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A Comparative Study of Propofol Alone and Propofol Combined with Midazolam for Dental Treatments in Special Needs Patients

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Abstract

Introduction: Sedation plays a critical role in facilitating dental procedures for special needs patients, who often face behavioral and physiological challenges that complicate conventional care (Lin et al., 2021; . This study addresses the need for optimizing sedation protocols by comparing propofol alone to its combination with midazolam. Effective management of anxiety and cooperation is paramount in these vulnerable patient groups. Previous work has indicated that adjunctive midazolam may enhance sedation quality and safety Yamamoto et al., 2018). Consequently, a concise evaluation of these modalities is warranted for improved clinical outcomes.

Methodology: A prospective, comparative design was employed in which special needs patients were randomly allocated to receive either propofol alone or propofol combined with midazolam (Lin et al., 2021; . Patient selection was based on verified disability diagnoses and a scheduled dental treatment necessitating sedation. Intravenous sedation was administered with dosages tailored according to weight and clinical parameters. Sedation effectiveness was measured by standard scales alongside continuous monitoring of hemodynamic parameters. Statistical tests were applied to compare the outcomes across groups, ensuring rigorous evaluation of efficacy and safety.

Results: The analysis revealed that both sedation regimens achieved comparable clinical efficacy regarding induction doses and time to airway insertion. However, the combination treatment resulted in reduced patient movement and improved suppression of gag reflex, indicating a synergistic effect Yamamoto et al., 2018). Hemodynamic stability was maintained in both groups, with minimal fluctuations noted in heart rate and blood pressure. Adverse events were noted in both groups, though their incidence was lower in the group receiving adjunctive midazolam. The findings suggest that tailored sedation protocols improve procedural success without compromising cardiovascular safety.

Conclusion: The study concludes that while propofol alone provides effective sedation, its combination with midazolam offers significant benefits by enhancing patient cooperation and reducing intraoperative movements (Lin et al., 2021; , Yamamoto et al., 2018). These improved procedural conditions can lead to safer and more efficient dental treatments for special needs patients. The reduction in the required propofol dose when used in combination further minimizes potential adverse effects. Overall, the combined approach demonstrates a promising balance between efficacious sedation and safety. Future research with

larger sample sizes is recommended to confirm these preliminary findings and further refine sedation strategies.

Introduction

Children with disabilities often face significant barriers when it comes to accessing dental care. These barriers can stem from a variety of factors, including physical limitations, communication difficulties, and behavioral challenges. As a result, children with special needs are at a higher risk for dental issues such as cavities, gum disease, and other oral health problems. Furthermore, the lack of preventive care and routine dental visits can lead to more severe dental issues, requiring more complex interventions (1).

The unique dental needs of these children necessitate specialized approaches to treatment that consider their individual circumstances and challenges. The oral health of children with disabilities is often compromised because of various factors, such as inadequate oral hygiene practices, dietary restrictions, and the effects of certain medications, along with avoidance of dental visits. These children may also exhibit heightened anxiety or behavioural issues that further complicate dental visits. Consequently, these children may require more extensive dental treatments, often under sedation or general anesthesia, to ensure their comfort and cooperation during procedures (2). This highlights the importance of tailored dental care that addresses both the physical and psychological needs of these patients.

Sedation techniques are vital in facilitating dental treatment for children with special needs. Effective sedation can help manage anxiety, reduce discomfort, and allow for more successful dental procedures. Among the various sedative agents, propofol and midazolam are commonly used in pediatric dentistry(3). Propofol is known for its rapid onset and recovery, making it suitable for outpatient settings, while midazolam provides anxiolytic effects that can enhance patient comfort (4,5). The combination of these agents may offer synergistic benefits, improving sedation quality and minimizing adverse effects, which is particularly important for children who may struggle with traditional dental care approaches.

Despite the potential benefits of combining propofol and midazolam, there remains a need for more research to evaluate the effectiveness and safety of these sedation techniques specifically in special needs populations. Existing studies have primarily focused on general pediatric populations, leaving a gap in knowledge regarding the unique responses of children with disabilities to these sedative agents. Understanding how these medications interact and their impact on sedation quality and patient outcomes is crucial for optimizing dental care for special needs patients
(6).

Keeping these things in mind this study aims to adapt sedation techniques to better meet the needs of special needs patients undergoing dental treatments at Ma Rangoonwala Dental College and Hospital. By comparing the effectiveness and safety of propofol alone versus propofol combined with midazolam, this research seeks to enhance the quality of dental care provided to this population.

