Session 6: A Fibromyalgia Roadmap: Practical Steps in Diagnosis and Management

Learning Objectives
- Discuss the differential diagnosis of fibromyalgia and strategies to assess patients for common comorbid conditions such as depression.
- Analyze the benefits and adverse effects of current pharmacologic and nonpharmacologic therapies in the treatment of fibromyalgia in order to select treatment that balances efficacy, safety, and tolerability.

Faculty
Edgar L. Ross, MD
Director, Pain Management Center
Brigham and Women’s Hospital Pain Clinic
Boston, Massachusetts

Edgar L. Ross, MD, is director of the Pain Management Center at the Brigham and Women’s Hospital in Boston, Massachusetts. Dr Ross, a nationally known expert in the field of pain management, has expertise in treating a wide variety of chronic pain types. His recent research interest is the treatment of angina with spinal cord stimulation. His interest and work in disease state management have resulted in several patents, some granted and some pending, in that specialty. Dr Ross has also published many articles and several book chapters on pain management, disease state management and the development of chronic pain management centers. Most recently, he published a book for primary care physicians on chronic pain, a subject of his many national and international lectures.

Dr Ross has consulted for many organizations, including the Harvard School of Public Health, national network television stations, leading pharmaceutical firms, and medical consulting companies. Under his directorship, the Brigham and Women's Pain Center has become one of the largest and most respected academic pain centers in the country and has received recognition for conducting one the country’s leading fellowship programs in chronic pain. With its large patient base as a foundation, the Brigham and Women’s Pain Center has become an active and well-respected clinical trials center.

Dan Diamond, MD, FAAFP
Clinical Assistant Professor
University of Washington School of Medicine
Seattle, Washington

As an experienced family physician and an award winning educator, Dr Diamond delivers practical information with creativity and skill. Participants experience learning through a variety of effective strategies that foster rapid mastery of new information. Well known for creating an exciting learning environment through the use of dramatic multimedia presentations, audience participation, and live game shows, Dr Diamond engages the mind of the learner leaving participants with experience and information they will never forget.

Dr Diamond is a family physician in private practice in Silverdale, Washington and he serves as clinical assistant professor for the University of Washington School of Medicine, Seattle, Washington.

After earning his medical degree from University of Washington, Dr Diamond completed a residency in family medicine in Milwaukee, Wisconsin. The American Academy of Family Physicians awarded Dr Diamond the degree of Fellow, and he is board certified with the American Board of Family Physicians. He is a member of the editorial board for the Primary Care Companion to the Journal of Clinical Psychiatry. Recognized as a national keynote speaker, Dr Diamond has delivered presentations on such topics as “The Impact of Depression on Learning.”

In 1998, Dr Diamond was awarded the JC Penney Golden Rule Award recognizing his contributions in teaching gifted children in the public schools. Dr Diamond founded and serves as the director of the nation’s first state-affiliated medical disaster response team and has responded to a variety of international disasters. He was the director for the Mass Casualty Triage Unit at the New Orleans Convention Center following hurricane Katrina. In addition, Dr Diamond is a contributing consultant to corporations developing innovative healthcare computer solutions. He also serves on the Executive Committee for the Kitsap Medical Reserve Corps and is on the board of directors for Children of the Nations.

Faculty Financial Disclosure Statements
The presenting faculty reported the following:
Dr Ross is on the speakers bureau for Cephalon, Inc.; Eli Lilly and Company; Endo Pharmaceuticals; and Pfizer, Inc.
Dr Diamond is on the speakers bureau of AstraZeneca LP; Boehringer Ingelheim Pharmaceuticals Corporation; Eli Lilly and Company; Novartis Pharmaceuticals Corporation; Takeda Pharmaceuticals North America, Inc.; and Wyeth Pharmaceuticals; and is a consultant for Eli Lilly and Company and Wyeth Pharmaceuticals.
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The content collaborators at Turnkey Solutions, LLC have reported the following:
Emily A. Bakeman RN, MS, APN-C, executive vice president, has nothing to disclose.

