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The effect of different irrigation activation methods preferred during root canal treatment on postoperative pain: A randomized clinical trial

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Purpose: This study evaluates the effects of EDDY and passive ultrasonic irrigation (PUI) activation methods on postoperative pain in mandibular premolar and first molar teeth with asymptomatic apical periodontitis.

Methods: A randomized clinical trial was conducted at Ordu University, Faculty of Dentistry, Department of Endodontics between 12.02.2024 and 03.06.2024. Volunteer patients were randomly assigned to groups. Treatments were performed by a single operator (M.S.). Of 57 patients, 45 completed the study (control: 15, EDDY: 14, PUI: 16). Postoperative pain was recorded at the 8th, 12th, 24th, and 48th hours, and on the 7th day using a visual analog scale. Statistical analyses included Kruskal-Wallis, Friedman, and Chi-square tests.

Results: Gender had no significant impact on pain ($p > 0.05$). No significant intergroup differences in pain were found at any time point ($p > 0.05$). PUI caused more pain at the 8th and 12th hours, while EDDY caused more pain at the 24th and 48th hours, though not statistically significant. Pain significantly decreased by the 7th day in the control ($p = 0.007$) and PUI ($p < 0.001$) groups but not in the EDDY group ($p = 0.050$).

Conclusion: EDDY and PUI show comparable effects on postoperative pain, with no influence of gender.

Keywords: EDDY; endodontics; irrigation activation; postoperative pain; PUI.

Introduction

Pain is the most common reason for patients to seek dental care. It is well-established that this pain is primarily caused by inflammation resulting from bacterial infections (1). Postoperative pain following endodontic treatment is an undesirable outcome affecting both for patient comfort and the clinician's professional reputation. This pain typically results from acute inflammation triggered by the extrusion of microorganisms through the apical foramen or the extrusion of other materials, such as debris or irrigants, during the treatment (2,3).

The effectiveness of irrigation solutions depends on their ability to reach all root canal walls. However, due to the complex anatomy of the root canal system, this effect may not be fully achieved using conventional syringe-needle or

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side-vented endodontic needles. To improve irrigation efficiency, various activation techniques have been proposed. These methods include the activation of the solution using gutta-percha cones, canal brushes, laser systems, negative pressure, and sonic/ultrasonic devices (4).

The Passive Ultrasonic Irrigation (PUI) activation method is introduced to enhance the disinfecting efficacy of the irrigation solution by agitating it (5). An ultrasonic tip is activated within the canal up to the working length and is passively moved in an up-and-down motion to ensure it does not contact the root canal walls (5). PUI has been shown to effectively reduce bacterial biofilm adhesion due to the high shear stress generated in the apical third (6,7).

EDDY is a sonic activation technique that provides three-dimensional movement through cavitation and acoustic streaming, similar to ultrasonic devices (8). Irrigation solutions interact with dentin walls to clean the complex root canal anatomy without the limitations associated with ultrasonic devices (8).

The aim of this study is to evaluate the change in postoperative pain in mandibular premolar and first molar teeth with asymptomatic apical periodontitis when using EDDY and PUI activation methods.

The null hypothesis of this study is as follows: "There is no difference between irrigation activation systems in terms of postoperative pain following root canal treatment in mandibular first molar and premolar teeth."

Materials and Methods

This manuscript has been written according to Preferred Reporting Items for Randomized Clinical Trials in Endodontics. This study was conducted at the Department of Endodontics, Faculty of Dentistry, Ordu University, and was approved by the Clinical Research Ethics Committee of Ondokuz Mayıs University on February 9, 2024 (Ethics No: 2024/38). A clinical trial registration has not been submitted. The study was conducted under the principles of the Declaration of Helsinki.

Volunteer patients who met the inclusion criteria were recruited from those who visited the Department of Endodontics at Ordu University Faculty of Dentistry between February 12, 2024, and June 3, 2024.

Patient Selection Criteria

Sample size calculation was performed using G*Power 3.1 software (Heinrich Heine University, Düsseldorf, Germany) with the following parameters: $\alpha = 0.05$, power = 0.81, and effect size = 0.27. Based on the variance statistical test, it was determined that a minimum of 14 teeth per group would be required for statistical significance. Considering potential complications during the follow-up period, it was decided to include 16 teeth in each group, resulting in a total of 48 teeth for the study (9).

