

Fibromyalgia Primary Care CHE Program

Introduction:

NEEDS ASSESSMENT in FM

Disclosure

- Pfizer, Janssen-Ortho, Purdue Pharma, Boehringer-Ingelheim, Valeant, Biovail, Merck-Frosst, Bayer.
- Program is sponsored through an unrestricted educational grant from Pfizer Canada Inc.

Fibromyalgia Primary Care CHE Program

Introduction:

NEEDS

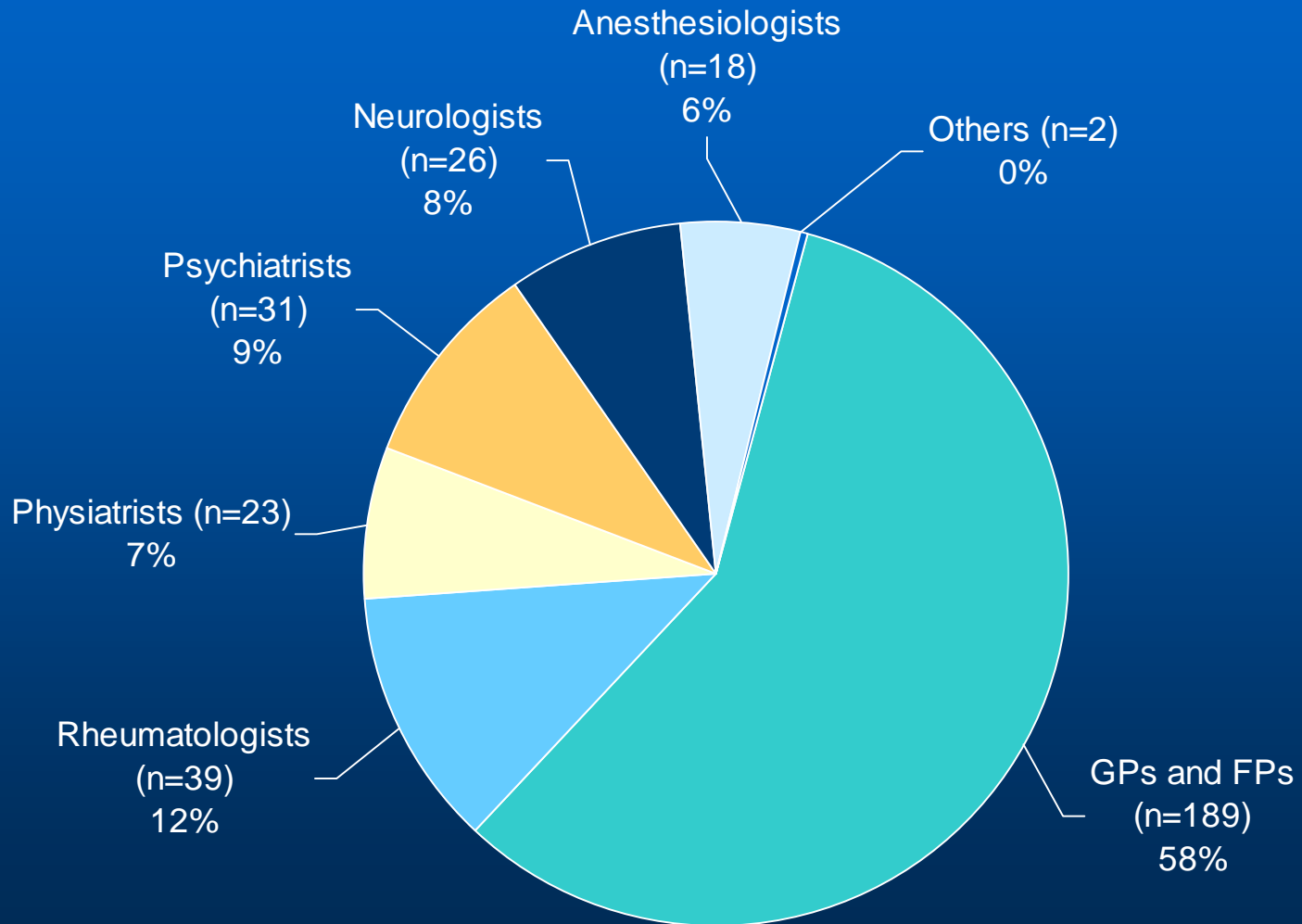
ASSESSMENT in FM

Methods

- **Phase 1:** Exploratory Phase (completed – Sept '07)
 - Literature, guidelines, patient advocacy groups, KOLs, specialists, GPs, patients
 - *IRB approval*
 - Six discussion groups; 5 key informant interviews

- **Phase 2:** Validation Phase (completed – Jan '08)
 - *IRB approval*
 - Online survey to validate findings

Total Sample (n=328)



Key Gaps

1. Knowledge: Quantifying disability and filling forms and letters for insurance purposes
2. Skills: Struggle to engage patients, provide psychological support and manage patients' expectations
3. Attitude: Physicians feel frustrated, isolated, and professionally unfulfilled in providing care to fibromyalgia patients

Additional Gaps

Lack of:

- available tools and algorithms for reliable diagnosis and monitoring
- effective, indicated treatment options

Development Committee

- University of Calgary
 - Dr. Rick Ward
- Université de Sherbrooke
 - Dr. Christian Cloutier
 - Dr. Serge Marchand
- Dr. Monique Camerlain
- Dr. Manfred Harth
- Dr. Harvey Moldofsky
- Dr. Eleanor Stein

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- Larry McClure (British Columbia)
- Ken Stakiw (Saskatchewan)
- Kevin Saunders (Manitoba)
- Alan Kaplan (Ontario)
- Jean-Marc Bigonesse (Quebec)
- Brian Craig (New Brunswick)
- John Hickey (Nova Scotia)
- Randy MacKinnon (Prince Edward Island)
- Lydia Hatcher (Newfoundland)

Learning Methods

- Slides presentations
 - Expert opinion
- 'Small' group discussion
(communication')
- Patient interview
- Hands on demonstration
- Optional role play

A couple is seen from behind, embracing on a mountain ridge. The man is wearing a dark jacket and a patterned beanie, while the woman is wearing a light-colored hoodie. They are looking out over a vast mountain landscape under a sunset sky with soft, warm light and lens flare effects. The mountains are covered in green vegetation, and the overall atmosphere is serene and hopeful.

New Horizons

in Fibromyalgia

Bringing Hope Through Better Patient Care

Disclosure



UNIVERSITÉ DE
SHERBROOKE

- This program was developed by the University of Calgary and University of Sherbrooke through an educational grant from Pfizer Canada Inc.
- Speaker disclosures [to be added]

What is your greatest clinical challenge in fibromyalgia?

