Original Article

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Dentistry Section

Efficacy of Prophylactic use of Antibiotics to Avoid Flare up During Root Canal Treatment of Nonvital Teeth: A Randomized Clinical Trial

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ABSTRACT

Objectives: Flare-up during root canal treatment of non vital teeth is a common clinical incident. The aim of the present study was to assess the effect of prophylactic use of antibiotics to avoid flare up during root canal treatment of the teeth having asymptomatic necrotic pulp.

Materials and Methods: A randomized double blind clinical trial with parallel design was conducted on 100 subjects with asymptomatic non vital teeth. They were randomly divided into two groups. The first group (50 participants) was given two gram amoxicillin one hour before the first visit of root canal treatment; the second group (50 participants) did not receive any treatment (control group). In both groups, root canal treatment was performed in two visits. The flare up was assessed by the pain visual analogue scale and based on the swelling criteria. The data were processed and analyzed using SPSS statistical software 17. A p-value of 0.05 or less was considered statistically significant.

Results: A total of 80% of participants in the experimental group had flare up while 12% of participants had flare up in the control group. Prophylactic Amoxicillin had no effect on inter-appointment flare up ($p > 0.05$). There was no relationship between flare up and patient's age, gender and tooth type ($p > 0.05$).

Conclusion: Prophylactic use of Amoxicillin in asymptomatic non vital teeth before root canal treatment had no effect on the incidence of flare-up.

Keywords: Asymptomatic non vital teeth, Endodontic treatment, Inter-appointment flare up, Prophylactic amoxicillin

INTRODUCTION

The flare up has been defined as developing pain, swelling or both within few hours to few days after the initiation of the root canal treatment [1]. Mild pain after root canal treatment is common even when the treatment is performed with proper clinical accepted standards, and it should be expected by the patients. However, an inter appointment flare up is an unusual event. It is agonizing for both patients and the attending dentist and requires emergency visit to the dentist [2,3].

Flare up is a polyaetiological phenomenon, whereas mechanical, chemical and microbial factors contribute to its appearance. In fact, regardless of the type of factor, the flare up depends on the extent of the periradicular tissue injury, its severity and intensity of the inflammatory response. The mechanical factors include cleaning and shaping behind apical constriction, over instrumentation, over extending gutta percha or pushing infected dentin/necrotic pulp into the periapical area [4]. All instrumentation techniques are reported to cause apical extrusion of contaminated debris, even when the file is maintained short of the apical terminus, but minimum amount of debris is extruded with crown down technique and engine driven NiTi systems. Various chemicals are used during root canal treatment such as irrigating solutions, intracanal medicaments and root canal sealers. All these chemicals can cause flare up during root canal treatment [5].

Infection is the most significant factor in flare up pathogenesis. During biomechanical preparation of root canals, most microorganisms are removed but some may inadvertently be pushed beyond apex. These microbes also cause endodontic flare up. Microbial injury to the periapical tissues is the most common cause of flare ups and some Gram-negative anaerobic bacteria may play an important role in the development of post operative symptoms [6].

A long standing non vital tooth with necrotic pulp becomes a reservoir for infection. If such a tooth is root canal treated, microbial insult coupled with iatrogenic trauma to periapical tissues through instrumentation or use of chemicals produces periradicular inflammation, the intensity of which depends on the virulence and number of microorganisms [7]. Some researchers showed that flare up following single visit endodontic treatment was significantly higher in non vital teeth than vital ones, and ranged from 1.5% - 20% [8].

The preventive measures against infectious flare up include selection of instrumentation techniques that extrude lesser amount of debris apically; completion of the chemo-mechanical preparation in a single visit; sealing of the access cavity between visits and maintaining aseptic environment during root canal treatment. Some researchers recommended the systemic use of antibiotics to prevent flare up during or after root canal treatment [9,10]. Penicillin and amoxicillin, having capacity of being absorbed quickly, are drugs of choice for this purpose but many patients having allergy to these medicines cannot take them. To such patients Erythrosine and Flagyl are prescribed. For administration of prophylactic antibiotics, recommendations of American Heart Association are followed [10,11].

