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ORAL HEALTH-RELATED QUALITY OF LIFE AFTER FOUR TREATMENT PROTOCOLS OF IRREVERSIBLE PULPITIS WITH APICAL PERIODONTITIS (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

Aim: To evaluate the effect of four root canal treatment protocols on the oral health-related quality of life (OHRQoL) of patients diagnosed with symptomatic irreversible pulpitis with apical periodontitis.

Methodology: A total of 40 participants randomly divided into four groups: Group 1; root canal preparation with hand files and final irrigation with room temperature saline solution(control group). Group 2; root canal preparation with hand files and final irrigation using cold saline solution as cryotherapy. Group 3; root canal preparation with Protaper Next rotary file system and final irrigation with room temperature saline solution. Group 4; root canal preparation with Protaper Next and final irrigation using cold saline solution as cryotherapy. All patients received root canal treatment in two visits and all canals were obturated using gutta-percha lateral compaction technique. Pain values were recorded using visual analogue scale and OHRQoL data were assessed before the root canal intervention (baseline), 6, 12 and 24 hours after first visit treatment. Data were analysed using Kruskal-Wallis and Mann Whitney Tests at ($P \leq 0.05$).

Results: All tested root canal treatment protocols significantly decreased pain and enhanced patients' OHRQoL. There were statistically significant differences among tested groups and between different assessment periods in each group.

Conclusions: cryotherapy by cold saline solution as a final rinse decrease postoperative pain and improve patient quality of life. Using rotary files is better than manual files regarding postoperative pain and quality of patient life.

KEYWORDS: cryotherapy, irreversible pulpitis, periapical periodontitis, quality of life, rotary files

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INTRODUCTION

Pulpal and peri-radicular diseases should be initially treated by conventional root canal therapy as a conservative therapeutic option.[1] postoperative pain control is one of the challenges during root canal therapy.[2] It may be affected by a variety of variables including; preoperative state of the pulp and peri-radicular tissues, preoperative discomfort, treatment approaches, and endodontist experience.[3,4]

Quality of life is a multidimensional construct reflecting mental, psychological and emotional well-being, as well as health, education, social relationships and other parameters affecting human life.[5] Oral health entails the ability of patients to perform daily activities such as eating, talking and smiling, as well as being able to contribute creatively to society.[6]. Oral health-related quality of life (OHRQoL) reflects the extent to which oral conditions affect an individual's behaviour and social functioning over time.[5] This patient-centred outcome is complementary to other factors assessing the efficacy of oral health procedures, and it supports clinicians in clinical decisions making.[7] Various systematic reviews have demonstrated that root canal treatment can positively impact the OHRQoL, but these reviews declared that the lack of well-designed trials impairs the possibility of providing strong evidence.[8-10]

Postoperative pain can be controlled by several techniques. Intracanal cryotherapy, using cold saline irrigation, had been proposed to have local anti-inflammatory impact in peri-radicular tissues. So, it may have positive effect on postoperative pain.[11] In addition, engine-driven nickel-titanium root canal systems used in crown down technique showed little debris extrusion than manual instrumentation which may have impact on postoperative pain.[12]

In fact, knowledge about the impact of endodontic treatment on OHRQoL remains limited.[10,13] Pragmatic clinical trials assessing this outcome allow us to comprehend the effects of endodontic treatment on functional limitation, physical pain, psychological discomfort and social inability. This provides support for clinical decisions, enhances the quality of services received by the patient and improves clinical research settings used to compare different treatment protocols.

Therefore, this study aimed to compare the impact of four root canal treatment protocols on OHRQoL. It was hypothesized that three tested protocols result in a similar and positive effect in the OHRQoL reported by participants enrolled in this clinical trial in comparison to control group.

MATERIALS AND METHODS

Sample size

Forty patients were enrolled in this study. The recruited participants were patients who had scheduled a root canal treatment in Endodontic Department, Faculty of Dentistry, Tanta University. The sample size was determined using power calculations (G Power version 3.1.9.; Franz Faul, University of Kiel, Kiel, Germany), a minimum sample size of 36 would be required to demonstrate results with a 5% significance level, more than 80% power and confidence interval of 95%.The required sample size was increased to be 40 to compensate for incomplete treatment and to increase the validity of results.

