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Clinical efficacy of G32™ gum-paint and crushable tablets in diabetic patients: A randomised controlled trial

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Abstract

Periodontitis has a bidirectional relationship with diabetes mellitus. Due to impaired wound healing in diabetes mellitus patients, a great interest has been ensued in the use of adjuncts. Ayurvedic medication G32™ has been used as an adjunct to avoid the side effects of chemicals. Objective: To evaluate the efficacy of G32™ gum paint and tablets as an adjunct to Scaling in Diabetic patients with Chronic Periodontitis. Material and methods: 60 patients selected for the study were divided in three groups: Group A – Only Scaling and Root planing, Group B - Scaling and Root planing followed by topical application of G32™ gum paint and Group C - Scaling and Root planing followed by topical application of crushable G32™ tablets. Baseline levels and indices were recorded and patients were recalled after 1 month to record the clinical parameters. Results: Statistically significant differences were recorded between Groups A vs B and Groups A vs C and insignificant differences between Groups B vs C. Conclusion: G32 is effective as an adjunct when used in diabetic patients with chronic periodontitis with minimal side-effects.

Keywords: Ayurvedic, G32, diabetes, periodontitis

1. Introduction

Periodontitis is a common chronic inflammatory disease characterised by destruction of the supporting structures of the teeth. Periodontitis is highly prevalent since severe periodontitis affects 10–15% of adults and has multiple negative impacts on the quality of life. Epidemiological studies showed that diabetes is a major risk factor for periodontitis and the susceptibility to periodontitis is increased by approximately threefold in people with diabetes [1]. Diabetes mellitus is a clinically and genetically heterogeneous group of metabolic disorders. It shows abnormally high levels of glucose in the blood. It is the result of a deficiency of insulin secretion caused by pancreatic B-cell dysfunction or of resistance to the action of insulin in the liver and muscle or a combination of these [2]. Diabetes mellitus is usually characterized by the classic triad of polydipsia, polyuria and polyphagia.

In 1997, the American Diabetes Association stated periodontal disease as the sixth complication of Diabetes mellitus after retinopathy, nephropathy, neuropathy, macroangiopathy and delayed wound healing [3]. The classification included type 2 diabetes addressed in this study which was previously defined as noninsulin-dependent diabetes. It is now known that type 2 diabetic patients have insulin resistance and altered insulin production [4]. Type 2 is the form of diabetes present in 90–95% of patients with the disease [5]. The International Diabetes Federation estimates that approximately 382 million people have diabetes and a 55% increase in its prevalence is expected by the year 2035 [6].

1.1 Diagnostic Criteria for Diabetes

The American Diabetes Association issued new classification and diagnostic criteria for diabetes in 1997 [7] (Table 1). These criteria were modified in 2003 to include the diagnosis of impaired fasting glucose and impaired glucose tolerance [8].

Diabetes mellitus is considered to be present when fasting plasma glucose levels are at or below 126 mg/dl or 2-hour post-glucose loading plasma levels are at or above 200 mg/dl. Patients with diabetes mellitus symptoms and random plasma glucose levels at or above 200 mg/dl should be re-tested on the subsequent day using fasting plasma glucose or 2-hour post-glucose loading plasma levels [7].

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The hemoglobin A1c (HbA1c) test is used to monitor the overall glycemic control in diabetic patients. Numerous proteins in the body are capable of being glycosylated. Glycohemoglobin is formed continuously in the erythrocytes as a product of non-enzymatic reaction between the hemoglobin protein which carries oxygen molecules and glucose. Binding of glucose to hemoglobin is highly stable. Thus, hemoglobin remains glycosylated for the life span of the erythrocyte (123 ± 23 days)^[10]. So, measurement of HbA1c is of major clinical value and accurately reflects the mean blood glucose concentration over the preceding 1–3 months^[11]. The recommended HbA1c target value for people with diabetes is <7% (normal is <6%). Achieving this goal is difficult, and a recent population study showed that only 36% of people with type 2 diabetes achieved a target HbA1c of <7%^[12].

