ORIGINAL ARTICLE

# Efficacy of *Aloe vera* Gel as an Adjunct to Scaling and Root Planing in Management of Chronic localized Moderate Periodontitis: A Randomized Clinical Trial

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## ABSTRACT

**Background:** *Aloe vera* has been in use for medical and dental therapy since historical time for its anti-inflammatory, antioxidant, antimicrobial, healing-promoting, and immune boosting properties. This study aims to invest the clinical effectiveness of locally delivered *A. vera* gel used as an adjunct to scaling and root planing (SRP) in the treatment of chronic localized moderate periodontitis.

**Materials and Methods:** A total of 71 patients were enrolled in the study: Test group of 33 and control group of 38. After supragingival scaling, patients with chronic localized moderate periodontitis (probing pocket depth [PPD] 4–7 mm) were recalled after 1 week. The patients were randomly allocated into test and control group by computer-generated random number table method. Total sites of the two groups were 266. Baseline parameters were measured. For patients in the test group along with SRP, 2.5% *A. vera* gel and, for control group along with SRP, placebo gel were given. PPD, clinical attachment level (CAL), gingival index (GI), and plaque index (PI) were reassessed at 1st, 2nd, and 4th months. The data obtained were statistically analyzed using independent *t*-test.

**Results:** There was a statistically significant difference in PPD, CAL, and GI in the test group as compared to control group on 1st month. There was statistically significant difference in PI for both the test and control groups in the 2nd month, and there was no statistically significant difference in PI for both the test and control groups in the 1st and 4th months. Similarly, there was no statistically significant difference in PPD, CAL and GI between test and control groups in the 2nd and 4th months.

**Conclusion:** Short term, data of this clinical trial showed that *A. vera* as an adjunct to SRP can be useful in management of chronic moderate periodontitis, for reducing pocket depth, gaining CAL, and reducing gingival inflammation as evident by significant reduction obtained in baseline parameters and 1 month.


**Keywords:** *Aloe vera gel,* Chronic localized moderate periodontitis, Local drug delivery, Scaling and root planing

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## INTRODUCTION

Periodontal disease is an inflammatory disease characterized by the destruction of the supporting structures of the teeth. The primary etiologic factor of periodontitis is dental plaque and the microorganisms that are present in it. The biofilm nature of dental plaque provides a specialized environment for the microorganisms, thereby ensuring its vitality and pathogenicity.[1]

The aim of periodontal therapy involves the removal of supra- and sub-gingival plaque and calculus, thereby returning the tissues to a state of health.[1] Mechanical control alone may not be sufficient to prevent the onset or occurrence of disease.[2] To overcome this, the addition of antimicrobials both systemically and locally would enhance a treatment protocol and serve as adjuncts to mechanical therapy.[3] Systemic antimicrobial agents may reduce or eliminate bacteria that cannot be removed by scaling and root planning (SRP) but have several adverse effects which limit their use.

To override these shortcomings, local delivery of antibacterial agents into periodontal pockets has been extensively studied. Local drug delivery appears to be a suitable form to deliver drugs into periodontal pocket[4] and its periodic use helps to reduce probing depths, stabilize attachment levels, and minimize bleeding.[5]

Commonly used local drug delivery agents are tetracyclines including doxycycline, minocycline, metronidazole, and chlorhexidine.[6] However, they have disadvantages which include hypersensitivity reactions, phototoxicity, and staining of teeth and relatively are expensive. Since historical times, various herbal and natural products have been used for chemotherapeutic purposes in the field of medicine and dentistry, with the advantage of fewer side effects and cost-effectiveness.[5,7] Commonly used herbs and herbal combinations are *Aloe vera*, green tea, bloodroot, chamomile, eucalyptus, neem, tulsi, turmeric, and *Centella asiatica*.[8]

*A. vera* has anti-inflammatory, antioxidant, antimicrobial, hypoglycemic, healing-promoting, and immune boosting properties. It has proven its health benefits in medical condition such as cancer, protection of liver and kidney, diabetes, infections, and osteoarthritis.[9]

### Aims and Objectives

The aims and objectives of this study were to determine the efficacy of subgingivally delivered 2.5% *A. vera* gel as an adjunct to SRP in the treatment of chronic localized moderate periodontitis as compared to placebo gel.

