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Efficacy and safety of *Gymnema inodorum* tea consumption in type 2 diabetic patients

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Bespinyowong R, Pongthananikorn S, Chiabchalard A. Efficacy and safety of *Gymnema inodorum* tea consumption in type 2 diabetic patients. Chula Med J 2013 Sep - Oct; 57(5): 587 - 99

- Background** : *Diabetes mellitus (DM) is a global epidemic and its prevalence increases in many region of the world. *Gymnema inodorum* is a medicinal plant that has been used as drug and food for a long time in Thailand. It has hypoglycemic effect in healthy subjects without serious side effects. However, today there has not been any clinical study evaluating its effect in type 2 diabetic patients.*
- Objective** : *To evaluate the effect of consumption of *G. inodorum* tea on clinical outcomes in type 2 diabetic patients.*
- Design** : *Before and after quasi-experimental study.*
- Setting** : *Diabetes Clinic, Outpatient Department, Lerdsin Hospital, Bangkok.*
- Materials and Methods** : *Type 2 diabetic patients voluntarily participated in the study which comprised of 2 consecutive phases. In the controlled phase, the patients received only prescribed drugs (week 0 – week 8) and later in the treatment phase, *G. inodorum* tea was supplemented (week 8 – week 16). The biochemical parameters, and nutrients and caloric intakes were evaluated at week 0, 8, and 16.*

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- Results** : *The biochemical parameters including fasting blood sugar (FBS), hemoglobin A_{1c} (HbA_{1c}), total cholesterol (Total-C), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglyceride (TG), aspartate aminotransferase (AST), alanine aminotransferase (ALT), and serum creatinine (SCr) did not significantly change throughout the study. So did the nutrient and caloric intakes.*
- Conclusion** : *G. inodorum tea had no effect on blood sugar and lipid profiles in this study. It also did not affect hepatic and renal functions.*
- Keywords** : *Type 2 diabetes mellitus, Gymnema inodorum, hypoglycemic effect, lipid profiles, safety.*

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รพงษ์ เบศรภิญโญวงศ์, สุญาณี พงษ์ธนานิกร, อัญชลี ฉะยบฉลาด. ประสิทธิศักร์และความปลอดภัยของการดื่มชาผักเชียงดาในผู้ป่วยเบาหวานชนิดที่ 2. จุฬาลงกรณ์เวชสาร 2556 ก.ย. - ต.ค; 57(5): 587 - 99

เหตุผลของการทำวิจัย : โรคเบาหวานเป็นปัญหาสำคัญทางสาธารณสุขระดับโลก เนื่องจากความชุกที่เพิ่มขึ้นทุกปี ๆ ในหลายภูมิภาค ผักเชียงดาเป็นพืชสมุนไพรชนิดหนึ่งที่มีการใช้เป็นอาหารและสมุนไพรเป็นเวลายาวนาน การศึกษาในคนที่มีสุขภาพดีพบว่าผักเชียงดาช่วยลดระดับน้ำตาลในเลือดได้โดยปราศจากอาการข้างเคียงที่ร้ายแรง อย่างไรก็ตามในปัจจุบันยังไม่มีการศึกษาทางคลินิกถึงผลของชาผักเชียงดาในผู้ป่วยเบาหวานชนิดที่ 2

วัตถุประสงค์ : เพื่อประเมินผลทางคลินิกของการบริโภคชาผักเชียงดาในผู้ป่วยเบาหวานชนิดที่ 2