Teeth that met the inclusion and exclusion criteria listed below were selected for the study.

Inclusion Criteria

- Patients aged 18-55 years
- Patients with asymptomatic apical periodontitis
- Teeth without calcification, root resorption, periodontal problems, incomplete root development, history of endodontic treatment, traumatic occlusion, or severe coronal destruction.
- Teeth with a curvature of the root canal of 5° or less (10).
- Patients with a Periapical Index (PAI) score of 3-5
- Mandibular premolars and first molars

Exclusion Criteria

The following conditions led to exclusion from the study:

- Patients took analgesic or anti-inflammatory medication in the previous 12 hours
- Patients have a history of a drug allergy
- Pregnant or breastfeeding patients
- Teeth where the apical area could not be reached with a #8K file
- Teeth with an apical diameter larger than #20K file
- Teeth with extra root canals
- Teeth requiring a second local anesthesia during treatment
- Teeth where a file fractured within the canal during preparation
- Vital teeth
- Teeth with clinical symptoms such as percussion or palpation sensitivity
- Teeth with persistent purulent discharge

Clinical Procedures

Patient recruitment continued until each group included at least 16 participants.

After obtaining informed consent, all participants were asked to choose one of the 48 black envelopes containing the intervention to be performed and the dental history obtained from Cohen's Pathways of the Pulp for randomization and blinding.

The patients' systemic and dental histories, along with age and gender, were recorded. A clinical examination was per-

formed, including inspection, percussion, and palpation tests. Pulp vitality was evaluated using an electric pulp tester (Ai-Pex, Woodpecker, China) and a cold test (Cerkamed, Poland). Periodontal examination and radiographic assessments of the relevant tooth were conducted, with the symptoms documented.

The initial periapical radiograph of the teeth was evaluated. According to the classification by Schneider, (1971), straight root canals (curvature ≤ 5°) were selected for the study. Then, teeth with PAI scores of 1 and 2 were considered periapically healthy and excluded, while teeth with PAI scores of 3, 4, and 5 were included. All root canal treatments were performed in a single session by a single operator (M.S.). Prior to treatment, patients were instructed in detail on how to complete the Visual Analog Scale (VAS). Patients were asked to mark their pain levels on a 10 cm line based on the severity of pain experienced after the procedure. Pain intensity was numerically documented on a scale of 0 to 10.

Patients were administered an inferior alveolar nerve block using 2 mL of articaine hydrochloride with 1:100,000 epinephrine (Ultraver DS fort; Haver, Türkiye). Rubber dam isolation was applied, and caries were removed using a sterile diamond round bur (DIMEI Royal, Türkiye). Access cavities were prepared. A #10 K-file (Dentsply Maillefer, Switzerland) was placed into the canals to establish the glide path. Working length was determined using an electronic apex locator (AiPex; Woodpecker, China) and confirmed with periapical radiographs to ensure it was 0.5-1 mm shorter than the radiographic apex.

Group 1: Control Group

The root canals were shaped with reciprocating Ni-Ti files (T-endo Must; Dentac, Türkiye) up to a size of 25/0.6, following the manufacturer's instructions, and finally up to 40/0.4 size using a gaggling motion. During the shaping process, the root canals were irrigated with a total of 15 ml of 2.5% NaOCl (NaOCl; Wizard, Ankara, Türkiye) using 31 G closed end, side vented irrigating needles (NaviTip; Ultradent, Güney, Türkiye). Recapitulation was performed with a #15K file after each file change (11).

After completing the root canal preparation, 5 ml of 17% EDTA (IMICRYL, Türkiye) was applied to each canal for 1 minute using a 31 G irrigation needle (NaviTip), placed 2 mm short of the working length. To neutralize the EDTA residues, 5 ml of distilled water was applied for 30 seconds (12). The canals were then irrigated with 5 ml of 2.5% NaOCl, followed by 30 seconds of irrigation with 5 ml of distilled water to remove the NaOCl residue from the canals. A total of 20 ml of NaOCl, 5 ml of EDTA, and 10 ml of distilled water were used per canal. A total of 60 ml of NaOCl, 15 ml of EDTA, and 45 ml of distilled water were used for one molar tooth.

Group 2: EDDY Group

Root canal preparations were performed by following the steps used in Group 1.