1.2 Influence of Diabetes on Periodontal Health

Diabetes is considered a risk factor for gingivitis and periodontitis^[13, 14]. Epidemiological studies have shown that diabetes increases the risk of alveolar bone loss and attachment loss by three-fold when compared to nondiabetic individuals^[15, 16]. These findings have been confirmed in the meta-analyses of studies in various diabetic populations^[14]. Mealey thus concluded that diabetic patients had a three-fold higher risk of periodontal disease compared with non-diabetic patients^[17].

1.3 Influence of Periodontal Infection on Diabetes

Periodontal diseases may alter glycemic control since it is a chronic inflammatory condition. Studies have shown that diabetic patients with periodontal infection have a greater risk of worsening glycemic control over time compared to diabetic subjects without periodontitis^[18]. Periodontitis is thus regarded as having a bidirectional relationship with diabetes mellitus^[19].

Type 2 diabetes mellitus has been treated by diet control and various hypoglycemic agents usually first or second generation sulfonylureas^[20]. The well-controlled diabetes mellitus patient with periodontal disease is often an acceptable candidate for complete periodontal therapy including surgical procedures when indicated. All diabetic patients should thus be encouraged to maintain meticulous oral hygiene and to receive supportive periodontal therapy at intervals necessary to sustain a high level of periodontal health^[21].

1.4 Role of an Adjunct in Diabetes Mellitus

The most prevalent infectious oral diseases in humans which include periodontal diseases are associated with dental plaque. The removal of bacterial biofilm is an important component in the prevention and treatment of these diseases. There exists some difficulty to ensure adequate removal of plaque by mechanical means and also due to impaired wound healing in diabetic patients. Therefore, a great interest has been ensued in the use of antimicrobial agents to be used as adjuncts to the mechanical approaches.

Due to the etiology of periodontal disease it has been widely accepted that mechanical disruption of the plaque biofilm via scaling and root planing (SRP) to reduce the pathogenic burden is the primary treatment of choice^[22-26]. The term “adjunctive therapy” applies to all additional or ancillary means of reducing the inflammatory burden by the use of anti-infectives (local or systemic) and/or host immune modulating agents. Chlorhexidine (CHX) is considered one of the most

effective antimicrobial agents for plaque control^[27].

Chlorhexidine is an antiplaque agent that prevents plaque formation. Chlorhexidine’s superior antiplaque effect can be explained in terms of its superior degree of persistence at the tooth surface or its superior persistence of antibacterial effect (both bactericidal and bacteriostatic) at the tooth surface^[28].

1.5 Side Effects of Chlorhexidine

The reported side effects of Chlorhexidine are alteration in taste, increase of calculus formation, staining of teeth and mucous membranes, oral mucosa desquamation and parotid swelling. However, the most obvious and important local side effects are brown staining of the teeth, restorative materials and dorsum of the tongue and supragingival calculus formation^[27].

1.6 Ayurvedic Medication

Despite several chemical agents being commercially available, these can alter oral micro biota and have undesirable side-effects^[29, 30]. Also, the standard Western medicine has had only limited success in the prevention of periodontal disease and in the treatment of a variety of oral diseases. Therefore, the search for an alternative product continues and natural products isolated from plants used in traditional medicine are considered as good alternatives to chemicals^[31]. G32™ is one such ayurvedic product. G32™ is available for local application in two ways - in an easily crushable tablet form and as gum paint. The main ingredients in this *ayurvedic* preparation include *Bakul*, *Chok*, *Katha*, *Laving*, *Fatakdi*, etc. It has anti-inflammatory, antiseptic, antibacterial, astringent, anodyne, styptic and healing actions. Various studies have shown it to be effective in treating gingivitis^[32-34]. These studies have shown that it has minimal side effects and has good compliance of the patients.

