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Effectiveness of Functional Foods Containing Bitter Melon Peptide in Blood Glucose Controlling: A Preliminary Study

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Abstract: Literature has confirmed the bitter melon is useful to reduce the levels of blood glucose. A functional food was developed by extracting critical ingredients from bitter melon with advanced techniques. The new ingredient was generally termed as bitter melon peptide, of which had been used as major component of the product in this research. Purpose of this research is testing the effectiveness of this new product in controlling the blood glucose levels of the diabetes mellitus (DM) patients. As a preliminary study, 25 samples were recruited on the basis of volunteer through the participated pharmacies, 52% are female and 80% are aged 45 and above. After a three months period of experiment, the data indicated significant differences in the values of HbA1c and FG between starting (T0) and second month (T2), and T0, and the third moth (T3). The test concluded that the product was effective in reducing blood glucose.

Keywords: Bitter melon peptide, functional food, diabetes mellitus, blood glucose, HbA1c

INTRODUCTION

Threats of Diabetes to the life

Unhealthy living patterns have made Taiwan an "Island of diabetes" with a terrible complication that places a heavy burden on health and medical costs. 2013-2016 National Nutrition Health Status Survey that issued by the Ministry of National Health and Welfare revealed that prevalence rate of diabetes is less than 5% for the national 19 to 44-year-old and over 10% for women and more than 18% for men for those aged 45 to 64. The prevalence rates for the elderly (> 65 years old) are astonishing at 27.7% and 24% for men and women respectively.

As far as the region concern, the prevalence rates of diabetes in mountainous areas are the highest among men and women, accounting for 19.5% and 20.7% respectively, while the prevalence rates of diabetes in the Northern Taiwan are the lowest, at 7.2% for men and 3.6% for women respectively. Diabetes mortality ranks fifth of the top 10 death causes, accounting for 5.7% of all deaths. About one in 55 minutes dies of diabetes.

According to the Taiwan Nephrology Yearbook 2015, the proportion of newly diagnosed dialysis patients with diabetes has increased from 33% in 2000 to 45% in 2013. This means every one of two new dialysis patients is caused by diabetes. Diabetes caused severe function impairments that are mostly irreversible to the body, such as blindness, neuropathy, cerebrovascular disease, coronary heart disease, arterial kidney function and sexual dysfunction, of which badly affects the patient's quality of life. Government statistics shows that there were 1,839,222 cases applied for reimburse in 2014 in Taiwan, spending a total of 39.1 billion NTD on health insurance. Number of diabetic patients is only 2.5% of the health insurance population, but these patients spend 11.5% of the total reimbursement payment. In average, the average payment per diabetic patients spend is 4.3 times over that of non-diabetic patients. Delaying the progress of diabetes mellitus would be beneficial not only for the patients and their family, but also for the society and the country. Effective ways to control the patient's blood glucose thus attractive good amount of studies in both of the academics and the industry. The current research reports the effectiveness of bitter melon peptide, a newly invented ingredient, in stabilizing the patient's blood glucose.

Diabetic pathogenesis

Insulin-dependent diabetes patients, the pancreas is unable to produce and supply sufficient insulin in response to the body requirement, also known as Type I diabetes. Patients with non-insulin-dependent diabetes are either insulin-deficient or insulin-resistant, is known as Type II diabetes. No matter type I or type II diabetes, the body will have the symptoms of hyperglycemia, and cause extra high levels of osmotic pressure. As a result, this will continuously cause damages to the human nervous system, resulting in the development of neurological and vascular lesions.

Glycosylated hemoglobin (HbA1c)

Glycosylated hemoglobin (HbA1C) as an indicator is to reveal a stable, long-term blood glucose change in the human body. It represents an average of two to three months in patients with blood glucose levels with good reliability and validity of glycemic control [1]. Normal HbA1C is around 4% to 6%, the American Diabetes Association (ADA) suggested the glycosylated hemoglobin (HbA1C) at 7% or less is a good level of control, yet level exceed 9.2% means badly control, and expose to the risk of complications and higher the mortality rate. HbA1C can be controlled within 7.2% of diabetic patients, not only can reduce the incidence of complications, but also can reduce the exacerbation of existing complications.

Bitter melon peptide for Diabetes Mellitus

Bitter melon (or Bitter gourd), is part of Cucurbitaceae with a scientific terms as *Momordica charantia L*., generally grows in the tropical and subtropical regions. It has been widely used in the traditional medicine in China, Japan, Southeast Asia, India, Africa, and Latin America among others to treat and prevent diseases such as diabetes, menstrual pain, gout, eczema, kidney stones, pneumonia, scabies and so on. Bitter melon contains chemical components including saponins, alkaloids, triterpenoids, sterols and proteins. Steroid saponin compounds, such as charantins, and some other protein components are recognized active in hypoglycemic [2].

