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COMPARATIVE ANALYSIS OF AYURVEDIC, HOMEOPATHIC AND ALLOPATHIC MOUTH RINSES ON PLAQUE AND GINGIVITIS AS ADJUNCTS TO ROUTINE MECHANICAL TEETH CLEANING: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

The present clinical study was carried out to compare and assess the effectiveness of ayurvedic, homeopathic and allopathic mouth-rinses in controlling plaque formation and gingivitis when used as adjuvants to mechanical tooth brushing. Two-tone disclosing agent for examination of plaque and gingivitis using respective indices. Data was analyzed at baseline, 1 month and 2 month from the initiation of the study. All the 3 mouth rinses showed a considerable reduction in both plaque and gingival scores between baseline to 2 months interval. Allopathic mouth rinse showed a greater reduction of plaque and gingival scores followed by ayurvedic and homeopathic mouth rinses respectively.

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INTRODUCTION

Periodontitis is one of the most common afflictions of the oral cavity since time immemorial. It starts with inflammatory lesions of the gingival tissues, which may eventually progress to involve and compromise the entire periodontal attachment apparatus of the affected teeth. This fact suggests that the prevention of periodontal disease should essentially be based on measures of plaque control ¹(Loe, 1967). The efficacy of mechanical oral hygiene measures, supra gingival plaque control should prevent periodontal tissue inflammation and breakdown. However, since complete elimination of plaque is impractical, prevention may be achieved by (1) reducing the quantity of plaque below the individual's threshold for disease or (2) changing the quality of plaque to a more tissue friendly composition² (Kornman 1986). Mechanical tooth cleansing by means of a tooth brush is considered the most dependable mode of plaque control.

The main aim of controlling dental plaque is to prevent biofilm-associated diseases like caries and periodontitis. To overcome deficiencies in mechanical tooth cleaning as practiced by many individuals, the use of an effective antiseptic agent could have clear and better benefits.

Chlorhexidine (CHX), a biguanide, is the most effective chemical agent in plaque control. CHX is free from systemic toxicity in oral use, microbial resistance and supra-infection do not occur with its long-term usage. CHX as a 0.2% concentration has been readily available as “the leading oral antiseptic” for the last 2 decades. Rinsing for 60 seconds twice daily with 10 ml of a 0.2% (520 mg dose) CHX-digluconate solution in the absence of normal tooth cleaning, inhibits plaque re-growth and helps to prevent inflammation of the gums and tooth decay.³

Chlorhexidine is regarded as the ‘gold standard’ anti-plaque treatment and is particularly effective against gingivitis and

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widely used as an adjunct treatment for periodontitis. Nonetheless, most practitioners do not recommend long-term daily use of CHX as a mouth rinse, mainly because, there are side effects to chlorhexidine treatment such as an objectionable taste, tooth discoloration, desquamation, soreness of the oral mucosa. Its activity is pH-dependent and is greatly reduced in the presence of organic matter.^{3,4} These side effects limit the acceptability to users and the long-term employment of a 0.2% CHX antiseptic in preventive dentistry. Conventional drugs usually provide effective antibiotic therapy for bacterial infections but there is an increasing problem of antibiotic resistance which raises serious concern for the continued efficacy of antimicrobial agents in medicine, agriculture, and industry. Hence, there is a continuing need to search for new solutions which are effective with minimal side effects. With the increase in the prevalence of microbial resistance to conventional antiseptics and antibiotics, attention is now turning to the use of various agents used in alternative or traditional systems of medicine.

Ayurvedic medicine is a system of traditional medicine native to the Indian subcontinent and practiced in other parts of the world as a form of alternative medicine. Many hundreds of plants worldwide are used in traditional medicine as treatments for odontogenic infections. Medicines from alternative or traditional systems like Ayurvedic and Homeopathic remedies are based on natural medical science that works with our body to stimulate our own defenses. Homeopathic Medicine is a system of medicine that relieves symptoms by helping to put your body's systems into proper balance. Because Homeopathic medicine supports the body's own defenses they do not cause side effects. Few commercial companies are manufacturing and marketing homeopathic mouthwash. The advent of alternative systems of medicines, like Ayurveda and Homeopathy, which claim to offer similar, if not better results, with minimal side effects. Ayurvedic and homeopathic mouth rinses have seen the light of the day for the past few years.

