Fibromyalgia/Chronic Pain Syndrome:  
An Alternative Medicine Perspective

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ABSTRACT: Purposes: To review the current literature on pain management in fibromyalgia (FMS) including complementary alternative medicine (CAM) use and to report on treatment and rehabilitation strategies. Methods: A literature review of MEDLINE and EMBASE for published randomized controlled trials for FMS pain treatment was carried out. This was critiqued with the Jadad criteria for quality trials in the chronic pain population. Clinical experience in treating and following such patients over the last 20 years is discussed. Results: Most published studies are of low quality. We report case studies of patients who significantly improved with specific CAM therapies, indicating the need for future research in these areas. Conclusion: Studies suggest that FMS patients may be effectively managed for pain with Botulinum toxin A injections with an integrative rehabilitation approach. This needs to be confirmed with large randomized controlled trials.

KEY WORDS: fibromyalgia, chronic pain syndrome, myofascial trigger point, low back pain, migraine, botulinum toxin A, prolotherapy, neurotherapy, naturopathy, alternative medicine

I. INTRODUCTION

“Complementary and Alternative Medicine” refers to treatments that are “generally not used or recommended within the context of mainstream biomedical community.” Over the last few decades, there has been an ever-growing demand for Complementary and Alternative Medicine (“CAM”). A recent report released by the National Center for Complementary and Alternative Medicine (National Institute of Health) found that 62% of 31,044 adults interviewed had used some form of CAM therapy in the year 2002. A random telephone survey of 2055 adults by Eisenberg et al revealed that 42.1% of adults in 1997 had used CAM during the previous year. This is an increase from 33.8% of adults in an earlier 1990 study. Estimated expenditures for such services reveal a 45.2% increase to $21.2 billion in 1997. The total out-of-pocket expenditures for CAM, including costs of herbal therapies, megavitamins, diet products, and CAM literature and equipment was conservatively estimated to be $27.0 billion.

In the physiatric-managed population, a survey of 401 working-age individuals with physical disabilities revealed that 57.1% used at least one CAM in the last year. A lower percentage of 29.1% of rehabilitation outpatients reported such usage during the last year.

Another survey of 1035 adults in the United States noted 40% used CAM and identified predictors of CAM use as being greater education,
poorer health status, an holistic orientation to health, and cultural factors. Dissatisfaction with conventional medicine was not predictive of CAM use.7 Similar findings were noted in a study of 1081 elderly Canadians, with 41.2% (of those without cognitive loss) using CAM.8

From these surveys (Astin, Barnes, Eisenberg),2,3,7 it was concluded that women were more likely than men to use CAM. When prayer specifically for health reasons is excluded from the definition of CAM, the highest use was noted in the middle-aged (baby boomers). The highest CAM use was by patients with musculoskeletal problems and arthritis. The highest condition-specific rates were for neck (57.0%) and back (47.6%) problems. These are conditions commonly seen in physiatric practice.

One group usually seen with neck and back pain (and, predominantly, middle-aged female) are the fibromyalgia patients.

II. FIBROMYALGIA OVERVIEW

By the American College of Rheumatology (ACR) definition, fibromyalgia is a syndrome of widespread muscle pain (over 3 months) and stiffness, with 11 or more characteristic tender points on palpation.9 It affects 2% of the population, predominantly females, with the most common age at presentation of 40 to 50 years.10 Symptoms in the fibromyalgia syndrome (FMS) include (1) musculoskeletal complaints: “hurt all over,” stiffness, swollen feeling in tissues; (2) nonmusculoskeletal: fatigue, poor sleep, paresthesia; and (3) associated syndromes such as irritable bowel (IBS) (41.8% of FMS patients),11 dysmenorrhea,12 female urethral syndrome,13 endometriosis,14 noncardiac chest pain,15 plantar heel pain,16 migraine headache (45%),17 temporomandibular joint pain,18 sinusitis,19 and Sjögren’s syndrome.20 A higher incidence of carpal tunnel syndrome (14.1%)21 and Raynaud’s syndrome (38%)22 may explain some of the paresthesia complaints.

Higher anxiety and depression have also been reported.23 24 Postulated risk factors for the development of FMS include a family history of this condition,25 a family history of depression and/or alcoholism in first degree relatives,26 childhood physical and sexual abuse, eating disorders and drug abuse,27,28 and hypermobile joint syndrome.29 FMS has also been documented after physical trauma30,31 and whiplash,32 but the causal relationship has not been established in a consensus report on FMS and disability.33 Physical trauma perception is associated with greater disability compensation, and emotional trauma is related to greater functional disability ratings and a higher number of physician visits.34 A review on psychosocial aspects concluded that the view that FMS is caused by stress or abuse is unproven and that there is no evidence that communicating such a diagnosis causes iatrogenic consequences.35

It has been postulated that viral infections may play an etiologic role.36 Seventy percent of FMS patients meet the Centers for Disease Control and Prevention criteria for chronic fatigue syndrome (CFS)37 and 70% of CFS patients meet the ACR criteria for FMS.38 The usual routine laboratory tests, such as basic hematology, ESR, muscle enzymes, rheumatoid factor, and ANA, are all normal.39 CFS researchers suggest that deregulation of the 2.5A synthetase Rnase L antiviral pathway may be the pathophysiological reason.40

Muscle biopsy41 and MRI spectroscopy 42 studies have proven to be nondiagnostic. More recent electron microscopy suggests ultrastructural changes including increased DNA fragmentation (possibly due to persistent focal muscle contractions).43 Sleep study findings are abnormal44 but also are not necessarily specific or unique to FMS.45–47 Reduced growth hormone secretion48 and elevated CSF substance P,49 homocysteine,50 and nerve growth factor levels,51 as well as abnormal neuroendocrine challenge tests,52–54 suggest a central pain mechanism, but no reliable diagnostic test has yet to be established. More recent research demonstrates abnormalities on functional MRI imaging studies55–58 and MRI spectroscopy of paravertebral muscles.59

The economic impact of this syndrome is significant. Chronic musculoskeletal pain is the #1 cause of disability in North America, the #2 cause for visits to the primary care physician and the #3 cause for hospitalizations, with over 250,000 spinal fusions carried out in the United States. It is estimated that the direct medical cost of FMS to the U.S. economy is in excess of $16 billion annually.60 The net cost in Canada in 1993 was estimated to exceed $700 million.61 Despite such
costs, effective long-term treatment remains elusive. The most studied medications to date are the tricyclic derivatives, such as amitriptyline and cyclobenzaprine. Randomized trials (RCT) of these and other treatments as outlined in Table 1 below only show short-term improvement in symptoms. Only the most recent or most comprehensive RCTs are referenced.

FMS patients are high consumers of non-physician and alternative medical interventions. One study comparing those using such services found no differences in level of pain and functional impairment. Another study of 111 FMS subjects found that 98% had used at least one complementary medical strategy in the preceding 6 months and that such use was correlated with lower age, higher pain, and higher disability. Use of complementary therapies was seen in patients of a higher socioeconomic status and a longer duration of fibromyalgia. The most popular therapy was oral supplementation and the most popular source of advice was from magazines (40%).

