

LYRICA[®] (pregabalin) © eLearning System

Introduction to the Patient with Fibromyalgia

Pfizer Inc

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Introduction

The information contained in this training module is for your educational purposes only. This training piece is designed to provide you with information you need on the product, the disease, and the competitive environment. It is not to be used in detailing or distributed to any third parties.

Welcome to the LYRICA® (pregabalin) eLearning System! When learning about any disease, it is important to understand not only the perspective of the patient but also the perspectives of physicians who may be involved in the patient's care. In this introduction to the LYRICA eLearning System, we will briefly review some of the key aspects of **fibromyalgia** and let you hear the viewpoints of a patient with fibromyalgia and a healthcare provider (HCP) to see how they are impacted by and manage this disease. This module also includes a glossary of medical terms and a bibliography. LYRICA is FDA-approved for the management of fibromyalgia.

Section 1: Introduction to the Patient with Fibromyalgia

Objectives

- Define fibromyalgia
- Describe the patient with fibromyalgia
- Discuss the impact of fibromyalgia
- Identify the key healthcare providers who treat patients with fibromyalgia
- Discuss how patients with fibromyalgia are treated

Fibromyalgia is a common pain condition, and its hallmark symptom is characterized by chronic, widespread pain. In this section, you will learn what fibromyalgia is and gain a basic understanding of who the patient with fibromyalgia is. You will also learn who the healthcare providers (HCPs) are who treat patients with fibromyalgia and what basic treatment approaches they use to manage this disease.

Define fibromyalgia

Definition of Fibromyalgia

Fibromyalgia is a common pain condition, and its hallmark symptom is characterized by chronic, widespread pain. Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain. Patients may also present with a wide range of symptoms, including tenderness, sleep disturbances, fatigue, and morning stiffness.

Fibromyalgia is not a "new" disorder. For example, it was sometimes known as **fibrositis** or **myofibrositis** in the past, suggesting that it was an inflammatory disorder of muscles related to the arthritic diseases. However, this disorder is not a form of arthritis, because there is no inflammation present. Today, it is known by the more general term fibromyalgia.

In 1990, the American College of Rheumatology (ACR) developed classification criteria for fibromyalgia consisting of:

- history of widespread pain for at least 3 months
- pain present in ≥ 11 of 18 **tender point** sites

A tender point is defined by the ACR as a prespecified anatomic site where an individual complains of pain when approximately 4 kg of pressure is applied. The development of these criteria was an important step in establishing fibromyalgia as a legitimate medical condition, and it also enabled the accumulation of a reliable body of clinical research data. As knowledge about fibromyalgia evolves, diagnostic criteria will need further refinement.

Describe the patient with fibromyalgia

The Patient with Fibromyalgia

Figure 1A shows some of the characteristics of a typical patient with fibromyalgia.

Figure 1A: Selected Characteristics of a Patient with Fibromyalgia



Adapted from Berger; Pfizer Data on File



Click on the icon to see a patient discuss her perspective on what it is like to be diagnosed with fibromyalgia.

PATIENT PERSPECTIVE

Julie — Asian-American Woman Aged 43 Years



For more than 3 years, I have been struggling with chronic pain. The pain first appeared in my neck. Over the next 3 years or so, the pain was present in several parts of my body, including my shoulders, shoulder blades, arms, legs, hips, and feet. The pain developed in the different parts of my body so gradually that I guess I just chalked it up to stress and the aches and pains that go along with aging. About 6 months ago, I was lying in bed one night trying to sleep, and my legs had this really deep, almost unbearable, aching feeling. That's when I knew something was wrong.

The next day, I decided enough was enough and made an appointment to go see my primary care physician. She examined me, took my blood and ran some tests, but didn't find anything abnormal. But I *knew* something was wrong with me, so I made an appointment with another physician in the practice, Dr. Schwartz. After examining me and looking at my previous blood work, Dr. Schwartz referred me to a neurologist. The neurologist did not find anything abnormal during the neurological exam, and the MRIs that she ordered were also normal. When I went back to see Dr. Schwartz, I told him that in addition to the pain, I had also been experiencing fatigue, constipation, and periodic migraine headaches. Dr. Schwartz told me that, based on all of my symptoms and the absence of any other clinical findings, it sounded like I could have fibromyalgia. Because he did not have a lot of experience with this condition, he was going to refer me to a local rheumatologist he knew, Dr. Kellogg.

Prior to the exam, I told Dr. Kellogg about my pain and other symptoms. Dr. Kellogg explained that what I was experiencing was not uncommon in patients with fibromyalgia, but he wanted to examine me before making a diagnosis. Dr. Kellogg examined me and, based on the number of tender points on my body — I had 16 of them — he diagnosed me with fibromyalgia. In addition to giving me a prescription for my pain, Dr. Kellogg recommended that I try taking yoga and that I should also consider speaking to a therapist to help me deal with living with chronic widespread pain.

