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ORIGINAL ARTICLE

Tolerability of a green tea-based mouth rinse: A pilot study☆

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Burning sensation

Abstract *Introduction:* Mouth rinse containing essential oil is one of the most popular, over the counter dental products which has been promoted to have anti-inflammatory, anti-plaque and anti-microbial properties. An essential oil alcohol-free mouth rinse with green tea has been introduced recently and promoted for management of periodontitis and gingivitis. As the role of chlorhexidine gluconate (CHX) mouth rinse in management of periodontal disease has been evaluated previously, the aim of this study is to compare the tolerability of none-alcohol containing green tea-based (NAGT) mouth rinse with CHX mouth rinse.

Methods: Forty healthy subjects were enrolled in September 2018 at King Abdulaziz University and allocated randomly to two study arms: NAGT mouth rinse and chlorhexidine gluconate mouth rinse. Study subjects were instructed to follow the manufacturer instructions and rinse twice daily for two weeks. Collected data included age, gender, smoking history in addition to subjective assessment using a validated questionnaire. Intraoral clinical examination was completed at baseline and 2-weeks time point.

Results: The data of 36 patients were included in this study and analyzed. At 2 weeks, NAGT group reported higher burning sensation score compared to chlorhexidine group (mean: 4.33 and

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☆ Summary sentence: The current data demonstrated an overall less tolerability of a non-alcohol containing green tea-based Listerine® mouth rinse compared to chlorhexidine gluconate mouth rinse.

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0.6 respectively; P < 0.05). Reported mucosal dryness was more evident in NAGT group (mean: 1.9 Vs 1.7 for chlorhexidine group). Oral examination revealed significant mucosal desquamation (27.8%) in NAGT group. However, oral ulceration was reported equally in both groups (5.6%).

Conclusion: The current data demonstrates an overall less tolerability of a non-alcohol containing green tea-based mouth rinse compared to chlorhexidine gluconate. Further long term randomized clinical trials are recommended to confirm our findings.

1. Introduction

Mouth rinses are solutions with various active ingredients used to reduce plaque formation, prevent and treat oral diseases such as gingivitis and caries, and to manage halitosis. Numerous mouth rinses products are commercially available and widely marketed to the public. These mouth rinses are formulated in different combinations to serve several purposes such as chlorhexidine gluconate (CHX), benzydamine hydrochloride, hydrogen peroxide, fluoride, and essential oils (Wirth et al., 2012). However, only few mouth rinses have been evaluated in clinical setting for effectiveness and patient tolerance (James et al., 2017; Nakamoto et al., 2018; Serbiak et al., 2018; Trombelli et al., 2018, Hall et al., 2019).

Periodontitis is a common chronic disease typically managed with scaling and root planning and anti-microbial mouth rinses (James et al., 2017). Listerine® is one of the most popular, over the counter mouth rinses which has been promoted to have anti-inflammatory, anti-plaque and anti-microbial properties (Gordon et al., 1985). It is available commercially in different formulations and active ingredients where some are either alcohol- or non-alcohol containing (Johnson and Johnson Middle East FZ – LLC, 2016). This green tea-based mouth rinse is alcohol-free (NAGT) which have been introduced recently and promoted for management of different forms of periodontal disease with minimal damage to healthy tissues. It contains eucalyptol, menthol, methyl salicylate, and thymol in addition to camellia sinensis leaf extract, and sodium fluoride (Johnson and Johnson Middle East FZ – LLC, 2016), Green tea extracts have long been considered a strong antioxidant agent with potential benefit on periodontal tissues (Kushiyama et al., 2009; Kamalaksharappa et al., 2018). As a result, it has been included as an active ingredient in several products including mouth rinses as in the recently introduced NAGT Listerine® mouth rinse.

