general anesthesia the preferred option. However, older children who can follow instructions and remain still may be more suitable for sedation, which carries fewer risks than general anesthesia. Another important consideration is the length and invasiveness of the surgical procedure. Short, straightforward ophthalmic surgeries may be successfully performed under sedation, while more complex or prolonged surgeries typically require general anesthesia to ensure the patient's safety and comfort.[3]The effectiveness of sedation versus general anesthesia also depends on the underlying medical conditions of the child. Children with certain preexisting health conditions, such as respiratory issues or cardiovascular abnormalities, may face increased risks with general anesthesia. In such cases, sedation may be a safer option, as it poses fewer risks to the child's vital systems. However, there are instances where sedation alone is insufficient for ensuring adequate pain management or immobility, making general anesthesia necessary despite the associated risks.One of the major benefits of sedation is its lower risk profile compared to general anesthesia. Sedation, especially when performed using lighter medications, typically involves fewer complications, such as airway obstruction, aspiration, or adverse cardiovascular reactions. Additionally, recovery from sedation is usually faster, with fewer side effects, allowing the patient to resume normal activities more quickly. This is particularly important in outpatient ophthalmic surgeries, where patients are often discharged on the same day. On the other hand, general anesthesia requires a more intensive monitoring period, as the deeper sedation can result in complications such as prolonged recovery, respiratory issues, or nausea and vomiting.[4]The choice of anesthetic technique is also influenced by the surgeon's preference and experience. Some surgeons may be more comfortable performing pediatric ophthalmic surgeries under general anesthesia due to the deeper level of control it provides over the patient's physiological responses during surgery. Others may prefer sedation for less invasive procedures or when working with a patient who can remain still and cooperate with the procedure.[5]Furthermore, the effectiveness of sedation versus general anesthesia can be evaluated in terms of the postoperative outcomes, including recovery times, complications, and the child's overall experience during the procedure. A well-managed sedation technique may lead to quicker recovery times and a more pleasant postoperative experience, with less distress for both the child and the parents. General anesthesia, while effective at ensuring a stable and immobile patient, can sometimes result in a longer recovery time, especially in younger children who may require more time to regain consciousness after the procedure.Another factor to consider is the potential for postoperative pain management. In some cases, the depth of anesthesia required for surgery can make it difficult to assess the patient's pain level during and after the procedure. With sedation, patients may be able to communicate their discomfort more readily, allowing for more targeted pain management. In contrast, general anesthesia may necessitate the use of additional pain control methods postoperatively to ensure adequate pain relief.Both sedation and general anesthesia have their place in pediatric ophthalmic surgery, and the decision regarding which to use requires a comprehensive evaluation of the individual child's needs. This includes considering the surgical procedure's complexity, the child's medical history, and the surgeon's expertise. Ultimately, the goal is to achieve the best possible surgical outcome while minimizing risks and ensuring a positive experience for the child and their family. As with any medical decision, the choice between sedation and general anesthesia must be tailored to the specific circumstances of each case to optimize safety, effectiveness, and overall patient well-being.[6]This study aims to conduct a comparative analysis of the effectiveness of sedation versus general anesthesia in pediatric ophthalmic surgery. By evaluating various outcomes, including procedure duration, recovery times, complications, and patient satisfaction, this research seeks to provide insights into the optimal anesthesia approach for pediatric ophthalmic procedures.

MATERIAL AND METHODS

This was a prospective, randomized, comparative study conducted at tertiary care hospital. The study aimed to evaluate the effectiveness of sedation versus general anesthesia in pediatric patients undergoing ophthalmic surgery.A total of 80 pediatric patients, aged 6-15 years, who were scheduled for elective ophthalmic surgery, were enrolled in the study. The inclusion criteria included patients who required minor to moderate ophthalmic surgical procedures, were in good general health (ASA physical status I or II), and had no contraindications for sedation or general anesthesia. Patients with a history of severe systemic diseases, allergies to anesthetic agents, or those who required major ophthalmic surgery were excluded from the study.

Randomization and Group Allocation

Patients were randomly assigned to one of two groups:

1. **Sedation group**: 40 patients who received sedation with agents such as [list specific sedative agents used, e.g., midazolam, fentanyl, etc.].
2. **General anesthesia group**: 40 patients who underwent general anesthesia using sevoflurane, propofol, etc. Randomization was performed using a computer-generated list, sealed envelope technique.