The EDDY tip was placed 2 mm short of the working length and activated with 2-3 mm vertical movements in three cycles, each lasting 20 seconds. After each 20-second irrigation activation, 1 ml of 2.5% NaOCl was applied to the canal to refresh the solution. To remove the NaOCl residues from the canal, 30 seconds of 5 ml distilled water irrigation was performed. Then, 3 ml of 17% EDTA was used to irrigate the canal, with activation in three 20-second cycles. After each cycle, 1 ml of 17% EDTA was added to the canal to refresh the solution. To remove the EDTA residues, 30 seconds of 5 ml distilled water irrigation was applied. To standardize the solution amount, 3 ml of NaOCl was re-applied, followed by 30 seconds of 5 ml distilled water irrigation to remove NaOCl residues. A total of 20 ml of NaOCl, 5 ml of EDTA, and 15 ml of distilled water were used per canal. A total of 60 ml of NaOCl, 15 ml of EDTA, and 45 ml of distilled water were used for one molar tooth.

Group 3: PUI Group

Root canal preparations were performed by following the steps used in Group 1.

The PUI tip (DTE; Woodpecker, China) was placed 2 mm short of the working length and was activated in three 20-second cycles. After each 20-second irrigation activation, 1 mL of 2.5% NaOCl was applied to refresh the solution. To remove NaOCl residues from the canal, 5 mL of distilled water was applied for 30 seconds. Next, irrigation was performed with 3 mL of 17% EDTA. EDTA activation was carried out in three 20-second cycles. After each 20-second activation, 1 mL of 17% EDTA was applied to refresh the solution. To remove EDTA residues, 5 mL of distilled water was applied for 30 seconds. To standardize the amount of solution used, 3 mL of NaOCl was applied, followed by 30 seconds of 5 mL of distilled water to remove NaOCl residues. A total of 20 mL NaOCl, 5 mL EDTA, and 15 mL distilled water were used for each canal. A total of 60 ml of NaOCl, 15 ml of EDTA, and 45 ml of distilled water were used for one molar tooth.

After the root canals were dried using #40 paper points (Dentac; Türkiye), suitable gutta-percha cones (Dentac; Türkiye) were selected as the master cone. The master and accessory cones were used to complete the root canal filling using the lateral condensation technique, with root canal sealer (Sealapex; Kerr, Australia). Zinc phosphate-

based cement was chosen for the temporary restoration. The quality of the root canal filling was verified through periapical radiographs. If patients experienced severe pain, the use of NSAIDs was recommended. The use of a matrix band could potentially cause damage to the periodontal ligament and gingiva, leading to periodontal-related pain in the affected area. To avoid the risk of patients confusing this pain with tooth pain, the permanent restoration was completed one week later after the patient recorded their pain scores. To ensure optimal sealing and minimize the potential risk of microleakage between treatment sessions, glass ionomer cement was utilized as the temporary restorative material. Composite resin (Kerr Herculite Classic, Kerr Dental Company, USA) was used for the permanent restoration.

Endodontic procedures were carried out in all canals of the included premolar and molar teeth in accordance with the standardized protocols described above.

Postoperative Pain Assessment

Patients were instructed to assess their postoperative pain scores. They were asked to record their pain levels on a given form at 8, 12, 24, and 48 hours, and on the 7th day. They were also asked to indicate any analgesic use on the same form. One week later, patients were called for their permanent restorations. Pain forms were collected from the patients.

Statistical Analysis

Chi-square tests were used to evaluate gender-related data. Postoperative pain scores were initially assessed for normality using the Shapiro-Wilk test ($p < 0.05$). Since the results indicated that the data did not follow a normal distribution, non-parametric tests, specifically the Kruskal-Wallis and Friedman tests, were applied. To determine which groups were responsible for the observed differences, a post hoc test with Bonferroni adjustment was performed. Statistical analyses were performed using IBM SPSS 22.0 (SPSS version 22.0; SPSS, Inc., Chicago, IL, USA). The tests were evaluated at a 95% confidence interval ($\alpha = 0.05$).

Results

A total of 57 patients were initially evaluated for inclusion in the study. The patient inclusion process is illustrated in Fig. 1.

The demographic data, including the participants' mean ages, distribution of male and female participants across the groups, as well as the types and numbers of teeth used in the study, are presented in Table 1. The PAI distribution of the included teeth is shown in Table 2.

