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Research Article

Effect of Diode Laser Activated Irrigation on Post-Operative Pain in Single Visit Endodontic Treatment : A Randomized Controlled Trial

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Abstract

Objective: Study via randomized controlled trial design, the effect of irrigation activation via either diode laser or ultrasonic on the post-operative pain, in single visit endodontic treatment of necrotic single canal teeth.

Materials and Methods: Forty four single canal anterior and premolar teeth with necrotic pulps were equally and randomly allocated to two different final NaOCl irrigation activation protocols. The patients were randomly allocated to either diode laser activated irrigation (Group A) or ultrasonic activated irrigation (Group B). Group A used the 320 nm flexible plain endodontic fibre of 970nm diode laser device. Group B used ultrasonic file (U-file) #15 in ultrasonic device for activation. Single visit endodontic treatment was done and post-operative pain was recorded after 24, 48, 72 hr and 1 week using a numerical rating scale (NRS). Data were analyzed using Chi–Square, Mann–Whitney and Friedman tests. A p-value ≤ 0.05 was considered statistically significant.

Results: Comparing the two groups; After 24, 48 and 72 hours pain score range was 0-2 with no statistically significant difference. Over the tested time intervals; in Group A: laser; there was no statistically significant difference in median NRS score (p=0.065). While in Group B: ultrasonic; there was statistically significant increase in median NRS scores comparing preoperative with 24 hr. (p=0.001).

Conclusion: The 970nm diode laser and ultrasonic activated irrigation proved to be equally effective in achieving low incidence and intensity of post-operative pain after single visit endodontic treatment of necrotic single canal teeth.

Keywords: Effect of Diode Laser; Activated Irrigation; Controlled Trial

Introduction

Post-operative pain is considered a common unwanted sensation following root canal treatment. Reports on the post obturation pain following either single or multiple visit endodontic treatment is controversial [1]. Since research supported single visit protocol [2]. Thus emphasis is set more on the disinfection phase during irrigation.

Using conventional syringe irrigation during the process of irrigation; two important factors are of concern; whether the irrigation device could deliver the irrigant to the whole length of root canal, and whether it is capable of debriding areas that cannot be reached with mechanical instrumentation, such as lateral canals and isthmi [3,4]. Root canal irrigation activation is important to overcome the limitation of the conventional manual technique.

In ultrasonic activated irrigation the irrigant is delivered to the root canal by a syringe needle. This is followed by irrigant activation with the use of an ultrasonically oscillating instrument. *Invitro* studies proved its efficiency in debridement and cleanliness of canal walls [5,6]. Moreover, when evaluated In vivo decrease in post-operative pain occurred [7]. Also, a randomized controlled trial on the effect endodontic treatments with and without ultrasonic activation on periapical healing concluded that the percentage of absence and reduction of the radiolucency was high; 95.1% for ultrasonic group [8].

The use of laser in activation could be done intra chamber via PIPS which operates by transferring the energy of Erbium: YAG laser applied in chamber to the irrigation molecules, resulting in rapid and powerful shock waves, forcing the irrigant throughout the entire root canal system. Despite efficiency of PIPS in removal of apically placed dentinal debris [9], it couldn't effectively remove the smear layer in the apical third of the root canal [10]. Moreover, pulsed Er:YAG showed considerable apical extrusion and caution should be taken when using it in combination with NaOCl [11].

Intracanal laser-activated irrigation (LAI) refers to using fiber delivery system with small diameter, which can be inserted inside the root canal and activation occurs via diode or Nd:YAG laser. The effectiveness of the use of intracanal diode laser activated irrigation in canal disinfection was proved *in vitro* [12].

Thus this randomized controlled study was formulated to achieve evidence based decision on the clinical effect of intracanal diode laser final irrigant activation on a patient relevant outcome; the incidence of post-operative pain. The null hypothesis was that there is no difference between ultrasonic and diode laser activated irrigation on postoperative pain in single visit treatment of single canal with necrotic pulp.

