IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Comparative Evaluation Of Efficacy Of Green Coffee And Chlorhexidine Gel As A Local Drug Delivery In Periodontal Pocket In Chronic Periodontitis Patients": A Randomized Controlled Clinical Trial.

1Dr. Ankita Ashok Katkurwar, 2Dr Swanpa Mahale, 3Dr. Amit Agrawal, 4Dr. Kunal Sethi, 5Dr. Triveni Kale

1MDS, 2Professor , 3Professor , 4Professor , 5Professor

1. INTRODUCTION:

Coffee is one of the most readily available and readily consumed beverages in the world owing to its pleasant odour, taste and safety. The phenolic chemicals present in coffee beans, such as chlorogenic acids (CGA), have many favourable effects like anti-inflammatory, antioxidant, antibacterial, anti-obesity, anti-diabetic, anti-hypertensive, anti-cancer, and neuroprotective properties. The majority of the chlorogenic acids are lost when coffee beans are roasted to extremely high temperatures. So, Green coffee beans are the normal coffee beans that haven not been roasted and are totally raw. Fat, protein, carbohydrates are the macro nutrients beside the minor components like such as chlorogenic acid, caffeine also trigonelline found in green coffee [1].

The periodontal therapy primarily targets arresting chronic inflammatory process to preserve the natural dentition and prevents further loss of the periodontal tissues. Though SRP is the most preferred treatment option, data suggests that SRP alone has limited applications as complete elimination of subgingival bacteria is not achieved as pathogenic bacteria can reside in soft tissues and root surface irregularities which limit the outcome of periodontal therapy. Also, inaccessible areas like deep pockets, furcation areas and abnormal topography of root surface can favour the failure of outcome of SRP. Thus, conventional therapy does not give a favourable response so antimicrobial therapy has grabbed the attention in the treatment of periodontal disease as an adjunct to SRP.

Chlorhexidine (CHX) mouthwash is a cationic which acts by disruption of cell membrane. In vitro within 30 seconds almost 100% of gram-negative and gram-positive bacteria are killed with CHX mouthwash. However, prolonged usage of chlorhexidine can cause xerostomia, stains on the tongue, teeth, and gingiva, as well as on resin and silicate restorations [2]. Thus its prolonged use is discouraged.

Phytochemicals can be a promising alternative to conventional synthetic drugs owing to its minimal side effects and desirable properties [3]. Green coffee beans extract are found to be active against the periodontal pathogens like P. gingivalis and P. intermedia, as well as Candida albicans [4]. So this randomized controlled clinical trial was directed to comparatively appraise the efficacy of green coffee and chlorhexidine gel as a local drug delivery in periodontal pocket in chronic periodontitis patients.

2. MATERIAL AND METHOD:

This was a single-centre, randomised clinical control trial with double blinding. The Institution Ethical Committee has assessed and approved our study protocol. . This study was registered at CTRI (CTRI/2020/07/026770).The study enlisted the participation of 45 patients .Before being enrolled in the trial, all the patients were specified verbal and written facts about the investigation, as well as written informed consent was obtained.

Patients included were systemically healthy patients diagnosed with mild and moderate chronic periodontitis having (According to 1999 classification) ,Generalised periodontitis Stage II Grade B ,currently unstable ,no specific risk factor (According to 2017 classification) ,minimum of 2-3 sites with persistent pocket depth of minimum 4 -6 mm .The exclusion criteria included patients who have taken drugs like anti-inflammatory, antibiotics, chemotherapeutics, corticosteroids, or immunological modulators that may modify the anticipated response of the oral tissues or with the history of some prior periodontal treatment in the previous 6 months .Patients with habit of tobacco consumption in any form or suffering from systemic disease which can impact the periodontal disease. Patients who are lactating, pregnant, with known allergic to chlorhexidine or green coffee, not ready to give the consent or found allergic to either green coffee or chlorhexidine. Follow-up not possible by the patient even after repeated calls were omitted. Even voluntary withdrawal by the patient was acceptable.

