

DIABETES MANAGEMENT™

The Complete Diabetes Disease State Management Resource

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Help your patients with diabetes enjoy a vacation

Advance planning keeps control on an even plane

Summer sun on a Greek isle. Balmy moonlit nights in exotic Aruba. Pina coladas on a Hawaiian beach at sunset. Even a rowdy trip to Disney World with the kids. What sounds like a dream vacation might pose health problems for your patients.

Not so, say experts. Those idyllic dalliances are easily within the grasp of anyone with diabetes Type 1 or Type 2 — with a little advance planning — and a little self-restraint in the diet department.

“People with diabetes should get to experience being on vacation just like anyone else. They can have a dessert, but maybe trade it for the potato at dinner,” says **Elizabeth Walker, MD**, the American Diabetes Association’s president for health care and education and associate professor of medicine at Albert Einstein College of Medicine in Bronx, NY. “They shouldn’t feel trapped by their diabetes. They shouldn’t let it ruin their lives.”

Traveling with diabetes means dealing with an unpleasant-sounding menu of management challenges: Different food and alcohol consumption, different exercise levels, time zone changes, jet lag, even new

KEY POINTS

- Advance preparation is essential to maintain diabetes control while traveling.
- Patients using insulin must be particularly vigilant while traveling and carry an extra supply of insulin and all other diabetic supplies.
- Clinicians are advised to be nonjudgmental about a small lapse in control during vacation and be supportive in helping patients get back on track when they return home.

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What to bring on vacation

If traveling by plane, keep a carry-on bag within reach at all times, containing:

- ✓ twice as much medication (insulin or oral agent) and supplies, including syringes, as anticipated will be needed;
- ✓ all monitoring equipment, including extra batteries for monitor;
- ✓ glucagon;
- ✓ glucose tablets;
- ✓ prescriptions for all medications;
- ✓ snacks: crackers, cheese, peanut butter, juice;
- ✓ names of physician and/or diabetes association at your destination.

In addition:

- ✓ Wear medical bracelet at all times.
- ✓ Obtain an American Diabetes Association affiliate identity card from the local diabetes association, preferably a version written in major languages.
- ✓ If traveling by plane, insulin should not be checked with baggage because the temperature extremes in cargo holds can diminish its effectiveness.

stresses caused by climatic changes and possible exposure to exotic diseases.

All it takes is a little preparation, particularly for patients who use insulin, says Walker.

Encouraging patients to discuss their vacation plans with you as far in advance as possible gives them time to optimize glycemic control and collect information to help them connect with health care professionals at the destination, should they be needed.

Here are some high-priority tips you should provide for travelers with diabetes regardless of their level of disease or their need for medications and/or monitoring:

- **Keep all diabetes supplies in a carry-on readily available at all times.** Patients should

never be separated from their supplies. In addition, insulin should never be checked with luggage because fluctuating temperatures in cargo holds may alter its effectiveness.

- **Pack at least twice as much medication, insulin, and other supplies that they expect to consume.**

- **Carry snack foods since meal times are often irregular during vacations.**

- **Carry a prescription for all medications, signed by a physician.** It's also a good idea to have a detailed letter from a physician describing the patient's condition and all medications and supplies needed to treat diabetes.

"Travel can throw the whole system off, especially if they are traveling across time zones," says Walker. "That's why it's essential for them to have snack foods like crackers, cheese, peanut butter, juice, and glucose tablets to help them deal with possible hypoglycemia."

Tweak dosage for time changes

Travel across time zones may require adjustments in insulin dosage, since days become shorter going from west to east and longer going from east to west.

Travel often means greater levels of physical activity, leading to increased insulin sensitivity, as well as the desire to indulge in exotic foods, drinks, or extra desserts, which may raise blood sugars. Either way, this can require adjustments in medication.

"In the long run, we don't recommend trying to 'cover' extra food intake with increased insulin dosing because it will lead to weight gain," says Walker. "But occasionally doing that on vacation isn't a big problem. I work with them and help them get back on track when they get home."

A big caveat: Patients shouldn't make assumptions about glucose levels. Frequent monitoring will prevent unpleasant mistakes.

Another recommendation: Care must be taken in filling syringes on an airplane because it can lead to introduction of pressurized cabin air into

COMING IN FUTURE MONTHS

■ How patients perceive their risk for major complications

■ ADA consensus statement on Type 2 diabetes in children

■ Managing diabetes through the Internet

■ Oldspeak-newspeak: Changing your language to encourage adherence

Where to get information

American Diabetes Association. If traveling in the United States, get a list of ADA affiliates and chapters that can give referrals to local health professionals. Web site: <http://www.diabetes.org>. Telephone: (800) DIABETES.

