EFFECT OF TRICLOSAN CONTAINING DENTIFRICES AND HERBAL BASED DENTIFRICES OVER GINGIVITIS AND PLAQUE PREVENTION- A CLINICAL STUDY

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By

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DEDICATED
TO
MY FAMILY

“NO WORDS CAN EVER BE STRONG ENOUGH TO EXPRESS MY GRATITUDE TOMY FAMILY SPECIALLY MY PARENTS FOR THEIR UNCONDITIONAL LOVE AND SUPPORT”

THANK YOU FOR ALWAYS BEING THERE FOR ME

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"A positive attitude can really make dreams come true - It did to me." Acknowledgement is possession. When you acknowledge, think or have conviction in something, it will actually will come true.

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ABBREVIATIONS

TCS	Triclosan
ZnCl	Zinc chloride
NaF	Sodium fluoride
SaE	Sanguinaria extract
API	Approximal plaue index
SBI	Sulcus bleeding
GI	Gingival index
PI	Plaque index
BI	Bleeding index
PPD	Pocket probing depth
BOP	Bleeding on probing
PBI	Papillary bleeding index
DRT	Dabur red toothpaste
DBT	Dabur Babool toothpaste
MDC	Marketed Dental Cream
UNC	University of North Carolina
USP	United state pharmacopeia
STD.	Standard
ENR	Enzyme enoyl lacyl carrier protein reductase
E.coli	Escherichia coli
SnF_2	Stannous fluoride

AmF	Amine fluoride
WMD	Weighted mean differences
ENR	Eoyl-acyl carrier protein reductase

Abstract

ABSTRACT

Background & Objective:

This study is to compare the efficacy of herbal dentifrices with Triclosan containing dentifrices.To Evaluate the Supragingival plaque - plaque Index (byTuresky-Gilmore- Glickman modification of the Quigley-Hein), Gingival inflammation-gingival Index (by Loe and Silness P in 1964), Pocket Depth (by UNC 15 Periodontal Probe) at different time over a 9-week time period.

Method:

A clinical comparative study was conducted on 60 volunteers between 18-35 years belonging to the Department of Periodontics, Babu Banarasi Das College of Dental Sciences (BBDCODS), for clinical evaluation of effect of Triclosan containing Dentifrices and herbal based dentifrices. 60 patients with Gingivitis, oral malodor and deep periodontal pocket of around >5mm were randomly divided into two groups. Group A (n=15) received triclosan based dentifrices i.e. Senquel-F. Group B used herbal dentifrices divided into 3 subgroups: subgroup1 (n=15) used aloevera gel containing dentifrices; subgroup 2 (n=15) used neem containing dentifrices; subgroup 3 (n=15) used babool containing dentifrices. Subjects were asked to use the allocated dentifrice, 2 times a day for 9 weeks. Values of patient hygiene performance Approximal plaque index (by Turesky-Gilmore-Glickman modification of the Quigley-Hein), Gingival index (by Loe and Sillness P in 1964), Pocket Depth (by UNC15 Periodontal Probe) were assessed at baseline, after that 3, 6, 9 weeks. Statistical data analyzed by Anova (Analysis of Variance) and post hoc Tukey's test.This assessment was done to determine the effect of Triclosan and Herbal based dentrifices.

Results: Oral hygiene (tooth brushing with dentfrices for 9 weeks) led to decrease in plaque accumulation, there was statistically no significant difference among the groups Senquel- babool ($p>0.05$) whereas there was statistically significant difference among the Senquel-Neem group and senquel- aloe vera group ($p<0.05$). Led to decrease in gingival inflammation,there was statistically significant difference among the groups: Senquel- Neem, Senquel-Babool and Senquel- Aloevera group ($p<0.05$). Led to decrease in probing depth, there was statistically no significant difference among the groups: Senquel-Neem, Senquel- Babool and Senquel-Aloevera ($p>0.05$) at 9 weeks.

Interpretion and Conclusion: Continuous application of dentifrice provided significant improvement of oral hygiene level. Neem was more effective than the aloe vera, babool, and Senquel-F for plaque accumulation reduction, Senquel-F was more effective than the herbal group for gingival inflammation reduction, whereas herbal dentifrices are as effective as non- herbal dentifrices for probing depth reduction.

Keywords: Herbal, Dentifrice, Gingivitis, Plaque, Tooth brushing.

Introduction

INTRODUCTION

Periodontal diseases areone of the most prevalentuniversal concerns. Many Paleopathological studies [1]have demonstrated this i.e through the investigation of fossils, mummified tissue, skeletal remains and analysis of coprolites.Gingival disease is more common as people get older, and it begins in childhood.[2]

Dental plaque is formed by the aggregation of bacteria and pellicle formation. It is wellknown that the microorganisms in plaque produce numerous enzymes, toxins andlipopolysaccharides. Throughout the world various studies conducted, and proved that periodontal disease occurrence and frequency is high and dental plaque more or less related to it.[3] It was believed that animals, which obviously had strong teeth, passthese attributes on to the humans when their body parts are used in dentifrices.Down the age the composition of the dentifrices has changed from being based onpopular beliefs and assumptions about ingredients to those based on scientific evidence.

Formation of plaque biofilm over the tooth occurs naturally, that must be managed by brushing our teeth on daily basis to forbid the development of caries and periodontal disease. [4,5] To control the efficacy of biofilm production, toothpaste with standard ingredients is used i.e., detergents and fluoride. [5,6] For avoidance, control and decrease of accumulation of cariogenic and periodontopathogenic microorganism, different antimicrobial agents have been proposed. [7,8]

The use of toothpaste has ancient roots. Toothpastes based on plant extracts have received great attention in gingivitis prevention. In recent times, there has been a modernized concern in using products based on herbal extract. In the ancient systems of medicine, many variety of plant of different ingredient have been used in preparations of medicines, denitrifies to maintain oral hygiene or to prevent oral disease such as periodontal disease.[9-11]Herbal ingredients have several benefits;chamomile has anti-inflammatory effect, Echinacea has immune stimulatory property, sage and rhatany have

anti-hemorrhagic properties, myrrh is a natural antiseptic, and peppermint oil has analgesic, antiseptic,and anti-inflammatory properties.[12] There are limitedstudies available regarding the efficacy of herbaldentifrices.

Triclosan abbreviated as TCS, is an antifungal and antibacterial agent. Its IUPAC name is 5-Chloro-2-(2,4-dichlorophenoxy) phenol). It has been widely used in soaps, deodorants, toothpastes shampoos, toys, surgical cleaning supplies, mouthwashes. At biocidal concentration, it is very effective against a microorganism of broad range, along with antibiotic-resistant bacteria.[13]Triclosan exhibits to reduce inflammation, and encourage inhibition of cyclooxygenase / lipooxygenase pathways, it is a low-toxicity, non-ionic, chlorinated bisphenol that is compatible with toothpaste components such as surfactants and fluoride. [5,14]

Ayurveda and Unani are medicine of Indian tradition, it is a rich reservoir of resources even for dental treatment.[15] The vast knowledge of ancient Indian medicine, some manufacturers of dentifrice have tried to incorporate the time-tested formulations that have been credited with having properties for antimicrobial and properties that provide general oral health and periodontal health in particular.

Toothpastes with herbal extract are efficacious as the conventional toothpastes in gingival inflammation and plaque prevention.[16]So the current study was undertaken to compare effect of triclosan containing dentifrices and Herbal based dentifrices for gingivitis and plaque prevention.

Aim & Objectives

AIM AND OBJECTIVES

The ***Aim*** of the present study was:

To compare the efficacy of herbal dentifrices with Triclosan containing dentifrices.

The ***Objectives*** of the present study was:

To Evaluate the:

- Supragingival Plaque - Plaque Index (by Turesky- Gilmore- Glickman modification of the Quigley-Hein)
- Gingival inflammation- Gingival Index (by Loe and Silness P in 1964)
- Pocket Depth (by UNC 15 Periodontal Probe)

Review of Literature

REVIEW OF LITERATURE

1. Mauriello SM et al. (1988)[17]conducted a six-month, double blind clinical test to see the effectiveness of a Sanguinarine-containing toothpaste in reducing plaque and gingival inflammation. 120 adult volunteers were arbitrarily appointed to a sway or experimental cluster. The test toothpaste contained 750 mcg/g of Sanguinaria extract. A toothpaste of similar composition with no Sanguinarine present in it was used as the placebo. Plaque and gingival tissue inflammation scores were recorded for four surfaces on each of twelve index teeth at baseline, 1st, 3rd and 6th months. Matched pair t-test analyses showed no significant differences between experimental and control groups for mean six-month changes in plaque and gingival inflammation scores in analyses using all 48 sites per subject or in analyses of solely the twenty-four interproximal sites. No long-term reduction was incontestible in plaque or gingival tissue inflammation with the utilization of a Sanguinarine-containing toothpaste.

2. Mallatt ME et al. (1989)[18]conducted a clinical study to evaluate the consequences of a Sanguinaria-zinc chloride dentifrice on the interference of plaque formation and gingival infflamation. A total of 59 young adults, 18 to 30 years of age, either performed supervised brushing with a 0.075% sanguinaria-0.05% Zncl toothpaste, a 0.24% sodium fluoride toothpaste, or rinsed daily with a 0.05% NaF solution. Clinical evaluations for plaque formation and gingival inflammation were performed after seven, fourteen, and twenty-one days of the test regimen. After twenty-one days, all subjects resumed double daily supervised brushing and flossing and post-test evaluations were conducted after two weeks. The results showed that after seven, fourteen, and twenty-one days each groups using toothpastes had significantly less plaque formation and gingival inflammation than the group using the rinse, and there were no significant differences between the two groups exploitation either the sanguinaria-ZnCl2 or the NaF dentifrices.

3. Palomo F et al. (1989)[19]Conducted a fourteen-week,double-blind clinical study to compare the effect of a toothpaste containing 0.3% triclosan and 2% of a copolymer of methoxyethylene and maleic acid on plaque formation and gingivitis. 118 male and

female adult subjects participated in the study. The subjects were stratified into two balanced groups according to baseline plaque scores. Then they undergone scaling and were adviced to the use of either a placebo toothpatse or the triclosan/copolymer toothpaste for the next fourteen weeks. They concluded that the triclosan/copolymer toothpaste was more helpful in plaque management and gingivitis interference as compared to the placebo over a fourteen weeks period.

4. Hannah JJ et al. (1989)[20]evaluated a sanguinaria-containing dentrifice and oral rinse regime during a six-month period to determine its effectiveness in controlling plaque, gingival inflammation, and sulcular bleeding. Oral hygiene instructions and a one-month prestudy brushing period failed to produce a significant management in health among the 24 subjects as determined by the three analysis parameters. After the oral hygiene period, the subjects were arbitrarily appointed to the active treatment (marketed Viadentdentrifice and oral rinse) or the placebo treatment (same base formulas with no sanguinaria). Treatments were examined using the Loe and Silness gingival index, the Silness and Loe plaque index, and the Muhlemann and Son sulcular bleeding index at baseline and monthly through 6 months. The sanguinaria regime decreased plaque by 57%, gingivitis by 60%, and sulcular bleeding by 45% from baseline when compared with placebo group decrease of 27% (plaque) and 21% (gingival inflammation), and an increase of 30% in bleeding index. Results of this study incontestible that the combined use of the toothpaste with sanguinaria and oral rinse controls and reduces plaque and gingivitis in an orthodontic population.

5. Kopczyk RA et al. (1991)[21]did a study to check the efficacy and safety of sanguinaria containing regime with and without fluoride using the American Dental Association guidelines for evaluating chemotherapeutic agents. The study was a six month, double-blind, 4-cell, placebo-controlled, parallel investigation involving a hundred and twenty subjects. Following screening procedures, subjects were arbitrarily appointed to four groups. Group 1 received a toothpaste containing 0.075% sanguinaria extract (SaE) and 2.0% zinc chloride (ZnCl2) in a dicalcium phosphate base, plus an oral rinse containing 0.03% SaE and 0.2% ZnCl2. Group 2 received same products without SaE or ZnCl2. Group 3 received a toothpaste containing 0.8% sodium

monofluorophosphate, 0.075% SaE, and 0.05% ZnCl2 in a silica base, plus an oral rinse containing 0.03% SaE and 0.2% ZnCl2. Group 4 products were same to those of Group 3 but without SaE and ZnCl. Supragingival plaque and gingival inflammation were scored at 0, 1, 2, 1.5, 3, 4.5, and 6 months; bleeding on probing was measured at 1, 1.5, 3, and 6 months. Microbiological samples were taken from palate, tongue, and cheek areas. The active products created statistically significantly lower scores than the placebo agents for all indices. Six-month plaque scores were 13.1% lower for Group 1 and17.4% lower for Group 3 compared to placebo products. When the Plaque Severity Index was applied, the percentage reductions were 33% for Group 1 and 41% for Group 3 compared to placebos. Gingival inflammation scores were 16.7% lower for Group 1 and 18.1% lower for Group 3 at six months compared to placebo scores.

6. Moran J et al. (1991)[22]evaluated a herbal/bicarbonate toothpaste in mouthrinse form using a 19-day, no oral hygiene, triple-crossover design in which it was compared with a commercial fluoride toothpaste rinse and the antiplaque mouthrinse chlorhexidine. Over the three periods of the study an increase in plaque and gingivitis was seen for all three products. However, while significant reductions in both parameters were seen with chlorhexidine compared to the toothpastes, there were no significant differences between the herbal and fluoride toothpaste. From these findings they concluded that in the long term, the herbal/bicarbonate toothpaste may not exert significant therapeutic effects on plaque and gingivitis beyond that of a conventional commercial paste. Nevertheless, where there is a demand for a natural product, the herbal/bicarbonate paste may be a worthwhile alternative.

7. Willershausen B et al. (1991)[23]investigated the effectiveness of medicinal herbs in both a toothpaste and oral rinse on dental plaque, sulcus bleeding, and the pH of total saliva was in a single-blind study on 50 dentistry students between the ages of 23 and 28 years. Over a period of 4 weeks, 25 students used either placebo or preparations containing medicinal herbs. Parameters measured were the approximal plaque index (API) and sulcus bleeding index (SBI). These were determined at the same time of day (12:00 P.M.), the last food intake having occurred at least 1 hour previously. The pH of the total saliva was significantly displaced into the alkaline range by the application of

the herbal products, whereas the placebo products had a contrary effect. The results of this study suggested that herbal ingredients could be employed supportively in the therapy of periodontal diseases and for routine prophylaxis.

