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Evaluation of Single Visit Endodontic Treatment Outcome in Teeth with Asymptomatic Necrotic Pulp and Apical Periodontitis Using EndoVac Irrigation Device: Randomized Controlled Clinical Trial

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Evaluation of Single Visit Endodontic Treatment Outcome in Teeth with Asymptomatic Necrotic Pulp and Apical Periodontitis Using EndoVac Irrigation Device: Randomized Controlled Clinical Trial

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ABSTRACT

Purpose: This study evaluated the effectiveness of using EndoVac irrigation device on microbial reduction and postoperative pain in single rooted teeth with necrotic teeth and apical periodontitis after single visit treatment. **Subjects and Methods:** Thirty six single rooted teeth from patients of age range between 20 and 50 years old were involved in this study. According to irrigation procedures, patients were assigned randomly and equally into two groups of 18 teeth per group. Group I (conventional irrigation) and Group II (EndoVac irrigation). Irrigating solution for both groups was 2.5% sodium hypochlorite. All patients were treated in a single visit. The access cavity was prepared, and a microbiological sample (S1) was obtained. The root canal was chemomechanically prepared with ProTaper rotary instruments up to #F4. Finally, after irrigation activation, the second microbiological sample (S2) was collected. Samples were cultured on plates of nutrient agar, incubated for one day at thirty seven °C, and colony forming units (CFU) were counted and recorded. The primary outcome assessed microbial reduction in both groups. The pain was measured using a Numeric rating Scale (NRS) at 6, 12, 24, and 72 hours to determine the secondary outcome. **Results:** The mean percentage reduction in microbial count in Group II was statistically significantly higher than in Group I ($P \leq 0.05$). Conventional group (G I) showed statistically significantly higher pain scores than EndoVac group (G II) ($P \leq 0.05$). **Conclusion:** In necrotic teeth with apical periodontitis, EndoVac could be utilized as an adjunct to conventional root canal irrigation.

KEYWORDS

EndoVac,
Postoperative pain,
Necrotic pulp

- Paper extracted from Doctor thesis titled “Evaluation of Single Visit Endodontic Treatment Outcome in Teeth with Asymptomatic Necrotic Pulp Using EndoVac Irrigation Device: A Randomized Control Trial”

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INTRODUCTION

Success of root canal therapy is depend on extermination of microorganisms, which are a major cause of pulpal and periapical diseases; thus, achieving a microbial-free environment will improve the outcome ⁽¹⁾.

Traditionally, debridement of root canal is accomplished through chemomechanical preparation which can result in debris and microbes being removed from the root canal system. However, obtaining microbial free root canal is difficult because nearly half of the dentinal walls of the root canal stay unreachable after instrumentation due to the complexity of root canal system's morphology and unexpected anatomy ^(1,2).

Irrigation must therefore be capable of reaching the apical terminus and isthmus regions. Conventional manual syringe irrigation using sodium hypochlorite as irrigation solution is widely used but it has limitations. Its safety was questioned because of the positive pressure effect which can result in extrusion through the apical terminus causing severe pain, bleeding and sometimes swelling ⁽³⁾.

In comparison to traditional procedures, EndoVac is a machined-assessed apical negative pressure device that has been industrialized. It's utilized to remove debris and passively delivers irrigant solution to the apical terminus. This is due to the EndoVac's unique design, which removes the vapour lock effect and increases endodontic treatment success significantly⁽⁴⁾. EndoVac can also result in significant reduction patients' pain postoperatively and enhance anti-microbial properties of irrigating solutions ^(5,6).

In single-visit root canal therapy, the root canal is being prepared, cleansed, and obturated in one visit eliminating the need to apply anaesthetics, rubber dam, or intracanal medication in a second visit ⁽⁷⁾. Single-visit endodontic therapy is thought to have a reduced risk of root canal reinfection; because no subsequent appointments are needed and the risk of losing the temporary seal is reduced ⁽⁸⁾.

