Impact of low-starch high-fiber pasta on postprandial blood glucose

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Received 1 April 2021; received in revised form 21 October 2021; accepted 24 October 2021
Handling Editor: L. Bazzetto
Available online

KEYWORDS
Starch; Carbohydrates; Postprandial blood glucose; Continuous glucose monitoring system

Abstract  Background and aims: Almost all of the energy in noodle dishes is derived from carbohydrates, particularly starch. Recently, we invented a pasta with reduced starch content to about 50% and increased dietary fiber content, designated low-starch high-fiber pasta (LSHFP). In this study, we investigated the ingestion of LSHFP on the postprandial glucose response as a breakfast meal.
Methods and results: This was a randomized, single-blinded, crossover study. The postprandial glucose area under the curve for 4 h (4h-gluAUC), as the primary outcome, and the extent of postprandial glucose elevation (maxΔBG) were evaluated using a continuous glucose monitoring system in healthy volunteers and patients with type 2 diabetes (T2DM) after intake of LSHFP, standard pasta (SP), and rice. The amount of total carbohydrate was matched between LSHFP and SP. Ten individuals with T2DM and 10 individuals who did not have T2DM and were otherwise healthy were enrolled in this crossover study. The 4h-gluAUC for LSHFP (137.6 ± 42.2 mg/dL · h) was significantly smaller than the 4h-gluAUC for rice (201.7 ± 38.7 mg/dL · h) (p = 0.001) and SP (178.5 ± 59.2 mg/dL · h) (p = 0.020). The maxΔBG for rice (118.6 ± 24.2 mg/dL) was significantly higher than those for SP (87.5 ± 19.9 mg/dL) (p < 0.001) and LSHFP (72.7 ± 26.2 mg/dL) (p = 0.001), while the maxΔBG for LSHFP (p = 0.047) was significantly lower than that for SP, in T2DM patients as well as in healthy participants.
Conclusions: This study demonstrated that LSHFP can reduce postprandial glucose elevation compared with SP in both healthy participants and patients with T2DM.

Introduction

The goal of diabetes management is to maintain plasma glucose levels as close to normal as possible, prevent the onset of diabetic complications, and stop the progression of existing complications. Postprandial hyperglycemia is a known risk factor for complications, particularly cardiovascular disease [1]. Consequently, management of
postprandial hyperglycemia is important for cardiovascular disease prevention. In addition, glycemic variability is a risk factor for exacerbation of arteriosclerosis and development of dementia [2,3]. Therefore, it is preferable to achieve glycemic control with minimal variability, even before the onset of diabetes.

Among the various factors affecting plasma glucose concentrations, the amount of carbohydrate intake is known to cause variations in postprandial plasma glucose concentrations. The association between carbohydrate intake and onset of diabetes has been demonstrated in otherwise healthy individuals [4,5]. Service et al. [6] applied the euglycemia glucose clamp technique to patients with type 1 diabetes and demonstrated that high-carbohydrate diets resulted in higher peak postprandial plasma glucose concentrations, prolonged elevation of plasma glucose concentrations, and increased postprandial insulin requirements. The recommended intake of carbohydrate is 50–60% of total daily energy intake for patients with diabetes and obesity [7,8]. According to the Dietary Guidelines for Americans, the recommended intake of carbohydrate-based foods (i.e. grains and fruits) is 45%–65% of the total energy. The United States Eatwell Guide recommends that one-third of the diet should consist of starchy foods and an additional one-third of the diet should consist of fruits and vegetables [9,10]. While rice and bread are often consumed together with meat and fish dishes, noodle dishes tend to be consumed as single items and thus the percentages of carbohydrates in the total meals tend to be high at around 80%. Meanwhile, starch is significantly involved in the increase in postprandial glucose concentrations [6], and dietary fiber is known to suppress the rapid rise in glucose concentrations [11]. Recently, we invented a pasta with reduced starch content to about 50% and increased dietary fiber content, designated low-starch high-fiber pasta (LSHFP).

