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Effectiveness of Local Anesthesia in Children's Pain Perception and Sedation During Dental Procedures Under General Anesthesia—A Randomized Clinical Study

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Aim: This study aims to assess the impact of 2% Lignocaine as a local anesthetic on children's pain perception and sedation during dental treatments performed under general anesthesia.

Materials and methods: The study is a double-blind, randomized clinical trial with a parallel design, involving 54 children (25 girls and 29 boys) aged 3 to 6 years, who underwent full-mouth rehabilitation under general anesthesia. Pain was measured immediately post-surgery and two hours later using the FLACC and Wong-Baker pain scales. Heart rate, blood pressure, and end-tidal CO2 levels were recorded five minutes before and after each procedure. Independent t-tests and Mann–Whitney U tests were used for statistical analysis.

Results: Significant differences in end-tidal CO2 levels were found after restoration (p=0.044). Heart rate, diastolic blood pressure, and end-tidal CO2 levels showed significant changes post-pulp therapy with p-values of 0.007, 0.023, and 0.001, respectively. No significant changes were observed in anesthesia depth based on PRST scores. FLACC scores remained similar across groups immediately and two hours post-procedure. However, subjective pain scores from the Wong-Baker scale indicated significant differences (p=0.003) two hours after the procedure.

Conclusion: Administering 2% Lignocaine as a local anesthetic helps stabilize intraoperative vital signs but does not significantly reduce postoperative pain.

Keywords: Dental treatment, general anesthesia, local anesthesia, pain perception, public health, vital signs

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Introduction

Dental caries affects most children, regardless of socioeconomic status, sex, race, or age.[1,2] Early treatment of dental issues is crucial, but fear and anxiety often prevent children from receiving proper dental care. Pediatric dentists must minimize pain and anxiety to ensure a positive experience and cooperation from children during dental visits.[3,4]

Local anesthetics cause temporary loss of sensation in specific body parts when applied topically or via injection.[5] In pediatric dentistry, it is crucial to administer the correct dosage to avoid toxicity and prolonged anesthesia, which can lead to self-inflicted injuries.[6] Vasoconstrictors in local anesthetics reduce absorption into the bloodstream, minimizing systemic toxicity risks and prolonging anesthetic effects. Children unable to cooperate for dental procedures may undergo these treatments under general anesthesia, which should provide immobility, amnesia, sedation, analgesia, and safety.[7]

Children who lack the ability to cooperate on a dental chair for simple to extensive dental procedures may undergo these procedures under general anesthesia. The ideal general anesthetic agent should provide the following: immobility, amnesia, sedation, analgesia/nociception, and arousal blockade with a pharmacological profile that possesses greater safety.[8] The interaction between local anesthesia and general anesthesia (GA) in dental patients is a relatively new concept in the field of pain control. The physiologically interpretable pain procedure is likely more complicated than currently recognized in the literature.[9]

The interaction between local and general anesthesia in dental patients is a relatively new concept in pain control. Lidocaine has been shown to provide intra- and postoperative analgesia, prevent chronic pain, reduce the need for volatile anesthetics and opioids, and shorten hospital stays by speeding up bowel function recovery. Additionally, lidocaine exhibits anti-inflammatory properties by reducing the production of various inflammatory markers.[10,11]

General anesthesia is increasingly popular for comprehensive pediatric dental treatment.[12] The efficacy of local anesthesia during treatment under general anesthesia remains debatable, prompting this study to evaluate pain perception and sedation in children treated with and without local anesthesia.

Materials and methods

Study Design

This double-blind, randomized clinical trial was conducted at the Department of Pediatric and Preventive Dentistry, Saveetha Dental College and Hospitals, Chennai, Tamil Nadu, India, following CONSORT guidelines.

Sample Size Calculation

Based on Townsend et al.'s methodology,[12] a sample size of 54 children was determined using G*Power 3.1.9.2 software, achieving 95% power with 95% confidence. Each group consisted of 27 children.

Recruitment of Participants

The study, conducted from October 2021 to June 2023, received ethical approval from the Institutional Scientific Review Board and Ethical Committee of Saveetha Institute of Medical and Technical Sciences (SRB/SDC/PEDO-1903/21/TH-015) and the Clinical Trial Registry – India: CTRI/2021/10/037426 (ICMR-NIMS), in line with the 1964 Declaration of Helsinki.

Fifty-four children aged 3-6 years were selected based on inclusion and exclusion criteria. Informed consent was obtained from parents or legal guardians, who were informed about the study's nature, treatments, and potential risks.