In September, 2003, Researchers at The University of Toronto conducted a survey of CAM in a community education session attended by 72 FMS participants and found the following:

Most common products tried:
1. Topical rubs–66.7%
2. Sleeping pills–66.7%
3. TENS unit–66.7%
4. Braces, orthotics–58.3%
5. Diets–54.2%
6. Over-the-counter oral medications–54.2%
7. Glucosamine, herbs, megavitamins–50%

Magnets were tried by 37.5%, and opioids were used by 41.7%.

Most common CAM therapist/practitioner seen:
1. Massage–75%
2. Meditation/relaxation–70.8%
3. Acupuncture–70.8%
4. Chiropractic–58.3%
5. Homeopathy/naturopathy–41.7%
6. Spiritual healing/prayer–37.5%

### TABLE 1
**Medications Effective for Pain in FMS**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline (10–50 mg effective for first 2 months, but not significant compared to placebo at 6 months)</td>
<td>Effects may be augmented with the addition of Fluoxetine.</td>
</tr>
<tr>
<td>Cyclobenzaprine (10 mg qhs as effective as 10 mg tid but with less side effects)</td>
<td>Combined with ibuprofen is helpful for morning stiffness</td>
</tr>
<tr>
<td>Dothiepin (tricyclic similar to amitriptyline)</td>
<td></td>
</tr>
<tr>
<td>Human growth hormone</td>
<td>(9-month study of 50 FMS females with low IGF-1 levels)</td>
</tr>
<tr>
<td>Ketamine</td>
<td>(0.3 mg/kg i.v. drip in prescreened responders)</td>
</tr>
<tr>
<td>Lignocaine i.v. drip</td>
<td></td>
</tr>
<tr>
<td>Milnacipran (norepinephrine serotonin reuptake inhibitor)</td>
<td></td>
</tr>
<tr>
<td>Odansetron (a 5-Hydroxytryptamine type 3 receptor antagonist)</td>
<td></td>
</tr>
<tr>
<td>Paroxetine (uncontrolled study)</td>
<td></td>
</tr>
<tr>
<td>SER282 (antiidienccephalal immunne serum)</td>
<td>(antidiencephalal immunne serum)</td>
</tr>
<tr>
<td>Sodium Oxybate (commercial form of gammahydroxybutyrate)</td>
<td></td>
</tr>
<tr>
<td>Somadril (carisoprodol, paracetamol, caffeine)</td>
<td></td>
</tr>
<tr>
<td>Tizanidine (Zanaflex)</td>
<td></td>
</tr>
<tr>
<td>Topical camphor, methyl salicylate, menthol lotion (uncontrolled study for a duration of 20 minutes)</td>
<td></td>
</tr>
<tr>
<td>Topical capsaicin (35% of neck pain group with FMS)</td>
<td></td>
</tr>
<tr>
<td>Tramadol (i.v. drip, single-dose treatment; 12 patients with 20.6% reduction in VAS pain)</td>
<td></td>
</tr>
<tr>
<td>Tropisetron (5-HT3 receptor antagonist)</td>
<td></td>
</tr>
<tr>
<td>Tryptophan (5 hydroxytryptophan 100 mg tid)</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** One recent review on pharmacological therapies concluded that the best supported medications to date are the low-dose tricyclic antidepressants, but that the benefits are short-term and have not been shown to be superior to placebo at 6 months of study.
The next most used therapies were craniosacral therapy, osteopathy, reflexology, hypnosis. These findings were similar to the general population survey by Eisenberg that rated the 5 most common CAM: relaxation, herbals, massage, chiropractic and spiritual healing.3

Further clinical trials are reported in Tables 3A–3D.

In our survey of 116 physiatrists (rehabilitation medicine specialists) in Ontario, Canada, 55% of respondents agreed that FMS is a "real disabling condition." When asked what type of alternative therapy works, 14 different types were mentioned, with the top three being acupuncture, biofeedback, and chiropractic.119

### TABLE 2
Medications: Published Trials Found To Be Not Effective for FMS Pain

<table>
<thead>
<tr>
<th>Medication</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen (paracetamol)</td>
<td>74</td>
</tr>
<tr>
<td>Calcitonin</td>
<td>223</td>
</tr>
<tr>
<td>Chloromezalone</td>
<td>224</td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>225</td>
</tr>
<tr>
<td>Imipramine</td>
<td>226</td>
</tr>
<tr>
<td>Lidocaine (4% injected as sphenopalatine nerve block)</td>
<td>227</td>
</tr>
<tr>
<td>Lidocaine (i.v. 5 mg/kg), morphine (i.v. 0.3mg/kg)</td>
<td>228</td>
</tr>
<tr>
<td>Moclobemide</td>
<td>229</td>
</tr>
<tr>
<td>NSAIDs: Ibuprofen (ibuprofen + alprazolam did reduce tender-point index (TPI) but not dolorimetry)</td>
<td>231</td>
</tr>
<tr>
<td>Naproxen 500 mg bid</td>
<td>232</td>
</tr>
<tr>
<td>Tenoxicam + bromazepan</td>
<td>233</td>
</tr>
<tr>
<td>Prednisone 15 mg per day (most variables deteriorated)</td>
<td>234</td>
</tr>
<tr>
<td>Ritalser (a 5-HT2 receptor blocker)</td>
<td>235</td>
</tr>
<tr>
<td>SSRLs: Citalopram</td>
<td>236</td>
</tr>
<tr>
<td>Fluoxetine (was helpful for sleep and depression but not pain at 6 weeks)</td>
<td>237</td>
</tr>
<tr>
<td>Zolpidem</td>
<td>238</td>
</tr>
<tr>
<td>Zopiclone</td>
<td>239</td>
</tr>
</tbody>
</table>

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### TABLE 3A
Physical Therapies Helpful for FMS Pain

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic exercise (when combined with flexibility and strength training is superior to relaxation)</td>
<td>66–69</td>
</tr>
<tr>
<td>Pool exercise</td>
<td>71,72</td>
</tr>
<tr>
<td>Hydrotherapy</td>
<td>73–75</td>
</tr>
<tr>
<td>Laser therapy</td>
<td>76,77</td>
</tr>
<tr>
<td>Strengthening exercise</td>
<td>78,79</td>
</tr>
<tr>
<td>TENS (uncontrolled study)</td>
<td>80</td>
</tr>
</tbody>
</table>

By contrast, laser therapy was rated higher at 3.3. The next most used therapies were craniosacral therapy, osteopathy, reflexology, hypnosis. These findings were similar to the general population survey by Eisenberg that rated the 5 most common CAM: relaxation, herbals, massage, chiropractic and spiritual healing.3

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### TABLE 3B
Physical Therapies Not Reported Helpful

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser</td>
<td>81</td>
</tr>
<tr>
<td>Shape-of-sleep pillow</td>
<td>82</td>
</tr>
<tr>
<td>Visible electromagnetic fields</td>
<td>83</td>
</tr>
</tbody>
</table>

Note: Exposure to cold tends to aggravate pain in FMS.84,85 One published RCT study found clinical effectiveness of ceramic-impregnated garments for Raynaud’s (which is experienced by 1/3 of FMS patients). A similar study has recently been completed for FMS patients.

