Fibromyalgia:
Simplifying Diagnosis and Treatment

Houston, TX

November 22, 2008
2:45 PM – 4:00 PM
Session 11: Fibromyalgia: Simplifying Diagnosis and Treatment

Learning Objectives

- Understand the basic anatomy, physiology, and brain regions involved in pain and the systemic consequences of undertreated pain conditions.
- Utilize your knowledge of the neurobiology of pain to further appreciate clinical relevance of early recognition and comprehensive treatment of fibromyalgia.

Faculty
Kurt Kroenke, MD
Professor of Medicine
Indiana University School of Medicine
Senior Scientist
Regenstrief, Institute Inc.

Kurt Kroenke, MD, is professor of medicine in the Division of General Internal Medicine and Geriatrics at Indiana University, and a research scientist in the Regenstrief Institute. He directs the master of science in clinical research degree program. He is a past president of the Society of General Internal Medicine, immediate past president of the Association for Clinical Research Training, a past council member of the Association of Subspecialty Professors, and a Master in the American College of Physicians (MACP).

His principal research interests include physical and psychological symptoms in medical patients including pain, depression, anxiety and somatization. He co-developed the PRIME-MD Patient Health Questionnaire (PHQ), which has become a widely-used clinical and research measure for diagnosing and monitoring common mental disorders in primary care. He has been a principal or co-investigator on multiple effectiveness trials for depression and recently pain, including IMPACT, RESPECT, AIM, ARTIST, SCAMP, and INCPAD. These trials have focused on primary care, geriatric, neurological, and cancer populations.

He was a member of the MacArthur Foundation Steering Committee on Depression in Primary Care, where he co-developed the Three-Component Model for enhancing depression care. Dr Kroenke has served on the National Institutes of Mental Health (NIMH) Services Research Initial Review Group. He has more than 230 peer-reviewed publications, has received sustained research funding from the NIH and other federal agencies, foundations, and industry, and is the recipient of numerous teaching awards.

Faculty Financial Disclosure Statement
The presenting faculty reported the following:
Dr Kroenke receives honoraria from Eli Lilly and Company and Forest.

Drug List

<table>
<thead>
<tr>
<th>Generic</th>
<th>Trade</th>
<th>Generic</th>
<th>Trade</th>
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</thead>
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<tr>
<td>acetaminophen</td>
<td>Tylenol</td>
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<td>Robaxin</td>
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<td>amitriptyline</td>
<td>Elavil</td>
<td>hydrocodone</td>
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<td>Flexeril</td>
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<td>duloxetine</td>
<td>Cymbalta</td>
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<td>escitalopram</td>
<td>Lexapro</td>
<td>pregabalin</td>
<td>Lyrica</td>
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<td>gabapentin</td>
<td>Neurontin</td>
<td>tramadol</td>
<td>Ultram</td>
</tr>
</tbody>
</table>

Suggested Reading List


Fibromyalgia: Simplifying Diagnosis and Treatment

KURT KROENKE, MD
Professor of Medicine
Indiana University School of Medicine
Senior Scientist, Regenstrief Institute
Indianapolis, Indiana

Audience Survey

In your clinical practice, how often do you tell a patient he or she has fibromyalgia?

1. Frequently (about once a week)
2. Occasionally (once or twice a month)
3. Rarely (a few times a year)
4. Never (I don't use the term "fibromyalgia" with my patients)

The most important clinical finding in making a diagnosis of fibromyalgia is:

1. Absence of objective findings of other rheumatological disorders
2. Chronic widespread pain
3. Multiple tender points
4. Co-existing psychological factors, such as depression and anxiety

The most important site of pathological disturbance in fibromyalgia is the:

1. Muscle cell
2. Fibrous tissue
3. Spinal cord (dorsal horn)
4. Central nervous system (cortex)

Fibromyalgia is typically a condition that:

