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Comparative Evaluation of Intrasulcular Articaine and Lignocaine Hydrogels for Pain Control during Management of Deep Carious Lesions in Children: A Randomized Controlled Trial

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Abstract **Objectives:** Effective pain control during management of deep carious lesions in children is challenging due to needle phobia and anxiety. Hydrogel-based topical anesthetic delivery offers a non-invasive alternative, but comparative pediatric evidence is limited. **Aim:** To compare the efficacy of intrasulcular articaine hydrogel and lignocaine hydrogel for pain control during management of deep carious lesions in children. **Methods:** This randomized, double-blind, parallel-group clinical trial included 60 children aged 5–9 years requiring restorative treatment for deep carious primary molars. Participants were allocated into articaine hydrogel, lignocaine hydrogel and placebo groups. Hydrogels were applied intrasulcularly for 5 minutes before caries excavation. Procedural pain was assessed using the Visual Analog Scale (VAS). Secondary outcomes included Wong–Baker pain scores, onset time, need for rescue anesthesia, physiological responses and postoperat0ive tissue reactions. Data were analyzed using appropriate statistical tests ($p<0.05$). **Results:** Both anesthetic hydrogels significantly reduced procedural pain compared to placebo ($p<0.001$). Lignocaine hydrogel showed lower pain scores, while articaine demonstrated faster anesthetic onset. The need for rescue anesthesia was lowest in the articaine group. No adverse effects were observed. **Conclusion:** Intrasulcular hydrogel-based anesthesia is an effective needle-free modality in pediatric dentistry. Lignocaine provides superior surface analgesia, whereas articaine offers faster onset, emphasizing formulation-dependent clinical performance.

Key Words Pediatric Dentistry, Local Anesthetics, Articaine, Lidocaine, Hydrogels, Pain Measurement

INTRODUCTION

Pain control in pediatric dental practice is one of the most demanding and sensitive areas in dental practice. It is not only important to have good pain control, which is necessary due to physiological demands, but it is also important to realize that the psychological aspects of pain are as significant, if not more, due to fear of dental pain and fear of dental treatment, which are significant sources of dental fear and avoidance behaviors in children [1].

Local anesthetics are the mainstay of pain management in dental practices and lignocaine hydrochloride and articaine hydrochloride have been some of the most widely studied and used local anesthetics [2]. Lignocaine, developed in the middle of the last century, is considered the gold standard of amide local anesthetics because of its well-recognized pharmacokinetics, large therapeutic index and proven safety profile for numerous decades in pediatric dental practices [3]. Articaine, a relatively newer amide local anesthetic, has drawn considerable attention due to its chemically distinct properties, which include the presence of a thiophene ring that imparts increased lipid solubility, along with an additional ester bond for easy hydrolysis in the plasma. These attributes translate into increased diffusion capacity, increased ability for both soft and hard tissue penetration, as well as increased protein binding (nearly 95% for articaine, which is double that of lignocaine, with a value of 65%) [4,5].

Concomitant with pharmacological progress, the development of drug delivery systems has occurred and hydrogels have emerged as promising delivery systems for local anesthesia. Hydrogels can be defined as a polymeric network structure with a three-dimensional structure, possessing the unique ability to hold a large amount of water while retaining viscoelastic character and bioadhesion.

The significant advantage here is their potential for sustained drug delivery, site-specific delivery and mucosal contact, making hydrogels extremely valuable for their applications in pediatric dental anesthesia. This is particularly relevant since the presence of needle phobia among children has already reached the level of 20–30% and this condition is closely linked to elevated physiological stress response, hyperalgesia and developments related to dental fear, respectively [6,7].

Although existing studies on topical anesthetics in pedodontics have concentrated on lignocaine gel or spray formulation, Sharma *et al.* [9] found decreased pain perception with the buccal infiltration technique after topical lignocaine application [8], while a study by Amorim *et al.* [10] suggested the practicality of needle-free palatal anesthesia with topical lignocaine. Yet aside from injectable anesthetics, most information in the literature revolves around adults or topical drugs given singly. No documented evidence exists on comparative clinical trials between the hydrogel formulation of articaine and lignocaine in dental pediatrics. Both the drug properties of articaine and the advantages of a hydrogel carrier make this a relevant consideration.

The challenges of managing deep carious lesions in children who are 5-9 years old are a clinical situation where atraumatic anesthesia is vital. The procedure of caries excavation, cavity preparation, or rubber dam placement has been invasive. It is also a procedure that causes the patient a lot of distress. Such procedures require effective analgesia. Infiltration anesthesia is not effective, as sensitivity is felt as pain and behavior issues arise from children. Effective analgesia has not been provided while increasing psychological distress in the patient, according to existing literature [7]. The existing literature does not contain a valuable comparison of the use of intrasulcular articaine and lignocaine hydrogels. Hence, this randomized controlled trial was framed to compare clinical performance of intrasulcular articaine and lignocaine hydrogels in relation to pain management while tackling deep carious lesions in children. Through the evaluation of parameters like onset of anesthesia, depth of analgesia, success rate and comfort of the child, this research aims to create practical evidence.

METHODS

Study Design and Ethical Considerations

This randomized, double-blind, parallel-group clinical trial was carried out at the Department of Pediatric and Preventive Dentistry, Saveetha Dental College, Chennai, Tamil Nadu, 600077, after obtaining approval from the Institutional Ethics Committee [Approval No. IHEC/SDC/PEDO-2401/25/065]. The study was prospectively registered with the Clinical Trials Registry of India [CTRI/2025/06/089676]. Informed consent was obtained from the parents or legal guardians of all participating children. Written informed consent was obtained from parents or legal guardians and verbal assent was obtained from children prior to participation.

Study Population

A total of 60 patients aged 5 to 9 years with deep carious lesions involving the primary molars that required restorative therapy were enrolled for this trial. Only those with reversible pulp changes, including provoked pain that lasted only briefly to thermal and sweet challenges and lack of symptoms indicating possible irreversible pulpitis, nocturnal pain, spontaneous pain, continuous pain, prolonged pain after removing the stimulus and tenderness to percussion, were chosen. The history of the present illness of all enrolled participants was taken. Preoperative radiographic assessment was done by standard periapical radiographs to measure the depth of the lesions and to confirm that no periapical pathologies existed. Satisfactory remaining dentin thickness after caries removal was standardized by determining that a minimum thickness of approximately 0.5 to 1.0 mm of dentin separated the deepest point of the removed carious lesions from the pulp chamber according to various previous literatures like Murray *et al.* The severity of lesions was analyzed against age to determine the relationship.

