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Research Article

Effects of a Fiber-Rich Nutritional Supplement on Postprandial Glycemic Response and Lipid Parameters in Overweight Adults with and without Impaired Fasting Glucose in India

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ABSTRACT

Objectives: This study evaluated the effects of a fiber-rich nutritional supplement on postprandial glycemic response and lipid parameters in overweight adults with and without impaired fasting glucose (IFG) in India. An ad-hoc analysis assessed the supplement's effects on glycemic and lipid parameters in overweight adults with and without IFG.

Methods: This was a randomized, double-blind, single-center study including 96 subjects. Among them, 26 subjects had IFG (100-125 mg/dL). After an overnight fast and a high-fat standardized breakfast, subjects were stratified according to IFG status and randomized to a fiber-rich drink or an energy-matched non-fiber control drink. Blood was drawn at 10, 20, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210- and 240-min following treatment administration to assess postprandial blood glucose, triglycerides, remnant-like particle-cholesterol (RLP-C) and insulin peaks. There was a 3-day washout period between treatments.

Results: Subjects with IFG displayed significantly lowered C_{max} for postprandial glucose with the fiber-rich supplement versus control (difference -4.64 mg/dL; p=0.0487). A lower postprandial triglyceride peak was also reported with the fiber-rich supplement; however, this difference was not statistically significant (difference -6.79 mg/dL; p=0.6116). In an ad-hoc analysis, in subjects without IFG, the fiber-rich drink had a larger effect than the control drink on the C_{max} for postprandial glucose (difference-4.75 mg/dL [95% CI -7.37, -2.14]), RLP-C (-0.18 mmol/L [-0.35, -0.02] and insulin (-23.33 µ IU/mL [-36.54, -10.13]). A single AE, that is mild diarrhea was reported but was not related to the experimental treatment.

Conclusion: The fiber-rich nutritional supplement reduced maximum concentrations of postprandial blood glucose levels in overweight subjects with IFG without much influence on postprandial triglycerides.

Keywords: Diet; Fiber; Glucose; Insulin; Postprandial; Remnant-like particle-cholesterol; Triglycerides

INTRODUCTION

One of the primary drivers of cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM) is the metabolic syndrome, a clustering of metabolic abnormalities including centrally-distributed obesity, decreased high-density lipoprotein (HDL) cholesterol, elevated triglycerides, elevated blood pressure and impaired fasting glucose (IFG) levels [1].

Postprandial hyperglycemia/hyperlipidemia is also a risk factor for CVD [2]. An elevated postprandial blood glucose level independently contributes to CVD risk in individuals with and without T2DM [3,4], possibly owing to the contribution of the acute glucose spike to oxidative stress, endothelial dysfunction and activation of the coagulation cascade, all culminating in arterial wall damage [5]. Postprandial hypertriglyceridemia contributes to the production of pro-inflammatory cytokines, recruitment of neutrophils and generation of oxidative stress,

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resulting in endothelial dysfunction. In general population, non-fasting elevated triglyceride levels have been shown to increase the risk of ischemic stroke [6], myocardial infarction, ischemic heart disease and death [7]; however, this association is not much clear in individuals with T2DM [8]. It should be noted that measurement of total serum triglycerides does not distinguish the various subspecies of triglyceride-rich lipoproteins (TRLs). Isolation of remnant-like particles (RLPs) allows the measurement of particles within TRLs, which are thought to be atherogenic [9] and are predictive of incident coronary heart disease [10].

Refined carbohydrates and sugars are known to cause exaggerated elevations in postprandial levels of blood glucose, triglycerides and fatty acids [11], while blunting of postprandial spikes has shown to improve inflammation and endothelial function [11]. Soluble dietary fiber reduces the postprandial glucose response after carbohydrate-rich meals and beneficially influences certain blood lipids [11]. These effects are explained by the viscous and gel-forming properties of soluble dietary fiber that slows down gastric emptying and macronutrient absorption from the gut [12]. Indeed, higher intake of dietary fiber has been shown to reduce the risk of CVD and T2DM [13,14].

