Effects of brown rice powdered drink on glucose control and lipid profile of type 2 diabetes patients.

Husna Mansor¹, Lili Husniati Yaacob¹*, Azidah Abdul Kadir¹, Wan Mohd Zahiruddin Wan Mohammad²

¹Department of Family Medicine, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia
²Department of Community Medicine, Universiti Sains Malaysia, Kota Bharu, Kelantan, Malaysia

Abstract

Diabetes mellitus causes multiple adverse health outcomes. Thus, control of the disease is paramount in preventing its complications. Brown rice, as a whole-grain staple, has been proven to be beneficial in many of these respects. However, due to taste and cost, many consumers avoid brown rice as an alternative to white rice. Our primary aim was to study the effects of a brown rice instant drink on glycemic control, lipid profile, weight, and blood pressure in patients with uncontrolled diabetes. This was a randomized, open-label clinical trial conducted over 12 w. Sixty-four participants were randomized into an intervention group and a control group. The intervention group received 18 g of powdered brown rice to be consumed in a drink three times daily for 12 w. The control group was given standard or their usual treatment. Fasting plasma glucose, HbA1c, plasma lipid, blood pressure, and weight were measured and recorded before and after the intervention. There were no significant differences between the two groups in terms of HBA1c levels at the end of the intervention (P=0.081). However, the BR group had a reduction in HbA1c with a mean of 0.11%, and the control group had an increase of HbA1c of 0.25%. There was significant improvement in total cholesterol, triglycerides, and blood pressure levels at the end of the intervention (P<0.005) in the intervention group. In conclusion, brown rice instant drink has improved total cholesterol, triglycerides, and systolic and diastolic blood pressure in subjects with type 2 diabetes.

Keywords: Brown rice, Glucose control, Lipid, Diabetes mellitus.
products, have been developed. None of the previous studies involving brown rice have studied its benefit as a supplement or in its powdered form. Therefore, in this study, we aimed to determine the overall effects of instant brown rice powder as an adjunct to concurrent medical therapy for the glycemic control of type 2 diabetic patients, as well as its effects on other related metabolic indices, namely lipid control, blood pressure, and weight.

Material and Methods

Participants were recruited from the outpatient clinic of Hospital Universiti Sains Malaysia Hospital, in Kelantan, Malaysia from July 2016 through November 2016. The inclusion criteria were as follows: ages 18 to 70 years old, diagnosis of type 2 diabetes mellitus for at least six months, HbA1c level between 6.5% and 9% within the last three months, use of oral hypoglycemic medication, and no ingestion of any other type of supplement or traditional herbal medication throughout the study. Patients with end-stage renal disease or proliferative retinopathy due to diabetes, as well as pregnant women and patients taking insulin, were excluded from the study.

Withdrawal criteria included any major changes in the participants’ concurrent medication which could have affected the results of the study, the ingestion of any other type of herbal or nutritional supplements at any time during the duration of the study, the occurrence of any intolerable or unacceptable adverse events, and/or if the investigator felt that a participant was unfit to continue the study for reasons unrelated to the product. Thus, at the end of the study, three participants were withdrawn for various reasons. One participant could not be contacted for follow-up two weeks after the randomization. Another participant was withdrawn because she did not consume any of her concurrent medication, which the investigator thought could be detrimental to her health. The other participant requested to be withdrawn from the study as she could not tolerate the taste of the product.

Powdered brown rice drink from the brand, “Nature’s Own,” was used in the intervention group as the adjunctive therapy product. This powdered brown rice is made of pure brown rice with no additives. Participants were instructed to mix 3 tablespoons of the powder, which is equal to 18 g, into 250 ml of water. They were instructed to take the intervention three times per day about 15 min prior to their next meal.

Participants in the control group were not given any supplement. They were only instructed to continue their medication and usual diet.

Sample size calculation

Sample size calculation was completed using power and sample size software with a power of study at 80% and α level of 0.05. The total number of participants was determined after calculating the sample size for each objective independently. The largest sample size was taken as the study’s sample size: 64 participants. This figure included a 20-percent drop-out rate. The sample size calculation was based on the HbA1c variable with a significant difference of 0.18% and a standard deviation of 0.23, taken from a study conducted by Hayakawa et al. in 2009 [14].

Study design and randomization

A randomized, open-label clinical trial was conducted without the blinding of the investigational product. All participants were advised not to consume any special diet or meals throughout the whole study. Participants were randomized into two groups: the control group (CG) and the intervention group (BR). A computer-generated randomization list using a block of 4 was used for the randomization process. The allocated sequence was concealed from the researcher enrolling and assessing the participants. The participants were sequentially numbered and the data were placed in opaque, sealed, and stapled envelopes.