Drug List

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Investigational

tropisetron                  Navoban
venlafaxine                  Effexor

Off-Label

cyclobenzaprine, gabapentin, tramadol, venlafaxine

Acronym List

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<td>Brief Pain Inventory</td>
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<td>CBT</td>
<td>cognitive behavioral therapy</td>
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<td>HC</td>
<td>healthy controls</td>
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<td>IBS</td>
<td>irritable bowel syndrome</td>
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<td>IC</td>
<td>interstitial cystitis</td>
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<tr>
<td>LOCF</td>
<td>last observation carried forward</td>
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<td>MMRM</td>
<td>mixed model repeat measures</td>
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<tr>
<td>OBT</td>
<td>operant behavioral therapy</td>
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<td>PTSD</td>
<td>posttraumatic stress disorder</td>
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<td>RA</td>
<td>rheumatoid arthritis</td>
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<td>SNRI</td>
<td>serotonin-norepinephrine reuptake Inhibitors</td>
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<td>temporomandibular disorders</td>
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<td>VAS</td>
<td>Visual Analog Score</td>
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Suggested Reading List

A Fibromyalgia Roadmap: Practical Steps in Diagnosis and Management

EDGAR L ROSS, MD
Director, Pain Management Center
Brigham and Women’s Hospital Pain Clinic
Boston, Massachusetts

Fibromyalgia (FM): Tough Questions Worth Asking

- Is it ‘real’? Is it physical or psychological?
- Can it be reliably diagnosed?
- Is a diagnosis helpful or harmful?
- Are any treatments effective?

Fibromyalgia: An Introduction

- Fibromyalgia: common, chronic pain disorder characterized by widespread pain and somatic symptoms
  - Prevalence in industrialized countries, ~2-4%
  - Most common rheumatologic disorder after osteoarthritis
  - Prevalent in all ethnic groups

Fibromyalgia: 3 Cardinal Associated Symptoms

1. Fatigue
2. Non-refreshing Sleep

Disability with Depression, Fibromyalgia, and Depression + Fibromyalgia

- Graph showing percentage of disability with depression, fibromyalgia, and depression + fibromyalgia.

A Patient’s Perspectives ...

Stacey: 38 year old RN, happily married, 2 children, 8 year old daughter and 6 year old son

Her perspectives before diagnosis of Fibromyalgia

“My symptoms kept changing. I felt like I was going crazy. To make matters worse, one doctor said ‘there was no such thing as fibromyalgia – it’s not an accepted diagnosis’.”

How has fibro affected you the most?

“I want to work. I’m a nurse but after 6 months at most jobs I have to quit due to some type of injury. Even part-time jobs are too much. The physical activity is too much – it’s so frustrating. I end up having to quit so I can recuperate.”

* Actual patient from Rakesh Jain, MD’s practice

References:

Fibromyalgia
■ 2-4% of population
■ Defined by widespread pain and tenderness
■ Has frequent cognitive dysfunction

Chronic Fatigue Syndrome (CFS)
■ 1% of population
■ Fatigue and 4 of 8 “minor criteria”

Somatoform Disorders
■ 4% of population
■ Multiple unexplained symptoms — no “organic” findings

Regional Pain Syndromes
■ IBS = Irritable Bowel Syndrome
■ PBS/IC = Interstitial Cystitis
■ TMD = Templeomandibular Disorder

Psychiatric Disorders
■ Major depression
■ OCD
■ Bipolar
■ PTSD
■ General Anxiety Disorder
■ Panic attack

But... “One Size Does Not Fit All”:
Not All FM Patients Have Depression and/or Anxiety

Overlap Between Fibromyalgia and Related Syndromes

Fibromyalgia
- Defined by widespread pain and tenderness
- Has frequent cognitive dysfunction

Chronic Fatigue Syndrome (CFS)
- 1% of population
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Psychiatric Disorders
- Major depression
- OCD
- Bipolar
- PTSD
- General Anxiety Disorder
- Panic attack

Overlapping Pain and/or Sensory Amplification

FM & Central Sensitization – Reason Why It’s Co-morbid with Other ‘Functional’ Disorders

Central sensitization

Genetics of Fibromyalgia
- Familial predisposition
  - Most recent work by Arnold LM, et al. suggests >8 odds ratio (OR) for first-degree relatives, and much less familial aggregation (OR 2) with major mood disorders
  - Much stronger with bipolarity, obsessive compulsive disorder
- Genes that may be involved
  - 5-HT2A receptor polymorphism T/T phenotype
  - Serotonin transporter
  - Dopamine D4 receptor exon III repeat polymorphism
  - COMT (catecholamine O-methyl transferase)

