Effectiveness of Single Dose Premedication of Piroxicam and Prednisolone on Post Endodontic Pain in One Visit Root Canal Treatment: A Randomized Trial

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Original Article

EFFECTIVENESS OF SINGLE DOSE PREMEDICATION OF PIROXICAM AND PREDNISOLONE ON POST ENDODONTIC PAIN IN ONE VISIT ROOT CANAL TREATMENT: A RANDOMIZED TRIAL

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ABSTRACT

BACKGROUND

Many approaches have been investigated for pain relief after root canal procedure. In this study we compare the effectiveness of premedication drugs, given single dose Piroxicam and Prednisolone separately to evaluate post endodontic pain at different time intervals (24, 48, 72 and 96 hours) using visual analog scale (VAS) after single visit root canal treatment.

METHODS

Total number of 120 patients identified with symptomatic irreversible pulpitis were made part of this research after signing informed consent. The pain intensity levels were marked through the use of VAS scale before the commencement of treatment. The participants were randomly placed in three groups (n=40) Group I: Control, Group II: Piroxicam (20 mg) and Group III: Prednisolone (20 mg). The drugs were administered thirty minutes before endodontic procedure was initiated. Root canal procedure was carried out followed by placement of provisional restoration on a single appointment. The patients were advised to continue marking their pain intensity levels after 24, 48, 72 and 96 hours using VAS. All patients were called for follow up after 4 days for clinical evaluation and placement of permanent restoration. The effectiveness of each drug over different time interval was studied employing repeated measure ANOVA. The significance level was considered p-value <0.05.

RESULTS:

Administration of pre-medication drug therapy with Piroxicam and Prednisolone was able to successfully alleviate post-endodontic pain. However, the long term effectiveness (96 hours) of both drugs to reduce post-endodontic pain was observed to be statistically insignificant.

CONCLUSION:

Pre-medication with either single dose Piroxicam and Prednisolone was found to be effective against post-endodontic pain, in patients presenting with symptomatic irreversible pulpitis.

TRIAL REGISTRATION: This single blinded, randomized clinical trial [registration no. NCT04124822(11/10/2019)] was performed in Operative Dentistry department of Dr. Ishrat-ul-Ebad Khan Institute of Oral Health Sciences.

KEYWORDS: Piroxicam, Prednisolone, Post-endodontic pain, Pre-medication

BACKGROUND:

Management of post endodontic pain (PostEP) is still a problem and a topic of interest (1). The tooth is restored by taking out the inflamed or necrotic pulp tissue and sealing the root canal system against the bacterial recontamination. However, at times pain relief is not instant and permanent (2, 3). There is a possibility of residual symptoms which can be attributed to the effects of inflammation regarded as PostEP. Roughly 25-69% patients reported moderate to severe post-operative pain. (2,4,5). Mild endodontic pain rarely lasts and is mostly handled with anti-inflammatory drug (NSAID or acetaminophen) (4, 5). Studies report that a preoperative symptomatic patient will experience moderate to severe pain 47-60% in the first 24 hours and 16–24% of patients at 72 hours (6).

Many approaches have been investigated for pain relief after root canal procedure. For example, pharmacological strategies such as narcotics, analgesics, intra-canal and systemic glucocorticosteroid (GCS), non-steroidal anti-inflammatory drugs (NSAIDs), long action anesthetics, antibiotics, trephination, occlusal reduction and hypnosis (7, 8). Many drugs have been tried and tested for the management of Post EP. The most commonly preferred drugs are NSAIDS and streroids or the combinations of these two (7).

Moreover studies have reported that making multiple appointments or using various intracanal medications have showed no significant reduction in post endodontic pain relief. (11, 12). Therefore, the newer models of pain control are more focused on using preventive measures, to control pain before the procedure which ultimately helps in reducing the post-operative pain. (13). In addition, studies have concluded that preoperative and postoperative pain shows strong relationship (9). Rationale of administration of preemptive analgesia is to allow the clinician to

extend the analgesic effect of the drug via prevention of peripheral sensitization (7, 8). Additionally, a single dose of anti-inflammatory drug administered before the procedure releases inflammatory mediators to combat with acute inflammation and reduces side effect commonly noticed with repeated drug dose regime during post-operative period (10, 11).

Traditionally, in order to relief postoperative pain, administration of local anesthesia was the preferred technique. Though the teeth with irreversible pulpitis, always shows difficulty in achieving effective anesthesia (12). Therefore, nowadays oral administration of drugs is a preferred clinical technique to manage patients` pain. The procedure holds the advantage of being convenient and effective which reduces patient anxiety and discomfort (13, 14). NSAIDs has the ability to inhibit PG synthesis and effectively lower pain threshold levels; making them the gold standard against which the efficacy of other analgesic drugs are evaluated (15).

Recent study conducted on pain control in 2017 by Parveen et al have reported that ketorolac group (short acting NSAID) showed significant reduction in pain scores till 6 hours; achieving peak analgesia in 2 to 3 hours. However, the drug failed to provide pain relief for longer duration when compared to Prednisolone (corticosteroid); which provided pain relief up to 12 hours (16). Similar results were observed when the efficacy of single pretreatment dose of Prednisolone was compared with placebo or ketorolac. Prednisolone showed to be more effective in alleviating Post EP compared with the other drugs (10, 17).

Numerous studies conducted have favored the use of Prednisolone over other groups as it is able to provide longer therapeutic effect (17, 18). This advantageous property is due to its longer half-life of 12 to 36 hours and the ability of the drug to reach peak plasma level in 1-2 hours (17, 19). Piroxicam is a nonselective NSAID, its half-life is 50 hours and it reaches peak level 1.5 to

2hours after oral administration. NSAID inhibits PG synthesis by slowing down the activity of the enzyme, COX-1 and COX -2 (19).

This study aims to evaluate the effect of preemptive drug on pain control. The effectiveness of long acting corticosteroid against long acting NSAID was evaluated up to 96 hours in order to determine the best pharmacological agent for the management of post-endodontic pain control

METHODS

This single blinded randomized clinical trial was conducted in the Department of Operative Dentistry at Dr. Ishrat-ul-Ebad Khan Institute of Oral Health Sciences (DIKIOHS) at Dow University of Health Sciences (DUHS). Patients of ages from 20-40 yrs, single rooted tooth diagnosed with symptomatic irreversible pulpitis with VAS score 5-10 and healthy periapical area, having negative history of painkillers administrated with 7 days before procedure were included in the study. Patients with any systematic problem, allergic to NSAIDs and/or Corticosteroids, Pregnant or lactating and previously treated/initiated root canal treatment were excluded from the study.

Non-probability (purposive) sampling technique was used for patient recruitment. Simple random method was used for group allocation via computer software (MS Excel).

Sample size was calculated using PASS version 11, paired sample t- test with 99% confidence interval and power of the test. Taking the mean and standard deviation, [23] the calculated sample size was 15 per group, which was increased up to 40 patients per group. Patients were divided into three groups: group 1 received no medication (control), group 2 received Piroxicam and group 3 received prednisolone. Therefore, total sample size for this study was 120 patients.