1. Persists in the majority of patients and is not particularly responsive to treatment
2. Persists in the majority of patients and often improves with treatment
3. Gradually resolves in >50% of patients
4. Usually is secondary to another physical or psychological disorder and resolves only with treatment of that disorder
Outline

• Diagnosis
• Neurobiology
• Treatment
• Case Discussions
• Questions & Answers

Prevalence of Fibromyalgia

• Prevalence estimated at 2.0% in the US general population\(^1\)\(^3\)
  – 3.4% in women
  – 0.5% in men
  – Prevalence increases with age
• In a 2007 survey of 2596 US patients with fibromyalgia:\(^2\)
  – 42.4% diagnosed by a rheumatologist
  – 35.4% diagnosed by family practice or internist
• Second most common disorder seen by US rheumatologists (after OA)\(^3\)
  – Yet rheumatologists provide care for <20% of US cases


Worldwide Prevalence of Fibromyalgia

<table>
<thead>
<tr>
<th>Country</th>
<th>Prevalence (%)</th>
<th>Year</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>2.0</td>
<td>1995</td>
<td>Wolfe et al.</td>
</tr>
<tr>
<td>US (Amish)</td>
<td>7.3</td>
<td>2003</td>
<td>White et al.</td>
</tr>
<tr>
<td>Canada</td>
<td>3.3</td>
<td>1999</td>
<td>White et al.</td>
</tr>
<tr>
<td>Pakistan</td>
<td>1.5</td>
<td>1998</td>
<td>Farooqi et al.</td>
</tr>
<tr>
<td>Spain</td>
<td>2.4</td>
<td>2001</td>
<td>Carmona et al.</td>
</tr>
<tr>
<td>Brazil</td>
<td>2.5</td>
<td>2004</td>
<td>Senna et al.</td>
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<tr>
<td>Sweden</td>
<td>1.3</td>
<td>2000</td>
<td>Lindell et al.</td>
</tr>
<tr>
<td>Sweden</td>
<td>1.0</td>
<td>1989</td>
<td>Jacobsson</td>
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<tr>
<td>Norway</td>
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<td>1992</td>
<td>Forseth et al.</td>
</tr>
<tr>
<td>Finland</td>
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<td>Makela et al.</td>
</tr>
<tr>
<td>Denmark</td>
<td>0.7</td>
<td>1993</td>
<td>Prescott et al.</td>
</tr>
</tbody>
</table>

Who Gets Fibromyalgia?

• No concurrent medical illness
  – 60-90% female in clinic, but < in population
  – Any age, but peak age 40-60
• Can often coexist with other:
  – Rheumatologic or medical disorders
  – Psychiatric disorders (depression, anxiety)
  – Functional somatic syndromes (irritable bowel, chronic fatigue, migraine/tension headaches
  – TMJ disorder, chronic pelvic pain, …)

ACR 1990 Fibromyalgia Criteria

• History of widespread pain ≥3 months; all of the following are present:
  – Pain in the left and right sides of the body
  – Pain above and below the waist
  – Axial skeleton pain
• Pain (stated by patient) in 11 of 18 tender point sites on digital palpation
  – Sites depicted in 1990 ACR guideline
  – Palpation force of about 4 kg


The 18 Tender Point Sites

- Occiput: Superior nuchal line insertions
- Trapezius: Dorsal part of the upper border
- Supraspinatus: Above the medial border of the scapular spine
- Gluteus: Upper outer quadrants of buttocks
- Greater trochanter: Posterior to the trochanteric prominence
- Low cervical: Inferior aspect of the transverse process of C5-C7
- Second rib: Second costochondral junction
- Lateral epicondyle: 2 cm distal to the epicondyle
- Knee: Medial fat pad involved in the pes anserine
**Clinical Features of Fibromyalgia**

- Widespread body pain and tenderness
- Fatigue
- Cognitive problems
  - Trouble concentrating
  - Forgetfulness
  - Disorganized thinking
- Sleep disturbance
- Stiffness
- Depressive and anxiety symptoms
- Impaired social and occupational functioning