1.7 Constituents of G32^[32-35] (Fig. 1)

Bakul (Mimosops elangi) - 80 mg.
Chok (Calcium Carbonate) - 75 mg.
Katho (Acacia catechu) - 40 mg.
Laving (Myrtus caryophyllus) - 20 mg.
Chikani Sopari (Areca catechu) - 20 mg.
Fatakadi (Alumen) - 20 mg.
Mayafal (Quercus infectoria) - 20 mg.
Elaichi (Elettaria cardamomum) - 10 mg.
Sonageru (Silicate of Alumina and Iron Oxide) - 10 mg.
Jiru (Carum carvi) - 10 mg.
Majith (Rubia cordifolia) - 10 mg.
Pashanbed (Saxifrua ligulata) - 10 mg.
Vavding (Embelia ribes) - 10 mg
Pipala ni Lakh (Ficus religiosa) - 10 mg.
Samudrafin (Os sapiae) - 10 mg.
Vajradanti (Barleria prionitis) - 10 mg.
Taj (Cinnamimum cassia) - 5 mg.
Mari (Piper nigrum) - 5 mg.
Sajikhar (Sodium carbonate impure) - 5 mg.
Kulinjan (Alpinia chinensis) - 5 mg.
Pipar (Piper longum) - 5 mg.
Kapur (Camphora officinarum) - 5 mg.
Kuth (Uncaria gambier) - 5 mg.

1.8 Aim of the Study

To introduce a natural adjunct that effectively reduces inflammation in Diabetic patients with Chronic Periodontitis.

1.9 Objective of the Study

1. To evaluate the efficacy of G32™ gum paint and tablets as an adjunct to Scaling in Diabetic patients with Chronic Periodontitis.
2. To compare the efficacy of G32™ gum paint with tablets in Diabetic patients with Chronic Periodontitis post scaling.

2. Materials and Methods

This was a Clinical, Interventional, Case control, Open-labelled, Single centre study involving the use of G32™ gum paint and tablets after scaling. The study was approved by the Nair Hospital Dental College Ethics Committee, Mumbai (EC-58/PERIO-12ND/2017).

2.1 Source of Data

A total of 60 Diabetic patients with Chronic Periodontitis were selected from Outpatient Department of Periodontics, Nair Hospital Dental College, Mumbai whose written and video consent was taken prior to the study and if the patient was willing to discontinue the treatment procedure during the study, he or she was allowed to do so.

2.2 Protocol: Inclusion Criteria

1. Age group between 25-70 years.
2. Patients with controlled diabetes (on oral hypoglycemic drugs) with glycosylated haemoglobin (HbA1c) levels < 7
3. Patients with chronic periodontitis having periodontal pocket depth less than 4mm
4. Patients with a minimum of 20 teeth.
5. Patients who have not received any type of periodontal therapy for the past 6 months

Exclusion Criteria

1. Patients on insulin therapy
2. Patients suffering from any other systemic disease or with compromised immune system.
3. Patients with a known history of drug allergy
4. Patients taking any drug known to cause gingival enlargement
5. Patients taking any immuno-suppressive drugs like corticosteroids.
6. Patients with periodontitis.
7. Pregnant and/or lactating mothers.
8. Patients with any bleeding disorders.
9. Patients on anticoagulant therapy.
10. Patients with smoking and tobacco chewing habits.

The patients fitting the inclusion criteria were divided into three groups using Computer assisted randomization - Group A, Group B and Group C as follows:

- a) Group A: Scaling and root planing only (n=20)
- b) Group B: Scaling and root planing along with application of G32™ gum paint (n=20)
- c) Group C: Scaling and root planing along with application of G32™ tablets (n=20)

Full mouth scaling was done using Ultrasonic Scaler.

2.3 Clinical Parameters

The following clinical parameters were recorded at baseline before scaling and root planing and 1 month post treatment:

1. Plaque index (PI) (Tureskey-Gilmore-Glickman Modification Of Quigley Hein, 1970)

2. Gingival index (GI) (Loe and Silness, 1963)
3. Probing pocket depth (PPD)
4. Clinical attachment level (CAL)

2.4 Procedure

Following initial examination and assessment of HbA1c levels of diabetic patients with chronic periodontitis, baseline levels and indices were recorded and then the subjects were divided into Groups A, B and C using computer generated randomization method. Scaling and Root planing (SRP) was performed on all the patients in groups A, B and C. The patients were recalled after 1 month to record the clinical parameters. Oral hygiene methods were standardised by providing standard toothpaste and standard toothbrush using modified bass technique of tooth brushing twice daily.

