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CLINICAL STUDY

Effect of modified fasting therapy on body weight, fat and muscle mass, and blood chemistry in patients with obesity

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Abstract

OBJECTIVE: The aim of this study was to investigate the effects and safety of modified fasting therapy using fermented medicinal herbs and exercise on body weight, fat and muscle mass, and blood chemistry in obese subjects.

METHODS: Twenty-six patients participated in a 14-day fast, during which they ingested a supplement made from fermented medicinal herbs and carbohydrates (intake: 400-600 kcal/d). The schedule included 7 prefasting relief days and 14 days of stepwise reintroduction of food. The patients also took part in an exercise program that incorporated Qigong, weight training, and walking exercises. The efficacy of treatments was observed by assessing body fat mass and muscle mass, and alanine aminotransferase (ALT), aspartate aminotransferase (AST), cholesterol, and triglycerides in each study period. Specific symptoms or side effects were reported.

RESULTS: Body weight and body fat mass both decreased significantly by (5.16 ± 0.95) and (3.89 ± 0.79) kg (both $P < 0.05$), while muscle mass decreased by an average of (0.26 ± 0.22) kg, without statistical significance. ALT levels were significantly decreased ($P < 0.05$), while AST levels decreased without statistical significance ($P = 0.052$). The levels of total cholesterol and triglycerides were also significantly decreased (both $P < 0.05$). There were few adverse events except for mild dizziness, which did not affect everyday living.

CONCLUSION: These results suggest that modified fasting therapy using fermented medicinal herbs and exercise could be effective and safe on obese patients.

Key words: Obesity; Fasting; Houttuynia Cordata; Saururus Chinensis; Exercise; Blood chemical analysis; Medicine, Korean traditional

INTRODUCTION

Obesity is generally defined as excess body fat, and is caused by complex interactions between the environment, genetic predisposition and personal behavior.[1] World Health Organization (WHO) estimates showed that in 2005, approximately 1.6 billion people worldwide were overweight, and at least 400 million adults were obese.[2,3] A greater body weight (BW) is associated with increased incidence of a number of conditions, including diabetes mellitus, cardiovascular disease, non-alcoholic fatty liver disease and an increased risk of disability. Evidence suggests that even a moderate amount of weight loss can be beneficial in terms of reducing levels of some negative risk factors, such as blood pressure.[1] The initial goal of weight loss therapy

for overweight patients is a reduction in BW and maintaining a lower BW over the long term. Effective weight control involves multiple techniques and strategies including dietary therapy, physical activity, behavior therapy, pharmacotherapy, and surgery.[4] Many studies of dietary and behavioral treatments, however, have shown that maintenance of weight loss is difficult.[1]

Among a variety of dietary treatments, very-low-calorie diet (VLCD) is an effective therapeutic method to efficiently reduce BW over a relatively short period of time. The VLCD is defined as intake of 400-800 kcal/d, and it focuses on minimizing protein loss.[5] However, low compliance rates due to side-effects such as hunger and short durability for weight loss, are major limitations of VLCD. Many experts recommend VLCD combined with exercise or behavioral treatments as an effective method for the management of obesity to maintain weight loss.[6-8] Recently, a new type of VLCD that includes fermented medicinal herbs and carbohydrates, which is based on fasting therapy of traditional Korean medicine, has attracted growing popularity in Korea as an effective method for the treatment of obesity. This modified fasting therapy (MFT) reduces stress because it satisfies basic energy demands of the essential organs (such as the brain and the heart) with carbohydrates, prevents overeating by preventing hunger, and helps maintain active bowel movements through enzymes and probiotics.[9,10] Despite the perceived advantages of MFT using fermented medicinal herbs, few clinical reports have examined this treatment.[11,12]

We describe the preliminary experience of the Obesity Clinic at Kyung Hee University Korean Medical Hospital in selected cases treated with MFT using fermented medicinal herbs combined with exercise therapy. The aim of this retrospective study was to investigate the effects of MFT on BW, body fat mass (BFM) and muscle mass (MM), and blood chemistry, and to observe the safety of MFT in obese patients.