The formula of sample size

Sample size = Z2 P (1-P)/ C2

Where:

Z = Z value (1.96 for 95% confidence level)

p = percentage picking a choice, expressed as decimal

c = confidence interval, expressed as decimal.

Ethical consideration

This study was approved by the Human Research Ethics Committee of the Faculty of Dentistry, Tanta University. All patients were informed about the

study nature, and signed informed consents for study participation.

Inclusion criteria

Age range between 18 and 40 years old

Both genders

Patient with acceptable mental status and ability to understand the study procedures

Mandibular premolars with symptomatic irreversible pulpitis with apical periodontitis.

Restorable teeth

Accepted periodontal health

Exclusion criteria

Patients with allergy to any material in the study

Medically compromised patients

Pregnant, breast feeding females

Teeth with internal or external resorption

Teeth with immature apices

Random sequence generation and allocation concealment

A random list was created using the website www.Randomizer.org. The treatment to be performed in each patient concealed from the operator using the sequentially numbered opaque sealed envelope (SNOSE) technique, in which treatment was placed into opaque and sealed envelopes by a party not involved in the study and endodontists who performed the clinical procedures opened the envelope at the beginning of the intervention.

Study interventions

First appointment

All included patients were diagnosed with symptomatic irreversible pulpitis with apical periodontitis after taking their medical and dental history, performing extra-oral and intra-oral examinations and pre-operative radiographic interpretation. All participants responded to a modified Oral Health Impact Profile (OHIP-14) questionnaire to measure the OHRQoL at baseline. It include questions regarding difficulty in mouth opening, chewing, speaking, sleeping, going to work or school, daily activity, and social relations. Patients selected one of 5 pre-established choices (0-not at all,1-very little, 2-some, 3-quite abite, and 4-very much). Pre-operative pain was assessed using Visual analogue scale (VAS) which is made of 10cm line, where 0 means no pain and 10 means unbearable pain.

After administration of local anaesthesia (4% Articaine HCL,Artpharmadent, Artpharma, Egypt) and placement of the rubber dam (Sanctuary Health Sdn Bhd, Malaysia), carious lesions were removed, access cavities were prepared and teeth were reconstructed with resin modified glass ionomer (gc Fuji iilc, gc corp, Tokyo, Japan)

In group 1; A glide path was established with stainless steel K Files (Dentsply Sirona Endodontics, Ballaigues, Switzerland) up to size 15. Then, a crown-down technique was performed initially with Gates-Glidden burs, which were used in a step-down manner to enlarge the orifice, prepare the cervical and middle thirds of the canal, and provide straight-line access to its apical third. Working length (WL) was determined with an electronic apex locator (Morita Corp; Kyoto, Japan), and confirmed radiographically. Apical preparation was then performed using stainless steel hand file, starting with the selection of the first file to bind at the working length. The final instrumentation file was set at three sizes larger than the first file used.

Root canal irrigation was performed throughout instrumentation using 2.5% sodium hypochlorite (NaOCl) solution (Clorox Co, 10thof Ramadan, Egypt) delivered into the canal by a syringe with a 30-G side-vented needle (FANTA dental materials, China) 1 mm short of WL. To remove the smear layer after root canal preparation, root canals were

irrigated with 1 mL of 17% EDTA solution (Adam Dent, Egypt) for 1 min. Final irrigation was done using 5 mL of room temperature sterile saline solution (Ultimate Pharma, Egypt).

