

## Fibromyalgia Disability: Is There Any Hope?

Gordon D. Ko, MD, CCFP(EM), FRCPC, FABPMR, FABPM

When fibromyalgia syndrome (FMS) is severe, and in some cases disabling, a multidisciplinary approach is needed, combining tailored non-pharmacological and pharmacological treatments to manage pain, secondary symptoms and functional restoration.<sup>1</sup> Ideally, the family physician, who usually has lengthy familiarity with the clinical and psychosocial aspects, should initiate this approach. Patients should be strongly encouraged to maintain as normal a lifestyle as possible, with every effort to continue in the work force. Once the patient stops working, reorientation back into the workforce becomes more difficult.

### *Non-pharmacological treatment*

Non-pharmacological treatment options should be considered for all patients. Strong evidence supports aerobic and strengthening exercise,<sup>2</sup> cognitive behavioural therapy (CBT), patient education, and multidisciplinary therapy. CBT provides worthwhile improvements in pain-related behaviour, self-efficacy, coping strategies, and overall physical functioning;<sup>3</sup> meta-analyses show strong evidence of efficacy.<sup>4</sup>

For those incapable of weight-bearing exercise, aquatherapy is a useful approach.<sup>5</sup> Water exercise improves both physical and emotional aspects of FMS.<sup>6</sup> There is moderate evidence for acupuncture, hypnotherapy, biofeedback, and balneotherapy (spa therapy). There is limited evidence for spinal manipulation, movement-body awareness, vitamins, herbs and dietary modification.<sup>7</sup>

### *Emerging hopeful treatments: case reports*

The Four-Component Theory, introduced by Dr. Dietrich Klinghardt, proposes an approach to find and treat the

root cause of symptoms in each of four areas: biochemical, neurological, psychological, and structural. This can lead to long-term remission or resolution of symptoms.

Case reports are summarized to illustrate this. More detailed descriptions are in the referenced publications.

### *Biochemical Case Report: Significant Improvement with Functional Medicine and Bioidentical Hormone Replacement Therapy (bHRT)*

A 58-year-old sign language instructor has an 11-year history of FMS and chronic fatigue syndrome (CFS). Her FMS risk factors include stress from family deaths: mother (aneurysm), father (multiple myeloma), and brother (lymphoma.); and a sister and niece with FMS. Medical history includes colon cancer surgery in 1999, IBS, partial hysterectomy in 1977, left knee arthroscopy in 1984, shingles (left T6-7, C2) in 2000, and bunions surgery in 2008. Medications include amlodipine, pravastatin, fluoxetine 20 mg q.h.s., lorazepam 4 mg q.h.s., and ibuprofen 9 per week p.r.n. The patient quit smoking 20 years ago. A sleep study showed moderate  $\alpha$ - $\delta$  non-REM abnormality. Previous treatments that were helpful included pool exercise and CBT. The patient stopped amitriptyline due to nausea and diarrhea. She has tried cortisone injections, gabapentin and tryptophan, and has declined pregabalin, duloxetine and tramadol.

### *Initial assessment on Dec 16, 2009*

Recorded outcome measures are listed in Table 1.

Labs 06/2009 (normal values in brackets):

- Normal CBC, liver & renal function, immunoelectrophoresis, CK, B12, ferritin, uric acid, fasting insulin and lumbosacral spine X-rays

- ↑ FSH/LH (due to menopause)
- ↓ 25(OH)vitD3: 64 (75-200 nmol/L)
- ↑ ESR: 33 (0-20)
- ↑ HS-CRP: 7.2

Initial treatment:

- VitaminD3 [Biotics] 3000 IU q.d.
- EPA-DHA ES [Metagenics] ii q.d. (to lower ESR, CRP)<sup>8</sup>
- Probiotics
- Coenzyme Q10 200 mg q.d.
- Physiotherapy
- Sacroiliac belt

*Follow-up Feb 17, 2010: Patient felt 40% improved*

Labs 03/2010:

- DHEA-S: 1.2 µmol/L (< 5.4)
- Cortisol a.m.: 496 nmol/ L (101-536)
- DHEA/cortisol ratio (x1000) = 2.4 (15-25)
- 25(OH)vitD3 improved to 100 nmol/L;
- TSH 2.48 mU/L (0.3-4.7)
- FT4 11.3 pmol/L (9.1-23.8)
- FT3 3.4 (2.5-5.7)
- Estradiol < 37 pmol/L (postmenopausal: 0-103)
- Estrone 118 pmol/L (pmp: 52-330)
- Progesterone 3 nmol/L (foll: 0-4; luteal: 4-51)
- Free testosterone: 6.1 pmol/L (< 14.2)

Prescribed bhRT:

- DHEA 1.25mg/0.2ml cream, 0.4ml q.a.m.; 0.2ml q.p.m.
- Progesterone 75 mg/1.25ml b.i.d.
- Estriol 1mg/0.1ml cream: 0.1ml vaginally 3 days per week
- Testosterone 1.25mg/0.1ml cream 0.1ml/ day
- Dessicated Thyroid 30mg q.a.m.