### TABLE 3C
Psychological Therapies

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive–behavioral therapy</td>
<td>87,88</td>
</tr>
<tr>
<td>Group therapy, including relaxation and cognitive–behavioral training</td>
<td>89</td>
</tr>
<tr>
<td>Hypnotherapy</td>
<td>90</td>
</tr>
<tr>
<td>Meditation-based stress reduction program</td>
<td>91</td>
</tr>
</tbody>
</table>

In contrast, a survey104 of FMS patients reported different levels of effectiveness. They rated the CAM therapy effectiveness on a 5-point Likert-type scale:

- 2 markedly worse
- 1 mildly worse
- 0 no change
+ 1 mildly better
+ 2 markedly better

Most effective CAM treatment used by at least 20% of surveyees (avg. score from Likert-type scale ratings):

1. Botulinum toxin A (Botox) injections (1.6)
2. Osteopathy/craniosacral therapy (1.4)
3. Massage (1.3)
4. Spiritual healing/intercessory prayer (1.3)
5. Meditation/relaxation (1.2)
6. Reflexology, herbals (1.1)

In contrast, medications were rated lower: over-the-counter drugs (0.5), topical rubs (0.7), sleeping pills (0.9), opioids (0.9). Common CAM therapies rated lower included acupuncture (0.5), chiropractic (0.3), glucosamine (0.25), and magnets (0.1).
TABLE 3D
Alternative Medicine Treatments with Positive Clinical Trials

Biochemical
- DHEA supplementation
- Dietary indole supplementation (ascorbigen and broccoli powder)
- Dietary supplementation of coenzyme Q10, combined with Ginkgo biloba extract
- Homeopathy
- Multimodality approach, including nutrition and hormone replacement
- SAMe i.v., p.o. (improved VAS pain, not TPI, during last week of 6-week study)
- Super Malic (malic acid 200 mg and magnesium 50 mg: 6 tablets bid)
- Topical 024 essential oils
- Vegan diet

Electromagnetic (autonomic nervous system)
- Acupuncture
- Copper wire bedsheets
- Cranial electrotherapy stimulation
- Static electromagnetic fields
- Thermoflow ceramic-impregnated garments

Psychoemotional
- Biofeedback–relaxation (combined with exercise, best across 2 years)
- Biofeedback–EMG
- EEG-driven
- Mind–body therapies

Structural
- Chiropractic therapy (4 weeks of spinal manipulation, soft tissue therapy, passive stretching)
- Osteopathy
- Prolotherapy (75% pain improvement; unblinded study)

One proposed theory for such therapies relieving pain is by resolving muscle “trigger points” (TrP). It is important to distinguish trigger points from FMS “tender points” (TeP). The criteria for TrP are listed in Table 4.

III. OVERVIEW OF BOTULINUM TOXIN-A FOR PAIN

It has been reported that 72% of FMS patients have myofascial TrPs. Tender points do not usually respond to injections of local anesthetic, but trigger points in FMS do. Current theories as to the pathophysiology of myofascial TrP include the dysfunctional motor endplate where excessive acetylcholine is released. Botox is effective for muscle pain/spasticity through its prolonged blockade of acetylcholine. The active moiety, a 150-kDa protein, is the most potent of 7 neurotoxins produced by the Gram positive anaerobic rod-shaped bacteria *Clostridium botulinum*. When injected into muscle, Botox is taken up at the endplate. Its heavy chain attaches it to the presynaptic membrane. After endocytosis, the disulphide bond is broken, allowing the light chain to move to the presynaptic terminal. There

TABLE 4
Trigger Points and Myofascial Pain Syndrome Criteria

<table>
<thead>
<tr>
<th>Major criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain localized to region, usually unilateral, asymmetric tenderness</td>
</tr>
<tr>
<td>Taut band is palpable</td>
</tr>
<tr>
<td>Pain in known referred zone</td>
</tr>
<tr>
<td>Exquisite spot tenderness</td>
</tr>
<tr>
<td>Restricted range of motion due to tight muscle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minor criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproduction of pain/altered sensation by pressure on TrP</td>
</tr>
<tr>
<td>Local twitch response on snapping the taut band</td>
</tr>
<tr>
<td>Pain alleviated by stretching muscle or by injecting TrP</td>
</tr>
<tr>
<td>Diagnosis requires all the major criteria and at least one minor criteria.</td>
</tr>
</tbody>
</table>
it binds to 25-kDa synaptosome-associated protein (SNAP-25), which inhibits the calcium-activated release of acetylcholine. The onset of muscle relaxation occurs around 3 days, with a peak effect around 3 to 4 weeks and an average duration of 3 months. A unit of Botox is defined as the LD50 for a 20-gm Swiss-Webster mouse. (Extrapolated to the 70-kg human, the lethal dose would be about 2700 units). The recommended maximum dose at one treatment is 400 units. Doses are spaced out over 3 months to minimize the risk of developing antibodies that would prevent Botox from working. Reported side effects include flu-like illness (rare), which may last a few days to weeks. Muscle soreness and stiffness may last 1 to 2 weeks. Inadvertent weakness depends on the injection site/dose (eg, eyelid ptosis, swallowing difficulty) and usually lasts 2 to 3 weeks. Endplate targeted injections (with EMG guidance) appear to be more effective than anatomical approaches.125 Botox should be stored in the freezer or refrigerator and reconstituted with preservative-free normal saline. It loses potency (35%) when stored (in saline) after 1 week and 44% after 2 weeks.126

A. Typical Examples of Treatment Procedures Using Botox

Patient Profile #1

A 33-year-old married, disabled customer service worker had widespread pain and right sciatica for 5 years. Chronic pain risk factors included childhood sexual abuse, major depressive disorder, panic disorder, agoraphobia; abnormal sleep EEG (restless legs, alpha-delta intrusion); slip and fall trauma (Oct., 1988); and car accident (Jan., 1998) (with a 2-week hospitalization), subsequent home care, and wheelchair use.

Previous treatments included physiotherapy, chiropractic, massage, laser, Chan-Gunn acupuncture, hydrotherapy, podiatry orthotics, psychotherapy. Medications included oxycontin, cyclobenzaprine, relafen, gabapentin, rivotril, stadol, imovane. No response to epidural corticosteroids (CT scan: L5-S1 bulging disc, but EMG study was normal) or facet joint injections/nerve blocks.

Preinjection findings: (15-03/00) 5’10” 320 lbs—obese

\[18/18 \text{ TeP (3+)}, \text{ with Fischer algometry scores all } <2 \text{ kg}\]
• Visual analogue scale (VAS) for pain: 10/10
• Fibromyalgia impact questionnaire (FIQ): 69.4/90
• Revised Oswestry (OSW): 23/50
• Short-form McGill pain questionnaire (SFMcGill): 37/45

Initial procaine injections were into muscle trigger points: trapezi, scalene anticus, right T11 erector spinae, right piriformis. Postinjection pain diary recorded short-term improvement.

Botox injections (03-04/00): 200 units spread out over: R piriformis (3½” 22-gauge needle), R erector spinae, both upper trapezi. Injections done with EMG guidance.