In general, tolerability of mouth rinses (with- or without alcohol) differ between patients which plays a role in patients' compliance level with prescribed therapy. CHX is considered as the gold standard anti-microbial mouth rinse with anti-plaque effect similar to Listerine® (James et al., 2017; Marchetti et al., 2017). The role of CHX in management of periodontal disease has been evaluated extensively in the literature. In addition, reported common side effects include teeth discoloration, mucosal erosions, taste alteration, burning sensation, and xerostomia. Some of the secondary adverse events have been attributed to 11.6% alcohol content of CHX mouth rinse which could be less tolerated by oral tissues (Kerr et al., 2015). Hence, CHX has been suggested for short-term, intermittent therapy based on patient's dental need (Jones, 1997; Arweiler et al., 2006).

Considering NAGT as a recently introduced mouth rinse in the international market, the aim of this study is to evaluate its overall tolerability compared to CHX mouth rinse.

2. Material and methods

Human research ethical approval No. 054-04-18 was obtained from King Abdul Aziz University - Faculty of Dentistry (KAU-FD). All participants were consented prior to participation in the study. The study was designed as an unblinded, randomized clinical trial conducted at KAU-FD. Inclusion criteria included healthy subjects who were 18 years or older and had not been using any oral rinses (including fluoride or bleaching rinse) for the past 2 weeks. In addition, study subjects had stable oral condition with no pain at baseline. Subjects with an allergy to any component of the study mouth rinses were excluded. Pregnant or lactating women, subjects with current alcohol consumption, recent periodontal surgery or extraction (at least for the past 3 months), taking any analgesics, participating in any other clinical trial (at least for the past 30 days), and regularly using any other mouth rinse were excluded from the study as well. Prior to participation in the study, subjects were briefed on the study and consented.

Study Subjects were assigned randomly using a computerized random number generator (https://www.randomizer.org/) in September 2018 to either NAGT or chlorhexidine gluconate %12 mouth rinse. According to the manufacture instructions, NAGT Listerine® group were instructed to rinse with 20 ml undiluted solution for 30 s twice a day and for CHX group to rinse with 10 ml undiluted solution for 1 min twice a day. All study subjects were instructed to use the rinse following their daily oral hygiene routine and refrain from eating and drinking for 30 min afterword.

Collected data included demographics, smoking history, and subjective findings at baseline and after 14 days. It included measurement of mouth burning sensation, mouth dryness, mouth pain, and dental sensitivity using a scale of 1–10 (1 indicates the lowest level and 10 indicates the highest level). In addition, subjects were asked if they complained of malodor using yes/no question. At day 14, subjective parameters were recorded again in addition to any change in taste sensation (1–10 scale), the texture of the mouth wash (too thin, good, too thick), and whether they liked the mouth rinse following application of mouth rinses using 9-point hedonic scale for assessment of taste and smell (Lim, 2011). All study subjects had intraoral examination assessing for erythema, ulceration, desquamation and chronic bite injury at baseline and day 14. Data collection and subject examination was performed by the research team following two consecutive sessions about calibrations.

Collected data was analyzed using non-parametric tests. Mann Whitney *U* test was used to compare independent groups with continuous measurements. Dichotomous and categorical data were analyzed using chi-square and Fisher exact test. The statistical analysis of the collected data was done with the Statistical Package for Social Sciences software (SPSS, Version 20.0).

3. Results

Initially, forty subjects were recruited for the study. However, four subjects were excluded from the study due to associated adverse events of transient unilateral parotid gland swelling (one subject) and lack of compliance (three subjects). The data of 36 participants was divided equally over two groups and analyzed. The mean age of participants was 24.6 ± 1.6 in NAGT group and 26.9 ± 7.0 in CHX group ($p = 0.086$). Females accounted for 72.2% of NAGT group and 50.0% of CHX group ($p = 0.171$). Active smoking was reported in 27.7% of subjects in each group ($p = 0.637$) (Table 1).

