

CME PSYCHCAST™

CLINICAL CASE UPDATE IN FIBROMYALGIA MANAGEMENT ADVANCES IN THE MANAGEMENT OF FIBROMYALGIA

FACULTY

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A related Expert Panel Supplement was published in *CNS Spectrums* [*CNS Spectr* 14:10 (Suppl 8)] and *Primary Psychiatry* [*Primary Psychiatry* 16:10 (Suppl 6)].

CME .25

ABSTRACT

Fibromyalgia (FM) syndrome is a common clinical disorder characterized by severe widespread soft-tissue pain, chronicity, and allodynia. Diagnosed by chronic widespread body pain and unusual tenderness in response to digital pressure at anatomically identified soft tissue sites, FM is increasingly being recognized as a central nervous system disorder. FM patients commonly suffer from insomnia and depression, as well as other comorbidities that complicate the diagnosis, such as anxiety, fatigue, headaches, cognitive impairment, and stress intolerance. Important differential diagnoses include the various rheumatological disorders as well as sleep disorders. Because the presentation of FM is heterogeneous, the goal of treatment is an individualized approach that considers the severity of the patient's pain, the presence of other symptoms and comorbidities or stressors, and the degree of functional impairment. New pharmacologic treatments approved by the Food and Drug Administration offer important options to FM patients, and are expected to improve both diagnosis and treatment of FM. In most cases, the management of patients with FM involves both pharmacologic and nonpharmacologic treatments.

In this Expert Review PsychCast™, Lesley M. Arnold, MD, psychiatrist, reviews the current pharmacologic and psychotherapeutic treatment options for patients with FM as well as overall management strategies for patients with this condition.



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Activity Review Information

The activity content has been peer-reviewed and approved by **Stelian Serban, MD**.

Review Date: September 2, 2009.

Faculty Affiliations

Lesley M. Arnold, MD, is professor of psychiatry and director of the Women's Health Research Program at the University of Cincinnati College of Medicine in Ohio.

Faculty Disclosure Policy Statement

It is the policy of the Mount Sinai School of Medicine to ensure objectivity, balance, independence, transparency, and scientific rigor in all CME-sponsored educational activities. All faculty participating in the planning or implementation of a sponsored activity are expected to disclose to the audience any relevant financial relationships and to assist in resolving any conflict of interest that may arise from the relationship. Presenters must also make a meaningful disclosure to the audience of their discussions of unlabeled or unapproved drugs or devices. This information will be available as part of the course material.

Faculty Disclosures

Dr. Arnold is a consultant to Allergan, Boehringer Ingelheim, Cypress Biosciences, Eli Lilly, Forest, Organon, Pfizer, sanofi-aventis, Sepracor, Takeda, UCB Pharma, Theravance, Vivus, and Wyeth; is on the speaker's bureaus of Eli Lilly, Forest, and Pfizer; and receives grant/research support from Allergan, Boehringer Ingelheim, Cypress Biosciences, Eli Lilly, Forest, Pfizer, sanofi-aventis, and Wyeth.

CME Course Director James C.-Y. Chou, MD, is associate professor of psychiatry at Mount Sinai School of Medicine in New York City. Dr. Chou has received honoraria from AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Janssen, and Pfizer.

Dr. Serban is assistant professor of anesthesiology and director of acute and chronic inpatient pain service in the Department of Anesthesiology at Mount Sinai School of Medicine in New York City. Dr. Serban reports no affiliation with or financial interest in any organization that may pose a conflict of interest.

Learning Objective

At the completion of this activity, participants should be better able to:

- Integrate available therapy options to develop evidence-based multidimensional treatment plans for patients with fibromyalgia.

