

INSIDE: MEETING THE WORLD'S CHALLENGE

The Healthy Living Magazine of the American Diabetes Association for More Than 50 Years

Diabetes Forecast®

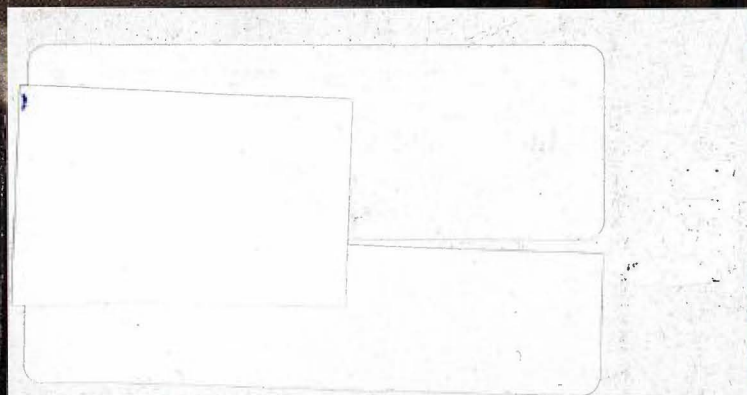
NOVEMBER 2007

Pumpkin
Pecan Cake
PAGE 70

One of a dozen
great new
recipes inside!

Celebrate

A special guide to entertaining
for a happy, healthy holiday season
with menu ideas from **Asia, Italy, and America**



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PLUS:

ON THE SLOPES

One Skier's Journey

PILL SPLITTING

What You Need To Know

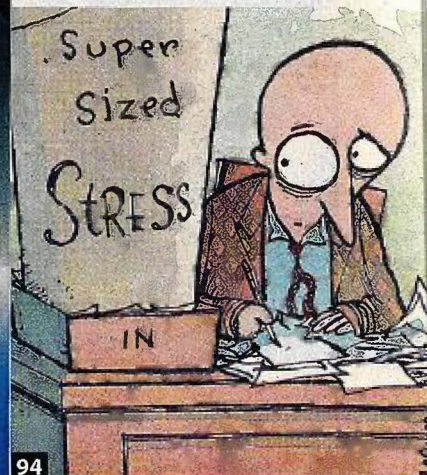
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November 2007

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Diabetes Forecast

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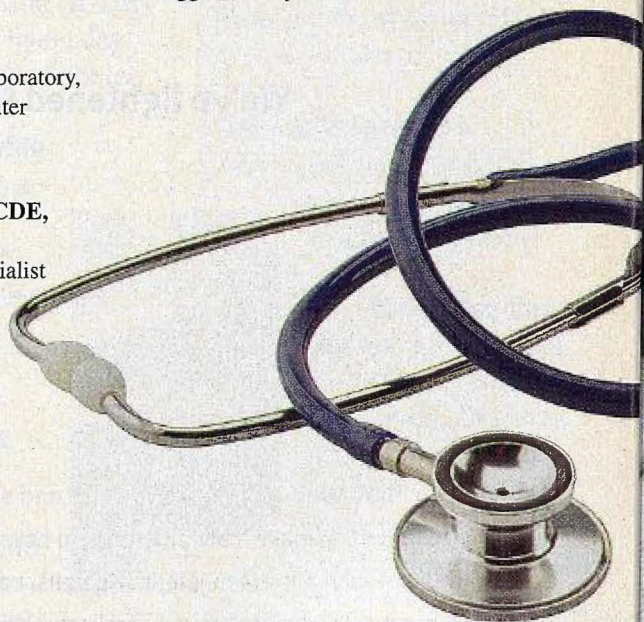
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November 2007 Volume 60 Number 12

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The Mission of the American Diabetes Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

■ The American Diabetes Association recommends that all people with diabetes be educated health care consumers. We encourage you to read labels, ask questions, and be an active participant in your own health care.

■ The American Diabetes Association recommends that consumers familiarize themselves with nutritional information about food products.

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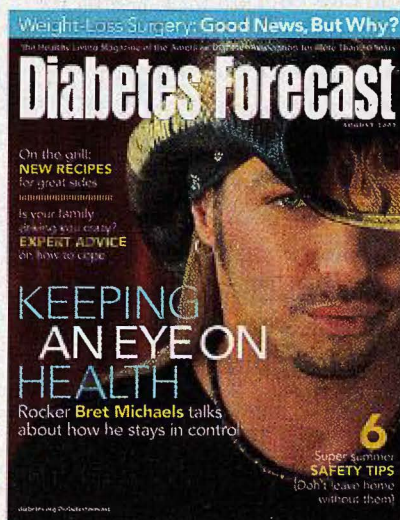
Thanks, Lt. Col. Watson

I want to thank you for your Guest Editorial about U.S. Air Force (USAF) doctors and nurses, and Lt. Col. Nina Watson in particular, in your August issue (p. 9). I have been a military dependent all of my life, first of my father, who retired from the Army, and then my husband, who retired from the Air Force in 2005. The majority of my medical care for type 1 diabetes, which I've had for 23 years, and other issues has been administered by the USAF medical system. I have seen many doctors in many places around the world, and they do an excellent job. They cannot be commended enough.

In 2000, when we were stationed at Keesler Air Force Base in Biloxi, Miss., I was seen by Lt. Col. (then Maj.) Watson. She was instrumental in getting me an insulin pump and worked many hours with me, making sure that I knew how to use the pump and got the most benefit out of it. Because of that pump I was able to have a little girl in May 2001. My pregnancy was a lot of work, but not nearly as much as it would have been without the pump. My A1C stayed down around 5.8 for the duration of my pregnancy, and my daughter was born with no complications.

Thank you, Lt. Col. Watson, for your dedication and work for so many people with diabetes. Good luck on your deployment and stay safe!

JoAnne Beall
Columbus, Miss.



Rock of Love

I am a 38-year-old female with type 2 diabetes and an avid reader of *Diabetes Forecast*. I wanted to let you know how excited I was to see Bret Michaels on the cover of your August issue. I have always liked him and his group, Poison. I really enjoyed reading the article about him and found it inspirational. If he can take four shots a day and check his glucose six to 10 times a day, I can improve my diet and exercise. After all, I am not even insulin-dependent, and don't have anywhere near the busy schedule that he does!

I also found it interesting that he struggles with food choices, as I do. My favorite part of the article was when he said, "You're occasionally allowed to throw a tantrum, but you have to keep your humor about it. Humor is essential to winning at diabetes."

Lori Schettler
Salt Lake City, Utah

Byetta Fan

In the August Mail Call, Hillary S. Liber asked why you did not mention Byetta and Symlin in your May article about insulin and weight gain ("A Matter of Balance: Insulin And Weight Gain," p. 16). I too have been looking for articles about Byetta.