Neurobiology of Fibromyalgia

Fibromyalgia Subjective pain control Stimulus pressure control

14 12 10 8 6 4 2 0
4.5 1.5 2.5 3.5
Stimulus intensity (kg/cm²)

Pain intensity

fMRI Studies Show Cortical/Subcortical Augmentation of Pain Processing in FM

fMRI Evidence of Central Sensitization in FM

FM patients vs. 10 healthy controls

fMRI = functional magnetic resonance imaging


Grey Matter Loss in FM—is Pain Toxic to the Brain?

FM patients were losing 10.5 cm³ of GM annually since the year of their diagnosis

FM patients had significantly less grey matter volume in posterior cingulate, insular cortex, medial frontal cortex, and parahippocampal gyrus. Rate of age-related decline was significantly greater in FM patients than healthy controls (P < .001)


Diagnosing Fibromyalgia

Diagnosing Fibromyalgia

ACR Classification Criteria for Fibromyalgia

History of widespread pain for at least 3 months and Pain on both sides of the body

ACR Classification Criteria for Fibromyalgia

History of widespread pain for at least 3 months and Pain in >11 of 18 tender points

The Basic Tools Required for FM Diagnosis

- History of widespread pain has been present for at least three months
- Pain is considered widespread when all of the following are present:
  - Pain in both sides of the body, above and below the waist
  - Pain in 11 of 18 tender point sites on digital palpation

Pressure Application Techniques

1. The standard procedure for applying pressure in the Manual Tender Point Survey (MTPS) uses the thumb pad of the examiner’s dominant hand. This method was adopted because it has been shown to be as reliable as the use of a dolorimeter.
2. Survey sites are first located visually and then with light palpation.
3. Then apply thumb pad pressure perpendicular to each survey site.
4. Each survey is pressed for a total of 4 seconds only once to avoid sensitization that may occur with repeated palpation.
5. The force is increased by 1 kg per second until 4 kg of pressure is achieved.
6. Whitening of the examiner’s nail bed usually occurs when applying the 4 kg force.

Wish to Be Even More Precise? Introducing a Dolorimeter

For FM Tender Point Examination, the threshold is 4 kgs/cm²

Treatment of Fibromyalgia

Fibromyalgia: Treatment Options

**Nonpharmacologic**
- Exercise
- CBT
- OBT
- Acupuncture
- Chiropractic manipulation
- Psycho-education

**Pharmacologic**
- FDA Approved:
  - Pregabalin
  - Duloxetine
  - Milnacipran
- Not FDA Approved
  - TCAs
  - Cyclobenzaprine
  - Tramadol

Key Elements of Cognitive Behavioral Therapy for Fibromyalgia

- Psycho-Education
- Identifying dysfunctional thought patterns
- Realistic goal setting
- Communication skills training
- Relaxation training
- Relapse prevention
- Behavioral pacing

PsychoPsycho-
Education
Realistic
goal setting
Relaxation
training
Behavioral pacing

Cognitive Behavioral Management of Chronic Pain

- Six weekly 50 minute group sessions
- Based on CBT Attention management manual

Data for individuals completing 6 month follow-up

Exercise in Fibromyalgia: A Meta-analysis of Studies

- Worsening %
- Improvement %

Aerobic Performance
Tender Point Pain Pressure Threshold
Change in Pain

Exercise Intervention Group
Control Group

Impact of Multi-disciplinary Treatment in FM

3 Weeks of Multi-disciplinary Treatment Consisted of Education, Stretching, CBT, Relaxation Training and Aerobic Exercise

- Pre-treatment
- Post-treatment

Change from Baseline Scores

Depression CES-D
Anxiety STAI
Pain Interference BPI - Interference

Mind-Body Intervention for Older Adults with Chronic Pain

- CES-D
- STAI
- BPI - Interference

Pharmacologic Rx Options in Fibromyalgia

Elomaa MM et al., European Journal of Pain, 2009; ahead of publication.
**TCA in Fibromyalgia: A Meta-analysis**

TCAs in the various studies were: amitriptyline, dothiepin, cyclobenzaprine, clomipramine, and maprotyline.

