Pooled-Analysis of Anti-gingivitis Effects of a 67% Sodium Bicarbonate Dentifrice

Poster No. 1294

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Aim

- By way of a pooled-analysis of GSKCH gingival health clinical studies, determine the response, by tooth site and area, of brushing with a 67% w/w sodium bicarbonate dentifrice in reducing and controlling dental plaque and gingivitis compared to a regular dentifrice.

Background

- Gingivitis is an inflammatory response to the presence of dental plaque, which typically presents as redness, swelling, and/or bleeding of the gums at the gingival margin. Gingivitis is a reversible condition but, if left untreated, can progress to the irreversible phase of periodontitis. Maintenance of good gingival health is important in preventing gingivitis.
- Toothpastes containing high levels (67% w/w) of sodium bicarbonate have been shown to be effective at removing plaque and treating gingivitis. A number of GSK sponsored clinical studies conducted across 3 continents have consistently demonstrated statistically significant improvements in plaque control and gingivitis, relative to control dentifrice.

Methods

- Thirteen GSKCH sponsored clinical studies were identified.
- Inclusion of studies in the pooled analysis was determined based on those meeting the pre-specified criteria and in agreement with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.
- Study design inclusion criteria were inclusion of a pre-treatment full-mouth prophylaxis; subject eligibility (>20 bleeding sites and mild-moderate gingivitis at Screening); comparable indices of gingivitis and plaque accumulation; 67% w/w sodium bicarbonate dentifrice; repeat brushing for a period of at least 4 weeks.
- 7 studies were excluded: duration <4wks (5), no prophy (1), no comparable indices (1).
- In all included studies, twice-daily toothbrushing (unsupervised), and clinical outcomes were measured over a 6 week, 12 or 24-week period using the number of bleeding sites (BS), Bleeding Index (BI), Modified Gingival Index (MGI) and plaque (TPI).

Overview of studies selected for inclusion in pooled analysis

Study Reference Number	Kakar (2014) (a)	Newby (2014)	Kakar (2014) (b)	Lomax (2017)	Jose (2018)	Akwagyiram (2018)
Design	Single-center, examiner-blind, parallel group, stratified, randomized					
Study period	2012	2013	2013	2014	2015	2015
Product application	Subjects brushed teeth with a full strip of dentifrice for 1 minute					
Time points	Baseline, wks 6, and 12			Baseline, wk 6	Baseline, wks 6, 12, 24	
Study location	India	China	India	India	USA	USA
No. randomized subjects	330	342	288	148	246	247
ITT Population	309	336	279	135	235	240
Gender (male / female)	51/ 49%	25/ 75%	51/ 49%	43/ 57%	38/ 62%	43/ 57%
Stratification	Baseline no. bleeding sites and smoking status					

- Treatment comparisons were analysed using ANCOVA with factors for treatment, study, number of bleeding sites (high/low) and smoking status (yes/no) and inclusion of the baseline value as a covariate. For the analysis of BS the factor for number of bleeding sites was not included as the actual baseline levels was included as a covariate.

Results

Visit	Comparison of 67% Sodium Bicarbonate with Negative Control			
	Adj Mean Diff (SE)	95% CI	p-value	% Diff
Bleeding Sites (BS)				
Wk 6	-10.77 (0.562)	(-11.87, -9.66)	<.0001	-29.64
Wk 12	-12.34 (0.569)	(-13.45, -11.22)	<.0001	-40.42
Wk 24	-14.84 (0.837)	(-16.48, -13.19)	<.0001	-48.22
Bleeding Index (BI)				
Wk 6	-0.12 (0.006)	(-0.13, -0.11)	<.0001	-30.88
Wk 12	-0.14 (0.007)	(-0.15, -0.12)	<.0001	-41.28
Wk 24	-0.16 (0.010)	(-0.18, -0.14)	<.0001	-47.80
Modified Gingival Index (MGI)				
Wk 6	-0.30 (0.020)	(-0.34, -0.26)	<.0001	-15.43
Wk 12	-0.28 (0.027)	(-0.34, -0.23)	<.0001	-13.06
Wk 24	-0.42 (0.026)	(-0.47, -0.37)	<.0001	-19.42
Plaque (TPI)				
Wk 6	-0.27 (0.020)	(-0.31, -0.23)	<.0001	-8.86
Wk 12	-0.30 (0.021)	(-0.34, -0.26)	<.0001	-10.32
Wk 24	-0.45 (0.028)	(-0.50, -0.40)	<.0001	-15.33