GROUP A – Only Scaling and Root planing (SRP) was done
GROUP B - Scaling and Root planing (SRP) followed by topical application of G32™ gum paint

For G32™ mouth paint: Patients were instructed to take 2-3 drops on a finger tip, apply it over the gums and gently massage the affected parts with the finger. Then hold and swirl with cheek movements for 5 minutes followed by rinsing and gargling with fresh water. This procedure was repeated two times a day at regular intervals for the first 15 days followed by once in the morning for the next 15 days. (Fig. 2)

Group C: Scaling and Root planing (SRP) followed by topical application of easily crushable G32™ tablets

For G32™ tablets: Patients were instructed to crush 1 to 3 tablets to a fine powder and massage this powder over the gums and on the affected parts properly with the help of a finger tip. Keep it for a minimum of five minutes for effective action followed by rinsing with fresh water. This procedure was repeated two times a day at regular intervals for the first 15 days followed by once in the morning for the next 15 days. (Fig. 3)

2.5 Data Analysis

All the data was analysed using the SPSS version 16.0 software. Inter-group and intra-group analysis was done by Repeated measure ANNOVA followed by post-hoc test. A p-value ≤ 0.05 was considered to be statistically significant.

3. Results and Discussion

A total of 60 patients were selected for the study who fulfilled the inclusion criteria and consented for the study. These patients were further divided into three groups by computer generated randomisation. A total of 10 patients were lost to follow-up (Group A – 3, Group – 2 and Group C – 5). So the final sample size was 50.

The mean baseline plaque index scores were 3.62 (± 0.50), 3.85 (± 0.34) and 3.36(± 0.52) for Groups A, B and C respectively. The mean baseline gingival index scores were 1.95 (± 0.21), 1.98 (± 0.14) and 1.93(± 0.19) for Groups A, B and C respectively.

Similarly, the mean baseline periodontal pocket depth scores were 5.46 (± 0.60), 5.32 (± 0.64) and 4.38(± 0.60) for Groups A, B and C respectively. The mean baseline clinical attachment level scores were 6.16 (± 0.77), 6.43 (± 0.55) and 5.30(± 0.75) for Groups A, B and C respectively. (Table 2)

The plaque index scores reduced from 3.62 (± 0.50) to 2.90 (± 0.40) in Group A, 3.85 (± 0.50) to 1.70 (± 0.52) in Group B

and 3.36(± 0.52) to 1.61 (± 0.52) in Group C. The gingival index scores reduced from 1.95 (± 0.21) to 1.49 (± 0.29) in Group A, 1.98 (± 0.14) to 0.58 (± 0.20) in Group B and 1.93(± 0.19) to 0.52 (± 0.12) in Group C.

Similarly, the periodontal pocket depth scores reduced from 5.46 (± 0.60) to 4.69 (± 0.54) in Group A, 5.32 (± 0.64) to 2.98 (± 0.43) in Group B and 4.38(± 0.60) to 2.39 (± 0.28) in Group C. The clinical attachment level scores reduced from 6.16 (± 0.77) to 5.28 (± 0.89) in Group A, 6.43 (± 0.55) to 3.54 (± 0.43) in Group B and 5.30(± 0.75) to 3.33 (± 0.38) in Group C. (Table 3)

The results show statistically significant difference between Groups A vs B and A vs C and no statistically significant difference between Groups B vs C except for CAL values. (Table 4)

The study was a Clinical, Interventional, Case control, Open-labelled, Single centre study involving use of G32™ gum paint and tablets after scaling. The aim of the study was to evaluate the efficacy of G32™ gum paint and tablets as an adjunct to Scaling in Diabetic patients with Chronic Periodontitis. Plaque index, Gingival index, Probing Pocket Depth and Clinical Attachment Levels were used to assess the oral health status of the subjects.

