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The Effect of Nano Bio Fusion Gel as an Adjunct to Conventional Therapy in Gingivitis Patients



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INTRODUCTION: Gingival and periodontal diseases are still the most common prevalent oral diseases affecting a community/individual people and can lead to irreversible consequences, both local (bone loss, tooth mobility etc.) and systemic (Cardiac Disease etc.)

AIM: To compare the efficacy of NBF gingival gel alone and as an adjunct to conventional therapy in patients with gingivitis

MATERIALS AND METHOD: This randomized study design (parallel arm study design) consisted of 7 patients with 21 quadrants and having a score 2 (moderate gingivitis) & 3 (severe gingivitis) based upon the gingival score given by Loe & Silness (1964). All the subjects were evaluated by two parameters i.e. gingival index [Loe & Silness (1964)] and Papillary Bleeding Index [Muhleman (1977)] at baseline and after one month of rendering treatment. Following random allocation (flip of coin), the first Group was given conventional therapy [Scaling and Root Planing(SRP)] followed by NBF gingival gel application, while the 2nd Group was given NBF gel application alone and the 3rd Group was given conventional therapy (SRP) alone. Statistical analysis was done using SPSS version 19.0 using paired t-test as well as the Wilcoxon Signed Rank test.

RESULTS: After follow up, the highest percentage of mean scores of gingival index decreased among all the groups was seen in group 1 (38.15 \pm 5.46), followed by group 3(32.54 \pm 7.58) and group 2(18.91 \pm 7.62). Similarly, in the Papillary Bleeding Index, the highest percentage reduction was seen in group 1 (82.30 \pm 2.39), followed by group 3(53.54 \pm 6.02) and group 2(31.71 \pm 4.34). All observed values were significant with p \leq 05.

CONCLUSION: NBF gel seems to provide to boost the immunity of the gingiva and periodontium, and when used as an adjunct to conventional therapy (SRP) can benefit the patient immensely.

KEYWORDS: Gingivitis, Gingival Index, Root Planing, Dental Scaling

INTRODUCTION

The term "healthy gingiva" describes optimal gingival health attained by patients who follow meticulous oral hygiene practices.¹ As per the global review of oral health (WHO), dentistry has achieved significant achievements to improve the oral health status of people, yet a variety of oral problems are still plaguing various communities, especially among underprivileged groups across both developing and developed countries. Dental diseases comprising of, but not limited to dental caries, periodontal disease, tooth loss and oral mucosal lesions constitute of major public health problems across the globe.²

There are two common diseases affecting the periodontium namely: 1). Gingivitis and 2). Periodontitis. These diseases commonly occour as a result of imbalance in the microbial flora of the host and can lead to redness, swelling and bleeding on probing from gingiva.

The first disease, i.e. gingivitis, is defined as inflammation of the gingiva in which the connective tissue attachment to the tooth remains at its original level. The disease is limited to the soft-tissue compartment of the gingival epithelium and connective tissue.³ In the second disease, i.e., periodontitis, is an inflammation of the supporting tissues of the teeth with progressive attachment loss and bone destruction.⁴

A variety of chemical agents ranging from Nonsteroidal Anti-Inflammatory Drugs (NSAIDS), antimicrobial agents, chlorhexidine to cetylpyridinium chloride have gained popularity for the treatment of gingival diseases, but their frequent prescription has led to as drug resistance and/or drug allergy in patients. Thus, there has been an increased emphasis on the usage of herbal agents such as propolis, Aloe vera, green tea extracts, neem, and curcumin for gingival/periodontal diseases in patients.⁵

In the same context, a Nano-Bio Fusion (NBF) Gingival Gel is a patented scientifically formulated, bio-adhesive antioxidant gel containing Vitamin C, Vitamin E and Propolis which are naturally occurring antioxidants for targeted action and disease causing microbes in periodontal disease. However, there is very little or scarce data regarding its efficacy in the scientific literature and hence, this study was undertaken with the aim to compare the efficacy of NBF gingival gel alone and as an adjunct to conventional therapy in

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patients with gingivitis

MATERIALS AND METHODS

This randomized clinical trial (parallel arm study design) was carried out in the Department of Periodontics, School of Dental Sciences, Sharda University after obtaining an ethical clearance. This preliminary study recruited seven patients comprising 21 quadrants (three quadrants each). An informed consent was taken from all the patients before the start of the study.

The inclusion criteria were systemically healthy participants visiting the department within the age group of 22–55 years, with a minimum of twenty teeth present and classified as score 2 (moderate gingivitis) & 3 (severe gingivitis) based upon the gingival score given by Loe & Silness 1964.⁶ The exclusion criteria included systematically compromised patients, on medications, Grade II and grade III mobile teeth, pregnant and lactating women, subjects who underwent periodontal treatment within a period of one year, smokers and alcoholic subjects.

CLINICAL PARAMETERS

All the subjects were evaluated by two parameters i.e. Gingival Index [Loe & Silness (1964)]⁶ and Papillary Bleeding Index [Muhleman (1977)]⁷ at baseline and after one month of rendering treatment.

Following the initial examination, quadrants were divided randomly into three groups (21 quadrants) based on the flip of a coin.

