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Original article

Double blind, Split mouth, randomized clinical trial of evaluation of postoperative pain associated with and without apical clearing technique

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Abstract

Objectives: The study evaluated the incidence and intensity of pain following conventional apical preparation (CAP) and apical clearing technique (ACT) in mandibular molars with necrotic pulp and apical periodontitis.

Methods: 20 subjects with 40 teeth were divided into two groups based on the type of apical preparation as group I and group II. For group I, apicalpreparation three sizes larger [Master Apical File (MAF)] than the first apical binding file was performed. For group II, apical preparation three sizes larger than that MAF was done, followed by dry reaming. Patients were instructed to record their pain between 1st to 7th days. Data was statistically analyzed using Mann Whitney, Chi Square and z tests.

Results: There was a statistically significant difference in the mean pain scores (p=0.003), intensity of pain (mild, moderate, severe) (p=0.024) and number of analgesic doses required (p=0.029) between groups 1 and 2 at 24 hrs interval, but after 24 hrs there was no statistically significant difference in either mean pain scores or intensity of pain.

Conclusion: Apical clearing technique was associated with post-endodontic pain and required higher dosages of analgesic only at 24 hrs. However from the 2nd day, there was no difference in any of these factors.

Keywords: apical clearing technique, conventional apical preparation, dry reaming, visual analogue scale

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Introduction

Post-endodontic pain caused by acute inflammatory response in theperiapical tissues shows wide variation in its incidence due to differences in type and pulpal status of a tooth, study design, treatment protocols,-method of pain evaluation and experience or qualification of the dentist [1,2]. It is a result of injury to periapical tissues due to apical extrusion of infected debris during chemo-mechanical preparation [3]. Extrusion of debris is affected by various factors such as instrumentation technique, instrument type, apical diameter, apical patency, preparation end point, irrigant needle type (side or end venting, gauge etc), irrigation methodologies etc [4-6]. Apical part of the root canal is critical zone for chemo-mechanical preparation as its thorough disinfection is difficult to achieve due to presence of lateral canals and apical ramifications. Significant numbers of residual bacteria found in apical ramifications lead to treatment failure [7]. Removal of such apical ramifications is possible if canal is widened properly in the apical area. Hence apical size is the most important aspect of biomechanical preparation in root canal therapy.

Traditional approach of endodontic preparation involves enlarging the apical constriction three sizes larger (Master Apical File) than the first apical binding file. However Waltonand Torabinejad introduced a technique of apical clearing to increase the size of apical preparation in small canals for eliminating apical ramifications, to maximize debridement-irrigation and to minimize the procedural errors [8]. Apical clearing technique involves sequential use of files two to four sizes larger than the master apical file (MAF) at established working length followed by dry reaming to remove loose debris from canal. Till date there is no published study that evaluated the effect of apical clear-

ing on post-endodontic pain. The present randomized split mouth clinical trial was conducted to comparatively assess the incidence and intensity of pain following conventional root canal treatment and apical clearing technique in mandibular molars with necrotic pulp and apical periodontitis. The primary outcome measure was to evaluate the effect of apical clearing on incidence and severity of postoperative pain, whilst the secondary outcome measure was to determine the postoperative use of analgesics. It was hypothesized that apical clearing would not result in an increased post-endodontic pain as compared to conventional root canal procedure.

Subjects and methods

The present study was conducted in the Department of Conservative Dentistry and Endodontics. Institutional Ethical Committee gave the ethical clearance for the study. Twenty five patients of either gender between the age group of 15-35 years with asymptomatic, non-vital bilateral, mandibular molars exhibiting comparable periapical index (PAI) scores around one/or both roots were recruited. Subjects were selected from a similar education level as the patient's education levels could affect the use of pain scales and the outcomes.Subjects with pre-operative pain, history of use of antibiotics during the previous 1 month or analgesics during past 72 hours and previously accessed tooth were excluded from the study. Once the eligibility was confirmed, treatment protocol was explained to the patients and written informed consent was obtained from twenty selected patients. Double blinding was assured by concealing the treatment protocol for both operator as well as patient. Computer generated random number table was used for block randomization of subjects and based on the type of apical preparation, 40 teeth (twenty subjects) were equally distributed as group I [Conventional apical preparation (CAP) (n=20)] and group II [Apical clearing technique (ACT) (n=20)].