3.1. Subjective findings

At baseline, no burning sensation was reported by study subjects. However, at day 14, both groups developed burning sensation which was higher in NAGT group compared to CHX group (4.33 ± 3.7 and 0.6 ± 1.7 respectively) which was statistically significant ($p = 0.004$) (Table 2). Oral dryness was present in CHX group only (mean score 0.6 ± 1.4) at baseline. However, at day 14 oral dryness score was 1.9 ± 2.1 in NAGT group and 1.7 ± 2.5 in CHX group ($p = 0.519$). In terms of mouth pain, the mean score at baseline in NAGT group and CHX group was 0.2 ± 0.7, while at day 14 a mean of 0.3 ± 1.2 was recorded in both groups ($p = 1.0$). Dental

Table 1 Study subject's demographic data.

	NAGT group (n = 18)	CHX group (n = 18)	p-value
Age (mean ± SD)	24.0 ± 1.6	26.9 ± 7.0	0.086[†]
Gender (female)	13 (72.2%)	9 (50.0%)	0.171[¥]
Smoking status (Yes)	5 (27.8%)	5 (27.8%)	1.0[¥]
Type of smoking:			
• Cigarettes	1 (5.6%)	3 (16.7%)	0.637[F]
• Hooka	3 (16.7%)	1 (5.6%)	
• Cigarettes and Hooka	1 (5.6%)	1 (5.6%)	

[†] Mann Whitney *U* test.
[¥] Chi-square test.
[F] Fisher Exact test.
[*] Statistically significant $p < 0.05$.

Table 2 Subjective findings for study participants.

	NAGT group	CHX group	p-Value
Mouth Burning			
• Baseline (mean ± SD)	0.0 ± 0.0	0.0 ± 0.0	NA
• Day 14 (mean ± SD)	4.33 ± 3.7	0.6 ± 1.7	0.004[†,*]
Mouth Dryness			
• Baseline (mean ± SD)	0.0 ± 0.0	1.7 ± 2.5	0.037[†,*]
• Day 14 (mean ± SD)	1.9 ± 2.1		0.519[†]
Mouth pain			
• Baseline (mean ± SD)	0.2 ± 0.7	0.2 ± 0.7	1.00[†]
• Day 14 (mean ± SD)	0.3 ± 1.2	0.3 ± 1.2	1.00[†]
Dental sensitivity			
• Baseline (mean ± SD)	0.7 ± 1.6	1.0 ± 1.4	0.199[†]
• Day 14 (mean ± SD)	0.3 ± 1.4	0.2 ± 1.0	1.00[†]
Change in Taste			
(mean ± SD)	2.2 ± 2.4	2.6 ± 2.8	0.650[†]
Malodor			
• Baseline (Yes)	2 (11.1%)	3 (16.7%)	1.0[F]
• Day 14 (Yes)	2 (11.1%)	1 (5.6%)	
Texture			
• Too Thick	0 (0.0%)	2 (11.1%)	0.180[F]
• Good	10 (55.6%)	12 (66.7%)	
• Too Thin	8 (44.4%)	4 (22.2%)	

[¥] Chi-square test.
[†] Mann Whitney *U* test.
[F] Fisher Exact test.
[*] Statistically significant $p < 0.05$.

Table 3 Acceptance of NAGT and chlorhexidine mouth rinse textures and consistency by study subjects using a 9-points hedonic scale for assessment of taste and smell (Lim, 2011).

	NAGT group	CHX group
Like extremely	1 6.7%	2 11.1%
Like very much	3 20.0%	1 5.6%
Like moderately	1 6.7%	4 22.2%
Like slightly	2 13.3%	2 11.1%
Neither like nor dislike	2 13.3%	6 33.3%
Dislike slightly	1 6.7%	1 5.6%
Dislike moderately	1 6.7%	1 5.6%
Dislike extremely	4 26.7%	1 5.6%
Total	15	18

