

**Research Article****EFFICACY OF ORNIDAZOLE GEL AS AN ADJUNCT TO SCALING AND ROOT PLANING IN CHRONIC PERIODONTITIS PATIENTS: A CLINICAL AND MICROBIOLOGICAL STUDY.**M.NAGASREE<sup>1</sup>, P.BINDU MADHURI<sup>2</sup>, S.V.V.S MUSALAIAH<sup>3</sup>, P.ARAVIND KUMAR<sup>4</sup>, P.INDEEVAR<sup>5</sup><sup>1</sup> PROFESSOR, DEPARTMENT OF PERIODONTICS, ST.JOSEPH, DENTAL COLLEGE AND HOSPITAL.<sup>2</sup> PG STUDENT, DEPARTMENT OF PERIODONTICS, ST.JOSEPH DENTAL COLLEGE AND HOSPITAL.<sup>3</sup> PROFESSOR, AND HEAD OF THE DEPARTMENT, DEPARTMENT OF PERIODONTICS, ST.JOSEPH DENTAL COLLEGE AND HOSPITAL.<sup>4</sup> PROFESSOR, DEPARTMENT OF PERIODONTICS, ST.JOSEPH DENTAL COLLEGE AND HOSPITAL.<sup>5</sup> SENIOR LECTURER, DEPARTMENT OF PERIODONTICS, ST.JOSEPH DENTAL COLLEGE AND HOSPITAL

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**ABSTRACT**

**INTRODUCTION:** Periodontitis is an inflammatory disease of the supporting tissues of teeth caused by specific group of microorganisms resulting in destruction of periodontal ligament, alveolar bone with pocket formation, recession or both.

**AIM:** To evaluate the efficacy of Ornidazole gel as adjunct to scaling and root planing in chronic periodontitis patients.

**MATERIALS AND METHODS:** A split mouth study was done in ten patients having probing pocket depths of  $\geq 4$  mm and diagnosed with chronic periodontitis with at least two sites, each site is randomly assigned to either SRP+Ornidazole(Group A) or SRP alone(Group B). Assessment of plaque index (PI), gingival index (GI), probing pocket depth(PPD), and clinical attachment levels (CAL) was done at baseline and 3 months. Microbiologic assessment with polymerase chain reaction was done for Porphyromonas gingivalis, Tannerella forsythia, and Treponema denticola by collection of plaque samples.

**RESULTS:** Both the groups A and B have shown statistically significant results in terms of all clinical and microbial parameters pre operatively and post operatively with more significance observed in Group A

**CONCLUSION:** Group A which was treated with Ornidazole + SRP had shown better efficacy in terms of all clinical parameters and microbial analysis when compared to that of Group B who were treated with SRP alone.

**Keywords:** Periodontitis, Ornidazole gel, Scaling and root planing, Microbial analysis.

**Introduction:**

Periodontal diseases are induced by variety of organisms that colonise and proliferate supra and subgingivally in susceptible individuals. The progression of the disease is related to the colonization of chief microorganisms such as Actinobacillus actinomycetemcomitans, Porphyromonas gingivalis, and Prevotella intermedia.<sup>1</sup>

Non surgical periodontal therapy is the main therapeutic approach in the treatment of periodontal diseases and has been used as the "gold standard" for mechanical therapy.<sup>2</sup> Data have demonstrated that this approach has limited effect on some pathogenic species and total

suppression of subgingival bacteria is often not achieved. This may be due to the fact that some of these species can reside in soft tissues, dentinal tubules, or in root surface irregularities thereby contributing to treatment failure.<sup>3</sup>

The limitations of mouth rinsing and irrigation have prompted research for the development of alternative delivery systems. Recently advances in delivery technology have resulted in the controlled release of drugs. The requirements for treating periodontal disease include a means for targeting an anti infective agent to infection sites and sustaining its localized concentration at effective levels for sufficient time evoking minimal or no side effects.<sup>4</sup>

Goodson et al in 1979 discovered that local drug delivery systems has many advantages as it delivers the drug directly in the pocket, has the potential to provide greater concentrations directly to the infected area and reduces possible systemic side effects.<sup>5</sup>

