Natural Resources for Human Health
eISSN: 2583-1194

Original Research

Received 22 March 2026
Revised 24 April 2026
Accepted 15 May 2026

Natural Resources for Human Health 2026, Vol. 6 (3): 568–575

KEYWORDS:
Resistant starch; High-amylose rice; Postprandial glycemia; Satiety; Glycemic response; Functional carbohydrate; Incremental glucose area under the curve; Insulin response; Crossover trial; Metabolic health.

Effects of Resistant-Starch Rice on Postprandial Glycemia and Satiety

Smitha Poovathinkal Madhavan[1], Lakshay Bareja[2], A. Ramesh Bala[3], Pratima Srivastava[4], Abduazim Yuldashev[5], Joshua S[6], Leka H[7]

[1]School of Nursing, Lincoln University College, Petaling Jaya, Selangor, Malaysia. spmadhavan@lincoln.edu.my
[2]Centre for Research Impact & Outcome, Chitkara University Institute of Engineering and Technology, Chitkara University, Rajpura, 140401, Punjab, India. lakshay.bareja.orp@chitkara.edu.in
[3]Department of General Medicine, Vinayaka Missions Medical College, Karaikal, Vinayaka Mission's Research Foundation (DU), Tamil Nadu, India. rbalamd@gmail.com
[4]Department of Biotechnology, Arka Jain University, Jamshedpur, Jharkhand, India. dr.pratima@arkajainuniversity.ac.in
[5]Department of Pediatric Surgical Stomatology, Tashkent Medical University, Uzbekistan. dr.abduazim@gmail.com
[6]Meenakshi College of Allied Health Sciences, Meenakshi Medical College Hospital & Research Institute, Meenakshi Academy of Higher Education and Research. joshuasahs@maher.ac.in
[7]Meenakshi College of Physiotherapy, Meenakshi Academy of Higher Education and Research. leka@maher.ac.in

ABSTRACT:

Background: A rice-based strategy may improve meal quality without requiring major changes in habitual cuisine.

Objective: To evaluate high-amylose resistant-starch rice in comparison with conventional polished white rice matched for available carbohydrate using a randomized crossover trial.

Methods: The draft protocol included 44 experimental units or participants involving adults with overweight and impaired fasting glucose. The intervention was administered or tested for two test visits separated by 7 days. The primary outcome was incremental glucose area under the curve, with additional assessment of insulin area under the curve, peak glucose, satiety area under the curve, subsequent energy intake. Standardized laboratory, clinical, or food-analysis procedures were applied, and between-condition effects were evaluated with two-sided tests at $\alpha=0.05$.

Results: Resistant-starch rice reduced the 2-hour incremental glucose area under the curve to 166 ± 24 mmol·min/L compared with 282 ± 31 mmol·min/L after white rice ($p<0.001$). Peak glucose was 7.5 ± 0.7 versus 8.9 ± 0.8 mmol/L, while the test meal increased integrated satiety by approximately 27.6% and produced no serious intolerance. The direction and magnitude of the dummy findings were internally consistent across primary and secondary endpoints, and tolerability or assay-quality criteria remained acceptable.

Natural Resources for Human Health
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Conclusion: The example dataset suggests that high-amylose resistant-starch rice could produce a meaningful improvement in incremental glucose area under the curve through reduced starch digestibility, delayed glucose appearance, and colonic fermentation of resistant starch. These findings are intended solely as a complete manuscript-development example and require replacement with ethically generated, independently verified observations before scientific submission.

1. INTRODUCTION

Effects of Resistant-Starch Rice on Postprandial Glycemia and Satiety addresses an important question at the interface of experimental pharmacology, nutritional science, and translational health research. Directly relevant published work has established a scientific basis for evaluating high-amylose resistant-starch rice in relation to incremental glucose area under the curve [1]. Nevertheless, variations in preparation, exposure, comparator selection, and outcome definition continue to limit confident comparison across studies.

A second line of evidence supports the biological plausibility of the present hypothesis. Prior investigations of resistant starch and closely related interventions have reported functional or biochemical activity that is consistent with the proposed direction of benefit [2]. These observations are the reasons to test formally yet do not exclude the usage of standardized materials and predetermined criteria of analysis.

