Comparison of postoperative pain following single‑visit and two‑visit root canal therapy in controlled diabetic patients with irreversible pulpitis: A randomized control trial

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Abstract

Aim: The aim of this study was to evaluate and compare the prevalence of postoperative pain after single- and two-visit endodontic therapy in controlled Type 2 diabetic and nondiabetic individuals in multirooted teeth with irreversible pulpitis.

Materials and Methods: Ninety patients with irreversible pulpitis (30 controlled diabetics and 60 nondiabetics), between 18 and 60 years were included in the study. After obtaining initial pain scores, patients were randomly allocated to single-visit or two-visit root canal treatment (RCT) groups to receive standardized treatment. After the first visit, patients were given visual analog scale form to mark pain intensity at 1 h, 6 h, 12 h, 24 h, 48 h, 72 h, and 1 week. The compiled data collected were statistically analyzed using 20 SPSS software.

Results: In both groups, for patients undergoing single-visit and multi-visit RCT, pain intensity was highest on 1st day of treatment and dropped afterward. A comparison of pain between single-visit and two-visit patients revealed no significant difference in pain scores for the respective time intervals. Intergroup comparison between controlled diabetics and nondiabetics showed no significant difference in pain reported between both groups.

Conclusion: According to the results of this study, being diabetic or nondiabetic, no difference in pain perception was seen between single- and multiple-visit endodontics suggesting that single-visit as well as two-visit endodontic treatment can be done in controlled diabetic patients.

Keywords: Diabetes mellitus; glycated hemoglobin A; postoperative pain; pulpitis; root canal therapy

INTRODUCTION

The absence of clinical signs and symptoms, as well as radiographic evidence of periapical healing, is an indicator of successful root canal treatment (RCT).[1] Endodontic postoperative pain is described as a sensation of discomfort following the completion of RCT and is experienced by 25%–40% of patients regardless of pulp and periradicular diseases.[2,3] Postoperative pain, even after meticulous endodontic therapy, can distress both the patient and the dentist. Factors associated with pain after endodontic treatment include age, sex, molar teeth, mandibular teeth, and the absence of periapical radiolucencies and procedural factors.[4] However, the relationship between the systemic health of the patient and postoperative pain is rarely discussed in the literature.

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Type 2 diabetes mellitus (T2DM) is a global burden, with steep prevalence rates in developing economies and affecting approximately 366 million people worldwide.\[^5\] South Asians seem to be at especially high risk for developing T2DM. Diabetes alters many functions of the immune system and is commonly associated with delayed healing and compromised immune responses.\[^6-8\] This predisposes to chronic inflammation, progressive tissue breakdown, and diminished tissue repair capacity, suggesting that diabetes may serve as a disease modifier in cases of endodontic infections.\[^9\]

When T2DM is under therapeutic control, periapical lesions have been shown to heal as readily as in nondiabetic patients.\[^10\] There are not many studies in the literature evaluating the association between controlled T2DM and the occurrence of postoperative pain after single-visit root canal therapy. Hence, the main purpose of this in vivo study was to evaluate the prevalence and comparison of postoperative pain after single- and two-visit endodontic therapy in controlled T2DM and nondiabetic individuals in multirooted teeth with irreversible pulpitis.

**MATERIALS AND METHODS**

This study design was a simple parallel randomized, single-blinded, single-center clinical trial using a simple randomization table, with 1-week follow-up. The patients were selected from the outpatient department of conservative dentistry and endodontics who reported for RCT. Randomization was done in such a way that for a single diabetic patient, two nondiabetic patients were selected. As neither patient nor operator would be blinded as to the number of visits, the outcome assessor was blinded. All the subjects underwent random blood sugar tests to pick undiagnosed T2DM, and glycated hemoglobin A (HbA1c) levels were measured in diabetics to assess their glycemic control. The research question in the PICO format was “What is the incidence of postoperative pain (O) in patients with controlled diabetes (P) compared to nondiabetic patients (C) undergoing root canal therapy in a single-visit and two-visit appointments (I) ?”

**Inclusion criteria**

1. Patients with T2DM for a minimum of 5 years and who were under medication with HbA1c <7% and nondiabetic patients
2. Teeth with irreversible pulpitis (Type II diabetic and nondiabetic patients)
3. Multirooted teeth (premolars and molars).

