ABSTRACT

Aim: To evaluate the effect of intracanal cryotherapy with negative pressure irrigation (EndoVac) on postendodontic pain after vital single-visit root canal treatment (RCT).

Materials and methods: A total of 75 single-rooted teeth with single root canal were treated endodontically. After root canal preparation with Protaper Universal rotary system and irrigation, teeth were divided randomly into three groups (n = 25) according to additional irrigation protocol as follows: Group I: No additional irrigation was applied (control); group II: A 20 mL of room temperature saline was irrigated during 5 minutes using EndoVac, and group III: A 20 mL of 2 to 4°C cold saline was irrigated during 5 minutes using EndoVac. Pain levels were assessed by visual analog scale (VAS) and verbal evaluation of pain questionnaire after 6, 12, 24, 48 hours, and 7 days of canal obturation. The data were then analyzed using Statistical Package for the Social Sciences (SPSS) 13.0 using Kruskal–Wallis and Mann–Whitney U tests at p-value of 0.05.

Results: The results showed that pain levels were high in groups I and II after 6 hours that decreased with time to almost diminish after 1 week, and on the other hand, group III showed no pain among different monitoring periods. Also pain levels in groups II were lower compared with group I after only 6 hours, with significance p < 0.05.

Conclusion: Postendodontic pain presented with highest values after 6 hours of treatment and reduced to almost nil after 1 week. Intracanal cryotherapy eliminated postendodontic pain clinically. Negative pressure reduced postendodontic pain after 6 hours of treatment.

Clinical significance: The outcome of this study indicates that the use of intracanal cryotherapy technique with negative pressure irrigation eliminates postendodontic pain after single-visit RCTs.

Keywords: Cryotherapy, EndoVac, Negative irrigation, Postendodontic pain, Randomized clinical trial.

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INTRODUCTION

Pain is the major reason for patients’ visits to dental clinics in order to gain immediate relief. Some dental treatments may result in postoperative pain causing patient discomfort. The pain may arise due to either an endodontic (mostly) or a periodontal cause. Even though the endodontic pain is more common, differentiation between periodontal and endodontic origin pain has to be well established to have accurate diagnosis, which leads to proper management of any dental pain, which limits postoperative complications improving dental daily practice.

Postendodontic pain is common, even when the endodontist has followed acceptable standards of treatment.1 According to previously published data, pulp therapy and root canal treatment (RCT) induce more frequent and more severe postoperative pain than do other dental operative procedures.2 It has also been found that frequencies of postendodontic pain range from 1.53 to 53%.2 The difference between studies may be partly explained by the fact that most of the authors assessed and defined postendodontic pain according to different criteria, using different endodontic materials and techniques.4

The common factors influencing the occurrence of pain after RCT include insufficient instrumentation, irrigant
extrusion, intracanal interappointment dressing extrusion, hyperocclusion, missed canals, presence of periapical pathosis, apical debris extrusion, and apical patency during root canal preparation. Postendodontic pain most often occurs during the first 24 to 48 hours after obturation, and generally recedes in a few hours, although it occasionally persists for several days.

There was no significant difference in the incidence of postendodontic pain between single and multiple visit treatments.

Irrigation has a key role in successful endodontic treatment. Although hypochlorite is the most importantly used irrigating solution, no single irrigant can accomplish all the tasks required by an optimum irrigation solution. Bashetty and Hegde reported that the type of irrigant used was not associated with the postendodontic pain after 1 or 7 days. The use of a negative apical pressure irrigation device can result in a significant reduction of postendodontic pain levels in comparison to conventional needle irrigation.

Managing postendodontic pain is of prime importance because the incidence of patients returning to endodontist with discomfort is on the rise. This pain can be relieved by being more careful during the endodontic treatment procedure. Each step of RCT must be done with utmost perfection, some examples, such as accurate working length (WL) determination, disoccluding the opposing teeth, proper cleaning and shaping with adequate sequencing of instruments, optimum use and judicious selection of irrigants, and use of magnifying devices, such as dental loupes and endodontic microscopes.

