



A COMPARATIVE STUDY TO ASSES THE EFFICACY OF NANOBIO FUSION GEL AS AN ADJUNCT TO SCALING AND POLISHING IN CHRONIC PERIODONTITIS. A CLINICAL STUDY

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ABSTRACT

Introduction: Various chemical agents such as nonsteroidal, anti-inflammatory drugs and antimicrobial agents has gained popularity in treatment of periodontal disease but simultaneously lead to condition such as drug resistance and drug allergy. Hence, the topical application of herbal agents such as propolis, aloe vera, green tea extracts, Neem reduces the potency and effectiveness to prevent progression of periodontal disease. NanoBioFusion(NBF)gel contains the natural antioxidant power of propolis, vit C, vit E which allows the ultrafine antioxidant to surpass the moist intraoral environment to enter the cells and rejuvenate, revitalize, support, protect and optimize gum and soft oral tissue. Hence the present study is aimed to evaluate the clinical effect of locally delivered NBF gel as an adjunctive therapy to scaling and polishing in the treatment of Periodontitis. **Materials and Methods:** Chronic Periodontitis patients with 40 sites and probing pocket depth (PD) between 5 and 7 mm were selected in a randomized controlled clinical trial. SRP was performed in both control and test group followed by NBF gel application in 40 sites. The plaque index, gingival index and probing Pocket depth, were recorded at baseline, 6 weeks, and 3 months. The statistical analysis with paired t-test was used to compare the test and control sites. **Results:** From baseline to a period of 3 months, a statistically significant difference was seen between both groups for Pocket probing depth and from baseline to 6 weeks the mean GI and PI score have a statistically significant result was obtained ($P=0.01$ & 0.00). **Conclusions:** Locally delivered NBF gel exhibited a significant improvement compared with SRP alone in chronic periodontitis.

KEYWORDS : Local Drug Delivery, Nano-bio Fusion Gel.

INTRODUCTION:

Periodontal Disease is an infectious inflammatory disease of multifactorial etiology. Periodontal disease progression occurs due to the shift in the composition of microorganism from supragingival plaque to subgingival plaque.

In the periodontal pocket, the bacteria present apically forms a complex biofilm leading to accomplish effective oral hygiene efforts. It is mandatory to treat the periodontal pockets by mechanical removal of local factors and disruption of subgingival plaque biofilm itself. Though scaling is a gold standard treatment of periodontal diseases, many chemical formulations were also used as an adjunctive to scaling in the past, which found to be efficacious in the past, such as non-steroidal, anti-inflammatory drugs and anti-microbial agents such as chlorhexidine and cetylpyridinium chloride have gained popularity but simultaneously lead to conditions such as drug resistance and drug allergy along with staining of teeth. Hence, a shift towards the herbal remedies has gained popularity in present which were once used in the near past. Thus, there is an emphasis on usage of herbal agents such as propolis, aloe vera, green tea extract, neem and curcumin.¹

The first scientific work with Propolis, was published in 1908 revealing its chemical properties and composition. In 1968, the first privilege was obtained in Romania. Apitherapy or therapy with bee products (e.g pollen, propolis, herb honey) is an old tradition which has been revived by recent researches.² Propolis invariably contains pollen grains which are a rich source of essential elements e.g Ca, Mg, Fe, Cu, Zn,

Mn, Ni.⁴ Propolis balsam (a 70% alcohol extract of propolis which contains the bud exudate components) is used as a popular herbal medicine containing a number of phenolic constituents with antimicrobial, anti-inflammatory and antioxidative activities.^{5,7}

In dentistry it is widely used for reducing dentinal hypersensitivity, to prevent caries, affects the improvement of oral mucositis and found to be useful for oral cancer with no side effects.

Products based on nanotechnology, which contain natural antioxidant may be an excellent adjunctive in the treatment of periodontal diseases, the only such product is NANOBIOFUSION GEL(NBF) gingival gel which contains propolis, Vit C and Vit E in the form of nano-emulsion or in other words it's a stable and active nano gel with a highly functional and biocompatible nano-emulsion from sodium ascorbyl phosphate and magnesium ascorbyl phosphate. When NBF gel is applied directly on gingiva, it gets absorbed rapidly at cellular level which allows the ultrafine antioxidant to surpass the moist intraoral environment to enter the cells and then stays on the gingiva and mucosa by usage of nano-bioactive protective film. Thus, the present study was aimed to evaluate the clinical effectiveness of locally delivered NBF gel as an adjunctive therapy to scaling and root planing in the treatment of periodontitis.

METHODOLOGY:

The clinical trail was carried out in the department of

periodontology of HKEs S.N.Dental College, Gulbarga, Karnataka in a randomized controlled design. Patients with Chronic Periodontitis (comprising of 40 sites) were recruited in the study. Informed consent form was taken from all the patients before the start of the study.

The inclusion criteria were systemically healthy patients with the age group of 20-55 years. The exclusion criteria include, patients on chemical/herbal drugs for the past 3 months, teeth with furcation involvement, patients allergic to drugs, pregnant or lactating women, smokers and tobacco chewers.

The patients were randomly divided into two groups:
 • GROUP 1 : Scaling and Polishing
 • GROUP 2 :Scaling and Polishing is followed by application of NBF gel

The initial examination recorded plaque index(PI), gingival index(GI) and probing pocket depth(PD) were measured from the gingival margin to the depth of the pocket using UNC-15 probe/Williams graduated probe at baseline. Scaling and polishing was done for both the groups.(Fig1)

Following the initial examination, NBF gel was filled in the pockets through a blunt cannula until it was detected at the gingival margin in group 2(Fig2). Postoperative home care instructions including brushing two times daily with a soft brush were given. The patients in both the groups were evaluated at baseline, 6weeks and 3 months interval.