Thankfully, while I was spending a winter in Austin,

continued on page 13

mail call

Send letters to Mail Call, *Diabetes Forecast*, 1701 North Beauregard St., Alexandria, VA 22311. You can also send e-mail messages to mailcall@diabetes.org. Because of the large volume of mail we receive, we are not able to publish all letters and reserve the right to edit for length.

Although we will honor requests for anonymity, all letters to *Diabetes Forecast* must include your full name and home address.



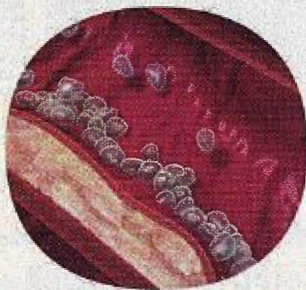
You can help protect against the formation of clots and reduce your risk of a future heart attack or stroke.

This is important information if you've been hospitalized with heart-related chest pain or had a heart attack.

That's because these conditions, known as Acute Coronary Syndrome—or ACS—are usually caused when blood platelets stick together and form clots that block blood flow to your heart. And if you've already had a clot, you're at an increased risk for a future heart attack or stroke.

PLAVIX, taken with other heart medicines, helps provide greater protection against heart attack or stroke than other heart medicines alone.

That's because prescription PLAVIX works differently than your cholesterol and blood pressure medications, focusing on your blood platelets to help keep them from sticking together and forming clots.



IMPORTANT INFORMATION: If you have a stomach ulcer or other condition that causes bleeding, you should not use PLAVIX. When taking PLAVIX alone or with some other medicines including aspirin, the risk of bleeding may increase so tell your doctor before planning surgery. And, always talk to your doctor before taking aspirin or other medicines with PLAVIX, especially if you've had a stroke. If you develop fever, unexplained weakness or confusion, tell your doctor promptly as these may be signs of a rare but potentially life-threatening condition called TTP, which has been reported rarely, sometimes in less than 2 weeks after starting therapy. Other rare but serious side effects may occur.

See important product information on the following page.

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INDICATIONS AND USAGE

PLAVIX (clopidogrel bisulfate) is indicated for the reduction of atherothrombotic events as follows:

Recent MI, Recent Stroke or Established Peripheral Arterial Disease

For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, PLAVIX has been shown to reduce the rate of a combined endpoint of new ischemic stroke (fatal or nonfatal), new MI (fatal or nonfatal), and other vascular death.

Acute Coronary Syndrome

For patients with ST-segment elevation acute coronary syndrome (unstable angina/non-Q-wave MI) including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention (with or without stent) or CABG, PLAVIX has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI, or stroke as well as the rate of a combined endpoint of cardiovascular death, MI, stroke, or refractory ischemia.

For patients with ST-segment elevation acute coronary infarction, PLAVIX has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, re-infarction or stroke. This benefit is not known to pertain to patients who receive primary angioplasty.

CONTRAINDICATIONS

The use of PLAVIX is contraindicated in the following conditions:

Hypersensitivity to the drug substance or any component of the product.

Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

WARNINGS

Thrombotic thrombocytopenic purpura (TTP)

TTP has been reported rarely following use of PLAVIX, sometimes after a short exposure (<2 weeks). TTP is a serious condition that can be fatal and requires urgent treatment including plasmapheresis (plasma exchange). It is characterized by thrombocytopenia, microangiopathic hemolytic anemia (schistocytes [fragmented RBCs] seen on peripheral smear), neurological findings, renal dysfunction, and fever. (See ADVERSE REACTIONS.)

PRECAUTIONS

General

PLAVIX prolongs the bleeding time and therefore should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions (particularly gastrointestinal and intracranial). If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.

Due to the risk of bleeding and undesirable hematological effects, blood cell count determination and/or other appropriate testing should be promptly considered, whenever such suspected clinical symptoms arise during the course of treatment (see ADVERSE REACTIONS). In patients with recent TIA or stroke who are at high risk for recurrent ischemic events, the combination of aspirin and PLAVIX has not been shown to be more effective than PLAVIX alone, but the combination has been shown to increase major bleeding.

G bleeding: In CAPRIE, PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0% vs. 2.7% on aspirin. In CLARITY, the incidence of major gastrointestinal bleeding was 1.3% vs. 0.7% (PLAVIX + aspirin vs. placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX. Use in Hepatically Impaired Patients: Experience is limited in patients with severe hepatic disease, who may have bleeding diatheses. PLAVIX should be used with caution in this population.

Use in Renally-impaired Patients: Experience is limited in patients with severe renal impairment. PLAVIX should be used with caution in this population.

Information for Patients

Patients should be told if they may take them longer than usual to stop bleeding, that they may bruise and/or bleed more easily when they take PLAVIX or PLAVIX combined with aspirin, and that they should report any unusual bleeding to their physician. Patients should inform physicians and dentists that they are taking PLAVIX and/or any other product known to affect bleeding before any surgery is scheduled and before any new drug is taken.

Drug Interactions

Study of specific drug interactions yielded the following results:

Aspirin: Aspirin did not modify the clopidogrel-mediated inhibition of ADP-induced platelet aggregation. Concomitant administration of 500 mg of aspirin twice a day for 1 day did not significantly increase the prolongation of bleeding time induced by PLAVIX. PLAVIX potentiated the effect of aspirin on collagen-induced platelet aggregation. PLAVIX and aspirin have been administered together for up to one year.

Heparin: In a study in healthy volunteers, PLAVIX did not necessitate modification of the heparin dose or alter the effect of heparin on coagulation. Coadministration of heparin had no effect on inhibition of platelet aggregation induced by PLAVIX.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs): In healthy volunteers receiving naproxen, concomitant administration of PLAVIX was associated with increased occult gastrointestinal blood loss. NSAIDs should be administered with caution.

Warfarin: Because of the increased risk of bleeding, the concomitant administration of warfarin with PLAVIX should be undertaken with caution. (See PRECAUTIONS-General.) Other Concomitant Therapy: No clinically significant pharmacodynamic interactions were observed when PLAVIX was administered with atenolol, nifedipine, or both atenolol and nifedipine. The pharmacodynamic activity of PLAVIX was not also significantly influenced by the administration of phenobarbital, cimetidine, or estrogen.

The pharmacokinetics of digoxin or theophylline were not modified by the coadministration of PLAVIX (clopidogrel bisulfate).

