

Diabetes: the all-American disease; Given the rise in diabetes, nutraceutical solutions are in demand.



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Diabetes is one of the deadliest--and most difficult--diseases to treat. That's not because there aren't plenty of safe, effective methods for controlling diabetes, a disease in which the body either does not produce enough insulin or does not use insulin efficiently. Rather, treatment is difficult because diabetes is often a disease of denial. "Being diagnosed with diabetes doesn't create an event the way heart disease does," explained Stacey Antine, MS, RD, director of corporate communications for Nutrition 21, Purchase, NY. While surviving a heart attack can inspire profound lifestyle and dietary changes, being pronounced diabetic doesn't usually have as much of an impact.

[ILLUSTRATION OMITTED]

Dissecting the disease

Diabetes is the sixth leading cause of death in the U.S., affecting over 18 million people, 90% of whom suffer from the preventable type 2 diabetes (1). One-third of those with diabetes don't even know they have it (1). And many more people are affected by pre-diabetes, a term used to describe people at high risk of developing diabetes. If the results of one cross-sectional study of American adults were extrapolated to the entire population, about 41 million, or 14%, would be in the pre-diabetic category (1).

Experts agree the diabetes situation in America is critical. Diabetic adults are two to four times more likely to die from heart disease than non-diabetics. They also have a two to four times higher risk of stroke. Blindness, kidney disease, nervous system diseases, amputations and dental disease are also far more common in diabetics than in the general population (1).

Unfortunately, the situation is only projected to get worse. The U.S. Centers for Disease Control & Prevention (CDC), Washington, D.C., recently issued the alarming news that children born in 2000 have a one in three chance of developing type 2 diabetes in their lifetimes (2). The dramatic rise in the incidence of diabetes is widely attributed to two main factors--an increasingly overweight and sedentary population.

For reasons that aren't completely understood, obesity decreases insulin sensitivity and exercise increases it. According to the U.S. Surgeon General, 61% of Americans are overweight or obese, as are 13% of children and adolescents (3). However, these statistics should be taken with a grain of salt, as the federal government changed its measurement standards in 1998, reclassifying 30 million adults as overweight with the new changes. Still, according to the CDC, only 15% of Americans regularly engage in vigorous physical activity, which is defined as three times a week for at least 20 minutes

per session (2).

There's more to diabetes than just being overweight and sedentary, however. Genetics also play a major role. A family history of diabetes places one at high risk for the disease, and certain races are also disproportionately affected, particularly African Americans, Latinos, Native Americans, Asian Americans and Pacific Islanders.

What is Syndrome X?

Insulin resistance, at the heart of type 2 diabetes, is also a key factor in the development of Syndrome X (also called metabolic syndrome), which encompasses a series of conditions including visceral obesity (fat in the abdominal area), elevated blood sugar, elevated triglycerides, low levels of HDL cholesterol and high blood pressure. A person is diagnosed as having Syndrome X if three of these factors are present. If the insulin resistance is severe enough, many people with Syndrome X eventually develop type 2 diabetes.

Results from the third National Health and Nutrition Examination Survey (NHANES), conducted by the CDC, found that an astonishing one in five Americans are affected by Syndrome X, and that the problem gets worse with age. Indeed, more than 40% of Americans in their 60s and 70s have syndrome X (4). Similar to diabetics, those with Syndrome X are two to three times more likely to experience heart disease and stroke than healthy individuals (5).

Diabetes Treatment/Management Trends

The good news is that diabetes and Syndrome X are largely preventable--and manageable--with lifestyle and dietary changes. In fact, one landmark trial studied over 3000 overweight non-diabetic individuals who had impaired glucose tolerance over a three-year period. Diet and exercise were found to reduce the incidence of diabetes by 58% compared to placebo. It was nearly twice as effective as simply taking the prescription drug metformin, which reduced diabetes incidence by 31% (6).

Another study, which involved 1441 young adults with type 1 diabetes, discovered that intensive treatment--which included a diet and exercise plan, along with close monitoring of blood glucose levels and four daily insulin injections or use of an insulin pump--resulted in a 76% reduced risk of eye disease, a 60% reduced risk of nerve disease and a 50% reduced risk of kidney disease compared to the group that received only one or two daily injections of insulin (7).

Today's diabetics appear to be approaching the disease through a combination of dietary choices and supplements. As Americans' understanding of the relationship between food and blood sugar evolves, the term "glycemic index" (GI) is becoming better known. GI refers to the ranking of carbohydrates based on their ability to increase blood sugar over a period of two to three hours after a meal. The quicker a carbohydrate is broken down--and the more of a spike it causes in blood sugar levels--the higher the ranking. A GI of 70 or more is considered high, 56 to 69 medium, and 55 or less low. Glucose has a GI of 100.

