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Effects of cinnamon extract on blood sugar levels of type 2 diabetes mellitus patients: Randomized Controlled Trial (RCT)

Pengaruh ekstrak kayu manis terhadap kadar gula darah pasien diabetes melitus tipe 2: Randomized Controlled Trial (RCT)

Dilma'aarij Agustia[1*], Sutan Sahala Muda Marpaung[2], Dita Anggriani Lubis[3]

[1] Satya Terra Bhinneka University, Medan, North Sumatra, Indonesia.
E-mail: dilmaagustia@satyaterrabhinneka.ac.id
[2] Politeknik Pertanian Negeri Kupang, Nusa Tenggara Timur, Indonesia.
E-mail: sutanmarpaung@gmail.com
[3] Satya Terra Bhinneka University, Medan, North Sumatra, Indonesia.
E-mail: ditalubis@satyaterrabhinneka.ac.id

***Correspondence Author:**
Universitas Satya Terra Bhinneka, Jl. Sunggal Gg. Bakul, Sunggal, Kec. Medan Sunggal, Kota Medan, Sumatera Utara 20128, Indonesia.
E-mail: ditalubis@satyaterrabhinneka.ac.id

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Abstract

Cinnamon is an herbal remedy proven to lower blood sugar levels in patients with type 2 diabetes mellitus (DM). Cinnamon contains coumarin, which reduces the blood sugar levels. This study aimed to determine whether administration of a higher dose of cinnamon could lower blood sugar levels in individuals with type 2 diabetes mellitus. Methods: This study employed a randomized controlled trial (RCT) design and was conducted at the Medan Denai Health Center from November to December 2023. Participants were randomly selected and divided into two groups: the intervention group, which received cinnamon extract (n= 15), and the control group (n= 15), which did not receive any treatment. The dose was 10 mg/day. Blood sugar levels were measured using a standardized instrument and data were analyzed using the Kruskal–Wallis test. Results, before receiving cinnamon extract, the average blood sugar level was 238,80 mg/dL in the intervention group and 225,33 mg/dL in the control group. After cinnamon extract administration, the intervention group showed a significant reduction of 127,73 mg/dL, whereas that of the control group remained at 222,20 mg/dL. Statistical analysis revealed a significant difference in the blood sugar levels following cinnamon extract administration (p< 0,001). In conclusion, cinnamon extract supplementation can help lower blood sugar levels in patients with type 2 diabetes mellitus.

Keywords: Blood sugar, Diabetes mellitus type 2, Cinnamon extract

Abstrak

Kayu manis salah satu obat herbal yang terbukti dapat menurunkan kadar gula darah pada penderita diabetes melitus (DM) tipe 2. Kayu manis mengandung kadar kumarin yang dapat menurunkan kadar gula darah. Penelitian ini bertujuan untuk mengetahui apakah pemberian kayu manis dalam jumlah lebih banyak dapat menurunkan kadar gula darah pada penderita diabetes melitus tipe 2. Metode, penelitian menggunakan desain uji klinis acak terkontrol (randomized controlled trial) dan dilakukan di Puskesmas Medan Denai pada November hingga Desember 2023. Responden dipilih secara acak dan dibagi menjadi dua kelompok: kelompok intervensi yang diberikan ekstrak kayu manis (n= 15) dan kelompok kontrol (n= 15) tanpa perlakuan. Dosis yang diberikan adalah 10 mg per hari. Pengukuran kadar gula darah dilakukan menggunakan instrumen standar. Data dianalisis menggunakan uji Kruskal–Wallis. Hasil, rata-rata kadar gula darah pada penderita diabetes melitus tipe 2 sebelum diberikan ekstrak kayu manis adalah 238,80 mg/dl pada kelompok intervensi, dan pada kelompok kontrol 225,33 mg/dl. Setelah diberikan ekstrak kayu manis, pada kelompok intervensi terjadi penurunan sebesar 127,73 mg/dl, dan pada kelompok kontrol hanya 222,20 mg/dl. Analisis statistik menunjukkan perbedaan yang signifikan dalam kadar gula darah setelah pemberian ekstrak kayu manis (p< 0,001). Kesimpulan, pemberian ekstrak kayu manis dapat membantu menurunkan kadar gula darah pada penderita diabetes melitus tipe 2.