**Limited Role of Diagnostic Tests**

- Commonly ordered: CBC, ESR, TSH
- Serologic tests (RA, ANA, Lyme, ...)
  - Beware of false positive tests
  - Selective ordering (only if history or physical exam suggests another rheumatologic dx.)
- X-rays – typically not helpful

**Possible Mimics of Fibromyalgia**

- Early stages of inflammatory arthritis
- Polymyalgia rheumatica
- Inflammatory myopathies
- Metabolic myopathies
- Endocrine disorders
- Post-infectious syndrome
- Myofascial pain
- Depression/anxiety

- Joint abnormalities, RA, ANA
- Severe am stiffness
- Elevated ESR / CRP
- Elevated CK
- Consider MRI, EMG
- Metabolic lab testing
- Consider “statins”
- TSH, FTI
- Other viral features
- Resolves in weeks to months
- Localized (not widespread)
- Psychological symptoms

**Health-Related Quality of Life in Patients With Fibromyalgia**

![Graph showing health-related quality of life metrics for fibromyalgia patients.](image)

**Healthcare Utilization and Costs Over 12 Months**

![Graph showing mean total healthcare cost per patient.](image)

**Outline**

- Diagnosis
- Neurobiology
- Treatment
- Case Discussions
- Questions & Answers
What Causes Fibromyalgia?

- Genetics
  - 8 times more common in families
  - No single gene (COMT, 5-HTT haplotype)
- “Triggers”
  - infection, physical, emotional trauma
- Pathophysiology
  - Relationship between physiological and psychological factors
  - Disordered sensory processing
  - Autonomic/neuroendocrine dysfunction

Pain Abnormalities in Fibromyalgia

- Lower mechanical and thermal pain thresholds (allodynia)
- High pain ratings for noxious stimuli (hyperalgesia)
- Altered temporal summation of painful stimuli (windup)

Fibromyalgia: Evidence of Neural Pain Dysregulation

- “Windup”: Pain augmentation at dorsal horn neuron
- Elevated CSF substance P levels in fibromyalgia
- Neuroimaging studies show changes in pain pathways

Pain Augmentation: Windup

- Central sensitization
- Summation of action potential in second-order neuron

CSF Levels of Substance P in Patients with Fibromyalgia and Controls

- CSF substance P levels: Fibromyalgia (n=32) vs Controls (n=30)
- Substance P levels: 42.8 fmol/ml vs 16.3 fmol/ml, p<.001

Pain Sensitivity in the General Population

- Like most other physiological processes, we have a “volume control” setting for brain and spinal cord processing of pain and other sensory information
- This is likely set by the genes that we are born with, and modified by environmental influences
- The higher the volume control setting, the more pain we will experience, irrespective of peripheral nociceptive input


In healthy normal individuals there is a tightly controlled threshold for the activation of pain associated neurons.

In fibromyalgia, this threshold is reduced.

**In healthy normal individuals there is a tightly controlled threshold for the activation of pain associated neurons.**

**Hypoalgesia**

**Hyperalgesia**

**Pain Sensitivity in Fibromyalgia**

The "pain THERMOSTAT" is turned too HIGH.

... or the "pain AMPLIFIER" is turned too LOUD.

**Am I Safe?**

CRH Release

ACTH

Cortisol

Sympathetic activation

Epinephrine

**Neuroendocrine Changes in Fibromyalgia**

- Alterations in CRH in FM. Abnormal pain sensitivity is of central origin.
- HPA axis links pain, other stressors to endocrine, autonomic and behavioral responses. Interaction of pain neuropeptides (substance P) with serotonin, dopamine, noradrenaline.
- Environmental, genetic influences.