Pain that appears after the start of endodontic therapy is referred to as post-operative pain. It develops as a result of a severe inflammatory response in the periradicular tissues following mechanical, chemical, or microbial irritation. During root canal therapy, extrusion chipping of dentin fragments, bacteria, pulp tissue, and/or irrigants into the periradicular tissues may induce postoperative pain, chronic inflammation, and swelling ⁽⁹⁾. Pain is mostly a subjective and fluctuating feeling that is influenced by a variety of emotional and physical factors. The Numeric Rating Scale (NRS) is commonly used to measure the degree of pain in clinical studies; because of its reliability ⁽¹⁰⁾.

To the best of our knowledge, with the advent of various irrigation methods in the endodontic field, this study was conducted to evaluate single-visit endodontic treatment outcomes using two irrigation modalities by: First: Monitoring root canal microflora and Second: Recording post-operative pain.

The current study's null hypothesis was that there was no significant difference among the EndoVac irrigation device and conventional needle irrigation in single visit endodontic treatment regarding to microbial reduction and postoperative pain.

Clinical question was addressed in terms of PICO question which involves 4 elements: {problem (P), intervention (I), comparison (C) and outcome (O)} as following:

- P. (problem): fully formed permanent teeth with necrotic pulp and apical periodontitis.
- I. (intervention): root canal treatment in a single visit using EndoVac irrigation system.
- C. (comparison): root canal treatment in a single visit using conventional irrigation.
- O. (outcome): microbiological assessment (primary outcome) and post-operative pain (secondary outcome).

SUBJECTS AND METHODS

Study design:

The current investigation was conducted in the clinic of the Endodontic Department, Faculty of Dental Medicine for Girls, Al-Azhar University, as a randomized controlled clinical trial with a 1:1 allocation ratio. The Consolidated Standards of Reporting Trials (CONSORT 2010) checklist of information was used to design, analyze, and evaluate the trial ⁽¹¹⁾. The institute’s Research Ethics Committee (REC) with the code number: (REC-EN-22-02) gained ethical approval for the human research in compliance with rules. All patients were given an informed consent form, which included information on the trial as well as the therapy’s advantages and dangers. Patients were asked to read it carefully and sign it.

Sample size calculation:

Sample size estimation was detected by data from previous study (Ramamoorthi et al 2015) ⁽¹²⁾ showed a difference between the 2-tested group to be 1.7 (corresponding to means of 5.4 versus 3.7)

and the common within-group standard deviation is 1.3 used to estimate the total sample size of 28(14 for each group) were sufficient to have a power of 90% to yield a statistical significant, and a significance level of 5%. The Sample size was increased by 25% to deal with dropout out so the total sample size was 36 patients (18 was allocated to each group).

Patients’ selection, randomization and blinding: (Figure 1)

After clinical and radiographic examination, overall 36 patients in this trail were chosen from cases referred to the Endodontic clinic. Patients satisfied the inclusion criteria being between the ages of 20 and 50, had no contributing medical conditions, and had asymptomatic single-rooted, single canal, lower second premolar, with necrotic pulp and apical periodontitis.

Patients who reported using antibiotics or anti-inflammatory analgesics in the previous month or within few days, pregnant women, and teeth showing root resorption, blocked canals, sinus tract, periodontal problem, or drastic crown destruction were all excluded.

