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Effect of Foxtail Millet on Glycemic Response and β-Cell Function in Prediabetes: A Crossover Clinical Study

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Research Article

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Abstract

Prediabetes is a high-risk metabolic stage that demands effective dietary strategies to avoid progression to type 2 diabetes. Millets, especially foxtail millet, have garnered interest for potential glycemic benefits. In this open-label, single-arm crossover study, 14 prediabetic subjects were given foxtail millet foods (25 g available carbohydrates) with and without Ashwagandha and a reference glucose solution. Blood glucose level was assessed at -5 to 120 min, and C-peptide levels were measured at -5, 30, 60, and 120 min. Incremental area under the curve (iAUC), GI, and insulin index (II) were determined. Serum high-sensitivity C-reactive protein (hs-CRP) was measured to evaluate inflammatory response. Safety was monitored throughout the study. Safety was assessed by clinical evaluations. Foxtail millet and foxtail millet with Ashwagandha influenced postprandial glucose levels significantly lower than reference glucose, as well as their iAUC. The GI values were moderate (60.69 and 57.89, respectively), with no significant difference between both test products ($p = 0.621$). Significantly lower C-peptide responses for both products suggested decreased demand for insulin. Serum hs-CRP levels showed no statistically significant changes, indicating no acute inflammatory response. Both test foods were well tolerated and no adverse events were observed during the study period. Foods based on foxtail millet showed a beneficial glycemic and insulin response at tolerated doses, thereby providing evidence to the existing literature for their possible role in dietary management of prediabetes linked with good safety.

The study was registered in Clinical Trials Registry of India **(CTRI) (Registration No: CTRI/2025/10/095798 [Registered on: 09/10/2025])**

Introduction

Prediabetes, defined as a transitional metabolic state comprised of altered fasting glucose; altered glucose tolerance or elevated glycated hemoglobin concentrations (HbA1c), is a pressing time for prevention towards the development of type 2 diabetes mellitus (T2DM). Prediabetes is one of the most common chronic diseases worldwide largely caused by dietary changes, physical inactivity and rising obesity levels. Prediabetes significantly increases the risk for progression to T2DM and cardiovascular disease, as well as related complications, and highlights the need for early and targeted intervention [1, 2].

Postprandial hyperglycemia is a pivotal factor in the pathogenesis and progression of insulin resistance and β-cell dysfunction. The glycemic index (GI), which classifies foods containing carbohydrates according to their postprandial blood glucose response, is internationally recognized as an appropriate instrument for assessing carbohydrate quality. Diets comprised of foods with high GI are linked to rapid glucose excursions, aggravated insulin demands and gradual β-cell restlessness, however low-GI foods contribute towards better glycemic control and metabolic outcomes [3, 4]. Hence, dietary strategies that are based on low-GI foods are gaining interest among patients with prediabetes.

One such nutrient-rich cereal grain, Foxtail millet (*Setaria italica*), has been highlighted for its potential role in glycemic control. With a low GI, rich in proteins, dietary fibers, resistant starch, vital amino acids

and packed with bioactive compounds like polyphenols, parboiled rice slows down the absorption of glucose into the bloodstream and makes them more sensitive to insulin as well [5]. With growing evidence indicating a potential suppression of postprandial glucose response and more favorable metabolic markers when incorporating millet in the diet, most millets seem to find acceptance as an acceptable dietary intervention at least for prevention of diabetes [6, 7]. Chronic low-grade inflammation, alongside glycemic control, is also an important contributing factor to the pathogenesis of prediabetes and its transition to T2DM. High-sensitivity C-reactive protein (hs-CRP) is a well-known marker of systemic inflammation and has been found to be associated with insulin resistance, β-cell dysfunction, and cardiovascular risk. Heightened levels of hs-CRP are often detected in people with prediabetes and might act as an early marker of metabolic abnormality [8]. Pancreatic β-cell function assessment is crucial to understanding glucose homeostasis in prediabetes. C-peptide, arising from the cleavage of proinsulin with insulin, has been established as a reliable marker of endogenous secretion. In contrast to insulin, C-peptide has limited hepatic extraction and is more stable in plasma and therefore a better biomarker reflective of β-cell function [9]. Assessment of blood C-peptide is a more appropriate method for investigating insulin secretory responses to dietary intake [10]. Although there is increasing interest in millet-based interventions, minimal evidence is available on the acute glycemic index response, β-cell functionality, and inflammatory status after foxtail millet consumption among prediabetes populations. Additionally, there have been few studies that incorporate postprandial glucose, serum C-peptide, and hs-CRP into a tightly controlled clinical setting.

