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Original Article

Dentistry Section

Incidence of Postoperative Pain after Single Visit and Two Visit Root Canal Therapy: A Randomized Controlled Trial

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ABSTRACT

Introduction: Root Canal Treatment (RCT) has become a mainstream procedure in dentistry. A successful RCT is presented by absence of clinical signs and symptoms in teeth without any radiographic evidence of periodontal involvement. Completing this procedure in one visit or multiple visits has long been a topic of discussion.

Aim: To evaluate the incidence of postoperative pain after root canal therapy performed in single visit and two visits.

Material and Methods: An unblinded/ open label randomized controlled trial was carried out in the endodontic department of the Dental Institute, where 78 patients were recruited from the regular pool of patients. A total of 66 maxillary central incisors requiring root canal therapy fulfilled the inclusion and exclusion criteria. Using simple randomization by biased coin randomization method, the selected patients were assigned into two groups: group A (n=33) and group B (n=33). Single visit root canal treatment was performed for group A and two visit root canal treatment for group B. Independent sample t-test was used for statistical analysis.

Results: Thirty three patients were allotted to group A where endodontic treatment was completed in single visit while 33 patients were allotted to group B where endodontic treatment was completed in two visits. One patient dropped-out from Group A. Hence in Group A, 32 patients were analysed while in Group B, 33 patients were analysed. After 6 hours, 12 hours and 24 hours of obturation, pain was significantly higher in Group B as compared to Group A. However, there was no significant difference in the pain experienced by the patients 48 hours after treatment in both the groups.

Conclusion: Incidence of pain after endodontic treatment being performed in one-visit or two-visits is not significantly different.

Keywords: Calcium hydroxide, Multiple-visits, Root canal treatment, Visual analog scale

INTRODUCTION

The goal of root canal therapy is thorough disinfection and obturation of the root canal system in all its dimensions [1,2]. Root canal treatment can be done using two approaches; first, completing the treatment in multiple-visits where residual bacteria are eliminated or prevented from repopulating the root canal system by introducing an intracanal medicament during the root canal treatment, and second, removing the remaining bacteria by entombing them in a complete three-dimensional obturation, completing the treatment in one visit [3].

Dentists are often reluctant to abandon predictable treatment procedures like multiple visit endodontic treatment for the fear that relatively newer modality such as single visit endodontic treatment may not result in the same outcome or rate of success they have come to expect [4]. The resistance to the acceptance of single visit treatment procedure could be attributed further to controversies such as postoperative pain, flare-ups, rate of successful healing and patient acceptance [5].

Until the 1970's, opinions opting single visit against multiple visit procedures were based on few clinical observations and inadequate scientific studies [6]. In more recent years, studies were attempted to answer the major concerns about postoperative pain, flare- ups and success rate. Even after many studies comparing incidence of postoperative pain and flare-ups between single and multiple visit procedures, till date, the evidence for recommending either one or multiple visit root canal therapy is not consistent.

The most common and reliable method for evaluating the outcome of treatments is randomized controlled clinical trial (Elwood 1998), because of minimum confounders and maximum control over the trial environment [7].

Hence this randomized controlled trial was done to re-establish a consensus concerning the relationship between the postoperative pain and the number of treatment appointments using crown down technique with rotary NiTi (Nickel Titanium) instruments.

MATERIALS AND METHODS

It was a single-center, open-label, parallel, randomized controlled clinical trial. Approval for this clinical trial was obtained from institutional ethical committee on human research of K.L.E. University, India.

Sample size determination

Taking level of significance at 5% and power of the test as 80% we get $Z\alpha = 1.96$ and $Z\beta = 0.84$. From the previous articles [8] sample size was determind.

$$\text{Using the formula } n = \frac{(Z_\alpha + Z_\beta)^2 \, 2s^2}{(\overline{X}_1 - \overline{X}_2)^2}$$

From the article [8] $X_1 = 37.36$; $X_2 = 63.28$, $s_1 = 32.61$, $s_2 = 37.78$

We get the minimum sample size as 29. To compensate for the study subject's dropouts during follow-up, sample size was set at 33 per group.

