

Master Amino Acid Pattern[®] as Substitute for Dietary Proteins During a Weight-Loss Diet to Achieve the Body's Nitrogen Balance Equilibrium With Essentially No Calories

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ABSTRACT

Results of this multicentric study have shown that by giving 10 g (10 tablets) of Master Amino acid Pattern (MAP[®]) as a substitute for dietary proteins, once a day, to 114 overweight participants undergoing the American Nutrition Clinics/Overweight Management Program (ANC/OMP), the participants' nitrogen balance could be maintained in equilibrium with essentially no calories (MAP 1 g=0.04 kcal), thereby preserving the body's structural and functional proteins, eliminating excessive water retention from the interstitial compartment, and preventing the sudden weight increase after study conclusion commonly known as the yo-yo effect. Study results have shown that the use of MAP, in conjunction with the ANC/OMP, has proven to be safe and effective by preventing those adverse effects associated with a negative nitrogen balance, such as oversized or flabby tissue, stretch marks, sagging of breast tissue, increased hair loss, faded hair color, and fragile or brittle

nails. Also preventing those anomalies commonly associated with weight-loss diets, such as hunger, weakness, headache caused by ketosis, constipation, or decreased libido, the use of MAP, in conjunction with the ANC/OMP, allowed for mean weight loss of 1.4 kg (3 lb) per week.

Keywords: | body mass index; dietary protein substitute; mandatory daily physical activity; Master Amino acid Pattern; nitrogen balance equilibrium

INTRODUCTION

A weight-loss diet, to be safe and effective, should both (1) reduce the amount of nonessential nutrients, to obtain the negative energy balance necessary to induce the catabolism of fat tissue, and (2) provide the required amounts of essential nutrients, such as essential amino acids, vitamins, minerals, trace elements, and essential fatty acids, to assure a healthy and productive life.¹

Nevertheless, most weight-loss diets have failed to provide the daily protein requirement (DPR) due to the following scientific dilemma: if the diet provides the DPR, unwanted calories may also be supplied, making weight loss minimal or even absent, especially among sedentary individuals. As a result, most weight-loss diets by reducing calorie intake also reduce DPR, thus causing a body's negative nitrogen balance, which leads to a reduction of structural and functional proteins, such as skin, muscles, tendons, bones, organs, antibodies, and certain enzymes and hormones.¹⁻⁴ This, in turn, can cause life-threatening physical and physiologic anomalies such as impairment of the immune system, thus increasing the risk for infections¹⁻⁴; decreased body muscle volume that causes a void under the skin, thus leading to oversized and flabby skin; loss of normal skin tone and texture, causing stretch marks and sagging of breast tissue; increased hair loss; faded hair color; nail fragility; decreased muscle strength and endurance that limits physical performance; decreased bone density that increases risk for bone fracture and worsens current osteoporosis; increased body water retention in the interstitial compartment, thereby augmenting body weight⁵; and a sudden increase in weight after conclusion of a weight-loss diet, popularly known as the yo-yo effect.⁵

The safety and nutritional effectiveness of the Master Amino acid Pattern (MAP® [SON Formula®, International Nutrition Research Center, Coral Gables, Fla, USA]), a dietary protein substitute, has been confirmed by results of a comparative, double-blind, triple-crossover net nitrogen utilization (NNU) clinical study.⁶ Study results have shown that the participants, while taking MAP as a sole and total substitute of dietary proteins, achieved a body NNU of 99%.⁶ This means that 99% of MAP's constituent amino acids followed the anabolic pathway, thus acting as precursors of the body's protein synthesis. By comparison, dietary proteins only provide between 16% and 48% NNU. This demonstrates that MAP is more nutritious than dietary proteins.⁶ This has been confirmed by observing that each participant's nitrogen balance was maintained in equilibrium by taking MAP at a dosage of only 400 mg/kg per day, which provided less than 2 kcal/d (MAP 1 g=0.04 kcal),⁶ thus demonstrating that body's nitrogen balance equilibrium could be achieved, for the first time, with essentially no calories.⁶ The study results have also shown that 1% of MAP's

constituent amino acids followed the catabolic pathway, thus releasing only 1% of nitrogen catabolites and energy.⁶ By comparison, dietary proteins release between 52% and 84% nitrogen catabolites and energy. This demonstrates that MAP is safer than dietary proteins and provides the lowest amount of energy compared with any dietary protein.⁶

