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Original Article

Comparative Evaluation of Ornigreat Gel and Placebo (Hexigel 0.25%) as a Local Drug Delivery System in Association with Scaling and Root Planing in Patients with Chronic Periodontitis – An *In vivo* Study

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Abstract

Aim: The aim of the study was to evaluate the comparative effect of Ornigreat gel and Hexigel as a local drug delivery system in association with scaling and root planing (SRP) in patients with chronic periodontitis.

Materials and Methods: A double-blind trial was conducted to test the comparative efficacy of the two commercially available Ornigreat gel and Hexigel at Indira Gandhi Govt. Dental College and Hospital, Jammu. These indices were recorded at baseline ("0 day"), 15th day, 30th day, 60th day, and 90th day in 40 sites, >4 mm pockets in 11 patients among which 20 sites received Ornigreat gel and other 20 sites receive Hexigel following SRP were compared.

Results: The results of the study showed that the combination of SRP and Ornigreat gel therapy was more effective in reducing the mean values of gingival index and sulcus bleeding index though not statistically significant, but the values of plaque index showed statistical significance on the 60th day and 90th day, and the probing pocket depths showed statistically significant difference from the 15th day to the 90th day at $P < 0.05$ in comparison with Hexigel.

Conclusion: The Ornigreat gel could be an efficient local drug delivery system when used in adjunct to SRP in comparison with Hexigel.

Key words: Gingival sulcus, Hexidine, Local drug delivery, Ornidazole

INTRODUCTION

Periodontitis is the most common type of periodontal disease, which results from extension of the inflammatory process started in the gingiva with progression to the supporting structures of the tooth in the presence of modifying/risk factors.[1]

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It has been very well documented that microorganisms play an important role in the etiology of periodontal diseases, and specific organisms are responsible for specific disease processes.[2] The use of chemotherapy as an adjunct in the treatment of periodontitis has received considerable attention during the past decade.[3]

Scaling and root planing (SRP) may fail to eliminate the bacteria because of their location within the gingival tissues or in tooth structures inaccessible to periodontal instruments.[4]

The various measures, which are employed for plaque control, include chemical and mechanical aids such as

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mouthwashes, toothbrushes, dentifrices, interdental cleaning aids, and oral irrigation devices.[5]

It has been noted that long-term regimens of various chemotherapeutic agents and systemic drugs are not advisable because of the possible development of resistant bacterial strains and it also causes common side effects such as gastrointestinal problems, hypersensitivity reactions, drug eruptions, and superinfections.[4,6]

Hence, local drug delivery systems have been explored as an alternative means of bypassing systemic complications and delivering the drug only at the specific diseased site.

Longer antimicrobial duration, therefore, requires systems to establish drug reservoirs in the periodontal pockets able to release active medication in sufficient quantities to counteract the expected continuous loss overtime affected by the flow of crevicular fluid. Goodson[7] pointed out that pharmacological agent to be effective *in vivo* must reach its site of action and be maintained there at a sufficient concentration long enough for the intended pharmacological effect to occur. These three criteria (site, concentration, and time) are strictly correlated.[7]

Local drug delivery devices or control release devices for periodontal applications are mostly based on diffusion of the drug across a membrane as the release controlling feature. They are of different types such as reservoir devices (membrane diffusion system), monolithic devices, gels, and hybrids. The mechanism of drug release may be either by pure diffusion, chemical reaction, counter-current diffusion, and externally imposed controls.[8]

It has also been observed that irrigation for longer periods of time with more concentrated solution resulted in higher levels of tetracycline substantivity.[7]

However, solid devices showed more sustained drug release with an accompanying prolonged alteration of subgingival microflora and improvement in clinical status, but unfortunately, solid drug delivery systems require clinician to both places and then remove the devices at the end of therapy.[3]

Various chemotherapeutic agents, including tetracycline, minocycline, doxycycline, metronidazole, ornidazole, and chlorhexidine, are available for local application. They come in the form of gels, paste, films, strips, and fibers.

