MEDIFAST NEWS

Updates on clinical obesity management with Medifast

Medifast

spring 2008

Welcome to *Medifast News*!

Here's what's new from Medifast, your resource for clinical management of obesity.

This month:

Program update - Medifast outperforms American Diabetes Association (ADA) diet in weight loss

Food science - Medifast introduces its new **Super Omega-3 dietary supplement**

Nutrition - Medifast's **soy-based** meal replacement consumption for patients on thyroid hormone therapy

Compliance - Effectively managing goals and expectations

Medifast Program Updates and News

Medifast outperforms American Diabetes Association (ADA) diet in weight loss

A study at a major university teaching hospital found that the Medifast Program outperformed a diet based on the American Diabetes Association (ADA) recommendations for patients with type 2 diabetes.

The study findings were published in the January/February 2008 issue of *The Diabetes Educator*, the peer-reviewed official journal of the American Association of Diabetes Educators.

Overview: The impact of type 2 diabetes

- Type 2 diabetes affects 1 in 4 Americans and often results in significant morbidity and mortality.
- Adults with diabetes are 2 to 4 times more likely to have a stroke or a fatal MI than adults without diabetes.
- Obesity and type 2 diabetes are strongly linked, as more than 70% of individuals with diabetes are overweight.

The role of weight loss

Weight loss is an effective method of managing type 2 diabetes. Losing just five to ten percent of one's body weight can greatly help to normalize blood sugar levels, and reduce the likelihood of complications such as heart disease.

Unfortunately, there is ample evidence in the scientific literature to suggest that obese individuals with type 2 diabetes have greater difficulty losing weight, and maintaining the loss, than those without diabetes. Statistics show that people with type 2 diabetes are likely to regain one-third to one-half of initial weight loss within the first year.

Portion-controlled meal replacements have been shown to improve long-term weight loss and dietary compliance among overweight individuals, and a controlled study tested their effectiveness among overweight subjects with type 2 diabetes mellitus.

Details of the study

Participants were 112 overweight and obese (BMI between 25 and 40 kg/m2) men and women with type 2 diabetes. They were prescribed either a 25% energy-deficient diet in accordance with the ADA standard diet (SD) or an equicaloric, portion-controlled diet using Medifast meal replacements (PCD). Body weight, biochemical markers (e.g., glucose), and retention were evaluated after a 34-week weight-loss phase, and an 86-week weight-maintenance period.

The main study finding was that participants randomized to the Medifast group lost twice the amount of body weight (7.3 ± 6.2 kg, 6.84% vs. 3.7 ± 3.2 kg, 3.70%, p=0.039) as those randomized to the SD group after 34 weeks.

Overview of findings

- 61% of Medifast participants lost ≥5% of initial body weight versus 23.5% of SD participants.
- 29.03% of Medifast participants lost ≥10% versus 5.88% of the SD participants. After 86 weeks,

continued on page 2

43.75% of the Medifast group maintained a ≥5% weight loss compared to 25% in the SD group.

- Blood glucose decreased 22.2 mg/dl in the Medifast group vs. 11.17 mg/dl in the SD group.
- Insulin levels decreased 2.97 µU/ml among Medifast subjects, whereas the SD group saw a 1.09 µU/ml increase at 34 weeks.
- Using a HbA1c of 7.0% as a cutoff to indicate adequate control of diabetes, 74.2% of the Medifast group achieved adequate glucose control, compared with only 35.3% of the SD group (p=0.008).

Significant improvements in other biochemical outcomes among the Medifast group were also observed at 34 weeks, including decreased triglycerides, lower systolic and diastolic blood pressure, and increased HDL. At 86 weeks, significant decreases in systolic blood pressure and increases in HDL were maintained.

Reduced need for medications

A significant clinical implication of the study was the reduced need for glucose-reducing medications in the Medifast group. For patients and the clinicians who care for them, this has important clinical, financial, and quality-of-life implications.

- 24% of Medifast participants reduced their use of medications compared with 0% in the SD group after the initial weight-loss phase.
- 36.3% of Medifast participants versus 33.3% of the SD participants reduced their use of medications at 86 weeks.

Increased compliance

A significant practical implication of the study was the ability of the Medifast group to adhere better to the weight-control program, as reflected by significantly fewer dropouts than in the SD group. At 34 weeks, 54.7% of the Medifast group was still on diet, versus 29.3% of the SD group, and at 86 weeks, 29.6% of the Medifast users were still adhering compared to 13.8% of the standard dieters. (p=0.02). The self-reported ease of compliance by the Medifast group compared to the SD group (64.2% vs. 56.0%) may be one reason these participants followed their program for a longer period.

Conclusions

Overall, the results of this research study indicate that the Medifast Program outperformed the ADA recommended diet in terms of weight loss, blood glucose control, and participant compliance.