8. Mankodi S et al. (1992)[24]Conducted double-blind clinical trial designed to evaluate the effects of a dentifrice which contained 0.3% triclosan in conjunction with 2% of a methoxyethylene/maleic acid copolymer in a 0.243% sodium fluoride/silica base, relative to a control dentifrice, on supragingival plaque accumulation and gingivitis. A total of 294 adult male and female subjects completed the 6-month clinical trial. Plaque and gingivitis were scored after 3 and 6-month use of the assigned dentifrice. At the end of the study, the triclosan group showed an average reduction, relative to the control group, of 12% in plaqueaccumulation and 20% in gingivitis. The effect of the triclosan dentifrice was most pronounced on the more severe manifestations of plaque and gingivitis. It was concluded that the twice-daily use of the triclosan-containing dentifrice resulted in significant reduction in supragingival plaque formation and a significant improvement in gingival health without the presence of any extrinsic staining or objectionable taste.

9. Palomo F et al. (1994)[25]conducted a double-blind clinical study over six months to compare the antiplaque and antigingivitis activity of three commercially-available triclosan containing dentifrices with that of a placebo dentifrice without triclosan. Following baseline supragingival plaque and gingivitis examinations and a complete oral prophylaxis, subjects were stratified by their whole mouth baseline plaque (modified Quigley-Hein) and gingivitis (modified Loe-Silness) scores and then randomly assigned to one of four dentifrice using groups. Plaque and gingivitis examinations were then performed after six weeks, three months and six months use of the dentifrices. Subjects brushed twice daily in their customary manner. They concluded that antiplaque and antigingivitis activity of triclosan/copolymer dentifrice was superior than the placebo dentifrice.

10. Kanchanakamol U et al. (1995)[26]conducted a 6-month, single-blind and parallel clinical study to compare the effects of dentifrice containing 0.3% triclosan and 2.0% of

copolymer (methoxyethylene and maleic acid) with a customary oral hygiene procedure on supragingival plaque formation and gingivitis. 124 subjects were stratified into two balanced groups on the basis of their baseline plaque and gingivitis scores. After complete oral prophylaxis, subjects were assigned to use either atriclosan/copolymer dentifrice or to practice their customary oral hygiene care for 6 months. Plaque formation and gingivitis were scored at 3 and 6 months. These results indicated that the triclosan/copolymer dentifrice was better than the customary oral hygiene care in preventing supragingival plaque formation up to 6 months and in reducing gingivitis up to 3 months.

11. Mullally BH, et al (1995)[27]conducted a double-blind controlled clinical trial with parallel groups was designed to investigate the effectiveness of a herbal-based toothpaste in the control of plaque and gingivitis as compared with a conventional dentifrice. 70 subjects with gingivitis completed the 6-week study. At baseline, both groups were balanced for the parameters measured: plaque index, plaque vitality, gingival index, bleeding on probing and gingival crevicular fluid flow. They concluded that the herbal-based toothpaste was as effective as the conventionally formulated dentifrice in the control of plaque and gingivitis.

12. Saxer UP et al (1995)[28]conducted a double-blind study comparing the effective of Parodontax, a dentifrice containing herbal ingredients and sodium bicarbonate abrasive, to a non-marketed new toothpaste containing herbal ingredients and calcium hydrogen phosphate as the abrasive. Plaque, gingivitis and gingival bleeding parameters were scored. The periodontal probe-bleeding index of Ainamo and Bay was modified to score slight and moderate bleeding. In the first four-week period all subjects used the new toothpaste. They concluded that both dentifrices were equally effective as the conventionally formulated dentifrice in the control of plaque and gingivitis.

13. Estafan D. et al (1998)[29]Conducted a three-month, double-blind, parallel-design clinical study to compare the efficacy of two commercially available dentifrices, Herbal Toothpaste and Gum Therapy and Colgate Total, in controlling gingivitis, gingival bleeding, plaque and stain. Forty healthy adult volunteers from the Junior

Comprehensive Care Clinics at New York University College of Dentistry were accepted as subjects for this clinical trial. To be eligible for a baseline clinical examination, subjects had to first indicate that during the previous six months they habitually brushed their teeth two or more times per day, and had noticed "bleeding gums" or "blood in the toothpaste" after brushing or flossing their teeth. At the baseline examination, subjects were enrolled in the study if they had at least five Loe-Silness gingival bleeding sites and 20 natural teeth, including all anterior teeth and four molars. The results obtained in this study supported the clinical efficacy of both products in reducing gingivitis and plaque, and demonstrate the efficacy of Herbal Toothpaste and Gum Therapy in maintaining reductions of plaque and stain.

14. Nogueira-Filho GR et al. (2000)[30]Evaluated the antiplaque and antigingivitis effect of 3 dentifrices using the 21-day partial-mouth experimental model of gingivitis. 25 volunteers took part in this crossover, double-blind study, carried out in 4 phases of 21 days each. For each phase of the study, a tooth shield of the IV quadrant was constructed for each volunteer. 2 antiplaque dentifrices from the market, one containing triclosan + pvm/ma and the other triclosan + Zn, were compared with an experimental formulation and its placebo. The experimental dentifrice contained triclosan + pvm/ma + Zn + PPi and the placebo (control) did not contain these substances. The subjects were stratified according to their whole-mouth baseline plaque (PI), gingivitis (GI) and bleeding (BI) index scores, and then randomly assigned to 1 of 4 dentifrices. During each phase,while the volunteers brushed their teeth with one of the dentifrices, the IV quadrant was protected by the toothshield filled with thedentifrice used. After each phase, dental plaque, gingivitis and bleeding indices were determined. It was concluded that a dentifrice containing the combination of triclosan + pvm/ma + Zn + PPi should be formulated for dental plaque control.

15. Bruhn G et al (2002)[31]conducted a 28-week double-blind study to evaluate the plaque inhibitory and antigingivitis efficacy of a fluoride toothpaste containing 0.3% triclosan and essential oil (Dental Kosmetik, Dresden, Germany) in comparison with a control toothpaste. One hundred twenty subjects previously treated for chronic periodontitis were included in the study. At baseline, 8, 18, and 28 weeks, plaque

accumulation (PlI) and gingival status (GI) were assessed. Probing pocket depth (PD) and bleeding on probing (BOP) were measured at baseline and week 28 using a Florida probe. No professional hygiene was delivered during the study period. Mean plaque scores decreased between baseline and week 8 in both groups. It was concluded that the triclosan/essential oil additive in a fluoride-containing dentifrice exhibited distinctive antigingivitis as well as plaque-inhibitory effects during a 28- week maintenance period in periodontitis patients.

16. Grossman E et al. (2002)[32]conducted a double blind, parallel, randomized and controlled clinical trial to assess the effects of a 0.28% triclosan/5% pyrophosphate (with NaF/silica) dentifrice on dental plaque and gingivitis as compared to a NaF/silica negative control dentifrice. 186 subjects participated over six months. An initial examination was performed to assess the health of the oral soft and hard tissues and to measure plaque (by Turesky modified Quigley-Hein Plaque Index), gingivitis (by Loe-Silness Gingival and Ainamo and Bay Gingival Bleeding [GBI] indices). Only those subjects with a GBI score > or = 5 were accepted into the study. Each enrolled subject received an oral prophylaxis and was requested to brush and floss twice per day with the negative control NaF/silica dentifrice. After one month, the subjects were recalled and a baseline examination was performed for each of the previously described parameters. Following the baseline examination, the subjects received another oral prophylaxis. Possible explanations of these results are that thetriclosan/pyrophosphate dentifrice may be uniquely different from other triclosan dentifrices relative to its effects on gingivitis, or alternatively, the clinical design utilized here may not be optimized for triclosan/pyrophosphate dentifrice.

17. Mankodi S et al (2002)[33]Carried out a six-month, double-blind clinical study, conducted in harmony with American Dental Association guidelines.The aim was to provide a comparison between Colgate Total Toothpaste and Crest Gum Care Toothpaste with respectto their levels of efficacy for the control of supragingival dental plaque and gingivitis, and with respect to the levels of tooth staining associated with their use. Adult male and female subjects from the Edinburgh, Scotland area were entered into the study and stratified into two treatment groups which were balanced for

age, sex, baseline Quigley-Hein Plaque Index scores and baseline Loe-Silness Gingival Index scores. Subjects received an oral prophylaxis, and were instructed to brush their teeth twice daily (morning and evening) for one minute with their assigned dentifrice, using a soft-bristled toothbrush. Examinations for plaque, gingivitis and extrinsic tooth staining were conducted after three months' and again after six months' use of the study dentifrices. One hundred and nine (109) subjects complied with the protocol and completed the entire six-month clinical study. At both the three- and six-month study examinations, the Colgate Total Toothpaste group exhibited statistically significantly less plaque, gingivitis and extrinsic tooth staining compared to the Crest Gum Care Toothpaste group. Thus, the results of this six-month clinical study supported the conclusion that Colgate Total Toothpaste provides a statistically significant, substantive advantage in efficacy for the control of plaque and gingivitis over Crest Gum Care Toothpaste, while, at the same time, providing better control against the development of extrinsic tooth staining.

18. Winston JL et al. (**2002**)[34]undertook a study was to prospectively test how subjects with a range of baseline disease levels (which encompassed the range of gingivitis severity documented in the triclosan literature) benefit from a triclosan dentifrice. This trial was a randomized, double blind, parallel group, six-month study where subjects brushed twice daily with either triclosan/pyrophosphate, triclosan/copolymer, triclosan placebo or sodium fluoride control (NaF) dentifrice following a prophylaxis. Both gingivitis and bleeding were measured using the Loe-Silness Gingival Index (GI) and plaque was measured using the Turesky Plaque Index. Comparisons between treatments were performed using an analysis of covariance. There was evidence of modest anti-gingivitis efficacy in the triclosan placebo. In an effort to better understand how baseline disease severity may have impacted the trial outcome, additional analyses were performed to investigate whether the magnitude of a triclosan effect was related to baseline gingivitis levels. An analysis of covariance model incorporating a baseline group interaction effect indicated that the magnitude of the treatment differences depended on the baseline scores.The effect was most pronounced for GI bleeding sites. Further analysis showed that differences between triclosan dentifrices and the NaF

control dentifrice were only present for subjects with more than 33 to 63 bleeding sites, depending on the specific comparison. The magnitude of the treatment effect for both GI andGI bleeding sites increased with each succeeding subset. Unlike that required for other antimicrobial agents used in oral care products, these findings suggested that a study design, which includes subjects with more severe gingivitis at baseline, has the required sensitivity to demonstrate treatment benefits for triclosan dentifrices.

19. Pistorius A et al. (2003)[35]investigated the efficacy of an herbal-based mouthrinse in combination with an oral irrigator in reducing gingival inflammation. A total of 89 patients (45 females, 44 males; mean age 49.1 +/- 1.31 years) were included in this prospective, randomized, double-blind clinical study and allocated to 3 treatment groups: group 1 (n =34), treated with an oral irrigator with subgingival tips and an herbal-based mouthrinse; group 2 (n = 29), the oral irrigator was applied in combination with a conventional mouthwash; and group 3 (n = 26), treated with the conventional mouthwash without subgingival irrigation. Probing depths were not reduced significantly in any group. They concluded that subgingival irrigation with an herbal-based mouthrinse led to a significant reduction in both SBI and GI. This regimen can, therefore, be recommended as an adjunctive procedure to reduce gingival inflammation.

20. Pannuti CM et al. (2003)[36]conducted randomized, double-blind clinical trial was to evaluate the effect of the Paradontax dentifrice on the reduction of plaque and gingivitis. Subjects were randomly allocated into either the test group (n = 15, Paradontax) or the control group (n = 15, standard dentifrice with fluoride). Plaque levels were measured using the Turesky modification of the Quigley & Hein Plaque Index (PI), and gingivitis was evaluated with the Gingival Index (GI). Subjects were asked to brush their teeth with the allocated dentifrice, three times a day, for 21 days. There was no significant difference between groups in relation to the PI and GI medians, at baseline and at the end of the 21-day period. There was no significant reduction in PI in either the test or control groups. There was a significant decrease in GI in the test group. The authors concluded that there was no difference between the dentifrices in the reduction of plaque and gingivitis.

21. OliveriaSMA et al. (2008)[37]conducted a randomized, parallel and double-blind clinical trial to see the effect of *Aloe vera* on the reduction of plaque and gingivitis. Subjects were randomly allocated to the test group (n=15) – dentifrice containing *Aloe vera* - or the control group (n=15) – fluoridated dentifrice. Plaque index (PI) and gingival bleeding index (GBI) were assessed at days 0 and 30. Subjects were asked to brush their teeth with the control or test dentifrice, three times a day, during a 30-day period. There was asignificant reduction on plaque and gingivitis in both groups, but no statistically significant difference was observed among them. The dentifrice containing *Aloe vera* did not show any additional effect on plaque and gingivitis control compared to the fluoridated dentifrice.

22. Srinivasa S et al. (2011)[38]conducted a study to evaluate plaque and gingival status in children by daily supervised tooth-brushing for a period of 21 days with commercially available herbal dentifrice in comparison with non-herbal dentifrice. 30 children between ages 8 to 10 years with full complement of dentition were subjected to the study after scaling. Plaque and gingival scores were recorded throughout the course of the study at 0, 7 and 21 days. The mean scores were subjected to statistical analyses. There was significant reduction in plaque and gingival score from day 0 to the end of the study in both groups. Though herbal dentifrice showed more effectiveness than the non-herbal dentifrice on the reduction of gingival scores, there was no statistically significant difference between the two groups.

23. Kalyan P et al. (2014)[39] conducted a clinical, randomized, double-blind comparative study on 60 volunteers above 18 years belonging to the Sumandeep Vidyapeeth. Dentifrice containing 1% Chloramine T and a commercially available Triclosan containing dentifrice (Colgate Triple Action) were used in the study. The study subjects were divided into group Group I and Group II and were given dentifrice containing 1% Chloramine–T(experimental) and Triclosan (commercially available) respectively. Among the 60 volunteers the dentifrices were provided in identical, color-coded tubes, and were instructed to use the dentifrices three times a day for the duration of 7 days.They concluded that Chloramine-T and Triclosan had almost similar effect on

gingival status and plaque. Chloramine-T can be used as an economical and affordable dentifrice at the community level.