On April 21, 2010, the patient felt 70% improved. She reported “feeling the best in 11 years.” On Nov 17, 2010, the patient phoned in and reported 90% improved. Lorazepam dosage was decreased to 1 mg q.h.s. (Table 1).

Other FMS patients with a previous head injury may have low IGF-1 (somatomedin-C) levels that can be significantly improved with human growth hormone replacement therapy.<sup>9,10</sup>

*Psychological Case Report Summary: Resolution of “Fibrofog” Using EEG-Biofeedback “Neurotherapy”<sup>11</sup>*

A 48-year-old, married dog-breeder was involved in a motor vehicle accident in 1999 and suffered a closed head injury (concussion), whiplash and subsequent FMS. She was seen by psychotherapist Bob Gottfried PhD, in December 2002, complaining of “fibrofog” – problems with concentration, sleep and multi-tasking ability. Treatment involved CBT and neurotherapy (using audio and visual EEG biofeedback to retrain brain

Outcome Measure	NRS Pain	Back Depression	FIQ	SFM Pain	FMQ	Tender Points	Jamar Grip
Initial assessment 16-12/2009	6/10 Best 3 to Worst 9	17/54 lorazepam 4 mg q.h.s.	65.6/100	24/45	17/18	15/18	L: 19 lbs R: 30 lbs
After Supplements 17-2/2010	3/10	–	–	–	8/18	14/18	–
After Bioidentical Hormone Rx 21-04/2010	2/10 Stopped Ibuprofen	6/54 lorapezam 3 mg q.h.s.	32.4/100	18/45	8/18	11/18	L: 25 lbs R: 35 lbs

NRS = Numerical Rating Scale      FIQ = Fibromyalgia Impact Questionnaire  
SFM = Short-form McGill Pain Questionnaire      FMQ = Fibromyalgia Moldovsky Questionnaire

**Table 2**  
**Data from Psychological Case Report**

Outcome Measure	NRS Pain	Beck Anx	Beck Dep	PDQ	FSS	FIQ
Pre Rx	7/10	11/63	26/63	69/80	42/63	65/90
Post Rx	2/10	2/63	8/63	22/80	13/63	19/80

Beck Anx = Beck Anxiety Score    Beck Dep = Beck Depression Score  
PDQ = Perceived Deficits Questionnaire    FSS = Fatigue Severity Scale

function; see Figure 1). After 20 sessions, she reported: “I can laugh,” “I am awake again and feel as if I have been reborn,” and “No more fibrofog!” She returned back to full-time work (Table 2).

### *Structural Case Report Summary: Complete Resolution of Sacroiliac Joint Instability Post-Motor Vehicle Accident (MVA) with Platelet-Rich Plasma (PRP) Injections<sup>12</sup>*

A 45-year-old RN with pre-existing Ehlers-Danlos syndrome, FMS, and anterior L3-S1 spinal fusion for scoliosis (at age 19), developed new onset, disabling, left-sided, low back pain (unstable left sacroiliac joint) following an MVA on April 20, 2007. Tests were negative for any fracture or inflammatory disorder. She was unable to sit comfortably in her wheelchair or sleep without awakening with pain. She tried Tramacet, ibuprofen, acupuncture, heat, transcutaneous electrical nerve stimulation (TENS), physiotherapy and prolotherapy (with limited relief). Pregabalin reduced neuropathic pain of the left leg and back. Functional medicine (including 4 IV Myers’ infusions) helped with her fatigue. After one series of PRP sacroiliac ligament injections, she returned to her full pre-accident level of function (Table 3). She shared her experiences on national TV (CTS network show “On-the-Line,” August 27, 2010).