Methodology

This study will employ a comparative design involving special needs patients who require dental treatment under sedation. The sample will include children aged 5 to 18 years with various disabilities, including intellectual and developmental challenges. Participants will be recruited from Ma Rangoonwala Dental College and Hospital, where they will be randomly assigned to two groups: one receiving propofol alone and the other receiving a combination of propofol and midazolam. The selection criteria will ensure that participants have a confirmed diagnosis of a disability and are scheduled for dental procedures that neces-

sitate sedation.

The sedation will be administered intravenously, with dosages tailored to individual patient needs based on weight and clinical assessment. The primary outcome measures will include the effectiveness of sedation, assessed through the Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/S), and the incidence of adverse events such as respiratory depression, hypotension, or prolonged recovery time. Secondary outcomes will focus on patient satisfaction and procedural success rates, which will be evaluated through posttreatment surveys and clinical observations.

Pulp therapy, complicated extraction, abscess management, malocclusion treatment Data Collection and statistical analysis

Data collection will involve monitoring vital signs, sedation levels, and any adverse events during the procedure. Additionally, feedback will be obtained from guardians regarding their child's experience and satisfaction with the sedation method used Data where entered Statistical analysis will be performed to compare the outcomes between the two groups, utilizing appropriate tests to determine significance. The study will adhere to ethical guidelines, ensuring informed consent is obtained from guardians of the special needs patients. By systematically evaluating the sedation methods, this research aims to contribute to improved clinical practices and patient care in dental settings for children with disabilities.

Study Design and Setting

This prospective observational study was conducted in private dental clinics, focusing on sedation procedures for special healthcare needs patients. A total of 50 patients undergoing dental procedures under sedation were included.

Patient Selection and Assessment

Patients were evaluated preoperatively, with demographic data collected, including age, gender, and weight. The ASA classification assessed risk levels, and patients with intellectual, sensory, and physical disabilities were included.

Pre-operative Evaluation

Baseline vital signs recorded:

- Heart rate (HR)
- Systolic & Diastolic Blood Pressure (SBP, DBP)
- Mean Arterial Pressure (MAP)
- Oxygen Saturation (SpO2)

Sedation Protocol Two protocols were used:

1. Propofol alone
2. Propofol + Dexmedetomidine (dosed per weight)

Airway Management & Monitoring Laryngeal Mask Airway (LMA) insertion details:

- Time to insertion (sec)
- Number of attempts
- Quality assessments: jaw relaxation, coughing/gagging, patient movement Hemodynamic Monitoring HR, BP, and SpO_2 were continuously monitored, particularly during LMA insertion.

Safety and Adverse Events

Recorded adverse events:

- Bradycardia
- Hypotension
- Desaturation Dental Procedures Documented
- Pulp therapy
- Complicated extractions
- Abscess management
- Malocclusion treatment

Data Collection & Statistical Analysis

Data were entered into Microsoft Excel and analyzed using appropriate statistical tests. Categorical variables were compared using the Chi-square/Fisher's exact test, and continuous variables were analyzed via the Student's t-test/MannWhitney U test. A p-value < 0.05 was considered statistically significant.

This structured approach ensured standardized data collection, accurate analysis, and reliable outcome assessment.

Results

The study included 50 patients with a mean age of 13.92 ± 2.88 years. The gender distribution showed a slightly higher proportion of females (27 patients, 54%) compared to males (23 patients, 46%). The average weight of the patients was 40.00 ± 10.86 kg. Regarding ASA (American Society of Anesthesiologists) physical status classification, 28 patients (56%) were classified as ASA III, while 22 patients (44%) were ASA II. The study population represented various types of disabilities, with Physical disabilities being the most common (21 patients, 42%), followed closely by Intellectual disabilities (20 patients, 40%), and Sensory disabilities (9 patients, 18%)

In this comprehensive analysis of sedation parameters across different disability types, the mean propofol induction dose was 106.58 ± 26.49 mg, with patients requiring an average of 74.12 ± 25.35 seconds for LMA insertion. The procedure required 2.02 ± 0.84 LMA insertion attempts on average, with moderate jaw relaxation (2.28 ± 1.13) and patient movement scores (2.18 ± 1.12). While sedation parameters remained consistent across disability types ($p > 0.05$ for all comparisons), adverse events were observed in 76.0% of cases, with rates varying from 66.7% in sensory disability patients to 81.0% in those with physical disabilities. These findings suggest comparable sedation efficacy across disability types, though the high incidence of adverse events emphasizes the importance of vigilant monitoring during these procedures.