Bitter melon contains hypoglycemic ingredients both in the fruit and its stems and seeds. Current research on bitter gourd in diabetes mellitus can reduce blood glucose in normal animals [3] and is resistant to *alloxan* and *streptozotocin*-induced hyperglycemia [4], or increase the function of the pancreas to achieve hypoglycemic effect [5].

Bitter melons regulate blood sugar is mainly performed by a small-molecular-weight protein [6]. Insulin-stimulated fat cells regulate the amount of glucose transport molecule (GLUT4) on the cell membrane via the two main pathways to promote the uptake of extracellular glucose into the cell. The captioned material is developed and produced by a local company, Greenyn Biotechnology. Unlike *Momordicin* or other commercially available regulatory blood sugar products, bitter melon of Greenyn is very first of the pioneers (if not the solo) of natural plant insulin that can target insulin receptors.

MATERIAL AND METHODS

Material

Objects are diabetes mellitus patients that are identified and confirmed by a physician, or those suspects who meet one of the following criteria, either FG is greater than 125 mg/dL or HbA1C is higher than 6.5 mmol/L. Objects are recruited by participating pharmacy through poster advertisement. There are 25 participants from 5 pharmacies in the west-central part of Taiwan.

Intervention material in this research is a newly invented products, termed as bitter melon peptide (BMP), of which was invented by local biotech company and have gained government license to sell in the market.

Object first examine the process of the experiment and signed the written consent to confirm the participation. The process starts with providing the object a blood biochemical examination (BBE) on the time enter into the research. A pack of bitter melon peptide (BMP) for a month was supplied free. The objects provide new BBE report before s/he comes for the second and third pack of BMP. By the end of the experiment, the objects provide the final BBE report. All BBEs are performed in the same laboratory. Items of BBE include total cholesterol, HDL-C, LDL-C, triglycerides, GOT, GPT, BUN, creatinine, glycohemoglobin (HbA1C), insulin, fasting blood sugar.

Methods

A descriptive analysis is conducted to present the profile of objects and other data information. A paired t test is performed to examine the differences of two periods to see whether the differences are significant or not. There are six pairs of comparison: 1. T0 (the beginning) and T1 (end of first month), 2. T0 and T2 (second), 3. T0 and T3 (third), 4. T1 and T2, 5. T1 and T3, and 6. T2 and T3. Gender of the objects is included to see the differences of change between men and women.

RESULTS AND DISCUSSION

Analysis

Objects in this research, as shown in table 1, are composed by 12 women and 12 men. There are 20 (or 80%) objects aged 45 and above, and 5 (20%) aged under 36. Distribution of age levels of the objects in this research is rather consistent to the national observation, of which the rate of suffering diabetes mellitus sharply upward after the age of 40. There are 7 objects are 67 and older, representing 28% of the total samples. It is roughly consistent to the distribution as well.

Table-1: Profile of objects

	Category	n	%
Gender	Male	12	48.00
	Female	13	52.00
Age	33	2	8.00
	36	3	12.00
	45	4	16.00
	52	3	12.00
	58	3	12.00
	59	3	12.00
	67	1	4.00
	74	3	12.00
	82	3	12.00
	Sum	25	100.00

Paired t-test analysis

The study conducts several paired t-test analyses to examine the effectiveness of intervention. Table 2 shows selected information regarding the objects. WE observed the FG, HbA1C to examine the effectiveness of intervention. In the meantime, we monitor the indicator of Creatinine for the health of kidney. Data in table 2 reveals that average FG values are decreasing month by month from 119.76 at the starting to 108.32 at the end of experiment. HbA1C values are decreasing as well from 7.49 at the starting to 7.00 at the end.

Table-2: Data profile of objects

	n	Min.	Max.	Avg.
Height (cm)	25	157.00	172.00	164.44
Weight (kg)_T0	25	57.80	81.00	67.73
Weight _T1	25	54.90	80.00	66.08
Weight _T2	25	57.00	80.30	65.80
Weight _T3	25	55.00	80.10	65.38
FG(mg/dl)	25	82.00	189.00	119.76
FG_T1	25	83.00	202.00	115.40
FG_T2	25	68.00	175.00	108.80
FG_T3	25	81.00	189.00	108.32
HbAlc(%)_T0	25	6.70	9.30	7.49
HbAlc_T1	25	6.50	9.00	7.35
HbAlc_T2	25	6.50	8.90	7.17
HbAlc_T3	25	6.40	8.20	7.00
Creatinine(mg/dl)_T0	25	.84	9.90	1.97
Creatinine_T1	25	.87	6.00	1.77
Creatinine_T2	25	.90	9.80	2.06
Creatinine_T3	25	.92	5.70	1.64