For ethical consideration approval was obtained from Institutional Review Board at DUHS (Ref: IRB- 142/DUHS/Approval/2018/54). The research was also registered with the clinical trial registry[Reg. No. NCT04124822(11/10/2019)]. As for confidentiality and anonymity of patient's data, verbal and written consents were taken with written consent form.

The diagnosis of symptomatic irreversible pulpitis was made from the chief complaint as well as the clinical examination. Pre-operative pain was the main diagnostic sign of symptomatic irreversible pulpitis. Pulp sensitivity was confirmed by a positive response to an electric pulp test and a prolonged exaggerated response (>10 s) with moderate-to-severe pain to a cold test, using ethyl chloride spray. After obtaining informed consent (verbally and written), baseline pain score using Visual analog Scale (VAS) was recorded for the patient on the proforma.

Patients were randomly divided into following 3 groups; with an equal sample of 40 patients (n=40) in each group. Group I: Control, Group II: Piroxicam (20 mg), Group III: Prednisolone (20 mg).

Patients allocated in control group did not receive any medication before root canal therapy was initiated whereas patients allocated in groups II and III received Piroxicam and Prednisolone respectively, 30 minutes before the procedure.

A random sequence of the participants was generated via computer software (MS Excel). A certified dental hygienist was responsible for administration of the pre-medication protocol for each patient before commencement of root canal therapy. To ensure blinding protocol, grouping was not revealed to the principal investigator till the end of the study.

Root canal treatment (RCT) was initiated 30 minutes after the administration of pre-medication. A second reading of pain score was recorded on the proforma before the RCT procedure was carried out.

An emergency drug (ibuprofen, 200mg) was prescribed to the patient at the end of the RCT procedure. The patients were instructed to take the drug only if they experience moderate-severe pain within 96 hours. The patients who took the rescue drug were excluded from the study.

For the assessment of pre-operative and post-endodontic pain (up to 96 hours) was measured using the visual analog scale (VAS). The scale consists of a 10-cm line fixed by 2 extreme ends, ‘‘no pain’’ and ‘‘severe pain.’’ The scale is divided into mild, moderate and severe categories as below (20):

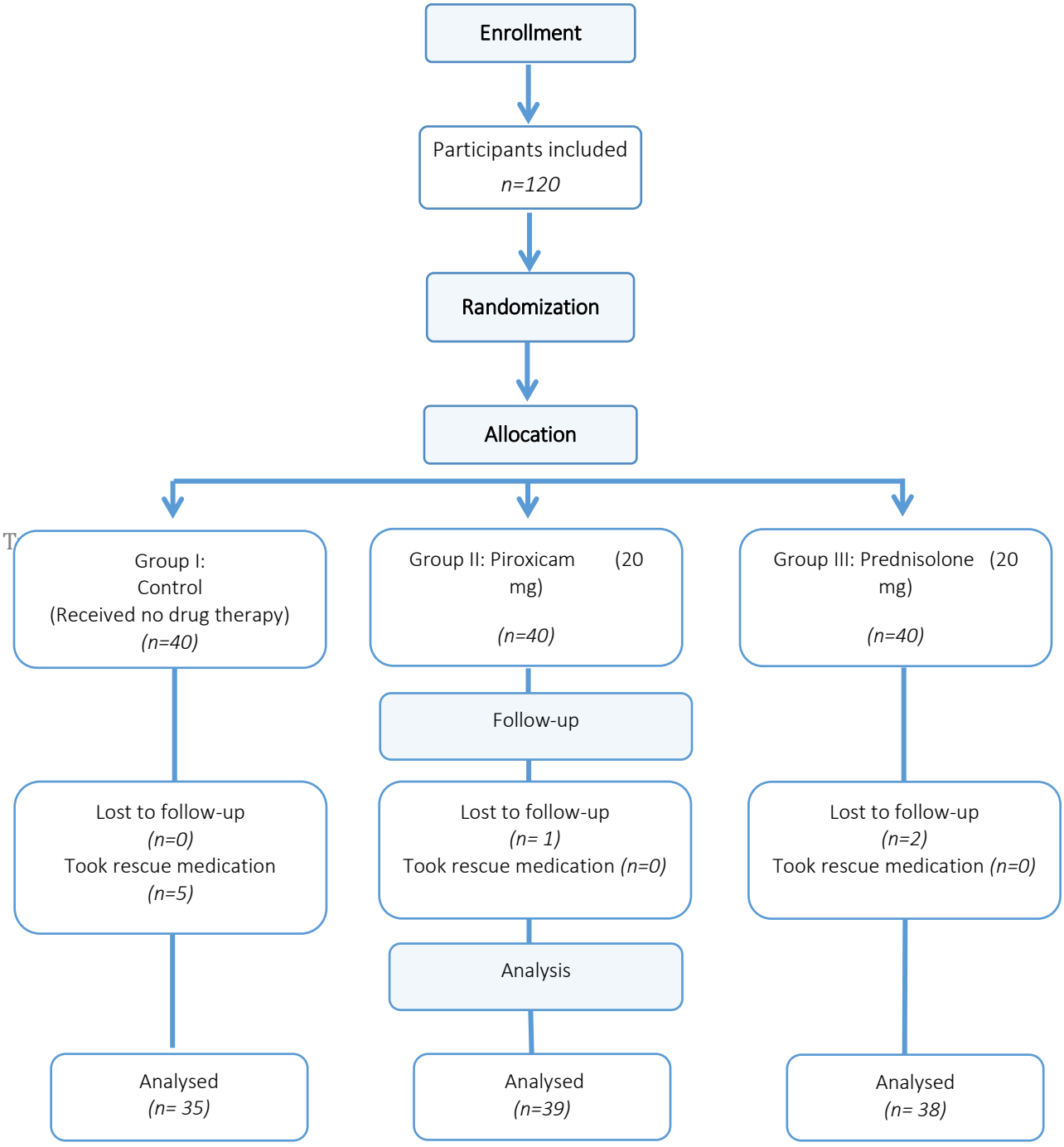
- No pain : range of 0-1
- Mild pain: range of 2-4
- Moderate pain : range of 5-7
- Severe pain : range of 8-10

Patients were thoroughly educated about the questionnaire and asked to mark their pain intensity level at 24, 48, 72 and 96 hours after the procedure. Follow up was taken on call or by message. All patients were re-called for follow up after 4 days for a clinical and radiographic evaluation and placement of core buildup by the principal investigator.

Data was entered and analyzed using SPSS version 23 (Chicago IL). Demographic and clinical variables (such as age, gender and tooth type) were analyzed using descriptive statistics. Paired sample t-test was used for intra-group comparison between all study groups. For inter-group

comparisons ANOVA was used followed by Ducan and LSD post-hoc tests. A confidence interval of 95% and p-value of < 0.05 was considered significant.