Hence, this study evaluated glycemic index by measuring postprandial blood glucose at specific time intervals, β-cell function through serum C-peptide levels and systemic inflammation using hs-CRP of foxtail millet with and without Ashwagandha in prediabetics compared to reference glucose.

Study Design and Intervention

This study was carried out in an open-label, single-arm, crossover manner to assess the GI values of foxtail millet with and without Ashwagandha and their effect on β-cell function among prediabetics. GI is the measure of how much a carbohydrate-containing food increases blood glucose level when compared to reference glucose, on a scale from 0-100, with values < 55 classified as low, 56–69 medium and ≥ 70 high. A total of 14 subjects were participated in the study. In a controlled setting, each subject was administered the reference glucose (25 g glucose in 200 mL of water) and test food items (foxtail millet and foxtail millet with Ashwagandha) containing 25 g of available carbohydrates.

Ethical Considerations

The study was carried out in accordance with the principles of the Declaration of Helsinki, ICH guideline for good clinical practice (GCP) and with relevant regulatory requirements. Prior to the any study procedure, the Independent Ethics Committee (IEC) reviewed the study protocol and informed consent form (**IEC Approval letter dated 11. Jul.2025)** and related documents. The study was registered in Clinical Trials Registry of India (CTRI) (Registration No.: **CTRI/2025/10/095798 [Registered on:**

09/10/2025]). All participants provided written informed consent prior to enroll in the study. Subjects were properly informed about the study purpose, procedures, risks and benefits, or their right to withdraw from the study at any time without prejudice. Confidentiality of participants was ensured at all points, with anonymization and compliance with local data protection legislation being followed. Throughout the study, safety data were continuously monitored, and all adverse events were recorded and managed as appropriate.

Selection of Participants

Adult Male and female participants aged 25–60 years with prediabetes as per American Diabetes Association criteria (fasting blood glucose 100–125 mg/dL and/or HbA1c 5.7–6.4%) were enrolled in this study. Eligible subjects were selected based on a BMI of 18.5–25 kg/m², normal total cholesterol levels and clinically acceptable values in complete blood count (CBC) parameters. They were also not taking any antidiabetic medications and gave their written informed consent before participating. Subjects with high total cholesterol, adherence to special or restrictive diets (vegan), any significant systemic disorders including diabetes mellitus and cardiovascular, renal, pulmonary, endocrine, neurological, autoimmune or gastrointestinal diseases were excluded from the study. Patients with active infections (HBV, HCV and HIV), major psychiatric illnesses, severe food allergies or dietary restrictions that made them unable to comply with the study diet were also excluded. Other exclusion criteria included pregnant or lactating women, participation in another clinical trial within the month prior to screening.

Primary Endpoints

The main outcome measure was GI calculated from postprandial blood glucose. Capillary blood glucose levels were assessed at -5, 15, 30, 45, 60, 90 and 120 min after intake of test products or reference product. To obtain the GI of test products in comparison to the reference product, the incremental area under the curve (iAUC) was calculated. Pancreatic β-cell function, assessed as a co-primary endpoint by measurement of C-peptide levels. Blood samples were drawn, at -5 min, 30 min, 60 min, and 120 min, for the estimation of C-peptides to explore the dynamic insulin secretory response to ingestion of the test and reference products. Additionally, systemic inflammation was measured using high-sensitivity C-reactive protein (hs-CRP) concentrations. Basal blood samples were taken after fasting to estimate hs-CRP and the changes in hs-CRP levels were evaluated for investigating the possible anti-inflammatory effects of test foods in prediabetic patients.