In India, CVD is the leading cause of death, and is responsible for one quarter of all the deaths [15]. Indian meals often consist of high-calorie foods that are high in processed carbohydrates and saturated fats. Such meals can cause transient and pronounced elevations in postprandial blood glucose, free fatty acids and triglycerides [11], which are likely to increase CVD risk. This is particularly concerning in individuals with co-existing metabolic risk factors such as obesity and IFG. Hence, to address this growing concern a fiber rich nutritional supplement was developed. This supplement is mainly composed of two fibers Nutriose (18%) and Fibersol-2 (8%). Nutriose is a wheat fiber dextrin with clinically proven digestive tolerance; while fibersol is a corn fiber dextrin that is digestion-resistant, a low-calorie soluble fiber and bulking agent. The primary objectives of this study were to evaluate the effects of a fiber-rich nutritional supplement on the postprandial blood glucose peak and serum triglyceride peak in overweight adults with IFG in India. As the primary endpoints were not satisfied, a priori analyses on secondary endpoints was not performed. Instead, an ad-hoc analysis of the secondary endpoints that were statistically significant in the primary analysis was conducted in overweight adults with and without IFG.

METHODS

Study design and participants

This randomized, double-blind, two-treatment, two-period, cross-over study was conducted at a single center (Lamdba Therapeutic Research Ltd, Ahmedabad, Gujarat, India) between September and October 2013. The protocol was approved by an Independent Ethics Committee before any study procedures were initiated and the study was performed in full accordance with local laws and regulations and the Declaration of Helsinki. The study was registered at ClinicalTrials.gov (NCT02119325).

Subjects aged between 18 and 75 years having good general health with no clinically significant or relevant abnormalities in their medical history, physical examination or clinical and laboratory evaluations and a body mass index (BMI) ≥ 25 and <35 kg/m^2 were included in the study.

Subjects having diabetes mellitus or fasting blood glucose (FBG) >125 mg/dL during screening; hemoglobin <10 g/dL; aspartate transaminase (AST), alkaline phosphatase (ALP), serum creatinine or serum albumin levels that were greater than three times the upper limit of the normal (ULN) reference range; those receiving any medications (such as anti-hyperlipidemic drugs or oral antihyperglycemic drugs) that could affect the metabolism or absorption of the study product; had known or suspected intolerance/hypersensitivity to the study materials; were pregnant or lactating; or had participated in another clinical study or received an investigational drug within 30 days of the screening visit were excluded from the study. Every subject provided voluntary written informed consent and demonstrated the ability to understand and comply with study protocols before procedures commenced.

Study products

Treatment randomization was performed according to a schedule provided by the Biostatistics Department of GSK Consumer Healthcare. Subjects were stratified according to their IFG status (IFG: FBG 100-125 mg/dL; non-IFG: FBG <100 mg/dL). Subjects were then randomized (1:1) to:

Fiber-rich nutritional product: A powdered beverage with an active component of 25% of fiber (resistant maltodextrin) packaged as a 30 g individual sachet and reconstituted in water;

Control product: An energy-matched non-fiber powdered beverage packaged as a 25 g individual sachet and reconstituted in water.

The macro- and micro-nutrient breakdown of the study products is shown in **Table 1**.

Table 1: Nutritional composition of fiber-rich nutritional supplement and control product.

Nutrient (unit)	Fiber-rich nutritional supplement		Control product	
	30 g	100 g	25 g	100 g
Energy (kcal)	91.2	304	93.75	375
Carbohydrate (g)	12.7	42.6	18.75	75
Protein (g)	4.5	15.2	3.9	15.9
Fat (g)	0.75	2.5	0.42	1.7
Fiber 1 (wheat) (g)	5.2	17.3	–	–

Fiber 2 (corn) (g)	2.3	7.7	–	–
Vitamin A (µ g)	166.8	556	–	–
Vitamin D (µ g)	1.8	6.17	–	–
Vitamin E (mg)	3.69	12.3	–	–
Vitamin K (µ g)	4	13.6	–	–
Vitamin B1 (mg)	0.33	1.11	0.05	0.2
Vitamin B2 (mg)	0.36	1.2	0.18	0.74
Vitamin B3 (mg)	4.4	14.8	–	–
Vitamin B6 (mg)	0.48	1.6	–	–
Vitamin B12 (µ g)	0.88	2.96	–	–
Folic acid (µ g)	148.2	494	–	–
Iron (mg)	3.9	13	0.15	0.63
Pantothenic acid (mg)	0.9	3.09	–	–
Vitamin C (mg)	16.6	55.6	0.56	2.25
Biotin (µ g)	5.55	18.5	–	–
Calcium (mg)	185.1	617	154.2	617
Zinc (mg)	0.88	2.94	0.45	1.8
Selenium (µ g)	12.6	42	–	–
Magnesium (mg)	48	160	21.6	86.4
Copper (mg)	0.08	0.28	–	–
Chromium (µ g)	6.4	21.6	–	–

