Osteopathic Research: Part 1
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Objectives

- Hurdles for OMT research
- Amount of current research
- Needs for the future
- Definition of EBM
- Study types and designs
Who I am...
What I Do!

- Full time pediatrician at Nationwide Children’s Hospital
- 5 sessions per week exclusively pediatric OMM
- 4 sessions per week of general pediatrics
- Teach residents, med students, and more!
- Co-director of Dual Pediatric Residency program
Evidence-based medicine – first “coined” in 1991 (JAMA)

“Conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”

“Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough.”

BMJ 1996
What Is Evidence-Based Medicine?

Clinical Judgment

Relevant Scientific Evidence

Patients’ Values and Preferences

EBM

Osteopathic Roots in EBM

- Following in Still’s footsteps
  - Basis of osteopathic medicine is “of such exact, exhaustive, and verifiable knowledge of the structure and function of the human mechanism.” (Still, 1897)
  - “DO means Dig On.” (Still, personal papers)

http://osteopathichistory.com/pagesside2/Analects.html
NIH budget for manual therapy research was <0.5% of the total budget (2013)

Unprecedented growth of the field

ACGME/AOA residency merger
  - Students and residents already undertrained

“Schools of Osteopathy” rank last for NIH funding in 17 types of institutions
  - “Schools of Medicine” received 800 times more!
National Institutes of Health (NIH) research funding in 2011 sorted by educational institution type using data extracted from NIH's RePORT (Research Portfolio Online Reporting Tools). The 7 lowest-funded institution types are shown in the inset to increase discrimination clarity, with “Schools of Osteopathy” last. The NIH categorizes osteopathic medical schools as “schools of osteopathy.”
For Our Future

- Increased validity within the field and beyond
- More evidence/studies = more funding
- Improved reimbursement for OMT
- Promote the osteopathic profession
- Change the culture of osteopathic medicine starting at the student level
- Influence policy changes – locally and beyond
Strategic roadmap to recovery. Key drivers and interventions necessary for the advancement of the reputation of the osteopathic medical profession by means of increased research productivity and scholarly activity at colleges of osteopathic medicine.

Abbreviations: AOA COCA, American Osteopathic Association Commission on Osteopathic College Accreditation; CEU, continuing education unit; COM, college of osteopathic medicine; EBM, evidence-based medicine.
Evidence-based Medicine Spectrum

Practice Experience

Clinical Research

Evidence Review

Evidence Synthesis

Consensus Statement

Clinical Decision Support

Medical Education

Quality Improvement

Healthcare Policy

E-Decision Support

EMRs/e-reminders

Checklists pocketcards, etc

CME/non-CME

Simulation/VR

Other education

PMs

PIMs

Other PI projects

Reimbursement

Facilities planning/approvals
EBM for OMM

Evidence-Based Manual Medicine
A Problem-Oriented Approach

MICHAEL A. SEFFINGER
RAYMOND J. HRUBY

THE EVIDENCE
The Evidence...

- Lack of good evidence for many reasons
  - Individualized nature → protocols are difficult
  - Small numbers of patients enrolled in pilot studies
  - Strength of evidence
  - Number of D.O.s doing OMT
  - Subjective nature
  - Sham treatments
  - Lack of training and funding starting in medical school
Individualized Nature

- Standardized protocols are difficult
  - Patients with low back pain
    - Pelvis/sacrum vs lumbar spine
    - Muscles vs ligaments vs nerves
    - Viscerosomatic
  - Patients with headaches
    - Trauma history
    - Migraines
    - Sinus headache
Many of the current OMM studies are very small

- 19 studies with 0-24
- 20 studies with 25-50
- 10 studies with 51-75
- 2 studies with 76-100
- 11 studies with 100+
*TRIP searches filtered AND unfiltered information simultaneously.
Small Number of D.O.s

Ohio, 2002
- 871 physician responses
- 75% had not or had rarely used OMT
  - 44% using none
  - 31% <10 pts/week prior to the survey
  - 25% treated >10/week
  - 6% treated >30/week

National, 1998
- 955 physicians surveyed
- ~85% rarely or no OMT use
  - 53.5% have <5% of OMT pts
  - 30.1% have 5-25%
  - Only 6.1% have 76-100%

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Subjective Nature

- Some things are hard to quantify
  - Increased appetite
  - Better mood
  - Quality of life
  - “Blacking out”
  - Improved sleep
Sham Treatments?

- Light touch
  - Pediatrics
  - Cranial osteopathy
- Ultrasound
- What else?

Medstandard.org
Where do I begin!

- What is your passion?
- Evidence gap
- Large volume of a diagnosis in your practice
- Know limitations
  - Time
  - Funding
  - Resources
Case Study

- Specific case write-up about one patient
- Example: Concussions and Osteopathic Manipulative Treatment: An Adolescent Case Presentation (JAOA, Mar 2016)

- Great for unique cases or as foundation for future needs/studies!
- What are some examples of cases people would like to write up?
Case Series

- Tracks series of patients with similar known exposure (e.g., treatment with OMT) to observe their outcomes


- Who has seen a series of diagnoses that could be converted to case study?
Case Control Studies

- Observational
- 2 groups with different outcome are identified and compared on a supposed causal attribute

- Example: Osteopathic Manipulative Treatment in Prenatal Care: A Retrospective Case Control Design Study (JAOA, December 2003)
  - Compared those who got OMT to those who did not and looked at meconium staining, preterm delivery, use of forceps, and cesarean delivery