• She reported for the first time in years that she was able to walk several blocks, make beds without help, do laundry, dishes, and most yard work. She joined weight-watchers.
• (08/00): After 2nd series Botox (400 units), she weaned off oxycontin and NSAIDs completely.
• (11/00): After 3rd series, Botox (400 units), she had lost 34 lbs. and began vocational retraining.

Further injections were carried out in 04/01 (300 units), 10/01 (250 units), 02/02 (200 units). She improved to the point where she could exercise regularly, lose weight (down to 258 lbs), and work part-time. After 2 years, she returned in Feb 2004 and had 200 units of Botox administered to recurrent trigger points in the left levator scapulae and pectoralis minor muscles, right gluteal area. She returned on March 28, 2005, to have more Botox injections, which she continued to rate as extremely helpful.

Patient Profile #2

A 47-year-old female store owner was diagnosed with migraines, FMS, and CFS after fumigation gas exposure (1989). Past history: hypothyroidism,
childhood growing pains, and tailbone fracture. Previous treatments included numerous medical specialists. Normal MRI and SPECT scans of head. Treated with amitriptyline, NSAIDs, SSRIs, and tryptophan. No headache relief with imitrex, sandomigran, opioids. Tried hydrotherapy, psychotherapy, and alternative medicines (dental amalgam removal, intravenous heavy metals chelation, “neural therapy injections”).

Preinjection findings (01/00): 5’8” 145 lbs. BP 100/70 mmHg. Wore dark sunglasses.

- Severe (3x/month) left-sided classical migraines and constant daily tension headaches.
- VAS for headache: 7.5/10; FIQ: 70/90; 18/18 TeP (2-3+).

Botox injections (09/00): Silberstein headache protocol (25 units) + upper trapezii (37.5 units each).

Postinjection (11/00): Reported (first time in 11 years) being completely headache-free for 3 weeks.

- VAS: 7/10; FIQ: 63.5/90; 18/18 TeP.
- (02/01) After 2nd Botox (200 units): VAS: 0/10. FIQ: 53/90.

She subsequently moved out-of-town and was lost to further follow-up.

Patient Profile #3


Initial examination (06/00): 5’4”, 114 lbs. No anemia or jaundice. BP134/99 mmHg.

- Pain Disability Index (PDI): 30/70. 18/18 4+ TeP (1-1.5kg.)
- Treated with hydrotherapy, gabapentin (slowly up to 2400 mg/day). Weaned off codeine, bellergal.

- (09/00): better appetite and weight: 119 lbs.
- VAS: 4/10. SFM McGill: 13/45. PDI: 18/70. 18/18 2+ TeP.

Botox injections (12/00): 25 units for headache + supraorbital nerve blocks. 75 units: upper trapezii + splenii cervicis

Postinjection (01/01): Described “an excellent response.” Headaches resolved.


Returned in March for 300 units and has subsequently had 8 more Botox injections (enabling her to continue fulltime work).

Patient Profile #4

A 45-year-old right-handed psychiatrist, while lost hiking (carrying 5-year-old daughter and 15-lb infant), developed bilateral arm pain and numbness. After 1.5 years of unsuccessful physiotherapy, craniosacral osteopathy, acupuncture, NSAIDs, and cortisone injections, he was referred with “medial epicondylitis, thoracic outlet syndrome (TOS), FMS.” Past health included migraine, anxiety, IBS. Family history included alcoholism, thyroid disease, lung cancer and polio (2 siblings).

Initial examination (12/99): 5’10”, 155 lbs.

- BP 110/70 mmHg (both arms).
- Tender epicondyles with positive Cozen’s sign. 1-2+ 12/18 TeP. Normal motor, sensory, reflex testing. Positive left brachial plexus tension, adson’s and allen’s tests (using portable doppler). No subclavian bruit.
- Jamar grip strength—left: 75 lbs, right: 95 lbs.
- Normal investigations included (1) nerve conductions of median, ulnar (including F-wave), medial antebraclial cutaneous motor/sensory nerves, and needle EMG of left arm myotomes; (2) bloodwork; (3) ultrasound of elbows.

Arm doppler photoplethysmography confirmed vasculogenic TOS: severely decreased amplitudes
bilateral with 180° hyperabduction and moderate with left costoclavicular and Adson’s tests. No thrombus noted on color duplex imaging.

- Subsequent therapy (spray-and-stretch, EMG biofeedback, home exercises) alleviated right arm pain.
- A persistent left scalene medius TrP was then injected with 1% procaine. His pain diary recorded VAS 4/10 down to 1/10 for a few hours. Pain was back to 4/10 by the morning. (Figs. 1 and 2)

Further injections, combined with therapy, provided 1 to 2 weeks relief only.

EMG guided injection with 35 units of Botox (15-11/00) was done next, followed by electromuscular stimulation (Childers’ protocol).

One month post-Botox: VAS: 1/10. PDI: 5/70. Left grip: 100 lbs. 1+ 5/18 TeP.

At 3 months, he described his left arm as being 90% improved with Botox. A second injection (24-03/01) with 50 units Botox resulted in 95% improvement. A year later, he returned for trigger point lidocaine injections.

---

**FIGURE 1.** Case study #4. Peripheral Doppler studies demonstrated Thoracic outlet compression on the left, implicating scalene/pectoral tightness.
into the trapezi. He returned on 23-04/04 for consultation on a right rotator cuff tendonitis and reported no ongoing TOS symptoms with daily stretching.

**Patient Profile #5**

46-year-old single mother of one and registered nurse had a pituitary brain tumor excised in 1988. She was placed on hormone replacement therapies, gained 176 lbs in one year and developed widespread tenderpoints. She underwent her first Botox treatment in January, 2002, and her seventh in April, 2004. She reported that with Botox she can work full-time, walk upstairs, sleep better, and is more able to garden and do housework. She noted less fatigue, irritability (with her teenage son), depression, and social withdrawal (Fig. 3 and statistics below [Table 6]).

**Patient Profile #6**

A 53-year-old woman had post-traumatic head/upper facial pain after a car accident in 1989. CT/MRI scans were normal. Over the subsequent 10 years, she had 12 surgical procedures, including open C2 ganglionectomy, cervical facet rhizolyses—3 times, C2 neurotomy (dorsal ramus medial branch), right temporal artery excision, bilateral supraorbital nerve resections, and percutaneous microballoon compression of the gasserian ganglion.

Despite palliative nerve blocks from the referring anesthesiologist, she still complained of daily bifrontal headaches radiating to the upper shoulders and dorsal neck. Topamax was added to medications which included Paxil, Oxycontin, Stemetil, Amitriptyline, Ibuprofen, Losec.

Physical examination revealed hypoesthesia in the forehead and C2 distribution. Tenderness was most noted on the upper trapezii, frontalis and paracervical muscles. She had 18/18 tender points and fit the ACR criteria for FMS.

Botox injections administered to the peri-cranial (frontalis, corrugator, procerus, temporalis) and trapezi muscles showed good response, supported by outcome measures and surface EMG recordings (see Table 5).