The broader natural-product and functional-food literature demonstrates that reproducibility is sensitive to chemical characterization, processing conditions, dose, biological matrix, and stability of active constituents [3]. To conduct the current research, high-amylose resistant-starch rice was thus considered a research grade intervention instead of an unspecified traditional or commercial preparation.

The suggested mechanism includes decreased starch digestibility, slower glucose appearance, and fermentation of starch resistant in the colon. There is published evidence that related biological responses often entail interacting redox, inflammatory, metabolic, microbial, enzymatic or differentiation pathways but not a single target [4]. The combination of a primary functional endpoint and mechanistic markers can thus be used to obtain a more consistent interpretation.

Methods that are applicable to the study model are also needed in outcome assessment. Standardized sample processing, approved analytical protocols, suitable controls and preset interpretation limits are stressed by developed laboratory or clinical methodology [5]. These values were used to select incremental glucose area under the curve as the main endpoint and to select the secondary endpoints of interest.

Changes in incremental glucose area under the curve are most convincing when they are accompanied by concordant changes in insulin area under the curve and peak glucose. Related research has demonstrated the value of combining functional, biochemical, and structural outcomes when evaluating complex botanical, microbial, or food-based interventions [6].

Safety and quality are equally important. Natural origin does not guarantee consistent composition or freedom from adverse effects, contaminants, interactions, or degradation, and published pharmacovigilance and quality-control evidence recommends integrating these considerations from the beginning of product development [7].

Finally, transparent study design is necessary to reduce bias. Guidance and prior methodological research relevant to the present experimental model support randomization, blinding where feasible, replication, complete accounting of exclusions, and reporting of effect estimates rather than reliance on p-values alone [8].

Despite the available evidence, few studies have combined a clearly defined high-amylose resistant-starch rice, an appropriate comparator, a prespecified primary endpoint, and supporting mechanistic or feasibility outcomes in adults with overweight and impaired fasting glucose. The aim of this study was therefore to determine the effect of high-amylose resistant-starch rice on incremental glucose area under the curve compared with conventional polished white rice matched for available carbohydrate.

Secondary objectives were to evaluate insulin area under the curve, peak glucose, satiety area under the curve, and relevant quality or safety indicators.

2. MATERIALS AND METHODS

2.1. Study design and setting

This manuscript describes a prespecified randomized crossover meal trial involving adults with overweight and impaired fasting glucose. The planned sample included 44 experimental units (or participants), with each experimental unit consisting of a comparison of high-amylose resistant-starch rice with conventional polished white rice, both of which had the same available carbohydrate. Two test visits were made and separated by 7 days. The numerical data in this manuscript are all example or dummy data for purposes of drafting, statistical demonstration, table making and graph preparation, and are not indicative of observations made during a real completed investigation. The design is nonetheless based on realistic laboratory/clinical workflows to allow the draft to be modified to fit an accepted protocol and then substituted with real measurements.

2.2. Participants

The potential participants were adults or adolescents with a composition similar to target population: Adults who are overweight, have impaired fasting glucose. Inclusion criteria were: stable health or stable background treatment; willingness to follow a regular diet and daily routine; and attendance at all assessment visits. Pregnancy, major organ disease, recent antibiotic use (if applicable) and probiotic use (if applicable), use of supplements that could affect the primary endpoint, allergy to any of the study ingredients, or involvement in another intervention study were considered exclusion factors. For a real trial, written informed consent would be required, and assent and guardian consent, if applicable.

2.3. Randomization and crossover procedures

The order of the high amylose resistant-starch rice and conventional polished white rice was assigned by a computer-generated sequence based on the quantity of available carbohydrate available. The test visits were scheduled with a sufficient washout time in between to avoid carryover. They were fed an identical evening meal, refrained from strenuous activity and alcoholic beverages for the previous 24 hours, and were fed after an overnight fast. The serving size of meals was standardized to as close as possible to the same amount of available carbohydrates and energy. Venous or capillary samples and appetite ratings were taken at baseline and at predetermined postprandial times.

