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ORIGINAL ARTICLE

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Comparative evaluation of post operative pain after irrigation with different concentrations of sodium hypochlorite: a split mouth triple blinded randomized controlled trial

Avaliação comparativa da dor pós-operatória após irrigação com diferentes concentrações de hipoclorito de sódio: um estudo randomizado e controlado, triplo-cego, de boca dividida

Divya MUKUNDAN[1], **Vignesh RAVINDRAN**[1]

1 - Department of Pediatric and Preventive Dentistry, Saveetha Dental College and Hospitals, Saveetha Institute of Medical and Technical Sciences, Saveetha University, Chennai, Tamilnadu, India

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ABSTRACT

Objective: Post-endodontic pain is a frequently occurring adverse outcome that impacts a patient's recovery after a root canal procedure. A range of 4% to 50% of patients experienced moderate-to-severe discomfort after undergoing endodontic therapy. American Association of Pediatric Dentistry (AAPD) standards recommend treating primary teeth with 1% sodium hypochlorite irrigation. Despite its widespread use, there is no study comparing postoperative outcomes of 1% sodium hypochlorite and higher concentrations. The aim of this study was to compare the postoperative pain following pulpectomy procedures in primary teeth irrigated with 1% sodium hypochlorite versus those irrigated with a higher concentration of 3% sodium hypochlorite. **Materials and Methods:** This study was a split mouth trial. A total of 36 participants were allocated into two groups. In group 1, canal was irrigated using 1% sodium hypochlorite solution, and in group 2 canal was irrigated using 3% sodium hypochlorite solution. **Results:** Post operative pain after the procedure was evaluated using a visual analogue scale at four specific time intervals baseline, 6 hours, 12 hours and 24 hours. However, 8 participants who took analgesics were excluded, resulting in 28 participants. The paired t test was utilized to evaluate the difference between two groups. At 6 hours, the 1% NaOCl group reported considerably less pain than 3% NaOCl group with a p value 0.003. However, at 12 hours and 24 hours there was no statistical difference between the groups with a p value >0.005. **Conclusion:** This study indicates that, in comparison to higher concentrations, the use of 1% sodium hypochlorite showed reduced postoperative discomfort.

KEYWORDS

Irrigation; Pain; Primary teeth; Pulpectomy; Sodium hypochlorite.

RESUMO

Objetivo: A dor após um procedimento de canal radicular é um efeito adverso frequente que afeta a recuperação do paciente após um procedimento de canal radicular. De 4% a 50% dos pacientes apresentaram desconforto moderado a grave após a terapia endodôntica. Os padrões da Associação Americana de Odontologia Pediátrica (AAPD) recomendam o tratamento de dentes decíduos com irrigação de hipoclorito de sódio a 1%. Apesar de seu uso generalizado, não há nenhum estudo que compare os resultados pós-operatórios do hipoclorito de sódio a 1% e de concentrações mais altas. O objetivo deste estudo foi comparar a dor pós-operatória após procedimentos de pulpectomia em dentes decíduos irrigados com hipoclorito de sódio a 1% com aqueles irrigados com uma concentração mais alta de hipoclorito de sódio a 3%. **Material e Métodos:** Esse estudo foi um ensaio de boca dividida. Um total de 36 participantes foi alocado em dois grupos. No grupo 1, o canal foi irrigado com solução de hipoclorito de sódio a 1% e, no grupo 2, o canal foi irrigado com solução de hipoclorito de sódio a 3%.

Resultados: A dor pós-operatória após o procedimento foi avaliada por meio de uma escala visual analógica em quatro intervalos de tempo específicos: 6 horas, 12 horas e 24 horas. No entanto, 8 participantes que tomaram analgésicos foram excluídos, resultando em 28 participantes. O teste t pareado foi utilizado para avaliar a diferença entre os dois grupos. Em 6 horas, o grupo do NaOCl a 1% relatou consideravelmente menos dor do que o grupo do NaOCl a 3%, com um valor de p de 0,003. Entretanto, após 12 horas e 24 horas, não houve diferença estatística entre os grupos, com um valor de p >0,005. **Conclusão:** Este estudo indica que, em comparação com concentrações mais altas, o uso de hipoclorito de sódio a 1% reduziu o desconforto pós-operatório.

PALAVRAS-CHAVE

Irrigação; Dor; Dentes decíduos; Pulpectomia; Hipoclorito de sódio.