**Outline**

- Diagnosis
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Pharmacotherapy for Fibromyalgia

**ANALGESICS**
- Tramadol

**ANTIDEPRESSANTS**
- Tricyclics (also cyclobenzaprine)
- SNRIs (duloxetine, milnacipran)

**ANTICONVULSANTS**
- Pregabalin
- Gabapentin

Analgesic Trials in Fibromyalgia

<table>
<thead>
<tr>
<th>Drug</th>
<th>Author (Yr)</th>
<th>N</th>
<th>Wks</th>
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<td>1</td>
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<td>Tramadol</td>
<td>Russell (2000)</td>
<td>100</td>
<td>9</td>
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<tr>
<td>Tramadol +</td>
<td>Bennett (2003)</td>
<td>315</td>
<td>13</td>
<td>Yes</td>
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<tr>
<td>Tramadol +</td>
<td>Bennett (2005)</td>
<td>313</td>
<td>13</td>
<td>Yes</td>
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<tr>
<td>Morphine</td>
<td>Sorenson (1995)</td>
<td>9</td>
<td>1</td>
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<td>Opioids</td>
<td>Kemple (2003)</td>
<td>38</td>
<td>200</td>
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</table>

+ = combined with acetaminophen

Tricyclics in Fibromyalgia

**AMITRIPTYLINE**
- Four placebo-controlled trials
  - Goldenberg, 1985
  - Carette, 1986
  - Carette, 1994
- Dose 25 – 50 mg
- Duration 6 – 26 weeks
- All showed modest efficacy

**CYCOBENZAPRINE**
- Four placebo-controlled trials
  - Quimby, 1989
  - Carette, 1994
  - Reynolds, 1991
- Dose 10 – 40 mg
- Duration 4 – 12 weeks
- 2 showed efficacy

Positive RCTs of Newer Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Author (Date)</th>
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<td>Pregabalin</td>
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<td>Pregabalin</td>
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<td>Gabapentin</td>
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<td>Arnold (2005)</td>
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<td>12</td>
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<td>Duloxetine</td>
<td>Russell (2008)</td>
<td>520</td>
<td>26</td>
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<tr>
<td>Milnacipran</td>
<td>Gendreau (2005)</td>
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<td>Milnacipran</td>
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<td>Milnacipran</td>
<td>Clauw (2007)</td>
<td>1196</td>
<td>24</td>
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</table>

Kroenke et al., "Treatment of Chronic Pain", in APA Textbook of Psychopharmacology (in press)

Pregabalin and Gabapentin

- Bind to \( \alpha 2 \delta \) subunit of voltage-gated calcium channels of neurons
- Reduces calcium influx at nerve terminals and therefore inhibits release of neurotransmitters
  - Glutamate, Substance P, Norepinephrine
- Effective in trials of epilepsy, neuropathic pain and generalized anxiety

Nonpharmacological Treatments for Fibromyalgia

**EDUCATION**
- Individual or Group
- Support Groups & Websites

**EXERCISE**
- Aerobic in particular

**COGNITIVE-BEHAVIORAL THERAPY (CBT)**
Group Illness Education

- **Format**
  - Doctor, nurse, etc. structured information
  - Group format with spouse, family
  - Open-ended questions at end
- **Ideal for chronic illness like** headaches, back pain, fibromyalgia, diabetes, obesity
- Learn from others, establish contacts
- Reimbursement a concern

Aerobic Exercise in Fibromyalgia

- **2007 Cochrane review**
- 34 trials involving 2276 subjects
- **Effect size metric**
  - Small 0.2
  - Moderate 0.5
  - Large 0.8

<table>
<thead>
<tr>
<th>Effect Sizes</th>
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<tbody>
<tr>
<td>Global well-being*</td>
<td>0.44 (0.13, 0.75) * p&lt;0.05</td>
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<tr>
<td>Physical function*</td>
<td>0.68 (0.41, 0.95)</td>
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<tr>
<td>Pain</td>
<td>0.94 (-0.15, 2.0)</td>
</tr>
<tr>
<td>Tender points</td>
<td>0.26 (-0.28, 0.79)</td>
</tr>
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</table>


Exercise as it Relates to FM

- **Moderate aerobic exercise (60-75% of age adjusted maximum heart rate) (210-age), at least 3X weekly**
- Exercise should be slowly and carefully introduced
- Strength and stretching should be incorporated gradually

What is a Typical Outcome in Fibromyalgia?

