Original Article

LOCAL DRUG DELIVERY SYSTEMS IN THE TREATMENT OF AGGRESSIVE PERIODONTITIS: A PILOT STUDY

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ABSTRACT:

Objective: The present study was designed to evaluate the clinical effects of topical application of CHLO-SITE (Chlorhexidine gel) in management of aggressive periodontitis.

Material and Methods: This study was carried out on 5 patients (aged 25-50) with aggressive periodontitis. They were received scaling and root planning (SRP) alone in one side and SRP plus CHLO-SITE (Chlorhexidine gel) in other side.

Each individual was subjected to the following measurements; (1) Evaluation of the clinical parameters pre and post treatment to detect the outcome of the treatment modality, or at1, 3, 6, months were obtained for microbiological evaluation.

Results: Results showed that (1) CHLO-SITE (Chlorhexidine gel) delivered locally into periodontal disease sites reduced all subgingival bacteria and (2) Both treatment and modality led to a highly statistically significant reduction in microbiological counts as well as clinical parameters applied. No clinical relevant side effects were observed.

Key words: Local Drug Delivery, Antimicrobial Agents, Medical Periodontal Therapy, CHLO-SITE Gel.

INTRODUCTION:

Periodontal diseases are poly microbial infection affecting the supporting tissues of the teeth. Dental plaque is considered as the primary etiological agent for causing periodontal disease.[1] Plaque exists in a state of bio film where microbes live as community instead of planktonic state. Bio film environment provides nutrition and protection to the microorganisms.[2-3]

During the non-specific plaque era (1965-1975), therapeutic goals were directed at total elimination of microbial deposits in the gingival area. During the bacterial specificity era (1975-1985), therapy was directed towards suppression and elimination of putative periodontal pathogens. Now, during the host bacterial interaction era, the emphasis remains on elimination or control of microbial organisms but attention is also directed toward how the host responds to these organisms. With the increasing awareness of the bacterial etiology of periodontal

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diseases a more direct approach using antibacterial agents has become an integral part of the therapeutic armamentarium.[4]

In contrast, local drug delivery can provide high drug concentration, minimal side effects, less reliance on patient compliance for taking the medication, and avoids treating the patient systemically.[5] Controlled delivery systems produce concentration profiles which are more constant and last longer than the other delivery systems. The basic components of controlled delivery devices may be divided into three basic elements: the drug reservoir, the rate controlling element, and the biological platform. The biological platform represents the controlled delivery and is equivalent to substantivity.[6]

Chlorhexidine is a highly effective antimicrobial agent extensively studied and shown to be effective as a mouthrinse in concentrations of 0.12% to 0.2% against supragingival plaque bacteria. It has been shown to bind to the tissues from where it is released over 6-12 hours, prolonging the bactericidal effect. Recently, a new local drug delivery system, xanthan based chlorhexidine gel, has been developed. The chlorhexidine confers the characteristic of active and passive sterility to the formulation, which prevents re-colonizationof pathogenic microorganisms in the application site, and also increases the mucoadhesion of the xanthan gel, occluding the application site. Chlorhexidine is present at a concentration of 1.5%, of which 0.5% is in

the form of fast releasing digluconate and 1.0% is in the form of slow releasing dihydrochloride.[7]

The aim of the present study was evaluate the Chlosite[R] a xanthan based chlorhexidine gel (GHIMAS, Italy) used as an adjunct to SRP in the treatment of aggressive periodontitis.

MATERIAL AND METHODS:

This clinical trial was designed as a prospective, single centre, randomized, controlled, split mouth study of 3 months duration.

Patient Sample: A total of 5 adult patients with aggressive periodontitis were recruited from the outpatient Department of Periodontics Teerthanker Mahaveer Dental College and Research Centre Moradabad.

Inclusion Criteria: The total subjects of age group between 17-50 years were included in this study if they had:

- Completed a satisfactory health history questionnaire.

- Voluntarily signed an informed consent agreement.

- Probing depth of each patient should be 5mm to 8 mm that bled on probing at the initial visit.

Exclusion Criteria: Subjects were excluded if they:

- Had received sub gingival instrumentation (SRP) less than 2

months prior to the baseline examination

• Had any teeth with a periodontal pocket extending to the apex because of possible endodontic/periodontal complications.

Instruments used are as follows: All measurements were performed using a manual probe; the instruments which were used in this study are as follows:

• Chlosite ^{R} a xanthan based chlorhexidine gel(GHIMAS, Italy)

• Mouth mirror

• Explorer (no.17/23)

• Tweezers

• Gloves

• Mouth mask

• Cotton Gauze

• William's periodontal probe (Hu-Freidy, USA)

• Sterillium rub- in hand disinfectant (Bode Chemie, Hamburg, Germany) with a visual read out that was not force controlled.

