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Postoperative Pain After Different Root Canal Irrigant Activation Methods; (Randomized Clinical Trial)

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Postoperative Pain After Different Root Canal Irrigant Activation Methods; (Randomized Clinical Trial)

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ABSTRACT

Objective: This study was designated to evaluate postoperative pain in irreversible symptomatic teeth after different irrigation activation methods using visual analogue scale.

Materials and Methods:78 Patients having symptomatic irreversible pulpitis in mandibular first molar (vital pulp) with no periapical involvement were involved in the study. Cases were classified into three groups according to the the final irrigation agitation method used, twenty-six patients each group (n=26). Group A: Root canals were irrigated using NaOCl2* 2.6% with NaviTip (31-gauge 27mm) with double side port irrigator tip (SVN). Group B: Root canals were irrigated using 2.6% NaOCl with manual dynamic agitation using master cone for 60 seconds. Group C: Root canals were irrigated using 2.6% NaOCl with mechanical agitation using ultrasonic device ultra-x for 60 seconds. Postoperative pain was evaluated after 6,12,24, 48, and 72 hours and 1 week. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests and showed parametric (normal) distribution. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

Results: Severity of postoperative pain was more intense at 6- 12and 24-hour time intervals in group 2 patients than those patients in groups 1and 3 ($P < .05$). There was no significant difference among the groups at the other time intervals ($P > .05$). Severity of postoperative pain in all groups decreased over time.

Conclusion: After endodontic therapy in lower molars with acute pulpitis manual dynamic agitation caused greater postoperative pain in comparison with the other methods in the first 24 hours.

1. INTRODUCTION

Postoperative pain (PP) after root canal treatment is an unpleasant sensation and an important issue for both clinicians and patients. The prevalence of PP ranges from 3%–58%. Apart from intraoperative factors, PP may be associated with various components, including microbial, inflammation, and/or immune-related factors as well as psychological elements. Studies have assessed the association between different irrigation solutions and related irrigation techniques on PP in patients undergoing root canal treatment [1]. Determination of the degree of post- operative pain after different activation is of prime importance to choose the least painful and the most efficient technique in cleaning of root canals. The success of endodontic treatment depends on the elimination of the existing bacteria in root canal system and preventing their regrowth. Removing debris, biofilm, microbes, and necrotic tissues from the root canal system are performed manually or through rotary shaping, as well as frequently canal irrigation. The main objective of preparation and canal shaping is to facilitate canal irrigation, disinfection, and obturation. There is no irrigant that is capable of providing all the expected characteristics.

Accordingly, the chemical composition of canal irrigant has been changed to improve penetration and the effects of irrigation. Irrigant must be brought into direct contact with the entire canal wall surfaces for effective action particularly for the apical portions of small root canals [2].

Irrigation using Sodium hypochlorite is mainly performed by a syringe and a needle, but this simple method is unable to clean remote areas of the root canal system [3]. The apical 3mm of an infected root canal system is considered to be the “Critical Zone” when it comes to the chemo-mechanical preparation. Agitation techniques have been recommended to hasten the penetration of the irrigant into the complexities of root canal morphology with the aim of enhancing the contact of the solution with the canal wall surfaces removing microbes, debris and reducing postoperative pain [4,5]. These techniques include sonic agitation, ultrasonic agitation, the cheapest and simplest of all, manual dynamic agitation.

Manual dynamic agitation is moving a well-fitting gutta-percha master cone up and down in short 2- 3mm strokes within an instrumented canal can produce an effective hydrodynamic effect and significantly improve the displacement and exchange of any given irrigant. Despite being the cheapest method for activation, it doesn’t show a significant effect on postoperative pain as passive ultrasonic activation irrigation do.

Passive ultrasonic irrigation was first described by Weller *et al*. There are two methods of delivery of the irrigant during ultrasonic activation: continuous and intermittent flush [6]. One of the recent ultrasonic devices is “EIGHTEETH MEDICAL ULTRA X – ULTRASONIC ACTIVATOR”; cordless endodontic ultrasonic device works at 45kHz ultrasonic frequencies. It reduces the

irrigation time and utilizes the principle of acoustic microstreaming, agitation and cavitation. Its rapid movement enables penetration into non instrumented areas and enhances shear stress on tissue remnants leading to minimize the postoperative pain [7].

