

Master Amino Acid Pattern® as Sole and Total Substitute for Dietary Proteins During a Weight-Loss Diet to Achieve the Body's Nitrogen Balance Equilibrium

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ABSTRACT

Results of this multicentric study have shown that by giving Master Amino acid Pattern (MAP®) as a sole and total substitute of dietary proteins to 500 overweight participants undergoing the American Nutrition Clinics/Overweight Management Program (ANC/OMP), the participants' body 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

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regimen, 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, the sagging of breast tissue, increased hair loss, faded hair color, and fragile or brittle nails. Also prevented were those anomalies commonly associated with weight-loss diets, such as hunger, weakness, headache caused by ketosis, constipation, and decreased libido. The use of MAP in conjunction with the ANC/OMP also allowed for mean weight loss of 2.5 kg (5.5 lb) per week, achieved through reduction of excessive fat tissue and elimination of excessive water retention from the interstitial compartment.

Keywords: | ANC/OMP diet; daily protein requirement; dietary protein substitute; mandatory daily physical activity; 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 the body's 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, by reducing calorie intake, most weight-loss diets also reduce DPR. The reduced DPR causes 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, 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 adding to body weight⁵; and 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 an 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 which has been confirmed by observing that each participant's nitrogen balance was

maintained in equilibrium by taking MAP in 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 for the first time that a body's nitrogen balance equilibrium may be achieved with essentially no calories.⁶ The 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}

Later results of a multicentric study have shown that by giving MAP 10 g (10 tablets) as a dietary protein substitute, either at lunch or dinner, to 114 overweight participants undergoing the American Nutrition Clinics/Overweight Management Program (ANC/OMP),⁵ the participants' body nitrogen balance could be maintained in equilibrium with essentially no calories, thus 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.⁹ Study results have shown that the use of MAP in conjunction with the ANC/OMP regimen has proven to be safe and effective by preventing those 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. The combined regimen also prevented those anomalies commonly associated with weight-loss diets, including hunger, weakness, headache caused by ketosis, constipation, and decreased libido, and allowed for a substantial mean weight loss of 1.4 kg (3 lb) per week.⁹

Because of MAP's unique characteristics, the investigators considered conducting a multicentric study to evaluate anthropometric and physiologic parameters and quality of life in 500 overweight participants taking MAP as a sole and total daily dietary protein substitute while undergoing the ANC/OMP.⁵

PATIENTS AND METHODS

Study Population

Participants included 500 overweight outpatients, randomly chosen: 407 women and 93 men with a mean age of 43 years (SD 13.8, range 15–76 years); mean height of 165 cm (SD 8.5, range 147–194 cm); mean initial weight of 80.6 kg (SD 16.6, range 50–138 kg); and a mean initial body mass index (BMI) of 29.6 (SD 5.3; range 19.9–49.8) (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 gave informed consent.

Table 1. Characteristics of Study Population

	Mean±SD	Range
Age, y	43.0±13.8	15–76
Height		
ft, in	5'5"±8.5"	4'10"–6'4"
cm	165.0±8.5	147–194
Initial weight		
kg	80.6±16.6	50–38
lb	177.3±16.6	110–304
Initial BMI	29.6±5.3	19.8–49.8

Study Design

Each participant was evaluated for a period ranging from 1 to 30 consecutive weeks. The mean study period was 3 weeks (SD 2.1, range 1–30). Participant evaluations were performed each day of the first week, from Monday through Friday; during the second week, at least on Monday, Wednesday, and Friday; and during the third and following weeks, at least on Mondays and Thursdays. Participant evaluations comprised 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 the ANC/OMP Diet

The ANC/OMP diet⁵ (Table 2) provided the required amounts of essential nutrients, such as (1) MAP, in a dosage of 400 mg/kg per day (Table 3),* as a sole and total dietary protein substitute; (2) fresh fruit, as listed in Table 4; (4) fresh vegetables, as listed in Table 5; and (5) VIT-formulaTM (International Nutrition Research Center, Coral Gables, Fla, USA), 3 tablets per day, which provided vitamins, minerals, and trace elements in accordance with the US Recommended Daily Allowance (RDA).

*MAP dosage of 400 mg/kg per day has been shown in a comparative, double-blind, triple-crossover NNU clinical study to be adequate as a sole and total dietary protein substitute to maintain participants' nitrogen balance in equilibrium.⁶ Therefore, each participant's daily MAP dosage was calculated by multiplying his/her daily DPR by 0.4,⁵ applying the following formula:

$$\text{MAP dosage} = (\text{DPR} \times 0.4) \text{ g}$$

For example, the DPR for a 170-cm (5 ft 7 in) man is 61 g. $61 \times 0.4 = 24$. Therefore, the individual's daily MAP dosage is 24 g.