Subsequently, comparative study results have shown that participants, by taking MAP as a dietary protein substitute and performing physical activity, experienced (1) increased body muscle mass, strength, and endurance; (2) decreased fat mass; (3) increased basal metabolic rate; (4) a greater improvement in performance of the nonprevailing muscles compared with prevailing muscles; and (5) improved muscular and hematologic lactate clearance, allowing for better muscle performance and faster muscle recovery after physical activity.^{7,8}

Because of MAP's unique characteristics, the investigators considered conducting a multicentric study to evaluate anthropometric and physiologic parameters and quality of life in 114 overweight participants taking MAP as a dietary protein substitute either at lunch or dinner and enrolled in the American Nutrition Clinics/Overweight Management Program (ANC/OMP).⁵

PATIENTS AND METHODS

Study Population

A total of 114 overweight participants (outpatients: 108 women, 6 men) were randomly selected. Their mean age was 43 years (SD=13.8, range 15–75 years), mean height 164 cm (SD=6.3, range 145–182 cm), mean initial weight 73.9 kg (SD=12.5, range 53–115 kg), and mean initial body mass index (BMI) 27.4 (SD=4.4, range 21.0–46.4) (Table 1). Participants were selected if they satisfied all inclusion criteria and none of the exclusion criteria. Inclusion criteria were overweight condition in a male or female older than 15 years of age. Exclusion criteria were current pregnancy, breast-feeding, or current disease. All enrollees provided informed consent.

Study Design

Each participant was evaluated once a week for a period ranging from 1 to 8 consecutive weeks. The mean study period was 3 weeks (SD=1.5, range 1–8). Participant evaluations included assessments of (1) heart rate; (2) blood pressure; (3) body weight after urination and after removing jacket, shoes, and pocket contents; (4) quality-of-life, by assessing presence or absence of adverse effects commonly associated with a negative nitrogen balance, such as oversized or flabby tissue, stretch marks, sagging of breast tissue, increased hair loss, faded hair color, and fragile or brittle nails; and (5) the presence or absence of anomalies commonly associated with weight-loss diets such as hunger, weakness, headache caused by ketosis, constipation, or decreased libido.

Definition of ANC/OMP Diet

The ANC/OMP diet⁵ (Table 2) provided the required amounts of essential nutrients, specifically (1) MAP in a dosage of 10 g (10 tablets), equivalent to 0.4 kcal, once

a day, either at lunch or dinner, as a dietary protein substitute*; (2) 350 g of chicken or fish, once a day, either at lunch or dinner (Table 2); (3) fresh fruit as listed in Table 3; (4) fresh vegetables as listed in Table 4; and (5) VIT-formula™ (International Nutrition Research Center, Coral Gables, Fla, USA), 3 tablets per day, which provides vitamins, minerals, and trace elements in accordance with the US Recommended Daily Allowance (RDA).

Table 1. Characteristics of Study Population

	Mean±SD	Range
Age, y	43.0±13.8	15–75
Height		
ft, in	5'0"±6.3"	4'10"–6'4"
cm	164.0±6.3	145–182
Initial weight		
kg	73.9±12.5	53–115
lb	162.6±12.5	116–253
Initial BMI	27.4±4.4	21.0–46.4

Table 2. ANC/OMP Diet

Breakfast	
1 multivitamin tablet	Mandatory
700 g (1.5 lb) of fresh fruit	Mandatory
Coffee, tea, or other infusions	Optional
Lunch	
10 g of MAP	Mandatory
1 multivitamin tablet	Mandatory
700 g (1.5 lb) of fresh fruit	Mandatory
250 g (0.5 lb) of fresh vegetables	Optional
Dinner	
1 multivitamin tablet	Mandatory
350 g (0.75 lb) of chicken or fish	Mandatory
500 g (1.0 lb) of fresh fruit	Mandatory
250 g (0.5 lb) of fresh vegetables	Optional
Snack	
Fresh fruit, as much as desired, at any time	

*This dosage has been demonstrated by the results of a comparative, double-blind, triple-crossover, clinical study of NNU to provide a body's protein synthesis equivalent to that provided by approximately 25 g of high biologic value protein.⁶

