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비만환아에서 복약기간에 따른 비만탕의 치료효과 비교연구

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Abstract

Comparisons of Effects of Biman-tang according to Administration Period in Childhood Obesity

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Objectives

The purpose of this study is to investigate the safety and effect of Biman-tang (BMT) on two different administration periods in the treatment of childhood overweight and obesity.

Methods

In retrospective study, 39 overweight and obese (85^{th} percentile ≤ Body Mass Index (BMI)) children were treated with BMT from January 2006 to April 2013 at Korean Medical Clinic in Suwon, Korea. The primary outcomes were the changes in BMI and Obesity Index (OI) from baseline to the treatment groups. Secondary outcomes included the changes in height, weight and safety of the medicine. Comparisons of BMI, OI, height and weight between the short-period (SP) treatment group and the long-period (LP) treatment group were done by using ANCOVA.

Results

The change of the mean of BMI (-0.5 ± 0.6 kg/m^2 vs -1.4 ± 0.8 kg/m^2, respectively; p=0.003) and OI (-3.6 ± 3.9% vs -9.7 ± 4.7%, respectively; p<0.001) showed significant reduction both in SP (n=16) and LP treatment group (n=23). The mean height showed no significant difference in both groups. The mean weight of LP treatment group showed significant reduction compared to SP treatment group (-0.2 ± 1.3 kg vs -1.6 ± 1.6 kg, respectively; p=0.006). Most of the children were compliant to the medication and no serious adverse events were found in two groups.

Conclusions

These findings emphasize that BMT is effective in the treatment of childhood obesity and it requires at least 45 days of treatment for the best result.

Key words : Children and adolescence, Obesity, Overweight, Korean traditional medicine, Herbal medicine

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Ⅰ. Introduction

Currently, the prevalence of obese and overweight children is increasing and the global health concern on the issue is escalating.[1)] Rapid increase of obesity in children and adolescents is also observed in Korea. The overall prevalence of overweight or obesity increased from 13.0% in 1997 to 19.0% in 2005 according to KNHANES III (The Third Korea National Health and Nutrition Examination Survey, 2005) and 2005 Korean children and adolescents' growth standard program.

Childhood obesity has been described as the primary childhood health problem in developed nations, having been linked to many serious physical, social and psychological consequences[1)]. These include the increased risk of cardiovascular dysfunction, type 2 diabetes, and pulmonary, hepatic, renal and musculoskeletal complications; lower health-related quality of life; negative emotional states such as sadness, loneliness and nervousness, and increased likelihood of engagement in high-risk behaviors; and undesirable stereotyping including perceptions of poor health, academic and social ineptness, poor hygiene and laziness[2-6)]. Childhood obesity is associated with not only current but also future morbidity[7)]. Around 70% of obese children become obese adults and childhood obesity increases the risk of adulthood cardiovascular and all-cause mortality.

Weight loss medications are an accepted adjunct to the usual approaches of dietary management and exercise[8)]. The use of pharmacotherapy of weight loss in children has been suggested[9-11)]. However, few drugs are currently approved for the treatment of obesity[12)]. Studies on the effect of herbal medicine in treating childhood obesity have been consistently reported. Most of studies were either based on short period of treatment[13-15)] or simply a result of preliminary survey without prescription[16)]. In addition to its modest efficacy, safety concerns including cardiovascular and psychiatric adverse events have restricted the use and development of several obesity drugs in children. Thus, medications that allow the safe and greater weight loss would be more desirable to both the patients and physicians.

Biman-tang (BMT), derived from Taeeumjowi-tang (TJT), is an herbal medicine for treating obesity. TJT, prescription listed in Donguisusebowon Tae-eumin pathology[17)], is reported to show a clinical effect in treating obesity[15,18-21)]. BMT is a prescription containing three herbs of *Ephedra sinica, Coix lacryma-jobi* and *Liriope platyphylla* derived from TJT with additional herbs to enhance its clinical effect on childhood obesity. TJT is known as a medication for Tae-eumin whereas BMT is showing clinical effect in other types of constitution as well. BMT is also shown to be effective in suppressing excessive exhalation nature of TJT.