The present market is thus flooded with a myriad of mouthwashes, each claiming to be more effective than the other. There are very few studies that have compared the relative efficacy of various mouthwashes further fewer studies have explored the relative efficacy of ayurvedic mouth rinses but no studies have been done with homeopathic mouth rinses against allopathic mouth rinses. Hence, there is a definite need to know the comparative efficacy of ayurvedic and homeopathic mouth rinses against allopathic mouth rinses. Therefore, the present study was conducted with the following aims and objectives.

AIMS AND OBJECTIVE

To assess the effect of ayurvedic, homeopathic and allopathic mouth rinses on plaque and gingivitis as adjuncts to routine mechanical teeth cleaning.

Objectives

1. To evaluate the efficacy of ayurvedic, homeopathic, and allopathic mouth rinses on plaque and gingivitis using Turesky, Gilmore and Glickman modification of Quigley – Hein plaque index and Loe and Silness gingival index.
2. To compare the efficacy of three mouth rinses on plaque and gingivitis using Turesky, Gilmore and Glickman

modification of Quigley –Hein plaque index and Loe and Silness gingival index.

METHODOLOGY

The present study was conducted to evaluate and compare the effect of 3 different mouth rinses (1) Ayurvedic (Be Fresh) mouth rinse with 2) Allopathic (Chlorhexidine 0.2%: Nitra-Hex) mouth rinse and 3) Homeopathic mouth rinse (Throceptol)] on dental plaque and gingivitis status of study subjects. The present study was a randomized, double-blind, parallel design 3-cell clinical study.

Ethical clearance was obtained from the institutional ethical committee, after obtaining informed consent patients who fulfilled the inclusion/exclusion criteria's were included in the study

Inclusion criteria

- They had a minimum of 20 sound natural teeth.
- Good general health/ Good periodontal health.
- Male and Female subjects aged between 18 to 45 years.
- Selected subjects will have no more than six periodontal pockets < than 5 mm.
- A gingivitis score of >1.0 using Loe - Silness Index (Loe & Silness 1963).
- A plaque score of > 2.5 using the Turesky modification (Turesky et al, 1970) of the Quigley-Hein Index (Quigley & Hein 1962).
- Available for the entire duration of the study.

Exclusion criteria

- Orthodontic appliance or more than one incisor with a prosthetic crown.
- Required immediate health care/Destructive periodontal disease.
- Pregnant and lactating women.
- Undergoing antibiotic, steroid therapy or any anti-inflammatory drugs in the preceding month.
- History of allergies to dental products or their ingredients.
- Oral prophylaxis in the preceding month or periodontal treatment in the preceding 3 months.

Oral prophylaxis and polishing (Axelsson & Lindhe 1974) were carried out to make the plaque score 0 and to minimize existing gingivitis. Subjects were then recalled after 15 days for the baseline examination of plaque and gingivitis. The study subjects were asked to refrain from other forms of oral hygiene practices like other commercially available mouth rinses, flossing, inter-dental aides.

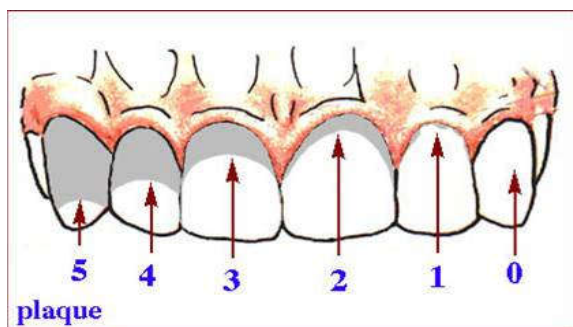
Obtaining baseline data

After evaluating oral soft tissues & performing oral prophylaxis patients were recalled after 15 days, baseline examination of all the study subjects was done by a single investigator under natural light. The study subject's teeth were disclosed using Alpha-plac Two-tone disclosing agent for examination of plaque and gingivitis using respective indices.

Plaque Index

Turesky, Gilmore, Glickman modification of Quigley-Hein Plaque indices were utilized to evaluate.

Scoring Criteria



The index is based on a numerical scale from 0 to 5.