Continuous glucose monitoring (CGM) has recently become part of diabetes management to assess daily changes in glucose concentrations. Although studies have examined the decreases in postprandial blood glucose elevation after reducing the carbohydrate content in a meal or delaying the order of carbohydrate intake, these studies were performed by changing the protein/fat/carbohydrate balance or the order of their intake [12,13]. Few reports have described the evaluation of glucose concentration fluctuations in daily life without changing the proportion of carbohydrates in the diet itself.

Therefore, we hypothesized that LSHFP with reduced starch and increased fiber but no change in the protein/fat/carbohydrate balance of the food content would suppress postprandial glucose elevation. To test this hypothesis, we conducted a prospective randomized crossover study using CGM to investigate postprandial glucose concentrations and glycemic variability following intake of LSHFP.

Materials and methods

Participants

Outpatients with type 2 diabetes (T2DM) at the Sapporo Diabetes and Thyroid Clinic, a specialized hospital for diabetes and endocrinology, and healthy subjects were included in the study. For patients with type 2 diabetes, the selection criteria included HbA1c level in the range of 6.0%–9.0%, and the exclusion criteria included use of rapid-acting insulin secretagogues, alpha-glucosidase inhibitors, sodium glucose cotransporter disodium inhibitors, or bolus insulin preparations. There was no upper limit for the number of diabetic medications. In healthy subjects, the selection criteria included that they had never been diagnosed with glucose intolerance. The common selection criteria for both groups were age of 20–79 years, and the common exclusion criteria were inability to participate in the study due to concomitant severe hepatic, renal, or cardiac disease, history of hypersensitivity to any ingredient of the foods used in the study, and pregnancy or lactation. The study content was explained to the participants, and written informed consent was obtained before entry into the study. The study was approved by the Sapporo Medical Association’s Ethical Review Board (approval date: 12 September 2017) and conducted in accordance with the tenets of the Declaration of Helsinki. The study was registered with UMIN (UMIN 000029390).

Methods

This was a randomized, single-blinded, crossover study. A CGM device (FreeStyle Libre Pro; Abbott, Chicago, USA) was placed on the participants to monitor their glucose concentrations after receiving their written informed consent. Measurements were obtained for 14 days until the CGM device was removed. The data for the first two days were excluded from the analysis. Three types of test meals were prepared, and the participants were instructed to eat each test meal twice (total: six times). The mean values for the individual test meals eaten twice were used as the data for each subject. All test meals were eaten as the first meal after waking up after an overnight fast (as breakfast). The participants were instructed to fast from 21:00 on the day before the test, and alcohol consumption of more than 20 g was prohibited. In addition, the participants consumed a unified meal as lunch (Calorie Mate® 80 g; Otsuka Pharmaceutical Co. Ltd., Tokyo, Japan) at 5 h after each test meal to evaluate the second meal effect. The participants were able to eat freely from 3 h after the unified meal (lunch). The three test meals were as follows: (1) standard pasta (SP) (Nama Pasta®; Marutaka Co. Ltd., Sapporo, Japan); (2) LSHFP (Tekimen®; Marutaka Co. Ltd.); and (3) rice (Sato No Gohan®; Sato Foods Co. Ltd., Niigata, Japan). Table 1 shows...
the energy and macronutrient breakdown of the three test meals (breakfast) and the unified meal (lunch). For the contrast meal of rice, 200 g of cooked rice was used in accordance with the Japanese Association for the Study of Glycemic Index. The mass of each type of pasta was adjusted to match for total carbohydrate. The test meals were blinded to ensure that the participants would not know which pasta was SP or LSHFP. The order of intake of SP/rice/LSHFP or LSHFP/rice/SP was decided by random allocation through a separate organization (static allocation using a random number table) for the first set of intakes, and then crossed over for the second set of intakes (Fig. 1). The amount of water that could be consumed when eating the test meals was set to 200 mL as a condition for intake of the test meal or unified meal.