Commercially available Chlorhexidine gluconate gel as 1% Hexigel (ICPA, India) was used in this study . 20 % green coffee gel was formulated using unroasted green coffee bean extract in the pharmacy department of our institute. For drug delivery into the periodontal pocket, an injectable system was used as it is easy and rapid.

For green coffee gel preparation 20 Gms of crushed green coffee beans was added to 80ml of water. This mixture was boiled and concentrated to make final aqueous extract of 20gms (20% green coffee extract). 1.4 Gms of carbopol 974P which is a gelling agent was added to 40ml of purified water. In another 30 ml of purified water a chelating agent Disodium EDTA 0.05gm and preservatives like Sodium methyl paraben 0.2gm and Sodium propyl paraben 0.02gm were added. A mixture of carbopol and water as well as aqueous green coffee extract prepared earlier was mixed. pH was adjusted to 5.24 using Sodium hydroxide. Finally weight was calibrated to 100gm using purified water. This gel was packed in aluminium collapsible tube.

45 patients were assigned randomly to three different groups using the lottery method (15 patients in respective group).

Group A (15 patients): Scaling and root planning (SRP) + subgingival placement of Green coffee gel.

Group B (15 patients): Scaling and root planning (SRP) + subgingival placement of chlorhexidine (CHX) gel.

Group C (15 patients): Scaling and root planning (SRP).

3. CLINICAL PROCEDURE

All the patients on diagnosis and screening from OPD for inclusion/exclusion criteria were informed about the study design in the language they understand .Written copy of the inform consent was given for voluntary signature. Detail medical and dental history was taken. Alginate impressions were taken for corresponding arch and customized acrylic stents were fabricated.

SRP was completed at the first visit. On the following appointment after 3-4 weeks, only those patients having persistent periodontal pockets of 4-6mm were recruited for the study.

At baseline (just before gel placement) clinical and microbiological parameters were assessed. Clinical parameters like Plaque Index (PI)[5,] Gingival Index (GI)[6] , Sulcus Bleeding Index (SBI)[7], Probing Pocket Depth (PPD), and Relative Attachment Level (RAL) were documented by the examiner manually with a UNC-15 periodontal probe. For evaluation of CFU (Colony Forming Units) plaque samples were collected.

To avoid contamination from saliva, test sites were isolated with cotton rolls. Using a syringe and blunt cannula, the experimental drug, Green coffee gel and Chlorhexidine gel (CHX gel), were delivered subgingivally in the targeted sites until the pocket was overfilled with the gel.

Coe-Pak was used to cover the test sites to retain the drug in the pocket and to inhibit oral fluid ingress. On the 7th day follow-up visit periodontal dressing was removed and oral hygiene maintenance instructions were given. After 1 and 3 months of placement of experimental drugs reassessment of the clinical parameters were done. Microbiological parameter was assessed at 3 months of placement of experimental drugs. Patients were asked to maintain their dental hygiene between the follow-up. No added chemical plaque control measures were used during the trial period.(Figure1,2 and 3)

Figure1. Procedure in Group A (Green coffee gel)