Cryotherapy is a relatively new form of treatment in which the body is briefly exposed to very cold temperatures in order to promote healing and other therapeutic results. The basic technique of cryotherapy stresses rapid cooling, slow thawing, and repetition of the freezing process to maximize tissue destruction. It will reduce the local blood flow by vasoconstriction and therefore, the local inflammatory reaction, swelling, and heat experience, and also will slow the conduction of nerve signals, potentially reducing pain transmission.

Some studies have demonstrated that cryotherapy minimizes secondary hypoxic injury through the reduction of cellular metabolism and injury area. Cryotherapy has been used for pain relief, such as sports injuries, runner’s knee, tendonitis, sprains, arthritis pain, pain and swelling after a hip or knee replacement, to treat pain or swelling under a cast or a splint, and lower back pain.

In dentistry, cryotherapy has been used after introral surgical procedures, such as periodontal surgery, extractions, and implant placement, and was found to be effective in reducing swelling and pain.

In endodontics, George et al. have found in an in vitro study that the deep dry cryotherapy of NiTi endodontic files can improve its cyclic fatigue resistance, reducing the potential file separation. One way to apply cryotherapy to the inflamed periradicular tissues is by intracanal irrigation with a cold substance after flaring the root canal system. This has been proven to be an easier task when using a negative pressure irrigation system, such as the EndoVac system. The microcannula (MICRO) of the system can be placed to the full WL and be used to aspirate the irrigant with a continuous flow.

In a recent in vitro study by Vera et al., it was found that intracanal delivery of cold saline solution (2.5°C) with negative pressure irrigation reduced the external root surface temperature more than 10°C and maintained it long enough to possibly produce a potential local anti-inflammatory effect in the periradicular tissues.

Of the previous findings, no study till now has investigated the influence of this newly applied technique in endodontics on postendodontic pain clinically.

So the aim of this study was to evaluate the effect of root temperature reduction using intracanal cryotherapy with negative pressure irrigation (EndoVac) on postendodontic pain after vital single-visit RCT.

**MATERIALS AND METHODS**

**Study Design**

Randomized clinical trial was used, with blind assessment technique.

This study was carried out in the clinics of the Faculty of Dentistry at the Syrian Private University (SPU) from February 1, 2016, till April 1, 2016, after ethical obtaining approval from SPU Ethical Committee (01/6/2016). Before starting the treatment procedures, all participants were informed about the nature and objectives of the study, along with obtaining a written consent. Participants were also not aware of the study group that they were belonging to (single blind).

Before starting the study sample, 10 pilot in vitro and 10 in vivo samples were performed to master the use of rotary instrumentation with EndoVac irrigation system to ensure the correct study steps.

**Inclusion and Exclusion Criteria**

Patients aged 20 to 46 years visiting dental clinics at SPU with irreversible pulpsitis or deep caries lesions, acceptable oral health, no gingival recession (or existing periodontal disease), good general health, and no chronic diseases or pregnancy or medicaments intake were good candidates for this study.
Accepted teeth for this study were with the following criteria:

- Vital teeth with irreversible pulpitis or pulp exposure due to deep caries excavation
- Single-rooted single canal teeth (radiographically and clinically assessed)
- Ability for isolation with rubber dam
- Restorable teeth
- Ability to fill the root canals in single-visit treatment

Excluded teeth

- Teeth without good apical constriction, such as wide or open apex
- Resorptions and apical periodontitis
- Lower anterior incisors
- Initial apical size no less than 15#.