Study procedure

Upon their consent, participants’ basic information and demographic data were collected, including current morbidities and medications. Blood was then drawn to determine baseline biochemical levels of fasting plasma glucose, fasting lipid profile, and HbA1c levels. Physical examination of the participants was performed to measure their blood pressure, height, and weight.

Those in the CG group were given general advice on compliance with medication requirements and an update on their baseline results. They were seen after two weeks to ensure compliance and to assess any side effects of the product. They were then given more brown rice powder for the remaining 10 w of the study period. The final follow-up took place after 12 w of product consumption to collect final data on biophysical parameters, product compliance, and confirmation of concurrent medications being taken (Figure 1).

Any side effects of the product were evaluated as well. Blood was also drawn for biochemical evaluation of the study post-intervention. Compliance was determined by weighing the residual product remaining within the participants, which was calculated against the total amount of product given.

The study protocol was reviewed and given clearance by the Institutional Review Board of the Research Ethics Committee (Human), Universiti Sains Malaysia (IRB No.: IRB00004494). This research was registered with the Thai Clinical Trials Registry (TCTR) with identification number TCTR20170608002.
Statistical analysis

Statistical analysis was conducted using SPSS software version 22 (SPSS Inc., USA). Baseline characteristics and clinical data were calculated using descriptive statistical analysis. Normally distributed continuous variables were analysed using independent t-tests to determine differences between means.

The primary endpoint, to determine the effects of instant brown rice drink on glycemic control, specifically HbA1c and fasting plasma glucose, was analysed using RM-ANOVA. The secondary endpoint, which was to assess the effects of the brown rice drink on total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, weight, body mass index (BMI), systolic blood pressure (SBP), and diastolic blood pressure (DBP), were also calculated using RM-ANOVA. Statistical significance was based on the overall group × time outcome of each variable.

Results

Demographics and clinical and biochemical results at baseline

Results were based on the remaining 61 participants. Of them, the mean age was 56.41 ± 8.09. Participants comprised 33 men and 28 women. Baseline HbA1c, FBS, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, weight, BMI, SBP, and DBP are shown in Table 1 and were comparable between the control and intervention groups.

Table 2 shows a summary of the results for all participants at baseline and at 12 w, as well as the mean difference after intervention with the instant brown rice drink compared to the control group. There was a non-significant trend in favor of the intervention group in the reduction of HbA1c. A mean reduction of 0.11% was seen in the intervention group. Whereas in the control group, there was an increase in the mean HbA1c of 0.25%. As for FBS levels, there was a non-significant increase in both groups, albeit with a greater increment in the control group.

There was a significant improvement of total cholesterol and triglyceride levels in the BR group (TC: P=0.016; TG: P=0.018). LDL cholesterol showed a non-significant trend in favor of the BR group, with the mean of the control group increasing by 0.05 mmol/L in contrast to the BR group, which improved by 0.23 mmol/L. HDL cholesterol did not show much change in the mean difference in both groups (P=0.41).

The weight and BMI of both groups showed a non-significant incremental trend (weight: P=0.431; BMI: p-value=0.401). However, interestingly, SBP and DBP showed a significant reduction in the BR group for the group × time interaction (SBP: P=0.02; DBP: P=0.001).

