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HYALURONAN GEL (0.2%) AN ADJUNCT TO SCALING IN CHRONIC GINGIVITIS.

Dental Science

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ABSTRACT

Background: Hyaluronic acid (Hyaluronan) is an extracellular constitute of the connective tissue acts as a barrier to plaque bacteria and maintains the health of gingival tissue. Recently, 0.2% Hyaluronic acid is introduced as an anti-inflammatory agent for topical application in the treatment of chronic gingivitis.

Aims: To evaluate the clinical efficacy of topically applied 0.2% Hyaluronic acid containing gel as an adjunct to scaling in plaque induced moderate to severe chronic gingivitis subjects.

Materials and Methods: 40 subjects of both gender; and ages ranging 18-35 years diagnosed with plaque-induced moderate to severe chronic gingivitis, were divided into two groups of 20 each: Test Group (scaling along with application of 0.2% hyaluronic acid) and Control Group (scaling alone). Plaque index (Silness and Loe 1964), gingival index (Loe and Silness, 1963), and sulcus bleeding index (Muhlemann and Son, 1971) of each subject were recorded at baseline, 2 and 4 weeks period.

Statistical analysis: Data was analysed using Student's unpaired't' test.

Results: Intergroup comparison of the two treatment modalities revealed a statistically significant improvement in the clinical parameters for both groups at 4th week. Mean reductions in Gingival Index score (GI) was 1.06 ± 0.35 (Test Group) and 0.76 ± 0.23 (Control Group), respectively and Sulcus Bleeding Index score (SBI) was 1.21 ± 0.26 and 0.97 ± 0.22, respectively, which were statistically significant ($P \leq 0.05$).

Conclusions: Topically applied 0.2 % Hyaluronic acid containing gel as an adjunct to scaling was more effective in treating plaque induced moderate to severe gingivitis than scaling alone.

KEYWORDS:

Gingivitis, scaling, 0.2% hyaluronic acid gel, local drug delivery

INTRODUCTION

Plaque-induced inflammatory gingivitis is very common, and generally follows a cyclic or relapsing pattern. Early stages of gingivitis may regress with correct oral hygiene, whereas the more advanced forms of gingival inflammation may not heal without specific dental treatment. As a part of non-surgical therapy, local drug therapy is a common mode of therapy. Topical delivery has the advantage of bringing a high concentration of drug where needed without exposing the whole body. The scarcity of topical preparations is probably due to the sensory unacceptability of the possible active constituents and partial ingestion of the drug. Viscous preparations (gels, pastes etc.), adhere to the gingiva and thus guarantee the active constituent to perform its effect in situ for a longer period, thus viscous preparations are preferred[1].

The endogenous hyaluronan (HA) is a high-molecular weight (10,000-10,000,000 Da), non-sulfated polysaccharide component of the glycosaminoglycan family, which is present in the extracellular matrices of many tissues such as skin, synovial joints and periodontal tissues. Hyaluronan has been identified in all periodontal tissues, being particularly prominent in the non-mineralized tissues such as gingival and periodontal ligament. It is present in only low quantities in mineralized tissues such as cementum and alveolar bone[2].

Hyaluronan has many structural and physiological functions within tissues. It is also a key component in the series of stages associated with the wound-healing process in both mineralized and non-mineralized tissues[3,4]. It is evident that hyaluronan has a multifunctional role in wound-healing processes, with similar mechanisms of healing potentially existing within periodontal tissues. As a consequence of its non-toxicity, biocompatibility and numerous biochemical and physiochemical properties, the use of exogenous hyaluronan or hyaluronan-based biomaterials, applied topically to inflamed periodontal sites, would appear to offer beneficial effects in modulating and accelerating the host response, which has already been demonstrated in fields such as ophthalmology, dermatology and rheumatology[5,6].

The topical application of a high-molecular weight exogenous hyaluronan-based gel has been proposed to have some potential in inducing periodontal healing in subjects with inflammatory gingivitis, during both open and randomized, controlled double-blind studies conducted by Vangelisti et al[1] and Pagnacco et al[7].

Gengigel® (0.2% hyaluronic acid containing gel)

It is a gel containing high-molecular weight sodium salt of exogenous hyaluronic acid (mean m/w 1,500,000) at the concentration of 0.2%, obtained by the biotechnology method. It is nontoxic and has been used as a topical agent. Its antibacterial and antiseptic activity is boosted by the addition of 2, 4-dichlorobenzene methanol. The formulation consisted of a pleasant gel sweetened with the non-cariogenic sugar xylitol[8].Gengigel® provides maximum adhesion and thus allows hyaluronic acid (which would otherwise be eliminated by constant salivary drainage) to remain in situ.