- Flip chart

- At the end of the session, please return to these challenges

Learning Objectives

- **Following this course, participants will be able to:**
 - Give the prevalence and etiologic theories for fibromyalgia
 - List the diagnostic criteria, differential diagnosis and investigations for fibromyalgia
 - Explain the diagnosis to patients with fibromyalgia in a positive, hopeful and respectful manner
 - Provide a treatment strategy for patients diagnosed with fibromyalgia
 - Obtain resources to assist patients in the management of their fibromyalgia

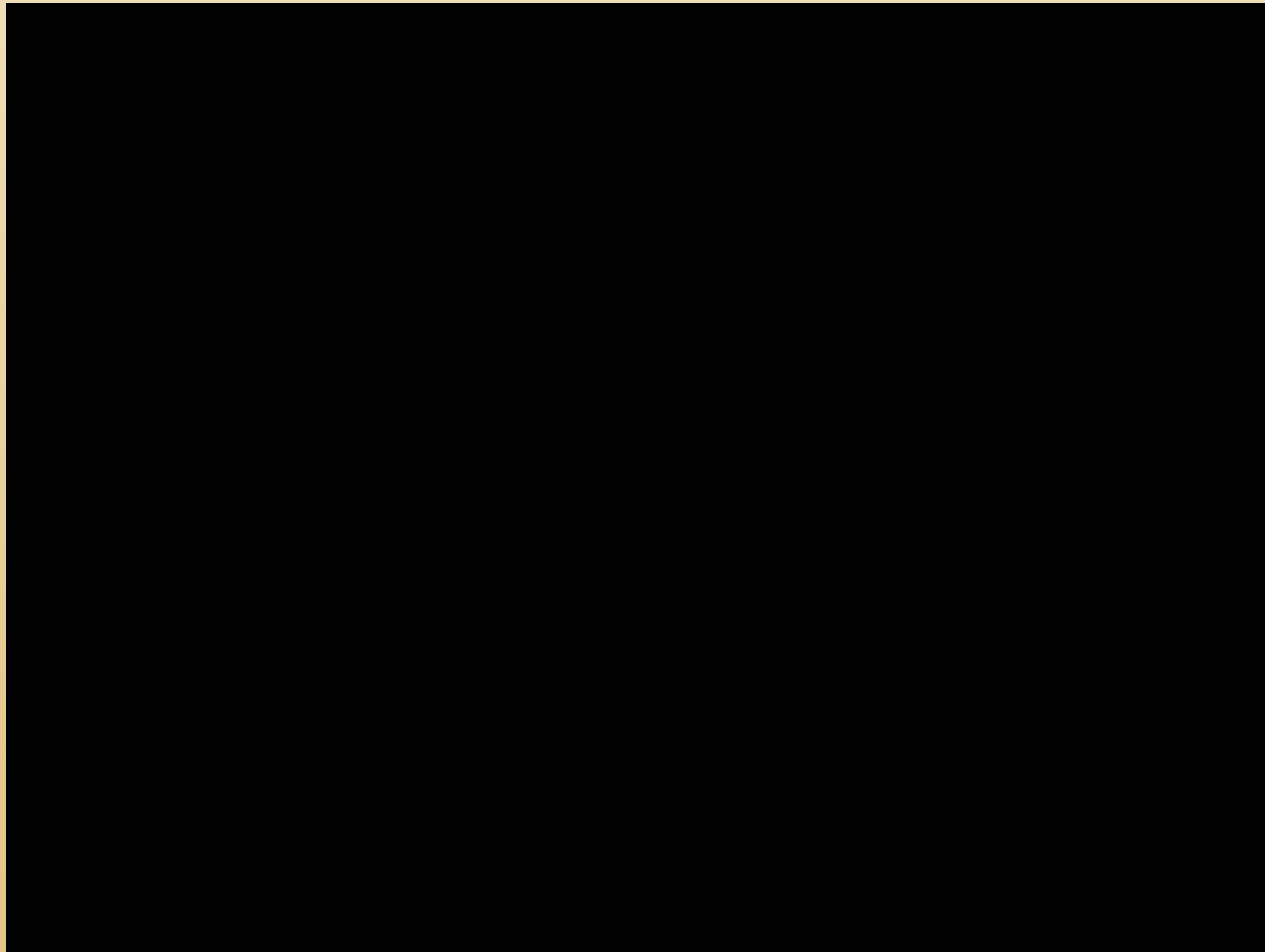
Clinical Presentation

- **Patty is a 32-year-old woman in your practice.**

- History:

- Under your care for 10 years
- Unremarkable past history
- Slipped on ice 4 months ago and has had progressive generalized pain and fatigue
- Saw a locum 2 weeks ago who ran a battery of tests for multiple symptoms of generalized pain, fatigue and sleep problems

Video Clip



Pair up with a partner and answer the following questions... (< 5 mins)

- **What is the incidence and gender distribution of fibromyalgia?**
- **How do you make the diagnosis of fibromyalgia?**
- **What are the differential diagnoses in this patient?**
- **What investigations would you have ordered 2 weeks ago?**
- **How do you feel about seeing this kind of patient at present?**

Prevalence of Fibromyalgia

- **Fibromyalgia occurs in all ages, both sexes and all cultures, but occurs more frequently in:**
 - Women
 - Patients between the ages of 35 – 60 years
 - (noted in pediatric and adolescent populations)
- **In Canada:**
 - Fibromyalgia affects an estimated 4.9% of adult women (8% in women 55-64) and 1.6% of adult men
 - Female to male ratio of approximately 3:1

Wolfe et al. *Arthritis Rheum.* 1995;38:19-28.
Lawrence et al. *Arthritis Rheum.* 1998;41:778-799.
Neumann et al. *Curr Pain Headache Rep.* 2003;7:362-368.
Wolfe F. *Journal of Musculoskeletal Pain.* 1993;3:137-148.
Prescott et al. *Scand J Rheumatol.* 1993;22:233-237.
Lindell et al. *Scand J Prim Health Care.* 2000;18:149-153.
Cardiel et al. *Clinical and Experimental Rheumatology.* 2002;20:617-624.
Carmona et al. *Ann Rheum Dis.* 2001;60:1040-1045.
White et al. *Journal Rheumatol* 1999; 26:1570-1576.