Table 1. Baseline biochemical and clinical characteristics of participants between CG and BR groups.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean (SD)</th>
<th>Mean diff (95% CI)</th>
<th>t-statistics (df)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Brown rice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7.68 (0.49)</td>
<td>7.71 (0.61)</td>
<td>-0.03 (-0.31, 0.25)</td>
<td>-0.23 (59)</td>
</tr>
<tr>
<td>FBS (mmol/L)</td>
<td>7.65 (1.56)</td>
<td>7.13 (2.20)</td>
<td>0.52 (-0.45, 1.49)</td>
<td>1.08 (59)</td>
</tr>
<tr>
<td>TC (mmol/L)</td>
<td>4.73 (1.14)</td>
<td>5.07 (1.05)</td>
<td>-0.34 (-0.91, 0.22)</td>
<td>-1.21 (59)</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>1.32 (0.24)</td>
<td>1.30 (0.28)</td>
<td>0.02 (-0.11, 0.15)</td>
<td>0.28 (59)</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>2.75 (0.90)</td>
<td>2.99 (0.85)</td>
<td>-0.23 (-0.68, 0.22)</td>
<td>-1.03 (59)</td>
</tr>
<tr>
<td>TG (mmol/L)</td>
<td>1.46 (0.49)</td>
<td>1.74 (0.98)</td>
<td>-0.28 (-0.70, 0.13)</td>
<td>-1.37 (38.33)</td>
</tr>
</tbody>
</table>
Table 2. Biochemical and clinical outcomes of participants.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control Group (CG) (n=29)</th>
<th>Brown Rice Group (BR) (n=32)</th>
<th>Group × time interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean diff (95% CI)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>7.68 (0.49)</td>
<td>0.25 (-0.03, 0.52)</td>
<td>7.71 (0.61)</td>
</tr>
<tr>
<td>FBS</td>
<td>7.65 (1.56)</td>
<td>1.25 (0.62, 1.89)</td>
<td>7.13 (2.20)</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>4.73 (1.14)</td>
<td>0.21 (-0.06, 0.49)</td>
<td>5.07 (1.05)</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>1.32 (0.24)</td>
<td>0.00 (-0.05, 0.05)</td>
<td>1.30 (0.28)</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>2.75 (0.91)</td>
<td>0.05 (-0.17, 0.27)</td>
<td>2.99 (0.85)</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>1.46 (0.49)</td>
<td>0.35 (0.09, 0.60)</td>
<td>1.74 (0.98)</td>
</tr>
<tr>
<td>Weight</td>
<td>71.37 (13.32)</td>
<td>0.65 (0.16, 1.11)</td>
<td>70.42 (11.48)</td>
</tr>
<tr>
<td>BMI</td>
<td>27.95 (4.85)</td>
<td>0.27 (0.08, 0.45)</td>
<td>26.91 (3.36)</td>
</tr>
<tr>
<td>SBP</td>
<td>131.24 (15.66)</td>
<td>1.27 (-3.23, 5.77)</td>
<td>138.50 (12.93)</td>
</tr>
<tr>
<td>DBP</td>
<td>78.42 (10.37)</td>
<td>82.39 (7.66)</td>
<td>77.61 (9.48)</td>
</tr>
</tbody>
</table>


Discussion

In this study, instant brown rice powder was shown to be promising in reducing HbA1c, although the reduction was not significant. The improvement in HbA1c levels in the BR group may be explained by the fact that brown rice generally has a low glycemic index and lower area under the glucose curve, which produces low glycemic responses [15,16]. Our results are similar to those of a previous study, which substituted a white rice diet with a brown rice diet [17]. The non-significant finding may have been due to the short-term duration of the study, participants’ lower HbA1c levels upon recruitment, and the similar level of the glycemic index of the products given to both arms of the study. Another study demonstrating a significant reduction in HbA1c used brown rice as part of a vegetarian diet. In that study, HbA1c levels upon recruitment were between 6.0% and 11.0%, with a mean HbA1c level of 7.7% ± 1.3 [18]. The difference between these results and those of the current study may be due to the former study’s addition of brown rice as part of a vegetarian diet and the complete replacement of white rice with brown rice instead of taking the latter as a supplement, as in our study. Similarly, a non-significant trend in favor of the BR group was found for fasting blood sugar (FBS).

Lipid outcomes

The results in this study showed a significant reduction in total cholesterol and triglyceride levels. Various studies have shown the benefits of rice bran in lowering cholesterol levels [5,6]. Gamma-oryzanol, which is in rice bran, interferes with the intestinal absorption of cholesterol in the diet [19]. In vitro studies have also shown that the contents of rice bran are capable of binding to bile acids and reducing the activity of HMG-CoA reductase, the key enzyme in the endogenous pathway of cholesterol metabolism [20].

Another possible mechanism by which brown rice could affect cholesterol in the body is through its fiber content. A meta-analysis completed in 1999 found that soluble fiber was able to reduce total cholesterol and LDL cholesterol levels [7]. There is a dose-response relationship between the amount of soluble fiber and the reduction in total cholesterol and LDL cholesterol levels. The contents of dietary fiber in our investigational product were 1 g per serving. Thus, with three servings per
day, the participants in the intervention group should have received an additional 3 g of dietary fiber in their daily diet.

In our study, as the investigational product was pure brown rice powder, it shared similar biochemical and nutritional properties of rice bran in brown rice—thus the notable improvements in triglycerides and total cholesterol. However, the failure to yield any difference in HDL and LDL cholesterol levels may be attributable to the use of the investigational product as a supplement as well as to the short study duration.

Surprisingly, there is a significant reduction in the blood pressure in the BR group. This reduction in blood pressure in the brown rice group was also demonstrated in a number of other studies [8,9]. These blood pressure effects may be attributable to the higher fiber content and multiple micronutrients and vitamins contained in brown rice [21].

**Conclusion**

Instant brown rice as a dietary supplement in patients with type 2 diabetes shows promising beneficial effects, especially for improving total cholesterol, triglyceride levels, and blood pressure. However, further studies with larger sample sizes and longer durations are needed to further evaluate the long-term effects of brown rice as a dietary supplement among diabetic patients.

**Acknowledgement**

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*Correspondence to
Lili Husniati Yaacob

Department of Family Medicine
School of Medical Sciences
Health Campus Universiti Sains Malaysia
Malaysia