**NEW DRUGS**

**Lapatinib (Tykerb) For Advanced Breast Cancer**

The Food and Drug Administration (FDA) has approved lapatinib (Tykerb, GlaxoSmithKline), a targeted anti-cancer treatment, to be used in combination with the cancer drug capecitabine (Xeloda, Roche) for patients with advanced metastatic breast HER2-positive cancer.

The combination treatment is indicated for women who have received prior therapy with other cancer drugs, including an anthracycline, a taxane, and trastuzumab (Herceptin, Genentech).

Lapatinib, a molecular entity, is a kinase inhibitor that helps to deprive tumor cells of signals needed to grow.

Lapatinib is available in 250-mg tablets. An undivided dose of 1,250 mg should be taken orally once daily for 21 days and in combination with capecitabine on days one to 14 of a 21-day cycle.

(Source: FDA, March 13, 2007.)

**Aliskiren (Tekturna) For Hypertension**

The U.S. has become the first country to approve aliskiren (Tekturna, Novartis) tablets, a new type of blood pressure medication in more than a decade. Aliskiren, also known as Rasilez, is awaiting approval in Europe.

Aliskiren is a direct renin inhibitor. As a once-daily oral therapy, it targets renin, an enzyme responsible for triggering a process that can contribute to hypertension. Available in 150-mg and 300-mg strengths, it can be used as monotherapy or with other antihypertensive drugs.

More information on aliskiren is available in this month’s issue of P&T in the Pharmaceutical Approval Update feature (page 235) and in Meeting Highlights (page 232).

(Source: FDA, Novartis, March 6, 2007.)

**Eculizumab (Soliris) Therapy For Rare Blood Disease**

Alexion Pharmaceuticals, Inc., has received marketing approval from the FDA for eculizumab (Soliris). This is the first therapy approved for paroxysmal nocturnal hemoglobinuria (PNH), a rare, life-threatening blood disorder characterized by chronic red blood cell destruction (hemolysis).

In patients with this acquired genetic blood disorder, the red blood cells are destroyed by complement, a component of the body’s immune system. PNH affects 8,000 to 10,000 people in North America and Europe.

Hemolysis can cause severe anemia, blood clots, disabling fatigue, recurrent pain, shortness of breath, pulmonary hypertension, dark-colored urine, kidney disease, and impaired quality of life.

The product label includes a boxed warning of an increased risk of meningococcal infections. Patients should be vaccinated with a meningococcal vaccine at least two weeks before they receive the first dose of eculizumab.

Before beginning therapy, all patients and their physicians will be enrolled in the Soliris Safety Registry, part of a risk-management program.

Pre-approval trials of eculizumab are discussed in this month’s Meeting Highlights feature (page 232).


**NEW INDICATIONS**

**Conivaptan HCl (Vaprisol) For Hypervolemic Hyponatremia**

Conivaptan HCl injection (Vaprisol, Astellas Pharma US) has been approved for the intravenous treatment of hypervolemic hyponatremia in hospitalized patients. The drug was originally approved for euvolemic hyponatremia in December 2005.

This arginine vasopressin receptor antagonist is the first drug indicated specifically for the treatment of both euvolemic and hypervolemic hyponatremia. These potentially life-threatening conditions occur when blood sodium levels fall significantly below normal.

Hyponatremia can result from elevated levels of arginine vasopressin, which regulates water and salt balance. This common electrolyte disorder is one of the most difficult to treat.

Dilutional hyponatremia includes euvolemic and hypervolemic hyponatremia and is the most common form of the condition; it occurs when retained water dilutes serum sodium content. Patients with hyponatremia are classified as hypervolemic if swelling of body tissues (edema) is present and as euvolemic if the total body water content is increased without edema.

Conivaptan is discussed in the Pharmaceutical Approval Update column of this issue of P&T (page 235) and was reviewed in last month’s Drug Forecast.

(Source: Astellas, March 2, 2007.)