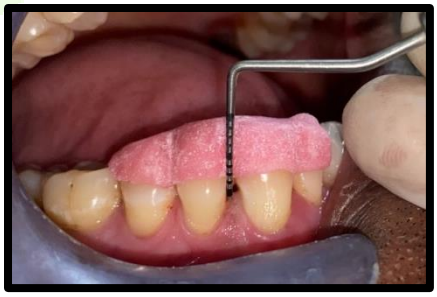


Fig 1a: Baseline probing pocket depth

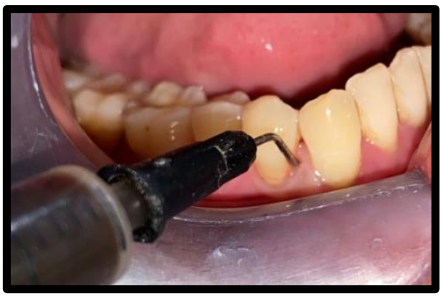


Fig1b: Subgingival delivery of Green coffee gel

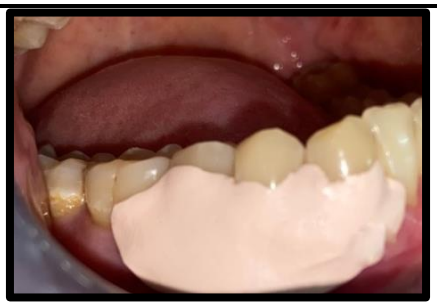


Fig1c: Periodontal Dressing

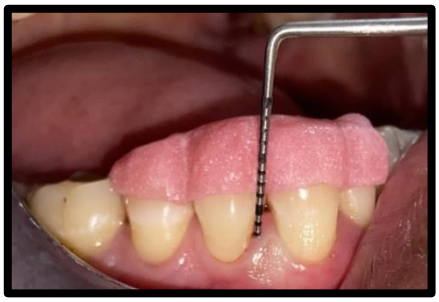


Fig1d: PPD at 1 month

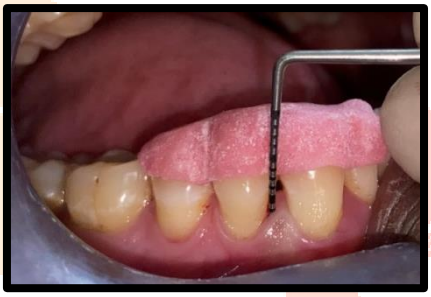


Fig1e: PPD at 3 month

Fig 1f: CFU at baseline

Fig1g: CFU at 3 months

Figure 2: Procedure in Group B (Chlorhexidine gel)

Figure 2a: Baseline Probing Pocket Depth

Fig 2b. Subgingival delivery of chlorhexidine gel

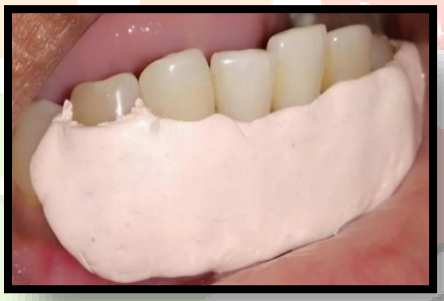


Fig 2c: Periodontal Dressing

Fig 2d: PPD at 3 month

Fig 2e: PPD at 3 month

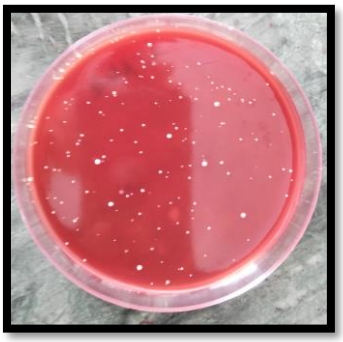


Fig 2f: CFU at baseline

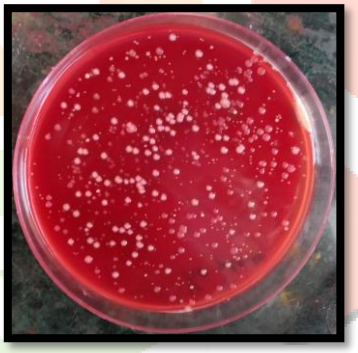


Fig 2g: CFU at 3 months

Figure3.Procedure in Group C (scaling and root planing)