Mean index scores and between treatment differences by index and timepoint

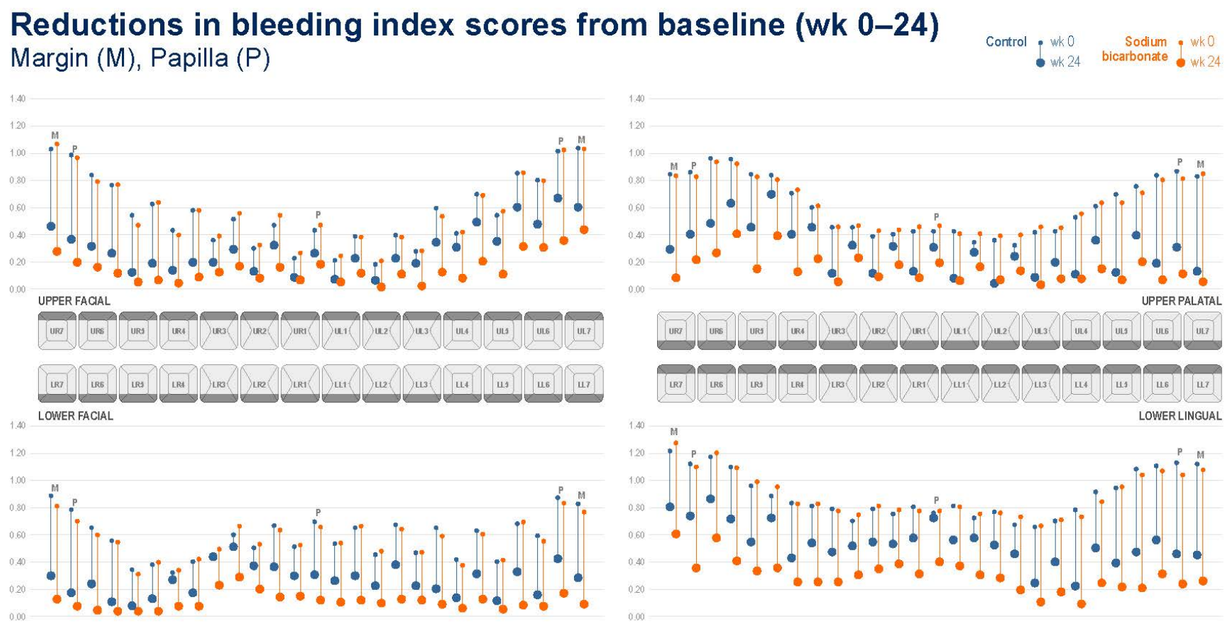

Figure 1a Bleeding index change from baseline for treatment and control product by tooth site