Hence, a study was conducted to evaluate the efficacy of 0.2% HA gel as an adjunct to scaling in plaque induced moderate to severe chronic gingivitis subjects.

MATERIAL AND METHODS

40 subjects of both genders, diagnosed with chronic gingivitis were selected for the study and randomly assigned into two groups of 20 each;

Test Group: scaling along with application of 0.2% hyaluronic acid containing gel.

Control Group: scaling alone.

The clinical parameters namely: plaque index, gingival index and sulcus bleeding index were recorded at baseline, 2-week and 4-week period.

INCLUSION CRITERIA

Systemically healthy and co-operative subjects between age range of 18- 35 years with no history of any periodontal treatment in last 6 months having clinical signs of gingivitis (bright red discolouration of gingiva, bleeding on probing, oedematous gingiva), and Probing depth of < 3 mm with no evidence of clinical attachment loss.

EXCLUSION CRITERIA

Medically compromised subjects, subjects having habit of smoking or tobacco chewing, pregnant and lactating females and those taking oral contraceptive pills were excluded. Subjects with history of intake of medications such as antibiotics and analgesics within past 6 weeks, subjects with history of over the counter anti- oxidants like Vitamin C, Vitamin E or β- Carotene within the past 3 months were excluded.

Ethical clearance was obtained from the institutional ethical committee.

All the study subjects underwent full mouth scaling. Oral hygiene instruction were given to all the subjects. Test Group subjects were instructed for application of 0.2% hyaluronic acid containing gel.

APPLICATION OF GENGIGEL®

Gengigel was taken on the cotton bud applicator and applied onto the gingival surface with gentle pressure. Subjects were instructed to avoid eating, drinking or rinsing for 1 hour after gel application. The application of the gel was repeated by the subjects using the gel tube supplied to each subjects in the similar manner twice daily for 28 days. Clinical parameters were assessed at baseline, 2 weeks and 4 weeks.

Data obtained was tabulated and subjected to statistical analysis. Different subgroups were compared using Student's't' test.The mean value and p value were calculated.

RESULTS

There were no dropout cases and all the 40 subjects maintained their appointments.

On intragroup comparison mean plaque score for test group at baseline was 2.26 ± 0.25, at 2 weeks mean was 1.68 ± 0.19 and at 4 weeks was 1.48 ± 0.22 and for control group at baseline was 2.14 ± 0.28, at 2 weeks 1.61 ± 0.19 and at 4 weeks 1.43 ± 0.21, respectively.

On intergroup comparison of change in plaque index score between test group and control group from baseline to 4 weeks were 0.78 ± 0.29 and 0.71 ± 0.24, respectively. The P value was statistically non-significant. (P = 0.432) (Table 1).

On intragroup comparison mean gingival index score for test group at baseline was 2.05 ± 0.23, at 2 weeks was 1.19 ± 0.18 and at 4 weeks was 0.98 ±0.24 and for control group at baseline was 2.04 ± 0.27, at 2 weeks was 1.44 ± 0.19 and at 4 weeks was 1.28 ± 0.19, respectively.

On intergroup comparison of change in mean gingival index score between test group and control group from baseline to 4 weeks were 1.06 ± 0.35 and 0.76 ± 0.23, respectively. The P value was statistically significant. (P = 0.003) (Table 2).

On intragroup comparison mean sulcus bleeding index score for test group at baseline was 2.29 ± 0.30, at 2 weeks was 1.29 ± 0.24 and at 4 weeks was 1.08 ±0.25 and for control group at baseline was 2.29 ± 0.32, at 2 weeks was 1.49 ± 0.21 and at 4 weeks was 1.32 ± 0.20 respectively.

On intergroup comparison of change in sulcus bleeding index score between test group and control group from baseline to 4 weeks were 1.21 ± 0.26 and 0.97 ± 0.22, respectively. The P value was statistically significant. (P = 0.004) (Table 3).

Table no.1: Comparison of change in plaque index scores in the test and control groups

		Test group	Control group	P value (student unpaired t test)
Change in plaque index scores(baseline to 4 weeks)	mean	0.78	0.71	0.432
	SD	0.29	0.24	
	% reduction	34.5%	33.1%	

Table no.2: Comparison of change in gingival index scores in the test and control groups

		Test group	Control group	P value (student unpaired t test)
Change in gingival index scores(baseline to 4 weeks)	mean	1.06	0.76	0.003*
	SD	0.35	0.23	
	% reduction	51.7%	37.3%	

Table no.3: Comparison of change in sulcus index scores in the test and control groups

		Test group	Control group	P value (student unpaired t test)
Change in sulcus index scores(baseline to 4 weeks)	mean	1.21	0.97	0.004*
	SD	0.26	0.22	
	% reduction	52.2%	42.4%	

*P≤0.05 is statistically significant

DISCUSSION

Gengigel (0.2% hyaluronic acid), which is used in the treatment of gingivitis, proved practically tasteless, and very easy to spread in a thin, even layer on the gingivae and also produced a prolonged sensation of "smoothness" of the gingivae, which suggests that the gel may remain in situ for an equal length of time[1]. Gengigel has also been used subgingivally in the treatment of chronic periodontitis. Brandimorte[9] stated that it can be used in subjects with periodontal disease, especially gingivitis. It also reduces the severity of gingival inflammatory infiltrate in periodontal subjects as mentioned by Mesa et al[10].