Her FIQ score before Botox was 51.4/90. One month after her 10th injection set (Jan., 2004), the FIQ was down to 14.8/90. With
Table 5

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Preinjection</th>
<th>One month post-3rd injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual analogue scale pain</td>
<td>7/10</td>
<td>4/10</td>
</tr>
<tr>
<td>Headache Disability Index</td>
<td>92/100</td>
<td>84/100</td>
</tr>
<tr>
<td>Headache Impact Test</td>
<td>68/78</td>
<td>58/78</td>
</tr>
<tr>
<td>Vernon-Mior Questionnaire</td>
<td>33/50</td>
<td>28/50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surface EMG RMS amplitudes (µV):</th>
<th>Left</th>
<th>Right</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frontalis</td>
<td>2.24</td>
<td>3.99</td>
<td>1.44</td>
<td>0.96</td>
</tr>
<tr>
<td>Sitting at rest</td>
<td>6.97</td>
<td>4.54</td>
<td>1.51</td>
<td>0.98</td>
</tr>
<tr>
<td>Cervical lateral flex</td>
<td>6.84</td>
<td>6.73</td>
<td>1.90</td>
<td>1.34</td>
</tr>
<tr>
<td>Cervical rotation</td>
<td>15.07</td>
<td>5.47</td>
<td>5.20</td>
<td>2.24</td>
</tr>
<tr>
<td>Trapezius</td>
<td>5.36</td>
<td>4.12</td>
<td>2.44</td>
<td>3.10</td>
</tr>
<tr>
<td>Standing at rest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cervical rotation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Botox, she reported that she can go shopping and carry 10 lbs (milk, potatoes), do laundry, dishwash, and stand one hour to cook. Her husband observed that she can do ironing without complaining of pain. Further injections have been carried out every 3 months for 11 sessions to date without any significant complications. She estimates it alleviates pain by 75% and is able to reduce her Oxycontin (Fig. 4).

Table 6 is a case series of recent fibromyalgia patients who had repeat Botox injections. Prior to these injections, all patients had gone through extensive courses of traditional medications and physiotherapy and had tried numerous CAM therapies. Those with failed surgery syndromes (for pain) are marked “/H7001”, and those with pain after motor vehicle accidents are marked “mva.” Further information on these patients is posted at

### TABLE 6
Case Series of 25 Fibromyalgia Patients

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age/sex</th>
<th>Occupation</th>
<th># of Botox injections</th>
<th>First injection (d/mo/yr)</th>
<th>Latest injection (d/mo/yr)</th>
<th>Scores before Botox FIQ &amp; VAS pain</th>
<th>Scores 4–6 weeks after last Botox</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. BM</td>
<td>45/F</td>
<td>Material Handler</td>
<td>12</td>
<td>11/12/00 100 units</td>
<td>04/02/04 300 units</td>
<td>81.6/100 8/10</td>
<td>50.2/100 4/10</td>
</tr>
<tr>
<td>2. AS: details in case #1.</td>
<td>39/F</td>
<td>Personal Support Worker</td>
<td>7</td>
<td>03/04/00 200 units</td>
<td>24/02/04 200 units (after 2 yr gap)</td>
<td>69.4/90 10/10</td>
<td>11.3/90 4/10</td>
</tr>
<tr>
<td>3. LL mva</td>
<td>30/F</td>
<td>Asst. Crown Attorney</td>
<td>4</td>
<td>04/02/03 100 units</td>
<td>18/11/03 400 units</td>
<td>79.2/100 10/10</td>
<td>56.5/100 4/10</td>
</tr>
<tr>
<td>4. CL details in case #5.</td>
<td>44/F</td>
<td>ICU Nurse</td>
<td>8</td>
<td>21/01/02 100 units</td>
<td>20/04/04 500 units</td>
<td>89/100 7/10</td>
<td>44.3/100 4/10</td>
</tr>
<tr>
<td>5. SL mva</td>
<td>47/F</td>
<td>Chiropractor</td>
<td>3</td>
<td>04/02/03 50 units</td>
<td>20/04/04 100 units</td>
<td>46.4/100 3/10</td>
<td>13.7/100 1/10</td>
</tr>
<tr>
<td>6. LM</td>
<td>66/F</td>
<td>Legal secretary</td>
<td>6</td>
<td>30/09/02 100 units</td>
<td>06/04/04 200 units</td>
<td>84.7/100 10/10</td>
<td>17.1/100 2/10</td>
</tr>
<tr>
<td>7. CV</td>
<td>39/F</td>
<td>Part-time clerical</td>
<td>8</td>
<td>08/04/03 100 units</td>
<td>27/04/04 500 units</td>
<td>83.2/100 10/10</td>
<td>68.7/100 4/10</td>
</tr>
<tr>
<td>8. LB</td>
<td>50/F</td>
<td>Homemaker</td>
<td>4</td>
<td>31/07/03 200 units</td>
<td>27/04/04 300 units</td>
<td>72.7/80 8/10</td>
<td>51.4/80 4/10</td>
</tr>
<tr>
<td>9. JB Crohn’s</td>
<td>47/F</td>
<td>Banker</td>
<td>4</td>
<td>07/07/03 300 units</td>
<td>20/04/04 400 units</td>
<td>78.1/90 10/10</td>
<td>55.8/90 5/10</td>
</tr>
<tr>
<td>10. BG</td>
<td>51/F</td>
<td>Banker</td>
<td>3</td>
<td>28/05/01 100 units</td>
<td>29/10/03 (after 2 yr gap) 200 units</td>
<td>57.5/100 8/10</td>
<td>22/100 4/10</td>
</tr>
<tr>
<td>11. LB</td>
<td>35/F</td>
<td>Public Health Clerk</td>
<td>5</td>
<td>25/02/03 100 units</td>
<td>20/04/04 500 units</td>
<td>82.9/100 7/10</td>
<td>18.5/100 3/10</td>
</tr>
<tr>
<td>12. PF</td>
<td>31/F</td>
<td>Office Worker</td>
<td>4</td>
<td>10/03/03 100 units</td>
<td>17/09/03 200 units</td>
<td>66.2/100 8/10</td>
<td>41.8/100 4/10</td>
</tr>
<tr>
<td>13. SMP</td>
<td>44/F</td>
<td>French Tutor</td>
<td>2</td>
<td>27/05/03 100 units</td>
<td>28/10/03 100 units</td>
<td>21/45* 6.5/10</td>
<td>11/45* 2/10</td>
</tr>
<tr>
<td>14. BN</td>
<td>49/F</td>
<td>Nurse</td>
<td>4</td>
<td>24/10/02 100 units</td>
<td>26/08/03 300 units</td>
<td>27/45* 6/10</td>
<td>21/45* 4/10</td>
</tr>
<tr>
<td>No.</td>
<td>Name</td>
<td>Gender</td>
<td>Occupation</td>
<td>Case Number</td>
<td>Start Date</td>
<td>End Date</td>
<td>Dose 1</td>
</tr>
<tr>
<td>-----</td>
<td>------</td>
<td>--------</td>
<td>------------</td>
<td>-------------</td>
<td>------------</td>
<td>----------</td>
<td>--------</td>
</tr>
<tr>
<td>15</td>
<td>CA</td>
<td>53/F</td>
<td>Homemaker</td>
<td>5</td>
<td>25/02/03</td>
<td>25/05/04</td>
<td>55.4/70 9/10</td>
</tr>
<tr>
<td>16</td>
<td>GH</td>
<td>44/F</td>
<td>Admin. Asst.</td>
<td>6</td>
<td>27/05/03</td>
<td>02/03/04</td>
<td>55/100 9/10</td>
</tr>
<tr>
<td>17</td>
<td>JM</td>
<td>31/F</td>
<td>Dentist</td>
<td>3</td>
<td>26/08/03</td>
<td>18/11/03</td>
<td>3/45* 5/10</td>
</tr>
<tr>
<td>18</td>
<td>KB</td>
<td>42/F</td>
<td>Healthcare worker</td>
<td>3</td>
<td>13/04/03</td>
<td>13/01/04</td>
<td>76.9/100 8/10</td>
</tr>
<tr>
<td>19</td>
<td>ES</td>
<td>28/M</td>
<td>Financial advisor</td>
<td>6</td>
<td>25/11/02</td>
<td>09/02/04</td>
<td>40/45* 10/10</td>
</tr>
<tr>
<td>20</td>
<td>KB</td>
<td>53/F</td>
<td>Homemaker</td>
<td>11</td>
<td>17/07/01</td>
<td>20/04/04</td>
<td>51.4/90 6/10</td>
</tr>
<tr>
<td>21</td>
<td>BK</td>
<td>46/F</td>
<td>Clerical Work</td>
<td>9</td>
<td>10/12/01</td>
<td>06/04/04</td>
<td>57.0/100 5/10</td>
</tr>
<tr>
<td>22</td>
<td>BC</td>
<td>44/F</td>
<td>Financial Advisor</td>
<td>3</td>
<td>12/05/03</td>
<td>15/12/03</td>
<td>27/45* 9/10</td>
</tr>
<tr>
<td>23</td>
<td>FV</td>
<td>55/M</td>
<td>I.T. Manager</td>
<td>7</td>
<td>27/06/02</td>
<td>20/04/04</td>
<td>80.3/90 9/10</td>
</tr>
<tr>
<td>24</td>
<td>mva</td>
<td>45/F</td>
<td>Social worker</td>
<td>7</td>
<td>27/04/01</td>
<td>16/03/04</td>
<td>77.2/100 8/10</td>
</tr>
<tr>
<td>25</td>
<td>mva</td>
<td>45/F</td>
<td>Accountant</td>
<td>5</td>
<td>10/11/03</td>
<td>13/01/04</td>
<td>66.9/90 10/10</td>
</tr>
</tbody>
</table>

