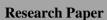
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Comparative evaluation of efficacy of 0.1 gram placentrex gel and 0.2% hyaluronic acid gel as an adjunct to scaling and root planing in chronic periodontitis patients: A Randomized Clinical Trial.

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ABSTRACT: Periodontal disease is the multifactorial disease that leads to the destruction of the tooth supporting structures. Delivery of therapeutic agents into the local milieu act as drug reservoirs could alter pathogenic flora & promote its repair & wound healing. Human fibronectin type III peptide, found in placenta has high efficacy of stimulating cell migration and wound repair. On the other hand, Hyaluronan, a non sulfated glycosaminoglycan, is a critical component of the extracellular matrix and helps in migration and proliferation. Hence, this study was carried out to check the effectiveness of the components in chronic periodontitis patients. Aim: To assess the clinical effects of placentrex and hyaluronic acid gel and compare it with scaling and root planing in patients with chronic periodontitis. Methodology: A sample of 50 patients and 150 sites were randomly selected from the OPD of the Department of Periodontology and Oral Implantology, Kothiwal Dental College and Research Centre, Moradabad. Selected sites were distributed randomly into three groups by chit method. Group A- control group, Group B - placentrex gel as local drug delivery was used, Group C - hyaluronic acid gel as local drug delivery was used.

Results: Inter-group comparisons of plaque index, gingival index, clinical attachment level and probing depth at each follow up revealed significant difference between the groups during the follow-up. More better results were observed in group C. Intra-group comparison revealed that there was a statistically significant reduction in the parameters at each follow up as compared to baseline. Conclusion: Thus, to conclude that all the groups revealed significant reduction. But upon comparing the three groups 0.2% hyaluronic acid revealed better outcomes.

KEYWORDS: Local drug delivery, Placentrex gel, Hyaluronic acid gel.

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I. INTRODUCTION

Periodontal disease is the multifactorial disease that leads to the destruction of the tooth supporting structures. It is one of the most prevalent global chronic disorder affecting the structure surrounding teeth resulting in inflammation initiated by bacterial aggregation & alteration in their profile. Conventional periodontal therapeutics has focused on the control of etiologic agents which promotes healing and repair of tissues. Delivery of therapeutic agents into the local milieu act as drug reservoirs could alter pathogenic flora & promote its repair & wound healing. Human fibronectin type III peptide has high efficacy of stimulating cell migration and wound repair. Human Placental extracts can directly facilitate the process of wound healing through fibronectin type III active biomolecules. Hyaluronan, a non sulfated glycosaminoglycan, is widely distributed throughout connective tissue and epithelial and neural tissues. It is a critical component of the extracellular matrix and helps in migration and proliferation. Hyaluronan is also produced by fibroblasts in the presence of endotoxin. It also has an anti-inflammatory role through the inhibition of tissue destruction and can

facilitate healing.^{5,6}Thus, the present study aimed to assess the clinical effects of placentrex and hyaluronic acid gel and compare it with scaling and root planing in patients with chronic periodontitis.

II. METHODOLOGY

A sample of 50 patients and 150 sites which fulfilled the eligibility criteria were randomly selected from the OPD of the Department of Periodontology and Oral Implantology, Kothiwal Dental College and Research Centre, Moradabad. Selected sites were distributed randomly into three groups by chit method. Inclusion criteria included subjects between the age group of 25 and 60 years, subjects with minimum of 20 teeth, subjects who readily gave informed consent for the study and patients with mild to moderate periodontitis in at least 1 tooth in 3 quadrants⁷. Exclusion criteria included patients who consumed tobacco in any form, those who had undergone periodontal therapy in the last 6 months, patients who had received antibiotic therapy in the previous 3 month, patients who were taking or had consumed vitamin supplements, anti-inflammatory agents, or statins in the previous 3 months, patients with any systemic disorder affecting periodontal health, pregnant and lactating mother, regular users of mouthwash and chronic alcoholics. All study subjects underwent an oral examination. Plaque index (PI)⁸, gingival index (GI)⁹, clinical attachment level (CAL) and probing depth(PD) were recorded by a single examiner. Prefabricated stent was used to record PD and CAL. Sites were selected and divided into three groups. GROUP A: Control group in which scaling and root planing was performed. GROUP B: Test group in which scaling and root planing with 0.1 gram placentrex gel as local drug delivery was used. GROUP C: Test group in which scaling and root planing with 0.2% hyaluronic acid gel as local drug delivery was used. Scaling and root planing was performed in all the three groups. The experimental sites were gently dried using an air syringe and isolated with cotton rolls. This was followed by subgingival administration of 0.1 gram placentrex and 0.2% hyaluronic acid gel in the required site. Co - pak was placed for retention of the material. Each subject was told to report immediately if the pack was dislodged before the scheduled recall visit or if any sort of discomfort, pain, burning sensation, or any allergic reaction occurred. Patients were recalled after 15th day, 1 month and 3 months. GI and PI were assessed at baseline, 15 days, 1 month and 3 months and CAL and PD were assessed at baseline and 3 months.

STATISTICAL METHODS

The statistical software SPSS 19.0 is used for analysis of data. The descriptive statistics like mean and S.D. of data were calculated. The significance difference of parameters between two groups (inter group comparison) was tested by t test and within group (intra group comparison) was done by ANOVA Test The 95% C.I. and 5% level of significance was used for analysis of data.

