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Case Report

Reversing Mets (Metabolic Syndrome) with MSRP (Metabolic Syndrome Reversal Program) Through Integrative Whole Food Dietary Outlines and Sprint Interval Training

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Abstract

Objective: To determine the level of the reversal of Metabolic Syndrome (MetS) and the individual subsets of the condition among clients following an integrated lifestyle changing 12 week program called MSRP. The motivations in designing the MSRP program were twofold: The complete reversal of MetS and the maintenance of the reversal of the condition.

Study Design: This is a case series of clients with metabolic syndrome that were put on an integrated dietary and exercise program for 12 weeks. Inclusion in this program was determined through the inclusion criteria of the MSRP (Metabolic Syndrome Reversal Program) and the diagnosis of MetS through a licensed Health Care Provider. The study was done through a chart review of 73 clients age 30 -81 seen over a little more than a one year period, August 2010 to October 2011.

Results: The mean age of the clients in this series was 55.5, 28 of whom were males (38.4%) and 45 were females (61.6%). There were 57 (78.1%) clients whose serum cholesterol were above the normal (>200mg/dL) range while 36 (49.3%) clients had elevated (>150mg/dL) serum triglyceride. There were 49 (67.12%) clients whose LDL cholesterol were above (>130) and 22 (30.1%) had below average HDL (<50mg/dL females, <40mg/dL males). 40 (54.8%) clients had a BMI > 30 kg/m², thus clinically defining them as obese.

Conclusion: The MSRP shows significant changes in the overall condition of MetS and its subsets after completion of the 12 week integrative program.

Keywords: Lifestyle Modification Programs; Metabolic Syndrome

Introduction

Metabolic Syndrome (Mets) is a combination of risk factors and progressive metabolic changes in the body that could lead to cardiovascular disease and diabetes [1-4]. In this trial the correlation to MetS and all its subsets were investigated to see if the MSRP program could show clinical/statistical significance in reversing the condition as a whole and individual subsets. The MSRP incorporates a unique integration of whole food diets that individually shows some clinical evidence through literature to reduce individual MetS risk factors, like: Glycemic Index/Load Diet [5-8], Brown Rice Diet [9-14], Raw Vegan Diet [15-20], Paleolithic Diet [21-28], Gluten Casein Free Dietary principles [29-40] with High Intensity Interval Training (HIIT) [41] as the only exercise component. The restrictive nature of each of these diets individually makes it hard to maintain the results. The MSRP provides the client the opportunity to utilize bits and pieces of all these outlines to maintain the results. It is 12 weeks in duration with consistent supervision, intervention and evaluation.

Methodology

This is a case series of patients with MetS diagnosed by a licensed Healthcare provider at the MSRP Health Centers (California and New Jersey) aiming to describe the clinical profile with

special emphasis on the prevalence of the metabolic syndrome. The study was done through a chart review of 73 selected patients aged 30 years old and above with a diagnosis of MetS seen over a one year period between August 2010 to September 2011 at the MSRP Health Centers. MSRP Health Centers include clinical and exercise components, all dietary and exercise education were done "on site" and "in house". Clients were seen as outpatient, with 3 times per week Sprint Interval Training, once every two weeks of weigh in on Tanita Segmental Bio-Impendence Scale to measure BMI, Fat Mass, Fat Free Mass and segmental analysis and monthly nutritional seminars about dietary protocols, there were also bi-weekly meetings with a MSRP Lifestyle Educator (LE) to determine compliancy. A LE is a former client that graduated the program and has maintained success post the one year mark at least. Lifestyle Educators are a great asset to the program due to the fact that they have been through the program steps, have done all the dietary protocols and can be very motivating for the new client as a support unit. A minimum of 2 out of 3 exercise classes per week and following the dietary protocols were deemed compliant. Compliancy in the dietary section was measured through questionnaires evaluated by a clinical nutritionist bi-weekly, any foods that were supposed to be eliminated due to inflammatory potential in a protocol needed to be adhered to 100%, thus if gluten were to be eliminated there had to be 100% adherence etc. To further assure dietary compliance the meals were cooked through local restaurants so the clients did not have to be worried about preparing the exact meal plans. There were group meetings going over every new protocol in Weeks 1, 4, 8 and 12 evaluating the upcoming protocols and the next step once completing program. These meetings were educational in nature to inform clients how to integrate these dietary changes permanently. The dietary protocols for the 12 weeks were as follows:

1. Week 1 - 4: Follow the Glycemic Index Protocol [42]
2. Week 5 - 8: Follow Integrated 21 Day Protocol [43]
3. Week 9 - 10: Follow Paleo Diet for "Athletes" [44]
4. Week 11 - 12: Follow Combination and Maintenance Protocol [45]

Every client had 24 hour access to e-mailing any questions and concerns about program, these questions were answered by clinical nutritionists.