The entire contents of the study product sachet were emptied into a graduated drinking tumbler and made up to 200 mL using warm water (45-55°C). The subjects, investigator and other employees of the sponsor were blinded to treatment allocation. Following reconstitution, the products were indistinguishable in appearance, taste and smell, and were dispensed by an independent dispensing group, thus maintaining the double-blind status of the study.

Clinical procedures

On Day 1 of visit 1, subjects who met all eligibility criteria were admitted to the clinic for an overnight stay. Subjects fasted overnight (approximately 12 h) and were only able to consume water. On Day 2, subjects were randomized to a treatment group and blood was collected from each subject, 35 min prior to dosing to assess FBG levels. All subjects received a standardized high-fat breakfast (60 g fat, 34 g protein and 65 g carbohydrate, providing approximately 1000 kcal, of which 50% of energy was from fat) approximately 30 min prior to dosing.

Following breakfast, subjects were administered a single serve of either the fiber-rich nutritional supplement or the control product, according to the randomization schedule. Designated dosing personnel checked that the subject had consumed the entire 200 mL of study product over 5 min. If a subject was unable to consume the entire drink in the scheduled time then they were excluded from the study. All the subjects were required to fast for 4 h post-dose, with water allowed from 1 h post-dose onwards. Blood (8 mL) was drawn at 10, 20, 30, 40, 50, 60, 75, 90,105, 120, 150, 180, 210 and 240 min following the administration of the study product. A washout period of 3 days followed visit 1; subjects then returned to the clinic for visit 2, where the procedures were repeated with the alternative study product.

Subjects were only permitted to consume standard meals and drinks supplied by the study site during each session, as per the session schedule. Subjects were also asked not to undertake any unusually strenuous physical activity during the study period. Adverse events (AEs) and vital signs were recorded for all the subjects throughout the course of the study. AEs were graded on a three-point scale (mild, moderate or severe) and the potential relationship to the study product was determined by the investigator. AEs occurring during the wash-out period were assigned to the study product received during the previous study period.

Assessments

Height was measured using a portable stadio-meter, to the nearest 0.1 cm. Weight was measured on a standardized weighing scale to the nearest 0.1 kg. Blood glucose was measured by a glucose oxidase/peroxidase method. Insulin estimation was performed by Cobas e411 insulin assay using a monoclonal insulin-specific antibody. Triglycerides were measured using an enzymatic glycerol kinase method. RLP cholesterol (RLP-C) was quantified using an enzyme linked immunosorbent assay (ELISA).

Statistical analysis

It was estimated that a sample size of 24 subjects with IFG and 80 subjects overall would provide 91.59% power to detect a difference of 18.02 mg/dL for postprandial blood glucose and 4.5 mg/dL for postprandial serum triglycerides, assuming a within-subject standard deviation (SD) of 0.67 for glucose and

0.25 for triglycerides. The marginal power for both the parameters was 99.9% for blood glucose and 91.68% for triglycerides. Sufficient subjects were screened so that, approximately 100 subjects who fulfilled all the entry criteria (30 subjects with IFG) could be randomized to ensure that at least 80 evaluable subjects (24 subjects with IFG) completed all study visits. The per-protocol (PP) population was the primary population for the analysis and the intent-to-treat (ITT) analysis was only to be performed if there was a >10% difference in the number of subjects in each population. As the difference was <10%, the PP population was used for analysis. The safety population included all subjects who received at least one dose of a study treatment.