Nitroimidazole compound is one such agent that acts by inhibiting DNA synthesis. It works on the principle that inactive form passively diffuses into cell where it is activated by chemical reduction. The nitro group gets reduced to anion radicals which causes oxidation of DNA, leading to strand breakage and cell death. Hence, it has both antimicrobial and mutagenic effect. This effect is primarily seen on obligate Gram-negative anaerobes such as *Porphyromonas gingivalis*, *Prevotella intermedia*, *Fusobacterium*, selenomonas sputigina, and *Bacteroides forsythus* and the Grampositive anaerobes such as *Peptostreptococcus* and *Campylobacter rectus* which are implicated in periodontal disease.[9]

The present study was conducted to evaluate the comparative effect of Ornigreat gel and Hexigel as a local drug delivery system in association with SRP in patients with chronic periodontitis.

MATERIALS AND METHODS

Case Selection

A total number of 40 sites in 11 cases both males and females in nearly equal numbers with chronic periodontitis visiting the Department of Periodontics, Indira Gandhi Govt. Dental College, Jammu, were selected for the study.

Inclusion criteria were as follows: A 30–60-year-old individual and in good health with no history of diabetes, rheumatic fever, blood dyscrasias, and immunologic anomalies; selected patients should show negative response to the allergic test against tetracycline antibiotic; no periodontal therapy within the previous 6 months; the selected site (sextant) should have at least three teeth with two sites having periodontal probing depth of 4 mm or more; both single and multirooted teeth. Exclusion criteria were as follows: Exposure to antibiotics within the previous 6 months; long-term exposure to anti-inflammatory medications or known hypersensitivity to antibiotics; female patients were excluded if they were pregnant or anticipated becoming pregnant during the course of the experiment; and active lactating mothers.

Material Used

Ornigreat was procured from humankind representative, Jammu, and placebo was made in Govt. Pharmacy.

Composition

Ornigreat – Chlorhexidine gluconate 0.25% W/W+Ornidazole 1 %W/W

Placebo (Chlorhexidine gel 0.25%) – the variant being without Ornidazole.

The stock solution of chlorhexidine gluconate (20% w/w) was subsequently added into the polymer solution to obtain chlorhexidine final concentration of 0.25% w/w. The physical properties of the gels (color, homogeneity,