International Diabetes Federation. Provides information about prescription laws and standards in other countries. IDF: 1 Rue Defacz, B-1000, Brussels, Belgium.

International Association for Medical Assistance to Travelers has a free pocket guide to English-speaking doctors worldwide who are familiar with Western medicine. Write IMAT at: 417 Center St., Lewiston, NY 14092. Telephone: (716) 745-4883.

Other recommendations:

MedicAlert emergency medical identification is available through the MedicAlert Foundation International, (800) 825-3785.

Medical insurance. Patients should check with medical insurers to see if health insurance is effective in other countries. If it is not, they should check into supplemental short-term policies.

the insulin bottle, making it more difficult to measure and administer the dose.

Refrigeration is another insulin issue that may arise while traveling. This is an individual choice, and most patients have good results with unrefrigerated open insulin bottles as long as they are consumed within 30 days. Those who prefer to refrigerate their insulin can carry it in insulated bags, such as cooler-type lunch bags and check ahead at their destination to be sure refrigeration will be available.

And insulin, available in U-100 concentrations the United States, is not sold in that form in some countries, where the concentrations are sometimes diluted to U-40 to U-80. Tell patients to check ahead.

For extended trips, it may not be possible to carry all supplies needed. In all but the most remote areas of the world, however, they can be shipped overnight or in a few days by Federal Express or UPS.

Other things to remind your patients before it's too late:

- **Be sure to have comfortable, well-broken-in shoes to avoid blisters.** Not only can blisters cause painful and potentially serious foot ulcers, the open skin can also lead to infections that affect glucose control. Proper footwear, even at the beach, can prevent injuries. Don't go barefoot.

- **If you are traveling to a remote area or to an area where there are frequent disease outbreaks, check in advance with the Centers for Disease Control and Prevention and see what, if any, immunizations are needed.** Illness during a vacation is no fun for anyone, but it could be doubly complicated for someone with diabetes.

- **When traveling abroad, avoid tap water and ice cubes.**

- **See a physician at first sign of illness.** Delay could lead to glucose problems that could make a minor illness much more serious when you're away from home.

Children require extra planning

Advance planning is even more crucial when traveling with children with diabetes, says Juvenile Diabetes Association volunteer **Sandra Silvestri** of Carmel, CA. Silvestri is not a health care professional, but has even more intimate experience with Type 1 diabetes through her 10-year-old son, Joey, who was diagnosed with diabetes when he was 2 years old.

The Silvestri family has always loved to travel, and Joey's diabetes hasn't changed that.

She became such an old hand at traveling with a backpack of insulin and other supplies Joey needed that she volunteered to chair the Juvenile Diabetes Foundation's Children's Congress in Washington, DC, a year ago.

"This was a big group of people, many of whom had never traveled at all after their children were diagnosed," says Silvestri. "They needed the confidence to know they can do this."

So she got her thoughts together and sent out a set of guidelines.

"I think of you all as 'my kids' and 'my family,' so I say to you as I do to my kids, 'Plan ahead!' and 'Be prepared!'" Silvestri wrote to prospective participants in the congress. "Try to think ahead and plan for the inevitable delays that summer travel often brings to the airlines. When I travel with Joey, I always make sure to have cheese and crackers, juice, and Starbursts in my backpack. I cannot tell you how many times this has saved

the day for us as we wait in airline terminals.”

Joey, who now uses an insulin pump, always carries a spare pump. “I always have a backup for everything, just to be sure,” Silvestri says. “And a new pump can be delivered within 48 hours almost anywhere.”

Silvestri also says children with diabetes don’t seem to adjust to time changes as easily as adults.

“We make a gentle segue to the new schedule as soon as possible,” she says. “We test every two hours and get a carb count. If we’ve traveled over several time zones, we’ll use Humalog for 48 hours until we get a grasp of where we’re going.”

One last warning from Silvestri that applies to adults, as well: “Feed the child, don’t feed the insulin!”

[Contact Elizabeth Walker through the American Diabetes Association. Telephone: (703) 549-1500. Sandra Silvestri can be contacted through the Juvenile Diabetes Foundation. Telephone: (800) 533-2873.] ■

Diets for Syndrome X: Which carb is best?

Opinions vary on approaches to insulin resistance

The epidemic of obesity in America and the consequent avalanche of diets, fad diets, information, and disinformation may be bogging patients into a quagmire of uncertainty. With weight loss a major consideration for a high proportion of patients with Type 2 diabetes, they are asking questions such as: “High-carb? Low-carb? Zone? Atkins?”