- Most patients have chronic, persistent symptoms
- Most patients continue to work, but 10-15% are disabled
- There is often adverse impact on work and leisure activities
- Duration of time without a diagnosis adversely affects outcome

Fibromyalgia and Mood Disorders

- At the time of FMS diagnosis, mood disorders are present in 30-50%, mainly depression and anxiety
- Increased prevalence of mood disorders are primarily in tertiary-referral patients
- Increased lifetime and family history of mood disorders in FM vs RA (Odds = 2.0)
- FMS aggregates in families and co-aggregates with mood disorders. Odds of having FMS in relatives is 8.5 in FMS vs RA proband


“Fibromyalgia: Not All in My Head”
Newsweek, May 19, 2003
Case 1 – 39 year old female

- Widespread muscle and joint pain for 10 years
- Poor sleep
- Bouts of anxiety and depression – never treated
- Years of vague abdominal pain with alternating constipation and diarrhea
- Multiple food intolerances
  - “Do I have multiple chemical sensitivity?”
- Pelvic pain and bladder irritability

Evaluation

- Past Medical History:
  - Chronic headaches since age 9
  - Treated as migraine and tension headaches
- Social history:
  - Accountant; married; no children
  - No history of sexual abuse
- Physical exam – normal
- Labs – ANA, ESR, RF, CBC – normal
- X-rays of knees, back, hands - normal

? Which of the following diagnoses is the patient least likely to have?

1. Fibromyalgia
2. Hypothyroidism
3. Irritable bowel syndrome
4. Somatization disorder
5. Major depression

Symptom Syndrome Overlap
(Aaron & Buchwald -- 53 studies)

<table>
<thead>
<tr>
<th>Syndrome</th>
<th>No. Studies</th>
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<tbody>
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<td>Fibromyalgia</td>
<td>34</td>
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<tr>
<td>Irritable bowel syndrome (IBS)</td>
<td>21</td>
</tr>
<tr>
<td>Chronic fatigue syndrome (CFS)</td>
<td>18</td>
</tr>
<tr>
<td>TMJ syndrome</td>
<td>8</td>
</tr>
<tr>
<td>Migraine/tension headache</td>
<td>8</td>
</tr>
<tr>
<td>Multiple chemical sensitivity (MCS)</td>
<td>7</td>
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</tbody>
</table>

Symptom Syndrome Overlap

<table>
<thead>
<tr>
<th>Syndrome Combination</th>
<th>Overlap</th>
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</thead>
<tbody>
<tr>
<td>Fibromyalgia &amp; CFS</td>
<td>35-70%</td>
</tr>
<tr>
<td>Fibromyalgia &amp; IBS</td>
<td>32-80%</td>
</tr>
<tr>
<td>CFS &amp; IBS</td>
<td>58-92%</td>
</tr>
<tr>
<td>Fibromyalgia &amp; MCS</td>
<td>33-55%</td>
</tr>
<tr>
<td>CFS &amp; MCS</td>
<td>30-67%</td>
</tr>
</tbody>
</table>


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. Normal ESR (sed rate)
5. Normal X-rays

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 (e.g., elevated ESR or X-ray findings) are generally discriminatory only if they are abnormal
- Tender points in FM are not limited to the joints but are on right and left sides of body, upper and lower halves, proximal and axial.

Which symptom would be most helpful in diagnosing comorbid depression?

