

Anti Disclosing Chlorhexidine Mouthwash *Versus* Chlorhexidine Mouthwash in Orthodontic Patients: A Comparative Clinical Study

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ABSTRACT

The goal of this study is to evaluate the clinical efficacy and degree of staining recent mouthwash Chlorhexidine with an antidiscoloration system (ADS) versus Chlorhexidine mouthwash (conventional) in orthodontic fixed bracket patients.

Method: This comparative study is carried out on a sample of 50 orthodontic patients under going fixed brackets therapy at Department of Dentistry, Patna Medical College & Hospital, Patna, Bihar. All patients used either 0.2% chlorhexidine mouthwash with ADS (bottle A) or 0.2% chlorhexidine (bottle B) for 21 days. Each patient first rinsed with a randomly assigned mouthwash for 21 days followed by a 15-day washout period. Subsequently, each patient used a second mouthwash. Before each cycle, a full oral prophylaxis was performed. Clinical efficacy and degree of staining was evaluated using parameter in the plaque, gingival, and Brex staining indexes. **Results:** The results showed less tooth staining with the test group ($P < 0.01$). No statistically significant differences were observed in plaque accumulation ($P = 0.1496$) and gingival indexes ($P = 0.1688$). Seventy-nine percent of patients followed the instructions outlined in the protocol of study. In terms of other adverse effects, four patients reported a bad taste with both mouthwashes.

Conclusions: The test group with chlorhexidine with antidiscoloration system had less staining than the control group with chlorhexidine during a usage period of 21 days in patients undergoing orthodontic fixed bracket therapy. However, the two mouthwashes seem to be equally effective in antiplaque and anti-gingivitis activities.

Keywords: Chlorhexidine mouthwash (CHX), Chlorhexidine-Antidiscoloration System (CHX-ADS), Orthodontic Fixed Bracket.

INTRODUCTION

Today's modern era of aesthetic world seeking considerably increase in orthodontic patients for better

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facial appearance and enhanced smile. Fixed orthodontic outcome of treatment largely depends on the periodontal status of patients. Orthodontic treatment with fixed appliances having bands, brackets, arch wires, cleats, ligature wires, coil springs, buccal tubes as attachments on the tooth surface. These attachment complicates the cleaning¹, increases plaque amount², alters oral environment, changes the composition of the flora³ and provide additional retentive area the deposition of food debris. Maintenance of proper oral hygiene for undergoing fixed orthodontics patients is of greatest

concerns to orthodontists because it can lead to the development of enamel decalcification, white spot lesions, hyperplastic gingivitis, periodontitis⁴ and increase risk of caries. Therefore, adequate plaque removing only through mechanical methods is not sufficient enough, so antimicrobial agent is usually prescribed as an adjunct to conventional mechanical methods⁵ especially in orthodontics patients. Chlorhexidine (CHX) is one of the most widely used gold standard antimicrobial agent used in dentistry and proven to be effective for control of plaque accumulation as well as treatment for periodontal diseases⁶. CHX is adsorbed rapidly on dental surfaces, mucous membranes, and salivary proteins and is released gradually over 8-12 hours⁷. But the prolonged usage of CHX is burdened by some side effect that could affect patient compliance. The most notable of these is staining CHX produces. Recently a new mouth wash, which contains CHX and additionally an anti-discoloration system (ADS) promise to provide same efficacy as CHX but also avoid staining.

Therefore, the purpose of this study was to determine and compare whether the use of Chlorhexidine anti-discoloration mouthwash having same efficacy without causing staining with Chlorhexidine in orthodontic patients.

AIMS AND OBJECTIVE

To determine the efficacy of Chlorhexidine anti-discoloration mouthwash in plaque reduction, gingival inflammation reduction without causing staining.

Compare the efficacy and non-staining property of chlorhexidine anti-discoloration mouthwash with chlorhexidine.

MATERIAL AND METHOD

Study Population

A total of 50 patients (eighteen male and thirty two female, aged 15-20 years; mean age: 17.5 years) undergoing orthodontics fixed brackets treatment were included in the study. Third molars of patients were excluded from study. Six patients were excluded because they did not follow the study protocol. The study was conducted at the Department of Dentistry, Patna Medical College & Hospital, Patna, Bihar, India from January to June 2017. All patients had given duly signed written informed consent for study.

Study Design

This study was done to check the efficacy of 0.2% chlorhexidine with ADS in orthodontics patients. Also a comparative, crossover, double-masked study between a mouthwash that contains 0.2% chlorhexidine ADS and a mouthwash containing 0.2% chlorhexidine. Patients were comprised of satisfactory oral hygiene, non-smokers, not having habit of chewing any form of tobacco, without any systemic medical conditions or infectious diseases and without any periodontal diseases. Patients who were pregnant, nursing, or using antibiotics or anti-inflammatory drugs were also excluded.

