

DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

September 12, 2007 - Issue #381

Top Diabetes Stories:

Screen for PAD and Treat as CAD*

<http://www.diabetesincontrol.com/results.php?storyarticle=5119>

Pramlintide Used To Promote Weight Loss*

<http://www.diabetesincontrol.com/results.php?storyarticle=5116>

Perindopril/Indapamide for All Type 2's? *

<http://www.diabetesincontrol.com/results.php?storyarticle=5114>

The Newest Information on Alcohol Use For Diabetics*

<http://www.diabetesincontrol.com/results.php?storyarticle=5112>

Can A1c Predict Diabetes and Prediabetes? *

<http://www.diabetesincontrol.com/results.php?storyarticle=5111>

Metformin and Sitagliptin Work Synergistically in Type 2 Diabetes*

<http://www.diabetesincontrol.com/results.php?storyarticle=5110>

Why Obesity May Not Lead to Diabetes*

<http://www.diabetesincontrol.com/results.php?storyarticle=5108>

The Final Word on TZD's*

<http://www.diabetesincontrol.com/results.php?storyarticle=5107>

From the editor's desk

Dr. Sheri Colberg, author of *The 7 Step Diabetes Fitness Plan: Living Well and Being Fit with Diabetes*, has great information on Exercise Concerns with Use of Newer Diabetic Medications. Be sure to read this and all of Dr. Colberg's Articles. <http://www.diabetesincontrol.com/results.php?storyarticle=5120>

The Diabetes Cruise: We are putting together a Diabetes CE/CME cruise for medical professionals for next March, 2008. It is a 9 day cruise to the Caribbean with 20 hours of CME/CE that will teach Dr. Richard K. Bernstein's diabetes treatment methods. For more information on the cruise click here.

<http://www.diabetesincontrol.com/cruise.php>

Kimberly West, Doctor of Pharmacy Candidate, University of Florida College of Pharmacy recently reviewed Know Your Numbers, Outlive Your Diabetes written by **Richard Jackson, MD and Amy Tenderich**. To find out why she thought this would be an excellent resource [click here](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=5121>

Next FREE LIVE WEBCAST: September 19, 2007, we will be having another live webcast and teleconference call with Dr. Richard K. Bernstein, who will answer questions from medical professionals and patients and it is free. Just go to www.diabetes911.net and register and ask a question if you like!

<http://www.diabetes911.net/askdrb/index.php>

September 16, 7PM ET on CNBC

Learn about a program that puts pharmacists at the head of diabetes care and provides free medication for patients. And the inspirational story of a former pro-athlete who gave the gift of life to his NFL teammate. Also, dLife's Jim Turner tackles the tough question of drinking alcohol with diabetes, and actress Delta Burke chats about her diabetes routine. Tune in to this all-new episode of dLifeTV on: Sundays on CNBC at 7 PM ET, 6 PM CT, and 4 PM PT Check your local listings for details.

We can make a difference!

This week's overview:

Item #2: Sugary Drinks, Not Fruit Juice Linked to Insulin Resistance

- Item #3: 'Skinny Gene' Does Exist
- Item #5: New Imaging Technique Reveals Fatty Hearts in Pre-diabetics
- Item #7: Diabetics at Increased Risk of Hearing Loss
- Item #11: Increased Risk Of Death In Patients Who Stop Using Statins After Stroke
- Item #14: Eli Lilly and Takeda End Agreement to Co-Develop Ruboxistaurin Mesylate
- Item #15: Acute Myocardial Infarction Leads to Diabetes

Check out this weeks **“Test Your Knowledge”** question. This week’s question deals with CGMS.
<http://www.diabetesincontrol.com/results.php?storyarticle=5122>

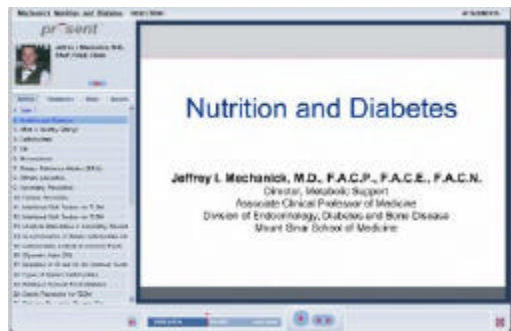
Dave Joffe, *Editor-in-Chief*

NEWS FLASH:

Eli Lilly and Takeda End Agreement to Co-Develop Ruboxistaurin Mesylate
See This Weeks’s Item #14

Tools for your Practice:

Nutrition and Diabetes CE by Jeffrey Mechanick, MD, FACP, FACE, FACN, from our CE partners at Present Diabetes



This Week's Lecture
"Nutrition and Diabetes"
 by Jeffrey I. Mechanick, MD, FACP, FACE, FACN

Click on image to view lecture

New Product:

Cordaptive, an investigational drug from Merck, reduced LDL cholesterol and triglyceride levels, and increased HDL cholesterol levels in a Phase III clinical trial, the company announced. significantly less flushing compared with patients using extended-release niacin alone, Merck said. The drug combines niacin with laropiprant, a novel inhibitor designed to reduce the flushing often associated with niacin treatment, the company said.

This Week’s Items:

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ITEMS For The Week:

Item 1

Screen for PAD and Treat as CAD

Screening for peripheral arterial disease (PAD) should be performed routinely in all elderly patients and younger ones with cardiovascular risk factors, and should be aggressively treated just as coronary artery disease (CAD).
<http://www.diabetesincontrol.com/results.php?storyarticle=5119>

The time has come to stop treating patients with peripheral arterial disease as second-class citizens, say the authors of a new study. In getABI, they showed that simple screening of the ankle/brachial index by primary-care doctors can help identify patients with PAD, who have a significantly increased risk of death regardless of whether or not they have symptoms. These patients are also terribly undertreated.

Dr Curt Diehm (Affiliated Teaching Hospital, Karlsbad-Langensteinbach, Germany), who reported the results of the German epidemiological study on ankle brachial index (getABI) also found that, those to have PAD should be treated in the same way as patients with coronary artery disease (CAD), he said, stressing that PAD patients are currently undertreated.

GetABI shows that PAD patients have a substantially increased risk of death — dying, on average, 10 years earlier than their peers — and that asymptomatic PAD patients are as much at risk as symptomatic ones, a vital fact that was not previously appreciated, he said. This latter point is very important; "This is the first time, in such a big study, that we have found no difference in mortality between asymptomatic and symptomatic PAD patients. We learned that PAD patients are usually asymptomatic, and we say in the guidelines that symptomatic patients have to be treated in a different way, but now we need to change the guidelines."