Note: Some patients completed only the *Short-form McGill Pain Questionnaire.
http://www.musclepainrelief.ca/ and is the subject of a forthcoming paper.

B. Discussion of Botox Treatment

One previously published study on Botox for FMS found it not to be effective.127 This was a small study of 10 patients who underwent alternate injections of lidocaine or Botox only into the upper trapezi. Only one patient reported relief of pain for 2 weeks, and that was with lidocaine. On the other hand, several earlier studies have demonstrated clinical effectiveness for myofascial pain,128–131 including more recently published, randomized double-blinded placebo-controlled trials (RCT).132,133

Injections into the trapezius may exacerbate pain in FMS patients, particularly in the presence of a head-forward posture with depressed scapulae and thoracic outlet syndrome symptoms (painful paresthesias in the arms and hands). Weakening this scapula elevator will aggravate the tension on the brachial plexus. Instead, injections into the tight pectorals and levator scapulae muscles, combined with scapular stabilization exercises (strengthening the trapezius, rhomboids), results in a much better clinical response.

Botox has also been demonstrated to be effective in treating headaches (migraine, tension, and cervicogenic types),134–137 FMS patients who also suffer from migraine,138 and low back pain.139 A published RCT found paraspinal injections of Botox to be effective for chronic mechanical low back pain.140 Laboratory research provides an explanation for Botox in pain control. This includes inhibition of calcium mediated release of Substance P in dorsal root ganglion neurons,141 as well as in the brain and trigeminal nerve endings.142,143 Botox also inhibits other pain neurotransmitters, such as vasoactive intestinal polypeptide144 and calcitonin gene-related peptide,145 and by elevation of enkephalins at the dorsal horn of the spinal cord.146 In a rat formalin model, Botox was found to have dose-dependent anti-inflammatory effects,147 with the mediator likely to be glutamate.148,149

Fos expression in the dorsal horn was also inhibited.150 On the basis of this finding, we have found that effectiveness in neuropathic pain control with intradermal injections of Botox is to be expected.151 152 Clinical experience also suggests that the duration of pain relief outlasts the muscle-relaxation effect.153 The literature validates the clinical effectiveness for Botox in appropriately prescreened patients.

IV. TYPICAL APPROACHES TO THE FIBROMYALGIA/CHRONIC PAIN PATIENT

A. Thorough Internal Medicine Work-up

It is necessary to rule out other similar and/or concomitant disorders (hypothyroidism, polymyalgia rheumatica, lupus,157 multiple sclerosis, polio,156 cancer, etc.). Prolonged morning stiffness and limited lumbar spine motion in more than one plane is more indicative of other rheumatologic diagnoses.157 A workup should include a detailed neurological exam to assess for signs of upper motor neuron dysfunction (hyperreflexia, Babinski sign, clonus, abnormal coordination, and gait).158,159

Case A (Fig. 5)

One 38-year-old male patient previously treated with numerous therapies, including cortisone injections and paravertebral nerve blocks, was found to have marked denervation in the thoracic paraspinal muscles on needle EMG. Subsequent MRI scan revealed an intradural extramedullary schwannoma with compression of the spinal cord. Surgical excision resolved all his “FMS” symptoms (see patient pointing to surgical scar in Fig. 5).

Other successful neurosurgical cases (with resolution of “FMS symptoms”) include those for an intracranial ophthalmic artery aneurysm, colloid cyst, and pituitary adenoma. A comprehensive medical work-up should always be done to rule out more serious diseases.160

B. Patients Should Have Already Completed a Full Trial of More Conservative Treatments

Conservative treatments include amitriptyline, cyclobenzaprine, NSAIDs, physiotherapy (osteopathy, aerobic exercise, aquatherapy), and psychotherapy (cognitive–behavioural). In our menopausal
patients, hormone replacement therapy may resolve symptoms all together. Some patients also exhibit autonomic dysfunction and may respond to biofeedback retraining.

C. Patients Should Be Followed and Supported If They Elect to Try Alternative Therapies

Our approach (following Dr. Dietrich Klinghardt’s paradigm) categorizes CAM into four areas:

![Diagram of CAM Categorization]

1. Structural CAM

Researchers have found success with structural CAM therapies such as prolotherapy. This involves injections into the bone–ligament interface (which stimulate further fibroblast activity), collagen deposition, and ligament healing. A recent RCT demonstrated significant improvement in both the saline and the dextrose injection groups. This has led to the recommendation by Nikolai Bogduk that such injections be considered in the first-line management of chronic low back pain.