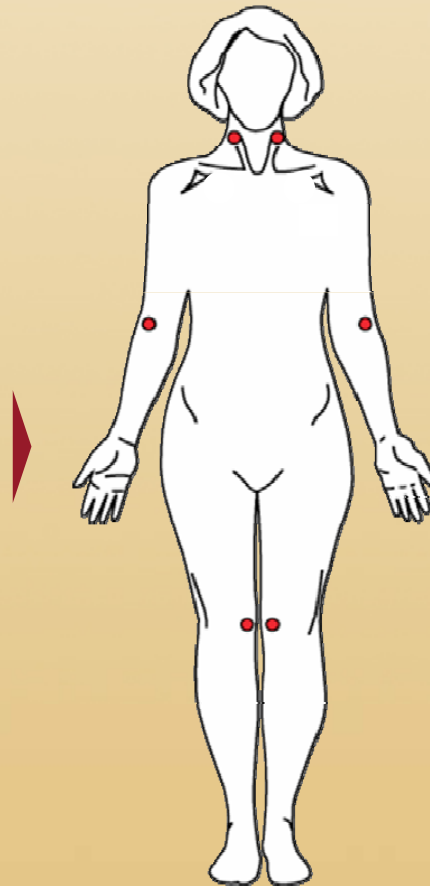
Prevalence in your clinic:

- For GPs:
- For rheumatologists:
- For physiatres:
- For multidisciplinary pain clinic:

Core Clinical Features of Fibromyalgia

Widespread Pain

- Chronic, widespread pain is the defining feature of Fibromyalgia
- Patient descriptors of pain include: aching, exhausting, nagging, and hurting
- Presence of tender points



Neurocognitive Impairment (“FibroFog”)

- Characterized by confusion, slowed processing of information and reaction time, difficulty in word retrieval or speaking, concentration, attention, short-term memory consolidation, disorientation

Sleep Disturbance

- Characterized by nonrestorative sleep and increased awakenings
- Abnormalities in the continuity of sleep and sleep architecture

Fatigue

- Patients describe it as physically or emotionally draining

Stiffness

- Stiffness in the morning is a common characteristic of Fibromyalgia

Wolfe et al. *Arthritis Rheum.* 1995;38:19-28.
Leavitt et al. *Arthritis Rheum.* 1986;29:775-781.
Wolfe et al. *Arthritis Rheum.* 1990;33:160-172.
Roizenblatt et al. *Arthritis Rheum.* 2001;44:222-230.
Harding. *Am J Med Sci.* 1998;315:367-376.
Henriksson. *J Rehabil Med.* 2003;(suppl 41):89-94.
Carruthers et al. *J Chron Fat Synd.* 2003;11:7-115.

What are the differential diagnostics

-
-
-
- Others...

Is it Fibromyalgia or Chronic Fatigue Syndrome (CFS)?

● CFS

- Primary symptom is post exertional malaise, fatigue
- No current diagnostic test but mitochondrial dysfunction is suspected
- Score of <50 on SF-36 physical function scale can help differentiate from major depression
- 75% also meet criteria for fibromyalgia¹

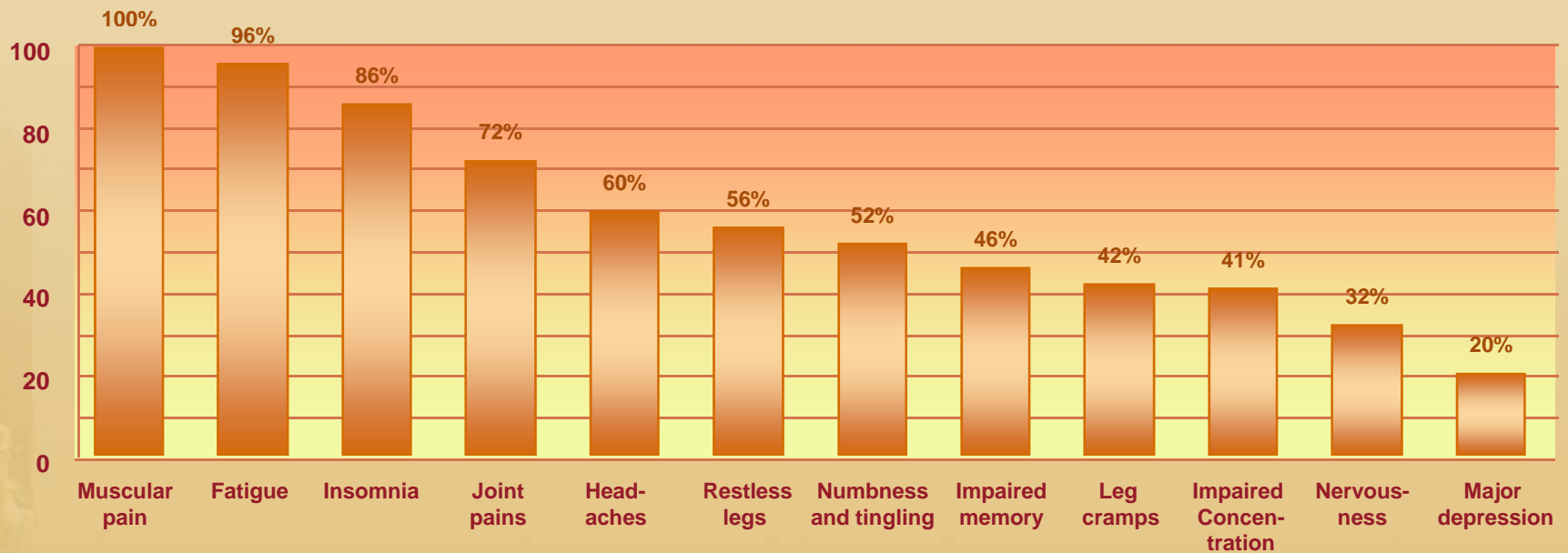
● FM

- Primary symptom is generalized muscle pain
- Primary sign is pain at >11 of 18 tender points
- 20-70% meet criteria for CFS²

1. Goldenberg DL, et al. *Arth Rheum.* 1990;33:381-387.
2. Aaron LA, et al. *Arch Intern Med.* 2000;160:221-227.

Symptoms of Fibromyalgia

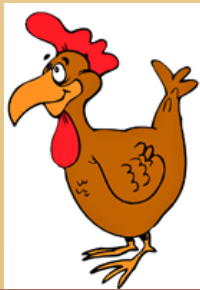
- Pain, fatigue, and sleep disturbance are present in at least 86% of patients*



* US data

Mood Disorders in Fibromyalgia

- **At time of diagnosis, approximately 20-40% of individuals with fibromyalgia have an identifiable current mood disorder (e.g., depression or anxiety)**
 - Lifetime prevalence of depression: 74%
 - Lifetime prevalence of anxiety disorder: 60%
 - In many cases, depression or anxiety may be the result of chronic pain



or



Katon et al. *Ann Intern Med.* 2001;134:917-25.
Boissevain et al. *Pain.* 1991;45:227-38.
Boissevain et al. *Pain.* 1991;45:239-48.
Giesecke et al. *Arthritis Rheum.* 2003;48:2916-2922.
Arnold et al. *Arthritis Rheum.* 2004;50:944-952.
Fishbain et al. *Clin J Pain.* 1997;13:116-137.