It is also imperative that the traditional view of PAD is changed, he said. "It used to be considered a disease of impaired walking distance, quality of life, or of amputation, or just a smoker's disease — so-called smokers leg," Diehm said. But they found that half of the patients who had PAD had never smoked: "Today we see this disease in a new light."

Mortality Almost Twice as High in PAD Patients: GetABI began in 2001 and included a total of 6,880 unselected patients who underwent ankle brachial index (ABI) testing by their primary care physician in 344 offices. The mean age of the patients was 72.5 years, 46% were past or current smokers, 74% had hypertension, 24% diabetes mellitus and 52% lipid disorders.

Diehm explained that in healthy individuals, the systolic blood pressure at the ankle should be at least as high as the pressure in the arm — ie, ABI should be 1 or greater. An ABI of < 0.9 indicates PAD, and an ABI of < 0.5

indicates severe PAD. In the study, asymptomatic PAD was defined as an ABI of < 0.9 and symptomatic PAD as ABI < 0.9 with intermittent claudication or PAD-related amputation or revascularization.

At the end of the five-year observation period, all-cause mortality was 23.9% in the 596 patients with symptomatic PAD (hazard ratio 1.8; $p < 0.001$), 19.1% in the 835 patients with asymptomatic PAD (HR 1.6; $p < 0.001$) and 9.4% in the 5390 patients without PAD. Even after adjusting for all other known cardiovascular risk factors, PAD has the best ability to predict future death, stroke or MI, Diehm said.

ABI: An Important Prognostic Factor — Simple, Quick, and Cost-Effective: Screening for PAD using ABI is very simple, he explained — measurement is quick, taking just eight minutes, the equipment costs only a few hundred dollars and nurses can be trained in its use "within 15 minutes." It is also highly specific for leg artery stenosis (> 50%) and highly sensitive (> 95%), he noted.

Diehm added that in this trial, they used the higher of the two values for blood pressure in the leg, as per the **American Heart Association** recommendations, "but in our opinion, this is absolutely wrong because you miss distal occlusions." He said if the lower of the two leg values is used, the prevalence of PAD comes out as much higher.

The new results illustrate the feasibility of using ABI in primary care, he says. "The good news is that the ABI test is not limited to expert use but can be performed in general practice. We need to implement ABI as a screening tool in GPs [general practitioners] offices to identify high-risk patients, and we have to change this very quickly now."

Treat PAD Patients as You Would CAD Patients: Diehm explained that PAD patients are severely undertreated compared with CAD patients. Most PAD patients should be on aspirin or clopidogrel, he said, plus a statin, beta-blocker and angiotensin-converting enzyme inhibitor. Sub-group analyses of large trials such as 4S with a statin, or HOPE-2 with an angiotensin-converting enzyme inhibitor, have shown the benefit of these agents in patients with intermittent claudication, he noted.

Despite this data, "many doctors are still afraid that beta-blockers are contra-indicated in this disease, which is absolute nonsense," Diehm said. Poldermans agreed wholeheartedly. "We have known since 1990 that beta-blockers are not contra-indicated in PAD. We all know that these patients will benefit from medical therapy, but we just don't do it. We need to keep medical therapy optimized."

Diehm concluded: "Family physicians can identify high-risk patients and initiate and maintain effective treatment in this large group. PAD patients should no longer be treated as second-class atherothrombotic patients — whether you are asymptomatic or symptomatic, you die 10 years early. A huge number of lives could be saved if patients with atherosclerosis would be identified with ABI and treated timely."

Practice Pearls

- ?? GetABI, a study in which 6880 unselected patients were screened with ABI, showed that 5-year all-cause mortality was 23.9% in the 596 patients with symptomatic PAD (ABI < 0.9 with intermittent claudication or PAD-related amputation or revascularization), 19.1% in the 835 patients with asymptomatic PAD (ABI < 0.9 without symptoms), and 9.4% in the 5390 patients without PAD. After adjustment for all other known cardiovascular risk factors, PAD was the best predictor of future death, stroke, or MI.
- ?? Screening for PAD with ABI is very simple, quick, inexpensive, and highly specific and sensitive for leg artery stenosis, making it feasible to use in primary care. Patients in whom PAD is detected should be further screened for aortic aneurysms, carotid disease, and CAD and treated aggressively with aspirin or clopidogrel plus a statin, beta-blocker, and angiotensin-converting enzyme inhibitor.

European Society of Cardiology (ESC) World Congress 2007. Presented September 4, 2007.

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Item 2

Sugary Drinks, Not Fruit Juice Linked to Insulin Resistance

Consumption of sugar-sweetened drinks, not including 100 percent fruit juice, may be associated with insulin resistance, even in otherwise healthy adults

<http://www.diabetesincontrol.com/results.php?storyarticle=5118>

Steady increases in consumption of sugar-sweetened beverages over the last several decades, as well as rates of Type 2 diabetes mellitus, led nutritional epidemiologists at the Jean Mayer USDA Human Nutrition Research Center on Aging to explore the relationship between sugar-sweetened beverage consumption and insulin resistance, a precursor to Type 2 diabetes. Their findings suggest that higher consumption of sugar-sweetened drinks, but not 100 percent fruit juice, may be associated with insulin resistance, even in otherwise healthy adults.

“Study participants who consumed two or more sugar-sweetened beverages per day had significantly higher fasting blood levels of insulin as compared to participants who did not report consuming any such beverages, regardless of age, sex, weight, smoking status, or other dietary habits,” says senior author Paul Jacques, professor at the Friedman School of Nutrition Science. “Higher fasting levels of insulin mean these study participants are more at risk for developing Type 2 diabetes. In contrast,” he says, “consumption of 100 percent fruit juice was not significantly related to any of our measures of insulin resistance.”

Study participants were 2,500 healthy men and women in the Framingham Offspring Study, a community-based study of cardiovascular disease among offspring of people in the original Framingham Heart Study. Participants reported their usual dietary intake for the previous year, which researchers used to determine average intakes of sugar-sweetened drinks (regular and caffeine-free colas and other carbonated beverages containing sugar), diet soft drinks (low-calorie colas with and without caffeine and other low-calorie carbonated beverages), and fruit juice (e.g., apple juice or apple cider, orange juice, and grapefruit juice). One serving of a sugar-sweetened drink or diet soda was considered equivalent to 12 fluid ounces, or a regular-sized can of soda. One serving of fruit juice was considered equivalent to six fluid ounces.