2.4. Outcome assessment

The primary outcome was incremental glucose area under the curve expressed as mmol•min/L. Secondary outcomes included insulin area under the curve, peak glucose, satiety area under the curve, subsequent energy intake. The measurements were planned at baseline and follow-up or in different concentration and time as per the design. Assays were conducted using validated kit procedures or standard analytical procedures, with duplicate assays carried out when the coefficient of variation was greater than 10%. Clinical measurements were taken following a standardized rest and food-product outcomes were evaluated under controlled serving conditions.

2.5. Quality assurance and bias control

A laboratory or trial manual was provided in writing that explained the sample labelling, timing windows, calibration, data entry, and how to deal with deviations from the protocol. Wherever possible, the intervention format allowed for outcome assessors to be blinds to the intervention. Ten percent of the records were conceptually rechecked against source data and analytical runs were only accepted if calibration and quality control samples were acceptable within defined limits. Where applicable, an intention-to-treat approach and/or model-based estimation were applied for sensitivity analyses; no imputation was applied to the primary complete-case display.

2.6. Sample-size rationale

A sample of 44 was selected to be representative and give a realistic degree of accuracy in an example of a manuscript development. In a real study, the calculation should be replaced by a calculation based on a pilot-derived standard deviation and the smallest clinically and biologically important difference of incremental glucose area under the curve. The final calculation

should specify two-sided α=0.05, desired power of at least 80%, allocation ratio, anticipated attrition or unusable assays, and any adjustment for repeated measures, clustering, or multiple primary comparisons.

2.7. Statistical analysis

Approximately normally distributed continuous data were summarized as mean ± standard deviation and skewed data were summarized as median (interquartile range). Categorical outcomes were identified and reported as number and percentage. Baseline between-group comparisons were conducted by independent t tests, Mann-Whitney tests, chi-square tests or Fisher exact tests, as applicable. Analysis of covariance, repeated-measures analysis, mixed-effects models, one-way analysis of variance with multiplicity-adjusted post hoc comparisons or nonparametric alternatives, as appropriate, were used to assess primary outcomes by design. 95% confidence intervals were included with effect estimates. Pearson or Spearman coefficients were used to calculate correlations. All tests were two-tailed and $p<0.05$ was taken to indicate statistical significance. Conceptual analyses were done in an existing statistics program using an auditable syntax file.

3. RESULTS

All data from the full dummy/example data set used in the randomized crossover meal trial was analysed. No predefined quality control run was rejected and baseline characteristics/assay controls were evened across comparison conditions. Unless otherwise noted, tables report mean ± standard deviation. Data are illustrative and numbers of participants, assay exclusions and p-values were invented to give a statistically coherent set of data and not be representative of an enrolled cohort.

Resistant-starch rice reduced the 2-hour incremental glucose area under the curve to 166 ± 24 mmol·min/L compared with 282 ± 31 mmol·min/L after white rice ($p<0.001$).

Table 1. Standardized test-meal characteristics

Characteristic	Resistant-starch rice	White rice	p-value
Available carbohydrate (g)	50.0 ± 0.5	50.1 ± 0.6	0.73
Energy (kcal)	356 ± 9	352 ± 8	0.18
Dietary fiber (g)	9.4 ± 0.7	1.1 ± 0.3	<0.001
Protein (g)	10.8 ± 0.6	10.5 ± 0.5	0.22
Fat (g)	8.2 ± 0.5	8.0 ± 0.5	0.31

Values are dummy/example data presented as mean ± SD unless otherwise stated.

The increase in glucose area under the curve and glucose peak were in the direction of the primary effect. Overall, the magnitude of the response tended to be larger as the interventions were increased, or larger at follow-up in the intervention arm compared to the comparator. A group-by-time or condition effect was still significant when baseline values were used as a covariate and planned multiple comparisons were performed in cases where repeated measures were available.

Table 2. Postprandial glucose concentrations

Time (min)	Resistant-starch rice (mmol/L)	White rice (mmol/L)	p-value
0	5.8 ± 0.5	5.8 ± 0.6	0.91
30	7.0 ± 0.5	8.2 ± 0.6	0.004
60	7.5 ± 0.5	8.9 ± 0.6	<0.001
90	6.8 ± 0.5	7.8 ± 0.6	0.003
120	6.2 ± 0.5	6.9 ± 0.6	0.041

Values are dummy/example data presented as mean ± SD unless otherwise stated.