KEY POINTS

- Syndrome X is a cluster of changes that encourages the onset and development of heart disease and diabetes, characterized by arterial plaque buildup due to elevated levels of circulating insulin.
- Two recently published books suggest opposite approaches to diet to prevent digression to diabetes — one high carbohydrate with fat component heavily tied to monounsaturated fats and the other with a high protein content, low carbohydrate content, emphasizing avoidance of refined carbohydrates and consumption of monounsaturated fats.

Risk factors for Syndrome X:

- ✓ fasting glucose greater than 100 mm/dL or OGTT at 140 or greater after two hours;
- ✓ fasting triglyceride level greater than 200;
- ✓ fasting HDL cholesterol lower than 35;
- ✓ blood pressure greater than 145/90 mm Hg;
- ✓ more than 15 pounds over ideal weight;
- ✓ family history of heart disease, high blood pressure, or diabetes;
- ✓ lifestyle characterized by physical inactivity in both work and leisure hours.

Source: Reaven G. *Syndrome X: Overcoming the Silent Killer that can Give You a Heart Attack*. New York City: Simon & Schuster; 2000.

How to answer?

Almost universally the answer comes back: Approach weight loss with sense and reason.

“The success formula for weight loss is so individualized that there is no one-size-fits-all cookie-cutter plan,” says **Sheila Kelly**, MS, RD, LD, CDE, clinical nutrition manager at Providence Hospital in Washington, DC.

Syndrome X, a cluster of changes that encourages the onset of diabetes and heart disease, has been a medically accepted condition since Stanford endocrine researcher **Gerald Reaven**, MD, first used the term a dozen years ago. But the complex compilation of factors leading up to insulin resistance and subsequent cardiovascular risks has been acknowledged for 50 years or more.

Two sides of the same coin

From insulin resistance to diabetes is only a very short leap, says Reaven, an endocrinologist and professor of medicine at Stanford University in Palo Alto, CA.

“The difference between the two is artificial. In both situations, a patient cannot put out enough insulin to keep blood glucose from going up. It’s two sides of the same coin,” says Reaven, author of *Syndrome X: Overcoming the Silent Killer That Can Give You a Heart Attack*.

Routine tests and physical examinations reveal Syndrome X (see above chart), which is characterized by elevated fasting blood glucose, elevated triglycerides, low HDL cholesterol, being overweight, elevated blood pressure, sedentary lifestyle, and a family history of heart disease,

Compare the Makeup of Popular Diets:

Diet	Protein	Saturated Fat	Mono- and Poly-unsaturated Fat	Carbohydrate	Cholesterol
American Heart Association	15%	5-10%	20%	55-60%	300 mg/day
Syndrome X	15%	5-10%	30-35%	45%	300 mg/day
Zone Diet*	30%	6%	24%	40%	210 mg/day
Atkins*	22%	25%	35%	18%	880 mg/day

*Those diets make no specific recommendations; proportions were calculated from recommended menu plans.

Source: Gerald Reaven, MD. *Syndrome X: Overcoming the Silent Killer that Can Give You a Heart Attack*, New York City: Simon & Schuster; 2000.

hypertension, or diabetes.

Reaven's hypothesis: Eating up to 45% of calories in dietary fat will actually help overcome insulin resistance, as long as the vast proportion of those fats (30%-35% of daily caloric intake) comes from poly- and monounsaturated fats like olive oil, soft margarine, nonfat milk products, nuts, poultry, and fish. **(See chart, above.)**

He also disagrees with the American Heart Association's recommendation that a healthy diet contains 55% to 60% of calories from carbohydrates — at least for people with Syndrome X and diabetes. Instead, he recommends much lower carbohydrate consumption at about 45% of total caloric intake.

New book complicates matters

Then there are the more extreme diets, like the much-criticized Atkins Diet, which encourages high protein and high fat intake of all types with very low carbohydrate consumption. And there's the somewhat more moderate Zone diet.

To further complicate matters, a recently published book, *Syndrome X: The Complete Nutritional Program to Prevent and Reverse Insulin Resistance*, by **Burton Berkson**, MD, PhD, a cellular biologist and president of Integrative Medical Centers of New Mexico in Las Cruces, recommends a relatively high protein and low carbohydrate diet for Syndrome X.

"It's a steady diet of refined carbohydrates that causes Syndrome X," theorizes Berkson, so he recommends what has been called a Paleolithic diet

— one rich in animal protein and a wide variety of unprocessed grains, fruits, and nuts, much like our distant ancestors might have consumed.

That still doesn't give us a clear picture of what diet is best for patients with diabetes or impaired glucose tolerance. And, unfortunately, the answer to that question isn't going to make a clinician's job any easier.

"Each patient is individual, so we have to devise an individual plan for each patient," says Kelly. "It depends on the individual's unique metabolism and on what that person is willing to do, so generic approaches just don't work."