Fig 3a: PPD at baseline

Fig 3b: PPD at 1 month

Figure 3c: PPD at 3 month

Fig 3d:CFU at baseline

Fig 3e:CFU at 3 month

MICROBIOLOGIC ASSESSMENT**:**

At baseline, with the cotton rolls the study sites were isolated. By sterile curette the subgingival plaque sample was collected .Then transferred into 5 ml of thioglycolate broth and moved to laboratory of microbiology. Thioglycolate medium is an enrichment medium .It contains many nutrient factors, including

yeast, casein, vitamin, beef extract, resazurin, hemin and dextrose. Thioglycolate Medium was chosen as it recommended for the cultivation of anaerobic, aerobic and microaerophilic microorganism. Then, 0.1ml of this sample was transferred to blood agar plate (Figure 4). To spread the sample evenly on the blood agar L shape spreader was used. The plates were kept into anaerobic gas pack (Figure 5). Anaerobic condition of the gas pack was assured where it contains methylene blue as an indicator. Oxygen absorption and carbon dioxide generation starts immediately on contact with air so the gas pack was sealed carefully. Following which for 72 hours the gas pack was placed into the incubator at 37°C [8]. The agar plates after the incubation period were evaluated for the total number of colony forming units of anaerobic bacteria. To aid in counting the plate was divided into grids. By summing up the grids the total colony forming units were then attained. The above procedure was repeated after 3 month follow-up visit.

Figure 4-.Blood agar plate

Figure 5-Anaerobic gas pack

4. STATISTICAL ANALYSIS

Data obtained was compiled on a MS Office Excel Sheet (v 2010, Microsoft Redmond Campus, Redmond, Washington, United States). Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 21.0, IBM). Inter group comparison (>2 groups) was done using one-way ANOVA followed by pair wise comparison using Tukey's post hoc test. Intra group comparison was done using repeated measures ANOVA (for >2 observations) followed by post Hoc test. Comparison of frequencies of

categories of variables with groups was done using chi square test. For all the statistical tests, p <0.05 was considered to be statistically significant

5. RESULTS

All patients reported for the follow-up and showed good compliance. In all the groups the healing was uneventful, with no signs of swelling, inflammation or allergy signifying the biocompatibility of the materials

The patients included in the study were in age group of 30-56yrs .Number of female subjects were more than male but no statistical significance was noted.

For PI,GI,SBI,PPD on overall comparison there was highly statistical significant (p<0.001) decline in respect to change during study period in all 3 groups .

For PI at 1 month difference was found to be non-significant (p=0.825) between group A and B but was significant between group A and C (p=0.001) as well as Group B and C (p=0.004). At 3 month the difference was found to be non-significant between group A and B (p=0.987) but was significant between group B and C (p=0.006) as well as Group A and C (p=0.009). (Graph 1)

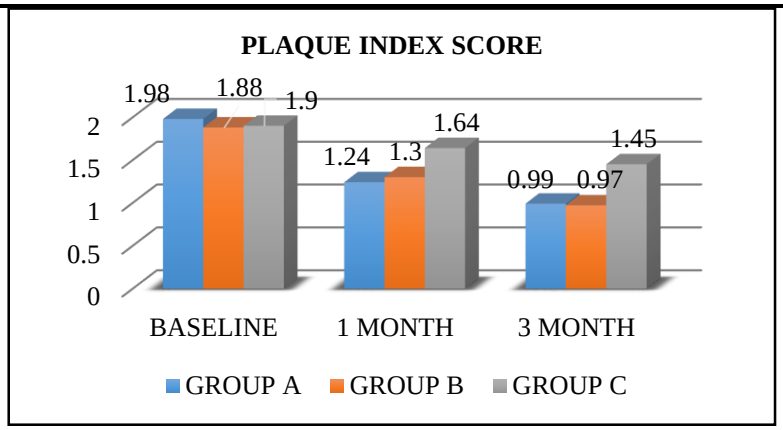
For GI at 1 month difference was found to be of non-significant between group A and B (p=0.733), group A and C (p=0.951) as well as group B and C (p=0.547). At 3 month difference was found to be of non-significant between group A and B (p=0.972), significant between group A and C (p=0.041) as well as Group B and C (p=0.047). (Graph 2)

For SBI at 1 month the difference was found to be of non-significant between group A and B (p=0.961), group A and C (p=0.655) as well as group B and C (p=0.490). At 3 month, difference was found to be of non-significant between group A and B (p=0.856), significant between group A and C (p=0.006) as well as Group B and C (p=0.001).(Graph 3)