<table>
<thead>
<tr>
<th></th>
<th>SPa</th>
<th>LSHFPa</th>
<th>Riceb</th>
<th>Unified meal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbohydrates (g)</td>
<td>77.3</td>
<td>77.3</td>
<td>67.4</td>
<td>43.7</td>
</tr>
<tr>
<td>Starch (g (%))</td>
<td>73.2 (70.2)</td>
<td>44.4 (47.3)</td>
<td>66.7 (89.5)</td>
<td>41.7 (41.7)</td>
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<tr>
<td>Dietary fiber (g (%))</td>
<td>14.6 (14.0)</td>
<td>17.2 (18.4)</td>
<td>5.2 (7.0)</td>
<td>8.0 (8.0)</td>
</tr>
<tr>
<td>Protein (g (%))</td>
<td>6.4 (13.8)</td>
<td>7.0 (16.8)</td>
<td>0.0 (0.0)</td>
<td>21.9 (49.3)</td>
</tr>
<tr>
<td>Lipids (g (%))</td>
<td>4.1 (2.0)</td>
<td>32.9 (17.6)</td>
<td>0.7 (0.5)</td>
<td>2.0 (1.0)</td>
</tr>
<tr>
<td>Energy (kcal)</td>
<td>417.1</td>
<td>375.5</td>
<td>296</td>
<td>400</td>
</tr>
</tbody>
</table>

SP, standard pasta; LSHFP, low-starch and high fiber pasta. a Pasta sauce included. b Furikake condiment for rice included.

The primary endpoint was postprandial interstitial glucose area under the curve for 4 h (4h-gluAUC) following the test meal. The secondary endpoints were: 1) extent of postprandial interstitial glucose elevation (maxΔBG)

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**Table 1** Energy and macronutrient breakdown of each test food and the unified meal.

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**Figure 1** Study outline. A, Outline of the study. B, Schedule of the test day. During the period from 2 days to 2 weeks after wearing the device, consume one serving of each test meal per day in the order as directed. The period of time and order as instructed does not matter the number of days between each test meal. CGM, continuous glucose monitoring; SP, standard pasta; LSHFP, Low-starch and high fiber pasta.

Please cite this article as: Oba-Yamamoto C et al., Impact of low-starch high-fiber pasta on postprandial blood glucose, Nutrition, Metabolism & Cardiovascular Diseases, https://doi.org/10.1016/j.numecd.2021.10.019
following a test meal (difference between postprandial maximal interstitial glucose and pre-meal interstitial glucose concentrations); 2) extent of post-meal interstitial glucose variability (mean amplitude of glycemic excursions [MAGE] and %CV for 4 h after breakfast); 3) 4h-gluAUC and maxΔBG after lunch (as the second meal); 4) differences in patterns between participants with and without diabetes; 5) scores of satisfaction levels for each meal using the questionnaire.

Analysis methods

Data were shown as means ± standard deviations. Statistical analyses were performed by repeated-measures one-way ANOVA. Values of p < 0.05 were considered to indicate statistically significant differences. Ekuseru-Toukei 2015 software (Social Survey Research Information, Tokyo, Japan) was used for the statistical analyses. The sample size was calculated on the basis of a previous report [13], which confirmed changes in 4h-gluAUC depending on the order of eating carbohydrates and proteins. The study found that the mean 4h-gluAUC for fish before rice was 2326.6 ± 114.7 mmol/L × min, while that for rice before fish was 2475.6 ± 87.2 mmol/L × min. Therefore, for a detection rate of 80% and statistical significance of 5%, it was determined that nine participants per group (10 participants with an estimated dropout rate of 10%) were needed to detect a significant difference.