**Five New Uses For Atorvastatin (Lipitor)**

Pfizer has announced the FDA’s approval of atorvastatin calcium (Lipitor) tablets for reducing the risk of non-fatal heart attacks, fatal strokes, and non-fatal strokes; certain types of heart surgery; hospitalization for heart failure; and chest pain in patients with heart disease. This is the first cholesterol-lowering medication to receive FDA approval for reducing the risk of hospitalization for heart failure.

The drug was previously approved to reduce cardiovascular events in patients without heart disease. This new approval expands the use of atorvastatin to patients at high risk for cardiovascular events because of established heart disease such as prior heart attack, prior...
heart surgery, or chest pain with evidence of clogged arteries.

In a five-year study, patients taking atorvastatin 80 mg had a significant 22% reduction in the risk of major cardiovascular events over and above patients taking 10 mg and a significant 26% reduction in the risk of hospitalization for heart failure.

(Sources: FDA; Pfizer, March 7, 2007.)

NEW FORMULATIONS
Once-a-Day Beta Blocker Carvedilol (Coreg CR)

GlaxoSmithKline has announced that carvedilol phosphate (Coreg CR) extended-release capsules, a once-a-day beta blocker, is now available nationwide. Approved in 2006, Coreg CR is indicated for treating hypertension, post-myocardial infarction left ventricular dysfunction, and mild-to-severe heart failure. Patients previously had to take the drug twice a day.

Coreg CR is available in strengths of 10 mg, 20 mg, 40 mg, and 80 mg.

This is the first FDA-approved medication that uses Flamel’s Micropump technology, which controls delivery of the drug over a 24-hour span.

(Source: GlaxoSmithKline, March 22, 2007.)

Needle-less Coagulation Factor Replacement Kit

The FDA has approved four enhancements for Wyeth’s BeneFIX Coagulation Factor IX (Recombinant): a 2,000 IU vial, a needle-less reconstitution device, a prefilled syringe, and a reduced volume of diluent.

The R2 Kit is easier to prepare than the original BeneFIX kit. BeneFIX replaces clotting factor IX to stop or prevent bleeding in people with hemophilia B who do not have enough factor IX of their own.

The new features allow patients currently using the most common dosage strength—1,000 IU—to use a lower volume of diluent to administer the product. The final infusion volume can be reduced up to 75%, and the risk of needlesticks during reconstitution is also reduced.

(Source: Wyeth, March 27, 2007.)

DRUG NEWS
Boxed Warning for Anti-anemia Drugs: Aranesp, Epogen, and Procrit

The FDA has warned that the aggressive use of erythropoiesis-stimulating agents for patients with anemia was associated with serious and life-threatening side effects or death. The agency ordered a boxed warning for three anti-anemia drugs and recommended the lowest possible dose to slowly raise hemoglobin concentrations to the lowest level that would obviate the need for a blood transfusion.

The FDA also said that there has never been any evidence that treatment with darbepoetin (Aranesp, Amgen), epoetin alfa (Epogen, Amgen), or epoetin alfa (Procrit, Ortho Biotech) could increase energy or ease fatigue in patients undergoing cancer therapy.

For cancer patients who are not receiving chemotherapy, the FDA said that these agents did not benefit anemia and appeared to shorten time to death.

Patients treated preoperatively with epoetin alfa to reduce allogenic red blood cell transfusions had a higher incidence of deep vein thrombosis. Darbepoetin is not approved for this indication.

For all patients, physicians should measure hemoglobin twice a week for two to six weeks and should withhold the dose if an increase in hemoglobin exceeds 12 g/dl or if the hemoglobin level rises by 1 g/dl in any two-week period.

The Centers for Medicare & Medicaid Services said it will deny reimbursement for darbepoetin alfa and epoetin alfa when they are used for anemia of cancer, although it will continue to cover the drugs when they are used to treat anemia caused by chemotherapy.

Doctors should use the lowest dose necessary to help patients avoid blood transfusions. The new warnings are likely to prompt physicians to cut back on the use of these agents.

Cardiovascular events and tumor progression have been moved to the warnings section from the precautions section of all labels.