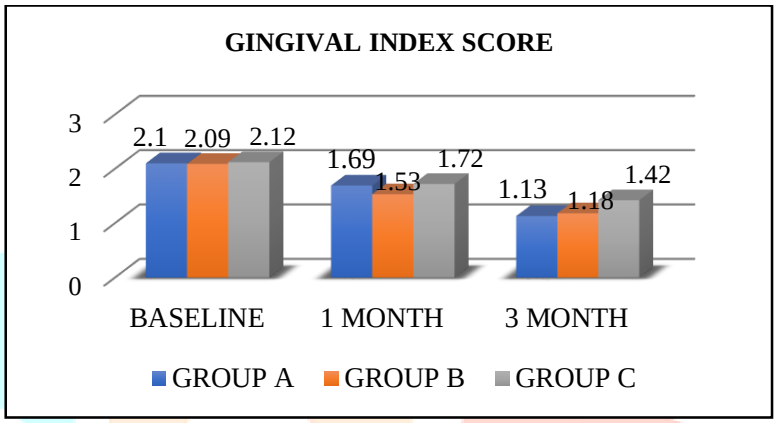
For PPD at 1 month difference was found to be statistically non-significant between group A and B (p=0.849), group A and C (p=0.241), group B and C (p=0.086).At 3 month difference was found to be statistically non-significant between group A and B (p=0.507) as well as group A and C (p=0.225), significant between group B and C (p=0.021). (Graph 4)

For RAL no statistical significant gain was found at 1 month (p =0.088). At 3 month gain was statistically non-significant between group A and B (p=0.856), significant between group B and C (p=0.001) as well as Group A and C (p=0.006). (Graph 5)

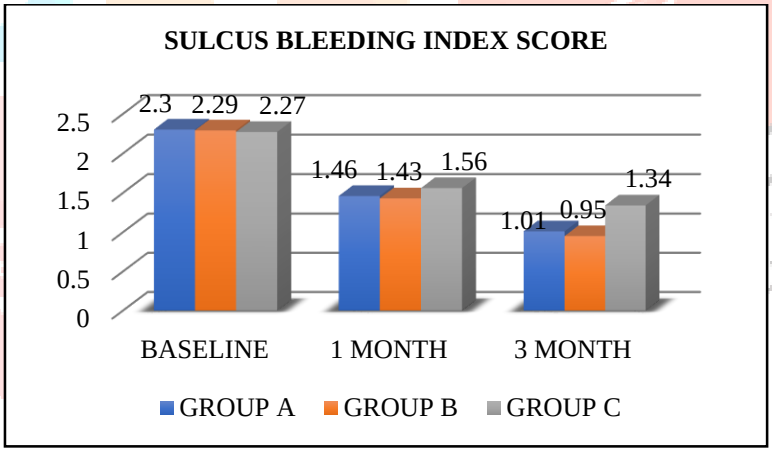
For CFU at 3 month difference was found to be of non-significant between group A and B (p=0.846), was significant between group B and C (p=0.015) as well as Group A and C (p=0.039). (Graph 6)



