



Efficacy of G32 in Treating Pregnancy Gingivitis A Randomised Controlled Trial

Research Article

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Abstract

Background: Pregnant females are susceptible to oral conditions like gingivitis and pregnancy tumour, which affect both the mother and the developing foetus. Chlorhexidine, conventionally used to treat these conditions, causes side effects on long term use. *Ayurvedic* medications like G32 have been used for treating gingivitis.

Objective: To compare efficacy of G32 with Chlorhexidine in treating pregnancy gingivitis after topical application.

Materials and Methods: This was a double blind, randomised controlled trial conducted in a sample of 37 pregnant females, in second trimester, with gingivitis. They were randomly divided into two groups and were allotted Chlorhexidine gel (n=18) or G32 gum-paint (n=19) for local application for one month. Plaque index (Silness and Loe, 1964) and Gingival index (Loe and Silness, 1963) were recorded at baseline and follow-up by a calibrated examiner. Statistical analysis was performed using paired t-test for intragroup comparison of mean plaque and gingival scores, and independent t-test for intergroup comparison of mean percentage reduction in plaque and gingival scores.

Results: Both test and control groups showed a significant reduction in plaque and gingivitis. The percentage reductions in plaque and gingivitis were similar among the two groups.

Conclusion: G32 is effective in treating pregnancy gingivitis and can be economical alternative to Chlorhexidine, with lesser side effects.

Keywords: *Ayurvedic*, Pregnancy, Gingivitis, Chlorhexidine, G32, Trial

Introduction:

Pregnancy has far-reaching systemic effects extending beyond the reproductive organs. These effects are the

end results of complex hormonal, immunologic, dietary, and behavioural changes occurring during pregnancy (1). These can include changes in the cardiovascular, respiratory and gastrointestinal systems, as well as changes in the oral cavity and increased susceptibility to oral infection (2). The oral effects are primarily seen as gingival manifestations; mainly causing pregnancy-associated gingivitis and pyogenic granuloma or pregnancy tumour. So maintaining a good oral health is important during pregnancy.

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The occurrence of pregnancy gingivitis has been acknowledged for a substantial period of time. The term was first described in 1877 (3), although descriptions of the condition had been given even earlier in 1840 (4). It is extremely common and affects 30-75% of all pregnant women (5, 6).

Gingival inflammatory changes in pregnancy usually begin during the second month and increase in severity through the eighth month, after which an abrupt decrease occurs in the symptoms (7, 8). The greatest involvement appears to be in gingivae of the anterior teeth, with interproximal sites most commonly affected (9). The interproximal papillae become red, oedematous and tender to palpation, and they bleed easily if subjected to trauma (2). Various studies have confirmed that the prevalence and severity of gingival inflammation is significantly higher in pregnant women compared to postpartum, and appears unrelated to the amount of plaque present. Also pre-existing gingivitis or periodontitis in pregnant women has been noted to worsen dramatically (9).

Even a healthy pregnancy causes major changes in maternal anatomy, physiology and metabolism. These patients have a heightened awareness of and sensitivity to taste, smell and environmental temperature. Unpleasant tastes and odours can cause severe nausea or even gagging and vomiting (2). Although these adaptations of maternal body are normal, they do necessitate consideration and adjustments in treatment by any dentist, who is providing oral health care and prescribing medications for the patient.

Routine general dentistry should be done in the second trimester of pregnancy only, due to organogenesis occurring during the first trimester and increased uterine size in the third trimester, making sitting in the dental chair uncomfortable. Also nausea generally ceases by the end of

the first trimester. Any treatment should be directed toward controlling disease, maintaining a healthy oral environment and preventing potential problems that could occur later in pregnancy or during the postpartum period.

Nevertheless, a treatment for gingivitis is definitely needed, as the lack of care of gums and teeth affects both the mother and the foetus. Severe gingival disease during pregnancy and the periodontal disease, which progresses from untreated gingivitis, can lead to premature delivery and low birth weight of the baby (10, 11). Thorough oral hygiene measures, including tooth brushing and flossing, are recommended to prevent occurrence of these diseases. Patients with severe gingivitis may require professional cleaning, along with mouth rinses like Chlorhexidine. More severe cases, if do not regress, need surgical therapy (12) which is not advisable during pregnancy. So the non-surgical treatment is the best approach.