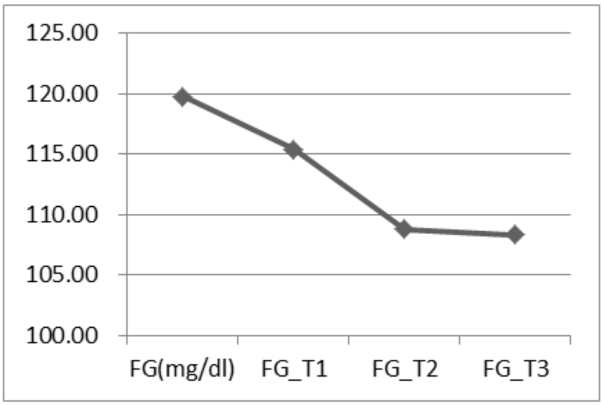

Fig-1: Average changes of FG

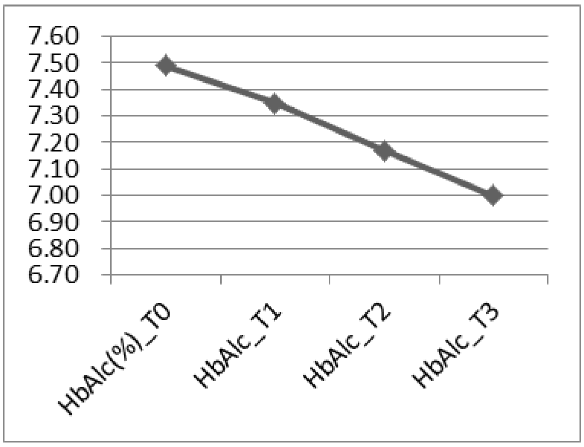

Fig-2: Average changes of HbA1c

Intervention is effective

In diabetes mellitus, higher amounts of glycated hemoglobin, indicating poorer control of blood glucose levels. Therefore, HbA1C is one the most reliable indicator for health professional to monitor the patient's glucose levels, and usually is included as an important factor for physicians to monitor the incurrence or progress of cardiovascular disease, nephropathy, neuropathy, and retinopathy.

Table-3: Intervention is effective

Pairs	Periods	Differences					t	d.f.	p
		Avg.	SD	SE	95% CI				
					Lower	Upper			
1	HbAlc_T0- T1	0.14	0.23	0.05	0.04	0.24	2.98	24	.006
2	HbAlc_T0 - T2	0.32	0.40	0.08	0.16	0.48	4.03	24	.000
3	HbAlc_T0 - T3	0.49	0.50	0.10	0.28	0.70	4.87	24	.000
4	HbAlc_T1 - T2	0.18	0.29	0.06	0.06	0.30	3.10	24	.005
5	HbAlc_T1 - T3	0.35	0.36	0.07	0.20	0.50	4.85	24	.000
6	HbAlc_T2 - T3	0.17	0.35	0.07	0.03	0.31	2.49	24	.020

HbA1c values significantly improved in pairs 2, 3, 4, and 5, and not significant for the pairs of 1 and 6.

Pair 1, represents the difference between T0 and T1. This indicates the effect is not significant one month after the intervention, yet the figure shows improvement in average. Noteworthy is the value of glycated hemoglobin is measured primarily to identify the two to three-month average plasma glucose concentration.

Pair 2, represents the difference between T0 and T2. This indicates the intervention starts to help drawing down the glucose levels two months after the intervention.

Pair 3, represents the difference between T0 and T3. Comparing with the data of pairs 2 and 3, pair 3 can be interpreted as the intention remains effective, although the increase is not as high as the second month (pair 2).

Pair 4, represents the difference between T1 and T2. This indicates the effectiveness significantly increases in the second month of period. This consistent to the pair 2 that is showing a significant difference for the second month after intervention.

Pair 5, represents the difference between T1 and T3. Difference between the end of first month and the third month is significant, of which confirms the effectiveness of intervention starts to work and remain valid till the end.

Pair 6, represents the difference between T2 and T3. This can be interpreted as the intervention remains effective in the third month of period, yet the increase is not significant from T2 to T3.

CONCLUSIONS

Statistics analysis of the bitten melon peptide as intervention to examine the changes of HbA1c in each individual period has been proved to be effective. Bitter melon peptide has positive effects in help stabilizing the object's glycated hemoglobin levels. Although change of HbA1c in the first month intervention is not statistically significant, a lower level of HbA1c has been observed. It is concluded that the bitter melon is helpful in controlling the diabetes mellitus patient's blood glucose levels. The intervention starts working in the second month, and the effectiveness remain valid along with the repeat taking of the intervened material.

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