A gate-keeping strategy was used to ensure that multiplicity was addressed. The inclusion of multiple hierarchically ordered objectives allows for more robust interpretation of results obtained from clinical trials [16]. The primary endpoint of the study was the maximum concentration (C_{max}) of blood glucose and serum triglycerides following a single administration of the fiber-rich nutritional supplement or energy-matched non-fiber control product in overweight subjects with IFG (FBG 100–125 mg/dL). Maximum concentration was calculated by subtracting the fasting value from the highest postprandial value. The primary parameters were analyzed using the mixed effects model (analysis of variance, ANOVA) with glucose and triglyceride concentration as the dependent variables, respectively, and treatment and period as fixed effects. Subject was a random effect. Pair-wise treatment comparisons were provided.

Least squares estimate of treatment effects were calculated and a 95% confidence interval (CI) for the treatment difference was computed. No adjustment for multiplicity was performed. If statistical significance at the 5% level was not achieved for both the primary endpoints, then further analyses would not be performed. Secondary endpoints were C_{max} for blood glucose and serum triglycerides in overweight subjects without IFG; C_{max} and incremental area-under-the-curve (iAUC) for blood glucose, RLP- C and insulin in subjects with and without IFG; and time of maximum concentration observed (T_{max}) for blood glucose, RLP-C, triglycerides and insulin in subjects with and without IFG. Furthermore, C_{max} was determined as described previously and iAUC was calculated using the trapezoidal rule and actual time points. In case of one missing value in between baseline (-35 min) and 240 min, all available values were used. If there was more than one missing value or either of the start or end values were missing, no iAUC was calculated for that subject/period combination. All the concentrations below the lower level of quantification were set to zero for the pharmacokinetic analysis. The RLP-C data was noted to violate assumptions of normality; hence a non-parametric Wilcoxon signed rank was used. Time of maximum concentration of glucose, RLP-C and insulin were analyzed using the non-parametric method, Wilcoxon signed rank test for paired differences. Median differences between treatment groups were presented with 95% confidence for the median difference based on the method by Hodges and Lehman (Ad-hoc analysis).

RESULTS

Subjects

Of the 210 subjects screened for the study, 96 were randomized to treatment. Reasons for not being considered in the study included; not meeting eligibility criteria (n=42), being lost to follow-up (n=5) or other reasons (e.g. non-IFG subjects, n=67). Demographic and baseline clinical characteristics for the safety population are shown in Table 2. All the included subjects were Asian males having an IFG of 26 (27.1%). A total of 95 subjects completed both the periods of the study; one subject failed to complete the first period owing to an AE.

Table 2: Subject demographics and baseline characteristics (safety population).

Gender, n (%)	
Male	96 (100)
Female	0 (0)
Race, n (%)	
Asian	96 (100)
Age (years)	
Mean (SD)	33.9 (7.42)
Median (range)	35.0 (20–57)
Weight, kg	
Mean (SD)	77.4 (7.26)
Median (range)	77.0 (62.5–103.0)
BMI, kg/m^2	
Mean (SD)	27.7 (1.79)
Median (range)	27.3 (25.2–34.4)
IFG status, n (%)	
IFG	26 (27.1)
No IFG	70 (72.9)

Data is presented as mean (SD) unless otherwise specified; BMI: Body Mass Index; IFG: Impaired Fasting Glucose; SD: Standard Deviation; *IFG defined as fasting blood glucose of 100–125 mg/dL.

Primary endpoints: blood glucose and serum triglyceride peaks in subjects with IFG

In subjects with IFG, the C_{max} was significantly lower following administration of the fiber-rich nutritional supplement compared with the control product (Table 3; p=0.0487). A lower postprandial serum triglyceride peak was also reported with the

fiber-rich nutritional supplement compared with the control product (Table 3; p=0.6116); however, this difference did not reach statistical significance. It should be noted that the final triglyceride measure recorded (at 240 min) was the maximum value for 13 subjects in the test product group and seven subjects in the control group; therefore, the postprandial triglyceride C_{max} may not have been observed for all the subjects.

Table 3: Primary endpoints: C_{max} for glucose and triglycerides in subjects with IFG (PP population).

C_{max}, adjusted mean* (SE)	Fiber-rich (n=26)	Control (n=26)	Treatment difference (95% CI)	p-value
Glucose (mg/dL)	42.8 (4.7)	47.4 (4.7)	-4.64 (-9.26, -0.03)	0.0487
Trigycerides (mg/dL)	121.1 (12.0)	127.9 (12.0)	-6.79 (-34.02, 20.44)	0.6116

*From ANOVA model with factors for treatment and period as fixed effect and subject as a random effect. C_{max} was calculated by subtracting the fasting value from the highest postprandial value.

