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HUMAN CLINICAL STUDY OF *ALOE VERA* RAW GEL (THE ALOE PRIME ALOE GEL™) ON BLOOD LIPIDS AND OBESITY

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ABSTRACT

This study was designed to investigate the effects of *Aloe vera* raw gel (THE ALOE PRIME ALOE GEL™) on blood lipid concentrations and obesity. Obesity is a major health concern in the modern world, and triglyceride and cholesterol levels in particular are strongly associated with cardiovascular disease. In this context, it is important to determine the potential health-improving effects of *Aloe vera* gel. The study was conducted on 47 adult men and women, of which 30 were included in the final analysis. The aim of the study was to evaluate the effects of *Aloe vera* gel on blood lipid concentrations and body markers. The experimental group consumed *Aloe vera* gel for eight weeks, and blood triglyceride, total cholesterol, HDL cholesterol, and LDL cholesterol concentrations were measured. Changes in body weight, BMI, and waist and hip circumference were also recorded. The results showed that triglycerides, total cholesterol, and LDL levels decreased and HDL cholesterol levels increased in the *Aloe vera* gel group compared to the control group. Physically, BMI, weight, and hip and waist circumference decreased compared to the control group. This study suggests that *Aloe vera* gel may have potential benefits for weight management and metabolic health, and provides an important basis for the development of dietary supplements.

KEYWORDS: *Aloe vera*, Gel, Triglyceride, Cholesterol, Physical Measurements.

INTRODUCTION

Over the past decade, the prevalence of obesity has continued to increase in both adult men and women. In 2021, the prevalence of abdominal obesity in adults aged 20 years and older was 38.4%. The prevalence among women was 27.8% and 49.2% among men, meaning that one out of every two adult males is obese.[1] Thus, obesity has already emerged as a major problem in our society. Furthermore, obesity has a significant impact on quality of life and lifespan,

as it can lead to diabetes, hypertension, hyperlipidemia, coronary artery disease, degenerative arthritis, sleep disorders, and sleep apnea syndrome.[1-3]

Triglycerides are stored in the hypodermis of the body and are used as a source of energy when needed. However, excessive calorie intake or low calorie expenditure are converted to triglycerides and accumulate, causing hypertriglyceridemia.[4] The accumulation of triglycerides in blood vessels contributes to various cardiovascular diseases, and triglycerides stored in fat cells are very stable and contribute to abdominal obesity.[5,6] Abdominal obesity can lead to metabolic disease, a clustering of risk factors for cardiovascular disease and diabetes.[7] This leads to insulin resistance due to excess calories and lack of exercise, and elevated insulin in the blood contributes to additional metabolic disorders, including diabetes, hypertension, and lipid abnormalities.[8]

Currently, more than 95% of adults have triglyceride levels between 150 and 500 mg/dL, which is between normal triglyceride levels and hypertriglyceridemia.[9] However, treatments for triglycerides are prescribed only for patients with levels above 500 mg/dL, but they are rarely prescribed due to side effects, and there are not many competing dietary supplements, let alone pharmaceuticals.[10,11] Therefore, there is an increasing interest in the development of biohealth materials rather than pharmaceuticals, which require a long development time, to induce triglyceride improvement through diet and alcohol control.[12,13]

Aloe is a perennial succulent plant that botanically belongs to the Liliaceae. It's one of the oldest cultivated plants because it's easy to grow in harsh climates. There are more than 500 species of aloe plants worldwide, but only six or seven are edible. In Korea, *Aloe vera*, *Aloe Aponaria*, and *Aloe Arborescence* are allowed to be sold as health functional foods. Among them, *Aloe vera* is the most commercialized variety in Korea and is mainly used in gel form.[14] Substances from the sap of *Aloe vera* leaves are used for therapeutic purposes. The leaves contain two components, gel and latex, which differ in chemical composition and properties. The gel contains polysaccharides such as glucomannans, pectic acid, and other organic and inorganic compounds.[15,16] Therefore, *Aloe vera* gel can have a positive effect on several health problems related to metabolic syndrome. *Aloe vera* may have glycemic control effects in diabetics, helping to lower blood glucose levels and improve insulin sensitivity[17,18]; it may also have effects on chronic diseases associated with metabolic syndrome, reducing inflammation and improving metabolic function[19]; it may help to increase basal metabolic rate, helping to restore immunity, especially in the winter due to the cold and lack of exercise; and it may help to recover from fatigue and eliminate toxins from the body due to overwork.[20,21] However, *Aloe vera* gel has not been clinically proven to improve many of these metabolic conditions, so more scientific evidence is needed.

