Data Article

Data on effect of Tempeh Fermentation on patients with type II diabetes

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A B S T R A C T

Type II diabetes (T2D) arises through insulin resistance and a progressive decrease in insulin secretion, which may be partly related to pancreatic beta-cell function decline, obesity, and eventual hyperglycemia [1]. The first line for managing hyperglycemia in patients with T2D includes lifestyle modifications and metformin monotherapy. However, many patients still showed poor glycemic control due to progressive deterioration during the course of T2D [2, 3]. On streptozotocin-induced T2D rats, tempeh fermentation has been shown to be a potentially beneficial dietary supplement for abnormal carbohydrate metabolism [4]. This study was a prospective open-label clinical trial. The data were collected from Kaohsiung Veterans General Hospital Pingtung Branch, Taiwan from August 2018 to July 2019. 35 eligible T2D participants with a mean age of 57.91 ± 10.17 years

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were enrolled. After taking 2 g tempeh capsules daily for a period of 3 months, the levels of HbA1C and triglyceride were noticeably decreased in the participants. A regression analysis revealed that cholesterol concentration had a significant positive correlation with the concentrations of LDL, but triglyceride concentration had a significant negative correlation with the concentrations of HDL in the pre- and the post-tempeh treatment.

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### Specifications Table

| Subject                        | Biological sciences |
|-------------------------------|---------------------|
| Specific subject area         | Type II Diabetes    |
| Type of data                  | Table               |
| How data were acquired        | This data was acquired from 35 eligible participants recruited from outpatient clinics at the Kaohsiung Veterans General Hospital, Pingtung Branch who provided informed consent before entering the study. |
| Data format                   | Raw, analyzed.      |
| Parameters for data collection| Physical indicators: age, height, weight, body mass index, and blood pressure Serum biochemical parameters: glycated hemoglobin A1C, fasting blood sugar, blood urea nitrogen, creatinine, glutamate oxaloacetate transaminase and glutamate pyruvate transaminase, triglyceride, cholesterol, high-density lipoprotein, and low-density lipoprotein |
| Description of data collection| HbA1c levels were measured using a high-performance liquid chromatography (HPLC) analyzer. AC sugar concentrations were determined using the glucose Hexokinase method. Fasting serum lipid profile [triglyceride, total cholesterol, HDL, and LDL], creatinine and BUN concentrations were measured using commercially available enzymatic reagents. |
| Data source location          | From Kaohsiung Veterans General Hospital Pingtung Branch, Pingtung, Taiwan |
| Data accessibility            | Data is within this article |

### Value of the Data

- The data presented new information about the use of dietary supplementation in type II diabetes patients.
- Reported data has the potential to guide future studies evaluating therapies of tempeh in diabetes.
- These data are useful to clinicians and academia for further research.

### 1. Data Description

A total of 44 patients with type II diabetes were screened for this prospective open-label trial between August 2018 and July 2019. Among them, 35 eligible participants were enrolled in the study (Fig. 1). The average age was 57.91 ± 10.17 years; body mass index (BMI) was 26.58 ± 3.70 kg/m²; mean arterial pressure (MAP) was 95.12 ± 9.88 (mmHg) (Table 1); glycated hemoglobin A1C (HbA1C) was 6.99 ± 0.14 (%), and fasting blood sugar (AC sugar) was 140.09 ± 4.18 (mg/dL) (Table 2).

There are many different types of tempeh. Different kinds of tempeh have different characteristics and nutritional changes which might yield different results [5]. To further investigate
the effects of this laboratory-made tempeh fermentation on diabetes, an analysis of serum biochemical parameters was made between the pre- and the post-tempeh treatment, the result of which are presented in Table 2. Compared with the pre-treatment, 2 g tempeh daily for a period of 3 months results in no significant differences in the levels of AC sugar (140.09 ± 4.18 vs. 136.68 ± 5.01 mg/dL, p = 0.251), blood urea nitrogen (BUN) (13.80 ± 0.67 vs. 13.92 ± 0.63 mg/dL, p = 0.757), creatinine (0.83 ± 0.04 vs. 0.83 ± 0.04 mg/dL, p = 0.539), glutamate oxaloacetate transaminase (GOT(AST)) (23.22 ± 1.35 vs. 27.06 ± 1.95 IU/L, p = 0.931), glutamate pyruvate transaminase (GPT(ALT)) (25.15 ± 2.27 vs. 31.03 ± 3.24 IU/L, p = 0.531), cholesterol (168.62 ± 5.53 vs. 165.03 ± 5.01 mg/dL, p = 0.781), high-density lipoprotein (HDL) (48.09 ± 1.82 vs. 48.79 ± 1.65 mg/dL, p = 0.243), and low-density lipoprotein (LDL) (109.85 ± 5.56 vs. 108.44 ± 5.05 mg/dL, p = 0.621). However, the level of HbA1C was noticeably decreased from the pre-treatment (6.99 ± 0.14 %) to the post-tempeh treatment (6.79 ± 0.14%, p = 0.038). Furthermore, the level of triglycerides was lessened from the pre-treatment (152.26 ± 10.77 mg/dL) to the post-tempeh treatment (131.29 ± 9.08 mg/dL, p = 0.039).

