# DOUBLE BLIND STUDY ON EMORFAZONE AND IBUPROFEN IN DENTAL PAIN AND INFLAMMATION

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## INTRODUCTION

Emorfazone (4-ethony-2-methyl-5) morpholino(2H-Pyrodazinone) is a nonacidic anti-inflammatory analgesic preparation with a new chemical structure selected from a series of pyridazinone den yates. It is an effective analgesic, anti-inflammatory and anti pyretic drug in animal models, as well as in humans[1-4] however, the efficacy of this drug on post-surgical dental pain and inflammation is lacking. Ibuprofen, belongs to the group of propionic acid derivates, non-steroidal, anti-inflammatory, analgesic and antipyretic drugs. Its clinical application is well documented[5-11]. The aim of this study was to. compare the post-operative pain relief and anti-inflammatory effect of emorfazone with that of ibuprofen in a short term trial.

## PATIENTS, METHODS AND RESULTS

Seventy two healthy outpatients of both sexes, over 18 years of age requiring removal of impacted lower third molar, at the Department of Dental Surgery, Shaikh Zayed Federal Postgraduate Medical Institute, Lahore were included in the study. Patients with hepatic or renal disease, immunosuppression, peptic ulceration, asthma, infection in mouth or history of recent medication that might confound the quantifidation of pain, swelling or trismus and patients with known allergy to NSAIDS or aspirin or local anaesthetic were excluded from the study.The surgical procedure was performed using a standardized technique by the same dental surgeon under local anaesthesia (2% lignocaine, 1: 100,00 adrenaline) employing a mean volume of 2.5 ml. Neither sedation nor antibiotics were given; the duration of surgery and the maximum mouth opening prior to surgery was measured between the incisal edges of the upper and lower central incisors. The horizontal distance between the corner of the mouth and the lobe of the ear and the vertical distance between the outer canthus of the eye and the angle of the mandible were also measured by means of a silk suture[12]. The type of impaction was assessed according to the method of Amin and Laskin[13]. The clinical trial was conducted as a prospective double blind parallel study in random permuted blocks[14]. Emorfazone 400 mg thrice daily or ibuprofen 600 mg four times a day for two days followed by emorfazone 200 mg thrice daily/ibuprofen 600mg thrice daily for the next four days, were given to the patients. The patients were re-examined 24 hours, 48 hours and one week after the surgery, the percentage of trismus and swelling was calculated as described by Carillo et al12. Pain intensity (0 = no pain; 1 = slight; 2 = moderate; 3 = severe) was recorded on the first 24 hours after the surgical procedure. Patients were given first dose soon after the procedure and were given a card to record the time and intensity of pain. If supplementary analgesic was required, paracetamol 500 mg every six hours was given. Patient's overall subjective evaluation was graded as excellent, good, fair or poor. Of 72 patients included in the trial, 8 were lost to follow-up and excluded from the study. Patient's profile at the entry were balanced in respect to age, sex, maximum mouth opening, degree of difficulty index and the duration of surgery (Table I).

**TABLE I. Comparison of patients profiles at entry.**

| | Ibuprofen | Emorfazone |
|---|---|---|
| Sample size | 32 | 32 |
| Age (years) | 23.2 ± 3.4 | 22.7 ± 3.6 |
| Sex:Male/Female | 12/20 | 11/21 |
| Maximum mouth opening (mm) | 44.8 ± 1.2 | 46.1 ± 1.8 |
| Facial measure (FM) (mm) | 100.5 ± 1.3 | 100.1 ± 1.1 |
| Degree of difficulty index | 6.25 ± 0.25 | 6.25 ± 0.25 |
| Duration of surgery (min) | 38.30 ± 0.30 | 36.00 ± 1.0 |

Five patients on ibuprofen and nine patients on emorfazone required paracetamol for 24 hours; one patient on emorfazone required it for more than 24 hours. Table II gives details of pain scores after 24 hours, 48 hours and one week. Although patients on ibuprofen had a higher percentage score of 0 and 1, the difference was not significant. There was also no statistically significant difference in the percentages of swelling and trismus among the treatment groups (Table II).

**TABLE II. Assessment of analgesic efficacy, swelling and tresmus.**

| | 24 hours | | 48 hours | | 1 week | |
|---|---|---|---|---|---|---|
| | Ibuprofen | Emorfazone | Ibuprofen | Emorfazone | Ibuprofen | Emorfazone |
| No pain | 21 (66%) | 18 (56%) | 25 (78%) | 20 (62%) | 27 (84%) | 25 (78%) |
| Slight | 6 (19%) | 5 (16%) | 4 (13%) | 4 (13%) | 4 (13%) | 5 (16%) |
| Moderate | 4 (12%) | 7 (22%) | 3 (9%) | 7 (22%) | 4 (13%) | 2 (6%) |
| Severe | 1 (3%) | 2 (6%) | | 1 (3%) | - | |
| Percentage of swelling (Mean SD) | 20.3 ± 4.7 | 22.6 ± 3.4 | 17.6 ± 2.3 | 19.5 ± 2.5 | 6.7 ± 1.3 | 7.6 ± 1.4 |
| Percentage of tresmus (Mean SD) | 30.6 ± 2.7 | 31.2 ± 2.3 | 36.2 ± 3.6 | 38.6 ± 3.4 | 21.3 ± 2.7 | 22.9 ± 2.7 |

## COMMENTS

This study compared emorfazone and ibuprofen in eliminating pain, swelling and trismus after removal of impacted third molar tooth. The difference in the percentage of facial swelling was not significant among the two treatment groups before and after the treatment. Anti-inflammatory effect of ibuprofen was demonstrated only with doses in range of 1.6-2.4 mg daily[15]. Contrarily, although ibuprofen was

administered at a maximum dose of 2.4 gms daily for first two days, a measurable anti-inflammatory effect was not obtained. Emorfazone, administered at maximal dose, produced no measurable anti-inflammatory effect. The analgesic properties of ibuprofen in dental pain have been reported before[6,7,9] and are similar to this trial. The analgesic properties of emorfazone in dental pain model have not been reported so far, which proved similar to ibuprofen in this study. The reduction of trismus among both treatment groups was significantly less than expected after six days of therapy. This could be explained in the light of previous studies[16,17] which showed an inter-relationship between pain and trismus.

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