Effects of High-Fiber Biscuits on Lipid and Anthropometric Profile of Patients with Type 2 Diabetes

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Summary This study aimed to evaluate the efficacy of two types of high-fiber biscuits on the lipid and anthropometric profile of patients with type 2 diabetes mellitus (DM). This study involved a pre- and posttest randomized controlled trial design conducted on 33 subjects of the first first group given caromma biscuit (made from modified cassava flour mixed with koro sword flour and date jam) and 31 subjects of the second first group given temma biscuit (made from a mixture of tempeh flour with date jam). Each group consumed 100 g of biscuit each day for 4 wk. The anthropometric data collected included body mass index (BMI), waist–hip circumference ratio (WHCR), body fat percentage (BFP), blood pressure, and fasting blood glucose (FBG). The lipid profile included total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglyceride collected before and after the study. The two types of biscuits had similar nutritional contents in terms of energy, carbohydrate, and fat contents, and their glycemic indices were low. However, the fiber content of caromma was higher than that of temma. After 4 wk, the anthropometric profiles, such as BMI (24.47 ± 5.62 to 24.56 ± 5.55; p = 0.008), BFP (32.18 ± 6.83 to 32.68 ± 7.22; p = 0.4), and WHCR (0.85 ± 0.67 to 0.86 ± 0.65; p = 0.015), were unchanged in the caromma and temma groups (BMI 26.68 ± 3.82 to 26.75 ± 3.92; p = 0.072; BFP 35.96 ± 5.34 to 35.90 ± 5.15; p = 0.907; WHCR 0.86 ± 0.66 to 0.88 ± 0.4; p = 0.006), except reducing FBG (167.06 ± 82.8 to 154.85 ± 95.0; p = 0.150 in the caromma group and 173.19 ± 92.72 to 150.06 ± 73.64; p = 0.095 in the temma group). A significant improvement was observed in the lipid profile of the caromma group (cholesterol, 239.73 ± 53.5 to 195.70 ± 34.13; p = 0.000; LDL, 145.18 ± 29.89 to 122.24 ± 29.00, p = 0.000; HDL, 61.00 ± 17.76 to 51.12 ± 15.40, p = 0.000; triglyceride 175.09 ± 112.64 to 123.67 ± 73.89, p = 0.000) and temma group (cholesterol, 264.42 ± 75.10 to 204.68 ± 37.11, p = 0.000; LDL, 154.97 ± 53.59 to 125.45 ± 30.56, p = 0.001; HDL, 59.68 ± 1.328 to 49.48 ± 11.52, p = 0.000; triglyceride, 226.00 ± 172.56 to 152.48 ± 99.88, p = 0.007). Lipid and animal protein intake should be limited among patients with type 2 DM. A high lipid profile, which is dangerous for patients with type 2 DM, can be prevented. Originality: Caromma and temma biscuits can be consumed by patients with diabetes. Although these biscuits cannot improve the anthropometric profiles of the subjects, their consumption has positive effects on the blood lipid profile.

Key Words Type 2 diabetes mellitus, caromma biscuit, temma biscuit, anthropometric profile, lipid profile.

Obesity, smoking, lack of fruit and vegetables in the diet, excessive consumption of sweet food, and lack of physical activities (such as exercise) are the risk factors of diabetes mellitus (DM) (1). DM is often asymptomatic; thus, for a long time, the patients are unaware of having DM. When DM is finally diagnosed, their blood glucose level is already elevated. Lifestyle modification, including healthy eating habits and physical activity, are preventive measures for type 2 DM. This type of DM occurs mostly in developing countries among patients aged over 45 y without insulin dependency (2).

Patients with DM are recommended to regulate their caloric, carbohydrate, fat, and protein intake in the seven groups of food classification. One way to regulate food or diet is by choosing the amount and type of appropriate carbohydrates on the basis of the glycemic index (GI). Foods containing high GI increase blood glucose level rapidly after consumption. Foods high in gluten, such as flour, should be avoided by patients with DM because they can increase blood glucose levels. Foods high in gluten can hinder metabolism in the form of nutritional absorption disorder in rheumatoid arthritis, Parkinson’s disease, autism, ataxia, Down syndrome, osteoporosis, type 1 and 2 DM, and anemia, leading to malnutrition (3).