Each patient had a 21-day cycle using an undiluted 10-ml dose of a first mouthwash for 1 minute, twice daily (morning and evening). The mouthwash samples for study were previously labeled, assigning the letters A (0.2% chlorhexidine mouthwash plus ADS; test group) and B (0.2% chlorhexidine mouthwash; control group). The delivery of each mouthwash to patients was done randomly by the help of a dental hygienist. Before each mouthwash cycle, patients were instructed and advised not to drink coffee, tea, cold drinks, alcohol 1 hour before or after using the mouthwash; a full supragingival prophylaxis was performed and intraoral photographs were taken.

At 1st and 21st days of each cycle the plaque index (PI)^{8,9}, gingival index (GI)^{10,11} and Brex staining index (BI)¹² were recorded. All the three indexes were evaluated on all the teeth in the patient's mouth, excluding third molars as per exclusion criterion. The GI and PI were evaluated in the four gingival units of the same teeth (mesial, distal, vestibular, and palatal/lingual), and the BI was assessed only in two gingival units (buccal and palatal/lingual)⁸⁻¹¹.

All patients remained 15 days without using any rinse (washout period). Then they performed the second 21-day cycle with a second mouthwash, after which the same clinical parameters were assessed at the end of this second cycle.

An orthodontic tooth brush of soft texture and interdental brush were given. The brushing technique used during the study corresponded was modified Bass technique¹³ along with interdental brushing. Toothpaste without sodium lauryl sulfate and with 0.05% fluoride to prevent interaction with chlorhexidine. In addition, during course of study the survey included questions

related to the side effects (taste modification or injury to oral mucosa) of the mouthwash in the mouth experienced by patients was also recorded. After each cycle patients brought a filled questionnaire showing their compliance and the two empty mouthwash bottles. A single masked trained doctor performed clinical assessments and data collection. The data collection period was approximately 1.9 months per patient.

Data Analysis

Above gathered data's were evaluated with factorial analysis of variance. The primary outcome variable was patient pigmentation. Other variables tested were plaque reduction, gingival inflammation in test group and other side effects (food taste, mucosal irritation etc). All the variables were tested between the two different mouthwashes within the same patient and over time, between 2 and 3 weeks. Also considered was the interaction between treatment and time, exploring potential differences in the effect of the mouthwashes at 14 and 21 days. All the mean data gathered was well documented with comparative bar graphs. (Fig.1-3)

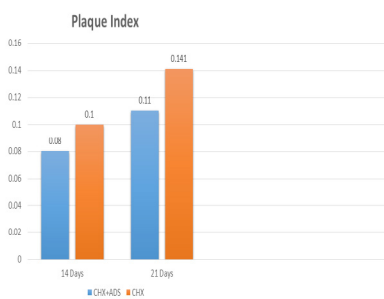


Fig.1 : Mean PI in group A (CHX with ADS) and group B (CHX) at 14 days and 21 days

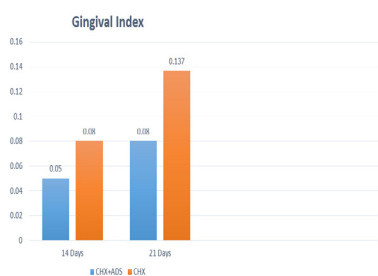


Fig.2 : Mean GI in group A (CHX with ADS) and group B (CHX) at 14 days and 21 days

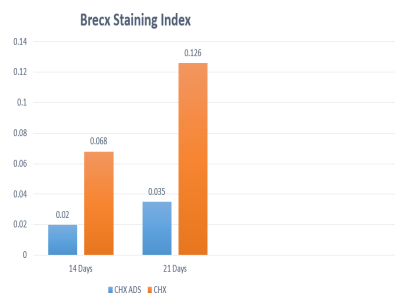


Fig.3 : Mean BI in group A (CHX with ADS) and group B (CHX) at 14 days and 21 days

RESULTS

A total of 50 patients undergoing fixed orthodontic treatment were included but six patients were excluded because they did not follow the sequence of use of the mouthwashes as per protocol thus completing the study with only forty four patients. All patients were treated with a full mouth oral prophylaxis before each mouthwash cycle and were reevaluated at days 14 and 21 when using each mouthwash. Figure 1 shows PI⁸ over time, either at 14 or 21 days ($P = 0.641$). The means and standard deviations of the PI for mouthwash A (0.2% chlorhexidine plus ADS) at 14 and 21 days were 0.071 – 0.089 and 0.09 – 0.121, respectively. For mouthwash B (0.2% chlorhexidine) the means and standard deviations of the PI at 14 and 21 days were 0.89 – 0.11 and 0.139 – 0.148, respectively. The two mouthwashes (test and control group) were equally effective in reducing plaque in the patient. No statistically significant differences were observed in plaque reduction ($P = 0.1312$) between the two mouthwashes. Regarding the GI¹⁰ no statistically significant difference ($P = 0.2253$) was found in the GI over time, either at 14 or 21 days. The two mouthwashes presented a similar effectiveness on gingival inflammation, with no statistically significant difference ($P = 0.1688$). The means and standard deviations of the GI for mouthwash A (0.2% chlorhexidine plus ADS) at 14 and 21 days were 0.039 – 0.059 and 0.068 – 0.094, respectively. The means and standard deviations of the GI for mouthwash B (0.2% chlorhexidine) at 14 and 21 days were 0.59 – 0.99 and 0.086 – 0.148, respectively (Fig. 2). The staining with usage of mouthwash shown in Figure 3 illustrate that more days the patients use each mouthwash, the greater is the staining. With