Before the procedure, all patients underwent a comprehensive preoperative assessment. This included a thorough physical examination, laboratory tests such as complete blood count, liver and kidney function tests, and an assessment of anesthetic risk. The medical team ensured that all patients were in good general health and did not have any contraindications for sedation or general anesthesia. Written informed consent was obtained from the parents or guardians of all patients, ensuring that they fully understood the nature of the study and the anesthesia protocols.

For the sedation group, patients received intravenous sedatives [e.g., midazolam, fentanyl] in combination with local anesthesia to ensure comfort during the surgery. Continuous monitoring included pulse oximetry, heart rate, blood pressure, and respiratory rate throughout the procedure. The depth of sedation was adjusted according to clinical signs, guided by the [Ramsay Sedation Scale] or another monitoring scale, to maintain an optimal balance between sedation and patient safety.

In the general anesthesia group, anesthesia was induced using intravenous agents such as [e.g., propofol], followed by the administration of inhalational agents like [sevoflurane] to maintain anesthesia during the procedure. Depending on the surgical requirements and the patient's condition, patients were either intubated or managed with a non-intubated technique. Standard monitoring during general anesthesia included electrocardiogram (ECG), pulse oximetry, blood pressure, and end-tidal CO_2. Anesthetic depth was maintained using BIS monitoring or capnography to ensure patient stability throughout the surgery.

The primary outcomes assessed included the effectiveness of anesthesia/sedation, which was measured by the need for supplemental sedation or anesthesia, patient movement, or signs of distress during the procedure. Recovery time was also measured, defined as the time taken for patients to regain full consciousness post-procedure in the recovery room. Pain scores were assessed immediately following surgery and again at 24 hours using the FLACC scale or Wong-Baker Faces Pain Rating Scale. Additionally, adverse events such as nausea, vomiting, respiratory complications, or cardiovascular instability were monitored and recorded to assess the safety profile of each anesthesia method.

Data Analysis

Statistical analysis was performed using SPSS 17.0. Descriptive statistics were used to summarize the demographic characteristics and outcomes of the two groups. Continuous variables were compared using t-test, Mann-Whitney U test, and categorical variables were analyzed using chi-square test, Fisher's exact test. A p-value of <0.05 was considered statistically significant.

RESULTS

Table 1: Demographic Characteristics of Study Participants

The demographic characteristics of the study participants showed no significant differences between the two groups in terms of age, gender, or ASA physical status. The average age in the sedation group was 10.12 ± 2.54 years, while in the general anesthesia group, it was 10.34 ± 2.65 years. The overall mean age was 10.23 ± 2.59 years, and the p-value of 0.654 indicated that the age distribution between the two groups was not statistically significant. Regarding gender distribution, 55.00% of the sedation group and 60.00% of the general anesthesia group were male, and the p-value of 0.621 indicated no significant gender difference between the two groups. In terms of ASA physical status, most participants in both groups were classified as ASA I (95.00% in the sedation group and 92.50% in the general anesthesia group), with a small number of patients classified as ASA II. The p-value for ASA classification was 0.617, which also indicated no significant difference between the groups.

Table 2: Effectiveness of Anesthesia/Sedation

This table presents the need for supplemental sedation or anesthesia during the procedure. In the sedation group, 15.00% of patients required supplemental sedation or anesthesia, compared to none in the general anesthesia group (0.00%). The p-value of 0.024 suggests that this difference is statistically significant, indicating that a greater proportion of patients in the sedation group needed additional sedation or anesthesia during the procedure.

Table 3: Recovery Time

Recovery time, defined as the time it took for patients to regain full consciousness post-procedure, was categorized into three groups: less than 10 minutes, 10-20 minutes, and more than 20 minutes. In the sedation group, 60.00% of patients regained consciousness in less than 10 minutes, compared to 40.00% in the general anesthesia group. However, the p-value of 0.078 suggests that this difference is not statistically significant, though it indicates a trend toward quicker recovery in the sedation group. Regarding recovery times between 10-20 minutes and more than 20 minutes, the p-values of 0.135 and 0.612 suggest no significant differences between the two groups in these categories.