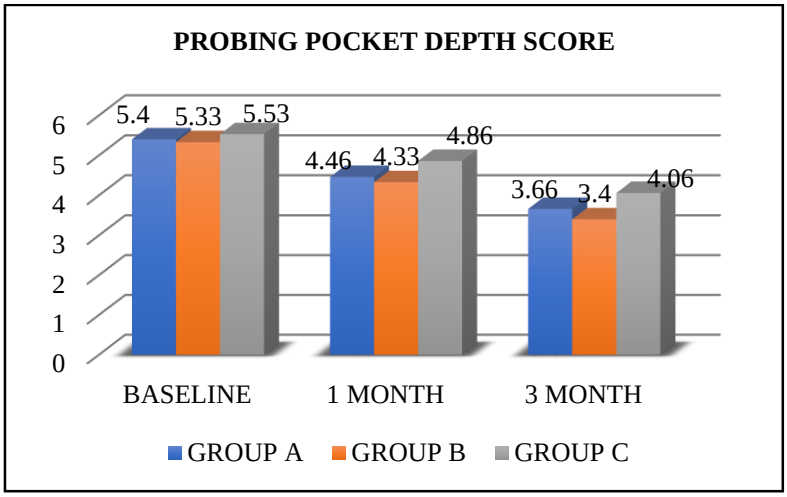
Graph 1:Comparison of Plaque Index



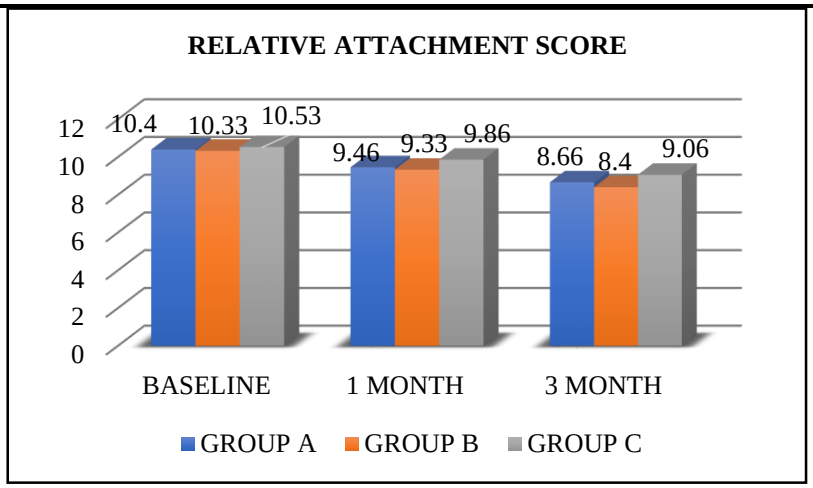
Graph 2: Comparison of Gingival Index



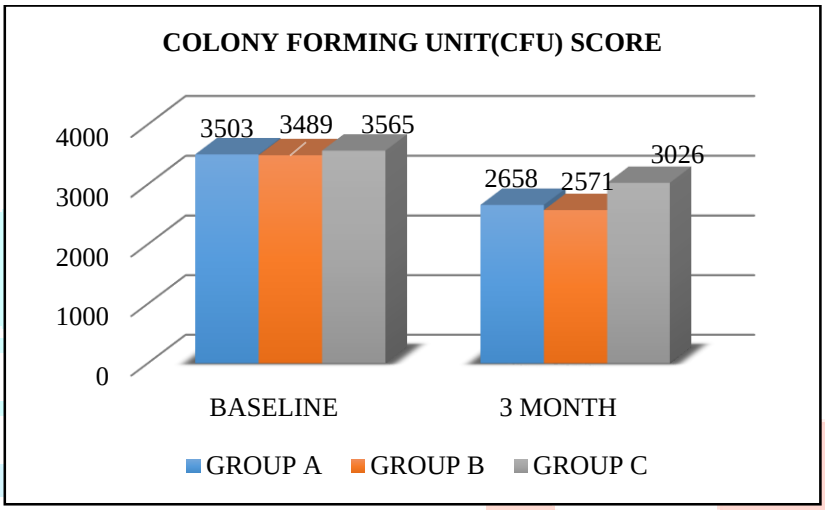
Graph 3: Comparison of Sulcus bleeding Index



Graph 4: Comparison of Probing Pocket Depth



Graph 5: Comparison of Relative Attachment Level



Graph 6: Comparison of CFU

6. DISCUSSION

Green coffee beans are found to be active against the periodontal pathogens like P. gingivalis and P. intermedia, as well as Candida albicans thus opened new horizon for its application in the treatment of periodontitis[9].In the study CHX and Green coffee gel are used owing to the least dosage frequency , sustained drug release pattern ,ease of making and administration and less drug toxicity. Wide port needle syringes are used to gently inject gels containing therapeutic ingredients into the subgingival pocket, ensuring a homogeneous dispersion