Sources: Amgen; The New York Times, March 9, 2007.)

Diabetes Drugs and Fractures: Alert for Pioglitazone (Actos)

Health care professionals have been notified about recent safety data concerning products containing the anti-diabetes drug pioglitazone (Actos, Takeda/Eli Lilly). Women with diabetes mellitus who were taking pioglitazone were reported to have experienced more fractures than those taking a comparator drug.

Most fractures observed were in the distal upper limb (forearm, hand, and wrist) or distal lower limb (foot, ankle, fibula, and tibia). The women were treated with pioglitazone for up to 3.5 years.

The Drug News column in the March issue of P&T also mentioned an increased risk of fractures in association with rosiglitazone (Avandia, Avandamet, GlaxoSmithKline).

(Sources: FDA; Takeda/Lilly, March 3, 2007.)

FDA Alert: Linezolid (Zyvox) And Gram-Negative Infections

The FDA has alerted prescribers of new safety concerns about linezolid (Zyvox, Pfizer).

A recent open-label, randomized trial compared linezolid with vancomycin
(Vancocin, Viro Pharma), oxacillin (Bactocill, SmithKline Beecham; Prostaphlin, Apothecon), or dicloxacillin (Dycill, GlaxoSmithKline; Dynapen, Apothecon) in seriously ill patients with intravascular catheter-related bloodstream and catheter-site infections. Patients receiving linezolid had a higher chance of dying than those treated with any of the comparator antibiotics.

Patients with gram-positive infections experienced no difference in mortality according to their antibiotic treatment; however, the mortality rate was higher in patients receiving linezolid who were infected with gram-negative organisms alone, in those who had both gram-positive and gram-negative organisms, and in those who had no infection when they entered the study.

Linezolid is not indicated for the treatment of catheter-related bloodstream infections, catheter-site infections, or gram-negative infections. If infection with gram-negative bacteria is known or suspected, appropriate therapy should be started immediately. (Source: FDA, March 16, 2007.)

**Heart Disease: A Heightened Risk for Firefighters?**

Nearly 50% of deaths that occur among firefighters while they are on duty are related to cardiovascular events.

Researchers examined mortality data among U.S. firefighters from 1994 to 2004 except for deaths that occurred during the terrorist attacks on September 11, 2001. The study did not actually show an overall increased risk of death from coronary heart disease, but it did reveal that such an event was more likely during the activities of suppressing a fire and responding to an alarm.

Although the risk of dying from heart disease was small, it was discovered that more than 70% of fire departments lack programs to promote fitness and health and do not require firefighters to exercise regularly, to have periodic medical examinations, or to undergo return-to-work evaluations after a major illness. Firefighters begin their careers in good health, but they do not necessarily maintain it over time.

Firefighting work can be physically demanding. Contributing factors for mortality from cardiovascular events include irregular bursts of physical exertion, handling heavy equipment and materials, heat stress, and psychological stressors. Workers engage in heavy lifting, perform difficult maneuvers while wearing heavy clothing and protective gear in extreme heat, and are exposed to toxic chemicals from smoke and burning materials.

Heavy exertion can trigger sudden myocardial events, but regular exercise can be protective. Preventive steps are recommended for fire departments, such as providing annual medical examinations; wellness and fitness programs; and annual physical performance evaluations for their firefighters.

The study authors also recommend a heart-healthy diet, avoiding tobacco and excessive alcohol use, regular exercise, and modifying conditions that pose additional cardiovascular risk such as hypertension, diabetes, and obesity. (Source: *N Engl J Med* 2007;356:1207–1215; editorial, 1261–1263.)

**Efalizumab (Raptiva) Beneficial In Atopic Dermatitis**

Patients with severe atopic dermatitis are often treated with systemic corticosteroids, cyclosporine, and other drugs that can have serious adverse effects. Moreover, immunosuppressants should be taken only for a limited time because of the risk of organ toxicities.

