Mal J Nutr 28(2): 163-175, 2022

Soy flour snack bars lower glycaemic response in type 2 diabetes mellitus subjects: A randomised cross-over design

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ABSTRACT

Introduction: Low glycaemic snacks may help to improve blood glucose control. However, data on the effect of soybean snack bars on postprandial glucose levels of the diabetic population is scarce. Therefore, the current study aimed to examine the effect of consuming soy flour snack bars on glycaemic response (GR) over a 180-minute period in individuals with diabetes by estimating postprandial glucose levels variation and total area under the curve (AUC). **Methods:** Nine subjects (age: 54.6±4.0 years; BMI: 25.0±2.5 kg/m^2) with type 2 diabetes mellitus (T2DM) diagnoses without complication enrolled in this randomised, open-label, cross-over trial. On three separate sessions, they consumed glucose standard solution, soy flour snack bar (SF), and wheat flour snack bar (WF) containing 25 g of available carbohydrate, respectively. Finger prick capillary method was executed to measure blood glucose levels at 30, 60, 90, 120, 150, 180 minutes after test product ingestion. **Results:** Overall, significantly lower postprandial glucose levels were observed at 30, 60, 90, and 120 minutes (122.3±17.6, 136.3±24.9, 125.7±25.3, and 107.2±24.1 mg/dL; p<0.001) in those who consumed SF snack bars than WF snack bars (147.9±41.3, 168.0±43.6, 152.6±30.0, and 140.6±33.4 mg/dL). The AUC level after the ingestion of SF snack bar was 2044.8±503.1 mg.min/dL, >20% lower compared to ingestion of WF snack bar (4735.0±666.8 mg.min/dL), p<0.001. These glycaemic control benefits can be explained due to the high fibre and protein content linked to the physicochemical properties of SF. **Conclusion:** With high nutritional properties, SF snack bar has a low GR and might help control blood glucose in T2DM subjects.

Keywords: glycaemic response, hyperglycaemia, snack, soy food, T2DM diet

INTRODUCTION

Diabetes is a prevalent public health disease. Nearly 90% of diabetic cases are type 2 diabetes mellitus (T2DM) (Goyal & Jialal, 2020). According to the latest data, the prevalence of diabetes was 10.9% or equivalent to more than 10 million Indonesian people in 2018 (MOH Indonesia, 2018). It is estimated that this number will sharply increase to 16.6 million in 2045, among whom 7.9 million are undiagnosed (IDF, 2019). The development of T2DM is caused by the reduction of insulin release and glucose

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doi: https://doi.org/10.31246/mjn-2021-0054

utilisation, as well as elevation of glucose synthesis, which lead to significant changes in postprandial blood glucose on a frequent basis (Mouri & Badireddy, 2020). Moreover, the HbA1c level in T2DM patients is higher than normal, and it is positively correlated with body mass index (BMI) (Babikr *et al.*, 2016). A previous study found that T2DM subjects with an excess weight status have a higher risk of poor blood glucose control (Bae *et al.,* 2016). However, a study by Wang *et al.* (2017) showed that blood glucose levels at 30 and 120 minutes (min) postpandrial were higher in T2DM patients who were underweight or normal weight (BMI <24 kg/m^2) than those who were overweight or obese (BMI ≥24 kg/m^2).

In individuals with diabetes, hyperglycaemia is related to poor glucoregulation (glycaemic control) and the development of serious complications, including diabetic retinopathy (eye), nephropathy (kidney), neuropathy (nerves), and cardiomyopathy (heart) (Mouri & Badireddy, 2020). The current review recommends new efforts to control hyperglycaemia, i.e. by selecting foods with low glycaemic index (GI) and glycaemic load (GL) (Yari *et al.,* 2020). Evidence widely documents that consuming low GI foods is capable of attenuating 24-hour blood glucose profile and decrease postprandial glucose level (Kaur *et al.,* 2016). Moreover, the type and amount of carbohydrates consumed and the physical form of food are the other known factors associated with postprandial blood glucose fluctuation level (Franz *et al.,* 2002). Thus, glycaemic control through diet modification is a well-known strategy for managing postprandial blood glucose, while limiting the risk of hyperglycaemia or elevated blood glucose greater than normal level [>140 mg/dL (7.8 mmol/L)] (Soelistijo, Lindarto & Decroli, 2019). In addition, regular practice of an eating plan such as having small and frequent portions, and accounting for snack time between meals, would also improve blood sugar control in subjects living with T2DM (Gray & Threlkeld, 2019).

Soy foods have long been a staple of the Asian cuisine, and their popularity is now spreading worldwide and reflecting today's global health, nutrition and lifestyle trends (Dukariya *et al.,* 2020). A wide variety of soy foods are available, such as traditional soy foods (soy milk, tofu, *tempeh*, natto) and other foods that use soy flour as a functional ingredient (bakery, pasta, snack bar) (Jideani, 2011). For the past 25 years, nutritional and health benefits of soy foods have been extensively explored, especially for their role in managing postprandial blood glucose in diabetic cases (Dukariya *et al.,* 2020; Lecerf *et al.,* 2020). *Tempeh*, one of the most widely consumed soy-based foods in Indonesia, has been found to be negatively correlated with insulin resistance (Febrianti *et al.*, 2019).