Kata Kunci: Gula darah, diabetes melitus tipe 2, ekstrak kayu manis

Introduction

Type 2 diabetes mellitus is a non-communicable disease that continues to be a global problem is type 2 diabetes mellitus (Beigi et al., 2019). Type 2 diabetes is diagnosed at all ages, ranging from children to seniors. A class of metabolic disorders known as type 2 diabetes mellitus is characterized by hyperglycemia caused by anomalies in insulin action, secretion, or both. Hyperglycemia (high blood glucose) and changes in lipid metabolism are hallmarks of diabetes mellitus, caused by insufficient amounts of insulin in circulation or decreased insulin activity. Every organ in the body may be affected by diabetes mellitus, which can lead to various medical concerns (Sujarwoto et al., 2020).

Type 2 diabetes mellitus is a non-communicable disease (NCDs) that continues to be the world's leading cause of death, particularly in low-income nations. Approximately 41 million people will die (Uthman et al., 2022). Therapy and medication adherence in patients with type 2 diabetes mellitus are concerns. The main drugs used to treat type II diabetes are sodium-glucose co-transporter-2 (SGLT2) inhibitors, amylin antagonists, insulin secretagogues, biguanides, insulin sensitizers, alpha-glucosidase inhibitors, and incretin mimetics. Dual-drug therapy is commonly recommended when patients cannot achieve their treatment goals using first-line oral hypoglycemic medicines as monotherapy (Padhi et al., 2020). In addition, there are several treatments for diabetes mellitus, such as lifestyle modifications and herbal remedies that have the ability to improve hyperglycemia, one of which is cinnamon. Non-pharmacological therapy in patients with type 2 diabetes mellitus has been proven to provide a lower risk of side effects than pharmacological therapy (Padhi et al., 2020).

Cinnamon species exhibit insulin-enhancing activity in vitro. Cinnamon, which is usually used as a spice, is effective in the treatment of type 2 diabetes mellitus. Compared to metformin, C. burmanii appears to be more successful in lowering plasma blood glucose levels (Jamali et al., 2020). It increases the expression of proteins that control dyslipidemia, insulin signaling, and glucose transport. The fundamental and clinical pharmacology of cinnamon are discussed in this article (Sharma et al., 2020). Cinnamon can decrease blood sugar levels because herbal plants contain polyphenol-active substances that increase cellular insulin receptors. Cinnamaldehyde, which acts as an antioxidant against free radicals, can help neutralize blood glucose levels. In addition, polyphenol content plays a role in activating tyrosine phosphorylation and reducing phosphatase activity, which activates insulin receptors (Zare et al., 2019). Sipirok produces the highest-quality cinnamon in significant amounts. The coumarin content was significantly different between the sipirok cinnamon and local cinnamon. Coumarin has significant anticoagulant properties and may be harmful to the liver (Hugo & Souza, 2024). While coumarin levels in sipirok cinnamon are significantly higher and may be harmful if regularly ingested in large quantities, the coumarin concentration in sipirok cinnamon is quite low and is not known to have any negative health consequences (Abu-Odeh & Talib, 2021). Some countries have restricted the routine use of Cinnamomum cassia because of the potential health hazards associated with high levels of coumarin.

Previous studies have not discussed how the effects of cinnamon can be influenced by cultural factors or local diets; therefore, few studies have been conducted on this population in Medan City using sipirok cinnamon. The novelty of this study compared to other studies is the use of local wisdom in cinnamon materials, namely, sipirok cinnamon. A previous meta-analysis showed that 16 studies using randomized consoles showed that cinnamon significantly reduced blood glucose levels compared to placebo (Deyno et al., 2019). The antidiabetic effects of native cinnamon extract have been studied previously, but no research has been conducted on how the native variety of sipirok cinnamon affects people with type 2 diabetes (Zhu et al., 2020).