รูปแบบการวิจัย : การศึกษารูปแบบกึ่งทดลองแบบก่อนและหลัง

สถานที่ทำการศึกษา : คลินิกเบาหวาน แผนกผู้ป่วยนอก โรงพยาบาลเลิดสิน กรุงเทพมหานคร

รูปแบบการวิจัย : การศึกษารูปแบบกึ่งทดลองแบบก่อนและหลัง

สถานที่ทำการศึกษา : คลินิกเบาหวาน แผนกผู้ป่วยนอก โรงพยาบาลเลิดสิน กรุงเทพมหานคร

ตัวอย่างและวิธีการศึกษา : ผู้ป่วยโรคเบาหวานชนิดที่ 2 เข้าร่วมในการศึกษานี้ ซึ่งประกอบด้วย 2 ระยะ ได้แก่ ระยะควบคุม ผู้ป่วยได้รับเฉพาะยาที่แพทย์สั่ง (สัปดาห์ที่ 0 ถึงสัปดาห์ที่ 8) และระยะทดลอง ผู้ป่วยได้รับชาผักเชียงดาคู่กับยาที่แพทย์สั่ง (สัปดาห์ที่ 8 ถึงสัปดาห์ที่ 16) เมื่อผู้ป่วยเข้าสู่การศึกษาจะได้รับการประเมินตัวแปรทางชีวเคมี และปริมาณอาหารและพลังงานที่ได้รับในสัปดาห์ที่ 0, 8 และ 16

ผลการศึกษา : ผู้ป่วยโรคเบาหวานชนิดที่ 2 ผ่านการศึกษาทั้งสองระยะ ไม่พบการเปลี่ยนแปลงอย่างมีนัยสำคัญของระดับน้ำตาลในเลือดหลังอดอาหาร (FBS), เฮโมโกลบินเอวันซี (HbA_{1c}), ค่าคอเลสเตอรอลรวมในเลือด (Total-C), แอลดีแอลคอเลสเตอรอล (LDL), เอชดีแอลคอเลสเตอรอล (HDL), ไตรกลีเซอไรด์ (TG), แอสพาร์เทตอะมิโนทรานส์เฟอเรส (AST), อะลานีน อะมิโนทรานส์เฟอเรส (ALT) และซีรัม ครีเอตินิน (SCr) ปริมาณสารอาหารและพลังงานที่ได้รับไม่แตกต่างกันอย่างมีนัยสำคัญในทั้งสองระยะ

- สรุป** : ชาผักเชียงดาไม่มีผลต่อระดับน้ำตาลและระดับไขมันในเลือด และไม่
มีผลกระทบต่อการทำงานของตับและไต
- คำสำคัญ** : โรคเบาหวานชนิดที่ 2, ผักเชียงดา, ฤทธิ์ลดระดับน้ำตาลในเลือด,
ระดับไขมันในเลือด, ความปลอดภัย.

Diabetes mellitus (DM) is the global epidemic because of its increasing prevalence around the world each year.⁽¹⁾ The global prevalence of DM in all age groups was estimated to be 7.7% in 2030.⁽²⁾ In Thailand, a survey revealed that in 2009 the prevalence of diabetes mellitus in Thai people aged 15 years and above was 6.9%.⁽³⁾ Although there are four types of DM including type 1 DM, type 2 DM, other specific types, and gestational DM, type 2 DM accounts for 90 - 95% of diabetic patients.⁽⁴⁾

Medicinal plants become interesting alternatives as they are believed to have fewer side effects than western medications. *Gymnema inodorum* is a medicinal plant used as food and herbal drugs in the northern and north-eastern regions of Thailand for a long time. Its uses in the folklore medicine of Tai Yai tribe are antiallergic, antipyretic, and antidiabetic.⁽⁵⁾ Shimizu et al. ⁽⁶⁾ found that *G. inodorum* leaves extract could inhibit glucose absorption in guinea pigs and improved glucose tolerance of rats. The active phytochemicals of this medicinal plant are triterpenoid saponins.⁽⁷⁾ The study in healthy subjects showed that *G. inodorum* tea can reduce blood glucose level without any serious adverse effects.⁽⁸⁾ However, there have not been any studies emphasizing the effect of *G. inodorum* on blood sugar levels in type 2 DM patients. So, the present study is aimed to evaluate the clinical outcomes of the consumption of *G. inodorum* tea in type 2 diabetic patients. The data of this study could be beneficial to the development of inexpensive functional food or herbal medicine from Thai medicinal plants.