In this study, we investigated the effects and safety of BMT on two different treatment periods in the treatment of childhood overweight and obesity.

Ⅱ. Materials and methods

A. Patients and Medication

1. Patients

We conducted a retrospective electronic chart analysis of the medical records of overweight ($85^{th} \leq$ Body Mass Index (BMI) $< 95^{th}$ percentile for age and sex) and obese (a BMI $\geq 95^{th}$ percentile for age and sex) children treated with herbal medicine from January 2006 to April 2013 at Korean Medical Clinic in Suwon, Korea.

Inclusion criteria were the followings: [1] children with a BMI $\geq 85^{th}$ percentile, [2] 4~11 years of age, [3] treated with herbal medicine based on BMT for at least 30 days, [4] recorded height and height before and after treatment, [5] had prescription of more than twice within three months. Exclusion criteria included: [1] diagnosis of diabetes mellitus (type 1 or type 2), [2] use of medications known to affect insulin sensitivity or glucose/lipid metabolism (metformin, insulin, growth hormone, etc.), [3] weight loss $\geq$ 3 kg in the last 3 months, [4] history of psychiatric disease, weight loss treatments within the last 6 months, genetic disease associated with obesity, cancer, blood disease and gastrointestinal surgery, [5] had been treated with corticosteroids, antidepressants, drugs for weight loss, nasal or respiratory anti-con-

Table 1. Prescription Contents of Biman-tang

Herbal prescription	Constituent herbs	Part	Amount (g)
Biman-tang	*Ephedra sinica* STAPF	STEM	4
	Trichosantes kirilowii MAXIM	FRUCTUS	4
	Coix lacryma-jobi var. mayuen (ROMAN.) STAPF	SEMEN	3
	Liriope platyphylla WANG et TANG	TUBER	2
	Asparagus cochinchinensis MERR.	HERBA	2
	Citrus unshiu MARKOVICH	PERCARPIUM	2
	Angelica gigas NAKAI	RADIX	2
	Schizonepet tenuifolia BRIQ.	HERBA	2

gestives, gastrointestinal prokinetics or antihistamines within 30 days prior to the first visit.

In order to evaluate the effects of BMT in obese and overweight children depending on the periods of treatment, they were divided into two groups of short-period (30 days) and long period (45~90 days). This study was exempted from IRB Review due to its retrospective study method.

2. Medication

Herbal medicine was individually prescribed by a KM Doctor who has been practicing medicine for 18 years. He had attended a number of continuing medical education lectures on evidence-based herbal medicine interventions. Each child received a personal diagnosis. The dried herbs were purchased from H Oriental Pharm Center (Yongin, Korea). The samples were identified by Seong Ku Youm Oriental Pharmacy.

The common basis of each prescribed herbal medicine was BMT. Table 1 shows the composition of BMT. For each hospital visit, medical examination was performed to modify the prescription either by adding or eliminating its herbal constituents. In case of rhinitis, *Magnolia denudate, Saposhnikovia divaricate* and *Mentha piperascens* were added to the medication. In case of constipation, *Rheum plamatum* and *Prunus persica* were included and for nausea, *Scutellaria baicalensis* was added. Fifteen days dose of herbal medicine was boiled with 4180~5380cc of water and a single dose of 80~120cc was administered twice a day.

3. Diet and Exercise Counseling

All children received the identical diet and exercise advices in the form of generalized instructions before the beginning of the medication. The KM doctor reviewed each topic of instructions with the children and their parent. The instructions were given to encourage the children to intake nutritionally balanced meals and avoid instant food as well as the food containing large amount of sugar, salt and fat. The children were recommended to have consistent amount of three balanced meals per day at regular time. All children were advised to perform 30 minutes of physical activity of their choice for at least 3 days per week. No additional counseling on the modifications of dietary or exercise behaviors was provided during the course of the treatment.

The changes of dietary intake and exercise behaviors before and after the treatment were recorded in terms of increased, unchanged and decreased.

B. Measures

The primary outcomes were the changes in BMI and Obesity Index (OI) from baseline to the treatment groups. Secondary outcomes included the changes in body height, weight and safety of the medicine.

