EFFECT OF 0.2% CHLORHEXIDINE GLUCONATE ON GINGIVAL HEALTH AMONG ORTHODONTIC PATIENTS- A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objectives: *The objective of this study was to compare the effect of chlorhexidine mouthwash on gingival health in orthodontic patients using manual brushing as a control in terms of reduction in gingival and bleeding indices scores.*

Methods and materials: *This randomized clinical trial was conducted on August 2021 to December 2021 at Department of Orthodontics, Bacha Khan Dental College, and Hospital Mardan. A sample size of 50 orthodontic patients divided into two groups. Group A (experimental) and enrolled 25 participant ,and Group B (control) enrolled 25 participants used non-probability convenient sampling technique. Group A used chlorhexidine mouth wash along with manual brushing while in group B the participants maintained oral hygiene with manual brushing only. Patient's age between 12 to 35 years, undergoing fixed orthodontic treatment, with no anterior composite restorations and no decalcification of teeth were included. At baseline and after period of one month the gingival and bleeding indices were recorded. Comparison of mean gingival and bleeding indices score was done between both groups using Paired T test. P≤0.05 was considered significant.*

Results: *The mean gingival index score was less in cases using Chlorhexidine (1.77±0.75) than control group (2.19±0.52) statistically significantly (P=0.026, 95% CI =0.053, 0.786). Similar results were found for bleeding index (P=0.034, 95% CI =0.027, 0.670). The females (n=29, 58%) were more than males (n=21, 42%). The mean age was 19.94±4.48 years with range from 13 to 34 years. The comparison of age (P=0.066), baseline gingival index (P=0.397) and bleeding index (0.377) were not different statistically.*

Conclusion: *Chlorhexidine mouth wash additional to the daily oral hygiene regimen can reduce gingivitis in orthodontic patients.*

Key words: *Mouthwash, chlorhexidine, orthodontic patients, oral hygiene*

INTRODUCTION

Among human population gingivitis is the most prevalent diseases and can be noticed among almost all age groups. Severity of gingivitis becomes stronger with increasing age.[1,2] The pathogenesis of gingivitis involves stagnation of food debris on tooth surfaces and subsequently oral bacteria accumulate in plaque responsible for gingival disease progression.. These bacterial colonies causing inflammation of gingiva called gingivitis.[3,4] Gingivitis is a reversible condition but if untreated, through oral hygiene measures and debridement, can lead to an irreversible condition called periodontitis in which loss of attachment apparatus happens.[5,6]

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The prime objective of orthodontic therapy is to improve esthetic and function of dentition but it is not without side effects.[7] Orthodontic fixed appliance therapy involved the use of multibracket system along with steel or elastomeric ligatures which aids in food stagnation and gingivitis. Plaque accumulation can results in gingivitis, gingival hyperplasia and white spot lesions.[8,9]

In literature myriad of methods have been proposed to resolve the issue of gingivitis in orthodontic patients. These are regular brushing after each meal, minimal snacks, use of fluoride in various forms (dentifrices, varnishes and mouth rinses), herbal mouthwashes, use of chlorhexidine mouth rinses, and ozonated therapy etc.[7,10-12]

Chlorhexidine is an antimicrobial and antifungal agent belong to bis-biguanides family and it has strong affinity for oral structures.[13] Chlorhexidine has found to be highly effective in reduction of plaque, gingival and bleeding indices scores.[10,12] Brightman et al.[14] performed a randomized control trial on 34 orthodontic patients to determine the effect of chlorhexidine mouthwash on reduction of plaque and gingival indices score as compared to control. They reported that the chlorhexidine reduced both indices scores statistically significantly than control group. Similarly another study by Anderson et al.[15] reported that mean plaque and gingival indices score in orthodontic patients were less in chlorhexidine than control group. A randomized clinical trial conducted in India reported in orthodontics patients the chlorhexidine reduces plaque, gingival and bleeding indices significantly more than manual brushing only.[1]

There is scarcity of local literature on this topic in Pakistan. So, this study will help the clinician in awareness about plaque control in orthodontic cases. Results can be different across various populations due to compliance of patients, genetic and ethnic variability. This randomized clinical trial can provide best evidence about the efficacy of chlorhexidine in improving gingival health of orthodontic patients in our population.

The objective of this study was to compare the effect of chlorhexidine mouthwash on gingival health in orthodontic patients using manual brushing as a control in of term reduction in gingival and bleeding indices score.

MATERIALS AND METHODS

This Randomized clinical trial was conducted from August 2021 till December 2021 at the Department of Orthodontics, Bacha Khan Dental college, Mardan, after taking ethical approval from hospital review committee. A total of 50 orthodontic patients were enrolled in the study by non-probability convenient sampling technique. Sample size was calculated at 95% confidence interval and 0.10% margin of error using WHO calculator19. After taking verbal informed consent the patients were divided randomly into two groups by lottery method. The two groups, Group A were experimental (n=25) and Group B control (n=25). Group A (experiment) were given 0.2% chlorhexidine gluconate (trade name Enziclore mouthwash) to rinse mouth twice a day along with usual brushing. Group B (Control) group was instructed to brush their teeth regular only.

The inclusion criteria were age range from 12 to 35 years, of healthy patients having active orthodontic fixed treatment and Pakistani nationals. Patients with restorations, decalcified teeth, periodontitis, allergic to chlorhexidine digluconate, medical problem (like diabetes) and using antibiotic therapy currently were excluded.