Materials and Methods

Subjects

Type 2 diabetic patients aged 35 - 70 years at Lerdsin Hospital, Bangkok, Thailand, voluntarily participated in this study. The subjects had sulfonylureas and/or metformin as their hypoglycemic drugs. They did not have other herbal medicine or dietary supplements, and renal or hepatic diseases. The subjects were excluded from the study when they had other hypoglycemic drugs besides sulfonylureas and/or metformin, drugs affecting carbohydrate metabolism, other herbal medicines or dietary supplements, renal or hepatic diseases, serious side effects from *G. inodorum*, and inability to comply with the study protocol. All patients signed consent forms before participating in the study.

The following equation and the data of hypoglycemic effect of *Scaphium scaphigerum* drink in type 2 diabetic patients were used to calculate the sample size in this study :^(9 - 10)

$$n = \frac{(z_{\alpha} + z_{\beta})^2 S_p^2}{D^2}$$

where n = the number of samples

Z_{α} = the critical value which is statistically significant at the confidence level of 50%. This value is 1.64 when α is 0.05 (one-sided).

Z_{β} = the critical value which the power to test the difference between groups. This value is 1.28 when β = 0.20 (one-sided).

S_p^2 = the pooled variance of the means of fasting plasma glucose of the treatment group and controlled group at week 8. This value is calculated by following equation:

$$\begin{aligned}
 s_p^2 &= \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2} \\
 &= \frac{(32 - 1)(23^2) + (31 - 1)(47^2)}{32 + 31 - 2} \\
 &= 1355.23
 \end{aligned}$$

D = the difference between the means of fasting plasma glucose of the experimental group and controlled group at week 8. This value is 169 - 141 = 28 mg/dL

From the above method, n was 14.74. However, there might have a loss of data. So, the rate of missing data should be considered to maintain the desired n by the following method: ⁽¹¹⁻¹²⁾

$$n_{\text{new}} = \frac{n}{1 - L}$$

where L was 0.10 which is the rate of missing data.

From the mentioned method, this study required 17 type 2 diabetic patients.

Gymnema inodorum tea

Gymnema inodorum tea was prepared by Food Technology Department, Thailand Institute of Scientific and Technological Research (TISTR), Pathum Thani, Thailand. One bag of tea contained 1.2 g of ground *G. inodorum* dried leaves. Before use, it was soaked in 150 ml of boiling water without adding sugar, other sweeteners, or milk.

Study Design

The study protocol was approved by the Ethics Committee of Lerdsin Hospital, Bangkok. This quasi-experimental study comprised of two consecutive phases: the controlled phase (8 weeks)

and the treatment phase (8 weeks). In the controlled phase which the subjects received only the prescribed drugs from the hospital, they were interviewed about their basal data including socioeconomic factors, disease history, and medication history at week 0. Their anthropometric parameters including body mass index (BMI), waist circumference (WC), and waist-to-hip ratio (WHR), and biochemical parameters including FBS, HbA_{1c}, Total-C, LDL-C, HDL-C, TG, AST, ALT, and SCr were evaluated. Moreover, they were asked to do 3-day food records. The biochemical parameters and nutrients and caloric intakes from 3-day food record were evaluated again at week 8 and week 16. In the treatment phase, the subjects drank *G. inodorum* tea in 15 minutes after their three regular meals.

Determination of Biochemical Parameters

Ten milliliters of venous blood was collected at week 0, 8 and 16. All biochemical parameters including FBS, total-C, HDL, LDL, TG, ALT, AST and SCr were measured by the colorimetric methods while HbA_{1c} was measured by the turbidimetric method, using a Siemens Dimension RXL chemistry analyzer (Siemens, Erlangen, Germany) at Clinical Chemistry Unit, Department of Pathology, Lerdsin Hospital, Bangkok.