Therefore, further research on the use of cinnamon in individuals with type 2 diabetes mellitus is necessary. Patients may attempt to heal safely by using traditional Mambu herbal therapies. Therefore, this study aimed to ascertain whether cinnamon lowers blood sugar levels in individuals with type 2 diabetes mellitus.

Methods

Blood sugar levels of patients with type 2 diabetes mellitus were measured before and

after receiving additional cinnamon in each sample group as part of this randomized controlled trial (RCT) design. All patients with type 2 diabetes mellitus at the Medan Denai Health Center between November and December 2023 were included in the study. Sampling was performed using random selection. The minimum sample size was calculated to be 15 participants per group, resulting in a total of 30 participants. The sample size calculation followed a formula designed to ensure statistical robustness and relevance to the research objective. The inclusion criteria for this study were respondents who had been diagnosed with type 2 DM by a doctor based on the diagnostic criteria and patients aged 30-70 years. Patients using oral drugs such as metformin at a stable dose for the last 1-3 months and willing to follow all research procedures and provide informed consent. Patients with severe complications such as advanced diabetic nephropathy, severe retinopathy, acute cardiovascular disease, and allergies to cinnamon extract were excluded.

Sample calculations were performed based on the variables of individuals with type 2 diabetes mellitus. Sampling was performed using a simple random sample formula with calculation of the sample size, which required the population size, z-score with a confidence level of 95%, and an estimate of the proportion of the population with the desired type 2 diabetes mellitus error (5%).

Thirty patients with type 2 diabetes mellitus participated in the study. They were randomly divided into two treatment groups at a 1:1 ratio: the control group, which included 15 participants, and the intervention group, which included additional cinnamon (15 individuals). Random allocation was critical to ensure that each participant had an equal chance of being placed in one of the two treatment groups, thus minimizing selection bias. The allocation process aimed to balance participant characteristics at the start of the study and strengthen the link between the observed outcomes and the implemented intervention. After group assignment, participants in each group received the prescribed intervention: the intervention group received cinnamon extract at a dose of 10 g/day within 7 days, and the control group did not receive cinnamon extract consumption (Hafizur et al., 2015). Cinnamon extract was administered in solid dosage form.

In the process of data collection, before the researchers carried out the intervention, we gave informed consent to respondents to be willing to become respondents in this study. Before the intervention, we measured the blood sugar levels using a standardized tool for all respondents. During the data collection process, each respondent received predetermined treatment. In its implementation, the treatment was carried out for seven days consuming cinnamon brew extract, which was consumed as much as 5 g in the morning and 5 g in the afternoon without any additions, such as honey and sugar. Within seven days of treatment, we followed up with and reminded respondents to consume the cinnamon extract provided, while also observing any complaints or obstacles encountered during the intervention.

Furthermore, to assess the impact of this intervention, all groups underwent blood sugar measurements on the seventh day after the intervention in both the control and intervention groups. Blood sugar measurements were obtained from patients with high blood sugar levels, as assessed by a Continuous Glucose Monitoring (CGM) result of <200 mg/dL. Blood glucose measurements were performed in patients with high blood sugar levels, as assessed by a CGM <200 mg/dL. Blood sugar measurements were performed using a 3-in-1 glucometer test with one med brand, year of manufacture 2022.

Additional data were also collected using tools such as intervention observation sheets to record details of patient complaints and obstacles during the implementation of the intervention, documentation, and respondent compliance. This comprehensive approach ensured a systematic and thorough evaluation of the impact of the intervention and the overall work experience.

