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A randomised clinical study to evaluate the effect of different irrigation needles during pulpectomy in primary teeth

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Introduction
Microorganisms are the primary cause of pulpal and periapical infections. Endodontic therapy is an effective treatment for eradicating these microorganisms from the root canal. This therapy aims to thoroughly clean, shape, and hermetically obturate the root canals. Despite its effectiveness, post-operative pain following a pulpectomy remained a significant issue for both patients and clinicians.
Aim
The aim of the study was to evaluate the effect of microbial reduction and intensity of post-operative pain following pulpectomy in primary molars, using three irrigation needles.
Materials and Methods
The study included patients aged 5-8 years who required pulpectomy. Fifteen participants were randomly divided into three groups: those using a conventional open-ended needle, a side-vented needle, and a double side-vented needle. Microbial samples were collected before and after irrigation and sent for microbial assay. Pre- and postoperative observations were recorded to determine the mean reduction in bacterial colony-forming units (CFU)/mL. The teeth were then obturated and permanently restored. Post-operative pain was assessed at six, 12, 24, 48, and 72 hours, and again after one week, using the Wong-Baker FACES Pain Rating Scale. The scores were statistically analyzed.
Results
Data analysis revealed significant differences in microbial reduction among the three groups ($p < 0.05$). The double side-vented needle demonstrated superior performance in reducing microbial load compared to the other two types. In terms of post-operative pain, Group C reported lower VAS scores at all time points compared to Groups A and B ($p < 0.05$).
Conclusion
This randomized clinical trial highlighted the importance of selecting appropriate irrigation techniques in pediatric dentistry. The double side-vented needle not only significantly reduced microbial load but also minimized post-operative discomfort for patients undergoing pulpectomy.

I. Introduction

Pulpectomy is a vital dental procedure performed primarily on primary teeth affected by irreversible pulpitis or necrosis. The primary goal of this treatment is to remove infected pulp tissue, disinfect the root canal system, and fill the space with a biocompatible material to maintain the tooth's function until natural exfoliation occurs. Given the unique anatomical features of primary molars, including their complex root canal systems and

the presence of accessory canals, effective cleaning and disinfection are crucial for successful treatment outcomes.[1]

Managing pulpally involved primary teeth remains a clinical challenge due to their complex root canal anatomy and the high bacterial load within the canals. Coll JA et al. (2020) emphasized the pivotal role of microbial presence in the progression of pulpal disease and the development of periapical pathology. Consequently, effective microbial reduction during pulpectomy is crucial to minimize the risk of postoperative complications such as pain, swelling, and reinfection..[2]

In pediatric dentistry, where patient comfort and safety are of utmost importance, minimizing postoperative pain is a key concern. Effective pain management following dental procedures plays a vital role in enhancing patient satisfaction and promoting cooperation in future visits. Studies have shown that postoperative pain is influenced by multiple factors, including the degree of tissue trauma during treatment, the efficacy of irrigation protocols, and the child's individual pain perception and response..[3]

Irrigation is a critical component of endodontic therapy, as it aids in flushing out debris, dissolving organic matter, and disinfecting the canal system. Various irrigating solutions, such as sodium hypochlorite and chlorhexidine, have been utilized for their antimicrobial properties. However, the efficacy of these solutions can be significantly influenced by the irrigation technique employed. The design of irrigation needles is particularly important; different needle types can affect fluid dynamics within the canal, impacting how effectively irrigants reach all areas of the root canal system.[4]

Among various irrigation techniques, needle design significantly affects the efficacy of irrigation in removing debris and reducing bacterial load. Traditional open-ended needles deliver irrigants directly but may lack sufficient lateral distribution, leading to incomplete disinfection.[5] Side-vented needles, designed to disperse the irrigant laterally, improve the distribution of the solution while minimizing apical extrusion, thereby enhancing safety and efficacy.[6] The latest advancement in irrigation technology, the double side-vented needle, optimizes irrigant flow dynamics by providing two lateral outlets, thereby ensuring more uniform dispersion and improved microbial reduction.[7]

This study focuses on evaluating three different irrigation needle designs: open vented, side vented, and double side vented needles. Each design has unique characteristics that may influence both microbial reduction and post-operative pain. The open vented needle allows for unrestricted flow but may not effectively deliver irrigants to all parts of complex canal systems.[8] The side vented needle directs fluid flow laterally from the tip, which may enhance cleaning efficacy in certain situations.[9] In contrast, the double side vented needle is designed to provide dual outlets for irrigation fluid, potentially improving disinfection by allowing for better distribution of irrigants throughout the canal.