Inclusion criteria:

- Children needing full-mouth rehabilitation under general anesthesia
- Healthy children aged 3-6 years with an ASA score of 1

- Anxious, uncooperative children classified as "negative" or "definitely negative" on the Frankl Behavior Classification Scale

Exclusion criteria:

- History of systemic disease
- Children weighing less than 13 kg
- Children younger than 3 or older than 6 years
- Children with special health care needs
- Known drug allergies

Randomization:

Clinical and radiographic examinations and medical history were conducted before randomization. Participants were randomly allocated to one of two groups using sealed, sequentially numbered brown envelopes.

Clinical Procedure

After screening, subjective pain perception was recorded. Naso-tracheal intubation was performed, followed by standard surgical scrubbing and draping. Baseline values were recorded.

In Group 1, no local anesthetic was administered. In Group 2, 2% lignocaine with adrenaline (1:80000) was given as an infiltration or nerve block, not exceeding the recommended maximum dosage (7 mg/kg). Decayed teeth were treated, and heart rate, blood pressure, and end-tidal CO2 were recorded five minutes before and after each procedure. Pain perception was recorded immediately and two hours post-recovery. Adverse effects such as vomiting, bleeding, or allergic reactions were monitored.

Outcome Measures

The primary outcomes were pain perception and overall sedative effect before, during, and after the procedure, assessed using the Wong-Baker Faces Pain Rating Scale, PRST, and FLACC scales. Secondary outcomes included blood pressure, heart rate, end-tidal CO2 concentration, and adverse effects.

Statistical analysis

Data were tabulated in Microsoft Excel and analyzed using SPSS software version 21. Normality was tested with the Shapiro–Wilk test. Independent t-tests were used for intergroup comparisons of heart rate, blood pressure, and end-tidal CO2. The Mann–Whitney U test compared mean FLACC scores and Wong-Baker Pain Scale scores. The significance level was set at 0.05.

Results

Age and sex distribution of participants is shown in figure 1. Sedation levels (PRST scale) showed no significant differences across procedures in both groups (figure 2).

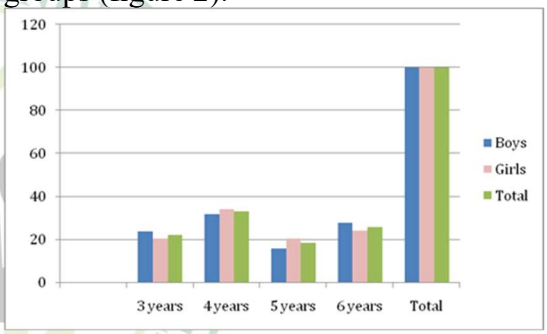

Figure 1: Demographic data according to age and sex

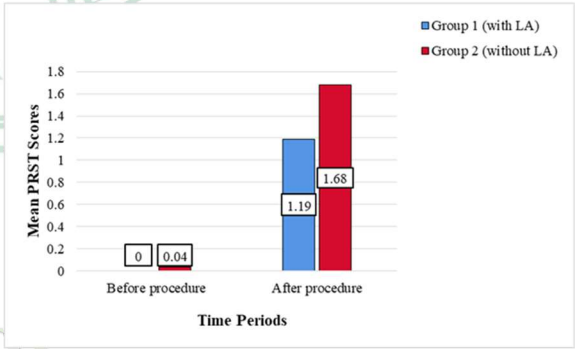

Figure 2: Bar chart representing the mean scores using the PRST between groups at different intervals.

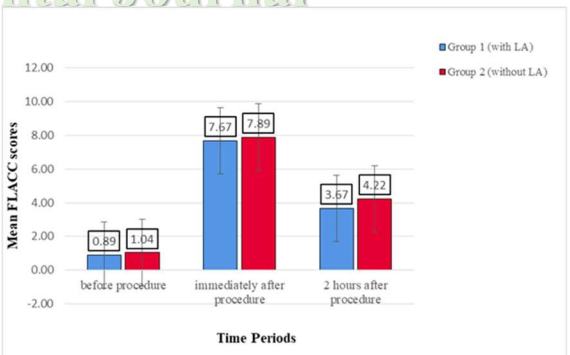

Figure 3: Bar chart representing the mean pain scores according to the FLACC before, immediately after and 2 hours after the procedure between group 1 and group 2.

