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A DOUBLE BLIND TRIAL OF G32 IN CONTROL OF GINGIVAL INFLAMMATION AND BLEEDING IN 100 ADULT CASES OF GINGIVITIS AND PERIODONTITIS

By

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Paper presented at
1st International & 34th National Dental Conference Bombay

INTRODUCTION:

We undertook a double-blind clinical trial totally in 100 cases of Gingivitis and Periodontitis both conditions associated with bleeding gums, to assess the effect of G32, an Ayurvedic drug, used as topical application and massage in control of Gingival inflammation and bleeding.

G32:

G32 is available in easily crushable tablet form; it is to be powdered and applied to the gums etc.

Each tablets contains	(in mg)
Bakula (Mimosops elangi)	80
Chok (Calcium carbonate)	75
Katha (Acacia catechu)	40
Laving (Myrtus caryophyllus)	20
Chikani sapari (Areca catechu)	20
Fatakadi (Alumen)	20
Mayaphal (Quercus infectoria)	20
Gundar (Acacia arabica)	20
Elaichi (Elettaria cardamomum)	10
Sonageru (Silicate of aluminium and iron oxide)	10
Jiru (Canum carui)	10
Majith (Rubia cordifolia)	10
Pashanbhed (Sexifruga ligulata)	10
Vavding (Embelia ribes)	10
Pipal lukh (Ficus religiosa)	10
Samudratim (Os sapiae)	10
Vajradanti (Baloeria prionitis)	10
Taj (Cinnamomum cassia)	5
Mari (Piper nigrum)	5
Sajikhar (Sodium carbonate impura)	5
Kulinjan (Alpinia chinensis)	5
Piper (Piper Longum)	5
Kapur(Camphora officinarum)	5
Kuth (Uncaria gambier)	5

Astringent, anti-inflammatory, anodyne, styptic, deodorant, aromatic, cooling and healing properties

MATERIALS AND METHODS:

100 adults patients suffering from Gingival bleeding in chronic gingivitis and periodontitis were taken at random for this study which lasted for a 7 days

G32 was specially supplied for this clinical trial in powder form in packets, each packet equivalent to two commercially available G32 tablets. Similar packets of placebo were also supplied. One set of packets was marked as XXX and the other set was marked as YYY. The identity of XXX and YYY packets was revealed only after the clinical trial was over. There were 59 cases in XXX Group and 41 cases in YYY Group. The placebo used was a fine Ayurvedic powder having no properties of G32.

The trial period was of seven days. Each patient was examined by the first author before the commencement of the clinical trial and on III, V and VII days, and all the clinical data and G. I. Index were recorded at each visit. No other drug or cleaning agent was allowed during the seven day period of G32 trial.

No surgical procedures were done before or during the period of the trial.

The Gingival Index of Loe & Silness was used to assess Gingival bleeding. There was no index used to judge Periodontitis which was diagnosed only clinically.

Each patient was given 14 of XXX or WY packets to last for seven days. The patient was advised to apply and massage the gingiva and the surrounding parts with the powder of one packet at a time, once in the morning and once in the night, preferably at bed time. After about 10 minutes, the patient was asked to rinse and gargle the mouth with lukewarm water. This was done for seven days. The packets were distributed by the second author only and the assessee (First author) did not even know whether the patient received XXX or YYY powders till the end of the trial.

AGE GROUPS & SEX:

There were 47 males and 53 females in the study. The largest age group was of 21-25 years (31 %), and the next one was of 26-30 years. (26%).

Table I

Age Group	L-Age Groups & Sex		Total	%
	Male	Female		
16-20 years	4	18	22	22%
21-25 years	13	18	31	31%
26-30 years	16	10	26	26%
31-35 years	16	7	20	20%
40 years	1	-	1	1%
Total	47	53	100	100%

CHEWING AND OTHER HABITS:

79% of patients had one or more habits, and 21 % had no habits. Betel chewing habit was present in 61%, smoking was present in 19% (all males), and tobacco chewing was present in 23% of patients

Table II

Habit	No. of cases	%
Smoking: (All males)	19	19%
Betel chewing	16	61%
Tobacco chewing	23	23%
No habits	21	21%

DIAGNOSIS & ASSOCIATED SYMPTOMS:

There were 60 patients with Chronic Gingivitis and 40 patients with periodontitis. All the 100 patients had Bleeding Gums, and 53 patients had associated Pain. Gingival enlargement type was papillary, marginally papillary or generalised.

Table III

Symptoms/Diagnosis	No. of cases	%
Chronic Gingivitis	60	60%
Periodontitis	40	40%
Bleeding Gums	100	100%
Pain	53	53%

RESULTS:

Among the total of 100 cases, 17 cases showed Very Good response and all these cases belonged to XXX (G32) Group (100%). 16 patients showed Good response and all these belonged to XXX (G32) Group (100%). 25 Patients showed Moderate response, out of which 21, patients (84.0%) belonged to XXX (G32) Group and 4 patients (16%) belonged to YYY (Placebo) Group. 26 patients showed Poor response, out of which 5 patients (19.2%) belonged to XXX (G32) Group and 21 patients (80.8%) belonged to YYY (Placebo) Group.16 patients showed no response and all these case belonged to YYY (Placebo) group. (100%) (Table IV).