Score	Criteria
0	No plaque.
1	Separate flecks of plaque at the cervical margin of the tooth.
2	A thin continuous band of plaque (up to one mm) at the cervical margin of the tooth.
3	A band of plaque wider than one mm, but covering less than one-third of the crown of the tooth
4	Plaque covering at least one-third but less than two-third of the crown of the tooth.
5	Plaque covering two-thirds or more of the crown of the tooth.

Calculation of Plaque Score: The scores of the upper jaw and lower jaw were added and divided by the total number of teeth examined.

Plaque score = Sum of total scores / Total number of surfaces examined.

Gingival Index (GI): (Loe and Silness).

The gingival index (GI) was developed by Loe and Silness in 1963.⁵ It was developed for the purpose of assessing the severity of gingivitis and its location in six possible areas by examining only the qualitative changes (i.e. severity of the lesion) of the gingival soft tissue. The GI does not take into account periodontal pocket depth, degrees of bone loss, or any other quantitative changes in the periodontium. The gingival index is one of the most widely accepted and used gingival indices due to its documented validity, reliability and ease of use.

Score	Criteria
0	Absence of inflammation/ normal gingiva.
1	Mild inflammation, slight change in colour, slight, oedema: no bleeding on probing.
2	Moderate inflammation: moderate glazing, redness, oedema, and hypertrophy. Bleeding on probing
3	Severe inflammation: marked redness and hypertrophy ulceration. Tendency to spontaneous bleeding.

Calculation of Gingival Scores

Totalling all of the scores per tooth and dividing by the number of teeth examined provides the gingival index score per person. Numerical scores of the gingival index may be associated with varying degrees of clinical gingivitis as follows:

Gingival scores	Condition
0.1 – 1	Mild gingivitis
1.1 – 2.0	Moderate gingivitis
2.1 – 3.0	Severe gingivitis

Randomization, Blinding and Coding

Randomization: After performing baseline data of plaque and gingivitis, study subjects were randomly allotted into 3 groups of mouth rinses of 40 each, group A (homeopathic), group B (allopathic) and group C (ayurvedic). Later, study subjects were asked to pick up a single envelope containing mouth rinse and had equal probabilities of picking any of the 3 envelopes which were included in the study.

Blinding and Coding

Blinding was adopted to ensure objective assessment of the study subjects and to avoid bias. The present study employed a double blinding procedure. The brand names of the three commercially available mouth rinses were erased and placed in a coded envelope which was stapled.

The investigator was blinded as to which study subject was allocated to which group, also the study subjects were unaware regarding which particular mouth rinse was issued to them. Instructions regarding the use of mouth rinses were orally explained and written instructions were also kept in the respective envelopes. The envelopes were coded from 1-120 by the statistician and were kept in a separate box and shuffled to avoid bias.

Instructions to Use Mouth Rinses

Group A rinsed with 10 drops of homeopathic mouth rinse in 10ml of water for 60 seconds twice daily (in the morning and night). The members of Group B rinsed with 10ml of Chlorhexidine (0.2%) mouth rinse preparation (5ml water + 5ml of water) for 30 s twice daily (in the morning and night). The members of Group C rinsed with 10ml of the herbal mouth rinse preparation for 30s twice daily (in the morning and night). To check for compliance, subjects were asked to note down the times at which they rinsed. During this study, subjects followed their usual brushing habits but were instructed to refrain from using other commercial mouth rinses and any other medications. Subjects were recalled for follow up examination for plaque and gingival status at 1 and 2 months following the initiation of rinsing.

Mouth Rinses Use At Home

Subjects were provided with their assigned products and they were instructed to use those products as per the manufacturer's guidelines. Subjects were monitored by the examiner weekly to ensure that they were using the assigned products and were following the given instructions properly. Further, the subjects were informed that any loss of the issued mouth rinse has to be reported to the investigator on his subsequent visit

Oral Hygiene Instructions

For standardization, a common brushing technique, i.e., modified Bass technique was taught to all the study subjects. The following oral instructions were given to the study subjects:

- The subject should use the allocated mouth rinses regularly two times daily.
- The subject should brush twice daily.
- The subject should not use any other type of oral hygiene aids during the period of the study.