Inclusion Criteria

- Children aged 5 to 9 years who are accompanied by parents and are willing for informed consent and report to the pediatric dental clinic
- Children with deep carious lesions not requiring pulp therapy procedures
- Children requiring full coverage Stainless Steel Crowns
- Children who are attending the dental clinic for the first time
- Children who are healthy and able to understand and respond to pain assessment scales

Exclusion Criteria

- Children who had received prior dental treatment.
- Children with developmental or linguistic disorders who cannot communicate properly
- Children on medications that affect behavior or pain perception
- Children who are medically compromised patients [congenital cardiac issues like ASD and VSD]
- Children with cognitive impairments or special health needs
- Children with active gingivitis were excluded (Children with active gingivitis were excluded to avoid confounding due to inflammation-induced alterations in pain perception and drug absorption)

Sample Size Calculation

Based on a pilot study involving 10 children per group, the mean difference in Visual Analog Scale (VAS) pain scores between the groups was 1.5, with a standard deviation of 1.6. Sample size calculation using GPower software (v3.1.9.2), with a power of 80% and an alpha level of 0.05, indicated that a minimum of 20 participants per group was required.

To account for potential dropouts, the sample size was increased to 25 children per group. Accordingly, the study included three groups: Lignocaine, Articaine and Control, totaling 75 participants.

Randomization and Blinding

Participants were randomly allocated into three groups Group 1: Articaine hydrogel, Group 2: Lignocaine hydrogel and Group 3: Vaseline (Vaseline was selected as an inert comparator due to its lack of anesthetic properties; however, it does not replicate the physicochemical properties of the hydrogel base, which may limit its validity as a true placebo) using a computer generated block randomization table (Block size: 4). Allocation concealment was maintained through sequentially numbered, opaque, sealed envelopes. Both the participants and the outcome assessor were blinded to the assigned interventions.

Preparation of the Hydrogels

The hydrogel formulations were prepared under aseptic conditions in the laminar airflow laboratory. Articaine Hydrogel (0.24%): A 4% articaine hydrochloride solution with adrenaline 1:100,000 (Septanest®, Septodont) was diluted with sterile distilled water and incorporated into a carbopol-based gel, as described by Das *et al.* [11]. Carbopol 940 was used as the gelling agentat a concentration of 1% w/v. Final pH was adjusted to approximately 6.8-7.0, the hydrogel stability over 7 days was based on preliminary pilot observations of consistency and drug performance it was prepared under aseptic conditions; however, no microbiological assay was performed, Carbopol is not cytotoxic and can even be used intrasulcularly. Muniz *et al.* [12] narrated the use of nanocapsules in drug delivery for the purpose of achieving controlled release for various conditions although involving nanocarriers, highlights controlled release principles relevant to hydrogel systems, whereas Kumbhar *et al.* [13] used hydrogel in dentistry for local anesthetic release properties and demonstrated formulation and evaluation of lignocaine gel for topical delivery. For this, 6 mL of 4% articaine was added to 94 mL of hydrogel base to get a final concentration of 0.24%. The pH was neutralized with the addition of triethanolamine to attain optimal viscosity. Lignocaine Hydrogel (0.6%): Similarly, 30 mL of 2% lignocaine hydrochloride was diluted and homogenized into the same carbopol base to yield a final concentration of 0.6%. Both gels were stored in amber-colored syringes at 4-8°C and used within 7 days to ensure stability. They were visually identical in consistency, color and packaging to maintain blinding integrity, as noted in Figure 1. The concentrations were selected based on clinically safe topical dosing limits and formulation feasibility rather than equipotency, as articaine has higher lipid solubility and potency compared to lignocaine, the concentrations were selected based on known surface anesthetic efficacy and safety margins rather than equipotency, reflecting real scenario topical clinical use.

Figure 1: Shows Lidocaine and Atricaine Gels were Stored in Amber-Colored Syringes at 4–8°C

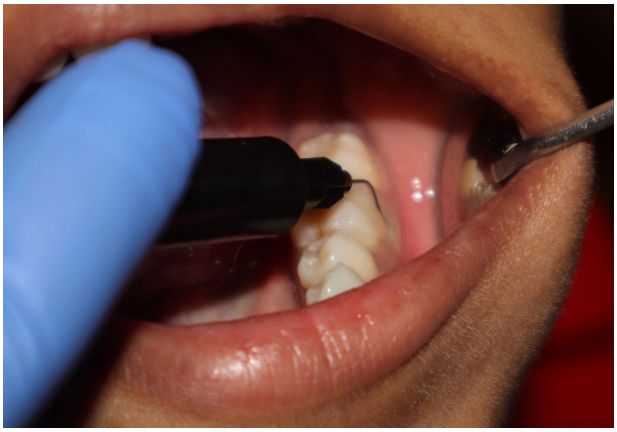

Figure 2: Shows Hydrogel Application using a Syringe Type Injectable Applicator

Clinical Procedure

The children were comfortably positioned and the target tooth was isolated with either cotton rolls in non-cooperative patients or rubber dams in cooperative patients. The gingival sulcus near the carious lesion was dried, to minimize anatomical variability, the hydrogel was applied circumferentially into the sulcus using a standardized 0.2 mL volume with a blunt applicator, limited to the treated tooth, as described in (Figure 2). The hydrogel remained in contact with the tooth for 5 minutes, recorded with a stopwatch, before commencing the excavation of cavities using a round bur. Then, depending on crown size, crown seating was performed using a 169L bur and then a green stone bur for smoothing.