In group 3; coronal flaring was done using Protaper Gold SX file (Dentsply Sirona, USA) after establishing glide path and WL determination as in group 1. Root canal preparation was done using Protaper NEXT rotary files (Dentsply/ Maillefer, Ballaigues, Switzerland) in a crown-down technique to master apical file X3 (30 / 0.07) at a rotational speed of 300 rpm along with torque values of 2 NCM. Each file was used with a brushing motion circumferentially within the root canal using 20:1 gear reduction hand piece powered with a torque limited endodontic motor (E-CONNECT, Changzhou City, China) following the manufacturer's instructions. Root canal irrigation throughout instrumentation and the final irrigation were done as in group 1.

In groups 2 and 4; root canal preparation were done as in group 1 and 3 respectively. However, the final irrigation was done using 5 mL of cold saline solution at a temperature of 2-4°c.

In all groups, root canals were dried with paper points (Sure endo, Sure Dent Corporation, Korea) and calcium hydroxide paste (Metapex, META Biomed Co, Chengcheongbuk-do, Korea) was applied inside the canal 3 mm short of WL. Intermediate restoration (Litark, Lascod s.p.a, Italy) was placed in between two appointments. Patients were asked to fill out OHRQoL questionnaire and VAS at 6, 12, and 24 hours after first visit treatment. Scoring of pain was done according to Jensen, et al[14] :

Score 0: no pain (0-4mm) the treated tooth felt normal. Patients don't have any pain

Score 1: mild pain (5-44mm)recognizable, but not discomforting pain which required no analgesics

Score 2: moderate pain (45-74mm) discomforting, but bearable pain (analgesics, if used, are effective in relieving the pain)

Score 3: severe pain (75-100mm) difficult to bear (analgesics have little or no effect in relieving the pain)

Second appointment

In all groups, the intermediate restoration was removed, field isolation was done and calcium hydroxide was removed. The lateral compaction filling technique was used to fill the canals with an epoxy resin-based sealer (AH Plus; Dentsply DeTrey, Konstanz, Germany). Post operative radiographic imaging was done to ensure proper obturation and the access cavity was restored using composite restoration (Tokuyama Dental Corporation, Japan). The root canal treatments were performed by four endodontists, all of whom had at least five years of clinical experience.

Statistical analysis

All analysis were performed using Statistical Package for Social Sciences software (SPSS for Windows desktop version 20.0; SPSS In. Chicago, IL, USA). Kruskal-Wallis Test was used to compare among groups at each time interval and among different time intervals in each group and Mann Whitney test was used to detect pair-wise comparisons whenever significance was found and the level of significance was set at P-values ≤0.05.

RESULTS

Different OHRQoL questionnaire and VAS scores at 6, 12, and 24 hours after treatment in comparison to preoperative scores and their statistical analysis are summarized in Tables 1-7. No roll out of any participant had occurred and all tested root canal treatment protocols significantly enhanced patients' OHRQoL and decreased pain.

Using Kruskal-Wallis Test, significant differences among groups were found at 6 hours

time interval regarding difficulties with sleeping, missed work, school or daily activities and affected social relations. While at 12 hours time interval, significant differences among groups were found considering difficulties with mouth opening, difficulties with chewing, difficulties with sleeping and pain. Similarly, significant differences among groups were found considering difficulties with mouth opening, difficulties with chewing and pain at 24 time interval.

Mann Whitney test was used to detect pair-wise comparisons and it revealed that at 6 hours time interval, regarding difficulties with sleeping, control group was significanty worse than group 2 (p=.002) and group 4(p=.001). In addition, group 3 was significanly worse than both groups 2(p=.009) and 4(p=.004). The same significant differences were recorded among groups regarding affected social relations recording .007, .007., .020 and .020 respectively. Considering missed work, school or daily activities, control group recorded worse scores than both groups 2 and 4 (p=.030).

At 12 hours time interval, considering difficulties with mouth opening, difficulties with chewing and difficulties with sleeping, both groups 1and 3 were significantly different than group 2 and 4 recording p. values ≤ 0.05. While regarding pain, only group 1 was significantly different than both groups 2 and 4 recording P-values of 0.028 and 0.008 respectively.