The classification of blood sugar reduction into “decrease” and “increase” involves categorization based on measurements before and after the administration of extract cinnamon. The “decrease” classification was applied when there was a decrease in blood sugar level measurements from the pre-intervention assessment to the post-intervention evaluation of at least >10 mg/dL. Conversely, the “Increase” classification is given when there is an increase in blood sugar level measurements from the pre-intervention assessment to the post-intervention evaluation of > 10 mg/dL. These operational definitions provide clear guidelines for consistent

categorization during assessment of blood sugar levels.

STATA Statistics/Data Analysis software (version 6.0) was used for all statistical analyses to ensure a robust and comprehensive evaluation of sociodemographic characteristics and decreases in blood sugar levels in the intervention and control groups. Age, early cervical opening (opening of labor), and gravida (number of previous pregnancies) were analyzed using the Kruskal-Wallis test. This non-parametric test compares the characteristics of the intervention and control groups. Levene's test further ensured equality of variance between groups, which is an important assumption for the Kruskal-Wallis test.

Kruskal-Wallis test was used to assess the impact of the intervention (cinnamon extract administration and control) on reducing blood sugar levels. This test, which is suitable for non-normally distributed data, compares blood sugar level scores between the groups. Additionally, the link between the groups and reduction in blood sugar in patients with type 2 diabetes mellitus was examined using an Independent T-test on the numerical data before and after the test. The association between the groups and ensuing drop in blood sugar levels was examined using an Independent T-test.

All procedures were approved by the ethics committee of Satya Terra Bhinneka University Medan (number 001/SK/KE-STB/I/2024, and all participants provided written informed consent. Before the study began, written informed consent was provided by each participant, who received comprehensive information regarding the purpose and methodology of the study. In addition, assurance of confidentiality of their information was provided, and the participants were free to leave the study whenever they wanted.

Result and Discussion

The above information contrasts several factors between the two groups, the control group and the intervention group, which received cinnamon extract. In terms of age, no significant difference was observed, with a mean age of 61,67±10,48 for the intervention group, and 66,20±11,25 for the control group (p= 0,110).

Similarly, BMI showed no significant variation between the groups, with a mean of 28,35±4,00 for the intervention group, and 27,64±3,51 for the control group (p= 0,430). The pre-blood sugar level examination variable representing the blood sugar levels of the groups also showed no significant difference, with a mean of 238,80±65,20 for the intervention group and 225±74,01% in the control group (p = 0,724). In summary, the analysis showed no statistically significant differences in age, BMI, blood sugar level measurements, or pre-intervention between the intervention and control groups, indicating comparable characteristics in these parameters. Homogeneity values with an age of 0,602 years, BMI of 0,318, and blood sugar level measurement before intervention of 0,679 showed a degree of similarity between the two groups for these variables. The lack of significant differences in the sociodemographic data of the intervention and control groups indicated homogeneity of these variables among the study participants. This homogeneity of sociodemographic data increased the internal validity of the study, indicating that the effects or outcomes observed in the intervention group were less likely to be influenced by demographic variations among respondents.

Table 1. Characteristic sociodemographic of respondents

Variable	Intervention Blood Sugar	Control Blood Sugar	p value*	Homogeneity**
Age (y.o)				
Mean ± SD	61,67±10,48	66,20±11,25	0,110	0,602
Range	34-73	34-77		
BMI (kg/m^2)				
Mean ± SD	28,35±4,00	27,64±3,51	0,430	0,318
Range	22,91-35,14	23,73-35,14		
Systolic (mmHg)				
Mean ± SD	140,20±8,65	137,67±12,62	0,480	0,915
Range	125-154	117-163		