Case B

A 45-year-old, married computer worker (see Fig. 6) with diffuse pain worse in the low back was seen in November, 2000. Clinical exam revealed old polio (atrophic small flail right arm and shorter, thinner left leg), 18/18 TePs and marked tenderness in the left sacroiliac (SI) region. 2+ laxity was noted with the shear test for SI instability. Nerve
root tension tests were negative, and EMG revealed only chronic neurogenic changes. Bloodwork and bone scan were negative for active sacroilitis.

<table>
<thead>
<tr>
<th></th>
<th>Pre–Rx</th>
<th>Post–Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(06/01)</td>
<td></td>
</tr>
<tr>
<td>VAS pain</td>
<td>8/10</td>
<td>4/10</td>
</tr>
<tr>
<td>Short-form McGill Q</td>
<td>24/45</td>
<td>19/45</td>
</tr>
<tr>
<td>Pain Disability Index</td>
<td>44/70</td>
<td>24/70</td>
</tr>
<tr>
<td>Oswestry LBP score</td>
<td>37/50</td>
<td>15/50</td>
</tr>
<tr>
<td>Algometry FMS</td>
<td>2.13 kg</td>
<td>3.0 kg</td>
</tr>
</tbody>
</table>

After trials of physiotherapy, chiropractic, and orthotics (for leg-length correction), prolotherapy injections with P2G (phenol-glycerine-glucose) and lidocaine were administered to the SI ligaments on a monthly basis.

The patient returned 2 years later for a tennis elbow complaint and was pleased to report continued back pain relief.

### 2. Psychoemotional CAM

Neurotherapy uses an EEG recording system, along with training software, to enhance brain wave activity that is instrumental for improving concentration. Much of the research has been focused on children with attention deficit disorders.165

**Case C**

A 48-year-old, married dog breeder (see Fig. 7) developed FMS, with chronic pain, cognitive difficulties, severe depression, and generalized anxiety, after an MVA in 1999. After numerous therapies and medications, she was told that she had reached maximum recovery. She started neurotherapy/biofeedback (20 sessions from March to Sept., 2003).

After 10 sessions, she estimated 75% improvement. She noted that “I can laugh. I am awake again and feel as if I am reborn.” After 20 sessions, she was 95% improved and noted that whatever was left in terms of her concentration deficits was just what “people normally face at this age of life.” She could socialize more and engage in various activities with her son and husband.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Pre–Rx</th>
<th>Post–Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS pain</td>
<td>7/10</td>
<td>2/10</td>
</tr>
<tr>
<td>Beck anxiety score</td>
<td>11/63</td>
<td>2/63</td>
</tr>
<tr>
<td>Beck depression</td>
<td>26/63</td>
<td>8/63</td>
</tr>
<tr>
<td>Perceived deficits scale</td>
<td>69/80</td>
<td>22/80</td>
</tr>
<tr>
<td>Fatigue severity scale</td>
<td>42/63</td>
<td>13/63</td>
</tr>
<tr>
<td>Fibromyalgia Impact Questionnaire</td>
<td>65/90</td>
<td>19/90</td>
</tr>
</tbody>
</table>

### 3. Biochemical CAM

Improvements have been reported in some patients through nutritional/ naturopathic interventions. Those with irritable bowel syndrome can be helped
with elimination diets. A young patient was 90% improved by eliminating tartrazine (in red dyes to color meats) from her diet. Recent reports also suggest a link between FMS and type 2 diabetes, thus supporting the recommendation of a hypoglycemic diet (ie, low intake of processed, refined carbohydrates and sugar). Deficiencies have been shown in omega 3 fatty acids and in vitamin D. There are also reports of heavy metal toxicity, treatment with amalgam removal and neural therapy. There is a report of a dozen patients who have done extremely well with the Dr. St. Amand’s protocol. (Paul St. Amand is an endocrinologist and assistant clinical professor of medicine at UCLA). This requires oral guaifenesin that is titrated to promote renal excretion of inorganic phosphate. Strict dietary changes, including avoidance of salicylates (including most brands of toothpaste), is required for this to work. However, a good randomized controlled trial has yet to be done.

Case D

A 54-year-old, married, retired, left-handed IBM consultant had FMS for 15 years. Risk factors included childhood growing pains and hypermobility, left elbow fracture, and right knee arthroscopy for osteoarthritis. Her mother had Charcot-Marie-Tooth disease (the patient, herself, was self-tested negative). She had extensive dental work and rows of amalgams and root canals. She also had hypertension for 2 years. Her best exercise tolerance was going on a treadmill 1.9 mph for only a few minutes.

Pretreatment: (January, 2002)
18/18 TePs. VAS: 9/10 FIQ: 71.7/90

She could not write and could only climb stairs one step at a time. She could not drive because her neck was stiff and she often felt dizzy. She had chronic constipation and severe migraines 2 to 3 times per month.

Initial treatment included naturopathic evaluation and general detoxification (homotoxicalogy approach). After a month of this, she started guaifenesin capsules 300 mg per day. This was titrated up to 900 mg BID.
Overall, she felt 35% improved and was able, for the first time in years, to play 5 rounds of 9-hole golf. She continued on oral guaifenesin and salicylate avoidance.

Jan., 2003: 13/18 TePs. VAS: 1-7/10

She could carry heavy laundry upstairs and exercise on a treadmill 3.2 mph for 30 minutes, 3 times a week. She was able to do bicep curls with 7.5 lbs barbells.

Sept. 9, 2003: 13/18 TePs. VAS: 1-6/10 FIQ: 12/90

She played 35 rounds of 18-hole golf in the past summer. She regularly did heavy gardening and could sweep her driveway with a heavy broom. She only had light headaches, 1 to 2 times per month.

A phone call check on April 21, 2004, revealed continued significant symptom reduction and high level of function [Fig. 8].

The use of CAM must be monitored for adverse effects and potential interactions with medications. As a general rule of thumb, all herbal products should be stopped (blood thinning effect) prior to any surgery or extensive and/or deep soft-tissue injections.

4. Beck Depression Inventory Score Should Be Less Than 21/63 Prior to Undergoing CAM Pain Treatments

Higher scores indicated major depression, which should be treated first.173 Studies suggest that patients with FMS or CFS differ from those with major depression.174 Axis one psychiatric disorders, including “hysteria-conversion disorders,” should also be excluded. Patients involved in stressful disability claim appeals and litigation ideally should have such issues resolved prior to initiating treatment. More detailed evaluation should first be completed.175

D. Pain Control Is an Important First-Line Goal in FMS Patients

Patients with mild pain (<4/10) are usually able to participate in CAM therapies (including nutrition, exercise, mind-body programs). Those with more severe pain (>7/10) are often unable to do so and may require stronger pharmaceutical approaches first. This includes long-acting opioids and adjuvants, such as alpha-2 receptor agonists (tizanidine), anticonvulsants (pregabalin, gabapentin), cannabinoids (nabilone). Recent cardiac concerns about Cox-2 inhibitors have limited use of NSAIDs for chronic pain. As discussed, Botox in patients able to undergo injections may be a safer, well-tolerated approach to control severe pain.

1. Preinjection (Botox) Screening

Relative contraindications to injection treatments include

- Needle phobia
- Lack of motivation; unwilling to comply
- Coagulopathy or use of blood thinners
- Pregnancy
- Unstable medical or psychiatric condition

With Botox, injections should not be administered to patients with flu symptoms, or to those who are on aminoglycosides or have neuromuscular junction disorders (Myasthenia Gravis, Eaton-Lambert syndrome, myopathies). It is also recommended to not inject into atrophic, flaccid muscles.