II. Materials And Method

The present study was conducted in the department of paediatric and preventive dentistry Peoples College of Dental Sciences and Research Centre, Bhopal, India. We obtained ethical clearance for the study from the institutional review board.

Study design

The patients' parent(s) were given adequate information regarding the required treatment. Patients in the study were voluntary, and written consent of the parents was received.

Inclusion criteria

- Primary molar teeth requiring pulpectomy
- Patients with no history of taking analgesics and antibiotic 12 hours before the pulpectomy
- Cooperative patients in ages ranging from 5 to 8 years
- Absence of internal or external pathologic root resorption
- Sufficient coronal tooth structure
- Teeth with at least 2/3nd roots remaining

Exclusion criteria

- Greater than grade 1 mobility
- Patients with systemic disease
- Patients with special healthcare need

Randomisation and allocation

A total of 54 children were enrolled in the study. Participants were randomly assigned into three groups (n=18) each based on the type of irrigation needle used during the pulpectomy procedure:

1. **Group A**: Open vented irrigation needle(n=18)

2. **Group B**: Side vented irrigation needle(n=18)
3. **Group C**: Double side vented irrigation needle (n=18)

Patient-related factors, including age and sex, as well as preoperative tooth-related factors such as baseline pain levels, were recorded for all participants.(figure 1).

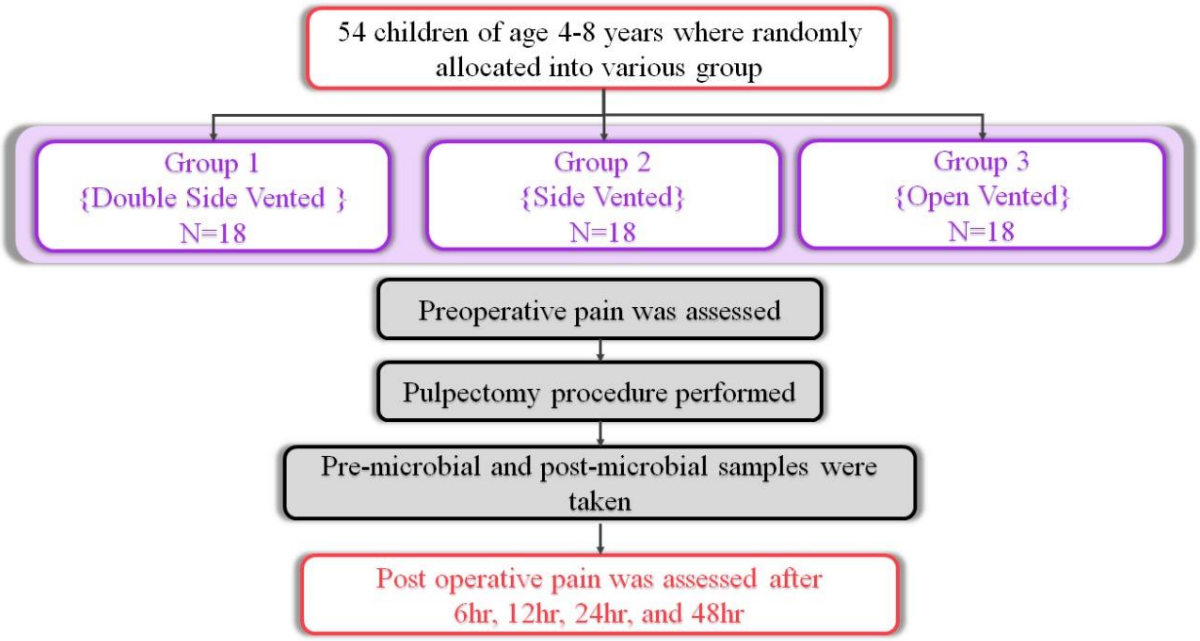

Figure 1 Group Allocation Flow Diagram

Figure 2 Different Types of Irrigation Needles

Preoperative Assessment

Prior to the procedure, a thorough clinical examination was performed, including radiographic evaluation to confirm the diagnosis and assess the extent of pulp involvement. The Wong-Baker Faces Pain Scale was used to evaluate preoperative pain intensity.

