

学位論文の内容の要旨

Summary of the Substance of Dissertation

専攻 Major Field	医学	部門 Department	
学籍番号 Student No.	19D720	氏名 Name	Salimah Binti Japar
論文題目 Thesis Subject	A pilot study on the effect of D-allulose on postprandial glucose levels in patients with type 2 diabetes mellitus during Ramadan fasting		
(論文要旨) Summary	<p>Background: Reports from the International Diabetes Federation revealed that about 451 million people worldwide had diabetes in 2017, and the number is projected to increase to 693 million by 2045. Approximately 90 million Muslims worldwide have diabetes. In Malaysia, the prevalence of diabetes is estimated as 18.3% affecting 3.9 million adults aged 18 years and above. The prevalence of diabetes increased rapidly from 13.4% in 2015 to 18.3% in 2019. Obesity due to higher intake of sweetened foods, carbohydrates, and sedentary lifestyles was revealed as the main factor of type 2 diabetes mellitus (T2DM) in Malaysia. Fasting during Ramadan (the ninth month of the Islamic Calendar) is one of the five pillars of Islam. During Ramadan, all healthy Muslims are required to fast for a whole month from dawn to sunset. Despite Ramadan fasting having several benefits, fasting in individuals with uncontrolled diabetes increased the risk of hypoglycemia, hyperglycemia, diabetic ketoacidosis, and thrombosis due to dehydration. Furthermore, the most frequent risk is postprandial hyperglycemia which observed after the <i>iftar</i> (break of fast at sunset) meal. Although the holy Quran has explicitly exempted sick people from this obligation, many Muslim diabetic patients choose to fast despite the associated risks. A potential solution to these issues may be D-allulose (a C-3 epimer of d-fructose) that is found in small quantities in nature. D-allulose is a monosaccharide, a rare sugar type with 70% the sweetness of sucrose and has zero calorie. Extensive studies have reported that D-allulose provides several health benefits, particularly the suppression of increase in postprandial glucose levels. The present study investigates whether D-allulose (a C-3 epimer of D-fructose) improves the postprandial glucose in patients with type 2 diabetes mellitus (T2DM) during Ramadan. This study is the first attempt to elucidate the effects of D-allulose in response to normal routine meals consumed by patients with type 2 diabetes mellitus during Ramadan <i>iftar</i>. In this study, we hypothesized that supplementation with 8.5 g D-allulose prior to carbohydrate intake during <i>iftar</i> will reduce the postprandial blood glucose.</p> <p>Methods: This was a pilot, prospective single-arm study design that was conducted for 10 consecutive days in the fasting month of Ramadan; 5 days of control and 5 days of consumption. This study was conducted at the diabetes outpatient clinic of a tertiary government hospital located in East Peninsular Malaysia. All Muslim patients with controlled T2DM aged between 20-70 years old who intending to fast for Ramadan</p>		

were recruited in this study. The primary outcome was postprandial peak glucose levels, whereas the secondary outcomes were: (1) percentage of time in which postprandial glucose levels were in the target range (%TIR), (2) percentage of time in which glucose levels were above the target range (%TAR), (3) the percentage of time in which glucose levels were below the target range (%TBR), (4) side-effects of d-allulose, and (5) hypoglycemia or hyperglycemia symptoms reported by the participants. During the consumption period, 8.5 g of D-allulose was consumed by the participants before *iftar* meal. Participants dissolved one pack of D-allulose (8.5 g) in plain water and finish the drink before consuming their main *iftar* meal. Postprandial glucose was measured using a continuous glucose monitoring system. The study protocol was registered on ClinicalTrials.gov (identifier: NCT05071950) and the National Medical Research Register (NMRR-19-3457-51288), whereas approval to conduct the study was obtained from the Medical Research Ethics Committee (MREC), Ministry of Health Malaysia (KKM/NIHSEC/P19-2734). Data analyses were undertaken using SPSS version 25 (IBM Corp, New York, USA) software. Glucose levels between the control and consumption periods and differences within repeated days were assessed using the one-way repeated measure of ANOVA with Bonferroni post hoc test. The paired sample *t* test was used to compare the average glucose TIR, TAR, and TBR percentages. A *p*-value less than 0.05 was considered for statistical significance.

Results: A total of 12 participants with a mean age of 55.2 years completed the study. Results showed that, significant lower ($p < 0.01$) postprandial glucose values and the glucose incremental area under the curve (iAUC) were observed from 0 to 180 min during the consumption period compared to the control period. The consumption period demonstrated significantly higher percentages of time (%TIR) in which glucose values were found in the target range ($p = 0.0032$), and when the glucose levels above the target range (%TAR) were reduced ($p = 0.0015$). No severe side-effects of D-allulose and symptomatic hypoglycemia and hyperglycemia were reported by participants.

Conclusions: Our findings suggest that supplementation with 8.5 g of D-allulose has the potential to improve postprandial hyperglycemia in patients with T2DM after *iftar* during Ramadan. This study also confirmed that no severe side effects of D-allulose or symptomatic hypoglycemia or hyperglycemia were reported throughout the study period. Further studies among a larger sample size of participants are needed to confirm these findings.

掲 載 誌 名 Magazine to publish the thesis	Diabetology & Metabolic Syndrome			第 卷 第 号 Vol. 14 No. 86
(公表予定) 掲 載 年 月 Estimated Date of Publication	年 月 year 2022 month 6	出版社 (等) 名 Name of the Publisher	BioMed Central Ltd.	
Peer Review	有 With	無 Without		

(備考) 論文要旨は、日本語で1, 500字以内にまとめてください。
(Recital) Sum up the within 1500 letters.