Treatments: Two sites were selected in subject one is *test* and other one is *control* in two different quadrants were randomly assigned according to split mouth design.

• Xanthan based chlorhexidine gel + SRP (CHX+SRP)

• SRP alone as a control

Subjects were evaluated at baseline, 1,3 and 6 months. Clinical examinations included the following variables:

• Gingival index (GI) [8]

• Probing pocket depth (PPD): the distance between gingival margin and the bottom of the probable pocket assessed by the use of a UNC no. 15 manual probe and recorded to the nearest whole mm.

• Clinical attachment level (CAL): the distance from cemento-enamel junction (CEJ) to the base of the pocket.

Chlosite^R (GHIMAS, Italy) is a xanthan based syringable gel system. The gel is a combination of two chlorhexidine formulations: 0.5% chlorhexidine digluconate and 1.0% chlorhexidine dihydrochloride incorporated in a saccharidic polymer, xanthan. The chlorhexidine xanthan based gel (CHX) undergoes a progressive process of imbibition and is physically removed in 10-30 days. Chlorhexidine digluconate is liberated in the first day and achieves a concentration >100 µg/ml which is maintained for an average of 6-9 days which is greater than the minimum inhibitory concentration (MIC) for chlorhexidine (0.10µg/ml). Chlorhexidine dihydrochloride is released in the following days and maintains the bacteriostatic and bactericidal concentrations for at least 2 weeks and prevents recolonization. The CHX gel is supplied with a special needle having a blunt tip and a lateral opening. This facilitates the application of the gel without traumatizing or damaging the

periodontal tissues. After isolating and drying the sites, CHX gel was injected into the periodontal pocket and no periodontal dressing was used.[9]

Indications: [3]

- Deep pockets with difficult access to scaling and root planning

- Deep pockets that fail to respond scaling

- Refractory sites

- Pockets exuding pus

- Sites with acute lateral abscess

Local Delivery Agents: [10] The choice of the antimicrobial agents in periodontal diseases must be based on the bacterial etiology of the infection. Several antibiotics have been tested for their clinical and microbiological efficacy in periodontal diseases. It can be noted that only a limited number of antimicrobial agents have been used so far in formulations of local delivery systems. There are distinct phases in a periodontal treatment plan where a dental practitioner can use a sustained release device. It can be used as an adjunct to scaling and root planning and for periodontal maintenance therapy. It can be safely used in medically compromised patients for whom surgery is not an option or those who refuse surgical treatment. It is highly contraindicated in patients with known hypersensitivity to the antimicrobial used as local drug and the delivery of antimicrobial using ultrasonic devices is contraindicated in

asthmatics and infective conditions such as AIDS, Tuberculosis.

Treatment Procedures: All subjects received a full mouth supra- and sub gingival SRP using an ultrasonic scaler and curettes. Subjects were given careful instructions in self performed oral hygiene measures; twice daily brushing using the modified Bass brushing technique with a soft toothbrush and a regular toothpaste with fluoride. The use of antimicrobial mouth rinses was not allowed during the study period. The level of oral hygiene was checked at each recall visit and further instructions were given when indicated.

RESULTS:

All subjects showed statistically and clinically significant improve in full mouth, gingival, and plaque indices at both follow up visits when compared to the baseline levels.(Table 1-6 and Figure 1-3)

DISCUSSION:

Treatment Effect: Both the gingival and plaque indices remained satisfactory during the entire study period, suggesting patients complied with the oral hygiene instructions. The reduction in plaque and gingival scores could be due to the proper oral hygiene maintenance and the thoroughness of SRP.

Clinically, improvement gingival and plaque indices, reduction in PPD, seen following extensive SRP (alone), are apparently due to reduction of inflammation secondary to alteration in the subgingival bacteria [11, 12] In addition

to the elimination of local etiological factors, it has been recently proposed a scaling procedure may also elicit a local and systemic host response that would aid in eliminating local infection and promote healing.

In the chlorhexidine treated group, CHX+SRP, PPD reduction can be attributed to the bactericidal concentrations achieved within day 1 at the selected sites, and these higher concentration levels were maintained for 2 weeks thereafter. Therefore, enhanced healing may have occurred at the test sites in the absence or following reduction of microbial load. [13]

CONCLUSION:

Local drug therapy markedly improves the benefits of SRP, and by the use of these agents the threshold for surgical

periodontal therapy might be moved towards deeper pockets.

In conclusion, the publications dealing with efficacy studies suggest that the controlled delivery devices are a useful adjunct to conventional surgical or non-surgical treatments, but are no substitute for these measures. In particular, controlled delivery systems are of interest as an adjunct for aggressive periodontitis. Despite the large number of studies, there are insufficient comparative data to support any one of the local delivery systems as superior to another and several questions related to the optimal use of such new therapies remain.

