Sandy

38 year old complaining pain in her neck, upper back, lower back and knees.
Fatigue, difficulty sleeping, decreased libido, a “foggy” feeling and occasional abdominal pain and bloating.
Mild neck pain after a low speed motor vehicle accident three years.
X-rays and a cervical MRI revealed only some mild degenerative changes. She’s seen multiple MD’s.
Can no longer work as a nurse.
Pain as the 5th Vital Sign

- Unrelieved pain has adverse physical and psychological consequences; no patient should have to endure pain unnecessarily.
- Much like our approach to hypertension, however, we have focused on pain as a symptom or “score” to be reduced.
- This focus has led to increased and often injudicious use of pain meds.
- The result is often less pain but more suffering.

“Pain is inevitable. Suffering is optional.”
- Buddhist proverb
Consequences of a Unifocal Approach

- Increase in opioid addiction
- Increase in opioid overdose and death
- Need to view the approach to chronic pain differently
- Need to find ways to limit reliance on medications
- Increased interest in Integrative Medicine
Consortium Growth

Number of Institutions

Year

Current Members

Albert Einstein/Yeshiva University
Allina Health Systems
Aurora Health Care
Boston University
Cleveland Clinic
Columbia University
Duke University
Georgetown University
George Washington University
Harvard Medical School
Johns Hopkins University
Mayo Clinic
McMaster University, Ontario
MD Anderson
Mount Sinai Medical Center
Northwestern University
Ohio State University
Oregon Health & Science University
Rutgers New Jersey Medical School
Scripps Health
Stanford University
Sutter Health Systems
Tecnologico de Monterrey
Temple University
Texas Tech University
Thomas Jefferson University
Tufts University
Universidad Autónoma de Guadalajara
University of Alberta
University of Arizona
University of Calgary
University of California, Irvine
University of California, Los Angeles
University of California, San Diego
University of California, San Francisco
University of Chicago
University of Cincinnati College of Medicine
University of Colorado at Denver
University of Connecticut
Univ. of Hawaii at Manoa
University of Kansas

University of Kentucky
University of Maryland
University of Massachusetts
University of Miami
University of Michigan
University of Minnesota
University of New Mexico
University of North Carolina, Chapel Hill
University of Pennsylvania
University of PA, Hershey
University of Pittsburgh
University of Southern California
University of Texas, MB
University of Vermont
University of Washington
University of Wisconsin, Madison
Vanderbilt University
Wake Forest University
Yale University

What is Integrative Medicine?

KEY TENETS

1. Places the patient at the center
2. Inclusive approach
3. Focus on health optimization
Patient (Person) Centered Care

• Redefining health & well-being
• The person is more than their disease
• Treating the whole individual
• Understanding values and goals
• What else is important?

Meet Mike, a diabetic with chronic pain. But also a…

Husband
Duke Alum
Runner
Gardener
Dad to Maggie & Max
What is Integrative Medicine?

KEY TENETS

1. Places the patient at the center
2. Inclusive approach
3. Focus on health optimization
Goal

Implement and assess successful methodologies that transform the health trajectory of the individual, the community, and the healthcare system.
We all have a life-health trajectory
Global Spending on Health Care

Exhibit 1. International Comparison of Spending on Health, 1980–2007

- **Average spending on health per capita ($US PPP)**
  - United States
  - Canada
  - Netherlands
  - Germany
  - Australia
  - United Kingdom
  - New Zealand

- **Total expenditures on health as percent of GDP**
  - United States
  - Canada
  - Netherlands
  - Germany
  - Australia
  - New Zealand
  - United Kingdom

Note: $US PPP = purchasing power parity.
Diabetes Trends, 1980-2014
Obesity Trends, 1960-2020

Trend of obesity among US Adults

Use of Opioid Pain Relievers (OPRs)

Prescriptions of Hydrocodone, Oxycodone, and total OPRs from 1991 to 2013.
Individual Health Trajectory
Know the Individual

“It is more important to know what sort of person has a disease than to know what sort of disease a person has.” - Hippocrates
Mind, body & spirit

The Approach

Patient-centered

Holistic

Whole person

Comprehensive

MASLOW’S HIERARCHY OF NEEDS

- Self Actualization
- Esteem
- Love/Belonging
- Safety
- Physiological
Influencing the trajectory

- Luck
- Awareness
- Spirituality
- Stress management
- Environment
- Genetics
- Relationships
- Nutrition
- Socioeconomics
- Exercise
- Complementary Medicine
- Access

Complementary Therapy for Pain

- Acupuncture
- Mind-body techniques
- Massage therapy
Acupuncture: Ancient Treatment for Pain

off the mark.com

THAT'S ODD... MY NECK SUDDENLY FEELS BETTER...