G32™ is an ayurvedic formulation, known for many years, effective in treating gingivitis [36, 37]. The mean plaque and

gingival index scores, probing pocket depth and clinical attachment loss reduced significantly during the entire duration of the study. The difference in the reduction of those scores was statistically significant among groups A vs B and A vs C but statistically insignificant between groups B vs C except for clinical attachment loss values. The clinical attachment loss was statistically significant between groups B vs C.

The participants when enquired about the product reacted that the crushable tablets were found to be coarse on the gingiva. The participants supplied with gum paint did not have any problems with regard to texture.

Regarding side-effects of the sample, few patients reported with a strong smell of the sample. No other side effects were noted.

G32™ is a water based product with minimal side-effects even on long term use. It has a pleasant taste and is economical. So the compliance of the patients was better [37].

The limitations of the study included a small sample size and short duration of follow-up. This study is the first so far comparing the efficacy of G32™ tablets and gumpaint in diabetic patients. More such studies are encouraged with a larger sample size and longer follow-up.

3.1 Tables and Figures

Table 1: American Diabetes Association criteria for the diagnosis of diabetes mellitus is as follows [9]:

	Normal	Diabetes
FASTING GLUCOSE (mg/dl)	<100	≥126
RANDOM GLUCOSE (mg/dl)		≥200
2-h PG* (mg/dl)	<140	≥200
*2-h Post-loading glucose using the 2-h oral glucose tolerance test.		

Table 2: Baseline characteristics of participants

	PI	GI	PPD	CAL
GROUP A	3.62 (± 0.50)	1.95 (± 0.21)	5.46 (± 0.60)	6.16 (± 0.77)
GROUP B	2.90 (± 0.40)	1.98 (± 0.14)	5.32 (± 0.64)	6.43 (± 0.55)
GROUP C	3.36(± 0.52)	1.93(± 0.19)	4.38(± 0.60)	5.30(± 0.75)

Table 3: 1 month characteristics of participants

	PI	GI	PPD	CAL
GROUP A	2.90 (± 0.40)	1.49 (± 0.29)	4.69 (± 0.54)	5.28 (± 0.89)
GROUP B	1.70 (± 0.52)	0.58 (± 0.20)	2.98 (± 0.43)	3.54 (± 0.43)
GROUP C	1.61 (± 0.52)	0.52 (± 0.12)	2.39 (± 0.28)	3.33 (± 0.38)

Table 4: Comparison between experimental groups

	A vs B	A vs C	B vs C
PI	<0.001	<0.001	0.31
GI	<0.001	<0.001	0.96
PPD	<0.001	<0.001	0.08
CAL	<0.001	<0.001	<0.001