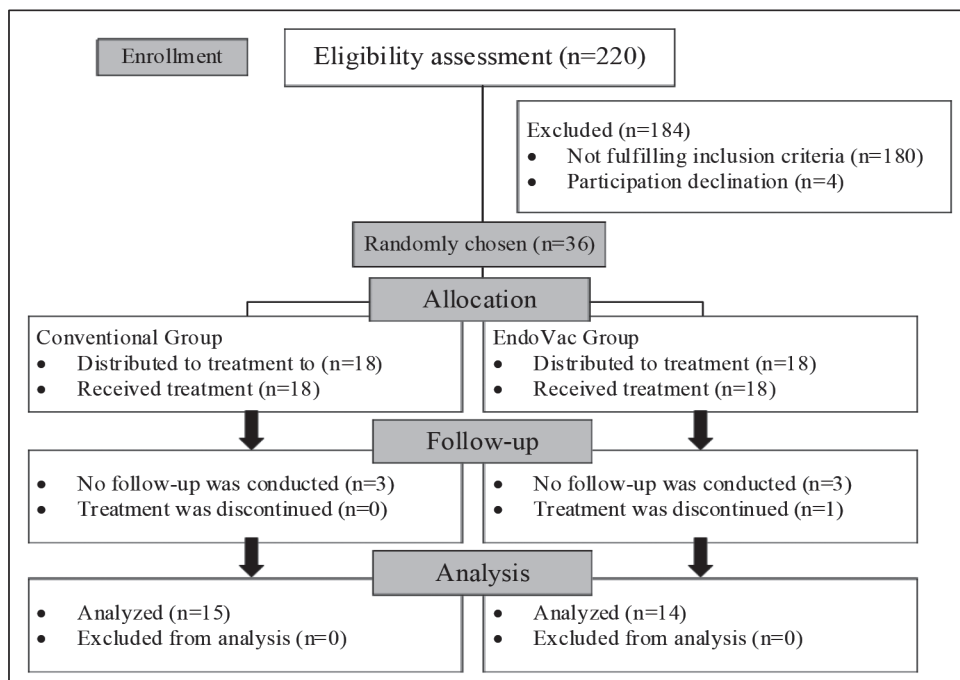


Figure (1): Enrollment and randomization of patients

The thirty-six patients were arbitrarily allocated into two groups (18 cases each) according to the irrigation technique used: Group I (conventional irrigation) and Group II (EndoVac irrigation). Patients chose sealed opaque envelopes holding printed pieces of paper with numbers to confirm randomization, and the patient was assigned to conventional irrigation group or EndoVac group depending on the number written in the paper inside the envelope. Over the course of the trial, only one endodontic operator performed the treatment operations.

Treatment protocol:

Group I (Conventional group):

Throughout the root canal treatment and sample collection, strict aseptic approach was employed. The operative field was disinfected with 30 percent H₂O₂ for 30 seconds, followed by 5.25 percent NaOCl for another 30 seconds. Following to local anaesthetic administration (4 percent articaine with 1:100,000 epinephrine) and isolation by rubber-dam; removal of previous coronal restoration and caries was performed using sterile round and tapered high speed diamond burs and the proper access cavity was produced (Dentsply, Maillfer, Switzerland).

Initial Microbiological Sample (SI):

After confirming canal patency with a sterile #15K file (Kerr UK, Peterborough, UK) and irrigation with 1 ml saline. The first sample (SI1) was taken with two sterile paper points and a # 15 K file that were held in the root canal for 1 minute, then transferred through a sterilized test tube containing the transport media (brain heart infusion broth).

An electronic apex locator (DentaPort ZX: Morita Co., Tokyo, Japan) was used to establish the working length, which was then validated using a periapical radiograph. ProTaper Universal rotary files (Dentsply, Maillfer, Switzerland) were used to prepare the root canals up to #F4 in crown-down

technique, with speed and torque adjusted according to the manufacturer's instructions.

All groups' biomechanical preparation was achieved using 2.5% NaOCl as a root canal irrigating solution. Throughout preparation of access cavity and initiation of coronal instrumentation, ten mL were used. After that, 5 mL were used after each rotary instrument use⁽¹³⁾. Irrigation was performed throughout instrumentation in the conventional group using a 27-gauge side-vented needle (Ultra-dent, South Jordan, UT) placed into canal in order to be far away from the apex by 2 mm and with upward and downward motion to increase irrigant flow rate^(13,14). The irrigation was completed with 5 ml 17% EDTA followed by saline solution (5 ml)⁽¹⁵⁾. After instrumentation and irrigation, a second microbiological sample (SI2) was taken using three sterile paper point size 40 which were taken, stored, and transferred in the same way as the first (SI1). Finally, the root canal system was obturated with a # F4 gutta-percha cone (Dentsply-Maillefer, Ballaigues, Switzerland) and ADSEAL resin-based sealer (Meta Biomed Co, Cheongju, Korea) using the cold lateral compaction method, and the final coronal restoration direct composite filling (Filtek Bulk Fill, 3M ESPE, USA) was performed in the same visit.