At 24 hours time interval, considering difficulties with mouth opening, difficulties with chewing and pain, group 4 recorded significantly better scores than 1,3. In addition, group 2 was significantly different than group 1 and 3 regarding difficulties with chewing and only group 1 regarding pain scores recording P-values ≤0.05.

At each group, OHRQoL was improved by time. OHRQoL scores at time intervals were compared using Kruskal-Wallis Test and it showed significant differences among time intervals in all criteria except in difficulties in mouth opening. Using Mann Whitney test, there were significant differences between preoperative scores and scores at 6 hours in all groups in all OHRQoL criteria except in group 3 in difficulties with speaking, missed work, school or daily activities and affected social relations. In comparing preoperative scores to scores at 12, 24 hours, there were significant differences in all groups in all OHRQoL criteria. Significant differences were also found between 6 and 12 hours time intervals in group 1 in difficulties with sleeping, missed work, school or daily activities and affected social relations and in group 3 in difficulties with sleeping only (P-values ≤0.05).

Regarding differences between 6,24 hours time intervals, significant differences were recorded in difficulties with chewing in groups 2,3,4, in difficulties with sleeping in groups 1,3, in missed work, school or daily activities significant difference was only found in group 1, in Affected Social Relations in groups 1 and 3, while regarding pain significant differences were found in all groups. A pair-wise comparison between 12,24 hour time intervals showed significant differences in difficulties with chewing in group 3, difficulties with sleeping in group 1 and in pain in all groups (P-values ≤0.05).

TABLE (1). Scores of difficulties with mouth opening of different groups at different time intervals and their statistical analysis

			Group1 (control)	Group2 Hand+ cryotherapy	Group3 Rotary+ normal saline	Group4 Rotary+ cryotherapy	Kruskal-Wallis Test p-value
Difficulties with mouth opening	Preoperative	0 not at all	6	5	5	6	.958
		1 very little	2	4	3	3	
		2 some	1	1	2	1	
		3 quite a bite	1	0	0	0	
	After 6 hours	0 not at all	2	7	3	8	.051
		1 very little	6	2	5	1	
		2 some	2	1	2	1	
	After 12 hours	0 not at all	3	9	4	9	.008*
		1 very little	4	1	4	1	
		2 some	3	0	2	0	
	After 24 hours	0 not at all	5	9	6	10	.031*
		1 very little	4	1	3	0	
		2 some	1	0	1	0	
Kruskal-Wallis Test p-value			.482	.159	.633	.118	

TABLE (2). Scores of difficulties with chewing of different groups at different time intervals and their statistical analysis

			Group1 (control)	Group2 Hand+ cryotherapy	Group3 Rotary+ normal saline	Group4 Rotary+ cryotherapy	p-value
Difficulties with chewing	Preoperative	1 very little	0	1	0	1	.195
		2 some	1	2	2	4	
		3 quite a bite	4	4	3	3	
		4 very much	5	3	5	2	
	After 6 hours	0 not at all	0	2	0	1	.213
		1 very little	4	5	5	6	
		2 some	5	3	4	3	
		3 quite a bite	1	0	1	0	
	After 12 hours	0 not at all	0	5	0	4	.013*
		1 very little	6	4	7	5	
		2 some	4	1	3	1	
	After 24 hours	0 not at all	0	7	1	7	.001*
		1 very little	8	2	9	3	
		2 some	1	1	0	0	
p-value			.000*	.000*	.000*	.000*	

means significant difference at P-values ≤0.05

TABLE (3). Scores of difficulties with speaking of different groups at different time intervals and their statistical analysis

			Group1 (control)	Group2 Hand+cryotherapy	Group3 Rotary+normal saline	Group4 Rotary+ cryotherapy	p-value
Difficulties with speaking	Preoperative	0 not at all	5	5	6	6	.893
		1 very little	3	3	3	3	
		2 some	2	2	1	1	
	After 6 hours	0 not at all	9	10	9	10	.562
		1 very little	1	0	1	0	
	After 12 hours	0 not at all	10	10	10	10	1.000
	After 24 hours	0 not at all	10	10	10	10	1.000
p-value			.004*	.001*	.021*	.005*	

means significant difference at P-values ≤0.05

TABLE (4). Scores of difficulties with sleeping of different groups at different time intervals and their statistical analysis