The researchers obtained blood samples from participants who fasted for at least eight hours, and measured the participants' blood levels of insulin as well as glucose. High fasting glucose levels, like high fasting insulin levels, are a pre-cursor to Type 2 diabetes. “Unlike fasting insulin levels, fasting glucose levels were not significantly different between those who consumed sugar-sweetened drinks and those who did not,” says Jacques, “However, participants consuming two or more daily servings of 100 percent fruit juice had modestly lower fasting glucose levels, compared with those who did not consume fruit juice.” Although this observation might be due to the additional nutrients or other phytochemicals found in the juices, Jacques notes this also may be a consequence of the healthier lifestyle and dietary habits of fruit juice consumers. They were less likely to smoke than non-consumers, and consumed diets relatively lower in saturated fat and higher in total fiber.

Despite these results, Nicola McKeown, PhD, corresponding author, does not advise increasing consumption of fruit juice. “While 100 percent fruit juice can be a healthful beverage, too much fruit juice can add excess calories and sugar to the diet. Whole fruit is often a better choice.”

Yoshida M, McKeown NM, Rogers G, Meigs JB, Saltzman E, D'Agostino R, Jacques PF. Journal of Nutrition. 2007 (September); 137:2121-2127. “Surrogate Markers of Insulin Resistance are Associated with Consumption of Sugar-Sweetened Drinks and Fruit Juice in Middle and Older-Aged Adults.”

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DID YOU KNOW:

Hemoglobin A1c can predict type 2 diabetes in women: Among healthy middle-aged and older women, the hemoglobin A1c level -- a measure of blood sugar control -- is an independent predictor of type 2 diabetes, a study shows. They observed a graded increase in risk for both diabetes and heart-related events, such as heart attack, with increasing levels of HbA1c. HbA1c remained a strong predictor of diabetes, but not heart-related events, in analyses adjusting for multiple factors that might influence the results. *American Journal of Medicine, August 2007. See This Week's Item #9*

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<http://www.diabetesincontrol.com/ads/atkins/dest.shtml>

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Item 3

'Skinny Gene' Does Exist

Researchers at UT Southwestern Medical Center have found that a single gene might control whether or not individuals tend to pile on fat, a discovery that may point to new ways to fight obesity and diabetes.

<http://www.diabetesincontrol.com/results.php?storyarticle=5117>

"From worms to mammals, this gene controls fat formation," said Dr. Jonathan Graff, associate professor of developmental biology and internal medicine at UT Southwestern. "It could explain why so many people struggle to lose weight and suggests an entirely new direction for developing medical treatments that address the current epidemic of diabetes and obesity.

"People who want to fit in their jeans might someday be able to overcome their genes." The gene, called adipose, was discovered in fat fruit flies more than 50 years ago by a graduate student at Yale University, but few people knew about it. Its mechanism was unknown, and whether it's important in other genes was a mystery.

In the current study, the UT Southwestern researchers examined how adipose works by analyzing fruit flies, tiny worms called *C. elegans*, cultured cells, and genetically engineered mice, as well as by exploiting sophisticated molecular techniques. Using several methods, they manipulated adipose in the various animals, turning the gene on and off at different stages in the animals' lives and in various parts of their bodies.

It was discovered that the gene, which is also present in humans, is likely to be a high-level master switch that tells the body whether to accumulate or burn fat.

In the mice, the researchers found that increasing adipose activity improved the animals' health in many ways. Mice with experimentally increased adipose activity ate as much or more than normal mice; however, they were leaner, had diabetes-resistant fat cells, and were better able to control insulin and blood-sugar metabolism. In contrast, animals with reduced adipose activity were fatter, less healthy and had diabetes.

The researchers' work on flies showed that the gene is "dose-sensitive" – that is, the various combinations of the gene's variants lead to a range of body types from slim to medium to obese.

"This is good news for potential obesity treatments, because it's like a volume control instead of a light switch; it can be turned up or down, not just on or off," Dr. Graff said. "Eventually, of course, the idea is to develop drugs to target this system, but that's in the years to come."

This genetic mechanism makes survival sense, he said, because if a population has many versions of the gene scattered among many different individuals, at least some will survive in different conditions. For instance, a fat fruit fly may be able to survive famine, but a sleeker model might be better at evading predators.

Dr. Graff said the next step is to understand better the exact mechanisms by which adipose exerts its control.

But for people in developed countries, this trait has backfired. It's all feast and no famine, so the fat builds and builds. "Even a pound a year adds up over a lifetime," Dr. Graff said.

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Do you have patients who could benefit from an insulin pen with memory? HumaPen® MEMOIR for use with Humalog® (insulin lispro) is the first insulin pen with a memory that records date, time, and amount of the last 16 doses, including priming doses. As part of a multiple-daily injection regimen, your patients can gain greater flexibility. Depending on your patients' lifestyles, a Humalog® or Humalog® Mixture insulin may be prescribed. Find important safety and prescribing information on Humalog® and Humalog® Mixture insulins at www.humalog.com
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Item 4

Pramlintide Used To Promote Weight Loss

Treatment with the amylin analog pramlintide has been shown to reduce weight in obese patients, according to researchers.

<http://www.diabetesincontrol.com/results.php?storyarticle=5116>

The lead investigator Dr. Christian Weyer tells us that, "These findings are the most robust clinical proof of concept reported to date for the anti-obesity potential of a satiogenic peptide hormone."

In his published article Dr. Weyer of Amylin pharmaceuticals notes that it has been very effective in reducing A1C and weight in type 2 diabetics.

They studied 204 subjects with a body mass index of 37.8. Then they were randomized to pramlintide or placebo, and both were injected three times a day subcutaneously, before meals.

Subjects started at pramlintide doses of 30 mcg and were allowed to incrementally increase this to 240 mcg.

The agent was generally well tolerated and 88% of the subjects were able to escalate to the maximum dose over the 16-week study period. Twenty-nine percent of the pramlintide subjects withdrew from the study, compared to 25% of placebo patients.

Pramlintide patients who completed the study had a placebo-corrected reduction in body weight of 8.8 pounds and a 3.6 cm drop in waist circumference.

