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Research Article

Comparative Clinical Evaluation of Local Drug Delivery System of Tetracycline Fiber, Hyaluronan Gel and Chlorhexidine Gel, as Adjunct to Scaling and Root Planing with Scaling and Root Planing Alone in the Treatment of Chronic Periodontitis

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Abstract

Aim: The aim of this study was to evaluate the effects of hyaluronan (HA) and chlorhexidine (CHX) gels as adjunct to scaling and root planing (SRP) in the treatment of chronic periodontitis.

Materials and Methods: 40 patients within the age group of 25 - 55 year participated in the study were randomly equally divided into four groups. Complete SRP and subgingival debridement were performed within all the patients. For control (Group IV) patients, SRP was the only treatment modality given; for group I, II and III patients, at least 10 teeth with 4 - 8 mm probing pocket depth (PPD) were selected for subgingival application of Tetracycline fiber, HA gel and CHX gel, respectively. Clinical periodontal parameter such as gingival index, PPD, and clinical attachment level (CAL) were recorded at baseline and 3 months, whereas plaque index was recorded at baseline, 1 month, and 3 months.

Results: In all the four groups, a significant reduction in PPD and gain in CAL were observed between baseline and 3 months follow-up ($P < 0.05$); however, at 3 months, PPD was decreased more in group II. In group III pocket depth decreased less than group I but it is not significant. Group IV shows fewer changes in pocket depth than group I, II and group III, but the difference was non-significant, and group IV (control) showed less changes in PPD and CAL than all experimental groups.

Keywords: *Chlorhexidine; Chronic Periodontitis; Hyaluronan*

Introduction

Scaling and root planing (SRP) is effective means of treating and controlling periodontal disease; however, the ability of the clinician to gain access to deep pockets often results in a substantial variation in its effectiveness, and therefore to compensate this technical limitations, and to prevent early microbial re-colonization, the adjunctive use of antimicrobial so anti-inflammatory-agents-may-be-indicated-to-ensure-the-best chance for clinical improvements [1]. The recent development of sophisticated, subgingivally placed delivery systems has provided the possibility of maintaining effective, intra pocket levels of antimicrobial agents for extended periods of time.

Tetracycline Fiber (periodontal plus AB), advanced xanthan-based 1.5% chlorhexidine (CHX) gel (CHLO-SITE®, Ghimas, Italy) is supplied in syringe (0.5 mL) with a special needle having a blunt tip and a lateral opening. The rationale for the adjunctive use of xanthan gum in a subgingival gel carrier relates to the increased viscosity of the carrier and in the bio adhesive properties of the polysaccharides, both of which may limit the clearance of CHX (occluding effect) from the periodontal pocket [2]. Hyaluronan (HA) gel (GENGIGEL® Ricerfarma, Milan, Italy) is an ovel product that contains high molecular weight fraction of hyaluronic acid that is produced by a non animal derived biotechnological process. Hyaluronan is a linear polymer derived from two repeating disaccharide subunits (D-Glucuronic acid and N-acetylglucosamine), and is a natural constituent of the body's glycosaminoglycan (GAG) population [3]. Johannsen., *et al.* [3] reported that the adjunctive use of hyaluronic acid after thorough mechanical debridement potentially has major clinical benefits in terms of improved healing after non-surgical periodontal (NSP) therapy.

Recent years have seen the revival of the concept that periodontitis may have an etiological or modulating role in other systemic diseases; however, there is still much debate regarding the nature and degree to which this may happen [4].

Aim of the Study

The aim of this study was to evaluate clinical and systemic effects of CHX and hyaluronan gels as adjunct to SRP in the treatment of chronic periodontitis. All systemic parameters were recorded at baseline, after 24h, 1 month, and 3 months.

Materials and Methods

This study was conducted in the Department of Periodontology, Chandra Dental College and Hospital Safedabad Barabanki, UP. Ethical clearance for the study was obtained from Chandra Dental College and Hospital Safedabad Barabanki, UP. Motivated, non-smoker, non-alcoholic patients with non-contributory medical history suffering from generalized chronic periodontitis were selected among the patients visiting the Department of Periodontics for this randomized clinical study. An informed consent was obtained after fully explaining about possible risk and procedure.

Inclusion criteria

Patients between the age group of 25 - 55 years, who were diagnosed as moderate to severe generalized chronic periodontitis, having at least 20 teeth, minimum of 10 teeth with probing pocket depth (PPD) of 4 - 8 mm, and should not have received any antibiotic and periodontal therapy for past 6 months were included for the study.

Exclusion criteria

Patients with known allergy to hyaluronic acid and CHX, pregnant women, and nursing mothers were excluded. Teeth with periapical disease and sites with over hanging restorations were also not included for the study.

