RCT Comparing Post-Prophylaxis Use of Two-Step Hygiene or Chlorhexidine

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Objectives: A randomized controlled trial compared post-prophylaxis gingivitis prevention, extrinsic stain accumulation, and tolerability of two-step oral hygiene to a marketed prescription rinse. Methods: At the first visit, consent, eligibility and baseline measurements were obtained. A week later, a prophylaxis was administered, after which, test products were randomly dispensed balancing for baseline. Test groups were 1) two-step oral hygiene with a 0.454% SnF$_2$ paste followed by a 3% H$_2$O$_2$ gel (Crest® Pro-Health [HD]™) or 2) twice daily rinsing with 0.12% chlorhexidine gluconate (Peridex™) plus regular brushing with 0.76% NaMFP (Colgate® Cavity Protection). Products were over-labeled and dispensed in blinded kits with a soft flat manual brush and instructions. Subjects were evaluated monthly over 3 months. Gingivitis was measured by bleeding at 168 sites using the Loe-Silness Index, extrinsic stain was measured on 12 anterior teeth using the Lobene Stain Index, and safety was assessed from clinical examination. Results: A total of 44 subjects were randomized (mean age = 36.3 yr), and 35 (19 with two-step and 16 with rinse, respectively) completed the study. Baseline bleeding ranged from 10-33 sites. Both groups showed significant (p<0.001) reductions in bleeding sites at all post-prophylaxis time points. At Week 4, adjusted mean (SD) bleeding sites were 7.5 (0.8) and 9.8 (1.3) in the two-step and control, respectively. Comparing treatments, the two-step group exhibited up to 42% lower bleeding scores than chlorhexidine at the monthly visits, similar or superior (p<0.05) to control at all times. There was no evidence of stain accumulation (p>0.62) in the two-step group. In contrast, the rinse group exhibited staining (p<0.003) at Week 4, and differed (p<0.01) from the two-step group at each time point. Conclusions: After prophylaxis, two-step hygiene provided similar or superior gingivitis improvement to chlorhexidine without stain accumulation.

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