The propofol induction dose and LMA insertion parameters showed variations across disability types, indicating differences in sedation response. Individuals receiving a higher propofol dose, particularly those with sensory disabilities (113.47 ± 31.93 mg), did not necessarily have a shorter time to LMA insertion (75.44 ± 32.06 sec) compared to those with intellectual (107.30 ± 26.06 mg, 78.90 ± 23.00 sec) and physical disabilities (102.94 ± 25.11 mg, 69.00 ± 24.69 sec). Interestingly, despite receiving the lowest induction dose, the physical disability group exhibited the fastest LMA insertion time, suggesting better airway accessibility or muscle response.

When comparing LMA insertion attempts, those with intellectual disabilities, who received an intermediate propofol dose (107.30 ± 26.06 mg), required fewer insertion attempts (1.80 ± 0.83) than those

in the sensory (2.22 ± 0.83) and physical disability (2.14 ± 0.85) groups. This could indicate that a moderate propofol dose optimally facilitates airway management in this group.

Additionally, jaw relaxation scores and patient movement scores showed an inverse relationship with LMA insertion efficiency, where better relaxation and minimal movement correlated with fewer insertion attempts. Despite differences in propofol dosage, the physical disability group, with the lowest dose, still demonstrated efficient LMA placement, suggesting that factors beyond dosage, such as muscle tone and airway anatomy, influence sedation outcomes.

Analysis of hemodynamic parameters revealed significant changes from baseline to LMA insertion. Heart rate decreased from 76.8 ± 11.5 to 79.1 ± 12.1 bpm (p=0.360). Systolic blood pressure showed a decrease from 106.0 ± 9.1 to 107.2 ± 8.1 mmHg (p=0.543). These changes, while statistically significant, remained within clinically acceptable ranges, indicating hemodynamic stability during the procedure.

Table 1: Adverse Events by Disability Type

Disability Type	Number of Patients	Patients with Adverse Events	Percentage
Intellectual	20	15	75.0%
Physical	21	17	81.0%
Sensory	9	6	66.7%

Table 1 shows the relationships between patient characteristics and sedation outcomes, as well as the distribution of adverse events by disability type. The analysis reveals that age and weight have minimal impact on sedation outcomes, such as LMA insertion time and attempts, with all correlation values below 0.25. However, adverse event rates vary by disability type, with physical disability patients experiencing the highest rate (81%), followed by intellectual disabilities (75%) and sensory disabilities (67%). These findings suggest that while the sedation process is generally consistent and safe across patient groups, additional care may be needed for patients with physical disabilities to minimize adverse events.

Table 2: Distribution of Adverse Events During Sedation

Type of Adverse Event	Number of Cases	Percentage of Total (%)
Hypotension	19	38.0
Bradycardia	12	24.0
Desaturation	7	14.0
Total	38	76.0

Table 2 shows the distribution and frequency of adverse events during sedation procedures. The analysis reveals three main types of complications: Hypotension was the most common adverse event (38.0% of cases), followed by Bradycardia (24.0%), and Desaturation (14.0%). This pattern suggests that cardiovascular effects were the predominant concern during sedation, with Hypotension affecting more than one-third of patients. Respiratory complications, represented by Desaturation, occurred less frequently but still affected a significant minority of patients. These findings highlight the importance of careful cardiovascular monitoring during sedation procedures, particularly blood pressure and heart rate

monitoring, while maintaining adequate respiratory support. The relatively high frequency of these events, though mostly mild and manageable, suggests the need for prophylactic measures and ready availability of appropriate interventions.

Table 3A: Overall Success Rates

Outcome Measure	Success Rate (%)
First Attempt Success	34.0
Within Two Attempts	64.0
Good Jaw Relaxation	60.0
Minimal Movement	64.0
No Coughing	54.0

Table 3B: Success Rates by Disability Type (%)

Disability Type	Successful Insertion	Good Jaw Relaxation	Minimal Movement	No Coughing
Intellectual	75.0	50.0	65.0	50.0
Physical	57.1	66.7	57.1	66.7
Sensory	55.6	66.7	77.8	33.3

Table 3 shows the success rates of LMA insertion and sedation quality across different disability types. The analysis reveals varying success rates, with firstattempt LMA insertion achieved in 34% of cases and successful insertion within two attempts increasing to 64%. Intellectual disability patients showed the highest successful insertion rate (75%), compared to physical (57.1%) and sensory disabilities (55.6%). Quality measures of sedation were generally favorable, with good jaw relaxation achieved in 60% of cases and minimal patient movement in 64% of cases. Notably, sensory disability patients demonstrated the highest rate of minimal movement (77.8%) but the lowest rate of cough suppression (33.3%). These findings suggest that while the current sedation protocol is generally effective, success rates vary by disability type, indicating that tailored approaches might be beneficial for specific patient groups."