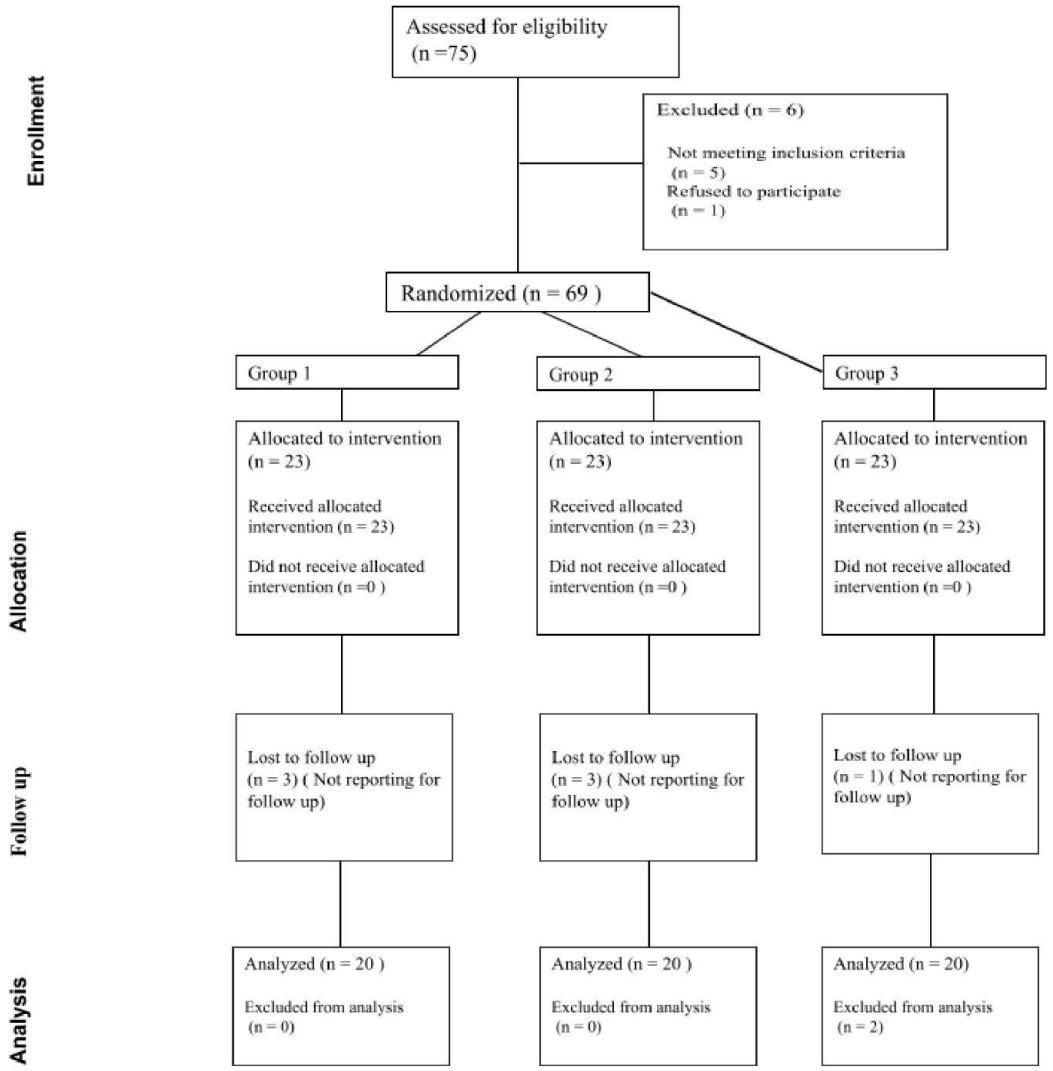

Figure 3: CONSORT Flow Diagram Illustrating Participant Recruitment, Randomization, Allocation and Analysis of 75 Pediatric Participants into Articaine, Lignocaine, and Placebo Hydrogel Groups

The outcome variables were measured during proximal seating and crown seating sessions. The children were asked to report back the next day for recording the ginigival irritation or inflammation as a follow up.

Outcome Measures

The subjective perception of pain was evaluated using the 100 mm Visual Analogue Scale, following caries excavation. Other secondary outcomes included the objective measure of pain, which was assessed with the Wong-Baker Faces Pain Rating Scale, rated by the experimenter and the physiological reaction, in which the pulse rate was measured before and following the caries excavation process, utilizing the fingertip pulse oximeter. VAS scores were recorded immediately after caries excavation, which was considered the primary painful stimulus.

Statistical Analysis

SPSS Statistics, version 26.0 software was used to analyze the collected data. Descriptive statistics with mean and standard deviation were calculated for all the continuous variables. The Shapiro-Wilk test was used to check the normality of the data. Comparison between groups on VAS score, Wong-Baker score and Parametric and non-parametric tests were selected based on data distribution, including ANOVA and Kruskal-Wallis tests. Comparison between groups regarding HR values before and after the intervention was done by repeated measures ANOVA with post-hoc tests. The significance level was set at $p<0.05$. The agreement between raters on Wong-Baker scores was measured by calculating Cohen's kappa coefficient (Figure 2).

Of the 75 children assessed for eligibility, 69 were randomized equally into three groups. After losses to follow-up (the patients were asked to report the next day to analyze and evaluate any gingival irritation or inflammation, the people who did not report back were recorded as losses to follow-up), data from 60 participants (20 per group) were included in the final analysis, ensuring balanced group sizes for outcome evaluation.

Participants who required rescue anesthesia during the procedure were considered as treatment failures and were included in the intention-to-treat analysis. However, for per-protocol analysis, only those who completed the procedure without rescue anesthesia were included.

RESULTS

The overall distribution for gender was similar between all the groups, thus reducing any gender imbalance as shown in Table 1. The analysis for behavior through the use of Frankl's rating scale had similar medians with overlapping ranges for all the groups, which reflected uniformity in the mean level of cooperation. The overall distribution for treated tooth numbers was similar between all the groups.