Physical measurements were measured at the beginning and the end of the treatment. Body weight and standing height were measured by a trained medical assistant, wearing light weight clothing and no shoes in the upright standing position with heels together at a maximal inhalation. Body weight was measured on a calibrated mechanical scale with 0.01 kg gradations (CAS, Korea). Height was measured to the nearest 0.1 cm using a stadimeter (JENIX, Korea). BMI was calculated as weight in kilograms divided by the height in meters squared. And OI was calculated as (Actual weight-

Table 2. General Characteristics of Common Terminology Criteria for Adverse Events Grading

Grade	General characteristics
1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL.
3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL.
4	Life-threatening consequences; urgent intervention indicated.
5	Death related to AE.

Not all grades are appropriate for all AEs. Therefore, some AEs are listed with fewer than 5 options for grade selection. Instrumental ADL refers to a higher functioning level such as preparing meals, shopping for groceries or clothes, using telephone, or managing money. Self-care ADL refers to basic daily functions such as bathing, dressing and undressing, feeding self, using toilet, or taking medications.

Semicolon indicates 'or' within description of grade. ADL, Activities of Daily Living; AE, Adverse Event.

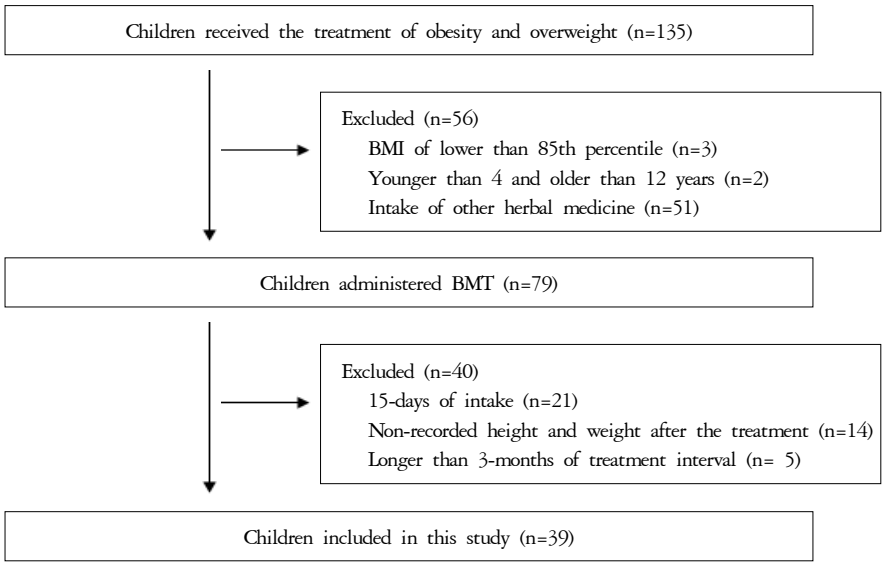

Figure 1. Flow chart

Average weight of each height sector)/ Average weight of each height sector*100. BMI percentile was expressed using a z-score based on the average weight of each height sector and gender-specific BMI for each age group in the 2007 Korean National Growth Charts[22].

C. Safety

Adverse events were recorded after the first 15 days of treatment and at the end of treatment. Children were encouraged to contact the doctor if any new symptoms were observed during the administration of herbal medicine as well as after the end of the treatment.

Safety and tolerability were analyzed using Common Terminology Criteria for Adverse Events (CTCAE). CTCAE v4.0 was published in May 2009[23]. Grade refers to the severity of the adverse event. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each adverse event based on this general guideline (Table 2).

D. Statistical Analysis

Data were analyzed using IBM SPSS Statistics 21 (SPSS Inc., Chicago, USA). The changes in baseline anthropometric data between pre-treatment and post-treatment were tested using paired *t*-tests. Comparisons of height, weight, BMI and OI between Short-period (SP) treatment group and long-period (LP) treatment group were made using ANCOVA, adjusted for covariates. The covariates were: (1) age, sex and percentile of variables at pre-treatment (height and weight variables); (2) age, sex and variables at pre-treatment (BMI and OI variables). Chi-square test for categorical variables was used to compare the rele-