DM initiates various complications to parts of the body, starting from the blood vessels (atherosclerosis) to the heart (coronary artery disease/CAD) caused by hyperlipidemia. Studies on patients with type 2 DM in India found a significant increase in their triacylglycerol, VLDL, and cholesterol/HDL levels (4). The common nutritional status profile found in patients with
type 2 DM includes over-nutrition to obesity, waist–hip circumference ratio (WHCR) over the cutoff point, high body fat percentage (BFP), and hypertension. The most common conditions diagnosed among patients with type 2 DM include obesity, hypertension, and dyslipidemia. Dyslipidemia commonly found in patients with DM is accompanied with insulin deficiency and resistance, thereby affecting enzymes and the lipid metabolism pathway (5). Dyslipidemia in patients with type 2 DM is characterized by increased triglycerides, decreased HDL, and increased LDL (6).

BFP and BMI have significant correlations among patients with DM. The majority of patients with DM experience lipid disorder, that is, dyslipidemia characterized by increased triglycerides, decreased HDL, and increased LDL. This abnormality can lead to CAD, which aggravates the health status of patients with DM (7). Type 2 DM is managed through pharmacological and nonpharmacological therapy to maintain the normal blood glucose level (BGL). One of the non-pharmacological approaches is the consumption of food with low GI to manage normal BGL. Functional food consumption may improve this condition.

Modified cassava flour or mocaf (gluten free), koro sword flour (Canavalia ensiformis), tempeh flour, and dates are some of the functional foods that can be consumed safely by patients with DM. Retna et al. (8) found that koro sword flour has high fiber, protein, and mineral contents but low GI and fat; this finding is similar for mocaf flour, tempeh (9), and dates (10). These functional foods may be developed as a biscuit for patients with diabetes. Most people like to eat biscuit because practically consumed and easily accepted by people.

Riccardi and Angela (11) and Shreya et al (12) revealed that increase in consumption of fiber-rich foods diet significantly improve blood glucose control and reduces plasma cholesterol levels in diabetic patients compared with a low-carbohydrate/low-fiber diet. A pilot study on the effects of caromma biscuit on BGL changes in 141 patients with diabetes in Depok in 2015 showed an increase of BGL at postprandial 2 h after consuming biscuit was the lowest (6.4 points) in the first group (caromma biscuit) compared with that in the second group (temma), modified cassava flour mixed with tempeh flour and date jam/cutemma, and date biscuits (13). However, the effects on the changes in the anthropometric and lipid profiles among patients with DM have not yet been studied. This study aimed to evaluate the effects of two types of high-fiber biscuits on the anthropometric (BMI, WHCR, and BFP) and blood lipid profiles (total cholesterol, LDL, HDL, and TG) of patients with type 2 DM.

**MATERIALS AND METHODS**

**Study design.** This study with a quasi-experimental design included 66 patients with type 2 DM at Depok City. Ethical clearance was obtained from the Research Ethics Committee of the Health Research and Development Board of The Indonesian Ministry of Health. The research design was a single-blind randomized controlled trial. Patients with DM were randomized into two groups. The researcher knew the type of biscuit given to the intervention and the second groups (14).

**Subject.** Subjects were included if they met the following inclusion criteria:

- Male or female, 35–75 y of age, and diagnosed with DM for at least 12 mo
- Non-consumption of oral diabetic medication or drinking of herbal medicines, such as sour sop leaves, god’s crown leaves, roselia tea, and other food that might decrease blood glucose
- Not diagnosed with a chronic disease, such as cancer, CAD, and stroke
- Diagnosed with type 2 DM by a medical doctor (based on fasting blood glucose level examination with the result of >200 mg/dL and 2 h after eating if >126 mg/dL (15)
- Reported symptoms of DM (such as polyphagia, polydipsia, and polyuria) and rapid weight loss

The exclusion criteria were as follows:

- Diagnosed with chronic diseases due to complications with DM
- Taking insulin at the time of the study

The number of subjects needed in this study was calculated using a minimum sample size for estimating differences among means between groups with the result of 35 subjects for each group (14). Seventy subjects were randomly divided into two groups. Group 1 received caromma biscuit (n = 35), and group 2 received temma biscuit (n = 35). The reason behind the different treatment in the two groups was caromma has a little higher fibre and cholesterol contents than temma.