More than 30% of the active treatment group achieved a weight loss of 5% or more, compared to only 2% of placebo patients. Improvements in appetite control were reported by 72% and 31%, respectively. Results were similar for those reporting that their well-being had improved (52% versus 17%).

From these findings, Dr. Weyer feels that pramlintide deserves further evaluation as a possible treatment for obesity.

There are now several clinical studies are currently underway in which pramlintide is being evaluated in combination therapy, either with approved oral weight loss medications, or with other neurohormones," he added.

"In animal models of diet-induced obesity," he concluded, "these combinatorial regimens have yielded marked, additive or even synergistic weight loss."

J Clin Endocrinol Metab 2007;92:2977-2983.

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FACT:

Cheap Pill 'Cuts Deaths From Diabetes: A combination pill consisting of perindopril and indapamide can save thousands of lives: Diabetic patients who were put on the combination drug Coversyl Plus were 18 per cent less likely to die from heart-related illnesses, according to the study, the largest of its kind. The results could have implications for the treatment of Type 2 diabetes and significantly reduce the risk of heart disease, the biggest killer of diabetics. The trial involved more than 11,000 people with Type 2 diabetes in 20 countries, including Britain. It concluded that the effects of adding the drug to their regime was so effective that all diabetic patients should be on it, whether they had hypertension or not. **See this week's Item #6**

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Item 5

New Imaging Technique Reveals Fatty Hearts in Pre-diabetics

A simple imaging technique has revealed fat buildup in the hearts of pre-diabetic people long before symptoms of heart disease or diabetes appear.

<http://www.diabetesincontrol.com/results.php?storyarticle=5115>

The technique detects fat accumulation in cells of the beating heart in a way no other clinical method can, the researchers said, and may provide a way to screen patients for early signs of heart disease in diabetes.

“Hearts beat; people breathe; and magnetic resonance imaging is very sensitive to motion, so we had to find a way to electronically ‘freeze’ the image of the heart,” said Dr. Lidia Szczepaniak, assistant professor of internal medicine at UT Southwestern and senior author.

Dr. Szczepaniak and her colleagues developed a noninvasive technique that captures the signal from a beating heart as a person lies in an ordinary magnet used for MRI scanning.

The researchers knew that fat builds up in the hearts of people with heart failure or non-insulin-dependent diabetes (type 2) from earlier studies involving patients undergoing heart transplants, but they didn’t know if this fatty buildup occurred before or after the diabetic conditions developed.

“There is currently no way to clinically evaluate the fatty heart,” Dr. Szczepaniak said. “Using this technique, which analyzes magnetic signals, we might be able to determine if people are prone to heart disease very early before the disease progresses. This method might also allow us to measure the effectiveness of medical treatments targeted toward lowering fat in the heart.”

In the new study, they used an ordinary MRI system, but added the newly developed computer software to convert the signals from a moving heart into a single image.

They looked at lean and obese people with normal blood sugar, obese people beginning to show abnormal sugar metabolism, and obese people with full-blown type 2 diabetes.

Their most important finding, was that fat buildup in the heart develops before the onset of diabetes. They also found that the amount of fat in the heart of people with abnormal sugar metabolism was significantly higher than in those with normal blood sugar, whether obese or lean.

The amount of fat in the heart was unrelated to the amount of fat in the bloodstream or liver, indicating that measuring any of those factors could not predict accumulation of fat in the heart. Fat in the heart did correspond to the amount of fat in the stomach region, however.

Detecting fat in heart cells is especially important because once a heart cell dies, it is not replaced by a new one, as happens in many other tissues, said Dr. Roger Unger, professor of internal medicine at UT Southwestern. “When you lose a heart cell, that’s it – you can’t get it back.”

Some researchers, including those at UT Southwestern, believe that as a person becomes over-weight, fat accumulates in normal fat cells, but eventually fat cells can’t store fat any more. Eventually the excess of fat kills other cells – a hypothesis supported by a recent study by Dr. Unger in mice.

Circulation, Sept 4, 2007

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<http://www.diabetesincontrol.com/annodyne/index.php>

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Item 6

Perindopril/Indapamide for All Type 2's?

If the benefits seen in the study were applied to just half the population with diabetes worldwide, more than a million deaths would be avoided over five years.

<http://www.diabetesincontrol.com/results.php?storyarticle=5114>

Routine administration of a fixed combination of perindopril and indapamide to a broad range of patients with type 2 diabetes was associated with reduced risks of major vascular events, including death, in the Action in Diabetes and Vascular disease: preterAx and diamicroN-MR Controlled Evaluation (ADVANCE) study.

The authors say that if the benefits seen in ADVANCE were applied to just half the population with diabetes worldwide, more than a million deaths would be avoided over five years, and there is thus a case for considering routine treatment with perindopril/indapamide for patients with type 2 diabetes.

But in an accompanying comment published in the *Lancet*, Dr Norman M Kaplan (University of Texas Southwestern Medical Center, Dallas) cautions against overinterpretation of ADVANCE and suggests that other drugs that lower blood pressure (BP) as much and do not have metabolic side effects would be just as protective.

In the paper, the ADVANCE authors, note that BP is an important determinant of the risks of macrovascular and microvascular complications of type 2 diabetes but that traditional strategies set arbitrary BP levels at which treatment is initiated, which neglects those diabetic patients without what is typically defined as hypertension. They also point out that this strategy is resource-intensive, needing multiple patient visits, careful monitoring of both BP and side effects, and the coordination of complex drug regimens.

They suggest an alternative approach — adding a fixed-dose combination of BP-lowering drugs irrespective of initial BP level or the use of other antihypertensive drugs. They say that while this approach might not produce the largest BP reductions possible, it will shift the entire distribution of BP values down in patients with diabetes, with minimum requirements for titration and, potentially, with fewer side effects.

To investigate this idea, they conducted the ADVANCE trial, in which 11,140 patients with type 2 diabetes underwent a six-week active run-in period and were then randomized to treatment with a fixed combination of perindopril and indapamide or matching placebo in addition to current therapy. The combination therapy was given at a dose of perindopril 2 mg and indapamide 0.625 mg for the first three months and then the dose of both agents was doubled. The use of concomitant treatments during follow-up, including BP-lowering therapy, remained at the discretion of the responsible physician, with two exceptions — the use of thiazide diuretics was not allowed, and open-label perindopril, to a maximum of 4 mg a day, was the only angiotensin-converting enzyme (ACE) inhibitor allowed, thus ensuring that the maximum recommended dose of 8 mg for perindopril could not be exceeded by patients randomly assigned to active treatment.