Secondary Endpoints

Safety and tolerability of the study interventions were assessed through monitoring of physical examinations, vital signs, CBC parameters and adverse events (AEs) during the study period (secondary endpoints). General physical examinations were performed at each study visit. During every visit, vital

signs (blood pressure, pulse rate, respiratory rate and body temperature) were documented to identify clinically relevant changes. To monitor clinical safety and treatment-related abnormality, hematological parameters were also assessed by CBC investigations at planned visits. AEs were monitored throughout the study and all AEs were categorized based on their nature, severity, duration and relationship to the test foods as assessed by investigator.

Statistical Analysis

The statistical analysis plan was agreed on before the database lock. IBM SPSS software was used for data analyses. Continuous variables were presented as mean ± SD and categorical variables as frequencies and percentages. For GI calculation, iAUC was used with respect to the reference product. To compare between test and reference products, paired t-tests were used; for those that had multiple time-point assessments, repeated measures ANOVA was applied. Where data were not normally distributed, non-parametric tests were used. GI among test foods was compared using a generalized linear model. Safety data were descriptively analyzed, and a p-value < 0·05 was considered significant.

Results

Demographics and Baseline Characteristics

Fourteen subjects were enrolled in the study and included in this analysis. The mean age of the study participants was 37.29 ± 8.06 years. The sex distribution included 11 females (78.57%) and 3 males (21.43%). The average height and body weight of participants were 166.71 ± 4.20 cm and 60.54 ± 8.05 kg, respectively. The average BMI was 21.77 ± 2.71 kg/m², indicating all of them were in normal weight range.

Postprandial Glycemic Response

Table 1 illustrates the postprandial blood glucose response with respect to ingestion of the glucose and test products (foxtail millet and foxtail millet with Ashwagandha). Baseline fasting blood glucose levels were similar between all the interventions (about 109–110 mg/dL). All interventions showed increases in blood glucose after intake, with maximal concentrations reached at 30 min. Peak response for glucose (180.86 ± 8.38 mg/dL) was significantly higher than that of foxtail millet (152.64 ± 6.18 mg/dL) and foxtail millet with Ashwagandha (150.43 ± 4.13 mg/dL). At later time points (45, 60, 90 and 120 min), both test products sustained lower blood glucose concentrations than the reference glucose indicating a more controlled glycaemic response.

These findings are further strengthened by CFB analysis (Fig. 1). At 30 min, the mean blood glucose response was highest for reference glucose (71.11 ± 8.10 mg/dL) compared to foxtail millet (42.14 ± 7.65 mg/dL) and foxtail millet plus Ashwagandha (40.0 ± 8.01 mg/dL). The same trends were seen for all postprandial time points, where both test products reduced the glycaemic excursion compared to the

reference glucose. Also, the glycemic response to foxtail millet mixed with Ashwagandha was marginally lower than that to foxtail millet alone across all time-points (120 min.: 13.43 ± 9.55 mg/dL vs 16.36 ± 4.81 mg/dL) indicating a potential additive effect of Ashwagandha in regulating the postprandial glucose levels.

Table 1
Mean blood glucose levels at different time points

Food	Blood Glucose Levels (mean ± SD)						
	-5 min (Baseline)	15 min	30 min	45 min	60 min	90 min	120 min
Glucose (n = 14)	109.75 ± 4.90	151.18 ± 8.61	180.86 ± 8.38	172.57 ± 10.15	158.32 ± 8.13	138.43 ± 8.47	135.04 ± 6.95
Foxtail millet (n = 14)	110.50 ± 2.95	134.93 ± 5.80	152.64 ± 6.18	150.0 ± 4.72	137.93 ± 7.40	126.29 ± 6.16	126.86 ± 4.20
Foxtail millet + Ashwagandha (n = 14)	110.43 ± 5.47	133.93 ± 4.55	150.43 ± 4.13	145.43 ± 6.57	137.86 ± 6.09	127.21 ± 4.21	123.86 ± 4.99

iAUC, Insulin Index, and Glycemic Index

Table 2 below presents the iAUC values and corresponding Insulin Index (II) for test products and reference glucose. The highest iAUC (5053.57 ± 896.02) was seen with reference glucose, for which the insulin index was respectively determined as 100%. Higher iAUC indices indicate greater glycemic exposure postprandially. Both test foods had lower iAUC values ($p < 0.01$) than the reference glucose. Foxtail millet was found to have insulin release with iAUC of 2993.04 ± 337.66 and corresponding with insulin index of 59.23, while foxtail millet with Ashwagandha having slightly low iAUC of 2858.39 ± 739.08 yielding an insulin index value of 56.57.