Indeed, outcome measures in Table 2 showed statistically significant differences among the three groups regarding most of the pain- and anesthesia-related parameters. Non-parametric Kruskal–Wallis (K-W) tests were conducted for ordinal and non-normally distributed variables like VAS scores, Wong–Baker scores and ICDRG ratings, which have shown significantly higher pain scores and discomfort in Group 3 compared to Groups 1 and 2. A one-way ANOVA was conducted for normally distributed continuous variables: A significantly longer onset time was observed for Group 3 when compared to the other groups, while no significant difference was found as regards the procedure time. The need for rescue anesthesia was different among groups, with the highest number in Group 3. The Friedman test showed a significant decrease in the discomfort scores over time within each group, with repeated measures of discomfort taken at immediate, 24-hour and 1-week follow-ups. Taken altogether, these results document that Groups 1 and 2 provided better pain control and quicker anesthetic onset compared to Group 3, with appropriate choices of statistical tests reflecting the distribution and scale of the outcome variables.

As presented in Table 3, the chi-square test of overall comparison showed that there was a statistically significant difference in the need for rescue anesthesia between the groups, implying that the intervention groups influenced the success of anesthesia. The need for rescue anesthesia was lowest in the articaine group, followed by the lignocaine group, while the highest need was in the placebo group. Comparison between the groups showed that articaine significantly decreased the risk of needing rescue anesthesia therapy, in comparison to the placebo group. Although lignocaine lowered the risk of needing rescue anesthesia therapy in comparison to the placebo, this was not statistically significant. Comparison between articaine and lignocaine did not show statistical significance, implying that both are equally effective in lowering the need for rescue anesthesia.

The regression test in Table 4 and 5 revealed that the type of anesthetic groups and the onset time were important predictors of procedural pain perception during treatment, while age and initial behavior had no significant effect on pain perception. Both the articaine and lignocaine intervention groups produced a decrease in pain scores relative to the control group. Articaine showed the fastest onset of anesthesia, followed by lignocaine and placebo, with a statistically significant difference observed among the three groups, indicating a moderate effect of hydrogel type on onset time. In the logistic regression model, the type of anesthetic group had a significant effect on requiring rescue anesthesia injections, with Articaine interventions being significantly less likely to require additional anesthesia, while age and behavioral ratings had no significant effect.

Table 1: Baseline Demographic and Clinical Characteristics of the Three Groups

Variable	Group 1	Group 2	Group 3	Statistical Test	p-value
Age (years)	7.43±1.20	7.31±1.40	7.56±1.00	ANOVA	0.74
Sex (Male/Female)	1:1	0.8:1	0.8:1	χ^2	0.97
Frankl's Rating (median [IQR])	3 [3-4]	3 [3 – 4]	3 [3-4]	Kruskal–Wallis	0.84
Tooth Number (mode)	85	75	85	χ^2	0.66

Values are expressed as mean ± standard deviation unless otherwise indicated. $p<0.05$ is considered statistically significant. Age: one-way ANOVA; Sex and Tooth number: Chi-square test; Frankl's rating: Kruskal-Wallis test

Table 2: Comparison of Pain Scores, Anesthetic Onset, Procedural Parameters and Postoperative Discomfort among the three Study Groups

Outcome	Group 1	Group 2	Group 3	Test	Effect size	p-value
VAS during procedure (0-100 mm)	28.6±6.9 [25.1–32.1]	30.2±7.4 [26.5–33.9]	47.1±8.0 [43.0–51.2]	K-W	$\varepsilon^2 = 0.42$	<0.001
Wong-Baker (During)	2 [1–3]	2 [1–3]	4 [3–5]	K-W	$\varepsilon^2 = 0.38$	<0.001
Wong-Baker (1 hr after)	1 [1–2]	1 [1–2]	2 [1–3]	K-W	$\varepsilon^2 = 0.24$	0.012
Onset time (min)	1.2±0.3 [1.1–1.3]	1.4±0.4 [1.2–1.6]	2.8±0.5 [2.6–3.0]	ANOVA	$\eta^2 = 0.55$	<0.001
Procedure time (min)	21.5±2.1 [20.5–22.5]	20.8±2.4 [19.6–22.0]	22.3±2.0 [21.3–23.3]	ANOVA	$\eta^2 = 0.08$	0.14
Need for rescue anesthesia (n / %)	0 (0%)	1 (5.6%)	4 (22.2%)	χ^2	—	0.031
ICDRG (Immediate)	0 [0–0]	0 [0–0]	1 [0–1]	K-W	$\varepsilon^2 = 0.22$	0.018
ICDRG (24 hr)	0 [0–0]	0 [0–0]	1 [0–1]	K-W	$\varepsilon^2 = 0.24$	0.013
ICDRG (1 week)	0 [0–0]	0 [0–0]	0 [0–1]	K-W	$\varepsilon^2 = 0.18$	0.045
Friedman (Immediate → 24 h → 1 wk)				$\chi^2 = 21.5$		<0.001

Table 3: Comparison of Need for Rescue Anesthesia among Study Groups with Risk Estimates and Number Needed to Treat

Group	n (%) Need for Rescue Anesthesia	χ^2 (2)	p-value	Pairwise Comparison	Risk Ratio (95 % CI)	NNT
Articaine	1 (5 %)			Articaine Vs Placebo	0.20 (0.03 – 0.87)	6
Lignocaine	3 (15 %)	6.23	0.044	Lignocaine Vs Placebo	0.60 (0.18 – 1.75)	10
Placebo	5 (25 %)			Articaine Vs Lignocaine	0.33 (0.04 – 1.54)	—

Table 4: Multiple Linear Regression Identifying Predictors of Procedural Pain (VAS During) showing Significant Effects of Group and Onset Time

Predictor	β (Coefficient)	t	p-value	95% CI
Intercept	43.12	—	—	—
Group (Articaine)	–15.80	–4.73	<0.001	–22.6 to –8.9
Group (Lignocaine)	–8.21	–2.45	0.018	–14.9 to –1.6
Onset Time (min)	4.12	2.33	0.023	0.6 to 7.6
Age	0.31	0.88	0.38	–0.4 to 1.0
Frankl's Rating	–0.24	–0.64	0.53	–1.1 to 0.6

Table 5: Binary Logistic Regression Modeling the Likelihood of Requiring Rescue Anesthesia; Articaine Hydrogel Reduced Adjusted Odds by ≈ 82% Versus Placebo (OR = 0.18, 95% CI 0.03–0.92)