Therefore, we manufactured *Aloe vera* raw gel (THE ALOE PRIME ALOE GEL™, KimJeongMoon Aloe Ltd, 20150010021) through a continuous filtration process and planned a human clinical trial on the function of regulating blood lipid concentration based on the results of the pilot human trial. Through this study, we scientifically verified the link between the lipid-lowering function, human intestinal health and the cholesterol-lowering function of *Aloe vera* gel, and evaluated the effectiveness and safety.

MATERIALS AND METHODS

This study was approved by the Jeonbuk National University Hospital Functional Food Clinical Support Center (IRB No. 2024-07-005-011) and conducted between May 7 and July 10, 2024, in accordance with FDA clinical trials guidance.

1. Study Population

The study was open to adult men and women aged 18 to 65 years with blood triglyceride levels greater than 200 mg/dL and less than 500 mg/dL. Subjects were excluded if they had systemic diseases such as metabolic disorders or tumors, had taken or were currently taking metabolic medications within 2 weeks prior to study entry, had psychiatric disorders that would make them unable to comply with the study, had metabolic disorders that could affect the evaluation of efficacy, or had any other joint disease that was deemed incompatible with participation in this study. Subjects gave agreement after being fully informed of the need for the study, its procedures and possible side effects. Subjects were withdrawn from the study midway through the study if they received any medication that could be expected to affect the evaluation of the safety and efficacy of the investigational product, if they requested that the investigational product be discontinued during the study, if they withdrew their consent to participate in the study, if they experienced a serious adverse event, if a new protocol violation, including inclusion/exclusion criteria, was discovered during the study, if they took any concomitant prohibited medications during the study, or if the principal investigator/responsible person deemed it necessary to stop the study.

2. Test substance (THE ALOE PRIME ALOE GEL™) preparation process

The raw leaves of *Aloe vera*, which are 3-5 years old, are collected from the Jeju farm of KimJeongMoon Aloe, and only those suitable for human consumption are carefully selected and screened, washed three times with purified water in a KGMP facility, and then peeled and cut into small pieces using continuous filtration. After that, aloe gel, aloe gel powder, and auxiliary ingredients are mixed according to the formulation ratio in the Table1 below. The mixed gel is transferred to the sterilizer using a transfer pump and sterilized at 85±5ºC for 20 minutes to obtain aloe gel.

Table 1: Formulation ratios of raw materials and ingredient.

Raw material / Ingredient	Combination Ratio (%)	Remarks
Aloe Gel	93.36%	Functional component content: 0.06%
Aloe Gel Powder	0.71%	Functional component content: 9%
High Fructose Corn Syrup(HFCS)	3.35%	
Pear Extract	1%	
Lemon Extract	0.95%	
Xanthan Gum	0.3%	
The other Processed Products	0.2%	Mixed Scutellaria baicalensis Extracts
Scutellaria Baicalensis Root Extract	36.8%	Root
Glycyrrhiza Uralensis(Licorice) Root Extract	27.2%	Root
Dextrin	10%	
Lactic Acid	10%	
Zizyphus Jujuba Fruit Extract	8.8%	Root

Astragalus Membranaceus Extract	7.2%	Root
Grapefruit Seed Extract	0.1%	Glycerin 59.1%, Seed Extract 40%, Pure water 0.9% Grapefruit
Vitamin C	0.03%	

3. Validity Evaluation

The test substance used in this study was THE AlOE PRIME ALOE GEL by KimJeongMoon Aloe, which is a highly concentrated gel extracted from *Aloe vera*. The aloe gel was provided to the subjects in liquid form, and they took 45 mL of liquid twice daily for a total of 8 weeks. The following measures were taken at 0, 4, and 8 weeks.

1) Serum Lipid Test (PP)

Triglyceride, total cholesterol, HDL-cholesterol, LDL-cholesterol concentrations were measured using Sigma-Aldrich's kit.

2) Physical Measurements Test

Weight, body mass index (BMI), waist circumference, and hip circumference were measured according to the THE KOREAN ASSOCIATION OF MEDICAL TECHNOLOGISTS and WHO guidelines.

RESULTS AND DISCUSSION

1. Study Population

A total of 47 subjects were screened and no subjects were excluded. Therefore, 15 subjects were allocated to the treatment group and 32 to the control group according to the randomization table. During the course of the study, 17 subjects were dropped from the control group based on the dropout and withdrawal criteria, resulting in a final total of 30 subjects, 15 in the control group and 15 in the test group.