Patient selection

Sixty six patients with maxillary central incisors seeking root canal therapy in accordance with inclusion and exclusion criteria described later were included in the study. These patients were recruited from the regular pool of patients in the Department of Conservative Dentistry and Endodontics, K.L.E. University, India.

Inclusion criteria

1. The patient should freely accept the proposed single or two visit treatment with the criteria for postoperative pain evaluation.
2. Only maxillary central incisors were selected for this study because they have almost straight roots.
3. Both vital and non-vital teeth were included in the study.
4. Teeth in which initial master file (K-type) binds at the apex was of ISO size #45 or less were included in the study.

Exclusion criteria

1. Patients with any systemic diseases.
2. Pregnant patients.
3. Patients who had been taking antibiotics, non steroidal anti-inflammatory drugs or coticosteroids at the time of treatment.
4. Patients of age below 15 and above 50 years.
5. Patients with acute apical periodontitis, acute apical abscess and weeping canals.
6. Necrotic painful teeth with absence of sinus tract for drainage
7. Retreatment cases.
8. Teeth with calcified canals.
9. Teeth with periapical radiolucencies of diameter greater than 0.5 cm (5 mm).

Treatment procedure: Before actual treatment, thorough medical and dental history was taken. For each patient, pre-operative data was recorded in the patient's history sheet which includes age, sex and intensity of pain before the treatment. The intensity of pain was measured using the visual analog scale. The proposed treatment and design of the study was explained to the eligible patient. An oral and written informed consent approved from the institutional ethical committee was taken from all the patients.

Randomization: Biased coin randomization, a method of simple randomization, was used for assigning the patients to the two study groups depending upon number of treatment appointments;

Group A (Single-visit) and Group B (two-visit). This is a dynamic randomization method which gives same number of patients in both the groups. Tossing coin, allocation and sequence was operated by a post-graduate student. 33 patients received treatment in single-visit (Group A) and 33 patients in two-visit (Group B)

Root canal therapy: All the patients received the proposed treatment by a single operator at Department of Conservative Dentistry & Endodontics, K.L.E. University, India.

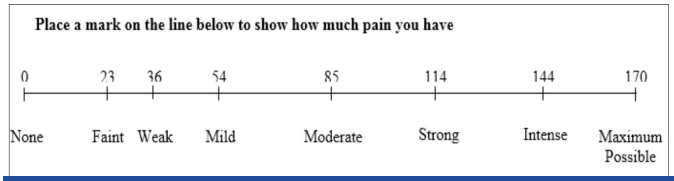
Teeth in Group A were treated in single visit and in Group B in two visits for the root canal therapy. The common procedure for both the Groups A and B at the first sitting was local anaesthesia infiltration followed by rubber dam application, caries excavation if present and access cavity preparation. Canal patency was checked with a size 15 K file. Then orifice openers taper 0.12 and 0.10 were used for enlarging the coronal and middle third of the canal. They were used at speed of 350 rpm with a slow gentle in and out movement. RC-Prep was used as a lubricant and 2.5% NaOCl, saline as irrigants. Then the working length was determined with K-file using apex locator (Dentaport ZX, J Morita corp.) and confirmed by a periapical radiograph.

Instrumentation was carried out using 0.06 taper K3 (Sybron Endo) NiTi rotary files in crown down manner along with copious irrigation using 2.5% NaOCl and saline. RC-Prep was used as a lubricant during filing. Instrumentation was done three file sizes larger than the initial apical file which binds to the apex. After completing instrumentation, canals were dried with paper points. Teeth in Group A were obturated at the initial appointment with gutta-percha cones and AH plus sealer, using lateral condensation technique and temporary restoration was done. Post obturation radiograph was taken.