### Primary Objective

The primary objective of this study was to evaluate the clinical efficacy of 2.5 % of *A. vera* gel in reducing periodontal pocket depth as compared to placebo gel as measured by change in pocket depth using UNC-15 probe in mm.

### Secondary Objective

The secondary objective of this study was to find whether there is any change in clinical attachment level (CAL) (mm) and gingival inflammation and plaque score as determined by gingival index (GI) and plaque index (PI), respectively.

## MATERIALS AND METHODS

This was a single-blinded randomized controlled clinical trial; patients were selected from outpatient section of the Department of Periodontics, Government Dental College, Thiruvananthapuram, with chronic localized moderate periodontitis having probing pocket depth (PPD) of 4–7mm. A total of 71 patients enrolled in the study: Test group of 33 and control group of 38. After supragingival scaling, patients with chronic localized moderate periodontitis (PPD 4–7 mm) were recalled after 1 week. The patients were randomly allocated into test and control groups by computer-generated random number table method. Total sites of the two groups were 266. The Institutional Ethical Committee provided ethics clearance for the study. The period of the study was from November 2014 to October 2015 (Clinical trials IEC/C/54/2013/DCT/9/12/2013).

### Intervention

The *A. vera* gel was developed at the College of Pharmaceutical Sciences, Medical College, Thiruvananthapuram, following the procedure described by Abdul Wadood Khan *et al*.[10]

### Statistical Analysis

Data were analyzed using computer software, Statistical Package for the Social Science version 17.0.

### Procedure

After supragingival scaling, patients with chronic localized moderate periodontitis (PPD 4–7 mm) were recalled after 1 week. The patients who satisfy the inclusion criteria (chronic localized moderate periodontitis greater than or equal to two sites with PPD of 4–7 mm and age - 20–60 years) were randomly allocated into test and control groups by computer-generated random number table method. Baseline parameters were measured. For patients in test group along with SRP, 2.5% *A. vera* gel was injected into the periodontal pocket using syringe and needle, and for control group along with SRP, placebo gel having same color and consistency of *A. vera* was injected into the periodontal pocket using a syringe and needle. After delivery, the viscosity of the prepared formulation decreased, swelling up, and occluding the periodontal pocket, precluding the need for placement of periodontal dressing. The baseline parameters such as PPD, CAL, GI, and PI were reassessed at 1$^{st}$, 2$^{nd}$, and 4$^{th}$ months.

## RESULTS

A total of 71 patients enrolled in the study include test group of 33 and control group of 38 patients. Total sites randomized into two groups were 266: 122 sites in test group and 144 sites in control group.Baseline parameters of both test and control group with respect to Probing pocket depth, clinical attachment level,plaque index and gingival index were measured. For test group the mean PPD score was 4.87 + 0.69,mean CAL5.08 + 0.66,mean GI 1.47 + 0.34,mean PI 1.26 + 0.51.For control group,it was 4.83 + 0.74mean PPD,mean CAL5.08 + 0.79,mean GI 1.48 + 0.30,mean PI 1.14 + 0.54 [Table 1]. The change in mean PPD between the group was analysed using independent t test.stastical analysis showed that on 1st month the change in PPD for test group was 0.82 + 0.89 and in control group was 0.54 + 0.86,with a p value 0.047 which was statistically significant.On 2nd months the change in PPD for test group was 0.68 + 0.90 and in control group was 0.57 + 0.92, ,with a p value 0.468 which was statistically not significant,Similarly on 4th months change in PPD for test group was 0.75 + 0.99 and in control group was 0.55 + 0.89,with a p value 0.185 which was statistically not significant [Table 2].