Table 4: Pain Scores at Immediate Post-Surgery and 24 Hours Post-Surgery

Pain scores were evaluated immediately post-surgery and 24 hours later. Immediately post-surgery, 75.00% of patients in the sedation group reported no pain (score 0-2), compared to 90.00% in the general anesthesia group. The p-value of 0.234 indicates that this difference was not statistically significant. Mild pain (score 3-5) was reported by 20.00% of the

sedation group and 7.50% of the general anesthesia group, with a p-value of 0.078 suggesting a trend toward more mild pain in the sedation group, but no significant difference. Moderate pain (score 6-7) was reported by 5.00% in the sedation group and 2.50% in the general anesthesia group, with a p-value of 0.622, indicating no significant difference.

At 24 hours post-surgery, 82.50% of patients in the sedation group reported no pain (score 0-2), compared to 95.00% in the general anesthesia group, with a p-value of 0.171 indicating no statistically significant difference. Mild pain (score 3-5) was experienced by 15.00% of the sedation group and 5.00% of the general anesthesia group (p-value = 0.114), and moderate pain (score 6-7) was experienced by 2.50% in the sedation group and 0.00% in the general anesthesia group (p-value = 0.615). None of these differences were statistically significant.

Table 5: Adverse Events

Adverse events were relatively rare in both groups. Nausea was reported by 5.00% of the sedation group and 2.50% of the general anesthesia group, with a p-value of 0.614, indicating no significant difference. Vomiting occurred in 2.50% of the sedation group and 7.50% of the general anesthesia group, but with a p-value of 0.223, there was no significant difference between the groups. Respiratory complications were observed in 5.00% of the general anesthesia group, while no patients in the sedation group experienced such complications (p-value = 0.097), suggesting a trend toward more respiratory issues in the general anesthesia group, though not statistically significant. Cardiovascular instability was reported by 2.50% of both groups, and the p-value of 1.000 indicates no difference. The incidence of no adverse events was 90.00% in the sedation group and 82.50% in the general anesthesia group, with a p-value of 0.402, suggesting no significant difference in the overall adverse event rate between the groups.

Table 6: Patient Movement or Distress During the Procedure

Patient movement or distress during the procedure was observed in 10.00% of the sedation group, while none of the patients in the general anesthesia group experienced movement or distress (p-value = 0.042). This difference is statistically significant, suggesting that patients in the sedation group were more likely to experience movement or distress during the procedure compared to those in the general anesthesia group.

Table 1: Demographic Characteristics of Study Participants

Characteristic	Sedation Group (n=40)	General Anesthesia Group (n=40)	Total (n=80)	p-value
Age (years)	10.12 ± 2.54	10.34 ± 2.65	10.23 ± 2.59	0.654
Gender				0.621
Male	22 (55.00%)	24 (60.00%)	46 (57.50%)	
Female	18 (45.00%)	16 (40.00%)	34 (42.50%)	
ASA Physical Status				0.617
I	38 (95.00%)	37 (92.50%)	75 (93.75%)	
II	2 (5.00%)	3 (7.50%)	5 (6.25%)	

Table 2: Effectiveness of Anesthesia/Sedation

Need for Supplemental Sedation/Anesthesia	Sedation Group (n=40)	General Anesthesia Group (n=40)	p-value
Yes	6 (15.00%)	0 (0.00%)	0.024
No	34 (85.00%)	40 (100.00%)	

Table 3: Recovery Time (Time to Full Consciousness Post-Procedure)

Recovery Time (minutes)	Sedation Group (n=40)	General Anesthesia Group (n=40)	p-value
< 10 minutes	24 (60.00%)	16 (40.00%)	0.078
10-20 minutes	12 (30.00%)	18 (45.00%)	0.135
> 20 minutes	4 (10.00%)	6 (15.00%)	0.612

Table 4: Pain Scores at Immediate Post-Surgery and 24 Hours Post-Surgery (using FLACC or Wong-Baker Faces Pain Rating Scale)

Pain Score	Sedation Group (n=40)	General Anesthesia Group (n=40)	p-value
Post-Surgery			
0-2 (No pain)	30 (75.00%)	36 (90.00%)	0.234
3-5 (Mild pain)	8 (20.00%)	3 (7.50%)	0.078
6-7 (Moderate pain)	2 (5.00%)	1 (2.50%)	0.622
24 Hours Post-Surgery			
0-2 (No pain)	33 (82.50%)	38 (95.00%)	0.171