Periodontitis being localized to oral cavity , local therapy is chosen above systemic therapy to elude the complications related to systematic administration [10].To allow for soft tissue maturation and healing, assessment of the periodontium's response to mechanical nonsurgical therapy should be done no earlier than 3–4 weeks after treatment[11]. Therefore in all the groups clinical parameters were documented at baseline, 1 and 3 months after gel placement.

In Green coffee Group, there was a highly significant reduction in the mean PI from baseline to 3 months ($p<0.001$). This could be in accordance with the study done by **Signoretto C (2010)** [12] were coffee drinker group generated the lowest numbers of bands for both supragingival and subgingival plaque than the control group with a statistically significant difference. Thus coffee has a number of compounds like chlorgenic acid which are known to possess antimicrobial, antiadhesive, and antiplaque activities . Reduction in GI is

attributed to the reduction in inflammation. In Green coffee, there was a highly significant reduction in the mean GI from baseline to 3 months ($p<0.001$).**Choi. S(2018)** [13] showed coffee bean reduces most of the inflammatory markers. Among those anti-inflammatory compounds flavonoids as CGAs and their metabolites together with the extracts of green coffee have shown strong anti- inflammatory effect in various animal models. Improvement found in the CHX Group is in accordance with studies done by **Vinholis AH et al. (2001)**[14]

In Green coffee Group SBI was significantly reduced from baseline to 3 months ($p<0.001$). This can be attributed to the anti-inflammatory and antioxidant property exhibited by green coffee extract owing to its capability to induce upregulation of cytoprotective enzymes. In CHX group, the mean SBI at baseline was statistically significant from baseline to 3 months ($p<0.001$). Similar results were found by **Sathwara JD (2014)** [15] who showed significant reduction in SBI when chlorhexidine was used as an adjunct to SRP.

In Green coffee gel group there was highly significant reduction in mean PPD from baseline to 3 months ($p<0.001$). This can be correlated with elimination or reduction of pathologic microbial flora. Similar effect of reduction in periodontal flora was found by **Bharath N(2015)** 9 who evaluated the antibacterial effect of green coffee gel extract on periodontogenic bacteria.

In Green coffee gel group highly significant gain in RAL from baseline to 3 month ($p<0.001$) can be attributed to anti-inflammatory, antioxidant, wound healing and antimicrobial property of green coffee gel. **Masek A et al(2020)** [16] reported after volumetric analysis of green coffee extract to have high antioxidant activity owing to its polyphenolic compounds.

In Green coffee gel group CFU showed highly significant reduction from baseline to 3 months ($p<0.05$). This might be attributed due to the antimicrobial activity of green coffee gel**.** Similar antimicrobial activity was observed by **Bharath N et al (2015)** [9].

Chlorhexidine has proven its usage in treating periodontal diseases for many years. But continuous use of chlorhexidine can cause stains on teeth, tongue and gingiva also on silicate and resin restorations, alters taste sensation and xerostomia [17]. As green coffee is a non-toxic has anti-inflammatory, antioxidant, antibacterial, anti-obesity, anti-diabetic, anti-hypertensive, anti-cancer, and neuroprotective properties which can overcome these side effects and is found to be as efficacious as chlorhexidine, it can be used as an alternative approach in treating periodontal disease.

7. LIMITATION

According to the finding of our study green coffee is as efficacious as chlorhexidine in treating periodontal disease. However, larger sample size studies with long term follow-up are advisable for predicting more conclusive and definitive result for its application in clinical practice.

8. CONCLUSION

The results exhibited that treating chronic periodontitis patients with subgingival delivery of green coffee gel following SRP was just as effective as treating them with subgingival delivery of chlorhexidine gel. Thus Green coffee can be used as a non-surgical intervention to treat chronic periodontitis in an era where interest in phytochemicals is gaining interest.