PARTICIPANTS AND METHODS

Patient eligibility

Thirty inpatients with obesity [body mass index (BMI) ≥25 kg/m^2] were treated with MFT between March 2009 and February 2012 at the Obesity Clinic of Kyung Hee University Korean Medicine Hospital. All patients met the following criteria for inclusion: (a) completed at least 7 days of prefasting, 14 days of fasting, and 14 days of refeeding; (b) were measured at least four times in the following ways: BW, BFM and MM before prefasting (BP), before fasting (BF), after fasting (AF), and after refeeding (AR); (c) had blood chemistry measurements taken at least twice BF and AR. We excluded the following patients: one patient with fewer than 7 days of fasting, one patient with fewer than four body measurements of BW, BFM and MM, and two patients with fewer than two blood chemistry measurements. In addition, patients who had experienced any of the following: weight changes greater than 3 kg within 2 months, received any treatment for obesity in the previous 6 months, were or might be pregnant or who had given birth during the previous 6 months, were also excluded. Finally, 26 inpatients aged between 18 and 55 years were included in our analysis. There were no patients with severe cardiovascular diseases or malignant tumors that needed aggressive treatment. The entire procedure, effects and possible side effects of MFT and any accompanying treatments were explained in detail to the included patients, and written informed consent was obtained from all patients before treatment began. The protocol for the research project was approved by the Institutional Review Board of Kyung Hee University Hospital and conforms to the provisions of the Declaration of Helsinki in 1995.

Treatment

The patients agreed to participate in a 14-day fast with a supplement made from fermented medicinal herbs and carbohydrates (intake: 400-600 kcal/d) following 7 prefasting relief days, which were then followed by 14 days of stepwise reintroduction of food. Patients were hospitalized during the 14 day fasting period and received intensive care and special monitoring by specialized practitioners. Vital signs, general condition, specific symptoms and adverse events were checked every 6 h. The fasting patients also participated in an exercise program including Qigong, weight training and walking exercises for at least 1 h every day during the entire period of MFT.

During the prefasting days, participants consumed less than half of their usual food intake and ate a low-salt diet mainly composed of brown rice, vegetables and fruits. Meat, caffeine, soda and processed food as well as drinking alcohol and smoking were prohibited during prefasting days. On the last day of prefasting, only three meals of porridge or a thin gruel of rice and some fruit were permitted along with antacid and laxative medications before retiring to bed.

During the MFT fasting period, patients were allowed unlimited intake of mineral water, and limited intake of 200-300 mL of the Signature supplement made of fermented extracts of Houttuynia cordata Thunb and Saururus chinensis Baill and probiotics twice a day (Duolac^{TM}7, Cellbiotech Co., Ltd., Gyunggi-do, Korea). The Signature supplement represents a heat value of 61 kcal per 30 mL. During the fasting period, all medications for other diseases, such as hypertension, dyslipidemia and depression, were discontinued, except those for thyroid diseases, which were prescribed under consultation with a Korean medicine doctor.

Only porridge or gruel was permitted on the first day of the refeeding period. On the second day, participants were allowed additional vegetables and fruits, and then brown rice and meat were gradually added

during the stepwise reintroduction of food. The basic menu during the refeeding period was equally offered to all patients. Thorough chewing, eating small amounts of food, and adhering to a low-salt diet were principles emphasized throughout the entire refeeding period.

Measurements

Patient characteristics, medical history, clinical data, body composition measurements (Inbody 4.0, Biospace, Seoul, Korea), and blood chemistry were recorded in patient charts. We observed the efficacy of treatments by collecting data for body composition and blood chemistry during each MFT period. Data for body composition included BW (kg), body-mass index (BMI, kg/m^2), body-fat mass (BFM, kg), and muscle mass (MM, kg). Blood chemistry included aspartate aminotransferase (AST, IU/L), alanine aminotransferase (ALT, IU/L), total cholesterol (T-chol, mg/dL), and triglycerides (TG, mg/dL). At least four different body composition measurements (BP, BF, AF, and AR) and two separate blood chemistry measurements (BF and AR) were required. Changes in specific symptoms that appeared at any time during the study period were reported. Continuous monitoring of participants for any adverse events and periodic assessments of vital signs were performed to ensure safety. Participants were asked to subjectively record unexpected events during treatment, such as mild dizziness, hunger, fatigue, constipation, nausea, diarrhea, or gallstone, which are possible adverse effects of a VLCD based on the guidelines of the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) of the National Institutes of Health (NIH).[13]