INTRODUCTION

Primary teeth are essential for phonetics, aesthetics, mastication, and maintaining space for permanent teeth. Hence, preserving primary teeth holds important significance. Children who have poor dental hygiene practices are prone to experiencing frequent occurrences of severe dentinal caries, discomfort, and swelling [1]. Pulpectomy is a procedure that refers to the removal of the roof of the pulp chamber to provide access to the root canals. These canals are then cleaned, shaped, disinfected, and filled with a material that is resorbable. Consequently, the tooth can be preserved in the dental arch while maintaining the tooth's functionality [2].

Pulpectomy is considered as an alternative option to tooth extraction in cases of irreversible pulpitis or dental pulp necrosis. Bacteria and the byproducts they produce in root canal systems are a major cause of pulpal and periapical infections [3]. Therefore, in order to eradicate infection from the root canal, it is essential to perform chemo mechanical preparation and irrigation using antibacterial solutions. This is necessary to reduce the presence of microorganisms and their byproducts. Because of the complexities of the root canal, chemical irrigation and mechanical preparation play an important role in achieving appropriate disinfection [4,5].

Sodium hypochlorite (NaOCl) is well recognized as the predominant irrigation solution in endodontics for over 70 years because of its potent antibacterial characteristics and exceptional ability to dissolve tissues. The effectiveness of NaOCl in dissolving organic soft tissue and biofilms is directly linked to its concentration. This higher concentration has an ability to irritate the periapical tissues [6]. The toxicity of endodontic irrigant to periapical tissues is a serious concern, especially when treating children in paediatric dentistry. Because of the possibility of resorption areas, it is crucial to exercise caution when it comes to the overflow of irrigating solution via the apical region of primary teeth. This might result in damage to the permanent tooth bud underneath.

A study by Wang et al. [7] showed that a higher concentration of 6% NaOCl resulted in enhanced antibacterial efficacy, nevertheless, the adverse consequence was that it had the potential to harm the periapical tissues and increase cytotoxicity if it was forced out beyond the apical foramen. An in vivo study by Liapis et al. [8] revealed a notable difference in the cytotoxicity of varying concentrations of NaOCl employed as the irrigant. This finding implies a greater probability of experiencing post-operative pain in clinical scenarios when a higher concentration of 3% NaOCl was used.

Post-endodontic pain is a frequently occurring adverse outcome that impacts a patient's recovery after a procedure. A range of 4% to 50% of patients experienced moderate-to-severe discomfort after undergoing endodontic therapy, regardless of whether their pulps were necrotic or vital [9]. Multiple reports have specifically addressed these potential complications [10,11]. There are, however, few evidence-based studies that assessed postoperative pain using various NaOCl irrigation concentrations.

In accordance with the American Association of Pediatric Dentistry (AAPD) guidelines [12], the use of 1% sodium hypochlorite irrigation has been established in the treatment of primary teeth. However, despite its common practice, there remains a gap in research specifically comparing the postoperative outcomes between the utilization of 1% sodium hypochlorite and higher concentrations. Thus, this study was conducted to compare the postoperative pain following pulpectomy procedures in primary

teeth irrigated with 1% sodium hypochlorite versus those irrigated with a higher concentration of 3% sodium hypochlorite.

MATERIAL & METHODS

Study design

The present investigation was conducted as a split-mouth, triple blinded, randomized controlled experiment.

Study setting

The study was carried out at a private dental institution in Chennai in the Department of Paediatric and Preventive Dentistry.

Ethical clearance

The institutional ethics committee (IHEC/SDC/PEDO-2101/23/140) authorized the study before its commencement. The study was registered with the Clinical Trials Registry India (CTRI) with a registration number CTRI/2023/11/059520. Parents gave written informed consent. The participants remained anonymous.

Study population

Patients visiting the Paediatric dental outpatient department between November 2023 and December 2023, aged 4 to 8 years, were included in the study. A total of thirty six children were assigned to two groups using a random allocation process.

Inclusion criteria

Children requiring pulpectomy procedure for two primary mandibular posterior teeth, children belonging to Frankl 2 and 3 ratings during the examination process, participants belonging to American Society of Anaesthesiologists 1 category.

Exclusion criteria

Teeth with calcified canals, crowns that cannot be restored, or showing evidence of significant internal or external root resorption. Children with any systemic disorder or medically compromising conditions and children who had been administered antibiotics within 2 weeks prior to the procedure.