Table 1: Comparison of vital signs across various quadrants for restorative procedures and crown placement.

variables	Before procedure				P value	After procedure				P value
	Group 1		Group 2			Group 1		Group 2		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Heart Rate	112.04	16.42	115.73	15.87	0.449	110.03	17.64	116.41	16.75	0.222
Systolic Blood pressure	91.13	14.23	90.82	13.13	0.939	90.61	14.55	90.50	13.92	0.980
Diastolic Blood pressure	47.91	11.20	47.25	11.19	0.840	47.48	11.26	47.42	11.21	0.985
EtCO2	32.17	0.98	32.04	0.95	0.642	32.13	0.92	32.75	1.11	0.044*

*Independent t test, p value obtained ($p < 0.05$)

Table 2: Comparison of sedation levels across various quadrants for pulp therapy procedures.

variables	Before procedure				P value	After procedure				P value
	Group 1		Group 2			Group 1		Group 2		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Heart Rate	128.92	12.09	128.10	15.29	0.832	118.73	11.96	130.17	17.21	0.007*
Systolic Blood pressure	89.11	12.69	88.41	11.93	0.833	12.39	2.38	12.59	2.33	0.310
Diastolic Blood pressure	48.42	9.71	40.72	7.67	0.002*	47.38	10.04	41.55	8.74	0.025*
EtCO2	34.67	2.13	33.93	1.66	0.154	33.00	1.14	34.34	2.14	0.005*

*Independent t test, p value obtained ($p < 0.05$)

Table 3: Comparison of the level of sedation across various quadrants for extraction procedures.

variables	Before procedure				P value	After procedure				P value
	Group 1		Group 2			Group 1		Group 2		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Heart Rate	125.50	9.18	129.80	21.75	0.66	123.83	7.41	133.20	15.53	0.22
Systolic Blood pressure	100.33	2.80	85.40	9.94	0.06	98.00	11.87	82.20	11.30	0.05
Diastolic Blood pressure	45.00	7.34	46.40	8.91	0.78	44.50	7.37	48.00	8.57	0.48
EtCO2	32.83	1.72	35.80	2.28	0.04*	33.50	1.76	35.60	3.05	0.18

*Independent t test, p value obtained ($p < 0.05$)

Table 4 – inter group Comparison of mean pain scores using the Wong Baker Faces Pain at different intervals.

Time Intervals	Group 1		Group 2		P value
	Mean	SD	Mean	SD	
Pre	0.67	0.96	.83	0.96	0.543
Post	8.89	1.01	8.90	1.01	0.97
After 2hrs	5.41	0.93	6.34	1.31	0.003*

*Independent t test, p value obtained ($p < 0.05$)

Vital signs comparison revealed significant differences in heart rate ($p<0.007$), diastolic blood pressure ($p<0.025$), and end-tidal CO2 ($p<0.005$) during pulp therapy (Tables 1-3). FLACC scores before, immediately after, and two hours post-procedure showed no significant differences (Graph 3). The Wong-Baker scale indicated significant differences in pain perception between the groups at all time points ($p<0.003$) (Table 4).

Discussion

Dental rehabilitation under general anesthesia is the preferred behavior management technique for both pediatric dentists and parents because it is a painless procedure that induces less anxiety. However, clinical experience and previous literature suggest that pain is often undertreated and misinterpreted in children.[13-15] Children also find it easier to accept sedative management compared to the normal chair-side approach for dental procedures.[14]

The beneficial effect of local anesthesia during treatment under general anesthesia is controversial. Lignocaine (LIGNOX) (2%) combined with adrenaline (1:80000) was used as an interventional agent in this study due to its longer duration of action on soft tissues (3 hours) and 1 hour of dental anesthesia.[16] Given the long duration of general anesthesia required for full-mouth rehabilitation, a local anesthetic with a similar duration of action was selected to minimize postoperative adverse effects. Pooled pilot study data from previous authors revealed that "per procedure" changes were more significant than "per patient" changes.[17-19] Heart rate, systolic and diastolic blood pressure, and ET-CO2 levels during restorative procedures and crown placement were not significantly different. These minimally invasive procedures are less traumatic and stressful, hence they did not cause major changes in vital signs despite the presence or absence of local anesthetic.[17-19]

Following the same protocol, values obtained for pulp therapy procedures, which included direct pulp capping, pulpotomy, and/or pulpectomy procedures, showed significant differences in diastolic blood pressure and heart rate. Surgical stress from access opening and pulp extirpation activates the sympathetic nervous system, increasing catabolic hormone release and pituitary gland suppression. In clinical practice, these activities cause changes in heart rate, blood pressure, and biochemical fluctuations in noradrenaline, adrenaline, dopamine, and cortisol concentrations.[20,21] It has been revealed that there are fluctuations in vital signs, but a significant decrease in vital signs was observed following the administration of local anesthetics.

