



ISSN NO. 2320-5407

Journal Homepage: - www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/2605
DOI URL: <http://dx.doi.org/10.21474/IJAR01/2605>



INTERNATIONAL JOURNAL OF
ADVANCED RESEARCH (IJAR)
ISSN 2320-5407
Journal homepage: <http://www.journalijar.com>
Journal DOI: 10.21474/IJAR01

RESEARCH ARTICLE

A RANDOMISED CONTROLLED TRIAL OF CLINICAL EFFICACY BETWEEN A PROBIOTIC AND A CHLORHEXIDINE MOUTH RINSE.

Dr. R. Prasaanthini Varun¹, Dr. C. Vishnu Rekha², Dr. Varun Ramamurthy³, Dr. Sankar Annamalai⁴, Dr. Ditto Sharmin⁴ and Dr. Parisa Norouzi Baghkomeh⁵.

1. Post graduate student, Department of Pediatric and Preventive Dentistry, Meenakshi Ammal Dental College, Chennai, Tamil Nadu, India.
2. Professor and Head of the Department, Department of Pediatric and Preventive Dentistry, Meenakshi Ammal Dental College, Chennai, Tamil Nadu, India.
3. Assistant Professor, Department of Anesthesiology, Saveetha Medical College, Saveetha University, Chennai, Tamil Nadu, India
4. Reader, Department of Pediatric and Preventive Dentistry, Meenakshi Ammal Dental College, Chennai, Tamil Nadu, India.
5. Senior Lecturer, Department of Pediatric and Preventive Dentistry, Meenakshi Ammal Dental College, Chennai, Tamil Nadu, India.

Manuscript Info

Manuscript History

Received: 28 October 2016
Final Accepted: 27 November 2016
Published: December 2016

Key words:-

Chlorhexidine, Gingival bleeding index, Mouth rinse, Oral hygiene, Plaque index, Probiotic.

Abstract

Background: With the increasing antibiotic resistance of bacteria, new methods such as whole bacteria replacement therapy for decreasing oral cavity pathogens are needed.

Aim: To clinically compare the efficacy of a Probiotic mouth rinse to a Chlorhexidine mouth rinse on the level of plaque accumulation and gingival inflammation.

Methods: Sixty children, between 6 and 8 years of age, with a similar baseline scoring of Plaque index and Sulcus bleeding index were given a thorough oral prophylaxis and oral hygiene instructions. They were then divided into two groups: Group 1: Probiotic mouth rinse group and Group 2: Chlorhexidine mouth rinse group. On the 14th day all the participants were recalled for re-examination of the level of plaque accumulation and gingival inflammation.

Results: Probiotic mouth rinse group had a statistically lower plaque and gingival bleeding index on the 14th day as compared to the baseline.

Conclusion: Probiotic mouth rinses can also be considered as one of the effective regimens in maintaining oral hygiene.

Copy Right, IJAR, 2016., All rights reserved.

Introduction:-

The unfortunate development of antibiotic resistance, with the emergence of multiple-resistant strains has led scientists to seek other means of combating infectious diseases.¹

Chemical agents have been traditionally used as an adjunct to mechanical plaque control, of which Chlorhexidine gluconate is the most widely and effectively used anti plaque & anti gingivitis agent so far. Going along with the

Corresponding Author:- Dr. R.Prasaanthini Varun.

Address:- Post graduate student, Department of Pediatric and Preventive Dentistry, Meenakshi Ammal Dental College, Chennai, Tamil Nadu, India.

increasing antibiotic resistance of bacteria, new methods such as whole bacteria replacement therapy for decreasing oral cavity pathogens is the need of this era.⁴

The World Health Organization in 2001 defined probiotics as "live micro-organisms which, when administered in adequate amounts, confer a health benefit on the host".² Probiotics have proved to inhibit plaque formation by lowering the salivary pH and producing antioxidants which utilize the free electrons required for mineralization of plaque. Plaque associated bacteria is unable to form plaque in this new condition, therefore, indirectly helping to prevent periodontal diseases.³

Probiotics have an amazing potential for not only preventing the attack of oral pathogens but also the ability to treat various oral diseases, thereby, assuring healthy living and increased longevity.¹

The aim of this study was to clinically compare the efficacy of a Probiotic mouth rinse to that of a Chlorhexidine mouth rinse on the level of plaque accumulation and gingival inflammation.

