"ROLE OF NANO BIO – FUSION GEL AS AN ADJUNCT TO SCALING AND ROOT PLANING" – A SPLIT MOUTH RANDOMISED CLINICAL CONTROLLED TRIAL

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ABSTRACT Aim And Objective – To evaluate the clinical efficacy of Nano bio fusion gel as an adjunct to scaling and root planing in chronic periodontitis patients.

Materials And Method – 20 patients suffering from chronic periodontitis with mean probing depth of 4 - 6 mm were selected for a split mouth randomised control clinical trial. SRP was given in both control group and test group followed by NBF GEL. The plaque index (PI), gingival index (GI), probing pocket depth (PPD), and clinical attachment level (CAL) were recorded at baseline, 1 month and 3 months.

RESULTS – Frombaseline to 3 months, a statistically significant difference were observed between the groups in PI (p =0.003), GI (p=0.001), PPD (p=0.003) andCAL (p=0.005). In addition, a mean absolute reduction and percentage reduction were observed.

Conclusion- This study established the beneficial effect of NBF GEL as an adjunct to scaling and root planning.

KEYWORDS –
propolis, NBF gingival gel, chronic periodontitis.

Conflict of interest: Nil
No conflicts of interest : Nil

INTRODUCTION : Periodontal diseases are chronic inflammatory disorder characterised by inflammation and progressive destructionof surrounding structures, which includes gingiva, alveolar bone, periodontal ligament and cementum (1). The recent Global Burden of Disease Study (GBD, 2016) indicates that severe periodontal disease, which may result in tooth loss, is the 11th most prevalent disease worldwide. (2)

The disease starts with bacterial invasion around the gingival sulcus and the epithelium of the gingiva migrates along the tooth surface forming periodontal pockets, which if left untreated can leads to deposition of inflammatory agents by the microbes and consequently results in the destruction of the periodontal structures and loss of teeth(3) .

The treatment of periodontal pockets by mechanical removal of local factors and disruption of sub gingival plaque biofilm is mandatory. Therefore, scaling and root planingis treatment of choice for these conditions. As an adjunct to scaling, many chemical agents and herbal agents such as Propolis, Aloe vera, green tea extracts, neem, and curcumin have gained popularity in present.

Propolis is one of the herbal agents, which is a resinous mixture produced by honeybees from substances collected from parts of plants, buds and exudates.

Humankind has extensively employed Propolis since ancient times. The first scientific work with Propolis, reporting its compositionand chemical properties, has published in 1908. In 1968, the first patent has obtained in Romania.Since then, Propolis has been using as a natural remedyin different forms for topical application,mouthwashes and toothpastes to

prevent caries and treat gingivitis and stomatitis(3).Vitamin C, a key processor of cell growth, healing, and repair of tissue, influences the metabolism of collagen within the periodontium. Vitamin E serves as an antioxidant to limit free radical and to protect cells from lipid peroxidation. Vitamin E works in synergistic with Vitamin C and maintains the integrity of the cell membranes. (4)

Nano-Bio Fusion (NBF) gingival gel is a patented scientifically formulated, bio adhesive antioxidant gel harvesting naturally occurring antioxidants for targeted action. NBF technology allows the ultrafine antioxidants to penetratethe moist oral environment and directly absorbed into the tissue acting asbioactive protective film.

Nano Bio-Fusion technology also amplifies the natural antioxidant power of Propolis, vitamin C, and vitamin E.

Thus, the aim of the present study was to compare the efficacy of NBF GEL as an adjunct to scaling and root planing in patients with chronic periodontitis.

METHODS

STUDY DESIGN AND POPULATION

A randomised controlled split mouth single centre study was conducted in Department of Periodontology, Sardar Patel postgraduate institute of dental and medical sciences, Uttar Pradesh.

The selected patients were from the OPD clinics with inclusion criteria (1) Patients under the age group of 30-50 years. (2)Sites with bleeding on probing and periodontal probing depth 4mm-6mm at initial visit. (3)Patients without definitive periodontal therapy in last 6 months. (4)Patients without antibiotic therapy in last 6 months were included.

The exclusion criteria were medically compromised patients and those on medications known to be associated with altered periodontal tissue growth/repair,Severe periodontitis patients

(CAL 5mm) (5), and former/current smokers.

20 subjects, satisfying the above criteria, were recruited in the study. After thorough medical and dental examination, an initial examination with baselinedata were recorded which includes plaque index (PI), gingival index (GI), periodontalprobing depth (PPD), clinical attachment level (CAL).

Following the initial examination, the selected subjects wererandomlydivided into two groups.