Discuss the impact of fibromyalgia

Impact of Fibromyalgia

Fibromyalgia is one of the most common chronic, widespread pain conditions in the United States. The ACR estimates that fibromyalgia affects 2% to 5% of Americans, or 5.3 million people. Patients tend to present between the ages of 20 and 50. It is estimated that women are more likely to be diagnosed with fibromyalgia than men. It's estimated that between 75% and 90% of people affected by fibromyalgia are women.

The outcomes for patients with fibromyalgia are variable. Symptoms may wax and wane in some patients but are persistent in others. The chronic pain, stress, fatigue, and sleep disturbances that these patients experience can result in psychologic distress. In turn, stress can exacerbate the pain of fibromyalgia. The symptoms of fibromyalgia also have effects on function, such as work capacity and quality of life.

Fibromyalgia also represents a burden on the healthcare system. For example, patients with fibromyalgia may be more likely to:

- have both pain-related and non-pain-related comorbid medical conditions
- use substantially more medications
- have more physician, other outpatient, and emergency room visits

These effects on costs also suggest that fibromyalgia can have an impact on employers, due to employee disability and reduced productivity.



Click on the icon to see a patient discuss her perspective on the impact of fibromyalgia on her life.

PATIENT PERSPECTIVE

Julie — Asian-American Woman Aged 43 Years



Living with fibromyalgia has been a challenge. In addition to the pain, I feel exhausted most days — like a car that has run out of gas. A year ago, before I was diagnosed, I had to cut back my hours to part-time so I could rest an extra 2 days a week — not that it helped much. No matter how much I rest, I always seem tired. I used to really enjoy gardening in my yard, but these days my body just hurts too much to get outside and take care of my plants. It's been difficult to watch the weeds take over my gardens while I have to sit inside because I'm in pain and too tired.

On the plus side, I am proud of myself for recognizing that I had a problem and for seeing as many doctors as it took to get my fibromyalgia diagnosed. It wasn't easy getting to all of those appointments, sitting through examinations and tests, and waiting for results, but my persistence paid off, I think. Now I can put a name to my pain and take steps to get better. I'm hoping the medication I just started taking for my pain will help me, and I'm also starting a yoga class next week. I also made an appointment with a psychologist who specializes in treating patients chronic pain conditions. So, even though I am frustrated with this disease, I have a lot of hope that things will start to improve soon.

Identify the key healthcare providers who treat patients with fibromyalgia

Key Healthcare Providers Who Treat Patients with Fibromyalgia

Throughout the patient care process, many hands will touch the patient with fibromyalgia. These may include:

- primary care physicians (PCPs)
- rheumatologists
- pain specialists
- neurologists
- psychiatrists
- orthopedists
- physical medicine rehabilitations
- nurse practitioners
- physician assistants



Click on the icon to see an HCP's perspective on the key individuals who treat patients with fibromyalgia.

H C P
P E R S P E C T I V E

Key HCPs Who Treat Patients with Fibromyalgia



When treating a patient with fibromyalgia, I am rarely the only healthcare provider treating the patient. The mix of healthcare providers and specialists on the healthcare team for a patient with fibromyalgia can vary depending on the geographical location and the patient's individual needs. While 75% of patients with fibromyalgia present to PCPs, approximately 25% are referred to 3 primary specialties:

- rheumatologists, to rule out any rheumatological disorders, and to make or confirm the fibromyalgia diagnosis and provide a treatment
- neurologists, to rule out any neurological disorders
- psychiatrists, to rule out any psychiatric disorders

The majority of fibromyalgia patients who are referred to a specialist are sent back to their PCPs for management. However, it is important to note that rheumatologists are considered the leading experts in fibromyalgia. Overall, I think there is a need for greater awareness of the diagnostic criteria for fibromyalgia among healthcare providers.

As the patient's healthcare requirements change and evolve, additional healthcare providers and specialists may be added to or removed from the mix of medical expertise.

Discuss how patients with fibromyalgia are treated

Treatment of Fibromyalgia

The management of fibromyalgia often requires a multifaceted approach that includes both pharmacologic therapy and nonpharmacologic therapy.



Click on the icon to see an HCP's perspective on treating patients with fibromyalgia.

HCP
PERSPECTIVE

Treating Patients with Fibromyalgia



When I treat a patient with fibromyalgia, I commonly use an individualized, multi-modal approach to achieve the treatment goals my patients and I have set. Those include decreased pain, improved coping, and increased function.

A number of pharmacologic agents have been used to treat fibromyalgia, including opioids and other analgesics, antidepressants, and anticonvulsants. Patients with fibromyalgia take, on average, 3 prescriptions to manage their symptoms, with 33% of patients taking 4 or more medications.

Nonpharmacologic therapies that I can prescribe for my patients with fibromyalgia include patient education; lifestyle measures such as exercise, nutrition, relaxation, and stress-reduction; and behavioral support.

Fibromyalgia can be a challenging condition for me to treat. For example, for many fibromyalgia treatments, weeks may be needed before a benefit is seen. In addition, some trial and error may be required before I find a treatment that a patient responds to. And because treatment responses are rarely durable, my patients and I have to keep in mind that successful treatment of fibromyalgia may involve regular reassessment and possible rotation of medications.