9. REFERENCES

1. Antonio AG, Iorio NL, Farah A, dos Santos KR, Maia LC. Effect of Coffea canephora aqueous extract on microbial counts in ex vivo oral biofilms: a case study. Planta medica. 2012 May;78(08):755-60

2.Brookes ZL, Bescos R, Belfield LA, Ali K, Roberts A. Current uses of chlorhexidine for management of oral disease: a narrative eview. Journal of dentistry. 2020 Dec 1;103:103497.

3. Ramesh A, Varghese SS, Doraiswamy JN, Malaiappan S. Herbs as an antioxidant arsenal for periodontal diseases. Journal of intercultural ethnopharmacology. 2016 Jan;5(1):92

4.Sachin M, Jiji J, Poonam S, Abhishek S, Sweety S, Pooja B. To Evaluate The Antimicrobial Efficacy Of Green Coffee Bean Extract On Periopathogens-A Clinico-microbiological Study. National Journal of Integrated Research in Medicine. 2016 Sep 1;7(5)

5.Silness J, Löe H. Periodontal disease in pregnancy II. Correlation between oral hygiene and periodontal condition. Acta Odontol Scand 1964 Jan 1;22(1):121- 35

6.Löe H, Silness J. Periodontal disease in pregnancy I. Prevalence and severity. Acta Odontol Scand 1963 Jan 1;21(6):533-51

7.Muhlemann HR, Son S. Gingival sulcus bleeding: A leading symptom in initial gingivitis. Helv Odontol Acta 1971;15:107-13.

8.Schwalbe R, Steele-Moore L, Goodwin AC, editors. Antimicrobial susceptibility testing protocols. Crc Press; 2007 May 22

9.Bharath N, Sowmya NK, Mehta DS. Determination of antibacterial activity of green coffee bean extract on periodontogenic bacteria like Porphyromonas gingivalis, Prevotella intermedia, Fusobacterium nucleatum and Aggregatibacter actinomycetemcomitans: An in vitro study. Contemporary clinical dentistry. 2015 Apr;6(2):166

10.Greenstein G. Local drug delivery in the treatment of periodontal diseases: assessing the clinical significance of the results. Journal of periodontology. 2006 Apr;77(4):565-78.

11.Lowenguth RA, Greenstein G. Clinical and microbiological response to nonsurgical mechanical periodontal therapy. Periodontology 2000. 1995 Oct;9(1):14-22.

12.Signoretto C, Bianchi F, Burlacchini G, Sivieri F, Spratt D, Canepari P. Drinking habits are associated with changes in the dental plaque microbial community. Journal of clinical microbiology. 2010 Feb;48(2):347-56

13.Choi S, Jung S, Ko KS. Effects of coffee extracts with different roasting degrees on antioxidant and anti-inflammatory systems in mice. Nutrients. 2018 Mar;10(3):363.

14.Vinholis AH, Figueiredo LC, Marcantonio Junior E, Marcantonio RA, Salvador SL, Goissis G. Subgingival utilization of a 1% chlorhexidine collagen gel for the treatment of periodontal pockets. A clinical and microbiological study. Brazilian dental journal. 2001 Nov 7:209-13.

15.Sathwara JD, Sathwara CJ. Therapeutic effect of topical subgingival application of 1.5% chlorhexidine gel as local drug delivery system in chronic periodontitis--a clinical and microbiological study. International Journal of Dental Clinics. 2014 Apr 1;6(2):8-12

16.Masek A, Latos-Brozio M, Kałużna-Czaplińska J, Rosiak A, Chrzescijanska E. Antioxidant properties of green coffee extract. Forests. 2020 May;11(5):557

17.Selvakumar R, Np M. Comparison in benefits of herbal mouthwashes with chlorhexidine mouthwash: A review. Asian Journal of Pharmaceutical and Clinical Research. 2017 Feb 1;10(2):3.