Stressors

- **Stressors that may trigger fibromyalgia (supported by case control studies)**
 - Peripheral pain syndromes
 - Physical trauma
 - Infections (e.g., parvovirus, EBV, Lyme disease, Q fever)
 - Psychological stress/distress, including sleep disturbances

Any external noxious stimuli may trigger fibromyalgia, but it is not a prerequisite for the development of the condition. In many cases, the onset of fibromyalgia is gradual, with no identifiable trigger.

Fibromyalgia as a Consequence of Trauma (such as MVA)

Factors Triggering Fibromyalgia or Associated with its Onset (n=136)

	Trigger Factors %	Associated Factors*%
Cold	0	15
Stress	9	35
Emotions	5	35
Overwork	0	22
Trauma	24	24
Surgery	4	13
Death in the family	0	13
Family problems	2	25
Fatigue	0	23
No cause/association	55	5

In most cases of fibromyalgia, there is no predisposing trigger.

Diagnosing Fibromyalgia: Overview

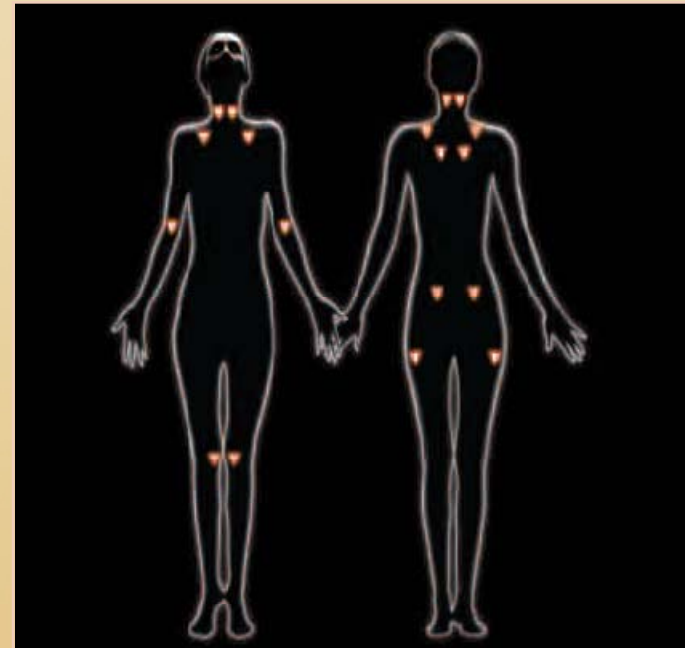
- **Patient history of fibromyalgia or related conditions**
 - Personal history
 - Family history
- **Physical examination**
 - Established diagnostic criteria
 - Tender point evaluation
- **Differential diagnosis**
 - Clinical/laboratory evaluation to exclude other conditions such as:
 - Osteoarthritis, rheumatoid arthritis, PMR, hypothyroidism, lupus, and Sjögren's syndrome

Note: Extensive lab evaluation is usually not necessary to rule out fibromyalgia. In some cases, a TSH may be called for. PMR is usually not a problem as it seldom occurs under the age of 60, whereas the onset of fibromyalgia after 65 is rare.

Assessment of Fibromyalgia:

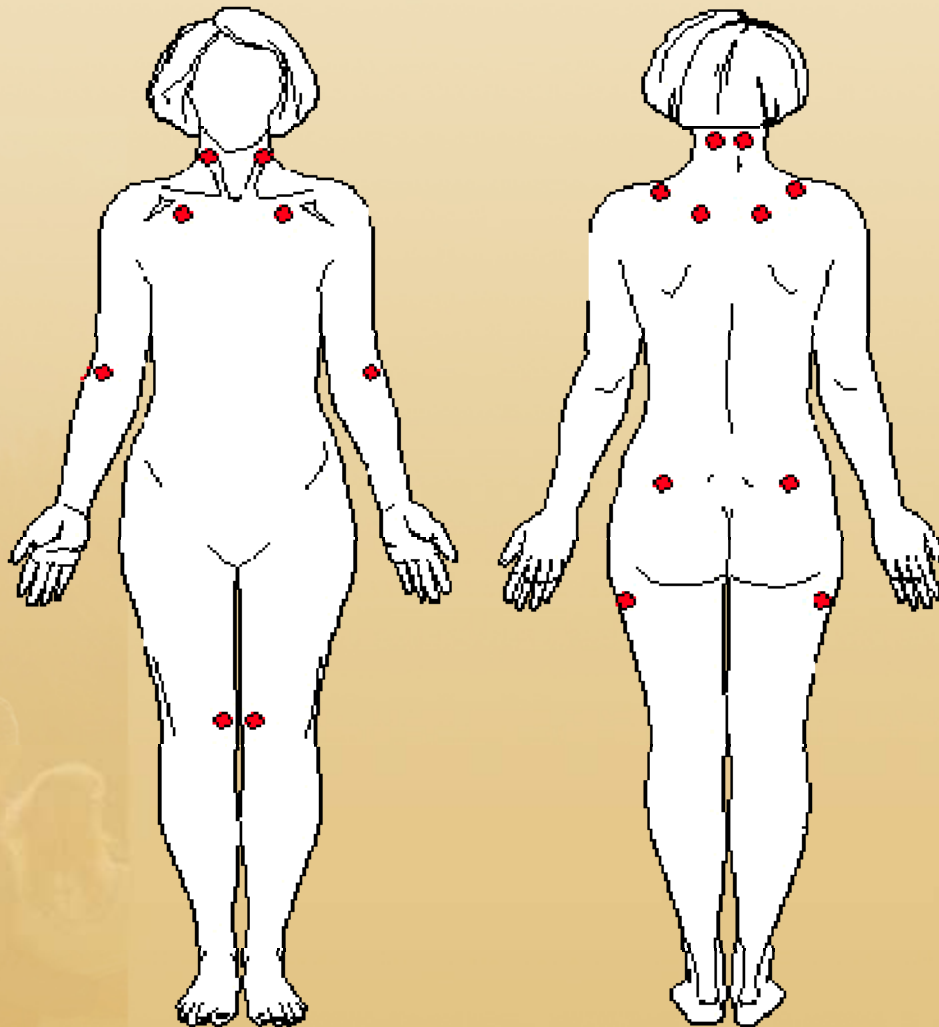
American College of Rheumatology (ACR) Classification Criteria

- **History of widespread pain that has been present for at least 3 months (ALL of the following should be present):**
 - Pain on both sides of the body
 - Pain above and below the waist
 - Axial skeletal pain
 - Pain in at least 11 of 18 tender point sites on digital palpation



ACR criteria are both sensitive (88.4%) and specific (81.1%)

Illustration of Tender Points



- **Occiput (2)** - at the suboccipital muscle insertions
- **Low cervical (2)** - at the anterior aspects of the intertransverse spaces at C5-C7
- **Trapezius (2)** - at the midpoint of the upper border
- **Supraspinatus (2)** - at origins, above the scapula spine near the medial border
- **Second rib (2)** - upper lateral to the second costochondral junction
- **Lateral epicondyle (2)** - 2 cm distal to the epicondyles
- **Gluteal (2)** - in upper outer quadrants of buttocks in anterior fold of muscle
- **Greater trochanter (2)** - posterior to the trochanteric prominence
- **Knee (2)** - at the medial fat pad proximal to the joint line