Table 3. Characteristics of the Patients Included in the Present Study

	Short-period treatment group			Long-period treatment group			
	Male (n=6)	Female (n=10)	Total (n=16)	Male (n=13)	Female (n=10)	Total (n=23)	p-value
Age, months	87.8 ± 13.7	107.4 ± 22.9	100.1 ± 21.8	98.2 ± 26.2	97.9 ± 20.7	98.0 ± 23.4	0.787
Height, cm	124.7 ± 11.7	135.2 ± 9.5	131.3 ± 11.3	132.0 ± 11.8	127.9 ± 11.3	130.2 ± 11.6	0.780
Weight, kg	34.0 ± 9.1	41.4 ± 7.3	38.6 ± 8.5	43.9 ± 11.3	38.8 ± 11.6	41.7 ± 11.4	0.360
BMI, kg/m^2	21.4 ± 2.0	22.4 ± 1.5	22.1 ± 1.7	24.8 ± 3.1	23.3 ± 3.1	24.1 ± 3.1	0.012
OI, %	39.0 ± 22.5	44.3 ± 13.0	42.3 ± 16.7	61.4 ± 28.7	45.1 ± 23.2	54.3 ± 27.1	0.125

BMI, Body Mass Index; OI, Obesity Index. Values are mean ± SD. Independent t-test was used for analyzing changes on total data in both groups.

Table 4. Dose of *Ephedra sinica* Stapf in Biman-tang

Order of case	Total days	2 g	4 g	6 g	8 g	10 g	12 g	16 g	18 g
1	30	15	15						
2	30		30						
3	30		30						
4	30		15	15					
5	30		15	15					
6	30		15	15					
7	30		15	15					
8	30		15	15					
9	30		15	15					
10	30		15	15					
11	30		15		15				
12	30		15		15				
13	30		15		15				
14	30		15		15				
15	30			15	15				
16	30			15		15			
17	45		15	15	15				
18	45		15	15	15				
19	45		15	15		15			
20	45		15		15		15		
21	45		15				15	15	
22	45			15	15		15		
23	60	15	30	15					
24	60		15	30	15				
25	60		15	15	15	15			
26	60		15	15	15	15			
27	60		15	15	15	15			
28	60		15	15	15	15			
29	60		15	15	15		15		
30	60		15		15		15	15	
31	75	30	15	15		15			
32	75		15	15	15	15	15		
33	75		15	15	30	15			
34	75		15	15	15		30		
35	90	15	15	60					
36	90		30	30	15		15		
37	90		30	15	15	15	15		
38	90		15	15		15	15	15	15
39	90		15		30		30	15	

vance of the changes on dietary intake and exercise intensity between groups. Fisher's exact test was used to compare the relevance of the adverse effects between groups.

All statistical tests (two-tailed) were conducted at the 0.025 level of significance. All data are expressed as the mean ± standard deviation (SD).

Table 5. The Changes of BMI and OI

	Short-period treatment group			Long-period treatment group		
	Pre-treatment	Post-treatment	Δ value	Pre-treatment	Post-treatment	Δ value
BMI, kg/m^2	22.1 ± 1.7	21.6 ± 1.6*	-0.5 ± 0.6	24.1 ± 3.1	22.7 ± 3.1*	-1.4 ± 0.8^{++}
OI, %	42.3 ± 16.7	38.7 ± 16.9*	-3.6 ± 3.9	54.3 ± 27.1	44.6 ± 26.8*	-9.7 ± 4.7^{++}

BMI, Body Mass Index; OI, Obesity Index. Values are mean ± SD, $^{*}P<0.01$, $^{**}P<0.001$ versus pre-treatment group. $^{+}P<0.01$, $^{++}P<0.001$ versus SP treatment group. ANCOVA was used for analyzing changes in both groups.