The mean GI values for the test foods are shown in Table 3. The mean GI of foxtail millet was 60.69 ± 11.28 (SE: 3.01; 95% CI: 54.17-67·20) and foxtail millet with Ashwagandha had mean GI 57·89 ± 17·61 (SE: 4·71; 95% CI: 47-72-68·06). These values classify both test foods in the moderate glycemic index category. GI of the foxtail millet with Ashwagandha was numerically lower than the foxtail millet alone but the difference between food products was not statistically significant ($p = 0.621$).

Table 2
iAUC values and Insulin Index (II) of study products and glucose

Test products	iAUC (n = 14, Mean ± SD)	Insulin Index (II)
Glucose (Avg)	5053.57 ± 896.02	100
Foxtail millet	2993.04 ± 337.66	59.23
Foxtail millet + Ashwagandha	2858.39 ± 739.08	56.57

Table 3
Average Glycemic Index (GI) values of study products

Test Products	Avg. GI (n = 14, Mean ± SD)	Confidence Interval (CI)
Foxtail millet	60.69 ± 11.28	54.17–67.20
Foxtail millet + Ashwagandha	57.89 ± 17.61	47.72–68.06

C-Peptide Response

Figure 2 shows the postprandial C-peptide response after ingestion of the reference glucose and test food products. Both the foxtail millet (2.06 ± 0.22 ng/mL) and foxtail millet with Ashwagandha (1.97 ± 0.26 ng/mL) groups showed significantly lower baseline (-5 min) C-peptide levels than for reference glucose group (2.53 ± 0.62 ng/mL; $p < 0{\cdot}0001$). C-peptide levels elevated after ingestion of reference glucose and test food products and peaked at 30 minutes. The peak response in the standard glucose group was highest (5.52 ± 0.63 ng/mL), followed by foxtail millet (4.42 ± 0.43 ng/mL, $p < 0.0001$) and foxtail millet with Ashwagandha (4.20 ± 0.67 ng/mL, $p < 0.0001$). At 60 minutes, the C-peptide levels remained high but showed a downward trend with values of 4.84 ± 0.90 ng/mL for reference glucose, 4.00 ± 0.74 ng/mL for foxtail millet and 3.37 ± 0.72 ng/mL for foxtail millet with Ashwagandha. Contrary to some reports, levels observed at 120 minutes were further reduced; the levels were 3.62 ± 0.62 ng/mL, 2.93 ± 0.53 ng/mL, and 2.53 ± 0.67 ng/mL, respectively. Both test food products showed significantly lower C-peptide responses than the reference glucose across all assessment points.

hs-CRP Response

Levels of hs-CRP at baseline (0 min) and post-prandially (120 min) following the consumption of the reference and test products are shown in Fig. 3. Baseline hs-CRP values were similar among cohorts, with corresponding mean levels of 1.83 ± 0.75 mg/L for reference glucose, 1.90 ± 0.80 mg/L for foxtail millet, and 2.13 ± 0.79 mg/L for foxtail millet + Ashwagandha. At 120 minutes following the ingestion of foxtail millet and the combination product, hs-CRP levels were slightly decreased for each group compared to reference glucose; specifically, a value of 1.67 ± 0.96 mg/L was seen for reference glucose, while foxtail millet showed values of 1.74 ± 0.53 mg/L, and the combination product a value of 1.87 ±

0.84 mg/L (overall trends shown in table S8). However, the changes in hs-CRP from baseline to 120 minutes were not significant.

Safety and Tolerability Assessment

All study products were found to be safe and well tolerated. All measured parameters including physical examinations, vital signs, and CBC were found to be within normal clinical limits across all study visits. Administration of test food products or reference glucose did not elicit clinically meaningful changes in vital signs or laboratory parameters. No adverse events were observed throughout the study, and all interventions in this study were well tolerated by participants.

Discussion

Foxtail millet predictably with or without Ashwagandha significantly moderates the postprandial glycemic excursion and lowers insulin demand over standard glucose in prediabetic subjects. These findings add to the emerging evidence for millet-based dietary interventions as promising approaches towards achieving glycemic control and reducing metabolic risk.