Teeth in Group B were sealed with a sterile dry cotton pellet and double sealed with cavit and zinc phosphate cement. Patients were recalled after one week for obturation with similar method and materials as used for Group A.

Postoperative pain evaluation: It was done using modified Heft-Parker Visual Analogue Scale (VAS) shown in [Table/Fig-1]. Patients could place a mark anywhere on the horizontal VAS having values between 0 and 170. Patients recorded their preoperative pain levels in the presence of the clinician to ensure that they understood the instructions. Then further four readings were recorded for postoperative periods of 6, 12, 24 and 48 hours respectively. The patient carried the VAS form along with them. Telephonic reminder was given to them to note their pain readings and return the form duly filled. After one week of obturation, final clinical evaluation for pain was done with the vertical percussion method.

Each patient was given a prescription for 600 mg of Ibuprofen with instructions to avail the same only if needed for pain.



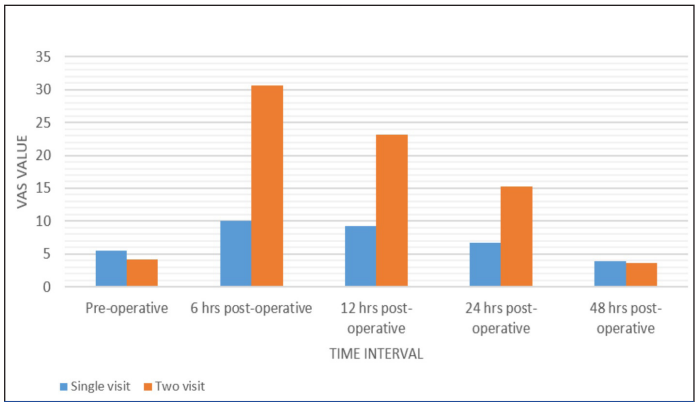
[Table/Fig-1]: Visual Analog Scale (VAS).

STATISTICAL ANALYSIS

Independent sample t-test was used to analyse VAS data to compare the incidence of pre and post- operative pain at 6,12,24 and 48 hours time intervals between the two groups. To compare the postoperative pain between vital and non-vital teeth in both the

Interval	Number of appoint-ments	n	Mean VAS	Standard Deviation	Maximum possible VAS Mark	*p-value
Pre-operative	1	32	5.5000	2.1402	170	0.0379 S
	2	33	4.2121	2.7129	170	
6 hours Post-operative	1	32	10.0938	12.5707	170	7.2277x10-6 HS
	2	33	30.6970	20.3508	170	
12 hours Post-operative	1	32	9.2188	10.4554	170	0.0023 VS
	2	33	23.0909	22.4087	170	
24 hours Post-operative	1	32	6.6563	5.8343	170	0.0167 S
	2	33	15.2424	18.8928	170	
48 hours Post-operative	1	32	3.9063	3.8130	170	0.6248 NS
	2	33	3.5758	0.6139	170	

[Table/Fig-2]: VAS Pain measurements for all cases (n=65).
*P< 0.05 statistically significant, S – Significant, HS – Highly Significant, VS – Very Significant, NS – Not significant, VAS – Visual Analog Scale
Test of significance used: Independent sample T-test



[Table/Fig-3]: Graph showing comparison of pain between Group A and Group B at different time intervals.

groups, again independent sample T-test was used. Differences were considered significant when probabilities were <0.05. Software used was SPSS- Version 12.

RESULTS

Sixty six maxillary central incisors were treated for root canal therapy in one visit (n=33) and two visit (n=33) groups.