Statistical analysis

Data were presented as mean ± standard deviation ($\bar{x}$ ± *s*). Paired *t*-tests and Wilcoxon signed rank tests were conducted to evaluate the mean differences between patients both before and after MFT. Analysis of variance was conducted to evaluate the difference of MFT in inducing changes of body composition over time. Statistical significant level was $P < 0.05$. The statistical analysis was carried out using SPSS or Windows (version 12.0; SPSS Inc., Chicago, IL, USA).

RESULTS

Baseline characteristics

At baseline, patient demographic characteristics (age, sex, BW and BMI) were as follows. Of the 26 participating patients, 9 were male and 17 female. The averageof age (years), BW (kg) and BMI (kg/m^2) were 39 ± 9, 71.60 ± 6.55, and 28.9 ± 1.7, respectively. When classified according to WHO guidelines, 19 patients were obese, and seven severely obese.

Body weight, fat mass and muscle mass

During the prefasting period, BW, BFM and MM significantly decreased by (1.98 ± 0.65), (0.96 ± 0.50) and (0.91 ± 0.26) kg, respectively ($P < 0.05$). During the fasting period, BW, BFM and MM decreased by (2.99 ± 0.82), (1.48 ± 0.57) and (0.82 ± 0.35) kg, respectively ($P < 0.05$). During the refeeding period, BW decreased, but not significantly, by (0.19 ± 0.50) kg. The BFM decreased to (1.46 ± 0.49) kg, while MM increased by (1.47 ± 0.36) kg during the refeeding period, and both changes were significant (both $P < 0.05$). During the entire MFT period, BW and BFM decreased significantly by (5.16 ± 0.95) and (3.89 ± 0.79) kg (both $P < 0.05$), while MM decreased, but not significantly, by (0.26 ± 0.22) kg. The F values over time for BW, BFM and MM were 102.119, 71.892 and 64.576, respectively (all $P < 0.05$) (Table 1).

Blood chemistry

We also investigated the efficacy of treatments by analyzing blood samples for AST, ALT (IU/L), T-chol, and TG (mg/dL) of patients during the BF and AR periods. The AST level decreased from (24.1 ± 4.3) to (19.5 ± 2.9) IU/L, without statistical significance ($Z = -1.942$, $P = 0.052$), while the ALT level significantly decreased from (30.1 ± 12.8) to (20.5 ± 4.12) IU/L ($Z = -2.125$, $P < 0.05$). The levels of T-chol and TG were both significantly decreased from (181.5 ± 17.4) to (156.0 ± 12.7) mg/dL ($Z = -3.738$, $P < 0.05$) and from (103.9 ± 22.8) to (90.5 ± 18.4) mg/dL ($Z = -1.999$, $P < 0.05$), respectively. (Table 2).

Specific symptoms and adverse events

Among the 26 patients included in this study, 10 were followed-up for 1 month after MFT and continued to show positive results regarding changes in BW, BFM

Table 1 Changes of body weight, fat mass and muscle mass after modified fasting therapy using fermented medicinal herbs ($\bar{x}$ ± *s*)

Item	Baseline (before prefasting)	1 week (before fasting)	3 weeks (after fasting)	5 weeks (after refeeding)	*F* value
Body weight (kg)	71.6±6.6	69.6±6.2[a]	66.6±5.8[a]	66.4±5.9	102.119[c]
Body fat mass (kg)	24.6±4.3	23.7±4.1[a]	22.2±3.7[a]	20.7±3.7[a]	71.892[c]
Muscle mass (kg)	25.7±2.6	24.8±2.5[b]	23.9±2.4[b]	25.4±2.5[b]	64.576[c]

Notes: statistical significance was evaluated by paired sample *t*-test ([a]$P < 0.05$). Statistical significance was evaluated by Wilcoxon signed ranks test ([b]$P < 0.05$). Statistical significance was evaluated by repeated measures analysis of varince ([c]$P < 0.05$).