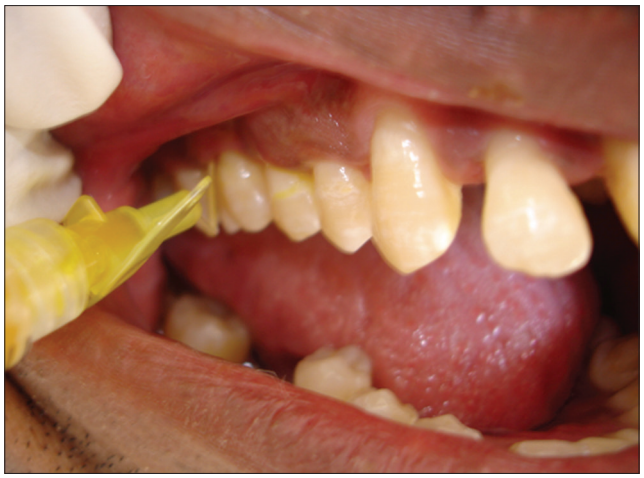

Figure 1: Tip of cannula at base of pocket

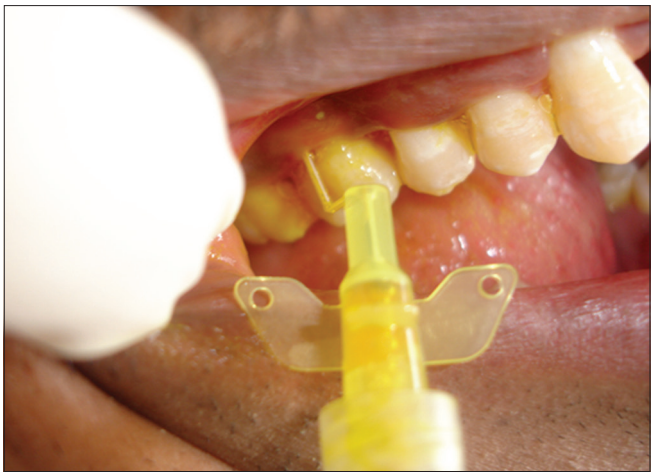

Figure 3: Gel filled up to the margin of the sulcus

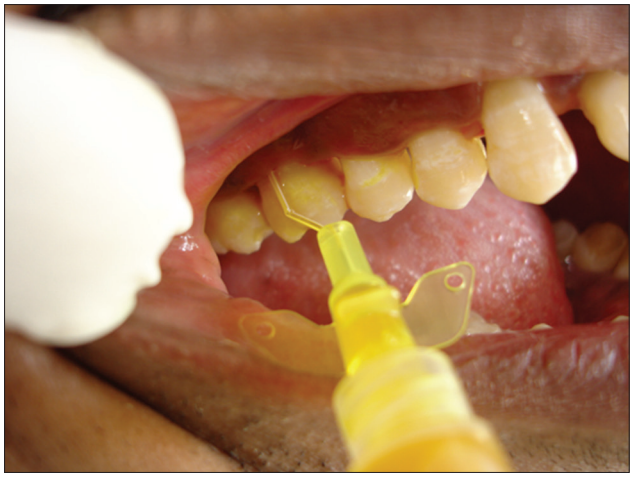

Figure 2: Tip of cannula extrudes as the gel is being placed

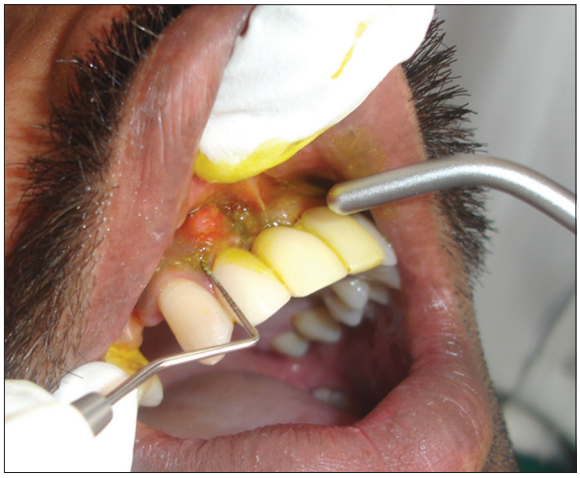

Figure 4: Thin layer of gel formed after the gel is dried

and taste) were observed. The pH values of the gels were measured. The sol-gel transition was observed at 4°C and 28°C. The viscosity response to temperature was investigated at various temperatures (20–50°C) using a viscometer (Remi Lab, Mumbai).

Placement of placebo gel using 24 gauge cannula:

Methods

After the subject selection, all patients were appraised of possible risk, discomfort, and inconvenience associated with the study. A written informed consent was taken from the patients who were to be a part of the study. Patients were advised to continue their present routine of oral hygiene maintenance and no special instructions were given. A total of 40 sites were included for the study. Therapy was divided into two groups, namely, Group A: 20 sites treated with SRP and polishing and then Ornigreat gel was placed in these sites. Group B: Other 20 sites are also treated with SRP and polishing and then placebo gel was placed in these sites. SRP was accomplished with ultrasonic and hand instruments. Teeth not selected for the experiment were treated with SRP only. A single investigator performed all treatment and clinical measurements. Clinical parameters such as plaque index (Turesky, Gilmore, and Glickman Modified Quigley-Hein index), gingival index (Ramfjord index), probing pocket depth (measurement is done by UNC 15 probe), and sulcus bleeding index (Muhlemann and Son, 1971) were recorded at baseline ("0 day" 0), 15th day, 30th day, 60th day, and 90th day in 40 sites, 20 received Ornigreat gel and other 20 received placebo gel following SRP and comparison was made between these two groups. The obtained data were tabulated and statistical analysis was applied using t-test and Chi-square test.

RESULTS

Plaque Index

The mean values were not statistically significant between the two groups ($P > 0.05$) at baseline (0), 15th day, and 30th day, but there was a statistically significant difference between the groups ($P < 0.05$) at 60th and 90th days

[Table 1]. Sulcus bleeding index and gingival index: Mean values were not statistically significant throughout the study period between these two groups [Tables 2 and 3]. Probing pocket depth: The mean value was not statistically significant between the groups ($P > 0.05$) at baseline (0 day), but it was statistically significant between the groups ($P < 0.05$) at the 15th day, 30th day, 60th day, and 90th day [Table 4 and Figures 1-4].