Chlorhexidine is a known therapeutic agent used for treating gingivitis in general and also in pregnancy gingivitis. It is a dicationic bisguanide with pronounced antiseptic, antibacterial, antifungal and antiplaque properties. It is available as oral rinse (0.2% and 0.12%) and gel (1%). Many studies have shown that the long term use of Chlorhexidine may cause side effects ranging from as mild as staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue and a transient alteration in taste perception, to as severe as hypersensitivity, generalized allergic reactions and oro-pharyngeal cancer (13). High content of alcohol (12%) in this product has been a point of concern for use in pregnancy and so it has been placed under category 'B' for usage in pregnant females (14).

Under such circumstances, it has become vital to explore safe alternatives to Chlorhexidine. Many *ayurvedic*



formulations have been tested and have been proved to be effective in treating gingival diseases, with fewer deleterious effects. Many formulations like *Salvadora persica* (Miswak), *Triphala*, Propolis, *Azadirachta indica* (Neem) have been widely used (15-18).

G32, used in this study, is one such *ayurvedic* preparation. It is available for local application, in an easily crushable tablet form and as gum paint. The main ingredients in this *ayurvedic* preparation include *Bakul*, *Chok*, *Katha*, *Laving*, *Fatakdi*, etc. (Appendix A). It has anti-inflammatory, antiseptic, antibacterial, astringent, anodyne, styptic and healing actions. Various studies have shown it to be effective in treating gingivitis (19-21) and pregnancy-induced gingivitis (22). These studies have shown that it has minimal side effects and has good compliance of the patients. However, no studies have been conducted till this date that compare G32 with Chlorhexidine, the existing 'gold standard' for gingivitis (23). So this study was conducted with an aim to compare the effectiveness of *ayurvedic* formulation, G32 with Chlorhexidine in treating pregnancy gingivitis.

Constituents of G32 (19-22)

<i>Bakul (Mimosops elangi)</i>	- 80 mg.
<i>Chok</i> (Calcium Carbonate)	- 75 mg.
<i>Katho (Acacia catechu)</i>	- 40 mg.
<i>Laving (Myrtus caryophyllus)</i>	- 20 mg.
<i>Chikani Sopari (Areca catechu)</i>	- 20 mg.
<i>Fatakadi</i> (Alumen)	- 20 mg.
<i>Mayafal (Quercus infectoria)</i>	- 20 mg.
<i>Elaichi (Elettaria cardamomum)</i>	- 10 mg.
<i>Sonageru</i> (Silicate of Alumina and Iron Oxide)	- 10 mg.
<i>Jiru (Carum carvi)</i>	- 10 mg.
<i>Majith (Rubia cordifolia)</i>	- 10 mg.
<i>Pashanbed (Saxifrua ligulata)</i>	- 10 mg.
<i>Vavding (Embelia ribes)</i>	- 10 mg.

<i>Pipala ni Lakh (Ficus religiosa)</i>	- 10 mg.
<i>Samudrafin (Os sapiae)</i>	- 10 mg.
<i>Vajradanti (Barleria prioitis)</i>	- 10 mg.
<i>Taj (Cinnamimum cassia)</i>	- 5 mg.
<i>Mari (Piper nigrum)</i>	- 5 mg.
<i>Sajikhar</i> (Sodium carbonate impure)	- 5 mg.
<i>Kulinjan (Alpinia chinensis)</i>	- 5 mg.
<i>Pipar (Piper longum)</i>	- 5 mg.
<i>Kapur (Camphora officinarum)</i>	- 5 mg.
<i>Kuth (Uncaria gambier)</i>	- 5 mg.

Objectives:

- To evaluate the effectiveness of G32 gum-paint in reducing dental plaque and gingivitis in pregnant females.
- To compare its effectiveness with Chlorhexidine gel.

