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CASE REPORT

A DOUBLE BLIND STUDY COMPARING THE EFFICACY OF IBUPROFEN, DICLOFENAC SODIUM AND PLACEBO AFTER PERIODONTAL SURGERY

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ABSTRACT

Background: This study examined the efficacy of Ibuprofen, Diclofenac sodium and Placebo on the intensity of pain relief and on the gingival crevicular fluid levels before and after periodontal surgery**.**
Methods: A double blind study was conducted on 25 male patients. Pain intensity and, GCF levels were assessed by Cooper and Beaver's criteria and Mann's method respectively. Statistical analysis was done by Kruskall Wallis and Friedmans test and p values were obtained**.**
Results: Post operative mean pain intensity scores were significant (p value<0.01). Mean pre and post operative GCF levels were statistically significant at 1%.
Conclusion: Patients who had Diclofenac sodium showed greater analgesic effect when compared to Ibuprofen and placebo. Similar reduction in the levels of GCF were observed with Ibuprofen and Diclofenac sodium than placebo.

INTRODUCTION

Ibuprofen is a commonly prescribed drug for adequate control of pain and inflammation following periodontal surgical procedures (Salvi and Lang, 2009). Ibuprofen a 2-propionic acid derivative discovered by the research arm of the British Boots Group in the 1960's is a peripherally acting analgesic with a potent anti inflammatory action that works through a reversible and balanced cox-1/cox-2 inhibition (Pillati *et al*., 2004; Ferreira, 1993). It became available for clinical use in 1969 (Salvi and Lang, 2009). Adams, Mccullough and Nicholson (Adams *et al*., 1969) showed that ibuprofen acts symptomatically by abolishing pain and inflammation in joints and soft tissues by inhibiting thromboxane production. (Seymourr and Warton, 1984) document that drugs with both analgesic and anti-inflammatory action are able to control postoperative dental pain. According to (Mills *et al*., 1970) Ibuprofen is rapidly metabolised and excreted mainly via the kidneys within 24 hours and no accumulation occurs in the body after prolonged therapy.Godfrey and Dclacruz (Godfrey and De Lacruz, 1974) showed that 1200-1800mg of ibuprofen taken daily was well tolerated and gave better therapeutic control.

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Diclofenac sodium was the first of a series of phenyl acetic acid derivatives that had been developed as anti inflammatory agent.However it came into existence for clinical use after the approval by FDA in 1988 (Salvi and Lang, 2009). Diclofenac sodium is an inhibitor of cyclo oxygenase and is rapidly and completely absorbed after oral administration.(Brill and Krasse, 1958) were the first to make a detailed study about gingival crevicular fluid. (Brill and Krasse, 1958[6];Brill and Bjorn, 1959; Egelberg, 1966) demonstrated that gingival crevicular fluid flow reflects an inflammatory increase in the permeability of the vessels underlying the sulcular and junctional epithelium. Recent studies have shown that GCFcan be used as a biomarker of periodontal disease. Brill (Brill, 1960)[4]was the first to suggest that measurements of the fluid recovered from gingival pockets by means of filter paper strips might be used for determining the degree of inflammation of gingiva. (Arnold *et al.,* 1966) showed that the process of healing of the gingival tissues after gingivectomy or open flap procedures could be followed by measurements of gingival crevicular fluid production. Heasman and Seymour showed that gingival crevicular fluid was found to decrease considerably after administration of non steroidal anti inflammatory drugs. The clinical significance of gingival crevicular fluid are now known with more precision and have significantly helped in understanding the pathogenesis of periodontal disease. The aims and objectives of this study was to compare the intensity

of pain relief and to compare the preoperative and post operative levels of gingival crevicular fluid following administration of Ibuprofen, Diclofenac sodium and placebo after periodontal surgery.

MATERIALS AND METHODS

The study was conducted in the division of periodontics, Rajah Muthiah Dental college and Hospital Annamalai University, Tamilnadu, India. Twenty five male patients in the age group ranging from 30 to 40, who attended the dental op and diagnosed as suffering from chronic periodontitis were chosen for the study.

Inclusion and exclusion criteria

Patients who were free from any allergic reactions following drug intake or any systemic complications like epigastric pain, mild dyspepsia, heartburn, diabetes mellitus, bronchospasm, urinary retention and skin rashes were chosen to be the subjects for study.

Experimental parameters

1. Probing pocket depth index (Ramjford, 1967)
2. Gingival crevicular fluid volume (Quantitative assessment- MANN'S Method 1963)
3. Pain intensity index (Cooper and Beaver 1976)

The above parameters were recorded in a suitable proforma before and after periodontal surgery.

Criteria for pain intensity score (Cooper And Beaver 1976)

The intensity of pain was recorded in a pain intensity scale of 0 to 3 based on Cooper and Beavers criteria of recording pain intensity.(0= absent, 1=slight, 2=moderate, 3=severe). After surgery was completed each patient received randomly under double blind conditions a questionnaire and an envelope containing six capsules of either Ibuprofen-400mg,diclofenac sodium-50mg or placebo with code number on it (Fig. 1).