Materials and Methods

The study protocol was approved by scientific committee of endodontic department, evidence based committee and ethics committee of the faculty of dentistry. The protocol was registered on ClinicalTrials.gov. Study subjects were recruited from the university clinic of endodontics. Treatment was done in national research center clinic due to availability of the laser device and single compartment safety. Participants were male or female patients with age range 20 - 45y. Asymptomatic necrotic single rooted single canal mature permanent teeth with or without chronic periradicular lesion were selected. The following were excluded from the study; pregnant females, medically compromised patients, teeth with vital pulp, patients with facial swelling or acute infection, non-restorable teeth, previously endodontically treated teeth, periodontally affected teeth and in presence of anatomic or pathologic abnormalities.

The treatment protocol and its associated risks and benefits were explained to the eligible patients. After obtaining written informed consent, the patients were randomly assigned to one of the two groups based on the final irrigation protocol: diode laser activated irrigation (Group A) and ultrasonic activated irrigation (Group B). For sample size calculation; prior data indicated that the probability of pain among controls is 41% [7]. Twenty patients are needed in each group to be able to reject the null hypothesis that the exposure rates for case and controls are equal with probability (power) 0.8. The Type I error probability is 0.05. This number was increased 22 in each group to compensate for losses during follow up. Participants were randomly allocated into two groups according to sequence generation via random.org done by principle supervisor. An equal proportion allocation ratio was followed and envelopes containing concealed assignment codes to the sequentially eligible patients. It was ensured that both the patient and the operator were unaware of the treatment protocol assigned until completion of chemo-mechanical preparation.

Endodontic procedure for all patients was performed by a single operator (Z.M.). Primarily if caries was present, it was removed by round bur size 2 (Dia–bur, Mani, Japan). An access cavity was performed using round bur and endo-z bur (Endo-Z bur, Mani, Japan). The tooth was properly isolated with rubber dam. Paper point size #45 (PP, META BIOMED CO, Korea) was used for initial absorption of gross content of necrotic debris of the canal. Pulp chamber was irrigated with 2ml NaOCl 2.5%. Flaring of the coronal 1/3 of the canal was done using Gates Glidden drills #2, #3 (G G, Mani, Japan). Initial canal negotiation and glide path were done by K-file #15and #20 (K-file, Mani, Japan). Working length was determined using an electronic apex locator (iPex II, NSK, Japan) and confirmed radiographically. Mechanical preparation of root-canals was done by crown-down technique using rotary NiTi I-RACE (Race, FKG, Switzerland) instruments. Standard file size sequence was done for all cases using 4% taper of sizes 25, 30, 35, 40 using an endodontic motor (Endo mate, NSK, Japan) with adjusted torque and speed according to the manufacturer's instructions (450 rpm and 1.4 Ncm). During instrumentation; the canals were thoroughly irrigated using 2ml of NaOCl 2.5% at a rate of 0.1ml /3 sec between every subsequent instrument using 30 gauge side-vented needle (ENDO-TOP, PPH KERKAMED, Poland) reaching to maximum of 1 mm short of working length. Master cone (G.P, META BIOMED CO, Korea.) was selected corresponding to MAF# and its length was confirmed radiographically (Kodak Dental film, Carestream, USA).