			Group1 (control)	Group2 Hand+cryotherapy	Group3 Rotary+normal saline	Group4 Rotary+cryotherapy	p-value
Difficulties with sleeping	Preoperative	1 very little	0	0	0	0	.832
		2 some	2	2	1	1	
		3 quite a bite	3	2	2	3	
		4 very much	5	6	7	6	
	After 6 hours	0 not at all	1	7	2	8	.000*
		1 very little	3	3	3	2	
		2 some	3	0	3	0	
		3 quite a bite	3	0	2	0	
	After 12 hours	0 not at all	3	9	4	9	.005*
		1 very little	7	1	6	1	
	After 24 hours	0 not at all	8	9	8	10	.484
		1 very little	2	1	2	0	
p-value			.000*	.000*	.000*	.000*	

means significant difference at P-values ≤0.05

TABLE (5). Scores of missed work, school or daily activities of different groups at different time intervals and their statistical analysis

			Group1 (control)	Group2 Hand+cryotherapy	Group3 Rotary+normal saline	Group4 Rotary+ cryotherapy	p-value
Missed work, school or daily activities	Preoperative	0 not at all	2	4	3	3	.867
		1 very little	2	1	1	2	
		2 some	3	3	3	3	
		3 quite a bite	3	2	3	2	
	After 6 hours	0 not at all	6	10	7	10	.037*
		1 very little	2	0	1	0	
		2 some	2	0	2	0	
	After 12 hours	0 not at all	10	10	10	10	1.000
	After 24 hours	0 not at all	10	10	10	10	1.000
	p-value		.000*	.000*	.000*	.000*	

means significant difference at P-values ≤0.05

TABLE (6). Scores of affected social relations of different groups at different time intervals and their statistical analysis

			Group1 (control)	Group2 Hand+ cryotherapy	Group3 Rotary+normal saline	Group4 Rotary+ cryotherapy	p-value
Affected social relations	Preoperative	0 not at all	1	1	1	1	.777
		1 very little	2	4	3	3	
		2 some	3	3	4	4	
		3 quite a bite	2	1	1	1	
		4 very much	2	1	1	1	
	After 6 hours	0 not at all	3	9	4	9	.004*
		1 very little	5	1	4	1	
		2 some	1	0	1	0	
		3 quite a bite	1	0	1	0	
	After 12 hours	0 not at all	8	9	8	9	.858
		1 very little	2	1	2	1	
	After 24 hours	0 not at all	9	10	9	10	.562
		1 very little	1	0	1	0	
	p-value		.000*	.000*	.000*	.000*	

means significant difference at P-values ≤0.05

TABLE (7). Scores of pain of different groups at different time intervals and their statistical analysis

			Group1 (control)	Group2 Hand+ cryotherapy	Group3 Rotary+normal saline	Group4 Rotary+cryotherapy	p-value
Post operative pain	Preoperative	Score 0	0	0	0	0	.484
		Score 1	0	0	0	0	
		Score 2	1	0	2	1	
		Score 3	9	10	8	9	
	After 6 hours	Score 0	0	0	0	0	.069
		Score 1	2	6	4	7	
		Score 2	6	4	5	3	
		Score 3	2	0	1	0	
	After 12 hours	Score 0	0	0	0	0	.024*
		Score 1	3	8	5	9	
		Score 2	7	2	5	1	
		Median					
	After 24 hours	Score 0	3	8	4	9	.012*
		Score 1	6	2	6	1	
		Score 2	1	0	0	0	
p-value			.000*	.000*	.000*	.000*	

means significant difference at P-values ≤0.05

DISCUSSION

The present study evaluated and compared the effect of four different treatment protocols of irreversible pulpitis with apical periodontitis on the OHRQoL of patients as its assessment is essential because it focus on how diseases and treatment modalities affect a person's social, emotional and physical functioning, and can help to define appropriate treatment goals. [15]

Patients included in this study were chosen according to certain inclusion criteria to improve the standardization of samples where age range between 18 and 40 years old was chosen as patients under this age may lack the ability to express exactly their pain and other OHRQoL criteria. On the other hand, older patients are more likely to experience postoperative discomfort due to changes in humeral or cell-mediated immunity caused by aging process. [16] Both genders were included as some studies[17,18] confirmed the absence of correlation between patient gender and postoperative pain.