Table IV

RESULTS AFTER THERAPY, XXX (G32) & YYY (PLACEBO) GROUPS.

Gingival index	No. of cases	XXX Group	%	YYY Group	%
Very Good (0.7to1+)	17	17	100.0%	0	-
Good (0.5 to 0.6)	16	16	100.0%	0	-
Moderate (0.3 to 0.4)	25	21	84.0%	4	16.0%
Poor (0.1 to 0.2)	26	5	19.2%	21	80.8%
Nil (0)	16	0	-	16	100.0%
Total	100	59	59.0%	41	41.0%

Among 59 patients of XXX Group (G32). 91.5% showed satisfactory Response (Very + Good + Moderate), while 8.5% showed Poor response.

Among 41 patients of the YYY Group (Placebo), 9.8% showed satisfactory response while 90.2% showed Poor or No response. (Table V).

Table V

OVERALL RESULTS

Group	Satisfactory	%	Poor	%	Total	%
	(Vgood Good Moderate)		(Poor-Nil)			
XXX Group	54	91.5%	5	8.5%	59	100%
YYY Group	4	9.8%	37	90.2%	41	100%
Total	58	58%	42	42.0%	100	100%

CRITERIA FOR ASSESSMENT OF RESULTS:

The results were assessed as follows:

Very Good: Bleeding from gums stopped (G. I. Index reduced by 0.7 to 1.0+)

Good: Bleeding from gums stopped. (G. I. Index reduced by 0.5 to 0.6.)

Moderate : Bleeding from gums stopped (G. I Index reduced by 0.3 to 0.4.)

Poor: Bleeding from gums present. (G. I Index reduced by 0.1 to 0.2.)

Nil: Bleeding from gums not stopped and there was practically no reduction in G. I. Index.

STATISTICAL STUDY:

Out of the total of 100 patients, Good results (Very Good + Good) were seen in 33 patients, and the rest of 67 patients showed Moderate or Poor or Nil results. Using Chi2 test it is observed that there is highly significant improvement in XXX Group (G32) with reference to Gingival Bleeding and inflammation, when compared to YYY Group (Placebo). The beneficial effects of G32 in control of bleeding and inflammation in case of Chronic Gingivitis is found to be statistically significant at P<0.001. (Table VI).

Table VI

CHI2 TEST. P<0.001

Group	Very Good + Good cases	Moderate + Poor + Nil cases.	Total
XXX Group (G32)	30	26	59
YYY Group (Placebo)	0	41	41
Total	33	27	100

STUDENTS PAIRED 'T' TEST:

Using Student's Paired 'T' test for the mean decrease difference of G. I. Index due to treatment with XXX Powder and YYY Powder, it is found that decrease in G. J. Index due to XXX Treatment (G32) is highly significant at P/0.001.

Table VII

MEAN DIFFERENCE IN G.I INDEX BEFORE AND AFTER AND STUDENT'S 'T' TEST (PLACEBO GROUP)

XXX (G32)	Before Treatment	III Day	V Day	VII Day	Difference I VII
Mean	1.95	1.74	1.60	1.38	0.57
S.D.±	0.3923	0.3836	0.4241	0.3877	0.2499
YYY (Placebo)					
Mean	1.92	1.90	1.82	1.80	0.12
S.D.±	0.3807	0.3665	0.3681	0.3681	0.0894

Student's Paired 't' Test : P < 0.001..

DISCUSSION:

No scaling or surgical procedures were done before, during or after the trial. Surgical intervention as part of secondary prevention requires the removal of pockets etc.

SUMMARY:

A double blind trial in cases of chronic gingivitis as assessed by Gingival Index of Loe & Silness and 40 cases of Periodontitis as assessed only clinically (a total of 100 cases), associated with bleeding gums, were taken up for a double-blind study. 59 patients received packets of powder marked XXX and 41 patients received packets of powder marked YYY. The identity as to G32 or the placebo was revealed only after the treatment was over. The patients were advised to use the powder as topical application and massage for the gums two times a day. the trial period was 7 days. Each patient was examined before starting the treatment and then on the III, V and VII days.

It was observed that the response to treatment was satisfactory in 91.5% with XXX powder (G32), while with YYY powder (placebo) the satisfactory response was only 9.8%. G. I. Index was noted in all the 100 cases before treatment and III, V and VII days. The difference in G. I. Index before and after treatment was noted in both the group.

The data of XXX treatment and YYY treatment were put to statistical study. The results showed that they are highly significant at P<0.001. It is observed that in this trial of 7 days period on 100 cases of gingival bleeding and inflammation, G32 exerts beneficial effects in reducing gingival inflammation and bleeding.

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