Predictor	Adjusted OR (95% CI)	p-value
Group (Articaine Vs Placebo)	0.18 (0.03-0.92)	0.037
Group (Lignocaine Vs Placebo)	0.56 (0.14-2.07)	0.39
Age	1.08 (0.83-1.40)	0.59
Frankl's Rating	0.87 (0.63-1.23)	0.45

Table 6: Reliability Indices (κ and ICC) for Behavioral and Tissue Reaction Assessments

Assessment	Reliability Statistic	Value (95% CI)
Wong–Baker Facial Pain Scale (During procedure) Inter-rater agreement between two independent evaluators	Weighted κ	0.84 (0.72-0.96)
ICDRG Grading (24 h Vs 1 week) Test–retest reliability of local tissue reaction scores	ICC (2,1)	0.88 (0.79-0.93)

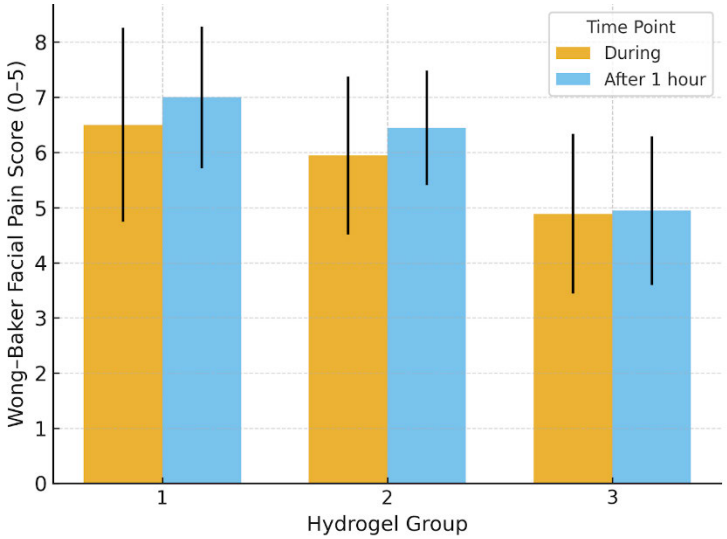

Figure 4: Wong-Baker Facial Pain Scores During and 1 Hour after Procedure

The results of the reliability analysis in Table 6 indicated a very high level of consistency in terms of both behavioral pain responses and tissue reaction scores. The high reliability observed can be attributed to the use of standardized, validated assessment scales and prior calibration of the evaluators before data collection. The Wong–Baker Facial Pain Scale relies on clear visual cues that are easily interpreted by both children and clinicians, resulting in consistent scoring between examiners. Similarly, the ICDRG tissue reaction grading follows objective clinical criteria, which minimizes subjective variation and ensures stable scoring across different time points. A single calibrated pediatric dentist performed all procedures to minimize operator-related variability.

The Articaine hydrogel group demonstrated significantly lower Wong–Baker pain scores during the procedure compared with the other groups, whereas pain scores decreased in all groups one hour post-procedure with no significant intergroup difference, as shown in Figure 4.

This correlation heatmap in Figure 5 displays the relationships between pain assessment and anesthetic response variables: A very strong positive correlation, showing strong agreement between the two pain assessment scales, between VAS scores during the procedure and Wong–Baker pain scores during the procedure. In contrast, onset time correlates only weakly with both pain measures, indicating that the speed of anesthetic onset had little relation to perceived pain during treatment. Overall, this heat map reveals that subjective pain ratings are highly related to one another, yet are time-independent of the onset time and tissue response variables.

The forest plot in Figure 6 presents the effect size for each outcome: VAS and Wong-Baker pain scores are highly affected by treatment because these outcomes are a direct reflection of the anesthetic efficacy of hydrogels.

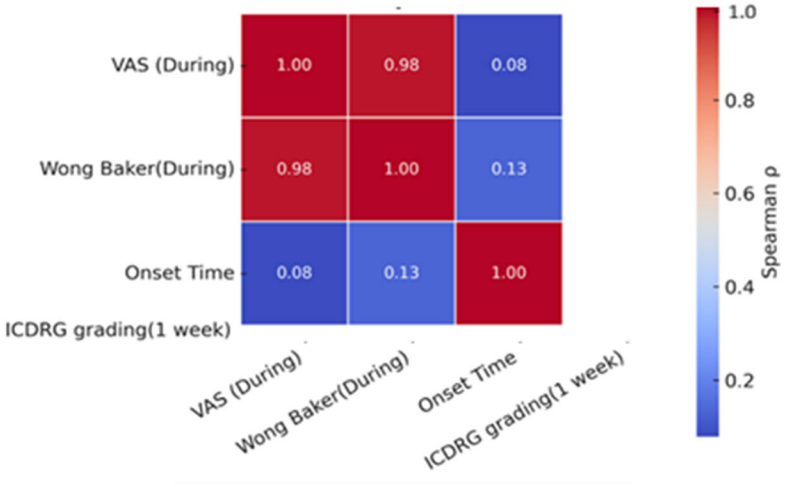

Figure 5: Correlation Heatmap of Pain and Tissue Reaction Variables

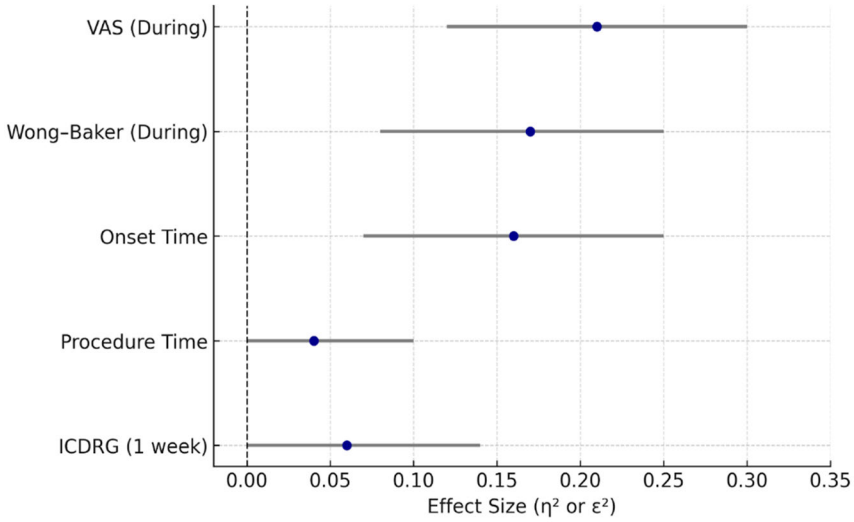

Figure 6: Forest Plot of Effect Sizes with 95% Confidence Intervals summarizing across major outcomes

Onset time shows a moderate effect because different hydrogels release anesthetic agents at different speeds. In contrast, procedure time and tissue reaction scores exhibited only a small effect because both outcomes are highly operator-dependent and tissue-healing-response-dependent rather than formulation-dependent.