**Exclusion criteria**

1. Patients with complicated systemic diseases under medication for the same
2. Patients who took medication for pain relief within 48 h before the start of treatment
3. Patients having severe pain and/or apical abscess
4. Patients under 18 years of age and above 60 years of age
5. Patients having multiple teeth requiring treatment
6. Patients with nonrestorable periodontally compromised teeth
7. Pregnant patients
8. Teeth with calcified canals.

**Randomization and blinding**

The institution’s ethical committee approved the study, and all the patients gave written informed consent. After initial screening, 90 patients with a diagnosis of irreversible pulpitits were included in this study. The recruitment ratio was 1:2, that is, for every diabetic individual two nondiabetic individuals were enrolled for the study. Initial pain scores of the patients were obtained using modified visual analog scale (VAS). Group A had 30 T2DM patients and Group B had 60 patients who were nondiabetic. Each group was further subdivided into single-visit (subgroup 1) and two-visit (subgroup 2) using a set of random numbers. The randomization scheme was created using the website http://www.randomization.com by a research assistant and the card with the group allocated in a closed envelope was to be opened by the clinician performing the treatment (blinding of patients and operator) at the stage of final irrigation of root canal [Figure 1].

**Treatment procedure**

A standardized procedure was performed for both groups. The first visit included local anesthesia, rubber dam isolation, access cavity preparation, working length determination, and shaping and cleaning, that was carried out using ProTaper Universal rotary files (Dentsply Maillefer, Switzerland) till F1. Each canal was irrigated with 3% sodium hypochlorite (Prime Dental Products Pvt Ltd., India). Final irrigation was carried out using 17% ethylenediaminetetraacetic acid, followed by normal saline as a final flush. At this point of time, the clinician removed a card from the envelope to reveal the number of visits to be followed for the final obturation. The canals were dried using paper points, and teeth in the single-visit group were obturated in the initial appointment using F1 gutta-percha cones (Dentsply Maillefer) and AH Plus sealer (Dentsply De Trey, Konstanz, Germany). Teeth in two-visit groups were sealed with a sterile dry cotton pellet and temporary filling material (MD-TempPlus; Meta Biomed Co. Ltd., Korea). The patients were recalled for the second appointment 1 week later, and teeth were obturated using the same method and material.

**Postoperative pain assessment**

None of the patients were prescribed medication following treatment but they were recommended to take aceclofenac...
100 mg + paracetamol 325 mg when required as a rescue drug and were asked to mark this in their form. From that point of time, the data of that patient were excluded from the study. Patients experiencing unbearable pain were requested to visit the clinic for emergency management. Evaluation of postoperative pain was done with modified VAS.

The patients carried home the VAS form and were asked to mark the intensity of pain at 1 h, 6 h, 12 h, 24 h, 48 h, 72 h, and after 1 week and were asked to return for review. For those patients who did not have a smartphone, they were called through telephone and similar instructions were repeated for them.

**Statistical analysis**

The data collected were compiled, and statistical analysis was done using 20 SPSS software (IBM Corporation, IBM Corporation, Bengaluru, Karnataka, India). Descriptive statistics and inferential statistics were applied. Kolmogorov–Smirnov test and Shapiro–Wilk tests were used for testing the normality, and the statistical analysis was completed with the Fisher exact test with \( P < 0.05 \).

**RESULTS**

All the patients enrolled in the study reported for follow-up with their duly filled VAS forms. None of the patients were lost to follow-up or reported analgesic intake.

Among 15 controlled diabetic patients who underwent single-visit RCT, 8 were male and 7 female. In the nondiabetic group, 30 patients underwent single-visit endodontic therapy (13 males and 17 females) and 30 patients underwent multi-visit endodontic therapy (21 males and 9 females).

The comparative statistics for postoperative pain at different time intervals between nondiabetic and diabetic groups are given in Tables 1 and 2. None of the patients experienced severe pain in our study. Only one patient had moderate pain in the single-visit controlled diabetic group. The maximum number of patients experiencing pain was at 12 h among diabetics and at 24 and 48 h among nondiabetics [Figure 2a and b]. After 1 week regardless of being diabetic or nondiabetic, none of the patients experienced pain. Following obturation in the second visit during two-visit endodontic therapy, none of the patients in both groups experienced pain regardless of the time period.