2. Validity Evaluation

1) Serum Lipid Test (PP)

The results of concentrations of blood triglycerides, total cholesterol, HDL cholesterol, and LDL cholesterol are shown in Table 2. Triglycerides decreased by 53.83 mg/dl in the test group and increased by 6.82 mg/dl in the control group, but there was no statistically significant difference between the two groups (p=0.215). Total cholesterol also increased by 0.50 mg/dl in the treatment group and 18.27 mg/dl in the control group, with a greater increase in the control group, but not statistically significant (p=0.185). Comparing HDL- cholesterol in the treatment and control groups after 8 weeks, there was a 2.83 mg/dl increase in the treatment group and a 1.91 mg/dl increase in the control group, with no significant difference between the groups (p=0.742). LDL-cholesterol decreased by 1.00 mg/dl in the treatment group and increased by 9.00 mg/dl in the control group, with no statistically significant difference between the two groups (p=0.387). When comparing pre- and post- treatment changes within each group, the experimental group showed a statistically significant change in triglycerides from pre-treatment to 8 weeks (p=0.029), and the control group showed a statistically significant change in total cholesterol after 8 weeks (p=0.023).

Table 2: Serum lipid (Triglyceride, Total Cholesterol, HDL-Cholesterol, LDL-Cholesterol) test results.

Experimental Group (n=15)			Control Group (n=15)	p-value
Triglyceride(mg/dl)	0wk	277.67 ± 49.37	302.45 ± 71.32	0.463
	4wk	207.33 ± 64.79	318.55 ± 160.57	0.129
	8wk	223.83 ± 52.19	309.27 ± 128.87	0.145
	8wk-0wk	-53.83 ± 43.39	6.82 ± 108.86	0.215
	p-value	0.029	0.840	
Total Cholesterol (mg/dl)	0wk	223.00 ± 34.67	188.64 ± 48.00	0.145
	4wk	218.33 ± 29.61	189.45 ± 40.34	0.146
	8wk	223.50 ± 30.68	206.91 ± 45.50	0.439
	8wk-0wk	0.50 ± 29.73	18.27 ± 22.59	0.185
	p-value	0.969	0.023	
HDL-Cholesterol (mg/dl)	0wk	41.17 ± 9.17	41.55 ± 7.55	0.928
	4wk	44.83 ± 10.67	39.09 ± 7.18	0.203
	8wk	44.00 ± 9.72	43.45 ± 9.06	0.909
	8wk-0wk	2.83 ± 4.17	1.91 ± 5.97	0.742
	p-value	0.157	0.314	
LDL- Cholesterol (mg/dl)	0wk	163.33 ± 28.74	134.09 ± 41.99	0.151
	4wk	160.67 ± 27.49	134.73 ± 36.84	0.154
	8wk	162.33 ± 26.40	143.09 ± 32.15	0.231
	8wk-0wk	-1.00 ± 24.13	9.00 ± 21.00	0.387
	p-value	0.923	0.186	

2) Physical Measurements Test

After 8 weeks, the subjects' weight, BMI, and waist/hip circumference were analyzed.

Weight change in the control group without aloe gel was, from 73.47 ± 6.65 at baseline, 72.87 ± 6.49 after 4 weeks, to 72.51 ± 7.09 after 8 weeks, a weight gain of 0.32 kg over 8 weeks.

The aloe gel treatment group weighed 77.48 ± 8.98 before treatment, 77.35 ± 8.28 after 4 weeks, and 77.80 ± 9.45 after 8 weeks, a weight loss of 0.96 kg over 8 weeks. When comparing the test and control groups, the aloe gel group lost more weight, but the difference was not statistically significant (p=0.057).

Comparing the BMI after 8 weeks, the test group lost 0.34 kg/m^2, from 25.74 ± 2.18 to 25.54 ± 2.18 after 4 weeks to 25.40 ± 2.3 after 8 weeks, and the control group lost 0.11 kg/m^2, from 27.14 ± 2.30 after 4 weeks to 27.10 ± 2.14 after 8 weeks to 27.25 ± 2.54, showing a statistically significant difference between the two groups. (p=0.048).

After 8 weeks, waist circumference changed over time to 92.36 ± 6.82, 90.59 ± 6.15, and 89.91 ± 6.79 in the experimental group, a decrease of 0.45 cm, and 90.33 ± 5.49, 89.58 ± 5.04, and 90.00 ± 5.48 in the control group, a total decrease of 0.33 cm, with no significant difference between the groups (p=0.215).