Results

Patient background characteristics

The study was conducted in the period of October 2017 to November 2017. Ten volunteers who did not have T2DM and were otherwise healthy (5 men; 5 women) and 10 patients with T2DM (5 men; 5 women) participated in the study. All participants completed the full crossover study. No participants developed hypoglycemia or gastrointestinal symptoms during the study period. No adverse events were observed. Regarding the background characteristics, the patients with T2DM had an age of 62.3 ± 7.1 years, HbA1c level of 7.0% ± 0.9%, and BMI of 26.1 ± 6.9 kg/m², while the healthy volunteers had age of 37.4 ± 10.0 years, HbA1c level of 5.1% ± 0.3%, and BMI of 20.4 ± 2.7 kg/m² (Supplemental Table 1).

Comparisons among healthy participants

The changes in interstitial glucose concentrations for 4 h after initiation of each test meal in the healthy participants are shown in Fig. 2A. While there was no significant difference in 4h-gluAUC between rice (75.9 ± 31.1 mg/dL-h) and SP (85.1 ± 43.6 mg/dL-h) (p = 0.235), the 4h-gluAUC for LSHFP (51.6 ± 27.9 mg/dL-h) was significantly smaller than those for SP and rice (p = 0.001 and p = 0.009, respectively) (Table 2; Fig. 3). The maxΔBG for rice was significantly higher than those for SP and LSHFP (p = 0.037 and p < 0.001, respectively), and the maxΔBG for LSHFP was significantly lower than that for SP (p = 0.037) (Table 2). The MAGE and %CV for rice were both significantly higher than those for SP and LSHFP (MAGE: p = 0.014 and p < 0.001, respectively; %CV: p = 0.010 and p < 0.001, respectively). There were no significant differences between LSHFP and SP in MAGE and %CV (Table 2).

Comparisons among patients with T2DM

The changes in interstitial glucose concentrations for 4 h after initiation of each test meal in the patients with T2DM are shown in Fig. 2B. The 4h-gluAUC for LSHFP was 137.6 ± 42.2 mg/dL-h, which was significantly smaller than the 4h-gluAUC for rice (201.7 ± 38.7 mg/dL-h, p = 0.001) and SP (178.5 ± 59.2 mg/dL-h, p = 0.020) (Table 2, Fig. 3). The maxΔBG for rice was significantly higher than those for SP and LSHFP (p = 0.001 and p < 0.001, respectively), while the maxΔBG for LSHFP was significantly lower than that for SP (p = 0.047) (Table 2). The MAGE for rice was significantly higher than those for SP and LSHFP (p < 0.001 and p < 0.001, respectively), while the MAGE for LSHFP was significantly lower than that for SP (p = 0.005) (Table 2). Similarly, the %CV for rice was significantly higher than those for SP and LSHFP (p < 0.001 and p < 0.001, respectively), while the %CV for LSHFP was significantly lower than that for SP (p = 0.010) (Table 2).

Unified meal test for lunch

Although there were trends toward lower maxΔBG for LSHFP (76.7 ± 37.1 mg/dL) compared with those for rice and SP in patients with T2DM (102.3 ± 38.2, p = 0.056 and 100.5 ± 45.4, p = 0.056, respectively), no significant differences were detected in any of the comparisons (Supplemental Table 2).

Questionnaires

The changes in the scale scores in the questionnaire before and after each meal were analyzed for all participants. There were no differences in the responses to any of the questions regarding feelings of hunger, fullness, and satisfaction with meal volume among the three meals (Supplemental Fig. 1). For the question on which pasta was preferred at the end of the study, two chose SP, four chose LSHFP (40%), and four had no particular preference among the healthy participants, while three chose SP (30%), three chose LSHFP (30%), and four had no particular preference among the patients with T2DM.

Discussion

In this randomized crossover study, we demonstrated that postprandial interstitial glucose elevation was reduced after eating LSHFP compared with that after eating SP or rice in both healthy participants and patients with T2DM without worsening of the eating satisfaction. In addition to
the postprandial glycemic changes, the daily glycemic variability (MAGE and %CV) was significantly improved in patients with T2DM after eating LSHFP compared with that after eating SP or rice. This is the first report to demonstrate beneficial effects on postprandial glucose elevation and glycemic variability using CGM after changing the starch and fiber content of pasta without changing the balance of protein/fat/carbohydrate.

