

June 2007 Clinical Briefs

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Patch Approved For Parkinson's Treatment

The Food and Drug Administration (FDA) last month announced the approval of Neupro (rotigotine transdermal system), a skin patch designed to treat symptoms of early Parkinson's disease. Rotigotine is a drug not previously approved in the United States. Neupro, manufactured by Schwarz Bioscience of Research Triangle Park, N.C., is the first transdermal patch approved for the treatment of symptoms of Parkinson's disease.

Parkinson's disease, which belongs to a group of conditions called motor system disorders, results from the loss of dopamine-producing brain cells. Rotigotine, a member of the dopamine agonist class of drugs, is delivered continuously through the skin (transdermal) using a silicone-based patch that is replaced every 24 hours. A dopamine agonist works by activating dopamine receptors in the body, mimicking the effect of the neurotransmitter dopamine.

The effectiveness of Neupro was demonstrated in one fixed-dose response study and two flexible-dose studies. The parallel group studies were randomized, double-blinded, and placebo-controlled, and involved 1,154 patients with early Parkinson's disease who were not taking other Parkinson's medications.

The most common side effects for Neupro included skin reactions at the patch site, dizziness, nausea, vomiting, drowsiness and insomnia, most of which are typical of this class of drugs. Other potential safety concerns include sudden onset of sleep while engaged in routine activities such as driving or operating machinery (sleep attacks), hallucinations, and decreased blood pressure upon standing up (postural hypotension).

Surgical Sealant Approval Expanded

Last month the Food and Drug Administration (FDA) approved Evicel Fibrin Sealant, a liquid product that when applied topically helps control oozing from small blood vessels during surgical procedures.

"Evicel provides an effective means to stop oozing from small vessels during vascular surgery when suturing, compression or other standard techniques are not effective or practical," said Dr. Jesse Goodman, director of FDA's Center for Biologics Evaluation and Research, in a statement.

The sealant is derived from pooled human plasma and consists of a fibrinogen concentrate and thrombin, two substances used to promote clotting. Both substances go through a two-stage process to reduce the risk of viral transmission in manufacturing, although the potential risk for the transmission of bloodborne viruses cannot be totally eliminated.

In a study of 147 patients, the effectiveness of Evicel was compared with the standard bleeding control technique of applying pressure to a plastic covering (graft) placed over the open blood vessel. Eighty-three per cent of those who received Evicel stopped bleeding within four minutes, compared with 39.7 per cent in the control group.

Adverse events, such as anemia and graft site infection, were generally mild and occurred at about the same frequencies in the Evicel-treated group and the control group.

FDA originally licensed the predecessor of Evicel (Crosseal) in 2003 for use during liver surgery. Evicel is manufactured by OMRIX biopharmaceuticals LTD, of Kiryat Ono, Israel.

Generic Versions Of Ambien Approved

The first generic versions of Ambien (zolpidem tartrate) immediate-release tablets, the popular sedative-hypnotic used for the short-term treatment of insomnia, were approved for marketing last month by the Food and Drug Administration.

Zolpidem tartrate tablets in formulations of five milligrams and 10 milligrams are manufactured by multiple generic drug companies in the United States. The following 13 manufacturers have received FDA approval for zolpidem tartrate tablets: Mylan Pharmaceuticals Inc., TEVA Pharmaceuticals USA, Roxane Laboratories Inc., Watson Laboratories Inc., Ranbaxy Laboratories Ltd., Dr. Reddy's Laboratories Ltd., Apotex Inc., Synthon Pharmaceuticals Inc., Genpharm Inc., Mutual Pharmaceutical Company Inc., Caraco Pharmaceutical Laboratories Ltd., Carlsbad Technology Inc., and Lek Pharmaceuticals.

In March, FDA requested that all manufacturers of sedative-hypnotic drug products, a class of drugs used to induce or maintain sleep, strengthen their product labeling to include stronger language concerning potential risks. These risks include severe allergic reactions and complex sleep-related behaviors, which may include sleep driving. Sleep driving is defined as driving while not fully awake after ingestion of a sedative-hypnotic product, with no memory of the event. Generic versions of these drugs will also include this labeling.

Alternative Care Focus At Clinical Center

The National Center for Complementary and Alternative Medicine (NCCAM) has established an Integrative Medicine Consult Service at the National Institutes of Health (NIH) Clinical Center, the world's largest hospital devoted to research. This service will provide physicians, nurses, and other members of the Clinical Center health care staff the ability to discuss complementary and alternative medicine (CAM) therapies with knowledgeable medical staff from the consult service and learn how various CAM practices might complement or interact with a patient's care as a research participant at the Clinical Center.

CAM is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine, such as herbal supplements, meditation, chiropractic manipulation, and acupuncture. Integrative medicine combines treatments from conventional medicine and CAM for which there is high-quality evidence of safety and effectiveness.

According to NIH, the 2002 National Health Interview Survey showed that more than one-third of all American adults use some form of CAM. And a recent consumer survey of older Americans revealed that less than one-third of those who had used CAM discussed this information with their physicians. Since patients at the Clinical Center are participating in research studies, it is important to know what CAM therapies are being used and how they might affect the treatments being studied.

The Clinical Center's Pain and Palliative Care Service and the Rehabilitation Medicine Department already offer alternative therapies such as acupuncture, Reiki, hypnosis, guided imagery, massage therapy, acupuncture, tai chi, and qi gong training. The Clinical Center's pharmacy department consults on herbals and herb/drug interactions and has conducted research in these areas.