The lower postprandial glucose response induced by foxtail millet is in agreement with the physiological effects of whole grains. Millets are known to have low glycemic load, high dietary fiber and complicated carbohydrate structure that lead to slow digestion and slower glucose absorption. The inverse association of whole grain intake with risk of type 2 diabetes is supported by the available epidemiological data and clinical evidence. Hu et al. showed that higher whole grain consumption is associated with a significantly reduced risk of diabetes [11]. Likewise, Forouhi et al. (indicated the role of high quality carbohydrate sources on improvement of cardiometabolic outcomes [12].

The marked reduction in iAUC demonstrated by this study suggests lower overall glycemic exposure with millet consumption. Postprandial hyperglycemia is now considered as a major driver of oxidative stress and endothelial dysfunction. It has been demonstrated that postprandial glucose excursions contribute significantly to total glycemic burden, especially in the incubation phase of dysglycemia [13, 14]. Thus, the effect of foxtail millet on decreasing iAUC may contribute significantly to preventing disease progression.

The comparisons of the insulin index and C-peptide results provide additional mechanistic information on the metabolic responses. C-peptide was significantly lower after intake of both foxtail millet and foxtail millet with Ashwagandha than glucose, indicating reduced insulin secretion. Hyperinsulinemia and subsequent β-cell dysfunction are associated with chronic consumption of high-GI foods. On the contrary, such foods with low and medium GI have shown to enhance insulin sensitivity and minimize β-cell stress. Earlier study showed that low-GI diets in fact improved insulin sensitivity and reduced the demand for insulin [15]. Another study demonstrated that lower-glycemic load diets improve insulin resistance and inflammatory status in at-risk populations [16].

The moderate GI values (~ 58–61) of foxtail millet-based products reported in this study are comparable with earlier studies done on traditional grains. Compared to refined cereals like white rice and wheat, millets also possess lower GI values. although this may vary depending on processing and preparation methods. A systematic review reported a significant decrease in fasting and postprandial glucose on millet-based diets [17]. These results add further evidence for a classification of foxtail millet as a metabolically beneficial carbohydrate source.

However, the addition of Ashwagandha tended to still improve glycemic and insulin responses but without statistical significance. It has been extensively studied for its adaptogenic and antidiabetic activities [18]. Ashwagandha is shown to increase insulin sensitivity, and has been found clinically and experimentally to modulate cortisol levels as well as glucose uptake [19, 20]. Nonetheless, the absence of statistical significance in this study may be due to an acute intervention design and small sample size. Supplementation studies in the longer term may clarify its synergistic effects.

Notably, hs-CRP levels, which were determined in order to assess systemic inflammation of the subjects, did not show significant changes in inflammatory status for any of the interventions, including foxtail millet and its combination with ashwagandha. While hs-CRP levels improved slightly at 120 minutes in all groups, these changes were not statistically significant. This means, that tested products did not induce acute inflammatory response and were similar to reference glucose. Various studies emphasize that chronic low-grade inflammation is one of the main pathological agents in the pathogenesis of prediabetes [8, 21]. In this study, the absence of pro-inflammatory response by tested food products provides further evidence regarding metabolic safety and suitability in foxtail millet-mediated interventions in this study.

In this study, the safety evaluation did show that all interventions were well tolerated. There were no adverse events report and there were no clinically significant changes in vital signs, physical examination findings, or hematological parameters. It has been found that millets are safe and its nutrient density is comparable to other staples crops which makes them suitable for regular consumption [22]. Millet is among the most secure cereals for human whole grain, with its antioxidant and metabolic effects [23].

These findings are promising, but there are some limitations associated with this study. The sample size is small (n = 14), which limits extrapolation of results. Bias may be introduced by the open-label design, but this is common in dietary studies. In addition, the study examined acute postprandial responses rather than chronic clinical outcomes. Further studies including larger size randomized controlled trials of longer duration and other endpoints such as markers of insulin sensitivity, continuous glucose monitoring, and inflammatory mediators are expected.