Group II (EndoVac group):

The same technique and instruments were used to take the first microbiological sample (SI1) and biomechanical preparation as in group I. The EndoVac system (Komet; Brasseler, Lemgo, Germany) was used as directed by the manufacturer. During mechanical preparation, the EndoVac master delivery tip (MDT) was being placed above the opening of the access to continuously deliver and evacuate 2.5 percent NaOCl solution⁽¹⁶⁾.

Once the master apical file had reached the working length, the canal had been macroirrigated for 30 seconds with a 2.5 percent NaOCl solution. This was accomplished by delivering the irrigant

with the EndoVac MDT while moving the macrocannula linked to the handpiece upward and downward in the root canal from a position in which it began to bind to a level just below the orifice sucking the irrigant⁽¹⁵⁾.

Three microirrigation cycles were performed using a microcannula that was positioned at the entire WL for six seconds and then moved 2mm away from of the WL. This procedure was repeated five times in 30 seconds⁽¹⁵⁾. The first and third cycle were done using 2.5 mL of 2.5% NaOCL. The second cycle was done for 1 min using 5mL of 17% EDTA.

After instrumentation and irrigation, a second microbiological sample (SII2) was taken using three sterile paper point size 40, which was taken, maintained, and transferred in the same way as SI2. The root canal obturation and coronal restoration were done as in group I.

All samples were transferred to the microbiological laboratory at the Regional Center for Mycology and Biotechnology (RCMB), Al Azhar University for microbiological analysis.

Methods of evaluation:

1. Microbiological count: A microbiological count of samples was performed by determining the colony forming units (CFU) number per milliliter of the culture plate in order to assess the reduction in the number of CFU. For microbial culture, nutrient agar was chosen. The plates of agar were incubated for one day at 37°C. The colony forming units per milliliter (CFU/ml) of microbes were calculated and reported.
2. The Numeric Rating Scale (NRS) was used to evaluate postoperative pain. Using an 11-point NRS. Patients were asked to mark on the number that represented their level of pain. Pain intensities were assigned into 4 categorical scores: none (0); mild (1–3); moderate (4–6); and severe (7–10)⁽¹⁰⁾. The patients were given

a NRS home questionnaire form to rate the level of discomfort at 6, 12, one day and 72 hours following the treatment. After finishing the treatment, no medication was provided. All patients were told not to take any medication until they spoke with a doctor first.

Statistical Analysis:

The qualitative findings were presented in the form of percentages and frequencies. All data display normal (parametric) pattern, on the other hand pain (NRS) score, the data relating were non-normal (non-parametric) pattern. Data clarified that 95% Confidence Interval for the mean difference (95% CI), median and range values. Paired T test was used to examine between Log10 CFU of microbial counts in both groups. The Student's t-test was performed to examine the mean percentage reduction in microbial counts in both groups for parametric data. The Mann-Whitney U test was performed to compare the both groups with non-parametric data. $P \leq 0.05$ was used as the significant level. IBM SPSS Statistics was used to conduct the statistical analysis for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS

1. Primary outcome: microbiological assessment

Comparison between the groups:

Before irrigation, there was no statistical significance different in the mean Log10 CFU/ml of total microbial counts in both groups (P -value = 0.275). After irrigation, Conventional group (group I) had a statistically significantly higher mean Log10 CFU/ml of total microbial counts than EndoVac group (group II) (P -value <0.001). (Table 1)

The percentage of microbial reduction in EndoVac group was 99.99% which was statistically significantly higher than Conventional group (97.8%) $p = 0.009$. (Table 2)

Table (1) Descriptive data finding and results of Paired T test for comparing Log10 CFU/ml of total microbial counts in both groups