1. Fatigue
2. Trouble concentrating
3. Sleep complaints
4. Loss of interest (anhedonia)
5. Multiple pain complaints

“SPACE DIGS”

[9 DSM-IV Symptoms of Depression]

S - Sleep
P - Psychomotor
A - Appetite
C - Concentration
E - Energy
D - Depressed
I - Interest
U - Ulit
S - Suicidal


PHQ-4

<table>
<thead>
<tr>
<th>Symptoms of Depression</th>
<th>Not at all (0)</th>
<th>Several days (1)</th>
<th>More than half the days (2)</th>
<th>Nearly every day (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeling nervous, anxious, or on edge</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not being able to stop or control worrying</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Little interest or pleasure in doing things</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeling down, depressed, or hopeless</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Items 1 & 2 screen for anxiety; items 3 & 4 for depression
Score ≥ 3 on either two-item screen is positive screen

Kroenke et al. Psychosomatics, in press.
Fibromyalgia: Overlap with Depression and Anxiety Disorders


Prevalence of Pain Symptoms by Severity of Depression in 3000 Medical Outpatients


Case 2 – 52 year old male
- Presents with chronic neck pain, headache, sleep and mood disturbances
- Has been out of work for 5 years
- Past Medical History:
  - Chronic back pain x 20 yrs
  - Back surgery 5 years previous (HNP)
  - Multiple course of physical therapy and Injections for pain
- Physical Exam: Normal, except widespread tenderness
- Laboratory findings: Within Normal Limits
- MRI of back: degenerative disc disease, no cord or spinal nerve compression

What would you prescribe to treat the fibromyalgia component of this man’s illness?
1. Naproxen
2. Acetaminophen
3. Escitalopram
4. Amitriptyline
5. Methacarbamol

Treatment of Fibromyalgia with Antidepressants: A Meta-analysis


The patient does not tolerate the tricyclic antidepressant, and fails to improve with a trial of cyclobenzaprine.

All of the following are reasonable medications to try next EXCEPT
1. Tramadol
2. Hydrocodone
3. Pregabalin
4. Duloxetine
5. Gabapentin
The patient partly improves with combined medications. He is not interested in a regular exercise program. The most evidence-based nonpharmacologic treatment to add at this point is:

1. Physical therapy
2. Interpersonal psychotherapy
3. Cognitive-behavioral therapy
4. Acupuncture
5. TENS unit

Cognitive-Behavioral Therapy (CBT)

- CBT effective in fibromyalgia – 4 of 6 trials involving 596 patients
- CBT effective in functional somatic syndromes (FSS) – 20/28 trials, including back pain (3/5), IBS (3/3), chronic fatigue syndrome (2/3), noncardiac chest pain (2/3), and FSS (7/11)
- CBT effective in somatoform disorders and unexplained symptoms – 11/13 trials

Therapies with No to Mixed Evidence in Fibromyalgia

<table>
<thead>
<tr>
<th>No Evidence</th>
<th>Mixed Evidence</th>
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<tbody>
<tr>
<td>NSAIDs</td>
<td>SSRI s</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Opiates</td>
<td>Massage</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>Strength exercises</td>
</tr>
<tr>
<td>Trigger or tender point injections</td>
<td>Hypnosis</td>
</tr>
<tr>
<td>TENS units</td>
<td>Biofeedback</td>
</tr>
<tr>
<td></td>
<td>Balneotherapy</td>
</tr>
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</table>

Conclusions

- FM is common and affects 2 – 5% of the population
- Majority of patients between 35-60 years
- Women more likely to be diagnosed than men
- Patients have heightened sensitivity to pain (hyperalgesia); in addition, non-noxious stimuli may result in pain (allodynia)
- Patients may present with a wide range of additional symptoms including tenderness, sleep disturbances, fatigue, cognitive complaints, and mood disorders
- Evidence-based treatments include exercise, CBT, TCA and SNRI antidepressants, tramadol, pregabalin

Outline

- Diagnosis
- Neurobiology
- Treatment
- Case Discussions
- Questions & Answers
Questions & Answers

kkroenke@regenstrief.org