DISCUSSION

The findings of this randomized controlled trial highlight the clinical relevance of intrasulcular hydrogel-based delivery of local anesthetic agents in pediatric dentistry. Contrary to initial pharmacological expectations, intrasulcular lignocaine hydrogel demonstrated superior pain control compared with articaine hydrogel during caries excavation in children, as also supported by observations reported by Singh and Koul [14] Children in the lignocaine group exhibited significantly lower VAS and FLACC pain scores, along with more stable physiological parameters, indicating effective analgesia and enhanced patient comfort achieved without the need for injectable anesthesia, consistent with findings reported by Krishna *et al.* [15]

Although the rapid onset and profound anesthesia effects achieved by articaine compared to lignocaine when used topically are established facts due to its increased lipid solubility and tissue diffusibility properties, as reported by Snoeck [16], this current study has used a topical intrasulcular hydrogel formulation system, which completely changes drug properties. In a controlled release formulation, mucosal exposure rather than tissue diffusibility is now the chief governing factor in establishing a drug's anesthetic effect. Although articaine's rapid hydrolysis rate might affect its surface activity in a controlled release system, established mucosal absorption and systemically predictable surface anesthetic properties appear to prefer advantages in a hydrogel formulation system. The reason behind this difference in anesthetics possibly would be due to

established principles governing drug release in a hydrogel system as outlined by Li and Wang [17]

The relevance of non-invasive anesthetic modalities in pediatric dental practice cannot be underestimated. Needle phobia and fear have been identified as two of the most prominent psychological hindrances to successful dental outcomes in pediatric dental practices [18]. The practice of using hydrogel anesthesia within the sulci is in keeping with modern approaches to care that stress a reduction in discomfort, reduced trauma and improved patient compliance. Moreover, there were neither adverse reactions nor allergic reactions within either of the two groups, ensuring that both lignocaine and articaine are safe in their conservative doses.

The pediatric dental literature evaluating injectable anesthetics has constantly favored articaine over lignocaine in terms of onset and anesthetic efficacy. While Taneja *et al.* [19] showed significantly lower pain scores and higher success rates with articaine compared to lignocaine in pediatric dentistry procedures, this finding was also shared by Jaikaria *et al.* [20], where they demonstrated an improved anesthetic success rate and reduced pain perception with articaine in the extraction of primary maxillary molars. Kulkarni *et al.* [21] demonstrated the success of topical lignocaine in decreasing procedural pain among children and highlighted the reliable surface anesthesia properties of the drug, which is in tune with the findings of the present study. The results revealed marginally faster onset and less pain associated with articaine during inferior alveolar nerve block as stated by Koul and Singh [22], although it was not found to be statistically significant [13]. The present study showed significantly superior pain management with intrasulcular lignocaine hydrogel compared to articaine hydrogel, in that anesthetic efficacy is more highly dependent on the mode of delivery or formulation than on pure pharmacological features.

Xiao-min *et al.* [23] demonstrated exceptionally high anesthetic efficacy when articaine was administered injectatively in deciduous molars, underpinning articaine's "supremacy" specifically due to its thiophene ring-mediated high lipid solubility and protein binding that promotes rapid diffusion in soft tissues and cancellous bone, thus ensuring a more consistent pulpal anesthetics during buccal infiltration/nerve block injections (in other words, direct injections in vascularized tissues near nerve endings). By contrast, studies analyzing topically/formulated (surface) preparations (sprays, gels and eutectic formulations) have uniformly demonstrated that lignocaine offers superior surface desensitization due to rapid peripheral nerve blockage in the epithelial/mucosal layers in direct opposition to peripheral nerve endings in a validated manner [22].

Various clinical trials performed with the aid of injections, as reported by Ram and Amir [24,25], Mittal [26], Rathi *et al.* [27] and Maruthingal *et al.* [28], have found articaine superior (or at least more reliable) in the aspect of greater anesthetic effect when it came to extractions and infiltration procedures, which was followed up and agreed upon in systematic reviews and meta-analyses conducted later, specifically Tong *et al.* [29] and Yu *et al.* [30], establishing the point that articaine is generally superior when it comes to lignocaine, especially with the aid of infiltration and/or blocks. Other trials and comparisons set up specifically for injections, as indicated in the study conducted and followed up with in the trial set up by Chopra *et al.* [31], similarly indicated an improved effect when it came to articaine use, based again on the improved anesthetic success and reduced need for supplemental injections. Notably, these are indicated for an agent injected into the body and distributed around areas where diffusion paths are used for the anesthetizing effect, which have no tangible or practical applicability with regard to the study's approach with the aid of an intrasulcular hydrogel. Based on this, the existing topical lignocaine, with lignocaine-based and retained in the sulcus available topically, has better addressed the existing need based on sustained local availability within the sulcus in reducing procedural pain during caries excavation, which explains why the present study results diverge from injection-dominant evidence while still remaining pharmacologically plausible.

However, the above findings cannot be extrapolated directly to topical or intra-sulcular delivery systems. Evidence has begun to emerge of the predictable surface diffusion and sustained mucosal anesthetic effect of lignocaine in gel formulation systems [20]. The present study commends itself in support of this indication, in as much as lignocaine appears capable of being more effective than other anesthetics, such as articaine, when incorporated in a hydrogel formulation and administered through the sulcus [32,33]. Evidently, the anesthetic effect has more to do with the method of delivery than with the pharmacologic mechanism of action.