At high concentrations *in vitro*, clopidogrel inhibits P₄₅₀ [2C9]. Accordingly, PLAVIX may interfere with the metabolism of phenytoin, tamoxifen, tolbutamide, warfarin, toremide, fluoxetine, and many non-steroidal anti-inflammatory drugs, but there are no data with which to predict the magnitude of these interactions. Caution should be used when any of these drugs is administered with PLAVIX.

In addition to the above specific interaction studies, patients entered into clinical trials with PLAVIX received a variety of concomitant medications including diuretics, beta-blocking agents, angiotensin converting enzyme inhibitors, calcium antagonists, cholesterol lowering agents, coronary vasodilators, antidiabetic agents (including insulin), thrombolytics, heparins (unfractionated and LMWH) GPIIb/IIIa antagonists, antiepileptic agents and hormone replacement therapy without evidence of clinically significant adverse interactions.

There are no data on the concomitant use of oral anticoagulants, non-study oral antiplatelet drugs and chronic NSAIDs with clopidogrel.

Drug/Laboratory Test Interactions

None known.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no evidence of tumorigenicity when clopidogrel was administered for 78 weeks to mice and 104 weeks to rats at dosages up to 77 mg/kg per day, which afforded plasma exposures >25 times that in humans at the recommended daily dose of 75 mg.

Clopidogrel was not genotoxic in four *in vitro* tests (Ames test, DNA-repair test in rat hepatocytes, gene mutation assay in Chinese hamster fibroblasts, and metaphase chromosome analysis of human lymphocytes) and in one *in vivo* test (micronucleus test by oral route in mice). Clopidogrel was found to have no effect on fertility of male and female rats at oral doses up to 400 mg/kg per day (52 times the recommended human dose on a mg/m² basis).

Pregnancy

Pregnancy Category B. Reproduction studies performed in rats and rabbits at doses up to 500 and 300 mg/kg/day (approximately 65 and 75 times the recommended daily human dose on a mg/m² basis), revealed no evidence of impaired fertility or fetotoxicity due to clopidogrel. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of a human response, PLAVIX should be used during pregnancy only if clearly needed.

Nursing Mothers

Studies in rats have shown that clopidogrel and/or its metabolites are excreted in the milk. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the nursing woman.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

Geriatric Use

Of the total number of subjects in CAPRIE, CLARITY and CLARITY controlled clinical studies, approximately 50% of patients treated with PLAVIX were 65 years of age and older and 15% were 75 years and older. In COMMIT, approximately 58% of the patients treated with PLAVIX were 65 years and older, 26% of whom were 70 years and older. The observed risk of thrombotic events with clopidogrel plus aspirin versus placebo plus aspirin by age category is provided in Figures 3 and 6 for the CLARITY and COMMIT trials, respectively (see CLINICAL STUDIES). The observed risk of bleeding events with clopidogrel plus aspirin versus placebo plus aspirin by age category is provided in Tables 5 and 6 for the CLARITY and COMMIT trials, respectively (see ADVERSE REACTIONS).

ADVERSE REACTIONS

PLAVIX has been evaluated for safety in more than 42,000 patients, including over 9,000 patients treated for 1 year or more. The clinically important adverse events observed in CAPRIE, CLARITY and COMMIT are discussed below.

The overall tolerability of PLAVIX in CAPRIE was similar to that of aspirin regardless of age, gender and race, with an approximately equal incidence (13%) of patients withdrawing from treatment because of adverse reactions.

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

In CLARITY, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 5). There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence of intracranial hemorrhage (0.1%), and fatal bleeding (0.2%), were the same in both groups.

The overall incidence of bleeding is described in Table 5 for patients receiving both PLAVIX and aspirin in CLARITY.

Table 5: CLARITY Incidence of bleeding complications (% patients)

Event	PLAVIX (+ aspirin)* (n=6259)	Placebo (+ aspirin)* (n=6303)	P-value
Major bleeding †	3.7 ‡	2.7 §	0.001
Life-threatening bleeding	2.2	1.8	0.13
Fatal	0.2	0.2	
5 g/dL hemoglobin drop	0.9	0.9	
Requiring surgical intervention	0.7	0.7	
Hemorrhagic strokes	0.1	0.1	
Requiring intubation	0.5	0.5	
Requiring transfusion (≥4 units)	1.2	1.0	
Other major bleeding	1.6	1.0	0.005
Significantly disabling	0.4	0.3	
Intracranial bleeding with			
significant loss of vision	0.05	0.03	
Requiring 2-3 units of blood	1.3	0.9	
Minor bleeding ¶	5.1	2.4	<0.001

* Other standard therapies were used as appropriate.

† Life threatening and other major bleeding.

‡ Major bleeding event rate for PLAVIX + aspirin was dose-dependent on aspirin:

<100 mg=2.6%; 100-200 mg= 3.5%; >200 mg=4.9%

§ Major bleeding event rates for PLAVIX + aspirin by age were: <65 years = 2.5%, ≥65 to <75 years = 4.1%, ≥75 years 5.9%

¶ Major bleeding event rate for placebo + aspirin was dose-dependent on aspirin:

<100 mg=2.0%; 100-200 mg= 2.3%; >200 mg=4.0%

Major bleeding event rates for placebo + aspirin by age were: <65 years = 2.1%, ≥65 to <75 years = 3.1%, ≥75 years 3.6%

¶ Led to interruption of study medication.

Ninety-two percent (92%) of the patients in the CLARITY study received heparin/LMWH, and the rate of bleeding in these patients was similar to the overall results.

There was no excess in major bleeds within seven days after coronary bypass graft surgery in patients who stopped therapy more than five days prior to surgery (event rate 4.4% PLAVIX + aspirin; 5.3% placebo + aspirin). In patients who remained on therapy within five days of bypass graft surgery, the event rate was 9.6% for PLAVIX + aspirin, and 6.3% for placebo + aspirin.

In CLARITY, the incidence of major bleeding (defined as intracranial bleeding or bleeding associated with a fall in hemoglobin ≥ 5 g/dL) was similar between groups (1.3% versus 1.1% in the PLAVIX + aspirin and in the placebo + aspirin groups, respectively). This was consistent across subgroups of patients defined by baseline characteristics, and type of fibrinolytics or heparin therapy. The incidence of fatal bleeding (0.8% versus 0.6% in the PLAVIX + aspirin and in the placebo + aspirin groups, respectively) and intracranial hemorrhage (0.5% versus 0.7%, respectively) was low and similar in both groups.

The overall rate of noncerebral major bleeding or cerebral bleeding in COMMIT was low and similar in both groups as shown in Table 6 below.