24. Roopavathi K M et al. (2015)[40]conducted an*in vitro* study comprised of seven toothpastes which have been tested for their antimicrobial activity against three oral pathogens namely, *Streptococcus mutans, Escherichia coli* and *Candida albicans* by well agar diffusion assay at the dilution of 1:1, 1:2, 1:4, 1:8 and 1:16.Study results showed that toothpaste 'five' with sodium fluoride and sylodent as main ingredients showed maximum zone of inhibition against *Streptococcus mutans* whereas against *Candida albicans,* toothpaste 'six' with xylitol and sodium fluoride as main ingredients showed maximum zone of inhibition. And against *E. coli,* toothpaste 'one' with Triclosan and Zinc sulphate as main ingredients showed maximum zone of inhibition among all toothpastes. It was observed that tooth paste 'six' with sodium fluoride and Neem, Meswak as main ingredient showed minimum zone of inhibition against Streptococcus mutans at 1:1 dilution among seven toothpastes used in the present study.In the present study, it has been demonstrated that triclosan containing toothpastes formulations are more effective in control of oral micro flora.

25. Anushree B et al. (2015)[41]conducted a study to assess antimicrobial efficacy of different toothpastes against various oral pathogens. A total of nine toothpastes in three groups were tested for their antimicrobial activity against *Escherichia coli* (ATCC 25922), Staphylococcus *aureus* (ATCC 25923), *Streptococcus mutans* (ATCC 0266P) and C*andida albicans (*Laboratory Strain) by modified agar well diffusion method. Statistical Analysis was performed using MinitabSoftware.Triclosan-based dental formulation with combination of fluoride (1000 ppm) exhibited higher antimicrobial activity against test organisms than the combination of lower fluoride-concentration or sodium monofluorophosphate. Among herbal dentifrices, formulation containing Neem, Pudina, Long, Babool, Turmeric and Vajradanti showed significant antimicrobial activity against all the four tested microorganisms. However, against *Streptococcus mutans*, all three herbal products showed significant antimicrobial activity. Homeo products showed least antimicrobial activity on the tested strains. Formulation with

kreosoutm, Plantago major and calendula was significantly effective only against *Streptococcus mutans*. In the present study, antimicrobial activity of the toothpaste containing both triclosan and fluoride (1000ppm) as active ingredients showed a significant difference against all four tested microflorae compared to that of with lower fluoride-concentration or sodium monofluorophosphate. Of herbal groups, the only dentifrice containing several phytochemicals was found to be significantly effective and comparable to triclosan-fluoride (1000ppm) formulation. Thus, this herbal toothpaste can be used as alternative to triclosan-based formulations. However, these results might not be clinically useful unless tested invivo.

26. Upadhye k et al. (2017)[42]To comparatively evaluate the dentifrice containing herbal agents and Triclosan/polymer containing PVM/MA in its ability to control Plaque and Gingival inflammation. Subjects for the study were selected from the outpatient department of Periodontics from a Dental College, Navi Mumbai, India. 60 subjects with established dental plaque and gingivitis were randomly assigned to either Triclosan or Herbal dentifrice group in a randomized controlled crossover clinical trial. The plaque index, sulcus bleeding index and gingival index scores at baseline and 3 weeks were assessed. Statistical analysis was performed using Paired t-test and Unpaired t-test. There was a statistically significant reduction in plaque index, sulcus bleeding index and gingival index scores in both groups at 3 weeks compared with the baseline. Intergroup comparison was statistically significant in favour of the Triclosan group as opposed to the Herbal group. No adverse events were reported and both the dentifrices were well-tolerated.Triclosan/polymer with PVM/MA containing dentifrice was more effective than the herbal based dentifrice in reducing plaque and gingival inflammation.

27.Sugiarta AP et al. (2019)[43]conducted a study aimed to evaluate the effect of an herbal toothpaste containing neem leaves extract against gingivitis. A total of 40 subjects were divided into two groups (n=20 each): Experimental and control. Those in the test group were instructed to brush their teeth twice a day for 7 days with neem leaves extract toothpaste, whereas the control group subjects were asked to continue with the non-herbal paste they used for tooth brushing. Plaque index (PI) and papillary

bleeding index (PBI) were measured on day 0 and day 7. Significant reductions in PI and PBI were noted between the test and control groups. They concludedthat neem leaf extracts are effective in reducing gingivitis.

28. Nivethaprashanthi S et al. (2020)[44]conducted astudy to compare randomized control trials and clinical trials which used herbal toothpaste with non-herbal toothpaste in prevention of plaque and gingivitis. Clinical trials without randomization and other experimental studies were also included. The outcome measures were improvement in duration, objective and subjective difference in plaque accumulation, and gingivitis. Randomized control trial and nonrandomized control trial has shown a remarkable reduction in plaque and gingival scores on an average duration of using herbal toothpaste. Studies (five randomized control trials and four clinical trials) state statistically equal reduction in plaque and gingival scores on using herbal and non-herbal toothpastes. No reports of adverse reactions (bad taste and odor, hard to accept, and allergic reactions) on using herbal toothpaste are evident. Nowadays, there is an increased interest on using herbal products among people. Herbal toothpastes are as effective as nonherbal toothpastes in controlling plaque and gingivitis. There are also no adverse reactions on using herbal toothpaste and can be used as an alternative to conventional (non-herbal) toothpaste. Henceforth, it depends upon the preference of people to choose natural (herbal) or conventional (non-herbal) toothpaste.

29. Shanmugapriya R et al. (2020)[45]conducted a study to compare the antiplaque effectiveness of a prepared herbal and commercially available dentifrice. Thirty healthy individuals within the age group of 18–25 years were recruited to participate in the study. After achieving induced gingivitis and measuring plaque levels using Turesky modification of the Quigley Hein Plaque index in all the subjects, they were randomly divided into test arms A and B. Commercial dentifrice was distributed to one group, whereas the other group received prepared herbal dentifrice. Supervised brushing was carried out for 5 min, and plaque amounts after brushing were noted. After a washout period of 1 week, the same steps were repeated as per the cross-over study protocol. Unpaired *t*-test and paired *t*-tests were employed. Both the toothpastes show the

difference in plaque scores immediately after brushing when compared to baseline and was statistically significant. The mean plaque scores of commercial dentifrices were less than that of the prepared herbal dentifrice after brushing. The prepared herbal dentifrice had good antiplaque action. However, the plaque inhibitory action of self-prepared herbal toothpaste was marginally less when compared to commercial dentifrice.

30. Kumar S et al. (2022)[46] conducted a study aimed at assessing the efficacy and safety of two herbal active toothpastes DaburRed Toothpaste (DRT) and Dabur Babool Toothpaste (DBT) in dental caries, toothache, plaque, and oral hygiene in comparison to achemical active-based marketed dental cream (MDC).The study was an open-label, randomized, controlled,parallel-group, monocentric, efficacy, and safety study. One hundred and twenty healthy male and female subjects between 12 and65 years who satisfied inclusion and exclusion criteria were randomized equally (1:1:1) into three groups. Each subject was assignedto use one of the three randomized study products, which was to be used twice daily for 24 weeks. Efficacy was assessed on the basisof changes in parameters such as caries, plaque, gum bleeding, halitosis, dental stains, oral hygiene, toothache, and salivary pH;and the subject's self-assessment of bad breath, toothache, plaque/ yellowish or sticky deposit on the teeth, and the mouth feel oftoothpastes. Safety was assessed on the basis of monitoring of adverse events from baseline study completion.Reductionin gum bleeding, halitosis (bad breath), microbial growth, and improvement in oral hygiene were seen in all the tested toothpastes.A significant reduction in tooth pain, stain intensity, and stain area was also observed. No deterioration in the condition of caries wasobserved in any of the groups. They concluded thatall the tested toothpastes were effective and safe in dental conditionssuch as dental caries, toothache, and oral hygiene and they were assessed to be well tolerated and safe.

Materials & Methods

MATERIALS AND METHODS

A clinical study was carried out in the Department of Periodontics, Babu Banarasi Das College of Dental Sciences (BBDCODS), Lucknow, India.

Systemically healthy individuals are selected based on the inclusion and exclusion criteria to be followed by:

Inclusion criteria: -

1. Age 18-45 years
2. Noncontributing medical history
3. Gingival inflammation
4. Periodontal pocket of around 3-4 mm

Exclusion Criteria: -

1. Immunodeficiency disease.
2. Uncontrolled systemic diseases.
3. Periodontal pockets more than 4 mm.
4. Subjects already using the dentifrice to be used in study
5. Patients, who are likely not to maintain their oral hygiene.
6. Subjects with fixed or removable prosthetic or orthodontic appliances or those who were planning to undergo orthodontic or Prosthodontic treatment in the next six month.
7. Non – cooperative patients

Methodology: -

At baseline, 3 weeks, 6 weeks, 9 weeks the following clinical parameters were recorded:

- Supragingival Plaque - Plaque Index (byTuresky- Gilmore- Glickman modification of the Quigley-Hein)
- Gingival inflammation- Gingival Index (byLoe and Silness P in 1964)
- Pocket Probing Depth (PPD) (by UNC 15 periodontal Probe).

Recording of Plaque and Gingivitis indices:

Plaque was assessed using the Turesky-Gilmore-Glickman modification of the Quigley-Hein

Plaque index (Turesky et al 1970).
The deposits were first stained with erythrosine dye after which plaque formation was assessed on a numerical scale according to the following criteria:
0 = No plaque
1 = Separate flecks of plaque of the cervical margin of tooth
2 = thin continuous band of plaque(upto 1mm)
3 = band of plaque wider than 1 mm but covering less than 1/3rd of the surface of the crown of the tooth.
4 = Plaque covering at least 1/3rd but less than 2/3rd of the crown of the tooth
5 = Plaque covering more than 2/3rd of the crown of the tooth
Plaque was measured on all teeth present other than the index teeth and the third molars at 6 locations around each tooth namely; mesiobuccal, mid buccal, distobuccal, distolingual, mid lingual and mesio lingual. The values were added and divided by 6 to get the score for each tooth. The individual tooth score was summed up and divided by number of teeth scored to get the individuals plaque score.

Gingivitis was assessed using the gingival index system (Loe and Silness 1964)

The gingival index examines gingival inflammation on a numerical scale according to the following criteria:

0 = Absence of inflammation/ normal gingiva

1 = Mild inflammation, slight change in color, slight edema, no bleeding on probing

2 = Moderate inflammation, moderate glazing, redness, edema, hypertrophy, bleeding on probing

3 = Severe inflammation; marked redness and hypertrophy ulceration, tendency to spontaneous bleeding.

The subjects were then given a thorough oral prophylaxis including the removal of supra gingival and sub gingival plaque and calculus deposits. The teeth were then polished and complete plaque removal was verified by use of an erythrosine disclosing solution. Then Group A was assigned to use Triclosan based dentrifice and the Group B was assigned to use anherbal dentifrice. The dentifrices were distributed to the subjects. All the subjects instructed to brush their teeth twice daily (morning and evening) for one minute, by modified bass technique. Then examined after3-week, 6-week, 9-week interval.

A single examiner recorded all the indices. At the end of the study all the subjects were given a thorough and complete oral prophylaxis.

Materials: -

Armamentarium for Diagnosis and Pre-clinical Assessment:

1. Mouth mirror
2. UNC 15 Periodontal probe
3. Tweezers
4. Explorer
5. Hufriedy's Williams Graduated periodontal probe
6. Erythrosine (Plaksee) disclosing agent

Armamentarium for study:

1. 1 Triclosan containing dentrifice (Senquel- F toothpaste**)**
2. 3Herbal dentrifices

   - Alovera gel containing dentrifice (Forever Bright)
   - Neem containing dentrifices (Neem active toothpaste)
   - Babool containing dentrifices (Babool toothpaste)