Treatment protocol

Under rubber dam isolation, tooth was anaesthetized (LOX 2%, Neon lab limited, Mumbai, India) and access to the pulp chamber was achieved. It was refined with ultrasonic tips (Pro Ultra Endo Tips, DentsplyMaillefer, Ballaigues, Switzerland) and irrigated with distilled water. Pre-flaring of the coronal and middle thirds was done using an orifice shaper (ProTaperSx rotary files, DentsplyMaillefer, Ballaigues, Switzerland) with a brushing outstroke action to ease in apical gauging of canal. Root canal was prepared in a standard crown-down technique with 0.02 taper NiTi flex K hand file (DentsplyMaillefer, Ballaigues, Switzerland). The electronic working length (Root ZX; J Morita, Tokyo, Japan) was established and confirmed radiographically. For group I [Conventional apical preparation (CAP) (n=20)], apical preparation three sizes larger [Master Apical File(MAF)] than the first apical binding file was performed. For group II [Apical clearing technique (ACT) (n=20)], Master Apical File (MAF) was determined and apical preparation three sizes larger (Final apical file, FAF) than that MAF was done, followed by dry reaming which entailed placing the Final apical file (FAF) to the established working length and rotating it clock-wise at 360°. The irrigation protocol for either group involved the use of 5.25% sodium hypochlorite (Dentpro, Mohali, India) and 15% ethylenediaminetetraacetic acid (Septodont, Codex, France). This was followed by photoactivated disinfection (PAD™ red system, Denfotex Light Systems Ltd., Fife, United Kingdom). Entire procedure was accomplished by the same operator. Canals were thoroughly dried with sterile paper points and filled with calcium hydroxide paste (Prime Dental, Mumbai, Maharashtra, India). The tooth was temporarily restored with intermediate restorative material (Caulk DENTSPLY,Milford, DE).