She recommends against extremes, like the Atkins Diet, which she calls "incredibly dangerous in terms of dangers of kidney failure and bone loss" because of its high animal fat and subsequent high cholesterol content. "I tried the Atkins Diet myself for a paper I was writing, and fell off it after five days," Kelly says. "There's no way you can support a modicum of physical activity on that diet, and we all know how important exercise is to managing diabetes."

Kelly recommends starting on a 55-20-30 ratio of carbohydrates to proteins to fats "and then take it from there — see what works, how well the patient adheres to the diet, and make whatever adjustments need to be made."

Kelly's clincher, which seems to keep refined carbohydrate intake in check: Her recommended diet includes 35 grams of fiber a day to control blood glucose absorption and prevent cholesterol synthesis. "If they get that, by default they won't be able to get their carbs from cakes or candy or

even white bread,” she says.

Columbia University associate research scientist **Wahida Karmally**, MS, RD, CDE, agrees with Kelly — to a point. “One description doesn’t fit all, but some come close to it,” she says.

And to Karmally’s thinking Reaven’s Syndrome X diet is a model for moderation. It comes closest to providing what patients with diabetes need, Karmally says.

“Nobody has shown scientifically that high-protein diets increase satiety and thereby reduce caloric intake,” she says. “And we don’t know the effect of high protein on kidneys, but certainly it makes them work harder.”

This could present unique problems for patients with diabetes who are at risk of renal disease, she says.

In addition, Karmally says, low carbing excludes consumption of whole grains that have well-documented benefits, including prevention of heart disease and certain types of cancers. “For diabetics, I have to do it with each patient,” she explains. “I work with them and look at blood sugar levels, postprandial glucose, whether they’re on insulin or oral meds, and then we look at it together. That’s the key. I can give them diets forever, but it’s useless if they won’t stick to them.”

Movement key to prevention

The American Diabetic Association falls more into the Reaven camp in its dietary recommendations, according to **Marion Parrott**, MD, the Arlington, VA-based ADA’s vice president for clinical affairs.

“We eat too many calories and we’re too inactive,” says Parrott. “We could just as easily call diabetes an inactivity disease.”

Parrott says anything that improves energy levels and keeps people moving will help prevent and control diabetes, although she doesn’t recommend high-protein, high-fat, or high-carbohydrate diets because of possible nutritional shortcomings and stress on other organs.

“The Syndrome X diet is not off the wall, not at all. And it might be helpful for people with certain lipid abnormalities that make up the syndrome,” Parrott concludes.

Another prominent nutrition researcher also falls firmly on the side of Reaven’s Syndrome X diet and just as strongly against the diets like Berkson’s and Atkins’.

“The Berkson diet is essentially the Atkins Diet, which is bad for the heart and kidneys,” says

Victor Herbert, MD, professor of medicine at the Mount Sinai School of Medicine in New York and director of hematology and nutrition research at the Bronx Veterans Affairs Medical Center.

[Contact Gerald Reaven at (650) 266-7450, Burton Berkson at (505) 526-8320, Sheila Kelly at (202) 269-7000, Wahida Karmally at (212) 305-6639 and Marion Parrott at (703) 549-1500.] ■

Beta-blockers raise risk of diabetes

Experts differ on interpreting the message

Beta-blockers increase the risk of diabetes by about 28%, say Johns Hopkins University researchers, who add their data indicate a lower risk associated with the popular antihypertensive medication than was shown by earlier studies.

While those who conducted the study say the results should be considered encouraging, the findings have raised red flags for others who suggest clinicians should screen for Type 2 diabetes risk factors before prescribing beta-blockers.

“This is not a bad message for beta-blockers,” says lead author **Todd Gress**, MD, MPH, who conducted the study as a fellow at Johns Hopkins Medical School in Baltimore. “It’s a positive message, especially compared to a few studies that have shown the increased risk of diabetes in patients taking beta-blockers could be 10 times more than we found.”

Can help screen those at high risk

Gress, who is now an assistant professor of medicine at Marshall University in Huntington, WV, notes that beta-blockers “seem to be of great

KEY POINTS

- Johns Hopkins study shows beta-blockers used to treat hypertension increase the risk of developing diabetes by 28%.
- Researchers says this is good news because the increased risk is only about 10% what earlier studies have shown.
- Joslin Diabetes Center calls for physicians to screen for risk factors before prescribing beta-blockers.

benefit” in people who already have diabetes.

While it is well known that hypertension is a risk factor for diabetes, Gress’ results of 12,550 patients in the Atherosclerosis Risk in Communities (ARICV) showed that patients who had hypertension and got no medication were at the same risk for developing diabetes as those who took the beta-blockers. The study appeared in the March 30 *New England Journal of Medicine*.