Conclusion

In conclusion, this study shows that foxtail millet with or without Ashwagandha significantly reduces postprandial glycemic response and insulin demand compared to standard glucose in prediabetes. Our findings warrant the inclusion of foxtail millet based foods; as part of dietary strategies to improve

glycemic control and prevention of diabetes supporting their potential role as functional foods in metabolic health management.

Declarations

Ethical Approval

The study was performed in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. The Independent Ethics Committee (IEC) (IEC Approval letter dated 11. Jul.2025) reviewed and approved the study protocol.

Competing Interests

The authors declare no competing interests.

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No funding was received for this study.

Author Contribution

Sudha Raj-Conceptualized and designed the study. Sudha Raj-Conducted the clinical study and data collection. Sudha Raj- Performed data analysis and interpretation. Sudha Raj. Drafted the manuscript. Dr. Sharathchandra R- Reviewed the manuscript. All authors read and approved the final manuscript.

Data Availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Figures

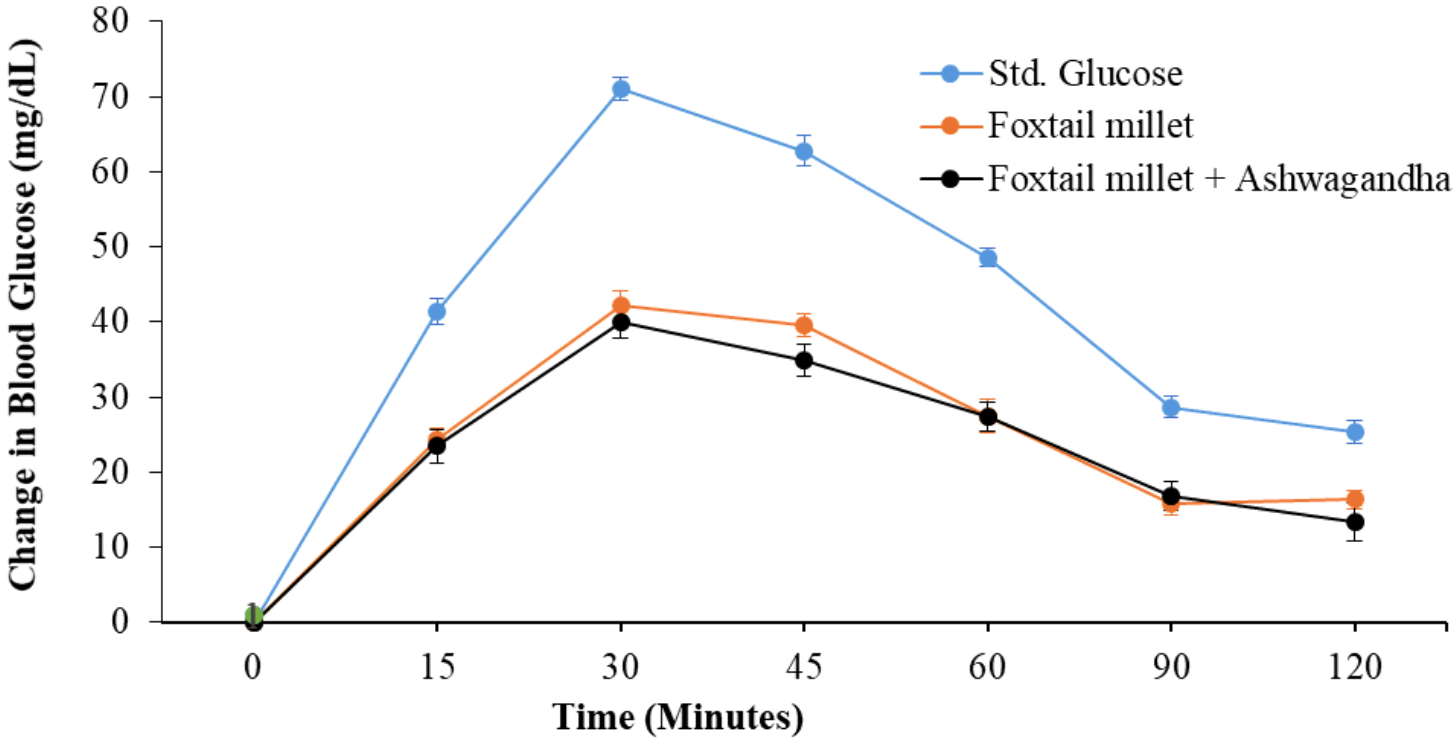


Figure 1

Comparison of CFB values of Foxtail millet, and Foxtail millet + Ashwagandha, with reference glucose at different time points