Ornidazole an antimicrobial agent belonging to 5-nitroimidazole group has been used successfully in treatment of chronic periodontitis as it is efficient strictly against anerobic bacteria and its antibacterial activity is due to reduction of the nitro group to a more reactive amine that attacks microbial DNA inhibiting further synthesis and causing degradation of DNA.<sup>6</sup>

The present study is designed to evaluate the efficacy of local drug delivery of ornidazole gel as an adjunct to scaling and root planing, its effect on clinical parameters like plaque, gingival Scores, Probing depth, CAL and its efficacy in suppressing the pathogenic anaerobic microflora by microbiologic analysis using polymerase chain reaction (PCR) in chronic periodontitis patients.

#### **MATERIALS AND METHODS:**

This was a single blinded split mouth study undertaken to evaluate the effect of ornidazole as an adjunct to Scaling and root planing. In this clinical trial 10 patients aged between 35-60 years who reported to the Department of Periodontics, St. Joseph Dental College, Eluru between April 2015 to March 2016 with chronic periodontitis were enrolled for the study. Approval of the study was obtained from the ethical committee of St. Joseph Dental College and an informed consent was taken from all participants before commencing of the study.

#### **INCLUSION CRITERIA:**

1) Patient having at least three teeth with probing pocket depth of 5-8 mm that bleed on probing at the initial visit, Patients with good systemic health who have not received local and/or systemic antibiotic therapy within the last 6 months prior to the baseline examination of the study, Patients diagnosed with chronic periodontitis.

#### **EXCLUSION CRITERIA:**

1) Pregnant women, Lactating mothers, Smokers, Patients who underwent previous periodontal surgery.

Before starting the trial, plaque samples were collected from all the sites and was stored in EDTA vial for microbial sampling, subsequently all the patients underwent full mouth scaling using an ultrasonic scaler and after 1 week SRP was done followed by placement of the drug and oral hygiene instructions.

The selected qualifying sites were randomly divided by coin toss method.

(1) Group A: Treated with SRP followed by placement of ornidazole gel.

(2) Group B: Treated with SRP alone.

Four clinical variables including plaque index (PI), gingival index, probing pocket depth, clinical attachment levels and microbiologic analysis of subgingival plaque samples for the "red complex" periodontal pathogens (*P.gingivalis*, *T. denticola*, *T. forsythia*) using PCR was measured at both 1 month and 3 months interval. Subgingival plaque samples was collected by using a Gracey curette by inserting it subgingivally into the deepest portion of the periodontal pocket. After isolating and drying the sites Subgingival administration of ornidazole gel was inserted into the base of the periodontal pocket without traumatizing or damaging the periodontal tissues by a flexible, blunt needle and no periodontal pack was given, in Group B only SRP was done.

**STATISTICAL ANALYSIS:** The data was analyzed using statistical package for social sciences SPSS v 10.5, ibm, Chicago, IL.

