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Clinical effects of a new mouthrinse containing chlorhexidine, cetylpyridinium chloride and zinc-lactate on oral halitosis

A dual-center, double-blind placebo-controlled study

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Abstract

Objectives: The aim of this double-blind, parallel study was to test the clinical efficacy of a newly developed mouthrinse in the treatment of oral halitosis in patients without periodontitis.

Material and methods: Forty volunteers, recruited in two centers, participated in this study. Patients were selected on the basis of (1) halitosis of oral origin, (2) full-mouth organoleptic score > 1, using an arbitrary 0–5 scale, (3) level of volatile sulfur compounds (VSC) > 170 parts per billion (ppb) and (4) Winkel tongue coating index (WTCI) > 4 (0–12). Intervention included gargling with a mouthrinse containing chlorhexidine (0.05%), cetylpyridinium chloride (0.05%) and zinc-lactate (0.14%) or with a placebo mouthrinse without active ingredients. At days 0 and 14 clinical variables were assessed in order of performance: (1) organoleptic assessments, (2) levels of VSC, and (3) WTCI.

Results: Treatment with the active mouthrinse resulted in a significant mean reduction in the organoleptic score from 2.8 to 1.5 ($p < 0.005$). In the placebo group, no significant reduction in the mean organoleptic score occurred. Consequently, this resulted, after 2 weeks, in a greater change of the organoleptic scores in the test group in comparison to the placebo group ($p < 0.005$). The mean VSC scores were reduced from 292 to 172 ppb in the test group ($p < 0.005$), whereas no reduction was observed in the placebo group. At the 2-week examination, the mean change of the VSC scores in the test group was significantly greater than the mean change in the placebo group ($p < 0.005$). Neither in the test nor in the placebo group a significant reduction in tongue coating was observed.

Conclusions: In conclusion, the tested mouthrinse is effective in the treatment of oral halitosis.

Key words: halitosis; volatile sulfur compounds; chlorhexidine; cetylpyridinium chloride; zinc-lactate; mouthrinse; double-blind placebo-controlled study

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Halitosis is a general term used to describe an unpleasant or offensive odor emanating from the oral cavity. Several nonoral pathological conditions have been related to oral malodor, including infection of the upper and lower respiratory tracts, the gastrointestinal tract, and some metabolic diseases involving the kidneys or the liver (Manolis 1983). However, clinical surveys have shown that around 90% of all bad breath odors originate in the mouth (Delanghe et al. 1997). Oral halitosis is the specific term used to define halitosis with an origin within the oral cavity. Other conditions that are associated with offensive body odours are bromidrosis (Leyden et al. 1981, Lukacs et al. 1991, Guillet et al.

2000), flatulence and excessive production of bowel gases (Suarez et al. 1999, Bell & Ciclitira 2000). These conditions have in common that bacteria play an essential role in the etiology. Most subjects suffer from bad breath after awakening. This condition is transitory and is attributed to physiologic causes, such as reduced salivary flow during sleep. Persistent bad breath may be indicative of either oral diseases, such as periodontal diseases or the presence of excessive bacterial reservoirs in the mouth, or systemic diseases, such as hiatus hernia, hepatic cirrhosis or diabetes mellitus. Due to the importance of social interactions in contemporary society, populations in several countries around the world are becoming more concerned about oral halitosis and now pay more attention to this condition. This has been reflected in the results of a telephone survey carried out in the United States, where 60% of American women and 50% of men reported the use of cosmetic breath-freshening products (Tessier & Kulkarni 1991). Information regarding the prevalence of oral halitosis, however, is scarce due to the lack of epidemiological studies. In Japan the prevalence of individuals with complains of halitosis is approximately 14% (National Survey 1999). A study from the Netherlands among 11,625 individuals revealed a prevalence of approximately 25% in subjects >60 years of age (De Wit 1966). In subjects <20 years of age, the prevalence of oral halitosis was 10%, indicating that the prevalence of this condition increases with age. In the USA, it is estimated that 10–30% of the adult population have an appreciable problem with bad breath (Meskin 1996).