sensitivity for NAGT group was 0.7 ± 1.6; while for CHX group it was 1.0 ± 1.4 at baseline ($p = 0.199$). At follow up, the sensitivity score was 0.3 ± 1.4 for NAGT group and 0.2 ± 1.0 for CHX group ($p = 1.0$). At day 14, the mean score of reporting a change in taste was slightly lower in NAGT group (2.2 ± 2.4) compared to CHX group (2.6 ± 2.8) but the difference was not statistically significant ($p = 0.650$). In addition, the total number of subjects in CHX group with reported mouth malodor dropped from 3 participants (16.7%) to 1 participant only (5.6%). However, no change in malodor status among NAGT group participants was noted. Mouth rinse texture was reported to be "good" (not too thin nor too thick) by about half of NAGT group (55.6%) and about two thirds of CHX group (66.7%). While 44.4 of NAGT group participants thought the mouthwash was too thick, only 22.2% of CHX group thought the mouthwash was too thick. There were no statistically significant differences between the two mouthwashes regarding texture. In NAGT group, 46.7% of participants liked the mouth rinse, 13.3% neither liked nor disliked it while 40.1% disliked it. In CHX group, 50.0% of participants liked the mouth rinse and 33.3% neither liked nor disliked it and 16.7% disliked it (Table 3).

3.2. Objective findings

Intraoral examination was completed at baseline and day 14 (Table 4). Oral mucosa was examined for all of the following: bite injury, desquamation, and/or ulceration. At baseline, 27.8% of NAGT group and 11.1% of CHX group had bite injury. At day 14 5.6% of NAGT group had bite injury, 27.8% had mucosal desquamation, 5.6% had ulceration and 5.6% had both ulceration and desquamation. However, 11.1% of CHX group had bite injury and 5.6% had ulceration while mucosal desquamation was not detected in any study subject. Mucosal desquamation was observed significantly more in the NAGT group compared to the CHX group ($p = 0.045$).

4. Discussion

Green tea is an ancient, and common beverage consumed at regular basis in many cultures worldwide, mainly in South-East Asia. In general, it is considered a rich dietary source of polyphenolic compounds specifically catechins (McKay and Blumberg, 2002). Experimental animal models have demonstrated anti-oxidant, anti-bacterial, anti-inflammatory and anti-viral properties for catechins (Wiseman et al., 1997; McKay and Blumberg, 2002; Higdon and Frei, 2003). As such, it has been promoted for better and healthy life and incorporated in many products used on daily basis (Kudva et al., 2011). It's benefits, including anti-caries, antibacterial and antiviral properties, had sparked scientific interest and encouraged wide and focused research to fully understand its benefit aspects in the dental field (Kudva et al., 2011). Several *In Vitro* studies demosnstrated green tea catechin potential to supress growth of perioodntal pathogens such as *Porphyromonas gingivalis (P. gingivalis)*, *Prevotella nigrescens* and *Prevotella intermedia*, and inhibits celluar adhesion of *P. gingivalis* (Sakanaka et al., 1996; Hirasawa et al., 2002; Kushiyama et al., 2009). As a result, it has been used in a local delivery systems to treat periodontal diseases induced by gram-negative anaerobic rods Hirasawa, 2002 #4} Therefore, green tea has been widely introduced as one of many other active components in toothpastes, dental floss, gums and lozenges as well as mouth rinses which brought people's attention to its potential dental benefit (Vlachojannis et al., 2016).

Patient compliance to prescribed mouth rinses is influenced by several factors including availability, cost as well as tolerability which include taste, texture and consistency (Mishra et al., 2016). In order to ensure patient compliance, these factors and others should always be considered when developing

Table 4 Objective findings for study participants at follow up.

	NAGT group n = 18; n (%)	CHX group n = 18; n (%)	Total n = 36; n (%)	p-value
No mucosal findings	10 (55.6%)	15 (83.3%)	25 (69.4%)	0.146[F]
Bite injury	1 (5.6%)	2 (11.1%)	3 (8.3%)	1.0[F]
Mucosal desquamation	5 (27.8%)	0	5 (13.9%)	0.045[*,F]
Mucosal ulceration	1 (5.6%)	1 (5.6%)	2 (2.3%)	1.0[F]
Mucosal ulceration and desquamation	1 (5.6%)	0	1 (2.8%)	1.0[F]

[F] Fisher Exact test.
[*] Statistically significant $p < 0.05$.