EARLY ACUPUNCTURE
Physiologic Effects of Acupuncture

Acupuncture results in:

- Increased release of endorphins & enkephalins
- Increased release of anti-inflammatory cytokines
- Increase in neurotransmitters (serotonin & dopamine)
- Enhanced immune system functioning

RCT on Acupuncture for Back Pain

- 2009 randomized controlled trial
- N = 638
- 10 treatments over 7 weeks
- Acupuncture (individualized, standardized, simulated) for patients with chronic low back pain
- Primary outcomes: Roland-Morris Disability Questionnaire and symptom bothersomeness

At 8 weeks, the proportion of participants improving at least 3 points on the Roland scale was about 60% in the real and simulated acupuncture groups, vs. only 39% in the usual care group. P < 0.001.
Acupuncture for Osteoarthritic Pain

- 2010 systematic review
- N = 16 clinical trials, 3498 subjects
- Acupuncture for peripheral joint osteoarthritis (OA)
- Acupuncture showed improvements in OA pain vs. sham control (9 trials)
- Standardized mean difference -0.28, 95% confidence interval -0.45 to -0.11

Compared with sham control at short-term follow-up, acupuncture showed improvements in OA pain:

- $P = .002$

**Figure 1.** Effects of acupuncture versus a sham control group on the pain outcome at the short-term measurement point (Manheimer et al., 2010)
Acupuncture for Musculoskeletal Pain

• 2016 systematic review
• N = 59 sham-controlled RCTs, 4980 subjects
• Aim: assess the analgesic effect of real acupuncture and whether sham acupuncture is related to the effect of real acupuncture for musculoskeletal pain
• Real acupuncture led to a moderate reduction in musculoskeletal pain
• Sham acupuncture did not appear to be related to the estimated effect of real acupuncture

Acupuncture for Non-Cancer Pain

• 2007 retrospective review/case analysis
• N = 5981 electronically stored case histories
• Context: 9-year period, Pain Treatment Unit within the Andalusian Public Health System (Spain)
• In the 5690 patients who completed treatment, the mean success rate was about 80% (79.7%)
• Average weekly spending on analgesics was reduced by 7 Euros per patient

Acupuncture for Opiate Drug Addictions

- Acupuncture therapy has been used to treat opiate abuse as well as cocaine and alcohol dependency.
- Many clinical studies confirm the efficacy of acupuncture as a strategy for the treatment of opiate addiction.
- A 2013 review of 48 clinical trials on opioid, cocaine, nicotine or alcohol dependence linked acupuncture with:
  - reduced craving and withdrawal symptoms but no significant impact on abstinence or attrition.
  - positive results for all 4 outcomes with electroacupuncture.

Electroacupuncture

Electro-stimulation of specific points seems to best activate opioid & non-opioid analgesic mechanisms.
Acupuncture for Pain Conditions

• Musculoskeletal pain
• Osteoarthritic pain
• Fibromyalgia
• Various neuralgias
• Phantom limb pain
• Headaches
• Fractures
• Autoimmune disorders
  – Lupus
  – Rheumatoid arthritis
  – Ulcerative colitis
Mind-Body Medicine

“The pain of the mind is worse than the pain of the body.”
- Publilius Syrus, Latin writer (85–43 BC)

- Breathing
- Guided imagery
- Relaxation techniques
- Mindfulness meditation
- Yoga
- Prayer
- Journaling
- Biofeedback
- Hypnosis
Mind-Body Therapies

- Relaxation training, coping skills training, cognitive restructuring, and self-hypnosis for low back pain
- Cognitive behavioral therapy, when combined with educational component for arthritis (RA & OA)
- Relaxation and biofeedback for recurrent migraine or tension headache
- Imagery, hypnosis, and relaxation pre-surgically can improve recovery time and reduce post-op pain
- Mind-body approaches during invasive procedures

Hypnotherapy for Pain

• 2014 meta-analysis of hypnosis for chronic pain problems: a comparison between hypnosis, standard care, and other psychological interventions

• Hypnosis provided moderate treatment benefit when compared with standard care

• Also showed a moderate superior effect compared to other psychological interventions for a non-headache group

• The results suggest that hypnosis is efficacious for managing chronic pain

What is MBSR?