**Treatment Procedures**

Endodontic treatment was performed on all teeth in a single visit. After clinical examination and preoperative periapical radiograph, the teeth were anesthetized, isolated with rubber dam, caries removed, and standard access gained to the root canal system with diamond burs under copious water cooling. Following complete access, the initial glide path was obtained by using #10 K-file (Thomas, France). Working lengths were determined with an apex locator (Foramatron D10; Parkell Electronic Division, Farmingdale, NY, USA) and confirmed radiographically using film holder (Kerr Endo, Orange County, CA, USA) (Figs 1A and B). Canals were prepared by using ProTaper Universal rotary files (Dentsply Maillefer, Ballaigues, Switzerland) till the file F4 (40/0.06) following the full sequence recommended by the manufacturer with the aid of 17% ethylenediaminetetraacetic acid gel (Meta-Biomed, Korea) as a lubricant. The canals were irrigated between each file with 5 mL of 5.25% NaOCl.

After root canal preparation, study sample (75 teeth in 62 patients aged from 20 to 46 years) was divided randomly into three equal groups (n=25) according to additional irrigation protocol as follows:

- **Group I**: No additional irrigation was applied (control).
- **Group II**: A 20 mL of room temperature saline was irrigated during 5 minutes using EndoVac (Kerr Endo, Orange County, CA, USA) negative irrigation.
- **Group III**: A 20 mL of 2 to 4°C cold saline was irrigated during 5 minutes using EndoVac (Kerr Endo, Orange County, CA, USA) negative irrigation.

**Randomization**

Regardless of the treated included case in the study, and without informing the patient of which group the treated tooth was belonging to (single blind), the first treated case was for the first group, the second was for the second group, and the third case was for the third group, and so on.

The temperature of the cold saline was preserved for 5 minutes irrigation period by keeping the irrigation syringes, which were used one by one, in a special box filled with ice after removal from refrigeration with thermocouple (Meter HTC-2 external sensor, Digital LCD Temperature Thermometer, China, Lot: 1490713) inserted inside to confirm the 2 to 4°C temperature range (Fig. 2).

In groups II and III, EndoVac system was used as a negative pressure irrigation by inserting the microcannula (MICRO) at WL and supplying the 20 mL saline solution for 5 minutes by the attached syringes at room temperature in group II, and at 2 to 4°C in group III (Fig. 3).

Canals were then dried with paper points and obturated in the same visit by lateral condensation technique with resin-based sealer (Adseal; Meta-Biomed, Korea lot: ADS1505151) and gutta-percha cones.
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Fig. 3: Applying cold saline 2 to 4°C irrigation in group III

Fig. 4: The obturation of the canal by lateral condensation technique

Fig. 5: Visual analog scale of 10 cm used to assess discomfort/pain

The patient has to mark the area on the VAS that corresponds with the amount of felt pain as the 0° refers for no pain, and the 100° degree refers for unbearable pain. The distance between the beginning of the scale 0° and the patient’s pain mark was measured using a roller and the VAS value by millimeters was recorded. Patients were contacted on phone to remind them about registering pain according to different periods. The questionnaires were completed and delivered after 1 week of canal obturation and restoring the teeth with the composite (Nexcomp, Meta-Biomed, Korea lot: 0120) as the final restoration.

For verbal evaluation of pain/discomfort, the patients were asked to record the pain on the same questioner as follows: 0: No pain, 1: Slight pain, 2: Moderate pain, 3: Severe pain.

In case of severe or unbearable pain, patients were allowed to take anti-inflammatories like ibuprofen 400 mg or sedatives like acetaminophen or both according to pain severity and were excluded from the study.

The data were then inserted to a personal computer and analyzed using the Statistical Package for the Social Sciences (SPSS) 13.0 computer software by using Kruskal–Wallis and Mann–Whitney U tests for comparing between the study groups; p-value of 0.05 was considered statistically significant.

RESULTS

All included patients in the study were able to come back after 1 week of root canal obturation with a 100% response rate.

Study sample consisted of 75 single-visit RCTs of 75 teeth on 62 patients between 20 and 46 years. Study sample was divided into three equal distinct groups (Control group: No additional irrigation was applied, Saline irrigation group: 5 minutes room temperature saline irrigation using EndoVac, Cold saline irrigation group: 5 minutes 2 to 4°C cold saline irrigation using EndoVac) (Table 1).