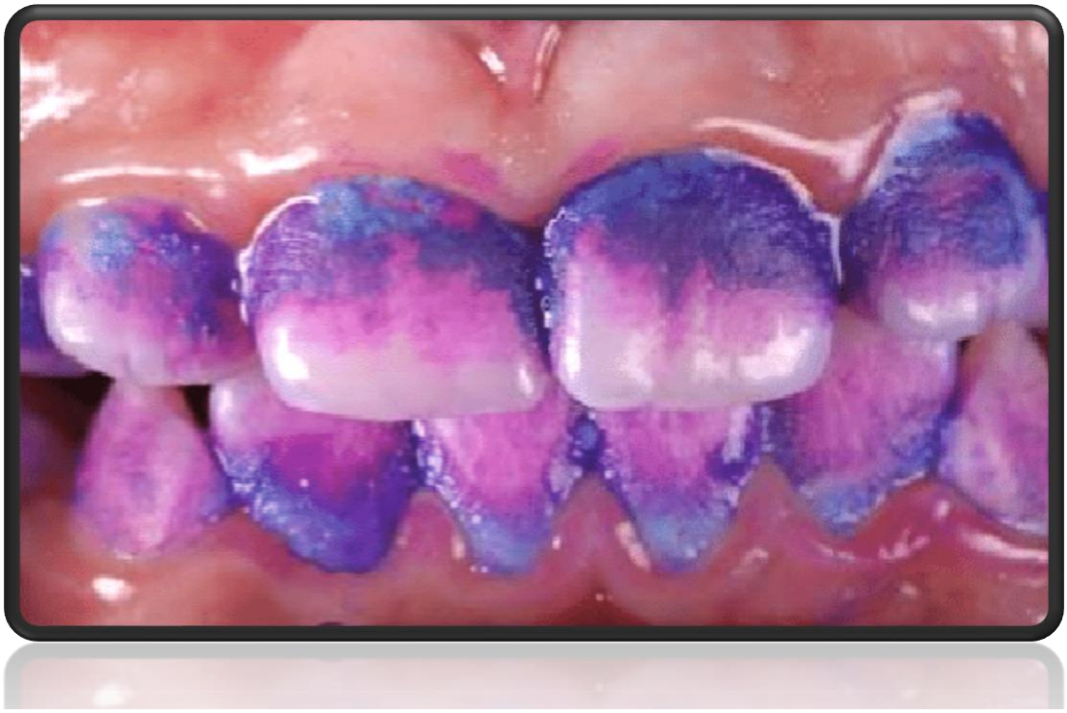

Figure1:- Dental Plaque after application of a Disclosing agent

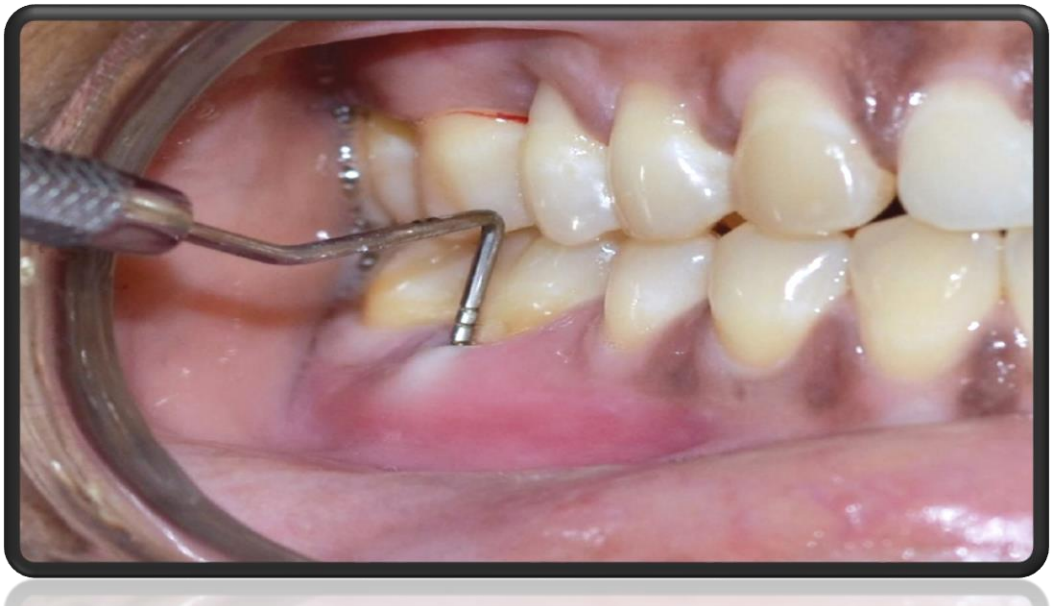

Figure 2 :-Measuring of probing Depth by UNC-15

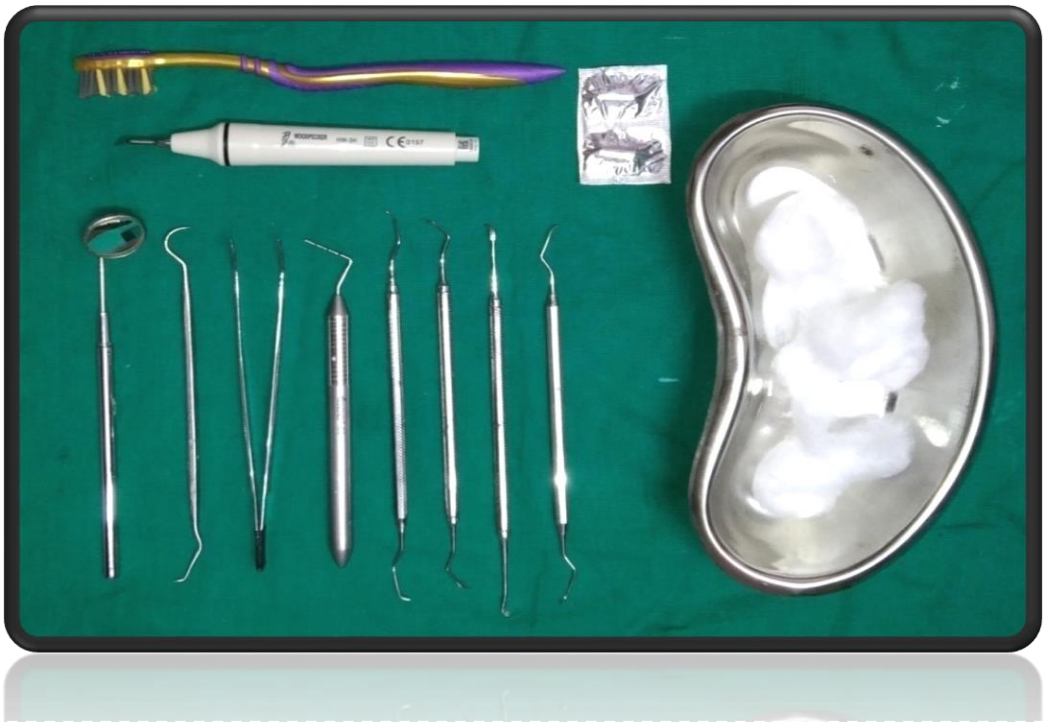

Figure3:- Armamentarium for diagnosis and pre-clinical assessment

Figure4: - FOREVER BRIGHT TOOTHPASTE (ALOVERA OF AMERICA, INC.)

Figure5: -NEEM ACTIVE TOOTHPASTE (JL- JYOTHY LABS LIMITED)

Figure 6: - SENQUEL-F TOOTHPASTE (DR. REDDY'S LABORATERIES LTD)

Figure7: - BABOOL TOOTHPASTE (DABUR INDIA LIMITED)

COMPOSITION OF DENTRIFICES

DENTRIFICES	INGREDIENTS AS LISTED ON PACKAGES
GROUP A: **1.** SENQUEL-FTOOTHPASTE (TRICLOSAN CONTAINING DENTRIFICES)	Triclosan USP (0.3% w/w), PotassiumNitrate BP, Sodium MonfluorophosphateUSP.
GROUP B: **1.**FOREVER BRIGHT TOOTHPASTE (ALOVERA GEL CONTAINING DENTRIFICES)	Aloe Barbadensis Leaf Juice (stabilized Aloe Vera Gel), Sorbitol, Hydrated Silica, Glycerine, Sodium Lauryl Sulfate, Chondrus Crispus (Carrageenan), Flavor (Aroma), Propalis Extract, Sodium Saccharin, Sodium Benzoate, Chlorophyllin- Copper Complex.
2. NEEM ACTIVE TOOTHPASTE (NEEM CONTAINING DENTRIFICES)	Neem Extract, Calcium Carbonate, Sorbitol, Aqua, Glycerine, Hydrated Silica, Sodium Lauryl Sulphate,Flavor,SodiumCarboxymethylcellulose, Carrageenan, Sodium Saccharin, Methylparaben, Sodium Monofluoro Phosphate, Sodium Dihydrogen Phosphate, Tea Tree Oil, CI 19140, CI 42090.
3. BABOOL TOOTHPASTE (BABOOL CONTAINING DENTRIFICES)	Babul (Acacia Arabica) Extract, Calcium Carbonate, Sorbitol, Water, Silica, Sodium Lauryl Sulphate, Flavor containing Clove Oil, CI No. 77891, Cellulose Gum, Xanthan Gum, Sodium Silicate, Sodium Saccharin, Formaldehyde.

TABLE 1: INGREDIENTS OF VARIOUS TOOTHPASTES

Study Design: -

Ethical clearance was obtained from the ethical committee of BBDCODS. Selected patients were motivated for the required treatment and the treatment procedure and prognosis were fully explained to them. A duly signed consent form was taken from each patient before initiating treatment. 60 patients with the inclusion and exclusion criteria were evaluated and assessed.All patients selected for the study were divided into two groups group A and group B. A clinical study for clinical evaluation of effect of Triclosan containing dentrifices and Herbal based dentifices for gingivitis and plaque prevention was carried out among patients who came to the OPD at the Department of Oral Medicine and Radiology, Babu Banarasi Das College of Dental Sciences (BBDCODS), Lucknow, India. Patients presenting with gingival inflammation were assessed by a single examiner to find the percentage of Gingivitis cases present. 60 patients of Gingivitis and periodontal pocket of around 1-2 mm were examined by recording plaque index (by Turesky-Gilmore-Glickman modification of the Quigley-Hein), Gingival index (by Loe and Sillness P in 1964), Pocket Depth (by UNC15 Periodontal Probe). This assessment was done to determine the effect of Triclosan and Herbal based dentrifices. The deposits were firstly stained with erythrosine dye after which plaque formation were assessed on a numerical scale. Plaque was measured on all teeth locations around each tooth surface namely; mesiobuccal, mid buccal, distobuccal, distolingual, mid lingual and mesio lingual. Gingivitis was assessed using the gingival index system (Loe and Silness P 1964). The gingival index examines gingival inflammation on a numerical scale. Gingivitis was measured on the tissues surrounding each tooth were divided into gingival scoring units: distal facial papilla. Facial margin, mesial facial papilla and the entire lingual gingival margin. Probing depth was measured by UNC-15 Periodontal Probe. Then followed by scaling and root planing, Group A were assigned to use Triclosan based dentrifice and the Group B were assigned to use a herbal dentifrices. The dentifriceswere distributed to the subjects. All the subjects were instructed to brush their teeth twice daily (morning and evening) for one minute, by modified bass technique. Then examined after 3-week, 6-week, 9-week interval.

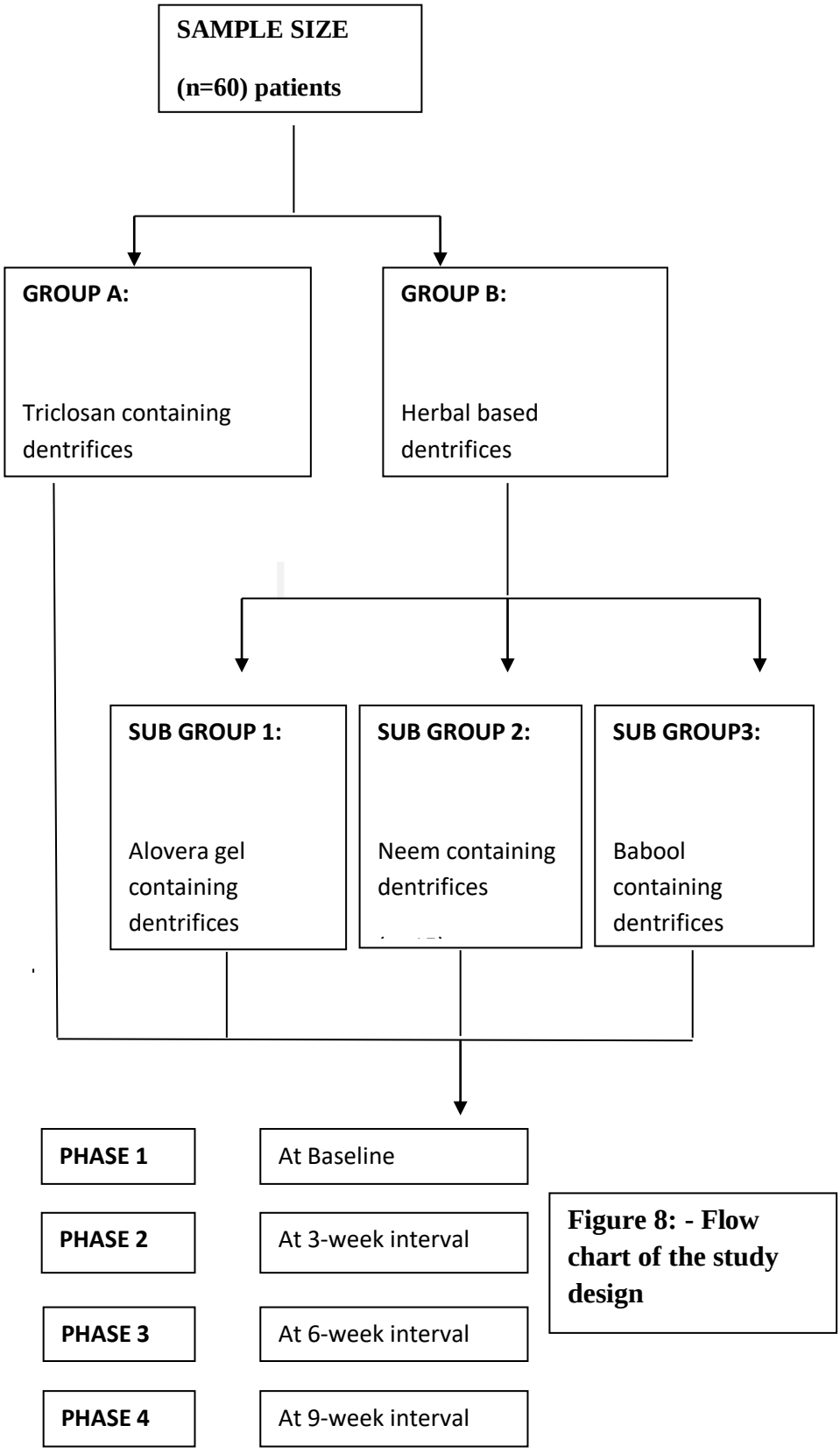

Figure 8: - Flow chart of the study design

Results & Observations

RESULTS AND OBSERVATIONS

The current study was conducted to compare the efficacy of herbal dentifrices with Triclosan containing dentifrices. In the in-vivo analysis Gingival index, Plaque index and Probing depth was assessed. Plaque index was assessed using the Turesky-Gilmore-Glickman modification of the Quigley-Hein, Gingival index was assessed using Loe and Silness method and Probing Depth by UNC 15 Probe.

The following treatment groups were evaluated:

Group A: Triclosan containing Dentifrices-Senquel F

Group B: Herbal based Dentifrices

Sub Group 1: Aloevera gel containing dentifrices

Sub Group 2: Neem containing dentifrices

Sub Group 3: Babool containing dentifrices

Groups was assessed at 4 phases: at baseline, at 3 weeks, at 6 weeks and at 9 weeks.

Table 2: Shows mean plaque distribution and intergroup comparison at baseline, 3 weeks, 6 weeks and 9 weeks among the groups.