**Proportion of Responders Pregabalin in Fibromyalgia**

Comparison of pregabalin with PBO in time to LTR (log-rank test): P<.001

**Duloxetine - BPI Average Pain Score**

Comparison of duloxetine with placebo: therapy by subgroup (P<.001 vs placebo)
Milnacipran – FDA Approved Treatment in FM

Weeks
Pain Intensity (%)
Baseline Dose Titration Treatment at MTD

P = .025 bid vs PBO

ITT Diary Weekly Pain (LOCF)

P = .191 bid vs PBO

ITT Diary Daily Pain (LOCF)

Milnacipran in FM: Early and Sustained Improvement in Pain Through 6 Months (OC)

Non-FDA Approved, but Commonly Utilized Pharmacological Treatments

Common Side Effects of Medications Used in FM

- Pregabalin, Gabapentin – dizziness, somnolence, dry mouth, blurred vision, weight gain, concentration, and memory difficulties
- SNRIs (duloxetine, venlafaxine, milnacipran) – nausea, dry mouth, constipation, somnolence, hyperhidrosis, and decreased appetite
- TCAs (amitriptyline, imipramine, desipramine, nortriptyline) – sedation, weight gain, dry mouth, blurred vision, and constipation
- Cyclobenzaprine – drowsiness, dry mouth, fatigue, and headache
- Tramadol – nausea, constipation, dizziness, and somnolence


Treatment Guidelines

Focus on APS Guidelines (American Pain Society)
American Pain Society (APS) Guidelines

**Step 1**
1. Confirm the diagnosis
2. Explain the condition to patient
3. Evaluate, treat comorbidities (mood, sleep)

**Step 2**
1. Trial with low dose TCAs or cyclobenzaprine
2. Begin cardiovascular fitness program
3. Cognitive behavioral therapy

**Step 3**
1. Refer to a specialist if needed (rheum, psych, pain mgmt)
2. Trial with SSRI or SNRI or tramadol
3. Medication combination or an anticonvulsant


In Conclusion – 4 Crucial Points

- FM is commonly encountered in PCP settings
- It is easily missed. Be watchful! ACR criteria have good sensitivity & specificity
- Robust neuro-biologic data points to a central pain processing etiology of FM
- It is an impairing disorder. There are now several well conducted studies of non-pharmacologic and pharmacologic treatment options

In Conclusion – Stacey – Let’s hear from her again *

Her perspective three years after diagnosis and treatment of fibromyalgia

“The diagnosis of fibro brought a sense of relief. The path to finding a diagnosis was frustrating because the diagnosis is so misunderstood. The diagnosis led to the right treatment and I spent fewer days in bed – I’m much more active now – the change is amazing.”

“Maintaining a routine is critical. Lifestyle changes all require baby steps. I have to take it slow. When I started walking I had to start slow: 10-15 minutes. The entire process was extremely frustrating.”

What is the most important piece of advice you’d give to those taking care of patients with fibro?

“Take time to listen. Learn how to do the fibromyalgia test to see if that’s a possibility. Be open to the diagnosis. Don’t judge patients with fibro – don’t treat us like chronic complainers – the pain is real.”

* Actual patient from Rakesh Jain, MD’s practice

Case Presentations

**DAN DIAMOND, MD, FAAFP**
Clinical Assistant Professor
University of Washington School of Medicine
Seattle, Washington

To Review Our Learning So Far:
Let’s Meet Ann, a 39-year-old Female

- Widespread muscle pain for 10 years. “I ache like a 100-year- old woman. It’s ridiculous.”
- Poor sleep (both initial and middle insomnia)
- Brief bouts of anxiety and depression in past– none for last four years
- Years of vague abdominal pain with alternating constipation and diarrhea
- Pelvic pain and bladder irritability

What Have We Learned So Far?

