

Comparative evaluation of pre-treatment medication on post-instrumentation pain: Randomized control trial.

ABSTRACT:

Aims and Objectives: To comparatively evaluate, the effect of preoperative single dose, of paracetamol and ibuprofen on PIP, using two different rotary instruments.

Materials and Methods: 60 patients were randomly premedicated, with either paracetamol or ibuprofen and canal was instrumented, with either Hyflex or Protaper Gold files. PIP was evaluated at 6, 12, 24, 48 and 72 hrs.

Results: Lower incidence and intensity of PIP, occurred in patients, premedicated with Ibuprofen and where canal was instrumented with Hyflex.

Conclusion: Use of Ibuprofen, as a premedication during endodontic treatment, with Hyflex rotary instruments, decreases PIP.

Keywords: Post-instrumentation pain, Ibuprofen, Paracetamol, Hyflex File, Protaper Gold.

Introduction:

Elimination of pain, is the major objective for performing root canal treatment, since pain is the primary concern, for majority of patients, seeking treatment. Although it usually diminishes, after the endodontic treatment but some residual symptoms may persist or it may be precipitated, when there was none, at the start of the treatment.

This post endodontic pain, is usually due to the inflammatory mediators that activate sensitive nociceptors and lead to central and peripheral hyperalgesia mechanisms.[1] To manage this pain, various approach, have been recommended including occlusal reduction, use of intracanal medication, analgesics and the use of steroidal and nonsteroidal anti-inflammatory drugs.[2] Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, ketorolac, diclofenac etc. are the most commonly prescribed drugs, to prevent and eliminate this post endodontic pain. They act by inhibiting the cyclooxygenase enzymes and preventing the generation of new prostaglandin molecules, but they do not have any effect against the existing molecules in circulation.[3]

Post-instrumentation pain (PIP), during endodontic treatment is found to occur in about 10-30% of cases and depends upon the intensity of preoperative pain. It has been the general observation, that patients with preoperative pain, are more likely to experience, post-operative pain. Pre-treatment analgesia, in the form of premedication with NSAIDs, has been advised as an effective approach for such cases.[4] Hence this study was conceived, to comparatively evaluate the effect of preoperative single dose, of paracetamol and ibuprofen on post-operative pain, using two different rotary instruments. The null hypothesis for this study was that, there will be no difference in the PIP experience with paracetamol and

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ibuprofen, moreover, after instrumentation with Protaper Gold and Hyflex, it will be similar.

Materials & Method:

Patients who reported to Outpatient department of Conservative Dentistry and Endodontics, with chief complaint of pain in mandibular molars were considered and screened, for this study. After taking detailed history, patients were clinically examined and evaluated radiographically by taking RVG of the involved teeth. They were further subjected to cold test followed by EPT and percussion and palpation test. Based on predetermined inclusion and exclusion criteria (as given in Table 1), sixty healthy patients without any gender discrimination, diagnosed with symptomatic irreversible pulpitis with normal peri-radicular tissue, requiring endodontic treatment in mandibular first and second molars were included in the study.

Patients were explained about this study and asked, to sign an informed consent form. Permission for carrying out this study was granted by Ethic society of Teerthanker Mahaveer University.

Table 1 : Criteria for case selection	
INCLUSION CRITERIA	EXCLUSION CRITERIA
Age 20–40 years	Open apex
Symptomatic irreversible pulpitis with normal peri-radicular tissue	Systemic diseases, Pregnant or lactating patient
Sharp, shooting exaggerated or spontaneous pain	Internal/external root resorption
Source of pain could be identified	Cracked teeth
Lingering pain on cold test	Patient with known history of allergy to LA or any of test medication
Exaggerated response on EPT	Patient who took analgesic or antibiotic for same tooth in last 3 months
Tooth non tender percussion	Periapical radiolucency
Fully mature root with no defects	
Disrupted lamina dura with widened PDL space	

The selected 60 patients, were randomly divided into two groups. Block randomisation was carried out for group allocation. Randomization for premedication, was achieved by placing each odd patient to group 1 and even patient to group 2. In group 1 and 2, patients were administered Ibuprofen and Paracetamol, respectively as premedication drug.