Performing a Tender Point Exam

- **Digital palpation with an approximate force of 4 kg**
 - Estimated pressure needed to turn the examiner's thumbnail white upon depressing
- **For a “positive” tender point, the subject must state that the palpation was painful**
- **Use of these criteria yielded an 88.4% sensitivity (measure of correctly diagnosed patients) and an 81.1% specificity (statistical probability of an accurate negative diagnosis) for diagnosing fibromyalgia**
- **Controversies regarding tender point evaluation**
 - Subjective
 - May not be necessary for diagnostic studies
 - What about fewer than 11 of 18 tender points?
 - ACR criteria were originally intended as a research tool
 - Since Vancouver consensus: Global dx

Tender Points vs. Trigger Points

- **Tender points:**

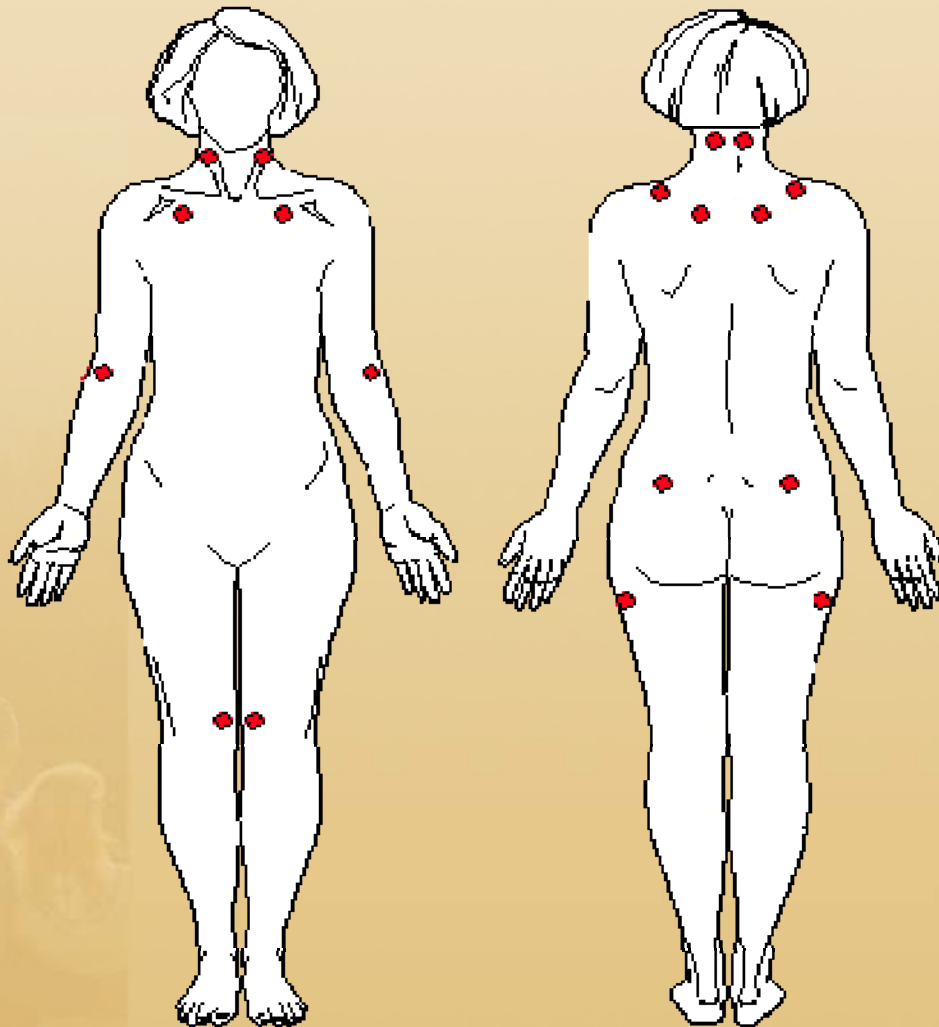
- Painful and tender areas occurring in muscle, ***muscle-tendon junction, bursa, or fat pad***
- Characteristic of fibromyalgia when they occur in a widespread manner

- **Trigger points:**

- Areas of muscle that are painful to palpation
- Characterized by presence of localized tender areas and generation of a referral pattern of pain
- Typically occur in a more restricted regional pattern
- Indicative of myofascial pain syndrome

Illustration of Tender Points

Hands on 5 mins



- **Occiput (2)** - at the suboccipital muscle insertions
- **Low cervical (2)** - at the anterior aspects of the intertransverse spaces at C5-C7
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How do you feel about patients like Patty?

- <1min
- Frustration
- Felt they are exaggerating or faking
- Consume time and energy
- Feel different if this case was a male rather than a female

Pathogenesis of Fibromyalgia: Overview

- Pathogenesis of fibromyalgia is unknown
- Central sensitization is currently the leading theory
 - Mechanisms of central sensitization



Excitatory mechanisms



Inhibitory mechanisms

Pathogenesis of Fibromyalgia

- **Increased levels of substance P (> 3 x) in patients with fibromyalgia**
- **fMRI studies show a marked regional increase in cerebral blood flow following a painful stimulus in patients with FM compared to controls not suffering FM**
- **Deficit in the endogenous pain inhibitory systems noted in fibromyalgia patients**

Objective findings = FM is a real disease!

**Should you make a definite
diagnosis of fibromyalgia?**

**Or is the label of fibromyalgia
more harmful to the patient?**

Diagnosis Can Improve Patient Satisfaction

- **Diagnosis of fibromyalgia improves health satisfaction**

- White et al conducted a prospective, community comparison of fibromyalgia patients in Canada that revealed significantly improved scores 36 months post-diagnosis
- Patients self-reported health satisfaction on a 5-point Likert scale