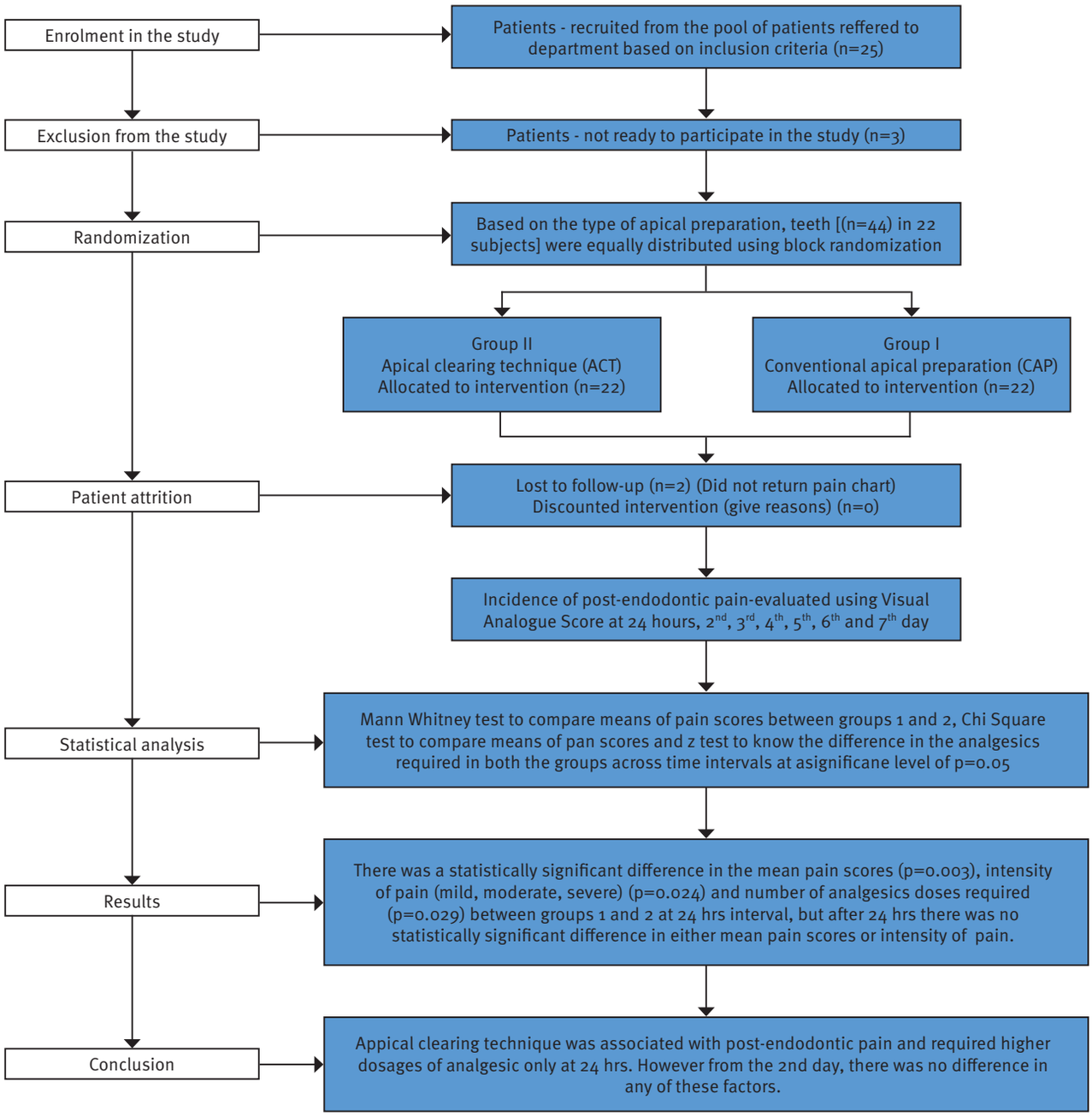
Assessment of treatment outcome

Patients were instructed to record their pain at 24 hrs, 2nd, 3rd, 4th, 5th, 6th,7th days using a visual analogue scale (VAS) and to use analgesics (ibuprofen 400 mg every 6–8 hrs) if needed with noting down the details of analgesic intake such as number of doses required, timing of the dose and whether it provided adequate pain relief or not. VAS consists of a 10cm line with two end-points representing 'no pain' and 'worst pain imaginable'. Corresponding to patients current level of pain, they were asked to rate their pain by placing a mark on the line. The distance along the line from the 'no pain' marker was measured with a ruler giving a pain score out of 10. Values of pain on 0–10 scale were grouped into three categories: 1–4 (mild pain), 5 or 6 (moderate pain) and 7–10 (severe pain). Complete study is depicted in the flowchart.

Statistical analysis

Data obtained was compiled on a MS Office Excel Sheet (v 2010) and was subjected to statistical analysis using Statistical package for social sciences (SPSS v 22.0, IBM). Comparison of means of pain scores between groups 1 and 2 was done using Mann Whitney test. Pain scores were coded as mild, moderate and severe and comparison of occurrence of varying pain scores in both the groups across time intervals was done using Chi Square test. At 24hrs, 45% of the patients (nine out of 20) in the apical clearing group and none of the patients (zero out of 20) in the conventional apical technique required analgesics for pain-control. z test was carried out to find out the difference in the analgesics required in both groups at 24hrs. There

Figure 1. Flowchart depicting details of study



was significant difference (p=0.029) in mean number of analgesic doses required between the apical clearing group and the conventional apical technique at 24hrs. For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

Results

Twenty five patients were included in the beginning of the trial. Three patients refused participation, and two did not return their pain score charts. Twenty patients with forty teeth were enrolled in the study (20 in each