Table 2 Changes of blood chemistry after modified fasting therapy using fermented medicinal herbs ($\bar{x} \pm s$)

Item	Before fasting	After refeeding	*Z* score
AST (IU/L)	24.1±4.3	19.6±2.9	− 1.942
ALT (IU/L)	30.1±12.8	20.5±4.2	− 2.125[a]
Total cholesterol (mg/dL)	181.5±17.4	156.0±12.7	− 3.738[a]
Triglycerides (mg/dL)	103.9±22.8	90.5±18.4	− 1.999[a]

Notes: AST: aspartate aminotransferase; ALT: alanine aminotransferase. Statistical significance was evaluated by Wilcoxon signed ranks test ([a]$P < 0.05$).

and MM. Three patients with insomnia, four patients with lower back pain and one patient with facial acne at the beginning of the study experienced improvements after MFT. Patients with insomnia withdrew from narcotic medication for the duration of the study. Although drugs for other diseases such as hypertension, dyslipidemia or depression were discontinued during the fasting period, no specific related problems were noted in any patient. During the entire period of MFT, five minor adverse events were reported, but these did not affect everyday living. Almost all of these events appeared during the fasting period and disappeared after a few days. No serious adverse events were reported.

DISCUSSION

Fasting therapy is a therapeutic method which aims to promote the self-healing power by eliminating poisonous and waste matter from the body, and at the same time utilize the energy stored in the body without interruption of the external energy supply. Historically, the reasons to fast have involved both religious and / or medical issues. Fasting was an established treatment method since the time of Hippocrates, and was then developed in the United States at the beginning of the twentieth century by the physicians Tanner, Dewey, and Hazzard. Their method of fasting consisted of water and tea, supported by enemas and physical exercise.[14] Based on the works of the physicians Buchinger, Bircher-Benner, and Mayr, medical fasting attracted a growing number of patients in Europe from the 1950s onwards. Buchinger's method of fasting included free intake of mineral water and limited intake of fruit juice (< 350 kcal/d), which substantially reduces protein loss by gluconeogenesis.[15,16] The fasting cure is further accompanied by bowel cleansing, exercise, nutritional advice, and mind/body techniques. Recently, MFT has attracted growing popularity as a self-care method for health and particularly for initiating lifestyle modification.[17]

The treatment method with fermented medicinal herbs used in this study is based on an MFT of traditional Korean medicine, which is widely used for the management of obesity in Korea.[9-12] It includes the free intake of mineral water and limited intake of a supplement made from fermented medicinal herbs and carbohydrates (intake: 400-600 kcal/d). This method is different from water fasting in that patients receive the VLCD in addition to water. A special feature of this VLCD is that it supplies basic energy sources for essential organs (such as the brain and the heart) in the form of easily absorbed carbohydrates from fermentation, and it is combined with an exercise program. During the fasting period, gluconeogenesis takes place through an acute stress response to obtain energy needed for activity.[15,16] The MFT slows the process of gluconeogenesis and reduces the loss of muscular mass and the drop in basal metabolic rate induced by the loss of lean body mass.

The many advantages of the MFT using fermented medicinal herbs include the reduction of stress on essential organs, preventing hunger, facilitating physical activities during the fasting period, and helping bowel recovery by supplying enzymes and probiotics.[9,10] However, few clinical studies on this form of MFT have been reported to date.[11,12] One is a retrospective observational study which concluded that BW and BMI decreased significantly while MM and basal metabolic rate did not show any significant decrease.[12] These results are consistent with our study but it did not assess changes in blood chemistry. The other study is a case report with similar results to ours, but it cannot be generalized because of the limitations of a case report.[11]