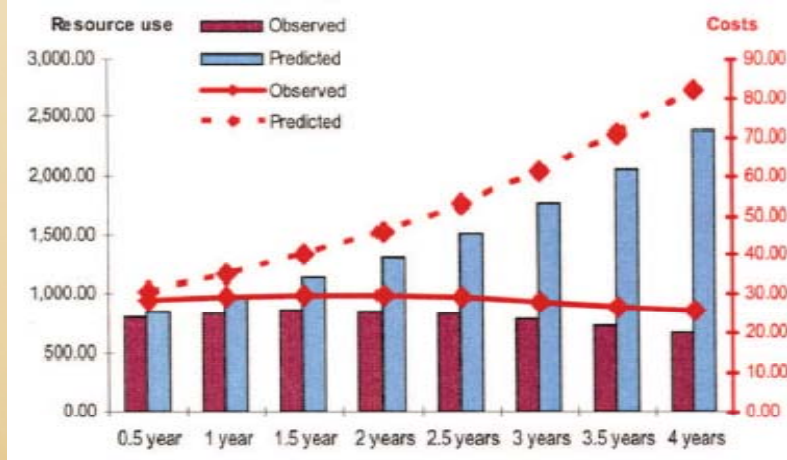
Improvement



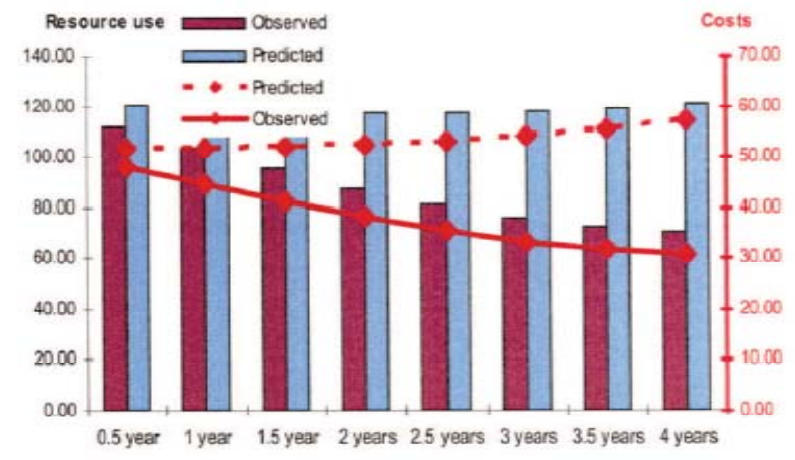
*Statistically significant versus baseline (Confidence Interval -1.2, -0.4).

Health Economic Consequences Related to the Diagnosis of Fibromyalgia

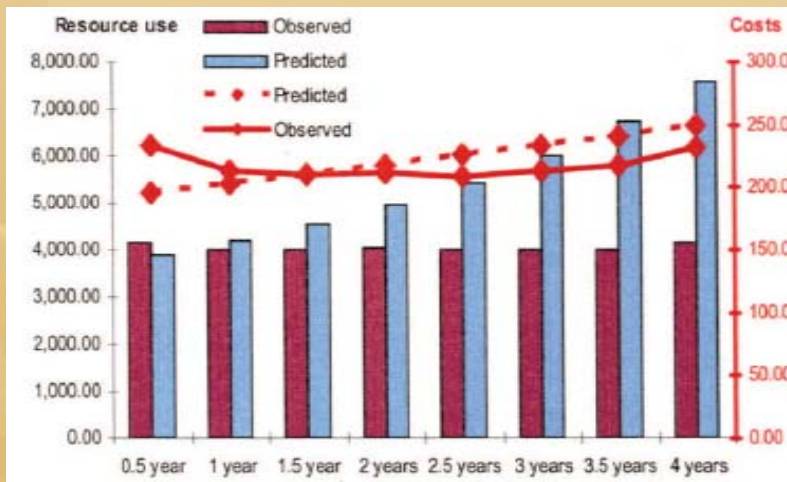
Tests and imaging



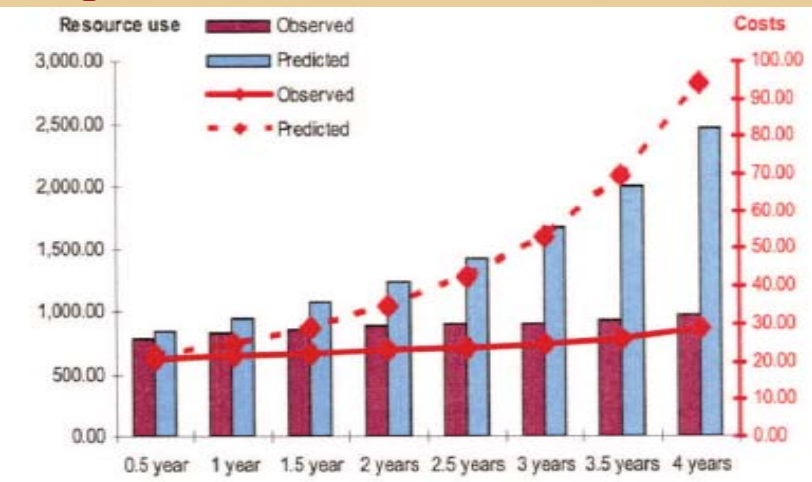
Referrals



GP visits



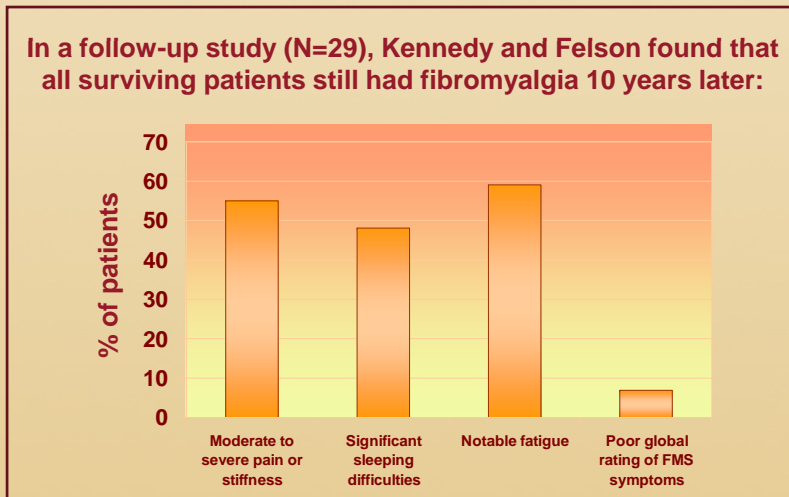
Drugs



Fate of Patients with Fibromyalgia

- Reassure patients that fibromyalgia need not be progressive and that symptoms remain stable over time

In a follow-up study (N=29), Kennedy and Felson found that all surviving patients still had fibromyalgia 10 years later:



However, 66% indicated some improvement over the 10 years

- Successful management requires an upbeat, optimistic approach and EARLY initiation of effective, individualized therapy
 - An Australian study of patients provided with a simple treatment regimen found that 2 years after diagnosis:
 - 47% no longer fulfilled Smythe or ACR criteria for fibromyalgia
 - Remission identified in 24.2% of assessed patients