To have the option of a targeted systemic drug that could work safely over the long term would be a welcome change. A small study at Oregon Health and Science University suggests that efalizumab (Raptiva, Genentech), already approved for the treatment of chronic moderate-to-severe plaque psoriasis, might be a solution. In the study, six of 10 patients improved by at least 50% over the 12-week treatment period.

The patients received the dose indicated for psoriasis: an initial conditioning subcutaneous dose of efalizumab of 0.7 mg/kg, followed by 1 mg/kg weekly for another 11 weeks.

The patients were monitored for 20 weeks. The mean Eczema Area and Severity Index (EASI) score at baseline was 37; at week 12, the mean score was 17.6. All 10 patients showed some improvement; six achieved an EASI score of 50, and two achieved EASI 75 at week 12.

The drug was well tolerated. Secondary bacterial infection was the most common adverse event during the study. With 120 doses administered, only one serious adverse event occurred. One patient had thrombocytopenia, which has also been reported in 0.3% of patients with psoriasis treated with efalizumab.

The 53% improvement rate seen in this study was better than improvements reported with interferon-gamma (e.g., Actimmune, InterMune) and azathioprine (Azasan, Imuran, Salix), and was comparable to results with cyclosporine and mycophenolate mofetil (CellCept, Roche). Moreover, the clinical response was almost three times the expected placebo response seen in a study of injectable interferon-gamma.

At the end of the study, five patients requested further efalizumab therapy. (Source: *J Am Acad Dermatol* 2007; 56:222–227.)

**Tiagabine (Gabitril) Helps Reduce Cocaine Use**

It came as a bit of a surprise, but tiagabine (Gabitril, Cephalon) was found to be superior to gabapentin (Neurontin, Vancocin, Viro Pharma), oxacillin (Bactocill, SmithKline Beecham; Prostaphlin, Apothecon), or dicloxacillin (Dycill, GlaxoSmithKline; Dynapen, Apothecon) in seriously ill patients with intravascular catheter-related bloodstream and catheter-site infections. Patients receiving linezolid had a higher chance of dying than those treated with any of the comparator antibiotics.

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It came as a bit of a surprise, but tiagabine (Gabitril, Cephalon) was found to be superior to gabapentin (Neurontin,
Pfizer) in reducing cocaine use among cocaine-dependent patients who were taking methadone.

Researchers at Yale University and the University of Arkansas in Little Rock randomly assigned 76 cocaine-dependent men to receive tiagabine 24 mg/day, gabapentin 2,400 mg/day, or placebo in a 10-week double-blind trial. Study medications were slowly increased to the full dosages by the end of the fifth week and were maintained through the 10th week.

The proportion of cocaine-free urine samples during weeks six to 10 was significantly larger in the tiagabine group. In addition to producing an increase in cocaine-free urine samples by 48%, tiagabine also led to an increase in cocaine abstinence rates to 35%, compared with a rate of only 11% in the gabapentin patients and 29% in the placebo groups. Basically, gabapentin was no better than placebo at reducing cocaine use.

Tiagabine was well tolerated, with no evidence of oversedation, seizures, or other significant side effects. The researchers suggest initiating tiagabine at night, then increasing the dose at night on a twice-daily schedule until reaching the target dosage.

(Source: Drug Alcohol Depend 2007; 87:1–9.)

FDA Warning on Buying Isotretinoin Online

The FDA is launching a special Web page to warn consumers about the dangers of buying isotretinoin (Accutane, Roche) online. Isotretinoin is approved for the treatment of severe acne that does not respond to antibiotics. If improperly used, isotretinoin can cause severe side effects, including birth defects. Serious mental health problems have also been reported with isotretinoin use.

The Web page (www.fda.gov/buyonline/accutane) will be positioned as a search result on Google and other search engines when consumers initiate an online search for the drug under any one of its four names. Isotretinoin is also sold as generic versions called Amnesteem, Claravis, and Sorret.

The Web page warns that the drug should only be taken under the supervision of a physician or a pharmacist.

The FDA and the manufacturers of isotretinoin have developed special safeguards to reduce the risks of isotretinoin, including a strict distribution program, called iPLEDGE, to ensure that women using isotretinoin do not become pregnant and that pregnant women do not use isotretinoin.