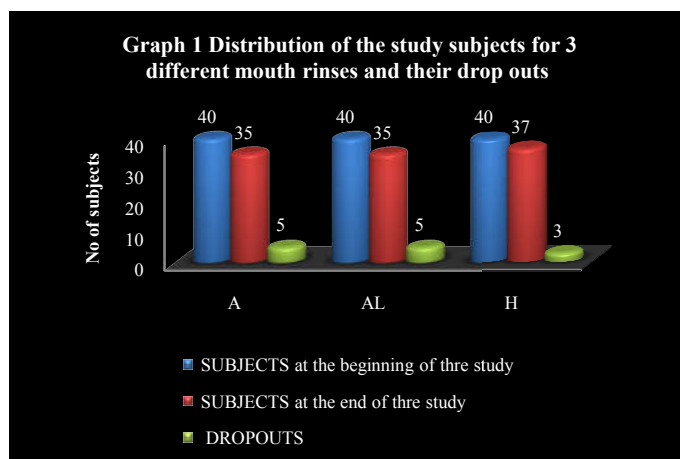
- The subjects were informed that anytime during the study he/she should not visit any dentist.

Follow Up: After one and two months of usage of assigned test products, subjects were recalled and evaluated by the same calibrated dental examiner for plaque and gingivitis by using Turesky, Gilmore, Glickman modification of Quigley-Hein Plaque Index⁶ and Loe and Silness Gingival Index. Data were recorded on the examination form. Soft tissue examination was also done to look for any adverse changes attributable to the usage of mouth rinses.

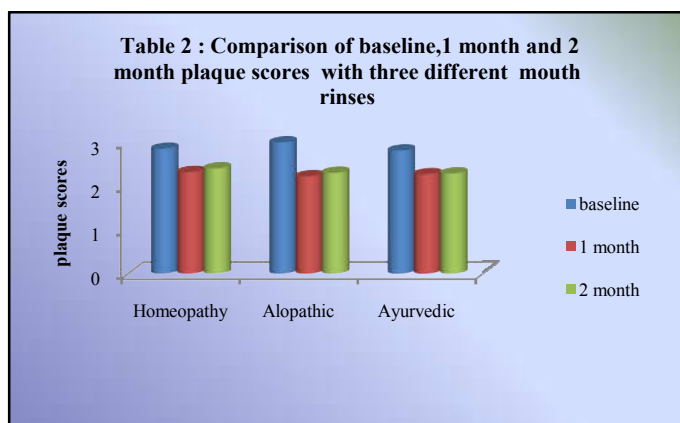
RESULTS

Graph 1 shows the distribution of study subjects at the beginning and at the end of the study period and dropouts (attrition) of the study subjects at the end of the study period.

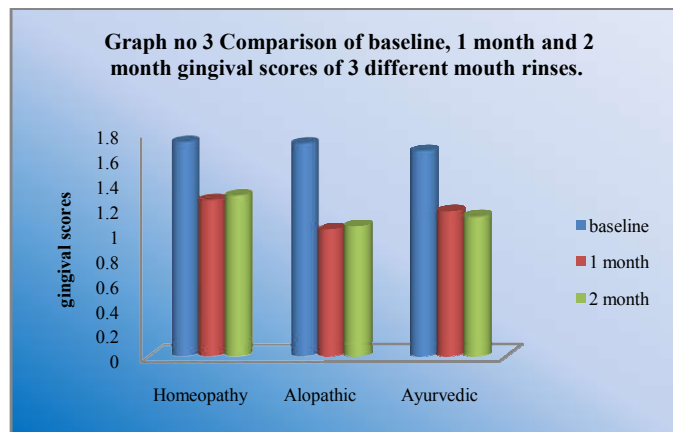
A total of 120 subjects (Male 68 & Female 52) were included in the present study and were randomly divided into three groups. Each of the 3 groups had 40 study subjects and followed for a period of 8 weeks after issuing the mouth rinses. At the end of study period, a total of 107 study subjects were available for follow up, with an overall attrition of (n = 13). Among the drop outs, 5 were from Ayurvedic and Allopathic group each & 3 from the homeopathic group.