Table 6: Number (%) of Patients with Bleeding Events in COMMIT

Type of bleeding	PLAVIX (+ aspirin) (N = 22961)	Placebo (+ aspirin) (N = 22891)	P-value
Major* noncerebral or cerebral bleeding**	134 (0.6%)	125 (0.5%)	0.59
Major noncerebral	82 (0.4%)	73 (0.3%)	0.48
Fatal	36 (0.2%)	37 (0.2%)	0.90
Hemorrhagic stroke	55 (0.2%)	56 (0.2%)	0.91
Fatal	39 (0.2%)	41 (0.2%)	0.81
Other noncerebral bleeding (non-major)	831 (3.6%)	721 (3.1%)	0.005
Any noncerebral bleeding	896 (3.9%)	777 (3.4%)	0.004

* Major bleeds are cerebral bleeds or non-cerebral bleeds thought to have caused death or that required transfusion.

** The relative rate of major noncerebral or cerebral bleeding was independent of age. Event rates for PLAVIX + aspirin by age were: <60 years = 0.3%, ≥60 to <70 years = 0.7%, ≥70 years = 0.8%. Event rates for placebo + aspirin by age were: <60 years = 0.4%, ≥60 to <70 years = 0.6%, ≥70 years 0.7%.

Adverse events occurring in ≥2.5% of patients on PLAVIX in the CAPRIE controlled clinical trial are shown below regardless of relationship to PLAVIX. The median duration of therapy was 20 months, with a maximum of 3 years.

Table 7: Adverse Events Occurring in ≥2.5% of PLAVIX Patients in CAPRIE

Body System Event	% Incidence (% Discontinuation) PLAVIX (n=9599)	Aspirin (n=9586)
Body as a Whole - general disorders		
Chest Pain	8.3 (0.2)	8.3 (0.3)
Accidental/Inflicted Injury	7.9 (0.1)	7.3 (0.1)
Influenza-like symptoms	7.5 (<0.1)	7.0 (<0.1)
Pain	6.4 (0.1)	6.3 (0.1)
Fatigue	3.3 (0.1)	3.4 (0.1)
Cardiovascular disorders, general		
Edema	4.1 (<0.1)	4.5 (<0.1)
Hypertension	4.3 (<0.1)	5.1 (<0.1)
Central & peripheral nervous system disorders		
Headache	7.6 (0.3)	7.2 (0.2)
Dizziness	6.2 (0.2)	6.7 (0.3)
Gastrointestinal system disorders		
Any event	27.1 (3.2)	29.8 (4.0)
Abdominal pain	5.6 (0.7)	7.1 (1.0)
Dyspepsia	5.2 (0.6)	6.1 (0.7)
Diarrhea	4.5 (0.4)	3.4 (0.3)
Nausea	3.4 (0.5)	3.8 (0.4)
Metabolic & nutritional disorders		
Hypercholesterolemia	4.0 (0)	4.4 (<0.1)
Musculo-skeletal system disorders		
Arthralgia	6.3 (0.1)	6.2 (0.1)
Back Pain	5.8 (0.1)	5.3 (<0.1)
Platelet, bleeding, & clotting disorders		
Purpura/bruise	5.3 (0.3)	3.7 (0.1)
Epistaxis	2.9 (0.2)	2.5 (0.1)
Psychiatric disorders		
Depression	3.6 (0.1)	3.9 (0.2)
Respiratory system disorders		
Upper resp tract infection	8.7 (<0.1)	8.3 (<0.1)
Dyspnea	4.5 (0.1)	4.7 (0.1)
Rhinitis	4.2 (0.1)	4.2 (<0.1)
Bronchitis	3.7 (0.1)	3.7 (0)
Coughing	3.1 (<0.1)	2.7 (<0.1)
Skin & appendage disorders		
Any event	15.8 (1.5)	13.1 (0.8)
Rash	4.2 (0.5)	3.5 (0.2)
Pruritus	3.3 (0.3)	1.6 (0.1)
Urinary system disorders		
Urinary tract infection	3.1 (0)	3.5 (0.1)

No additional clinically relevant events to those observed in CAPRIE with a frequency ≥2.5%, have been reported during the CLARITY and CLARITY controlled studies. COMMIT collected only limited safety data.

Other adverse experiences of potential importance occurring in 1% to 2.5% of patients receiving PLAVIX (clopidogrel bisulfate) in the controlled clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in CAPRIE) or placebo + aspirin (in the other clinical trials).

Autonomic Nervous System Disorders: Syncope, Palpitation. **Body as a Whole-general disorders:** Asthenia, Fever, Hernia. **Cardiovascular disorders:** Cardiac failure. **Central and peripheral nervous system disorders:** Cramps legs, Hypoaesthesia, Neuralgia, Paraesthesia, Vertigo. **Gastrointestinal system disorders:** Constipation, Vomiting, Heart rate and rhythm disorders: Fibrillation atrial. **Liver and biliary system disorders:** Hepatic enzymes increased. **Metabolic and nutritional disorders:** Gout, hyperuricemia, non-protein nitrogen (NPN) increased. **Musculo-skeletal system disorders:** Arthritis, Arthrosis. **Platelet, bleeding & clotting disorders:** GI hemorrhage, hematoma, platelets decreased. **Psychiatric disorders:** Anxiety, Insomnia. **Red blood cell disorders:** Anemia. **Respiratory system disorders:** Pneumonia, Sinusitis. **Skin and appendage disorders:** Eczema, Skin ulceration. **Urinary system disorders:** Cystitis. **Vision disorders:** Cataract, Conjunctivitis.

Other potentially serious adverse events which may be of clinical interest but were rarely reported (<1%) in patients who received PLAVIX in the controlled clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in the other clinical trials).

Body as a whole: Allergic reaction, necrosis ischemic. **Cardiovascular disorders:** Edema generalized. **Gastrointestinal system disorders:** Peptic, gastric or duodenal ulcer, gastritis, gastric ulcer perforated, gastritis hemorrhagic, upper GI ulcer hemorrhagic. **Liver and biliary system disorders:** Bilirubinemia, hepatitis infectious, liver fatty. **Platelet, bleeding and clotting disorders:** hemarthrosis, hematuria, hemoptysis; hemorrhage intracranial, hemorrhage retroperitoneal, hemorrhage of operative wound, ocular hemorrhage, pulmonary hemorrhage, purpura allergic, thrombocytopenia. **Red blood cell disorders:** Anemia aplastic, anemia hypochromic. **Reproductive disorders, female:** Menorrhagia. **Respiratory system disorders:** Hemothorax. **Skin and appendage disorders:** Bullous eruption, rash erythematous, rash maculopapular, urticaria. **Urinary system disorders:** Abnormal renal function, acute renal failure. **White cell and reticuloendothelial system disorders:** Agranulocytosis, granulocytopenia, leukemia, leukopenia, neutropenia.