Isotretinoin is available only at pharmacies registered for this program. The distribution program is designed to prevent the sale of isotretinoin over the Internet.

(Source: FDA, March 29, 2007.)

More Pain Relief Needed in Ovarian Cancer

Data from three large health maintenance organizations reveal that 85% of a group of 421 women who were dying of ovarian cancer had documented pain, but only about half of these women were given a high-intensity medication regimen (intended for severe pain). The study, funded by the Centers for Disease Control and Prevention, found “very little evidence of systematic assessment of pain or its management.”

The study used the World Health Organization (WHO) three-step ladder as a guide. Treatment usually starts with non-opioid analgesics and moves to strong opioids. At all steps of the ladder, adjuvant medications, such as antidepressants and corticosteroids, can be used. This approach, the researchers say, allows 90% of cancer patients and more than 75% of terminally ill cancer patients to control pain.

At five to six months before they died, 55% of women were either receiving no pain medication or they received medication generally indicated for mild pain. Only 9% were using the highest-intensity regimen. The percentage using the highest-intensity regimen increased to 22% at three to four months before death and to 54% at one to two months. Older women were less likely to receive the highest intensity of medication. This finding might reflect a possible lower tolerance in older women for the strong opioids, or it might be that younger women were more likely to ask for pain relief, the researchers suggest.

Reports of undertreatment are not new, of course. Even now, misconceptions associated with morphine use prevent adequate pain relief. The researchers cited a study in which 50% of health care providers said they would provide a weak opioid for a woman with bone metastasis and a predicted survival of more than 24 months. Other case studies have described providers who were unaware of the WHO ladder of treatment.

The researchers also state that a lack of communication between physicians and patients can be a barrier to adequate pain management. Providers might not be trained to comfortably—or at least willingly—discuss palliative and end-of-life issues with patients. And without direct communication, health care providers might not be aware of pain levels. Patients need to be given the opportunity and permission to raise the subject of pain.

(Source: J Pain Symptom Manage 2007;33:24–31.)

Beta Blockers: Not All the Same

In one of the few head-to-head comparisons of the three beta-blockers most commonly prescribed after acute myocardial infarction (AMI), atenolol (Tenormin, AstraZeneca) and acebutolol continued on page 205
Why Do Some Patients Bounce Back Faster Than Others?

They call it the “Lazarus phenomenon”—patients who respond unexpectedly and significantly to treatment. But which patients are they?

Researchers from Ohio State University in Columbus set out to identify factors that made a difference. They reported their findings at the International Stroke Conference in San Francisco from February 7 to 9, 2007.

The study involved 102 patients, 18 to 90 years of age, who had experienced an ischemic stroke. The Lazarus phenomenon, in this study, was defined as at least a 50% reduction in the patient’s score on the National Institutes of Health Stroke Scale 24 hours after treatment. One quarter of the patients responded to clot-busting drugs dramatically, with major improvement seen within one day of the stroke.

Physicians used microcatheters to deliver the medications directly into the blood clot in the artery. The method, not yet approved by the FDA, results in much higher local concentrations of drug, but it also can increase the risk of bleeding.

Only time to treatment and a reperfusion flow of 50% or more differed significantly between the two groups of patients. The average times to treatment were 208 minutes in the patients who recovered rapidly and 306 minutes in those who did not. Most patients received the treatment between three and six hours. Of those patients with reperfusion of 50% or more, 42% were considered to have demonstrated the Lazarus phenomenon.

(Sources: American Heart Association, www.americanheart.org; Medscape Medical News, February 12, 2007.)

Timing Antithyroid Drugs In Radioiodine Treatment

Antithyroid drugs are often used before, during, and after radioiodine therapy for hyperthyroidism. But the practice, which has been debated, may significantly raise the risk of treatment failure, say researchers from Switzerland, Denmark, Scotland, and Johns Hopkins University.