The primary endpoints were composites of major macrovascular and microvascular events, defined as death from cardiovascular (CV) disease, non-fatal stroke or non-fatal myocardial infarction (MI), and new or worsening renal or diabetic eye disease, and analysis was by intention to treat. The macrovascular and microvascular composites were analyzed jointly and separately.

Results showed that after a mean of 4.3 years of follow-up, compared with patients assigned placebo, those assigned active therapy had a mean reduction in systolic BP of 5.6 mm Hg and diastolic BP of 2.2 mm Hg. The relative risk of a major macrovascular or microvascular event was significantly reduced by 9%. The separate reductions in macrovascular and microvascular events were similar but were not independently significant. Death from CV and from any cause was also reduced in the active treatment group.

They add that the results suggest that for every 66 patients commencing long-term treatment with perindopril and indapamide, one patient would avoid at least one major vascular event in five years as a direct consequence of study treatment. They note that the major contributor to the 9% overall reduction in the risk of major macrovascular or microvascular events was an 18% reduction in the risk of death from CV disease, and from the results of ADVANCE, it seemed that over five years, one death would be averted in every 79 patients commencing treatment with the study drugs.

They conclude that: "These results support the provision of treatment, not on the basis of arbitrary cutoffs for blood pressure, but rather on assessment of vascular risk, which is raised in patients with type 2 diabetes, even in the absence of hypertension."

Practice Pearls

- ?? Use of a fixed-dose combination of perindopril and indapamide is associated with reduction in microvascular and macrovascular events in patients with type 2 diabetes during 4.3 years.
- ?? Use of a fixed-dose combination of perindopril and indapamide is associated with reduction in mortality in patients with type 2 diabetes during 4.3 years. There was no difference in rate of retinopathy, visual deterioration, neuropathy, cognitive function, and total hospitalizations.

ADVANCE Collaborative Group. Effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial): Lancet 2007. Published online before print September 2, 2007.

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Item 7

Diabetics at Increased Risk of Hearing Loss

Diabetics have twice the risk of developing hearing loss as are nondiabetics.

<http://www.diabetesincontrol.com/results.php?storyarticle=5113>

Catherine C. Cowie, PhD, director, diabetes epidemiology program, National Institute of Diabetes and Digestive and Kidney Diseases, reported data in 5,140 individuals aged 20 to 69 years who underwent audiometric testing from 1999 through 2004 as part of the National Health and Nutrition Examination Survey (NHANES).

"The pathologic changes that accompany diabetes could plausibly affect the vasculature or the neural system of the inner ear, resulting in sensorineural hearing impairment," Dr. Cowie explained in a presentation..

In the NHANES trial, pure tone thresholds over lower frequency were obtained for each ear at 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz using a calibrated audiometer in a soundproof booth. A pure tone average exceeding 25 decibels over a given frequency range in both ears indicated hearing impairment.

After adjusting for age, 31.6% of self-reported diabetics had hearing impairment at the lower frequency range versus 14.5% of the nondiabetic subjects. The figures were 56.8% and 35.8% for the two groups, respectively, at the higher frequency range.

The analysis also revealed that diabetics had higher age-adjusted mean pure tone thresholds at all frequencies than nondiabetics.

Dr. Cowie pointed out that the mechanism for hearing loss in diabetics has not been clarified but may be vascular or neurological.

"The high prevalence of hearing impairment among people with diabetes in our nationally representative sample suggests that screening diabetic patients for hearing impairment is appropriate," she said.

[Presentation title: Diabetes and Hearing Impairment: Audiometric Evidence From the National Health and Nutrition Examination Survey, 1999-2004. Abstract 991-P]

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Dr. Philip A. Wood has written a book for healthcare professionals and students of medicine, nursing, pharmacy, and graduate studies, as well lay people interested in understanding the influences of genetics, nutrition, activity level and drugs on diseases associated with excess fat such as obesity, insulin resistance, metabolic syndrome and type 2 diabetes. The book is composed of short, readable chapters with helpful figures to further explain the mechanisms discussed. For further information please click here.

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Item 8

The Newest Information on Alcohol Use For Diabetics

Accumulating scientific evidence indicates that light to moderate drinking done on a daily basis may significantly reduce the risks of coronary heart disease (CHD) and all-cause mortality.

<http://www.diabetesincontrol.com/results.php?storyarticle=5112>

James H. O'Keefe, MD, FACC writes, "In contrast, excessive alcohol intake and binge drinking are toxic to both the heart and overall health and are the third leading cause of premature death among Americans. The purpose of the present review is to: 1) outline the specific benefits and risks of alcohol, and the threshold of intake at which drinking becomes a health danger rather than an advantage; 2) detail the mechanisms whereby alcohol confers cardioprotection; and 3) discuss the ideal quantities, drinking patterns, and beverages, and which individuals are most likely to benefit."

Research to date has shown J-shaped relationships between alcohol consumption and several adverse health outcomes, including all-cause mortality, CHD, diabetes, hypertension, congestive heart failure, stroke, dementia, and Raynaud's phenomenon.

Some cardioprotective benefits have been demonstrated for light to moderate alcohol consumption (up to 1 drink daily for women and 1 or 2 drinks daily for men). Most studies have shown that light to moderate drinking is associated with risk reductions for CHD of approximately 30% to 35%.

Alcohol consumed in moderation seems to have an antiatherosclerotic effect, with decreased incidence of peripheral arterial disease and decreased atherosclerotic burden shown by coronary angiography, computerized tomography-detected coronary calcium, and carotid ultrasound.

Like exercise, alcohol consumption seems to be most cardioprotective when done daily and in moderation. However, increasingly excessive consumption is associated with proportional worsening of outcomes.

Because of the beneficial effects on high-density lipoprotein (HDL) cholesterol, insulin action, and inflammation, light to moderate alcohol intake may be particularly helpful for patients with abnormal glucose metabolism and/or insulin resistance. Light to moderate alcohol intake may be associated with reductions in the prevalence and incidence of diabetes, and a large meta-analysis with 12-year follow-up showed a 30% reduction in new diabetes in those who consumed 1 to 2 drinks daily.