Figure 3 SEQ Figure * ARABIC 2 Pain scale used in the study

Pulpectomy Procedure

The pulpectomy procedure for all patients was performed by an experienced operator. The participants were also blinded and not informed of their group allocation. After application of a topical anesthetic, the tooth was anesthetized with 2% lignocaine with 1: 200000 adrenaline. Following rubber dam isolation, caries were removed. After access opening with endo access burs (Mani EA 10, EA 13) and minimal instrumentation with 15-size K-file (Mani Inc., Japan),The working length (WL) was determined using a radiovisiography (RVG) system. The WL for each root canal was set at 1 mm shorter than the radiographic apex.

In all three groups, root canals were shaped using Kedo SG files at a rotational speed of 300 rpm. This shaping was performed to a predetermined working length (WL), which ensured that the root canal was adequately tapered and cleaned for obturation.

Microbial sampling was conducted at two stages:

- **Initial Sampling**: After access cavity preparation, three successive sterile paper points were introduced into the root canal to collect baseline microbial samples.
- **Post-Irrigation Sampling**: After biomechanical preparation and irrigation, three additional sterile paper points were placed in the canal for 60 seconds to absorb fluid before being retrieved for microbial evaluation.

Irrigation Protocol

In Group A(Open vented irrigation needle) canals were irrigated with 2.5 mL Chlorhexidine 2% using a syringe and a 30-G, the open ended needle was placed 2 mm short of the WL during the canal preparation.

In Group B, (Side vented irrigation needle) canals were irrigated with 2.5 mL Chlorhexidine 2% using a syringe and a 30-G, the side vented needle was placed 2 mm short of the WL during the canal preparation

In group C, (Double side vented irrigation needle) canals were irrigated with 2.5 mL Chlorhexidine 2% using a syringe and a 30-G double side vented needle (NT irrigating needle) was placed 2 mm short of the WL during the canal preparation

Once the canal shaping and irrigation were complete, the canals were thoroughly dried to remove any residual irrigation solution or debris. After drying, the canals were obturated with Vitapex paste, a root canal filling material. Following obturation, periapical radiographs were taken to assess the quality of the canal filling.

Microbiological Evaluation

Microbial samples collected using paper points were immediately transferred into Eppendorf tubes containing 1 ml of phosphate-buffered saline (PBS) as a transport medium. All necessary instruments and samples were maintained in a UV chamber under fluorescent light conditions to minimize contamination. From each Eppendorf tube, 100 µl of sample was pipetted onto nutrient agar plates. Samples were streaked using an L-shaped inoculating loop and then incubated for 24 hours in a Bio-Oxygen Demand (BOD) incubator at 37°C. After incubation, colony counting was performed using a digital colony counter to determine the total colony-forming units (CFUs) present in each sample.

Post-Operative Pain Assessment

A scale was given to the participants' parent(s) to note the PP intensity of their children at 6, 12, 24, and 48 hours after the pulpectomy. All Post-operative pain intensity was assessed using a questionnaire based on the Wong-Baker Faces Pain Scale at four time intervals. Participants or their guardians were instructed on how to use the scale to report pain levels accurately.

III. Results

Statistical Data Analysis

For the analysis of this study, IBM SPSS Statistics version 25.0 was used. One-way ANOVA was used to compare the microbial counts across the three groups both pre- and post-irrigation. Repeated Measures ANOVA was used to analyze the time-dependent changes in pain levels within each group, assuming normality. The 95% Confidence Intervals (CIs) was reported for the means and significant differences to provide more detailed information on the precision of the estimates. A p-value of less than 0.05 was considered statistically significant**.**

The differences between the groups concerning demographic data and pre-operative microbial counts were not statistically significant (P > .05) (figure 3). No participants were excluded from the study due to loss to follow-up. There was no difference concerning the distribution of treated teeth between the groups (P > .05).