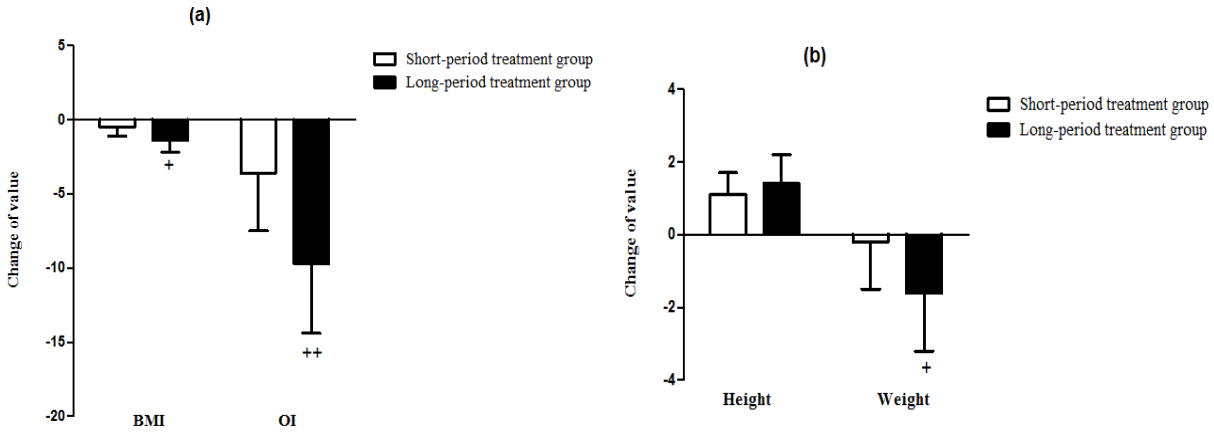

Figure 2. Comparison of SP treatment group and LP treatment group

Panel (a) shows the BMI and OI change and Panel (b) shows the height and weight change. Data are mean ± SD values. $^{+}P<0.01$, $^{++}P<0.001$ significantly different from SP treatment group. ANCOVA was used for analyzing hanges in both groups.

Ⅲ. Results

A. Patients

Out of 135 overweight and obese children admitted to Korean Medical Clinic from January 2006 to April 2013, 79 children were prescribed with BMT. The total number of the children included for the study was 39, and out of those children 19 were male and 20 were female (Figure 1). Table 3 shows the baseline characteristics of the patients. The mean BMI percentile of children was 97.5 ± 3.7% (range 87~100%).

B. Prescribed herbal medicine

Children were advised to come for hospital check-up once a week and the herbal medicine was prescribed in the interval of 15 days. SP treatment group was prescribed with the herbal medicine for 30 days and LP treatment group was prescribed for average of 65.2 ± 16.7 days. The amount of *Ephedra sinica* was either maintained or increased for each child. The amount of *Ephedra sinica* prescribed is shown in Table 4.

C. The changes of BMI and OI

Table 5 shows the changes of the mean BMI and OI. Compared to the result of SP treatment group, LP treatment group showed significant reduction of BMI (p=0.003) and OI (p<0.001), even after adjustments were made for the age, sex and baseline of value. The result comparison of SP treatment group and LP treatment group is shown in Figure 2(A). The mean changes of BMI and OI in total children were significantly reduced (-1.0 ± 0.8 kg/m^2 and -7.2 ± 5.3%, respectively; p<0.001). Of the 39 children, 36 (92.3%) had decreased the BMI change and 36 (92.3%) had decreased the OI change (Figure 3).

D. The changes of height and weight

Table 6 shows the changes of the mean height and weight. The mean height showed no significant difference in both treatment groups. Compared to the result of SP treatment group, LP treatment group showed significant reduction of body weight (p=0.006), even after adjustments were made for the age, sex and weight percentile at pre-treatment (Figure 2 (B)).

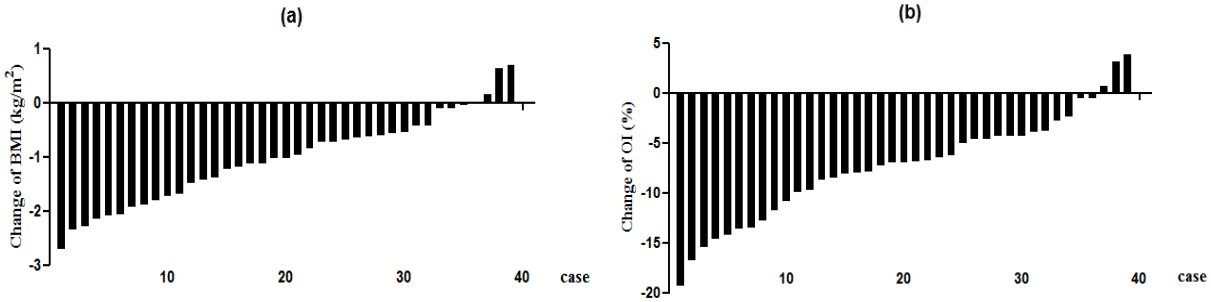

Figure 3. The Body Mass Index (BMI) (a) and Obesity index (OI) (b) changes of each child treated with herbal medicine, Biman-tang