Each of the 30 patients, in both groups, were asked to pick up a packet from a jar containing, 60 colour coded packets. These packets had either blue or red colour inside. Patients picking, blue colour packet, were placed in subgroup A and those who

picked red were placed in subgroup B. Protaper gold rotary files and Hyflex files were used, for root canal preparation in subgroup A and B, respectively. Patients were blinded and did not know the administered premedication, as well as the rotary instrument used, for their tooth. (Figure 1)

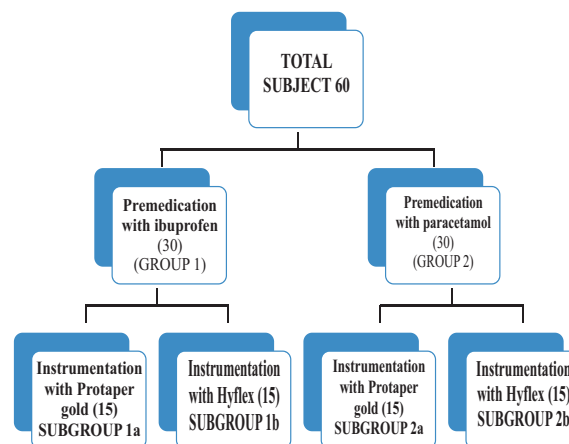


Figure 1: Grouping and Randomization of patients.

Prior to administration of premedication, each patient was asked to fill a questionnaire for assessment of pain. Premedication was administered, one hour before initiating the root canal procedure, according to the allocated group. After an hour of consumption of premedication, each patient was anesthetized using 2% lidocaine with 1:200,000 epinephrine, by way of inferior alveolar nerve block. Access cavity preparation was done after rubber dam application and working length of each canal was determined by using apex locator (Propex pixi, Dentsply) and confirmed by taking radiographs.

Cleaning and shaping of the root canal, was carried out in crown-down manner with either ProTaper gold or Hyflex rotary files, depending upon the allocated group. Following cleaning and shaping, dry cotton pellet without any medicament was placed in the pulp chamber and the access cavity was temporarily restored with temporary restorative material.

Patients were prescribed, a rescue analgesic to be taken only, as and when needed in cases of PIP. Each patient was handed a feedback evaluation form, to be filled at 6-, 12-, 24-, 48-, and 72-h intervals after root canal instrumentation. Patients were recalled after 72h for further treatment and feedback forms were collected. Assessment of the pain, pre-operatively and post-operatively was carried out, on the basis of the data filled by the patient, in the questionnaire. Heft parker scale was used for measuring the level of pain. (Figure 2)

Data was collected from the questionnaires and transferred to IBM SPSS software version 20.0 for statistical analysis. Comparison between groups was done based on one-way ANOVA, the chi-square and paired T-test. Significance level was kept at <0.0005 .

FIGURE 2 : HEFT PARKER EVALUATION SCALE

Department of Conservative Dentistry & Endodontics
PATIENT'S FEEDBACK & EVALUATION FORM

Comparative evaluation of different pretreatment anti-inflammatory medication on post-instrumentation pain using rotary instruments: randomized control trial.

- 1) Did you experienced any pain during:
 - a) 0.6 hours after the procedure YES / NO
 - b) 6-12h hours after the procedure YES / NO
 - c) 12-24h hours after the procedure YES / NO
 - d) 24-48h hours after the procedure YES / NO
 - e) 48-27h hours after the procedure YES / NO
- 2) If yes, what was the intensity of pain?

PATIENT'S NAME :- AGE :- DATE :-

PREOPERATIVE

0 23 23 54 85 114 144 170

6 HOURS

0 23 23 54 85 114 144 170

0 23 23 54 85 114 144 170

0 23 23 54 85 114 144 170

0 23 23 54 85 114 144 170

0 23 23 54 85 114 144 170

Results:

Patients experiencing pain, during the evaluation periods were considered as the failure, while those who did not experience any pain, were considered as success.

Higher success rate was achieved in patients, who were premedicated with Ibuprofen than Paracetamol. The success rate with Ibuprofen and Paracetamol ranged from 60-93% and 30-73%, respectively, at different time intervals. (Figure 3) There was significantly lesser intensity of pain, experienced following the use of ibuprofen as premedication, when compared to paracetamol across all time intervals. (Table 2)

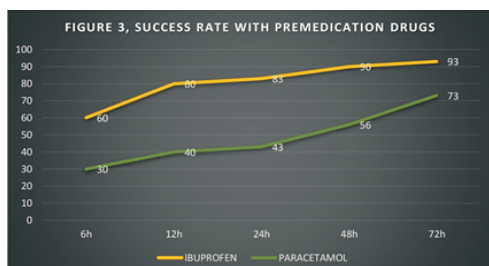


Table 2: Pain intensity at different time intervals.