Table 3. ANC/OMP Diet: Allowed Fruit

Name	Approx. Energy Value cal/3.5 oz (100 g)
Apple	58
Apricot	57
Cantaloupe	25
Cherry	63
Fig	62
Grape	68
Grapefruit	38
Guava	69
Honeydew	44
Lemon	29
Lime	32
Mango	59
Orange	42
Papaya	24
Peach	52
Pear	56
Pineapple	52
Plum	47
Pond apple (alligator apple)	52
Rose apple	63
Strawberry	36
Tangerine	43
Watermelon	22

Participants were informed that eating less than the daily mandatory minimum amount of fruit could result in hunger, weakness, headache by ketosis, and/or decreased libido.

- Allowed beverages: noncarbonated water, coffee, tea, and other infusions
- Allowed seasonings: lemon juice, vinegar, pepper, and natural herbs
- Allowed sweetener: aspartame
- Fresh fruits could be cooked or baked without using sugar or fat. Canned or dried fruits were not allowed
- Fresh vegetables could be steamed, grilled, or baked without using salt or fat. Canned vegetables were not allowed

Table 4. ANC/OMP Diet: Allowed Vegetables

Name	Approx. Energy Value cal/3.5 oz (100 g)
Artichoke	29
Asparagus	22
Broccoli	39
Brussels sprouts	50
Cabbage	28
Carrot	41
Cauliflower	33
Celery	19
Chicory	20
Cucumber	15
Endive	20
Lettuce	13
Onion	45
Radish	23
Spinach	30
Tomato	21

ANC/OMP Physical Activity

ANC/OMP physical activity⁵ during the study was mandatory. Each participant chose his/her preferred daily physical activity from Table 5. The physical activity had to be performed each day for the required time, without interruptions. Participants were informed that failure to perform the mandatory daily physical activity could result in weakness and/or decreased libido.⁶

RESULTS

Participants' anthropometric characteristics are shown in Table 1. Results of initial weight, final weight, weight loss per week, and BMI are shown in Table 6. Results of the quality-of-life report showed that all participants, while complying with the ANC/OMP, reported absence of hunger, weakness, headache caused by ketosis, constipation, and decreased libido; only 3 participants (3%) *who did not comply* either with ingestion of the daily mandatory minimum amount of fruits or with daily mandatory physical activity reported episodes of hunger and/or weakness. Of those 3, 2 (2%) who had eaten less than the daily mandatory minimum amount of fruits reported hunger a total of 4 times (range 1–2); 2 (2%) who had eaten less than the daily mandatory minimum amount of fruits reported feeling weak 3 times (range 1–1.5); and 3 participants (3%) who failed to perform the mandatory daily physical activity reported feeling weak a total of 4 times (range 1–1.3) (Table 7). Results of the quality-of-life evaluation have shown absence of adverse effects such as flabby or oversized skin, loss of skin

tone or texture, stretch marks, sagging of breast tissue, increased hair loss, faded hair color, or fragile or brittle nails (Table 8). Of the 114 participants, 86 (75%) reported that their skin, hair, and nail quality had improved; of those 86, 82 (72%) also reported that their hair was stronger and shinier than before.

Table 5. ANC/OMP Required Daily Physical Activity

Physical Activity	Minimum Time, h
Aerobics	1.0
Cycling (fixed or mobile)	1.0
Going up and down stairs	0.5
Jogging	0.5
Sitting down and standing up	0.5 (twice a day)
Skating	1.0
Skipping rope	0.5
Soccer	1.0
Swimming	1.0
Tennis	0.5
Volleyball	0.5
Walking	1.0

Table 6. Study Results

	Mean±SD	Range
Initial weight		
kg	74.0±12.5	53–115
lb	162.8±12.5	117–253
Final weight		
kg	69.9±11.9	50–111
lb	153.8±11.9	110–244
Weight loss per week		
kg	1.4±0.2	1.0–1.9
lb	3.1±0.2	2.2–4.18
BMI		
Initial	27.4±4.4	21.0–46.5
Final	25.9±4.2	19.8–44.6

Table 7. Quality-of-Life Report

	Absent, %	Present, %
Hunger	98	2
Weakness	98	2
Headache caused by ketosis	100	0
Constipation	98	2
Decreased libido	100	0

Table 8. Quality-of-Life Evaluation

	Absent, %	Present, %
Flabby or oversized skin	100	0
Loss of skin tone or texture	100	0
Stretch marks	100	0
Sagging of breast tissue	100	0
Increased hair loss	100	0
Faded hair color	100	0
Fragile or brittle nails	100	0

Safety and Tolerability

While complying with the ANC/OMP, participants did not report any side effects.