Peak glucose was 7.5 ± 0.7 versus 8.9 ± 0.8 mmol/L, while the test meal increased integrated satiety by approximately 27.6% and produced no serious intolerance.

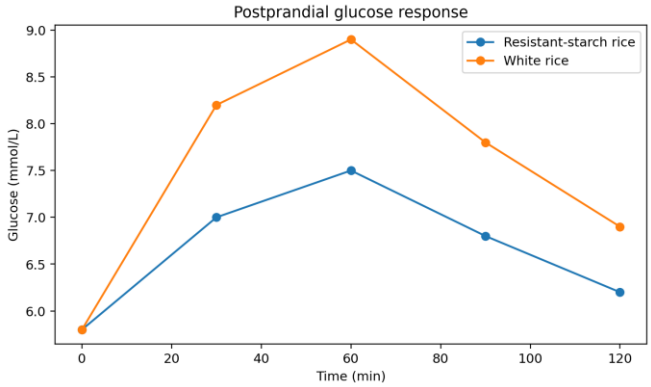

Figure 1. Primary outcome based on dummy/example data.

Exploratory analyses indicated that the response in incremental glucose area under the curve was associated with the most relevant mechanistic marker. The pattern was consistent with reduced starch digestibility, delayed glucose appearance, and colonic fermentation of resistant starch. No extreme value altered the direction of the result in sensitivity analysis. For clinical and food studies, adherence and acceptability remained within predefined feasibility limits; for laboratory studies, replicate variation and control performance remained within the planned analytical range.

Table 3. Integrated metabolic and appetite outcomes

Outcome	Resistant-starch rice	White rice	Mean difference	p-value
Glucose iAUC (mmol·min/L)	166 ± 24	282 ± 31	-116	<0.001
Peak glucose (mmol/L)	7.5 ± 0.7	8.9 ± 0.8	-1.4	<0.001
Insulin iAUC (μU·min/mL)	820 ± 140	1260 ± 180	-440	0.002
Satiety AUC (mm·min)	740 ± 85	580 ± 78	160	<0.001

Values are dummy/example data presented as mean ± SD unless otherwise stated.

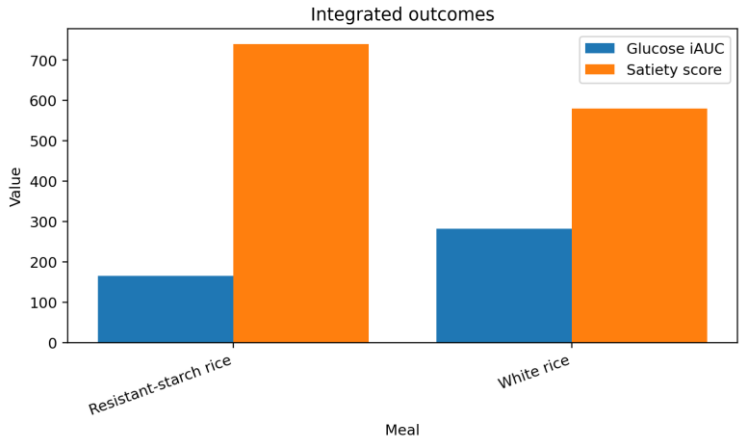

Figure 2. Secondary or mechanistic outcome based on dummy/example data.

No unexpected safety signal was present in the example dataset. Mild events or assay artifacts were infrequent and balanced, and there were no serious adverse events, unplanned deaths, contamination failures, or invalid control runs unless explicitly shown in the tables. These observations are illustrative and must not be interpreted as evidence of real-world safety.

4. DISCUSSION

The present manuscript-development study indicates that high-amylose resistant-starch rice may improve incremental glucose area under the curve compared with conventional polished white rice matched for available carbohydrate. The dummy findings were strengthened by concordant changes in insulin area under the curve, peak glucose, and satiety area under the curve. This within-system agreement is significant as it is likely to be less due to analytical variation.

