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Efficacy And Safety Of Intranasal Dexmedetomidine For Preoperative Sedation In Paediatric Ambulatory Surgery: A Randomized Controlled Trial.

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ABSTRACT

Paediatric ambulatory surgery requires effective preoperative sedation to alleviate anxiety and facilitate a smooth perioperative experience. Intranasal dexmedetomidine has shown promise as a sedative agent in various clinical settings, but its efficacy and safety in paediatric ambulatory surgery remain underexplored. In this randomized controlled trial conducted over one year, 40 paediatric patients aged 2 to 6 years were randomly assigned to receive either intranasal dexmedetomidine or normal saline as a preoperative sedative. Preoperative sedation levels, intraoperative variables, postoperative outcomes, and adverse events were assessed and compared between the two groups. Intranasal dexmedetomidine administration resulted in significantly improved preoperative sedation levels, reduced emergence delirium rates, and lower postoperative pain scores compared to the control group. No complications or adverse events were observed between the groups. Intranasal dexmedetomidine demonstrates efficacy and safety as a preoperative sedative in pediatric ambulatory surgery, with potential benefits including improved sedation levels and reduced postoperative complications.

Keywords: pediatric ambulatory surgery, dexmedetomidine, preoperative sedation

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INTRODUCTION

In pediatric ambulatory surgery, achieving adequate preoperative sedation is crucial for ensuring a smooth transition into the operating room and reducing anxiety in children [1]. Dexmedetomidine, a highly selective α2-adrenergic agonist, has gained attention for its sedative properties and favorable safety profile in various clinical settings [2]. However, its effectiveness and safety when administered intranasally for preoperative sedation in pediatric ambulatory surgery remain relatively understudied [3, 4]. This randomized controlled trial aims to investigate the efficacy and safety of intranasal dexmedetomidine as a preoperative sedative in pediatric ambulatory surgery settings. Understanding the potential benefits and risks of intranasal dexmedetomidine in this context could reform clinical practice and contribute to optimizing preoperative sedation strategies for pediatric patients undergoing ambulatory surgery [5].

METHODOLOGY

Our randomized controlled trial enrolled a total of 40 pediatric patients aged between 2 and 6 years scheduled for ambulatory surgery. The study was conducted over a duration of one year at a tertiary care hospital. Patients were randomly assigned to either the intranasal dexmedetomidine group or the control group using a computer-generated randomization sequence.

In the intranasal dexmedetomidine group, patients received dexmedetomidine at a dose of 2 μg/kg administered intranasally 30 minutes before the induction of anesthesia. The control group received an equivalent volume of normal saline intranasally using the same administration protocol. Preoperative sedation levels were assessed using standardized sedation scales, such as the Ramsay Sedation Scale and the Observational Scale of Behaviour Distress-Revised (OSBD-R). Additionally, vital signs, including heart rate, blood pressure, and oxygen saturation, were monitored throughout the preoperative period.

Outcome measures included the quality of preoperative sedation, emergence delirium, postoperative pain scores, and any adverse events related to dexmedetomidine administration. Data were analyzed using appropriate statistical methods, including t-tests for continuous variables and chi-square tests for categorical variables. The study adhered to ethical principles outlined in the Declaration of Helsinki and obtained approval from the institutional review board. Informed consent was obtained from the parents or legal guardians of all participants before enrolment in the study.

RESULTS

Table 1: Baseline Characteristics of Study Participants

Characteristic	Dexmedetomidine Group (n=20)	Control Group (n=20)
Age (years)	4.5 ± 1.2	4.3 ± 1.1
Gender (Male/Female)	12 (60%) / 8 (40%)	10 (50%) / 10 (50%)
Weight (kg)	18.2 ± 2.5	18.5 ± 2.3
ASA Physical Status		
I	16 (80%)	18 (90%)
II	4 (20%)	2 (10%)

Table 2: Preoperative Sedation score

Sedation Scale	Dexmedetomidine Group (n=20)	Control Group (n=20)
Ramsay Sedation Scale	4.1 ± 0.5	2.3 ± 0.7
OSBD-R Score	6.8 ± 1.2	8.5 ± 1.6

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Table 3: Intraoperative Variables

Variable	Dexmedetomidine Group (n=20)	Control Group (n=20)
Anesthesia Duration	45.6 ± 8.3 min	47.2 ± 9.1 min
Intraoperative Opioid Use	5 (25%)	10 (50%)
Intraoperative Complications	2 (10%)	3 (15%)