PLAQUE INDEX		BASELINE	3 WEEKS	6 WEEKS	9 WEEKS
SENQUEL F	MEAN	2.43	2.29	2.14	1.81
	SD	0.09	0.12	0.15	0.23
NEEM	MEAN	2.30	1.97	1.50	1.07
	SD	0.17	0.15	0.16	0.15
BABOOL	MEAN	2.25	2.17	1.90	1.60
	SD	0.44	0.44	0.41	0.33
ALOE VERA	MEAN	2.19	1.96	1.60	1.14
	SD	0.36	0.36	0.34	0.35
P-VALUE		0.181	0.008	0.000	0.000

The above table shows the mean plaque index distribution of the four groups at different time intervals. The results depicts that there was statistically no significant difference among the four groups at baseline ($p>0.05$). Whereas the results were statistically significant among the four groups at 3 weeks, 6 weeks and 9 weeks ($p<0.05$). The results show decrease in the plaque index from baseline to 9 weeks in all the groups.

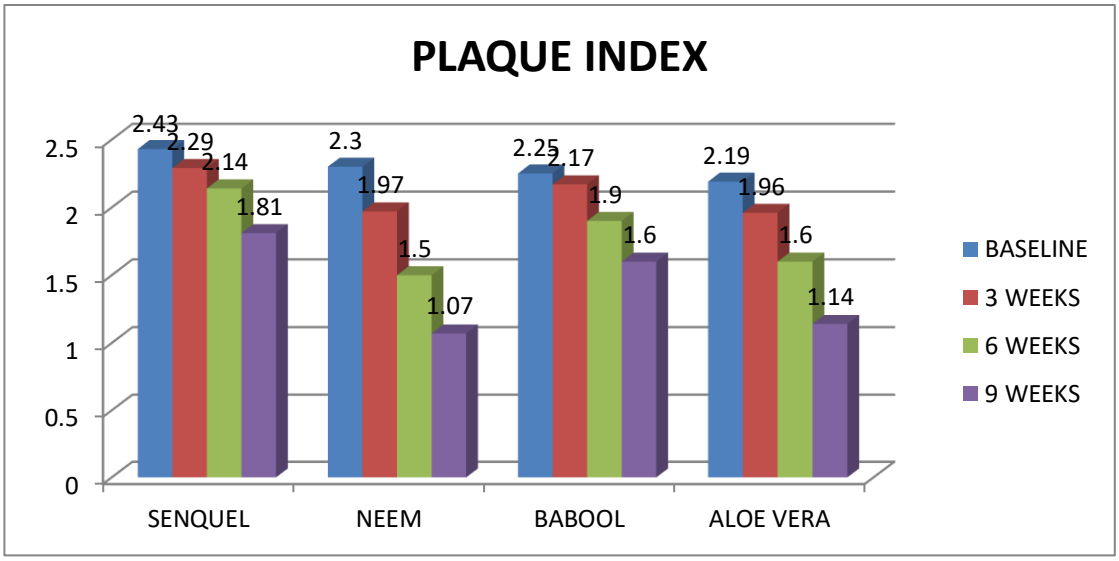

Figure 1: - Graphical representation of plaque distribution and intergroup comparison at different time interval.

Table 3: Shows mean gingival index distribution and intergroup comparison at baseline, 3 weeks, 6 weeks and 9 weeks among the groups.

GINGIVAL INDEX		BASELINE	3 WEEKS	6 WEEKS	9 WEEKS
SENQUEL F	MEAN	1.79	1.36	1.03	0.63
	SD	0.32	0.32	0.29	0.22
NEEM	MEAN	1.78	1.65	1.48	1.29
	SD	0.36	0.32	0.28	0.17
BABOOL	MEAN	1.88	1.72	1.53	1.27
	SD	0.38	0.34	0.27	0.21
ALOE VERA	MEAN	1.88	1.55	1.36	1.03
	SD	0.36	0.30	0.21	0.12
P-VALUE		0.782	0.022	0.000	0.000

The above table shows the mean gingival index distribution of the four groups at different time intervals. The results depicts that there was statistically no significant difference among the four groups at baseline ($p>0.05$). Whereas the results were statistically significant among the four groups at 3 weeks, 6 weeks and 9 weeks ($p<0.05$). The results show decrease in the gingival index from baseline to 9 weeks in all the groups.

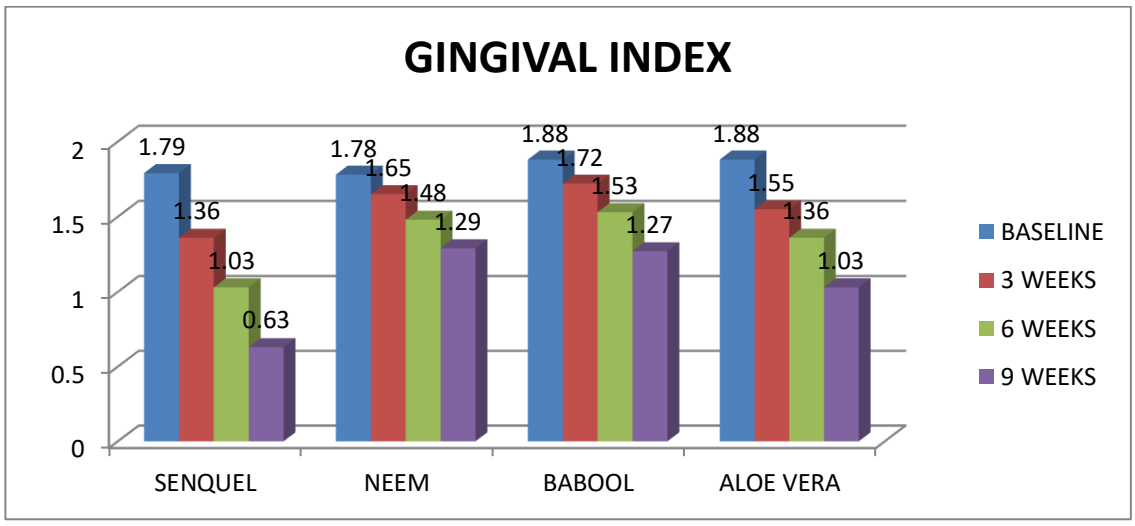

Figure 2: - Graphical representation of gingival index distribution and intergroup comparison at different time interval.

Table 4: shows mean probing depth distribution and intergroup comparison at baseline, 3 weeks, 6 weeks and 9 weeks among the groups.

PROBING DEPTH		BASELINE	3 WEEKS	6 WEEKS	9 WEEKS
SENQUEL F	MEAN	5.60	4.13	2.93	1.60
	SD	0.50	0.74	0.70	0.50
NEEM	MEAN	5.60	4.53	3.20	1.93
	SD	0.50	0.51	0.56	0.70
BABOOL	MEAN	5.66	4.53	3.33	2.06
	SD	0.48	0.51	0.48	0.59
ALOE VERA	MEAN	5.60	4.40	3.26	2.06
	SD	0.50	0.50	0.45	0.59
P-VALUE		0.978	0.202	0.233	0.125

The above table shows the mean distribution of probing depth of the four groups at different time intervals. The results depicts that there was statistically no significant difference among the four groups at baseline, 3 weeks, 6 weeks and 9 weeks ($p<0.05$). The results show decrease in the probing depth from baseline to 9 weeks in all the groups.

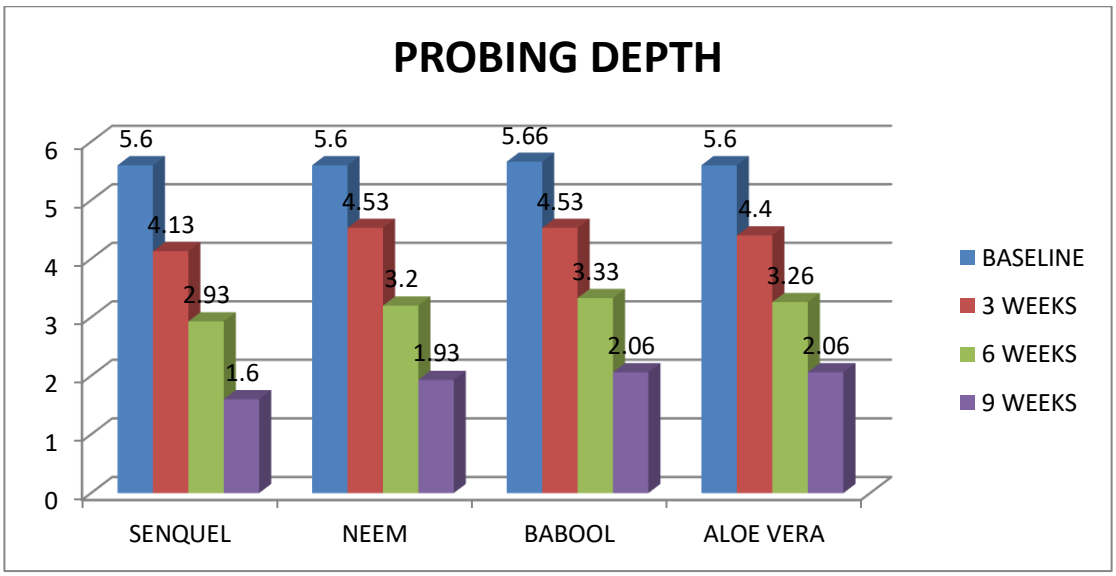

Figure 3:- Graphical representation of probing depth distribution and intergroup comparison at different time interval.

Table 5: shows mean plaque index comparison of Senquel group with Neem, Babool and Aloe vera group at baseline.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PLAQUE INDEX BASELINE	SENQUEL	NEEM	.13267	.11159	.636	-.1628	.4281
		BABOOL	.17933	.11159	.383	-.1161	.4748
		ALOEVERA	.24133	.11159	.146	-.0541	.5368

The above tables showthe plaque index comparsion of senquel group with the Neem, Babool and Aloe vera groups at baseline. The results shows that there was statistically non-significant difference among the groups: Senquel-Neem, Senquel- Babool and Senquel- Aloevera ($p>0.05$).

Table 6: shows mean plaque index comparison of Senquel group with Neem, Babool and Aloe vera group at 3 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PLAQUE INDEX-3 WEEKS	SENQUEL	NEEM	.32133*	.11037	**.026**	.0291	.6136
		BABOOL	.11733	.11037	.713	-.1749	.4096
		ALOEVERA	.33400	.11037	.019	.0418	.6262

*: statistically significant, P value ($P\leq0.05$)

The above tables showthe plaque index comparsion of senquel group with the Neem, Babool and Aloe vera groups at 3 weeks. The results shows that there was statistically non-significant difference among the groups: Senquel- Babool ($p>0.05$). whereas there was statistically significant difference among the Senquel-Neem and Senquel- Aloevera group ($p<0.05$).

Table 7: shows mean plaque index comparison of Senquel group with Neem, Babool and Aloe vera group at 6 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PLAQUE INDEX-6 WEEKS	SENQUEL	NEEM	.63867*	.10747	**.000**	.3541	.9232
		BABOOL	.24133	.10747	.124	-.0432	.5259
		ALOEVERA	.524267	.10747	**.000**	.2581	.8272

*: statistically significant, P value (P≤0.05)

The above tables show the plaque index comparsion of senquel group with the Neem, Babool and Aloe vera groups at 6 weeks. The results shows that there was statistically non-significant difference among the groups Senquel- Babool($p>0.05$). whereas there was statistically significant difference among the Senquel-Neem group and senquel-aloe vera group. ($p<0.05$).

Table 8: shows mean plaque index comparison of Senquel group with Neem, Babool and Aloe vera group at 9 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PLAQUE INDEX-9 WEEKS	SENQUEL	NEEM	.74133*	.10299	**.000**	.4686	1.0141
		BABOOL	.21533	.10299	.169	-.0574	.4881
		ALOEVERA	.67400*	.10299	**.000**	.4013	.9467

*: statistically significant, P value (P≤0.05)

The above tables show the plaque index comparsion of senquel group with the Neem, Babool and Aloe vera groups at 9 weeks. The results shows that there was statistically non-significant difference among the groups Senquel- babool ($p>0.05$). whereas therewas statistically significant difference among the Senquel-Neem group and senquel-aloe vera group. ($p<0.05$).

Table 9: shows mean gingival index comparison of Senquel group with Neem, Babool and Aloe vera group at baseline.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
GINGIVAL INDEX-BASELINE	SENQUEL	NEEM	.00067	.13132	1.000	-.3471	.3484
		BABOOL	-.09767	.13132	.879	-.4454	.2501
		ALOEVERA	-.09467	.13132	.888	-.4424	.2531

The above tables show the gingival index comparison of senquel group with the Neem, Babool and Aloe vera groups at baseline. The results shows that there was statistically non-significant difference among the groups: Senquel-Neem, Senquel- Babool and Senquel- Aloevera ($p>0.05$) at baseline.

Table 10: shows mean gingival index comparison of Senquel group with Neem, Babool and Aloe vera group at 3 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
GINGIVAL INDEX-3 WEEKS	SENQUEL	NEEM	-.28800	.11813	.082	-.6008	.0248
		BABOOL	-.35867*	.11813	.019	-.6715	-.0459
		ALOEVERA	-.19600	.11813	.355	-.5088	.1168

*: statistically significant, P value ($P\leq0.05$)

The above tables show the gingival index comparison of senquel group with the Neem, Babool and Aloe vera groups at 3 weeks. The results shows that there was statistically non-significant difference among the groups: Senquel- Neem and Senquel- Aloevera ($p>0.05$). whereas there was statistically significant difference among the Senquel-Babool group ($p<0.05$).

Table 11: shows mean gingival index comparison of Senquel group with Neem, Babool and Aloe vera group at 6 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
GINGIVAL INDEX-6 WEEKS	**SENQUEL**	**NEEM**	-.44067*	.09802	**.000**	-.7002	-.1811
		BABOOL	-.49533*	.09802	**.000**	-.7549	-.2358
		ALOEVERA	-.32400*	.09802	**.009**	-.5835	-.0645

*: statistically significant, P value (P≤0.05)

The above tables show the gingival index comparison of senquel group with the Neem, Babool and Aloe vera groups at 6 weeks. The results shows that there was statistically significant difference among the groups: Senquel- Neem, Senquel-Babool and Senquel-Aloevera group (p<0.05).

Table 12: shows mean gingival index comparison of Senquel group with Neem, Babool and Aloe vera group at 9 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
GINGIVAL INDEX-9 WEEKS	**SENQUEL**	**NEEM**	-.66133*	.06963	**.000**	-.8457	-.4770
		BABOOL	-.64200*	.06963	**.000**	-.8264	-.4576
		ALOEVERA	-.40000*	.06963	**.000**	-.5844	-.2156

*: statistically significant, P value (P≤0.05)

The above tables show the gingival index comparison of senquel group with the Neem, Babool and Aloe vera groups at 9 weeks. The results shows that there was statistically significant difference among the groups: Senquel- Neem, Senquel-Babool and Senquel-Aloevera group (p<0.05).