In the last few years, investigation on alternatives from wheat flour to soy flour has been conducted (Mohammed, 2019). The findings showed that soy flour has better nutritional properties than wheat flour, indicated by high levels of fibre, protein, healthy fat, isoflavones, as well as low carbohydrate and moisture content, which may make soy flour more beneficial to control blood glucose level than wheat flour. For instance, the latest study investigating the consumption of soy food products in the form of snack bars has been scientifically proven effective on controlling postprandial glucose levels, where significantly lower blood glucose levels and reduction in glycaemic response (GR) were observed (Nurdin *et al.,* 2020; Urita *et al.*, 2012). Also, studies by Nurdin *et al.* (2020) and Urita *et al.* (2012) observed that the consumption of wheat flour snack

bar was linked to significantly higher postprandial glycaemia than soy flour snack bar consumption.

Consequently, this study used soy flour snack bar as an alternative food form to investigate the effect of soy flour on postprandial glucose level. Moreover, to date, snack bars made from soy flour have not been previously explored in Indonesia. Following the previous study finding, which has been conducted among healthy subjects, we found that soy flour (SF) snack bar consumption was more effective to control blood glucose than wheat flour snack bar (WF); and SF snack bar can be recommended as a potential snack alternative for healthy subjects with blood glucose concerns (Nurdin *et al.,* 2020). Therefore, the present study is a follow-up study aiming to examine the effect of consuming SF snack bar on postprandial glucose levels in subjects with T2DM, in which variations in postprandial glucose levels were monitored at several time points over a 180-minute period. Also, different BMIs may give glycaemic variability; thus, as a secondary analysis, this study also compared GR by estimating the total area under the curve (AUC) of blood glucose according to BMI. It was hypothesised that consumption of SF snack bar would attenuate postprandial glucose level by having lower blood glucose level and low GR due to its low GI value, high fibre and protein content. Moreover, an increase in BMI would increase the risk of having poor GR, indicating impaired postprandial glucose levels.

MATERIALS AND METHODS

Study design and population

A cross-over randomised controlled trial with a seven-day wash-out period on the glycaemic control benefit of soy flour snack bar was executed in October 2019 to January 2020 at IPB University, Indonesia. A non-blinded (open-label) design was carried out to obtain additional scientific evidence about the GR of soy flour-based snack bar in people with T2DM. An available soy flour-based snack bar in the Indonesian market (SOYJOY®) was used as test food. The study procedure had three phases.

Phase 1 (Selection and enrolment phase)

Phase 1 was conducted one week prior to the first meal glucose tolerance test. In this selection and enrolment phase, subjects were enrolled through the Indonesian Diabetes Association (PERSADIA) chapter Bogor, IPB Bogor Clinic, and social media announcement. The inclusion criteria were 1) men or women aged 40 – 60 years, previously diagnosed with T2DM without complication, 2) blood glucose was controlled by one or two types of antidiabetic drugs (metformin and/or insulin secretagogue), 3) Haemoglobin A1c (HbA1c) level ≤8%, 4) no bowel issues (diarrhoea or soy allergy/intolerance), 5) no alcohol and smoking, and 6) able and comply with the study. A total of 96 subjects were enrolled and further screened by healthcare practitioners for health, including physical examinations; laboratory tests [HbA1c, aspartate aminotransaminase (AST), and alanine aminotransaminase (ALT)]; health interviews and family medical history. Most of the screened subjects were excluded for not meeting the inclusion criteria, had insulin therapy, had food allergy/intolerance history, phobia towards needles, or were not willing to be pricked on the fingers. Among those enrolled, only nine subjects passed the screening. Each subject gave his/her written consent for the study during the selection visit. Approval of the study protocol was obtained from the Human Research Ethics Committee of IPB University No. 142/IT3.KEPMSM-

IPB/SK/2019. Figure 1 explains the CONSORT study diagram.

Phase 2 (Preparation)
The preparation phase was the process of allocating the subjects into their respected groups for intervention purposes. This phase included two types of preparation, i.e. room and subject. A room with ambient temperature (maximum 20°C) was prepared for the process of blood sample withdrawal. A 10-hour overnight fast and no vigorous exercise were prerequisites for the subjects. The investigator instructed the subjects to start fasting at 8 p.m. the previous night until morning. In the fasting state, only plain water was permitted. Fasting blood glucose was taken between 8 to 10 a.m.