Out of the 73 clients only 4 opted to prepare the meals themselves, but were kept in the study as long as they adhered to the dietary rules and 2 out of 3 exercise classes per week. All prescription medications that clients were on were not interfered with, however all basic supplementation was stopped for this trial. The trial included no neutraceutical based supplements. Only ascorbic acid and "Superfood" [46] a dehydrated whole food green supplement was integrated with raw vegetable juicing. All of the clients included in the study underwent determination of the serum total cholesterol, triglyceride, HDL, LDL, some of the clients had fasting glucose measurements and blood pressure measurements. Metabolic syndrome also known as Syndrome X was diagnosed according to MSRP Inclusion criteria: A fasting blood glucose level greater than 100 mg/dl or are on glucose lowering medications or have Type II Diabetes, a waistline of 40 inches or more for men, 35 inches or more for women (measured across the belly) or BMI is >30 kg/m², central obesity can be assumed and waist circumference does not need to be measured, a High Density Lipoprotein (HDL) less than 40mg/dl (men) or under 50mg/dl (women), a blood pressure of 130/85 mm Hg or higher or are on blood pressure medications Raised triglycerides: > 150 mg/dL (1.7 mmol/L), or specific treatment for this lipid abnormality Raised low density lipoprotein: > 130 mg/dL, or specific treatment for this lipid abnormality, Raised total cholesterol: > 200 mg/dL, or specific treatment for this lipid abnormality, people with other clinical features of "insulin resistance" including skin changes ("dirty skin on the back of the neck or underarms) or skin tags (usually on the neck). 6 or 7 new clients were enrolled per month for a three month (12 week) period. The intake of the study was 12 months in duration, which meant the last group started in August 2011 and finished at the end of October 2011. Total intake were 79 clients, 73 finished the entire program, 6 dropped out, 4 citing financial reasons, 1 had a career change and moved, 1 undetermined. The program was an out of pocket expense for each client, a standard monthly fee that included all exercise, food and nutritional counseling and group meetings. This program was run in Long Branch, NJ, Blairstown, NJ and Palm Spring, CA. All these demographics were of above average income.

Results/Statistical Data

A total of 73 clients with findings of MetS were selected for the study, of which all charts were available for review. Out of the 73 none were excluded. The mean age of the clients in this series was 55.5, 28 of whom were males (38.4%) and 45 were females (61.6%). There were 57 (78.1%) clients whose serum cholesterol were above the normal (>200) range while 36 (49.3%) clients had elevated (>150) serum triglyceride. There were 48 (65.8%) clients whose LDL cholesterol were above (>130) and 22 (30.1%) had below average HDL (<50 females, <40 males). 43 (58.9%) clients had a BMI > 30 thus clinically defining them as obese. The uniqueness of MetS and its wide diagnostic criteria forces one to look at overall changes and subset data evaluation.

Including (n=73) in an overall evaluation the following statistical changes were observed, see Table 1. In an evaluation of the subset groups (triglycerides n = 36, total cholesterol n = 57, LDL n = 49, HDL n = 22, BMI n = 40), focusing only on the individual inclusion criteria and their individual results the following statistical changes were observed see Table 2.

Lab Test	n = 73	Mean Pre	Mean Post	Pt. +/-	% Change
Triglycerides	73	163.53	99.59	-63.94	-39.10%
LDL	73	143.82	110.11	-33.71	-23.44%
HDL	73	55.89	54.19	-1.7	-0.03%
Total Cholesterol	73	226.84	183.56	-43.28	-19.08%
Weight	73	203.26	177.75	-25.51	-12.60%

Table 1: Overall.

Lab Test	n= /73	Mean Pre	Mean Post	Pt. +/-	% Change	Ref. Range	Reversal	Reversal%
Triglycerides	36	235.69	121.01	-114.68	-48.66%	<150	29	49.31%
LDL	49	163.63	119.33	-44.3	-27.07%	<130	31	63.27%
HDL	22	38.05	41.96	3.91	10.28%	>40m/50f	4	18.18%
Total Cholesterol	57	242.71	191.46	-51.25	-21.12%	<200	34	78.08%
BMI	40	35.22	30.91	-4.31	-12.24%	<30	8	20.51%

Table 2: Subset.