The first Group was given conventional therapy [Scaling and Root Planing(SRP)] followed by NBF gingival gel application, while the 2nd Group was given NBF gel application alone and the 3rd Group was given conventional therapy (SRP) alone.

NBF gingival gel application was done by isolating particular quadrant with cotton rolls. Then the gel was applied on the gingiva through a blunt cannula. Patient was asked not to rinse for the next 30 minutes followed by proper oral hygiene measures. The data was recorded in a pre-validated proforma by a recording clerk who, along with the examiners was standardized prior to the study.

Statistical analysis was done using SPSS version 19.0 through a blinded, certified statistician who did the comparison of test and control sites using paired t-test as well as the Wilcoxon Signed Rank test. A p value of < 0.05 was considered statistically significant.

RESULTS

Of the seven patients enrolled in the study, there were three males and four females. The intra-group comparison of Gingival Index Scores Pre & Post-Operatively (after one month follow up) is shown in table 1. It was seen that while the mean scores of gingival index decreased among all the groups, the highest percentage reduction was seen in group 1 (38.15 ± 5.46), followed by group $3(32.54\pm7.58)$ and group $2(18.91\pm7.62)$.

The intra-group comparison of Papillary Bleeding Index Scores both pre & post-operatively (after one month follow up) is shown in table 2. Similar to the above results, it was observed that while the mean scores PBI decreased among all the groups, the highest percentage reduction was seen in group 1 (82.30 \pm 2.39), followed by group 3(53.54 \pm 6.02) and group 2(31.71 \pm 4.34).

All observed values were significant and it can be documented that the use of NBF gel along with conventional therapy can cause a higher improvement in gingival scores of the patient.

DISCUSSION

The present study which aimed to compare the efficacy of NBF gingival gel alone and as an adjunct to conventional therapy in patients with gingivitis strongly recommends the use of NBF gel as an adjunct to conventional therapy in patients suffering from gingival and periodontal disease.

NBF gel acts like a local delivery agent which when placed in the gingiva reduces the microbial load naturally leading to an improvement in the observed clinical signs of gingivitis.

The results of the present study is in agreement to Chatterjee et al. (2014)¹ and in partial agreement to Debnath K et al. (2016)⁹ who documented that locally delivered NBF gel exhibited a significant improvement compared with SRP alone in patients with chronic periodontitis. Since gingivitis can progress to periodontitis if left unchecked/untreated, NBF gel seems to play an important role in reducing the microbial load in both gingival and periodontal disease.

Propolis, a constituent in NBF gel, has been evaluated by Koo et al. $(2002)^{10}$ as a mouth rinse formulation and

GROUP	PRE-OPERATIVE		POST-OP	ERATIVE	PERCENT REDUCTION FROM BASELINE TO POST OP		P ^A VALUE
	MEAN	SD	MEAN	SD	MEAN	SD	
Group 1 (CONVENTIONAL THERAPY & NBF GEL)	1.61	0.10	0.99	0.05	38.15	5.46	0.018, S
Group 2 (NBF GEL ONLY)	1.60	0.10	1.30	0.13	18.91	7.62	0.018, S
Group 3 (CONVENTIONAL THERAPY ONLY)	1.49	0.08	1.00	0.12	32.54	7.58	0.017, S

Table 1. Intra-Group Comparison of Gingival Index among the Study Subjects.[S: Significant (p=<0.05)]</td>

	PRE- OPERATIVE		POST- OPERATIVE		PERCENT REDUCTION FROM BASELINE TO POST OP		P ^A VALUE
GROUP	MEAN	SD	MEAN	SD	MEAN	SD	
Group 1 (CONVENTIONAL THERAPY & NBF GEL)	2.59	0.21	0.46	0.56	82.30	2.39	0.018, S
Group 2 (NBF GEL ONLY)	2.65	0.17	1.81	0.18	31.74	4.34	0.018, S
Group 3 (CONVENTIONAL THERAPY ONLY)	2.71	0.19	1.25	0.09	53-54	6.02	0.018, S

Table 2. Intra-Group Comparison of Papillary Bleeding Index among the Study Subjects.[S: Significant (p=<0.05)]</td>

a significant reduction in PI was obtained at the 4th day of the study. Propolis used as a subgingival irrigant (Coutinho, 2012)¹¹ at a 6 weeks interval period which showed a significant improvement in clinical and microbiological parameters. Apart from propolis, the other constituents of NBF gel i.e. Vitamin C and E have also been documented to protect the periodontal tissue from oxidative damage and can contribute to health of the periodontium including collagen synthesis, and boost immune function.

The present study is prone to limitations. Firstly, due to the small sample size, it is difficult to generalize the results and secondly, a gender-wise comparison could not be done. However, since this randomized trial was designed to provide insights regarding the efficacy and feasibility of using NBF gel and the promising results encourage researchers to undertake further studies to further add to the evidence of the efficacy and feasibility of using the NPF gel as an adjunct to conventional treatment for gingival and periodontal diseases.

CONCLUSIONS

NBF gel seems to provide to boost the immunity of the gingiva and periodontium, and when used as an adjunct to conventional therapy (SRP) can benefit the patient immensely. Natural remedies can help reduce the growing menace of drug resistance and provide no side-

effects whatsoever. Its recommended use in the clinical settings can be advised based on scientific evidence provided by the present study as well as future studies.

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