GROUP	TREATMENT
A:Control	Scaling and root planing
B : Test	Scaling and root planing along with sub gingival administration of NBF gingival gel

Figure 1: Commercially available NBF GINGIVAL GEL and blunt end cannula

TREATMENT PROTOCOL

The initial examination recorded plaque index (PI) 1963, gingival index (GI) 1964(6), and probing pocket depth (PD) measured from the gingival margin to the depth of the pocket using UNC-15 probe, clinical attachment level was measured from cementoenamel junction to base of pocket usingUNC-15 probe at baseline[figure:2].Following the initial examination,scaling and root planing were performed on each tooth using ultrasonic and hand instruments.

In-group B, NBF Gingival gel [figure 1, 3]was administered subgingivally directly from the commercially supplied tube with the help of blunt cannula.

A periodontal dressing was placed to ensure retention of the gel for long duration to be effective in the pocket [figure: 4].Periodontal dressing was removed after 7 days. 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, 1 month, and 3 months interval.

Fig 2: Probing depth at baseline

Fig: 3 Administration of NBF GEL

Fig: 4 Periodontal dressing

Fig 5:Post-operative

RESULTS : The statistical analysis performed is ANOVA test to evaluate the results.

Table 1 observed both intergroup and intragroup comparison of mean PI between both Group A & Group B sites and demonstrated a statistically significant reduction in Mean PI from baseline to 1 month(P=0.003) but, no significant change was found in Mean PI from 1 month to 3 months between both Group A & Group B sites.[graph 1]

PI					
	Group A		Group B		P value of Intergroup comparison
	Mean	SD	Mean	SD	
At baseline	2.0160	.31766	1.9910	.17535	0.738. NS
At 1 month	1.0790	.27108	.7570	.10229	<0.0001, S
At 3 months	1.0653	.28437	.7648	.17834	<0.0001, S
P value of intragroup comparison	0.004, S		0.003, S		
Post hoc pairwise comparison	1>2,3		1>2,3		

Table 1: Intergroup & Intragroup comparison of Mean PI

Table 2 showed the mean GI scores with statistically significant at 1 month from the baseline(P= 0.001) but no statistically significant at 3 months from 1 month. [Graph 2]. Table 3 depicts mean PPD at various intervals which shows (P=0.129) at baseline and (P=0.03) at 1 month, a statistically significant result was obtained, but no statistically significant result was obtained at 3 month. [Graph 3]

Table 4 described the clinical attachment level, which at 1 month (p= 0.005) shows statistically significant from the baseline (p=0.494) but nostatistically significant at 3 months from 1 month [graph 4]
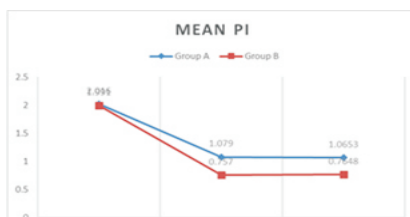
AT BASELINE   1 MONTH   3 MONTH
GRAPH1: MEAN VALUES OF PI ATVARIOUS INTERVALS

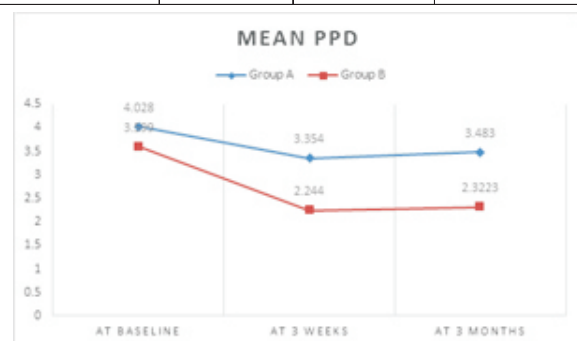Table 2: Intergroup &Intragroup comparison of Mean GI

GI					
	Group A		Group B		P value of Intergroup comparison
	Mean	SD	Mean	SD	
At baseline	2.0410	.39061	1.8860	.31809	0.192, NS
At 1 month	1.43840	.342970	.7100	.14611	<0.0001, S
At 3 months	1.44780	.386531	.7456	.14987	<0.0001, S
P value of intragroup comparison	0.007, S		0.001, S		
Posthoc pairwise comparison	1>2,3		1>2,3		
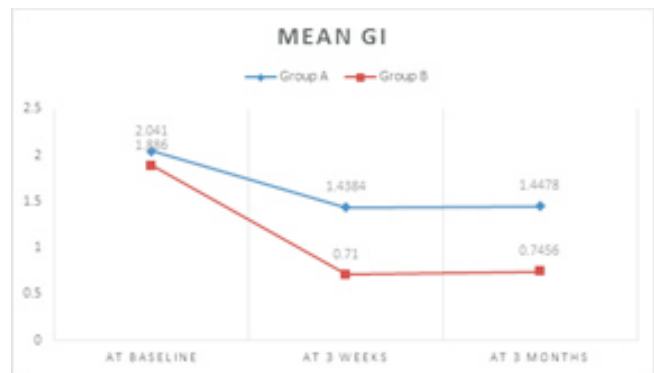
AT BASELINE   1 MONTH   3MONTH
GRAPH 2: MEAN VALUES OF GI AT VARIOUS INTERVALS
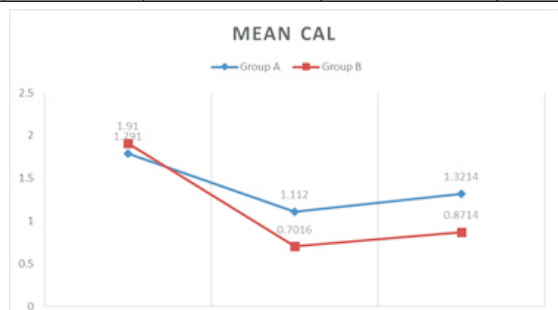
Table 3: Intergroup & Intragroup comparison of Mean PPD