While adhering to a calorie-controlled diet is difficult for anyone, meal replacements offer advantages such as ease of use, convenience, and built-in portion control. These factors may explain why dieters in Medifast's PCD group were twice as compliant and experienced twice the weight loss as those in the ADA's SD group.

The findings of this clinical trial indicate that portion-controlled meal replacements should be incorporated into comprehensive weight-loss programs among overweight or obese individuals with type 2 diabetes who want to lose weight.

Full-text article:

Cheskin, LJ, *et al.* "Efficacy of Meal Replacements Versus a Standard Food-Based Diet for Weight Loss in Type 2 Diabetes." *Diabetes Educator* 2008; 343(1):118-127.

In the next issue of

MEDIFAST NEWS

Program update: Antioxidants and resveratrol

Food science: Acesulfame K

Nutrition: Potassium

Compliance: Overcoming temptation

Food Science:

Medifast has recently introduced its new omega-3 fatty acid supplement, Super Omega-3. The recommended serving of two soft gels provides 720 mg of eicosapentanoic acid (EPA), 480 mg of docosahexanoic acid (DHA), and 100 mg of organic flaxseed oil.

Medifast's Super Omega-3 is enteric-coated, highly concentrated, molecularly distilled, and has been third-party tested for content. The enteric coating minimizes fishy eructation and facilitates greater absorption, while molecular distillation ensures a contaminant-free product. Perhaps more important, the enteric coating has been shown to increase bioavailability by a factor of three.

Cardiovascular disease

The cardiovascular benefits of fish oil are well documented and new information has emerged about how omega-3 fatty acids affect heart function (including anti-arrhythmic effects), hemodynamics (cardiac mechanics), and arterial endothelial function.

The mechanism of omega-3 fatty acids' impact on cardiovascular disease (CVD) risk continues to be studied. However, large-scale and randomized clinical trials have shown that omega-3 fatty acid from plant and marine sources decrease:

- risk of arrhythmias and subsequent sudden cardiac death
- triglyceride levels
- growth rate of atherosclerotic plaque
- blood pressure.

continued on next page

Food Science *continued from page 2*

Additional benefits

Although the most reported benefits of omega-3s center around heart health, these nutrients have been shown to benefit a wide range of other health issues. Increased omega-3 fatty acid intake is associated with improvements in autoimmune disorders, inflammatory bowel disease, psoriasis, depression, dementia/cognitive function, osteoporosis, and the risk of cancers of the breast, colon, and prostate.

Omega-3s have also been shown to have benefits specific to weight loss. Recent studies have shown improved body composition with the supplementation of omega-3 fatty acids:

- Together with moderate exercise, omega-3 supplementation can reduce body fat mass.[1]
- Omega-3 supplementation can reduce body fat mass in people with diabetes.[2]

How much should be taken?

The ideal serving size isn't clear; however, evidence from prospective secondary prevention studies suggests that taking a combined amount of EPA + DHA ranging from 0.5 to 1.8 grams per day (either as fatty fish or supplements) significantly reduces deaths from heart disease and all causes.

Two Medifast soft gels provide 1.2 gm of omega-3, which is more than the American Heart Association's recommendation of a minimum of 1.0 gm per day for those with existing cardiovascular disease.

In general, receiving necessary nutrients through foods is preferable and increasing omega-3 fatty acid intake is no different. However, not everyone is willing or able to consume fish regularly.

In addition, those with existing cardiovascular disease may not be able to get enough omega-3 by diet alone. Some individuals, such as those with hypertriglyceridemia, could benefit from high doses of omega-3s; in these cases, diet and supplements may both be used to reach the desired quantity of the nutrients.

As Medifast's Super Omega-3 is of particularly high quality and is free of contaminants and side effects, it is an appealing option for both physician and patient.

[1] Hill, A.M.; Buckley, J.D.; Murphy, K.J.; Howe, P.R.C. "Combining fish-oil supplements with regular aerobic exercise improves body composition and cardiovascular disease risk factors." *American Journal of Clinical Nutrition*. 2007; 85:1267-1274.

[2] Morvarid Kabir, G.; Skurnik, N.; Naour, V.; Pechtner, E.; Meugnier, S.; Rome, A.; Quignard-Boulange, H.; Vidal, G.; Slama, K.; Clement, M.; Guerre-Millo; and S.W. Rizkalla. "Treatment for 2 mos with n-3 polyunsaturated fatty acids reduces adiposity and some atherogenic factors but does not improve insulin sensitivity in women with type 2 diabetes: A randomized controlled study." *American Journal of Clinical Nutrition*. 2007; 86:1670-1679.

Nutrition Corner:

Soy consumption for patients on thyroid hormone therapy

For comments or questions regarding nutrition, please contact: NutritionSupport@ChooseMedifast.com

Do Medifast's soy-based meal replacement products pose a challenge to patients getting thyroid hormone therapy for hypothyroidism?