Fig 1: G32™ Gum paint and Crushable tablets



Fig 2: G32™ Gum paint



Fig 3: G32™ Crushable tablets

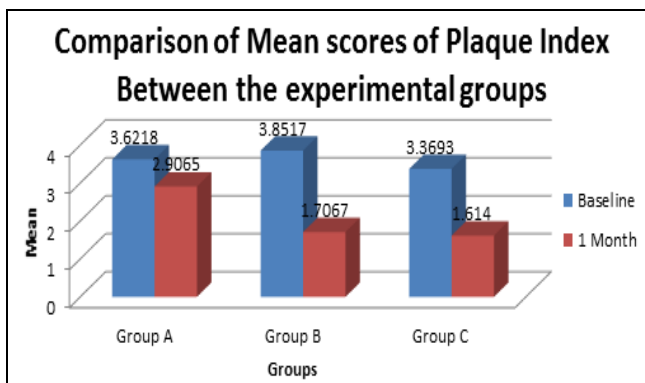


Fig 4: Comparison of Mean scores of Plaque Index between the experimental groups

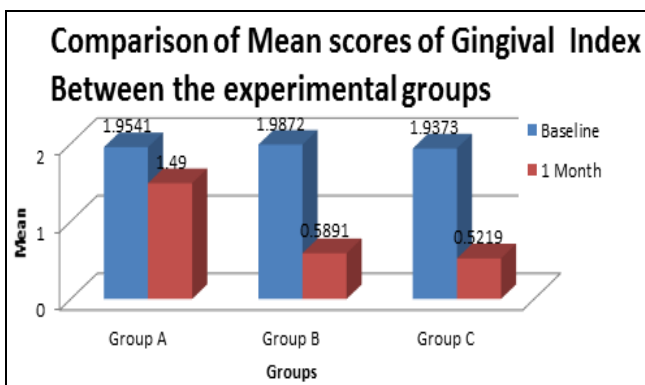


Fig 5: Comparison of Mean scores of Gingival Index between the experimental groups

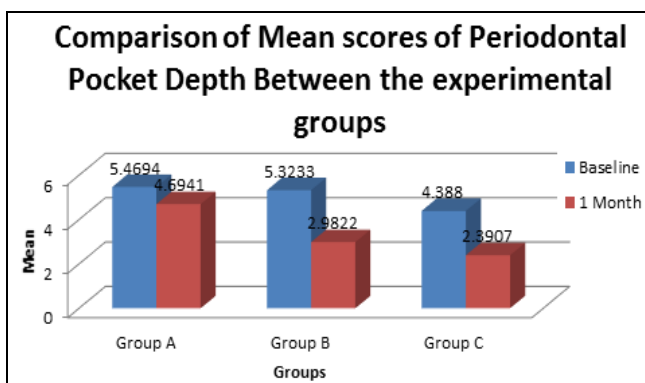


Fig 6: Comparison of Mean scores of Periodontal Pocket Depth between the experimental groups

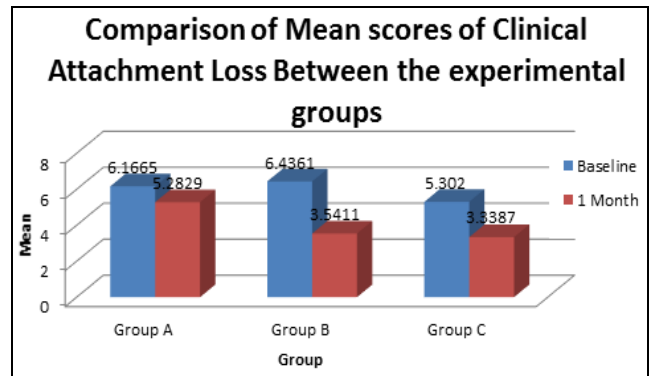


Fig 7: Comparison of Mean scores of Clinical Attachment Loss between the experimental groups

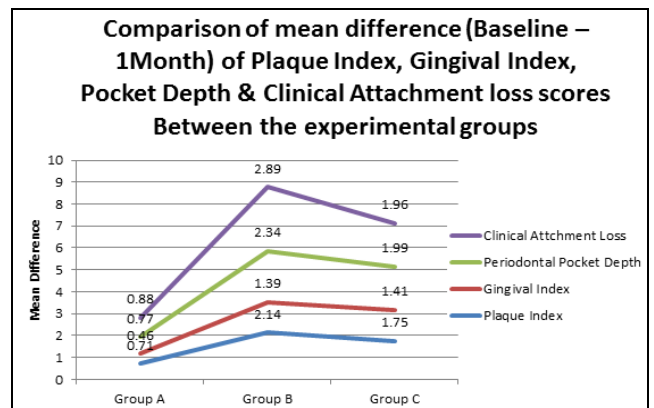


Fig 8: Comparison of Mean difference of Plaque Index, Gingival Index, Pocket Depth & Clinical Attachment Loss scores between the experimental groups



Fig 9: Group 'A' Pre-treatment and Post-treatment



Fig 10: Group 'B' Pre-treatment and Post-treatment



Fig 11: Group 'C' Pre-treatment and Post-treatment

4. Conclusion

This study has therefore evidently shown the effectiveness of both G32™ gum paint and crushable tablets. Hence, there is a need to propagate the fact that G32™ can be used as a safe adjunct in diabetic patients with chronic periodontitis.

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