Materials and Methods:-

Ethical clearance was obtained from the Institutional Review Board of Meenakshi Ammal Dental College & Hospital, Maduravoyal, Chennai – 600095, India.

The pilot study consisted of 60 children who visited the Department of Pediatric and Preventive Dentistry at Meenakshi Ammal Dental College and Hospital, Chennai.

Inclusion criteria:-

1. Children between 6 and 8 years of age.
2. Healthy children without any known systemic illness.
3. No recent history of use of antimicrobial agents/ any other drugs.
4. Children and parents willing to comply with the oral hygiene instructions.
5. Children having a plaque index of 2/ above 2.

Exclusion criteria:-

1. Children who have unmanageable behaviour.
2. Children using any other oral hygiene aids other than routine tooth brushing.
3. Children and parents who cannot comply with the oral hygiene instructions.
4. Children who cannot come for the recall visit.

A written informed consent was obtained from the parents/ guardians of children who participated in the study.

Oral examination was performed to assess the plaque (Silness & Loe) and the gingival bleeding index (Muhlemann & Son) on day one. Plaque index was recorded by visual examination of the designated teeth under room lighting. Sulcus bleeding index was measured by running a straight probe along the free gingival margin and waiting for about 30 seconds to record bleeding. The initial assessment was followed by a thorough oral prophylaxis and oral hygiene instructions. The children were then randomized by simple randomization into two groups:

Group 1: Probiotic mouth rinse (Darolac, Aristo pharmaceuticals)

Group 2: Chlorhexidine mouth rinse 0.02% (Hexidine® [ICPA])

The designated mouth rinses were dispensed to the respective groups through other staff of the department due to the double-blind design of the investigation.

The patients in Group 1 were given Darolac Sachets (a probiotic formulation containing *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Lactobacillus sporogenes*, *Bifidobacterium longum*, and *Saccharomyces boulardii*) and 10 ml ampules of distilled water. The parents/ Guardians were demonstrated and instructed to prepare the probiotic mouth rinse by mixing together the contents of the sachet and 10 ml of distilled water. Emphasis was made to clearly explain that the solution had to be stirred thoroughly until all the contents were completely dissolved in the distilled water. The preparation had to be made freshly each time and rinsed immediately once prepared and could not be stored.

The children were instructed to rinse their mouth with 10ml of their respective mouth rinses (1:1 dilution for chlorhexidine) after tooth brushing at night by swishing it for 60 seconds and then expectorating it. They were advised not to eat or drink after using their mouth rinse. The parents/ Guardians were asked to supervise the children during the use of mouth rinse.

All the participants were recalled on the 14th day for re-examination of the level of plaque accumulation and gingival inflammation.

Statistical Analysis:-

An Independent t test and Mann-Whitney test were performed in order to study the intra and inter group variability respectively. The confidence interval was kept at 95%.

Results:-

The plaque index had considerably reduced from 2.25 to 0.35 and 2.45 to 0.50 in the chlorhexidine and probiotic groups respectively. In terms of bleeding index the 14th day value was 0.00 for both the chlorhexidine and the probiotic groups as compared to the baseline which was 0.70 for chlorhexidine group and 0.85 for the probiotic group. A p value of 0.000 indicates a high statistical significance.

A Wilcoxon signed rank test also showed high significance for both the chlorhexidine and the probiotic groups in terms of both plaque index and gingival bleeding index.

Table 1:- Baseline characteristics

	<i>Chlorhexidine group</i>	<i>Probiotic group</i>
Males	55%	50%
Females	45%	50%
Average age	7.3 years	6.8 years
Plaque Index	2.5	2.3
Bleeding Index	0.6	0.7

Table 2:- Group statistics of the plaque index and gingival bleeding index on baseline and 14th day for both the chlorhexidine and the probiotic groups.

CHLORHEXIDINE GROUP	BASELINE	PLAQUE INDEX			BLEEDING INDEX		
		MEAN	STD. DEV.	P VALUE	MEAN	STD. DEV.	P VALUE
		2.25	0.444	0.000	0.70	0.571	0.000
	14 TH DAY	0.35	0.489		0.000	0.000	
PROBIOTIC GROUP	BASELINE	2.45	0.686	0.000	0.85	0.587	0.000
	14 TH DAY	0.50	0.513		0.000	0.000	

Table 3:- Wilcoxons signed rank test for the chx group.