Postmarketing Experience

The following events have been reported spontaneously from worldwide postmarketing experience.

- **Body as a whole:**
 - hypersensitivity reactions, anaphylactoid reactions, serum sickness
- **Central and Peripheral Nervous System disorders:**
 - confusion, hallucinations, taste disorders
- **Hepato-biliary disorders:**
 - abnormal liver function test, hepatitis (non-infectious), acute liver failure
- **Platelet, bleeding and clotting disorders:**
 - cases of bleeding with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage)
 - thrombotic thrombocytopenic purpura (TTP) - some cases with fatal outcome - (see WARNINGS)
- **Respiratory, thoracic and mediastinal disorders:**
 - bronchospasm, interstitial pneumonitis
- **Skin and subcutaneous tissue disorders:**
 - angioedema, erythema multiforme, Stevens-johnson syndrome, toxic epidermal necrolysis, lichen planus
- **Renal and urinary disorders:**
 - glomerulopathy, increased creatinine levels
- **Vascular disorders:**
 - vasculitis, hypotension
- **Gastrointestinal disorders:**
 - colitis (including ulcerative or lymphocytic colitis), pancreatitis, stomatitis
- **Musculoskeletal, connective tissue and bone disorders:**
 - myalgia

OVERDOSAGE

Overdose following clopidogrel administration may lead to prolonged bleeding time and subsequent bleeding complications. A single oral dose of clopidogrel at 1500 or 2000 mg/kg was lethal to mice and to rats and at 3000 mg/kg to baboons. Symptoms of acute toxicity were vomiting (in baboons), prostration, difficult breathing, and gastrointestinal hemorrhage in all species.

Recommendations About Specific Treatment:

Based on biological plausibility, platelet transfusion may be appropriate to reverse the pharmacological effects of PLAVIX if quick reversal is required.

DOSEAGE AND ADMINISTRATION

Recent MI, Recent Stroke, or Established Peripheral Arterial Disease

The recommended daily dose of PLAVIX is 75 mg once daily.

Acute Coronary Syndrome

For patients with non-ST-segment elevation acute coronary syndrome (unstable angina/non-Q-wave MI), PLAVIX should be initiated with a single 300 mg loading dose and then continued at 75 mg once daily. Aspirin (75 mg-325 mg once daily) should be initiated and continued in combination with PLAVIX. In CLARITY, most patients with Acute Coronary Syndrome also received heparin acutely (see CLINICAL STUDIES).

For patients with ST-segment elevation acute myocardial infarction, the recommended dose of PLAVIX is 75 mg once daily, administered in combination with aspirin, with or without thrombolytics. PLAVIX may be initiated with or without a loading dose (300 mg) was used in CLARITY; see CLINICAL STUDIES.

PLAVIX can be administered with or without food.

No dosage adjustment is necessary for elderly patients or patients with renal disease. (See Clinical Pharmacology: Special Populations.)

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Brief Summary of Prescribing Information Revised February 2007

PLA-FE07-B-Aa

Texas, a doctor there told me of the success patients were having with Byetta. After I did a bit of research online, the doctor had me drop Glucophage and begin taking Byetta the first of March. My life immediately turned from doom to hope. In fact, with the help of Byetta, I feel almost normal when it comes to food. It is a real blessing. My A1C is now 5.4.

When I began taking Byetta, the doctor weighed me in at 206. I now weigh 186. I am looking forward to being back at my normal weight of 145.

Ellie Martin
Jericho, Vt.

CGMs a Lifesaver

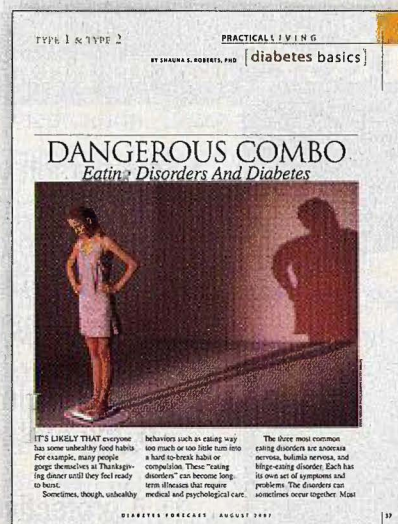
Continuous glucose monitors (CGM) are an awesome advancement in diabetes care! As a pregnant type 1, I could not have achieved my recent A1C of 5.7 without my MiniMed Paradigm Real-time system and pump with such a flexible diet and lifestyle. My finger-sticks went from an average of 10 per day, to 3 per day, and I can immediately correct any high/low blood glucose even before I "feel" them.

I would agree with the article in the August issue ("Continuous Glucose Monitors For Kids," p. 23), in that frequent alarms might be a concern for parents with

young children, although all preprogrammed alarms are adjustable. Low/high alarms may continue well after the actual (finger-stick) blood glucose is back to normal ranges, as the CGM is always 10–20 minutes behind actual blood glucose readings.

Dealing with maintenance can require a lot of patience from the user. However, for some people, including myself, this new CGM technology could be a lifesaver!

Nina Riethmaier
Collierville, Tenn.



Eating Disorders

I could identify with "Eating Disorders and Diabetes" in the August issue (p. 37).

I have been a compulsive eater since my early teens and was diagnosed with type 2 diabetes in 1983 at the age of 32. After years on oral meds, my endocrinologist switched me to regular insulin. I began

"chasing" my binge eating with more insulin to supposedly bring my blood glucose down. After years of this I wound up as an inpatient in an eating disorder program. Having an eating disorder of any kind certainly will corrupt one's ability to manage self-care. I have numerous complications and now, for the first time, at age 55 I have joined Overeaters Anonymous and am in better control.