The majority of the research to date has shown that manual dynamic agitation after root canal treatment results in relatively heigh debris and irrigant extrusion into periapical tissues than both needle and ultrasonic agitation. Therefore the present study was designed to compare the effect of different agitation methods versus syringe irrigation on postoperative pain. The primary outcome of this study was to assess the intensity of postoperative pain at different time intervals 6,12,24,48,72 and 1 week after chemo-mechanical preparation using visual analogue scale.

The null hypothesis was that there is no difference among the tested groups in the postoperative pain level.

2. MATERIALS AND METHODS.

78 cases with symptomatic irreversible pulpitis in mandibular first molar (vital pulp) without signs and/or symptoms of periapical pathology were involved in the study from the clinic of Faculty of oral and dental medicine, Future university in Egypt. This study was approved by research ethics committee (REC-FODM) (Future. REC code 19-10-2019) with respect to scientific content and compliance with applicable research and human subject's regulations. And written informed consent was obtained from all of the study participants. Figure (1) shows the consort flow diagram.

The trial design of this study was a parallel randomized clinical design. This design is one of the simplest and most powerful tools in clinical research. It is a form of study or scientific experiment in which people are allocated at random (by chance alone) to receive one of several clinical interventions.

Based on previous studies by **Ramamoorthi *et al*** [8]. The sample was divided into 3 groups. A total sample size of 60 (20 per group) was sufficient to detect an effect size of 0.2, a power of 80%, and a significance level of 5%. The number was increased to a sample size of 66 to allow for non- parametric distribution of the outcome variable. Further increase of 25% to allow for least frequently used (LFU), so a total sample size of 78 (26 per group) was needed to compensate for possible losses during follow up. Sample size was calculated using G*Power program.

Inclusion criteria:

- Patients in good health with no systemic disease: (American Society of Anesthesiologists / (ASA Class I or II).
- Age range is between 18 to 50 years.
- Patients having symptomatic irreversible pulpitis in mandibular first molar (vital pulp) with no periapical involvement.
- Patients who can understand visual analogue scale (VAS).
- Positive patient's acceptance for participating in the study was required.
- Patients able to sign informed consent.

Exclusion criteria:

- Medically compromised patients.
- Pregnant or lactating females.
- Need for prophylactic antibiotic.
- Psychologically disturbed patients.
- Patients with a history of allergy to any medication used in the study were excluded.
- Patients who had taken pre-operative drugs as anti-inflammatory analgesic or antibiotics in the 12 hours preceding the injection.
- Patients with swelling or acute peri-apical abscess.
- Teeth that have:
- Wide or open apex.
- Non vital pulp tissues.
- Association with swelling or fistulous tract.
- Acute or chronic periapical abscess.
- Periodontally affected with grade 2 or 3 mobility.
- No possible restorability.
- Pain on percussion.
- Abnormal anatomy and calcified canals.

Randomization

This sequence generation was done in which each participant was given a number from (1 to 78) using computer software (Microsoft Excel). seventy-eight numbers were generated and distributed randomly in a table on an Excel sheet, and in front of each number a letter (C) for control and (I1andI2) for intervention was typed. The random sequence was kept with the assistant supervisor.