The cardiovascular benefits associated with alcohol consumption protection are thought to be mediated by improvements in insulin sensitivity and HDL cholesterol. The major protective component seems to be the ethanol itself, and not the other ingredients found in different types of alcoholic beverages.

In a meta-analysis incorporating data from more than 1 million participants, consumption of 1 drink daily by women and 1 or 2 drinks daily by men was associated with an 18% reduction in total mortality, but daily intakes of more than 2 drinks in women and 3 drinks in men were associated with dose-dependent increased mortality.

Although low-dose, daily alcohol consumption has been linked to better health than less frequent use, binge drinking increases cardiovascular events and mortality, even in otherwise light drinkers.

"Alcohol should not be universally prescribed for health enhancement to nondrinking individuals owing to the lack of randomized outcome data and the potential for problem drinking," the study authors note. "Alcohol (ethanol) consumption is analogous to the proverbial double-edged sword, and perhaps no other factor in cardiovascular (CV) health is capable of cutting so deeply in either direction depending on how it is used."

"Sobering statistics warn that moderate daily drinking is a slippery slope that many individuals cannot safely navigate," the study authors conclude. "The latest American Heart Association guidelines caution people not to start drinking if they do not already drink alcohol, because it is not possible to predict in which people alcohol abuse will become a problem. Until we have more randomized outcome data, and tools for predicting susceptibility to problem drinking, it would seem prudent to encourage physicians and patients to focus on more innocuous interventions to prevent CHD."

The latest American Heart Association guidelines caution people not to start drinking alcohol if they do not already drink alcohol, according to a review of the advantages and disadvantages of alcohol intake on cardiovascular health.

Practice Pearls

- ?? Alcohol can improve cardiovascular outcomes primarily by increasing HDL cholesterol and improving insulin sensitivity and abdominal obesity.
- ?? The current review suggests that light to moderate use of alcohol can help improve rates of total mortality, myocardial infarction, stroke, peripheral arterial disease, diabetes, and the metabolic syndrome. However, because of the high rate of preventable deaths associated with alcohol use, the study authors recommend against the universal prescription of alcohol consumption.

J Am Coll Cardiol. Published online August 23, 2007.

FACT:

Fat Builds Up in Hearts Before Diabetes Onset: Technique giving researchers static image of beating heart could be new screening tool. Fat starts to build up in the hearts of pre-diabetic people before either diabetes or heart disease symptoms appear, according to a new study. Could become a new screening tool for people at risk for diabetes and heart disease. *Sept. 4 issue of Circulation* **See This Week's Item #5**

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<http://www.pharmacy.pitt.edu/dmeducatece>

Item 9

Can A1c Predict Diabetes?

Among healthy middle-aged and older women, Hemoglobin A1c is an independent predictor of type 2 diabetes, but not cardiovascular disease.

<http://www.diabetesincontrol.com/results.php?storyarticle=5111>

Dr. Aruna D. Pradhan, of Brigham and Women's Hospital, Boston, writes in a current journal that A1c (HbA1c) is a marker of cumulative glycemic exposure over the preceding 60 to 90 days.

The investigators continue to stat that, "Whether mild elevations of this biomarker provide prognostic information for development of clinically evident type 2 diabetes and cardiovascular disease among individuals at usual risk for these disorders is uncertain."

The researchers conducted a prospective cohort study, beginning in 1992, where they examined whether baseline HbA1c can predict diabetes and a first cardiovascular event in healthy middle-aged and older women.

Included in the analysis were 26,563 participants of the Women's Health Study who were at least 45 years of age and did not have diabetes or cardiovascular disease. The subjects were followed for a median of 10.1 years. At baseline HbA1c levels were 5%.

A total of 1238 cases of diabetes and 684 cardiovascular events occurred during follow-up. In age-adjusted analyses using quintiles of HbA1c, a graded risk increase was observed for both incident diabetes and

cardiovascular disease. HbA1c remained a strong predictor of diabetes after multivariable adjustment. However, it was no longer significantly associated with incident cardiovascular disease.

The authors repeated analyses according to clinically expedient cutpoints in 0.5% increments above 5.0% to examine threshold effects. The adjusted relative risks for incident diabetes ranged from 2.9 for HbA1c levels between 5.5% and 5.9%; to 29.3 for HbA1c levels between 6.0% and 6.4%; to 81.2 for HbA1c levels of 7.0% or higher.

Risk associations persisted after exclusion of cases diagnosed within 2 and 5 years of follow-up.

From the results, Dr. Pradhan's team concluded that, "Although these data do not support the use of HbA1c as a single measure of diabetes risk, our results do suggest that the significance of elevated HbA1c may warrant a greater emphasis in primary prevention."

Am J Med 2007;120:720-727.

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Item 10

Metformin and Sitagliptin Work Synergistically in Type 2 Diabetes

Forty-four percent of patients treated with metformin and sitagliptin were able to achieve A1c's below 6.5%

<http://www.diabetesincontrol.com/results.php?storyarticle=5110>

Metformin makes the body more responsive to insulin, while sitagliptin works to lower elevated blood sugars.

Dr. Debora E. Williams-Herman of Merck Research Laboratories, Rahway, New Jersey and colleagues write in the journal *Diabetes Care* that, "Because sitagliptin and metformin lower blood sugar through different, but potentially complementary, mechanisms the combination should provide effective, potentially additive, blood sugar control,"

To investigate, they randomized 1,091 type 2 diabetics to sitagliptin plus metformin, metformin alone, sitagliptin alone or inactive placebo. At the start of the study, the average A1C level -- a common measure of blood sugar control -- was 8.8 percent, which is considered high.

All patients on active treatment had "meaningful" reductions in blood sugar levels compared with those on placebo. At 24 weeks, 66 percent of patients treated with sitagliptin and metformin had an A1C of less than 7 percent, and 44 percent of this group reached a value of less than 6.5 percent.

This was significantly better than results with a single drug, the team notes, and "demonstrated an additive response."

There was a low incidence of hypoglycemia, or low blood sugar, which was not significantly different from that in the placebo group.

This study shows that the combination of sitagliptin and metformin provides "substantial and additive" improvement in blood sugar levels and is "generally well tolerated," the team concludes.

Diabetes Care, August 2007

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Item 11

Increased Risk Of Death In Patients Who Stop Using Statins After Stroke

Patients who stop taking cholesterol-lowering drugs within a year of surviving a stroke had a two-fold increased risk of death, researchers reported.