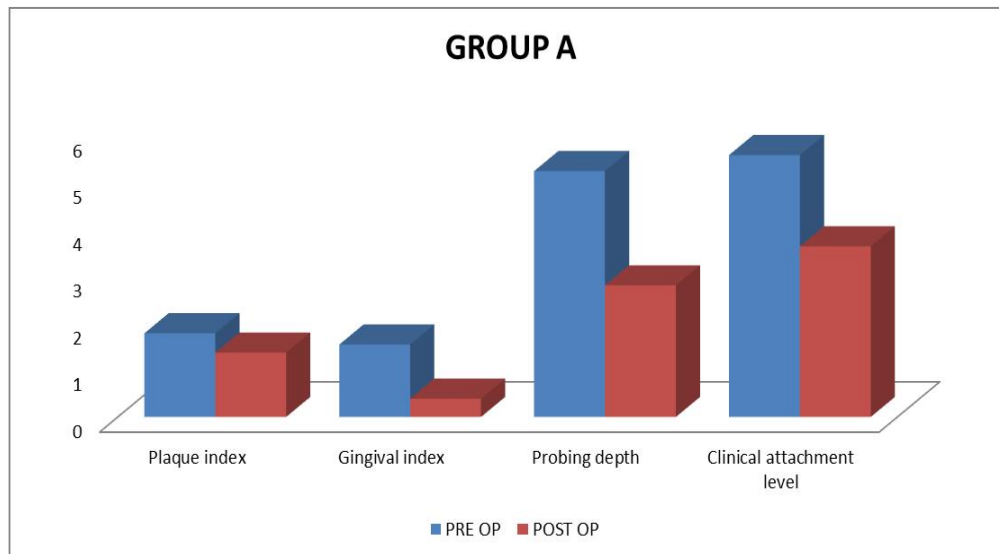
#### **RESULTS:**

There was a significant reduction in PI, GI, PDD, CAL values from baseline to follow up visit in both group A and group B. [Table 1, 2]. The microbiologic assay (PCR) has shown a proportionate reduction in *P. gingivalis*, *Tanerella forsythia*, *Treponema denticola* in group A, group B [Tables 3,4] but only in group A the mean values was significant.

**TABLE 1: MEAN, STANDARD DEVIATION AND TEST OF SIGNIFICANCE FOR PLAQUE INDEX, GINGIVAL INDEX, PROBING DEPTH , CLINICAL ATTACHMENT LEVEL PRE AND POST OPERATIVELY FOR GROUP A.**

VARIABLES IN GROUP A	PRE OPERTIVE		POST OPERTIVE		P Value
	MEAN	SD	MEAN	SD	
Plaque index	1.78	0.70	1.37	0.57	0.0007S
Gingival index	1.54	0.36	0.39	0.13	0.000S
Probing depth	5.23	1.14	2.80	1.19	0.000S
Clinical attachment level	5.57	0.82	3.63	0.67	0.000S

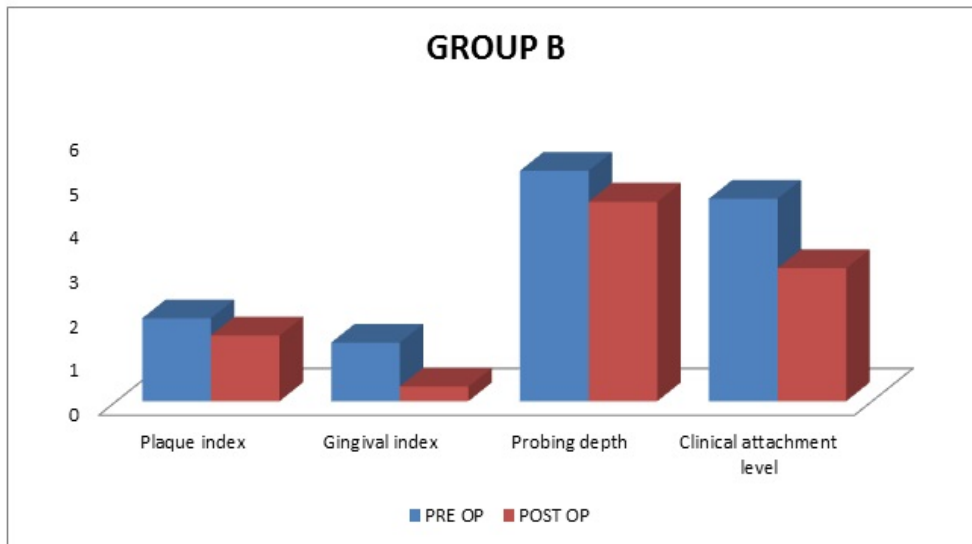
Statistical Analysis: Paired t test. Statistically significant  $P < 0.05$ .



**Graph 1: COMPARISION OF MEAN, STANDARD DEVIATION AND TEST OF SIGNIFICANCE FOR PLAQE INDEX, GINGIVAL INDEX, PROBING DEPTH, CLINICAL ATTACHMENT LEVEL PRE AND POST OPERATIVELY FOR GROUP A.**

**TABLE 2: MEAN, STANDARD DEVIATION AND TEST OF SIGNIFICANCE FOR PLAQUE INDEX, GINGIVAL INDEX, PROBING DEPTH , CLINICAL ATTACHMENT LEVEL PRE AND POST OPERATIVELY FOR GROUP B.**