When we examined the role of gender on pain, intra-group analyses revealed that gender had no statistically significant effect on the presence of pain in all three groups ($p > 0.05$). The results of the Chi-Square test conducted by gender are shown in Table 3.

Comparing the measurements between groups, the pain presence at different time points was as follows: at 8th hour, $p = 0.479$; at 12th hour, $p = 0.577$; at 24th hour, $p = 0.881$; at 48th hour, $p = 0.778$; and at the 7th day, $p = 0.830$. Since all p-values were greater than 0.05, no statistically significant differences were observed. Even though there was no statistically significant difference, the data indicated that the PUI group experienced more pain at the 8th and 12th hours, the EDDY group experienced more pain at the 24th and 48th hours, and similar distributions were observed in all groups at the 7th day. The mean and mean rank values for the measurements between groups are shown in Table 4.

When the data related to the groups were evaluated, no

Table 1. Demographic data and teeth used in the study

	Control Group (Mean ± Sd)	EDDY Group (Mean ± Sd)	PUI Group (Mean ± Sd)
Age	32.53 ± 8.66	28.64 ± 6.50	32.06 ± 9.62
Gender			
Female	9 (56.2(%)	8 (%57.1)	11 (68.8%)
Male	7 (43.8%)	6 (%42.9)	5 (31.2%)
Tooth Number			
34	-	1	3
35	2	1	2
36	4	4	3
44	1	-	-
45	3	4	2
46	5	4	6