Pocket Probing Depth					
	Group A		Group B		Pvalue of Intergroup comparison
	Mean	SD	Mean	SD	
At baseline	3.749	0.3902	3.5990	0.34618	0.129, NS
At 1 month	3.3540	0.5466	2.2440	0.44771	<0.0001, S
At 3 months	3.4830	0.5123	2.3223	0.42153	<0.0001, S
Pvalue of intragroup comparison	0.023, S		0.003, S		
Post hoc pairwise comparison	1>2,3		1>2,3		

AT BASELINE   1 MONTH   3 MONTH
GRAPH 3: MEAN VALUES OF PPD AT VARIOUS INTERVALS

Table4: Intergroup & Intragroup comparison of Mean CAL

CAL					
	Group A		Group B		P value of Intergroup comparison
	Mean	SD	Mean	SD	
At baseline	1.7910	.27926	1.9100	1.00357	0.494, NS
At 1 month	1.1120	.19061	.70160	.162853	<0.0001, S
At 3 months	1.3214	.18654	.87140	.15743	<0.0001, S
P value of intragroup comparison	0.03, S		0.005, S		
Post hoc pairwise comparison	1>2,3		1>2,3		

GRAPH 4: MEAN VALUES OF CAL AT VARIOUS INTERVALS

Table 5 described intergroup comparison of Mean Absolute reduction in PPD, CAL, PI & GI showed that mean absolute reduction in Mean PPD, CAL, PI & GI were found to be significantly higher among Group B as compared to Group A.
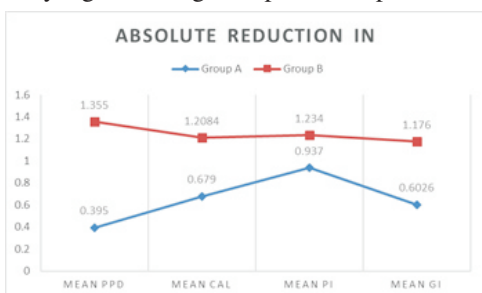
GRAPH: 5 MEAN ABSOLUTE REDUCTION IN PI, GI, PPD

Table 5: Intergroup comparison of Mean Absolute reduction in PPD, CAL, PI, and GI

Absolute reduction in		Mean	N	Std. Deviation	P value
PPD	Gr A	.3950	20	.30749	<0.0001, S
	Gr B	1.3550	20	.36850	
CAL	Gr A	.6790	20	.25733	0.005, S
	Gr B	1.2084	20	.90174	
PI	Gr A	.9370	20	.18604	0.001, S
	Gr B	1.2340	20	.25834	
GI	Gr A	.6026	20	.27041	<0.0001, S
	Gr B	1.1760	20	.35556	

Table 6 depicts intergroup comparison of Mean Percentage reduction in PPD, CAL, PI & GI showed that mean percentage reduction in Mean PPD, CAL, PI and GI was found to be significantly higher among Group B as compared to Group A.

Table 6: Intergroup comparison of Mean Percentage reduction in PPD, CAL, PI & GI

Percentage reduction in		Mean	N	Std. Deviation	P value
PPD	Gr A	10.54	20	8.17724	<0.0001, S
	Gr B	37.7794	20	10.15030	
CAL	Gr A	37.2064	20	11.31797	<0.0001, S
	Gr B	57.5516	20	14.42238	
PI	Gr A	46.7403	20	8.82913	<0.0001, S
	Gr B	61.3926	20	7.79599	
GI	Gr A	29.5672	20	12.51090	<0.0001, S
	Gr B	61.1431	20	11.74710	
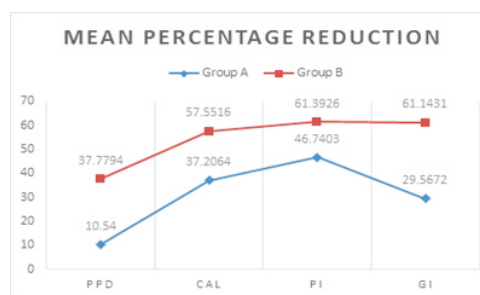
GRAPH 6: MEAN PERCENTAGE REDUCTION IN PI, GI, PPD AND CAL