The pathogenesis of oral halitosis is associated with the bacterial degradation of sulfur-containing amino acids (methionine, cystine and cysteine) into volatile sulfur compounds (VSC), of which hydrogen sulfide (H_2S) and methyl mercaptan (CH_3SH) are the major compounds. Diamines, such as putrescine and cadaverine, have also been associated with oral halitosis (Goldberg et al. 1994, Greenstein et al. 1997, Scully et al. 1997), although this is not universally accepted (Tonzetich 1977). Gram-negative, proteolytic bacteria are believed to play an essential role in the cause of oral halitosis, although Gram-positive bacteria such as *Peptostreptococcus* species have also shown an ability to produce VSC in vitro (Persson et al. 1989, Claesson et al. 1990, Persson et al. 1990).

Oral halitosis may be associated with gingivitis and periodontitis. In fact, deep periodontal pockets are associated with increased VSC in mouth air (Coil & Tonzetich 1992, Yaegaki & Sanada 1992a, b). It has also become clear however that oral halitosis may occur in individuals with a healthy periodontium (Kaizu et al. 1978, Bosy et al. 1994). In these cases, it is believed that the bacterial mass located at the posterior dorsum of the tongue is the principal site where malodorous compounds are produced (Bosy et al. 1994, De Boever et al. 1994). Individuals that suffer from oral halitosis have a significantly higher bacterial load on the dorsum of the tongue in comparison to individuals without oral halitosis (Yaegaki & Sanada 1992a, De Boever & Loesche 1995).

It has been shown that mechanical tongue cleaning has a significant effect on the VSC level in mouth air (Yaegaki & Sanada 1992a,b). In addition, the use of chemical antimicrobial agents, mainly used as a mouthrinse, has been advocated (Nachnani 1997). The efficacy of these products on oral halitosis however is not clear since the number of controlled clinical trials is scarce. In fact, after a thorough search in the scientific literature, only five studies were retrieved. From these, chlorine dioxide (Frascella et al. 1998, 2000) and a two-phase/oil–water mouthrinse (Rosenberg et al. 1992, Kozlovsky et al. 1996) have shown clinical efficacy. After scaling and root planing of all pockets within 24 h together with the application of chlorhexidine, Quirynen et al. (1998) found a reduction in organoleptic scores after the treatment of periodontitis patients with and without complaints of oral halitosis.

Recently, a mouthrinse specifically developed to treat halitosis has been marketed (Halita®, Dentaid SL, Spain). This product contains chlorhexidine (0.05%), cetylpyridinium chloride (0.05%) and zinc-lactate (0.14%). The aim of this study was to test the clinical efficacy of this mouthrinse in the treatment of halitosis in patients without periodontitis.

Material and Method

Study design

This study was designed as a parallel, dual-center, randomized, double-blind, placebo-controlled clinical trial of 2-week duration. It was carried out with the approval of the medical ethical committee of the University Complutense of Madrid.

Study population

A total of 40 volunteers participated in the study. Subjects were referred to the Clinic for Periodontology Amsterdam ($N = 20$) or the University Complutense of Madrid ($N = 20$) for diagnosis and treatment of halitosis. After a screening session, patients were selected on the basis of the following criteria:

(1) presenting halitosis of oral origin,
(2) an organoleptic score >1, using an arbitrary 0–5 scale (0 = no halitosis to 5 = offensive halitosis) (Rosenberg et al. 1991a; Rosenberg et al. 1991b),
(3) a level of VSC >170 parts per billion (ppb) determined with a portable sulfur compounds detector (Halimeter®),
(4) a Winkel tongue coating index (WTCI) >4 (for an explanation, see below) and
(5) probing pocket depths not exceeding 4 mm with the possible exception of distal sites of second molars and pockets at wisdom teeth if present.

Exclusion criteria were:

(1) systemic diseases, pregnancy and systemic medication related to oral dryness and
(2) systemic antibiotic therapy 1 month prior to the study.