Phase 3 (Blood glucose measurements)
Subjects were allocated in an open-label trial to consume the test product, i.e. glucose standard solution (glucose anhydrous, D-glucose MERCK®, SG) (reference food), soy flour-based snack bar (SOYJOY®, strawberry flavour, SF), and wheat flour-based snack bar (WF) (test food). A healthcare practitioner was in charge of taking the subjects' blood samples. Before subjects consumed the test product, fasting blood glucose was withdrawn at 0 minute time point (baseline). After the baseline blood was drawn, subjects ingested one of the test foods, i.e. SF, WF or SG reference food, with portions equivalent to 25 g of available carbohdyrate. The subjects were required to consume the reference food within 10 minutes, and for test food between 10 – 15 minutes. Following the study procedure, the test products were provided within a seven-day wash-out period. On three sessions, subjects consumed a glucose standard solution (25.0 g) on session 1, and either soy flour (SF, ±47.0 g) or wheat flour snack bar (WF, ±37.5 g) on sessions 2 and 3. Within a 180-minute observation time after ingestion of test product, as much as 2 μL of blood sample was withdrawn at 30, 60, 90, 120, 150, and 180 minutes via finger prick capillary method using *Accu-chek Active*® glucometer (Roche, Germany).

Outcome parameters
Baseline characteristics measurements
A standardised questionnaire was used to interview the subjects' personal and family health history. A physical examination, including body height and weight, was also conducted. Stadiometer and digital weighing scale (Omron BF508) were used to measure body height and weight, respectively. Both assessments were completed twice, and the mean value was used in the analysis. Laboratory tests using blood samples were also taken to measure HbA1c concentration and liver function tests (AST and ALT). Analysis of blood samples was conducted at an accredited clinical laboratory - Prodia Laboratory, Bogor.

Glycaemic response (GR)
This study used finger prick capillary blood samples by *Accu-chek Active*® to assess blood glucose concentration. The GR curve was plotted using a line graph with time interval (minutes) on the x-axis and blood glucose concentration (mg/dL) on the y-axis. It was illustrated using glucose AUC, which was calculated using the trapezoidal method with fasting blood glucose serving as the baseline for calculation.

Test food product
The test food product was a commercial snack bar (SOYJOY®, strawberry flavour, SF) made by PT. Amerta Indah Otsuka, Indonesia. SF is registered in the Indonesia National Agency for Drug and Food Control (NADFC) under BPOM RI