DISCUSSION : Propolis is a resinous bio chemical substance derived fromplant known as bioflavonoid by Apis mellifera bee. It is composed of resin and balsams (50 - 70%), essential oils and wax (30 - 50%), pollen (5 - 10%) and other constituents which are amino acids, minerals, vitamins A,B complex, E , phenols and aromatic compounds (Park et al., 2002; Almas etal., 2001)(7).Propolishas wide array of antibacterial, antifungal, antiviral, antioxidant and anti-inflammatory proprieties that leads to increase in medicinal demands and have pay back an interesting subject to study.

Koru et al., 2007 (8)discussed the antibacterial action against certain anaerobic oralpathogens and found to be very effective against Lactobacillus acidophilus, Actinomyces naeslundii, Prevotella oralis, Prevotella melaninogenica, Porphyromonas gingivalis, Fusobacterium nucleatum and Veillonella parvula. The antibacterial property of Propolis isdue to the presence of flavonoids and aromatic compounds such as cafeic acid. Anti-oxidant property of propolis could attribute to its radical scavenging ability, which was betterthan anti-oxidant property of vitamin C (9).Anti-inflammatory property of propolis is due to the presence of caffeic acid phenethyl ester (CAPE) in propolis. Propolis has shown to inhibit synthesis of prostaglandins, activate the thymus gland and aids the immune system by promoting phagocytic activity, and enhances the healing effects of

epithelial tissues. (10)

Due to the moist environment of oral cavity, local drug delivery systems finds difficulty in treating gingival and periodontal diseases. The most important issue is rapid transportation and stable retention of the drugs.Modern innovations uses nanotechnologyto manufacture with dimensions between1 and 100 nanometres to deliver the unique properties of the drugs to the target sites with better penetration. It facilitates the targeted delivery of vitamins, herbal agents, and other active ingredients into gingiva.(11)

Based on the use ofNano emulsion to carry drug, chang-et-al(12) did a study on the effect of Nano emulsion for the treatment of gingival inflammation, Nano emulsion was observed to be effective in protection of gingiva and treatment of gingival diseases.

NBF gel is a high functional nanobiofusion gel containing propolis, Nanovitamin C, E and herb extract. The Nano-complex nature renders direct penetration and absorptionwhen applied on oral tissueand stays on the tissue as bioactive protective film.

The present study evaluated various parameters in the treatment of chronic periodontitis with the single application of NBF gel as an adjunct to scaling and root planing.Both intergroup and intragroup comparisons of the mean PI, GI, PPD and CAL scoreshowed statistically significant difference at 1 month and clinically significance at 3 months, which proves the diverse properties of propolis. The intergroup comparison of mean absolute reduction and mean percentage reduction in various parameters were found to be higher in-group B as compared to group A.

The results obtained in the present study are in conformance with the previous studies where different efficacy of propolis has discussed.In accordance with the study conducted by Koo et al. (2002) (13) who evaluated the effect of a mouth rinse containing propolis on 3-day dental plaque accumulation, a significant reduction in PI was obtained at 4th day of the study. In a study conducted by Coutinho Amita, the clinical and microbiological parameters showed that the sub gingival irrigation with propolis extract as an adjuvant to periodontal treatment was more effective than scaling and root planing (14).

Moreover, Wolff et al. (1994) have also reported a reduction in the total viable counts of anaerobic bacteria at 2 weeks and the reduction was able tomaintain at 6 weeks after the irrigation procedures. (15)

Although propolis has reviewed in various formulations with different study design, the results are not comparable due to

the wide array properties of propolis. The present study showed periodontal health improvement in all the sites irrespective of the treatment rendered. However, with the usage of NBF gel as an adjunct to scaling and root planing showed better results (p<0.001) as compared to control sites.

Thus, Nano emulsion base along with active ingredient of propolis, Vitamin C, and Vitamin E significantly improved the clinical parameters of the patients, which could be alluded to activation of the nano?sized propolis and vitamins.

CONCLUSION : With the results obtained from the present study, it is concluded that propolis along with vitamin C and E plays a beneficial role in preventing disease progression and the nano technology amplifies this effect.

However, scaling still remains the gold standard treatment protocol and NBF gel can be used as an adjunct for improving the periodontal condition in chronic periodontitis. Further research with a larger sample size is needed to have a better understanding of the effectiveness of NBF gel in protection of gingiva and treatment of periodontal diseases.

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