From a dietitian's perspective, "Foods with lower glycemic index values are preferable, especially for diabetics, because they break down slowly into glucose, and thereby reduce the incidence of spikes in glucose levels," said Jeanette Fisher, R.D., national education manager for Soft Gel Technologies, Inc. (SGTI), Los Angeles, CA. In fact, it's good advice for everyone to follow a diet whose carbohydrate intake falls on the low GI side. Research indicates that a high GI diet is associated with a higher risk of birth defects (8) and cardiovascular disease risk factors (9), and may raise cancer risk (10).

Yet Brien Quirk, technical director, Draco Natural Products, San Jose, CA, said that labeling low-carb foods with a GI rating, which is already practiced in some countries such as Australia, can be "highly misleading and inaccurate because the size of the meal and other foods you eat with the low glycemic food will influence the overall blood sugar rise."

SGTI's Ms. Fisher agreed. "It (glycemic index) doesn't provide the quantity of carbohydrates found in a serving of a particular food," she explained "It also doesn't measure how well carbohydrates are processed through different pathways."

Yet for those watching their blood sugar levels, there's no denying the appeal of GI-labeled foods. Dr. Linda Douglas, scientific affairs manager for GTC Nutrition, Golden, CO, said one trend to keep an eye on is the manufacturing of healthier, diabetic-safe convenience foods. "The makers of Ensure[R] developed the successful Glucerna[R] line of shakes, meal bars and snack bars--featuring GTC's NutraFlora[R] ingredient--specifically for diabetics," she said. "While the products are not labeled with a GI number, they are marketed using the same concept: low-sugar foods that help consumers manage diabetes."

Nutraceuticals to the Rescue

Numerous nutraceuticals also show promise in diabetes management. Jocelyn Mathern, R.D., technical specialist for Acatris, Minneapolis, MN, observed that diabetics are particularly open to complementary and alternative medicine (CAM). "A study published in 2002 reported that diabetics were 1.6 times more likely to use CAM than individuals without diabetes," she said (11). "Another study found that 57% of individuals with diabetes used CAM (12)."

Aloe vera. A placebo-controlled, single-blind human clinical trial found that diabetics receiving 15 milliliters of aloe gel twice a day for 42 days experienced 43% and 44% reductions in blood sugar and blood triglycerides, respectively, while controls experienced no change (13). Aloe may also provide an alternative for patients unresponsive to glibenclamide, an antidiabetic drug. One study found that people whose fasting levels of blood glucose and triglycerides had been unchanged by glibenclamide experienced a 48% drop in blood sugar and a 52% drop in triglycerides after treatment with aloe vera juice (14).

Alpha lipoic acid. One of the most promising natural treatments for diabetes is alpha lipoic acid (ALA). One research review looked at the 15 clinical trials that had been performed with ALA to date. The researchers concluded that three-week treatment using 600 mg per day of the ingredient reduced the chief symptoms of diabetic neuropathy--a complication

of diabetes that affects the nerves--and that it may confer long-term improvement in motor and sensory nerve conduction in the lower limbs (15).

A collaborative study between the Mayo Clinic and a Russian medical center, published four years after the review, confirmed that intravenous preparations of ALA rapidly decreased the burning, pain, prickling and numbness of diabetic neuropathy. One of the researchers was quoted as saying, "We were surprised by the magnitude and the rapidity of the response (16)."

Banaba. Relatively new to the supplement world, the leaves of the banaba plant contain corosolic acid, which exhibits antidiabetic properties. SGTI manufactures GlucoTrim[™], which contains banaba standardized to contain 1% corosolic acid. According to the company, two placebo-controlled crossover trials demonstrated that GlucoTrim lowers blood glucose levels.

Bitter melon. A small collection of studies in mice, rats and rabbits shows that bitter melon reduces blood glucose levels. Results in humans are also encouraging. Two controlled short-term trials found the herb had acute effects on blood glucose and hemoglobin A1c in those with type 2 diabetes (17,18). Additionally, two small, uncontrolled trials reported the herb had positive effects on blood sugar control when used for seven to 11 weeks (19,20).

Chromium. Perhaps the most known of antidiabetic ingredients, chromium, a trace mineral, which potentiates the actions of insulin, is also widely researched. Nine out of 15 randomized controlled trials investigating chromium's ability to enhance insulin sensitivity and improve blood sugar control in diabetics showed significant benefit. "When you actually show an impact, it's not something you take and hope it will work," commented Nutrition 21's Ms. Antine. "We're actually showing efficacy on blood levels."

Fenugreek. A number of studies have confirmed fenugreek has a hypoglycemic effect. The herb's high fiber content forms a gel in the stomach, which slows gastric emptying and delays glucose absorption. One double-blind, placebo-controlled study compared diabetics practicing dietary control and exercise vs. those receiving 1 gm / day hydroalcoholic extract of fenugreek seeds. At the end of two months, researchers concluded that, "adjunct use of fenugreek seeds improves glycemic control and decreases insulin resistance in mild type 2 diabetic patients (21)." Acatris produces an odorless extract of fenugreek galactomannan (gum) called FenuLife[R] and has started a clinical research program for the product.