Table 1. Pain experienced by the patients in two groups along with its statistical analysis

		24hrs	2nd day	3rd day	4th day	5th day	6th day	7th day
Group I (CAP)	Mean±SD	3.45±1.93	1.45±.76	1.25±.44	1.00±.00[a]	.10±.31	.05±.22	.00±.00
Group II (ACT)	Mean±SD	5.50±1.91	1.80±.62	1.15±.37.37	1.00±.00[a]	.15±.37	.10±.31	.05±.22
	p-value	0.003*	0.081	0.602	1.000	0.799	0.799	0.799

a: cannot be computed because the standard deviations of both groups are 0.; CAP – Conventional Apical Preparation; ACT – Apical Clearing Technique; SD- Standard Error , * indicates $p<0.05$ statistically significant difference

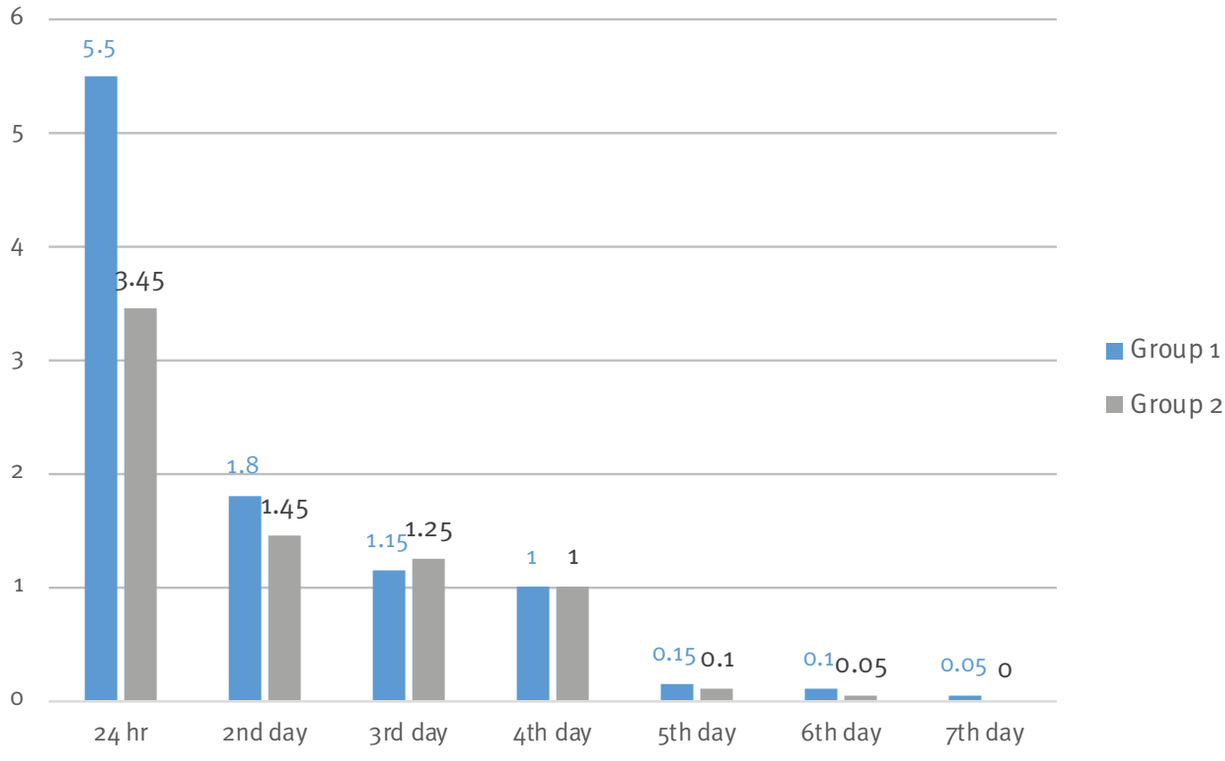
group). It was a split mouth study wherein bilateral teeth in the same patient were taken and hence there was no difference between the groups with respect to patient characteristics such as age, sex,gender and type of tooth. Table 1 gives details of the pain experienced by the patients in the two groups along with its statistical analysis. Figure 2 depicts the means of pain experienced by the patients in the two groups between 1st to 7th day. There was a statistically significant difference in the mean pain scores (p=0.003), intensity of pain (mild, moderate, severe) (p=0.024) and number of analgesic doses required (p=0.029) between groups 1 and 2 at 24 hrs interval, but after 24 hrs there was no statistically significant difference in either mean pain scores or intensity of pain.