Materials and methods:

This was a parallel design, randomised controlled trial, conducted on pregnant females with gingivitis, in their second trimester. The examinations were performed in the Ante-natal Gynaecological clinics of Dr. T.M.A. Pai Hospital, Udupi (Karnataka, India). The study was approved by the Kasturba Hospital Institutional Ethics Committee, Manipal (IEC 82/2011). An informed consent was taken from all the study participants before their inclusion.

Sample selection –

- The pregnant females, aged 20-35 years, who were in their second trimester and had signs of moderate to severe gingivitis, with or without plaque or debris, were included in the study.
- Those who had medical complications related to pregnancy, or any medical disorders or chronic/acute infections other than dental infection, requiring any kind of intervention, or reported a recent history of antibiotic



administration for any reason, were excluded from the sample.

The final sample comprised of 37 pregnant females who were randomly divided into two groups. 19 females in the test group were given G32 Alarsin gum-paint (ALARSIN, Mumbai), while 18 others formed the control group and were given Chlorhexidine gel (Hexigel, ICPA, Mumbai). Both the groups were instructed to apply the medicament and massage it over gums twice a day, along with their existing oral hygiene practices. The effects of the medicaments were assessed after one month of usage.

Examination

This trial was conducted from March, 2011 to June, 2011. All the pregnant females attending regular antenatal check-ups in the Gynaecology Dept. were examined for their oral health status by the principal investigator, while general medical examination was performed by other investigator. The females with moderate to severe gingivitis (gingival scores ≥ 1) were included in the study after taking consent.

The participants' information relating their demographics (age, education, income and address), months of pregnancy, personal oral habits, oral hygiene practices were recorded by one of the investigators, after interviewing them. Self-perceived oral health status was also recorded on a 5-point Likert scale, ranging from 'excellent' to 'poor'.

This was followed by clinical oral examination which was performed by the principal investigator. The Gingival and Plaque scores were assessed using the Löe and Silness Index (1963) (24) and Silness and Löe Index (1964) (25), respectively.

These indices were calculated on selected maxillary and mandibular teeth for all the patients, using a mouth mirror and dental probe. The Gingival scores ranged from 0-3 depending on the severity of inflammation in gingival margin. Similarly, the Plaque scores ranged from 0-3 depending upon the thickness of plaque at gingival area of the tooth. Only one trained examiner did all the examinations to prevent the inter-examiner bias. Intra-examiner reliability was assessed by the kappa coefficient. The kappa values for Gingival and Plaque scores were 0.81 and 0.78 respectively.

Followed by this, the participants were randomly allotted one of the two medicaments in wrapped bottles, for one month usage. These bottles were sequentially numbered by an investigator who was not a part of the clinical examination. The subjects were instructed to thoroughly massage the medicament over gums and surrounding areas, with the help of finger-tip and were advised to keep it for minimum five minutes, and then rinse with fresh water, without swallowing it. This procedure was to be repeated twice daily for the first 15 days, in morning and at bed time.

Interim Review

After the first 15 days, a reminder call was made by the investigator to enquire about the compliance to the instructions. The patients were asked if they experienced any change in the condition of their gums. They were instructed to continue using the medicament once daily (in morning) for the next 15 days.

**Follow-up**

All the females were examined at the end of one month for all the parameters evaluated at the baseline. The side effects, if any, were also recorded at this visit. The females were instructed for better oral hygiene methods and importance of oral health in pregnancy was reinforced. They were also advised for a dental visit soon after their delivery.

Data analysis

All the data were analysed using the SPSS version 16.0. The intragroup changes in pre-test and post-test plaque and gingival scores were evaluated using a Paired t-test. Post-test plaque and gingival scores between the test and control groups were compared using Independent t-test. A p -value ≤ 0.05 was considered to be statistically significant.

Results

A total of 400 pregnant females in their second trimester were examined, and 69 females that fulfilled the inclusion criteria were selected. From these, 37 females consented to participate in the study. The most common reason for not participating in the study was apprehension on part of the mothers about the possible risk to their foetuses. The females, who consented, were randomly

divided into Chlorhexidine (n=18) and G32 (n=19) groups.