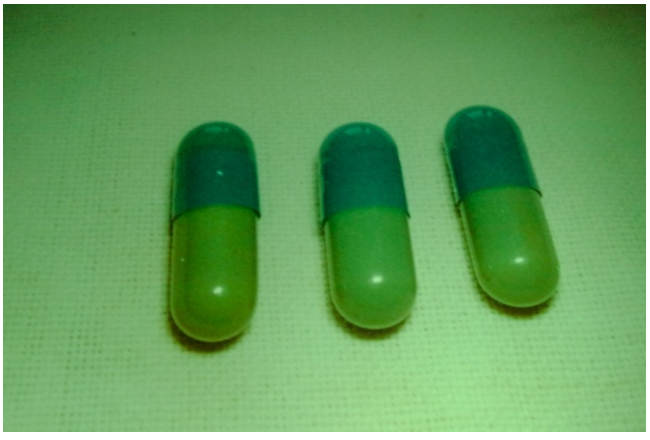

Fig:1 Identical Capsules for Double Blind Study

The three groups of drugs were given in the following two successive weeks after completion of the flap surgery in the second and third quadrant for the same patient. The patients were asked to record the pain intensity according to Cooper and Beaver at hourly intervals for upto 6 hours (1st, 2nd, 4th and 6th hour) respectively following ingestion of first drug immediately after surgery.

Gingival crevicular fluid volume (quantitative assessment- mann's method 1963)

Fluid was collected during a three minute period from the dried isolated orifice of the pockets using 6mm×2mm strips of What man's filter paper No.1. Three filter paper strips approximately 2mmwide and 6mm long were inserted side by side in the crevice and left in position for 3 minutes. This procedure ensures that any fluid collected after the drying does not originate in the crevice (Fig. 2). The central drying strip is then removed and immediately replaced by a collecting strip 1mm wide and 6mm long. The collecting strip does not have any contact with the two lateral drying strips and is left in place for 5 minutes and then removed for examination. The two drying strips which have acted as a dam to wall off fluid remainder of the crevice are removed and discarded. The strips were dried and then stained with 0.2% ninhydrin in acetone (Brill). Ninhydrin is specific for α-amino groups and gives a blue or purple colour. The area stained was measured with 10 x magnification using a graticule eye piece (Wilson and Mchugh). Fluid length was measured to the nearest 0.5mm.The results obtained in two groups after decoding were subjected to statistical analysis by using non-parametric Kruskwal wallis and Friedmans test.

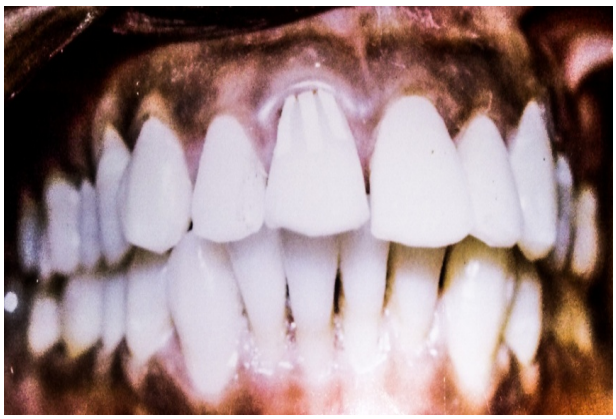

Fig.2. Filter paper strip placed in the gingival sulcus for the absorption of gingival crevicular fluid

RESULTS

The following can be inferred from Table 1 and Figure 3 given above:

1. In the placebo group reduction in pain was observed only in the fourth hour and only in the sixth hour there was a considerable reduction of pain.
2. Diclofenac sodium had better analgesic effect than Ibuprofen almost at every hour.

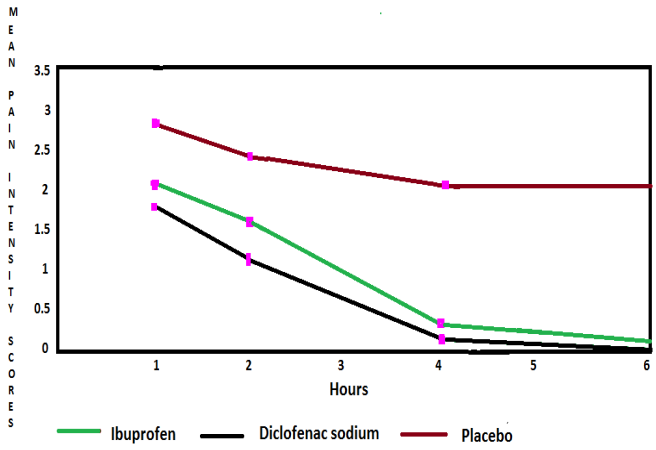

Figure 3. Post operative mean pain intensity scores after administration of Ibuprofen, Diclofenac sodium and Placebo following periodontal surgery