Table 13: shows mean probing depth comparison of Senquel group with Neem, Babool and Aloe vera group at baseline.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PROBING DEPTH-BASELINE	SENQUEL	NEEM	.00000	.18344	1.000	-.4857	.4857
		BABOOL	-.06667	.18344	.983	-.5524	.4191
		ALOEVERA	.00000	.18344	1.000	-.4857	.4857

The above tables show the probing depth comparison of senquel group with the Neem, Babool and Aloe vera groups at baseline. The results shows that there was statistically non-significant difference among the groups: Senquel-Neem, Senquel- Babool and Senquel- Aloevera ($p>0.05$) at baseline.

Table 14: shows mean probing depth comparison of Senquel group with Neem, Babool and Aloe vera group at 3 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PROBING DEPTH-3 WEEKS	SENQUEL	NEEM	-.40000	.21157	.244	-.9602	.1602
		BABOOL	-.40000	.21157	.244	-.9602	.1602
		ALOEVERA	-.26667	.21157	.592	-.8269	.2935

The above tables show the probing depth comparison of senquel group with the Neem, Babool and Aloe vera groups at 3 weeks. The results shows that there was statistically non-significant difference among the groups: Senquel-Neem, Senquel- Babool and Senquel- Aloevera ($p>0.05$) at 3 weeks.

Table 15: shows mean probing depth comparison of Senquel group with Neem, Babool and Aloe vera group at 6 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PROBING DEPTH-6 WEEKS	SENQUEL	NEEM	-.26667	.20471	.565	-.8087	.2754
		BABOOL	-.40000	.20471	.218	-.9420	.1420
		ALOEVERA	-.33333	.20471	.371	-.8754	.2087

The above tables show the probing depth comparison of senquel group with the Neem, Babool and Aloe vera groups at 6 weeks. The results shows that there was statistically non-significant difference among the groups: Senquel-Neem, Senquel- Babool and Senquel- Aloevera ($p>0.05$) at 6 weeks.

Table 16: shows mean probing depth comparison of Senquel group with Neem, Babool and Aloe vera group at 9 weeks.

Dependent Variable	(I) group	(J) group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
PROBING DEPTH-9 WEEKS	SENQUEL	NEEM	-.33333	.22039	.437	-.9169	.2502
		BABOOL	-.46667	.22039	.160	-1.0502	.1169
		ALOEVERA	-.46667	.22039	.160	-1.0502	.1169

The above tables show the probing depth comparison of senquel group with the Neem, Babool and Aloe vera groups at 9 weeks. The results shows that there was statistically non-significant difference among the groups: Senquel-Neem, Senquel- Babool and Senquel- Aloevera ($p>0.05$) at 9 weeks.

Discussion

DISSCUSION

Dental plaque is a major contributor to the onset and progression of periodontal disease. The majority of dental problems have a common etiological factor: dental plaque. Plaque accumulation is the primary goal of oral hygiene techniques.[47] Brushing teeth with toothpaste is one of the most popular plaque reduction strategies.

Because they are used in conjunction with tooth brushing, which is the most commonly utilised oral hygiene approach, dentifrices are perfect transporters for any active ingredient used as an oral health preventive strategy. However, there are certain drawbacks, such as the difficulty in formulating them due to the potential for interactions between the active agents and the other dentifrice constituents. Their pharmacokinetics are less predictable than mouthrinses, and they won't reach difficult-to-reach locations like the tonsils or the dorsum of the tongue. Furthermore, in some situations, such as after surgical interventions or in impaired individuals, their use in conjunction with toothbrushing may be impossible because patients may be told not to brush.[48]

The majority of people nowadays use a tooth brush and paste to maintain their oral hygiene. As a result, mechanical and chemical oral hygiene aids are a frequent weapon in the fight against dental disorders such as dental caries and periodontal disease. However, it is unclear how well these are functioning. Dental advertising is widely used. Many dental tooth pastes are well-known brands. Consumers are bombarded with toothpaste commercials touting its advantages. Many of these items advertise themselves as antibacterial agents. As a result, people feel conflicted about whether or not to utilize these goods. As a result, the current study was designed to evaluate the antibacterial activity of commercially available toothpastes in vitro.[49]

Only a few studies comparing different herbal dentifrices to fluoride-containing dentifrice and triclosan dentifrice on children were found after a thorough review of the literature. The herbal dentifrice's main constituents offer a variety of therapeutic

benefits. Chamomile is thought to offer anti-inflammatory and anti-inflammatory qualities, as well as the ability to reduce gingival inflammation. Sage is thought to have antibacterial, antifungal, and antiviral properties, as well as anti-hemorrhagic characteristics. Myrrh is a natural antiseptic with powerful cleaning and healing capabilities, as well as anti-inflammatory and analgesiceffects, and eucalyptus contributes as an aromatic stimulant and disinfectant (Mullally et al., 1995).[50]

Toothpaste containing sodium fluoride and sylodent, in addition to triclosan, has the highest zone of inhibition against E. coli. Sylodent is a polishing product that gently cleans and removes stains to help whiten teeth. Fluorinated products against E. coli and Candida are next. The main ingredient in this toothpaste is Xylitol. Fluorides are widely utilised in many oral health products, such as toothpastes and mouth rinses, because they help to prevent tooth decay.[51] When compared to no fluoride therapy, fluoride products such as toothpaste and mouth rinse formulations have demonstrated to reduce caries by 30 to 70%.[52]

Oral hygiene products used for chemical plaque control have been classified as follows according to their mechanism of action[53]: (a) antimicrobial agents, when demonstrating a bacteriostatic or bactericidal effect in vitro; (b) plaque-reducing/inhibitory agents, when demonstrating a significant quantitative or qualitative effect on plaque levels in vivo, but may not have a significant effect on gingivitis and/or caries; (c) plaque-reducing/inhibitory agents, when demonstrating a significant; (d) antigingivitis medicines, which show a considerable reduction in gingival inflammation in vivo without necessarily lowering dental plaque levels.

Delmopinol and octapinol are two specific agents. Because they disturb an already established biofilm, their mechanism of action is inhibition and destruction of the biofilm extracellular matrix. As a result, they are not antibacterial agents. They also prevent Streptococcus mutans from synthesising glycans, lowering bacterium acid production. [54,55] Delmopinol has been marketed as toothpaste at 0.2 percent concentrations, along with 0.11 percent fluoride as sodium fluoride (NaF). It has only

been tested as a mouthrinse at concentrations of 0.1 and 0.2 percent in clinical trials, but not as toothpaste. [56-58]

Zinc lactate, zinc citrate, zinc sulphate, and zinc chloride are examples of specific agents. Because of their potential to decrease bacterial adherence, metabolic activity, and growth, zinc salts have shown antibacterial efficacy. Zinc supplements have been studied for plaque management, as well as halitosis control [59-63], tartar control [64,65], and ulcer healing capabilities [66].

Since the 1940s, stannous fluoride has been used in dentifrices and gels. The stannous ion works by adhering to the bacterial surface, inhibiting colonisation, penetrating the bacterial cytoplasm, and interfering with bacterial metabolism [67]. Due to its lack of stability in the presence of water, the combination of stannous and fluoride, chemically SnF2, is difficult to synthesise in oral hygiene products [68]. Two systematic evaluations examining their efficacy in randomised clinical trials have been published. The 0.454 percent SnF2 formulation produced considerable gingival improvements in one of them [69]. Data pooling was done at the final study visit in the other systematic review [70], assuming no differences were observed at baseline and data availability was limited, preventing the meta-analysis. Furthermore, the results combined various SnF2 formulations, including the use of AmF. In terms of gingival index (WMD –0.15), modified gingival index, and plaque index, the results showed substantial differences favouring the test group, as well as significant heterogeneity. Gels made with 0.4 percent stannous fluoride have also been studied, with results showing reduced gingival irritation and probing haemorrhage [71,72]. After 3 months, there were 67 percent and 50 percent reductions in bleeding and gingival inflammation, respectively, when compared to the control group [73].

Triclosan [5-chloro-2-(2, 4 dichlorophenoxy) phenol] is a broad-spectrum antibacterial non-ionic bisphenolic agent [74]. Triclosan has been commonly used in dentifrices to increase substantivity and/or antibacterial action, usually in combination with polyvinyl-methyl ether maleic acid copolymer, zinc citrate, or pyrophosphate. It can be identified in dental plaque for up to 8 hours using these formulas [75]. Triclosan has also been

shown to have anti-inflammatory properties [76] by inhibiting the cyclooxygenase and lipoxygenase pathways, which reduces the production of prostaglandins and leukotrienes.11984

Neem, Pudina, Long, Babool, Turmeric, and Vajradanti are some of the main ingredients in this toothpaste. All three herbal preparations had considerable antibacterial efficacy against Streptococcus mutans (p0.05). There have been numerous investigations on the anti-plaque activity of herbal base toothpaste. Moran et al. observed in a systematic review that herbal toothpastes had less anti-plaque activity than conventional pastes [77]. Herbal-based medicines were found to be less efficient than triclosan formulations in a recent investigation by Manupati Prasanth [78].

The results of the study revealed that all the dentifrices brought down the plaque levels significantly from baseline to 9 weeks. The results are similar to that of studies done by Moran *et al.,*[79] Bhat *et al.,*[80] Ganavadiya*et al.,*[81] and Ozaki *et al.* [82] where different dentifrices were compared. In each of the studies, all the different dentifrices used as interventions brought about significant reduction in plaque levels.

The role of herbal products alone needs to be further evaluated to know its role in plaque reduction. Concurrently, the reduction in gingival bleeding and inflammation was also noted to be significant in the first week itself in both groups. Though there was no significant difference between the groups, the herbal group showed considerable decrease in gingival bleeding and inflammation than the non-herbal group. The possibilities could be due to the ingredients in the herbal dentifrice which contained more of anti-inflammatory and astringent properties. These were lacking in the non-herbal group.

These ingredients in the former had an added advantage in addition to plaque reduction. In conclusion, herbal dentifrice when compared to the non-herbal dentifrice has more benefit over restoring gingival health besides plaque formation reduction.

Native herbal medicines are gaining special interest in the dental field for preventing and curing dental diseases.[83] In controlling plaque and gingivitis, the herbal and non-herbal toothpastes are equally effective. Saxeret al. [84] and Mullaly et al. [50] found a significantly reduced plaque and gingival index score, but no significant difference was found between the herbal and non-herbal toothpastes. Ozaki et al. [82] found herbal dentifrices to be as effective as the non-herbal ones in reduction of gingivitis. George et al.[76], Mateu et al.,[85] and de Oliveira et al. found slightly lower efficacy of herbal products on gingivitis and gingival bleeding compared with conventional ones which is similar to the present study, whereas Sushma et al. and Pannuti et al. observed slightly higher gingivitis reduction with herbal products which is in contrast to our study. Various studies have concluded that herbal and non-herbal toothpastes are equally effective, and so people can conveniently use either of the toothpastes. Toothbrush and paste usage promote reduced plaque and gingival scores (Triratana et al. and Lindhe et al.). Clinical studies have proved herbal toothpastes are effective in reducing plaque and gingival scores demonstrating a significant plaque reduction from 7.17% to 61.2% and gingivitis reduction from 5.20% to 70.6%. Herbal toothpastes areeffective in reducing the plaque and gingivitis. Rubido et al. stated that medicated toothpaste significantly reduced bacterial count in the saliva.

In the present study, the use of Neem active (herbal) dentifrices showed considerable reduction ($P \leq 0.05$) in plaque accumulation. Plaque index score showed reduction from 2.30±0.17 at baseline to 1.07±0.15 at 9 weeks. The reduction in PI score may be attributed to the antibacterial activity of Neem. Study also showed reduction in plaque accumulation ($P \leq 0.05$) form Senquel-F (non-herbal) dentifrice, Babool and aloe vera (herbal) dentifrice. PI scores showed reduction from 2.43±0.09 at baseline to 1.81±0.23 at 9 weeks by senquel-F group, from 2.25±0.44 at baseline to 1.60±0.33 at 9 weeks by babool, from 2.19±0.36 at baseline to 1.14±0.35 at 9 weeks by aloe vera. Herbal toothpaste containing neem leaf extracts are effective in plaque reduction. Decrease in plaque scores may have been caused by the action of *Azadirachta*in neem leaf extracts, an antibacterial agent. Bhat et al. demonstrated that antibacterial solutions containing neem had the highest effectiveness in reducing the number of *S. mutans* when compared

with turmeric, chlorhexidine, and cetylpyridinium chloride.[86] Neem leaves are known to have antibacterial anti-inflammatory, anti-fungal, antiseptic, antitumor, antihyperglycemic, antiulcer and antiviral effects. In addition, they can reduce the counts of plaque forming bacteria in the oral cavity. A number of antiplaque agents such as chlorhexidine, delmopinol, hexetidine, stannous fluoride, triclosan, and other phenolic compounds have been incorporated in dental creams and evaluated for management of dental plaque. Synthetic toothpastes contain chemical substances that can produce harmful effects on prolonged usage. A number of studies have proved that herbal toothpastes do not cause adverse effects on the oral cavity and are equally effective in reducing plaque and gingivitis compared with fluoridated non-herbal dentifrice. Several studies have also proven the medicinal values of herbal products. Hence, medicated herbal toothpaste can be safely used to control plaque and gingivitis.

In the present study, the use of Senquel-F (non-herbal Triclosan based) dentifrice showed considerable reduction ($P \leq 0.05$) in gingival inflammation. Gingival index score showed reduction from 179±0.32 at baseline to 0.63±0.22 at 9 weeks. Study also showed reduction in plaque accumulation ($P \leq 0.05$) form herbal dentifrice group Neem, Babool and aloe vera. GIscores showed reduction from 1.78±0.36 at baseline to 1.29±0.17 at 9 weeks by Neem, from 1.88±0.38 at baseline to 1.27±0.21 at 9 weeks by babool, from 1.88±0.36 at baseline to 1.03±0.12 at 9 weeks by aloe vera respectively. Triclosan (2, 4, 4'-trichloro-2'-hydroxydiphenyl ether) is a broad-spectrum antibacterial and anti-inflammatory drug that has been proven to be effective against many of the bacteria linked to plaque and plaque-related gingivitis in in vitro experiments. Recent research suggests that triclosan inhibits lipid production by blocking the enzyme enoyl-acyl carrier protein reductase (ENR).[87] Systematic analyses of six-month clinical studies found that formulations containing 0.3 percent triclosan and copolymer improved plaque control and periodontal health significantly.