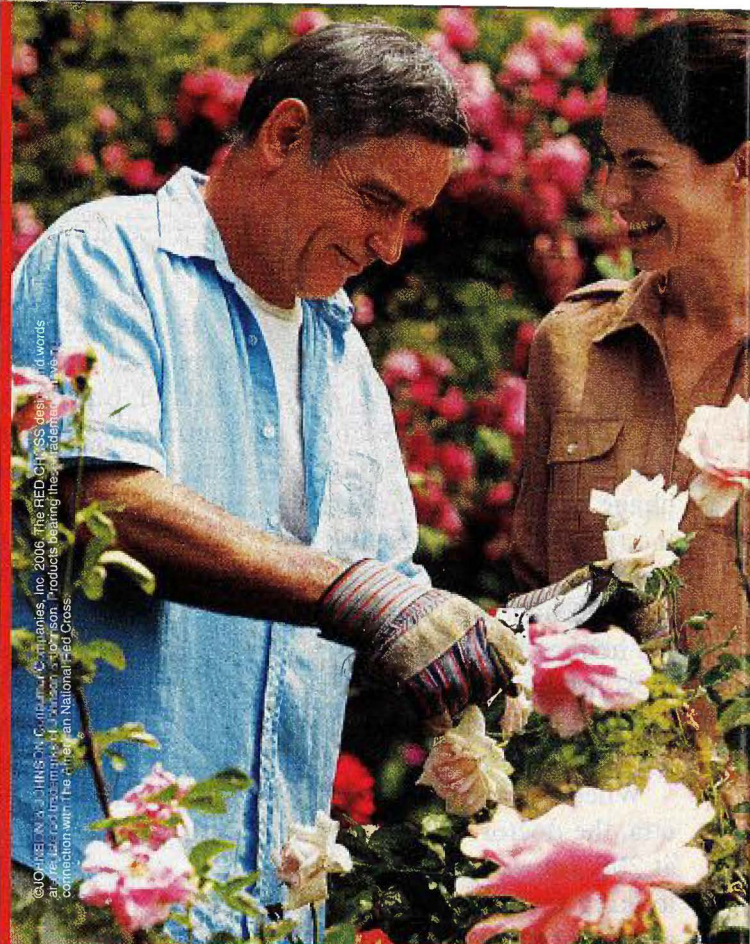
Roslyn Kaplan
Overland Park, Kan.

Insulin and Type 2

I am writing to you in regard to a question and response that appeared in the Mail Call section in the August issue (p. 11). The writer asked for clarification of insulin dependence in both type 1 and type 2 diabetes; he had always thought (as do many of us) that people who have type 2 diabetes are non-insulin-dependent. I was taken aback by the response offered by Roger Austin, MS, RPh, CDE, which includes the statement, "There is a progressive loss of insulin-producing capacity over time in patients with type 2, and sooner or later in the course of the disease, insulin treatment will become necessary...."

Anyone reading this would have to infer that a transition from oral medication to

continued on page 15



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insulin is inevitable for everyone with type 2 diabetes, regardless of any measures they might take to improve their condition. Can he provide concrete statistics to back up his statement? I would appreciate any further clarification he could offer.

Betty Ballinger
Tucker, Ga.

Roger Austin, MS, RPh, CDE, responds: While Ms. Ballinger is correct to point out that many patients with type 2 diabetes have successfully managed their condition with some combination of diet, weight loss, exercise, and type 2 drugs, it still holds that the degree of their success depends on many different factors, including ones that they cannot control.

Type 2 diabetes presents itself differently in every person who has the disease, but one characteristic of the disease is the same in everyone: the progressive loss of insulin-producing capacity over time. In some patients, the progression occurs more quickly than in others.

The rate of decline is dependent on both genes and lifestyle choices involving diet, exercise, smoking, and alcohol use. The point at which insulin is needed is determined, to a very large degree, by how much active beta cell mass remains in the body. So, those diagnosed with type 2 diabetes at age 17 will very

likely end up on insulin, because they are likely to have many years ahead of them during which their beta cell mass will continue to decline, even if they maintain excellent blood glucose management. On the other hand, it's true that some who are diagnosed with type 2 at an advanced age may never require insulin.

The CDC National Diabetes Fact Sheet (available at www.ndep.nih.gov) states that of adults diagnosed with diabetes, 16 percent take insulin only, 12 percent take both insulin and oral medication, 57 percent take oral medication only, and 15 percent do not take either insulin or oral medication. These numbers indicate that many people with type 2 never undergo insulin treatment. However, this same data is indicative of a problem with diabetes treatment in the United States: Diabetes is undertreated, and control could be greatly improved. Insulin tends to be underused, misused, and feared by both patients and their doctors. In many cases diabetes patients fail to use insulin—the most potent glucose-lowering agent available—until it's too late to alter the damage that has occurred while delaying its use. And that's simply tragic.

Meal Replacements

Thanks for the article in Practical Living about meal replacements ("Meal Replacements: Safe And



Effective?" p. 16, August). I have found that it is essential to test after using these products. Not all meal replacement bars are the same. Like all aspects of living with diabetes, it's a learning process to know how your blood glucose will be affected and to act accordingly.

I find that meal replacement bars fit very well into my lifestyle, where it is essential that I am able to carry food with me in case I cannot find suitable fare at the correct time. Sometimes there just is not an emporium available or all that I can get to is a junk food machine. So, out comes the meal replacement and on I go.

Bob Simmons
Litchfield Park, Ariz.

THE DIABETES ADVISOR

- Workplace Overload ■ Arthritis Relief
- How to Get the Sleep You Deserve

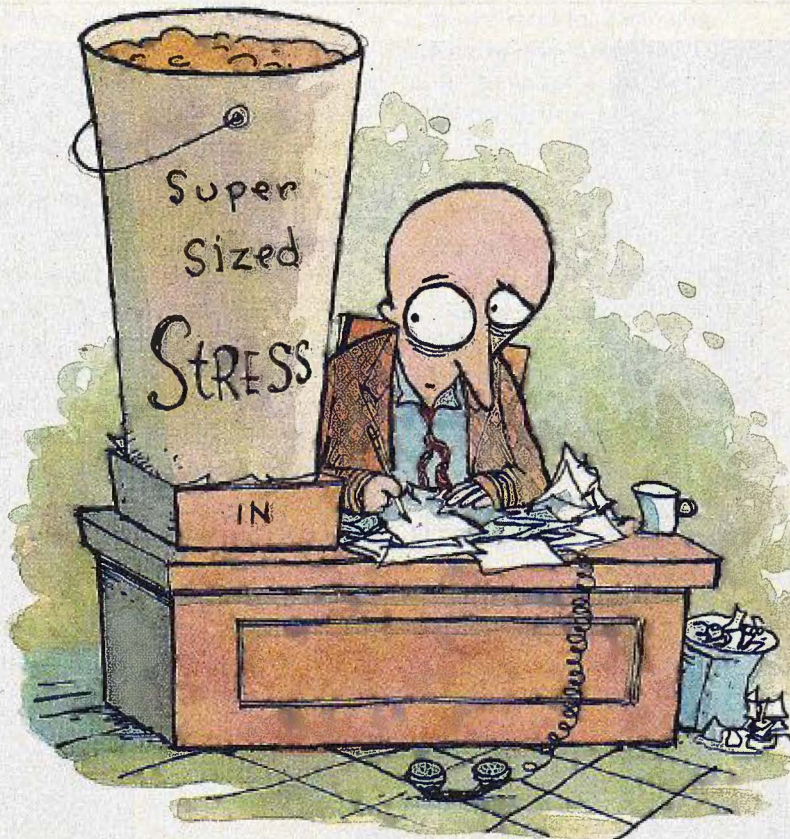
BY SHAUNA S. ROBERTS, PHD

Is your job the problem?