Researchers found no risks of diabetes associated with calcium channel blockers and ACE inhibitors, both of which are widely and successfully used to treat hypertension.

Gress says his results should not dissuade physicians from prescribing beta-blockers to treat hypertension because they can readily screen for those at high risk. “The use of beta-blockers appears to increase the risk of diabetes, but this adverse effect must be weighed against the proven benefits of beta-blockers in reducing the risk of cardiovascular events.”

Gress says his team did not discover the mechanism by which beta-blockers increase the risk. Researchers initially theorized that the drug might slow metabolism, causing weight gain, but the study showed no weight gain associated with beta-blockers.

Om Ganda, MD, director of the lipid clinic at Joslin Diabetes Center in Boston and associate professor of medicine at Harvard Medical School says Gress’ results are “cause for alarm.”

His advice: “If you’re going to treat people with hypertension, consider the options in those at risk for diabetes, especially those with a family history of diabetes.”

Ganda says he does not use beta-blockers as a drug of first choice because of the risk of diabetes developing where it might not have developed without the drugs. He also says that all beta-blockers may not act alike, and suggests further study.

ACE inhibitors are top choice

Antihypertensive drugs have been “life savers,” Ganda says, but calcium channel blockers and ACE inhibitors may be better treatment choices simply because they are not associated with the development of diabetes.

Gress even found evidence that patients taking ACE inhibitors and calcium channel blockers lowered their mean blood sugars. Ganda says ACE inhibitors are his first-choice drug.

While beta-blockers don’t seem to have adverse effects in treating patients already diagnosed with

diabetes, there is some evidence they can cause a delay in recovering from hypoglycemia, Ganda says.

For physicians who want to change medications for patients on beta-blockers, Ganda says they should not be abruptly stopped. “Taper them off for a few weeks and then start another drug.”

[Contact Todd Gress at (304) 691-1093 and Om Ganda at (617) 732-2400.] ■

Training helps teens better manage their diabetes

Yale program yields vastly improved control

Giving teen-agers with Type 1 diabetes some concrete tools to deal with real-world issues around their disease and around the transition to adulthood can make a major difference in metabolic control, Yale researchers have found.

Teens given cognitive restructuring and problem-solving training at the beginning of the four-year study not only dropped their HbA1c from an average of 9% to 7.8% in six months, but also improved overall metabolic control by 42%, according to **Margaret Grey**, RN, PhD, associate dean for research at the Yale School of Nursing in New Haven, CT.

The Coping Skills Training (CST) group and a control group received intensive medical management of their disease which included three or more daily insulin injections or an external insulin pump, self-monitoring at least four times daily, monthly outpatient visits, and interim telephone contacts over a four-year period.

The only difference in their treatment was that the CST group participated in at least four and as many as eight weekly sessions followed by monthly meetings that spread over six months.

KEY POINTS

- Teen-agers who got special training providing coping skills for their diabetes improved their metabolic control dramatically.
- Clinicians say teen-agers need guidance to find options in a given real-life situation and to recognize multiple possible solutions.
- Trial will continue to ascertain if long-term benefits are achieved with short-term training.

Grey says her team was so impressed with the results that they offered CST to the control group after the first year of the study.

Those sessions, modeled after alcohol and drug rehabilitation programs, were intended to “increase the ability of adolescents with diabetes to cope with the problems they face on a daily basis and to be more effective in achieving therapeutic goals,” Grey wrote.

Don't see possibilities in the middle

If such training can give teen-agers a sense of competence by retraining them to appropriate forms of behavior, Grey theorizes, they will be better equipped not only to manage their diabetes effectively, but to manage their more generalized life experiences in a better way.

“Teen-agers have a black-and-white viewpoint of the world,” says Grey. “They see a choice before them and they see it as entirely one way or another instead of the 100 possibilities in the middle.”

For example, Grey says, a teen-ager out with friends who needs to check his blood sugar might see only two choices: monitor in front of friends who don't know about his diabetes or don't monitor at all.

“Often he will chose not to monitor at all, when there may be several other options. The Coping Skills Training helps him to see what those other options might be,” Grey says.

Those same kinds of choices could bleed over into helping patients make healthy choices about what and when to eat, making decisions about drugs and even in handling conflict with parents and siblings.

The CST groups of two or three patients and a health care professional rely heavily on role playing, because it allows the adolescent to learn from a health care professional and from their peers.

“Most young kids with diabetes do really well,” says Grey. “We all know it's in adolescence that the problems begin. So if we can help them see alternatives, negotiate a win-win with them and sometimes with their parents we can help ease these transition difficulties.”

