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COMPARATIVE EFFECTS OF COMMERCIALLY AVAILABLE ALLOPATHIC AND AYURVEDIC COUGH SYRUPS ON SALIVARY PH AMONG YOUNG ADULTS: A RANDOMIZED CONTROLLED CLINICAL TRIAL.

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ABSTRACT

BACKGROUND:
Cough syrups, whether herbal or allopathic, are commonly sugar-based acidic liquids. These formulations have the potential to cause dental issues such as erosion of teeth, increased plaque attachment on tooth surfaces, and, subsequently, a higher incidence of dental caries. The aim of the present study is to compare and evaluate the effects of different commercially available cough syrups on the salivary pH of young adults.

AIM AND OBJECTIVES:
The primary goal of this study is to assess and contrast the impact of commercially accessible cough syrups, both those containing sugar and those without, on the salivary pH levels of young adults.

MATERIALS AND METHODS:
In this randomized controlled clinical study, 60 participants were included, either prescribed cough syrups or self-medicating. The total number of 12 cough syrups were divided into 2 groups, Group A and Group B. Group A - sugar containing cough syrup, Group B - Sugar free cough syrup. Saliva samples were collected at four intervals: before consumption, immediately after consumption, and at

10 and 30 minutes post-consumption of the respective cough syrup. Salivary pH levels were assessed using a Vanira LI613 digital pH meter.

RESULTS
After the ingestion of cough syrup across all groups, there was an immediate decrease in salivary pH, followed by a gradual increase at 10- and 30-minute intervals. These changes were statistically significant ($p<0.05$). The salivary pH in sugar-containing cough syrup groups was lower at all time intervals compared to the sugarfree groups, and the salivary pH variations was dependent on the time factor, and was not influenced by the presence or absence of the sugar in the cough syrup or the medication type i.e. herbal or allopathic.

CONCLUSION:
In order to address potential future complications, it is crucial to increase awareness among the general public, healthcare professionals, and pharmaceutical vendors about the oral health hazards linked to extended use of cough syrup.

KEYWORDS:
Cough syrup, Salivary pH, Sugar content, Allopathic cough syrup, Ayurvedic cough syrup, Dental caries

INTRODUCTION

Over the past decade, there has been a steady increase in the prevalence of "over-the-counter (OTC) medicine" usage. [1] Though self-medication is unsafe, OTC drugs for fever, headache, cold, cough, pain, indigestion, or heartburn are commonly bought by the population. [2] It must be emphasized that during and following COVID-19 pandemic outbreak, the usage of OTC drugs for colds and coughs has increased. This was because minor COVID cases were treated at home, and panicked individuals avoided visiting a hospital to prevent exposure to crowds. [3]

Cough syrups, both herbal and allopathic preparations, are the preferred medication for coughs, followed by cough drops or lozenges. [3] The cough syrups are mostly sugar based acidic liquids. The sugars, mainly sucrose and saccharin, are added in these pharmaceutical preparations to increase their palatability. The high sugar content and acidic liquid of the cough syrup preparation can cause tooth erosion, an increase in plaque attachment to the tooth surface, and subsequently an increased incidence of dental caries. [4, 5]

Various studies have reported 20.62% to 68.26% of sugar in the liquid pharmaceutical formulations. The salivary pH ranged from 3.82-5.44 in their study. [4-8] In recent years, sugar free cough syrups and herbal cough syrup preparations have also gained popularity among the Indian population. There is not sufficient literature to substantiate whether the sugar free cough syrup preparations have decreased changes in the oral environment compared to the sugar containing cough syrups.

Also, no studies have compared and evaluated the salivary pH following consumption of sugar containing and sugar free herbal cough syrup. As dental health professionals, it is necessary to evaluate and correlate the ingestion of cough syrup with oral health imbalances. The present study focuses on these lacunae and aims to evaluate and compare the effects of commercially available cough syrups (Sugar containing and sugar free) on the salivary pH of young adults.

MATERIALS AND METHODS

Study design, setting, and duration:

A randomized controlled clinical trial was conducted in ACPM Dental College in Dhule, Maharashtra state over a duration of one week. The study recruited college students who lived in the hostel. Using simple random sampling, participants were allocated into different groups. Institutional Ethics Committee approval was obtained before the study commenced.