III. RESULTS

150 sites were selected from 50 patients, showing PPD \geq 5 mm in at least one tooth in the contralateral quadrants. These patients, in the age group of 25–60 years, satisfied the inclusion criteria of having chronic periodontitis. All subjects completed the study. For PI and GI, site-specific scores were recorded and tabulated. For PPD the deepest probing depth and its corresponding CAL for the selected tooth were recorded and tabulated. These recordings were subjected to both intra and inter group comparisons. Inter-group comparisons of PI, GI, CAL and PD at each follow up revealed significant difference between the groups during the follow-up. More better results were observed in group C. Intra-group comparison revealed that there was a statistically significant reduction in the PI, GI, CAL and PD scores at each follow up as compared to baseline. (Table 1,2,3,4, Graph 1,2,3,4)

	Group A	Group B	Group C	P value
Baseline	3.88±0.824	3.88±0.824	3.90±0.839	0.073
15 th day	1.72±0.454	1.32±0.819	0.90±0.580	0.00
1 month	1.30±0.463	0.96±0.69	0.80±0.535	0.00
3 month	1.34±0.479	1.00±0.728	0.82±0.560	0.00

Table 1: Inter-group comparison of plaque index using Student's t-test

^{*}Significant p < 0.05, not significant p > 0.05

Table 2: Inter-group comparison of gingival index using Student's t-test

	Group A	Group B	Group C	P value
Baseline	2.48±0.646	2.48±0.646	2.48±0.646	0.105
15 th day	1.46±0.579	1.30±0.647	1.28±0.671	0.00
1 month	1.12±0.435	0.90±0.544	0.62±0.602	0.00
3 month	0.92±0.274	0.76±0.431	0.48±0.505	0.00

^{*}Significant p <0.05, not significant p>0.05

Table 3: Inter-group comparison of clinical attachment level using Student's t-test

	Group A	Group B	Group C	P value
Baseline	3.92±0.695	3.92±0.695	3.92±0.695	0.080
3 months	2.82±0.482	2.60±0.95	2.04±0.533	0.00

^{*}Significant p <0.05, not significant p>0.05

Table 4: Inter-group comparison of probing depth using Student's t-test

	Group A	Group B	Group C	P value
Baseline	5.32±0.621	5.32±0.621	5.32±0.621	0.105
3 months	3.22±0.910	2.92±0.829	1.08±0.535	0.00

^{*}Significant p <0.05, not significant p>0.05



Figure 1: Placentrex gel



Figure 2: 9 mm probing depth before application of Placentrex gel



Figure 3: 4 mm probing depth, 3 months after application of Placentrex



Figure 4: 0.2% Hyaluronic acid gel



Figure 5: 8 mm probing depth before application of Hyogel



Figure 6: 5 mm probing depth, 3 months after application of Hyogel

IV. DISCUSSION

Periodontal diseases are plaque associated infections and appears in a generalized form. They appear in local areas in a patient's mouth or is reduced to localized areas after Phase I treatment. 10 Nonsurgical therapy remains the cornerstone of periodontal treatment. 11 However, the ability of the clinician to gain access to deep pockets during scaling and root planing results in variation in its effectiveness. ¹⁰ To overcome these limitations, local drug delivery systems were developed.HA has been attributed a protective role in inflammatory damage. Hyaluronan in its various forms, shows bacteriostatic, fungistatic, anti-inflammatory, anti-edematous, osteoinductive, and pro-angiogenetic properties, thereby promoting wound healing in a variety of tissues. 12 Human Placental extracts directly facilitates the process of wound healing through fibronectin type III active biomolecules. It has been reported that human fibronectin type III peptide has high efficacy of stimulating cell migration and wound repair. ⁴A sudy by Akagi et al (2016)¹³ demonstrated that human placental extracts increased collagen type-1 production, linking to the regenerative capabilities of periodontal tissue, on primary human gingival fibroblasts in vitro. Another study by Sharma et al., in 2020¹⁴ revealed statistically significant improvement in clinical parameters with notable difference in probing depth reduction & gain of clinical attachment level in the treatment group subjected to scaling and root planing & placental extract delivery. Similar results were observed in our study with significant reduction in PI, GI, PD and gain in CAL.A study by Shah et al., in 2016 used hyaluronan as an adjunct to scaling and root planing versus scaling and root planing alone in the treatment of chronic periodontitis. Results revealed a statistically significant reduction in PI, GI, probing pocket depth and gain in relative attachment level. This study has similar results with our study which also revealed a significant reduction in PI, GI, PD and gain in CAL. ¹⁵ Another study by Mohammad et al., in 2023 revealed similar results to our study that used hyaluronic acid gel as an adjunct to scaling and root planing. This study have positive effects on probing depth reduction, attachment gain and gingival index. 16 The resuts in this study revealed similar outcomes as our study. A number of studies on hyaluronic acid gel have advocated its use as monotherapy or as adjunct to nonsurgical, surgical periodontal treatment to reduce inflammation and promote wound healing. 17-19In our study intragroup comparison revealed significant reduction in PI, GI, PD and CAL in all the three groups. Upon comparing all the three groups, better outcomes were observed in the 0.2% hyaluronic acid group in 15th day, 1 month and 3 months. To the best of our knowledge, this is the 1st randomized controlled trial study which compared 0.1 gram placentrex gel, 0.2% hyaluronic acid gel as an adjunct to scaling and root planing with scaling and root planing alone.

V. CONCLUSION

Thus, to conclude that all the groups revealed significant reduction in PI, GI, PD and CAL. But upon comparing the three groups 0.2% hyaluronic acid revealed better outcomes. This is because of its antiinflammatory, anti-microbial and regenerative properties, it is gaining interest in the treatment of periodontitis. However, further studies with larger sample size are and longer follow up period are required to establish better treatment outcomes.

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