In the present study, an attempt has been made to evaluate the effectiveness of Gengigel (0.2% hyaluronic acid) in the treatment of plaque-induced gingivitis with or without scaling when applied topically. The study period of 4 weeks follows the recommendations of Chilton and Fleiss[11] to undertake trials regarding gingival inflammation with a study period longer than 2 weeks and Jentsch H et al.[12], who compared clinical parameters between Gengigel and placebo gel group in gingivitis cases for a period of 3 weeks.

There was a consistent reduction in plaque score, gingival score and sulcus bleeding score at different time intervals from baseline to 4 weeks in each group. In the scaling group (control group), the percentage reduction in plaque score from baseline was 33.1 %. This was consistent with the findings of Pagnacco A et al[7]. In the scaling and topical application of Gengigel group (Test group), the percentage reduction in plaque score from baseline to 4 weeks was 34.5 %. This finding was similar to that of Pagnacco A et al.[6] In the scaling group (Control group), the percentage reduction in gingival score from baseline to 4 weeks was 37.3 %. In the Test group, the percentage reduction in gingival score from baseline to 4 weeks was 51.7 %.The percentage reduction in sulcus bleeding index was 52.8 % in test group and 42.4 % in control group which was statistically significant.

No adverse effects were observed on clinical examination and as reported by the subjects. These findings were similar to the findings of Pagnacco A et al[6] and Vangelisti R et al[1]. Subjects also presented good compliance with the regular use of Gengigel, with excellent acceptability, including acceptability of its sensory characteristics. Gengigel as a product for oral use has been evaluated by skin irritation test, sensitizing potentiality and percutaneous absorption test and has been proved to be a safe non-irritant product[13].

Further large-scale randomized, controlled clinical trials with longer evaluation period into the therapeutic effects of 0.2% hyaluronic acid gel (Gengigel®) must be carried out.

REFERENCES

1. Vangelisti R, Pagnacco O, Erra C. Hyaluronic acid in the topical treatment of gingival inflammations: Preliminary clinical trial. Attual Ter Internazionale 1997; 15:2-3.
2. Rahemtulla F. Proteoglycans of oral tissues. Crit Rev Oral Biol Med 1992; 3:3-67.
3. John Chen WY, Abatangelo G. Functions of hyaluronan in wound repair. Wound Rep

Reg 1999; 7:79-89.
4. Bertolami CN, Messadi DV. The role of proteoglycans in hard and soft tissue repair. Crit Rev Oral Biol Med 1994; 5:311-37.
5. Laurent TC, editor. The chemistry, biology and medical applications of hyaluronan and its derivatives, Wenner - Gren international series. Vol. 72. London: Portland press, 1998.
6. Goa KL, Benfield P. Hyaluronic acid A review of its pharmacology and use as a surgical aid in ophthalmology, and its therapeutic potential in joint disease and wound healing. Drugs 1994; 47:536-66.
7. Pagnacco A, Vangelisti R, Erra C, Poma A. Double-blind clinical trial vs. placebo of a new sodium-hyaluronate-based gingival gel. Attual Ter In 1997;15:1-7
8. Mantovani S, Sala Tesciat A, Fossati B. Preliminary clinical evaluation of a hyaluronic acid-based product in oral disorders: Double-blind trial. Attualita Terapeutica Internazionale 1998;16:1-5
9. Brandimorte. Hyaluronic acid and periodontopathies. Minerva Stomatol 1968; 17:140-56.
10. Mesa FL, Aneiros J, Cabrera A, Bravo M, Caballero T, Revelles F, et al. Antiproliferative effect of topic hyaluronic acid gel. Study in gingival biopsies of subjects with periodontal disease. Histol Histopathol 2002; 17:747-53.
11. Chilton NW, Fleiss JL. Design and analysis of plaque and gingivitis clinical trials. J Clin Periodontol 1986; 13:400-10.
12. Jentsch H, Pomowski R, Kundt G, Gocke R. Treatment of gingivitis with hyaluronan. J Clin Periodontol 2003; 30:159-64
13. Nowicki D, Vogel RI, Melcer S, Deasy MJ. The gingival bleeding time index. J Periodontol 1981;52:260-62