	PLAQUE INDEX - DAY 14 - PLAQUE INDEX - BASELINE	BLEEDING INDEX - DAY 14 - BLEEDING INDEX - BASELINE
Z	-4.089 ^a	-3.500 ^a
Asy mp. Sig. (2-tailed)	.000	.000

a. Based on positive ranks.

b. Wilcoxon Signed Ranks Test

Table 4:- Wilcoxon signed rank test for the probiotic group

	PLAQUE INDEX - DAY 14 - PLAQUE INDEX - BASELINE	BLEEDING INDEX - DAY 14 - BLEEDING INDEX - BASELINE
Z	-4.056 ^a	-3.690 ^a
Asymp. Sig. (2-tailed)	.000	.000

a. Based on positive ranks.

b. Wilcoxon Signed Ranks Test

Discussion:-

Oral hygiene habits among majority of the population include regular tooth brushing, but, a positive synergistic effect is seen in the oral cavity, when mouth rinse is used as an adjunct.

Mouth rinses are intended to augment and not to replace mechanical plaque control. Chlorhexidine has been reported to have a number of local side effects. These side effects are brown discoloration of the teeth and tongue, taste perturbation and oral mucosal erosion. These side effects associated with its use have stimulated the search for an alternative antiplaque agent.⁴ Antibacterial mouth rinses act by nonspecifically reducing the levels of both friendly and harmful oral bacteria whereas, probiotics has been developed using natural beneficial bacteria to promote a healthy balance of microorganisms in the mouth.¹

Milward and Wilson (1989)⁵ studied the effect of chlorhexidine on *Streptococcus sanguis* biofilm and found that 72-h biofilms were more resistant to chlorhexidine than 24-h plaque biofilms. But till date, *in vivo* resistance of *S. mutans* to chlorhexidine has not been documented in the literature.

Probiotic bacteria guard the oral health by competing with the oral pathogens for nutrients, site of adhesion and growth factors. Once adhered to the oral cavity, probiotic bacteria aggregate and inhibit the adhesion of the harmful microorganisms by producing bacteriocins or other antimicrobial compounds such as acids or peroxides. Thus, Probiotics help to prevent the inflammation of oral cavity and the oral tissue destruction by oral pathogens.^{6,7}

Probiotic first needs to adhere successfully to the surfaces of oral cavity in order to avoid or reduce its rapid exclusion from the oral cavity. Studies have shown that the pretreatment with lysozymes can increase adhesion properties of the lactobacilli without affecting its viability.⁸ The lactobacilli adhesion mechanism involves hydrophobicity and surface charge in addition to specific carbohydrate and/or proteinaceous components. Another factor that needs to be considered while evaluating establishment of probiotics in the oral cavity is saliva-mediate aggregation. Those microorganisms that have the ability to co-aggregate may have greater advantage over non-co-aggregating organisms which are easily removed from the mouth.⁹⁻¹²

Unlike adults who have an already established oral micro flora, in children the microbial ecosystem is still in the process of being established. An early installation and colonization of probiotics in the oral environment would be the first step for an anticipated long-term effect, but there are limited data available to support this event. Therefore, it seems especially important to carry out studies on infants because it is very likely that the chance of a permanent colonization of probiotics increases with a regular exposure from early childhood.¹³ Several studies suggest that consumption of products containing probiotic lactobacilli or bifidobacteria could reduce the number of mutans streptococci in saliva.

The advantages of using probiotic strains are, bacterial strains present in them are not harmful to the oral cavity, There is no antibiotic resistance occurring and there is no proven toxicities related to their use.

According to Hatakka *et al*¹⁴ Milk containing probiotic bacterium LGG has beneficial effect on children's dental health. Zahradnik *et al*.¹⁵ said that probiotics were safe for daily use as an aid in maintaining dental and periodontal

health. Keller and Twetman¹⁶ found that despite their strong acidogenic abilities, there was no evidence of an increase in plaque acidity after exposure to probiotic bacteria.

Jothika et al¹⁷ found a sustained decrease in the bacterial count of *S. mutans* in dental plaque after 30th day of usage of a probiotic mouth rinse. There was an increase in *S. mutans* count in dental plaque in a four week period after exposure to CHX, this increased plaque accumulation or *S. mutans* could have been due to development of drug resistance toward chlorhexidine.

The results of our study showed the anti-plaque and the anti-gingivitis effects of a probiotic mouth rinse to be similar to that of a chlorhexidine mouth rinse.