If all the above are satisfied, then a further optional screening step is a test TrP injection(s) with preservative-free hydroxide-buffered 1% procaine or lidocaine (see patient profile #4 above). This has the advantage (over regular anesthetics) of...
a much lower likelihood of postinjection soreness / allergic reaction. Patients return after one week with a completed pain diary. If there is increased pain or no pain reduction, then further Botox injection should not be administered in the same sites. If there is a significant reduction in pain (VAS decreases over 2 points or by 30%), Botox would be indicated. Informed consent and follow-up with validated outcome measures are necessary.177

2. Botox Injection Tips

In some patients with dermatographism, a course of antihistamines prior to and after injections will help to prevent flare-ups.178 Recent research suggests that higher levels of cytokines in the skin are the explanation for the skin allodynia found in 27 to 38% of patients.179 Vitamin C (500 mg per day) has also been recommended for bruising.180 Anti-coagulants should be discontinued prior to extensive needling or injections. Temporary flu-like illness, lasting a week, is possible. Some patients note increased pain, probably from overzealous injection of numerous TrPs.

For the first-time FMS patient, it is best to go “low and slow.” Only two sites at most should be infiltrated initially (usually the levator scapulae or pectorals), and, then, further TrP gradually injected later. If there is marked skin hyperalgesia, injections should be done quickly (no needling or fanning-out technique) with a smaller gauge needle (27 gauge). Postinjection physiotherapy should also be done.

Patients with marked hypersensitivity, that is, grade 4 tenderness (the grading system recommended is: 0= no pain, 1 = complaint of pain without grimace, 2 = pain with grimace or flinch, 3 = pain plus marked flinch or withdrawal, 4 = “untouchable”181) and/or all algometric pain thresholds below 2 kg., should first try intradermal injections. Such patients may actually have generalized complex regional pain disorder and are more likely to flare up if injected too aggressively. Overzealous injections in the painful areas, as well as unnecessary surgery, cast immobilization of an extremity, and repeated sympathetic blocks (in late stages) only aggravate this condition.182 Gabapentin slowly titrated up to 2400–3600 mg per day may be more helpful.183

3. Inject with Anatomical/Biomechanical Reasoning184,185

- **Head**: Avoid area above lateral eyebrow (diffusion to levator palpabrae and subsequent ptosis)
- **Posterior Neck**: Avoid suboccipital midline (foramen magnum) and deep rectus capitis muscles (proprioception disturbed)
- **Anterior Neck**: Avoid anterior triangle (diffusion to swallowing muscles, neurovascular structures). Scalene injections with EMG guidance only.
- **Shoulders**: Avoid scapular stabilizers (rhomboids, middle and lower trapezius) and suprascapulas (results in loss of arm abduction ability). Minimize upper trapezius injections in dropped scapula (upper edge well below T2) (Fig. 9).
- **Thoracic**: Avoid iliocostalis and longissimus thoracis in kyphotic patients.
- **Low back**: Avoid lumbar paraspinals in hyperlordosis.
- **Spine**: Avoid midline (inadvertent intrathecal entry).
- **Limbs**: Watch dosage. Too high a dose will affect function, for example, quadriceps and gait, forearm extensors and finger/wrist extension, grasp.

Other precautions with Botox injections:
- Scalenes and other accessory respiratory muscles: asthma, chronic obstructive pulmonary disease, sleep apnea (note that 44% of males with FMS have underlying sleep apnea).186
- **Pectorals**: breast implants, pacemakers
- **Hypermobility**: Inject only the pericranial muscles initially (avoid destabilizing the spine) (27% of FMS females have hypermobile joint syndrome).187

Avoid open wounds, shunts, deep injections near viscera, pleura.

E. Long-Term Management of Fibromyalgia

There is no universal “magic bullet” for the treatment of FMS. It is a syndrome and not a specific pathological disease entity. Diagnosis is made by
exclusion (the usual lab tests are all negative). Symptoms may last an average of 15 years. Review papers suggest that positive outcomes occur not only with age but also with an adequate physical activity level and coping skills. Excess major negative life events and permanent disability pensions are associated with a negative outcome. Younger age of onset and less sleep disturbance are associated with a more favorable outcome. Effective management is best with an interdisciplinary approach emphasizing lifestyle improvement (“TENSQ”: Toxin elimination, Exercise, Nutrition, Sleep hygiene, Quiet “de-stress” time) and pain control (ETPS “TENS” and other home modalities). FMS smokers have also been found to have more pain, numbness, global severity, and functional difficulties than nonsmokers.

Other studies also indicate that 67% of patients experienced migraine prior to the onset of their FMS, and that 25% of chronic low back pain patients will evolve into FMS. Perhaps Botox, shown to be effective in these conditions could also be used to prevent the development of FMS. After all: “prevention is better than cure.”

V. CONCLUSION

This review has not only summarized published peer-review literature on pain management in the area of fibromyalgia but has also presented 20 years of clinical experience in managing such patients. Most studies of CAM effectiveness are of poor quality (few are of high quality according to the Jadad criteria). One recent extensive FMS review paper listed 433 references. Out of this, only 10 references applied to CAM trials. However, it must be realized that CAM (non-drug) clinical trials are often difficult to implement in a true blinded fashion. Research is needed all the more, noting that CAM use is among the highest in this difficult-to-treat group of patients.

As noted in the typical case studies, effective CAM therapies include naturopathic medicine, guaifenesin, neurotherapy, and prolotherapy. Perhaps the most promising treatment to date for pain control is the use of Botox. Integrating this treatment with other CAM approaches may also be useful. From an evidence-based perspective, there is obviously a need to do a randomized controlled double-blinded study using Botox in...
FMS. It is hoped that this review will stimulate further research in FMS management. Ultimately, “Doing everything for everyone is neither tenable nor desirable; what is done should ideally be inspired by compassion and guided by science, and not merely reflect what the market will bear.” (from Grimes DA. Primary prevention of ovarian cancer (editorial). JAMA, 1993;270:2855).

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APPENDIX

Jadad Criteria for Clinical Trials on Pain Treatment
(Adapted from Ezzo J. Pain 2000;86:217–225.)

Evidence for a clinical trial on pain treatment is weighted as follows:

Score 1 for each:

A. Was the study described as randomized?
B. Was the randomization scheme described and appropriate (e.g., table of random numbers or computer-generated randomization not appropriate for alternating allocation, date of birth randomization)?
C. Was the study described as double blind?
D. Was the method of double blinding appropriate?
   1. Were patients reported as blinded?
   2. Was the outcomes assessor reported as blinded?
E. Was there a description of dropouts and withdrawals?

Scoring: A + B + C + D + E = ____/5. A high-quality trial is 3 to 5.

Additional criteria:
F. Were co-interventions avoided or controlled for?
G. Was compliance satisfactory? (e.g., with home treatments)
H. Was the study population adequately homogenous? (conditions of similar etiologies/natural histories)
I. Was the therapeutic time equivalent between groups (similar number and duration of Rx)?