Determination of Nutrients and Caloric Intakes

The 3-day food record was used to evaluate the subjects' nutrient and energy intakes. The subjects were asked to record name and quantity of their consumed food on three days comprising two weekdays and one weekend. The recorded data were transformed into calories, nutrients, and distribution

of protein, fat, and carbohydrate by NutriSurvey for Windows (Dr. Juergen Erhardt, University of Indonesia) and the food database collected by Professor Rungsunn Tungtrongchitr, Department of Tropical Nutrition and Food Science, Faculty of Tropical Medicine, Mahidol University, Bangkok. Mean caloric and nutrient intakes were expressed in kilocalories (kcal).

Data Analysis

The discrete data i.e. gender, education level, occupation, monthly income, marital status, adverse events and medication uses were presented as number and percentage; while the continuous data i.e. biochemical parameters, BMI, WC, HC, WHR, calorie and nutrient intake were presented as mean and standard deviation (mean \pm SD). Repeated measure one-way ANOVA was used to compare the mentioned parameters at week 0, week 8, and week

16. The parameters were significantly different when $p < 0.05$. The data analysis was performed by SPSS[®] software version 17 for Windows serial no. 5068054.

Results

Characteristics of the subjects

Nineteen type 2 diabetic patients participated in this study. However, there were six patients dropped out from this study. In addition, one patient had too low compliance. As a result, the data from twelve patients completed were analyzed. Socioeconomic and anthropometric parameters are shown in Table 1. Most of them were males. More than 50% of the subjects were 50 years old or above. The average age of the subjects was 56.9 ± 6.8 years. Fifty percent of the subjects had diabetic duration between 6 - 10 years and the average duration was 8.3 ± 3.9 years. Almost all subjects were overweight and had excess abdominal fat.

Table 1. Characteristics of the subjects ($n = 12$).

Characteristics	Number (%)
Gender	
Male	9 (75.0)
Female	3 (25.0)
Age distribution (years)	
40 - 49	1 (8.3)
50 - 59	6 (50.0)
60 - 69	5 (41.7)
Mean \pm SD	56.9 ± 6.8
Diabetic duration range (years)	
1 - 5	3 (25.0)
6 - 10	6 (50.0)
11 - 15	3 (25.0)
Mean \pm SD	8.3 ± 3.9

Table 1. Characteristics of the subjects ($n = 12$). (Continue)

Characteristics	Number (%)
Obesity categorized by BMI (kg/m^2) [†]	
18.5 – 22.9 (normal)	1 (8.3)
23 – 24.9 (overweight)	4 (33.3)
25 - 29.9 (obese)	7 (58.4)
Abdominal obesity categorized by WC	
Obese	10 (83.3)
Non-obese	2 (16.7)
Abdominal obesity categorized by WHR [‡]	
Obese	11 (91.7)
Non-obese	1 (8.3)

[†] From Kanazawa et al.⁽¹³⁾ ($\text{WC} \geq 90$ cm in men and ≥ 80 cm in women)

From Lear et al.⁽¹⁴⁾ ($\text{WHR} > 0.9$ in men and > 0.8 in women)

Nutrients and Caloric Intakes of the Subjects

Nutrients and caloric intakes of the subjects are shown in Table 2. Throughout the study, there were no significant differences in total energy intakes,

calories from carbohydrate, protein, and fat, and amount of dietary fiber. Carbohydrate accounted for the most proportion of energy intake while protein accounted for the least proportion.

Table 2. Nutrients and caloric intakes of the subjects at week 0, 8, and 16 ($n = 12$).