The classes of pharmacologic agents that have been used to treat patients with fibromyalgia are briefly summarized in Table 1A.

Table 1A: AEDs Used to Treat Epilepsy		
Generation/Agent	FDA-approved for Monotherapy	FDA-approved as Add-on Therapy?
<i>First Generation</i>		
• First-generation agents used for epilepsy have most commonly included:		
– phenytoin	Yes	No
– phenobarbital	Yes	No
– primidone	Yes	Yes
– ethosuximide	Yes	No
– carbamazepine	Yes	Yes
– valproic acid	Yes	Yes
<i>Second Generation</i>		
• Second-generation agents used for epilepsy include:		
– pregabalin	No	Yes
– gabapentin	No	Yes
– levetiracetam	No	Yes
– extended-release levetiracetam	No	Yes
– topiramate	Yes	Yes
– oxcarbazepine	Yes	Yes
– lamotrigine	Yes (adults only)	Yes
– extended-release lamotrigine	No	Yes
– tiagabine	No	Yes
– zonisamide	No	Yes
– felbamate	Yes	Yes
– lacosamide	No	Yes
– rufinamide	No	Yes

Glossary

fibromyalgia

a common condition characterized by the hallmark symptom of chronic, widespread pain; patients may also present with a wide range of symptoms, including tenderness, sleep disturbances, fatigue, and morning stiffness

fibrositis

inflammation of fibrous tissue

myofibrositis

inflammation of muscle tissue

tender point

an anatomic site where an individual complains of pain when approximately 4 kg of pressure is applied, as defined by the ACR criteria

Bibliography

Abeles M, Solitar BM, Pillinger MH, Abeles AM. Update on fibromyalgia therapy. *Am J Med.* 2008;121:555-561.

American College of Rheumatology (ACR) Web site. Fibromyalgia. Available at: http://www.rheumatology.org/public/factsheets/diseases_and_conditions/fibromyalgia.asp?aud=pat. Accessed April 13, 2009.

American Pain Society. *Guideline for the Management of Fibromyalgia Syndrome Pain in Adults and Children*. Glenview, IL: American Pain Society; 2005.

Berger A, Dukes E, Martin S, Edelsberg J, Oster G. Clinical characteristics and economic costs of patients with fibromyalgia syndrome. In submission.

Clauw DJ, Chrousos GP. Chronic pain and fatigue syndromes: overlapping clinical and neuroendocrine features and potential pathogenic mechanisms. *Neuroimmunomodulation.* 1997;4:134-153.

Gilliland BC. Fibromyalgia, arthritis, associated with systemic disease, and other arthritides. In: Kasper DL, Braunwald E, Fauci AS, et al, eds. *Harrison's Principles of Internal Medicine*. 16th ed. New York, NY: McGraw-Hill; 2005.

Goldenberg DL, Burckhardt C, Crofford L. Management of fibromyalgia syndrome. *JAMA.* 2004;292:2388-2395.

Henriksson KG. Fibromyalgia — from syndrome to disease overview of pathogenic mechanisms. *J Rehabil Med.* 2003;(suppl 41):89-94.

Jain AK, Carruthers BM, van de Sande MI, et al. Fibromyalgia syndrome: Canadian clinical working case definition, diagnostic and treatment protocols — a consensus document. In: Russell IJ, ed. *The Fibromyalgia Syndrome. A Clinical Case Definition for Practitioners*. Binghamton, NY: Haworth Medical Press; 2003.

Mosby's Medical Dictionary. 8th ed. St. Louis, MO: Mosby Elsevier; 2009.

National Fibromyalgia Association (NFA). Fibromyalgia prevalence. Available at: http://www.fmaware.org/site/PageServer?pagename=fibromyalgia_affected. Accessed April 13, 2009.

National Institute of Arthritis and Musculoskeletal and Skin Diseases. Questions and Answers About Fibromyalgia. US Dept Health and Human Services. Available at: <http://www.niams.nih.gov/hi/topics/fibromyalgia/fibrofs/htm>. Accessed February 26, 2007.

Pfizer Inc. Fibromyalgia Sufferer Flow Quantitative Findings. Pfizer Data on File; December 2, 2005.

Pfizer Inc. Fibromyalgia Market Opportunity Physician Survey. Pfizer Data on File; 2006.

Simms RW. Fibromyalgia is not a muscle disorder. *Am J Med Sci.* 1998;315:346-350.

Weir PT, Harlan GA, Nkoy FL, et al. The incidence of fibromyalgia and its associated comorbidities. *J Clin Rheumatol.* 2006;12:124-128.

Wolfe F, Smythe HA, Yunus MB, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: report of the Multicenter Criteria Committee. *Arthritis Rheum.* 1990;33:160-172.

Wolfe F, Ross K, Anderson J, Russell IJ, Hebert L. The prevalence and characteristics of fibromyalgia in the general population. *Arthritis Rheum.* 1995;38:19-28.

Wolfe F, Anderson J, Harkness D, et al. Work and disability status of persons with fibromyalgia. *J Rheumatol.* 1997;24:1171-1178.