It is evident that there are significant changes in both evaluations, however in the individual subset analysis (individual inclusion criteria) the results are even more profound statistically. In MetS due to the expanded inclusion criteria it is very rare to find a client with all MetS inclusion criteria. However the individual analysis shows that every category has potential of bettering or ultimately reversing the subset to more optimal criteria, as laid out by American Medical Association metabolic/lipid profile reference ranges.

Triglycerides overall (n=73) reduced by 39.10%, in the subset group (n=36) by 48.66% with an overall reversal to optimal criteria of 49.31%, thus 29/36 individuals did not only lower triglycerides but also changed their numbers to the reference ranges of optimal blood work (< 150mg/dl). LDL overall (n=73) reduced by 23.44%, in subset group (n=49) by 27.07% with an overall reversal to optimal criteria of 63.27%, thus 31/49 individuals did not only lower LDL but also changed their numbers to the reference ranges of optimal blood work (< 130mg/dl). HDL overall (n=73) reduced by 0.03% (thus no clear positive change), in the subset group HDL (n=22) there was an increase of 10.28% (positive increase), with an overall reversal to optimal criteria of 18.18%, thus 4/22 individuals did not only increase HDL but also reached optimal reference range status (F > 50mg/dl, M > 40mg/dl). Total cholesterol overall (n=73) reduced by 19.08%, in the subset group (n=57) by 21.12%, but a profound 78.08% reversal to optimal criteria in this subset group, thus 34/57 no longer have that inclusion criteria (> 200mg/dl). BMI in the subset group reduced by 12.24% (n=40), with a reversal of BMI to optimal (<30 kg/m2) at 20.51%. Overall weight loss did not need to be put into a subset group as weight is not a inclusion criteria directly, however (n=73) had a pre mean weight of 203.26 lbs and a post mean weight of 177.75 lbs thus an average weight loss of 25.51 lbs or 12.60% reduction in weight in 12 weeks.

Biases and Confounders

The major biases of the MSRP could be outlined as follows:

- The research study was done by the clinicians of the MSRP - bias
- There was no control group thus a standard case series study
- There was no selection bias – strict outline in inclusion criteria was followed
- There was no information bias – all information collected was standardized
- There was no surveillance bias – no changes in screening techniques
- There was no lead time bias - prescreening tests were all standardized
- There could be publication bias – MSRP clinicians did trial analysis

The confounders from a nutritional perspective were narrowed down extensively by the preparation of all meals through one restaurant. All participants ate the same foods, cooked with the same ingredients. All weigh-ins were done at the same time of the day every time. There was inconsistency in the measurement of fasting glucose by some physicians and blood pressure, thus those two criteria had to be eliminated from the final statistical data.

Conclusion

The literature shows that Therapeutic Lifestyle Modification (TLM) Programs show promise in reversing MetS [47-55]. How-

ever few TLM programs are combined into one standardized intervention modality, thus providing the client with an all inclusive program. The MSRP provides this and the following:

1. Proper effective exercise program, that has health benefits, not too time consuming and can be maintained by all ages
2. Proper dietary protocols that have enough variety and choices that people can make permanent lifestyle adjustments by incorporating them
3. Proper "recovery" protocols so that when a person goes off the MSRP, they can get back on track for future maintenance

From the results achieved in this study there is significant data to suggest that the MSRP has a strong connection to reversing MetS. One factor that can be addressed is the marginal decrease in the HDL (0.03%) in the total evaluation, it must be remembered that not all participants had levels of HDL lower than (F > 50mg/dl, M > 40mg/dl), thus there was not a significant increase. However only 4/22 in the subset group had a complete reversal of this category of HDL (18.18%) with the total increase in this group of (10.26% or 3.91 point increase in HDL) this is a good progression, but maybe adding in supplements for this component will be a helpful aid in further increasing the HDL in future studies. A lot more research needs to be done preferably comparing the MSRP to another similar program in a Randomized Controlled Trial. What makes the MSRP different is the integration of various dietary outlines from a whole food perspective to achieve its goals. This could account for the compliancy on this program. The MSRP is a cost prohibitive program, however if the costs of the illness are measured for the future, the cost of the reversal and maintenance is very little by comparison. The Case Series Study is the only true viable option for a small business or group of clinicians to evaluate the efficacy of their protocols. The case report and case series studies even though frowned upon can be a great tool in Evidence Based Nutrition. It is a great way to put a client/s on a monitored protocol and accumulate data to form a case series. This is the most practical way for a small EBN practice to put their therapies/interventions to the test like the MSRP. Recently there has been a vocal pressure group within the medical profession calling for the reinstatement of the humble case report as a useful and valid contribution to medical science [56].

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