Screening visit

The purpose of the study and the treatment procedures were fully explained to the patients, who demonstrated their willingness to participate by signing the appropriate informed consent. During this visit, extensive periodontal and halitosis examinations were performed in order to determine whether patients fulfilled the entrance criteria. Patients that met with the inclusion criteria and were willing to participate in the study received written instructions and a detailed medical and halitosis questionnaire. In these instructions subjects were asked not to: (1) consume food containing onions, garlic or hot

spices 48 h before the baseline measurements, (2) drink alcohol or smoke in the previous 12 h, (3) perform oral hygiene, including tooth brushing, interdental and tongue cleaning and not to use mouthrinses the morning of the examination, (4) eat and drink in the previous 8 h (drinking of water until 3 h before examinations was allowed) and (5) use scented cosmetics or after-shave lotions in the morning of the examination.

Study visits

Clinical examinations were carried out at baseline (day 0) and at 2 weeks. At baseline participants were randomly assigned, using a computer-generated list, to receive a coded study mouthwash, being either the active mouthwash or placebo. This placebo mouthwash had a similar color as the experimental product, a slightly bitter taste but lacked the active ingredients. The subjects were instructed to use their assigned mouthwash twice daily, i.e. in the morning and in the evening, after their normal oral hygiene procedures for the following 14 days. They were instructed to gargle with 15 ml of the mouthwash for 1 min and to avoid rinsing. During the 2-week study period they were provided with a lauryl-sulfate-fluoride-containing regular toothpaste and a regular toothbrush; however, no further instructions or modifications of their normal hygiene or dietary habits ensued. They were asked not to use other mouthwashes, toothpastes and/or other oral hygiene devices. To assess their compliance, participants were requested to return the empty bottles of the mouthwash and the remaining contents were measured.

Clinical evaluation

At each clinical center, one trained and calibrated examiner (SR, EGW) was responsible for all clinical measurements taken at baseline and at 2 weeks. The records of earlier examinations were not available to the investigator at the time of re-evaluation. The clinical investigators were unaware of the treatment at any time point of the study.

At days 0 and 14, the following clinical variables were assessed in order of performance:

1. full mouth organoleptic odor assessments, using an arbitrary 0–5 scale (0 = no halitosis to 5 = offensive halitosis);
2. levels of VSC scored by means of a portable sulfide compounds detector (Halimeter®, Interscan Corp., Chatsworth, CA, USA);
3. WTCI (for an explanation, see below);
4. Winkel tongue discoloration index (for an explanation, see below);
5. at baseline, unstimulated salivary flow rate during 1 min was measured using the Sialometer® (ProFlow Inc., New York, NY,USA);
6. evaluation of tooth staining at the buccal surface of the lower left anterior incisor (t. # 31).

At baseline, demographic and secondary variables such as age, sex, dry mouth sensation, smoking habits and number of daily liquid and alcohol consumptions were evaluated.

Organoleptic measurements

Organoleptic ratings were obtained only in the morning. For the organoleptic evaluation, participants were instructed to close their mouth for 1 min, and then to slowly exhale air, at a distance of approximately 10 cm from the nose of the examiner. Two independent and consecutive subjective organoleptic measurements were taken, using an arbitrary 0–5 scale (0 = no halitosis to 5 = offensive halitosis) (Rosenberg et al. 1991a, Rosenberg et al. 1991b). The mean of both scores represented the individual organoleptic score.

VSC measurement

A Halimeter®, connected to a pen recorder, was used to assess the level of VSC in mouth air. The monitor was calibrated to zero on ambient air prior to each measurement. The patient was asked to close the mouth for 1 min after which the mouth was opened and the tongue protruded. A disposable straw was placed at the dorsal posterior midpart of the tongue and fixed until the maximum peak value of VSC was recorded. Peak VSC level was registered in parts per billion. Identical-sized straws were used in both centers. Two independent and consecutive measurements were taken. The mean of both scores represented the individual VSC score.

WTCI

The dorsum of the tongue was notionally divided into six areas, i.e. three in the posterior and three in the anterior part of the tongue. The tongue coating in each sextant was scored as 0 = no coating, 1 = light coating and 2 = severe coating. The tongue coating value was obtained by the addition of all six scores, range 0–12 (WTCI).

Winkel tongue discoloration index

In the six areas of the tongue, each sextant was scored as 0 = no discoloration, 1 = light discoloration and 2 = severe discoloration. The tongue discoloration value was obtained by the addition of all six scores, range 0–12 (WTDI).