Stastical analysis showed that on 1st month the change in CAL for test group was 0.82 + 0.84 and in control group was 0.54 + 0.86,with a p value 0.042 which was statistically significant.On 2nd months the change in CAL for test group was 0.68 + 0.85 and in control group was 0.59 + 0.92, with a p value 0.507 which was statistically not significant,Similarly on 4th months change in CAL for test group was 0.75 + 0.96

**Table 1:** Baseline characteristic of test and control groups

| Parameters | Test group mean±SD | Control group mean±SD | *t*-value | *P* value |
|---|---|---|---|---|
| PPD | 4.87±0.69 | 4.83±0.74 | 0.31 | 0.755 |
| CAL | 5.08±0.66 | 5.08±0.79 | 0.02 | 0.980 |
| GI | 1.47±0.34 | 1.48±0.30 | 0.08 | 0.934 |
| PI | 1.26±0.51 | 1.14±0.54 | 1.37 | 0.173 |

PPD: Probing pocket depth, GI: Gingival index, PI: Plaque index, CAL : Clinical attachment level, SD: Standard deviation

**Table 2:** Comparison of change in PPD based on test and control groups

| Change in PPD (month) | Control | | Test | | *t* | *P* |
|---|---|---|---|---|---|---|
| | Mean±SD | *n* | Mean±SD | *n* | | |
| 1 | 0.54±0.86 | 87 | 0.82±0.89 | 72 | 2 | 0.047 |
| 2 | 0.57±0.92 | 87 | 0.68±0.90 | 72 | 0.73 | 0.468 |
| 4 | 0.55±0.89 | 87 | 0.75±0.99 | 72 | 1.33 | 0.185 |

SD: Standard deviation, PPD: Probing pocket depth,

and in control group was 0.56 + 0.87, with a p value 0.201which was statistically not significant.Hence the above results showed that the difference in change in CAL between test and control group was statistically significant at 1st month and in 2nd and 4th month not statistically significant [Table 3].

The change in mean GI between the group was analysed using independent t test.stastical analysis showed that on 1st month the change in GI for test group was 0.74 + 0.34 and in control group was 0.56 + 0.26,with a p value 0.000 which was statistically highly significant.On 2nd months the change in GI for test group was 0.72 + 0.36 and in the above results showed that the difference in change in GI between test and control group was statistically significant at one month and in 2nd and 4th month not statistically significant [Table 4].

The change in mean PI between the group was analysed using independent t test.stastical analysis showed that on 1st month the change in PI for test group was 0.59+0.41 and in control group was 0.53 + 0.43,with a p value 0.385 which was statistically not significant.On 2nd months the change in PI for test group was 0.70 + 0.55 and in control group was 0.51 + 0.51, with a p value 2.23 which was statistically significant,Similarly on 4th months change in PI for test group was 0.79 + 0.51 and in control group was 0.68 + 0.55, with a p value 0.192 which was statistically not significant.Hence the above results showed that the difference in change in PI between test and control group was statistically significant at 2nd month and in 1st and 4th month not statistically significant [Table 5].

## DISCUSSION

A total of 71 patients enrolled in the study include test group of 33 and control group of 38 patients. Total sites

**Table 3:** Comparison of change in CAL based on test and control groups

| Change in CAL (month) | Control | | Test | | *t* | *P* |
|---|---|---|---|---|---|---|
| | Mean±SD | *n* | Mean±SD | *n* | | |
| 1 | 0.54±0.86 | 87 | 0.82±0.84 | 72 | 2.05 | 0.042 |
| 2 | 0.59±0.92 | 87 | 0.68±0.85 | 72 | 0.66 | 0.507 |
| 4 | 0.56±0.87 | 87 | 0.75±0.96 | 72 | 1.28 | 0.201 |

CAL: Clinical attachment level, SD: Standard deviation

**Table 4:** Comparison of change in GI based on test and control groups

| Change in GI (month) | Control | | Test | | *t* | *P* |
|---|---|---|---|---|---|---|
| | Mean±SD | *n* | Mean±SD | *n* | | |
| 1 | 0.56±0.26 | 87 | 0.74±0.34 | 72 | 3.78 | 0.000 |
| 2 | 0.64±0.32 | 87 | 0.72±0.36 | 72 | 1.39 | 0.165 |
| 4 | 0.77±0.39 | 87 | 0.75±0.39 | 72 | 0.28 | 0.781 |