**Data collection and analysis.** Seventy subjects scattered evenly between two groups participated in this study. The first and second groups were given caromma and temma biscuits, respectively, for 4 wk. The compliance level of biscuit consumption was conducted by a home visit every 2 d to record daily food consumption and the amount of biscuit distributed. In addition, the anthropometric profiles, including BMI, fasting blood glucose (FBG), blood pressure, BFP, WHCR, and lipid profile (cholesterol, LDL, HDL, and triglycerides) were measured before and after the study. Baseline and end-line data were collected at the start and at the end of the study. Close-ended questionnaires were given to measure the characteristics of the subjects, history of DM, health status 2 wk before the interview, and 1 d food recall. A 3 d food recall instrument was used to collect the daily food intake including the biscuit consumption at the first, the middle, and the end of each week for 4 wk. Nutrition education was also given to the subjects three times during the study.

**Anthropometric profile.** Weight, height, BFP, waist circumference, and hip circumference were collected three times during the first, middle, and end of the study. The weight was measured by using a digital weighing scale (SECA), and the height was measured by a microtoise. The waist and hip circumferences were determined by tape measurements. Blood pressure and fasting blood sugar were determined using a sphygmo-
manometer and ACCU-CHEK Active instrument, respectively. Such anthropometric indicators were measured by a trained nutritionist.

**Lipid profile.** HDL, LDL, total cholesterol, and triglyceride levels were determined by a certified laboratory. The laboratory is well experienced in conducting health examinations, including lipid profile analysis.

**Statistical analysis.** Weight was analyzed using the 2007 World Health Organization (WHO) standard with WHO Anthroplus software version 02, 2009 in accordance with the weight/age indicator. Nutrisoft was used to analyze food intake, including macro and micronutrients. Univariate data analysis was performed using SPSS program version 13 and presented as mean±SD. Baseline and endline anthropometric and lipid profile data were compared using independent t-test and dependent t-test. Statistical significance was set at $p<0.05$.

### RESULTS

At the beginning of the study, 70 subjects were evenly spread between two groups (each consisting of 35 people). However, six subjects dropped out voluntarily or as decided by the author. The reasons for leaving were as follows: the subject felt bored and decided not to continue with the study; they went home without the assurance of returning; they were admitted to the hospital for a few days and biscuit consumption was stopped; or they complained of frequent urination after biscuit consumption. Table 1 shows that the majority of subjects in all groups were females with a dominant age of pre-elderly (less than 60 y old). The mean subject age was considered homogenous between the two groups with a range of 50–60 y. Subjects in the intervention and second groups mostly finished elementary school to junior high school. More than three-quarters of the total subjects in both groups were unemployed.

The pre- and post-study anthropometric and lipid profiles of the subjects are presented in Table 2. The anthropometric profiles consisted of body weight, BMI, waist circumference, hip circumference, WHCR, and blood pressure. The mean weight of the intervention and second groups increased by 0.2 kg at the end of the study. A difference in body weight was observed before and after the intervention ($p<0.05$) in the first group but not in the second group. The mean nutritional status of the first group was considered normal, whereas that of the second group developed over-nutrition at the end of the study. BMI changes were found in the first group at the end of the study. The body fat percentage of the first group increased by 0.5%, and that of second group decreased by 0.06%. A change in BFP in the intervention and second groups (between groups) was observed at the end of the study ($p<0.05$). However, the same finding was not applicable in each group (inter-group). The mean waist circumference increased by 2.93 cm for the first group and 3.47 cm for the second group. The mean hip circumference increased by 1.44 cm for the first group and 0.68 cm for the second group.