Prior to final irrigation activation; three plastic syringes were coded into no.1, 2, 3 for EDTA, saline and NaOCl solutions, respectively. Syringe no.1 was loaded with 2ml 17% EDTA (EDTA, PREVEST, Poland), syringe no.2 was loaded with saline, and syringe no.3 was loaded with 2ml 2.5% NaOCl. All syringes were attached to side-vented needle gauge #30. All irrigants were delivered at rate 3 sec/0.1ml up to 1mm short of the working length. Thus final irrigation sequence included EDTA irrigation for 1min using syringe no.1 followed by washing out with 1ml saline syringe no.2. Then a final 2.5%NaOCl using syringe no.3 and its activation in 3 sets of 20 sec each as follows:

In group A (diode laser activated irrigation)

A device that delivers 970 nm Diode laser was used (Siro Laser Advance class lllb, Sirona, Germany). It was set in pulsed mode at 2W. A 320 nm flexible plain endodontic fiber delivered the diode laser intracanal. The fiber was inserted parallel to root canal wall 1mm shorter than working length and withdrawn in a helicoid movement coronal-apical for 20 sec. Safety was assured by wearing protective eye glasses by both clinician and patient before the diode laser application.

In group B (ultrasonic activated irrigation)

The ultrasonic activation was performed with an ultrasonic device (Ultrasonic, Woodpecker, China) at setting endo mode (E mode). Ultrasonic file (U-file) #15 (U-file, Mani, Japan) was used

after fitting it to an adaptor module to be inserted in the ultrasonic device. Before activation the U-file was inserted 1mm short of working length and checked to be loose in the canal to avoid damping effect of canal walls.

In both groups, the process of 2.5% NaOCl irrigation activation was done for 20 sec and repeated for 3 times. The total time of activation process of final irrigation with NaOCl was 60 sec. Following irrigation activation, the root canal was dried and obturated by lateral compaction technique using resin sealer (ADSEAL, META Biomed CO., Korea.). After obturation, a cotton pellet was placed in the access cavity followed by temporary restoration (Temp., META Biomed CO, Korea.) and post-operative radiograph was taken.

Evaluation of pain

Each participant was given a chart containing five copies of Numerical pain Rating Scale NRS to record the pain level preoperatively and post operatively at four time intervals 24, 48, 72 hrs and one week. NRS is a 11 point scale start by 0 ending by 10 anchored by two extremes "No pain"=0 and "worst pain"=10. The pain dairy was explained to the patient. After one week each participant delivered the scale and was referred to restorative department for final restoration. For qualitative analysis of pain intensity; pain scores were converted to categories as follows: score 0= no pain, scores 1 - 3 =mild pain, scores 4-6= moderate pain and scores 7-10= severe pain.

Statistical analysis

Kolmogorov-Smirnov and Shapiro-Wilk tests were used for exploring normality. Comparisons between the 2 groups with respect to normally distributed numeric variables were done using the t-test. None normally distributed numeric variables were compared by Mann-Whitney test. Comparisons over time regarding numeric variables were done by Friedman test and pairwise difference were detected by the Wilcoxon signed rank test. For categorical variables differences were analyzed with chi square test and Fisher's exact test when appropriate. All p-values are two-sided. P-values ≤0.05 were considered significant.

Results

Out of 44 patients; three patients were lost in follow up due to loss of contact. Thus forty one patients (12 males and 29 females) who consented to participate in the study returned their NRS forms. Twenty patients (6 males and 14 females) in the laser group (Group A) and 21 patients (6 males and 15 females) in the ultrasonic group (Group B) (Figure1).

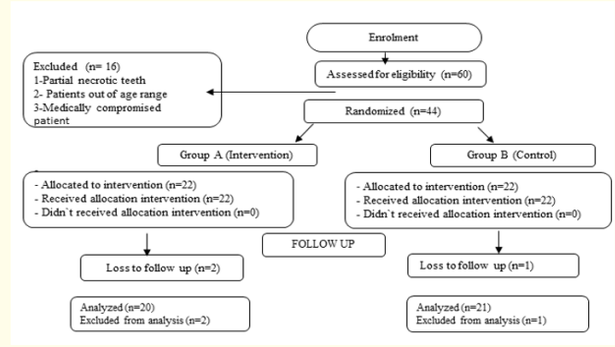

Figure 1: CONSORT flow diagram of the study.