Diastolic (mmHg)				
Mean ± SD	80,13±6,76	80,07±10,11	0,884	0,927
Range	67-92	62-96		
Abdominal Circumference (cm)				
Mean ± SD	83,73±13,67	80,67±12,59	0,575	0,381
Range	60-104	60-104		
Sex (%)				
Male	6 (40,0)	7 (46,7)	0,713	0,713
Female	9 (60,0)	8 (53,3)		
Education (%)				
Diploma/Bachelor's degree	6 (20,0)	4 (25,0)	0,615	0,615
Elementary / Junior / Senior High School	9 (80,0)	11 (75,0)		
Jobs (%)				
Housewife	6 (40,0)	6 (40,0)	0,801	0,603
Traders/Employed	1 (6,7)	2 (13,3)		
Retired	4 (26,7)	5 (33,3)		
Civil Servant	3 (20,0)	2 (13,3)		
Other	1 (6,7)	0 (0,0)		
Income (%)				
>2 million	4 (26,7)	4 (26,7)	1,00	1,00
1million-2million	11 (73,3)	11 (73,3)		
Marriage (%)				
Widow/Widower	3 (20,0)	2 (13,3)	0,624	0,624
Married	12 (80,0)	13 (86,7)		
Family History of DM (%)				
Available	4 (26,7)	8 (53,3)	0,136	0,136
None	11 (73,3)	7 (46,7)		
Smoking (%)				
Yes	3 (20,0)	0 (0,0)	0,068	0,068
No	12 (80,0)	15 (100,0)		
Excessive Sugar Consumption (%)				
Yes	7 (46,7)	10 (66,7)	0,269	0,269
No	8 (53,3)	5 (33,3)		
Excess Salt Consumption (%)				
Yes	4 (26,7)	3 (20,0)	0,666	0,666
No	11 (73,3)	12 (80,0)		
Excess Fat Consumption (%)				
Yes	10 (66,7)	7 (46,7)	0,269	0,269
No	5 (33,3)	8 (53,3)		

* Kruskal–Wallis's test
** Levene's test

Table 2. Effect of using extract cinnamon on blood sugar levels of patients with type 2 diabetes mellitus

Blood Sugar Levels	Intervention Mean ± SD	Control Mean ± SD	Delta (Δ)	p value*
Before (mg/dL)	238,80 ± 65,20	225,33 ± 74,01	13,47	0,724
After (mg/dL)	127,73 ± 46,95	222,20 ± 57,87	94,47	< 0,001

* Independent T-test

The sugar levels before and after the intervention with additional cinnamon in the intervention and control groups are shown in Table 2. The average amount of blood sugar levels after being given extract cinnamon showed the amount of blood sugar levels of 127,73 ± 46,95

for the intervention group and 222,20 ± 57,87 for the control group. Statistical analysis showed that there was a significant difference in blood sugar levels after the administration of cinnamon extract (p<0,001), in contrast to the blood sugar level data before the intervention, which showed a blood sugar levels of 238,80 ± 65,20 for the intervention group and 225,33 ± 74,01 showed no discernible variation in the blood sugar levels of patients with type 2 diabetes mellitus compared to the control group (p = 0,724).

Based on the findings of the analysis, the data demonstrated that administering 10 g of cinnamon extract daily for seven days significantly reduced blood sugar levels, and research demonstrated how well it might work to lower blood sugar levels in people with type 2 diabetes. In contrast, there was no appreciable increase in the blood sugar levels in the control group. This finding emphasizes the positive impact of cinnamon extract administration on reducing blood sugar levels compared to the control group.

Table 3. Effect of cinnamon extract administration on blood sugar levels of patients with type 2 diabetes mellitus

Glucose Level	Intervention (%)	Control (%)	Total (%)	p value*
Down	15 (100)	3 (20,0)	18 (60,0)	
Ties	0	6 (40,0)	6 (20,0)	<0,001
Up	0	6 (40,0)	6 (20,0)	

* Kruskal–Wallis's test

Table 3 shows how the intervention and control groups perceived their blood sugar level. Every member of the intervention group stated that their blood sugar levels had decreased. Twenty% of the control group's blood sugar levels decreased, whereas 40% remained unchanged and increased. However, the control group exhibited a different trend. Blood sugar levels were considerably higher in the intervention group than in the control group of patients with type 2 diabetes mellitus (p < 0,001).