The researchers analyzed data from controlled trials involving 1,306 patients. Giving the drugs in the week before treatment sometimes increased failure rates, whereas giving the drug afterward reduced rates of hypothyroidism. There was also a trend toward a higher risk of treatment failure in trials that used fixed radioiodine doses, compared with those that adapted dose calculation according to uptake when antithyroid drugs were given before radioiodine.

The antithyroid drugs may also affect the morbidity and mortality in the year after treatment. Failures of radioiodine treatment include persistent and recurrent hyperthyroidism, the researchers note, which increases cardiovascular risk and necessitates further treatment. Conversely, patients with hypothyroidism require regular and lifelong follow-up for titration of the optimal dose of levothyroxine (Synthroid, Abbott).

(Source: BMJ, February 19, 2007.)

Optimal Clopidogrel Therapy: Before or After Stent Insertion?

When is the best time to give clopidogrel bisulfate to patients needing diagnostic coronary angiography—immediately after unscheduled coronary stenting or before? Researchers from Hungary and Vienna say that starting treatment with clopidogrel (Plavix, Bristol-Myers Squibb/Sanofi-Aventis) before percutaneous coronary intervention (PCI) has several benefits.

The researchers compared 30-day outcomes in 2,679 patients with suspected coronary artery disease who received a loading dose of 300 mg of clopidogrel right after stenting and 1,481 who received the same dose six to 24 hours beforehand.

At 30 days, the patients who had received immediate treatment afterward were nearly twice as likely to have had an acute myocardial infarction (AMI), to have required repeated target vessel revascularizations, or to have died (4.74% vs. 2.77%). They were also significantly more likely to have stent thrombosis.

Pretreatment was associated with
more major bleeding (1.35% vs. 0.41%); however, major bleeding was less frequent than AMI and the composite cardiac primary endpoint.

Research has shown that the risk of acute and subacute stent thrombosis is highest within the first post-implantation days. Indeed, in this study, most of the cardiac events occurred within the first few days.

The benefit of giving clopidogrel more than six hours before the planned PCI might have been in preventing acute thrombotic occlusion during the first two to six hours after stent insertion. Within this time, the full dose of unfractionated heparin applied during PCI has mainly an anticoagulant effect, and only a moderate influence on platelet activity. They note, as well, that increased platelet reactivity has been documented in patients undergoing PCI.

(Source: Am Heart J 2007;153:289–295.)

New Drugs

Adverse Succinylcholine Effects May Inhibit Intubation

Succinylcholine, with its rapid onset and short duration, is used as an emergency standby for rapid-sequence intubation. However, one of its side effects—masseter muscle rigidity (MMR)—although rare, can be dangerous. Being ready with a prompt response to treat this potentially life-threatening complication is the key, say physicians from Carl R. Darnall Army Medical Center in Fort Hood, Texas.

A 36-year-old man had taken an overdose of clonidine and had imbibed an unknown quantity of alcohol about three hours before he was brought in to the emergency department. When he was found, he was unresponsive to verbal or painful stimuli. The staff administered naloxone HCl (Narcan, Endo) 4 mg but observed no response.

At the hospital, the staff gave the patient another 4 mg of naloxone. After a repeated Glasgow Coma Scale score of 3, they decided to try intubation. However, two intubation attempts were impeded by an inability to fully open the patient's mouth. After the diagnosis of MMR was confirmed, the patient received vecuronium 10 mg, which relieved the masseter rigidity. The third intubation attempt was successful.

Typically, the authors say, physicians manage MMR by stopping the paralytic agent and rescheduling the procedure after an evaluation for malignant hyperthermia. However, this is not a feasible option in the ED. Instead, anticipating the possibility of MMR can prompt a rapid rescue response.


Prevention of Venous Thromboembolism Still Overlooked in Hospitals

The results of DVT FREE, a prospective Sanofi-Aventis registry of deep-vein thrombosis (DVT), indicate that hospitalized medical patients are at a higher risk for developing blood clots than nonmedical patients.