Figure 1: Consolidated standard of reporting trials (CONSORT) flowchart of participants throughout the trial



Results:

Out of 120 patients treated, 3 patients were excluded due to loss on follow-up and 5 patients took ibuprofen as a rescue drug before the 92 hour time interval; as they experienced severe post-operative pain. Therefore, the sample size after exclusion of the above mentioned 8 patients were as follows: n=35 patients in group I (control), n=39 patients in group II (Piroxicam) and n=38 patients in group III (Prednisolone) (Figure 1).

The demographic and clinical data regarding the distribution of age range, gender and tooth type is shown in Table 1. There was no significant difference in demographic data in terms of age ($P = 0.14$), gender ($P = 0.12$), whilst tooth type ($P = <0.001$) showed statistically significant value.

The results of the present study revealed that a higher percentage of patients in all 3 groups, reported no post-operative pain at all evaluated time durations (24, 48, 72 and 96 hours).

At 24 hour interval, participants in group I (Control) showed 3.4% moderate pain while 13.8% patients with severe pain.In group II(piroxicam) showed no moderate to severe pain and in group III (prednisolone) only a small population of 7% showed postoperative severe pain.

At 48 hour interval, patients in group I (control) showed moderate pain in 3% and severe pain in 10.6% of the patients. While in group II (piroxicam) patients showed no pain and in group III (prednisolone) 7% of the patients experience mild pain only.

At 72 hour interval, group I (control) 10% patients showed severe pain post operatively. While in group II (piroxicam) and III (prednisolone) patients showed no moderate to severe pain. At 96 hour interval, group I (control) 7.4% of the patient showed severe Post EP. In contrast, group II (piroxicam) and III(prednisolone) showed no moderate to severe pain.

Thus the bar charts representing pattern of pain intensity levels of patients at different time intervals are shown in Figures 2 – 5

The present study also compared pre and post-medication pain intensity scores within each group. The results of the study showed substantial decrease in the pain intensity level in patients administered Piroxicam and Prednisolone ($p = <0.001$), where as in group I, p-value could not be calculated as there is no difference in its mean and standard deviation (table 2).

The pre and post-EP scores between control and experimental groups was also evaluated; statistically significant results were noted between groups I and II at 24,48 and 72 hours, whereas significant differences were recorded between group I and III at 72 hours only as shown in table 3)

Table 1: Data regarding the demographic and clinical variables of the study

Variables	Total *n =112*	Group I (Control) *n =35*	Group II (Piroxicam) *n =39*	Group III (Prednisolone) *n =38*
Age (years)				
20- 27	31	8	8	15
28-34	29	7	12	10
35-40	52	20	18	14
Gender				
Female	71	22	28	21
Male	41	13	10	18
Tooth type				
Incisors	21	2	12	7
Canine	15	3	9	3
Premolar	76	30	17	29

Figure 2: Bar chart representing the pattern of pain intensity scores at 24 hours interval of participants in all study groups

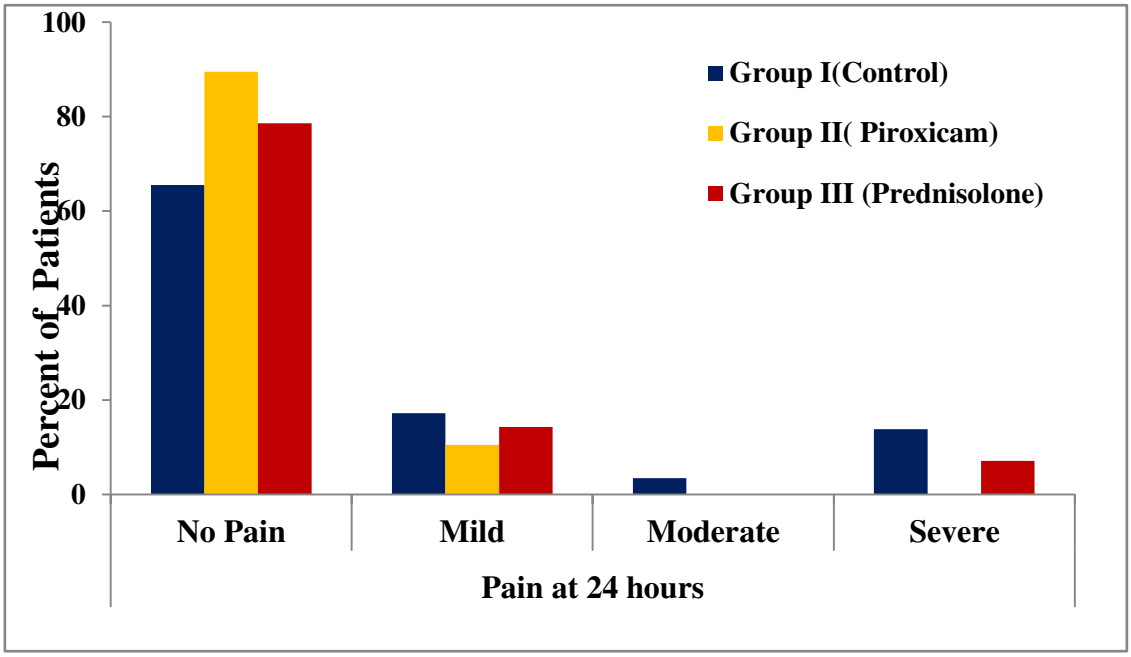


Figure 3: Bar chart representing the pattern of pain intensity scores at 48 hours interval of participants in all study groups