Although the study has many strengths, there are a few limitations to the study. The study only focused on evaluating pain within the procedural period and did not evaluate pain that may occur at a later period. Moreover, due to the use of validated pain questionnaires, the study still has variability while evaluating pain, especially within children. Another aspect that has not been considered within the study is systemic absorption related to the sulcular route. This is because levels of lignocaine and articaine were not considered within the study and the effect of the hydrogel on microbial flora within the subgingival area within caries active children. The use of Vaseline instead of a placebo hydrogel base without active drug may have introduced a formulation related bias. However, due to the promising results, multicenter studies with bigger and more varied research populations and prolonged study durations are necessary.

The strengths of this study include randomized double-blind design, standardized intervention protocol and use of both subjective and objective pain assessment. Certain methodological limitations should be acknowledged, including non-equipotent drug concentrations, use of a non-identical placebo, absence of long-term follow-up and limited physicochemical characterization of the hydrogel formulations. Additionally, exclusion of participants requiring rescue anesthesia from per-protocol analysis and the monocentric design may affect external validity. Future

studies should incorporate standardized placebo formulations, multicentric designs and extended follow-up to validate these findings.

CONCLUSION

In the context of this RCT, the results have clearly indicated that the intrasulcular method of lignocaine hydrogel is more effective in pain control during the procedure than articaine hydrogel when treating deep carious lesions in children. Though articaine is well established for its increased effectiveness in injectable form, its pharmacological superiority did not have any bearing when introduced through a topical hydrogel delivery system. The prolonged contact and predictable surface activity of lignocaine are possibly more suited for intrasulcular administration in a topical hydrogel. The results have highlighted the fact that for more effective pediatric dental analgesia, the formulation rather than the pharmacological properties of the drug plays a much more pivotal role. Intrasulcular lignocaine hydrogel can be very effectively utilized as a non-invasive measure for pain control in adequately compliant pediatric patients with the potential for lesser dependence on injectable analgesia, which is often subject to certain impediments for widespread popularity. While the present findings are encouraging, they should not be generalized to all clinical situations and further well-designed multicenter studies with larger sample sizes and longer follow-up are necessary to validate and extend these results.

REFERENCES

[1] Rajendran, K.R. and R. Ramesh. "Effectiveness of two distraction techniques for managing anxious pediatric patients during inferior alveolar nerve block procedure." *Community Practitioner*, vol. 21, no. 4, 2024, pp. 1258-1266. https://doi.org/10.5281/zenodo.11076068.

[2] Tirupathi, S. P., and Afnan L. "Effectiveness of 'Video-Based Interventions' of Toothbrushing over Other Interventions on Improvement of Oral Hygiene in Children with Autism Spectrum Disorders (ASD): A Systematic Review and Meta-Analysis." Evidence-Based Dentistry, vol. 26, no. 2, 2025, pp. 112–113. https://doi.org/10.1038/s41432-024-01099-z.

[3] Moore, P.A. and E.V. Hersh. "Local anesthetics: Pharmacology and toxicity." *Dental Clinics of North America*, vol. 54, no. 4, 2010, pp. 587-599. https://doi.org/10.1016/j.cden.2010.06.015.

[4] Janiani, P., D. Gurunathan, and S. Nuvvula. "Influence of Temperament on the Acceptance of Two Conscious Sedation Techniques in Toddlers Undergoing Dental Treatment: A Randomised Cross Over Trial." Pain Research and Management, vol. 2023, 2023, article 6655628. https://doi.org/10.1155/2023/6655628.

[5] Malamed, S.F. *et al.* "Articaine hydrochloride: A study of the safety of a new amide local anesthetic." *Journal of the American Dental Association*, vol. 132, no. 2, 2001, pp. 177-185. https://doi.org/10.14219/jada.archive.2001.0146.

[6] Rajendran, K.R. and R. Ramesh. "Effectiveness of two distraction techniques for managing anxious pediatric patients during IANB procedure." *Community Practitioner*, vol. 21, no. 4, 2024, pp. 1258-1266. https://doi.org/10.5281/zenodo.11076068.

[7] Peppas, N.A. *et al.* "Hydrogels in pharmaceutical formulations." *European Journal of Pharmaceutics and Biopharmaceutics*, vol. 50, no. 1, 2000, pp. 27-46. https://doi.org/10.1016/S0939-6411(00)00090-4.

[8] Sasikumar, R. and R. Ramesh. "Comparison of insulin and safety syringes for pain and anxiety reduction in pediatric dental anesthesia: A randomized controlled trial." *Cuestiones de Fisioterapia*, vol. 54, no. 3, 2025, pp. 2548-2561.

[9] Sharma, A. *et al.* "Comparative evaluation of efficacy of 2% lignocaine hydrochloride gel and spray in buccal infiltration anesthesia in children." *International Journal of Clinical Pediatric Dentistry*, vol. 7, no. 2, 2014, pp. 94-97. https://doi.org/10.5005/jp-journals-10005-1248.

[10] Amorim, K.S. *et al.* "Needle-free palatal anesthesia with transcutaneous jet injection system: Randomized clinical trial." *Scientific Reports*, vol. 10, no. 1, 2020, p. 22122. https://doi.org/10.1038/s41598-020-79120-w.

[11] Das, B. *et al.* "Topical gels of lidocaine HCl using cashew gum and Carbopol 940: preparation and *in vitro* skin permeation." *International Journal of Biological Macromolecules*, vol. 62, 2013, pp. 514-517. https://doi.org/10.1016/j.ijbiomac.2013.09.049.

[12] Muniz, B.V. *et al.* "Hybrid hydrogel composed of polymeric nanocapsules for controlled drug delivery." *Scientific Reports*, vol. 8, no. 1, 2018, pp. 1-12. https://doi.org/10.1038/s41598-018-36382-4.

[13] Kumbhar, S. *et al.* "Formulation and evaluation of lignocaine hydrochloride topical gel." *Research Journal of Pharmacy and Technology*, vol. 14, no. 2, 2021, pp. 908-910. https://doi.org/10.5958/0974-360X.2021.00161.X.