Parameters	Week 0	Week 8	Week 16
Total energy, kcal/day	1476.42 \pm 607.76 ^a	1426.42 \pm 563.96 ^a	1629.83 \pm 723.63 ^a
Carbohydrate, kcal/day	847.29 \pm 421.78 ^a	857.47 \pm 376.03 ^a	903.53 \pm 411.33 ^a
Protein, kcal/day	208.11 \pm 80.96 ^a	256.43 \pm 71.86 ^a	294.37 \pm 138.06 ^a
Fat, kcal/day	418.30 \pm 281.68 ^a	317.62 \pm 165.28 ^a	437.62 \pm 212.52 ^a
Dietary fiber, g/day	5.82 \pm 5.89 ^a	4.63 \pm 3.08 ^a	6.68 \pm 4.60 ^a
%Energy distribution (carbohydrate:protein:fat)	58:15:27 ^a	60:19:21 ^a	56:18:26 ^a

Value are expressed as mean \pm SD

g/day = gram/day, kcal/day = kilocalorie/day

Different superscript letters in the same row show statistically significant different ($p < 0.05$).

Biochemical profiles of the subjects

Blood sugar levels at week 0 (the beginning of the controlled phase), week 8 (the beginning of the treatment phase), and week 16 (the end of the treatment phase) are shown in table 3. There were no significant changes in blood sugar levels throughout the study. Other biochemical parameters including lipid profiles, hepatic and renal function (Table 3) also did not change significantly throughout the study.

Discussion

The present study is aimed to evaluate the clinical outcomes of *G. inodorum* tea. The characteristics of the subjects in the present study including age and obesity were similar to other studies.⁽¹⁵⁻¹⁸⁾ The average total energy intakes of male and female subjects throughout the study were 1570.8

± 663.1 and 1331.3 ± 470.7 Kcal/day respectively which were lower than Thai DRI recommendation (male = 2,100 Kcal/day and female = 1,750 Kcal/day).⁽¹⁹⁾ Percentages of energy distribution in the present study were similar to the recommendation for diabetic patients which states that the suitable energy distribution is 50-55% of total energy from carbohydrate, 10 - 20% of total energy from protein, and 25 - 35% of total energy from fat.⁽⁴⁾ However, the amount of dietary fiber consumed in the present study was lower than the recommendation (25 g/day).⁽¹⁹⁾ As the consumption of dietary fiber has an inverse relationship with obesity and can improve insulin sensitivity and blood sugar level^(20, 21), too low dietary fiber intakes in the present study may lead to the inappropriate anthropometric parameters and blood sugar level.

Table 3. Biochemical parameters at week 0, 8, and 16.

Parameters	n	Week 0	Week 8	Week 16
FBS (mg/dl)	12	180.42 \pm 41.86 ^a	158.08 \pm 41.59 ^a	177.50 \pm 48.43 ^a
HbA _{1c} (%)	12	7.93 \pm 1.66 ^a	7.48 \pm 1.09 ^a	8.15 \pm 1.57 ^a
Total-C (mg/dl)	11	157.45 \pm 38.23 ^a	157.27 \pm 39.30 ^a	167.00 \pm 37.44 ^a
HDL (mg/dl)	11	41.54 \pm 7.27 ^a	42.00 \pm 10.38 ^a	40.91 \pm 11.35 ^a
LDL (mg/dl)	11	84.16 \pm 21.11 ^a	82.00 \pm 31.11 ^a	90.22 \pm 26.79 ^a
TG (mg/dl)	10	133.00 \pm 65.01 ^a	118.50 \pm 64.12 ^a	133.50 \pm 56.98 ^a
ALT (U/l)	11	30.82 \pm 12.82 ^a	27.82 \pm 12.68 ^a	32.36 \pm 15.21 ^a
AST (U/l)	11	23.82 \pm 8.80 ^a	22.00 \pm 8.48 ^a	23.09 \pm 8.29 ^a
SCr (mg/dl)	11	1.11 \pm 0.19 ^a	1.13 \pm 0.21 ^a	1.07 \pm 2.22 ^a

Values are expressed as mean \pm SD.

mg/dl = milligram/deciliter, U/L = international unit/liter

Different superscript letters in the same row show statistically significant different ($p < 0.05$).