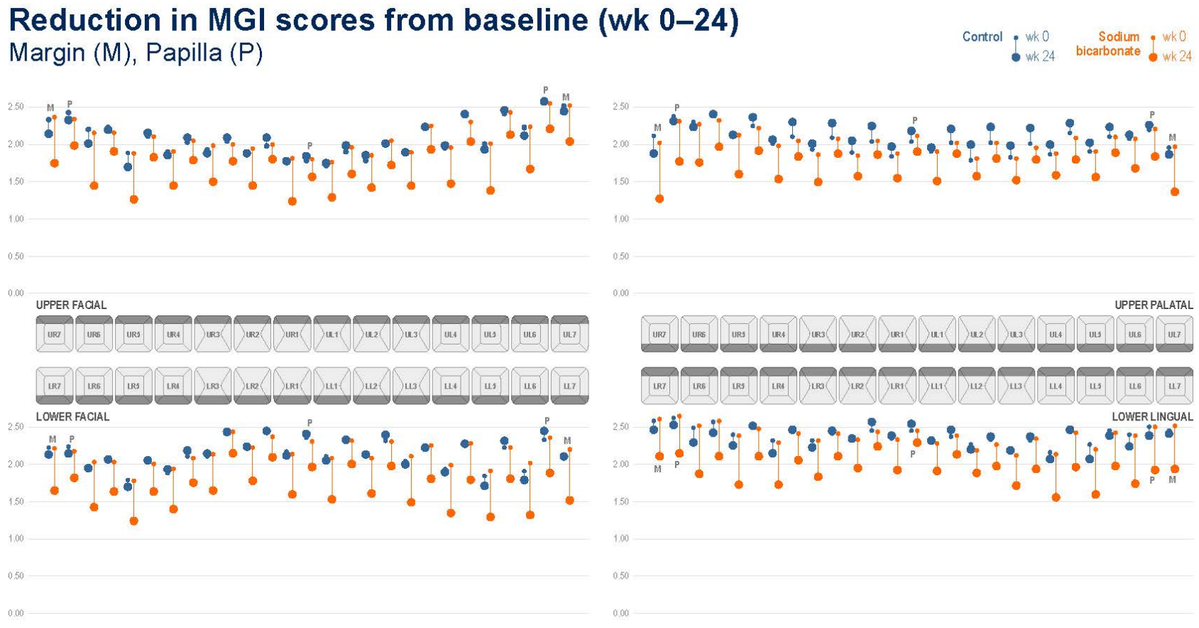

Figure 1b Gingival index change from baseline for test and control product by tooth site

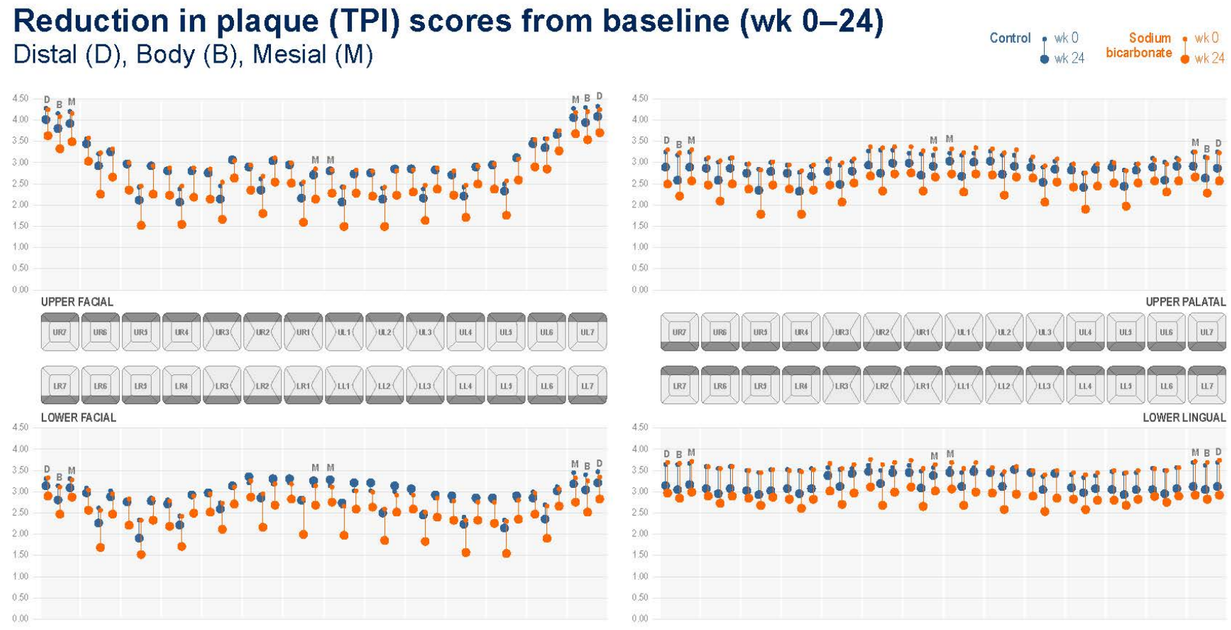

Figure 1a Plaque index change from baseline for test and control product by tooth site

Conclusions

- This pooled-analysis of six studies (across three countries) using subject-level data, demonstrated large, clinically meaningful improvements in measures of gingival health and oral hygiene, across all tooth sites and areas, following brushing with a 67% w/w bicarbonate dentifrice compared to a regular dentifrice.

References

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Acknowledgement's

- The presenting author declares the following real or perceived conflicts of interest during the last 3 years in relation to this presentation: Employed by GSKCH, a manufacturer of one of the products investigated in this study.
- The trial was registered at clinicaltrials.gov (NCT03703245). Anonymized data and study documents can be requested for further research from www.clinicalstudydatarequest.com.

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