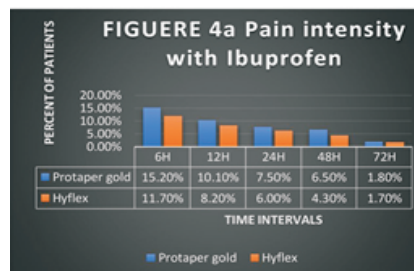
Time interval	IBUBROFEN	PARACETAMOL	
	Mean (SD)	Mean (SD)	p value
Preoperative	87.5 (± 15.97)	84 (± 15.34)	0.0025
6th	11.7 (± 2.13)	25.3 (± 4.62)	0.0029
12th	5.5 (± 0.03)	17.4 (± 3.18)	0.000
24th	4.7 (± 0.86)	13.5 (± 2.46)	0.0120
48th	2.7 (± 0.49)	9.2 (± 1.68)	0.0333
72th	1.9 (± 0.35)	5.7 (± 1.04)	0.0289
T statistic	40.783	22.048	
95% CI	106.220 to 121.7780	144.5251 to 165.6749	

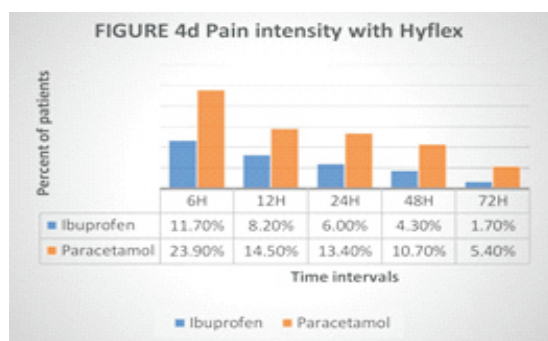
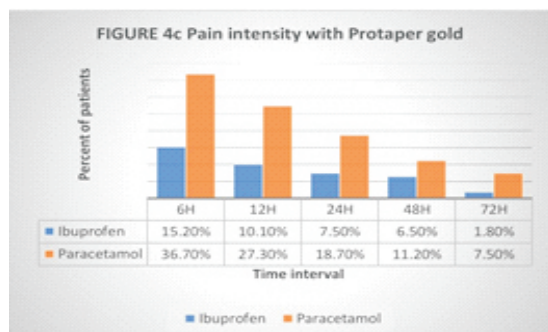
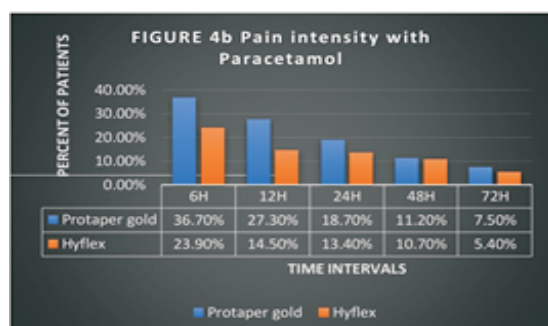
Hyflex rotary files, resulted in higher number of successful cases compared to Protaper gold, irrespective of the premedication agent used. Pain intensity was also found to be higher with Protaper gold, at almost all the time intervals. There was no statistical difference in pain intensity (mean intensity 1.53) at 72h between Protaper and Hyflex rotary files, when ibuprofen was used as premedication agent. Similarly, no statistical difference in pain intensity (mean intensity 9.2) was found, at 48h between Protaper and Hyflex rotary files, when paracetamol was used as premedication agent. (Table 3)

Table 3: Comparison of pain intensity with premedication drugs and different rotary instruments at different time intervals.

	PROTAPER	PROTAPER	HYFLEX	HYFLEX
Time intervals	Ibuprofen	Paracetamol	Ibuprofen	Paracetamol
Preoperative	84 (± 8.93)	81.93 (± 15.5)	91 (± 10.15)	85.93 (± 11.46)
6th	12.8 (± 2.55)	30.1 (± 2.24)	7.53 (± 2.69)	20.5 (± 2.87)
12th	8.53 (± 2.70)	22.4 (± 3.08)	5.46 (± 2.65)	12.46 (± 2.96)
24th	6.34 (± 2.73)	15.3 (± 3.15)	3.93 (± 2.4)	11.6 (± 2.97)
48th	5.46 (± 2.74)	9.2 (± 1.19)	2.4 (± 2.53)	9.2 (± 3.0)
72th	1.53 (± 2.79)	6.13 (± 3.25)	1.53 (± 2.70)	4.6 (± 3.05)
T statistic	29.221	12.038	29.174	16.395
Sig level	<0.0005	<0.0005	<0.0005	<0.0005
95% CI	106.1778 TO 131.1422	148.9394 TO 181.1806	98.2029 TO 124.2971	129.7366 TO 158.8434

With the passage of time, the PIP experience, declined in both incidence and intensity, irrespective of the premedication drug and rotary instrument use, which was statistically significant. (Figure 4a, 4b, 4c, 4d)





Discussion:

Elimination of PIP, is one of the major challenges during endodontic treatment.¹³ Occlusal reduction, use of intracanal medication, analgesics, nonsteroidal anti-inflammatory drugs are some of the commonly suggested remedies, towards this end. ¹³ NSAIDs block the COX pathways and their use as premedication drug, can prevent the pain sensation even before it begins.¹⁵ Ibuprofen and paracetamol, are the most widely prescribed drugs, during endodontic treatment. Hence, it is natural that, they be used as premedication, for prevention of PIP. Hyflex and Protaper gold file systems, are being used, quite widely for canal preparation, with successful outcome. ¹⁹ Hence these were comparatively evaluated, in this trial.