Table 4: Postoperative Outcomes

Outcome	Dexmedetomidine Group (n=20)	Control Group (n=20)
Emergence Delirium	2 (10%)	7 (35%)
Postoperative Pain Score (VAS)	3.2 ± 0.9	4.5 ± 1.2
Time to Discharge (minutes)	98.5 ± 15.6	102.3 ± 17.9

Table 5: Adverse Events

Adverse Event	Dexmedetomidine Group (n=20)	Control Group (n=20)
Hypotension	1 (5%)	2 (10%)
Bradycardia	0	1 (5%)
Respiratory Depression	0	0

DISCUSSION

Our present study aimed to investigate the efficacy and safety of intranasal dexmedetomidine in a dose of 2 μg/kg as a preoperative sedative in pediatric ambulatory surgery. Our findings suggest that intranasal dexmedetomidine administration significantly improved preoperative sedation levels compared to the control group, as evidenced by higher scores on the Ramsay Sedation Scale and lower scores on the Observational Scale of Behaviour Distress-Revised (OSBD-R). This improvement in sedation levels is consistent with previous research highlighting the sedative properties of dexmedetomidine in pediatric populations [6].

The baseline characteristics of the study participants were comparable between the dexmedetomidine group and the control group, indicating successful randomization and minimizing potential confounding factors [7]. However, it's noteworthy that the ASA physical status distribution was slightly different between the groups, with a higher proportion of patients classified as ASA I in the dexmedetomidine group. While this difference may have influenced the outcomes to some extent, it is unlikely to have significantly biased the results given the small magnitude of the difference [8]

Intraoperatively, we observed similar anesthesia durations between the dexmedetomidine group and the control group, indicating that intranasal dexmedetomidine did not prolong the time required for surgical procedures. This is important in ambulatory surgery settings where efficient turnover times are essential for optimizing resource utilization and patient flow. Additionally, the incidence of intraoperative complications was low and comparable between the two groups, suggesting that intranasal dexmedetomidine administration did not increase the risk of adverse events during the intraoperative period [9].

Postoperatively, patients in the dexmedetomidine group experienced significantly lower emergence delirium rates compared to those in the control group. Emergence delirium is a common phenomenon in pediatric patients undergoing anesthesia and surgery, characterized by agitation, disorientation, and hallucinations during the recovery phase. The reduced incidence of emergence delirium in the dexmedetomidine group suggests that intranasal dexmedetomidine may contribute to smoother and more tranquil recoveries, which can enhance the overall postoperative experience for both patients and caregivers [10, 11].

Moreover, postoperative pain scores were significantly lower in the dexmedetomidine group compared to the control group. Dexmedetomidine has been recognized for its analgesic properties, and our findings support its potential role in mitigating postoperative pain in pediatric patients. Lower pain

scores not only contribute to improved patient comfort but also facilitate early mobilization and ambulation, which are important aspects of postoperative recovery.

Despite the favourable outcomes observed with intranasal dexmedetomidine administration, it's essential to consider the occurrence of adverse events. In our study, the incidence of hypotension and bradycardia was minimal in both groups, with no significant difference between the dexmedetomidine group and the control group. These findings suggest that intranasal dexmedetomidine was well-tolerated and did not result in clinically significant hemodynamic disturbances in our study population. Additionally, there were no cases of respiratory depression observed in either group, further supporting the safety profile of intranasal dexmedetomidine for preoperative sedation in pediatric ambulatory surgery.

The strengths of our study include its randomized controlled design, which minimizes selection bias and allows for a more robust comparison between the dexmedetomidine group and the control group. Additionally, the use of standardized sedation scales and outcome measures enhances the validity and reliability of our findings. However, several limitations should be acknowledged. Firstly, the sample size was relatively small, which may limit the generalizability of our results to broader pediatric populations. Future studies with larger sample sizes are warranted to validate our findings and explore potential subgroup differences. Secondly, the single-center nature of our study may introduce institutional biases and limit the external validity of our findings. Multi-center studies involving diverse patient populations could provide more comprehensive insights into the efficacy and safety of intranasal dexmedetomidine in pediatric ambulatory surgery [12].

CONCLUSION

In conclusion, our study provides evidence supporting the efficacy and safety of intranasal dexmedetomidine in a dose of 2 μg/kg as a preoperative sedative in pediatric ambulatory surgery. Intranasal dexmedetomidine administration resulted in improved preoperative sedation levels, reduced emergence delirium rates, and lower postoperative pain scores compared to a control group receiving normal saline. Importantly, intranasal dexmedetomidine was well-tolerated and did not increase the risk of significant adverse events.

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