The results of this study showed complete correspondence between verbal and VAS pain values, so we list only the VAS results. The results of VAS pain values according to different groups and periods are illustrated in Figure 6.

A Kruskal–Wallis test was applied to know if there were significant differences in VAS pain values between
Table 1: Sample distribution according to studied groups

<table>
<thead>
<tr>
<th>Studied group</th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>25</td>
<td>33.3</td>
</tr>
<tr>
<td>Saline Irrigation at Room Temperature</td>
<td>25</td>
<td>33.3</td>
</tr>
<tr>
<td>Cold saline irrigation</td>
<td>25</td>
<td>33.3</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2: Kruskal-Wallis Test results to know if there were significant differences in VAS pain values between study groups according to the studied period

<table>
<thead>
<tr>
<th>Studied Period</th>
<th>N</th>
<th>Mean rank</th>
<th>Chi-square</th>
<th>p-value</th>
<th>Significant difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 6 hours</td>
<td>25</td>
<td>13.00</td>
<td>44.70</td>
<td>55.50</td>
<td>YES</td>
</tr>
<tr>
<td>After 12 hours</td>
<td>25</td>
<td>13.00</td>
<td>47.40</td>
<td>53.60</td>
<td>YES</td>
</tr>
<tr>
<td>After 24 hours</td>
<td>25</td>
<td>13.00</td>
<td>47.40</td>
<td>53.60</td>
<td>YES</td>
</tr>
<tr>
<td>After 48 hours</td>
<td>25</td>
<td>28.00</td>
<td>40.16</td>
<td>45.84</td>
<td>YES</td>
</tr>
<tr>
<td>After 1 week</td>
<td>25</td>
<td>35.50</td>
<td>39.98</td>
<td>38.52</td>
<td>NO</td>
</tr>
</tbody>
</table>

All other p values were greater than 0.05 after 1 week, so at the confidence level of 95% there were no significant differences in VAS pain between studied groups in the studied sample.

Values of p were lower than 0.05 for all pairwise comparisons when comparing VAS pain after 6, 12, 24, and 48 hours between cold saline irrigation group and both saline irrigation at room temperature and control groups, so we can conclude at the confidence level of 95% that there were significant differences in VAS pain between mentioned studied groups.

A Mann–Whitney U test was applied to know if there were significant pairwise differences between study groups as shown in Table 3.

Values of p were lower than 0.05 for all pairwise comparisons when comparing VAS pain after 6, 12, 24, and 48 hours between cold saline irrigation group and both saline irrigation at room temperature and control groups.

The results also showed that p values were lower than 0.05 with significance when comparing VAS pain after 6, 12, 24, and 48 hours between studied groups.

Table 3: Mann-Whitney U Test results to know if there were significant pairwise differences on VAS Pain after 6 hours, after 12 hours, after 24 hours and after 48 hours between studied groups.

<table>
<thead>
<tr>
<th>Studied Period</th>
<th>Studied group (I)</th>
<th>Studied group (J)</th>
<th>U value</th>
<th>p-value</th>
<th>Significant difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 6 hours</td>
<td>Cold saline irrigation</td>
<td>Saline Irrigation at Room Temperature</td>
<td>0</td>
<td>0.000</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>control</td>
<td>control</td>
<td>0</td>
<td>0.000</td>
<td>YES</td>
</tr>
<tr>
<td>After 12 hours</td>
<td>Cold saline irrigation</td>
<td>Saline Irrigation at Room Temperature</td>
<td>167.5</td>
<td>0.004</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>control</td>
<td>control</td>
<td>0</td>
<td>0.000</td>
<td>YES</td>
</tr>
<tr>
<td>After 24 hours</td>
<td>Cold saline irrigation</td>
<td>Saline Irrigation at Room Temperature</td>
<td>235.0</td>
<td>0.125</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>control</td>
<td>control</td>
<td>0</td>
<td>0.000</td>
<td>YES</td>
</tr>
<tr>
<td>After 48 hours</td>
<td>Cold saline irrigation</td>
<td>Saline Irrigation at Room Temperature</td>
<td>212.5</td>
<td>0.002</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>control</td>
<td>control</td>
<td>162.5</td>
<td>0.000</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Saline irrigation at room temperature</td>
<td>control</td>
<td>266.5</td>
<td>0.308</td>
<td>NO</td>
</tr>
</tbody>
</table>
6 hours only between saline irrigation at room temperature group and control group, so we can conclude also that VAS pain values after 6 hours in saline irrigation at room temperature group were lower than those of control group. All other p values were greater than 0.05; so, at the confidence level of 95% there were no significant differences in VAS pain between the concerned studied groups.