Tooth staining

Before and after treatment, standardized clinical photographs of the buccal surface of the lower anterior teeth (110 ASA films, size 1/1, and speed adjusted to TTL flash) were taken and compared for the evaluation of tooth staining using two different scales (Addy et al. 1995):

Surface stain coverage: 0 = no staining area, 1 = only proximal staining area, 2 = proximal staining area and points on the buccal surface, 3 = proximal and buccal staining area.

Surface stain intensity: 0 = no staining, 1 = light staining, yellow, 2 = medium staining, brown, 3 = dark staining, black.

Data analysis

For each of the outcome variables, the mean score per subject was calculated both at baseline and at the 2-week visit. At baseline and after therapy, differences between test and placebo group were analyzed, using Mann–Whitney tests (SPSS 8.0 package). Changes from baseline to the 2-week visits were compared with Mann–Whitney tests. A comparison between centers was performed for all data at each assessment, using Mann–Whitney tests. Where appropriate, Bonferroni corrections were made for multiple testing. No differences between the two centers were found when comparing changes from baseline to the 2-week visit. Values of $p < 0.05$ were accepted as statistically significant.

Results

A total of 40 subjects, including 19 females and 21 males, completed the study. The mean age of the study population was 43.8 years (*SD* 15.8, range 21–84). The mean age of the test group amounted to 40.9 years (*SD* 14.1) and 46.8 years (*SD* 17.1) for the placebo group. Seven patients from Spain and one patient from The Netherlands were current smokers (four in the test group, four in the placebo group). According to the questionnaire, eight patients in the test group and nine in the placebo group complained of dryness of the mouth at baseline. Nocturnal oral breathing was reported in six patients in the test group and nine in the placebo group. In the test group 14 patients complained of bad taste versus 10 in the placebo group. The total number of drinks per day is summarized in Table 1. The mean total number of drinks per day was 8.3 in the test group and 7.6 in the placebo group. Three patients consumed $\geqslant 8$ cups of coffee per day. The mean number of alcohol consumption per day in the test group was 1.1 (*SD* 1.3, range 0–4) and 0.9 (*SD* 1.2, range 0–4) in the placebo group. No significant differences in coffee or alcohol consumption between the groups were noted.

The mean salivary flow rate (ml/min) at baseline was 1.3 for the test group and 1.1 for the placebo group (Table 2).

The mean organoleptic and VSC scores at baseline and after 14 days of treatment are shown in Table 3. Baseline organoleptic and VSC scores were not significantly different between test and placebo groups.

Treatment with the active mouthwash resulted in a significant reduction in the organoleptic score and dropped from 2.8 to 1.5 ($p<0.005$). In the placebo group, no significant reduction in the mean organoleptic score occurred. Consequently, the change of organoleptic scores in the test group, at the 2-week examination, was significantly greater than in the placebo group ($p<0.005$).

Table 1. Number (standard deviation) and range of reported drinks per day in the test and the placebo group

$N=40$	Total consumption	Coffee consumption	Alcohol consumption
Test			
mean	8.3 (3.2)	3.2 (2.1)	1.1 (1.3)
range	3.5–16	0–8	0–4
Placebo			
mean	7.6 (3.2)	2.9 (2.4)	0.9 (1.2)
range	2.5–15	0–8	0–4

Table 2. Salivary flow rate (ml/min) at baseline

	Mean	Minimum	Maximum
test			
$n=20$	1.3 (0.8)	0.3	3.0
placebo			
$n=20$	1.1 (0.7)	0.2	3.0

n: number of patients; ( ): standard deviation.

Table 3. Mean organoleptic and VSC scores of the test and the placebo groups

	Organoleptic score			Peak VSC (ppb)		
	Baseline	After Tx	Mean change	Baseline	After Tx	Mean change
test						
$n=20$	2.8 (0.5)	1.5 (1.0)*	−1.3 (1.1)**	292 (141)	172 (104)*	−120 (92)**
placebo						
$n=20$	2.7 (0.8)	2.5 (1.1)	−0.2 (0.7)	352 (161)	360 (254)	8 (145)

n: number of patients; ( ): standard deviation; Tx: treatment; ppb: parts per billion;
*significant change from baseline ($p<0.005$);
**significant difference between groups after therapy ($p<0.005$).