mouthwash B, BI¹² is much higher than with mouthwash A. The values obtained are statistically significant ($P \leq 0.05$). The means and standard deviations of the BI for mouthwash A (0.2% chlorhexidine plus ADS) at 14 and 21 days were 0.009 – 0.021 and 0.0289 – 0.041, respectively. The means and standard deviations of the BI for mouthwash B (0.2% chlorhexidine) at 14 and 21 days were 0.471 – 0.821 and 0.0953 – 0.152 respectively. As for any other side effects reported after the use of the mouthwashes, the results suggest no significant difference between the two groups ($P = 1.0000$).

DISCUSSION

Usually, the adolescent patients undergoing orthodontic treatment with fixed brackets evidence shows significant improvement of oral hygiene status when antimicrobial mouthrinses are added to daily oral hygiene regimen¹⁴. The importance of chlorhexidine mouthwash is even greater in orthodontic patients as it is effective in reducing plaque and gingivitis¹⁵. Nevertheless, studies by McCoy et al¹⁶ had shown that the chronic use of chlorhexidine might cause side effects on dental surfaces such as stains, loss of taste, burning sensations or irritation of the mucosa. Thus stimulating the search for new chemical compounds that may minimize the side effects and being affordable to the population that is newly introduced chlorhexidine with antidisclosing system. With this objective, we evaluated the efficacy of chlorhexidine anti-discoloration mouthwash in plaque reduction without causing staining and compare the efficacy and non-staining property of chlorhexidine anti-discoloration mouthwash with chlorhexidine in the patient going orthodontic treatment with fixed brackets.

After analyzing the results obtained during our clinical study comparing 0.2% chlorhexidine mouthwash containing ADS to the standard 0.2% chlorhexidine, we observed that the mouthwash plus ADS has the same antiplaque and antigingivitis effects as the “classic” mouthwash with 0.2% chlorhexidine. Furthermore, a marked decrease in staining was observed with the tested mouthwash in orthodontic patients too. Similar study in healthy patient was conducted by Bernardi et al. (2004)¹⁷ and they concluded that there was no significant difference in relation to PI and GI between the two mouthwashes in healthy patients, but a statistically significant difference was observed in the adverse effect of staining, demonstrating that

the mouthwash with ADS prevented pigmentations. Thus our study, performed in patients with orthodontic fixed brackets, corroborates the findings of Bernardi et al¹⁷ and another paper by Basso et al (2006) confirmed both their results and ours, showing less staining with a 0.2% chlorhexidine with ADS. Another published study by Cortellini P et al (2008)¹⁸ using 0.2% chlorhexidine with ADS system compared it with a 0.2% chlorhexidine mouthwash for 1 week after periodontal surgery in 48 consecutive patients in treatment. The results were consistent with those obtained in our study: less staining was observed when using the 0.2% chlorhexidine mouthwash with ADS and similar effectiveness between the two mouthwashes in reducing gingival inflammation after surgery. In our study, we also observed less staining with the 0.2% chlorhexidine with ADS, but we did not observe any other differences in side effects between the two mouthwashes. Recently a clinical comparative study at International University of Catalunya, Barcelona, Spain under guidance of Carols Solis (2011)¹⁹ on 0.2% chlorhexidine mouthwash with an antidiscoloration system versus 0.2% chlorhexidine mouthwash in chronic periodontitis patients. Authors concluded that chlorhexidine with ADS mouthwash produces less dental staining in patients with chronic periodontitis, and it is equally effective as an antiplaque and antigingivitis agent compared to 0.2% chlorhexidine mouthwash during a 15-day period of use. Similar were results of our study in orthodontic patients using mouthwash for duration of 21 days.

The compliance factor has not been mentioned in previous comparative clinical studies reviewed. It is important to note that according to our questionnaire, 85% of patients followed the instructions outlined in the protocol. Some limitations have to be taken into account in our study. The sample is small, and the evaluation of the staining used is subjective.

CONCLUSION

The chlorhexidine with antidiscoloration system mouthwash produces less dental staining in patients with orthodontic patients having fixed bracket therapy, and it is equally effective as an antiplaque and antigingivitis agent as compared to 0.2% chlorhexidine mouthwash during usage of 21-days. The clinical manifestations and other possible adverse effects were minimal when using either mouthwash for same period. More clinical studies to be conducted with controlled, randomized and

on larger sample size.

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Conflict of Interest: Nil

Ethical Clearance: Taken from Ethical Committee

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