- That FM is common in all practices (primary care offices, specialty clinics, psychiatrist’s office)
- That its etiology is bio-psycho-social. And its neurobiology reveals it to be a ‘real’ disorder
- That it impacts patient lives significantly, and in many ways
- That identifying it and treating it early and vigorously is clinically important
Evaluation

Past medical history
- Chronic headaches since age 19
  Treated as migraine and tension headaches

Social history
- Married; no children
- Accountant
- No history of sexual abuse

Physical exam: no tenderness or swelling over joints

Labs: ANA, ESR, RF, CBC – normal
X-rays of knees, back, hands: normal

Test Your Knowledge

Which of the following diagnoses is the patient least likely to have?
1. Fibromyalgia
2. Hypothyroidism
3. Irritable bowel syndrome
4. Rheumatoid Arthritis
5. Interstitial Cystitis

Test Your Knowledge

Which of the following would be most helpful in distinguishing other rheumatologic disorders from fibromyalgia?
1. Fatigue and trouble sleeping
2. Tenderness only over the joints
3. Meets DSM-IV diagnostic criteria for major depression
4. Sleep disturbance
5. Normal x-rays

More Practical Information on Diagnosing FM

These are the typical signs and symptoms of Pain in FM patients:
- Current and lifetime history of widespread pain
- The more widespread, the more likely it is fibromyalgia
- "I hurt all over." Accompanied by stiffness
- Pain felt in any area of musculoskeletal and nonmusculoskeletal regions
- Often “unpredictable,” worsened by stress

Test Your Knowledge

Based on your assessment, patient is diagnosed with FM. Depression and anxiety disorders are ruled out. All of these can be considered important in creating her treatment plan, except:
1. Psychotherapy (focus on cognitive therapy)
2. Exercise routine (including aerobic and weight lifting)
3. Disease state education
4. Recommendation to take long-term disability leave
5. Recommendation to involve family in treatment planning

Distinguishing Fibromyalgia from Other Rheumatologic Disorders

- Nonspecific somatic symptoms, particularly fatigue and sleep complaints, are common in multiple rheumatologic and pain conditions
- Depressive and anxiety disorders are also prevalent in many rheumatologic conditions
- Laboratory tests (ESR or x-ray findings) are generally discriminatory only if they are abnormal
- The tender points seen with fibromyalgia are not limited to the joints but are on right and left sides of body, upper and lower, proximal and axial.
Fibromyalgia: Long-term Benefits of Disease Education and Exercise

6-week Intervention, End of 6-month Follow-up Data

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<tr>
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<th>Depression</th>
<th>Anxiety</th>
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P = .01; † P = .065; ‡ P = .265; § P = .017


Step Approach to a Patient with Fibromyalgia

Step 1: Confirm Diagnosis
Step 2: Create an Individualized Treatment Plan
Step 3: Consider Adjunctive Treatment Option

Nonpharmacologic Therapies

- **Strong Evidence**
  - Education
  - Aerobic exercise
  - Cognitive behavioral therapy

- **Modest Evidence**
  - Strength training
  - Acupuncture
  - Hypnotherapy, biofeedback, balneotherapy

- **Weak Evidence**
  - Chiropractic, manual and massage therapy, electrotherapy, ultrasound

- **No Evidence**
  - Tender (trigger) point injections, flexibility exercise

Pharmacologic Therapies

- **Strong Evidence**
  - Dual reuptake inhibitors such as Tricyclic compounds (amitriptyline, cyclobenzaprine)
  - Anticonvulsants (pregabalin)

- **Modest Evidence**
  - Tramadol
  - SNRIs and NSRIs (mirtazapine, duloxetine, venlafaxine*)
  - Selective serotonin reuptake inhibitors (SSRIs)
  - Gamma hydroxybutyrate
  - Dopamine agonists

- **Weak Evidence**
  - Growth hormone, 5-hydroxytryptamine, tropisetron*, S-adenosyl-L-methionine (SAMe)*

- **No Evidence**
  - Opioids, corticosteroids, nonsteroidal anti-inflammatory drugs, benzodiazepine and nonbenzodiazepine hypnotics, guanifenesin*


Case 2: Martha, a 52-year-old Female

- **Pre&nt;ents with:** chronic widespread pain, headache, and insomnia
- **Past medical history:** was in a car accident 10 years ago. Slow recovery from whiplash injury. But over last 5 years, pain has ‘migrated’ to her back, and limbs. “My muscles are sore all the time”
- **Physical exam:** normal, except widespread tenderness, has 14 out of 18 positive tender points – diagnosis of FM made
- **Laboratory findings:** within normal limits
- **MRI of back:** mild degenerative disc disease, no cord or spinal nerve compression

Test Your Knowledge

Patient wants to know why is her body hurting all over, though it was just her neck that was hurt in the car accident. Which of the following is incorrect information to give to the patient?