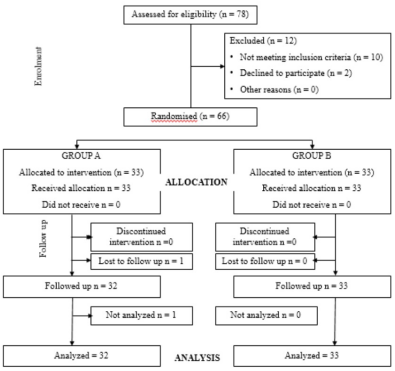
After 6 hours, 12 hours and 24 hours of obturation, pain was significantly higher in Group B (two visit) as compared to Group A (single visit). But after 48 hours, there was no significant difference between both the groups [Table/Fig-2]. Same is also shown by means of graph [Table/Fig-3]. No statistically significant differences were found in the pain levels between vital and non-vital teeth in both the groups at all the time intervals [Table/Fig-4,5].

Interval	Number of appoint-ments	n	Mean VAS	Standard Deviation	Maximum possible VAS Mark	*p-value
Pre-operative	1	15	6.2667	2.3442	170	0.0005 HS
	2	15	3.7333	0.8837	170	
6 hours Post-operative	1	15	4.3333	1.7995	170	0.0009 HS
	2	15	23.1333	19.4528	170	
12 hours Post-operative	1	15	3.8000	1.8593	170	0.0049 VS
	2	15	14.6667	13.6417	170	
24 hours Post-operative	1	15	5.0000	6.2906	170	0.0743 NS
	2	15	9.7333	7.6295	170	
48 hours Post-operative	1	15	4.5333	5.5532	170	0.4388 NS
	2	15	3.4000	0.6325	170	

[Table/Fig-4]: VAS Pain measurements for vital cases only (n=30).
*P< 0.05 statistically significant, HS – Highly Significant, VS – Very Significant, NS – Not significant, VAS – Visual Analog Scale
Test of significance used: Independent sample T-test

Interval	Number of appoint-ments	n	Mean VAS	Standard Deviation	Maximum possible VAS Mark	*p-value
Pre-operative	1	17	4.8235	1.7405	170	0.8265 NS
	2	18	4.6111	3.5833	170	
6 hours Post-operative	1	17	15.1765	15.6454	170	0.0009 HS
	2	18	37.0000	19.3755	170	
12 hours Post-operative	1	17	14.0000	12.5250	170	0.0272 S
	2	18	30.1111	26.0224	170	
24 hours Post-operative	1	17	8.1176	5.1464	170	0.0572 NS
	2	18	19.8333	23.9761	170	
48 hours Post-operative	1	17	3.3529	0.7019	170	0.0971 NS
	2	18	3.7222	0.5745	170	

[Table/Fig-5]: VAS Pain measurements for non-vital cases only (n=35).
*P< 0.05 statistically significant, S – Significant, HS – Highly Significant, NS – Not significant, VAS – Visual Analog Scale
Test of significance used: Independent sample T-test



[Table/Fig-6]: Participant flow diagram.

One patient from one visit group did not return the VAS form and hence was excluded from the study. A participant flow diagram is given in [Table/Fig-6].

DISCUSSION

The aim of this randomized controlled trial was to compare postoperative pain experienced by the patients after single-visit and two-visit root canal therapy. Mild discomfort in terms of pain is seldom occasional experience for the patients after root canal treatment. Pain is a subjective symptom and it is difficult to decide whether single or multiple factors cause this pain. To name few, over instrumentation, extrusion of debris, obturating materials, irrigating solutions, intracanal medicaments etc.

Single visit root canal treatment has become a common practice and offers several advantages both for patient as well as dentist. These are reduced number of visits, increased patient acceptance, lesser postoperative flare-ups, reduced chairside time, and practice management considerations [7,8]. But simultaneously, single visit procedure removes few controls available in the multivisit treatment like culturing [9]. Also, it precludes the opportunity to place intracanal medicament such as calcium hydroxide. However, the need to place calcium hydroxide remains questionable since it has been shown that calcium hydroxide fails to consistently produce sterile root canals and even allows regrowth in some cases [10]. Thus root canal treatment with an inter-appointment calcium hydroxide dressing gives no guarantee of healing in all cases and therefore its use does not appear to be practical in all the cases.