Over-filling was not evaluated in this study. However, microbial reduction and post-operative pain were the primary outcomes assessed. The mean microbial count values post-irrigation are presented in Figure 3. After irrigation, Group 1 (Double Side Vented Needles) demonstrated significantly lower microbial counts compared to Group 2 (Side Vented Needles) and Group 3 (Open Ended Needles) (P < .05).

The Wong-Baker Faces Pain Scale scores were recorded post-operatively at 6, 24, and 48 hours. At 6 hours, participants in Group 3 reported higher post-operative pain values compared to Groups 1 and 2 (P < .05). At 24 hours, Group 1 demonstrated the lowest pain scores, and this difference was statistically significant between the groups (P = .017). By 48 hours, no significant difference in pain intensity was observed among the groups (P > .05).

Location	**Intracanal medicament**	**Mean**	**S.D**	**95% Confidence Interval**		**'F' statistic**	**P value**
				Lower bound	**Upper bound**		
Pre - operative	Group 1	9.3333	1.00000	8.5647	10.1020	.304	.742 (NS)
	Group 2	9.1429	1.06904	8.1542	10.1316		
	Group 3	9.6000	.89443	8.4894	10.7106		
6 hours	Group 1	2.0000	1.41421	.9129	3.0871	3.155	.067 (NS)
	Group 2	1.4286	.97590	.5260	2.3311		
	Group 3	3.2000	1.09545	1.8398	4.5602		
12 hours	Group 1	.8889	1.05409	.0786	1.6991	.772	.477 (NS)
	Group 2	1.1429	1.06904	.1542	2.1316		
	Group 3	1.6000	.89443	.4894	2.7106		
24 hours	Group 1	.0000	.00000	.0000	.0000	5.167	.017*
	Group 2	.2857	.75593	-.4134	.9848		
	Group 3	1.2000	1.09545	-.1602	2.5602		
48 hours	Group 1	.0000	.00000	.0000	.0000	-	-
	Group 2	.0000	.00000	.0000	.0000		
	Group 3	.0000	.00000	.0000	.0000		

Table 1 Comparison of pain – Wong Baker Faces Pain Scale

In all groups, the highest post-operative pain intensity was recorded at 6 hours after treatment, with pain levels decreasing steadily over time (Table 1).

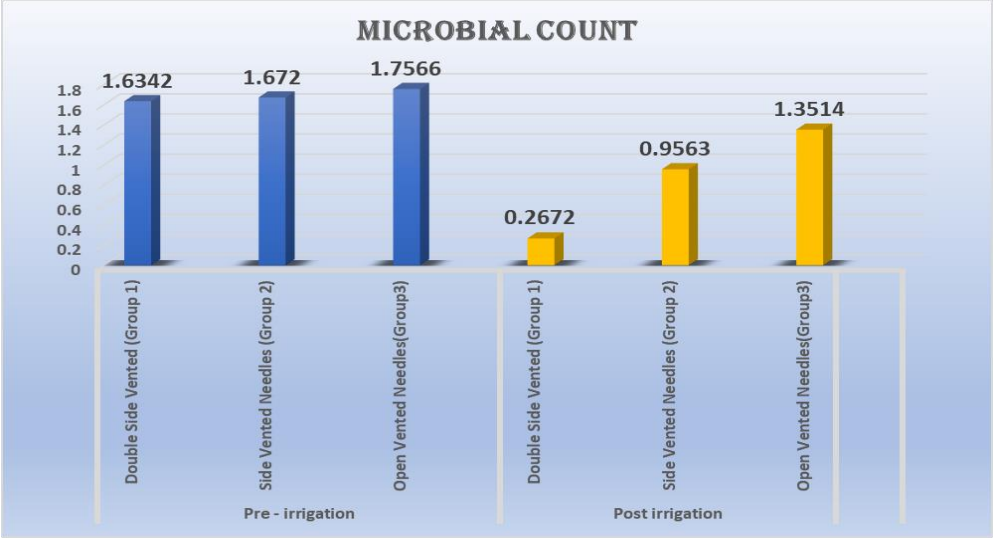

Figure 4 Microbial Count (post-irrigation)