Panel (a) shows the BMI changes of each child treated with BMT. The x axis indicates arbitrarily assigned children. The bars indicate the BMI changes from baseline. Panel (b) shows OI changes of children who were treated with BMT. The x axis indicates arbitrarily assigned children. The bars indicate the OI changes from baseline.

Table 6. The Changes of Height and Weight

	Short-period treatment group			Long-period treatment group		
	Pre-treatment	Post-treatment	Δ value	Pre-treatment	Post-treatment	Δ value
Height, cm	131.3 ± 11.3	132.4 ± 11.1**	1.1 ± 0.6	130.2 ± 11.6	131.6 ± 11.6**	1.4 ± 0.8
Weight, kg	38.6 ± 8.5	38.3 ± 8.3	-0.2 ± 1.3	41.7 ± 11.4	40.1 ± 11.1**	-1.6 ± 1.6^{+}

Values are mean ± SD, $^{*}P<0.01$, $^{**}P<0.001$ versus pre-treatment group. $^{+}P<0.01$, $^{++}P<0.001$ versus SP treatment group. ANCOVA was used for analyzing changes in both groups

Table 7. The Changes of Dietary Intake and Exercise Intensity Before and After the Treatment

Variable	Change	Number of patients	
		Short-period treatment group	Long-period treatment group
Physical activity level	Decreased	0	0
	Unchanged	9	9
	Increased	3	5
	Unknown	4	9
Dietary intake	Decreased	4	6
	Unchanged	5	10
	Increased	2	0
	Unknown	5	7

E. The changes of physical activity and dietary intake

The changes of physical activity and dietary intake are shown in Table 7. By the use of chi-square test, there were not significantly changes between groups.

F. Safety

Most of the children were compliant to the medication. No unexpected adverse events were observed. Only two children showed short-term mild gastrointestinal disorder and indigestion with stomachache, respectively. Other two children experienced mild nausea, but a child returned to normal. Another child was observed mild insomnia, but was able to sleep again after 3 days (Table 8). By the use of Fisher's exact test, there were not significantly changes between groups.

Ⅳ. Discussion

In this study, LP treatment group showed significant reduction in BMI, OI and weight compared to SP treatment group. The mean height showed no significant difference in both treatment groups and no unexpected and serious adverse events were observed in both groups.

In clinical practice, 30-days (1 month) of prescriptions were most common. And as the clinical trials were performed, it was assumed that LP treatment group were

Table 8. Adverse Events Based on Common Terminology Criteria for Adverse Events

CTCAEv4 term	Group	Grade		Number of patients (%)
Gastrointestinal disorders-Other, specify	SP	1	mild abdominal pain for 3 days at the first herbal medicine	2 (5.1)
	LP	1	mild indigestion for 5 days at the 4th herbal medicine	
Nausea	SP	1	mild nausea at the first herbal medicine	2 (5.1)
	LP	1	mild nausea in the morning at the 4th herbal medicine	
Insomnia	SP	1	mild insomnia for 3 days at the first herbal medicine	1 (2.6)

CTCAE, Common Terminology Criteria for Adverse Events; SP, Short-period treatment group; LP, Long-period treatment group.

showing clinically significant effect, compare to SP treatment group. Thus, the groups were divided into SP treatment group and LP treatment group to find out the most effective treatment period. In general, children with high BMI levels compared to with low BMI levels had long period-treatment. Therefore, in this study, baseline BMI of LP treatment group was significantly higher than of SP treatment group. Method of protection against chance bias is given by adjusting in the statistical analysis for baseline variables.