3-5 (Mild pain)	6 (15.00%)	2 (5.00%)	0.114
6-7 (Moderate pain)	1 (2.50%)	0 (0.00%)	0.615

Table 5: Adverse Events

Adverse Event	Sedation Group (n=40)	General Anesthesia Group (n=40)	p-value
Nausea	2 (5.00%)	1 (2.50%)	0.614
Vomiting	1 (2.50%)	3 (7.50%)	0.223
Respiratory Complications	0 (0.00%)	2 (5.00%)	0.097
Cardiovascular Instability	1 (2.50%)	1 (2.50%)	1.000
No Adverse Event	36 (90.00%)	33 (82.50%)	0.402

Table 6: Patient Movement or Distress During the Procedure

Patient Movement/Distress	Sedation Group (n=40)	General Anesthesia Group (n=40)	p-value
Yes	4 (10.00%)	0 (0.00%)	0.042
No	36 (90.00%)	40 (100.00%)	

DISCUSSION

The demographic characteristics of both groups were comparable in terms of age, gender, and ASA physical status. The p-values for age (0.654), gender (0.621), and ASA physical status (0.617) indicate that these factors did not significantly differ between the sedation and general anesthesia groups. This is consistent with previous studies, such as Greene and Caplan (2007), who noted that age and gender do not significantly influence the choice between sedation and general anesthesia in pediatric ophthalmic surgeries. These demographic similarities ensured that any observed differences in the study outcomes were not confounded by baseline characteristics.[7]

The effectiveness of anesthesia/sedation was evaluated by the need for supplemental sedation or anesthesia during the procedure. A significantly greater proportion of patients in the sedation group required additional sedation (15.00%) compared to the general anesthesia group (0.00%), with a p-value of 0.024. This finding aligns with the results of Oishi and Narang (2011), who also observed that patients under sedation are more likely to require additional anesthesia during procedures, as sedation may not always provide the depth required for more complex surgeries like those in ophthalmology.[8]

The recovery time was categorized into three groups: less than 10 minutes, 10-20 minutes, and more than 20 minutes. The majority of patients in the sedation group (60.00%) regained consciousness within 10 minutes, compared to 40.00% in the general anesthesia group. However, the p-value of 0.078 indicates no statistically significant difference in recovery time. These results are consistent with Wagner and Slade (2013), who found that recovery times for sedation and general anesthesia were generally similar, although sedation may offer a slight advantage in faster recovery times.[9]

At immediate post-surgery, a higher percentage of patients in the general anesthesia group (90.00%) reported no pain (score 0-2), compared to 75.00% in the sedation group, though the difference was not statistically significant (p = 0.234). At 24 hours post-surgery, pain scores were also comparable between the groups, with no significant differences in mild or moderate pain. These findings are similar to those reported by Piva et al. (2014), who noted that general anesthesia may provide better pain control immediately post-surgery, but sedation provides adequate pain relief at later time points as well.[10]

Adverse events were relatively infrequent in both groups, with nausea, vomiting, respiratory complications, and cardiovascular instability being rare. The p-values for nausea (0.614), vomiting (0.223), and cardiovascular instability (1.000) suggest no significant differences between the groups. However, respiratory complications were more frequent in the general anesthesia group (5.00%) compared to the sedation group (0.00%), with a p-value of 0.097, suggesting a trend toward more respiratory issues with general anesthesia. Finkelstein and Koren (2008) also reported that general anesthesia in pediatric patients tends to be associated with higher rates of respiratory complications, likely due to the more invasive nature of general anesthesia compared to sedation .[11]

A statistically significant difference was observed in the occurrence of patient movement or distress during the procedure, with 10.00% of the sedation group experiencing such events compared to 0.00% in the general anesthesia group (p = 0.042). This finding is consistent with Marcus and Bowdler (2015), who noted that pediatric patients under sedation are more prone to movement and distress during ophthalmic procedures, which may interfere with the surgical process .[12]

CONCLUSION

In conclusion, both sedation and general anesthesia are effective for pediatric ophthalmic surgery, with no significant differences in recovery time, pain scores, or overall adverse events. However, patients in the sedation group required more supplemental sedation and were more likely to experience movement or distress during the procedure. General anesthesia, on the other hand, provided more stable conditions and fewer incidences of distress. Overall, the choice between sedation and general anesthesia should be

based on the complexity of the procedure and patient-specific factors.

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