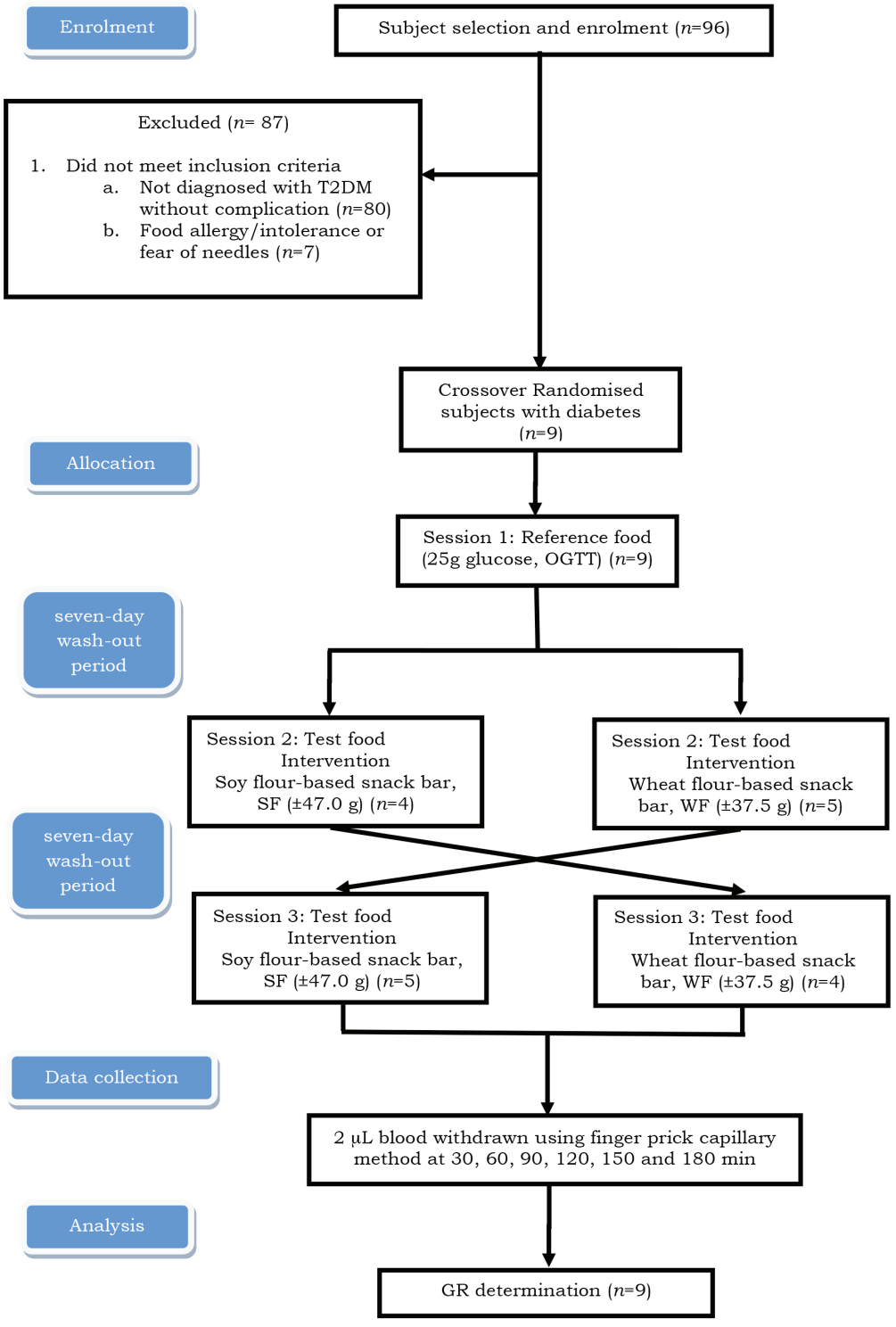

Figure 1. CONSORT flowchart of randomised controlled trial with a crossover design. Oral Glucose Tolerance Test (OGTT); GR (Glycaemic Response)

MD 636013005275 and is certified halal under LPPOM MUI No.00100086950118. In contrast, the comparison product, an unregistered and handmade snack bar was developed using similar formula and materials with SF, apart from soy flour that was changed into wheat flour (WF). The chosen justification of WF snack bar as one of the test products is described elsewhere (Nurdin *et al.,* 2020). Nutrient composition analysis of the test products was done in an accredited laboratory (PT. Saraswanti Indo Genetech, Indonesia). Table 1 summarises the nutrient composition of the test foods per 100 g.

Statistical analysis

IBM SPSS version 20.0 was used to analyse the data. The Shapiro-Wilk test was executed to see the normality in data distribution. It was used because the study sample size was less than 50. Two-way repeated measures analysis of variance (ANOVA) was mainly used to analyse the significant differences between postprandial glucose level at each time (0-180 minutes) and GR estimated by blood glucose AUC using the trapezoidal method. Bonferroni test was used to account for various comparisons to assess the significant magnitude difference of blood glucose peak. Significant difference was described as *p*-value less than 0.05. The sample size was set at 9, at a level of $p<0.05$, based on study references by Kim *et al.* (2020) and Urita *et al.* (2012).

RESULTS

Table 2 describes the general characteristics of the study population. In total, the present study recruited nine subjects with diabetes aged 54.6±4.0 years on average. The mean height and

Table 1. Nutritional composition of test food per 100 g

	Soy flour-based snack bar (SF)[†]	*Wheat flour-based snack bar (WF)*[‡]
Product name	SOYJOY	-
Form	Snack bar	Snack bar
Composition		
Serving size 100 g containing		
Energy, kcal	433	414
Protein, %	12.1	4.8
Total fat, %	15.2	11.9
Carbohydrate, %	61.9	71.9
Sugar, %	36.2	36.4
Fibre, %	8.9	5.1
Sodium, mg	98.9	119.1
Potassium, mg	408.1	75.5
Isoflavone, mg	48.9	N/A
Soy flour		
Moisture content, %	6	N/A

[†]Ingredients: soy flour (29%), pineapple and strawberry (14%), butter, egg, sugar, soluble food fibre, skimmed milk, salt, and synthetic flavour

[‡]WF was developed using similar formula and materials with SF, apart from soy flour that was changed into wheat flour.

Snack bar serving size (30g)

Soy flour (29%): 29%*30=8.7 g per serving size

body weight were 154.9±7.3 cm and 60.1±7.6 kg, respectively. Accordingly, mean BMI was 25.0±2.5 kg/m^2, with four subjects having normal BMI (18.5 – 22.9 kg/m^2) and five subjects having BMI over 23.0 kg/m^2, thus categorised as overweight.

The subjects had HbA1c <8% (7.1±0.9%, average), AST 10-35 U/L (21.3±5.1 U/L, average), and ALT 10-40 U/L (19.6±9.3%, average). Antidiabetic drugs consumed by subjects were metformin (50.0%), glimepiride (25.0%), Gliclazide (8.3%), Linagliptin (8.3%), and Pioglitazone (8.3%). There were 55.6% of subjects who consumed a single antidiabetic drug and 44.4% who consumed two types of antidiabetic drugs. There were no significant differences between groups on health parameters (HbA1c, AST, ALT).