a new mouth rinse for dental uses. The fact that NAGT Listerine® was recently introduced to the international market as an alcohol-free mouth rinse, its tolerability by patients was under-investigated. In the current study, NAGT Listerine® mouth rinse was evaluated for patients' tolerability in comparison to CHX. In general, both were tolerable and demonstrated similar side effects of minimal secondary xerostomia and dental sensitivity. However, participants reported more frequent secondary oral burning with NAGT Listerine® but similar frequency of oral dryness for both Listerine® and CHX. Historically, oral burning and dryness with mouth rinses have been attributed to alcohol contents. Even with CHX containing 11.6% alcohol, NAGT Listerine® mouth rinse resulted in similar mucosal dryness outcome more significant oral burning. Comparing NAGT Listerine® with CHX in terms of mouth pain and sensitivity, not difference was noted except for malodor which improved for 3 patients in the CHX group. This could be attributed to more potent anti-microbial effect of CHX. In addition, there was a trend for participant to "like" more CHX compared to NAGT Listerine® as a mouth rinse even if they were comfortable with the rinse texture and consistency. This finding was less anticipated considering its alcohol-free nature which may shift the focus on other Listerine® contents as possible offenders which include eucalyptol, menthol, methyl salicylate, and thymol in addition to camellia sinensis leaf extract, and sodium fluoride (Johnson and Johnson Middle East FZ – LLC, 2016). At this point, it is unclear which of these elements could be responsible for less patient tolerability and need to be further investigated. Until then, modification of Listerine®'s manufacturer directions is suggested which may include shortening of application time or mouth rinse dilution. The impact of such modification on the mouth rinse efficacy is still questionable.

In addition to subjective parameters, intra-oral changes were also recorded as part of this study. Desquamations and ulceration were both reported more frequently in the NAGT Listerine® group compared to CHX mouth rinse group (Alshehri, 2018). This finding was consistent with secondary oral burning and suggestive of less tolerability of NAGT Listerine® by oral mucosal tissues. The relation of Listerine® and oral desquamation has been reported in the literature previously and it was attributed to the alcohol content of the mouth rinse and burn-like effect on the oral mucosa if used for an extended period of time (Vlachojannis et al., 2016). This phenomenon could be seen histologically as tissue edema with epithelial detachment (Carretero Pelaez et al., 2004; Wirth et al., 2012). In the current study, subjects received a new alcohol-free green tea-based Listerine® which may suggest for other Listerine® component to induce oral desquamation other than alcohol. Current label on Listerine® include eucalyptol, menthol, methyl salicylate, and thymol in addition to camellia sinensis leaf extract, and sodium fluoride. The combination of menthol and methyl salicylate has been used as a topical application for several indication including insects' bites and muscle pain (Dolen et al., 2015; Vlachojannis et al., 2016). One of the reported side effects for this application is burning sensation which may explain the oral burning reported by dental subjects who received NAGT Listerine® in the absence of alcohol contents (Higashi et al., 2010).

The current study has several limitations. First, the small sample size and short follow up duration which may have not allowed for complete evaluation of both mouth rinses tolerability by participants. However, extended use of the mouth rinse may result in more unfavorable side effects experienced by participants which were already reported after 14 days. Second, patient compliance may have played a role in the current data through under- or over-use of the assigned rinse. Third, instructions given to study subjects were based on manufacturer's guidelines in order to standardize the application protocol. However, this may not truly represent the actual protocol used by the general public. Modifications of instructions through solution dilution and/or shorter tissue-solution contact time may have been helpful in comparing results which should be evaluated in future studies. Fourth, there was a difference in reported mouth dryness at baseline between participants in the two groups. Although the group assignment was random, we believe that due to the small sample size, the difference in mouth dryness at baseline occurred by chance.

5. Conclusion

Mouth rinse tolerability is key to promote patient compliance specifically in cases of active therapy for dental diseases. Based on the current data, patient tolerability of NAGT mouth rinse could be inferior to CHX mouth rinse more evident in terms of oral burning and dryness. Further prospective randomized clinical trials with larger sample and longer follow ups are recommended to confirm these findings.

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Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Declaration

We confirm to have the data and material available if needed.

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