The mean systolic blood pressure decreased by 5.76 and 10.97 mg/dL in the intervention and second groups, respectively. Likewise, diastolic pressure decreased by 2.12 and 1.61 mg/dL in the intervention and second groups, respectively. The differences in systolic decrease and mean increase were found in each group at the end of the study ($p<0.05$). The mean WHCR of the first group showed a slight increase at the end of the study by 0.01 and 0.02 points in the second group. The WHCR decreased in each group at the end of the study ($p<0.05$). The mean FBG of the first group showed a decrease of 12.2 and 23 points in the second group at the end of the study. The lipid profile included cholesterol, LDL, HDL, and triglycerides. The mean cho-

| Table 1. Sociodemographic characteristic of the subjects. |
|----------------------------------------------------------|
| Variable | caromma (n=33) | temma (n=31) |
|----------|----------------|-------------|
| Sex:     |                |             |
| Male     | 6, 18.2        | 3, 9        |
| Female   | 27, 81.8       | 28, 90.3    |
| Age:     |                |             |
| <60 y old| 19, 57.6       | 20, 64.5    |
| ≥60 y old| 14, 42.4       | 11, 35.5    |
| Mean±SD  | 57.4±9.9       | 53.4±8.7    |
| Education level: | |             |
| Low (did not graduate from elementary–junior high school)| 20, 60.6 | 21, 67.7 |
| Middle (graduated from senior high school–academy/university) | 13, 39.4 | 10, 32.3 |
| Current working status: | |             |
| Not working | 26, 78.8 | 27, 87.1 |
| Working    | 7, 21.2        | 4, 22.9     |
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The decrease in cholesterol in the first group was 44 and 59.7 points in the second group. Although no difference was found in the cholesterol changes at the end of the study between groups ($p > 0.05$), there was a reduction of high cholesterol to normal in the first group. The cholesterol level in the first group also reduced as well as the second group. Three other lipid profile indicators, namely, HDL, LDL, and triglycerides, also presented a decrease in each group after the intervention. The first group showed decreased mean HDL, LDL, and triglycerides of 9.9, 22.9, and 51.4 points, respectively. The mean cholesterol, LDL, and HDL decreased at the beginning of the study in each group ($p < 0.005$), except the difference in triglyceride mean was only found in the first group. The intervention and second groups showed changes in LDL from a high limit to close to optimal at the end of the study. HDL changed from high to low in each group post-intervention.

Table 2 shows the mean macronutritional intake before and after the intervention. The mean energy intake in the intervention and second groups decreased by 113 and 118.9 calories, respectively, at the end of the study. The mean protein and fat intake of 4.7 and 11.3 g in the first group and 2.8 and 11.2 g in the second group increased, respectively. The mean increase in the carbohydrate intake in the second group