There is a difference of opinion among researchers regarding the use of prophylactic antibiotics in endodontics. They consider that instituting antibiotics before the commencement of root canal treatment in teeth with necrotic pulps is therapeutic rather than prophylactic [12,13]. This is argued because necrotic pulps show periapical radiolucencies on radiographic examination. Such radiolucencies are invariably infected and use of antibiotics becomes therapeutically mandatory [14,15].

However, other researchers found that giving amoxicillin antibiotics before initiation of endodontic treatment was not suitable to prevent flare up following endodontic treatment of nonvital teeth [12].

The purpose of the present study was to determine the effect of prophylactic amoxicillin on flare up in asymptomatic non vital teeth during root canal treatment.

MATERIALS AND METHODS

The study was approved by the college ethics committee. This randomized double blinded clinical trial with parallel design study was carried out at Department of Endodontics, College of Dentistry, Aljouf University, Saudi Arabia from January to December 2013. The initial sample size has been calculated based on the power of 0.9 and the type 1 error of 0.05, with 55 patients in each group (totally 110).

The present trial was conducted in compliance with the ethics principles of the Helsinki declaration. After explaining the nature, purpose of the study and probable side effects of the drug to the participants, an informed consent was signed by each participant.

Diagnosis was based on history, clinical examination and periapical radiograph of the involved tooth. Participants were included in the study if they were healthy (ASA I or II) and have asymptomatic necrotic restorable teeth, non-endodontically treated teeth with negative pulp response to electric pulp test (Parkell, New York, United States) and no bleeding from pulp chamber on opening. Patients with systemic disease, taking antibiotics for the last one month, having allergy to penicillin, or having symptomatic necrotic teeth; teeth tender to percussion; or non-restorable teeth were not considered for this study. The single investigator and the patients both were blinded.

The patients were assigned into one of the two groups by random number table. The research assistant which was not part of the study generated the random allocation sequence, enrolled all the participants and assigned the participants to interventions. The allocation ratio was 1:1. The first group (n=50) was given two gram amoxicillin capsule (Amoxil, SmithKline Beecham plc. Worthing, United Kingdom) one hour before first visit of root canal treatment, while the second group (n=50) did not receive any drug (control group).

The standard protocol for the root canal therapy was followed. The rubber dam was applied. The biomechanical preparation of the root canal was performed by the step-back technique with k-files and Gates glidden drills (Mani, Inc. Tochigi, Japan). A periapical radiograph (parallel technique) was taken to determine the working length, which was 0.5mm short of the radiographic apex. 2.5% sodium hypochlorite solution was used as irrigant and non-setting calcium hydroxide, Metapex (Meta Biomed Co; Ltd, South Korea) was used as interappointment intracanal dressing. The cavity was sealed with temporary restoration Cavit (3M ESPE, Germany) and the occlusion was adjusted before discharging the patient.

In both groups the root canals were obturated with gutta-percha (Dentsply Maillefer, United States) using lateral condensation technique with AH26 (Dentsply, Germany) as sealer and a permanent restoration, amalgam (Southern Dental Industries Ltd, Australia) or composite (rok, Southern Dental Industries Ltd, Australia) was placed.

A proforma was given to each patient at the end of first visit. The patient had to mark if pain (absent, mild, moderate, severe) or swelling were present and to record it after 4 hours, then at 12, 24, 48 and 72 hours after the first visit. The visual analogue pain scale was used for recording the pain from 0 to 10 (No pain 0, mild pain 1-3, moderate pain 4-6 and sever pain 7-10). The moderate and sever pain experienced by the patients was considered as flare up. Similarly to record the swelling, the criteria were 0 no swelling, 1 mild swelling, 2 moderate swelling and 3 sever swelling. The patients were told not to take any medication without informing the investigator. After three days they were recalled to collect the proforma. The instructions were given to the patients to contact the investigator in case they experienced unbearable pain and /or swelling.

