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Efficacy Of *Prunus Pursica* On Plaque Accumulation And GingivalInflammation: A Double-Blind Clinical Trial.

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Abstract:

Background: Medicinal use of a plant's seeds, berries, roots, leaves, bark, or flowers is knownas herbal medicine, botanical medicine, or phytomedicine. The usage of herbs goes beyond the realm of traditional medicine, but this practice has a long history. Almost one fourth of pharmaceutical drugs are derived from botanicals. One such product is peach scientifically calledas "Prunus persica".
Aims: to evaluate the astringent and anti-inflammatory property of Prunus Persica in comparisonto chlorhexidine gel.

Settings and design: Randomized, Parallel Group Trial
Material and methods: The present research is a randomized control trial using mouth wash prepared from peach extract for a period of 28 days. The participants were given a random assignment to either the positive control group or the test group. A modified

version of the Quigley and Hein (1962) index developed by Turesky (1970) was used to provide a score to the amount of plaque. Following that, gingival inflammation was evaluated with the use of the

Gingival Index. Descriptive and inferential statistics were performed using SPSS, Post hoc

ANOVA, paired t and unpaired t test was used.

Results: When mean scores of gingival indices were compared for group 1 at baseline vs 14days, baseline vs 28 days, it was found to be statistically significant. In case of Quigley,

the plaque index significant difference was found only at baseline vs 28 days in both groups.

Conclusion: These studies revealed the anti-inflammatory effect of Prunus Persica by analyzing gingival condition before and after intervention. Statistically significant (<0.05) difference was seen by its regular usage. *Prunus Persica* has anti-allergic inflammatory properties via controlling calcium influx and NF-kB signaling.

Keywords: Anti-inflammatory, Plaque, Gingival inflammation.

1. Background

Medicinal use of a plant's seeds, berries, roots, leaves, bark, or flowers is known as herbal medicine, botanical medicine, or phytomedicine. The usage of herbs goes beyond the realm of traditional medicine, but this practice has a long history. Herbal medicine is gaining popularity as a result of advancements in analysis and quality control and clinical research demonstrating its efficacy in treating and preventing disease [1]. Almost one fourth of pharmaceutical drugs are derived from botanicals. One such product is peach scientifically called as "Prunus persica" is being derived from Persian area of Meditation which is Iran in today's time [2].

The Prunus persica tree are a rich source of many different nutrients necessary for human health. vitamin C (ascorbic acid) and Vitamin A, beta-carotene, are all found in abundance in peaches. As an added bonus, they are rich in essential nutrients like vitamin K (phylloquinone), vitamin E (alpha-tocopherol), vitamin B1 (thiamine), vitamin B3 (niacin), vitamin B2 (riboflavin), vitamin B-6, folate, and pantothenic acid [3].In addition, Prunus persica provides a plethora of essential minerals, including iron, calcium, manganese, potassium, magnesium, phosphorus, copper, and zinc. Prunus Persica have a low total number of calories, do not contain any saturated fat or cholesterol, and are an excellent source of dietary fiber [3].

Peaches can help people with cancer, hypokalemia, obesity, cholesterol, blood clotting, and neurological illnesses. It supports healthy bones, teeth, nervous system, and skin as well as healthy vision. It contains anti-aging qualities, aids in cleansing, enhances digestion, and promotes cellular health. It is rich in vital minerals and antioxidants that are beneficial during pregnancy and boost the immune system [4].

The antioxidant properties are very well accepted of Prunus Persica, but its anti-inflammatoryand astringent properties still need to be tested intraorally. With this aim the current study is being designed to evaluate the astringent and anti-inflammatory property of Prunus Persica in comparison to chlorhexidine gel.

2. Material and method:

The current investigation is a randomized controlled trial that was carried out over a period of one month utilizing a mouthwash that was made from peach extract. The participants in this study were undergraduate dentistry students who volunteered to participate. Prior to the beginning of the investigation, verbal and written details relating the study was provided to each of the subjects. In this study, every technique was carried out in a manner that was ethically sound and in accordance with the principles outlined in the Declaration of Helsinki.

Participants had to meet the following criteria in order to be included in the study: they had to be at least 18 years old, have at least 15 teeth, be in generally good health, and have an initial plaque score of at least 1.5.(Quigley and Hein [5], 1962, as improved by Turesky and colleagues [6], 1970, developed gingivitis considered as a baseline, provided by Loe and Silness [7], (1963) Gingival Index mean > 1.0.