IV. Discussion

Pulpectomy remains a cornerstone procedure in pediatric endodontics, crucial for preserving primary teeth and ensuring long-term arch integrity and function.[11] This treatment is particularly significant as it allows for the retention of primary teeth, which are essential for the proper development of the permanent dentition and the alignment of the dental arch. A critical determinant of the clinical success of pulpectomy is the efficacy of root canal irrigation, which is indispensable for eliminating bacteria, removing necrotic tissue, and disinfecting the complex canal system. [12] Traditionally, root canal irrigation has predominantly relied on positive-pressure irrigation systems, typically involving open-ended needles. These systems have long been considered the standard for root canal cleaning; however, they are associated with certain limitations, including apical extrusion of irrigants and insufficient debridement. These challenges have led to growing interest in alternative irrigation techniques, such as negative-pressure irrigation systems and side-vented needle designs, which have demonstrated superior outcomes in terms of minimizing these drawbacks. [13]

The present study aimed to investigate the comparative effectiveness of various irrigation systems in pediatric pulpectomy. To maintain consistency, treatment protocols were standardized across all groups, with the only variable being the type of irrigation needle used. Negative-pressure and side-vented systems were shown to optimize irrigant delivery while minimizing apical extrusion, thus improving root canal disinfection and reducing the likelihood of post-operative pain. [14, 15] These findings align with previous studies by Wan Abdul Rahman et al., [16] and Nilaya Reddy Venumbaka et al., [17] demonstrated the effectiveness of advanced irrigation systems in reducing bacterial load and limiting extrusion.

To control for potential confounding factors, the working length (WL) was determined consistently across all cases. This is a crucial consideration, particularly in pediatric endodontics, where the anatomical complexity of primary teeth and the physiological resorption that occurs in these teeth can make radiographic assessments of WL challenging.8,9 Given these difficulties, apex locators were employed to enhance the precision of WL determination and prevent over-instrumentation. Over-instrumentation is a known cause of apical extrusion and subsequent post-operative discomfort, and its prevention was a key objective of this study. [14]

Root canal preparation in this study was conducted using a standardized protocol aimed at minimizing the extrusion of debris (AED), a key factor contributing to post-operative complications. Continuous rotary systems, although not the primary focus of this study, have been previously shown to reduce AED compared to manual instrumentation. The principles of controlled canal preparation and conservative irrigation were adhered to throughout the study, given the well-documented association between AED and post-operative sequelae. [16]

Chlorhexidine 2% was selected as the irrigant for all groups in this study, based on evidence supporting its antimicrobial efficacy and its favorable safety profile in pediatric applications.[15]Chlorhexidine is well-known for its ability to effectively eliminate bacteria within the root canal system, and its use in primary teeth has been shown to reduce the risk of periapical tissue irritation when used in appropriate concentrations. The selection of Chlorhexidine reflects a balance between achieving sufficient antimicrobial activity and minimizing the potential for irritation of periapical tissues, which is crucial in the context of pediatric endodontics. [17]

Post-operative pain (PP) is a multifactorial outcome, influenced by several factors, including apical trauma resulting from AED, soft tissue injury due to rubber dam clamps, injection-site discomfort, or occlusal interference from final restorations. In this study, efforts were made to control for these variables, although it is

important to acknowledge that individual variations in pain perception could still influence the reported pain scores. These variations represent a limitation of the study that should be taken into account when interpreting the results. [19]

The positioning of the irrigation needles was carefully managed in accordance with best practices. Open-ended needles (OEN) were positioned 2 mm short of the WL, while side-vented and double side-vented needles were placed within 1 mm of the WL, following guidelines set forth by Boutsioukis et al. [22] The aim of this needle positioning was to reduce the risk of extrusion while maintaining effective irrigant flow within the root canal system. By positioning the needles appropriately, the study aimed to ensure that irrigants would reach the full extent of the canal without exerting excessive apical pressure, which could lead to extrusion.