STATISTICAL ANALYSIS

The data were analyzed using the SPSS computer software (Statistical Package for the Social Sciences, version 17.0, SPSS Inc, and Chicago, IL, USA). Frequency and percentages were calculated for the Patients' age, gender and tooth type. The Chi-square test was used for comparing the two groups. p-value of 0.05 or less was considered statistically significant.

RESULTS

Out of 110 total patients entering to the present study, only 100 (91%) patients returned the proforma regarding post endodontic pain and swelling. The remaining 10 (9%) participants were lost to follow. So, one hundred patients (55 males and 45 females) whose ages ranged from 18 to 60 years were studied. Their mean age was 34.59 ± 11.33 years. They were divided into two groups, one group was treated with two gram amoxicillin one hour before endodontic treatment (experimental group), and the other group did not receive any drug (control group). According to age; the patients were divided into four groups, 18 to 27 years, 28 to 37 years, 38 to 47 years, 48 to 60 years group [Table/Fig-1].

Flare up experienced by 4% of patients who aged 18 to 27 years, 3% of 28 to 37 years old, 2% of 38 to 47 years old, and 1% of 48 to 60 years old patients [Table/Fig-1]. Using chi-square analysis, no significant relation was found between age and flare up in experimental and control groups (p =0.972) [Table/Fig-1].

Regarding gender, only four males (7.3 %) while six females (13.3%) had flare up in their teeth. However, analysis using chi-square revealed no significant relation between gender and flare up (x^2= 1.010, df= 1 p= 0.315). Regarding tooth type, 42 maxillary and 58 mandibular teeth were included in the study. Mandibular teeth received more flare ups compared to maxillary teeth. Only three maxillary teeth (7.1%) were affected by flare up while seven mandibular teeth (12.1 %) were reported to have flare up. No significant differences were found between flare up in maxillary and mandibular teeth (x^2= 0.657, df= 1 p= 0.418).

A higher percentage of flare up was observed (12%) in control group compare to (8%) experimental group. However, the difference was not statistically significant (p= 0.505) [Table/Fig-2].

Patients age (years)*	Flare up (%)	No flare up (%)	Total (%)
18 -27	4 (10.5)	34 (89.5)	38 (100)
28-37	3 (11.1)	24 (88.9)	27 (100)
38- 47	2 (10)	18 (90)	20 (100)
48-60	1 (6.7)	14 (93.3)	15 (100)

[Table/Fig-1]: Patients' distribution by age and presence of flare-up of treatment (total n=100) data shown are n (%)
*Chi-Square (X^2) = 0.234; df =; 3; p = 0.972

Flare ups*	Experimental group	Control group	Total
Present	4 (8%)	6 (12%)	10 (10%)
Absent	46 (51.1%)	44 (48.9%)	90 (90%)
Total	50 (100%)	50 (100%)	100 (100%)

[Table/Fig-2]: Distribution of root canal flare-ups among the study population according to the number of groups (total n=100) data shown are n (%)
*Chi-Square (X^2) = 0.444; df =; 1; p = 0.505

DISCUSSION

Inter-appointment endodontic flare up commonly occurs during root canal therapy of non vital teeth [16]. In the past, it was a routine practice to give systemic antibiotics before commencement of the root canal therapy to prevent such flare up.

The literature supporting the use of antibiotics in preventing flare up after endodontic treatment has come from the researchers of

Temple University School of Dentistry. Mata et al., did a randomized control clinical trial to determine the incidence of flare up between the patients either receiving penicillin V or placebo control. The patients were given 250 mg penicillin V every hour for the first 24 hours followed by one tablet every six hours until all tablets were used. The patients were instructed to complete a pain and swelling questionnaire for two days after the treatment. They found that the incidence of flare up was 6% in penicillin group and 24% in the control group [9]. Torabinejad et al., in randomized control trial supported the use of penicillin and erythromycin in controlling flare ups after root canal instrumentation and before obturation [17]. Other researchers [10,18] also advocated the use of antibiotics before endodontic treatment as a routine procedure.