ANOVA: Analysis of Variance; C_{max}: Maximum Concentration; CI: Confidence Interval; IFG: Impaired Fasting Glucose: PP: Per Protocol; SE: Standard Error

One of the primary endpoints for this study was not satisfied; therefore, the statistical methods directed that a priori analyses on secondary endpoints would not be performed. However, the investigators considered that the analysis of data for secondary objectives would be of scientific value and instigated an ad-hoc analysis of selected secondary endpoints; triglycerides were not included in these analyses as they were not statistically significant in the primary analysis.

Secondary endpoints: ad-hoc analysis

A summary of the ad-hoc analysis of secondary endpoints is provided in Table 4. In overweight subjects without IFG, the fiber-rich drink had a larger effect than the control on the C_{max} for postprandial glucose (difference -4.75 mg/dL [95% CI -7.37, -2.14]), RLP-C (-0.18 mmol/L [-0.35, -0.02] and insulin (-23.33 µ IU/mL [-36.54, -10.13]), and the iAUC for insulin (difference - 3090.35 [95% CI -4638.12, -1542.57]). No apparent differences were observed for any of these parameters in subjects with IFG.

Table 4: Ad-hoc analysis: Treatment differences for secondary endpoints in subjects without and with IFG (PP population).

	Subjects without IFG (n=70)	Subjects with IFG (n=26)
Parameter	Treatment difference (95% CI)	Treatment difference (95% CI)
Glucose		
C_{max}* (mg/dL)	-4.75 (-7.37, -2.14)	N/A (Primary endpoint)
iAUC* (mg*min/dL)	-203.87 (-571.58, 163.83)	-255.42 (-967.22, 456.38)
T_{max}† (min)	0.00 (-5.00, 0.00)	5.00 (0.00, 10.00)
RLP-C		
C_{max}† (mmol/L)	-0.18 (-0.35, -0.02)	-0.15 (-0.63, 0.12)
iAUC† (mmol*min/L)	0.34 (-41.31, 41.44)	0.54 (-72.43, 85.28)
T_{max}† (min)	-15.00 (-45.00, 15.00)	0.00 (-65.00, 57.50)
Insulin		
C_{max}* (µ IU/mL)	-23.33 (-36.54, -10.13)	-24.00 (-50.00, 2.00)
iAUC* (µ IU*min/mL)	-3090.35 (-4638.12, -1542.57)	-2146.06 (-4814.50, 522.39)
T_{max}† (min)	0.00 (-5.00, 0.00)	0.00 (-10.00, 5.00)

*From ANOVA model with factors for treatment and period as fixed effect and subject as a random effect.

†Hodges-Lehmann estimator for median treatment difference and confidence interval from non-parametric analysis.

ANOVA: Analysis Of Variance; C_{max}: Maximum Concentration; CI: Confidence Interval; IFG: Impaired Fasting Glucose; iAUC: Incremental Area Under the Curve; min: minutes; PP: Per Protocol; RLP-C: Remnant-Like Particle Cholesterol; T_{max}: Time to Maximum Concentration.

Safety

The study products were well tolerated. Only one AE was reported (mild diarrhea); this was not considered to be related to the experimental treatment and occurred following administration of the control product. This AE resulted in the subject withdrawing from the study.

DISCUSSION

Abnormal glucose metabolism is often a precursor to T2DM or an independent risk factor for atherosclerosis and CVD [3-5,16]. Individuals with features of metabolic syndrome (such as being overweight or having IFG) may also exhibit a blunted first-phase insulin response to dietary glucose [17,18]. When the first-phase insulin response becomes impaired or fails, plasma glucose levels rapidly increase following a meal, resulting in oxidative stress,

inflammation and endothelial dysfunction [5]. Accumulation of postprandial triglyceride-rich lipoproteins in the artery wall of individuals with metabolic abnormalities may also contribute to endothelial dysfunction [19].