Out of these 37 pregnant females who were examined at the baseline, about 80% (29 females) perceived their oral health status as 'fair'. None of them perceived their oral status as 'excellent'.

Three females were lost to follow-up of 4 weeks. Two females prematurely withdrew from the study, because of nausea; one each from the test and the control groups. One female from the test group failed to return for the post-test examination. Hence, the final sample of 34 females was analysed, with 17 patients in each group.

The mean age of the females in Chlorhexidine and G32 groups was 28.3 (± 2.1) and 26.5 (± 3.6) years respectively, with a range of 20-33 years. The mean duration of pregnancy was 4.52 (± 0.8) and 4.32 (± 0.9) months respectively, with a range of 3-6 months. The mean baseline plaque scores were 1.93 (± 0.5) and 1.64 (± 0.4) for Chlorhexidine and G32 groups respectively. Similarly, the mean baseline gingival scores were 1.94 (± 0.5) and 1.76 (± 0.3) respectively. There was no statistically significant difference between the test and control groups for mean age ($p = 0.08$), duration of pregnancy ($p = 0.49$), and plaque ($p = 0.06$) and gingival ($p = 0.22$) scores. (**Table 1**)

Table 1 – Baseline characteristics of participants of Chlorhexidine and G32 groups

Treatment	No. of Patients	Mean Age (years)	Mean duration of pregnancy (months)	Mean Plaque Scores (\pm SD)	Mean Gingival Scores (\pm SD)
Chlorhexidine	17	28.37	4.52	1.93 \pm 0.52	1.94 \pm 0.49
G32	17	26.59	4.32	1.64 \pm 0.33	1.76 \pm 0.32

The plaque scores reduced from 1.93 (± 0.5) to 0.79 (± 0.4) in the Chlorhexidine group, while in G32 group, a reduction from 1.64 (± 0.4) to 0.87 (± 0.4) was seen in the



plaque scores. The paired t-test showed that reduction in the plaque scores in both the study groups was statistically significant ($p = 0.001$). (**Table 2**)

Table 2 – Comparison of pre- and post-test plaque scores in both the study groups

Treatment	Pre-test plaque (\pm SD)	Post-test plaque (\pm SD)	Mean Difference (\pm SD)	Percentage reduction	P-value
Chlorhexidine	1.93 \pm 0.52	0.79 \pm 0.39	1.14 \pm 0.48	59%	0.001*
G32	1.64 \pm 0.33	0.87 \pm 0.41	0.77 \pm 0.38	52.9%	0.001*

* – P-value <0.05 considered significant

Paired t-test – Comparing intragroup pre- and post- plaque scores

The gingival scores reduced from 1.94 (\pm 0.5) to 0.75 (\pm 0.3) in the Chlorhexidine group, while in G32 group, these reduced from 1.76 (\pm 0.3) to 0.72 (\pm 0.4). This reduction in both the study groups was found to be statistically significant ($p \leq 0.001$). (**Table 3**)

Table 3 – Comparison of pre- and post-test gingival scores in both the study groups

Treatment	Pre-test gingivitis (\pm SD)	Post-test gingivitis (\pm SD)	Mean Difference (\pm SD)	Percentage reduction	P-value
Chlorhexidine	1.94 \pm 0.49	0.75 \pm 0.32	1.18 \pm 0.37	61%	<0.001*
G32	1.76 \pm 0.32	0.72 \pm 0.38	1.04 \pm 0.44	58.7%	0.001*

* – P-value <0.05 considered significant

Paired t-test – Comparing intragroup pre- and post- gingival scores

The plaque scores showed a mean percentage reduction of 59% in Chlorhexidine group and 53% in G32 group. This difference was not found to be statistically significant following the independent t-test ($p = 0.48$). The gingival scores showed a mean percentage reduction of 61% in Chlorhexidine group and 58% in G32 group. The independent t-test showed that this difference was not statistically significant ($p = 0.64$). (**Table 4**)

Table 4 – Comparison of the percentage reduction of plaque and gingival scores between Chlorhexidine and G32 groups –

Characteristics	Percentage reduction Chlorhexidine	Percentage reduction G32	P-value
Plaque Scores	58%	53%	0.484
Gingival Scores	61%	58%	0.64

P-value <0.05 considered significant

Independent t-test – Comparing intergroup changes in scores

Discussion:

This study was a parallel designed, double blind, randomised controlled clinical trial conducted on pregnant

females with gingivitis, in their second trimester. It aimed to assess the effectiveness of G32 as compared to



Chlorhexidine in treatment of pregnancy gingivitis.