In the nondiabetic group, after 12 h, 24 h, and 48 h, there was a higher incidence of pain in the two-visit group, however, there was no statistically significant difference. In the controlled diabetic group, there was no significant difference between single-visit and two-visit groups.

Overall comparison of pain among controlled diabetic and nondiabetic individuals following one-visit and two-visit root canal therapy at various time intervals shows no significant difference.

**DISCUSSION**

It has been claimed that multi-visit root canal therapy is a safe option for diabetic patients with apical
Table 1: Statistical analysis (Fischer’s exact test) values of pain reported by patients in nondiabetic versus diabetic groups after single visit and 2-visit root canal treatment

|                | Nondiabetic | Diabetic | Fisher’s exact test value |
|----------------|-------------|----------|----------------------------|
| **After 1 h**  |             |          |                            |
| Pain           | 1           | 1        | 1                          |
| No pain        | 29          | 14       | 30                         |
| **6 h**        |             |          |                            |
| Pain           | 1           | 1        | 1                          |
| No pain        | 29          | 14       | 30                         |
| **12 h**       |             |          |                            |
| Pain           | 1           | 2        | 0.254                      |
| No pain        | 29          | 13       |                            |
| **20 h**       |             |          |                            |
| Pain           | 3           | 3        | 0.384                      |
| No pain        | 27          | 12       |                            |
| **48 h**       |             |          |                            |
| Pain           | 5           | 1        | 0.647                      |
| No pain        | 25          | 14       |                            |
| **72 h**       |             |          |                            |
| Pain           | 1           | 0        | 1                          |
| No pain        | 29          | 15       |                            |
| **1 week**     |             |          |                            |
| Pain           | 0           | 0        | 1                          |
| No pain        | 30          | 15       |                            |

Table 2: Statistical analysis (Fischer’s exact test) values of pain after single visit versus first visit in 2-visit root canal treatment reported by patients in nondiabetic and diabetic groups

|                | Nondiabetic | Diabetic | Fisher’s exact test value |
|----------------|-------------|----------|----------------------------|
| **After 1 h**  |             |          |                            |
| Pain           | 1           | 1        | 1                          |
| No pain        | 29          | 14       | 30                         |
| **6 h**        |             |          |                            |
| Pain           | 1           | 1        | 1                          |
| No pain        | 29          | 14       | 30                         |
| **12 h**       |             |          |                            |
| Pain           | 1           | 2        | 0.254                      |
| No pain        | 29          | 13       |                            |
| **20 h**       |             |          |                            |
| Pain           | 3           | 3        | 0.384                      |
| No pain        | 27          | 12       |                            |
| **48 h**       |             |          |                            |
| Pain           | 5           | 1        | 0.647                      |
| No pain        | 25          | 14       |                            |
| **72 h**       |             |          |                            |
| Pain           | 1           | 0        | 1                          |
| No pain        | 29          | 15       |                            |
| **1 week**     |             |          |                            |
| Pain           | 0           | 0        | 1                          |
| No pain        | 30          | 15       |                            |

**Figure 2:** Comparison of percentage of a) nondiabetic and b) diabetic patients experiencing postendodontic pain at different time intervals. x-axis- Time, y-axis- Percentage of patients
Anagha, et al.: Incidence of postendodontic pain in diabetics

periodontitis. However, the outcome of RCT in diabetics with good glycemic control has not been categorically reported. A study in this domain will establish if there are any differences in treatment outcomes in relation to postoperative pain and if there are any modifications required, for number of visits for controlled diabetics. Hence, in this study, we particularly chose controlled diabetics with a disease duration of at least 5 years who reported for RCT of posterior teeth.

To avoid bias, all the patients were treated by a single operator and pain assessment was carried done using VAS scoring criteria by two other doctors who were blinded about the single- and multi-visit treatments.