Table 2. ANC/OMP Diet

Breakfast	
Required dosage of MAP	Mandatory
1 multivitamin tablet	Mandatory
700 g (1.5 lb) of fresh fruit	Mandatory
Coffee, tea, or other infusions	Optional
Lunch	
Required dosage 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	
Required dosage 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
Snack	
Fresh fruit, as much as desired, at any time	

Table 3. Daily Protein Requirements, g

Height, ft, in	Height, cm	Male	Female
5'	152	45	40
5'1"	154	47	42
5'2"	157	50	44
5'3"	159	52	46
5'4"	162	54	48
5'5"	164	56	50
5'6"	167	59	52
5'7"	170	61	54
5'8"	172	63	56
5'9"	175	65	58
5'10"	177	68	60
5'11"	180	70	62
6'	183	72	64
6'1"	185	74	66
6'2"	188	77	68
6'3"	191	79	70
6'4"	193	81	72
6'5"	196	83	74
6'6"	198	86	76

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.⁵

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

Table 4. 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

Table 5. 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

Table 6. 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

ANC/OMP Physical Activity

ANC/OMP physical activity⁵ was mandatory during the study. Each participant chose his/her preferred daily physical activity from Table 6. 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.⁵

RESULTS

Participants' anthropometric characteristics are shown in Table 1. Initial weight, final weight, weight loss per week, and BMI are shown in Table 7. 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 25 participants (5%) *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 25, 21 (4%) who had eaten less than the daily mandatory minimum amount of fruits reported hunger a total of 28 times (range 1–2); 12 (2%) who had eaten less than the daily mandatory minimum amount of fruits reported feeling weak 15 times (range 1–2); and 13 participants (2%) who failed to perform the mandatory daily physical activity reported feeling weak a total of 16 times (range, 1–2) (Table 8).

Table 7. Study Results

	Mean±SD	Range
Initial weight		
kg	80.6±16.6	50–138
lb	177.3±16.6	110–304
Final weight		
kg	73.5±15.2	45–119
lb	161.7±15.2	99–262
Weight loss per week		
kg	2.4±0.9	1.0–7.5
lb	5.3±0.9	2.2–16.5
Weight loss during the first week		
kg	3.5±1.3	1.4–7.0
lb	7.7±1.3	3.0–15.4
BMI		
Initial	29.6±5.3	19.9–49.8
Final	27.0±4.8	18.5–46.2

Table 8. Quality-of-Life Report

	Absent, %	Present, %
Hunger	96	4
Weakness	95	5
Headache caused by ketosis	100	0
Constipation	100	0
Decreased libido	100	0

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 9). Of the 500 participants, 385 (77%) reported that their skin texture improved, hair was stronger and shinier, and nails were stronger. The remaining 115 (23%) participants reported that their skin, hair, and nail quality was unchanged.

Table 9. Quality-of-Life Evaluation

	Present, %	Absent, %	Unchanged, %	Improved, %
Flabby or oversized skin	0	100		
Loss of skin tone or texture	0	100		
Skin texture			23	77
Stretch marks	0	100		
Sagging of breast tissue	0	100		
Increased hair loss	0	100		
Hair quality			23	77
Faded hair color	0	100		
Fragile or brittle nails	0	100		
Nail quality			23	77

Safety and Tolerance

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

Poststudy Follow-up Evaluation

The poststudy evaluation was conducted after the study's conclusion in 2 groups of participants, designated as A and B. Group A included 107 randomly chosen participants, 90 women and 17 men with a mean initial weight of 76.3 kg. Group A was monitored for a 90-day period (Table 10). Group B included 73 randomly chosen participants, 62 women and 11 men with a mean initial weight of 74.2 kg. Group B was monitored for a 180-day period (Table 11). These poststudy evaluations assessed participants' variations in body weight and the presence or absence of the sudden weight increase that commonly occurs after a weight-loss diet, known as the yo-yo effect.⁵

Table 10. Group A: 90-Day Follow-up Results (n=170)

	Mean±SD	Range
Initial weight		
kg	76.3±12.9	46-114
lb	167.0±12.9	101-250
Final weight		
kg	73.3±11.8	45.5-108.3
lb	161.0±11.8	100.0-238.0
Weight variation		
kg	-1.2±4.5	-11.9-1.4
lb	-2.6±4.5	-26.0-3.0

Table 11. Group B: 180-Day Follow-up Results (n=73)

	Mean±SD	Range
Initial weight		
kg	74.2±13.4	46-114
lb	163.0±13.4	101-250
Final weight		
kg	72.9±12.6	45.5-108.3
lb	160.0±12.6	100.0-238.0
Weight variation		
kg	-1.3±2.5	-4.0-1.3
lb	-2.9±2.5	-30.0-2.9

Poststudy Follow-up Results

Results of the 90-day follow-up study demonstrated a mean weight decrease of 1.2 kg (2.6 lb) among the 107 participants (Table 10). Results of the 180-day follow-up study showed a mean weight decrease of 1.3 kg (2.9 lb) among the 73 participants (Table 11). Hence the absence of the yo-yo effect was demonstrated in both groups of participants.⁵

DISCUSSION AND CONCLUSIONS

Confirming previous findings, study results have shown that MAP given in a dosage of 400 mg/kg per day as a *sole and total substitute for dietary protein* was adequate to maintain participants' body nitrogen balance in equilibrium with essentially no calories (less than 2 kcal/d).^{6,8,9} This has been confirmed by the absence of anomalies 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 9). Indeed, validating previous findings,⁹ 77% of participants reported improved skin texture, stronger and shinier hair, and stronger nails.