In the present study, the use of Senquel-F non-herbal dentifrice group and herbal group i.e. Neem, Babool, Aloe vera dentifrices showed considerable reduction ($P \leq 0.05$) in probing depth from baseline to 9 weeks. Probing Depth showed reduction from

5.60±0.50 at baseline to 1.60±0.22 at 9 weeks, from 5.60±0.50 at baseline to 1.93±0.70 at 9 weeks by Neem active, from 5.66±0.48 at baseline to 2.06±0.59 at 9 weeks by Babool, from 5.60±0.50 at baseline to 2.06±0.59 at 9 weeks by aloe vera respectively.

These findings are supported by George J et al (2009)who established in a double blinded controlled clinical trial that the herbal-based toothpaste was as effective as the conventionally formulated triclosan containing dentifrice in the control of plaque and gingivitis. These findings are similar to Tatikonda A et al (2014) [88] who found that clinically, herbal dentifrices were as effective as triclosan (conventional) dentifrices in the control of plaque and gingivitis and showed statistical significance in intra group comparison ($p<0.05$). Additionally, these findings are in correspondence with Amrutesh S et al (2010) [89] who showed that herbal dental cream was as safe and effective as triclosan & fluoride containing dental cream in the treatment of gingivitis and the control of plaque.

However, the intergroup comparison revealed statistically significant ($p\leq0.05$) reduction in Plaque Index in NEEM ACTIVE- group B as compared to group A, Sulcus Bleeding Index scores in SENQUEL-F -group A as compared to herbal- group B. This might be attributed to the superior antimicrobial activity of triclosan which acts by inhibiting the enzyme enoyl-acyl carrier protein reductase (ENR) thereby blocking lipid biosynthesis and anti-inflammatory action [87]. However, the Gingival Index scores, although statistically significant in favour of Group A, did not show any significant difference in Group B (Herbal group). This may beattributed to the patient compliance and additionally to the inter-individual variation in reduction of inflammation despite reduction in plaque scores.

The results of the present study were in accordance with the work done by Deshpande R (2014) [90] who found that fluoridated triclosan toothpaste had maximum antimicrobial activity at all concentrations when compared to herbal toothpaste which was statistically significant ($p<0.05$).

Similarly a study was conducted by Gupta P(2012)[91] comparing the efficacy of commercially available over the counter herbal dentifrices in comparison with triclosan

containing conventional dentifrice(Colgate Total) on Streptococcus sanguis and found that amongst 9 herbal dentifrices , Miswak (Salvadora persica) & Promise (Clove oil) showed better results as compared to triclosan containing dentifrice. The results of present study is not in accordance with the study conducted by Tangade P et al (2012) [92] who found reductions in PI, GI and BOP% in the Acacia arabica containing toothpaste (test group) ($p<0.05$) compared with the triclosan containing toothpaste (control group). Gupta P (2012) [93] found that there were significant differences ($p < 0.05$) in the reduction of plaque by the herbal dentifrice, Meswak*(*Salvadora persica*)* in comparison with triclosan. These results are in contrast to the present study.

Conclusion

CONCLUSION

The results showed that there was reduction in the plaque index, gingivitis indexScores and probing depth when a comparison was done from the baseline to 9 weeks. At baseline the mean was non-significant among the four groups for gingival index, plaque index and probing depth using ANOVA test and at 3 weeks, 6 weeks and 9 weeks the gingival index, plaque index and probing depth showed significant difference among the four groups using. The inter group comparison using post hoc test in the gingival index, plaque index, probing depth parameter concluded that the Neem of herbalgroup was most effective among all in reducing the plaque accumulation followed by Aloe vera, Babool and Senquel-F, whereas Senquel-F of non-herbal group was most effective among all in reducing gingival inflammation followed by Neem, Aloe vera, Babool of herbal group and the use of Senquel-F non-herbal dentifrice group and herbal group i.e. Neem, Babool, Aloe vera dentifrices both showed considerable reduction in probing depth from baseline to 9 weeks.Thus, we can conclude that the Neem was more effective than the aloe vera, babool, and Senquel-F for plaque accumulation reduction, Senquel-F was more effective than the herbal group for gingival inflammation reduction, whereas herbal dentifrices are as effective as non- herbal dentifrices for probing depth reduction.

Depending on their activity, they can be categorized as antimicrobial, plaque inhibitory, antiplaque or antigingivitis. Antiplaque agents are those able to significantly affect plaque and gingivitis, and they should be preferred in the treatment of gingivitis and the prevention of periodontal diseases. The efficacy of these products should be demonstrated in well-designed, 6-month, home use, randomized clinical trials.Dentifrices, however, can be produced with complex formulations that may interfere with the activity of the therapeutic agents, and therefore the efficacy of any newly marketed dentifrice should be tested in well-designed randomized clinical trials.

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Annexures

Annexure- 1

IEC

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the VIII[th] Institutional Ethics Sub-Committee

IEC Code: 20 **BBDCODS/03/2020**

Title of the Project: Effect of Triclosan Containing Dentrifices and Herbal based Dentrifices Over Gingivitis and Plaque Prevention- A Clinical Study.

Principal Investigator: Dr. Pallavi Goswami **Department:** Periodontology

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr. Pallavi Goswami,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 18[th] March, 2020.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Sahana S. Member	Reader, Department of Public Health Dentistry, BBDCODS, Lucknow
4.	Dr. Sumalatha M.N. Member	Reader, Department of Oral Medicine & Radiology, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala 18/03/20

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. B. Rajkumar)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

Annexure-2

IRC

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Effect of Triclosan Containing Dentrifices and Herbal based Dentrifices Over Gingivitis and Plaque Prevention- A Clinical Study."** submitted by **Dr Pallavi Goswami** Post graduate student from the **Department of Periodontology** as part of MDS Curriculum for the academic year 2019-2022 with the accompanying proforma was reviewed by the Institutional Research Committee present on **19th December 2019** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

Annexure -3

Consent Form

Babu Banarasi Das College of Dental Sciences (Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study…….

Study Number…….

Subject's Full Name…….

Date of Birth/Age ……

Address of the Subject…….

Phone no. and e-mail address……

Qualification ……

Occupation: Student / Self Employed / Service / Housewife/ Other (Please tick as appropriate)

Annual income of the Subject……

Name and of the nominees(s) and his relation to the subject…….. (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated for the above study and have had the opportunity to ask questions. Or I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3.I understand that the sponsor of the project, others working on the Sponsor 's behalf,

the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I permit the use of stored sample (tooth/tissue/blood) for future research.

Yes [] No [] Not Applicable

6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative……..

Signatory 's Name……. Date…….

Signature of the Investigator……Date……..

Study Investigator 's Name.....Date……..

Signature of the witness……Date……..

Name of the witness……

Received a signed copy of the PID and duly filled consent form Signature/thumb impression of the subject or legally Date …..

Acceptable representative

Annexure – 4

PID Form

Babu Banarasi Das College of Dental Sciences

(A constituent institution of Babu Banarasi Das University) BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Participant Information Document (PID)

1. Study title

EFFECT OF TRICLOSAN CONTAINING DENTIFRICES AND HERBAL BASED DENTIFRICES OVER GINGIVITIS AND PLAQUE PREVENTION- A CLINICAL STUDY

2. Invitation paragraph

You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. What is the purpose of the study?

The purpose of this study is to compare the efficacy of herbal dentifrices with Triclosan containing dentifrices.

4. Why have I been chosen?

You have been chosen for this study as you are fulfilling the required criteria for this study.

5. Do I have to take part?

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you

still are free to withdraw at any time and without giving a reason.

6. What will happen to me if I take part?

You will be one of 60 patients enrolled in the study. These patients will be divided into two groups use of triclosan based dentifrice Senquel-f in 15 patients and use of herbal based dentifrices in 45 patients which will be divided into 3 subgroups i.e Alovera gel containing dentifrice, Neem containing dentifrices**,** Babool containing dentifrices with 15 patients in each subgroup with deep periodontal pocket of around > 5mm, gingival inflammation and oral malodor.

7. What do I have to do?

You do not have to change your regular lifestyles for the investigation of the study.

8. What is the procedure that is being tested?

The procedure will involve the evaluation of the efficacy of herbal dentifrices with Triclosan containing dentifrices.

9. What are the interventions for the study?

Patients with deep periodontal pocket of around >5mm, gingival inflammation will be included. We will involve 60 patients, these patients will be divided into two groups use of triclosan based dentifrice Senquel-f in 15 patients and use of herbal based dentifrices in 45 patients which will be divided into 3 subgroups i.e Alovera gel containing dentifrice, Neem containing dentifrices**,** Babool containing dentifrices with 15 patients in each subgroup will be incorporated..

10. What are the side effects of taking part?

There are no side effects on patients of this study.

11. What are the possible disadvantages and risks of taking part?

There is no risk or disadvantages of taking part in this study.

12. What are the possible benefits of taking part?

This study will help us to evaluate the efficacy of herbal dentifrices with Triclosan containing dentifrices.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study stops/finishes before the stipulated time, this will be explained to the patient/volunteer.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and Institutional ethical community.

16. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The results of the study will be used to compare clinical success. Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

This research study is organized by the academic institution (BBDCODS).

19. Will the results of the study be made available after study is over?

Yes.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Dept, and the IEC/IRC of the institution.

21. Contact for further information

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Member Secretary,
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Annexure –5

बाबूबनारसीदासकॉलेजऑफडेंटलसाइंसेज
(बाबूबनारसीदासविश्वविद्यालयकाएकघटकसंस्थान)
बीबीडीसिटी, फैजाबादरोड, लखनऊ - 227105 (भारत)

प्रतिभागीसूचनादस्तावेज (पीआईडी)

1-अध्ययनशीर्षक
ट्राईक्लोसनकन्टेनिंगडेंटरीजऔरहर्बलबेसेंटडेंटिस्ट्रीजकाहरक्षेत्रमेंइस्तेमालहोनेवालाऔरप्लेनप्रीवेंशन-एक क्लिनिकल स्टडी

2- आमंत्रण अनुच्छेद**?**

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है, इसलिए आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें। हमसे कोई स्पष्टीकरण या अधिक जानकारी के लिए पूछें। आप हिस्सा लेना चाहते हैं या नहीं यह आपका निर्णय है।

3- अध्ययन का उद्देश्य क्या है**?**
इसअध्ययनकाउद्देश्यट्राईक्लोसनकेसाथहर्बलडेंट्रिफिकेसकीप्रभावकारिताकीतुलनाडेंट्रिफिकसेकरनाहै।

4- मुझे क्यों चुना गया है**?**
इस अध्ययन के लिए आपको चुना गया है क्यों कि आप इस अध्ययन के लिए आवश्यकमानदंडों को पूरा कर रहे हैं।

5- क्या मुझे भाग लेना है**?**

अनुसंधान में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैं, तो आपको रखने के लिए यह सूचना पत्र दिया जाएगा और सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप अभी भी किसी भी समय और बिना कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6- अगर मैं भाग लेता हूं तो मेरे साथ क्या होगा
आपअध्ययनमेंनामांकित 60 रोगियोंमेंसेएकहोंगे।इनमरीजोंकोबांटाजाएगा 15
रोगियोंमेंट्राइक्लोसनआधारितडेंट्रिफिससेन्केल-एफकेदोसमूहऔर 45
रोगियोंमेंहर्बलआधारितदंतचिकित्साकाउपयोगकरतेहैं, जिन्हें 3
उपसमूहोंमेंविभाजितकियाजाएगाअर्थातएलोवेराजेलजिसमेंडेंट्रिफिस, नीमयुक्तडेंट्रिफिक, बाबूलयुक्तप्रत्येकउपसमूहमें

15 रोगियोंकेसाथदंतचिकित्साशामिलहैं।लगभग 5 एमएमकापीरियोडॉन्टलपॉकेट, मसूड़ोंकीसूजनऔरओरलमैलोडर।

7- मुझे क्या करना है**?**

अध्ययन की जांच के लिए आपको अपने नियमित जीवन शैली को बदल ने की ज़रूरत नहीं है।

8- परीक्षणकीजारहीप्रक्रियाक्याहै**?**

इसप्रक्रियामेंट्राईक्लोसनकेसाथहर्बलडेंट्रिफिसकीप्रभावकारिताकामूल्यांकनशामिलहोगाजिसमेंडेंट्रिफिसशामिलहैं।

9- अध्ययनकेलिएहस्तक्षेपक्याहैं**?**

लगभग 5 मिमीकीगहरीपीरियडोंटलपॉकेटवालेमरीजों, मसूड़ोंकीसूजनकोशामिलकियाजाएगा।हम 60 रोगियोंकोशामिलकरेंगे, इनरोगियोंकोट्राईक्लोसनआधारितडेंट्रिफिससेंकाइल-एफके 15 रोगियोंमेंउपयोगकेलिएदोसमूहोंमेंविभाजितकियाजाएगाऔर 45 रोगियोंमेंहर्बलआधारितदंतचिकित्साकाउपयोगकियाजाएगा, जो 3 उपसमूहोंमेंविभाजितकियाजाएगा। ,प्रत्येकउपसमूहमें 15 रोगियोंकेसाथदंतचिकित्सावालेबाबुलकोशामिलकियाजाएगा।

10- भागलेनेकेदुष्प्रभावक्याहैं**?**

इस अध्ययन के कोई दुष्प्रभाव नहीं हैं।

11- भाग लेने के संभावित नुकसान और जोखिम क्या हैं**?**

इसअध्ययनमेंभागलेनेकाकोईजोखिमयानुकसाननहीहै।लेकिनहमप्रत्यारोपणकेसाथ 100% सफलताकीगारंटीनहींदेतेहैं।यहव्यक्तिकेशरीरकीस्वीकृतिऔरअस्वीकृतिकीप्रतिक्रियापरनिर्भरकरताहै; प्रत्यारोपणउपचारकभी-कभीविफलहोसकताहै।