Study population:
The study included a total of 60 patients who had been prescribed cough syrups or were using them as self-medication. The total number of 12 cough syrups were divided into 2 groups, Group A and Group B. Group A- sugar containing cough syrup and Group B- sugar free cough syrup. These 12 cough syrups were commercially available brands (Cough syrup 1 to 12). The cough syrups 1, 2, 3, 7, 8, and 9 were sugar-containing cough syrups, whereas syrups 4, 5, 6, 10, 11, and 12 were sugar-free cough syrup preparations. Notably, syrup 1 to 6 were ayurvedic preparations, while syrup 7 to 12 were allopathic cough syrups. (Fig 1)

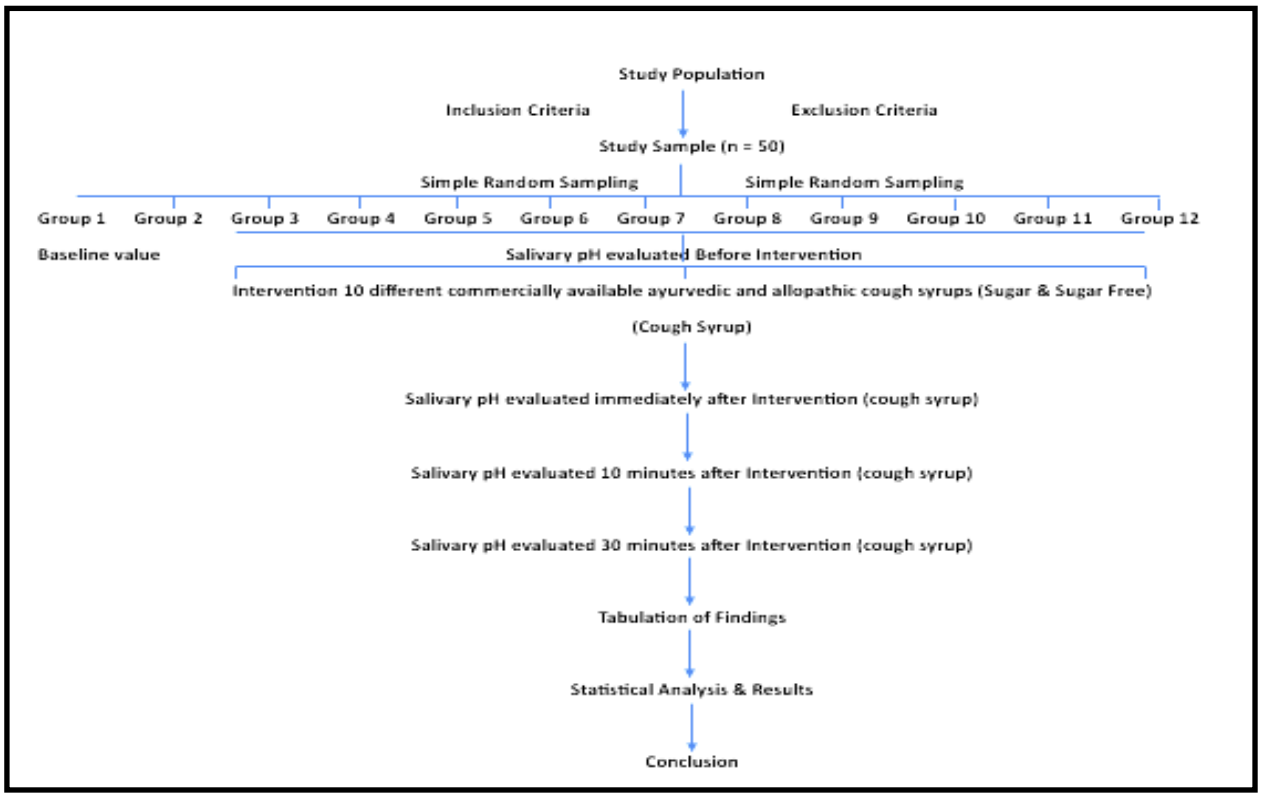


Figure 1: Overview of the study

Randomization and allocation:
"The table of random" method was followed for allocation of participants. Two investigators were intended for the study in which one of them is the principal investigator and the other investigator is the outcome assessor. The outcome assessor was blinded.

Selection Criteria:
Eligible participants meeting all inclusion criteria and none of the exclusion criteria, and who consented by signing an informed consent form (ICF) prior to the study, were included.