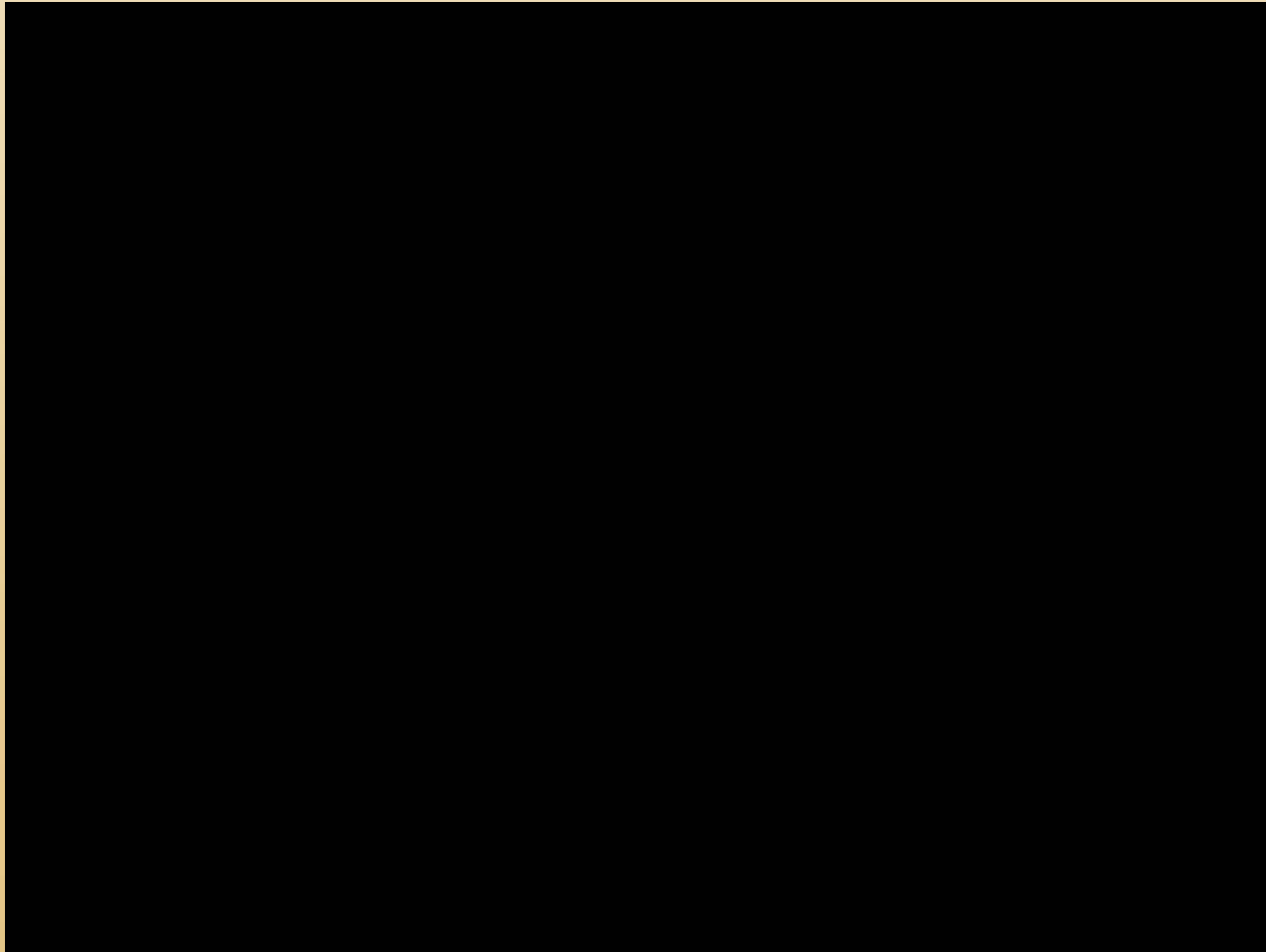
Kennedy et al. *Arthritis Rheum.* 1996;39:682-685.
Wolfe F, Anderson J, Harkness D, et al. *Arthritis Rheum.* 1997;40:1571-1579.
Bennett R: Web site. Available at: <http://www.myalgia.com>. Accessed January 25, 2008.
Felson DT, Goldenberg DL. *Arthritis Rheum.* 1986;29:1522-1526.
Granges G, Zilko P, Littlejohn GO. *J Rheumatol.* 1994;21:523-529.

Pair up with your partner and do the following....

- **Assume that Patty has fibromyalgia.
One of you take the role of the physician
and explain the diagnosis to Patty.**

When you have done this, switch roles.

Clinical presentation



Some tips on providing the diagnosis

- **Be specific about the diagnosis**
- **Be positive about the diagnosis**
- **Promote and encourage patient self efficacy around the disease but...**
- **Set realistic expectations**
- **Emphasize no cure but improved control of symptoms usually possible**
- **Active treatments generally superior to passive treatments**

Pair up with your partner and complete the treatment worksheet

Therapeutic intervention	Your experience prescribing this intervention	Level of Evidence? (None/Low/High)	Comments based on presentation
Aerobic Exercise			
Cognitive Behavioural Therapy			
Strength Training			
Patient education			
Acupuncture			
Biofeedback			
Balneotherapy			
Hypnotherapy			
Narcotics			
NSAIDs			
TCA's			
SSRIs			
SNRIs			
Analgesics/Anti-epileptics (gabapentin, pregabalin)			
Non-narcotic analgesics			

Management of Fibromyalgia: Recommended Treatment Approach

- Multidisciplinary therapy individualized to patients' symptoms and presentation is recommended
- A combination of non-pharmacological and pharmacological therapies may benefit most patients

Non-pharmacological

- Aerobic exercise
- Cognitive behavioral therapy
- Patient education
- Strength training
- Acupuncture*
- Biofeedback*
- Balneotherapy*

*Limited evidence for efficacy exists

Balneotherapy: treatment of disease or health conditions by bathing

Pharmacological

- Non-narcotic analgesics
- Analgesic antiepileptics
- Antidepressants
 - TCAs
 - SSRIs
 - SNRIs
- Muscle relaxants
- Other

Mease P. Fibromyalgia syndrome: review of clinical presentation, pathogenesis, outcome measures, and treatment. *J Rheumatol*. 2005;32(suppl 75):6-21.
Carville, Arendt-Nielsen, Bliddal, et al. EULAR evidence based recommendations for the management of fibromyalgia syndrome [published online ahead of print July 20, 2007]. *Ann Rheum Dis*. Doi:10.1136/ard.2007.071522.
Goldenberg et al. Management of fibromyalgia syndrome. *JAMA*. 2004;292:2388-2395.
Clauw DJ, Crofford LJ. Chronic widespread pain and fibromyalgia: what we know, and what we need to know. *Best Pract Res Clin Rheumatol*. 2003;17:685-701.
Arnold LM, Goldenberg DL, Stanford SB, et al. Gabapentin in the treatment of fibromyalgia: a randomized, double-blind, placebo-controlled, multicenter trial. *Arthritis Rheum*. 2007;56:1336-1344.