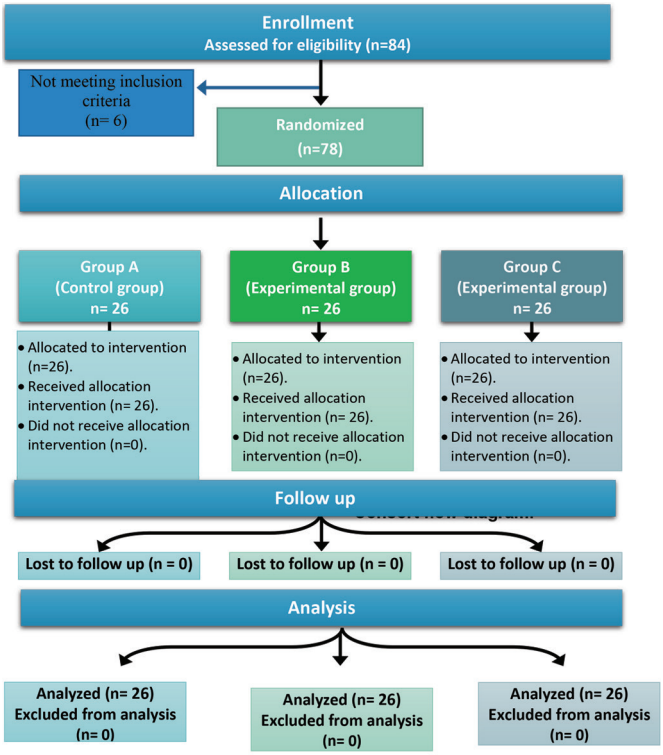

Figure (1): Consort flow diagram.

Treatment procedure

All procedures were carried out by the same specialist. At the first visit, thorough diagnosis was performed involving patient history, clinical findings and thermal testing to confirm the case as symptomatic irreversible pulpitis. Afterwards, each patient was given a pain scale chart (VAS) to record his/her pain level before any endodontic treatment. The tooth was anaesthetized by inferior alveolar nerve block* using 1.8–3.6 ml (1-2 carpoules) 4% mepivacaine with 1:100,000 epinephrine local anesthetic solution. The effectiveness of anesthesia was evaluated by subjective and objective

* UbisteinTM forte 4% mepivacaine forte, 3M Deutschland GmbH, Germany.

symptoms in the patient. Access to pulp chamber was performed using a small round bur and completed using Endo-Z Bur. The tooth was properly isolated with rubber dam. Working length was determined by an apex locator and confirmed by radiograph using parallel technique. Root canal instrumentation was done by crown down technique using Protaper NEXT rotary instrument. 2 ml of 2.6% NaOCl was expressed over 30 s after every use of each rotary instrument. After root canal preparation, patients were randomly classified according to the final flush into 3 groups as follows:

Group A (SVN group):

Root canals were irrigated with NaviTip double Side-port 31 G / 27 mm but without agitation.

Group B (MDA group):

2ml of 2.6 % NaOCl was delivered into the canal using double side-port irrigation needle (NaviTip Sideport 31 G / 27 mm) which was used passively without forceful dispensing of the irrigant.Intermittent manual agitation for 60 seconds in corono-apical movements using master cone was performed.

Group C (US group):

2ml of 2.6 % NaOCl was delivered into the canal using double side-port irrigation needle (NaviTip Sideport 31 G) which was used passively without forceful dispensing of the irrigant. After which the irrigant was ultrasonically activated for 60 seconds with an Ultrasonic device (ultra-x) at power 3 by using a #25 ultrasonic tip 1 mm short of the canal's working length.

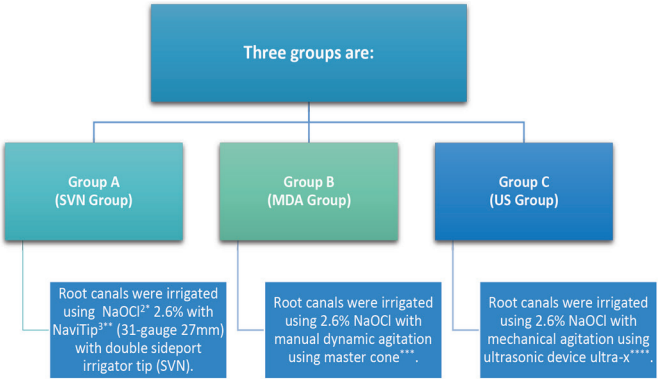

Figure (2): Illustrative diagram showing the study design

After completion of the biomechanical instrumentation of the root canals, the coronal access cavity was then restored by Cavit™ as a temporary restoration to ensure proper sealing with no leakage of any oral fluids inside the root canal.