Participants were excluded from the study if they had severe periodontal disease, which was determined by the presence of CPIT code four [8], were wearing braces, had taken antibiotics within the previous three months, or had regularly used mouthwashes containing chemicals in the previous three months.

Beta error of 0.2, a power of 90%, 20%Co-efficient of variation, 95% Confidence interval and 0.05% level of significance was set. Taking all of this information into consideration, the needed minimum number of sample subjects was 26.As a result, the sample size was raised to thirty after applying qualifying criteria and taking into consideration the unknowable mistakes caused by observers and instruments.

Subjects were randomly assigned to either the "positive control" group or "test" group. One of the authors, B, employed a table of random numbers in order to produce the random allocation sequence. The random allocation sequence was kept hidden from the primary researchers, and this knowledge was only shared with a single author. The author (A) was responsible forenrolling the subjects and performing initial oral health examinations for necessary selection criteria and performing oral prophylaxis. Allocation concealment and blinding were both under the author B's control throughout the study, who distribute the mouthwash in clear white bottles, referred as “group A and B” respectively. No one, including the researchers or the participants inthe study, was aware of what was contained in each bottle. After the duration of the experiment was complete, the author (B) disclosed what was contained within each bottle.

Collection of the sample

A sample was taken from the peach orchard, labelled with relevant information, and then delivered to the Department of Botany for examination. The samples that were finally approved for usage were put to use for this study.

Procurement and drying of the tree sticks, flowers, and leaves:

In India, there is a plethora of different kinds of peach trees. These trees' smaller branches were freshly cut. The leaves that were on the concerning branches that were procured were plucked, and immediately after that, the length of the branches that measured 4 inches was chopped. These chopped sticks were disinfected in a solution containing 2% povidone iodine and then rinsed in flowing water for approximately ten to fifteen minutes to remove any and all traces of extraneous contaminated material and dirt. The last rinse was performed with water that was distilled. These branches were dried under the sun by placing them on sheets of double-sided filter paper and exposing them to the rays. During the drying process, sticks were protected from contamination by being wrapped in filter paper. The sticks were allowed to dry until they had lost all of their moisture and had become brittle enough to be broken easily. They were kept in containers throughout the process.

Preparation of peach extract powder:

Following the drying process, the sticks were split into small pieces using a branch cutter, and then they were crushed into a powder using a Kenstar high-speed electric grinding machine for a period of fifteen minutes. After that, the powder was placed in sterile plastic containers that had lids and were airtight. After finishing the process of making the powder, the electric mixer was given a thorough cleaning with distilled water before being dried completely. In the end, the powder container that was obtained was stored in a dry and cool environment until further use. The maceration process was carried out at a cold temperature. Using an electronic scale known asa Digi weigh, we measured out 50 g of the acquired powder and stored it in clean containers. Ameasuring jar was used to add enough sterile deionized distilled water to the containers so that the final volume was 100 ml. After shaking the container for five minutes by hand, the powder

and water were completely mixed. The container was then chilled to 4 degrees Celsius in the refrigerator. The mixture was placed in the refrigerator and let to soak for 48 hours at 4°C. The mixture was then filtered by filter paper after 48 hours. To create the finished mouthwash, a sweetening ingredient (2% sorbitol, code E955), a preservative (0.01% sodium methyl paraben, code 218), and peppermint for aroma were added.

All of the participants were given little plastic bottles with markings ranging from 5 to 100 millilitres, and they were instructed to rinse their mouths with 10 millilitres of mouthwash twicea day for a period of 28 days. Every participant received a total of 140 millilitres (ml) of the finished solution to use at their own homes on a weekly basis. Before the beginning of the intervention, all of the participants were given the instruction to gargle for a duration of thirty seconds twice a day, in the morning and before going to bed, and to refrain from consuming anything for a period of at least thirty minutes after gargling. At several points along the process, positive reinforcement was provided.

The volunteers who participated in the test were given mouthwash that included peach extract. Chlorhexidine-containing mouthwash was administered to the participants in the control group. The author (B) provided a unique identification number and detailed schedule for recall to all theparticipants on the first day itself.

Plaque was highlighted on the participants by applying an erythrosine-based stain with cotton swabs. A modified version of the Quigley and Hein [6] (1962) plaque index developed by Turesky in 1970 [5] and used to assign a score to the amount of plaque that was present in the sample. The gingival index was then used to evaluate the level of gingival inflammation (GI)[7] which measures the redness and swelling of the gums. The investigators, C and D, who had been calibrated in beforehand, carried out all of the measurements themselves.