VARIABLES IN GROUP B	PRE OPERTIVE		POST OPERTIVE		P Value
	MEAN	SD	MEAN	SD	
Plaque index	1.87	0.58	1.48	0.47	0.000 S
Gingival index	1.32	0.39	0.33	0.19	0.000S
Probing depth	5.20	0.63	4.50	0.53	0.0013S
Clinical attachment level	4.57	0.94	3.00	0.95	0.000S

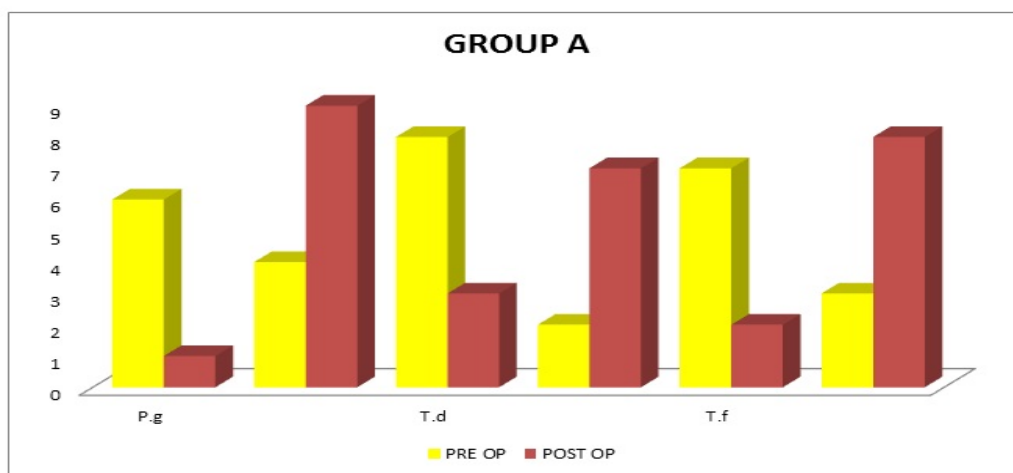


Graph 2: COMPARISON OF MEAN, STANDARD DEVIATION AND TEST OF SIGNIFICANCE FOR PLAQUE INDEX, GINGIVAL INDEX, PROBING DEPTH, CLINICAL ATTACHMENT LEVEL PRE AND POST OPERATIVELY FOR GROUP B

TABLE 3: COMPRISION OF PCR VALUES OF GROUP-A PRE AND POST OPERATIVELY.

GROUP A	PRE OP		POST OP		P value
	PRESENT	ABSENT	PRESENT	ABSENT	
P.g	6	4	1	9	0.019S
T.d	8	2	3	7	0.025S
T.f	7	3	2	8	0.025S

Statistical Analysis: Chi- square test.

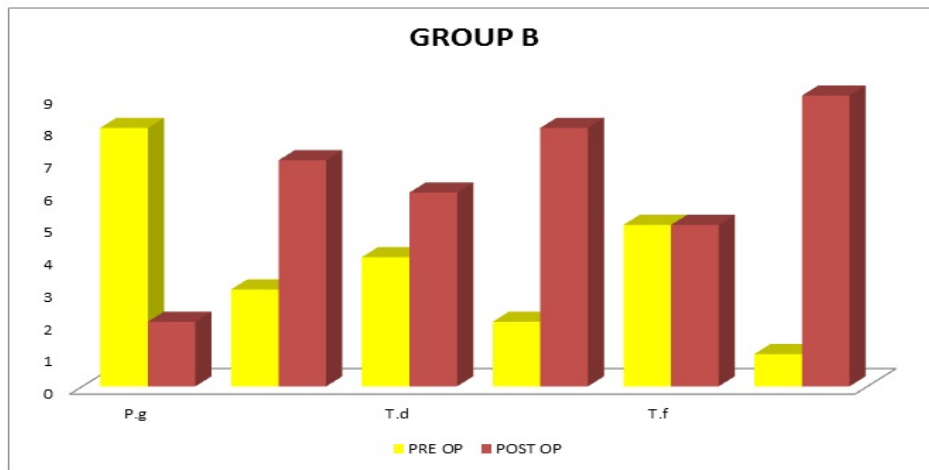


GRAPH 3: COMPRISION OF PCR VALUES OF GROUP A PRE AND POST OPERATIVELY.