At baseline Gingival index score and Bleeding index score were recorded and then after a period of one month, Gingival index score and Bleeding

Gingival index was recorded as follows;

Score 0:	**Normal gingiva; natural coral pink gingiva without any inflammation**
Score 1	**Mild gingival inflammation; slight change in color, slight edema, no bleeding on probing**
Score 2	**Moderate gingival inflammation; moderate glazing, redness, edema and hypertrophy. Bleeding on probing**
Score 3	**Severe gingival inflammation; marked redness and hypertrophy ulceration, tendency to spontaneous bleeding**

The bleeding index was recorded as;

Score 0:	**No bleeding on probing**
Score 1	**Slight bleeding on probing**
Score 2	**Bleeding on probing immediately**
Score 3	**Severe bleeding on probing spreading to adjacent area**

indices were recorded, To access the patients compliance of using plaque control measure according to guide line can be measured during orthodontic adjustment vist.

Data analysis was done in SPSS version 22.0. Continuous variables like age, gingival and bleeding indices score were computed as mean and standard deviation. Frequency and percentages were calculated for categorical variable like gender. Comparison of gingival and bleeding indices score was done between experimental and control group using paired T test. to access pre intervention and post intervention .At two tailed hypothesis the P-value less or equal to 0.05 was set as a significant level.

RESULT

The mean age was 19.94±4.48 years with rang from 13 to 34 years. At baseline gingival index (P=0.397) and bleeding index (P=0.377) were not statistically significant. The details are shown in (table 1)

The Paired T test is used and the mean gingival index score was less in cases using chlorhexidine (1.77±0.75) than control group (2.19±0.52) statistically significantly (P=0.026, 95% CI =0.053, 0.786). Similar results were found for bleeding index (P=0.034, 95% CI =0.027, 0.670). (Table 2).

DISCUSSION

This study was aimed to compare the effect of chlorhexidine mouthwash on gingival health in orthodontic patients using manual brushing as a control in term of reduction in gingival and bleeding indices score. Our results showed in table 1 that there was no statistical difference in age, baseline gingival index and baseline bleeding index between the experimental and control group. This shows that both groups were similar at the baseline and comparable. Previous studies also reported that baseline gingival and bleeding indices were similar in control and experimental groups.[1,13,16]

In our study females were more than males. This can be due to more esthetic concern in females in our population and hence more presentation for orthodontic treatment. Similar to our results in Farhadian's study females (n=55) were more than males (n=17).[16]

Our results showed that the mean gingival and bleeding indices scores were less in cases using chlorhexidine than control group statistically significantly. This shows that in orthodontic patients the gingival health can be improve and preserve by advising chlorhexidine rinse in addition to usual manual brushing. Gingival hyperplasia and gingivitis are very common in orthodontic patients.[17]

In study by Anderson et al.15 on effect of 0.12% chlorhexidine gluconate versus placebo mouth rinses on gingival health on thirty orthodontic cases in Texas population reported that the mean plaque and gingival indices score were less in chlorhexidine than control group. Their results were statistically significant. Though we did not recorded plaque index in our study but results on gingival index are similar to our

Table 1: Comparison of age, baseline gingival index and bleeding index

Variable	Group	Mean	P-value**	95% CI
Age	Group A Experimental(n=25)	19.7±3.10	.066	-.050, 4.990
	Group B Control (n=25)	21.2±5.29		
baseline mean GI	GroupA Experimental (n=25)	2.23±0.29	.397	-.301, .121
	GroupB Control(n=25)	2.14±0.43		
baseline mean BI	GroupA Experimental (n=25)	1.62±0.29	.377	-.304, .117
	GroupB Control(n=25)	1.53±0.43		

*GI, gingival index; BI, bleeding index; **Paired T test

Table 2: Paired T test Comparison of gingival and bleeding indices before and after at one moth interval

Variable	Group	Mean	P-value	95% CI
GI at one month	Group A (experimental)	1.77±0.75	0.026	.053, .786
	Group B (Control)	2.19±0.52		
BI at one month	Group A (Control)	1.245±0.63	0.034	.027, .670
	GroupB (experimental)	1.59±0.48		

Fig 1: Flow chart of the study according to CONSORT guidelines

Participants (n=50) qualifying inclusion criteria were randomly allocated to two intervention group	
INTERVENTION	
GROUP A n=25 Experimental group were given 0.2% chlorhexidine gluconate to rinse mouth twice a day along with usual brushing	GROUP B n=25 Control group was instructed to brush their teeth regular only.
FOLLOW UP	
Base line just before intervention ,Follow up after 1 month	Base line just before intervention ,Follow up after 1 month
ANALYSIS	
Paired T Test was applied to compare the means of gingival and bleeding score before and after intervention in each group.	

study. Another similar by in Zabokova-Bilbilova et al.[18] in Macedonia reported that chlorhexidine mouth rinse can reduce gingivitis and plaque retention in orthodontic patients. Brightman et al.[14] in a study on 34 orthodontic patients reported that a 0.12% chlorhexidine gluconate mouthrinse can significantly reduced gingival and bleeding indices scores. These findings are similar to our study.

In our chlorhexidine mouth rinse was used along with manual tooth brushing similar to previous studies.[6,11,16] This implies that daily tooth brushing can be never be replaced with any antimicrobial agents rather than chlorhexidine should be supplemented with it.

CONCLUSION

On basis of our findings we can concluded that Chlorhexidine mouth wash additional to the daily oral hygiene regimen reduces gingivitis in orthodontic patients. Within the limits of this study it can be concluded further large sample studies and multi centered study are needed to further explore this area.

RECOMMENDATION

Dental health education and awareness regarding plaque control measures need to be spread among public.

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