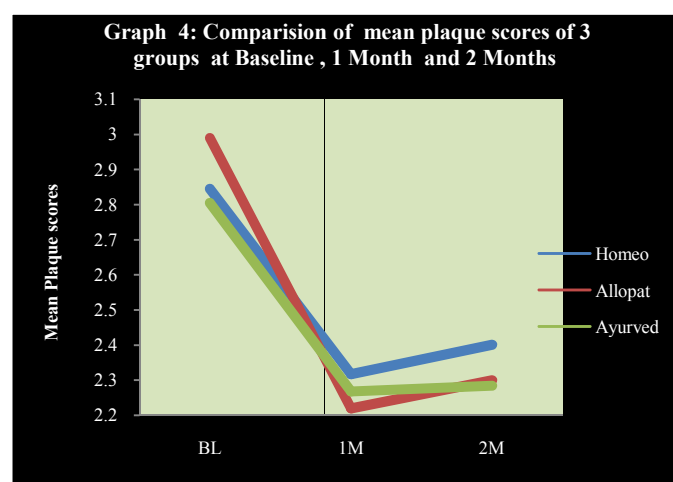
The data were subjected to statistical analysis using the statistical package. ANOVA along with Scheffe's multiple comparison procedure was also performed to know statistical significant differences within three groups and between three groups.



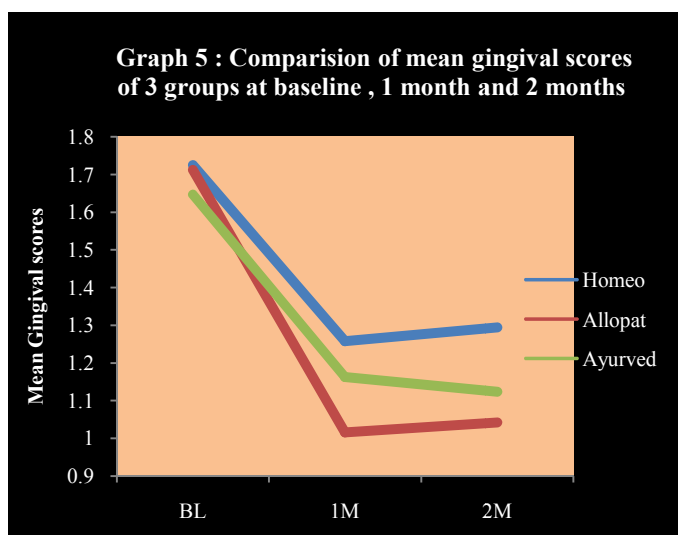
Graph 2 shows that in all three mouth rinses there is reduction of plaque scores from baseline to 1 month but there is not much differences when compared between 1 month and 2 months. Among 3 mouth rinses, allopathic mouth rinse showed maximum reduction from baseline to 1 month followed by ayurvedic and homeopathic mouth rinses. At 1 month to 2 months interval there is little change observed with plaque scores among all the 3 mouth rinses. By using Kruskal Wallis one way ANOVA, it is observed that there is no significant difference among 3 mouth rinses at baseline ($P = 0.1084$), 1 month ($P = 0.2671$), and 2 months ($P = 0.453$) interval.



Graph 3 shows that in all three mouth rinses there is reduction of gingival scores from baseline to 1 month but there is little difference when compared between 1 month and 2 months follow-up. Among 3 mouth rinses, allopathic mouth rinse shows maximum reduction from baseline to 1 month followed by ayurvedic and homeopathic group, there is minor difference, when compared to 1 month to 2 month in homeopathic and allopathic, but in ayurvedic group shows further reduction of gingival scores from 1 month to 2 months intervals. By using Kruskal Wallis one way ANOVA, it is observed that there is highly significant difference at 1 month ($P=0.0008$)* and 2 month ($P=0.0002$)* gingival scores among 3 different mouth rinses.



Graph 4: all 3 groups showed a reduction in plaque scores from baseline to 1 month period and there was a slight increase at the end of 2 months. Among 3 groups, allopathic (chlorhexidine) showed maximum reduction followed by Ayurvedic and Homeopathic group.