Time	Group I Conventional (n = 18)		Group II EndoVac (n = 18)		95% CI for the difference	P-value
	Mean Log10	SD	Mean Log10	SD		
Before irrigation	6.85	1.36	6.35	1.41	-0.44 , 1.44	0.275
After irrigation	4.66	1.13	2	0.69	1.94 , 3.38	<0.001*

*: Significant at $P \leq 0.05$

Table (2) Descriptive statistics and results of Student's t-test for comparison between percentage reduction in total microbial counts (%) in the two groups

Conventional (n = 18)		EndoVac (n = 18)		95% CI for the difference	P-value	Effect size (d)
Mean %	SD	Mean %	SD			
97.8	3.36	99.99	0.01	-3.8 , -0.59	0.009*	0.924

*: Significant at $P \leq 0.05$

2. Secondary outcome: Pain assessment

Comparison between the groups: (Table 3) (Figure 2)

After six, 12, 24 as well as 72 hours, Conventional group had statistical significance elevated median pain scores than EndoVac group (P-value = 0.025, Effect size = 0.723), (P-value = 0.021, Effect size = 0.749), (P-value = 0.026, Effect size = 0.686) and (P-value = 0.041, Effect size = 0.535), respectively.

Table (3) Descriptive data finding and results of Mann-Whitney U test for comparing pain (NRS) scores in both groups:

Time	Conventional (n=18) Median (Range)	EndoVac (n=18) Median (Range)	P-value	Effect size (d)
6 hours	4 (1-10)	0 (0-9)	0.025*	0.723
12 hours	2.5 (0-9)	0 (0-7)	0.021*	0.749
24 hours	1.5 (0-9)	0 (0-6)	0.026*	0.686
72 hours	0 (0-8)	0 (0-4)	0.041*	0.535

*: Significant at $P \leq 0.05$

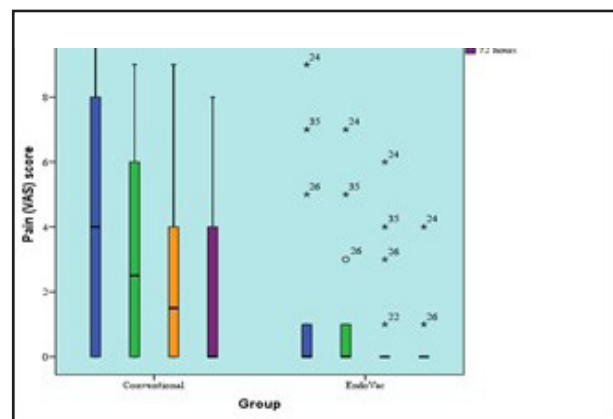


Figure (2): Box plot representing median and range values for pain scores in the two groups (Conventional and EndoVac). (Stars and circle represent outliers)

DISCUSSION

Root canal preparation is considered a significant aspect of endodontic treatment in terms of microbial eradication (17). In clinical investigations, rotary systems which consist of a series of nickel titanium (NiTi) instruments rotated continuously,

exhibited significant microbial reduction. Accordingly, the ProTaper universal rotary NiTi system was employed to prepare root canals in this investigation⁽¹⁸⁾.

In the field of endodontics, the EndoVac system is a revolutionary irrigation approach⁽¹⁹⁾. It is an apical negative pressure approach that allows for the evacuation of apical debris while also being safe because the irrigation solution is delivered passively, resulting in an improvement in effectiveness and success rate⁽⁴⁾. The current study was considered as a randomized clinical trial in which patients were randomly assigned to two groups based on irrigation methods to minimize bias, and all participants received treatment in one visit by a single endodontist to avoid endodontist variation, which could impair the results' dependability⁽²⁰⁾. Because of its broad antimicrobial activity and high dissolving capability, NaOCl was used as an irrigant solution throughout mechanical instrumentation in this work⁽²¹⁾. Since lower concentrations have a lesser dissolving capability and antibiofilm impact, while higher concentrations have a higher toxicity and detrimental effect on dentin structure, a medium concentration (2.5 percent) was employed. The inorganic part of the smear layer had been removed using EDTA, revealing the dentinal tubule apertures for the next irrigant or sealer⁽³⁾.