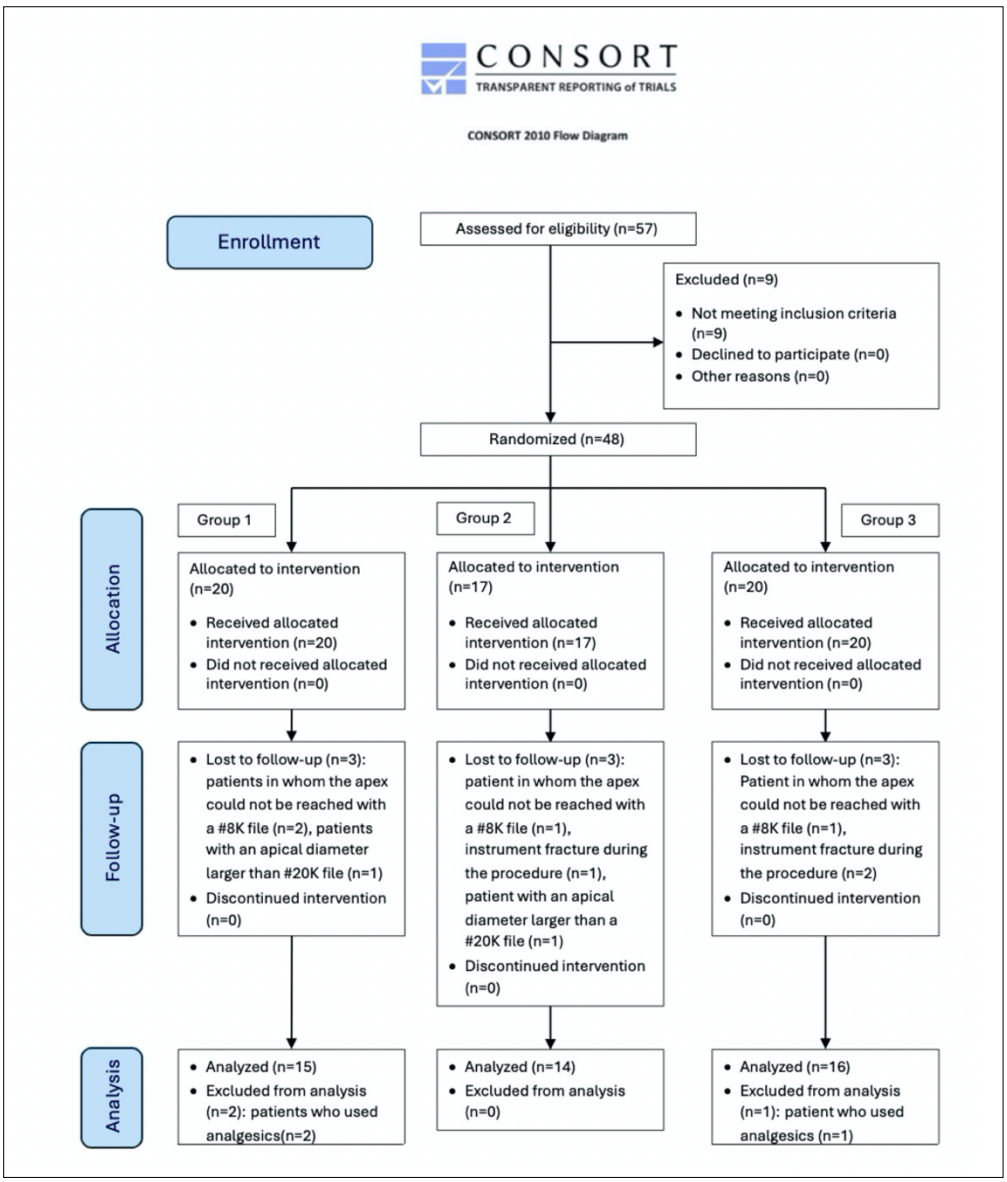

Fig. 1. Flowchart of the participant inclusion process.

Table 2. PAI Values of included teeth

PAI Score	PAI 1	PAI 2	PAI 3	PAI 4	PAI 5
Tooth Number					
34	-	-	1	1	2
35	-	-	2	1	2
36	-	-	6	3	3
44	-	-	1	-	-
45	-	-	5	1	3
46	-	-	5	5	4

statistically significant difference was found between the groups regarding postoperative pain values ($p > 0.05$).

When examining the intra-group values, a statistically significant reduction in pain levels was observed in the control and PUI groups by the 7th day, while no statistically significant result was found in the EDDY group (control

Table 3. Distribution of pain scores based on gender

Group	The Chi-Square Value	P	Degree of Freedom
EDDY	1.367	0.242295	1
Control	0.059	0.808732	1
PUI	0.485	0.486234	1

Table 4. The mean and mean rank values of pain measurement times across the groups

Group	N	Mean	Mean Rank	P
8th Hour				
Control	15		22.07	
EDDY	14	1.93	20.68	0.479
PUI	16		25.91	
Total	45			
12th Hour				
Control	15		22.43	
EDDY	14	1.68	20.96	0.577
PUI	16		25.31	
Total	45			
24th Hour				
Control	15		22.47	
EDDY	14	1.26	24.14	0.881
PUI	16		22.50	
Total1	45			
48th Hour				
Control	15		21.90	
EDDY	14	0.98	24.46	0.778
PUI	16		22.75	
Total	45			
7th Day				
Control	15		23.53	0.830
EDDY	14	0.16	22.04	
PUI	16		23.34	
Total	45			

Table 5. Intra-group postoperative pain assessment

	Control			PUI			EDDY			Total		
	Mean	Mean Rank	P	Mean	Mean Rank	P	Mean	Mean Rank	P	Mean	Mean Rank	p
8th Hour	1.81	3.73		2.47	3.91		1.42	3.25		1.93	3.64	
12th Hour	1.36	3.27		2.18	3.63		1.45	2.96		1.68	3.30	
24th Hour	0.82	2.73	0.007	1.12	2.75	< 0.001	1.89	3.32	0.050	1.26	2.90	< 0.001
48th Hour	0.37	2.73		0.83	2.47		1.78	3.11		0.98	2.76	
7th Day	0.09	2.53		0.31	2.25		0.07	2.36		0.16	2.38	

group p = 0.007, PUI group p =< 0.001, EDDY group p = 0.050). The mean and mean rank values for the postoperative pain levels of the groups are shown in Table 5.

Discussion

In this study, randomization and double blinding were applied. Patients were asked to select an envelope from a box

containing identical black envelopes, each labeled with the method to be used inside, but without any external identifiers. This ensured the randomization and blinding of the patients. The clinician learned which method would be used by referring to the envelope selected by the patient. Statistical calculations were performed by a different operator (U.M.), and when the data were shared, only numbers were used instead of group names. This way, second blinding was applied during statistical calculations.

In this study, a total of 45 mandibular first molars and mandibular premolars treated with different irrigation activation methods were included in the study. Of the treated patients, 14 were in the EDDY group, 16 in the PUI group, and 15 in the control group. No statistically significant differences were found in the inter-group and intra-group comparisons.