Our observational study of a clinical case series has several meaningful results. First, BFM decreased an average of (1.46 ± 0.49) kg, while MM increased (1.47 ± 0.36) kg during the refeeding period ($P < 0.05$). During the entire study period, BW and BFM decreased (5.16 ± 0.95) and (3.89 ± 0.79) kg ($P < 0.05$), respectively, while MM decreased (0.26 ± 0.22) kg, which was not statistically significant. These results are different from the study by Leibel *et al*,[18] which found that the loss of fat-free mass comprised a large proportion of weight loss when energy intake was extremely restricted. A report on VLCDs that supply enough protein (> 50 g) to minimize the loss of fat-free mass indicated that the loss of BFM was three times greater than that of fat-free mass.[9] In our study of the MFT, the loss of BFM was greater than three times that of the fat-free mass. When compared with the loss in conventional fasting therapy, which includes four distinct time periods to decrease the side-effects of fasting, the loss of MM was more than that of BFM, resulting in a de-

crease of basal metabolic rate. Therefore, our study's results have important implications.

The level of ALT also significantly decreased, while the level of AST decreased but was not statistically significant (P = 0.052). In particular, patients with abnormal ranges of AST and ALT levels before the study had recovered to the normal range. Levels of AST and ALT usually increase when hepatocytes are injured or MM is decreased during fasting therapy, but these levels decrease during other treatment programs for weight loss, such as diet therapy and exercise therapy, which supply a certain amount of calories.[10,19-21] Considering that several studies of the relationship between conventional fasting therapy and the levels of AST and ALT showed a significant increase of AST and ALT, the results of our study are noteworthy.

The levels of both T-chol and TG were also significantly decreased. T-chol levels usually increase during fasting periods through continuous biosynthesis and a decrease of emission and isolation from storage organs to blood, while they decrease during the AR period and the entire period. The results of our study coincide with those of previous studies.[22,23]

Existing studies reveal different opinions on TG levels. Some indicate that TG levels increase in response to the increase of free fatty acids induced from the decomposition of adipose tissue, which regulates the metabolism of TG. Others report that TG decreases as a result of the increase of utilization in the liver and peripheral organs as a form of alternative energy, which is in accordance with the results of our study.[22] The change of TG levels is likely to be related to the changes of insulin and glucagon levels as well as to the response of the sympathetic nervous system, but further study is needed.[23]

During the entire MFT period, no serious adverse events were reported with the exception of common complications such as mild dizziness or hunger. However, these symptoms did not have effects on everyday living. The patients that reported insomnia, lower back pain, and facial acne experienced improvements in these symptoms after MFT. Although medications for other diseases such as hypertension, dyslipidemia or depression were discontinued during the fasting period, no specific problems were recorded by the Korean medical doctors overseeing the treatments. These observations suggest that MFT results in both weight loss and improvements of clinical manifestations in some diseases. The results of this study were likely to be due to the maintenance of the basal metabolic rate and to improvements related to the modification of lifestyle with the gradual introduction of physical activities.

This study has a number of limitations, including the small sample size and the retrospective and observational study design that lowered the reliability. Only two types of blood chemistry measurements, BF and AR, were performed, which did not allow a detailed analysis of each period of MFT. Blood chemistry can vary according to the study period; for example, the level of T-chol usually increases during the fasting period through continuous biosynthesis, the decrease of emission and isolation from the storage organ to blood, while it decreases during the refeeding period and the entire period. Thus, more frequent measurements of blood chemistry were required. Further analyses of blood chemistry indicators will be needed in the future. Among the 26 patients included in our sample, 10 had been followed up for one month, and they continued to show positive results in BW, BFM and MM. Considering that the durability of a treatment method is the most important factor in the treatment for obesity, follow-up for longer periods of time is necessary.

This study investigated the effectiveness and safety of the MFT using fermented medicinal herbs by assessing changes of BW, BFM and MM and blood chemistry as a retrospective observational method. Given the finding that patients with MFT using fermented medicinal herbs and exercise had a statistically significant improvement, further investigation may be warranted. However, the limitation of a retrospective observational study raises questions about relative contributions of this form of MFT compared with other treatment tools for obesity. Therefore, additional studies with a greater sample size and a more reliable study design will be necessary.

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