Statement of Need and Purpose

Fibromyalgia (FM) syndrome is the most common chronic pain syndrome encountered in general medicine, estimated to affect 5 million adults in the United States. FM involves multiple clinical domains, including pain, fatigue, sleep disturbances, depression, and cognitive impairment. Patients with FM report significant negative impact of the illness on social and occupational function and overall quality of life. Much progress has been made in understanding FM, yet management of the condition continues to confound physicians and frustrate patients. Evaluating and treating the multiple domains of FM simultaneously presents a substantial challenge for clinicians. The complex interactions between neurobiological, psychological, and functional/behavioral components of FM, as well as the poor response of patients to conventional pain therapies, have proven particularly challenging. Patients report using an average of 3–4 medications to manage their FM. Research has shown that a multimodal management program yields the most benefit to patients. To implement this paradigm, physicians—including primary care physicians, neurologists, and psychiatrists—need direction regarding the diagnosis of FM, available pharmacologic and nonpharmacologic interventions, and clinical application. Using clinical case studies as an educational tool to discuss the clinical presentation, differential diagnosis, and treatment of FM, will help physicians to identify those patients with symptoms of FM and follow through with adequate treatment.

Target Audience

This activity is designed to meet the educational needs of psychiatrists and neurologists.

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Mount Sinai School of Medicine and MBL Communications, Inc. The Mount Sinai School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.



Credit Designation

The Mount Sinai School of Medicine designates this educational activity for a maximum of 0.25 *AMA PRA Category 1 Credit™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

To Receive Credit for this Activity

Listen to this Expert Panel PsychCast™, reflect on the information presented, and complete the CME posttest and evaluation. To obtain credit, you should score 70% or better. Early submission of this posttest is encouraged. Please submit this posttest by February 1, 2012 to be eligible for credit.



ADVANCES IN THE MANAGEMENT OF FIBROMYALGIA

By Lesley M. Arnold, MD

SLIDE LIBRARY

SLIDE 1

Overall Management Strategy in Fibromyalgia¹

Reduction of clinical pain

- Optimized when **all** pain sources are addressed
- Therefore, individualize treatment depending on pain symptoms
 - Treat visceral pain (eg, irritable bowel syndrome)
 - Treat peripheral pain generators (eg, osteoarthritis pain)
 - Treat fibromyalgia pain: central pain

Treatment of other symptom domains

Improvement in function and global health status

SLIDE 2

Pharmacologic Treatment of Fibromyalgia²

$\alpha\delta$ ligands

- Pregabalin (approved by the FDA in 2007 for the management of FM)

- Gabapentin*

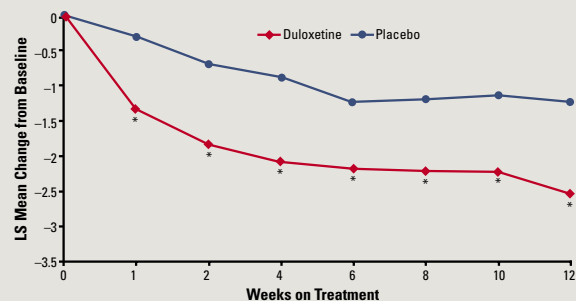
SNRIs

- Cyclic medications (eg, tricyclic antidepressants, cyclobenzaprine)*
- Duloxetine (approved by the FDA in 2008 for the management of FM)
- Milnacipran (approved by the FDA in 2009 for the management of FM)

* This information concerns a use that has not been approved by the United States Food and Drug Administration.

SLIDE 3

Duloxetine: Improvements in the Brief Pain Inventory Average Pain Severity Score Over Time³

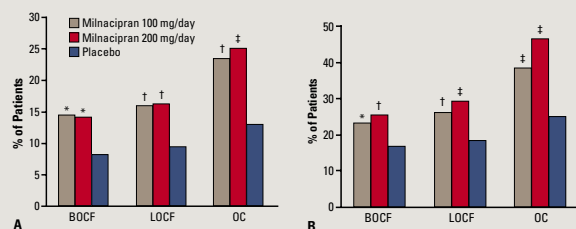


* $P < .001$. LS=least squares.