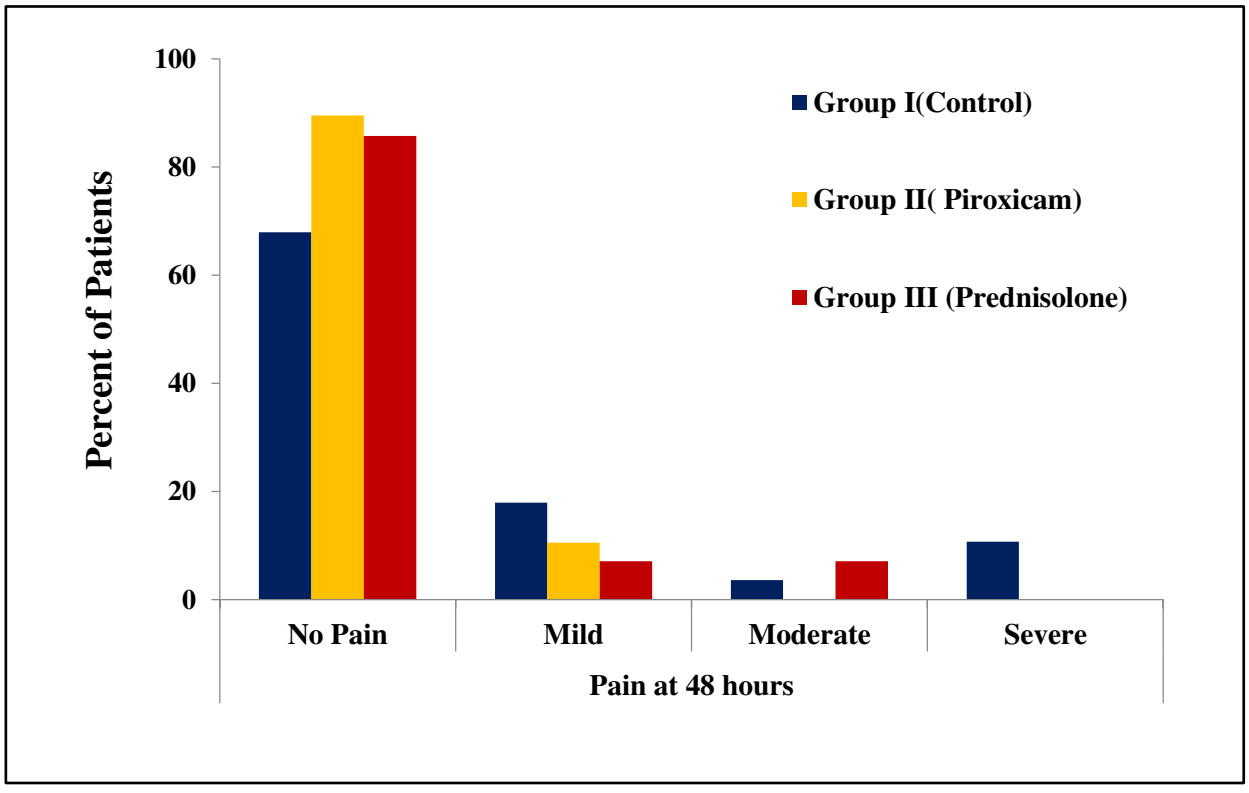


Figure 4: Bar chart representing the pattern of pain intensity scores at 72 hours interval of participants in all study groups

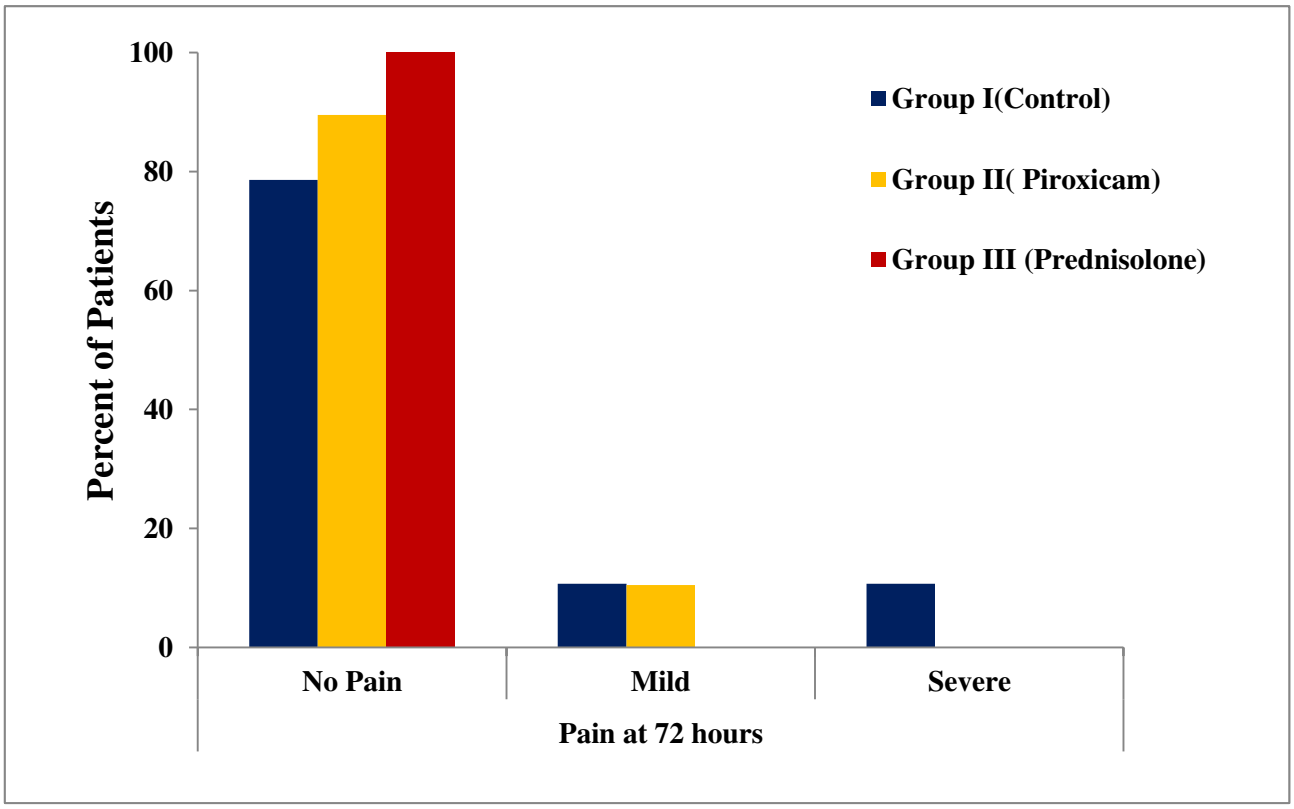


Figure 5: Bar chart representing the pattern of pain intensity scores at 96 hours interval of participants in all study groups