12- भागलेनेकेसंभावितलाभक्याहैं**?**

इसअध्ययनसेहमेंट्राईक्लोसनकेसाथहर्बलडेंट्रिफिसकीप्रभावकारिताकामूल्यांकनकरनेमेंमददमिलेगीजिसमेंडेंट्रिफिसशामिलहैं।

13- क्याहोगाअगरनईजानकारीउपलब्धहोजाए**?**

यदिअनुसंधानकेदौरानअतिरिक्तजानकारीउपलब्धहोजातीहै, तोआपकोइनकेबारेमेंबतायाजाएगाऔरआपअपनेशोधकर्ताकेसाथइसपरचर्चाकरनेकेलिएस्वतंत्रहैं, आपकाशोधकर्ताआपकोबताएगाकिक्याआपअध्ययनजारीरखनाचाहतेहैं।यदिआपवापसलेनेकानिर्णयलेतेहैं,

तोआपकाशोधकर्ताआपकीवापसीकीव्यवस्थाकरेगा।यदिआपअध्ययनजारीरखनेकानिर्णयलेतेहैं,

तोआपकोएकअद्यतनसहमतिपत्रपरहस्ताक्षरकरनेकेलिएकहाजासकताहै।

14- शोधअध्ययनबंदहोनेपरक्याहोताहै**?**

यदिअध्ययननिर्धारितसमयसेपहलेबंद / खत्महोजाताहै, तोयहरोगी / स्वयंसेवककोसमझायाजाएगा।

15- क्याहोगाअगरकुछगलतहोजाए**?**

यदिकोईगंभीरप्रतिकूलघटनाहोतीहै, याअध्ययनकेदौरानकुछगलतहोताहै, तोसंस्थान (एस),

औरसंस्थागतनैतिकसमुदायकोरिपोर्टकरकेशिकायतोंकोनियंत्रितकियाजाएगा।

16- क्याइसअध्ययनमेंमेराहिस्सागोपनीयरखाजाएगा**?**
हांइसेगोपनीयरखाजाएगा।

17- शोधअध्ययनकेनतीजोंकाक्याहोगा**?**
अध्ययनकेपरिणामोंकाउपयोगटेर्राासाइक्लिनफाइबरकेनैदानिकमूल्यांकनकीतुलनाकरनेकेलिएकियाजाएगा**,**
जिसमेंकर्क्यूमिननिगमितकोलेजनफाइबरशामिलहैं।किसीभीरिपोर्ट /
प्रकाशनकेमामलेमेंआपकीपहचानगोपनीयरखीजाएगी।

18- शोधकाआयोजनकौनकररहाहै**?**
यहशोधअध्ययनअकादमिकसंस्थानद्वाराआयोजितकियाजाताहै।आपकोशामिलकिसीभीप्रक्रियाकेलिएभुगताननहींकरना है।

20- अध्ययनकीसमीक्षाकिसनेकीहै**?**
इसअध्ययनकीसमीक्षाविभागकेप्रमुखऔरसंस्थानकेआईईसी / आईआरसीद्वाराकीगईऔरअनुमोदितकीगईहै।

21- अधिकजानकारीकेलिएसंपर्ककरें

डॉ। पल्लवी गोस्वामी

पीरियोडोंटोलॉजी और इम्प्लांटोलॉजी विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-227,105

मोबाइलनंबर -9012280778

डॉ। वंदना ए पंत (HOD)

पीरियोडोंटोलॉजी और इम्प्लांटोलॉजी विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-227,105

मोबाइल नंबर -9935957775

डॉ लक्ष्मीबाला
सदस्यसचिव
बाबूबनारसीकॉलेजऑफडेंटलसाइंसेज
लखनऊ
bbdcods.iec@gmail.com

पीआईकाहस्ताक्षर .....
नाम .....
दिनांक.....

Annexure – 6

Case History

DEPARTMENT OF PERIODONTICS

PATIENT'S CASE SHEET

Date: O.P.D. No.

Name: Age: Sex: Occupation

Address: Mobile No. :

CHIEF COMPLAINT(S):

HISTORY OF PRESENT ILLNESS

HISTORY OF PAST ILLNESS

A. Past Medical History

B. Past Dental History

(a) Periodontal Treatment Region

(b) **Other dental therapy**

Conservative

Prosthetics

Orthodontics

Oral Surgery

Any Other

C. Present Medical History

(a) General health

1. Bleeding Tendencies
2. Allergy
3. Cardiovascular Diseases
4. Endocrinal Diseases
5. Gastro Intestinal Diseases
6. Neurological Disorder
7. Respiratory Diseases
8. Genito Urinary Diseases
9. Hereditary/Genetic Disorder
10. Puberty/ Pregnancy/ Menopause
11. Any Infectious Disease(s)
12. Medication
13. Any other abnormality

(b) Nutritional Status: i) Well Built /Average /Poor
ii) Non Vegetarian / Vegetarian

D. PRESENT DENTAL HISTORY

(a) **Oral Hygiene Maintenance:** Brush/ Finger/ Stick / Paste/ Powder
Frequency: Once/ Twice/ Thrice
Direction

(b) **HABITS**

1.	Awareness of any Traumatising habits	Yes	No
2.	Grinding of Teeth	Yes	No
3.	Masticatory Muscle Tiredness	Morning	Evening
4.	Biting Habits	Lip/ Tongue/ Cheek/ Misc	
5.	Chewing	Betel/ Tobacco/ Mis.	
6.	Smoking	Beedi/ Cigarette/ Misc.	
7.	Mouth Breathing/ Tongue Thrusting		

CLINICAL EXAMINATION

EXTRA ORAL EXAMINATION

Face

Lips:	Competency
Skin:	Color: Normal or Palor
Neck	Swellings- Unilateral or Bilateral
Jaws:	Symmetry- Antero- Posterior relationship & movements Temporo-Mandibular Joint

INTRA ORAL EXAMINATION:

A. Soft Tissue

Labial & Buccal Mucosa:		Colour, texture
Cheek:		Colour, Stretchability, Consistency
Tongue:		Colour, Size, Mobility, Texture
Floor of the Mouth:		
Palate:	Hard:	Colour, Defect, Depth, Rougae, Tori.
	Soft:	Color, Defect
Vestibule:		
Saliva:		Flow: heavy/ diminished/ Normal Viscosity: thin/thick
Frenum/ Frenii		Number, Size, Attachment
Perio- Endo Problem		

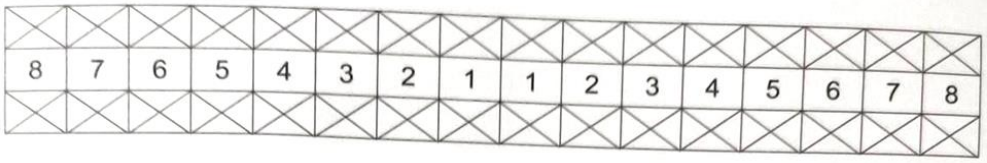
B. Gingival Status

1. Colour
2. Contour
3. Consistency
4. Surface Texture
5. Position
6. Size
7. Exudate

C. Hard Tissue

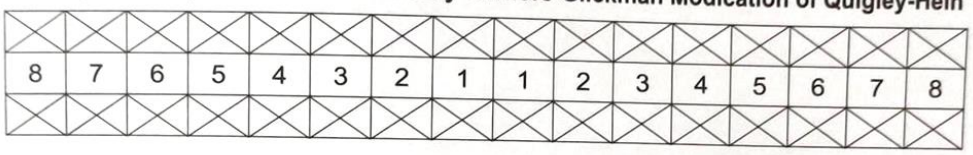
1. No. of teeth present
2. Hypersensitivity
3. Missing teeth (why, when)
4. Caries / Non-vital
5. Supernumerary
6. Proximal contact relationship
7. Plunger cusp
8. Crown size and Colour
9. Pathologic Tooth Migration
10. Mobility — Grade I / II / III
11. Hypoplasia
12. Occlusion — Angle's Classification : Class I / II / III
    Bite: Normal /Open/ Deep/Cross/Crowding
13. Retained / Impacted
14. Attrition/ Erosion/ Abrasion
15. Furcation Involvement
16. Trauma from Occlusion
17. Halitosis
18. Any dental anatomic factors
19. Calculus - Mild / Moderate / Severe
20. Stains - Mild / Moderate / Severe

19. Probing depth

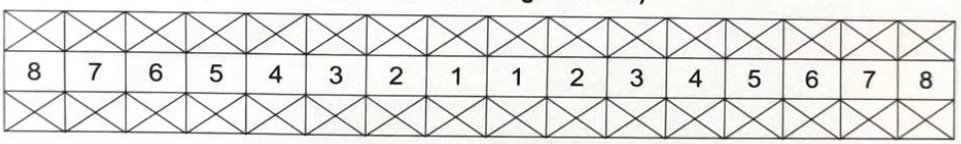


INDICES

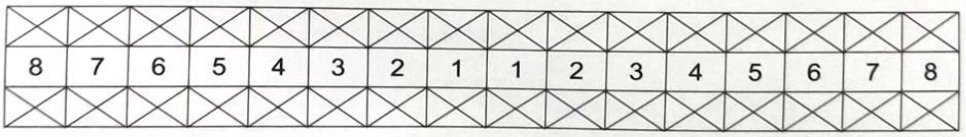
1. Plaque Index (Silness & Loe / Turesky-Gilmore-Glickman Modication of Quigley-Hein



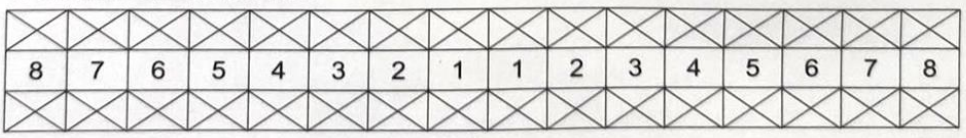
2. Gingival index (Loe & Silness / Modified Gingival Index)



3. Calculus index



4. Clinical attachment Level



DIFFERENTIAL DIAGNOSIS :

INVESTIGATION

1. ROENTENOGRAPHIC EXAMINATION :

OPG/IOPA/BITE WING/OCCLUSAL

	DESCRIPTION	REGION
1. Lamina dura		
2. Periodontal ligament space		
3. Root form		
4. Bone loss	Vertical	
	Horizontal	
	Infra bony crater	
	Miscellaneous	
5. Periapical pathology		
6. Any other finding		

2. LAB INVESTIGATIONS

Date	Investigation	Result
	BLOOD	
	Hb%	
	RBC	
	TLC	
	DLC	
	ESR	
	Random Sugar	
	Bleeding time	
	Clotting time	
	HbS Ag Status : Positive / Negative	
	HIV Status : Positive / Negative	

DIAGNOSIS

PROGNOSIS

TREATMENT PLAN

EMERGENCY -

PHASE I -

PHASE II -

PHASE III -

PHASE IV -

S.No.	Date	Procedure Done	Next Appointment	Staff Signature

DEPARTMENT OF PERIODONTICS
BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES
LUCKNOW

PROFORMA OF PATIENT'S INFORMED CONSENT

I..... son/daughter/wife of.....
aged..... years, resident of.....
being under the treatment of Dr..... do hereby willfully consent to the performance of a surgical procedure under local anaesthesia for the treatment of ..... (Diagnosis) upon myself / upon..... aged..... years, who is related to me as..... (for e.g. son, daughter, wife etc).

I have been informed regarding the inherent risk involved during and after the surgical procedure and that the success of the treatment cannot be guaranteed. I have signed this consent from voluntarily out of my free will without any compulsion or influence.

Date : Place :

Signature : Time :

(To be signed by parent / guardian in case of minor)

Annexure-7
Statistical Analysis

Statistical analysis: Data so collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS22.00forwindows; SPSSinc, Chicago, USA). For each assessment point, data were statistically analyzed using one way ANOVA and the level of significance was set at $p < 0.05$.

The statistical analysis for the present study was done by applying the following formulae:

1 **Mean**: The mean (or average) is the most popular and well-known measure of central tendency. It can be used with both discrete and continuous data, although its use is most often with continuous data. The mean is equal to the sum of all the values in the dataset divided by the number of values in the data set. So, if we have n values in a data set and they have values x_1, x_2, ..., x_n, the sample mean, usually denoted by $\bar{x}$ (pronounced x bar), is:

$$\bar{x} = \frac{(x_1 + x_2 + \cdots + x_n)}{n}$$

This formula is usually written in a slightly different manner using the Greek capitol i.e.:

Sample Mean	Population Mean
$\bar{x} = \frac{\Sigma x}{n}$	$\mu = \frac{\Sigma x}{N}$

where Σx is sum of all data values

N is number of data items in population

n is number of data items in sample

1 **Standard deviation**: the standard deviation (SD, also represented by the lower case Greek letter sigma σ or the Latin letter s) is a measure that is used to quantify the amount of variation or dispersion of a set of data values. A low standard deviation indicates that the data points tend to be close to the mean (also called the expected value) of the set, while a high standard deviation indicates that the data points are spread out over a wider range of values.

$$\sigma = \sqrt{\frac{\Sigma\ (x - \bar{x})^2}{n}}$$

σ = **lower case sigma**
Σ = **capital sigma**
$\bar{x}$ = **x bar**

2 **Anova test**: Analysis of variance (ANOVA) is a statistical technique that is used to check if the means of two or more groups are significantly different from each other. ANOVA checks the impact of one or more factors by comparing the means of different samples. This technique was invented by R.A. Fisher, and is thus often referred to as Fisher's ANOVA (F), as well.

ANOVA Table...

Source of Variation	Sum of Squares	d.f.	Variance	F	p
Between Groups:					
Within Groups:					
Total:					

Sum of square between groups: For the sum of the square between groups, we calculate the individual means of the group, then we take the deviation from the individual mean for each group. And finally, we will take the sum of all groups after the square of the individual group.

Sum of squares within group: In order to get the sum of squares within a group, we calculate the grand mean for all groups and then take the deviation from the individual group. The sum of all groups will be done after the square of the deviation.

F –ratio: To calculate the F-ratio, the sum of the squares between groups will be divided by the sum of the square within a group.

Degree of freedom: To calculate the degree of freedom between the sums of the squares group, we will subtract one from the number of groups. The sum of the square within the group's degree of freedom will be calculated by subtracting the number of groups from the total observation.

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