Postprandial blood glucose over 180 minutes was influenced by time (p<0.001) and test products (p=0.025), but no significant effect was found for BMI (p=0.070). Figure 2 shows the variations in postprandial blood glucose after the ingestion of test products. Following the ingestion of SF snack bar, WF snack bar, and glucose standard test products, blood glucose levels peaked simultaneously at 60 minutes, with SF

Table 2. General characteristics of the study population (n= 9), mean±*SD*

Characteristics	*Overall (n=9)*	*Body mass index (kg/m^2)*	
		Normal weight (BMI 18.5 – 22.9) (n=4)	*Excess weight (BMI ≥23.0) (n=5)*
Age, year	54.6±4.0	54.8±3.7	54.4±4.7
Height, cm	154.9±7.3	155.5±10.7	154.4±4.6
Weight, kg	60.1±7.6	55.1±7.6	64.0±5.3
Body mass index, kg/m^2	25.0±2.5	22.7±0.2	26.9±1.6
Sex, *n* (%)			
Men	1 (11.1)	1 (25.0)	-
Women	8 (88.9)	3 (75.0)	5 (100.0)
Visceral fat, %	7.4±2.9	7.3±1.5	7.6±3.9
Body fat, %	31.9±5.3	28.9±6.7	34.3±2.3
Laboratory test			
HbA1c level, %	7.1±0.9	7.3±0.8	7.1±1.1
AST level, U/L	21.3±5.1	19.0±1.2	23.2±6.4
ALT level, U/L	19.6±9.3	15.8±2.3	22.6±11.9
Diabetes prevalence, *n* (%)			
45-54 years	4 (44.4)	1 (25.0)	3 (60.0)
55-64 years	5 (55.6)	3 (75.0)	2 (40.0)
Antidiabetic drugs intake, tablet *n* (%)			
Metformin	6 (50.0)	3 (60.0)	3 (42.9)
Glimepiride	3 (25.0)	1 (20.0)	2 (28.5)
Gliclazide	1 (8.3)	0 (0.0)	1 (14.3)
Linagliptin	1 (8.3)	1 (20.0)	0 (0.0)
Piolitazone	1 (8.3)	0 (0.0)	1 (14.3)
Controlled antidiabetic drugs status, *n* (%)			
Single type	5 (55.6)	2 (50.0)	3 (60.0)
Combination type (2 drugs type)	4 (44.4)	2 (50.0)	2 (40.0)

snack bar having a considerably lower peak (140.0±21.9 mg/dL, $p<0.001$) than WF snack bar (171.4±38.9 mg/dL) and glucose standard (217.8±33.7 mg/dL). Moreover, significantly lower blood glucose levels were also found for SF snack bar at 30, 60, 90, and 120 minutes ($p<0.001$) (Figure 2A). A consistent decrease in blood glucose levels was noticed in both groups after a 60-minute observation period, with a steady decrease in the average blood glucose level in those who consumed SF snack bar. According to secondary analysis by BMI, similar trends were observed, where SF snack bar had lower