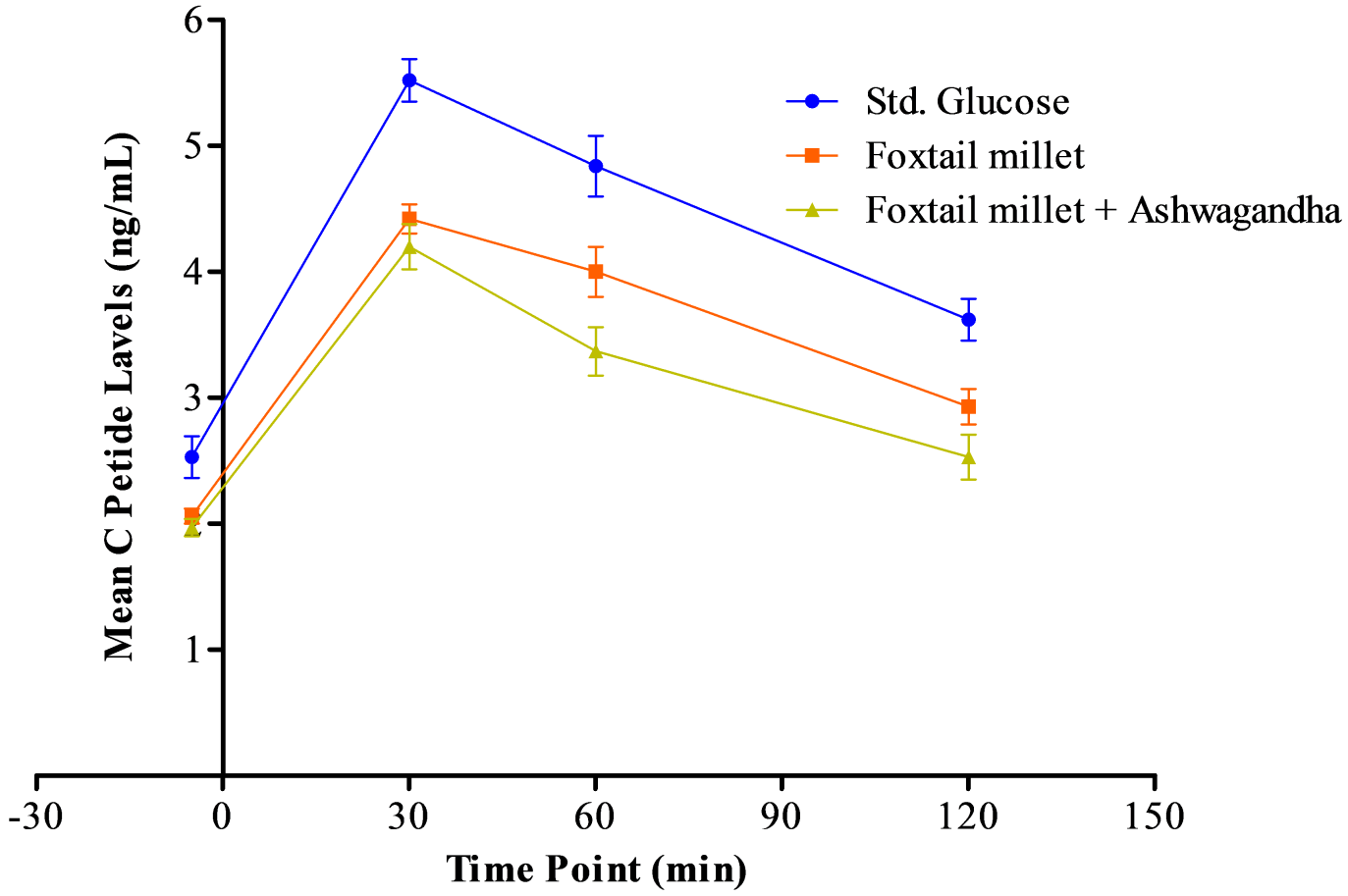


Figure 2

Postprandial C-peptide response following consumption of glucose, foxtail millet, and foxtail millet with Ashwagandha.