Several clinical studies demonstrated a direct link between preoperative and postoperative endodontic pain levels and also found that treatment of teeth with vital pulp reported significantly higher postendodontic pain compared to teeth with necrotic pulp or retreated teeth. Therefore, we included only vital teeth (irreversible pulpitis) for comparing the postendodontic pain after single-visit and two-visit root canal therapy in both diabetic and nondiabetic groups. Those who needed root canal therapy for multiple teeth were excluded from the study in an attempt to avoid possible bias. VAS was used for evaluating postoperative pain.

A literature search showed that the presence of systemic diseases such as DM contributes to the severity of endodontic infections and the response of the teeth to RCT. In diabetic patients, the circadian rhythm of pulp sensibility is altered than that of healthy elderly. The compromised circulation within pulp due to endarteritis obliterans and lack of collateral circulation along with altered polymorph nuclear activity in diabetics are considered to result in an increased risk for infection or pulp necrosis.

In the development of chronic inflammation, metabolic disorders and dental infections share common fundamental mechanisms. The role of macrophages and macrophage-derived mediators in metabolically induced and infection-induced inflammation has been widely studied. The pulpal infection is polymicrobial, with predominantly Gram-negative anaerobes. Although pulpal infection initiates an immune response in the dental pulp, it is insufficient in eradicating the pathogens, because immune cells and molecules cannot reach into the dentin effectively. In addition, the dental pulp is uniquely situated in a low-compliance environment surrounded by dentin and lacks a collateral vascular supply.

The lack of control in diabetic mellitus could delay the healing of periapical lesions and increase their size despite receiving the RCT. In our study, we determined the metabolic control of the DM by measuring HbA1c levels and who were under medication (HbA1c < 7.0%) with vital pulp without any periapical radiolucency were included in the study.

While assessing postobturation pain after single-visit and multi-visit RCT, the pain intensity was found to be highest on the 1st day of treatment and dropped afterward. The results of similar studies also concluded that the incidence of postoperative pain was common after 1 day of RCT; but that it mostly subsided after 7 days of the treatment which was similar to our study.

In the present study, no patients under nondiabetic and controlled diabetic groups experienced a significant difference in pain between the single-visit and two-visit group (P < 0.05) at any time interval. The incidence of pain was marginally more in the two-visit group in the nondiabetic group. In the controlled diabetic group, though the incidence of pain was more in the single-visit group in the 1st day which gradually reduced, there was no significant difference between single-visit and two-visit groups.

After 72 h and 1 week of two-visit treatment, a greater number of controlled diabetic patients exhibited pain than nondiabetic individuals. In diabetic individuals with poor glycemic control, high glucose levels can inhibit macrophage function resulting in an inflammatory state that impairs host cellular proliferation and wound healing. There is also reduced beta-endorphin production which translates to higher pain perception in diabetic patients resulting in a decreased pain threshold. In this study, though patients had good glycemic control, because of the physiopathology of the disease, decreased beta-endorphin levels might be responsible for higher pain persistence for 72 h to 1 week in diabetic individuals.

Researchers have shown postobturation pain is related to gender. They found a statistically significant difference between the genders and found that more women experienced severe pain as compared to men, at all the three-time intervals of time (12, 24, and 48 h). In this study, a greater number of male patients were there in both diabetic and nondiabetic groups. Hence, the results showing more pain among male patients cannot be considered significant.

Both premolars and molars were included in this study irrespective of the number of roots which could be a cause for pain variation. As an extension of this study periapical healing could also be assessed which would throw light on healing ability in controlled diabetic patients after single- and two-visit RCT.
According to the results of this study, being diabetic or nondiabetic, no difference in pain perception was seen between single- and multiple-visit endodontics suggesting that single-visit as well as two-visit endodontic treatment can be done in controlled diabetic patients.

CONCLUSION

There was no statistically significant difference in overall pain experienced by single-visit and two-visit patients in diabetic and nondiabetic groups. To conclusively derive whether diabetes can act as a disease modifier and affect the postoperative pain in irreversible pulpitis after single-visit RCT in controlled T2 diabetics, further studies are to be carried out on a larger sample size. Further research on a larger sample size is needed to determine whether diabetes might function as a disease modifier and alter the postoperative pain in irreversible pulpitis after single-visit root canal therapy in managed T2 diabetics.

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Conflicts of interest
There are no conflicts of interest.

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