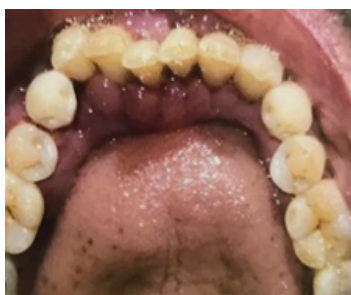


FIGURE 1:



FIGURE 2:

STATISTICAL ANALYSIS:

Statistical analysis was conducted for the results obtained. The comparison of test and control sites was done using paired t-test. $P < 0.05$ was statistically significant.

RESULTS:

Fig 3 depicts the mean GI scores after application of NBF gel alone at various intervals. At 6 weeks, a statistically significant result was obtained ($P=0.01$), but the P value at 3 months interval was 0.18, hence no statistically significant result were obtained. Fig 4 observed the comparison of mean PI which showed a statistically significant result at 6 weeks period ($P=0.000$) from baseline, but no statistically significant differences was observed at 3 months interval. Fig 5 describes the periodontal pocket depth, which at 6 week ($P=0.03$) and 3 months ($P= 0.04$) interval shows statistically difference.

Means of Gingival Index

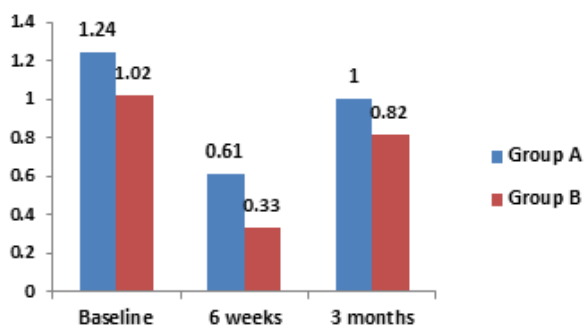


FIGURE:3

Means of Plaque Index

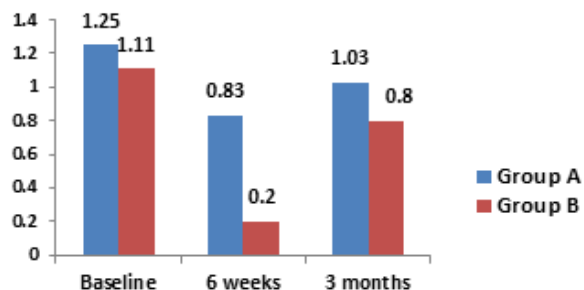


FIGURE:4

Means of Periodontal pocket depth

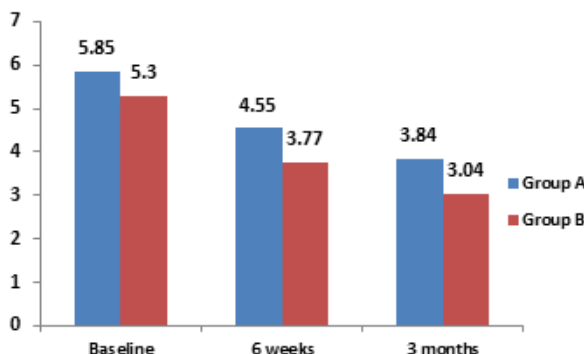


FIGURE:5

DISCUSSION:

Local drug delivery agents placed in periodontal pockets have authenticated the reduction in microbial load and improvement in clinical signs of periodontitis.

Nanotechnology uses the modern techniques to manufacture a material or structure purposefully with dimensions between 1 and 100 nanometers to leverage the unique properties it has at that size. It helps in delivery of vitamins, botanicals, and other active ingredients into gingiva. The smaller their size, the better is their penetrability. Propolis is a resinous mixture collected from trees by the Apismellifera bee. It has important pharmacological properties and it can be used for a wide range of purposes as an anti-inflammatory and hypotensive agent, immune-stimulant, bacteriostatic and bactericidal agent among many other uses. The present study evaluated the various parameters in the treatment of periodontitis with NBF gel. The PI score obtained at various intervals is in consistent with meticulous oral hygiene procedure, so at 3 months interval, intergroup analysis showed no significant results. With single application of NBF gel, GI and PI showed statistically significant difference at 6 weeks interval and clinically no significant difference at 3 months period is seen, where as the periodontal pocket depth, which at 6

week ($P=0.03$) and 3 months ($P= 0.04$) interval have shown a statistically significant difference which can be due to the various characteristic property of propolis. **Koo et al.**⁸ evaluated propolis in mouth rinse formulation and a significant reduction in PI was obtained at 4th day of the study. **Coutinho et al**⁹ used propolis as subgingival irrigation at 6 weeks interval period which showed a significant improvement in clinical and microbiological parameters. Propolis as an anti-inflammatory agent has shown to inhibit synthesis of prostaglandins, activate the immune system by promoting phagocytic activity, stimulate cellular immunity, and facilitate healing effects on epithelial tissues.

Propolis is a potent antioxidant and leads to reduction in reactive oxygen species (ROS) and limit lipid peroxidation activity. Propolis enhance synthesis of collagen due to the presence of iron and zinc elements.¹⁰ **Chang and Park**¹¹ have done a study to spectacle the effect of nanoemulsion on treatment of gingival inflammation, exhibited its effectiveness in protection of gingiva and treatment of gingival diseases. At a specific concentration, the anti-inflammatory and antimicrobial association was established.

CONCLUSION:

From the present study, it is concluded that the beneficial outcome of propolis along with Vitamin C, Vitamin E and the nanotechnology amplified this effect in preventing disease progression. Although SRP is a gold standard treatment protocol, NBF gel can be used as an adjunct for improving the periodontal status of an individual.

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