The mean VSC scores were reduced from 292 to 172 ppb in the test group ($p<0.005$), whereas no reduction was observed in the placebo group. At the 2-week examination, the change of the VSC scores in the test group was significantly greater than in the placebo group ($p<0.005$).

The mean WTCI values at baseline and after treatment are summarized in Table 4. Neither in the test group nor in the placebo group a significant reduction in WTCI was observed.

Adverse effects

The WTDI after treatment is shown in Table 5. Significant more discoloration was present after therapy in the test group ($p<0.001$) whereas no changes after therapy was present in the placebo group. After therapy the changes of the discoloration values in the test group were significantly higher when compared to the placebo group, 3.0 and 0.6 respectively ($p<0.002$).

The changes in tooth staining assessed on the buccal surface of tooth #31 both in regard to stain coverage scores or stain intensity scores did not reveal any statistically significant differences when the test group was compared to the placebo group (Table 6).

Compliance

The mean quantity of mouthwash used per rinse amounted to 13.2 ml (*SD* 2.4, range 8.3–17.9) for the test group and 12.4 ml (*SD* 0.6, range 6.3–15.8) for the placebo group. Most of the patients did not reach the mean value of 15 ml per mouthrinse. Since this was true for both the test and the placebo group, no significant differences in compliance were found between the test and the placebo group.

Discussion

In this clinical trial the effects of a mouthwash on treatment outcome variables (organoleptic and the VSC scores) in subjects suffering from oral halitosis without periodontitis were investigated. In order to evaluate the efficacy of the tested mouthrinse, the participants were instructed not to clean the dorsum of the tongue mechanically. Patients were instructed to use 15 ml mouthrinse twice a day for 2 weeks. Although the compliance of most patients was not optimal,

Table 4. Winkel tongue coating index at baseline and after treatment in test and placebo groups

	Baseline	After Tx	Mean change
test			
$n = 20$	8.0 (2.1)	8.5 (2.7)	0.5 (3.4)
placebo			
$n = 20$	8.6 (1.8)	8.1 (2.1)	− 0.5 (2.4)

n: number of patients; ( ): standard deviation; Tx: treatment.

Table 5. Winkel tongue discoloration index at baseline and after treatment in test and placebo groups

	Baseline	After Tx	Mean change
test			
$n = 20$	0.2 (0.7)	3.0 (3.2)*	2.8 (3.2)**
placebo			
$n = 20$	0.3 (1.3)	0.6 (1.8)	0.3 (1.3)

n: number of patients; ( ): standard deviation; Tx: treatment;
*$p < 0.0001$ before and after Tx;
**$p = 0.002$ between groups.

Table 6. Stain coverage score and stain intensity score of the lower left incisor 31 at 2 weeks

	Stain coverage score			Stain intensity score		
	Baseline	After Tx	Mean change	Baseline	After Tx	Mean change
test						
$n = 20$	0.9 (0.9)	1.0 (0.9)	0.1 (0.4)	0.6 (0.6)	0.8 (0.9)	0.2 (0.7)
placebo						
$n = 20$	0.9 (0.9)	0.9 (0.9)	0 (0.3)	0.8 (0.8)	0.8 (0.8)	0 (0.6)

n: number of patients; ( ): standard deviation; Tx: treatment.

the results showed a clear reduction of both organoleptic and VSC scores in the group using the active mouthwash. This indicates that a formulation using low concentrations of chlorhexidine, cetylpyridinium chloride and zinc-lactate is an effective combination of chemical compounds able to reduce the amount of volatile compounds in mouth air responsible for halitosis.

It has been reported that the dorsum of the tongue is the primary source of VSC both in periodontally diseased and healthy people (Yaegaki & Sanada 1992a). Mechanical removal of the tongue coating reduces VSC concentrations in the mouth air of periodontally healthy individuals by 52% (Yaegaki & Sanada 1992b). Since chlorhexidine and cetylpyridinium chloride are both antimicrobial agents, it seems reasonable to assume that the tested mouthwash acts by reducing the number of VSC-producing bacteria on the dorsum of the tongue. Moreover, zinc-lactate, besides its antimicrobial activity, may reduce VSC by transforming them into insoluble compounds (Rölla et al. 1996; Young et al. 2001).