Sticking with kids through those difficult times is an essential component of diabetes care for teen-agers, says **Loretta Clark**, RN, CDE, a diabetic nurse educator in the Johns Hopkins University Medical Center pediatrics unit in Baltimore.

Although Johns Hopkins does not provide specific coping skills training, Clark sees the value of

it. “We provide support even at the darkest times for these kids, and those do happen during the teen-age years,” she says.

Johns Hopkins' diabetes program doesn't have a specific coping skills component, but Clark says such training is provided on an informal basis.

Some health care professionals say any patient will do better if he receives additional attention.

Clark says it is part of her philosophy to give the teen-agers more nurturing, support, time, and recognition: “It's important to recognize when they meet their goals and let them know they are doing well.”

Grey rejects that the simple additional attention can be credited for the 42% improvement in metabolic control in the CST group. “They know perfectly well what they should do. What this program does is help them translate what they should do into what they are willing to do when they're out there in the real world.”

Coping skills tend to stick

Most importantly, says Grey, the short course in coping skills seemed to stick with the teen-agers, at least over the four years of the study. She recently received a grant from the National Institutes of Health to continue her study of the original group for four more years. If her results hold up, they could mean a 25% reduction in long-term complications for those patients.

After the first year, the reduction in HbA1cs in the CST group held.

“They told us their quality of life had improved. That surprised and excited us,” says Grey. “And they also said they could continue to take care of themselves better.”

Grey plans to expand her work to preadolescents and their parents on the theory that metabolic and social crises could be prevented if children entered their teen years with coping skills firmly under their belts.

Translating coping skills training into the real world is not a terribly difficult or expensive task, says Grey, who says she is currently analyzing data to determine the actual cost of the program.

“It doesn't take a highfallutin' person to run the program. It's quite straightforward,” she says. “And the relative cost for the benefits the kids get in terms of potential long-term outcomes is really quite good.”

Grey has made copies of her protocol available upon request for others. Contact her at (203) 737-2420. ■

Viagra: Safe or sorry?

Opposing viewpoints on the drug's safety

Viagra has been a boon to millions of men with erectile dysfunction, including men with diabetes, since it was introduced in March 1998.

But disturbing new information recently made public by a cardiologist at Cedars-Sinai Medical Center in Los Angeles indicates there may be a greater risk of death and adverse cardiovascular events associated with sildenafil (Viagra) than was originally believed.

This news is of particular concern for clinicians treating men with diabetes. The drug already is considered a high risk for heart disease.

However, another recent study from the University of California Los Angeles (UCLA) says that sildenafil caused no undue cardiovascular risks for men with diabetes who took it, and other studies have shown it is effective for about 60% of them.

Drug not for patients taking nitrites

Shortly after Viagra was introduced to the market, physicians were warned not to prescribe Viagra for patients using nitrate heart drugs, patients who had cardiovascular conditions for whom sexual activity was inadvisable, and patients whose heart disease could be aggravated by sudden drops in blood pressure.

Searching the records of the U.S. Food and Drug Administration (FDA) under a Freedom of

Information request, Cedars-Sinai critical care cardiologist **Sanjay Kaul**, MD, found reports of 522 deaths in men taking sildenafil in the first year the drug was on the market. Approximately 10% of those deaths occurred in men with diabetes, Kaul says.

In addition, Kaul found 1,473 major adverse events in the FDA database related to sildenafil. He reported his findings at the American College of Cardiology scientific sessions in March.

"Viagra is an effective treatment for erectile dysfunction," says Kaul in urging wider clinical trials on Viagra. "But not enough is known about its dangers even though it is so commonly prescribed and so widely used."

Kaul says that premarket clinical trials on Viagra had fewer than 10% of the subjects with cardiovascular disease and none with unstable cardiovascular disease. Men who experienced any of the following conditions 16 months before the trial began were excluded: angina, MI, stroke, history of high or low blood pressure, and congestive heart failure.

Kaul notes that the Federal Aviation Administration has prohibited airline pilots from using Viagra six hours before a flight because of the potential for fainting due to sudden drops in blood pressure and the visual disturbances some men have experienced.

"We present this to make a plea both to the company and the FDA to take these adverse events seriously. We need clinical trials in high-risk people," says Kaul.

He says he is not yet ready to call for the withdrawal of Viagra from the market, but he notes that other drugs have been withdrawn with far fewer deaths associated with their use, most notably Rezulin, a thiazolidinedione used to help control insulin resistance. Rezulin was withdrawn in March after 61 liver failure deaths were associated with its use.