Soy protein may interfere with the absorption of synthetic thyroid hormone and adversely affect proper thyroid functioning. A review of 14 clinical trials conducted by Messina & Redmond (2006) assessed the effects of soy on at least one thyroid function, and found that with only one exception, either no effects or only modest changes were noted. Thus, the researchers concluded that there is little evidence of soy foods adversely affecting thyroid function in euthyroid, iodine-replete individuals.[1]

In contrast, some evidence suggests that soy foods, by inhibiting absorption, may increase the dose of thyroid hormone required by hypothyroid patients. Further, in some individuals who consume marginal amounts of iodine, soy foods may, at least theoretically, increase the risk of developing clinical hypothyroidism.[Ibid.]

In response to this research, Medifast recommends that patients receiving synthetic thyroid hormones allow a two- to three-hour window between taking thyroid medication and consuming a soy-based meal replacement. Individuals are encouraged to use a non soy-based meal replacement as the first meal after medication is administered. We suggest the use any of eleven non-soy, whey protein products (in addition to Scrambled Eggs, which are egg-protein based) instead. Non-soy, whey protein meal replacement products include:

- Cappuccino
- Chai Latte
- Hot Cocoa
- Peach Iced Tea
- Raspberry Iced Tea
- Cranberry Mango Fruit Drink
- Tropical Punch Fruit Drink
- Cream of Broccoli Soup
- Cream of Tomato Soup
- Cream of Chicken Soup
- Whey Antioxidant Shakes (Cherry Pomegranate, Dark Chocolate, Blueberry) (available June 2008)

[1] Davis, Lisa. *The Bottom Line: Soy and Health: For the Healthcare Provider*. Lisa Davis, PhD, PA-C, CNS, LDN is Director Research & Development at Jason Pharmaceuticals, Inc., the parent company of Medifast, Inc.

Compliance:

"Are we there yet?" Effectively managing goals and expectations

When patients approach their healthcare providers with questions about weight loss, one of the first inquiries is how much they should weigh.

The answer can be tricky. Body mass index (BMI) is recognized as a reliable tool for assessing weight status based on height, and provides a context for labeling a patient healthy, overweight, or obese. It's a handy statistic, but there's more to weight-loss goals in the short run.

The practitioner's focus should be on reducing patients to a healthier weight and promoting healthy lifestyle habits, rather than focusing on an ideal. This approach provides a foundation for realistic expectations, and allows patients to achieve significant health benefits over a prolonged period.

Also, scientific data indicate that even moderate weight loss (5 to 10 percent of initial body weight) can significantly improve insulin sensitivity, reduce blood pressure, decrease plasma lipid levels, and reduce other risk factors in the obese patient. The National Heart, Lung, and Blood Institute (NHLBI) recommends that the initial goal of weight-loss therapy should be to reduce body weight by approximately 10 percent from baseline, with a secondary goal of further weight loss if indicated by assessment.

Patients may seek a more aggressive initial weight-loss goal, and may need additional counseling to convince them of the benefits of more modest weight-loss objectives. Realistic goals are motivators, whereas unrealistic goals produce anxiety, disappointment, and frustration - all counterproductive in terms of time, cost, and self-esteem.

Remind your patients that success is not just about losing a set number of pounds. Encourage them to look beyond the scale and seek to improve energy, self-confidence, stamina, sleep patterns, blood pressure, cholesterol, and glucose levels. Assure them that even modest weight loss can enhance overall quality of life and functioning.

The **SMART** mnemonic is an easy way to assess lifestyle goals:

- **S**pecific: Establish clear, short-term goals and particular means of accomplishing them. For example, rather than seeking to "get in better shape," the patient can commit to walking on the treadmill for 15 minutes, three times per week.
- **M**easurable: Make goals quantifiable so patients can track progress at defined intervals and understand when modifications are needed. Also, achieving benchmarks boosts morale and self-confidence. Duration and frequency of exercise would be an example.
- **A**chievable: Goals must be attainable to motivate patients. Running three times per week for 30 minutes is not a good goal for the patient who struggles walking up a single flight of stairs. Over time, they can push themselves with incremental objectives.
- **R**ealistic: Work with patients to devise a plan that is relevant and realistic for them and their life. For instance, a patient who struggles with emotional eating may vow, "I'll never eat out of emotion again." But a more realistic goal may be to recognize the triggering feelings and diffuse them with at least 2 distraction techniques, such as a 10-minute walk, brief meditation, glass of water, or a call to a friend, while reserving a couple of celery stalks as backup if the distraction is not successful.
- **T**ime-bound: Each goal should have a set time frame; without a deadline, patients may not have the sense of urgency they need to take action.

The bottom line: Partner with your patients from the start to establish realistic expectations, using **SMART** incremental lifestyle goals for modest weight loss, regular physical activity, and positive behavioral changes. At a steady pace, you'll help them advance toward their goals of weight management and a healthier life.

Medifast
11445 Cronhill Drive
Owings Mills, MD 21117