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Comparison of preoperative analgesics on the efficacy of inferior alveolar nerve block on patients with symptomatic irreversible pulpitis: a double blinded, randomized controlled trial.

Study Protocol:

The patients were inducted from the Out Patient Department of Endodontics in Baqai Dental College Hospital Karachi, Pakistan. A non-probability consecutive sampling was done and 120 patients were included and randomly divided in the 4 groups (n=30) using simple randomization as per the inclusion criteria. The study size was calculated with reference to previous reports, revealing that at least 30 individuals should be included as per the analysis of power of the study. The value of power used was 0.96, the effect size was taken as 0.4, and α was set as 0.05. A verbal informed consent was taken from each participant before including them in a group.

Inclusion Criteria:

- Patients between the ages of 18 - 65 years.

- Patients with no medical or systemic conditions.

- Patients with prolonged pain response on cold pulp testing of 1st and 2nd mandibular molars.

- Patient with 1st and 2nd mandibular molars having symptomatic irreversible pulpitis with no periapical pathology or tenderness on percussion.

- Preoperative moderate to severe pain on Heft Parker's visual analogue scale.

- Patients who can understand the recording of the pain using Heft Parker's visual analogue scale.

Exclusion criteria:

- Patients who are pregnant and/or breastfeeding.

- Patients with reported allergy to diclofenac sodium, piroxicam, and tramadol.

- Patients with periodontal pathologies, necrotized pulp, ankylosed or resorbed roots, open apex and non-restorable tooth.

- Patients who have taken an analgesic in the past 24 hours.

The study was designed to be a double blinded study, where the operators and the patients both were unaware of the groups of drugs that were used; this anonymity was achieved by marking the groups A, B, C and D on boxes for drugs containing a placebo, diclofenac sodium, piroxicam, and tramadol respectively. The Heft Parker's visual analogue scale was used to assess

the patients' pain levels prior to the drug ingestion, and the study was continued on the patients that reported moderate to severe pain on the visual analogue scale. On this scale, the pain intensities were
categorized as: no pain (0), mild pain (1-54 mm), moderate pain (55- 114 mm) and severe pain (> 114 mm). The patients were then given their respective group of drug where the control group received vitamin E (Evion, 400 mg) and three experimental groups received one tablet/capsule of diclofenac sodium (Voltral SR100, 100 mg), piroxicam (Feldene, 20 mg), and tramadol (Tramal, 50 mg). The patients were instructed to wait for 1 hour before they were administered inferior alveolar nerve block with 1.8 ml of 2% lidocaine with 1:100000 epinephrine using a non-aspirating syringe through a long needle of 27-Gauge. Standard root canal treatment was initiated after lip numbness was achieved, and pain levels were reassessed by Heft Parker's visual analogue scale during the root canal procedure. However, the patients who did not achieve the numbness of the lips were excluded from the study. Patients who reported discomfort and pain during the endodontic procedure were intervened appropriately; conversely, if the patient did not report any intraoperative pain, endodontic procedure was resumed.