YOU MAY ALREADY blame your work life for your headaches or insomnia. Now, scientists have discovered another health problem that may be caused by stressful jobs: weight gain. According to a long-term study published this year in the *American Journal of Epidemiology*, the more stress a person has at work, the more likely she or he is to be obese or to have a large belly, which is a particularly unhealthy place to carry fat.

The researchers were inspired to look at the link between job

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ILLUSTRATIONS BY DAVID CLARK

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THE DIABETES ADVISOR

stress and obesity because people whose jobs are continually stressful are more likely to get heart and blood vessel disease. They wondered whether the link might be the development of obesity.

The study started with about 10,000 middle-aged participants and lasted 19 years; participants had physical exams or filled out questionnaires every few years. Some people died or dropped out, and data on work stress were not complete for some participants. In the end, the researchers were able to analyze results for roughly half of the participants.

The researchers defined work stress as having a job that had high demands, gave the worker little control or ability to make decisions, and lacked supportive supervisors or coworkers. They discovered several factors linked with developing obesity in men, women, or both. These included older age, less education, low fruit and vegetable intake, low fiber intake, high alcohol intake, and low physical activity.

After taking these factors into account, the researchers found that for people who were not obese at the start of the study, obesity was more likely to develop as job stress increased. People who had suffered the greatest job stress were 50 percent more likely to be obese than people who had not suffered job stress. A similar effect was found for the development of fat around the abdomen. The researchers concluded that the study provided firm evidence that job stress is associated with obesity.

Job stress may lead to increased weight in many different ways. The study authors suggested that inactivity and drinking lots of alcohol play a role. Some people may eat more food or eat less healthfully when they're feeling stressed.

So what if you can't—or don't want to—quit that stressful job? Stress-management techniques may help. These include:

- getting regular aerobic exercise
- doing stretching exercises such as yoga and tai chi
- meditating
- taking deep breaths

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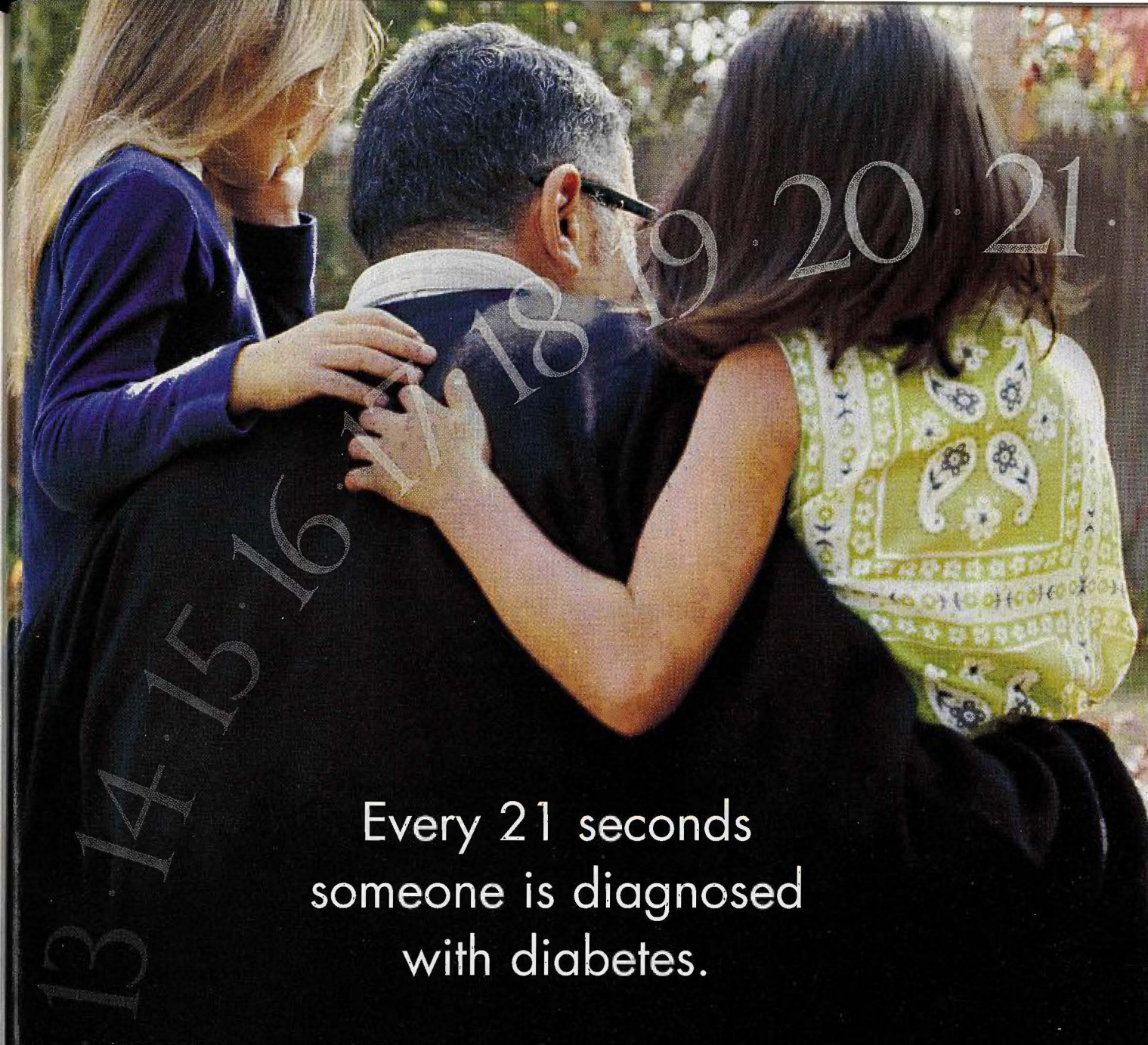
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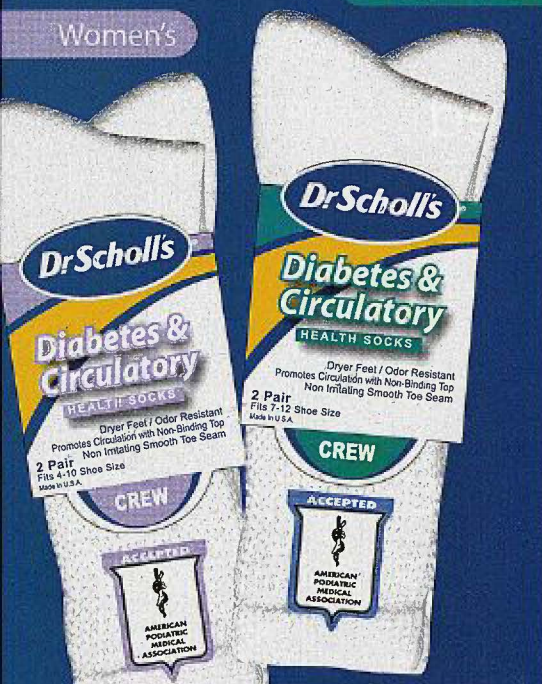


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THE DIABETES ADVISOR

- getting massages
- getting sufficient sleep
- developing a support system
- eating a nutritious diet
- cutting back on caffeine and sugar
- laughing
- sharing your feelings
- taking time for yourself
- keeping a journal
- seeing a counselor

What physical therapists can do for arthritis

WHEN ARTHRITIS STRIKES, some people can still carry on with their lives as before. But for others, pain, stiffness, swelling, or misshapen joints can make everyday tasks hard or impossible. Physical therapists can help many such people.