Postoperative Pain Evaluation

Pain was assessed by giving the patient visual analogue scale (VAS) to assess his/her pain at 6 time intervals 6, 12, 24, 48, 72 hours and 1 week post-operatively. This is a 10 cm line with 11 marks and 10 intervals. Pain level was documented in the range of 0-10 numerically as no pain (0), mild pain (1-3), moderate pain (4-6) and severe pain (7-10).Patients were phone-called at these times after the first visit to make sure that the pain had been listed on the VAS. all patients received one capsule of placebo to be taken 0-4 hours after treatment if needed. Prescribed tablets of 400 mg every 8 h if there was moderate or severe pain after consultation with the specialist. They were instructed to record the number of analgesic tablets taken.

At the second visit

Seven days later, a further postoperative evaluation was performed at the second visit before the beginning of obturation. The root canals were obturated using the modified single cone technique. Radiograph was taken to ensure proper length and preparation of the root canals.

3. STATISTICAL ANALYSIS

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests and showed parametric (normal) distribution. The mean and standard deviation values were calculated for each group in each test (Pain Evaluation and Bacterial count). Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Friedman test was used to test the difference between more than two groups in related samples while Wilcoxon test was used to test the difference between two groups in related samples. Mann–Whitney U test was used to compare the difference between two groups in non-related sample for Pain evaluation.

Results Demographic Data

Gender

Regarding the gender distribution, 12 males (46.2%) and 14 females (53.8%) participated in group A (SVN), 12 males (42.3%) and 14 females (57.7%) participated in group B (MDA) and 13 males (50%), and 13 females (50%) were presented in group C (US). There was no statistically significant difference between tested groups (*P* value = 0.858), as shown in (Table 1).

Age

The mean age value and standard deviation (SD) for group A (SVN) was 38.73 ±8.54 with the age ranged between (18-50) years, while, for group B (MDA), it was 39.27±7.06 with the age ranged between (18-49) years and for group C (US) it was 37.54±5.99 with the age ranged between (18-50 years There was no statistically significant difference regarding age between tested groups (P value =0.721), as shown in (Table 1).

Table (1): The mean and standard deviation (SD) of age and frequency & percentage of gender for tested groups.

Variables		Demographic data						
		SVN		MDA		US		p-value
		Mean/n	SD/%	Mean/n	SD/%	Mean/n	SD/%	
Age (Years)		38.73	8.54	39.27	7.06	37.54	5.99	0.721 ns
Gender (N, %)	Females	14	53.8%	15	57.7%	13	50%	0.858 ns
	Males	12	46.2%	11	42.3%	13	50%	

ns; non-significant (p>0.05)

Pain intensity at different time intervals

The distribution of the postoperative pain values for each treatment group by each time period is summarized in Table (2). At 6 ,12 and 24 hours, the intensity of pain experienced by patients in the MDA group was significantly higher than that of patients in the other groups (P < .05). At 24,48 hours, 72 hours, and 7 days, there was no significant difference among the groups in terms of pain severity (P > .05). In all groups, the highest PP scores were recorded at 6 hours and subsequently decreased over time.

Table (2) Intensity of pre & post-instrumentation pain of the tested groups after 6 hrs, 12 hrs, 24 hrs, 48 hrs, 72 hrs and 7 days.

Pre-Operative	Pain intensity			
	Group (A) SVN	Group (B) MDA	Group (C) US	p-value
	9.35^{a}	**9.38^{aA}**	**9.42^{aA}**	**0.846**
After 6 hrs	6.82^{b}	8.5 ^{bA}	3.73^{bB}	**<0.001***
After 12 hrs	6.31^{b}	8.46 ^{bA}	3.62^{bB}	**<0.001***
After 24 hrs	6^{b}	8.31 ^{bA}	3.42$^{b}{}_{B}$	**<0.001***
After 48 hrs	1^{c}	1.12 ^{cA}	0.96^{cA}	**0.677ns**
After 72hrs	0.96^{c}	1.08 ^{cA}	0.81^{cA}	**0.421ns**
After 7 days	0.73^{c}	0.81 ^{cA}	0.69^{cA}	**0.628ns**
p-value	**<0.001***	**<0.001***	**<0.001***	

*Means with different small letters in the same column indicates significant difference, means with the same capital letters in the same row indicate significant difference *; significant (p<0.05) ns; non-significant (p>0.05)*