Finally, hip circumference decreased by 1.41 cm in the treatment group from 98.82 ± 4.31 at baseline, 98.05 ± 3.5 at week 4, and 97.41 ± 4.01 at week 8, and decreased by 0.17 cm in the control group from 100.83 ± 5.19 at baseline, 100.50 ± 5.54 at week 4, and 100.67 ± 5.19 at week 8, with no statistically significant difference between the groups.(p=0. 250)

Therefore, when comparing the pre- and post-test changes within the group, the test group showed statistically significant changes in body weight and BMI from pre- to post-test (p=0.045, p=0.039), while the control group showed no significant changes within the group. (p=0.345, p=0.328. p=0.235)

The reason Aloe gel consumption has been linked to weight loss and BMI reduction is that it contains Anthraquinone, such as Aloin and Barbaloin. These ingredients can help stimulate digestive system movement, relieve constipation, and promote the elimination of toxins from the body. This active movement of the digestive system can boost metabolic processes. Aloe gel also contains high amounts of polysaccharides, and studies have shown that polysaccharides can boost the immune system, have anti-inflammatory effects, and boost metabolism. This may have a positive impact on weight management and energy expenditure. Finally, aloe gel may have contributed to weight loss and BMI reduction by regulating blood sugar levels.[22-24]

The lack of significant changes in waist and hip circumference may be due to the fact that fat loss in specific areas is more difficult to achieve in the short term than total body weight loss. In addition, waist and hip circumference reduction is not only influenced by diet, but also by exercise and lifestyle habits. Therefore, if the subjects had different levels of exercise or activity in their daily routine, this could affect fat loss in specific areas.

The results of the efficacy evaluation did not demonstrate a significant difference between the control and test groups. This may be due to the relatively small sample size, the relatively short duration of the study, and the fact that the dietary and lifestyle habits of the subjects were not fully controlled for in this study, which may have prevented some results from reaching statistical significance. Therefore, future studies should consider these factors to more clearly evaluate the effects of Aloe gel.

Table 3: Physical measurements and waist/hip circumference results (PP).

Experimental Group (n=15)			**Control Group (n=15)**	**p-value**
Weight (kg)	0wk	73.47 ± 6.65	77.48 ± 8.98	0.309
	4wk	72.87 ± 6.49	77.35 ± 8.28	0.235
	8wk	72.51 ± 7.09	77.80 ± 9.45	0.210
	8wk-0wk	-0.96 ± 1.40	0.32 ± 0.74	0.057
	p-value	0.045	0.345	
BMI (kg/m^2)	0wk	25.74 ± 2.18	27.14 ± 2.30	0.235
	4wk	25.54 ± 2.18	27.10 ± 2.14	0.176
	8wk	25.40 ± 2.32	27.25 ± 2.54	0.149
	8wk-0wk	-0.34 ± 0.47	0.11 ± 0.26	0.048
	p-value	0.039	0.328	
Waistline (cm)	0wk	92.36 ± 6.82	90.33 ± 5.49	0.542
	4wk	90.59 ± 6.15	89.58 ± 5.04	0.737
	8wk	89.91 ± 6.79	90.00 ± 5.48	0.978
	8wk-0wk	-2.45 ± 3.93	-0.33 ± 0.61	0.215
	p-value	0.065	0.235	
Hip Circumference (cm)	0wk	98.82 ± 4.31	100.83 ± 5.19	0.404
	4wk	98.05 ± 3.57	100.50 ± 5.54	0.282
	8wk	97.41 ± 4.01	100.67 ± 5.19	0.169
	8wk-0wk	-1.41 ± 2.27	-0.17 ± 1.51	0.250
	p-value	0.066	0.797	

CONCLUSION

The study examined the effects of *Aloe vera* gel on blood lipid concentrations and the body, and found that triglyceride levels decreased by -53.83 mg/dl in the experimental group and increased by 6.82 mg/dl in the control group. The test group also showed an increase in total cholesterol levels after eight weeks, but the increase was 13 mg/dl higher than the control group, indicating that *Aloe vera* gel may have an effect on cholesterol regulation. HDL cholesterol levels, which circulate in the blood and help prevent cardiovascular disease by clearing cholesterol buildup in peripheral

Vascular, increased more in the test group than in the control group, and changes in LDL cholesterol levels, also known as bad cholesterol, decreased in the test group and increased in the control group, suggesting that *Aloe vera* gel may help prevent disease by increasing the types of lipids the body needs and decreasing the types of lipids it doesn't need. In terms of physical changes, BMI and body weight were significantly reduced in the test group compared to the control group, indicating that *Aloe vera* gel may contribute to weight loss and BMI reduction. Waist and hip circumference also decreased in the test group compared to the control group, but the difference was not significant because the numbers were not large.

Given the limited sample size and short study duration of this study, some of the results did not reach statistical significance, and follow-up studies will require larger sample sizes and longer observations. In addition, the subjects' dietary habits and lifestyle were not controlled, which may have affected the results, so it is important to control these variables more strictly. Given the potential benefits of *Aloe vera* gel for weight management and improving metabolic health, this study provides an important foundation for the development of dietary supplements. However, future research will require additional clinical trials to more clearly validate these effects and find the optimal formulation and dosage. This suggests that *Aloe vera* gel could make a substantial contribution to preventing and managing conditions associated with obesity and metabolic syndrome.

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