Conclusion:-

Probiotic mouth rinses have a statistically similar and equivalent effect as compared to chlorhexidine mouth rinses. Probiotic mouth rinses can be considered as one of the effective regimens in maintaining oral hygiene.

Future research should be aimed at identifying the long-term effects of oral probiotics and to know whether the oral probiotics should come from the oral cavity or general lactobacilli products and whether it should be used as an adjunctive therapy or mono-therapy. This will aid in blossoming this mode of treatment.

References:-

1. Meurman JH. Probiotics: do they have a role in oral medicine and dentistry? Eur J Oral Sci 2005; 113:188-195.
2. Schlundt, Jorgen. "Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria". Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food Including Powder Milk with Live Lactic Acid Bacteria. FAO / WHO. October 22, 2012.
3. Pranay Jain, Priyanka Sharma. Probiotics and Their Efficacy in Improving Oral Health: A Review. J App Pharm Sci. 2012; 2 (11): 151-163.
4. Harini P M, Anegundi R T. Efficacy of a probiotic and chlorhexidine mouth rinses: A short-term clinical study. J Indian Soc Pedod Prev Dent 2010;28:179-82
5. Milward TA, Wilson M. The effect of chlorhexidine on Streptococcus sanguis biofilms. Microbios.1989;58:155-64.
6. Roberfroid MB Prebiotics and probiotics: are they functional foods? Am J Clin Nutr 2002; 71(6 Suppl): 1692S-7S
7. Strus M, Pakosz K, Gosciniak H, Przondo- Mordarska A, Rozynek E, Pituch H, Meisel-Mikołajczyk F, Heczko PB. Antagonistic activity of Lactobacillus bacteria strains against anaerobic gastrointestinal tract pathogens (Helicobacter pylori, Campylobacter coli, Campylobacter jejuni, Clostridium difficile). Med Doew Mikrobiol 2001; 53(2): 133-42
8. Stamatova I, Kari K, Vladimirov S, Meurman JH. In vitro evaluation of yoghurt starter lactobacilli and Lactobacillus rhamnosus GG adhesion to saliva-coated surfaces. Oral Microbiol Immunol 2009; 24:218-223.
9. He F, Ouwehand A, Isolauri E, Hosoda M, Benno Y, Salminen S. Differences in composition and mucosal adhesion of bifidobacteria isolated from healthy adults and healthy seniors. Curr Microbiol 2001; 43:351-354.
10. Lorca G, Torino MI, de Valdez GF, Ljungh A. Lactobacilli express cell surface proteins which mediate binding of immobilized collagen and fibrinogen. FEMS Microbiol Lett 2002; 26:31-37.
11. Carlen A, Rudiger SG, Loggner I, Olsson J. Bacteria-binding plasma proteins in pellicles formed on hydroxyapatite in vitro and on teeth in vivo. Oral Microbiol Immunol 2003;18: 203-207.
12. Nikawa H, Makihira S, Fukushima H, Nishimura H, Ozaki Y, Ishida K, Darmawan S, Hamada T, Hara Matsumoto A, Takemoto T, Aimi R. Lactobacillus reuteri in bovine milk fermented decreases the oral carriage of mutans streptococci. Int J Food Microbiol 2004;95:219-223.
13. Twetman S, Steckslen-Blicks C. Probiotics and oral health effects in children. Int J Paediatr Dent 2008;18:3-10.
14. Näse L, Hatakka K, Savilahti E, Saxelin M, Pönkä A, Poussa T, et al. Effect of long-term consumption of a probiotic bacterium, Lactobacillus rhamnosus GG, in milk on dental caries and caries risk in children. Caries Res 2001;35:412-20.
15. Zahradnik RT, Magnusson I, Walker C, McDonell E, Hillman CH, Hillman JD. Preliminary assessment of safety and effectiveness in humans of ProBiora3, a probiotic mouthrinse. J Appl Microbiol 2009;107:682-90.
16. Keller MK, Twetman S. Acid production in dental plaque after exposure to probiotic bacteria. BMC Oral Health 2012;12:44.
17. Mohan Jothika, Pranav Vanajassun. Effectiveness of probiotic, chlorhexidine and fluoride mouthrinse against Streptococcus mutans – Randomized, single-blind, in vivo study. J Int Soc Prev Community Dent 2015 May; 5(Suppl 1): S44-S48