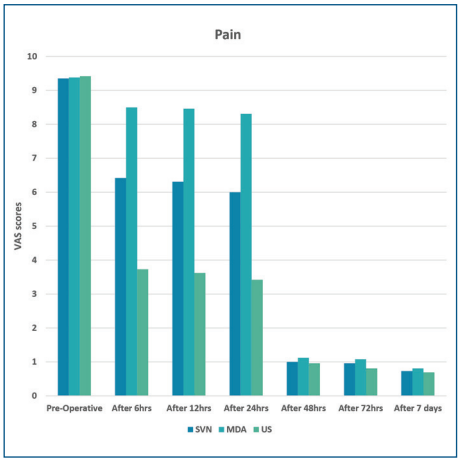

Figure (3)—Bar chart representing the intensity of pre-and post-instrumentation pain at different time intervals for each group.

Incidence of placebo and analgesic intake

The incidence of Placebo and analgesics intake (secondary outcome) are summarized in table (3 & 4). There was no statistically significant difference between the three tested groups regarding the incidence of Placebo intake (P= 0.689). There was statistically significant difference between the three tested groups regarding the incidence of analgesic intake (P<0.001). Where the highest number of analgesic intakes is recorded in group (B) (MDA).

Table (3)—Incidence of intake of Placebo of the three tested groups.

Variables		Placebo						p-value
		Group (A) SVN		Group (B) MDA		Group (C) US		
		n	%	n	%	n	%	
Incidence of Placebo intake	Yes	3	11.5%	4	15.4%	2	7.7%	0.689ns
	No	23	88.5%	22	84.6%	24	92.3%	

ns: non-significant (P>0.05)

Table (4)—Mean and standard deviation for the Incidence of intake of analgesics of the three tested groups.

Variables		ANALGESIC						p-value
		Group (A) SVN		Group (B) MDA		Group (C) US		
		n	%	n	%	n	%	
Incidence of Analgesic intake	Yes	17	65.40%	26	100%	8	30.80%	<0.001*
	No	9	34.60%	0	0%	18	69.20%	

s: -significant (P<0.05)

4. DISCUSSION

The basic goal of endodontic treatment is chemo-mechanical preparation of the root canal; including cleaning, shaping and disinfection and to hermetically seal it without any unpleasant outcome to the patient [9]. Several factors affects the postoperative pain it is considered to be a subjective variable. Measurement of subjective variable is a real challenge. Thus, different scales and methods have been used to evaluate postoperative pain[10]. Visual analogue scale was used ranging from 0 to 10 to measure the severity of PP. Validity, ease of use, simplicity and reliability was the main reason for the scale's choice. It was also used in different previous studies that evaluate postoperative pain after root canal treatment [11].

In this study the pain intensity was recorded preoperatively, after 6 hours, 12 hours, 24 hours, 48 hours, 72 hours and after 7 days after chemo-mechanical preparation. Pain was recorded at these intervals as preoperatively interval provides a reference point for postoperative pain after chemo- mechanical preparation. The 6-hour postoperative interval was chosen to provide sufficient time for the anesthetic effect to disappear. However, 12, 24 and 48 hours were chosen as studies showed that most of the postoperative pain occurred on the first day after chemo-mechanical preparation [12]. Nagendrababu *et al.* [13] found that most of the postoperative pain after chemo- mechanical preparation occurs between 24- and 48-hours interval, therefore in this study pain was also recorded at these intervals. Singh *et al.* [14] found that some patients may experience pain till 7 days after chemo-mechanical preparation, therefore pain was also recorded at 72 hours and 7 days after chemo-mechanical preparation.

Symptomatic irreversible pulpitis cases were selected as a main inclusion criterion as pain of pulpal origin (irreversible pulpitis) is the most feared among patients due to its intensity and severity. This severity is most likely because of increased exudative (acute) forces that cause an increase in the intra-pulpal pressure within the unyielding, closed pulpal space that surpasses the threshold limits of sensory fibers [15].

The dose of anesthetic solution used was 3.6 mL (equivalent to 2 cartridges) of 2% mepivacaine with 1:100,000 epinephrine in agreement with Gazal *et al.* [16] who revealed that a single cartridge (1.8 mL) of local anesthetic for IAN block injections is effective in only 30%–80% of patients with irreversible pulpitis. The success of injection technique was assessed by checking the lip numbness after 10-15 minutes.