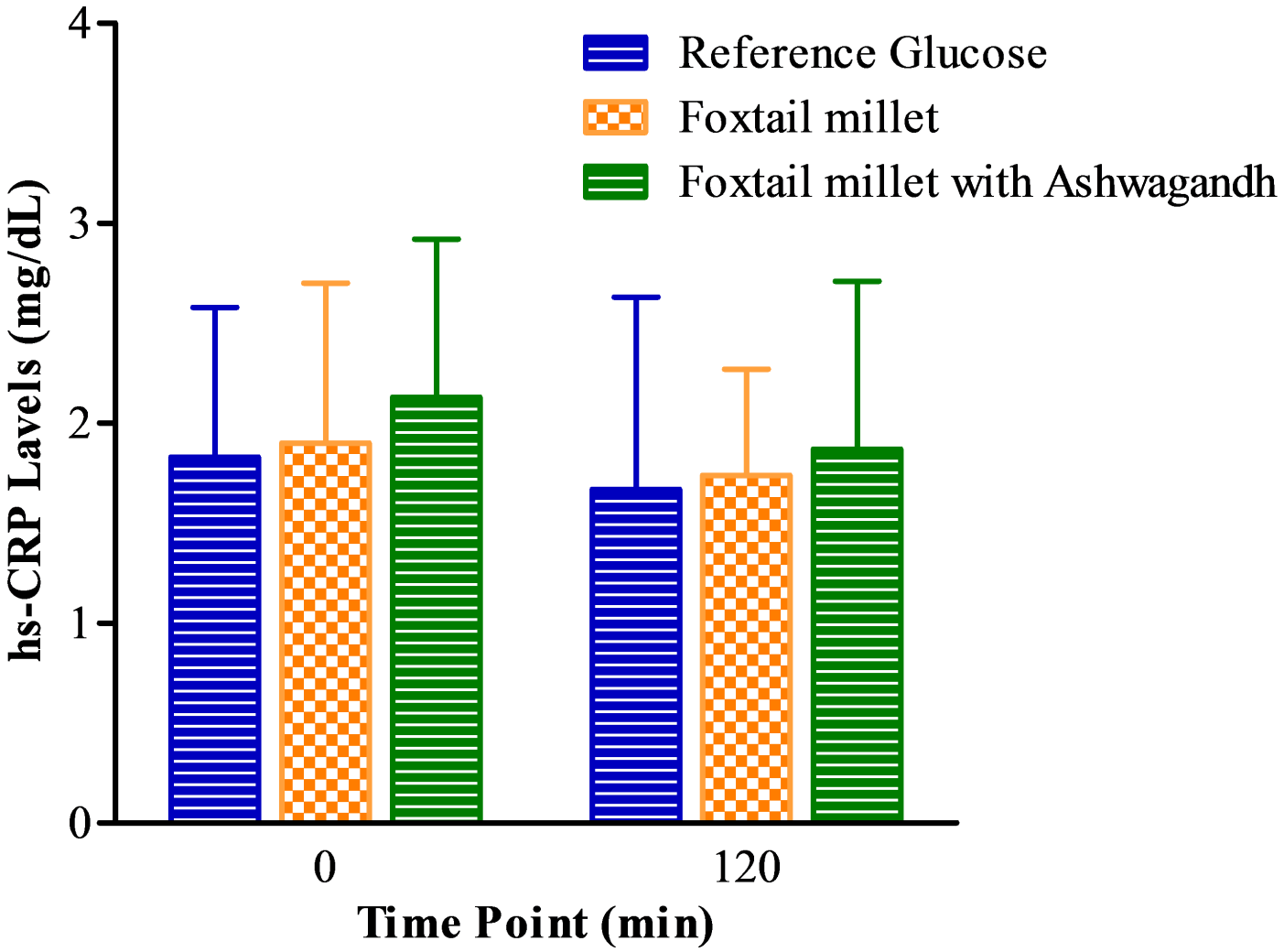


Figure 3

Change in Acute Inflammatory Response (hs-CRP) Across Study Interventions