Extrusion of canal filling materials was observed in a limited number of cases across all groups. However, in accordance with prior studies by Dai Y[23]., minor extrusion did not appear to significantly affect the clinical outcomes or correlate with elevated pain levels. While extrusion remains a concern, these findings suggest that its impact may be more limited than previously thought, particularly when advanced irrigation systems are employed.

In terms of microbial reduction, negative-pressure irrigation systems outperformed traditional positive-pressure systems. This finding corroborates results from studies by Zeng C, [24] and Nilaya Reddy Venumbaka et al., [25] both of whom observed enhanced bacterial clearance in root canals treated with negative-pressure irrigation. Similarly, the side-vented groups demonstrated superior canal cleanliness, a result that has been consistently confirmed in the literature by Urban K et al., [26] and Srivastava I et al. [27] The enhanced canal cleanliness observed with side-vented systems is likely due to their ability to better control irrigant flow and prevent debris from being forced apically.

Among the needle designs tested, double side-vented needles were associated with the most favorable pain outcomes, particularly at the 6-hour and 24-hour intervals. These findings are supported by studies conducted by Pozos-Guillen A et al., [28] Gondim E Jr et al., [29] and Topçuoğlu G et al., [4] who found that vented needle systems significantly reduced post-operative pain compared to traditional open-ended designs. By 48 hours, all groups in the current study reported complete resolution of pain, underscoring the transient nature of post-operative discomfort when appropriate irrigation protocols are followed.

Pain scores were recorded at various intervals post-operatively, and it was found that the OEN group reported higher pain levels during the first 24 hours compared to the side-vented and double side-vented groups. This result supports the hypothesis that open-ended needle designs may promote greater AED, which in turn can lead to heightened inflammatory responses and increased post-operative pain.[20] By contrast, the side-vented and double side-vented needles demonstrated reduced pain levels at both the 6-hour and 24-hour intervals, likely due to their ability to mitigate the apical pressure exerted by the irrigant and prevent excessive extrusion. [23]

Pain scores were evaluated using the Wong-Baker FACES Pain Rating Scale, a well-validated tool for pediatric populations. This scale allowed for effective, age-appropriate pain assessment. The higher pain scores observed in the OEN group during the first 24 hours are in agreement with earlier findings by Asghar S et al.[30], who demonstrated that traditional irrigation methods correlate with higher pain levels. Similarly, Srinivasan N et al. [31] and Ahuja B et al. [32] reported significantly lower pain outcomes with advanced irrigation techniques using the Wong-Baker scale, supporting the present study's conclusion that side-vented and negative-pressure systems mitigate post-operative discomfort. These studies affirm the importance of patient-friendly pain assessment tools and reinforce the clinical advantages of refined irrigation protocols.

While the results of this study are promising, several limitations must be acknowledged. The relatively small sample size and in vitro design may limit the generalizability of the findings to clinical practice. Variability in operator technique, as well as anatomical differences between primary teeth, may also influence outcomes. Additionally, patient-specific factors, such as pain thresholds and overall health, could impact the reported pain levels. Future research, particularly large-scale randomized controlled trials with larger sample sizes and long-term clinical endpoints, is necessary to validate these findings and further assess the benefits of advanced irrigation techniques in pediatric endodontics.

The present study reinforces the clinical advantages of negative-pressure and side-vented irrigation systems in pediatric pulpectomy. These techniques have been shown to reduce apical extrusion, improve microbial reduction, and mitigate post-operative pain. While the results are consistent with existing literature, it is important to interpret them with caution, as further empirical studies are required to confirm the long-term benefits of these irrigation strategies. Nevertheless, the data presented in this study support a gradual shift toward the adoption of these evidence-based irrigation techniques in pediatric endodontic practice, offering a promising avenue for improving patient outcomes.

V. Conclusion

1. Root canal irrigation using double side-vented needles resulted in less post-operative pain compared to side-vented and open-ended needles during the first 24 hours.
2. In the pulpectomy of primary teeth, double side-vented needles may be preferred to decrease the intensity of post-operative pain and enhance canal cleanliness.
3. Further randomized controlled studies are needed to assess the impact of different irrigation protocols on post-operative outcomes in pediatric endodontics.

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