Five patients were subjected to repeated inter-examination calibration under the watchful eye of the aforementioned author E until 80% agreement was reached. Subjects were given mouthwash based on their scores for plaque and gingivitis and were instructed to use it wisely and return to the lab on a regular basis so that the bottles could be checked for replacement and the material could be used effectively.

In order to prevent any sort of bias on the part of the investigator, the participants returned to the clinic after 28 days to have their plaque and gingival inflammation levels reassessed using afresh scoring form and a new, randomly assigned participant number. Participants were asked to return their used mouthwash tubes so that researchers could ensure they were using the prescribed amount. Participants were also questioned on the incidence of side effects such altered taste perception, mucosal sensitivity, and so on.

Statistical analysis:

Descriptive and inferential statistics were performed using SPSS 23.0 for Windows, Post hoc ANOVA, paired t and unpaired t test was used.

3. Results:

Table 1 represents the demographic characteristics of study population. In the present study 54.5% and 51.5% of the participants in the study group and control group respectivelywere females. The mean age of the participants was 20.33 ± 1.44, 20.35 ± 1.47 in the study and control group respectively.

Table 1: Demographic characteristics of study population

Groups	**Age (Mean ± SD)**		**Gender**			
	Mean	**SD**	**Male**		**Female**	
			N	**%**	**N**	**%**
Group 1(Peach mouth wash)	20.33	1.44	12	45.5	18	54.5
orohexidine mouthwash)	20.35	1.47	13	48.5	17	51.5

Table 2 showed the mean scores of different indices at baseline i.e., before intervention.The mean gingival index at baseline for study group and control group was 1.34 ± 3.60 and

1.67± 0.40 respectively. When mean gingival index and Quigley hein plaque index were compared statistically between group 1 and 2, it was found to be statistically insignificant.

Table 2: Baseline values of different indices before intervention

Variables	**Group 1**		**Group 2**		**t test**	**p value**
	Mean	**SD**	**Mean**	**SD**		
Gingival Index	1.34	3.60	1.67	0.40	0.51	0.61
Quigley hein plaque Index	1.78	4.18	1.69	0.46	0.12	0.90

Table 3 represents the values of different indices at 14 days and 28 days. It was observed

that when mean intragroup scores of gingival index and Quigley hein plaque index were compared statistically between 14 and 28 days, it was found to be statistically significant only in Group 2.

Table 3: Values of different indices at different time intervals post intervention

Variables	**Group 1**				**Group 2**			
	After 14 days		**fter 28days**		**After 14 days**		**After 28 days**	
	lean	**SD**	**lean**	**SD**	**lean**	**SD**	**lean**	**SD**
Gingival Index	0.81	2.18	0.64	1.77	1.24	0.41	0.99	0.39
Paired t test#	0.31				2.41			
p value	0.75				0.02*			
Quigley hein plaque Index	1.02	2.76	0.75	2.05	1.33	0.45	1.03	0.37
Paired t test#	0.42				2.81			
p value	0.67				<0.01*			

* - Statistically significant, # - In comparison to baseline data

The comparison of the mean scores of different indices within each group is shown in Table 4, which covers baseline, 14 days, and 28 days. When ANOVA test was applied to compare the mean values for gingival index at different time intervals in group 1, it was found to be statistically non-significant, whereas it was found to be statistically significant in group 2. Similar results were seen in case of Quigley Hein plaque index. Post hoc test was also applied forintragroup comparison of the gingival and Quigley hein plaque index i.e. baseline vs 14 days, baseline vs 28 days and 14 days vs 28 days. When mean scores of gingival indices werecomparedfor group 1 at baseline vs 14 days, baseline vs 28 days, it was found to be statistically significant. Similar results were found for group 2. In case of Quigley hein plaque index significant difference was found only at baseline vs 28 days in both groups.