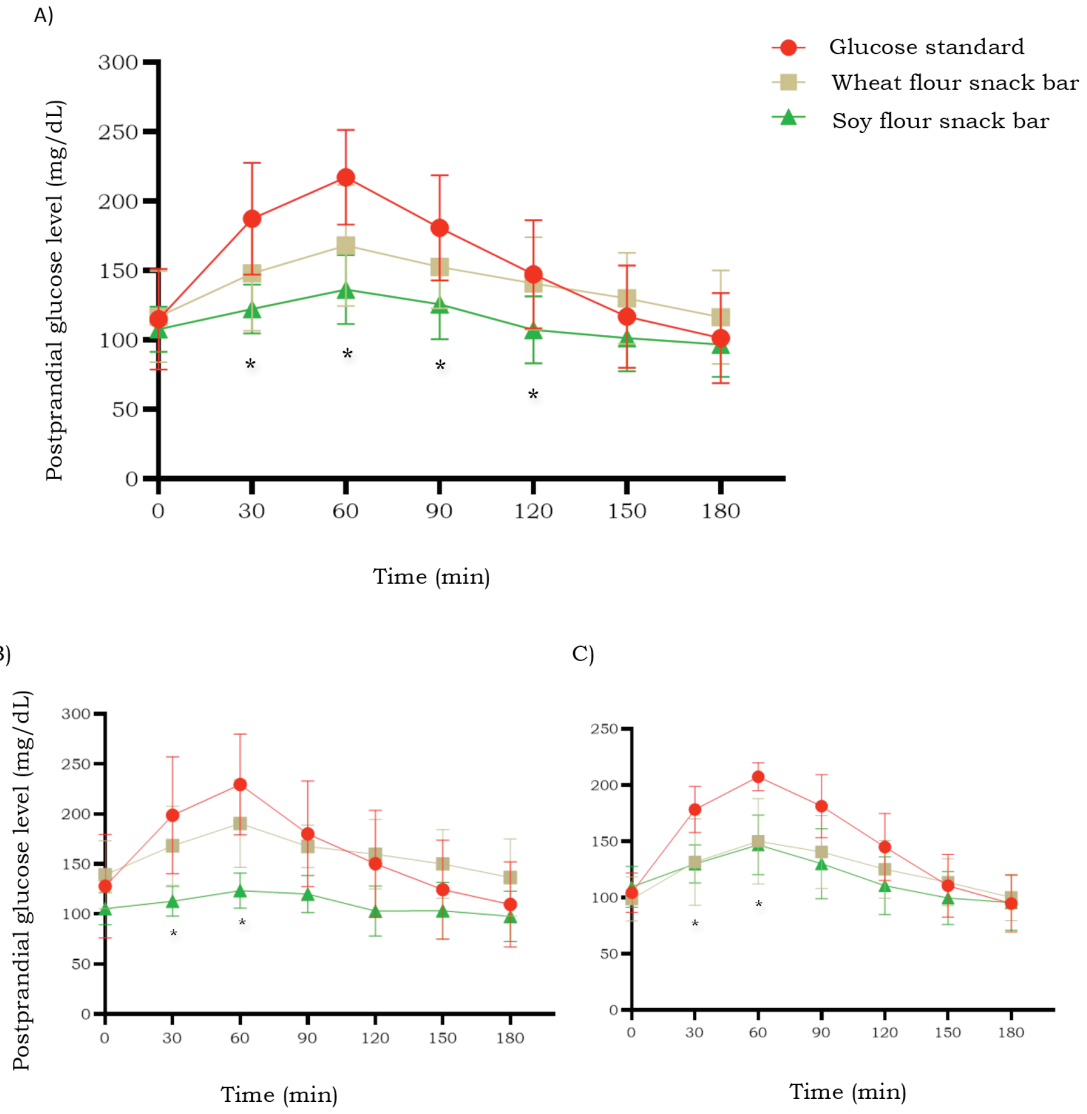

Figure 2. Variations in the postprandial glucose level after ingestion of test products at several time points over 180 minutes period [A (overall), B (BMI 18.5 – 22.9 kg/m^2), C (BMI ≥23.0 kg/m^2)]. SF snack bar induced significantly lower blood glucose at 30, 60, 90 and 120 min ($p<0.05$) than WF snack bar or glucose standard
*denotes statistical significance ($p<0.05$).

blood glucose levels than WF over a 180-minute observation period (Figures 2B and 2C). Lower blood glucose levels were found for SF snack bar at 30 and 60 minutes in subjects with normal BMI (18.5 – 22.9 kg/m^2) compared with WF snack bar (Figure 2B). Also, there were no differences in postprandial blood glucose variations between those who consumed SF and WF in overweight subjects with diabetes (BMI ≥23.0 kg/m^2), but there was a tendency for lower blood glucose levels to occur in SF snack bar than WF snack bar (Figure 2C).

Figure 3 describes the three-hour blood glucose AUC. After ingestion of SF snack bar, the AUC was significantly lower (2044.8±503.1 mg.min/dL, p<0.001) than WF snack bar (4735.0±666.8 mg.min/dL) and glucose standard (8392.3±654.2 mg.min/dL), which indicated a considerable >20% reduction in GR after ingestion of SF snack bar. When compared between BMI group, SF snack bar had lower blood glucose level AUC for both normal BMI (2132.0±975.1 mg.min/dL, p=0.038) and overweight BMI (1975.0±1957.0 mg.min/dL, p=0.362), respectively, than WF snack bar (5398.8±1051.1 mg.min/dL and 4204.0±2526.2 mg.min/dL).

DISCUSSION

The present study found significantly lower blood glucose level and low GR with a maximum peak of 140.0±21.9 mg/dL and >20% lower AUC after the ingestion of SF snack bar in T2DM subjects. This glycaemic control benefit is most probably related to soy flour's nutritional properties, i.e. low in carbohydrate and high in fibre, protein and isoflavones content (Mohammed, 2019), which distinguishes it from wheat flour. Although the mechanism of action is unknown, it is believed that the glycaemic control benefit may be linked to dietary fibre (DF), protein (DP) and isoflavones' physicochemical properties (Rivero-Pino, Espejo-Carpio & Guadix, 2020; Kurylowicz, 2020; Goff *et al.*, 2018).