SD: Standard deviation, GI: Gingival index

**Table 5:** Comparison of change in PI based on test and control groups

| Change in PI (month) | Control | | Test | | *t* | *P* |
|---|---|---|---|---|---|---|
| | Mean±SD | *n* | Mean±SD | *n* | | |
| 1 | 0.53±0.43 | 87 | 0.59±0.41 | 72 | 0.87 | 0.385 |
| 2 | 0.51±0.51 | 87 | 0.70±0.55 | 72 | 2.23 | 0.027 |
| 4 | 0.68±0.55 | 87 | 0.79±0.51 | 72 | 1.31 | 0.192 |

SD: Standard deviation, PI: Plaque index

randomized into two groups were 266: 122 sites in test group and 144 sites in control group. Four patients from both test and control group patients were shifted to periodontal surgical therapy which includes four sites in control group and eight sites in test group. The total number of patients who have completed the study was 38 which include test sites of 72 and control sites of 87. In the test group, five patients lost to follow up in the 1st month, four in the 2nd month, and three in the 4th month. Similarly, in control group, 8 patients lost follow-up in the 1st month, four in the 2nd month, and one in the 4th month.

The clinical parameters (PPD, CAL, PI, and GI) were recorded in the 1st month, and this was in accordance with the findings by Carranza *et al*.[11] Who concluded that epithelial and connective tissues healing after non-surgical therapy are completed by 4 weeks.[12] Clinical parameters were recorded in the 2nd and 4th months to know whether the obtained results are maintaining for a short period. They were recalled on 2nd and 4th months.

In the present study, there was a significant reduction of PPD in test group compared to control group from baseline to 1st month. For test group change in PPD was 0.82 + 0.89 and in control group 0.54 + 0.86 mm (t = 2, P = 0.04), which was statistically significant, and also there was a statistically significant gain of CAL for test group (0.82 + 0.84) compared to control group (0.54 + 0.86) (*t* = 2.05, *P* = 0.04) from baseline to 1st month.

Statistical analysis showed that, in the 2nd month, the change in PPD from baseline for test group was 0.68 + 0.90 and in control group was 0.57 + 0.92 ($t$ = 0.73, $P$ = 0.46) which was not statistically significant. Analysis showed that, in the 4th month, the change in PPD from baseline for test group was 0.75 + 0.99 and in control group was 0.55 + 0.89 ($t$ = 0.18, $P$ = 0.18) which was not statistically significant. The PPD reduction was almost similar in the 2nd and 4th monthS.

The results are in accordance with the study conducted by Virdi *et al*.[13] which demonstrated a probing pocket reduction following insertion of *A. vera* gel subgingivally when compared to SRP. Bhat *et al*.[14] also showed a significant probing pocket reduction following insertion of *A. vera* gel subgingivally when compared to SRP. The effects of *A. vera* gel on the activity of microbial and human metalloproteinases and found that a collagenase from *Clostridium histolyticum* was dose dependently inhibited by the *A. vera* gel.[15,16] Various studies reported that, due to some chemical structural similarity between aloins and tetracyclines, aloe derivatives inhibit the metallomatrix proteinases through a mechanism similar to that of inhibitory tetracyclines.[9]

In the present study, the change in PPD from baseline for test group and control group was not statistically significant. This may be due to GCF which has constant turnover and *A. vera* gel is not sustained due to single application. Furthermore, lost follow-up was high which might also affect the study.

In the present study, the mean GI in the test group 0.74 + 0.34 when compared to control group 0.56 + 0.26, in the 1st month (t = 3.78, $P$ = 0.00) which was highly statistically significant. Statistical analysis showed that change in GI from baseline to 2nd month in the test group was 0.72 + 0.36 and 0.64 + 0.32 for control group; however, this difference between the groups was not statistically significant ($t$ = 0.66, $P$ = 0.16). Similarly, change in GI from baseline to 4th month in the test group was 0.75 + 0.39 and 0.77 + 0.39 for control group, ($t$ =1.28, $P$ = 0.78) which was not statistically significant.