The correlation coefficients between the cholesterol, triglyceride, AC sugar, HDL, and LDL are shown in Table 3. In the pre- and the post-tempeh treatments, cholesterol concentration was positively and significantly correlated with the concentrations of LDL, but triglyceride concentration was negatively and significantly correlated with the concentrations of HDL.
Table 2
Baseline serum characteristics of diabetes population.

| Serum parameters    | pre-treatment | post-treatment | p values | Reference Range |
|---------------------|---------------|----------------|----------|-----------------|
| HbA1C (%)           | 6.99 ± 0.14   | 6.79 ± 0.14 *  | 0.038    | 4.2 - 6.0       |
| AC sugar (mg/dL)    | 140.09 ± 4.18 | 136.68 ± 5.01  | 0.251    | 70 - 110        |
| BUN (mg/dL)         | 13.80 ± 0.67  | 13.92 ± 0.63   | 0.757    | 7 - 20          |
| Creatinine (mg/dL)  | 0.83 ± 0.04   | 0.83 ± 0.04    | 0.539    | Male: 0.7 - 1.2 |
|                    |               |                |          | Female: 0.5 - 0.9|
| GOT(ALT) (IU/L)     | 23.22 ± 1.35  | 27.06 ± 1.95   | 0.931    | < 40            |
| GPT(ALT) (IU/L)     | 25.15 ± 2.27  | 31.03 ± 3.24   | 0.531    | < 42            |
| Triglycerides (mg/dL) | 152.26 ± 10.77 | 131.29 ± 9.08 | 0.039    | < 200           |
| Cholesterol (mg/dL) | 168.62 ± 5.53 | 165.03 ± 5.01  | 0.781    | < 200           |
| HDL (mg/dL)         | 48.09 ± 1.82  | 48.79 ± 1.65   | 0.243    | Male: > 35      |
|                    |               |                |          | Female: > 45    |
| LDL (mg/dL)         | 109.85 ± 5.56 | 108.44 ± 5.05  | 0.621    | < 130           |

Note: HbA1C, glycated hemoglobin; AC sugar, fasting blood sugar; BUN, blood urea nitrogen; GOT, glutamate oxaloacetate transaminase; GPT, glutamate pyruvate transaminase; HDL, high-density lipoprotein; LDL, low-density lipoprotein; Values are means ± SE.
* p < 0.05 vs. pre-treatment data by using the Wilcoxon matched-pairs signed rank test.

2. Experimental Design, Materials and Methods

2.1. Experimental Design and Patient Eligibility

The current prospective and open-label trial was reviewed and approved by the ethics committee of Kaohsiung Veterans General Hospital (IRB No. VGHKS18-CT7-31) on August 2, 2018. Study participants were recruited at the Kaohsiung Veterans General Hospital Pingtung Branch from August 2018 through July 2019. The major inclusion criteria included the following: a) patients between the ages of 45-75 years at the start of the study, b) an HbA1C of 6.5% or greater, and c) fasting plasma glucose readings of > 126 mg/dL. Participants were excluded because of allergy to soybeans, hyperuricemia, gout, or breast cancer. 44 eligible participants recruited from outpatient clinics provided their informed consent before entering the study. The flowchart designed for this clinical trial is shown in Figure 1.

2.2. Tempeh sample preparation and Interventions

Kaohsiung Number 9 soybeans were cleaned, washed, and soaked for 12 h, and the peel was removed. After washing thoroughly and added into boiling water containing 1% lactic acid for 30 min, followed by cooling to 37°C, the *Rhizopus oligosporus* (PT Aneka Fermentasi Industry, Bandung, Indonesia) was sprinkled on the soybeans and inoculated at 30°C in 1-2 cm thick plastic for 48 h. The fermented tempeh samples were then freeze-dried for 72 h, ground into a powder, and stored at 25°C for analysis. The fermented tempeh powder capsules, each weighing 500 mg, were encapsulated by Joben Bio-Medical Co., Ltd. After undertaking safety and quality testing to pharmaceutical standards, the study capsules were maintained in 25°C storage. The participants were instructed to take four capsules orally daily for a period of 3 months (Table 1).