Starch is significantly involved in the increase in postprandial glucose concentrations [6], with 1 g of starch generally considered to increase the postprandial glucose concentrations by 5 mg/dL in patients with type 1 diabetes and 3 mg/dL in patients with T2DM [14]. The starch content of the LSHFP used in this study was 44.4 g, which was lower than that of SP (73.2 g) and rice (70.2 g). Therefore, it can be assumed that the low level of starch is one of the reasons why the increase in glucose concentrations after the meal was suppressed.

In addition to its low starch content, LSHFP contained a large amount of dietary fiber derived from indigestible dextrin, and this fiber content is considered to have helped suppress the increase in postprandial glucose concentrations. Dietary fiber is known to prolong the retention time of meal contents in the stomach, slow digestion and absorption of carbohydrates in the small intestine, and suppress a rapid rise in glucose concentrations [11]. The LSHFP used in this study contained a large amount of dietary fiber (32.9 g) compared with SP (4.1 g), and the digestive and absorption-suppressing effects of this dietary fiber may have partially suppressed the postprandial glucose

![Figure 2](image-url) Changes in interstitial glucose concentrations. A. Healthy participants (n = 10). B. Patients with type 2 diabetes (n = 10). Dashed line, rice; dotted line, standard-starch pasta; solid line, low-starch pasta. Standard deviation; circle, rice; rhombus, standard-starch pasta; bar, low-starch pasta.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Mean (±SD) values for interstitial glucose concentrations and variability measures, measured using continuous glucose monitors, after consuming each test meal.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SP</td>
</tr>
<tr>
<td>Mean BG (mg/dL)</td>
<td>Healthy participants (n = 10)</td>
</tr>
<tr>
<td>max BG (mg/dL)</td>
<td>44.8 ± 17.9</td>
</tr>
<tr>
<td>%CV</td>
<td>13.5 ± 6.3</td>
</tr>
<tr>
<td>MAGE (mg/dL)</td>
<td>37.7 ± 22.5</td>
</tr>
<tr>
<td>Mean BG (mg/dL)</td>
<td>T2DM participants (n = 10)</td>
</tr>
<tr>
<td>max BG (mg/dL)</td>
<td>87.5 ± 19.9</td>
</tr>
<tr>
<td>%CV</td>
<td>20.8 ± 6.2</td>
</tr>
<tr>
<td>MAGE (mg/dL)</td>
<td>88.2 ± 21.7</td>
</tr>
</tbody>
</table>

Data are shown as mean ± standard deviation.
SP, standard pasta; LSHFP, Low-starch and high fiber pasta; BG, blood interstitial glucose; maxΔBG, extent of postprandial blood interstitial glucose elevation; CV, coefficient of variation; MAGE, mean amplitude of glycemic excursions; T2DM; type 2 diabetes.

Please cite this article as: Oba-Yamamoto C et al., Impact of low-starch high-fiber pasta on postprandial blood glucose, Nutrition, Metabolism & Cardiovascular Diseases, https://doi.org/10.1016/j.numecd.2021.10.019
concentrations. The dietary fiber intake itself is also expected to have beneficial effects on both patients with T2DM and healthy individuals. The indigestible dextrin in the LSHFP used in this study is a water-soluble dietary fiber that can be broken down into short-chain fatty acids by intestinal bacteria and may exert effects like suppression of appetite by affecting the hypothalamus [15], mediated by incretin secretion, the vagus nerve, and acetic acid. The nutritional guidelines also encourage the consumption of fiber [9,10]. As described above, LSHFP may have suppressed the postprandial glucose increase for two reasons: its low starch content and its high fiber content.