[14] Singh, S.S. and M. Koul. "A comparative evaluation of pain experience and time of onset of 2% lignocaine and 4% articaine in inferior alveolar nerve block among pediatric population: A clinical study." *International Journal of Clinical Pediatric Dentistry*, vol. 17, no. 1, January 2024, pp. 67-71. https://doi.org/10.5005/jp-journals-10005-2748.

[15] Krishna, S. *et al.* "Comparison of the efficacy between articaine and lignocaine in simultaneous bilateral orthodontic maxillary premolar extractions: A split-mouth comparative study." *Cureus*, vol. 15, no. 12, December 2023, e50078. https://doi.org/10.7759/cureus.50078.

[16] Snoeck, M. "Articaine: a review of its use for local and regional anesthesia." *Local and Regional Anesthesia*, vol. 5, 2012, pp. 23-33. https://doi.org/10.2147/LRA.S16682.

[17] Li, L. and Y. Wang. "Advancements in injectable hydrogels for controlled insulin delivery: A comprehensive review of the design, properties and therapeutic applications for diabetes and its complications." *Polymers*, vol. 17, 2025, p. 780. https://doi.org/10.3390/polym17060780.

[18] Leith, R. *et al.* "Articaine use in children: A review." *European Archives of Paediatric Dentistry*, vol. 13, no. 6, December 2012, pp. 293-296. https://doi.org/10.1007/BF03320829.

[19] Taneja, S. *et al.* "Anesthetic effectiveness of articaine and lidocaine in pediatric patients during dental procedures: A systematic review and meta-analysis." *Pediatric Dentistry*, vol. 42, no. 4, July 2020, pp. 273-281. PMID: 32847666.

[20] Baldawa, H., et al. "Effectiveness of Combined Extraoral Vibration and Cooling on Pain Perception Due to Inferior Alveolar Nerve Block Administration in Children: A Systematic Review and Meta-Analysis." Journal of Dental Anesthesia and Pain Medicine, vol. 25, no. 4, 2025, pp. 227–237. https://doi.org/10.17245/jdapm.2025.25.4.227.

[21] Kulkarni, M.M. *et al.* "A comparative study of 10% lidocaine spray versus eutectic mixture of 2.5% lidocaine and 2.5% prilocaine (EMLA) to attenuate pain of peripheral venous cannulation in children: A prospective randomized control trial at a tertiary care centre." *Indian Journal of Anaesthesia*, vol. 67, no. 2, February 2023, pp. 167-172. https://doi.org/10.4103/ija.ija_705_22.

[22] Singh, S.S. and M. Koul. "A comparative evaluation of pain experience and time of onset of 2% lignocaine and 4% articaine in inferior alveolar nerve block among pediatric population: A clinical study." *International Journal of Clinical Pediatric Dentistry*, vol. 17, no. 1, January 2024, pp. 67-71. https://doi.org/10.5005/jp-journals-10005-2748.

[23] Xiao, A. *et al.* "General anesthesia in children and long-term neurodevelopmental deficits: A systematic review." *Frontiers in Molecular Neuroscience*, vol. 15, 2022, pp. 972025. https://doi.org/10.3389/fnmol.2022.972025.

[24] Janiani, P. *et al.* "Pain and anxiety using lidocaine and articaine in children undergoing full mouth rehabilitation under general anesthesia: A randomized controlled trial." *Journal of Population Therapeutics and Clinical Pharmacology*, vol. 30, no. 10, 2023, pp. 24-31. https://doi.org/10.47750/ jptcp.2023.30.10.005.

[25] Ram, D. and E. Amir. "Comparison of articaine 4% and lidocaine 2% in paediatric dental patients." *International Journal of Paediatric Dentistry*, vol. 16, no. 4, 2006, pp. 252-256. PMID: 16759322.

[26] Mittal, M. *et al.* "Comparison of anesthetic efficacy of 2% lidocaine and 4% articaine for extraction of primary maxillary molars." *Anesthesia Essays and Researches*, vol. 9, no. 3, 2015, pp. 377-382. PMID: 26883609.

[27] Rathi, N.V. *et al.* "Anesthetic efficacy of single buccal infiltration of 4% articaine in comparison with 2% lidocaine for extraction of primary molars." *Journal of Dental Anesthesia and Pain Medicine*, vol. 19, no. 1, 2019, pp. 31-37. PMID: 30883236.

[28] Maruthingal, S. *et al.* "Comparison of anesthetic efficacy of articaine and lidocaine in children: A split-mouth study." *Journal of Pharmacy and Bioallied Sciences*, vol. 7, suppl. 1, 2015, pp. S166-S170.

[29] Tong, H.J. *et al.* "Anaesthetic efficacy of articaine versus lidocaine in children: A systematic review and meta-analysis." *International Journal of Paediatric Dentistry*, vol. 28, no. 4, 2018, pp. 347-360. PMID: 29635712.

[30] Yu, J. *et al.* "Can buccal infiltration of 4% articaine replace inferior alveolar nerve block with 2% lidocaine for dental treatment in children? A systematic review." *Journal of Dentistry*, vol. 113, 2021, p. 103792. PMID: 34564678.

[31] Chopra, R. *et al.* "Clinical evaluation of buccal infiltration using articaine versus inferior alveolar nerve block using lignocaine for pulpotomy in primary mandibular molars." *Journal of Clinical Pediatric Dentistry*, vol. 40, no. 6, 2016, pp. 452-455. PMID: 27805834.

[32] Mukundan, D., and D. Gurunathan. "Effectiveness of Nitrous Oxide Sedation on Child's Anxiety and Parent Perception During Inferior Alveolar Nerve Block: A Randomized Controlled Trial." Cureus, vol. 15, no. 11, 2023, article e48646. https://doi.org/10.7759/cureus.48646.

[33] Hisham, A. R. B., et al. "Effectiveness of Local Anesthesia in Children's Pain Perception and Sedation During Dental Procedures Under General Anesthesia: A Randomized Clinical Study." Ain Shams Dental Journal, vol. 35, no. 3, 2024, pp. 305–313. https://doi.org/10.21608/ASDJ.2024.295745.1310.