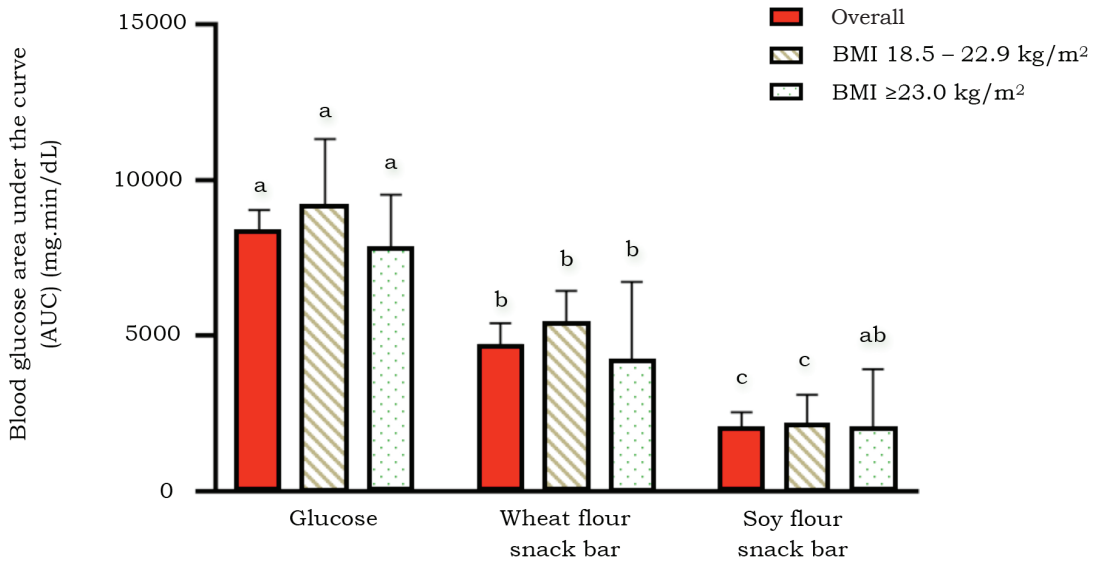

Figure 3. Blood glucose area under the curve (AUC). SF snack bar has lower blood glucose AUC level (p<0.05) than WF snack bar or glucose standard.
[abc] Different letters within the same bar column indicates difference between test product

In individuals with diabetes, DF intake can help improve glycaemic control in several mechanisms of action, i.e. by delaying gastric emptying, modifying the secretion of digestion- and fermentation-related hormones, inhibiting the activity of amylase and delayed starch hydrolysis, altering amylolysis progress, and improving the development of an absorptive barrier layer through interactions with the mucosa (Goff *et al.,* 2018). According to evidence-based data, to some extent, all of these mechanisms contribute to enhanced gut viscosity and as a consequence, slower glucose molecules absorption and greater insulin function. The mechanism of action caused by DP intake is associated with the elevation of gut endocrine cell hormone level, incretins (e.g. glucagon-like peptide-1, GLP-1) (Rivero-Pino *et al.*, 2020). Ultimately, GLP-1 stimulates insulin release whilst inhibiting glucagon release (incretin effect). By these mechanisms, blood glucose level is effectively controlled.

Furthermore, the latest review by Kurylowicz (2020) explained the action mechanism behind isoflavones' role in controlling blood glucose. The findings described that isoflavones are known to have anti-diabetic properties, indicated by their role in β-cell destruction prevention and insulin release stimulation, while contributing to glucose homeostasis by decreasing glucagon release and liver's lipolysis and inflammation. These mechanisms lead to enhanced insulin sensitivity, better glucose absorption in the muscles, and improved adipose tissue metabolism and secretory activity. The review also mentioned that isoflavones enhance hypothalamic appetite regulation, augment incretin effect, positively alter the gut microbiota composition, and affect glucose reabsorption. The reported findings, however, were based on distinct experimental models and circumstances, and the isoflavones concentrations administered in preclinical investigations were significantly greater than those found naturally in living organisms. Therefore, these mechanisms of action support our hypothesis that SF snack bar consumption per serving size (100g) containing fibre (8.9%), protein (12.1%) and isoflavones content (48.9 mg) would not cause any significant blood spike (hyperglycaemia) in individuals with T2DM. The magnitude of a 180-minute blood glucose profile attenuation in the present study, however, is small compared to a previous study on soy flour snack bar that reported a maximum peak of 136.9 mg/dL (7.6 mmol/L) and nearly 50% lower blood glucose AUC after the ingestion of SF snack bar in individuals with T2DM (Urita *et al.*, 2012).

To date, evidence have shown that the nutritional properties of soybean are not the only factor affecting postprandial blood glucose fluctuation level (Franz *et al.,* 2002). Findings have highlighted that the type and amount of carbohydrates consumed and the physical form of food are deemed equally relevant when evaluating its influence on postprandial blood glucose fluctuation level. The first evidence agreed by medical practitioners concluded that "soybean in some way causes a reduction in the percentage and total quantity of sugar passed in diabetic subjects on the usual dietary restrictions" (Holt, Muntyan & Likver, 1996). This finding might be due to soybean's low carbohydrate content, which differentiates it from other legumes (except peanuts) that contain mostly carbohydrates. Recently, an updated recommendation about the type and amount of carbohydrates consumed for T2DM management is explained by Yari *et al.* (2020). They suggested that particularly for diabetic subjects without complication, the strategic objective of nutrition treatment is to improve glycaemic control by selecting

foods with low GI/GL value. Looking at its characteristics (slow digestion), low GI/GL foods contribute to a slower and smaller rise in postprandial glucose level (Vlachos *et al.,* 2020).