Inclusion Criteria:
1. Hostel resident students who have been prescribed cough syrups by practitioners or are self-medicating for their upper respiratory tract infection (URTI) symptoms. These may include

symptoms such as coughing, sore throat, nasal congestion, or fever indicative of an URTI. This includes individuals actively using cough syrups as part of their treatment regimen.
2. Hostel resident students who are voluntarily consenting to be a part of the study. This indicates their willingness to participate in research activities related to their URTI and cough syrup usage.

Exclusion Criteria:
1. Hostel resident students who are suffering from long-standing chronic respiratory illnesses such as chronic obstructive pulmonary disease (COPD), or major illnesses such as tuberculosis (TB), bronchial asthma, or other severe respiratory conditions. This exclusion ensures that the study focuses specifically on URTI cases rather than chronic or severe respiratory diseases.
2. Hostel resident students who are on any other liquid-based medications apart from cough syrups for an extended period. This criterion ensures that participants are not concurrently using medications that might confound the study results or interfere with the assessment of cough syrup efficacy for URTI symptoms.
3. Individuals with habit of Smoking and alcohol were excluded

Study procedure:
Saliva was collected at three different intervals: before, immediately after, after 10 minutes, and 30 minutes after the cough syrup consumption. Salivary pH levels were assessed with Vanira LI613 digital pH meter. (Fig 2)

Figure 2: Salivary pH evaluation from the salivary samples at three different intervals (a) immediately after cough syrup consumption; (b) after 10 minutes; (c) after 30 minutes

Statistical analysis:
The collected data was compiled into a Microsoft Office Excel worksheet and then subjected to statistical analysis using SPSS software.

RESULTS
On comparing the salivary pH among sugar-free and sugar-containing syrups, it is evident that the salivary pH in sugar-containing cough syrup groups was lower at all time intervals compared to the sugar-free groups. (Table 1).

Table 1; Descriptive details of salivary pH among sugar free and sugar-containing syrups

Group	Interval	Mean	SD
Group A- Sugar free	**Baseline**	4.68	0.40

	Immediate	2.08	0.67
	10 minutes	3.72	0.53
	30 minutes	4.71	0.42
Group B- Sugar containing	**Baseline**	4.64	0.33
	Immediate	1.77	0.52
	10 minutes	3.56	0.52
	30 minutes	4.82	0.48

Upon assessing the interaction between sugar-free and sugar-containing cough syrups and the duration of time on salivary pH, a statistically significant difference was observed solely in the time variable, regardless of whether the syrups were sugar-containing or sugar-free. (Table 2 and table 3)

Table 2: Assessment of the effect of the interaction of sugar-free and sugar-containing cough syrups and time duration on salivary pH

Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Sugar content	0.585	1	0.585	1.078	0.308
Error (Sugar content)	15.735	29	0.543		
Time	311.421	3	103.807	538.295	<0.001*
Error (Time)	16.777	87	0.193		
Sugar content * Time	1.405	3	0.468	2.506	0.064
Error (Sugar content *Time)	16.257	87	0.187		

Two-way Repeated measures ANOVA test; * indicates a significant difference at $p \leq 0.05$

Table 3: Estimated marginal means of salivary pH for sugar-free and sugar-containing cough syrups

Syrup	**Mean**	**Std. Error**	**p-value**
sugar-free cough syrup	3.798	0.058	0.308
sugar-containing cough syrups	3.699	0.059	

Adjustments for multiple comparisons: Bonferroni test

Estimation of marginal means of salivary pH for different periods reveals that the mean salivary pH at immediate period was less than all time period, and salivary pH at 10th minute was lesser than baseline and 30 minutes but higher than immediate interval. (Table 4)

Table 4: Estimated marginal means of salivary pH for different periods

Interval	Mean	Std. Error	Pairwise comparison
Baseline	4.664	0.053	Baseline > Immediate, 10mins; Baseline = 30 mins Immediate < Baseline, 10 minutes, 30 minutes 10mins < Baseline, 30 mins; 10 mins > Immediate 30 minutes equals baseline; 30 minutes exceeds immediate; 10 minutes
Immediate	1.928	0.080	
10 mins	3.641	0.043	
30 mins	4.761	0.055	

Adjustments for multiple comparisons: Bonferroni test; * indicates a significant difference at $p \leq 0.05$