Because these medical patients are immobilized in the hospital, they face an increased risk of clot development. The study revealed that these patients were still not receiving the proper options for preventing DVT from their health care professionals. They received prophylactic measures far less often (25.4%) than non-medical patients (53.8%), even though they had a higher burden of blood clots and experienced pulmonary embolism more often (22.2%) than the non-medical patients (15.5%).

The types of prophylaxis provided include pneumatic compression devices, vascular compression stockings, subcutaneous unfractionated heparin, and low-molecular-weight heparin.

It was hoped that the report would spur further study of VTE prevention.

(Source: Sanofi-Aventis, March 25, 2007.)

Ongoing Debate: Do Heart Drugs Work as Well as Stents?

Many heart patients who routinely receive stents to open arteries after angioplasty might not be gaining any more permanent benefit than patients treated with drugs alone, according to a new controversial study. The researchers say that stents might be little better than the aggressive use of heart medications to prevent heart attacks and death and that stents are being used too often to treat stable, asymptomatic disease.

During a five-year clinical trial, called Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE), patients receiving stents in addition to using statins or other heart drugs had better blood flow to the heart than those using only drugs, but they did not live longer or have fewer heart attacks. It was concluded that angioplasty did not save lives or prevent heart attacks in non-emergency patients, and offered only slight or temporary relief from chest pain.

The trial enrolled patients from 1999 to 2004. More than 2,200 patients in the trial came largely from Veterans Administration hospitals in the U.S.

The older bare metal stents were usually used (drug-coated stents were approved in 2003). Almost 95% of patients took aspirin, 90% took statins, 85% took beta blockers, and two thirds took angiotensin-converting enzyme (ACE)–inhibitors. The drug therapy patients were also more likely to have taken calcium-channel blockers and nitrates for angina.

Stents were developed to combat the tendency of the vessels to close after angioplasty. Drug-coated stents help preserve the channel created by angioplasty.
The results raise new questions about the value of angioplasty and stenting, widely used since the mid-1990s. Each year, almost one million Americans get stents after angioplasty. Patients with drug-coated stents must usually take anti-clotting drugs indefinitely. Bare metal stents carry less late clotting risk but tend to lead to arterial reclogging.

Since 2002, American Heart Association and the American College of Cardiology guidelines have called for angioplasty and stenting (or bypass surgery) only after efforts have been made to treat symptoms with drugs, but patients and doctors have been choosing stenting, which provides relief sooner.

Attendees at the meeting said the new data should encourage more health care providers to follow the practice guidelines and to recommend drug therapy and healthier living to reduce the risk of heart attacks.


NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Mesomark Assay
Manufacturer: Fujirebio Diagnostics, Inc., Malvern, PA
Approval Date: January 25, 2007
Use Classification: This is the first in vitro test for mesothelioma, a rare form of cancer in which fluid accumulates in the lungs and chest cavity. Mesothelioma can also occur in the lining of the pleural cavity of the abdomen.
Description: The assay is a manual enzyme-linked immunosorbent assay (ELISA) for measuring soluble mesothelin-related peptides (SMRPs). SMRP is a biomarker that is released into the bloodstream by mesothelioma cells. Biomarkers are substances found in higher-than-normal concentrations in the blood, urine, or body tissues of patients with certain types of cancers. SMRP levels can be elevated years before the diagnosis of mesothelioma is made.
Purpose: By measuring the amount of SMRP in the bloodstream, physicians can monitor patients with biphasic or epithelioid mesothelioma.
Benefit: The assay test kit was developed to measure levels of the biomarker mesothelin in serum. The test can be used to monitor patients with mesothelioma, to determine the risk of recurrence in patients after surgery, or to measure the patient’s response to therapies.
Sources: www.pharmacyonesource.com; www.mesothelioma web.org; www.fda.com

Name: MammaPrint
Manufacturer: Agendia, Amsterdam, The Netherlands
Approval Date: February 5, 2007
Use Classification: This test can be used to determine the likelihood of
breast cancer recurrence within five to 10 years after a woman’s initial cancer.