| Group | Pre-study | Post-study | $p^*$ |
|-------|-----------|------------|-------|
|       | n | Mean | SD | n | Mean | SD |       |
| Weight (kg) | Caromma | 33 | 58.60 | 12.67 | 33 | 58.84 | 12.55 | 0.002 |
| | Temma | 31 | 61.18 | 9.33 | 31 | 61.37 | 9.60 | 0.057 |
| BMI (kg/m²) | Caromma | 33 | 24.47 | 5.62 | 33 | 24.56 | 5.55 | 0.008 |
| | Temma | 31 | 26.68 | 3.82 | 31 | 26.75 | 3.92 | 0.072 |
| Body fat percentage (%) | Caromma | 33 | 32.18 | 6.83 | 33 | 32.68 | 7.22 | 0.400 |
| | Temma | 31 | 35.96 | 5.34 | 31 | 35.90 | 5.15 | 0.907 |
| Waist circumference (cm) | Caromma | 33 | 80.16 | 13.73 | 33 | 83.09 | 13.43 | 0.000 |
| | Temma | 31 | 84.04 | 9.52 | 31 | 87.51 | 8.51 | 0.000 |
| Hip circumference (cm) | Caromma | 33 | 93.92 | 11.68 | 33 | 95.36 | 11.96 | 0.046 |
| | Temma | 31 | 97.63 | 9.84 | 31 | 98.31 | 7.88 | 0.504 |
| Waist/hip circumference | Caromma | 33 | 0.85 | 0.67 | 33 | 0.86 | 0.65 | 0.015 |
| | Temma | 31 | 0.86 | 0.66 | 31 | 0.88 | 0.60 | 0.006 |
| Systolic blood pressure (mmHg) | Caromma | 33 | 121.52 | 16.23 | 33 | 115.76 | 18.71 | 0.029 |
| | Temma | 31 | 128.39 | 16.55 | 31 | 117.42 | 19.66 | 0.001 |
| Diastolic blood pressure (mmHg) | Caromma | 33 | 87.88 | 9.60 | 33 | 85.76 | 7.92 | 0.182 |
| | Temma | 31 | 88.71 | 9.91 | 31 | 87.10 | 7.83 | 0.378 |
| Fasting blood glucose (mg/dL) | Caromma | 33 | 167.06 | 82.80 | 33 | 154.85 | 95.10 | 0.150 |
| | Temma | 31 | 173.19 | 92.72 | 31 | 150.06 | 73.64 | 0.095 |
| Cholesterol (mg/dL) | Caromma | 33 | 239.73 | 35.30 | 33 | 195.70 | 34.13 | 0.000 |
| | Temma | 31 | 264.42 | 75.10 | 31 | 204.68 | 73.11 | 0.000 |
| LDL (mg/dL) | Caromma | 33 | 145.18 | 29.89 | 33 | 122.24 | 29.00 | 0.000 |
| | Temma | 31 | 154.97 | 53.59 | 31 | 125.45 | 30.56 | 0.001 |
| HDL (mg/dL) | Caromma | 33 | 61.00 | 17.76 | 33 | 51.12 | 15.40 | 0.000 |
| | Temma | 31 | 59.68 | 13.28 | 31 | 49.48 | 11.52 | 0.000 |
| Triglycerides (mg/dL) | Caromma | 33 | 175.09 | 112.64 | 33 | 123.67 | 73.69 | 0.000 |
| | Temma | 31 | 226.00 | 172.56 | 31 | 152.48 | 99.88 | 0.007 |

$p$: independent $t$-test, $p^*$: dependent $t$-test.
was slightly larger than that in the first group. Alternatively, the mean fiber intake in the first group was slightly larger than that in the second group. The first group showed half an increase in mean vitamin A intake from the second group. The intervention and second groups showed a decrease in mean intake of vitamins E, B1, and B2 at the end of the study. The mean vitamin A intake in the first group decreased, whereas that in the second group increased. The second group showed a decrease in mean calcium, iron, zinc, and sodium intake, whereas that in the first group increased at the end of the study. Table 4 shows the macro- and micronutrients in both types of biscuits. The **caromma** biscuit showed lower energy, fat, Fe, and Zn than the **temma** biscuit. The fiber content in the **caromma** biscuit was slightly high, but its cholesterol content was slightly higher than that of the **temma** biscuit.

**DISCUSSION**

The anthropometric profiles of patients with DM showed that most subjects were overweight and obese due to high body fat level, especially in the abdomen, leading to insulin resistance. This finding was supported by the characteristics of the majority of subjects who had WHCR >0.9 (male) and >0.8 (female), suggesting that they were at risk of central obesity (16).
The lipid profiles of patients indicated that their high BFP, high cholesterol, high LDL, high triglyceride content, low HDL, and high blood pressure led to dyslipidemia. Patients with type 2 DM experienced dyslipidemia in the form of lipid metabolism disorder, that is, increased total cholesterol level, triglycerides, LDL, and decreased HDL (17).