The mean age of patients in the laser group was 36.4±7.2 years while it was 31.8±8.6 years in the ultrasonic group. There were no significant differences regarding the patients' age (P = 0.070) and gender (P = 0.920) between the two tested groups.

Pain incidence and intensity

The null hypothesis was accepted; there was no significant difference between ultrasonic and diode laser activated irrigation on postoperative pain incidence and intensity in single visit treatment of single canal with necrotic pulp. Overall pain scores ranged between 0 and 2 in both group. Regarding comparison of median NRS scores between the tested groups at each time interval, results showed that: preoperatively and after one week all patients recorded score 0. After 24, 48 and 72 hours the median score range was 0-2 with no statistically significant difference between groups as follows; (p = 0.416), (p = 0.506) and (p = 0.329) respectively (Figure 2).

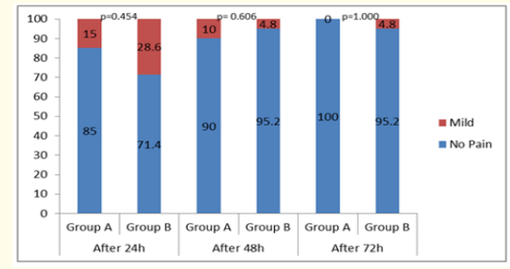

Figure 2: Bar chart representing pain% of each pain category (intensity) in the two tested groups (Group A: laser; Group B: ultrasonic) at each of 24 hr, 48hr, and 72hr.

Comparison of median NRS score within each group over the tested time intervals revealed that in Group A: laser; there was no statistically significant difference in median NRS score over the tested time intervals (P = 0.065), while in Group B: ultrasonic;

there was statistically significant increase in median NRS scores comparing preoperative with 24 hrs (p = 0.001). Moreover, statistical analysis of incidence of different pain categories (intensities) showed that there was no statistically significant difference comparing two tested groups (Figure 2).

Discussion

Irrigant activation procedure in necrotic teeth increased the belief towards better disinfection. This is of particular importance in necrotic cases with single visit protocol; hoping to improve their long term prognosis [13].

The present study evaluated the effect of LAI using diode laser in the activation of NaOCl irrigation. The activation process induces cavitation in aqueous fluids which enhances the removal of debris and smear layer in the root canal [14]. Efficient smear layer and debris removal in oval canals was reported by using 980nm diode activation of both NaOCl and EDTA [15]. Also, previous study showed that using of 810 nm diode laser in activation of 15% EDTA effectively removed the smear layer [16].

To assure the thermal safety of diode activated irrigation, the fibre was moved along the canal and replenishment of irrigation was used between laser exposures [17,15]. The Diode laser was used in suitable power setting of 2 W to allow controllable temperature rise [18]. Also, It was used at a pulsed mode similar to previous study [19].

In the current study ultrasonic was used as a standard procedure for activation due to its reported effectiveness in cleanliness [20, 21]. It could reduce the bacterial counts and decrease the incidence of positive cultures after chemo mechanical preparation of oval shaped root canals [22]. Also, efficient removal of debris from simulated canal irregularities, the apical third and artificially placed dentin debris plugs could be achieved [23-25]. Moreover, it was reported to decrease post-operative pain [7].

Based on the in-vitro effectiveness on debris removal, smear layer and disinfection achieved by diode laser in activation of irrigation and absence of studies necessary to prove its clinical efficiency, the current study was designed to compare the post-operative pain after irrigant activation either by ultrasonic or laser during single visit treatment of necrotic teeth. The study was parallel design, randomized clinical trial. The patients were randomly allocated and similarly distributed among the two groups. Patients' age range was 20 to 45 years; allowing for more standardization of results when relatively narrow age range. Both males and females were included, to allow more general inference of study results. There was no statistically significant difference between both groups regarding these criteria, to ensure their null effect as a confounding factor.