Description: This molecular technology is used to predict whether existing cancer will spread. The test depends on a microarray analysis, a powerful tool for simultaneously studying the patterns of behavior of large numbers of genes in biological specimens. The genetic profiles of a large number of women with breast cancer are compared with each other, and a set of 70 genes is identified. The activity of these genes confers information about the probability of tumor recurrence.

Purpose: The recurrence of cancer depends partly on the activation and suppression of certain genes located in the tumor. Prognostic tests such as the MammaPrint can measure the activity of these genes and thus help physicians understand the odds of metastasis. Of those women indicated by this genetic signature to be at high risk, 23% actually had a recurrence of cancer somewhere in the body within five years. Only about 5% of those women with a favorable genetic signature experienced a return of cancer in that time.

Benefit: The test measures the level of activity of each gene in a sample of the tumor after it is surgically removed. A formula (algorithm) is then used to produce a score that determines whether the patient is considered at low risk or high risk for metastasis.

Sources: www.pharmacyonesource.com; www.agendia.com; www.news-medical.net

Name: New-Generation Ultrasound Devices

Manufacturer: Paradigm Medical Industries Inc., Salt Lake City, UT/Meda Co. Ltd., China

Approval Date: February 12, 2007

Use Classification: Several devices have been approved for imaging in ophthalmology.

Description: The P2000 A-Scan is used to measure axial length of the eye. It weighs less than four pounds and has a fixation light, a built-in liquid crystal diode monitor, a printer, and a foot switch.

The P2200 Pachymeter is used to measure corneal thickness.

The P2500 A-Scan/Pachymeter is a combination of the two stand-alone devices (the P2000 and the P2200). It has a fixation light and a pachymeter probe with a built-in monitor and printer.

The P2700 A/B-scan is used to detect abnormalities within the eye. It has a 10-inch built-in monitor and a fold-up keyboard for portability.

The P37-II, a more advanced A/B-scan, provides portability for ophthalmology in animals. It has a fixation light for easy alignment and precise axial length measurements. The audible tone confirms corneal contact. Quiet and non-vibrating, the B-scan probe captures imagery at 40 and 60 degrees to ensure a thorough examination of the globe and orbit. The thermal video printer allows fast, low-cost printing of A-scan and B-scan images. The optional thermal line printer can produce 8.5- by 11-inch reports of data on biometry and intraocular lens measurements.

Purpose: The devices are indicated for clinical ophthalmologists to visualize and measure the eye.

Benefit: Customized and user-friendly examinations are faster and more accurate with the ocular diagnostic workstation’s responsive technology. Oscreen icons help screens guide the operator in running the system. Clinicians can observe intraocular anatomy and pathology in the finest detail and compare current patient data with case studies stored in memory.

The quad imaging feature of the A/B scan provides four different scans to view simultaneously. The clinician can compare real-time, serial imagery on the screen and identify complex pathology more easily.

Features include A-Scan vector display and dual calipers for measuring ocular structures on-screen. Zoom-and-pan features allow for magnification and optimal positioning of suspicious areas on the large, high-resolution display. The A/B scan provides full-function biometry capabilities with built-in third-generation intraocular lens formulas and easy-to-use, optional digital diagnostic A-scanning for tissue characteristics of intraocular and orbital lesions.

Source: www.pharmacyonesource.com; www.medicaldesignonline.com; www.paradigm-medical.com

FDA Warning: MRI Agents Linked to Skin Disorder in Patients with Renal Disease

The Centers for Disease Control and Prevention (CDC) has warned physicians to avoid using gadolinium-containing contrast agents in magnetic resonance imaging (MRI), when possible, in patients with advanced renal failure because of the risk of a serious skin disease.

Gadolinium agents were linked to nephrogenic fibrosing dermopathy (NFD), which can cause thickening and hardening of the skin. Researchers conducted a matched case-control study that included 19 cases from a St. Louis hospital. In a multivariate analysis, patients with renal disease who developed NFD were nearly nine times more likely to have been exposed to gadolinium contrast agents in the previous year compared with those who did not develop the skin condition. Peritoneal dialysis appears to confer a greater risk than hemodialysis.