TABLE 4: COMPRISION OF PCR VALUES OF GROUP B PRE AND POST OPERATIVELY.

GROUP B	PRE OP		POST OP		P value
	PRESENT	ABSENT	PRESENT	ABSENT	
P.g	8	2	3	7	0.025S
T.d	4	6	2	8	0.068NS
T.f	5	5	1	9	0.051NS

Statistical Analysis: Chi- square test.



GRAPH 4: COMPRISION OF PCR VALUES OF GROUP B PRE AND POST OPERATIVELY.

**DISCUSSION:**

The present study was designed to evaluate the clinical efficacy of locally delivered Ornidazole gel used as an adjunct to SRP.

Local drug delivery system for tetracycline antibiotic was first discovered by Goodson et al, in 1979 Since then, chlorhexidine, doxycycline, minocycline, metronidazole, ofloxacin and herbal products have been as local delivery drugs for the treatment of periodontitis.

Among the various locally delivered chemotherapeutic agents Ornidazole, a member of nitroimidazole class of antibiotics has bactericidal action against anaerobes, such as Prevotella intermedia, Porphyromonas gingivalis, Tannerella forsythia, Fusobacterium species which are generally believed to be the main pathogens associated with periodontitis<sup>7</sup>

Ornidazole gel manufactured by Mankind pvt ltd India which is Composed of Ornidazole 1% w/w + Chlorhexidine 0.25% . Ornidazole has been preferred over metronidazole as it has mean elimination half-life from human plasma is 1.7 times greater than that of Metronidazole i.e (14.4 hours for ornidazole, 8.4 hours for metronidazole )which is significantly longer than that of some nitroimidazole when administered locally.<sup>8</sup> It requires a very low minimum inhibitory concentration to inhibit the growth of periodontal pathogens as compared to that of Metronidazole. The present study was an interventional split mouth study conducted in 10 patients over a period of 3 months. The study showed a statistically significant reduction in PI values from baseline to follow up visit in both group A and group B (P = 0.0007, 0.000). This can be attributed to the fact that there was a reduction in supragingival plaque after SRP and maintenance

of oral hygiene measures. The results of this study were in accordance with sato K. Yoneyama et al et al(1994),<sup>9</sup> Cugini et al(2000)<sup>2</sup>, Bhavin patel et al(2014)<sup>10</sup>

There was a significant reduction in GI scores in both the groups. This may be due to elimination of local etiological factors like plaque and calculus. This was in accordance with Hinrichs et al.(1985)<sup>11</sup> and Cugini et al<sup>2</sup>, Becker et al(1985)<sup>12</sup>, Boretti G et al<sup>13</sup>, Bhavin patel et al<sup>10</sup>

There was a significant difference in mean PPD, CAL levels in both the groups before and after treatment for which more significance is observed in group A. This may be due to antimicrobial effect of ornidazole and also due to effectiveness of SRP that causes reduction in gingival inflammation and decrease in percent of sites with supragingival biofilm accumulation. This was in accordance with Noyan O, Yilmaz S et al(1997)<sup>14</sup>. Magnusson et al(1998),<sup>15</sup> Anusha Rajagopalan et al(2014).<sup>16</sup>

The microbiologic assay (PCR) has shown a proportionate reduction in *P. gingivalis*, *T. forsythia*, *T. denticola* in both groups, for which significance is observed in group A. The significant reduction could be because of the antibactericidal activity and mutagenic effect of ornidazole as it specifically acts on gram negative anaerobic, facultative bacteria which are responsible for periodontal disease, the added advantage is that it also requires a very low minimum inhibitory concentration to inhibit the growth of periodontal pathogens. These were in accordance with the studies conducted by Noyan O, Yilmaz S(1997)<sup>14</sup>. and Pedrazzoli et al.

#### CONCLUSION:

Hence, it can be concluded that SRP along with local application of Ornidazole gel showed better efficacy than SRP alone in terms of all clinical parameters and also reduction in microbial count. However larger sample size and long term clinical trials are needed for further evaluation.

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**CONFLICT OF INTREST:** THE AUTHOR HERE BY DECLARE THAT, THERE NO CONFLICT OF INTREST IN THE CONDUCTED STUDY