Sample size calculation

A preliminary pilot split mouth study was conducted on five patients to gather initial data on pain levels following pulpectomy using 1% and 3% sodium hypochlorite (NaOCl) solutions as irrigants. The pilot data provided estimates of variability and effect size, which were used in a sample size calculation performed using MedCalc software version 23.0.1. The objective was to determine the number of participants required to detect a significant mean difference of 20% in post-operative pain between the two groups, with a targeted study power of 95% and an alpha error of 0.05. The software program calculated a sample size of 28 taking the effect size, variability, and desired statistical power into account. A total of 36 participants were initially enrolled to account for potential dropouts, ensuring that the required sample size was maintained for the study. Data obtained from the pilot study were not included in the final trial.

Randomization

A computerized random number generator created a randomized list, the allocation ratio was 1:1 and the allocation sequence were placed within an opaque, sealed envelope. Based on the order of enrolment, the patients were assigned numbers. A dental assistant opened these envelopes at the time of the intervention. The participants were divided into two groups, each group consisting of 36 participants. In Group 1, the canals were irrigated using a 1% sodium hypochlorite solution, and Group 2 with 3% sodium hypochlorite solution. Data collection was carried out by a dentist. The data collection was conducted in a blinded manner, without any differentiation between the participants. Participants, operator and data collector were blinded during the procedure.

Procedure

Before any dental intervention, participants were instructed to record their perceived pain intensity using a Visual Analogue Scale (VAS), which provided a quantitative measure of pain. Baseline pain assessment was done on the day of the procedure. Each patient underwent a single-visit pulpectomy performed by a trained Paediatric dentist. An Inferior Alveolar Nerve Block and a lingual nerve block were administered following the application of topical

anesthetic gel (Progel B-Benzocaine Gel 20%) to both groups. A 30-gauge, 25 mm needle (Hindustan syringes-Dispo van) was used to deliver 1.5 mL of 2% lignocaine hydrochloride with 1:100,000 adrenaline.

To isolate the tooth, a rubber dam was used. Access to the pulp chamber was achieved with a high-speed diamond round bur (#330). Upon completion of the access cavity preparation, the root canals were located. A 10 size K-file (Mani files) was introduced into each canal, stopping approximately 1 mm short of the root apex as indicated by preoperative radiographs. Gentle filing was performed in a watch winding motion, followed by saline irrigation. The pulp tissue was extirpated using a 15 size H-file (Mani files), with subsequent irrigation using 1 ml of 1% or 3% sodium hypochlorite.

Canal preparation was completed to the working length using Kedo S Plus rotary files (Kedo Files) in a clockwise direction, followed by irrigation with 2 ml of 1% or 3% sodium hypochlorite. Final canal preparation was performed with Kedo S Plus rotary files, and canals were subsequently irrigated with 5 ml of saline. The canals were obturated with Calcium hydroxide and Iodoform paste (Metapex, Met Biomed, South Korea) and restored with Type IX GIC (Glassionomer FX Ultra – Shofu INC, Japan). Patients with under or over obturation were excluded from the study. Analgesics, Paracetamol 250 mg was prescribed three times daily (TDS), in cases of severe pain.

The pain was evaluated using a visual analogue scale (VAS) at four specific time intervals: baseline (before treatment), 6 hours, 12 hours and 24 hours after the procedure. The pain level was recorded on a number scale of 0-10, with 0 representing no pain, 1-3 representing mild pain, 4-6 representing moderate pain, and 7-10 representing severe pain. Patients were contacted by phone at certain intervals following their visit to ensure that their pain had been accurately recorded on the VAS. They were directed to record the number of analgesic pills if taken. Participants who have taken analgesics were excluded from the study.

After a one-week interval, a similar pulpectomy procedure was repeated on the contralateral molar of the same participant irrigating with 1% or 3% sodium hypochlorite solution. Post-procedural pain was evaluated and compared with the previous procedure, considering the VAS ratings provided by the child.

Statistical analysis

The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results reveal that values follow Normal distribution. Therefore, to analyse the data, parametric was applied. Descriptive statistics was expressed using mean and standard deviation. Inferential statistics was done using paired t test to analyse comparison of time interval between the groups. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019) was used. Significance level is fixed as 5% ($\alpha = 0.05$). P-value 0.05 is considered to be statistically significant.

RESULTS

The current split-mouth study involved 36 children aged 4 to 8 years who underwent pulpectomy. After 6 hours, 8 participants had taken analgesics and were excluded from the study. Consequently, 28 participants were included in the final analysis, with their demographic details provided in Table I.