Plaque and Gingival index were used to assess the oral health status of the subjects. Previous clinical trials have used these indices as effective parameters to evaluate the efficacy of the active components in preparations used in treatment of gingivitis (26-28).

Chlorhexidine is the gold standard for the treatment of gingivitis (23). It is also widely recommended for the treatment of pregnancy gingivitis (12). Previous studies have reported that the gel form of Chlorhexidine is more effective than the mouthwash (18). Hence, the gel form was used in this study, as it had an added advantage of better comparability with the *ayurvedic* medicament, as both are applied in similar manner.

G32 is an *ayurvedic* formulation, known for many years, effective in treating gingivitis (20, 21) and pregnancy gingivitis (22). These studies showed that scaling, curetting or surgical procedures for treating gingivitis could be avoided by the local application of G32. Similar findings were reported in this study. A mere local application of G32 had brought about 53% reduction in dental plaque and 58% reduction in gingival inflammation.

The mean Plaque and Gingival Index scores reduced significantly over the trial period for both the groups. The difference in reduction of these scores in both the groups was not statistically significant, indicating that G32 is as effective as Chlorhexidine in reducing the plaque and gingival scores in this sample of pregnant females.

The participants were enquired about any side effects of the drugs experienced during the duration of one month trial. Few of the participants had complaint of nausea during this trial. These females gave a history of severe nausea during their first trimester. While some of them continued using the drugs,

two of them withdrew themselves from the study prematurely.

Chlorhexidine formulations contain about 11.6% alcohol, as a preservative and a semi-active ingredient. Excessive use of alcohol based products cause allergy, desiccation of oral mucosa, staining and change in taste perception. A significant risk of developing oro-pharyngeal cancer exists with the long term use of these products (29). The use of these products in pregnant females is a matter of great concern. G32 is a water based product, causing none or minimal side effects of this nature, even on a long term use. It has a pleasant taste. Hence, the compliance of the patients would be better. Moreover, it was observed that G32 was economical to be used for a long duration than Chlorhexidine gel or mouthwash.

The major limitations of this study were the short duration of follow-up and small sample. Also, the sample could be drawn only from second trimester pregnant females due to ethical constraints. Further, no differentiation could be made for cases of 'Gingivitis' or 'Pregnancy Gingivitis', either through history or histologically.

Nevertheless, this study has evidently shown the effectiveness of G32 in treatment of pregnancy gingivitis. Future studies are recommended to evaluate the reduction in amount of bleeding, reduction of attachment loss, effect on initial caries and the microbiological changes brought about by G32. Also the effects on pregnancy outcomes can be examined in longitudinal trials in pregnant females. Additional larger studies are needed to determine whether these findings are applicable to other populations, and to the treatment delivered at other stages of pregnancy.

During the course of this study, it was noticed that most of the pregnant females did not perceive their oral hygiene status as poor. Many were not aware of any disease in their oral cavity, while others were not sure if they needed to get



some treatment for their ailments. Moreover, quite a few females with gingivitis refused to undergo any treatment for their gingival disease. It was evident that pregnant females were not aware of the importance and the harmlessness of the oral hygiene procedures during pregnancy. Hence, there is a need to propagate the fact that the chemical methods of oral hygiene, like G32 and also Chlorhexidine, are safe and harmless to be used even during pregnancy.

Conclusion:

This study concluded that G32 gum-paint is effective in reducing plaque and gingival inflammation in pregnant females. It can be an efficient, safe and cost-effective alternative to Chlorhexidine in the treatment of pregnancy gingivitis.

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