<http://www.diabetesincontrol.com/results.php?storyarticle=5109>

Statins can benefit patients who have suffered an ischemic stroke (caused by a clot). However, stroke survivors often stop taking these drugs -- an issue previously not studied in a clinical setting, said Furio Colivicchi, M.D., lead study author.

"To the best of our knowledge, this is the first evidence linking discontinuation of statin therapy to increased death rates in stroke survivors who have no other clinical evidence of heart disease," he and colleagues wrote.

The observational study ran for four-and-a-half years. Researchers identified 631 consecutive stroke survivors (322 men and 309 women, average age 70 years). None had any other major illness, including heart disease. All patients were discharged from the hospital with orders to take a drug regimen including statin therapy.

Trained nurses interviewed the patients and researchers examined their primary care physicians' records for 12 months after their stroke. Researchers recorded the date and possible reasons for any cardiovascular drug discontinuation.

By the end of the study, 38.9 percent of the patients -- 246 patients -- had stopped taking statins. The average time to discontinuation was 48.6 days.

Seventy-one patients (28.8 percent) cited mild side effects, the most common of which was indigestion. In the other 175 cases (71.2 percent), neither the patient nor the primary care physician could give specific medical reasons for discontinuation.

"Because medication costs are covered by the Italian National Health Service, except for a small co-pay, cost cannot be related to these patients discontinuing their prescribed therapy," said senior author Carlo Caltagirone, M.D., Scientific Director of Santa Lucia Foundation. "In these studies the specific reasons for discontinuation are usually unknown, and they are difficult to analyze. However, contributing factors are probably related to patients' and their healthcare providers' behavior and beliefs, and probably also to features of the healthcare system itself."

Compared to the entire study group, patients who stopped taking the statins were older (71.4 vs. 69.5, on average) and more often female. Patients were less likely to stop taking the statins if they had diabetes or a previous stroke.

During the study, 116 patients died. Eighty percent of these deaths were attributed to cardiovascular causes. Statistical analysis determined that discontinuing statin therapy was independently and significantly associated with increased risk of death from any cause. Patients who had stopped taking statins within a year of stroke were more than twice as likely to die (2.78 hazard ratio) than others in the study group.

"Patients who stop taking the statins have a significantly increased chance of death in the first year after their stroke -- and the earlier they stop, the higher the risk they face," Colivicchi said. "In fact, the risk factors for the association between statin discontinuation and death gradually decreased with time. Effective clinical strategies are needed to bring out a significant increase in patients who maintain their drug therapies." Researchers said future studies should also evaluate whether interventions designed to improve patients' self-care behaviors and lifestyles might also improve the percentage of patients who continue their medication.

Stroke September 2007

DID YOU KNOW:

PAD patients have a substantially increased risk of dying 10 years early: And that asymptomatic PAD patients are as much at risk as symptomatic ones. "This is the first time, in such a big study, that we have found no difference in mortality between asymptomatic and symptomatic PAD patients. We learned that PAD

patients are usually asymptomatic, and we say in the guidelines that symptomatic patients have to be treated in a different way, but now we need to change the guidelines."

See This Week's Item #1

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Item 12

Why Obesity May Not Lead to Diabetes

One reason for this is thought to be the chronic inflammation characterized by macrophage infiltration into adipose tissue that accompanies obesity, because it has been linked to the development of insulin resistance (which in turn often leads to type 2 diabetes).

<http://www.diabetesincontrol.com/results.php?storyarticle=5108>

New data generated in mice by Dennis Bruemmer and colleagues at the University of Kentucky College of Medicine, Lexington, provides support for this hypothesis.

Osteopontin is an extracellular matrix protein and proinflammatory cytokine that is required for macrophage infiltration of a tissue during an immune response. Bruemmer and colleagues found that although mice lacking osteopontin became obese when fed a high-fat diet, they did not become as insulin resistant as normal mice fed the same diet.

This decrease in insulin resistance was associated with decreased accumulation of macrophages in the adipose tissue leading the authors to conclude that osteopontin has a key role in linking obesity to the development of insulin resistance in mice.

"Osteopontin mediates obesity-induced adipose tissue macrophage infiltration and insulin resistance in mice," Journal of Clinical Investigation, Sept 2007

Item 13

The Final Word on TZD's

Thiazolidinediones Receive Black Box For Heart Failure: Careful monitoring of patients advised.

<http://www.diabetesincontrol.com/results.php?storyarticle=5107>

The labels of all thiazolidinediones now carry a black box warning about the risk of heart failure. The strengthened warning emphasizes that thiazolidinediones (TZDs) may "cause or exacerbate congestive heart failure in some patients," according to the FDA.

The agency sent the manufacturers letters requesting the labeling change in May. Product labeling for the TZDs rosiglitazone (Avandia), manufactured by GlaxoSmithKline, and pioglitazone (Actos), manufactured by Takeda, previously contained information about heart failure (HF) in the warnings and precautions sections, but the labeling is being strengthened following recent revelations about rosiglitazone's cardiovascular safety.

The FDA says that the concern over heart failure is "separate" from the concerns over the increased MI risk associated with rosiglitazone, which was the subject of a joint meeting of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee in July. The committees concluded then that data from meta-analyses of the rosiglitazone clinical program show an increased risk for myocardial ischemia for the type 2 diabetes therapy. The agency is currently reviewing similar pooled data from the pioglitazone clinical program.

"Despite the warnings and information already listed in the drug labels, these drugs are still being prescribed to patients without careful monitoring for signs of heart failure," Dr. Steven Galson, director of the FDA's Center for Drug Evaluation and Research, said in an FDA statement.

Health care professionals are advised to observe patients carefully for the signs and symptoms of heart failure, including excessive, rapid weight gain, shortness of breath, and edema after starting drug therapy. The updated labeling states that initiation of rosiglitazone or pioglitazone, or the combinations that include these drugs, is

contraindicated in patients with New York Heart Association class III or IV heart failure. After treatment with these products is initiated or after the dose is increased, patients should be carefully observed for signs and symptoms of heart failure. Patients who develop symptoms and are diagnosed with heart failure should receive appropriate treatment, and discontinuation or dose

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FACT:

Depression More Damaging Than Diabetes: People who suffer from depression often know just how serious a disease it is but few know just how damaging it can be to your overall health. It can be more damaging than arthritis, asthma and even diabetes. Major depression can interfere with the ability to work, sleep, eat or enjoy things in like. Symptoms can range from an empty feeling to irritability to thoughts of suicide. The study urged doctors to look more closely for symptoms of depression before the disease can worsen overall health.