Table 4: Intragroup comparison of the different indices at different time intervals

		Group 1			**Group 2**		
Gingival Index							
Anova test		15.29			11.63		
p value		0.74			< 0.01		
Tukey HSD post hoc	line vs 14days	Mean diff	CI U/L	p value	Meandiff	CI	p value
		0.53	0.52/0.32	0.03*	0.43	0.56/0.07	0.02*
	line vs 28days	0.70	0.44/0.23	0.01*	0.68	0.81/0.32	<0.00*
	ays vs 28days	0.17	0.80/0.59	0.16	0.25	0.49/0.004	0.08
Quigley hein plaque Index							
Anova test		0.44			16.42		
p value		0.64			< 0.01*		
Tukey HSD post hoc	ine vs 14day	Mean diff	CI	p value	Meandiff	CI	p value
		0.74	0.62/0.18	0.65	0.36	0.78/0.61	0.08
	line vs 28days	1.03	0.75/0.32	<0.01*	0.66	0.91/0.37	<0.01*
	ays vs 28days	0.59	0.35/0.08	0.27	0.30	0.28/0.56	0.26

* - Statistically significant

Table 5 revealed the intergroup comparison of different indices at different intervalsbetween group 1 and group 2. When mean scores of gingival index at 0 - 28 days was compared

statistically between group 1 and 2, it was found to be statistically significant.

Table 5: Intergroup comparison of mean difference of different indices at different intervals

	Group 1 (0-14 days)		**Group 2 (0-14 days)**		**Group 1 (14-28 days)**		**Group 2 (14-28 days)**		**Group 1 (0-28 days)**		**Group 2 (0-28 days)**	
	Mean diff	**SD**	**Mean diff**	**SD**	**Mean diff**	**SD**	**Mean diff**	**SD**	**Mean diff**	**SD**	**Mean diff**	**SD**
Gingival Index	0.53	1.4	0.43	0.01	0.17	0.41	0.25	0.01	0.70	1.89	0.68	0.005
t test#	0.38				1.22				0.02*			
p value	0.70				0.22				0.97			
Quigley Hein Plaque Index	0.74	2.05	0.36	0.01	0.59	0.70	0.36	0.07	1.03	2.7	0.64	0.09
t test#	1.13				0.27				0.79			
p value	0.26				0.78				0.43			

* - Statistically significant; # - Unpaired t test

4. Discussion:

The presence of dental biofilm in the mouth plays a significant role in the pathogenesis oforal disorders, which can have far-reaching effects on overall health and quality of life.

According to Chaves et al. (2000) and Golub et al. (2001), conventional mechanical periodontal treatment does not typically completely eradicate the Periodontopathic bacteria. This is due to the fact that sites such as grooves, periodontal pockets, concavities and furcations, are difficult areas for periodontal instruments to access. As a result of this, a number of different therapy approaches have been suggested and researched in order to battle and regulate periodontal bacteria. Therefore, antimicrobial compounds in the form of mouthwash can be

utilised as adjuvants in an effort to compensate for these challenges[9].

The use of an antimicrobial mouthwash has been linked to better gingival health and plaque control by removing plaque from difficult places of the teeth[10].

When it comes to eliminating dental plaque over time, chlorhexidine-based mouthwasheshave long been deemed superior to other options. However, it is generally accepted that it has negative effects, such as staining teeth, high alcohol content, and altered taste perceptions. Since it has such drawbacks, it can only be used temporarily[10].

Oral disorders, particularly periodontal diseases, have been treated with medicines derived from the Ayurvedic tradition. In periodontal therapy, oral rinses containing herbal content are used to decrease plaque and inflammation in the gums and mouth.Herbal mouthwashes, such the ones recommended by Dalirsani et al., Anupama et al., provide benefits like less side effects and lower costs than chlorhexidine[11].As a result of this, we decided to investigate the effect of Prunus persica on gingival health with its regular consumption.

It is well documented that *Prunus Persica* have anti-inflammatory property. The study conducted by Shin TY showed that flower of *Prunus Persica* has anti-allergic inflammatory properties via controlling calcium influx and NF-kB signaling [12]. Another study by GasparottoJ showed significant reduction in Tumor necrosis factor-α and interleukin-1β in fresh peach pulp

and peels [13]. By documenting the gingival state both before and after the intervention, our research was able to demonstrate that Prunus persica has an anti-inflammatory effect. Its consistent usage produced a difference that was statistically significant ($p<0.05$).

Although Prunus persica's astringent activity has been described, no comparable study assessing the property when taken orally has been done. Results from our study corroborated previous research showing that Prunus Persica has potent astringent properties, as measured by a significant reduction in bleeding scores.

Conclusion:

In spite of the fact that the participants who volunteered for this study were dental students, it is possible that the Hawthorne effect played a significant role in the findings of the study. This study provided substantial evidence that Prunus persica is effective at preventing the formationof plaque. This suggests that it can be utilized effectively and exclusively. As a result, it has been suggested that lobbying efforts could be organized to magnify the use of Prunus Persica based on the data of the current experiment, particularly in nations where there are budgetary limits and constrained oral health-care services for the general population.

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