Graph no 5: all 3 groups show a reduction of gingival scores. Among 3 products, allopathic (Chlorhexidine) had maximum reduction from baseline to 1 month period, followed by Ayurvedic and Homeopathic products. At the end of 2 months, there was a slight increase in gingival scores with respect to homeopathic and allopathic products whereas, Ayurvedic group showed further reduction of gingival scores.

DISCUSSION

Mechanical tooth cleansing utilizing tooth brush is considered the most traditional and dependable mode of plaque control. Use of mouth rinses has long been identified as an important adjunct to proper maintenance of optimal oral hygiene. The advent of mouth rinses containing chlorhexidine has been a breakthrough in the research for a chemical means to prevent oral diseases. However because of aesthetic side effects of chlorhexidine, other mouth rinses containing ayurvedic and homeopathic agents are now being considered.

The ayurvedic and homeopathic mouth rinses tested in this trial contained several different constituents with putative anti-inflammatory and anti-bacterial properties, which theoretically could be useful in controlling plaque and gingivitis and compared with the conventionally formulated allopathic (chlorhexidine) mouth rinses. The present study was a double blind, randomized trial conducted to assess the efficacy of three groups of commercially available mouth rinses on plaque and gingivitis. Oral prophylaxis (Axelsson & Lindhe 1974)⁶ was carried out on all study subjects to attain a plaque score of zero and also to minimize existing gingivitis. A double blinding technique was followed in the present study to minimize bias. The mouth rinses were placed in coded envelopes with serial numbers written on each of them. The mouth rinses were allocated randomly to the study subjects by a person other than chief investigator. The study subjects were thus divided into three groups of forty each i.e., Homeopathic (Thyroceptol), Allopathic (Nitra Hex) and Ayurvedic (Be- fresh) groups. The study subjects as well as the investigator were unaware as to which particular mouth rinse was issued to a particular study subject.

In the present study, reinforcement regarding the use of mouth rinse were provided every week by a person other than the chief investigator. Instructions regarding proper tooth brushing

technique were also provided by the chief investigator. This was done to ensure that the study subjects used mouth rinses regularly. Although mouth rinsing could not be supervised, compliance of the study subjects was monitored by observing the amount of mouth rinse that was remaining at the weekly interval basis.

In the present study, significant reduction of the plaque scores and gingivitis occurred in all 3 groups. Among 3 mouth rinses, allopathic mouth rinse showed maximum reduction from baseline to 1 month followed by ayurvedic and homeopathic mouth rinses. Between the periods of one month to 2 months interval, there was no much change observed with plaque scores among all the 3 mouth rinses, which is in line with the findings reported by Mankodi et al (2004)⁷.

During the initial 1 month period of observation, the individual mean plaque scores for all three groups reduced from 2.84 to 2.31 in homeopathic (H) group, 2.98 to 2.21 in chlorhexidine (AL) group and 2.80 to 2.26 (Ayurvedic A) group. Among 3 mouth rinses, allopathic mouth rinse showed maximum reduction and homeopathic mouth rinse showed least reduction of plaque.

Between 1 month and 2 months intervals, there is no much change observed with plaque scores among all the 3 mouth rinses. By using Kruskal Wallis one way ANOVA, it is observed that there is no significant difference among 3 mouth rinses at baseline ($P = 0.1084$), 1 month ($P = 0.2671$), and 2 months ($P = 0.453$) interval. prolonged usage.

Between baseline and 1 month, the mean gingival index scores also reduced from 1.72 to 1.25 homeopathic (H) group, 1.72 to 1.01 chlorhexidine (AL) group and 1.64 to 1.1. When comparing the adverse effects of various mouth rinses, it was found that 1 subject using homeopathic mouth rinses and 5 subjects using Ayurvedic (B- Fresh) mouth rinse experienced burning sensation of oral mucosa. Also in the Chlorhexidine Group 6 subjects complained of taste alteration while 4 subjects exhibited brownish discoloration of teeth and tongue.

Pair wise comparison of homeopathic, allopathic and ayurvedic groups concerning plaque scores showed that there is no statistical significant difference between homeopathic to allopathic, homeopathic to ayurvedic and allopathic to Ayurvedic A groups at baseline, 1 month & 2 months interval. Pair wise comparison of homeopathic, allopathic and ayurvedic groups concerning gingivitis showed that there is high statistically significant difference between homeopathic to allopathic at 1 month and 2 months, allopathic to ayurvedic at 1 month and homeopathic to ayurvedic at 2 months.