- It is a method of using meditation and yoga to cultivate awareness and reduce stress
- Participants practice present-moment awareness, deep relaxation, and gentle movement
- 8-week program that includes weekly 2.5-hr classes and suggested daily home practice for 45 minutes
- Draws from meditative spiritual traditions, but is not religious in nature
MBSR

- There is favorable evidence to support the use of MBSR for a wide range of issues
- Currently a thriving area of research
- 43 NCCIH-funded studies to date on MBSR (as of March 2015)
- In 2012, 8% of the U.S. population used meditation

MBSR

- 2014 systematic review
- N = 47 trials, 3320 participants
- Meditation for psychological stress and well-being
- RCTs with control group and clinical condition (mental health/psychiatric or physical)

MBSR

- Moderate evidence to improve:
  - Anxiety effect size, 0.38 [95% CI, 0.12-0.64] at 8 weeks and 0.22 [0.02-0.43] at 3-6 months
  - Depression 0.30 [0.00-0.59] at 8 weeks and 0.23 [0.05-0.42] at 3-6 months
  - Pain 0.33 [0.03- 0.62]
- Low evidence to improve stress/distress
- No effects on positive mood, substance use, eating, sleep and weight
MBSR

• 2014 systematic review
• N = 17 trials
• MBSR for stress management in healthy individuals
• 16 out of 17 studies showed positive changes in psychological or physiological outcomes related to anxiety/stress

MBSR

• 2014 randomized controlled trial
• \(N = 109\)
• MBSR for chronic pain
• MBSR had significant positive effects on the SF-36 vitality scale (Cohen’s \(d = 0.39\))
• Lower general anxiety & depression, better mental quality of life, feeling in control of pain, and higher pain acceptance (Cohen’s \(d = 0.37-0.71\))

Manual Medicine

- Osteopathic Manipulation
- Chiropractic
- Therapeutic Massage
Massage as a Therapeutic Intervention

- Practiced for thousands of years
- One of the most popular CAM therapies (~18 million U.S. users)
- Increases local circulation, muscle tone, and joint flexibility
- Frequently used for OA
- Often used to relieve pain from musculoskeletal disorders [1]
  - cancer; sports injuries; stress reduction/relaxation; anxiety; depression; general wellness
- Very little formal research on massage therapy for any condition
  - Even less mechanistic research

1. Ann Intern Med 138 898-906
Massage Therapy for Chronic Lower Back Pain (LBP)

- Evidence-based literature review of all published research from 1948 to 2010
- A total of 100 recommendations were formulated from 11 eligible articles, including 37 positive and 63 neutral recommendations.
- Massage therapy provided short-term improvement of sub-acute and chronic LBP symptoms and decreased disability.
- Conclusion: “Massage therapy is effective at providing pain relief and improving functional status”

Osteoarthritis: The Context

- A slowly progressive degenerative disease of the joints
  - affects ~27 million in the U.S. [1,2]
- Prevalence estimated to increase 40% by 2025 [3]
- Conventional therapies are not ideal
  - limited effectiveness
  - toxicities associated with effective drugs
  - surgery often undesirable

Pilot Clinical Trial (2006)

- CDC funded [1] larger project at YGPRC
  - Identified high priority treatment/condition pairs
  - Pilot study led by Adam Perlman (UMDNJ)
- Randomized controlled trial; n=68
  - Massage vs. wait list
- Intervention: Whole body, Swedish massage for 8 weeks
  - Standard techniques of petrissage, effleurage, and tapotement
  - 60 min twice weekly x 4 weeks
  - 60 min once weekly x 4 weeks
- Outcomes: function (WOMAC), pain (VAS), ROM, 50-ft walk
- Results: well tolerated, decreased pain, and improved function
- Effects persisted for weeks after cessation of massage

Source: Perlman et al. Archives of Internal Med. 2006;166:2533-2538
Massage therapy for osteoarthritis of the knee: A randomized dose-finding trial