Decreased FBG level, cholesterol, LDL, and triglycerides in the two groups of this study were in line with a study on patients with type 2 diabetes in India (18). Changes were noted in the FBG, blood pressure, lipid profile (decreased LDL and triglycerides; increased HDL) of the subjects after oyster mushrooms were given for 3 mo. However, the BMI and WHCR of patients did not significantly change.

Glycemic control is positively correlated with the blood triglyceride level. Excess glucose in the blood is stored in the form of fat, especially triglycerides during the advanced phase of the pathogenesis of type 2 DM. Glucose is transformed into triglycerides, leading to an increased triglyceride level; the HDL level decreases and the cholesterol level in the blood increases (19).

The findings of the study were in accordance with a pilot study, which found that the blood glucose post-prandial increases 2 h after consuming the caromma biscuit among patients with type 2 diabetes, with the lowest point of 6.4 among the other kind of biscuits (13). Caromma biscuit is made from modified cassava flour (mocaf) with koro sword flour and dates. Mocaf has a higher fiber content than wheat flour (8). Koro sword flour tested in diabetic white rat and in a human study was found to reduce the blood sugar level by 2.8% in 4 wk (20). Mocaf flour contains 2.72% of fat. The glycemic index value of the biscuit is 27.2 (21), suggesting that it has a low GI value (≤55) according to the criteria of the American Diabetes Association (15). Mocaf flour is derived from cassava flour modified by fermentation with lactic acid microbial activation. Mocaf flour contains higher soluble fiber than regular flour; thus, it can decrease cholesterol absorption, dilute toxins, and increase short-chain fatty acid production (22). Phenol, isoflavone, saponin, fiber, and niacin in mocaf flour can reduce LDL levels (23). The high-fiber content of mocaf flour is the main ingredient of caromma biscuit is assumed to help decrease cholesterol. This finding is in line with the study conducted on patients with type 2 DM. Cholesterol and LDL levels significantly decreased among patients with type 2 DM after they followed a low glycemic index diet (24–27). Date jam can increase the blood glucose level of diabetics because of its low GI (28).

Temma biscuits are made from tempeh flour and date jam. In 2015, Fatifa et al. (29) showed that tempeh can reduce blood glucose level because of its protein, isoflavone, and fiber contents and low GI. A diet low in GI can decrease weight, BMI, and hip circumference (30–32) among patients with type 2 DM. Dates contain several phytochemicals, such as carotenoids, polyphenols (phenolic acid), isoflavone, lignin, flavonoids, tannins, sterols, and fiber, which can inhibit the absorption of LDL cholesterol. A study on rats with a diet consisting of 1.5%, 2.5%, and 5.2% date content can decrease triglycerides and cholesterol. Another study conducted on date consumption among a healthy population showed that dates do not affect the subjects’ serum total cholesterol and cholesterol levels in terms of VLDL, LDL, or HDL fractions (33). Eventhough, caromma biscuits has little higher fibre content than temma, but the study unsuccessful prove a significant correlation between the effects of caromma biscuit consumption and changes in anthropometric profiles, such as BMI and WHCR. It might be be due to the limited subject size and duration of intervention. Further studies involving more subjects and longer duration are needed to prove such findings. In conclusion, the consumption of caromma and temma biscuits has positive effects on the blood lipid profile in terms of decreased cholesterol, LDL, and triglyceride levels.

Disclosure of state of COI
No conflicts of interest to be declared.

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Table 4. Nutrient contents of 100 g of biscuit.

| Type of biscuit | Energy (kcal) | Carbohydrate (g) | Protein (g) | Fat (g) | Natrium (mg) | Iron (mg) | Zinc (mg) | Vit. A (IU) | Fiber (g) | Cholesterol (mg) |
|----------------|--------------|------------------|-------------|--------|--------------|-----------|-----------|-------------|-----------|-----------------|
| Caromma       | 486          | 67.6             | 9.62        | 21.9   | 455          | 1.4       | 0.96      | 168         | 3.23      | 79.1            |
| Temma         | 490          | 61.8             | 9.62        | 22.7   | 267          | 1.9       | 1.9       | 139         | 2.93      | 62.4            |

Source: BBIA Laboratory 2016.
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