Clinical parameters

Clinical parameters, PPD and clinical attachment level (CAL),were measured using University of North Carolina(UNC)-15 probe (Hu-Fridey Instruments, Chicago, IL, USA) in the periodontal pocket parallel to the vertical axis of the tooth to nearest millimeter up to 1 mm. PPD, CAL, and gingival index (GI) (Loe and Silness) [5] were recorded at baseline and 3 months, whereas plaque index (PI) (Silness and Loe) [5] was recorded at baseline, 1 month, and 3 months.

Methodology

Fourty patients within the age group of 25 - 55 years were recruited to participate in the study. Complete SRP and subgingival debridement were performed within 6 using magnetostrictive ultrasonic scalars and tips No. TFI 3 and 10 (Cavitron, Dentsply), and

Gracey curettes (Hu-Fridey Instruments, Chicago, IL, USA). Local anesthesia in the form of in filtration and spray were used as and when required. After debridement, patients were randomly selected to form control (Group IV) and experimental (Group I, group II and group III) groups, consisting of 10 patients in each group.

For group IV (control) patients, SRP was the only treatment modality given and ten teeth with 4 - 8 mm PPD were selected for measuring the clinical parameters. For group I patients, at least ten teeth with 4 - 8 mm PPD received subgingival application of tetracycline fibers. For group II patients, at least ten teeth with 4 - 8 mm PPD received subgingival application of hyaluronan (HA) gel. Selected teeth were isolated and dried with cotton rolls. Pre-filled hyaluronan gel bulb was loaded into applicator. End of the bulb was cut and placed into the selected periodontal pockets up to the gingival margin (till material flowed out of sulcus) and Coe-pak was applied over the experimental sites. For group III patients, at least eight teeth with 4 - 8 mm PPD received subgingival application of CHX gel. Selected teeth were isolated and dried with cotton rolls. Blunt needle of prefilled syringe was inserted into the pockets in those sites that had been randomly assigned to receive it and Coe-pak was applied over test sites. All the participated patients were asked to maintain meticulous oral hygiene. Coe-pak applied was removed after 10 days.

Results

All recruited 40 patients (20 males and 20 females, mean age: 38.17 years ± 8.84 years) completed the study uneventfully. Over the following 3 months, no major changes in the medical history (BP: 132.03 ± 16.74/80.93 ± 10.31 mmHg; P: 78.6 ± 11.44 beats/mins; T: 37.56°C ± 0.78°C, R: 16.8 ± 1.23 breath/min) were reported at the time of all the study visits.

Clinical periodontal parameters

Clinical periodontal parameters in the four study groups are shown in table 1. In all the three groups, minimum values for PI and GI were observed at 3 months and maximum at baseline. Statistically, there was no significant difference at different time intervals (P = 0.05). The mean change in the PI was statistically significant (P = 0.005) in all the three groups, at both the follow up intervals as compared to baseline. Similarly, in all the three groups, the change in mean GI from baseline to 3 months follow up was significant statistically (P = 0.05). In all the three groups, a significant reduction in PPD and gain in CAL were observed between baseline and 3 months follow-up (P = 0.05); however, at 3 months, change in PPD and CAL was more in group II than group III, but the difference was non significant and group I (control) showed less changes in PPD and CAL than both experimental groups.

S. No.	Parameter	Group I (n = 10)		Group II (n = 10)		Group III (n = 10)		Group IV (n = 10)		Significance of difference	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	x^2	p
1	Plaque Index	2.88	0.1	2.87	0.1	2.89	0.11	2.85	0.1	0.89	0.64
2	Gingival Index	2.83	0.08	2.84	0.08	2.82	0.07	2.82	0.07	0.53	0.76
3	Probing Depth	5.44	0.55	5.93	0.6	5.95	0.31	5.9	0.27	0.08	0.95
4	Clinical Attachment Level	6.14	0.5	6.13	0.54	6.15	0.36	6.1	0.38	0.10	0.94

Table 1: *Clinical parameters comparison of changes in mm.*

S. No.	Group	Mean Change ± SD	z	P
1	Group I: TC Fibre + SRP	2.49 ± 0.27	2.826	0.005*
2	Group II: Gengigel + SRP	2.52 ± 0.42	2.829	0.005*
3	Group III: Chosite + SRP	2.47 ± 0.32	2.825	0.005*
4	Group IV: SRP alone control	1.60 ± 0.27	2.827	0.005*

Table 2: *Comparison of changes in mean plaque index.*

S. No.	Group	Mean Change ± SD	z	p
1	Group I: TC Fibre + SRP	2.18 ± 0.22	2.9	0.004*
2	Group II: Gengigel + SRP	2.15 ± 0.19	2.8	0.005*
3	Group III: Chosite + SRP	2.20 ± 0.21	2.9	0.004*
4	Group IV: SRP alone control	2.22 ± 0.22	2.9	0.004*