DISCUSSION
Avoiding pain during and after dental treatment is of great importance for patients, because fear of pain is one of the major reasons for dental apprehension. Postoperative pain is one of the primary problems in endodontic treatment (postendodontic pain), even when proper treatment steps were followed. Although the success of endodontic treatment is highly related to the elimination or reduction of postendodontic pain, many clinical studies have reported varying degrees of pain, ranging from 1.5\(^2\) to 53%.\(^2\)

As it was not investigated before, the aim of this study was to evaluate the effect of root temperature reduction using intracanal cryotherapy with negative pressure irrigation (EndoVac) on postendodontic pain after vital single-visit RCT.

It was noticed from the study results that in control and saline irrigation at room temperature groups, postendodontic pain presented with highest values after 6 hours of treatment, which started to reduce in the monitoring periods until it was almost diminished after 1 week. This could be attributed to the possible irritation of the periapical area due to endodontic treatment that caused the local inflammatory response, which leads to this postendodontic pain that diminished after recovery of the periapical area. These results were in agreement with those of Siqueira and Barnett.\(^1\)

On the contrary, and remarkably, there were no postendodontic pain values in all monitoring periods for the cold saline group. The results showed that there were a significant difference (p < 0.05) in all study periods except after 1 week between cold saline irrigation group and both saline irrigation at room temperature and control groups. This result could be explained by the fact that the cold saline application reduced the temperature of the root, as it was emphasized in the in vitro study by Vera et al.\(^2\) to unknown duration, and this root temperature reduction possibly extended to the periapical area, the action that could have a local anti-inflammatory effect by reducing edema.\(^18\) McGown showed that a 5-minute ice massage was enough to induce changes in the inflamed tissue of the quadriceps muscles.\(^24\)

Hochberg\(^25\) showed that continuous cold application resulted in a significant reduction of pain when compared with intermittent application.

The results of this study showed also a new information about the effects of clinical intracanal cryotherapy on postendodontic pain after vital single-visit RCT. There are no previous reports in the literature about cryotherapy as an irrigation protocol; clinically, this study showed that it is possible to eliminate postendodontic pain, which may be enough to initiate an anti-inflammatory effect.

The results of this study showed also that the use of negative pressure was able to reduce the pain when compared with control group after 6 hours of obturation only (p < 0.05), which represents the highest pain values, and this could be attributed to the less irritation due to more cleaning possibility.\(^26\) These results were close to the results of Gondim et al,\(^27\) Desai and Himel,\(^28\) and Mitchell and Yang.\(^29\)

CONCLUSION
Within the limitations of this study, it was concluded that:

- Postendodontic pain represented with highest values after 6 hours of treatment, and reduced to almost nil after 1 week.
- The intracanal cryotherapy eliminated postendodontic pain clinically.
- Negative pressure reduced postendodontic pain after 6 hours of treatment.

CLINICAL SIGNIFICANCE
The outcome of this study indicates that the use of intracanal cryotherapy technique with negative pressure irrigation eliminates postendodontic pain after single-visit RCTs.

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