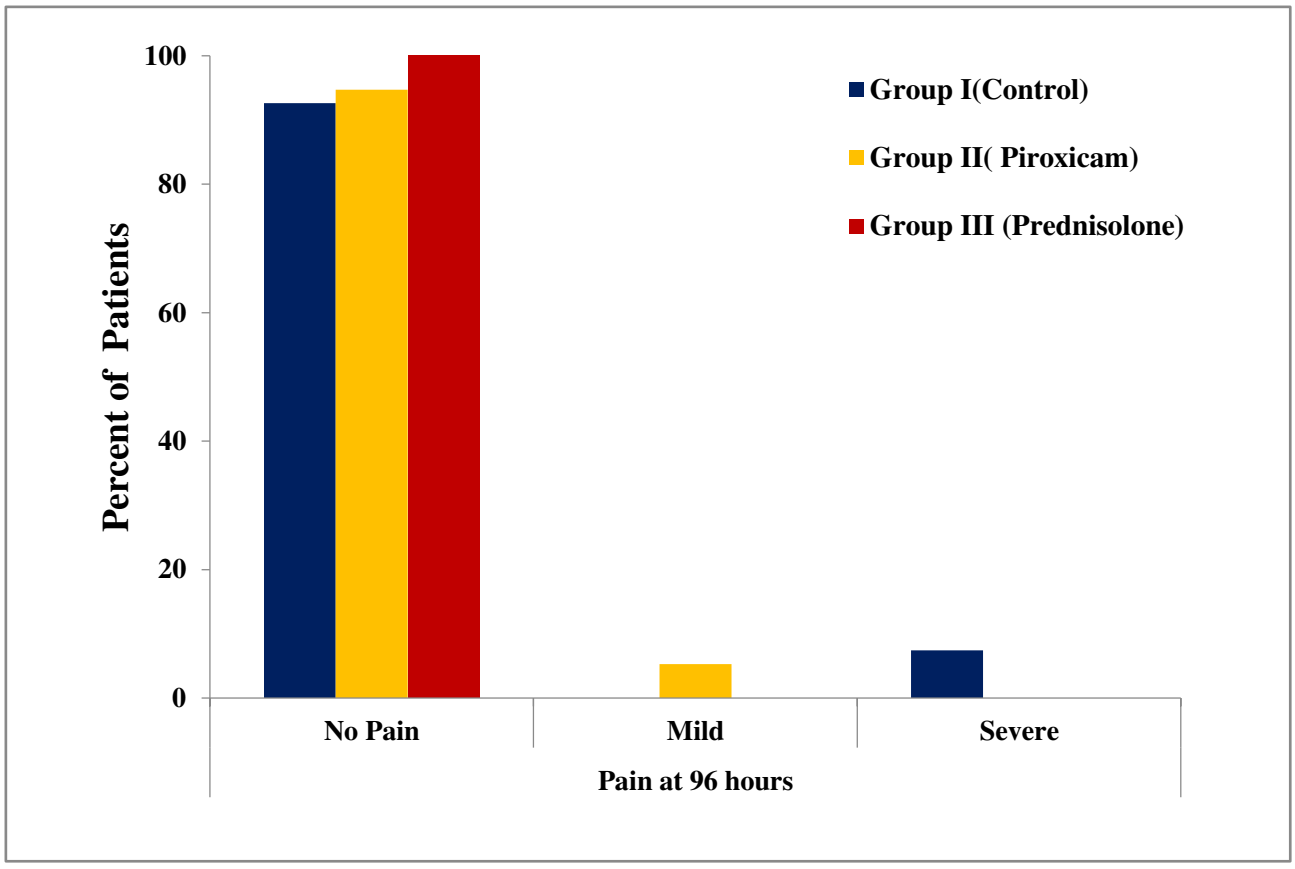


Table 2: Intra group comparison of VAS score Pre and Post medication.

	Visual Analog Scale (VAS) scores		
Groups	**Pre- medication**	**Post-medication**	
	Mean ± SD	**Mean ± SD**	**p-value***
Group I (Control)	8.48 ± 2.42	8.48 ± 2.42	-
Group II (Piroxicam)	8.63 ± 1.14	0.36 ± 0.94	<0.001
Group III (Prednisolone)	8.51 ± 1.44	0.10 ± 0.44	<0.001

*Paired sample t-test; level of significance <0.05

Table 3: Inter-group comparison of Visual Analog Scale (VAS) score at different time intervals

Time Intervals	Group I (Control)	Group II (Piroxicam)	Group III (Prednisolone)		Significant differences at Post-hoc**
	Mean ± SD	Mean ± SD	Mean ± SD	p-value*	
Pre-medication (30 mins)	8.48 ± 2.42	8.63 ± 0.14	8.51 ± 1.44	0.96	-
Post-medication (30 mins)	8.48 ± 2.42	0.36 ± 0.94	0.10 ± 0.44	0.075	-
24 hours	1.79 ± 0.40	0.26 ± 0.13	0.79 ± 0.40	0.007	I-II
48 hours	1.39 ± 0.36	0.21 ± 0.10	0.5 ± 0.30	0.014	I-II
72 hours	1.07 ± 0.35	0.16 ± 0.08	0 (0)	0.013	I-II, I-III
96 hours	0.67 ± 0.33	0.11 ± 0.07	0 (0)	0.129	-

*ANOVA; level of significance <0.05;

** Post-hoc Duncan and LSD test

DISCUSSION

Anticipation and experience of pain related to endodontic therapy (pretreatment, treatment, and post-treatment pain) is a major source of fear for patients and concern for dentists. Immediate pain relief increases patient confidence and reduces treatment anxiety and time.(21) It is reported that single dose of drug reduces the chances of adverse effect, as it can modulate the release of inflammatory mediators and reduce the occurrence of side effects compared with repeated drug doses during the post endodontic period (22). Previous studies on endodontic pain perception have measured pain levels directly at 6 hours interval after single visit endodontic treatment, which can be influenced by residual anesthetic effect. (23) where as this study was conducted to compare the long term efficacy of single dose premedication of Piroxicam and Prednisolone on post EP in one visit root canal treatment using visual analog (VAS) scale. Moreover, the VAS score of all three groups before the administration of anesthesiawere compared.

It was observed in the present study that patients in groups II and III did not take any rescue medication but in group 1 few patients took rescue medication; this further validates the importance of preoperative drug administration.Similar findings were also reported in previous studies suggesting the administration of Single oral premedication was beneficial to control post EP (22, 24)

In the current study significant difference in pain intensity levels were observed between group I (control) and group II (piroxicam) at different time intervals. Similar results were found in other studies which reduced post EP up to 48 hours as compared to placebo (21, 25). On contrary, a study by Parveen et al showed preoperative administration of Oxicams resulted in an insignificant reduction in postoperative analgesic consumption (26)

In the present study significant difference in pain intensity levels were observed between group I (control) and group III (prednisolone) at 72 hour interval only (table 3). During the entire 96 hour evaluation time period patients who received Prednisolone only experienced moderate pain during the initial 48 hours only, after which pain levels reduced significantly to no pain level (with Mean ± SD = 0) at 96 hour interval. Similar results were reported by previous authors, who showed effective reduction in post EP up to 48 hour interval ,using corticosteroid when used preoperatively.(27)

In the present study insignificant differences were observed between group II (Piroxicam) and group III (Prednisolone) at all-time intervals (table 3), therefore null hypothesis of the study was accepted. This finding suggests that both drugs reduce post EP to similar levels and carry similar efficacy and potency with anti-inflammatory activity for long term intervals.(26, 28)

A randomized, blinded, single center study design was chosen for the present study to minimize bias and allow powered study comparisons between the groups. The adaptation of a single-center, randomized controlled trial with large sample size and a single operator not only reduces bias but also allows generalization of the study results (24).

In this study, Negative placebo was used as control group in the study following the conventional method of root canal treatment to exclude psychological bias from the study . Studies showed that placebo has some amount of psychological effect on pre and post EP.(26)

Single centered study model with single rooted toth and subjective assesment of irreversible pulpitis were few of the limitations of the study. Hence, it is recommended further long term, multi-centre studies should be conducted to assess the clinical efficacy of premedication on teeth presenting with different pulpal diagnosis using multi-rooted tooth. Other methods of pain

assessment should be used and compared with VAS scale, which remains the gold standard method in research for assessing patient pain levels.