BMT, derived from TJT, is an herbal medicine prescribed to treat obesity. TJT is a prescription listed in Donguisusebowon Tae-eumin pathology[17]. It is reported to show a clinical effect in treating obesity[15,18-21]. BMT contains three herbs from TJT with *Trichosantes kirilowii* added in order to reduce Heated-water in body[24]. *Angelica gigas* and *Schinozepeta tenuifolia* from Fangfengtongsheng-san[25] are included as well to enhance its clinical effect in treating obesity. *Angelica gigas* in Samulansintang and *Citrus unshiu* in Ondamtang are known to treat stress-related obesity[26]. *Angelica gigas* is also effective in treating constipation that easily occurs during obesity treatment by helping a bowl movement. In animal test, *Citrus unshiu* with herbal combination reduced obesity in a high fat diet induced obese rat[27]. *Asparagus cochinchinensis* in Kamijowisengchungtang is commonly prescribed along with *Liriope platyphylla*, and it has been shown to be effective in treating obese children[28].

The previous clinical study of childhood obesity has been conducted based on short period of treatment[13-15]. According to other study[29] which investigated 19 overweight or obese children of the average age of 10.32 years, significant BMI reduction was observed after the treatment of 4 herbal prescriptions including TJT for the period of 4~8 weeks. In another study[30], 28 overweight children were studied to evaluate the clinical effect of I-razin, an herbal prescription, for 8 weeks. In this study, the longer periods of treatment and relatively low average age with the number of subject of relatively high should be noticed.

Ephedra sinica is highly effective in treating obesity. However, it is also known to cause many cases of adverse effects[31]. Some clinical studies have been conducted to investigate safe dose of *Ephedra sinica*[32-35]. In this study, any occurrence of adverse effect and the effect in the treatment of obesity were monitored as the dose of *Ephedra sinica* was gradually increased in two groups. But dose of *Ephedra sinica* were maintained within 24 g per a day according to Kim et al[33]. and total dose of *Ephedra sinica* for treatment period were considered[32]. In an animal study to evaluate clinical effect of different dose of *Ephedra sinica*, a significant weight reduction was observed in a group in which twice the dose of *Ephedra sinica* was added to the same prescription (TJT)[36]. In one of those studies, clinically reasonable dose of 12 g has been suggested[36]. However, it should be noted that those studies were merely a literary discussion or a clinical study on patient groups of older than 15 years. Although many clinical studies were conducted on adults between the age of 20 and 40 years, studies evaluating clinical effective and safe dose on children are not easily found. Adverse effects of BMT were mildly reported in five children. Three of them reported mild insomnia, mild abdominal pain and mild nausea when they were prescribed with herbal medicine containing 4 g of *Ephedra sinica*. The other two were prescribed with the medication containing 10 g and 16 g of *Ephedra sinica*, respectively. With 10 g of *Ephedra sinica*, mild indigestion was reported and

with 16 g, mild nausea was reported. Since there was no adverse effect with the herbal medicine containing less than 10 g of *Ephedra Sinica*, if there is no sign of adverse effect in the early stage of treatment, the clinical optimal amount of *Ephedra sinica* can be estimated.

The current recommendations for the treatment of overweight and obese children include increased physical activity and reduced calorie intake along with the behavioral program based on the family or the school life. Lifestyle programs can reduce the level of overweight in children[37-42]. However, the success of these lifestyle interventions is limited in that maintaining the results and adherence to treatment are difficult to achieve[43]. Therefore, besides herbal medicine prescription, exercise plans and diet-related overall lifestyle management were instructed for each individual child.

Its non-randomized study method, insufficient biochemical examination, no control group for efficacy of BMT and inadequate explanation on its mechanism in weight reduction are limits of this study. The analysis of body composition in children before and after the treatment, biochemical study as well as extended periods of treatment and its retrospective observation are to be further studied.

Ⅴ. Conclusion

We speculate that BMT is effective in the treatment of childhood obesity. And our results suggest that compared to SP treatment group, LP treatment group showed better result in reducing all of weight, BMI and OI, significantly. These findings emphasize that it is necessary to maintain the period of treatment for at least 45 days in treating childhood obesity.

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