Physical therapists are state-licensed health care professionals who diagnose and treat people who have health-related conditions that limit their ability to move or do everyday activities. The physical therapist aims to reduce pain, prevent disability, improve function, and increase mobility. Strengthening exercises and range-of-motion exercises are two important tools that are often used. The therapist may also use heat, ice, massage, ultrasound, and encouragement. The overall goal is to enable the person to carry out normal activities without problems.

People with arthritis often avoid movements that hurt. But

when a joint is not used, it can become stiff and lose its range of motion. A physical therapist can help a person lessen stiffness without injuring the joints.

If a person with arthritis has a joint replaced, physical therapy may be vital to a quick and full recovery.

Physical therapists also provide education. A physical therapist can teach you:

- the correct way to use a cane or a walker
- how to choose shoes suited to your condition
- the importance of taking rest breaks
- how to use heat and cold to reduce pain and swelling
- how to protect your joints
- the importance of good posture
- how to change the way you do things to reduce stress on arthritic joints
- what assistive devices (such as bath stools and toilet grab bars) are available
- how to safely become more fit

Before making an appointment with a physical therapist, you may want to check with your health insurance plan to see whether you need a doctor's referral first. Your plan may not cover your costs otherwise. Also, your doctor may be able to recommend a good therapist. If not, you can search for a member of the American Physical Therapy Association in your area at the Web site www.apta.org.

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Our son Billy plays golf and soccer, but his love is baseball—he dreams of playing catcher for the Dodgers; right now, he plays on two different teams plus the All-Stars. He's constantly on the go ... eats and sleeps on a different schedule almost every day... and still controls his diabetes better than he ever could with multiple daily shots.

With his MiniMed Paradigm insulin pump Billy is more independent and worries less about his diabetes. "Now I can go with my friends without my parents having to help with shots and everything. I even go on sleepovers!" It has also improved his control when playing sports, "My first season after getting diabetes—when I still took shots—I had a hard time dealing with my lows. Now it is so much easier and I also feel stronger."

Billy enjoys greater freedom. Before, when he was on shots, he was "locked in" to his last shot. With his MiniMed Paradigm insulin pump, he has flexible basal and bolus options. He can adjust his basal rate throughout the day and night—as often as every 30 minutes. He sets it for classes, for sleepovers, and for each game (so he never has to pull out because of going low). And multiple bolus options let him match his bolus to whatever—and whenever—he eats. "Before, I had to eat at set times—breakfast at six, a snack at ten, lunch at twelve ... another snack ... dinner at six ... another snack ... Now, I eat when I want."

Learn more. Ask a few questions. You'll be glad you did—we are. Call 1-800-646-4633, option 3, or visit www.medtronicdiabetes.com

All quotations and statements are from Billy and his mother. This testimonial tells the individual experience of someone using insulin pump therapy to manage his diabetes. Please remember that the experience is specific to the individual.

The effectiveness of insulin pump therapy versus shots is supported in numerous clinical studies.¹⁻⁵ Individual results may vary and not every response will be the same.

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4. Ravid E, et al. *Diabetes Care*. 1999; 22(10):1793-94.

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Goldman Sachs Global Investment Research, New York, NY; Goldman Sachs February 2005.

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#1 PRESCRIBED BRAND[®]



THE MiniMed
Paradigm[®] REAL-Time
INSULIN PUMP AND CONTINUOUS GLUCOSE MONITORING SYSTEM



Medtronic

Alleviating Pain • Restoring Health • Extending Life

What's your best bet for beating insomnia?

AMONG PEOPLE MORE than 55 years old, insomnia is common. Nine to 25 percent of older people have trouble functioning during the day because they don't get enough sleep or sleep poorly.

Doctors often prescribe sleeping pills for such people. But studies have shown that pills are more helpful for short-term bouts of poor sleep than for persistent insomnia.

A study in *The Journal of the American Medical Association* sought to determine how cognitive behavioral therapy stacked up as an insomnia treatment for older insomniacs versus zopiclone. Zopiclone is a sleeping drug closely related to eszopiclone (Lunesta).

Forty-six people who were

55 years old or older participated. They had had insomnia for at least three months and were not able to function as well as usual during the day. Sixteen people took zopiclone each night, 12 people took a placebo, and 18 people received cognitive behavioral therapy. This therapy consisted of six weekly sessions in which each person learned about lifestyle and environmental factors that influence sleep, analyzed beliefs about sleep, practiced relaxation techniques, and received a strict sleeping schedule.

Researchers measured improvement two ways. First, they looked at time spent sleeping at night, time spent awake, time spent in different sleep stages, and other sleep characteristics. Second, the participants completed sleep diaries.

Within six weeks, each group had reduced the length of time

it spent awake at night, with the cognitive behavioral group showing the most improvement. Between the six-week and the six-month follow-ups, the cognitive behavioral therapy group significantly increased its total sleep time, showing that effects of treatment were long-lasting. Compared with the zopiclone group, the cognitive behavioral therapy group fared significantly better in nearly every objective measure of sleep. Diaries reported increased sleep time in the behavioral therapy group after the six-week follow-up and reduced time spent awake compared with the group of zopiclone users.

The researchers concluded that cognitive behavioral therapy worked better over both the short term and the long term than zopiclone or placebo in older adults with insomnia. After six weeks and again after six months, zopiclone and placebo had equal effects on sleep—in other words, the drug appeared to add nothing (but may have had a short-lived effect early on).

The study authors say that sleeping pills should only be prescribed for people with short-term insomnia. They do point out, however, that interventions for insomnia based on cognitive behavioral therapy currently are not widely available in clinical practice.

Shauna S. Roberts, PhD, is a science writer in Riverside, Calif.