In a randomized double blind study, Walton and Chiappinelli studied to test the effect of the prophylactic penicillin on post endodontic symptoms. They divided 80 patients with asymptomatic periapical periodontitis into three groups. Group A (26 patients) received 2 g penicillin before the treatment and 1g after 6 hours of the treatment. Group B (24 patients) received a placebo with the same regimen and Group C (30 patients) received no medication. They used a visual pain analog and swelling questionnaire, postoperative symptoms such as pain and swelling were recorded at 4, 8, 12, 24 and 48 hours. Only one flare up was recorded which was in placebo group. In Group A (penicillin) 69% of the patients had mild-moderate pain, as compared with 79% in placebo Group B and 70% in group C (no medication). There was no difference statistically among these three groups regarding post treatment symptoms [12]. Pickenpaugh et al., [19] determined the effect of amoxicillin on endodontic flare up in asymptomatic necrotic teeth. Patients (34) were given a single dose of amoxicillin (3g) one hour before endodontic treatment and 36 patients received placebo. Every patient was given a 5½ diary to record post operative pain, swelling, number and type of pain medication taken. The results showed that 7 patients (10%) had flare up of which 4 (57%) were in the amoxicillin group and 3 (43%) were in the placebo group. They concluded that prophylactic amoxicillin had no effect on the occurrence of flare up.

Another trial evaluated the value of clindamycin in the prevention of postoperative infection. A total of 256 patients, 128 of them were given 600 mg clindamycin orally, while another 128 patients received placebo. Patients were evaluated 1, 2 and 4 weeks after surgery. The infection rate in the clindamycin group was 1.6% (2 patients) and in the placebo group 3.2% (4 patients), which showed no statistical significant difference [20].

The results of the current study concurred the results of the above later studies [12,19,20] as no statistical difference was found in incidence of the flare up regardless the use of amoxicillin before root canal treatment.

In this study the incidence of flare up was studied in relation to age, gender and tooth. As regard to age, no significant relationship was found in incidence of flare up in experimental and control group. This agrees with the results of previous studies [21-23]. However, Torabinejad et al., [24] in their study found that there was a higher incidence of flare-up in patients between 40 and 59 years old. The decrease in patients' responses was attributed by the author to the dentinal metamorphosis leading to reduced pulp canal size, decreased blood flow and decreased inflammatory responses. It is likely that the use of more canal friendly flexible instruments and reduction in number of files required to complete preparation may have reduced the frequency of flare up in younger patients in this study.

In the current study, no relationship was found between gender and rate of flare-up. This is in agreement with the previous studies [25,26]. However, results of a study done by Fox et al., were contradictory to these findings as they found a greater incidence of flare up in females [27].

Some researchers claimed that females suffer more commonly from psychosomatic illness and that their pain is governed by emotional factors [28]. However, this was not supported by the results of the present study, possibly due to sympathetic and careful handling.

According to tooth location, no significant differences were found in frequency of flare up between maxillary and mandibular teeth. A study by Walton [29] provided the same results. However, the results of the present study were contrary to the findings of some other previous studies [30,31] that found more significant frequency of flare-up in mandibular teeth than the maxillary teeth. The reason for involvement of more mandibular teeth may be due to thickness of cortical plate in mandible which may cause accumulation of exudates, thus causing more pressure as compared to maxilla [30,31]. The present study, contradicted these findings and this could be due to the use of rubber dam to avoid contamination during the procedure. More flare up occurs in mandibular teeth as they are potentially easier to contaminate with oral fluids than the maxillary teeth.

In summary, Root canal infections may well be treated by mechanical removal of infected debris from canals through appropriate use of instruments, irrigation and local application of medicament. Pretreatment systemic antibiotics should be prescribed only when clear indication of using antibiotics is present to treat any existing infection. Such a use of antibiotics is judicious and considered as therapeutic intervention. For medically compromised patients, however, prophylactic antibiotics are administered as per set guidelines of American Heart Association.

CONCLUSION

Prophylactic use of Amoxicillin in asymptomatic non vital teeth before root canal treatment had no effect on the incidence of flare-up.

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