Reprinted from: Arnold LM, Pritchett YL, D'Souza DN, Kajdasz DK, Iyengar S, Wernicke JF. Duloxetine for the treatment of FM in women: pooled results from two randomized, placebo-controlled clinical trials. *J Womens Health (Larchmt)*. 2007;16(8):1145-1156.

SLIDE 4

Milnacipran: Composite Responder Rates⁴



(A) Composite responder rate for fibromyalgia; (B) Composite responder rate for fibromyalgia pain.

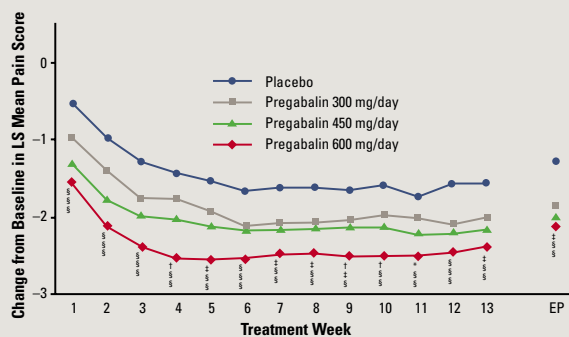
* $P < .05$ vs placebo; † $P \leq .01$ vs placebo; ‡ $P \leq .001$ vs placebo.

BOCF=baseline observation carried forward; LOCF=last observation carried forward; OC=observed cases.

Reprinted from: Clauw DJ, Mease P, Palmer RH, Gendreau RM, Wang Y. Milnacipran for the treatment of FM in adults: a 15-week, multicenter, randomized, double-blind, placebo-controlled, multiple-dose clinical trial. *Clin Ther*. 2008;30(11):1988-2004.

SLIDE 5

Pregabalin: Improvement in Weekly Mean Pain Scores⁵⁻⁷



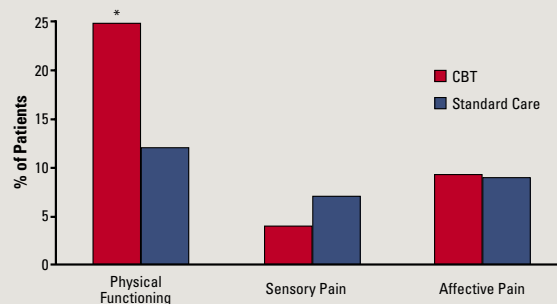
* $P < .05$; † $P < .01$; ‡ $P < .001$; § $P \leq .0001$. LS=least squares; EP=endpoints.

FDA-recommended doses are 300 mg/day and 450 mg/day.

Arnold LM et al. Abstract presented at the Annual European Congress of Rheumatology, EULAR 2007; June 13-16, 2007; Barcelona, Spain. Abstract #OP0036.

SLIDE 8

Improvements Noted With Cognitive-Behavioral Therapy Versus Standard Care Over 12 Months (N=122)¹⁰



* $P < .05$; OR=2.9.

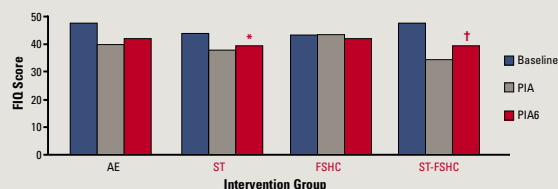
Physical functioning was measured using the 36-item Short Form physical component summary. The McGill Pain Questionnaire was used to measure sensory and affective pain.

CBT=cognitive-behavioral therapy.

Reprinted from: Williams DA, Cary MA, Groner KH, et al. Improving physical functional status in patients with FM: a brief cognitive behavioral intervention. *J Rheumatol.* 2002;29(6):1280-1286.

SLIDE 6

Benefits of Exercise Enhanced by Self-Management Education⁸



FIQ scores at baseline, post-intervention assessment (PIA), and 6-month follow-up (PIA6) in the four intervention groups.