"Viagra is a bit of a sacred cow because of what it does," says Kaul, comparing the drug's emotional impact on its users to the ill-fated weight-loss drug Redux used by millions of women.

Viagra's manufacturer, Pfizer Inc. reports 17 million prescriptions have been written for 6 million men and 130 million blue diamond-shaped tablets dispensed. Viagra retails for about \$10 per pill.

The message for now is one of caution, says Kaul: "We must assess patients very carefully before we prescribe this medication, but I know many patients will go straight to the Internet and get it if their doctors won't prescribe it."

KEY POINTS

- FDA records show 522 patients died while taking Viagra in the first year the drug was on the market, according to a Cedars-Sinai researcher who obtained information under the Freedom of Information Act.
- Warnings against the use of Viagra by patients using nitrates have been in effect for some time, but now there are suggestions that more research needs to be conducted looking at men at high risk for cardiovascular disease, including patients with diabetes, to determine the level of risk.
- Another study, however, shows Viagra is a safe treatment for erectile dysfunction and is effective for about 60% of the men with diabetes who use the drug.

New York City-based Pfizer did not respond to requests to discuss Kaul's findings. The FDA issued a routine statement that it is closely monitoring and evaluating adverse event reports as it does with all drugs.

The other side of the coin

Stanley Korenman, MD, professor of medicine at UCLA, agrees that more study of Viagra's effects is needed, but as author of a study of 252 men with diabetes using Viagra, Korenman falls firmly in the supportive camp.

In a paper presented to the Endocrine Society last year, Korenman found that men (average age 57) with diabetes who experienced erectile dysfunction for six months or more had significant improvement in the condition when they took 100 mg doses of Viagra.

However, other research shows Viagra is safe and well-tolerated by men with diabetes and is especially helpful in men who have few diabetic complications.

He is critical of Kaul's analysis of the FDA data because there is no name or contact for persons reporting those events and "there is no way to know if the data are correct or to follow up on an event," Korenman says.

He also explains that cardiovascular disease becomes more common as a person ages, so deaths from cardiovascular events in men taking Viagra may be coincidental. He suggests the deaths may have occurred with or without Viagra: "There have been a few hundred deaths among millions taking the drug, while 300,000 men die of heart disease every year."

Korenman's study showed Viagra is most effective in men with diabetes who have no complications or only one comorbidity and best given in 100 mg doses.

However, Korenman is cautious about screening his patients before he prescribes Viagra.

He is very strict about any patient using nitrates. "Oh, no, if they are even carrying nitrates around and even if they say they don't use them, I won't prescribe Viagra," says Korenman.

"I don't treat people with congestive heart failure, cardiomyopathy or liver cirrhosis and edema with Viagra because a reduction in blood pressure for these people could be a catastrophe," he says. "I'd give them a vacuum pump instead."

Korenman says Viagra is a first line of treatment in any man with diabetes for whom it is not contraindicated. "This is another motivation for

men with diabetes to really work at their control," he says. "It does such a wonderful job of bringing people back to life."

Yet there's a classic case of male-female priorities in dealing with a sensitive issue like erectile dysfunction, says Korenman. "Many women tell me they would rather have a living husband than a dead sexual partner," he says.

[Contact Sanjay Kaul at (310) 423-4876 and Stanley Korenman at (310) 794-1816.] ■

Rapid Onset may be a nonautoimmune form

Japanese authors suggest a viral cause

Adults who develop acute symptoms of Type 1 diabetes in a matter of days rather than months or years may be displaying what Japanese scientists are calling a subset of the disease.

Rapid Onset (RO) diabetes has not been seen widely in the United States, but the American medical community has been aware of the rare form of the disease for many years.

"This a nonautoimmune form of the disease which develops very abruptly. No diabetes antibodies are present and it may therefore be caused by an entirely different mechanism," said the Joslin Diabetes Center in Boston in a statement after the Japanese research was published in the Feb. 3 issue of the *New England Journal of Medicine*.

RO diabetes was characterized by HbA1c levels of 8.5% or lower, signifying the "remarkably abrupt onset" of the disease, the paper said. Excessive alcohol consumption as a trigger for the disease was ruled out since none of the subjects with RO diabetes were heavy drinkers.

Researchers at the University of Osaka in Japan wrote in their conclusion: "A viral cause is suggested by the rapid onset of diabetes, the presence of lymphatic filtrates in the exocrine pancreas and the affinity of several viruses for exocrine pancreatic tissue."

"If it is viral, it is a needle in a haystack in the gamut of known viruses," says **Mark Anderson**, MD, PhD, a Joslin fellow in immunology.