1. FM is thought to be as a result of ‘central’ pain processing abnormalities – that is, the brain and spinal cord over perceives pain
2. Pain is the result of overuse of her muscles and joints. Prolonged bed rest until pain goes away is the appropriate approach to helping her
3. Her pain must be a psycho-somatic reaction to her past trauma, that her conscious mind had suppressed until now
Brain & Spinal Influences on Pain and Sensory Processing

Facilitation
- Substance P
- Glutamate/EAA
- Serotonin (5HT2a)
- Nerve growth factor
- Cholecystokinin (CCK)

Inhibition
- Descending anti-nociceptive pathways
- Norepinephrine- serotonin 5HT2a, dopamine
- Opioids
- GABA
- Cannabinoids
- Adenosine

Substance P
Glutamate/EAA
Serotonin (5HT2a, 3a)
Nerve growth factor
Cholecystokinin (CCK)
Descending anti-nociceptive pathways
Norepinephrine-serotonin 5HT2a, dopamine
Opioids
GABA
Cannabinoids
Adenosine

Test Your Knowledge
The patient asks for medication recommendations for her FM symptoms. Which of the following is the LEAST appropriate as first-line therapy?

1. Hydrocodone
2. Pregabalin
3. Duloxetine
4. Milnacipran
5. Tramadol
6. Cyclobenzaprine

Test Your Knowledge
The patient reports three additional difficulties: memory difficulties, weight gain, and sexual difficulties. Which is the correct response?

1. Sexual difficulties, memory difficulties, and weight gain in this patient with FM is just a result of normal aging
2. There is a neuro-biological and psycho-social link between FM and memory difficulties, weight gain, and sexual difficulties

Neuro-endocrine and Neuro-immune Dysregulation in Pain Syndromes

Neuro-endocrine and Autonomic Dysregulation in FM May Lead to Metabolic Syndrome

Comparison of 109 Patients with FM and 46 Healthy Controls

Fibromyalgia & Sexual Dysfunction: Possible Connections

Physiological factors
- Vulvodynia
- Low pain tolerance
- Alobynia
- PMS Syndrome

Psychological factors
- Depression, Anxiety
- Fatigue
- Low confidence
- Relationship problems
- Performance worries
Cognitive Deficits in FM Patients: Comparison with Age-Matched Controls and Older Controls

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<td>Age-matched controls</td>
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Mean age: 47.84; mean age (older) = 66.94; Fibromyalgia n=23; Age-matched controls n=23; Older controls (age + 20 years) n=22


Diagnosis of FM Does NOT Affect Health Care Utilization (may actually diminish it)

A Primary Care Clinician’s Diagnostic Paradigm for FM

- Suspect fibromyalgia in all patients reporting significant pain/fatigue symptoms
- Conduct the ACR examination on all such patients (takes only minutes, and it is approximately 85% sensitive and specific for FM)
- Carefully screen for comorbidities: consider mood disorder, anxiety disorders, eating disorders, substance use disorders, etc.
- Create an individualized treatment plan.

ACR = American College of Rheumatology

In Conclusion – Let’s Hear From a Patient Bonnie... (56 year old lady)

Bonnie: “I was diagnosed with fibromyalgia 2 years ago at the age of 54. I began having problems about 15 years ago.”

“My body was breaking apart. I wasn’t able to function. I was practically incapacitated. My life was shattered.”

How has fibro affected you the most?

“Fibro is extremely confusing even to the person with it. The pain is very confusing. I always felt like nothing was wrong with me. I thought everyone had that much pain. If I hadn’t pushed through I would have died in the bed from depression.”

What is the most important piece of advice you’d give to those taking care of patients with fibro?

“Lots of doctors don’t pay attention to the diagnosis of fibromyalgia. Don’t give up – it takes patience.”