2.3. Physical indicators assessments

The physical age, height, weight, body mass index, and blood pressure of all participants were analyzed to investigate the baseline characteristics of the diabetes population. Body height was measured in the normal standing position without shoes. Body weight was measured using a digital scale. Body mass index (BMI) was calculated from weight and height measures [weight
Table 3
The correlation coefficients between the cholesterol, triglycerides, fasting blood sugar, high-density lipoprotein, and low-density lipoprotein.

|                    | Cholesterol (mg/dL) | Triglycerides (mg/dL) | AC sugar (mg/dL) | HDL (mg/dL) | LDL (mg/dL) |
|--------------------|---------------------|-----------------------|------------------|-------------|-------------|
|                    | correlation coefficient | correlation coefficient | correlation coefficient | correlation coefficient | correlation coefficient |
| pre-treatment      | post-treatment      | pre-treatment         | post-treatment   | pre-treatment | post-treatment | pre-treatment | post-treatment |
| Cholesterol (mg/dL) | 1.000               | 1.000                 | 0.257            | 0.374        | -0.098       | 0.164        | 0.340         | 0.355         | 0.955$^*$ | 0.951$^*$ |
| Triglycerides (mg/dL) | 0.257               | 0.374                 | 1.000            | 1.000        | 0.392        | 0.349        | -0.439$^*$    | -0.472$^*$    | 0.238     | 0.310     |
| AC sugar (mg/dL)   | -0.098              | 0.164                 | 0.392            | 0.349        | 1.000        | 1.000        | -0.417        | -0.146        | -0.172    | -0.142    |
| HDL (mg/dL)        | 0.340               | 0.355                 | -0.439$^*$       | -0.472$^*$   | -0.417       | -0.146       | 1.000         | 1.000         | 0.196     | 0.214     |
| LDL (mg/dL)        | 0.955$^*$           | 0.951$^*$             | 0.238            | 0.310        | -0.172       | -0.142       | 0.196         | 0.214         | 1.000     | 1.000     |

Note: AC sugar, fasting blood sugar; HDL, high-density lipoprotein; LDL, low-density lipoprotein; Values are means ± SE.
$^*$ p < 0.05 vs. pre-treatment data by using a Multiple linear regression analysis.
Blood pressure was measured in a sitting position using an electronic sphygmomanometer. Mean arterial pressure (MAP) was calculated from the systolic blood pressure (SP) and diastolic blood pressure: (DP) measures as [(systolic blood pressure * 0.33) + (diastolic blood pressure * 0.66)].

2.4. Serum biochemical indicators of the studied participants

In order to investigate the effects of fermented tempeh on diabetes, the serum indicators (glycated hemoglobin A1C (HbA1c), fasting blood sugar (AC sugar), lipid profile (triglycerides, cholesterol, low-density lipoprotein (LDL), and high-density lipoprotein (HDL), liver function index (glutamate oxaloacetate transaminase (GOT(AST)) and glutamate pyruvate transaminase (GPT(ALT)), and renal function index (blood urea nitrogen (BUN), creatinine) were measured routinely in a health check-up program. 5 ml blood samples were collected after overnight fasting from the participants before and after the experiment. HbA1c levels were measured using a high-performance liquid chromatography (HPLC) analyzer in standard mode. AC sugar concentrations were determined using the glucose hexokinase method (Roche Instruments Inc.). Fasting serum lipid profile [triglyceride, total cholesterol, HDL, and LDL], creatinine and BUN concentrations were measured using commercially available enzymatic reagents.

2.5. Statistical analyses

SPSS 12.0 (SPSS Inc.) software was used for all of the statistical analyses. The Wilcoxon matched-pairs signed rank test used to compare differences between the pre- and post-tempeh treatments. A multiple linear regression analysis was used to examine the relationship between fasting blood sugar, triglyceride, total cholesterol, HDL, and LDL. Descriptive data are expressed as means ± SD. A p-value < 0.05 was considered statistically significant.

Ethics Statement

This current prospective and open-label trial was reviewed and approved by the ethics committee of Kaohsiung Veterans General Hospital (IRB No. VGHKS18-CT7-31).

CRediT Author Statement

Hui-Kan Su: Conceptualization, Methodology, Investigation, Data collection, Writing: Original draft preparation. Jian-He Lu: Data analysis, Writing: Original draft preparation, Ming-Hsien Tsai: Visualization, Data curation, Software, Reviewing, and Editing, How-Ran Chao: Visualization, Validation, Reviewing, and Editing, Mei-Li Wu: Supervision, Reviewing, and Editing.

Declaration of Competing Interest

This study was supported by Kaohsiung Veterans General Hospital (T110-009). All authors declare that they have no known competing financial interests or personal relationships that have or could be perceived to have influenced the work reported in this article.

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Supplementary Materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.dib.2021.107310.

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