As there were no significant differences of nutrients and caloric intakes throughout the study, the effect of consumed food on blood sugar level and lipid profiles may be omitted. FBS and HbA_{1C} at week 0, 8, and 16 did not differ significantly. So, *G. inodorum* tea had no effect on blood sugar level in type 2 diabetic patients while in the study by Chiabchalard et al.⁽⁸⁾ found that it can reduce blood sugar level. The inconsistent result of both studies may be arisen from two factors. First, the subjects in this study were type 2 diabetic patients who had hypoglycemic drugs and abnormal anthropometric parameters while the subjects in the other study were healthy. Second, the carbohydrate intakes of the subjects in this study and the other were different. Given that the subjects in this study consumed 3 meals of food per day, the average carbohydrate intake per meal was 289.81 Kcal, while the standard meal used in the other study provided 225 Kcal. As Chiabchalard et al.⁽⁶⁾ discussed that the hypoglycemic effect of *G. inodorum* was dose-dependent, the dose of *G. inodorum* tea used in this study may be insufficient.

When the result of the present study was compared to those of *G. sylvestre* which is the medicinal plant in the same genus and has similar hypoglycemic triterpenoid saponins, it is still inconsistent. There are some factors that contribute to the different result. First, the dosage forms used in the present study and other studies were different. The present study used tea while those studies used extract or powder. So, the subjects in other studies may receive more hypoglycemic phytochemicals than those in the present study. Second, the average diabetic duration of the subjects in this study was more than other studies.^(22 - 24) Moreover, the more diabetic duration may affect the efficacy of *G. inodorum* tea

as the study from Japan showed that the more the diabetic duration was, the more FBS and HbA_{1C} levels were.⁽²⁵⁾

In this study, *G. inodorum* tea had no effect on lipid profiles because there were no significant differences of total-C, HDL, LDL, and TG throughout the study. To date, there are no both in vivo and clinical studies about the effect of *G. inodorum* on lipid profiles. So, the studies of *G. sylvestre* are used in this discussion. The study about the effect of *G. sylvestre* extract in rats showed that the extract could reduce total-C, LDL, TG, and very-low-density lipoprotein (VLDL). It also increased HDL.⁽²⁶⁾ The clinical study by Baskaran et al.⁽²²⁾ revealed that *G. sylvestre* alcoholic extract could reduce total-C, TG, phospholipids, and free fatty acids after the use of the extract about 18 - 20 months.

Effect of the consumption of *G. inodorum* tea on hepatic function was evaluated by AST and ALT. Hepatic injuries increase the activity of both enzymes in the serum.⁽²⁷⁾ There were no significant differences in both enzymes throughout the study. This indicated that *G. inodorum* tea did not have deleterious effects on the liver. The result was consistent with the study by Chiabchalard et al.⁽⁶⁾ which found that *G. inodorum* tea had no effect on liver function of healthy subjects. SCr, the product of creatine and phosphocreatine breakdown in muscle, is excreted through the kidney and had inverse relationship to the glomerular filtration rate.⁽²⁸⁾ SCr did not significantly change throughout the study and did not exceed the normal range. So, it could infer that *G. inodorum* tea had no effect on kidney function. This was consistent with the vivo studies in rats which found that *G. sylvestre* extract had no effect on renal function.^(29 - 30)

This study has some limitations, however. First, the sample size was relatively small and the study duration was short. Second, the parameters used in this study could be affected by other factors. For example, the nutrients and caloric intakes from 3-day dietary record may either be affected by the estimation of consumed amount by subjects or the investigators.⁽³¹⁾ SCr may also be affected by age, sex, exercise, some drugs, muscle mass, nutritional status, and meat intake.⁽²⁸⁾ Lastly, physical activities which also affect the glycemic control or other outcomes were not evaluated throughout the study.

Conclusion

The consumption of *G. inodorum* tea for 8 weeks had no effect on the level of blood sugar. It also did not affect lipid profiles, hepatic and renal functions. Further studies that use higher doses of *G. inodorum* tea, more subjects and/or longer durations are needed to evaluate the effect of *G. inodorum* tea on the mentioned parameters.

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