Treatment of all the cases was performed in two visits where complete pulpectomy and biomechanical preparation of the root canals were done in the first visit because this procedure has the least incidence of post-operative pain and obturation was done one week later, This to achieve more comfortable status by reducing the peri-radicular edema and tissue levels of factors that may stimulate peripheral nociceptors [17].

The working length of the root canals was determined using Root ZX apex locator, because of its high accuracy [18]. and it is confirmed by radiograph as using one of these techniques alone decreases accuracy and may lead to over instrumentation [19].

Mechanical preparation was done using ProTaper Next (PTN). PTN is the second generation of Pro taper Universal system manufactured from M-Wire nickel titanium alloy to enhance flexibility and cyclic fatigue resistance. It is designed with progressive and regressive percentage tapers, and an off-centered rectangular cross section for superior strength to improve canal shaping efficiency [20] . It has been proved to have the least amount of apical debris extrusion [21].

Root canals were irrigated using 2.6% sodium hypochlorite (NaOCl) between every subsequent file for its potent antimicrobial effect and tissue dissolving effect. The reduction of intracanal microorganisms is not any greater when 5.25% NaOCl is used as an irrigant compared to 2.6% [22].

To minimize the variations and ensure standardization, in all groups, the same treatment protocol was done with the exception of the final flush. Irrigation was done using a conventional syringe with side vented needle 27 gauge which seemed to have a lowering effect on irrigant extrusion into the periapical space compared to regular needle irrigation [23].

Placebos (Nido milk packed in capsules) were prescribed in order to prevent the immediate intake of analgesics due to psychological fear affecting the outcome of the study.[24]. After chemo- mechanical preparation, the participants were given Ibuprofen 400 mg and asked to take it in case of moderate or severe pain [25].

The postoperative pain (PP) records after chemo mechanical preparation were remarkably higher among patients in the Manual dynamic agitation (MDA) group than those in the other groups at 6- to 24-hour time intervals. This was due to squeezing out of irrigating solution and debris into periapical tissues in the manual dynamic agitation group than in the other groups [26].

Debris and irrigant extrusion during endodontic procedures is considered to be one of the main causes of postoperative pain. Unfortunately, it is inevitable unless a negative apical pressure irrigation system is used. However, the measured amounts of extruded debris or irrigants shown in ex-vivo studies are not confirmed to occur clinically or to be significant to stimulate pain or damage tissues [27].

MDA resulted in significantly more irrigant and debris extrusion than both needle and ultrasonic agitation. It was likely that oscillating instruments mainly generate a lateral flow towards the root canal wall, while a moving well-fitting gutta-percha cone to the full working length results in a flow with a considerable component in the apical direction and this was one of the causes of postoperative pain [28].Ultrasonic irrigation as a final irrigation protocol showed lowest pain intensity may be explained by the irrigation method using oscillating ultrasonic tips prevents the apical extrusion of the irrigant and debris compared with methods using positive pressure (MDA and needle [29].

The incidence of analgesics intake was also assessed as a secondary outcome. The frequency of analgesics taken by patients decreased by the time in each tested group. The highest mean value was recorded at 6 hours for all groups, while no pain after 24 hours in SVN group, 48 hours in MDA and 12 hours in US group. There was significant difference between the MDA and US groups this may attributed to MDA resulted in significantly more irrigant extrusion than both needle and ultrasonic agitation [30].

5. CONCLUSIONS

Considering this study, it can be concluded that:

Mechanical agitation technique is considered a reliable method as a final step irrigation protocol with a normal range of postoperative pain. Analgesics intake was not needed when ultrasonic activated irrigation was used as a final step irrigation protocol for endodontic treatment of symptomatic irreversible pulpitis of multirooted teeth. The incidence of post- operative pain decreased with time regardless the final irrigation protocol used.

Compliance with ethical standards

Conflict of Interest

The authors declare that they have no conflicts of interest with regard to this research.

Funding

This work was not supported by any funding source.

Ethical Approval

All of the procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee of future university in Egypt

Informed Consent

Each of the individual participants was informed and provided consent for their inclusion in this study.

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