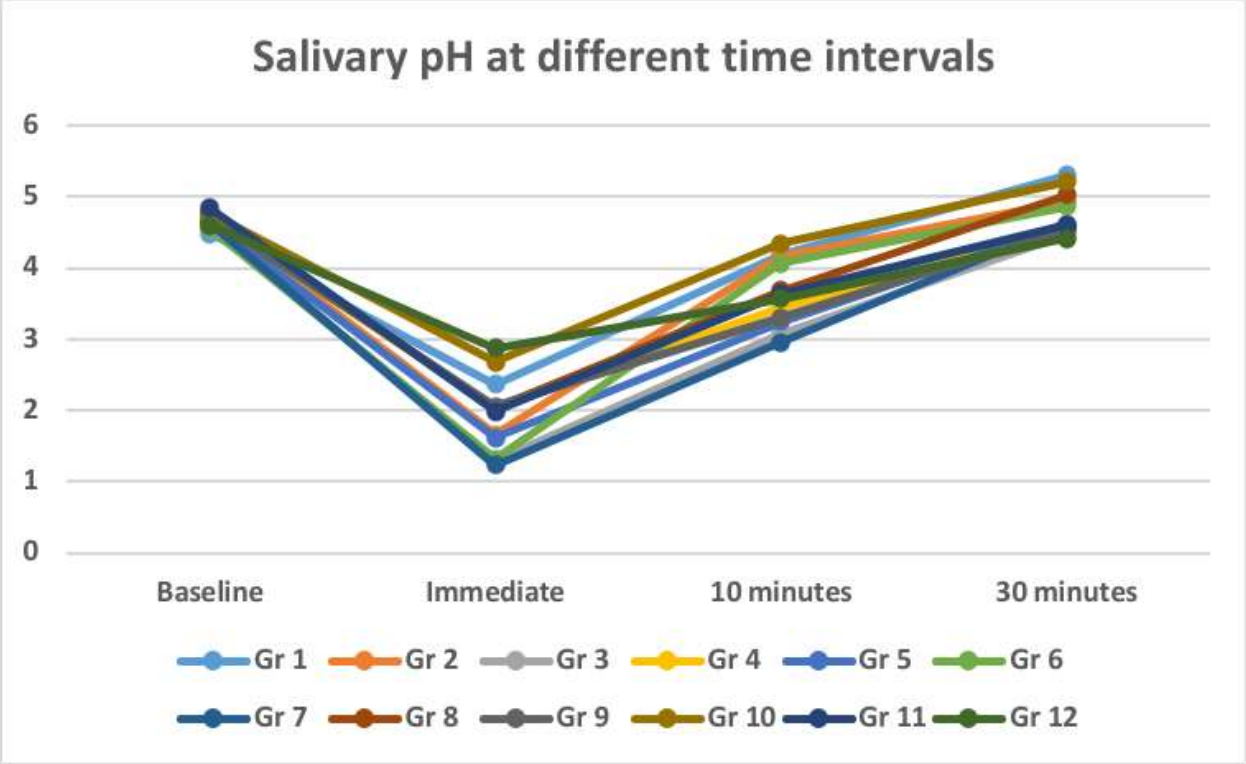
Table 5; Intragroup and intergroup comparison of salivary pH between the Cough syrups in the subgroups of group I and group II

Group	Baseline		Immediate		10 minutes		30 minutes		p-value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Syrup 1 (n=5)	4.48	0.38	2.37	0.20	4.19	0.07	5.31	0.18	<0.001*
Syrup 2 (n=5)	4.73	0.66	1.66	0.36	4.16	0.06	4.94	0.35	<0.001*
Syrup 3 (n=5)	4.57	0.19	1.30	0.57	3.08	0.22	4.46	0.46	<0.001*
Syrup 4 (n=5)	4.69	0.48	2.04	0.46	3.45	0.34	4.54	0.34	<0.001*
Syrup 5 (n=5)	4.64	0.62	1.61	0.32	3.25	0.25	4.60	0.33	<0.001*
Syrup 6 (n=5)	4.57	0.21	1.31	0.14	4.07	0.26	4.87	0.40	<0.001*
Syrup 7 (n=5)	4.63	0.15	1.23	0.02	2.96	0.15	4.62	0.56	<0.001*

Syrup 8 (n=5)	4.77	0.14	2.03	0.33	3.68	0.11	5.03	0.25	<0.001*
Syrup 9 (n=5)	4.69	0.22	2.05	0.34	3.30	0.22	4.53	0.52	<0.001*
Syrup 10 (n=5)	4.76	0.46	2.68	0.58	4.35	0.13	5.21ii	0.23	<0.001*
Syrup 11 (n=5)	4.84	0.05	1.98	0.39	3.64	0.77	4.60	0.47	0.001*
Syrup 12 (n=5)	4.60	0.48	2.87	0.43	3.57	0.33	4.41	0.31	<0.001*
p-value	0.969		<0.001*		<0.001*		0.003*		