In the present study, Ibuprofen proved to be more successful, in reducing the incidence of PIP, over Paracetamol and the finding was statically significant. This is in keeping, with the

findings of studies by Mokhtari et al [4] and Parirokh et al.[11] The onset of action of ibuprofen, takes 30 min, with the peak serum concentration being attained after 1-2 hours. It works by inhibiting the production of prostaglandins, by decreasing the activity of cyclooxygenase. It is a nonselective COX inhibitor.[4] The analgesic and anti-inflammatory activity is mainly through inhibition of COX-2. Paracetamol works similar to Ibuprofen, by blocking the production of prostaglandins and COX enzymes.[11] Both these drugs are indicated for mild to moderate pain, but the analgesic and anti-inflammatory effect of Ibuprofen is higher than Paracetamol.[4]

On the contrary, Juliana et al in a review, found no evidence supporting ibuprofen as better premedication agent than other drugs, in reducing the risk and intensity of post-endodontic pain.[14] Ibuprofen being an NSAID, has been established, as the preferred drug, in various studies for post-endodontic pain, being safe, cost effective, possessing excellent analgesic and anti-inflammatory action. [14]

During the canal preparation, nearly all employed instrumentation techniques and file systems, result in extrusion of canal contents. That may include dentinal chips, microorganisms, pulpal tissue remnants, irrigating solutions, or necrotic tissue, resulting in inflammation. Amount of extrusion, varies with the instrument used, thus potentially, affecting the intensity of PIP. [17]

In our study, Protaper gold rotary files resulted in higher incidence and intensity of PIP, compared to Hyflex rotary files, irrespective of the premedication agent used. This could be because of differences in the design of the two file systems, thus resulting in higher apical extrusion and in turn higher incidence and intensity of PIP with Protaper Gold.

Burklein et al found more apical debris extrusion after canal preparation with Protaper instruments, as they have three cutting edges. Protaper has triangular cross-section, that results in a lower cutting efficiency and this design enhances debris transportation toward the apex when used in combination with a reciprocal motion.[19] Chaudhury et al reported that Protaper Gold system owing to its off-centred mass and centring ability, ensures a greater percentage of dentin thickness retention in root canal, facilitating higher bacterial elimination. The convex triangular cross-section and progressive taper, enhance cutting efficacy of Protaper gold while decreasing rotational friction, between the blade and dentin, leading to increased apical debris extrusion.²⁰

Alani et al also reported, higher debris extrusion with Protaper system, due to convex triangular cross-sectional design and multiple taper within the shaft, that cuts the dentine more effectively, with increased risk of debris and irrigants extrusion. The long pitch design and taper, of the Protaper instruments, favours the early preparation of the apical third, causing greater apical extrusion of the debris. [22]

Surakanti et al found that Protaper rotary files, produced significantly more debris compared with Hyflex CM rotary instruments. They attributed this finding, to the cross-sectional designs of the instruments, as the cutting profile of Hyflex files, facilitates penetration in the canal and presents a root canal shape corresponding with the original anatomy [18] Labbaf et al reported significantly less apical debris extrusion with Hyflex system, attributing this to the unwinding of the spirals of Hyflex, that occurs during instrumentation. This phenomenon may lead to decreased cutting ability and cleaning efficiency, which results in lesser production of dentinal chips and debris and thus, less extrusion of debris.[23] On the contrary, a study by Caper et al proposed that the unwinding of the spirals of Hyflex instruments, during root canal preparation, results in lengthening the pitch and thereby causes increased apical extrusion of debris.[20]

The higher potential of debris extrusion with Protaper Gold instruments, may be the reason for higher incidence and intensity of PIP, reported with the use of these instruments, in our study. Thus, both parts of the nulls hypothesis for this study, stand rejected.

Conclusion:

Administration of Ibuprofen, as a premedication during endodontic treatment, can reduce the post-instrumentation pain more effectively than Paracetamol. Use of Hyflex rotary instruments, lead to lesser post-instrumentation pain than with Protaper Gold.

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