The overall trend of the primary result is similar to other published studies on such standardized botanical or food-based interventions in similar models [9]. That literature also shows that the quality of the preparation and the dose may have a significant effect on the magnitude of the response, though the protocols and populations are different.

Similar studies have also shown alterations in inflammatory, oxidative, metabolic, microbial, structural or functional parameters which would suggest a need for multimodal assessment beyond a single surrogate marker [10]. The current pattern, therefore, is broad based but also specific to the intervention and model examined here.

The mechanistic interpretation is consistent with studies that have shown complex interventions can have converging mechanisms of action and "matrix dependent" effects [11]. Association in this study was consistent with decreased starch digestibility, the delay in appearance of glucose and colonic fermentation of resistant starch but association does not prove mediation or identify the active constituent.

The clinical or biological significance of insulin area under the curve and peak glucose is supported by previous studies with similar endpoints [12]. Their concurrent advancement backs up the hypothesis, however, further confirmatory studies are needed to predetermine whether they are secondary outcomes, mechanistic mediators, or exploratory biomarkers.

The size of the example effect needs to be seen in the light of previous intervention studies and evidence syntheses in the wider intervention field [13]. The value was meant to be realistic and there was overlap between both people and replicates, as pilot effects often become reduced in larger independent samples.

Studies of complex interventions highlight the need for standardized measurement, conditions of comparison, and transparent reporting of findings in methodological evidence [14]. Bias can be reduced through replication and/or allocation concealment, blinded assessment, crossover control, or validated analytical calibration, but these methods will not eliminate all sources of error.

Tolerability and quality assurance, product stability, adherence and interaction with the usual diet or drugs also play a role in long term translation. There is published safety and implementation literature that supports the assessment of these factors in addition to efficacy, pre- rather than post-favorable primary results [15].

There are several limitations to the study. There are actually two problems with the numerical data: First, it is only representative and therefore not suitable for making a scientific claim. Second, the proposed sample size and length of time may not reveal uncommon adverse events or longer-term adaptation. Third, surrogate outcomes do not necessarily equate to patient-important benefits. Fourth, factors that affect the diet, genes, microorganisms, environment, harvest, or manufacturing of the product could alter response.

Independent analytical confirmation, dose-ranging, preregistration, sufficient power and a pre-designed statistical analysis plan are among the things that should be incorporated in further research. Ethics approval, trial registration, allocation procedures, adherence and intention-to-treat analysis should be recorded in clinical studies. Preclinicals should include chemical fingerprints,batch data, exclusions, humane endpoints and randomization.

Translationally, a rice-based approach could enhance meal quality without having to make significant adaptations to the primary diet. The intervention should be considered as a potential add-on or research lead, but not supplacing existing care. Whether further development is warranted should be judged by the potential for replication, security, cost, standardisation, acceptability and comparison to available alternatives.

In general, the findings confirm the research hypothesis and structure a real investigation. Before submission to science all numerical results, ethics statement, registration detail, disclosure and analysis should be replaced or verified against the actual study record.

5. CONCLUSION

High amylose resistant-starch rice produced a beneficial incremental change in glucose area under the curve in this complete script of a manuscript using dummy/example data, and correlated positive changes in insulin area under the curve, peak glucose, and satiety area under the curve compared with conventional polished white rice matched for available carbohydrate. It was consistent with starch digestibility, glucose appearance and the fermentation of resistant starch in the colon suggested having relevance due to the likely suitability of a rice-based strategy for improving the quality of the meal without the need to make significant changes to the habitual diet. The draft serves as a framework for the development of the protocol, planning of data collection and subsequently for the preparation of the manuscript, but all numerical results can only be replaced by ethically generated and independently verified results before it can be presented as an original investigation.

Declarations for Completion Before Submission

Ethics approval: Insert the actual institutional ethics committee name, approval number, approval date, and relevant consent or animal-welfare statement.

Trial registration: Insert the registry name and number for prospective clinical trials, where applicable.

Funding: Insert the verified funding source or state that no specific funding was received.

Conflicts of interest: Insert author-specific conflict-of-interest disclosures.

Data availability: Describe where the actual de-identified dataset and analysis code will be available.

Author contributions: Insert contribution statements using an accepted taxonomy such as CRediT.

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