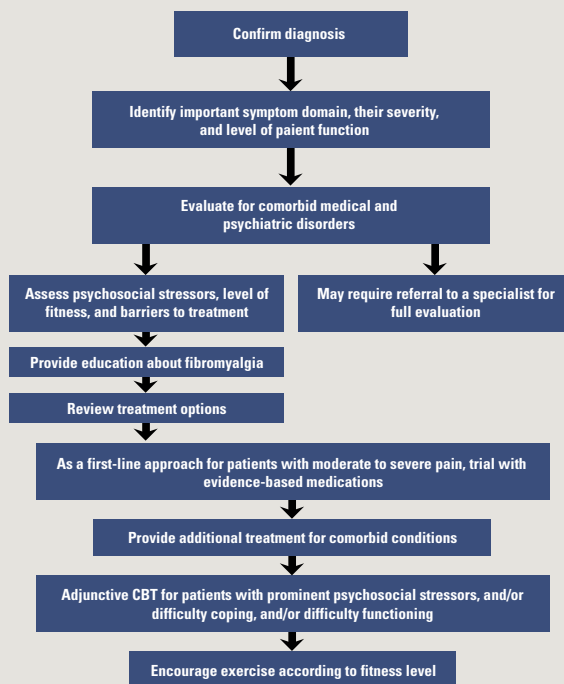
* $P < .05$ and † $P < .001$ at 6 months vs baseline.

FIQ=Fibromyalgia Impact Questionnaire; FAE=aerobic and flexibility exercise; ST=strength training, aerobic, and flexibility exercise; FSHC=fibromyalgia self-help course; ST-FSHC=a combination of ST and FSHC.

Reprinted from: Rooks DS, Gautam S, Romeling M, et al. Group exercise, education, and combination self-management in women with FM: a randomized trial. *Arch Intern Med.* 2007;167(20):2192-2200.

SLIDE 9

Stepwise Treatment of Fibromyalgia¹



multiple-dose clinical trial. *Clin Ther.* 2008;30(11):1988-2004.

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SLIDE 7

Exercise in the Management of Fibromyalgia⁹

- Aerobic training at moderate intensity likely improves overall well-being and physical function
- Attrition rates were high (range: 13% to 44%); adherence poorly documented
 - Small sample sizes (range: 16–51)
- Strength and flexibility training may decrease pain, tender points, and depression, and may improve overall well-being
- Need more high-quality studies

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- US Food and Drug Administration. Available at: www.accessdata.fda.gov/scripts/cder/drugsatfda. Accessed March 27, 2009.
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- Clauw DJ, Mease P, Palmer RH, Gendreau RM, Wang Y. Milnacipran for the treatment of FM in adults: a 15-week, multicenter, randomized, double-blind, placebo-controlled,

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CME QUESTIONS

- 1. Evidence-based treatments of fibromyalgia (FM) syndrome include all of the following except:**
 - A. Duloxetine
 - B. Pregabalin
 - C. Exercise
 - D. Hydrocodone
- 2. Which of the following statements is true?**
 - A. Exercise improves physical function in FM patients
 - B. Exercise can significantly improve FM pain
 - C. Cognitive-behavioral therapy does not improve function in FM patients
 - D. Education has no effect on other FM treatments
- 3. It is important to avoid any medication that has a high likelihood of abuse or dependence in FM patients.**
 - A. True
 - B. False
- 4. Evidence-based data on combination treatment for FM is robust.**
 - A. True
 - B. False

REGISTRATION

FEBRUARY 2010 CME POSTTEST



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ANSWER FORM

Expert Panel PsychCast™ – Clinical Case Update in Fibromyalgia Management
Advances in the Management of Fibromyalgia

TERMINATION DATE: February 19, 2012

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Please circle your answers

1. A B C D 2. A B C D 3. A B 4. A B

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B. Providing new information	1 2 3 4 5
C. Increased my knowledge and/or skills in delivering patient care	1 2 3 4 5
D. Communicated information in an effective, accessible manner	1 2 3 4 5
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1 2 3 4 5
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5a. If "no," please explain: _____
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