Table 3: *Comparison of change in mean gingival index.*

S. No.	Time Interval	Group I: TC Fibre + SRP		Group II: Gengigel + SRP		Group III: Chlosite + SRP		Group IV: SRP alone control		Significance of difference	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	x^2	p
1	Baseline	2.85	0.1	2.82	0.1	2.86	0.1	2.89	0.1	0.89	0.64
2	1 month	1.33	0.2	1.27	0.2	1.37	0.1	1.39	0.2	1.9	0.387
3	3 months	0.66	0.1	0.64	0.1	0.66	0.1	0.68	0.1	0.22	0.896

Table 4: *Comparison of change in mean probing pocket.*

S. No.	Group	Mean Change ± SD	z	p
1	Group I: TC Fibre + SRP	1.25 ± 0.16	2.877	0.004*
2	Group II: Gengigel + SRP	1.45 ± 0.20	2.913	0.004*
3	Group III: Chosite + SRP	1.19 ± 0.27	2.821	0.005*
4	Group IV: SRP Alone control	0.55 ± 0.16	2.877	0.004*

Table 5: *Comparison of change in mean clinical attachment level.*

Local drug delivery (Periodontal plus AB) group I

Figure 1: *After scaling and root planing.*

Figure 2: *Tetracycline fiber application.*

Figure 3: *Postoperative 3 months.*

Local drug delivery (GENGIGEL) group II

Figure 4: *Before scaling and root planing.*

Figure 5: *PPD measurement at baseline.*

Figure 6: *Gengigel application.*

Figure 7: *COE-PAK applied.*

Figure 8: *Postoperative 3 months.*

Local drug delivery (Chlo-site) group III

Figure 9: *Before scaling and root planing.*

Figure 10: *PPD measurement at baseline.*

Figure 11: *Chlo-site application.*

Figure 12: *COE-PAK applied.*

Figure 13: *PPD measurement at 3.*

Discussion

Periodontal diseases are primarily caused by bacterial infections that lead to inflammation and destruction of periodontal tissues [6]. Conventional management of chronic periodontitis involves scaling and root planing (SRP) along with maintenance of oral hygiene, which results in reduction of inflammation, probing pocket depth (PPD), and improvement in clinical attachment level (CAL) [7]. However, due to the complex structure of subgingival biofilms, mechanical therapy alone may not always eliminate pathogenic microorganisms. Therefore, adjunctive chemotherapeutic agents delivered locally into periodontal pockets have been proposed to enhance therapeutic outcomes [8].

The present study evaluated and compared the clinical efficacy of three local drug delivery (LDD) systems-0.8% Hyaluronan (HA) gel, tetracycline fibers, and xanthan-based 1.5% chlorhexidine (Xan-CHX) gel-when used as adjuncts to SRP, and compared them with SRP alone in patients with chronic periodontitis.

Hyaluronic acid is a high-molecular-weight polysaccharide naturally present in connective tissues and plays a significant role in tissue repair, regeneration, and modulation of inflammation [9]. Previous studies have demonstrated its anti-inflammatory, anti-edematous, and antibacterial properties [10,11]. In the present study, HA gel showed improvement in clinical parameters, particularly PPD reduction and CAL gain, which may be attributed to its role in facilitating cell migration, tissue healing, and extracellular matrix stabilization.

Tetracycline fibers provide sustained local release of tetracycline within the periodontal pocket for approximately 7 - 10 days [12]. The antimicrobial activity, substantively, collagenase inhibition, and anti-inflammatory effects of tetracycline contribute to reduction in bleeding, plaque accumulation, and periodontal pocket depth. The results of the present study demonstrated significant improvement in clinical parameters with tetracycline fibers used as an adjunct to SRP [12].

Chlorhexidine is a broad-spectrum antiseptic with high substantively. The xanthan-based CHX gel formulation improves drug retention within the periodontal pocket due to its bioadhesive and viscous properties, allowing maintenance of effective antimicrobial concentrations for extended periods [13]. In the present study, Xan-CHX gel also showed reduction in PPD and improvement in CAL when used as an adjunct to SRP.

Regarding clinical parameters, plaque index (PI) and gingival index (GI) showed significant reduction in all groups over the study period. However, intergroup comparisons revealed no statistically significant differences, indicating that improvements were mainly related to effective mechanical debridement and improved oral hygiene practices.

Probing pocket depth and clinical attachment level demonstrated greater improvement in groups receiving adjunctive LDD therapy compared with SRP alone. Among the test groups, the HA gel group showed comparatively greater reduction in PPD and gain in CAL at the 3-month evaluation.

Overall, the findings suggest that SRP remains the primary and effective treatment for chronic periodontitis. However, adjunctive local drug delivery systems such as hyaluronic acid gel, tetracycline fibers, and xanthan-based chlorhexidine gel may enhance clinical outcomes by improving periodontal healing and reducing microbial load.

The study was limited by a relatively small sample size and short follow-up period. Therefore, further long-term randomized controlled clinical trials with larger sample sizes are recommended to confirm the therapeutic benefits and anti-inflammatory effects of these local drug delivery agents.

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