CONCLUSION

Premedication with single dose of 20 mg prednisolone or piroxicam was effective for the control of postoperative endodontic pain up to 96 hours after single-visit root canal treatment, in patients with symptomatic irreversible pulpitis.

DECLARATIONS

Ethics approval and consent to participate

- Ethical Approval was obtained from Institutional Review Board at DUHS. (Ref: IRB-142/DUHS/Approval/2018/54)
- The research was also registered with the clinical trial registry (Reg. No. NCT04124822) on 11/10/2019
- Informed consents were taken from the patients
- All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

- Not applicable .

Availability of data and materials

- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

- The authors declare that they have no competing interests.

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- the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript all covered by corresenponding author.

Authors' contributions

A.T conceived and planned the experiments. S.A and U.W carried out the experiments and compute them.A.T and H.A contributed to the interpretation of the results. M.S and D.S took the lead in writing the manuscript. All authors provided critical feedback and helped shape the research, analysis and manuscript.

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Figures

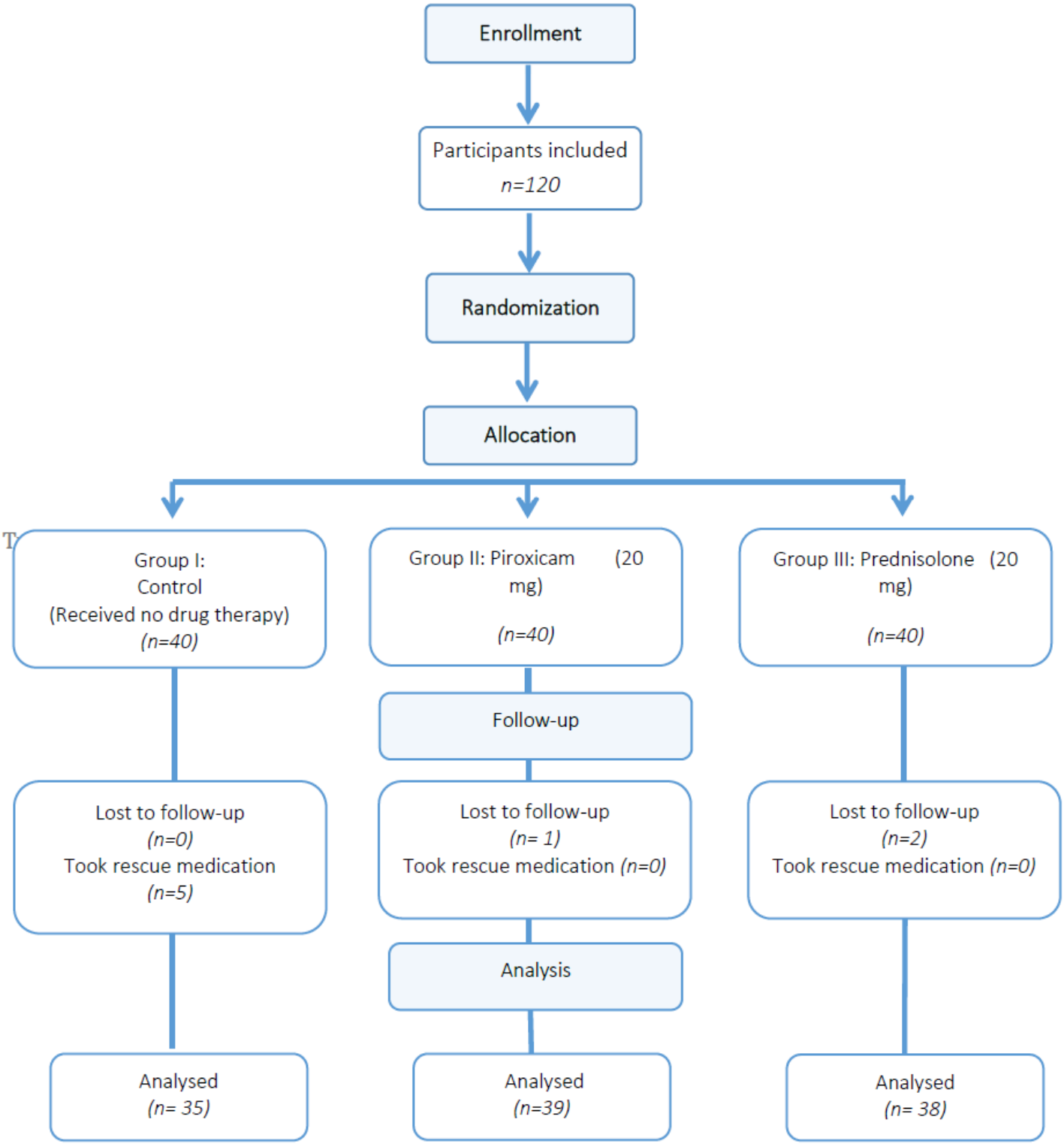

Figure 1

Consolidated standard of reporting trials (CONSORT) flowchart of participants throughout the trial