The culture technique was used primarily to assess changes in total microbial count. Although this technique has low sensitivity and specificity when compared to molecular techniques, it is recognized as a valuable primary method of research for rapidly quantifying cultivable microorganisms in samples, whereas other molecular techniques can detect uncultivable or difficult-to-grow microbes or investigate more specific effects⁽²²⁾.

Because microorganisms play a significant role in causing postoperative pain and negatively affecting endodontic treatment outcomes, the goal of the current study was to assess the effect of EndoVac on microbial reduction and postoperative pain.

The study's microbiological findings revealed a statistically significant higher percentage of reduction in microbial counts in EndoVac group compared to conventional group. The current study's findings agreed with previous study which reported that irrigation delivery using EndoVac revealed improved antimicrobial effectiveness with increased irrigation time ($p \leq 0.05$)⁽²³⁾. Another study also reported that EndoVac was found to be more efficacious than conventional needle irrigation in terms of microbial reduction⁽¹⁸⁾. These results highlighted the fact that (EndoVac) was able to achieve reaching full working length, which might be due to the special design of the micro-cannula, which performed unique strategy in elimination the apical vapor lock. As a result, the system was capable of performing apical irrigant exchange, which improved antimicrobial efficiency⁽¹⁹⁾.

Previous studies reported that⁽²⁴⁾ using EndoVac instead of conventional irrigation produced significantly better outcomes in cleaning the utmost apical part of the root canal, which support the present findings.

Postoperative pain evaluation is a difficult mission because pain is variable and influenced by many factors that are still unknown due to limitations in pain research⁽¹³⁾. In this study, postoperative pain was chosen as an outcome and measured using the Numeric Rating Scale (NRS), which uses a scale from 0-10 to record postoperative pain⁽²⁵⁾. Although there are various pain scales used to measure pain; NRS is considered simple, reliable, appropriate use and easily understood by patients⁽¹⁰⁾. As preoperative pain has such a strong influence on the occurrence of postoperative pain, asymptomatic teeth were chosen for this study⁽⁸⁾.

In the present study, EndoVac group had lower pain scores than conventional group with statistical significance different between both groups at all time periods. This literature discussed the mechanism by which EndoVac reduces postoperative pain and attributed it to its unique design, which allows the

irrigant solution to reach the whole working length of the root canal passively without producing any pressure along the root canal system ⁽²⁶⁾. This finding of the current study also agreed with another study which stated that pain experience in EndoVac group was significant lower than in the conventional needle group after 6 hours and 24 hours ⁽²⁷⁾.

Another study ⁽²⁸⁾ had a significant difference in pain between EndoVac and conventional groups after 6 hours. However, these findings are consistent with the finding of previously mentioned study ⁽¹⁵⁾ which found that apical positive pressure irrigation caused more pain at six hours, one day and two days postoperatively than apical negative pressure irrigation methods. Increased pain levels with traditional needle irrigation can be explained by increased debris extrusion apically, which causes positive pressure to build up in the root canal system ⁽¹⁵⁾. In addition, the inability to reach the entire working length of the canal and remove remnants of necrotic pulp and microorganisms could shed light on the cause of postoperative pain ⁽²⁹⁾. Furthermore, it was reported that EndoVac reduced post-operative pain than needle irrigation after single visit root canal treatment ⁽⁸⁾. Null hypotheses of the current study was rejected as there was a statistically significant difference between EndoVac and the needle irrigation regarding microbial reduction and post-operative pain.

CONCLUSION

As a result of this study, it was concluded that using EndoVac system (negative pressure irrigation) reduces microbial count and occurrence of post-operative pain compared to using a conventional needle irrigation.

RECOMMENDATION

In-vivo studies are needed to establish the outcomes in retreatment cases after using EndoVac irrigating device.

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