Another company involved with fenugreek is Technical Sourcing International, Missoula, MT, which manufactures Promilin[™], a proprietary bioactive complex of amino acids including 4-hydroxyisoleucine (4-OH-Ile) extracted from fenugreek. Following administration of glucose, 4-OH-Ile improves glucose tolerance in normal and insulin-resistant rats and dogs by increasing insulin release and reducing the spike in blood sugar (22).

Fish oils. Omega 3 fatty acids contained within fish may help prevent and treat diabetes. In one trial of overweight individuals with insulin resistance, 50% of participants showed a clinically significant change in insulin-related function after taking docosahexaenoic acid

(DHA) (23). Another study found that diabetic women who regularly ate fish reduced their risk of heart disease by as much as 64% (24).

Enzymotec manufactures carDiabet[R], a proprietary combination of enzymatically derived lipids including DHA and eicosapentaenoic acid (EPA). CEO Dr. Ariel Katz asserts that carDiabet does what current diabetes treatments don't: it supplies a specific solution for the major risk of death in diabetes patients--cardiovascular disease.

Ginsengs. Both Panax ginseng and American ginseng have been used to manage diabetes. Panax ginseng has been found to "remarkably reduce blood sugar levels" in normal and hyperglycemic mice (25). Two eight-week trials following patients with type 2 diabetes found American ginseng significantly decreased fasting blood glucose, hemoglobin A1c and postprandial blood glucose levels (26,27).

Gymnema sylvestre. Gymnema sylvestre is an herb widely used in Ayurveda. In the few non-randomized controlled clinical trials available on the herb, diabetics receiving an extract of gymnema showed improved glycemic control over those who received conventional treatment alone. Patients using insulin were able to decrease their insulin requirements (28,29).

Maitake. Several animal studies have shown that maitake fractions have glucose-lowering potential. Two small human trials have also been undertaken. The first showed that five patients with type 2 diabetes taking oral medication showed 30-63% declines in blood sugar levels after taking maitake powder containing SX-fraction for two to four weeks (30). According to Maitake Products, Inc., Ridgefield Park, NJ, an unpublished two-month Japanese trial involving 14 diabetic patients found that fasting blood glucose and hemoglobin A1c significantly decreased after a month of supplementation with the mushroom fraction, as did body weight, cholesterol and triglycerides

Pycnogenol. When blood sugar is elevated, oxidative stress increases, which may explain diabetics' high rate of cardiovascular disease. Pycnogenol[R] is an extract of French maritime pine bark with powerful antioxidant properties. A double-blind, placebo-controlled, randomized, multi-center study found Pycnogenol, used in conjunction with standard antidiabetic treatment, significantly lowered blood glucose compared to placebo. The study is slated for publication in the October issue of Life Sciences (31). The ingredient has also gained notoriety for its ability to halt or slow the progression of diabetic retinopathy, the leading cause of blindness in people under the age of 60. According to the company, five clinical studies in Europe consisting of more than 1000 patients have shown that Pycnogenol seals the leaky capillaries of the retina, preventing vision loss.

Soy. Soy protein has been observed in animal and human studies to have antidiabetic activity. Maintaining a low GI score, it is well known for its heart-protective properties. Solbar, Ashdod, Israel, produces soy protein (Solcon S) and soy isoflavones (Solgen 40), both of which have been clinically studied. One study found that diets supplemented with these two ingredients improved insulin resistance and blood sugar and cholesterol levels in post-menopausal diabetic women. In fact, soy was as effective at lowering blood sugar as some prescription diabetes drugs (32).

Looking Toward the Future

Due to the urgency of the diabetes situation, the future of nutraceuticals that can help manage the disease is bright. "With baby boomers entering their 50s, there's no doubt that the diabetes supplement market will continue to grow," predicted Allondra Stevens, marketing services manager for InterHealth Nutraceuticals, Benicia, CA.

On the other end of the age spectrum, Dr. Douglas pointed to the fact that diabetes diagnoses in children are steadily increasing. Because of this trend, she said, "It is fairly safe to assume that the market for diabetic-safe foods will remain strong for decades to come."

Several industry executives predicted that functional foods will be a hot category of growth within the diabetic market. "It is very difficult for a diabetic person to consume small portions in regular time intervals and then secure that these are low in saturated fats, and supply sufficient amounts of protein and slowly absorbed carbohydrates," noted Dr. Frank Schonlau, director of Scientific Communication for Natural Health Science, Hillsdale, NJ.

But as Draco's Mr. Quirk highlights, the success of any natural product for diabetes must take into account that there is an "addictive lifestyle" component. In other words, engrained unhealthy dietary and lifestyle patterns can be difficult to break and make any treatment plan challenging. Therefore, the simpler the solution, the better.

Ellen Shnidman, manager of scientific affairs for Maitake Products agreed. "Any product that's easy to buy and easy to take and that reduces blood sugar levels will have a potentially large market," she said.

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