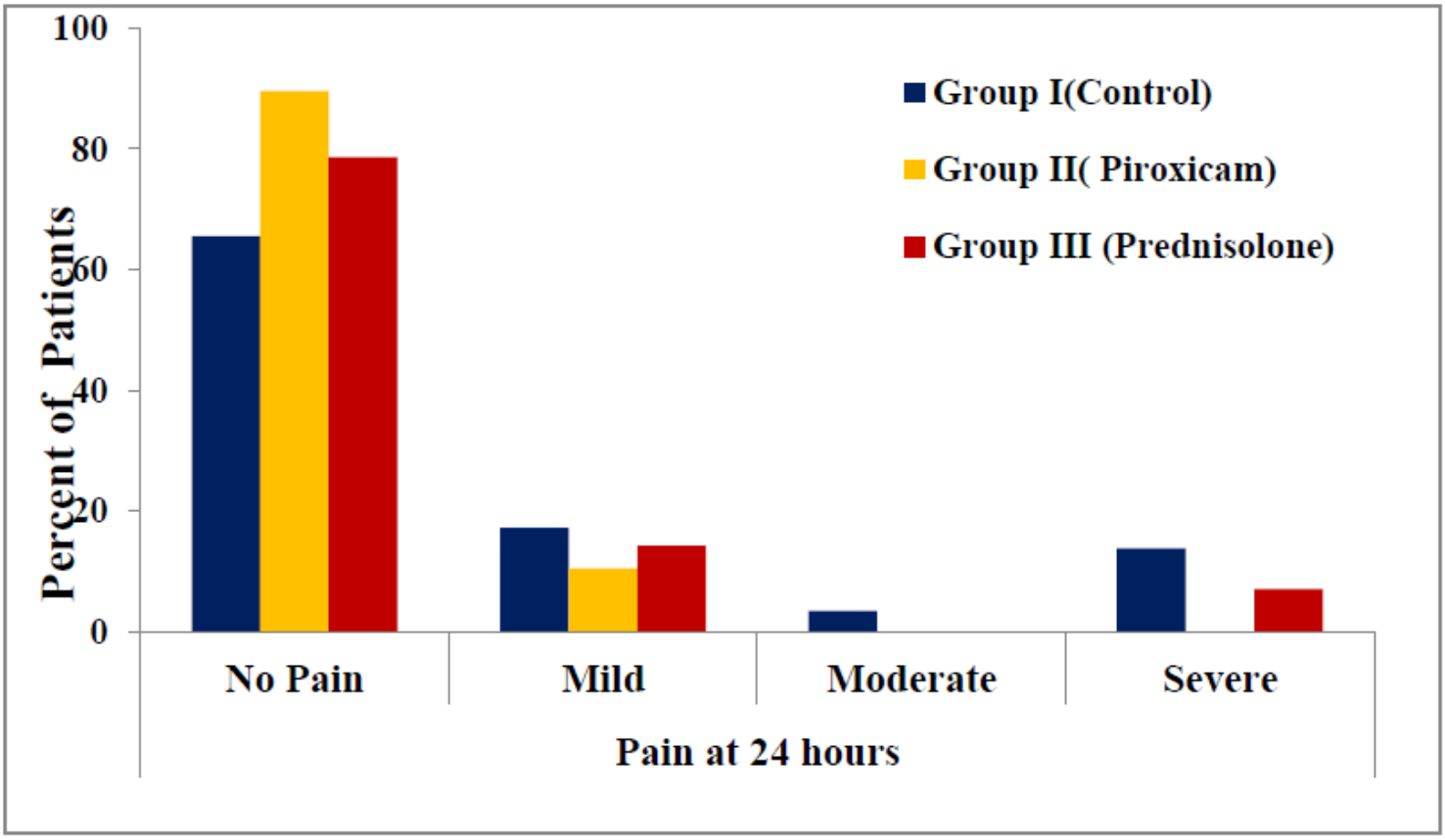

Figure 2

Bar chart representing the pattern of pain intensity scores at 24 hours interval of participants in all study groups

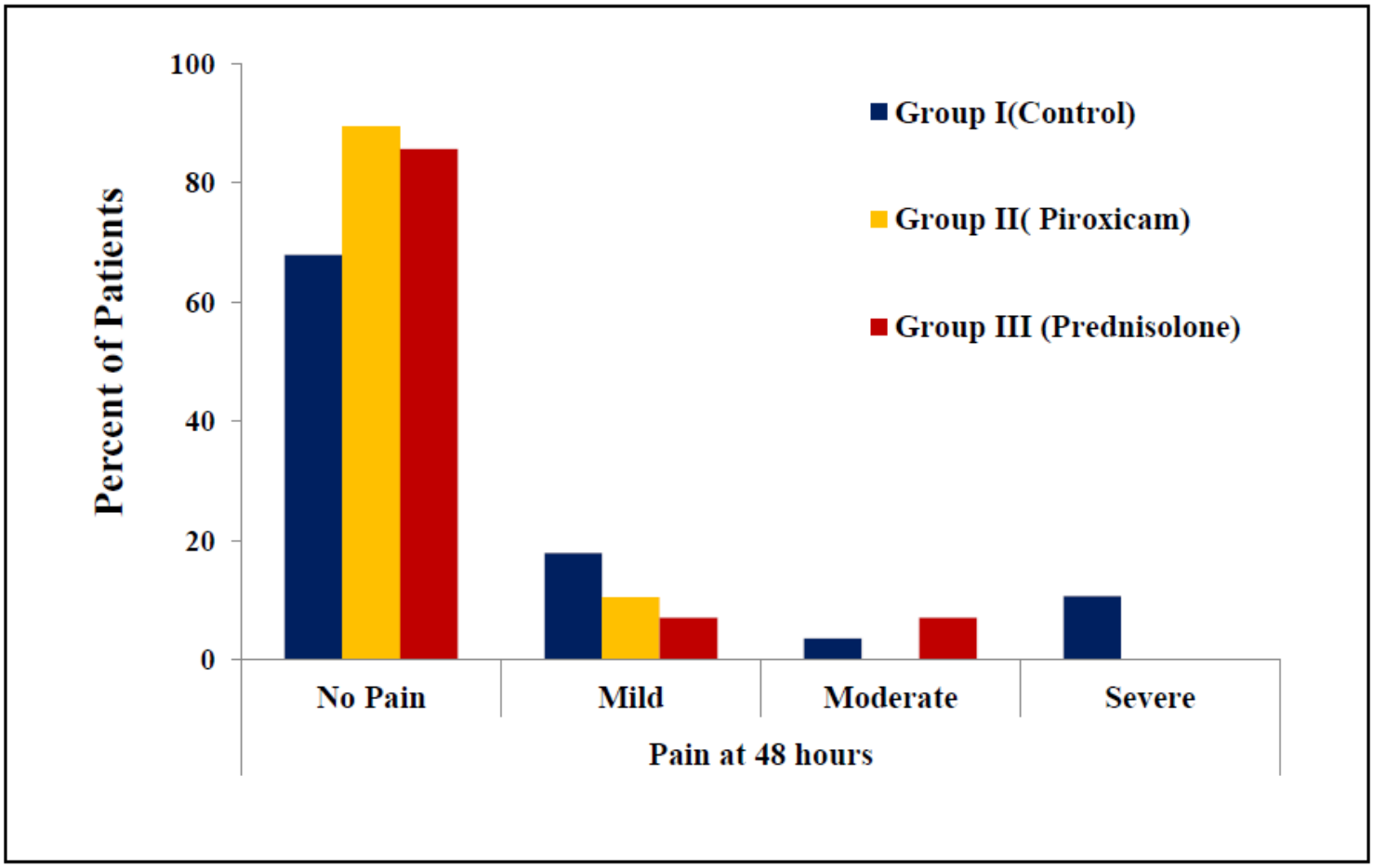

Figure 3

Bar chart representing the pattern of pain intensity scores at 48 hours interval of participants in all study groups