The Integrative Medicine Consult Service will coordinate the resources of these existing services to meet the needs of the Clinical Center staff and its patients. In addition to offering clinical consultation regarding CAM therapies, the service will establish a research program embedded in NIH's clinical and translational research structure and provide CAM education for NIH staff, patients, and their families.

Treatment Rare For Drug Users

Only 8 per cent of people identified as drug abusers, and fewer than 40 per cent of those diagnosed with drug dependence, have ever gotten any kind of intervention or treatment, according to the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC). The study was conducted by scientists from the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA). "Even though we know drug addiction treatment can work, lifetime treatment rates are substantially lower than corresponding treatment rates of other major psychiatric disorders," said NIH Director Dr. Elias Zerhouni in a statement. "This tells us that we should focus on strategies designed to help us close the treatment gap."

The survey results, published in the May 2007 issue of the Archives of General Psychiatry, show that rates of drug abuse and dependence are generally higher among certain populations, including men, respondents ages 18 to 44, and people who have never married. The study also confirmed that the onset of drug abuse and dependence typically occurs during late adolescence or early adulthood. These findings suggest that certain groups are more vulnerable and should be targeted for early intervention efforts.

This study and others indicate that significant associations exist between drug abuse and co-occurring mental illness, including mood and anxiety disorders, and personality disorders. In fact, help-seeking behavior was more common in those with co-occurring psychiatric disorders. The authors advise that a person with a substance use disorder should also be evaluated for mental illness, and conversely, a person with a mental disorder should be evaluated for possible substance abuse.

The authors analyzed data gathered from face-to-face interviews with more than 43,000 U.S. adults ages 18 and older, as part of the 2001-2002 NESARC, the largest study conducted on the co-occurrence of psychiatric disorders among U.S. adults.

In the survey, among those individuals with drug use disorders who received treatment, most went to physicians and other health care professionals, although many also used self-help groups. According to researchers, the findings underscore the continued importance of the detection and referral roles of primary care physicians. Future research efforts should focus on developing instruments to screen, identify, and refer patients with suspected drug abuse or dependence in primary care settings.

Bipolar Disorder Underrecognized

A new study supports earlier estimates of the prevalence of bipolar disorder in the U.S. population, and suggests the illness may be more accurately characterized as a spectrum disorder. It also finds that many people with the illness are not receiving appropriate treatment.

The study, published in the May 2007 issue of Archives of General Psychiatry, analyzed data from the National Comorbidity Survey Replication (NCS-R), a nationwide survey of mental disorders among 9,282 Americans ages 18 and older. The NCS-R was funded by the National Institute of Mental Health (NIMH).

NIMH researcher Kathleen Merikangas, PhD, and colleagues identified prevalence rates of three subtypes of bipolar spectrum disorder among adults. Bipolar I is considered the classic form of the illness, in which a person experiences recurrent episodes of mania and depression. People with bipolar II experience a milder form of mania called hypomania that alternates with depressive episodes. People with bipolar disorder not otherwise specified (BD-NOS), sometimes called subthreshold bipolar disorder, have manic and depressive symptoms as well, but they do not meet strict criteria for any specific type of bipolar disorder. Nonetheless, BD-NOS still can significantly impair those who have it.

The results indicate that bipolar I and bipolar II each occur in about 1 per cent of the population; BD-NOS occurs in about 2.4 per cent of the population. The findings support international studies suggesting that, given its multi-dimensional nature, bipolar disorder may be better characterized as a spectrum disorder.

Most respondents with bipolar disorder reported receiving treatment. Nearly everyone who had bipolar I or II (89 to 95 per cent) received some type of treatment, while 69 per cent of those with BD-NOS were getting treatment. Those with bipolar I or II were more commonly treated by psychiatric specialists, while those with BD-NOS were more commonly treated by general medical professionals.

However, not everyone who responded to the survey reported receiving treatment considered optimal for bipolar disorder. Up to 97 per cent of those who had some type of bipolar illness said they had coexisting psychiatric conditions, such as anxiety, depression or substance abuse disorders, and many were in treatment for those conditions rather than bipolar disorder. The researchers found that many were receiving medication treatment considered "inappropriate" for bipolar disorder, such as an antidepressant or other psychotropic medication in the absence of a mood stabilizing medication such as lithium, valproate, or carbamazepine. Only about 40 per cent were receiving appropriate medication, which is considered a mood

stabilizer, anticonvulsant or antipsychotic medication.

"Such a high rate of inappropriate medication use among people with bipolar spectrum disorder is a concern," said Dr. Merikangas in a statement. "It is potentially dangerous because use of an antidepressant without the benefit of a mood stabilizer may actually worsen the condition."

Dr. Merikangas and colleagues speculate that as people seek treatment for anxiety, depression or substance abuse disorders, their doctors, especially if they are not mental health specialists, may not be detecting an underlying bipolar condition in their patients.

"Because bipolar spectrum disorder commonly coexists with other illnesses, it is likely underrecognized, and therefore, undertreated. We need better screening tools and procedures for identifying bipolar spectrum disorder, and [we also need to] work with clinicians to help them better spot these bipolar symptoms," concluded Dr. Merikangas.

About the Author

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