Statistically nonsignificant differences were observed in vital signs during extraction, except for ET-CO2 levels ($p=0.054$, 0.036) before the procedure. These findings align with Watts et al., who noted nonsignificant changes in intraoperative vital signs other than ET-CO2.[13] It has been demonstrated that 79% of pediatric dentists use local anesthetics for extraction to improve patient recovery.[22] Although the difference was not significant, there was an increase in immediate postoperative discomfort/distress as indicated by the postoperative (0 hours) FLACC score between the two treatment groups. This can be attributed to the knowledge that patients experience sore throat, hoarseness, back pain, headache, and sometimes nausea and vomiting after extubation under general anesthesia.[23] These adverse effects, along with discomfort at the surgical site, contribute to postoperative pain in children.[24,25]

The findings of this study are supported by other findings in the literature that noted nonsignificant differences in postoperative discomfort between those who received local anesthesia and those who did not receive local anesthesia.[12,26-28] Townsend et al.[12] concluded that there was

minimal change in FLACC scores for any individual subject during the overall post stay. This finding is also supported by other researchers who noted that more than 5% of dental patients had a postoperative pain score greater than 0 at discharge, and approximately 30% had a pain score greater than 3 at discharge.[29,30] The change indicates that on average, patients who received local anesthesia experienced less postoperative distress than did those who did not receive local anesthesia, but the differences were not significant. Previous studies have noted postoperative pain using the verbal pain scale and visual analog scale and found the values to be statistically significant.[31,32] Although objectively the findings were not statistically significant, subjective pain perception according to the Wong-Baker scale was significantly different (p=0.003) from the baseline and postoperative values after 2 hours between the two treatment groups. Psychologically, parental/familial influences on children tend to calm them down over the postoperative period and are known to shape pain behavior, which was hence subjectively reflected in this study.[33,34] This shows that even if a significant difference was not present in the objective perception of pain, the children agreed that they felt “lesser pain” when treatment was performed with 2% Lignocaine.

Another parameter, the PRST score, was used to determine the depth of anesthesia. Heart rate, systolic BP, sweat and tears were evaluated to determine the depth of anesthesia in children following general anesthesia, and the results were not significant under the influence of local anesthesia, which is supported by a previous study.[35] A survey among dental anesthetists revealed that 93% of them stated that they used local anesthesia for the stabilization of vital signs and thereby improved the depth of general anesthesia. Although fluctuations in individual vital signs were observed during specific procedures at specific times, overall, no clinical effects were observed.[17,36] Elevated heart rate and CO2 levels during potentially stimulating treatments are good indicators of intraoperative patient pain.[37-41] No additional anesthesiologist intervention was required at any of the stimulation locations in this trial, which is a clinical point. As a result, the utility of local anesthesia for dental treatment under GA is still debatable, and further study is needed to determine its real value in terms of preventing central sensitization and managing postoperative pain in dental patients.

The study's limitations included a relatively small sample size and a short study duration. Future research should explore the effectiveness of local anesthetics across various clinical scenarios, including different concentrations of the same anesthetic, the use of different anesthetic agents, and various injection techniques. Advanced tools like bispectral monitoring with EEG can provide detailed assessments of anesthesia depth by monitoring brain activity during general anesthesia. Research should also investigate the depth of anesthesia for dental patients based on the location, extent, and duration of dental treatments, with analyses specific to tooth type. Improved standardization procedures and protocols are necessary for identifying postoperative pain and ensuring the reliability of pain scales for assessing postoperative dental pain in children after general anesthesia. Further studies could help validate the findings of this research and enhance our understanding of intraoperative vital sign stability with local anesthesia in dental patients under general anesthesia.

Conclusion

This clinical study found that using local anesthesia (2% Lignocaine) in children undergoing dental procedures under general anesthesia can stabilize intraoperative vital signs but does not significantly reduce immediate postoperative pain. The study's findings

support the potential benefits of local anesthesia in improving intraoperative stability and overall postoperative recovery experience for pediatric patients. Future studies with larger sample sizes are needed to validate these findings and develop comprehensive clinical guidelines for pediatric dental procedures under general anesthesia.

Conflicting interest

The authors declare no conflicts of interest.

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Regulatory Statement

The clinical trial and methodology received approval from the Institutional Scientific Review Board and Ethical Committee of the Saveetha Institute of Medical and Technical Sciences (SRB/SDC/PEDO-1903/21/TH-015) and the Clinical Trial Registry – India: CTRI/2021/10/037426 (ICMR-NIMS). This study adhered to the ethical standards established in the 1964 Declaration of Helsinki and its subsequent amendments.

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