Discussion

There is paucity of scientific information about apical clearing technique in the literature. Hence this split mouth, prospective; block randomized, double blind clinical trial was conducted to evaluate the post-operative pain associated with and without apical clearing technique in the mandibular molars with apical periodontitis.'Block randomization method' used for subject selection guaranteed a balance in sample size and ensured equal treatment allocation within each block. Double blinding was achieved by keeping subject as well as evaluator blind regarding the procedure. Selection of bilateral teeth in the same patient helped to standardize the study and isolatethe effect of apical clearing techniqueon pain by eliminating the perplexing effect of the patient perception about pain, tooth type and arch.

Molars are difficult to manage due to restricted access and the irintricate root canal anatomy [9]. Mandibular molars are at risk of developing pain that might help to assess the role of apical clearing on post-operative pain accurately [10]. Hence in the present study bilateral mandibular molars were selected. Teeth without any preoperative pain were taken into account during the study so as to eliminate any confounding bias in the evaluation of post-operative pain. Apical gauging is the measurement of the terminal diameter or shape of a canal after initial crown-down shaping and is used for determination of apical preparation size. It is recommended to pre-flare the coronal and middle thirds of root canal to determine the initial file that binds apically (Apical gauging). Hence in the presented study coronal pre-flaring was done in both the groups.

Thorough disinfection of the apical region, which is the critical zone for instrumentation, is an essential step in the cleaning and shaping process [11] Microorganisms penetrating the dentinal tubules in long standing infection remain untouched in conventional chemo-mechanical preparation and cause persistent peri-radicular inflammation. Removal of such intra-tubular pathogens needs deeper dentin removal. In conventional apical preparation,where apical canal diameter is enlarged three sizes larger than the first



Graph 1: Comparison of means of pain scores between groups 1 and 2 between 1st to 7th day

apical binding file, removal of circumferential heavily infected dentine is challenging [12,13]. Apical clearing technique was introduced by Walton and Torabinejad in 1989 [8]. It involves the sequential use of files two to four sizes larger than the master apical file (MAF) in a reaming motion at the established working length, copious irrigation followed by dry reaming using the largest apical file of the sequence. This technique has following advantages – it helps in removal of the existing and created soft tissue debris and dentin chips which are compacted in the apical region, it allows deeper placement of the irrigating needle, uniform enlargement in the apical region to facilitate obturation. It is effective in removing apical ramifications and results in decrease in colony forming units. These all factors together might have contributed to debris extrusion periapically. Hence apical clearing technique showed statistically significant post-endodontic pain at 24hrs. However between 2nd to 7th days, the difference in post-endodontic pain was not significant.

Analysis of postoperative pain is difficult as it is subjective in nature and is influenced by multiple clinical factors. However factors like age, sex, intensity of pre-operative pain, type of tooth were supervised in such a way that bias in the analysis of pain was eliminated. Subjects were selected from a similar education level as the education levels of the patients could affect the use of pain scales and the outcomes [14]. Present study cannot be generalized to teeth with vital pulps without apical periodontitis due to the specific nature of teeth included in the study.

Conclusion

Apical clearing technique in mandibular molars with apical periodontitis was associated with an increase in the risk of post-endodontic pain at 24 hrs. Also there was statistically significant difference in the dosages of analgesic required in both the groups at 24 hrs. However from the 2nd day, there was no statistically significant difference in any of these factors.

Declaration of interest

The authors declare no conflict of interest.

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