There are few controlled clinical trials that report on the clinical efficacy of antimicrobial mouthrinses in the treatment of oral halitosis (Rosenberg et al. 1992, Kozlovsky et al. 1996, Frascella et al. 1998, 2000, Quirynen et al. 1998). Frascella et al. (1998, 2000) demonstrated the efficacy of a chlorine dioxide-containing mouthrinse in reducing oral malodor after a one-time use in patients with ''unpleasant'' breath. These studies were of short-term duration, i.e. the effects were measured after a number of hours. The outcome variables were based on pleasantness scores and intensity scores. Their results, therefore, cannot be compared with the results of the present investigation. In a test group, using high dosages of chlorhexidine in combination with a subgingival debridement in 24 h, Quirynen et al. (1998) observed the reduction of organoleptic scores in severe periodontitis patients. No differences in VSC levels however were found between patients in the test group versus those who received conventional periodontal therapy. Rosenberg et al. (1992) found a significant reduction in VSC scores in mouth air using a two-phase/oil–water mouthrinse containing cetylpyridinium chloride. Kozlovsky et al. (1996) were not able to confirm these observations. They found however significant reductions in organoleptic and tongue odor scores. In both studies organoleptic and VSC baseline scores were low, presumably because the test populations consisted of students without complaints of halitosis. The abovementioned studies are difficult to compare with the present investigation, because none of the studies seems to be related to overt oral halitosis patients without periodontitis.

In the present study, patients were not allowed to clean the tongue mechanically. In this subject population, no differences were observed in the mean tongue-coating index before and after treatment in both groups. This indicates that the mere presence of a tongue coating does not necessarily lead to oral halitosis and that reduction of the VSC production can be achieved in the presence of a tongue coating. On the basis of these observations, one can hypothesize that the composition of the tongue coating rather than the thickness or extension of the tongue coating is a determining factor in oral halitosis.

Oral dryness has seldom been reported to occur simultaneously with complaints of halitosis (Locker 1993). Because of the known diuretic effects of coffee (Nussberger et al. 1990, Neuhauser et al. 1997) and alcohol (Jones 1990, Leppaluoto et al. 1992, Shirreffs & Maughan 1997), the daily intake was registered and seems to be within normal limits in both groups (Table 1). Theoretically, the salivary flow might influence the volatilization of malodorous components generated in the oral cavity. The unstimulated salivary flow in 1 min was tested in this study (Table 2). This registration has been validated as a useful measure of dryness (Sreebny 1989). The results showed that, although the study subjects presented moderate to severe levels of oral halitosis, the registered levels of unstimulated salivary flow rates were at normal levels (minimum = 0.2 ml/min) (Navazesh et al. 1992, Longman et al. 1997). No correlation could be found

with any of the evaluated halitosis-related parameters and the salivary flow rate. These results are in accordance with the finding of Oho et al. (2001) but in contrast with those of Yaegaki et al. (1992b).

The one adverse effect of the active mouthwash was staining of the dorsum of the tongue. No changes of the stain coverage or intensity scores were seen at indicator tooth #31. This indicates that the subjects mainly have gargled rather than rinsed with the mouthwash. In conclusion, Halita®, a mouthrinse containing low concentrations of chlorhexidine (0.05%), cetylpyridinium chloride (0.05%) and zinc-lactate (0.14%), is effective in the treatment of oral halitosis.

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Zusammenfassung

Klinischer Effekt einer neuartigen Chlorhexidin, Cetylpyridiniumchlorid und Zinklaktat enthaltenden Mundspüllösung auf Mundgeruch. Eine bizentrische plazebokontrollierte Doppelblindstudie

Zielsetzung: Untersuchung der klinischen Wirksamkeit einer neu entwickelten Mundspüllösung für die Behandlung von Mundgeruch bei Patienten, die keine Parodontitis haben, mittels einer parallelarmigen Doppelblindstudie.