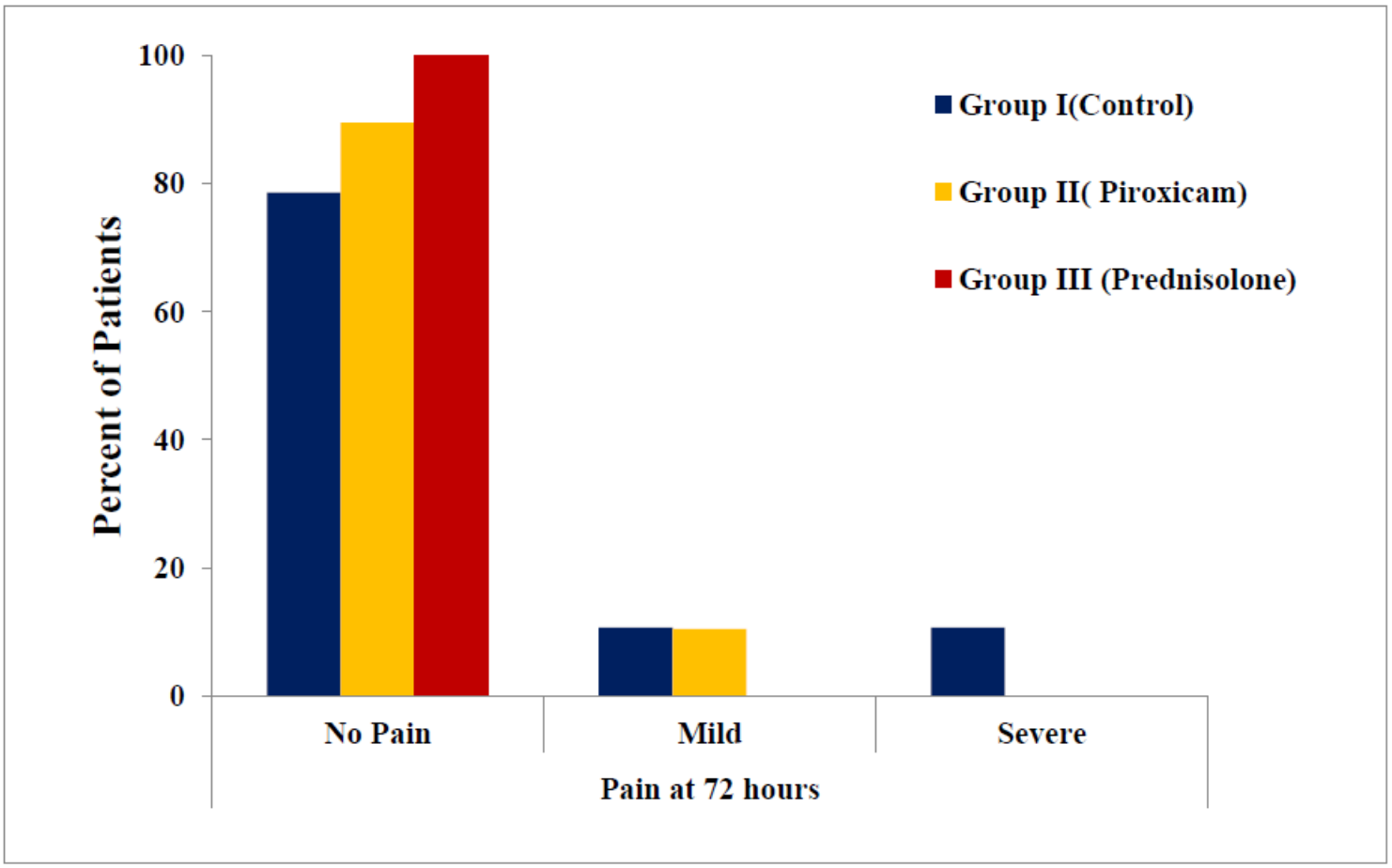

Figure 4

Bar chart representing the pattern of pain intensity scores at 72 hours interval of participants in all study groups

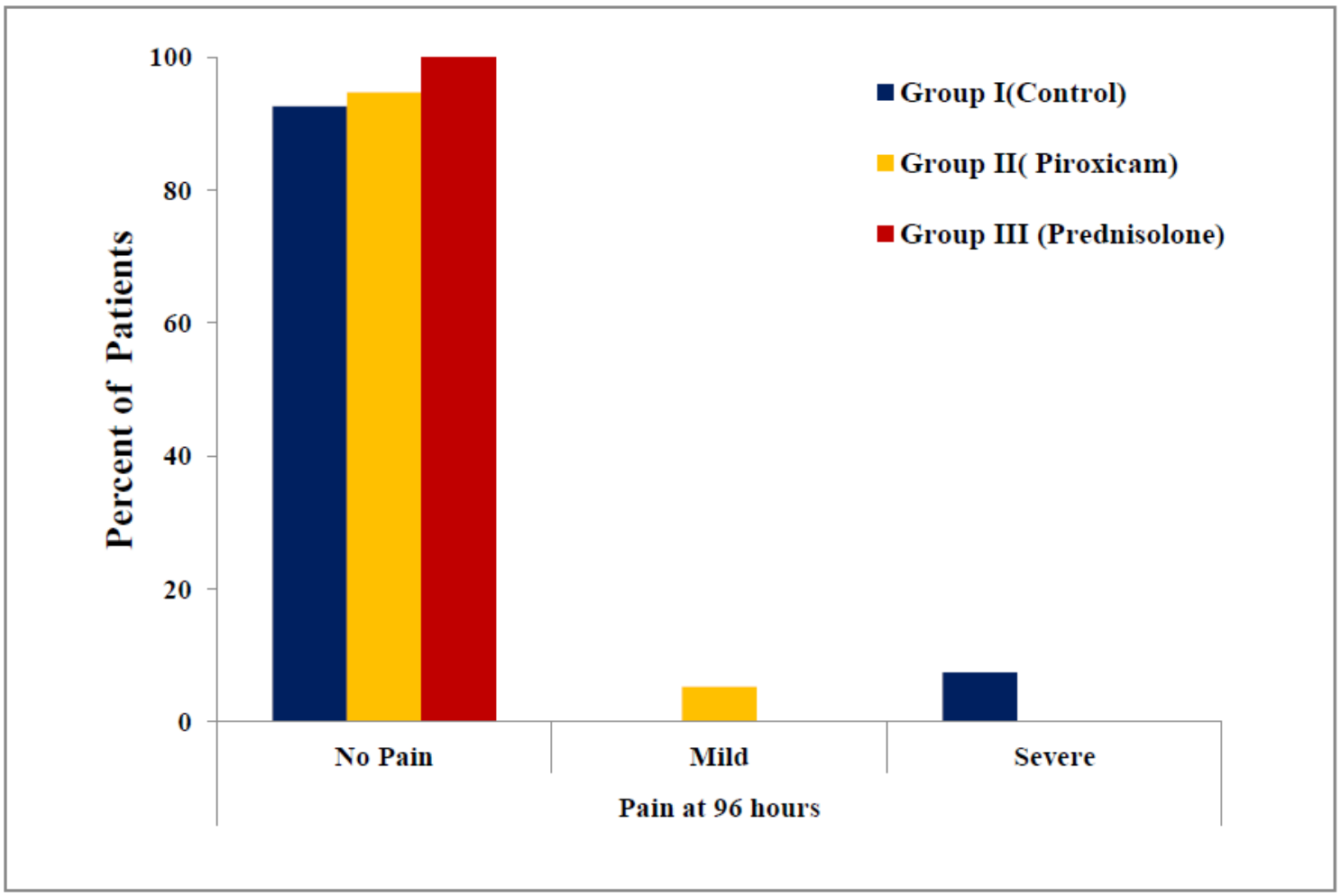

Figure 5

Bar chart representing the pattern of pain intensity scores at 96 hours interval of participants in all study groups