The pain scores for both the 1% and 3% sodium hypochlorite irrigation groups exhibited a decrease from baseline to 24 hours post irrigation. When intra group comparison was done using paired t test, there was a significant reduction in pain score from baseline to 24 hours with p value of 0.001 in both the groups (Table II, Graph 1). However, when intergroup comparison was done from baseline to 24 hours, there was significant difference at 6 hours with a p value 0.003 (Table III).

Table I - Demographic details of the patients participating in the study

AGE DISTRIBUTION	FREQUENCY (N)	PERCENTAGE (%)
4 years	5	17.9
5 years	13	46.4
6 years	7	25.0
7 years	1	3.6
8 years	2	7.1
GENDER DISTRIBUTION	**FREQUENCY (N)**	**PERCENTAGE (%)**
FEMALE	22	78.6
MALE	6	21.4

Table II - Comparison of pain score within the group using Paired t test

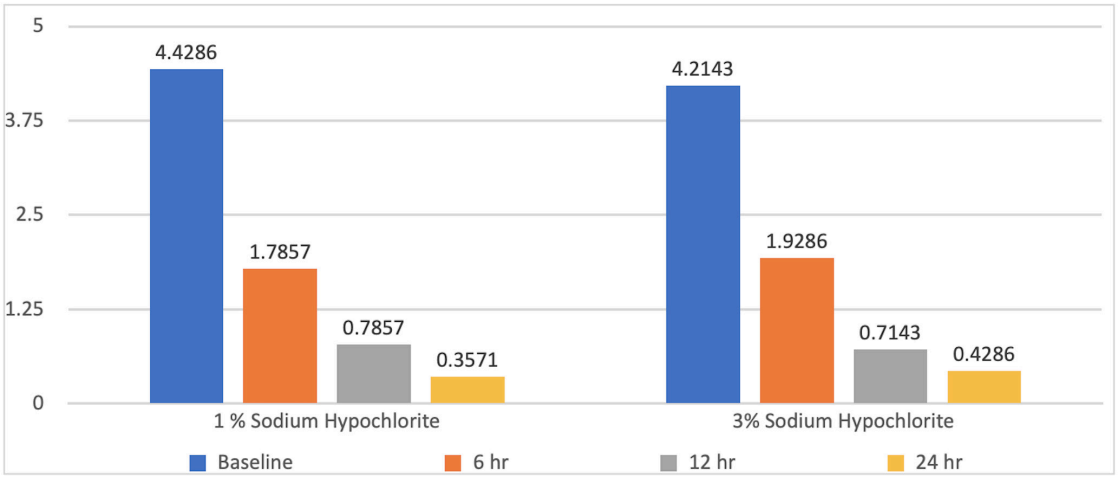
Groups	Mean ± Std Deviation				P value
	Baseline	6 hours	12 hours	24 hours	
1% Sodium hypochlorite	4.428 ± 2.062	1.785 ± 1.370	0.785 ± 0.994	0.357 ± 0.780	0.001*
3% Sodium hypochlorite	4.214 ± 1.912	1.928 ± 1.488	0.714 ± 0.975	0.428 ± 0.835	0.001*

*Denotes the value obtained was statistically significant as significance level was set at 0.05.

Table III - Intergroup Comparison of pain score using Paired t test

Post operative pain	1% Sodium hypochlorite	3% Sodium hypochlorite	P value
Baseline	1.474 ± 0.214	1.484 ± 0.326	0.449
6 hours	1.799 ± 0.142	1.892 ± 0.152	0.003*
12 hours	1.799 ± 0.071	1.878 ± 0.142	0.769
24 hours	1.274 ± 0.071	1.284 ± 0.091	0.713

*Denotes the value obtained was statistically significant as significance level was set at 0.05.



Graph 1 - Comparison of pain score within the group using Paired t test.

DISCUSSION

Ensuring the prevention and effective management of pain during endodontic therapy is crucial for successful treatment. The cause of pain or discomfort after pulpectomy procedure is multifactorial and depends upon the immunological response of the host, infection, and damage to peri apical tissues [13]. Nonsteroidal anti-inflammatory drugs (NSAIDs) have been found to have limited efficacy in young children. Research suggests that these medications may not provide significant relief for pain and inflammation in this age group [14,15].

The primary objective of pulpectomy is to thoroughly clean and shape the root canals, ensuring the removal of all debris and bacteria-laden tissue. By achieving this, the procedure aims to minimize post-operative pain for the patient. Irrigation plays an important role in post-operative care for maintaining optimal healing conditions. Hence the current study focused on comparing the effectiveness of different sodium hypochlorite concentrations on post-operative pain.