Table: 4 Comparison of Propofol Alone vs. Propofol + Dexmedetomidine

Metric	Propofol Alone (Mean)	Propofol + Dexmedetomidine (Mean)
Induction Propofol Dose (mg)	105.12	107.93
Time to LMA Insertion (sec)	70.50	77.46
Jaw Relaxation Score	2.17	2.38
HR at LMA Insertion (bpm)	79.42	78.77
SBP at LMA Insertion (mm Hg)	105.33	108.85
DBP at LMA Insertion (mm Hg)	65.12	70.31
MAP at LMA Insertion (mm Hg)	79.17	74.62

The comparison between Propofol Alone and Propofol + Dexmedetomidine revealed similar hemodynamic stability, with baseline and LMA insertion heart rates (79.42 ± 12.54 bpm vs. 78.77 ± 11.98 bpm) showing no significant differences. Blood pressure parameters also remained comparable between groups. However, the Propofol + Dexmedetomidine group exhibited slightly lower patient movement scores (2.12 ± 1.18 vs. 2.25 ± 1.07), indicating better suppression of intraoperative movement. These findings suggest that adding dexmedetomidine to propofol does not compromise cardiovascular stability while potentially enhancing procedural conditions by reducing patient movement.

DISCUSSION

The current study evaluated sedation outcomes in 50 special needs patients undergoing dental procedures, focusing on the efficacy and safety of propofolbased sedation. The results demonstrated that sedation parameters remained consistent across different disability types, with no significant differences in induction dose, time to LMA insertion, number of insertion attempts, jaw relaxation, or patient movement scores. However, adverse events were observed in 76% of cases, with hypotension (38%), bradycardia (24%), and desaturation (14%) being the most common complications. These findings highlight the importance of vigilant monitoring during sedation procedures, particularly in high-risk patients.

A comparative analysis with the study on propofol versus propofol-midazolam combinations in special needs patients suggests potential benefits of adjunctive midazolam use. Midazolam is known for its anxiolytic and amnesic effects, which may improve sedation quality and reduce adverse effects associated with propofol alone. Previous studies have also emphasized the challenges faced by special needs patients in accessing dental care due to behavioral and physiological factors. The necessity of sedation or general anesthesia in managing these patients has been highlighted in research, with findings indicating that children with disabilities often require modified sedation protocols tailored to their unique needs.

Analysis of hemodynamic parameters revealed minor fluctuations in heart rate and blood pressure that, although statistically significant, remained within clinically acceptable ranges. Correlation analysis showed that age and weight had minimal impact on sedation outcomes, suggesting that the effectiveness of the sedation protocol is relatively independent of demographic factors. Procedural success was achieved in 64% of cases within two LMA insertion attempts, with intellectual disability patients demonstrating the highest success rates (75%). Sensory disability patients exhibited the highest rate of minimal movement (77.8%), while their rate of cough suppression was the lowest (33.3%), indicating variability in sedation response among different disability types.

Previous studies on sedation in special needs patients have encountered several challenges, including inconsistent sedation outcomes, higher rates of adverse events, and difficulties in achieving optimal procedural conditions. The study by Nelson and Xu【9】 highlighted significant variability in sedation responses, making standardization of protocols difficult. Similarly, Andrade et al.【8】 reported higher rates of adverse effects when using propofol alone, raising concerns about its safety profile. To address these concerns, research such as the study by Sethi and Thompson【10】 explored the use of adjunctive medications, such as midazolam, to enhance sedation stability and reduce adverse effects. Additionally, advancements in monitoring technologies, as discussed by Dallman et al.【7】, have enabled real-time assessment of hemodynamic parameters, improving safety outcomes. However, despite these improvements, limitations remain, including small sample sizes in many studies, the lack of standardized

sedation protocols across diverse patient populations, and the need for further long-term studies to assess the impact of modified sedation strategies on overall patient health and procedural success rates.

Further studies have demonstrated the significance of optimizing sedation strategies to enhance procedural success and minimize risks. Research on the oral health of children with disabilities has shown that inadequate preventive care and increased anxiety contribute to a greater need for sedation-based dental interventions【5】. Additionally, the role of caregiver education in improving oral health outcomes and reducing the need for invasive procedures under sedation has been emphasized【6】. These studies reinforce the need for continued research on sedation techniques that prioritize both safety and efficacy for special needs patients

CONCLUSION

Overall, this study contributes valuable insights into the sedation management of special needs patients undergoing dental treatment. While propofol alone appears to provide effective sedation, the high incidence of adverse events suggests that alternative or adjunctive sedation protocols, such as combining propofol with midazolam, may enhance patient safety and procedural success. Future research should focus on refining sedation strategies through comparative trials and patient-centered approaches to optimize care for this vulnerable population.

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