Material und Methoden: 40 Freiwillige, die an 2 Zentren rekrutiert wurden, nahmen an dieser Studie teil. Die Patienten wurden nach folgenden Kriterien ausgewählt: 1) Mundgeruch, 2) organoleptischer Wert der gesamten Mundhöhle $>$ 1 auf einer arbiträren Skala von 0 bis 5, 3) Spiegel flüchtiger Schwefelverbindungen (VSC) $>$ 170 parts per billion (ppb), 4) Winkel Zungenbelagsindex (WTCI) $>$ 4 (0-12). Die Therapie umfasste Gurgeln mit einer Mundspüllösung, die Chlorhexidin (0,05%), Cetylpyridiniumchlorid (0,05%) und Zinklaktat (0.14%) enthielt oder mit einer Plazebospüllösung, die keine aktiven Bestandteile aufwies. Am Tag 0 und 14 wurden klinische Parameter in folgender Reihenfolge erhoben: 1) organoleptische Messungen, 2) VSC-Spiegel, 3) WTCI.

Ergebnisse: Die Behandlung mit der aktiven Spüllösung resultierte in einer signifikanten mittleren Reduktion des organoleptischen Werts von 2,8 auf 1,5 ($p<0{,}005$), während in der Plazebogruppe keine signifikante Verringerung des mittleren organoleptischen Werts beobachtet wurde. Konsequenterweise ergab sich nach 2 Wochen in der Testgruppe eine stärkere Veränderung des organoleptischen Werts als in der Plazebogruppe ($p<0{,}005$). Der mittlere VSC-Wert wurde in der Testgruppe von 292 auf 172 ppb reduziert ($p<0{,}005$), während in der Plazebogruppe keine Veränderung auftrat. Nach 2 Wochen wurde in der Testgruppe eine signifikant stärkere Veränderung des VSC-Werts beobachtet als in der Kontrollgruppe ($p<0{,}005$). Weder in der Test- noch in der Plazebogruppe wurde eine signifikante Reduktion des Zungenbelags beobachtet.

Schlussfolgerung: Die untersuchte Mundspüllösung ist wirksam zur Behandlung von Mundgeruch.

Résumé

Effets cliniques d'un nouveau bain de bouche contenant de la chlorhexidine, du chlorure de cetylpyridinium et du lactate de zinc sur l'halitose buccale. Une étude bi-centrique contrôlée par placebo en double aveugle.

Objectifs: Le but de cette étude bi-centrique en double aveugle en parallèle était de tester l'efficacité clinique d'un bain de bouche récemment développé pour le traitement de l'halitose buccale sans parodontite.

Matériel & Méthodes: 40 volontaires recrutés dans deux centres ont participé à cette étude. Les patients ont été sélectionnés sur les critères suivants : 1) halitose d'origine buccale, 2) score organoleptique de la bouche complète $>$ 1, en utilisant une échelle arbitraire allant de 0 à 5, 3) un niveau de composés volatiles sulfurés (VSC) $>$ 170 portions par billion (ppb) 4) un indice de recouvrement de la langue de Winkel (WTCI) $>$ 4 (0–12). L'intervention comprenait un gargarisme avec un bain de bouche contenant de la chlorhexidine (0.05%), du chlorure de cetylpyridinium (0.05%) et du lactate de zinc (0.14%) ou avec un placebo sans ingrédients actifs. Au jours 0 et 14 les paramètres cliniques furent relevés pour l'ordre d'exécution 1) estimation organoleptique 2)niveaux de VSC, 3) WTCI.

Résultats: le traitement avec le bain de bouche actif résultait en une réduction moyenne significative du score organoleptique de 2.8 à 1.5 ($p < 0.005$). Dans le groupe placebo, aucune réduction significative du score moyen organoleptique n'était par contre relevée. En consequence, ceci impliquait après 2 semaines un changement plus grand des scores organoleptiques dans le groupe test par rapport par rapport au groupe placebo ($p < 0.005$). Les scores moyens de VSC étaient réduits de 292 à 172 ppb dans le groupe test ($p < 0.005$), alors qu'aucune diminution n'était observée dans le groupe placebo. Lors de l'examen à 2 semaines, le changement moyen des scores de VSC dans le groupe test était significativement plus importants que le changement moyen dans le groupe placebo. ($p < 0.005$). Aucune réduction significative du recouvrement de la langue n'était par contre observée, ni dans le groupe test, ni dans le groupe placebo.

Conclusions: En conclusion, Le bain de bouche testé est efficace pour le traitement de l'halitose.

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