The progression of T2DM eventually causes loss of beta cell function that may require treatment with insulin despite of several hypoglycemic drugs; thus, increasing the individual cost burden [20]. Attenuating postprandial blood glucose or triglyceride excursions in individuals with signs of metabolic syndrome may reduce cardiovascular risk. Such modulation may be possible with dietary modifications or supplementation. For example, water-soluble dietary fiber reduced postprandial blood glucose levels in small studies performed in healthy adults [21,22] and overweight or obese adults without diabetes mellitus [23]. Likewise, soluble dietary fiber has also been shown to decrease postprandial triglycerides, RLP-C and insulin in healthy subjects [24]. Similarly, previous studies in subjects with T2DM have shown decreased postprandial blood glucose due to intake of dietary fiber [25,26], possibly via slowing gastric emptying [24].

Soluble fiber may also improve indices of insulin resistance [27,28] and help reduce the postprandial insulin level [25,28], FBG, C-peptide [27,28] and triglyceride levels [28], BMI and hemoglobin A1c [27]. These studies support our own findings in an overweight population with and without IFG.

In the primary analysis of our study, we showed that ingestion of a fiber-rich nutritional supplement, in the form of a drink, significantly reduced the postprandial blood glucose peak following a high-fat meal in overweight subjects with IFG. A reduction in postprandial triglyceride peak was also reported with the fiber-rich nutritional supplement; however, this did not reach statistical significance relative to the control product. Lack of statistical significance could be attributed to an insufficient time-frame in which to measure the triglyceride peak, making it difficult to draw robust conclusions.

Since, only one of the primary endpoints was satisfied in this study (statistically significant decrease in blood glucose C_{max} with the fiber-rich nutritional supplement compared with the non- fiber control in overweight subjects with IFG), the secondary endpoints relating to glucose, RLP-C and insulin (C_{max}, T_{max} and iAUC) were studied by ad-hoc analysis.

In the ad-hoc analysis, ingestion of the fiber-rich nutritional supplement significantly reduced the postprandial RLP-C and insulin peak, as well as insulin iAUC, in overweight subjects without IFG (although not those with IFG). This reduction in RLP-C is of particular interest as this is one of the first studies to evaluate RLP-C levels, which is rarely investigated in routine practice.

Furthermore, our study has helped establish methodologies in the analysis of RLP-C in the Indian population. Elevated RLP-C levels are associated with increased thickness of the carotid artery, independent of plasma triglycerides and low-density lipoprotein cholesterol [29], and patients with coronary heart disease have been seen to present with elevated levels of plasma RLP-C [30,31]. The reduction in insulin peak and iAUC in overweight subjects without IFG may be attributed to bacterial fermentation of the fiber in the intestine that generates the production of short chain fatty acids. This can diminish mobilization of fatty acids and gluconeogenesis; thus, reducing postprandial blood glucose levels, which in turn improves insulin sensitivity [32]. It is possible that the sample size of individuals with IFG was too small to achieve a statistically significant difference in RLP-C and insulin in the fiber-rich nutritional supplement group compared with the non-fiber control group.

The fiber-rich nutritional supplement was well tolerated in this study, with no AEs occurring that could be considered by the investigator to be related to treatment.

Any conclusions need to be made within the context of our study limitations, such as only male subjects being randomized from a single center. Future studies should incorporate more study centers and a higher number of screened subjects to ensure that females are included in the study population. Furthermore, the maximum triglyceride concentration was observed at the final time point of 240 min in 13 subjects in the test group, suggesting that the true peak of triglyceride may have occurred beyond the time scale of the study. It is recommended that future studies measure triglyceride levels for more than 4 h after ingestion of a high-fat meal.

CONCLUSION

In conclusion, intake of a fiber-rich nutritional supplement following a high-fat meal reduced maximum concentrations of postprandial blood glucose levels in overweight subjects with IFG; however, a reliable estimate of peak concentration for postprandial triglycerides could not be achieved. These effects should be further studied in larger randomized controlled trials.

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Dr. Rachana Bhoite wrote the paper; she was involved in the study design and conducting the study. Data collection was done by Lambda Therapeutic Research Ltd, while the statistics department of GSK was involved in statistical analysis of the data. Dr. Bhoite was an employee of the sponsor company at the time of the study and has no other conflicts of interest. Medical writing assistance was provided by Leading Edge Medical Education Ltd, Loudwater, UK and funded by GSK Consumer Healthcare.

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