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TABLES:

Table 1. Mean values of GI scores (Test) at baseline, 1, 3 month and 6 months.

Time period	Mean ± SD (in mm)	p-value
Base line	0.25 ± 0.18	
1month	0.15 ± 0.10	0.001
3 months	0.12 ± 0.15	0.001
6 months	0.32 ± 0.11	0.002

Table 2. Mean values of GI scores (Control) at baseline, 1, 3 month and 6 months.

Time period	Mean ± SD (in mm)	p-value
Base line	0.24 ± 0.14	
1month	0.26 ± 0.11	0.001
3 months	0.16 ± 0.12	0.001
6 months	0.13 ± 0.09	0.001

Table 3. Mean Value of PDD Scores (Test) At Baseline, 1, 3 Month and 6 Months

Time period	Mean ± SD (in mm)	p-value
Base line	0.13 ± 0.32	
1month	0.23 ± 0.12	0.001
3 months	0.21 ± 0.11	0.001
6 months	0.16 ± 0.32	0.003

Table 4. Mean Value of PDD Scores (Control) At Baseline, 1, 3 Month and 6 Months

Time period	Mean ± SD (in mm)	p-value
Base line	0.09 ± 0.22	
1month	0.24 ± 0.21	0.001
3 months	0.25 ± 0.31	0.002
6 months	0.18 ± 0.28	0.003

Table 5. Mean values of CAL scores (Test) at baseline, 1, 3 month and 6 months.

Time period	Mean ± SD (in mm)	p-value
Base line	1.31 ± 1.11	
1 month	0.20 ± 0.01	0.001
3 months	0.24 ± 0.01	0.001
6 months	0.25 ± 0.04	0.001

Table 6. Mean values of CAL scores (Control) at baseline, 1, 3 month and 6 months.

Time period	Mean ± SD (in mm)	p-value
Base line	0.21 ± 1.30	
1 month	0.30 ± 0.02	0.001
3 months	0.10 ± 0.01	0.001
6 months	0.41 ± 0.02	0.002

FIGURES:

Figure 1 Mean values of GI scores (Test and Control) at baseline, 1, 3 and 6 months.
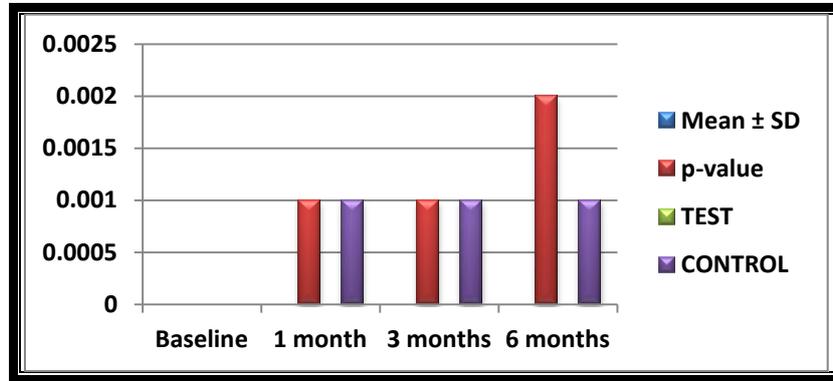

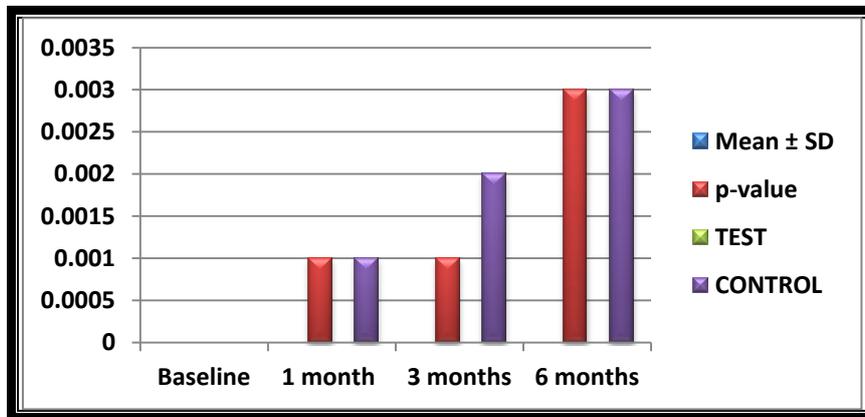Figure 2. Mean value of PDD scores (Test and Control) at baseline, 1, 3 and 6 months

Figure 3. Mean value of PI scores (Test and Control) at baseline, 1, 3 and 6 months.