Poststudy Follow-up Evaluation

A poststudy evaluation was conducted during 12 weeks in a subgroup of 73 randomly chosen participants (69 women and 4 men) with a mean initial weight of 70.5 kg. Variations in participants' body weight and presence or absence of the sudden weight increase that commonly occurs after conclusion of a weight-loss diet, known as the yo-yo effect, were evaluated.⁵

Poststudy Follow-up Results

Results of the 12-week follow-up demonstrated a mean weight decrease of 1.47 kg (3.2 lb) in the subgroup (Table 9), confirming the absence of the yo-yo effect.⁵

Table 9. Follow-up Study Results

	Mean±SD	Range
Initial weight		
kg	70.5±12.9	49.9–111.0
lb	155.1±12.9	109.8–244.2
Final weight		
kg	69.1±11.5	51.0–106.6
lb	151.8±11.5	112.2–234.5
Weight variation		
kg	-1.470±1.9	-6.9–1.1
lb	-3.2±1.9	-15.2–2.4

DISCUSSION AND CONCLUSIONS

Study results show that MAP, given in a dosage of 10 g/d (0.4 kcal) as a substitute for dietary protein and in conjunction with the ANC/OMP diet, was adequate to maintain participants' body nitrogen balance in equilibrium. This has been confirmed by the absence of those anomalies commonly associated with a body's negative nitrogen balance, such as loss of skin tone and texture, oversized or flabby skin, stretch marks, sagging of breast tissue, increased hair loss, faded hair color, or fragile or brittle nails (Table 8). Interestingly, 75% of participants reported that their skin, hair, and nail quality had improved; 72% of participants also reported their hair was stronger and shinier than before. Results have also shown a substantial mean weight loss of 1.4 kg (3.1 lb) per week, thus decreasing the mean BMI from 27.4 to 25.9. Validating previous findings,⁵ this mean weight loss can be attributed to both the loss of excessive fat tissue, obtained through a negative energy balance, which is a fat/energy-related phenomenon, and the loss of excessive water retention from the interstitial compartment, obtained by maintaining body nitrogen balance in equilibrium, which is not a fat/energy-related phenomenon.⁵ Results of the 12-week follow-up demonstrated a mean weight decrease of 1.47 kg (3.2 lb) (Table 9), thus confirming absence of the yo-yo effect.⁵ Overall, these results confirm that use of MAP in conjunction with the ANC/OMP diet is effective.

Study results show that all participants, while complying with the ANC/OMP, reported absence of anomalies commonly associated with weight-loss diets, such as hunger, weakness, headache caused by ketosis, constipation, or decreased libido (Table 7). Moreover, substantiating previous findings,⁶⁻⁸ no participant reported any side effects. This confirmed that the use of MAP in conjunction with the ANC/OMP diet was safe.

It was concluded that using MAP as a substitute for dietary protein either at lunch or dinner, in the recommended dosage of 10 g/d and in conjunction with the ANC/OMP, can provide unprecedented safe and effective overweight control. This is because the body's nitrogen balance can be maintained in equilibrium, thus preventing reduction of structural and functional proteins and potential life-threatening physical and physiologic consequences. As a result, excessive water retention from the interstitial compartment can be eliminated, thereby reducing weight that is not fat/energy related; the body's lean tissue can be preserved, thus preventing the consequent sudden weight increase after conclusion of a weight-loss diet, known as the yo-yo effect; and those anomalies associated with a negative nitrogen balance, such as loss of skin tone and texture, oversized or flabby skin, stretch marks, sagging of breast tissue, increased hair loss, faded hair color, and nail fragility, can be avoided. Further, body fat can be reduced safely, thus preventing those anomalies commonly associated with weight-loss diets such as hunger, weakness, headache caused by ketosis, constipation, or decreased libido.

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