Earlier findings have shown a mean weight loss of 1.4 kg (3.1 lb) per week among 114 overweight participants on the ANC/OMP regimen who were taking MAP as a dietary protein substitute once a day, either at lunch or dinner.⁹ By comparison, study results have shown a mean weight loss of 2.5 kg (5.5 lb) per week among 500 overweight participants on the ANC/OMP regimen who were taking MAP as a *sole and total daily substitute for dietary protein*. This confirms that in participants on the ANC/OMP regimen who were taking MAP as a *sole and total, instead of partial, daily substitute for dietary protein*, a 79% greater mean weight loss was noted compared with earlier findings.⁹

Validating previous findings,^{5,9} this mean weight loss should not be attributed only to fat catabolism because of the following reasons. If it is assumed that the mean weight loss of 2.5 kg was caused entirely by fat catabolism, the mean negative energy balance necessary to induce such fat catabolism should have been approximately 3214 kcal/d. Considering that the diet provided approximately 1600 kcal/d, the resulting energy expenditure per participant should have been approximately 4814 kcal/d. This was highly improbable, considering that each participant only performed between 30 minutes to 1 hour of physical activity per day. Therefore, in line with previous findings,^{5,9} this mean weight loss should be attributed to both the loss of excessive fat tissue, obtained through a negative energy balance, which is a fat/energy-related phenomenon,⁵ and to the loss of excessive water retention from the interstitial compartment, obtained by maintaining the nitrogen balance in equilibrium, which is not a fat/energy-related phenomenon.^{5,9}

Group A results showed a mean weight loss of 1.2 kg (2.6 lb) (Table 10); group B results showed a mean weight loss of 1.3 kg (2.9 lb) (Table 11). Both groups confirmed the absence of the yo-yo effect.^{5,9} This has confirmed that the use of MAP in conjunction with the ANC/OMP diet is effective.⁹

Consistent with earlier findings,⁹ study results have shown that all participants, while complying with the ANC/OMP, have reported the absence of those anomalies commonly associated with weight-loss diets, such as hunger, weakness, headache caused by ketosis, constipation, or decreased libido (Table 8). As well, as reported in

the literature, none of the participants reported any side effects.⁶⁻⁹ This has confirmed that the use of MAP in conjunction with the ANC/OMP diet is safe.⁶⁻⁹

It was concluded, as in previous findings,⁹ that the use of MAP, as a sole and total substitute for dietary protein, in conjunction with the ANC/OMP can provide unprecedented safe and effective control of overweight because body's nitrogen balance can be maintained in equilibrium, thus preventing the reduction of structural and functional proteins and their life-threatening physical and physiologic consequences. As a result, (1) excessive water retention from the interstitial compartment can be eliminated, thus reducing also that specific body's overweight, which is not fat/energy related; (2) body's lean tissue can be preserved, thereby preventing its regain and the consequent sudden weight increase after stopping the weight-loss diet commonly known as the yo-yo effect; and (3) those anomalies commonly associated with a negative nitrogen balance, such as the loss of skin tone and texture, onset of oversized or flabby skin, onset of stretch marks, sagging of breast tissue, increased hair loss, faded hair color, and nail fragility, can be avoided. Additionally, body's overweight can be reduced in a safe way; thus, preventing those anomalies commonly associated with weight-loss diets, such as hunger, weakness, headache caused by ketosis, constipation, or decreased libido.

REFERENCES

1. Lucà-Moretti M, Grandi A. The malnutrition treatment and prevention project. *JIMHA*. 1993; 2:21-27.
2. Chandra RK. Nutrition, immunity, and infection: present knowledge and future directions. *Lancet*. 1983;1:688-691.
3. Chandra RK, Gupta S, Singh H. Inducer and suppressor T-cell subsets in protein-energy malnutrition: analysis by monoclonal antibodies. *Nutr Res*. 1982;2:21-26.
4. Smythe PM, Brereton-Stiles GG, Grace HJ, et al. Thymolymphatic deficiency and depression of cell-mediated immunity in protein-calorie malnutrition. *Lancet*. 1971;2:939-943.
5. Lucà-Moretti M. The International Nutrition Research Center overweight management program. The US Library of Congress, 1999.
6. Lucà-Moretti M. The discovery of the Master Amino acid Pattern. *Ann Ro Acad Med Spain*. 1998; 2:397-416.
7. Lucà-Moretti M, Grandi A, Lucà E, et al. Comparative results between two groups of track-and-field athletes with or without the use of Master Amino acid Pattern® as protein substitute. *Adv Ther*. 2003;20:195-202.
8. Lucà-Moretti M, Grandi A, Lucà E, et al. Results of taking Master Amino acid Pattern® as a sole and total substitute of dietary proteins in an athlete during a desert crossing. *Adv Ther*. 2003;20: 203-210.
9. Lucà-Moretti M, Grandi A, Lucà E, et al. 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. *Adv Ther*. 2003;20:282-291.