Table 1. Post Operative Mean and Standard Deviation Of Pain Intensity Scores after Administration of Ibuprofen (Group 1), Diclofenac Sodium (Group2), and Placebo (Group 3) following periodontal surgery

Hours	Group 1		Group 2		Group 3		Kruskal Willis Test	P Value
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation		
1	2.00	0.46	1.75	0.64	2.95	0.22	29.9200	<0.01
2	1.50	0.51	1.05	0.60	2.35	0.49	26.8400	<0.01
4	0.35	0.49	0.10	0.31	2.00	0.00	40.163	<0.01
6	0.05	0.02	0.00	0.00	2.00	0.00	39.517	<0.01
Friedmans Test	49.095		45.465		28.920			
"P" Value	P <0.01		P <0.01		P <0.01			

(PValue < 0.01)-significant

Table 2. Pre Operative and Post Operative Mean and Standard Deviation of Gingival crevicular fluid level following administration of Ibuprofen (Group I), Diclofenac sodium (Group II)and Placebo (Grroup III)after periodontal surgery

Gingival Cervicular fluid	Gingival Cervicular fluid		Diclofenac sodium		Placebo		F Ratio	Significance
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation		
Pre Operative	3.46	0.264	3.43	0.27	3.37	0.15		
Post operative	2.60	0.340	2.38	0.38	2.83	0.16		
Difference	0.86	0.09	1.05	0.17	0.53	0.07	88.06	P <0.01

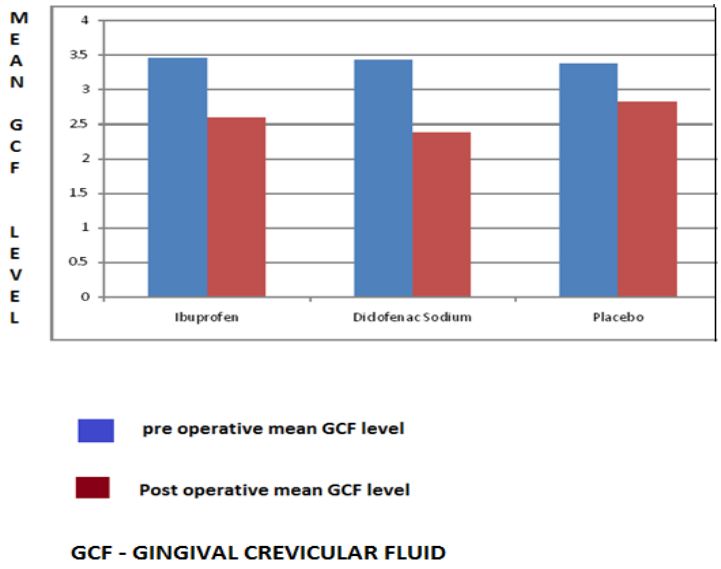

Figure 4. Pre and post operative mean gingival crevicular fluid level following administration of Ibuprofen, Diclofenac sodium and Placebo after periodontal surgery

The following can be inferred from Table 2 and Figure 4 given above:

1. The mean pre and post operative GCF value difference between Ibuprofen, Diclofenac sodium and Placebo is statistically significant at 1%.
2. The mean reduction in post operative GCF value was almost the same for Ibuprofen and Diclofenac sodium but their reduction was more when compared to Placebo.

DISCUSSION

The present study was undertaken to compare the efficacy of Ibuprofen, Diclofenac sodium and placebo on pain, inflammation and gingival crevicular fluid levels in a double blind study following modified Widman flap procedure, performed in three quadrants of the same patient for three successive weeks in twenty five male patients. Pain intensity scores were recorded on hourly basis upto six hours immediately following periodontal surgery forGroup1(Ibuprofen 400mg),Group 2(Diclofenac sodium 50 mg) and Group3 (Placebo) patients. The administration of diclofenac sodium 50 mg resulted in significant analgesic activity superior to ibubrufen 400 mg and placebo in controlling the postoperative pain. The results of the present study were consistent with the findings of Mathews *et al.* (1984). Group2 had superior analgesic effect when compared to Group 1 and3 during 1^{st},2^{nd},4^{th} and 6^{th} hour respectively. Gingival crevicular fluid is an extra vascular serum like fluid secreted from the underlying connective tissue into the sulcular spaces. The bio chemical analysis of the fluid offers a non invasive means of assessing the host response in periodontal disease.

In the present study it was observed that following administration of Ibuprofen, Diclofenac sodium and placebo and four weeks after periodontal surgery there was a decrease in gingival crevicular fluid in both Group I and Group 2 which was in concurrence with the studies of (Heasman and Seymour,1989) as well as (Tsuchidaand Hara,1981) as seen in Table 2 and Fig4.

Conclusion

With the limitations of the present study it may be concluded that Diclofenac sodium 50mg is superior to Ibuprofen 400mg and placebo in relieving pain and inflammation and in reduction of gingivalcrevicular fluid flow following periodontal surgery.

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