Non-pharmacological Treatments With Demonstrated Efficacy Currently in Use

- **Cognitive-behavioral therapy**
 - Positive effects on coping with and control over pain
 - Not proven to improve pain
 - Proven to improve physical function
 - Should be done by a trained professional
- **Aerobic and strengthening exercises**
 - Reduce pain, increase self-efficacy, improve QOL, and reduce depression
 - Aerobic exercise should be of low-to-moderate intensity, two to five times/week
- **Patient education**
 - Conflicting evidence but some studies have shown improvements in pain, sleep, fatigue, and quality of life

Vlaeyen JW, Teeken-Gruben NJ, Goossens ME, et al. Cognitive-educational treatment of fibromyalgia: a randomized clinical trial. I: clinical effects. *J Rheumatol*. 1996;23:1237-1245.

Nicassio PM, Radojevic V, Weisman MH, et al. A comparison of behavioral and educational interventions for fibromyalgia. *J Rheumatol*. 1997;24:2000-2007.

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

Busch et al. *Cochrane Database Syst Rev*. 2006.

Brosseau L, Wells GA, Tugwell P, et al.; Ottawa Panel Members. Ottawa Panel evidence-based clinical practice guidelines for strengthening exercises in the management of fibromyalgia: part 2. *Phys Ther*. 2008;88:873-86.

Brosseau L, Wells GA, Tugwell P, et al.; Ottawa Panel Members. Ottawa Panel evidence-based clinical practice guidelines for aerobic fitness exercises in the management of fibromyalgia: part 1. *Phys Ther*. 2008;88:857-71.

Pharmacological Therapies for Fibromyalgia

Treatment	Level of Evidence	Comments
TCA s	High	<ul style="list-style-type: none"> – Amitriptyline most widely studied – Short-term improvements in pain, fatigue, sleep and overall well-being – Benefits usually seen 2-4 weeks after initiation of therapy – Significant side effects, even at low doses
SSRI s	Moderate	<ul style="list-style-type: none"> – Inconsistent data, particularly vs. placebo – Fluoxetine: improvements in sleep, pain, fatigue and mood at higher doses – Paroxetine: improvements in pain, sleep and fatigue, but less effective than amitriptyline – Citalopram: improvements in mood at higher doses; appears to be less effective than fluoxetine and paroxetine
SNRI s	High (for duloxetine)	<ul style="list-style-type: none"> – Duloxetine: improvements in pain, tender points, stiffness and QOL; approved for fibromyalgia treatment in the US – Venlafaxine: open label studies show improvements in pain and mood at doses > 150 mg

TCA: tricyclic antidepressants; SSRIs: selective serotonin reuptake inhibitors; SNRIs: serotonin-norepinephrine reuptake inhibitors

Pharmacological Therapies for Fibromyalgia (continued)

Treatment	Level of Evidence	Comments
Analgesics/ Antiepileptics	High	Pregabalin: – Improvements in pain, sleep, fatigue and global measures of change, particularly at dose of 450 mg/day – Approved for treatment of fibromyalgia in Canada and US
		Gabapentin – Improvements noted in pain, sleep and FIQ scores, but not number of tender points
Non-narcotic analgesics	High	Tramadol – Improvements in pain and QOL – Caution in patients already taking SSRIs or SNRIs due to potential for serotonin syndrome
Muscle relaxants	Moderate	Cyclobenzaprine – Improvements in pain and sleep; similar outcomes to amitriptyline

Corticosteroids, strong opioids and NSAIDs have shown no benefit in patients with fibromyalgia and are NOT recommended.

Abeles M, et al. Update on fibromyalgia therapy. *Am J Med.* 2008;121:555-61. Arnold LM. Biology and therapy of fibromyalgia. New therapies in fibromyalgia. *Arthritis Res Ther.* 2006;8:212. Rao SG, Gendreau JF, Kranzler JD. Understanding the fibromyalgia syndrome. *Psychopharmacol Bull.* 2007;40:24-67 Crofford LJ. Pain management in fibromyalgia. *Curr Opin Rheumatol.* 2008;20:246-50. Carville, et al. *Ann Rheum Dis.* Doi:10.1136/ard.2007.071522.

And cannabinoids, diet, nicotine...

Efficacy in the Management of Fibromyalgia

- **For information regarding active and completed clinical trials of non-pharmacological and pharmacological therapies seeking to demonstrate efficacy in the management of fibromyalgia:**
 - Visit: www.clinicaltrials.gov, Key Word Search: FIBROMYALGIA
- **For the latest in scientific literature on the management of fibromyalgia:**
 - Visit: <http://www.ncbi.nlm.nih.gov/sites/entrez/>
 - Key Word Search: MANAGEMENT OF FIBROMYALGIA
- **For information regarding approved drugs and their labeling:**
 - Visit: <http://www.emea.europa.eu/>
 - Visit: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

Other Useful Websites/Patient Information

- **National ME/FM Action Network:**
<http://www.mefmaction.net>

- **EULAR, APS...**

- **Patient Workbooks/Materials:**

- ***Fibromyalgia and Chronic Myofascial Pain: A Survival Manual (2nd Edition)***
by Devin J. Starlanyl and Mary Ellen Copeland
- ***The Chronic Illness Workbook: Strategies And Solutions for Taking Back Your Life*** by Patricia A. Fennell. Albany Health Management Publishing.
- ***Hope and Help for Chronic Fatigue Syndrome and Fibromyalgia*** by A.C. Bested & A.C. Logan. Cumberland House, Nashville, Tennessee.

Local Resources

- **[FACILITATORS TO INCLUDE LIST OF LOCAL FIBROMYALGIA RESOURCES FOR PATIENTS/PHYSICIANS]**

A Word About Disability...

- **Many insurers will not accept this diagnosis – the key is to focus on functional limitations when completing assessments**
- **Consistent, organized, clear documentation over time is powerful even in the absence of hard medical data**
- **Document:**
 - Objective clinical observations of appearance, behaviour, speech, self-care, grooming
 - Impairments of functioning, work, daily activities, socialization
 - Medications prescribed/tried
 - Pain levels, physiological distress
 - Use additional medical information from consultants
- **Avoid advocacy statements, personal statements and non-medical opinions**
- **Emphasize the presence of impairment of functioning over time**
 - **For more information see *Assessing Occupational Disability* by Dr. I Esche, University of Calgary at:**
<http://podcast.med.ucalgary.ca/groups/cfs/blog/>

Summary

- **Fibromyalgia occurs in all ages, both sexes and all cultures, but occurs more frequently in women of middle age**
- **Core defining features: chronic widespread pain, sleep disturbance, fatigue, neurocognitive impairment and stiffness**
- **Establishing the diagnosis of fibromyalgia is an essential component of successful management**
- **Fibromyalgia need not be progressive and can be managed successfully through early, individualized therapy and an optimistic approach by the physician**
- **Treatment includes non-pharmacological and pharmacological strategies**

Challenges Reviewed