This result was in accordance with the study conducted by Virdi *et al*.[13] which demonstrated a probing pocket reduction following insertion of *A. vera* gel subgingivally when compared to SRP. Bhat *et al*.[14] also demonstrated a reduction in GI following insertion of *A. vera* gel subgingivally when compared to SRP.

Pradeep *et al*.,[17] whose study involved 90 patients diagnosed with chronic generalized gingivitis randomly divided into three groups. Toothpaste containing *A. vera* showed significant improvement in GI and PI scores as well as microbiologic counts compared with placebo dentifrice, but there was no statistically significant difference in change in GI between *A. vera* dentifrice and triclosan dentifrice at any interval of time recorded. Therefore, this finding was in agreement with the finding of the present study.

In the present study, the statistical analysis showed that, in the 1st month, the change in PI from baseline for test group and in control group ($t$ = 0.87, $P$ = 0.38) showed no significant difference in change in PI between the two group from baseline to 30th. A reduction in PI was observed from baseline to 2nd month in the test group with a change in mean PI of 0.70 + 0.55 for test group and 0.51 + 0.51 for control group; this difference between the groups was statistically significant ($t$ = 2.23, $P$ =0.02).

There was reduction in PI between baseline and 4th month with a change in mean PI of 0.79 + 0.51 for test group and 0.68 + 0.55 for control group ($t$ = 1.31, $P$ = 0.19) for difference in change between the groups; therefore, this difference was not statistically significant. More reduction of PI is noticed in the 2nd month due to hawthorne effect which is a type of reactivity to their awareness being observed. Here, OHI was reinforced in each visit which might improve patient's oral hygiene and brushing, subsequently reduced plaque accumulation.

Bautista-Pérez[18] showed that carboxypeptidase in *A. vera* had good anti-prostaglandin (PG) synthesis properties and compounds inhibiting oxidation of arachidonic acid, which might decrease inflammation. *A. vera* contains salicylate magnesium lactate decarboxylase, which is known to inhibit histidine, thereby preventing the formation of histamine from histidine in mast cells.[19] Heggers and Robson[12] showed that barbolin and aloe emodin in *A. vera* block PG synthesis. Vazquez *et al*. stated that *A. vera* decreases edema and number of neutrophils and also prevents migration of polymorphonuclear leukocytes. Barrantes and Guinea[16] stated that *A. vera* inhibits the stimulated granulocyte matrix metalloproteinases inhibiting cyclo- and lipo-oxygenase pathways. Yagi *et al*.[20] stated that the presence of glycoprotein with cell proliferation improves healing *A. vera* penetration and dilates capillaries going to an injured site, which improves healing. *A. vera* promotes wound healing by accelerating epithelial cell migration and collagen maturation facilitates tissue restoration.[9] From this trial, *A. vera* has the potential to manage periodontal disease, but more multicenter trials with sustained release and repeated application are needed to confirm the obtained results.

## CONCLUSION

Within the limits of the short-term clinical trial, the following conclusions were drawn. At 1 month,

1. *A. vera* gel as a local drug delivery was more effective in reducing PPD as compared to control.
2. *A. vera* gel as a local drug delivery was more effective in improving clinical attachment level as compared to control.
3. *A. vera* gel as a local drug delivery was more effective in reducing gingival inflammation as compared to control.

Statistical significance does not provide information about the effect size or the clinical relevance. Due to that, researchers often misinterpret statistical significance as clinical one. Both significances (statistical and clinical) are not mutually exclusive but complementary in reporting results of clinical research. Care should be taken to interpret with *P* value alone and importance must be given to the clinical relevance. Further trials with more sample size incorporating non-adherence should be undertaken to prove the efficacy of *A. vera* gel as an adjunct to non-surgical periodontal therapy.

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