A colleague at Joslin, **Diane Mathis**, PhD, co-director of the section on immunology, suggests the study's findings may not point toward a viral cause. "This form of diabetes may be autoimmune

in nature, but the target is the massive endocrine pancreas around the islets and the beta cells die as an indirect effect of the surrounding inflammation.”

Whatever the cause of RO diabetes, the treatment would be identical to the treatment that would be given any patient with diabetes.

“Just recognize there may be a pool of patients with a more rapid progression of symptoms. They may present with ketoacidosis with no prior history,” says Anderson. “But every emergency room knows how to treat them.”

Rapid progression means as little as four days from the development of the first symptoms, meaning the beta cells were destroyed suddenly, leaving no insulin reserves, says **Richard Furlanetto**, MD, PhD, scientific director of the Juvenile Diabetes Foundation in New York.

The normal progression of Type 1 diabetes usually begins to manifest in bed wetting, extreme thirst and hunger that can take place over the course of months or even years, says Furlanetto.

He noted that Japanese physicians gained this information about the beta cell function and the inflammation of the pancreas because they are permitted to biopsy the pancreases of patients, something that is not done in the United States.

Strangely, if RO patients become diabetic without an autoimmune response, they may be excellent candidates for transplants, concludes Anderson.

[Contact Mark Anderson at (617) 732-2400 and Richard Furlanetto at (800) 533-2873.] ■

Diet doesn't lower risk of Type 2 in black children

More fruits and veggies lower insulin resistance

Regardless of dietary patterns, African-American children are at higher risk of developing Type 2 diabetes than white children.

Those findings from the University of Alabama in Birmingham and the University of Southern California in Los Angeles published in the March issue of the *American Journal of Clinical Nutrition* served as a “myth buster” for researchers.

Researchers refuted a long-standing theory that the higher risk among African-American children is associated with high carbohydrate

and fat consumption which leads to obesity.

“Without exception, every child I see with Type 2 diabetes, regardless of racial group, is obese,” says **Lori Laffel**, MD, MPH, director of pediatrics at Joslin Diabetes Center in Boston. “While we all know diet contributes to insulin resistance, clearly there is something else at work here, probably something genetic.”

“No one doubts a predisposition to Type 2 diabetes exists in African-Americans, and we've found out at least one thing that *doesn't* cause the increased risk. So the multimillion dollar question is what *does* cause the differences?” says **Barbara Gower**, PhD, assistant professor of medicine at the University of Alabama and an author of the dietary study.

Of 54 white children and 41 black children selected from an ongoing study of childhood obesity in the Birmingham area, Gower says her team

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Editorial Questions

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was surprised to find that the African-American kids reported they ate twice as much in fruit, 25% more vegetables, but 40% less dairy products than the whites. However, the African-American group had a higher consumption of calories and fat than the whites. Subjects were asked to recall their food consumption over a two-week period.

Dietary factors do have a role

Researchers also found that black children from high socioeconomic classes had less risk of high cholesterol than white children, a result which lends credibility back to dietary factors having some role, says Gower. Across the board, children in higher socioeconomic classes were less at risk for diabetes than their poorer peers.

Gower and colleagues at the University of Southern California also found black children had significantly lower insulin sensitivity and nearly three times higher acute insulin response values. “It almost has to be genetic,” she says, “but I am also looking at the possibility that gestational diabetes in the mothers may be a factor, since so many African-American women have it and so many are prone to obesity. We just don’t know what that aspect of the insulin and glucose mechanisms means to the fetus later in life. It’s something we should look into.”

Blacks are at a greater risk of diabetes

These results present some alert flags in clinical practice, says Gower. “Clinicians need to be aware that African-Americans are different at any level of obesity and they are at a greater risk of diabetes.”

Even though the mechanism isn’t entirely understood, she says, “It is more important than ever to encourage a healthy lifestyle in these groups. While diet and physical activity levels don’t explain the increased risk, they still help. Weight loss always helps decrease risk.”

Laffel adds, “It’s not that diet doesn’t count, not at all. The main point here is to recognize the difference in insulin sensitivity and insulin secretion association with the African-American population.

Laffel says she “can’t stress enough” the importance of clinicians bringing home the weight control message to young patients. “If they go on to develop Type 2 diabetes, the risk of complications is extraordinary.

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CE objectives

After reading this month’s issue of *Diabetes Management*, the continuing education participant should be able to:

- Identify particular clinical, administrative, educational, or managerial issues related to the disease management of diabetes patients.
- Describe how those issues affect diabetes patients, diabetes management programs, and diabetes costs.
- Cite practical solutions to disease management problems associated with diabetes, based on overall expert guidelines from the National Institutes of Health, the American Diabetes Association, the American Association of Diabetes Educators, or other authorities, or based on independent recommendations from clinicians at individual institutions. ■