On comparing plaque scores of homeopathic mouth rinse at baseline, 1 month and 2 months, it was observed that there was a reduction in plaque scores from baseline to 1 month i.e., from 2.8451 to 2.3168 which is around (18.57 %). From baseline to 2 months the plaque reduction was 2.8451 to 2.4003 which is around (15.64 %) and from 1 month to 2 month it increased from 2.3168 to 2.4003 which is around (-3.60 %). This shows that from baseline to 1 month there is better reduction of plaque scores and between 1 month to 2 month there is increase in plaque scores.

When we compared gingival scores of homeopathic mouth rinse at baseline, 1 month and 2 months, it was observed that there is a reduction in gingival scores from baseline to 1 month i.e., from 1.72 to 1.25 which is around (27.04 %). From baseline to 2 months the plaque reduction was 2.84 to 2.40 which is around (24.52 %) and from 1 month to 2 month it increased from 2.3168 to 2.4003 which is around (-2.88 %). This shows that from baseline to 1 month there is better reduction of gingival scores, between 1 month - 2 months, there is again an increase in gingival scores. This shows plaque and gingival scores are following the same pattern between baseline to 1 month and 1 month to 2 months interval

When we compared plaque scores of allopathic mouth rinse at baseline, 1 month and 2 months, it was observed that there is a reduction in plaque scores from baseline to 1 month i.e., from 2.98 to 2.2194 which is around (25.76 %). From baseline to 2 months the plaque reduction was 2.98 to 2.29 which is around (23.07 %) and from 1 month to 2 month it increased from 2.21 to 2.29 which is around (-3.61 %). This shows that from baseline to 1 month there is better reduction of plaque scores, Between 1 month to 2 months, there is increase in plaque scores.

When we compared gingival scores of allopathic mouthrinse at baseline, 1 month and 2 months, it was observed that there is a reduction in gingival scores from baseline to 1 month i.e., from 1.712 to 1.01 which is around (40.62 %). From baseline to 2 months the plaque reduction was from 1.712 to 1.04 which is around (39.10 %) and from 1 month to 2 month it increased from 1.01 to 1.04 which is around (-2.88 %). This shows that, baseline to 1 month there is better reduction of gingival scores and there is an increase in gingival scores between 1 month and 2 months.

When we compared plaque scores of ayurvedic mouthrinse at baseline, 1 month and 2 months, it was observed that there is a reduction in plaque scores from baseline to 1 month i.e., from 2.80 to 2.26 which is around (19.16 %). From baseline to 2 months the plaque reduction was 2.80 to 2.28 which is around (18.56 %) and from 1 month to 2 month it increased from 2.27 to 2.28 which is around (-0.73 %). This shows that from baseline to 1 month there is better reduction of plaque scores and between 1 month and 2 month there is again increase in plaque scores.

When we compared gingival scores of ayurvedic mouth rinse at baseline, 1 month and 2 months, it was observed that there is a reduction in gingival scores from baseline to 1 month i.e., from 1.64 to 1.16 which is around (29.07 %). From baseline to 2 months the plaque reduction was 1.64 to 1.12 which is around (31.12 %) and from 1 month to 2 month again reduction of plaque from 1.16 to 1.1237 which is around (3.39 %). This shows that from baseline to 1 month there is better reduction of gingival scores and again from 1 month to 2 month there is reduction in gingival scores.

By observing the results of individual mouth rinses, we can infer that the plaque and gingival scores follow the same pattern for homeopathic and allopathic mouth rinses between baseline to 1 month & baseline to 2 months interval i.e., reduction of plaque and gingival scores between baseline to 1 month and a slight increase between 1 month to 2 months. But ayurvedic mouth rinse showed a consistent decrease of both plaque and gingival scores between baseline to 1 month and 1 month to 2 months interval.

CONCLUSION

1. All the 3 mouth rinses show a considerable reduction in both plaque and gingival scores between baseline to 2 months interval.
2. Allopathic mouth rinse shows a greater reduction of plaque and gingival scores followed by ayurvedic and homeopathic mouth rinses respectively.

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