In the current study single canal teeth were chosen because disinfection of oval canal remained an important issue [22]. Single visit endodontic treatment was chosen for many advantages as shorter chair side time, convenience for both patient and dentist, reduction of the inter appointment infection and reducing costs. Two systematic reviews concluded that the prevalence of post-obturation pain was significantly lower in single-visit approach than multiple visits [1,2].

NaOCl was used as a chief irrigant during instrumentation and for final activation; due to its potent antimicrobial effect against most of resistant bacteria on direct contact. It also effectively dissolves pulpal remnants, collagen, and the main organic components of dentin [26]. It was used at concentration of 2.5% as similar to other studies [23,18]. Activation of NaOCl was reported to aid in reaching inaccessible areas, [27-29]. Activation in the present study was done in cycles done for 20 sec repeated 3 times allowing more replenishment of irrigant [23,25,30]. The use of side vented needle 1 mm shorter than working length allowed the irrigant to reach the apex of root canal with limited apical extrusion.

The final irrigation sequence involved 2ml 17% EDTA as previously established [7,31]. It could remove the inorganic part of smear layer. Complete removal of smear layer was ensured by irrigation with both EDTA and NaOCl [26]. One ml of saline flushing solution was used in between NaOCl and EDTA application; to avoid the direct consecutive usage of EDTA and NaOCl which could result in the loss of NaOCl activity [26].

NRS was used in recording pain due to its applicability for assessment of pain intensity in most settings. It has good sensitivity for general purposes and for patients who seek a sensitive pain-rating scale [32]. The time intervals chosen were 24, 48, 72 hr and one week; as post-operative pain was usually expected within the first two days and may last to one week after endodontic treatment [33].

Results of the current study showed both low incidence and low intensity of postoperative pain in both group. Though non statistically significant; the higher incidence of no pain category which occurred after 24 hr. was more often in laser activation 85.0% versus ultrasonic activation 71.4%. Interestingly, in both groups there was absence of pain intensity beyond score 2 which is described as mild pain quality. Due to novelty of the present study regarding randomized controlled trial assessing the use of diode laser in activation of irrigation; few published articles were available for comparison.

The present study result of the ultrasonic activation group showed a percentage of no pain of 71.4% comparable to that reported by Middha., *et al*. 2017. This latter randomized clinical trial

showed that using continuous ultrasonic irrigation in mandibular molars with non-vital resulted in 68.6% absence of postoperative pain compared to 48.6% in the syringe irrigation (Middha., *et al.* 2017). Their higher pain incidence with syringe irrigation was attributed to apical irrigant extrusion. In the present study special precautions were taken to guard against apical extrusion of irritants including primary suction of any canal exudates by paper point, crown down sequence of preparation, using side vented needle in delivery of irrigant and constant slow rate of delivery of irrigant.

Comparison of pain over time revealed that most pain occurred in the first 24 hr. and it was of mild quality. In ultrasonic activation though there was statistically significant increase in median NRS scores comparing preoperative with 24 hr; however, the six patients who had pain were only score 1. This mild pain could be attributed to factors other than directly related to the endodontic treatment as occurring by injury of gingiva during application of rubber dam clamp.

Absence of flare ups in all cases of the current study is a point which cannot be neglected. It confirmed the evidence-based conclusion of the recommendation of the possibility of single visit endodontic treatment of asymptomatic necrotic single canal teeth based on the use of NaOCl final activation by either Diode laser or Ultrasonic according to the standards set in the present study. Worthy to note that the current treatment protocol was successful in all necrotic cases even those with periapical lesions. Thus it is recommended that further cohort studies would be designed to study the healing effect on cases with or without periapical lesions, using the successful protocol of LAI used in the present study.

Conclusion

The 970nm diode laser activated irrigation and ultrasonic activated irrigation proved to be equally be effective in incidence and intensity of post-operative pain after single visit endodontic treatment of necrotic single canal teeth.

Conflicts of Interest

"No potential conflict of interest relevant to this article was reported".

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