Diabetes mellitus is characterized by increased blood glucose concentration. As its prevalence increases annually, it is necessary to identify its main problems and solutions. This will be the basis for starting preventive measures and improving complications in patients with diabetes mellitus, especially type 2 diabetes mellitus (Harreiter, 2019). Treatment and medication adherence in diabetes mellitus need to be firm. Pharmaceutical therapy with metformin has many contraindications; therefore, other recommended pharmaceutical treatments include sulfonylureas and insulin. For patients with type 2 diabetes mellitus, two antidiabetic drugs are not recommended (Abu-Odeh & Talib, 2021; Pfeiffer, 2014). Accordingly, to reduce the risks already present, people with type 2 diabetes mellitus must receive herbal or traditional therapies (Zhu et al., 2020; Akilen et al., 2013).

Treatment with the cinnamon extract showed a significant relationship. The consumption of cinnamon in accordance with the recommended dose can help reduce blood sugar levels in patients with diabetes mellitus in reducing their blood sugar levels (Hugo & Souza, 2024; Hasanzade et al., 2013). Compared with metformin, cinnamon bark is more effective at lowering plasma blood glucose levels. It increases the expression of proteins that control dyslipidemia, insulin signaling, and glucose transport (Sharma et al., 2020). Cinnamon contains polyphenolic compounds that are known to be active components that inhibit enzymes that process and play a role in carbohydrate digestion by reducing the absorption of glucose from food into the bloodstream, thereby reducing the content of blood sugar spikes after eating (Ranasinghe et al., 2012; Talaei et al., 2017).

Cinnamon has been studied internationally for its potential to lower blood glucose levels via various mechanisms involving its bioactive compounds. Polyphenols and flavonoids in cinnamon can inhibit the activity of alpha-amylase and alpha-glucosidase enzymes, which are responsible for breaking down carbohydrates into glucose, so in this way, cinnamon slows down the absorption of glucose from the gastrointestinal tract, thus preventing a spike in blood sugar levels after a meal (Silva et al., 2022; Talaei et al., 2017). Cinnamon dosage decreases blood glucose levels in patients with type 2 diabetes mellitus (Hasanzade et al., 2013). A dose of 10 g was administered twice a day (5 g each). According to a recent meta-analysis, the proper dosage of cinnamon was less than 1,200

mg, or 12 g, which resulted in a decrease in fasting blood glucose levels (Yu et al., 2023). This is one of the bases for dosing patients with type 2 diabetes mellitus.

Chronic or ongoing hyperglycemia caused by insufficient or malfunctioning insulin production is a symptom of diabetes mellitus. Previous studies have shown that cinnamon supplementation can improve several glycolipid indicators in patients with diabetes mellitus. This dosage association between cinnamon therapies was also found in this study and can serve as a guide for further research (Yu et al., 2023). There was no correlation between the blood sugar levels of individuals with diabetes mellitus and a number of sociodemographic factors including age, occupation, education, and blood pressure. BMI in patients was substantially correlated with the incidence of type 2 diabetes mellitus, although education was not linked to this condition according to another study (Hikmah et al., 2023). In this trial, the blood sugar levels of patients with diabetes mellitus were affected by the cinnamon intervention. The researcher suggests that Future research should examine the effect of cinnamon coumarin concentration on the pattern of lowering blood sugar levels in individuals with type 2 diabetes mellitus. Cinnamon increases enzyme activity and has insulin-mimetic effects that regulate glucose metabolism in tissues (Silva et al., 2022).

Future research should examine how cinnamon extract affects blood sugar levels in people with type 2 diabetes mellitus, while accounting for their food, medications, and fasting blood sugar levels. Calculation of the overall blood sugar level is crucial.

Conclusion

In conclusion, this study demonstrated the potential of cinnamon herbs, especially the lawing sipirok cinnamon, as a non-pharmacological blood sugar reduction management strategy in patients with type 2 diabetes mellitus.

Future research should consider several parameters, including fasting blood sugar, alternative dosage, and the impact of cinnamon coumarin content on lowering blood sugar levels in patients with type 2 diabetes mellitus to further investigate and improve these findings.

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