Living with Fibromyalgia, Drugs Approved to Manage Pain

fter meeting on the Internet in 1997, Lynne Matallana and Karen Lee Richards discovered they had a lot in common. They both had seen numerous doctors before being diagnosed with fibromyalgia, a chronic condition characterized by fatigue and widespread pain in muscles and joints. They both had trouble finding medical information and support for coping with the illness. Seven months after meeting, they started gathering with five other people with fibromyalgia who also wanted to bring awareness to the issue.



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"We called ourselves 'the pillow posse' because we would meet and have our pillows to support our aching bodies," Matallana says. Those gatherings grew into the National Fibromyalgia Association (NFA), an organization that now provides support, research information, medical education, and messages of hope to millions.

Fibromyalgia affects 2 to 4 percent of the population, according to the American College of Rheumatology (ACR). It mostly affects women, and tends to develop in early to middle adulthood. But men and children also can have it.

"One of the challenges is that fibromyalgia hasn't always been recognized as a specific illness," says Jeffrey Siegel, M.D., clinical team leader in FDA's Division of Anesthesia, Analgesia, and Rheumatology Products. "In 1990, the American College of Rheumatology developed criteria for diagnosing it, and this marked a major step forward in helping more people

understand how to recognize the symptoms and how to treat them."

Approved Drugs

People with fibromyalgia have typically turned to pain medicines, antidepressants, muscle relaxants, and sleep medicines. In June 2007, Lyrica (pregabalin) became the first FDA-approved drug for specifically treating fibromyalgia; a year later, in June 2008, Cymbalta (duloxetine hydrochloride) became the second.

Both Lyrica and Cymbalta reduce pain and improve function in people with fibromyalgia. While those with fibromyalgia have been shown to experience pain differently from other people, the mechanism by which these drugs produce their effects is unknown. There is some data suggesting that these drugs affect the release of neurotransmitters in the brain. Neurotransmitters are chemicals that transmit signals from one neuron to another. Treatment

with Lyrica or Cymbalta reduces the level of pain experienced by some people with fibromyalgia.

Lyrica, marketed by Pfizer Inc., was previously approved to treat seizures, as well as pain from damaged nerves that can happen in people with diabetes (diabetic peripheral neuropathy) and in those who develop pain following the rash of shingles. Side effects of Lyrica including sleepiness, dizziness, blurry vision, weight gain, trouble concentrating, swelling of the hands and feet, and dry mouth. Allergic reactions, although rare, can occur.

Cymbalta, marketed by Eli Lilly and Co., was previously approved to treat depression, anxiety, and diabetic peripheral neuropathy. Cymbalta's side effects include nausea, dry mouth, sleepiness, constipation, decreased appetite, and increased sweating. Like some other antidepressants, Cymbalta may increase the risk of suicidal thinking and behavior in people

who take the drug for depression. Some people with fibromyalgia also experience depression.

Studies of both drugs showed that a substantial number of people with fibromyalgia received good pain relief, but there were others who didn't benefit.

Lyrica and Cymbalta are approved for use in adults 18 years and older. The drug manufacturers have agreed to study their drugs in children with fibromyalgia and in breastfeeding women.

Debilitating Effects

Matallana, who is now president of NFA, says she was a partner in an advertising firm when her life turned completely upside down because of her symptoms. "I finally had to stop working in 1995 and spent most of the next two years in bed," she says. Her husband quit his job and became a consultant working from home so that he could care for her.

"I had a yoga instructor coming to my house three times a week to help me get out of bed. The pain and exhaustion were so bad that there were days that the only activity I was able to do was walk from my bed to the mailbox and back to bed. Each day seemed like an eternity and so I had to focus on just getting through one day at a time."

People with fibromyalgia can experience pain anywhere, but common sites of pain include the neck, shoulders, back, hips, arms, and legs. In addition to pain and fatigue, other symptoms include difficulty sleeping, morning stiffness, headaches, painful menstrual periods, tingling or numbness of hands or feet, and difficulty thinking and remembering. Some people with the condition may also experience irritable bowel syndrome, pelvic pain, restless leg syndrome, and depression.

What Causes Fibromyalgia?

Scientists believe that the condition may be due to injury, emotional distress, or viruses that change the way the brain perceives pain, but the exact cause is unclear. People with rheumatoid arthritis, lupus, and spinal arthritis may be more likely to have the illness.

According to ACR, people with fibromyalgia can have abnormal levels of Substance P in their spinal fluid. This chemical helps transmit and amplify pain signals to and from the brain

Researchers are looking at the role of Substance P and other neurotransmitters, and studying why people with fibromyalgia have increased sensitivity to pain and whether there is a gene or genes that make a person more likely to have it.

Getting a Diagnosis

Matallana says she felt her suffering was being dismissed as she went from doctor to doctor looking for answers.

"Many doctors suggested that it was just stress," she says. "Some of them even made references that it was all in my head. I was eventually misdiagnosed as having lupus."

When Matallana was 39, a rheumatologist who was just starting his practice, finally diagnosed her with fibromyalgia. "With my doctor's help, I started to feel better," she says. "It made all the difference that I had a health care provider who could give me insights as to what fibromyalgia research was showing, and that there were other people feeling what I was feeling."

Family physicians, general internists, and rheumatologists are the doctors who typically treat fibromyalgia. There is no diagnostic test for it. Doctors make a diagnosis by conducting physical examinations, evaluating symptoms, and ruling out other conditions. For example, fibromyalgia can be distinguished from arthritis because arthritis causes inflammation of tissues and joints and fibromyalgia does not. Another condition with similar symptoms, hypothyroidism, can be confirmed with a blood test.

Diagnostic criteria set forth by ACR include a history of widespread pain for at least three months and pain in at least 11 of 18 tender point sites.

More than Medicine

People with fibromyalgia may find relief of symptoms with pain relievers, sleep medicines, antidepressants, muscle relaxants, and anti-seizure medications. But medication is just one part of the treatment approach.

What helped Matallana was a combination of medicines for pain and sleep, treatment for some of the overlapping conditions like migraines and irritable bowel syndrome, and a combination of water therapy, massage and yoga. Walking, jogging, biking, gently stretching muscles, and other exercises also can be helpful.

Emotional support also is essential, Matallana says. "My husband always believed me, and when you have that kind of support it makes a difference. It's really about facing chronic pain for the rest of your life. So dealing with the emotional impact and not just the physical side is very important."

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FDA Approves First Drug for Treating Fibromyalgia www.fda.gov/bbs/topics/NEWS/2007/ NEW01656.html

National Institute of Arthritis and Musculoskeletal and Skin Diseases www.niams.nih.gov/hi/topics/fibromyalgia/fffibro.htm

American College of Rheumatology www.rheumatology.org/public/factsheets/fibromya_new.asp

National Fibromyalgia Association www.fmaware.org

Fibromyalgia Network www.fmnetnews.com