According to Oliet [9], case selection for single visit root canal therapy is as follows:

1. Positive patient acceptance.
2. Sufficient available time to complete the procedure properly.
3. Absence of acute symptoms requiring drainage via canal and of persistent continuous flow of exudates or blood.
4. Absence of anatomical obstacles (calcified canals, fine tortuous canals, bifurcated or accessory canals) and procedural difficulties (ledge formation, blockage, perforations, inadequate fills).

In the present study, inclusion and exclusion criteria was based on above mentioned indications and contraindications. Only maxillary central incisors have been selected in this study because they have almost straight canals. Instrumentation was done three file sizes larger than the initial apical file which binds to the apex. K3 rotary instruments are available till ISO size 60 and hence teeth in which initial apical file that binds at apex was of ISO size #45 or less were only included in the study. Since extrusion is a problem common to all root canal preparation techniques, modern procedures have been advocated to minimize these situations. These problems can be minimized with the new cervical flaring techniques like 'crown down' technique; and hence this technique was used for cleaning and shaping. Proper use of NiTi instruments has made endodontics much less tiresome, more efficient and precise [11]. Better shaped canals means better irrigation and cleaner canal systems reducing the need for a dressing availing satisfactory disinfection of the canal system [12]. Thus saving time and the risk of inter appointment infection. Therefore, K3 rotary NiTi instruments have been used for mechanical instrumentation in this study.

In the present study, postoperative pain evaluation was done with a modified Heft-Parker VAS. The VAS was used because of presence of unequal spacing of words on this scale which shows perfect replica of spacing between different pain word descriptors perceived by patient [13]. When properly designed and administered, VAS is considered to be a valid and reliable ratio scale instrument for the measurement of human pain intensity and unpleasantness [14].

The results of this study are consistent with those of majority of the published reports on this topic, that is postoperative pain with

one appointment root canal treatment is generally the same as postoperative pain associated with multiple visit treatment [3,15-18]. Probably, it could be because of crown down technique of instrumentation which allows better irrigation and minimizes the extrusion of debris beyond the apex [19-21]. Also, important is the variable flute design of the K3 rotary NiTi file which carries debris out of the canal [22].

The results of the present study are also in agreement with a study which says that incidence of post-obturation pain was higher in multiple visit group than in the single visit group within 24 hours of obturation. The incidence of pain decreases thereafter with all patients being symptom free at the end of the observation period [23].

Thus with the crown down technique of instrumentation which minimizes the extrusion of the debris beyond the apex, rotary NiTi instruments which cleans and shapes the canals effectively along with irrigant like NaOCl, postoperative pain can be controlled irrespective of the number of treatment appointments.

LIMITATION

In multiple visit root canal therapy, intracanal medicament like calcium hydroxide is generally placed in the root canals to prevent the multiplication of residual microorganisms and also to eradicate them. But in the present study, in two visit group, calcium hydroxide was not used. It could be the limitation of this study.

Further studies are needed to compare the postoperative pain intensity in vital and non-vital teeth, male and female patients using single visit and multiple visit root canal treatment.

CONCLUSION

Within the limitations of this study, although after 6 hours, 12 hours and 24 hours of obturation, pain was significantly higher in Group B as compared to Group A, there was no significant difference in the pain experienced by the patients 48 hours after treatment in both the groups. Thus the present study shows that multiple visit endodontics does not reduce the pain incidence and that root canal treatment can be completed safely in single visit. At the same time, it certainly does not mean that all of the endodontic cases be easily treated with single visit root canal therapy. Therefore, one should carefully evaluate the case before making the decision to go for single visit or multi visit root canal treatment.

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"I affirm that I have no financial affiliation (e.g., employment, direct payment, stock holdings, retainers, consultant ships, patent licensing arrangements or honoraria), or involvement with any commercial organization with direct financial interest in the subject or materials discussed in this manuscript, nor have any such arrangements existed in the past three years. Any other potential conflict of interest is disclosed."

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