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Item 14

Eli Lilly and Takeda End Agreement to Co-Develop Ruboxistaurin Mesylate

Ruboxistaurin mesylate is used to treat diabetic macular edema and diabetic peripheral neuropathy. The companies said that after looking at the overall results, the trials did not meet the criteria for Phase III studies and therefore they have agreed to terminate the contract.

<http://www.diabetesincontrol.com/results.php?storyarticle=5106>

This agent is an investigational compound discovered and developed by Eli Lilly. In Japan, pursuant to an agreement concluded on December 18, 2003, phase 2 clinical studies for the treatment of diabetic peripheral neuropathy and diabetic macular edema have been conducted by Eli Lilly Japan and Takeda respectively.

Eli Lilly and Takeda judged that the overall results of diabetic peripheral neuropathy and diabetic macular edema clinical studies did not meet its pre-specified go/no go decision criteria for phase 3 clinical studies, and agreed to terminate the original agreement.

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Item 15

Acute Myocardial Infarction Leads to Diabetes

Compared with people who have not had an AMI, post-AMI patients have a significantly higher risk of developing diabetes or impaired fasting glucose and physicians should consider acute myocardial infarction (AMI) to be a prediabetes risk, authors of a new study say.

<http://www.diabetesincontrol.com/results.php?storyarticle=5105>

Senior author on the study, Dr Roberto Marchioli tells us, "We know that diabetes is a risk factor for CAD [coronary artery disease]," (Consorzio Mario Negri Sud, Chieti, Italy), "What was not well known is that after MI [myocardial infarction], a lot of patients are at risk of developing diabetes or disturbance of glycemic metabolism. And this is what we saw in our paper."

Over a five-year period, Mozaffarian and colleagues tracked new-onset diabetes or the development of impaired fasting glucose (IFG) in a cohort of more than 8000 non-diabetic men and women who had experienced a recent AMI at baseline. Study participants were originally followed as part of the GISSI-Prevenzione trial, one of the first studies to establish the benefits of a Mediterranean diet, high in n-3 polyunsaturated fatty acids. The investigators

also collected information on body mass index (BMI), cardiovascular risk factors, diet, lifestyle, and medication use at baseline and over the follow-up period.

Over a mean of 3.2 years (and a total of 26 795 person-years), 33% of the cohort developed diabetes or IFG, a number that rose to 62% when a lower cut-off for IFG was used (5.6 mmol/L). The annual incidence rate among the GISSI study group was 27.5% for IFG, using the 5.6 mmol/L cut-off, and 3.7% for diabetes. By way of comparison, Mozaffarian et al point out that studies in the general population indicate that middle-aged adults face an annual rate of developing IFG of 1.8% and of developing diabetes, 0.8-1.6%.

The authors identified older age, high blood pressure, use of beta-blockers or diuretics, higher BMI, smoking, and low Mediterranean diet score as independent risk factors for diabetes or IFG development. By contrast, use of lipid-lowering drugs, high intake of foods characteristic of Mediterranean diets, and increased physical activity levels seemed to be protective.

Marchioli hypothesized that lifestyle habits were likely "the most important determinant of diseased metabolism."

"We found that increased BMI was associated with the risk of developing diabetes and impaired fasting glucose and we also saw that weight gain after MI was associated with increased disease," he said. "Similarly we saw that patients who had bad dietary habits with a lower intake of fruit, vegetables, fish, and olive oil, had a higher risk of developing diabetes. The same was seen in patients who had the lowest physical activity. So there was a kind of cumulative indication saying that if you don't have good lifestyle habits, you are at high risk of becoming obese and developing diabetes."

The authors say their findings should prompt a rethinking of cardiovascular disease (CVD) and diabetes as both risk factors, and end points. "Just as diabetes can be considered a coronary heart disease risk-equivalent, acute myocardial infarction should potentially be considered a prediabetes risk-equivalent," they write.

But they are also careful to emphasize that they do not believe AMI itself increases the risk of diabetes; rather, some common pathways likely increase the risk of both MI and subsequent diabetes, including an increased likelihood of metabolic dysfunction. Indeed, in an accompanying editorial, Dr Lionel H Opie (University of Cape Town, South Africa), points out that the notion of AMI as an acute stress reaction precipitated in part by metabolic changes dates back more than 40 years.^[2] If stress mediates hyperglycemia, he notes, it is "logical" to expect that AMI survivors might also be at risk of developing diabetes. Opie hypothesizes that a tendency towards prediabetes at the time of AMI might get the necessary boost towards overt diabetes or IFG over ensuing years in the form of bad lifestyle habits, or even use of beta blockers and diuretics, both known to affect insulin sensitivity.

Both Opie and the study authors highlight the apparent benefits, in this setting, of the Mediterranean diet rich in fruit, vegetables and n-3 polyunsaturated fatty acids, but low in saturated fats and refined carbohydrates. Opie speculates that the combination of these foods may have a "double benefit": protecting against both cardiovascular events and new diabetes. Likewise, Marchioli and colleagues emphasize that counseling postinfarct patients about the importance of diet and lifestyle should not be overlooked, not only for secondary CVD prevention, but also to prevent the development of diabetes.

"I think that this study should be useful to remind people, starting with the physician, that lifestyle changes should always be assessed in the physician's office," Marchioli stated that, "Patients believe their physicians and if the physician emphasizes the importance of diet, physical activity and stopping smoking, that could be the most important message from our study."

Practice Pearls:

- ?? The incidence of IFG and diabetes is greater within 3.5 years of an acute MI.
- ?? Independent risk factors for diabetes or IFG after an MI include older age, greater BMI, hypertension, and current smoking, whereas a Mediterranean diet and use of lipid-lowering medication are associated with a lower risk.

The results of their study appear in the August 25, 2007 issue of *The Lancet*.

Sources

1. Mozaffarian D, Marfisi RM, Levantesi G, et al. Incidence of new-onset diabetes and impaired fasting glucose in patients with recent myocardial infarction and the effect of clinical and lifestyle risk factors. *Lancet* 2007;370:667-675.
2. Opie LH. Acute myocardial infarction and diabetes. *Lancet* 2007;370:634-635.

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Quote of the Week!

“Life is not over because you have diabetes. Make the most of what you have, be grateful.”

.....Dale Evans Rogers

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