Furthermore, several prior studies have investigated various forms of soy snack alternatives for people with diabetes, such as soy cookies and biscuits (Maya, Sulaeman & Sinaga, 2020; Kim *et al.,* 2020). The present study is the first to prove the glycaemic control benefit of consuming soy flour-based snack bars in T2DM subjects in Indonesia. Also, this study is the continuation of a larger study on the effect of SF snack bar consumption on postprandial blood glucose of healthy subjects (Nurdin *et al.,* 2020). The findings recommend soy flour snack bar as a low GI/GL source food that is potentially favourable for controlling blood glucose level and can be an alternative snack for healthy people with blood glucose concerns. Moreover, studies by Kim *et al.* (2020) and Yan *et al.* (2017) reported lower glycaemic impact after consuming snack bars in healthy older adults. The results showed comparable efficacy with our findings due to its high fibre or protein content. In the current study which involved individuals with diabetes, the glycaemic control benefit of consuming SF snack bar was shown to be better than WF snack bar, with GR fluctuation in the range of 100-140 mg/dL, which was considered to be well-controlled for individuals with diabetes 1-2 hours after the start of a snack (180 mg/dl).

Views vary on the link between weight status and glycaemic control on individuals with T2DM, but there is evidence supporting their association (Bae *et al.,* 2016). The finding concluded that T2DM individuals with excess body weight (overweight, obese class I, II, or III) have higher risk of poor glycaemic control and are linked to substantially increased likelihood of having high HbA1c levels. Hypothetically, poor glycaemic control can increase the probability of impaired postprandial glucose levels, which in turn covers the food effect under investigation. This hypothesis is in accordance with the current study finding, where abnormal postprandial glucose levels were observed in those who consumed SF snack bar and were overweight. The fact is that when an individual predisposed to diabetes has excess weight, the cells in the body become less responsive to insulin (insulin resistance) due to an increased amount of non-esterified fatty acids, glycerol, hormones, cytokines, proinflammatory substances, and other substances that lead to the impairment of β-islet cells of the pancreas, causing poor glycaemic control (Al-Goblan, Al-Alfi & Khan, 2014).

There are unique characteristics and drawbacks that must be acknowledged within this study. Firstly, equal amounts of available carbohydrate in snack bars as an alternative food form showed that glycaemic control of postprandial glucose levels is achievable by substituting wheat flour with soy flour snack bar. This study has confirmed the short-term effect of SF snack bar on GR of individuals with T2DM. However, future research should focus on evaluating the effect of long-term consumption of SF snack bar on glycaemic control in individuals with T2DM using HbA1c test as an outcome under investigation. Secondly, despite the statistical significance that those who consumed SF snack bar had lower postprandial glucose levels and low GR with blood glucose peak, the limited magnitude of the blood glucose AUC attenuation (>20%) may be attributable to the small sample size (n= 9). In future research, a larger sample size needs to be considered in order to obtain better precision and confidence in the results for clinical reasons. Thirdly, taking into account prior published study

on healthy (Nurdin *et al.,* 2020) and diabetic subjects (Urita *et al.*, 2012), the current study confirmed the feasibility of utilising SF snack bar to help blood glucose management in both healthy and diabetic subjects. Nonetheless, the findings of this study also strengthened the available evidence that weight status, particularly overweight, is associated with distinct metabolic responses. Future studies could investigate the effect of SF snack bar on overweight subjects with additional subject characteristics, such as age, race and co-morbidities for glycaemic control (Bae *et al.,* 2016).

CONCLUSION

To conclude, the current study found that consumption of snack bar made from soy flour contributed to lowering postprandial glucose levels over a 180-minute observation period, with a statistically significant attenuation of >20% lower GR (AUCs) and blood glucose peak than wheat flour snack bar. Overall, this study confirmed our hypothesis that consuming soy flour snack bar maintained postprandial glucose levels in normal range due to its nutritional properties (high fibre, protein, isoflavones and low carbohydrate). This finding might help control the blood glucose of T2DM subjects through diet modification by including SF snack bar as part of a regular eating plan practice (2-3 snack bars in a day as a snack alternative) in a well-balanced nutritious diet.

Acknowledgement

The authors valued the collaboration of several parties, including Pratama IPB Bogor Clinic and Indonesian Diabetes Association (PERSADIA). Special thanks to Dr. Widjaja Lukito for providing input during the review process of this manuscript.

Authors' contributions

NMN, principal investigator, conceptualised and designed the study, assisted in drafting of the manuscript, reviewed the manuscript; HFN, co-principal investigator, contributed in study design, advised on data analysis and interpretation, and reviewed the manuscript; KRE, prepared the draft of the manuscript, led the data collection in IPB University, data analysis and interpretation, reviewed the manuscript; MYK, reviewed and finalised the manuscript.

Conflict of interest

NMN, HFN and KRE declare no conflict of interest. MYK is the scientific supervisor at PT. Amerta Indah Otsuka. This study was funded by PT. Amerta Indah Otsuka. All authors disclose that the sponsor company had no influence in the execution of the study, including no input into the study design, data collection, analyses, or interpretation of the data, in the writing of the manuscript, and in the decision to publish the results.

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