It has been reported that postoperative pain is more frequently observed in younger patients due to a wider apical foramen compared to older individuals (13-15). Therefore, individuals underage of 18 and teeth with an apical diameter larger than or equal to a #20K file were excluded from the study.

There is no consensus in the literature regarding the effect of gender on postoperative pain. Ali et al. (16) and Shibu (17) noted that postoperative pain was more frequently observed in women compared to men. However, some authors also reported that gender did not play a significant role in postoperative pain outcomes (18-21). In line with these findings, the present study also found no statistically significant difference in pain scores between genders in terms of pain presence and duration ($p > 0.05$).

Ramamoorthi et al. (21), was observed less pain in the EDDY group across all time intervals compared to conventional needle irrigation, using a 3% NaOCl solution throughout the irrigation procedure. In our study, a 2.5% NaOCl solution was used during the entire irrigation process, and traditional needle irrigation was applied in the control group. No statistically significant difference was found when comparing the EDDY and PUI groups. Although the results were not statistically significant, lower pain levels were observed in the EDDY group at 8 and 12 hours, while an increase in pain levels was noted at 24 and 48 hours, and similar pain levels were observed among all groups on the 7th day. This difference may be attributed to the varying NaOCl concentrations used in the two studies.

Gündoğar et al. (4), the effects of traditional needle irrigation, EDDY, EndoActivator, and PUI on postoperative pain in symptomatic irreversible pulpitis of mandibular premolar teeth were evaluated. Significant differences between groups were only found at the 24th hour pain measurements. Erkan et al. (11), the effects of EDDY, Manual Dynamic Activation, SWEEPS, and PUI on postoperative pain in the root canals of mandibular premolar teeth diagnosed with symptomatic irreversible pulpitis were examined. No significant differences were found between the PUI, EDDY, and Manual Dynamic Activation groups at the 8th and 48th hours, but the highest scores and pain prevalence were recorded in the EDDY group on the 7th day. The differences in the findings of our study may be attributed to the selected patient profile, which consisted of patients diagnosed with asymptomatic apical periodontitis, as well as the inclusion of both premolar and molar teeth in the study.

Pak & White (22), evaluated the debris extrusion caused by irrigation activation systems like EDDY, PUI, and PIPS and found that EDDY led to statistically significant amounts of debris extrusion from apical root canals. In our study, intra-group evaluation showed that pain levels decreased significantly from the 8th hour to the 7th day in the control and PUI groups, while in the EDDY group, the reduction in pain levels was not statistically significant. The reason for this could be that the amount of debris extruded from the apical region in the EDDY group was higher, leading to an early inflammatory response from this apical debris (23).

Topçuoğlu et al. (5), examined the effects of traditional, EDDY, PUI, and manual dynamic activation techniques on postoperative pain intensity in symptomatic irreversible pulpitis of mandibular molar teeth. At the 6th and 24th hours, pain intensity in the manual dynamic activation group was significantly higher compared to other groups, but no significant differences in pain intensity were found at the 48th hour, 72nd hour, and 7th day. The highest postoperative pain scores were recorded at the 6th hour in all groups, with a decrease over time. They reported no significant differences between the traditional, EDDY, and PUI methods. In our study, pain levels were evaluated from the 8th hour to the 7th day, significant reductions were observed in the control and PUI groups, but the reduction was not statistically significant in the EDDY group. Pain levels in the EDDY group increased at the 24th and 48th hours. The difference in findings between the two studies seems to be seen in the EDDY group. This difference might be attributed to the use of non-vital teeth in our study, which resulted in inflammation due to bacterial and product extrusion with canal debris from the apical area.

The limitations of this study include the absence of standardized patient gender and age, variations in PAI scores among the treated teeth, the inclusion of both premolar and molar teeth, the reliance on patient-reported pain as-

sessment forms, and the inherent subjectivity in pain perception due to individual differences in pain tresholds.

Conclusion

Comparing the control, PUI, and EDDY groups, no significant difference was found in postoperative pain at specific time points (8, 12, 24, 48 hours, and 7 days). In the Control and PUI groups, pain levels showed a significant decrease over time; however, in the EDDY group, the reduction in pain levels was not statistically significant. Gender did not influence pain levels in this study.

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