Regarding the ideal NaOCl concentration for root canal preparation, there is currently no agreement. Although NaOCl has better tissue dissolving characteristics, it also shows more cytotoxicity at higher concentrations [16]. The majority of research on postoperative pain has utilized concentrations of sodium hypochlorite ranging from 2.5% to 5.25% or higher [17,18]. However, according to American Association of Paediatric Dentistry (AAPD) guidelines [12], the use of 1% sodium hypochlorite irrigation has been recommended in the treatment of primary teeth. Hence in the current study 1% NaOCl was compared with a higher concentration of 3% NaOCl.

The current investigation was a randomized split mouth study. Since pain perception varies among individuals and the main objective of this study was to evaluate the post operative pain, a randomized split-mouth design was implemented for this investigation. This study aimed to assess postoperative pain in patients following pulpectomy procedure with various irrigation solutions, including 1% and 3% NaOCl, at different time intervals. The current study utilized the Visual Analogue Scale (VAS) to evaluate the pain experienced after the procedure.

VAS is a well-recognized subjective pain evaluation scale, consisting of a 10-centimeter line with ends labelled as "no pain" and "worst possible pain" to measure pain severity. Children were instructed to mark their perceived pain level on the line, allowing for a subjective but reliable measure of pain intensity [19].

After 6 hours, 8 participants who had taken analgesics were excluded from the study, leaving 28 participants in the final analysis. Among the excluded participants, 2 participants were treated with 1% sodium hypochlorite and 6 with 3% sodium hypochlorite. Overall, there was no significant difference observed between the irrigants used at 12, and 24 hours. However, the group treated with a 1% concentration of sodium hypochlorite experienced lower levels of postoperative pain in the first six hours following the procedure. This can be due to higher concentrations of NaOCl can cause greater tissue irritation due to their strong antimicrobial and proteolytic properties. This increased irritant effect might lead to more inflammation and postoperative discomfort. Lower concentrations, like 1% NaOCl, may be gentler on periapical tissues, resulting in decreased irritation and subsequent pain [19].

The findings of the present study correlate with the research conducted by Mostafa et al. [20] who concluded that low concentration of NaOCl irrigation resulted in less post operative pain when compared to higher concentrations. Research indicates that even at lower concentrations, NaOCl effectively eliminates bacteria within the root canal [21]. Hence, in addition to efficiently cleaning the canal, use of the lower concentration solution may potentially reduce tissue inflammation and subsequent pain [22].

Moreover, according to Rôças and Siqueira [23] it is assumed that lower concentrations have a lesser detrimental effect on vital structures including periapical tissues and dentinal structures and the preservation of vital structures may contribute to reducing postoperative pain due to higher concentrations of NaOCl. However, in contrast to the current study result, a study by Farzaneh et al. [24] reported less postoperative pain in 5.25% NaOCl when compared to 2.5% NaOCl. It is important to recognize that postoperative pain can arise from multiple factors beyond the irrigation protocol. Variables influencing pain include pulp and apical status, size of the periapical lesion, irrigation pressure and size of the apical foramen.

The study has few limitations such as the limited sample size, the short-term follow-up period may not fully capture post-operative discomfort. The narrow range of sodium hypochlorite concentrations compared in the present study. These limitations highlight the need for larger, more diverse studies with longer follow-up durations to better understand the relationship between sodium hypochlorite concentrations and root canal post-operative pain.

CONCLUSION

Within the limitations of this study, the results indicate that using 1% sodium hypochlorite (NaOCl) was associated with lower post-operative pain, suggesting a potential advantage over higher concentrations.

Author's Contributions

DM: Conceptualization, Methodology, Formal Analysis, Investigation, Resources, Data Curation, Writing – Original Draft Preparation. VR: Conceptualization, Validation, Investigation, Writing – Review & Editing, Visualization, Supervision, Project Administration.

Conflict of Interest

The authors have no conflicts of interest to declare.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies of Clinical Trial Registry India. This study protocol was reviewed and approved by Saveetha Dental College – Institutional Human Ethical Committee (SD-IHEC), approval number IHEC/SDC/PEDO-2101/23/140. The study was registered with the Clinical Trials Registry India (CTRI) with a registration number CTRI/2023/11/059520

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Vignesh Ravindran
(Corresponding address)
Department of Pediatric and Preventive Dentistry, Saveetha Dental College and Hospitals, Saveetha Institute of Medical and Technical Sciences, Saveetha University, Chennai, Tamilnadu, India
Email: vigneshr.sdc@saveetha.com

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