Repeated measures ANOVA test; One-way ANOVA test; * indicates a significant difference at $p \leq 0.05$

Graph 1; Salivary pH among all subgroups at different time period



Intergroup and intragroup of the salivary pH are summarized in table 5 and- graph 1. In all groups, the salivary pH decreased immediately after cough syrup consumption and gradually increased after 10 and 30 minutes, which was statistically significant ($p<0.05$). The higher reduction of salivary pH was noted in syrup 7, followed by syrup 6, syrup 3 and syrup 5, while the lesser reduction of salivary

pH was noted in syrup 12, followed by syrup 10, and syrup 1. A statistically significant difference was noted immediately, after 10 minutes, and after 30 minutes ($p<0.05$).

Statistically significant differences were observed between the baseline and immediate time intervals across all subgroups. However, between baseline and the tenth minute, a statistically significant difference was obtained in syrup 3, 8, 9, and 12. A statistically significant difference was obtained between baseline and 30 minutes time interval only in syrup 1. (Table 6)

Table 6; Pairwise comparison of salivary pH at different time intervals within each subgroups of group I and group II

Group	Baseline vs Immediate	Baseline vs 10mins	Baseline vs 30mins
Syrup 1 (n=5)	0.002*	0.740	0.030*
Syrup 2 (n=5)	0.005*	0.814	1.000
Syrup 3 (n=5)	0.003*	0.003*	1.000
Syrup 4 (n=5)	0.014*	0.069	1.000
Syrup 5 (n=5)	0.001*	0.073	1.000
Syrup 6 (n=5)	<0.001*	0.072	1.000
Syrup 7 (n=5)	<0.001*	0.001*	1.000
Syrup 8 (n=5)	0.001*	0.002*	1.000
Syrup 9 (n=5)	<0.001*	0.003*	1.000
Syrup 10 (n=5)	0.012*	0.707	0.748
Syrup 11 (n=5)	0.001*	0.163	1.000

Syrup 12 (n=5)	0.003*	0.022*	1.000

Post hoc Bonferroni test; * indicates a significant difference at p≤0.05

An interaction effect of different cough syrups on salivary pH at different time intervals are summarized in table 7. A statistically significant result was obtained in the effects of different cough syrup on salivary pH, duration or time interval correlating the salivary clearance to the salivary pH and combination interaction of effects of different cough syrup and time interval on the salivary pH. (Table 7)

Table 7; Assessment of the effect of the interaction of different cough syrups and time duration on salivary pH

Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**p-value**
Group	15.763	11	1.433	9.291	<0.001*
Error (Group)	6.786	44	0.154		
Time	311.421	3	103.807	1569.375	<0.001*
Error (Time)	0.794	12	0.066		
Group * Time	17.228	33	0.522	4.198	<0.001*
Error (Group*Time)	16.418	132	0.124		

Two-way Repeated measures ANOVA test; * indicates a significant difference at p≤0.05

Syrup 3 and 11 demonstrated a statistically significant reduction in salivary pH when considering the marginal means across different syrups, after eliminating the effect of time on pH. Notably, syrup 11 exhibited a higher mean pH compared to syrup 3. (Table 8)

Table 8; Estimated marginal means of salivary pH for different syrups

Syrup	**Mean**	**Std. Error**	**Pairwise comparison**
Syrup 1	4.088	0.072	Gr 3 < Gr 11
Syrup 2	3.872	0.086	
Syrup 3	3.353	0.109	
Syrup 4	3.680	0.109	
Syrup 5	3.524	0.137	
Syrup 6	3.705	0.044	

Syrup 7	3.360	0.063	
Syrup 8	3.879	0.058	
Syrup 9	3.643	0.076	
Syrup 10	4.250	0.105	
Syrup 11	3.766	0.092	
Syrup 12	3.864	0.123	

Adjustments for multiple comparisons: Bonferroni test; * indicates a significant difference at p≤0.05

A statistically significant result of salivary pH with respect to different time intervals was noted. The mean salivary pH at the immediate period was less than all other time periods, and the salivary pH at the 10th minute was less than baseline and 30 minutes but higher than the immediate interval. (Table 9)