In a previous study, the increase in postprandial glucose concentrations was suppressed by cooking with artificial sweeteners instead of carbohydrate among patients with mild diabetes or borderline hyperglycemia [12]. However, in the previously reported study, there were differences in not only the carbohydrate content of the test and control diets but also the energy content, and consequently it was impossible to distinguish between the effect of the energy restriction and the effect of the carbohydrate restriction. In the present study, the test meal had the energy content equivalent to or higher than that of rice (296 kcal), and thus the suppression of elevated interstitial glucose concentrations can be attributed to reductions in starch as the energy content in the comparative meals that were the same or greater.

Although the increment in postprandial interstitial glucose was much higher, nearly double, in patients with T2DM compared with healthy participants, the patterns and differences among the three test meals were comparable (Fig. 2A and B). However, the relationship between LSHFP and SP at 60 min seemed to differ between the healthy participants and patients with T2DM. Specifically, the interstitial glucose concentrations at 60 min differed between LSHFP and SP in the healthy participants, but were similar in the patients with T2DM. Although the precise mechanism for the difference between the healthy participants and patients with T2DM was not determined, it may arise through degradation of the first-phase rapid insulin secretion or resistance of pancreatic β cells to incretin stimulation in patients with T2DM [16]. Unfortunately, we did not collect data on the changes in insulin secretion and incretin levels in the present study.

A variety of methods to suppress increases in postprandial plasma glucose concentrations have been reported, including intake of vegetables and proteins/lipids before carbohydrates [13,17,18]. However, these methods are difficult to put into practice with noodle meals, which tend to contain high carbohydrate levels. The LSHFP used in this study should also be available to overcome this problem associated with noodle meals.

In this study, there were no differences in the fluctuations of interstitial glucose concentration after lunch for any condition. Previous reports showed that the first meal affected glucose concentrations during intake of a second meal, which is known as the second meal effect [19–21]. This effect is assumed to arise because the first meal enhances the response of pancreatic β cells [19]. The second meal effect was not seen with the LSHFP used in this study. This matter requires further investigation with a larger sample size or the use of different lunch meals.

The first limitation of the present study is that although the amount of rice was matched to the energy in SP and LSHFP, the total carbohydrate amount was not matched. Matching the total carbohydrate content may have

Figure 3  Results for 4h-gluAUC, representing the interstitial glucose area under the curve for 4 h after ingestion of each test meal. A, Healthy participants (n = 10). B, Patients with type 2 diabetes (n = 10). * p < 0.05; ** p < 0.01; ns, not significant. SP, standard pasta; LSHFP, low-starch and high fiber pasta. Data are expressed as mean ± standard deviation. ANOVA with the Holm test was used to compare 4h-gluAUC values among the rice, SP, and LSHFP groups.
provided a clearer assessment of the effect of LSHFP on glycemic variability. The second limitation was the inability to completely unify factors other than diet, such as the amount of activity, because the study examined participants in their normal daily life. The third limitation was that insulin concentrations were not measured, and thus there was no analysis of the mechanism for the observed changes.

Conclusions

This study showed that LSHFP intake suppressed postprandial interstitial glucose and glycemic variability compared with SP intake. Therefore, the use of this pasta, which is low in starch and high in non-digestible dextrin, can be expected to improve blood glucose control while retaining a feeling of freedom in the diet.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author contributions

CO contributed to the data analysis. CO and HM wrote the manuscript and contributed to discussion. JT planned this study and contributed to the data analysis. HN, HK, KY, AN and TA contributed to discussion and revision of the manuscript. All authors contributed to manuscript revision, and read and approved the submitted version.

Conflict of interest

All authors declare no conflict of interest.

Acknowledgments

The authors thank the participants, their families, and all investigators involved in the study. The authors thank Yoshikazu Sudo for his help in the development of the pasta. The authors also thank Alison Sherwin, PhD, from Edanz Group (https://en-author-services.edanzgroup.com/ac) for editing a draft of this manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.numecd.2021.10.019.

References