Mandibular premolars were chosen as mandibular posterior teeth were related to a high incidence of postoperative pain compared to maxillary teeth due to thicker cortical plate which lead to accumulation of exudates and lower blood circulation which lead to healing delay.[19,20] Additionally, cases diagnosed with symptomatic irreversible pulpitis with apical periodontitis were included in this study as in cases of irreversible pulpitis only, the effect of different treatment protocols could not be tested as just pulp extirpation can result in pain relief.[21]

Medically compromised patients and pregnant, breast feeding females were excluded from the study as the former cases have diseases which might increase post treatment flare up and discomfort [22] and the later may have decreased pain threshold and more pain sensation due to hormonal changes. [16]Certain precautions were done during root canal treatment of study cases to reduce postoperative pain as possible by; careful rubber dam application, passive irrigation, crown down techniques, proper control of working length and careful application of calcium hydroxide paste. Cryotherapy using cold saline solution at 2-4°c was used in this study according to previous successful studies. [23-25] Moreover, two-visits treatment plan was chosen to allow periodontal ligament healing and prevent other causes of pain as extruded sealer. This selection based on a conclusion that number of treatment visits had no effect on postoperative pain.[26]

A modified Oral Health Impact Profile (OHIP-14) questionnaire was used by excluding certain criteria as swelling, bruises, bleeding, nausea, bad taste and odor as these criteria are not important in endodontic treatment of vital teeth. Certain time intervals were chosen for evaluation; 6, 12 and 24 hours after first visit as this is the most prevalent time of pain.[27,28] and most clinical trials evaluate changes on OHRQoL until only a few days after the end of endodontic treatment [10].

The study results revealed that cryotherapy in both group 2 and 4 improved OHRQoL and postoperative pain more than groups 1 and 3 using normal saline solution as a final rinse. This was in agreement and supported by different studies [21,23, 24,29-33] which proved efficacy of cryotherapy in reduction of postoperative pain and discomfort. This may be attributed to decreasing external root surface temperature which decelerate the inflammatory reaction, reduce the induction of pain producing substances, leading to local anti-inflammatory effects in the peri-radicular tissues.[11] In addition, cryotherapy lead to vasoconstriction of periodontal ligament blood vessels, thus reducing permeability, tissue effusion and swelling, besides decreasing stimuli conduction, stimuli speed deceleration, limiting tissue damage which finally lead to the apparent effect of cryotherapy in pain limitation.[34]

Statistically significant improvement of OHRQoL and postoperative pain were observed at 6,12 and 24 hours in all groups even in the control group. This may be attributed to that root canal treatment is very effective in pain relief if well performed [27] and only complete removal of inflamed pulp tissue and pulp space irritant can relieve pain and improve OHRQoL

Moreover, using Protaper Next and final irrigation with room temperature saline solution showed better results than using hand instrumentation and the same final irrigation which were insignificantly different than both groups 2 and 4, using cryotherapy, in some criteria. This may be due to less extrusion of debris caused by engine-driven rotary instruments than hand instrumentation as rotary instruments tends to pull the debris into their flutes, thus leading the debris out of the root canal in a coronal direction[35] which may decrease pain and sequentially improve quality of patient life.

CONCLUSIONS

Regarding pain relief and improving quality of life in patients diagnosed with symptomatic irreversible pulpitis with apical periodontitis;

- Well performed root canal therapy only can relief pain and improve OHRQoL.
- Intracanal cryotherapy provides a more effective approach.
- Rotary root canal preparation is more effective than hand files

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