Table 1: Mean plaque index at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	2.77	1.05	1.10	5.00
	15	20	1.75	0.58	1.10	3.20
	30	20	1.95	0.54	1.30	3.70
	60	20	2.00	0.41	1.00	2.50
	90	20	2.21	0.75	1.00	3.20
Group B	0	20	3.10	0.88	1.50	5.00
	15	20	1.97	0.53	1.10	3.00
	30	20	2.10	0.35	1.30	2.70
	60	20	2.34	0.41	1.70	3.40
	90	20	2.8	0.43	1.80	3.40

Table 2: Mean sulcus bleeding index at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	0.58	0.44	0.08	1.60
	15	20	0.43	0.36	0.02	1.40
	30	20	0.41	0.40	0.00	1.40
	60	20	0.44	0.39	0.10	1.50
	90	20	0.47	0.39	0.07	1.50
Group B	0	20	0.89	0.68	0.00	2.30
	15	20	0.64	0.35	0.20	1.50
	30	20	0.70	0.56	0.00	2.10
	60	20	0.71	0.58	0.00	2.10
	90	20	0.74	0.63	0.00	2.20

Table 3: Mean gingival index at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	1.41	0.23	1.10	1.80
	15	20	1.17	0.14	1.00	1.50
	30	20	1.19	0.21	1.00	1.70
	60	20	1.25	0.22	1.00	1.70
	90	20	1.32	0.19	1.10	1.70
Group B	0	20	1.41	0.24	1.00	2.00
	15	20	1.21	0.22	1.00	1.70
	30	20	1.29	0.31	1.00	2.00
	60	20	1.32	0.25	1.00	1.80
	90	20	1.36	0.28	1.00	2.00

Table 4: Mean probing pocket depth at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	4.34	0.25	4.00	4.90
	15	20	3.42	0.38	2.80	4.30
	30	20	3.50	0.37	2.80	4.10
	60	20	3.80	0.30	2.90	4.20
	90	20	3.94	0.24	3.50	4.40
Group B	0	20	4.32	0.19	4.00	4.60
	15	20	3.92	0.51	2.60	4.70
	30	20	3.94	0.59	2.70	4.80
	60	20	4.25	0.53	2.70	4.80
	90	20	4.35	0.38	3.30	4.50

DISCUSSION

The pathogenic specificity in certain types of periodontitis has led to treatment strategies, which are primarily aimed at suppression or elimination of specific periodontal pathogens. These therapeutic rationales may rely heavily on systemic or local administration of antimicrobial agents following conventional SRP. Antimicrobials used in conjunction with periodontal debridement will provide more effective and predictable clinical results.[4] An important site for antibacterial drug delivery would seem to be from within the periodontal pocket, where local concentrations at the disease site can be established and maintained at any desired level for any duration.[8]

Traditional therapy for periodontal disease includes mechanical SRP, which removes the deposits from the tooth surface and shifts the pathogenic microbiota to one compatible with periodontal health.[10-13] However, the pocket anatomy is a significant limiting factor in mechanical access, and sufficient reduction of the bacterial load is difficult to achieve.[14] An increased interest in antibiotic therapy as an adjunct to standard periodontal treatment regime began in the late 1970s with the realization that certain bacteria are frequently associated with the disease process. Thus, emerging evidence of bacterial specificity in certain types of periodontitis has led to treatment strategies, which are primarily aimed at suppression or elimination of specific periodontal pathogens. These therapeutic rationales rely heavily on systemic or local administration of antimicrobial agents. Since the use of systemic antibiotics is associated with some disadvantages such as inability of systemic drugs to achieve high gingival crevicular fluid concentration,[15] an increased risk of adverse drug reactions,[16] increased selection of multiple antibioticresistant microorganisms,[17] and uncertain patient compliance,[18] the local administration of drugs is recommended.

Ornidazole specifically acts on Gram-negative anaerobic, facultative bacteria which are responsible for periodontal disease. Ornidazole requires a very low minimum inhibitory concentration to inhibit the growth of periodontal pathogens as compared to that of metronidazole. The antimicrobial activity of ornidazole has been proposed due to the reduction of nitro group to a more reactive amine that attacks microbial DNA, inhibiting further synthesis and causing degradation of existing DNA.[19-21]

This present study shows better improvement in clinical parameters at test sites where treatment with ornidazole along with scaling was performed in comparison with chlorhexidine gel.

As home care regime, the use of antimicrobial agent proves as a useful mode of initial periodontal therapy and could prevent the need of a surgical phase in such patients. Further studies are needed to investigate its use in persistent periodontitis.

CONCLUSION

Hence, it can be concluded that the topical application of ornidazole gel was better than chlorhexidine gel alone and can give desired beneficiary effect.

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