Adam Perlman MD MPH¹, Ather Ali ND MPH³, Valentine Yanchou Njike MD MPH³, David Hom MS²,⁴, Anna Davidi BS³, Susan Gould-Fogerite, PhD², Carl Milak AA², David L. Katz MD MPH³

(1) Duke University
(2) University of Medicine and Dentistry of New Jersey
(3) Yale University School of Medicine
(4) Boston University Medical Center

Dose-Finding Trial - Design

- Randomized, wait list-controlled, clinical trial
- Four distinct ‘doses’
  - 1. 30 min/week x 8 weeks (240 min total)
  - 2. 30 min biweekly x 4 weeks, 30 min weekly x 4 weeks (360 min total)
  - 3. 60 min/week x 8 weeks (480 min total)
  - 4. 60 min biweekly x 4 weeks, 60 min weekly x 4 weeks (720 min total)
  - 5. Usual Care (no massage)
- Included:
  - Adults with radiographically confirmed OA of the knee
  - Self-reported pain between 4-9 on VAS
- Excluded:
  - RA, fibromyalgia, intraarticular injections, knee replacement
- Assessed: baseline, 8-, 16-, and 24-weeks
- Outcomes: WOMAC, VAS, ROM, 50-ft walk
Dose-finding Curve ($\Delta$ WOMAC Global @ 8 weeks)

![Dose-finding Curve Graph]

Plateau

Massage Dose
(total minutes over 8 weeks)
Conclusions

• Winner: 60-min once weekly
• ‘Optimal-practical’ = *best bang for the buck*
  – producing the greatest ratio of desired effect compared to costs
  – costs = time, labor, and convenience
• Reinforced results of pilot study
• Dose used for most recent study
EMBARK Trial

- Phase 2b Efficacy Trial
  - NIH/NCCAM funded R01
  - Using 60-min once weekly dose
  - Massage vs. light touch vs. wait list
  - 52-week follow-up
  - N=219 at three sites: Duke, Rutgers, Yale
  - Cost-effectiveness
**Baseline Assessment**

**Swedish Massage**
- 1 hour per week, 8 weeks

**Light Touch**
- 1 hour per week, 8 weeks

**Usual Care**

**8 week Assessment**

**16 week Assessment**

**24 week Assessment**

**36 week Assessment**

**52 week Assessment**

**Maintenance: 1 hour Swedish Massage every 2 weeks**

**Maintenance: 1 hour Light Touch every 2 weeks**

**Usual Care**

**ENROLLMENT**

**UC Baseline Assessment**

**UC 8 Assessment**

**UC 16 Assessment**

**UC 24 Assessment**

**Weeks**

0  2  4  6  8  10  12  14  16  18  20  22  24  26  28  30  32  34  36  38  40  42  44  46  48  50  52
Week 8 Primary Outcome

- Primary outcome: WOMAC Global
- At 8 weeks, massage group showed greatest therapeutic effect
- Reinforces findings of pilot study
Change in WOMAC at 8 Weeks

* *p = 0.001; statistically significant
Between-Group Improvement at 8 Weeks (WOMAC)

 Massage vs. LT: *p = 0.008
 Massage vs. UC: *p = 0.001
 LT vs. UC: p = 0.867
Long-Term Treatment Effect at 52 Weeks (WOMAC)

*\( p = 0.707; \) not statistically significant
VA EMBARK: Pilot Study of Swedish Massage for Veterans with Knee Osteoarthritis

Qualitative result: Benefits extended beyond pain-relief for majority of subjects. Examples:

“I’ve been walking to work and back almost every day. My mental attitude has changed quite a bit, knowing that I can do something to help myself. I am not helpless.”

“There are more advantages and benefits through massage than I realized. For example, I believe massage not only works physically but also mentally for PTSD….”

The Toll on Providers

• Normal to feel frustration, guilt and hostility in caring for chronic pain patients

• Important to employ reflective practices acknowledging these issues

• Despite our efforts, it is not possible and likely not desirable to divorce emotion from the clinical encounter
Suffering as the 5th Vital Sign?

- The goal is to manage or minimize pain while improving one’s overall quality of life
- Integrative pain management strategies can contribute to relief of suffering
- Includes judicious use of pain meds and other therapies coupled with complementary therapies
- Acupuncture, Mind-Body Therapies and Massage Therapy
- More research is needed to assess the long-term potential
- Care for the care taker