Table 9; Estimated marginal means of salivary pH for different syrups

Interval	Mean	Std. Error	Pairwise comparison
Baseline	4.664	0.053	Baseline > Immediate, 10 minutes; Baseline = 30 minutes Immediate < Baseline, 10 minutes, 30 minutes 10mins < Baseline, 30mins; 10mins > Immediate 30 mins= Baseline; 30 mins > Immediate, 10mins
Immediate	1.928	0.052	
10 mins	3.641	0.029	
30 mins	4.761	0.059	

Adjustments for multiple comparisons: Bonferroni test; * indicates a significant difference at p≤0.05

DISCUSSION

The utilization of over-the-counter (OTC) cough syrup for colds and coughs is widespread, particularly in developing countries like India. It's noteworthy that in India, the term "OTC" lacks legal recognition.[1] "OTC" cough syrup usage is widely accepted as it is effective, relatively inexpensive, and barely has any side effects. [2-3]

To enhance palatability and improve acceptance, sugar is often incorporated into cough syrup formulations. Additionally, to augment the taste-masking efficacy of sweeteners, acids such as citric acid or sugar alcohols like lactitol, maltitol, and sorbitol are commonly included. [4]

Numerous studies have indicated sugar content ranging from 20.62% to 68.26% and salivary pH levels between 3.82 and 5.44 in liquid pharmaceutical formulations. [4-8] In our study, after the ingestion of cough syrup, a notable decline in salivary pH was noted at the tenth minute, followed by a gradual return to baseline levels after 30 minutes. These observations are consistent with the findings reported by Dave et al. [5]

The elevated sugar content in cough syrup contributes to the onset of dental caries, while the acidic oral environment facilitates the demineralization of dental hard tissues. [10, 11, 13]

In the present study, the salivary pH was lower in sugar free cough syrups compared to sugar containing cough syrups. The non fermentable sugars such as sucralose, sorbitol, aspartame, and saccharin are major ingredients in sugar free cough syrups.[8-10] An in-vitro study reported that "sugar-free" cough drops containing a mixture of Isomalt and sorbitol as sweetener, caused a drop of salivary pH and subsequently were sufficient to demineralize the enamel. [9]

It's important to highlight that in the results of our study, the salivary pH in sugar-containing cough syrup groups was lower at all time intervals compared to the sugarfree groups, and the salivary pH variations was dependent on the time factor, and was not influenced by the presence or absence of the sugar in the cough syrup or the medication type i.e. herbal or allopathic. Notably, even the sugar-free syrups showed a substantial reduction in pH. These findings indicate that regardless of whether the cough syrup contains sugar or is sugar-free, and irrespective of its medical composition, all the cough syrups altered the oral environment, inducing acidity.

In a recent study, it was found that 60% of pediatricians were unaware of the sweetness of prescribed medications, and, even if they knew about the sugar content, strikingly 90% did not provide oral health instructions. Consequently, it is imperative for pediatricians and pedodontists to educate parents about oral hygiene maintenance and ensure adequate oral clearance after each medication dose. This proactive approach is essential for minimizing the risk of dental caries. [4]

As dental health professionals, it is imperative to raise awareness among the general public, healthcare providers, and pharmaceutical retailers regarding the potential risks to oral health associated with the prolonged use of cough syrup.

Several measures can be taken to prevent or reduce the future complications in oral health of long-term use of cough syrups. They are; 1) Recommending medications in tablet form or dispersible Tablet form; 2) Brushing with toothpaste after consumption of cough syrups; 3) Avoiding consumption of the medicine before bed; 4) chewing sugar-free gum after consumption of cough syrups; 5) Consuming syrups at meal time and avoiding between meals; 5) Regular preventive dental care. [5-10]

It should be carefully considered whether the sugar free cough syrup can actually decrease the incidence of dental caries. Further studies should be performed from this perspective. Also, there are no studies evaluating the changes in salivary pH in the herbal cough syrup. In the future, it's advisable to conduct studies on herbal cough syrup preparations, considering the equal acceptance of herbal medications in the Indian pharmaceutical market, particularly for addressing conditions such as colds and coughs.

CONCLUSION

The noteworthy findings of the present study are that all cough syrups altered the oral environment making them acidic and thereby there may be increased incidence of caries if used for long-time. To prevent potential future complications, it's crucial to increase awareness among the general public, healthcare providers, and pharmaceutical retailers about the dangers of oral health imbalances linked to extended use of cough syrup.

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