PRP works through platelet activation and release of growth factors that stimulate stem cell activity and ligament/tendon regeneration.<sup>13,14</sup> Evidence is also emerging

**Table 3**  
**Data from Structural Case Report**

Outcome Measures	Pre-treatment 16-10/2008	After PRP Rx on 07-07/2009	
		3-12/2009	23-03/2010
NRS Pain	6.5/10 (Best 6 to Worst 9)	3/10	0/10
SFM	34/45		0/45
Oswestry Back Pain Score	46/50		5/50
FMQ	14/18		5/18

regarding Botulinum Toxin-A (BTX-A) use in pain management. A previously published case series demonstrates efficacy when BTX-A is injected into muscles using a biomechanical approach (e.g., for neck-interscapular pain, targeting the tight pectoral muscles that cause anterior protracted shoulders and head forward posture).<sup>15</sup> BTX-A can be injected intradermally for neuropathic pain, and intra-articularly (along with Synvisc and Traumeel) for joint inflammation (Figures 2 and 3).<sup>16,17</sup> Long-term safety has been documented in our patients undergoing their 20th or more set of BTX-A injections.<sup>18</sup> Such treatments work best when combined with corrective physical therapy and exercises.

### *Applying RCT Evidence to Clinical Practice*

Clinical trials are necessary to identify efficacy for treatment intervention; however, they do not accurately reflect real-world clinical practice. Choosing patients for



Figure 1: Patient receiving EEG-biofeedback neurotherapy treatment




Figure 2: Ultrasound (Sonosite) guided Traumeel injection into scalene muscle



Figure 3: BTX-A injection into Pec minor muscle (Myoguide EMG guidance used in Cervical dystonia)

clinical trials is a highly selective process, those with severe co-morbidities are often excluded, and therefore they may not accurately reflect the true patient population. As well, most studies compare a single active agent to placebo, with almost no studies examining the effect of a combination of treatments. Most FMS-related clinical trials are of short duration, and in many instances, involve a relatively small number of patients. In addition, the high-dose regimens (*e.g.*, pregabalin, pramipexole) used in drug trials may not always be achieved in clinical practice due to problems with tolerability. Other trials of interventional pain approaches (acupuncture,

injections), are often negated due to a strong placebo response. FMS patients commonly report that they are hypersensitive and less tolerant to medications and injections; as a result, the “start low/go slow” approach is often required. 



**Dr. Ko** is Medical Director, Psychiatry Fibromyalgia Integrative Treatment Clinics at Sunnybrook Health Sciences Centre, University of Toronto, and the Canadian Centre for Integrative Medicine, Markham, Ontario; and Assistant Professor, Department of Medicine, University of Toronto, Toronto, Ontario

## Additional Comments and Take-Home Message

- None of the available medications and nutraceuticals for FMS have been demonstrated effective beyond one year of study
- Observance of continued benefit or the development of side effects for any treatment is required
- Depressive symptoms are common in FMS patients; SNRIs (*e.g.*, duloxetine) offer benefits for both mood and pain, and gabapentoids (*e.g.*, pregabalin) are effective for sleep problems and pain
- Although many patients require more than one pharmacologic-nutraceutical agent to treat symptoms, attention should be paid to the risk-benefit ratio and cost of polypharmacy
- Healthy lifestyle habits for FMS management include “TENSQ”: Toxin elimination (*e.g.*, smoking cessation), Exercise (stamina, strengthening, stretching), Nutrition, Sleep hygiene and Quiet time (spiritual purpose and gratitude journal)<sup>19</sup>
- The following tools are recommended:
  - FM Impact Questionnaire (FIQ): a disease-specific composite instrument that measures function and symptoms in FM patients. A recent analysis indicated that a 14% change in the FIQ total score is clinically relevant<sup>20</sup>
  - Pain diagram and region specific pain questionnaires (*e.g.*, the Oswestry for low back pain). We have found the Fibromyalgia Moldofsky Questionnaire to be a useful screening tool (to be validated and published)
  - Objective measures (*e.g.*, algometry of tender points) are needed in medicolegal third-party cases, but are not routinely used in clinical practice. Future tools include Quantitative Sensory Testing and the Nociceptive Flexion Reflex<sup>21</sup>
- Emerging FMS treatments, including BTX-A and PRP injections, are based on clinicians’ experience and patients’ preference and tolerability, rather than on evidence from clinical trials. Treating the spectrum of symptoms that may be present in an individual patient is vital to successful management and improvement in well-being
- For the FMS patient, validation of their condition by the family physician is a crucial first step. Asking “**What worries you the most about your symptoms?**” will draw out underlying concerns that need to be addressed and help the clinician discern any secondary gain issues
- The Four Component paradigm is a useful model to delineate root causes of FMS symptoms. Asking “**What specifically happened at the very onset of symptoms?**” is an important step in detecting such causes (*e.g.*, structural ligamentous laxity, biochemical hormonal-nutritional deficiencies, psychoemotional stress, neurological HPA-axis dysfunction). Innovative therapies based on those causes require further research in certain patient subgroups<sup>22</sup>

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