Efficacy of Two Experimental CPC Mouthrinses in a 6-Month Study

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ABSTRACT

Objective: The objective of this study was to evaluate the longitudinal effects of two experimental CPC (cetylpyridinium chloride) mouthrinses containing .075% and 0.10% CPC, respectively, on the development of gingivitis and plaque versus a placebo control. **Methods:** This was a double blind, 6-month, parallel group, placebo controlled study involving 366 subjects who were balanced and randomly assigned to treatment groups. For study validation purposes, a 0.12% chlorhexidine rinse (Peridex) served as the positive control. The CPC mouthrinses were formulated to pass proposed performance assays by the FDA for OTC CPC mouthrinses. At study start, subjects received a dental prophylaxis and began rinsing twice a day with 15 ml. of their assigned mouthwash for 30 seconds after brushing their teeth under both supervised and unsupervised conditions. Subjects were assessed for gingivitis and gingival bleeding by the Gingival Index (GI) method and plaque by the Turesky Plaque Index (MQH) at baseline and after 3 and 6 months of product use. Oral soft tissue health was also assessed. **Results:** Results show that after 3 and 6 months subjects rinsing with either 0.075% or 0.100% CPC had significantly ($p < 0.05$, 2-tail) less gingivitis, gingival bleeding, and plaque than those on placebo. The 6 month reductions in GI, gingival bleeding, and plaque for the 0.075 and 0.10% CPC rinses versus placebo were 23%, 30% and 17%, and 20%, 27% and 19%, respectively. There was no difference in efficacy between the 2 CPC mouthrinses. Reductions at 3 months were similar to those seen at 6 months. Significant benefits were observed with chlorhexidine, validating the study. **Conclusion: This study clearly demonstrated that properly formulated CPC mouthrinses when used twice daily can significantly prevent the development of gingivitis, gingival bleeding, and plaque over a 6 month period following a prophylaxis.**

INTRODUCTION

"The (OTC Plaque & Gingivitis) Subcommittee concludes that cetylpyridinium chloride (CPC) at concentrations of 0.045 to 0.1% with at least 72 to 77% chemically available CPC is safe and effective for use in mouthrinse formulations as an OTC antigingivitis/antiplaque agent."from "Advance notice of proposed rulemaking" Federal Register Vol. 68, No. 103/Thursday May 29, 2003/Proposed Rules, 32247.

PURPOSE

With this as background, the objective of this study was to evaluate the anti-gingivitis and anti-plaque efficacy of two properly formulated experimental CPC mouthrinses containing .075% and 0.10% CPC, respectively, over a 6 month period of time versus a placebo control.

MATERIALS AND METHODS

This was a double-blind, longitudinal (6 month) parallel group, placebo-controlled study. Planned measurements at baseline, and after 3 and 6 months of product use included assessments for gingivitis and gingival bleeding sites by the Gingival Index (GI) method, plaque by the Turesky modification of Quigley and Hein Plaque (MQH) Index, and Oral Soft Tissue Health (OST) by a visual examination of the Oral Cavity. Eligible subjects had to have a minimum of 16 gradeable, uncrowned natural teeth with 4 molars, a whole mouth GI score of $\geq$ 0.50, gingival bleeding in at least 10 sites as determined by the GI method, and a whole mouth MQH Plaque score of $\leq$ 3.0. A total of 366 subjects were accepted into the study. After grading for all parameters at baseline, subjects were provided a dental prophylaxis and were randomly assigned and balanced to one of 4 mouth rinse treatment groups: CPC placebo, 0.075% CPC, 0.10% CPC, or 0.12% chlorhexidine (CHX served as the positive control for study validation purposes). Subjects were instructed to rinse with 15 ml of their assigned mouthrinse under both supervised (morning) and unsupervised (evening and weekends) conditions for 30 seconds twice daily for the next 6 months following brushing. The demographics and balance for the various treatments for subjects completing the study are shown below.

Study Demographics and Balance for Subjects Completing 6 Months

Treatment	N	Male/ Female	Mean Age	Mean GI	Mean Bleeding Sites	Mean Plaque
CPC Placebo	86	24/62	34.3	.81	20.2	2.11
0.075% CPC	82	24/58	34.1	.79	18.8	2.15
0.100% CPC	90	27/63	33.5	.81	20.3	2.12
0.12% CPC	40	11/29	34.5	.81	18.7	2.03

Covariance-Adjusted Study Validation Results

Treatment	Gingivitis (GI)		GI Bleeding Sites		Plaque (MQH)	
	Mean	%red.	Mean	%red.	Mean	%red.
3 Month Results						
CPC Placebo	0.70		15.5		1.95	
0.12% CHX	0.45	35	7.5	52	1.29	34
6 Month Results						
CPC Placebo	0.68		15.9		1.97	
0.12% CHX	0.46	33	8.8	45	1.35	32

0.12% CHX significantly different from CPC placebo at $\propto$ = 0.05, one-tailed test

RESULTS

Covariance-Adjusted Experimental Rinse Results

3 Month Results

Treatment	Gingivitis (GI)		GI Bleeding Sites		Plaque (MQH)	
	Mean	%red.	Mean	%red.	Mean	%red.
CPC Placebo	0.70		15.5		1.95	
0.075% CPC	0.54^{A}	22	11.0^{A}	29	1.53^{A}	22
0.100% CPC	0.54^{A}	22	9.6^{A}	38	1.47^{A}	25

6 Month Results

Treatment	Gingivitis (GI)		GI Bleeding Sites		Plaque (MQH)	
	Mean	%red.	Mean	%red.	Mean	%red.
CPC Placebo	0.68		15.9		1.97	
0.075% CPC	0.52^{A}	23	11.1^{A}	30	1.63^{A}	17
0.100% CPC	0.55^{A}	20	11.6^{A}	27	1.60^{A}	19

Means labeled ^{A} are not significantly different at $\propto$ = 0.05, 1-tailed test

CONCLUSION

This study clearly demonstrates that properly formulated CPC mouthrinses when used twice daily can significantly prevent the development of gingivitis, gingival bleeding, and plaque over a 6 month period following a prophylaxis.

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