- Examples or ideas for future case control?
Cohort Studies

- Longitudinal follow-up of a group of people with documentation of relevant characteristics or events (risk factors that lead to a disease for example)

- Predictive Relationship of Osteopathic Manual Medicine Grades and COMLEX-USA Level 1 Total Scores and Osteopathic Principles and Practice Subscores (JAOA 2014)

- Ideas for future cohort studies?
Randomized-Controlled Trials

- “Gold standard” for clinical trial
- Randomized to a group – treatment or not
- Controlled – compared to group receiving no treatment
- Example: Recovery from Chronic Low Back Pain After Osteopathic Manipulative Treatment: A Randomized Controlled Trial (JAOA, March 2016)
- Ideas for the future!
Systematic Review

- Literature review that collects and critically analyzes multiple studies/papers

- Ideas for review?
Meta-Analysis

- Conducting research about prior research
- Aims to give higher statistical powers and minimize error
- Example: American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients with Low Back Pain (JAOA, Nov 2010)

- Need more research before can do more meta-analysis!
Current Studies
Chart Review Study

- Review of OMM charts at Nationwide Children’s Hospital Pediatric OMM Clinic
- 350 charts
- Diagnoses
- Referrals
- No show rates
- Demographics
- Financial reimbursement
<table>
<thead>
<tr>
<th></th>
<th>Completed Appts</th>
<th>No Shows</th>
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</thead>
<tbody>
<tr>
<td>Hilltop OMM</td>
<td>82.3%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Overall PCN</td>
<td>74.7%</td>
<td>25.3%</td>
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Overall PCN and OMM No Show Rate
Visit Date: Sep '13 – Sep '15
OMM Visit Type: OMM TESTING
Excludes Cancelled Appointments

Hilltop OMM Has a Lower No Show Rate Than the Overall Primary Care Network
The Hilltop OMM Clinic Has a Much More Favorable Payor Mix Than The Overall Primary Care Network

**Overall PCN and OMM Payor Mix**
Visit Date: Sep ’13 – Dec ’15
OMM Visit Type: OMM TESTING

- **Hilltop OMM**
  - Commercial: 64%
  - Medicaid MC Cap: 31%
  - Medicaid Non-Cap: 3%
  - Other: 2%
  - Self Pay: 1%
  - Total: $440,636

- **Overall PCN**
  - Commercial: 69%
  - Medicaid MC Cap: 9%
  - Medicaid Non-Cap: 4%
  - Other: 2%
  - Self Pay: 1%
  - Total: $128,393,573
The Hilltop OMM Clinic Has a Higher Reimbursement Rate Than The Overall Primary Care Network Payor Mix

Overall PCN and OMM Reimbursement
Visit Date: Sep '13 – Dec '15
OMM Visit Type: OMM TESTING

- **Hilltop OMM**
  - Derived Payments: $308,112
  - Derived Adjustments: $132,525
  - Total: $440,637

- **Overall PCN**
  - Derived Payments: $61,579,693
  - Derived Adjustments: $66,813,880
  - Total: $130,393,573
Most of Hilltop OMM Patients Live in Central Ohio With Some Coming From Outlying Counties

OMM Patient Origin
Visit Date: Sep '13 – Dec '15
Visit Type: OMM TESTING
1 Kentucky Patient Not Captured
Patient Survey

- The first 350 patients from pediatric OMM clinic at NCH will be surveyed
- Assessing knowledge/exposure to OMM prior to clinic visit
- Adverse effects
- Benefits
- Would they recommend to others
- Overall satisfaction
Focus Group/Focused Interview

- Respond to initial survey with diagnosis of concussion
- Secondary more in-depth survey
- Personal or group interviews
- Case series write-up
RCT on Concussion

- Proposal drafted
- Working on funding
  - OMT is an “intervention”
- Randomize to standard of care (SOC) vs SOC + OMT
- Work in conjunction with sports medicine
- Analyze Balance Error Scoring System, Total Symptom Score, and AXON neurocognitive testing
- Multi-center study would be next step!
Asthma and OMT

- RCT
- SOC + OMT vs SOC
- Receiving rib raising and suboccipital release
- Comparing PFTs pre- and post-OMM
- Currently enrolling patients at NCH
- Challenge: lost our research assistant and time is limiting factor
Latch Dysfunction

- RCT
- Randomized to OMT + SOC or SOC (lactation)
- Blinded – done in nursery away from parents
- Lactation doing LATCH scores

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<tbody>
<tr>
<td>L</td>
<td>Latch</td>
<td>Repeated attempts</td>
<td>Grasps breast</td>
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<td></td>
<td>Too sleepy or reluctant</td>
<td>Hold nipple in mouth</td>
<td>Tongue down</td>
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<tr>
<td></td>
<td>No latch achieved</td>
<td>Stimulate to suck</td>
<td>Lips flanged</td>
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<td>Rhythmic sucking</td>
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<td>A</td>
<td>Audible swallowing</td>
<td>A few with stimulation</td>
<td>Spontaneous and intermittent</td>
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<td></td>
<td>None</td>
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<td>&lt;24 hrs old</td>
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<td>Spontaneous and frequent</td>
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<td>&gt;24 hrs old</td>
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<td>T</td>
<td>Type of nipple</td>
<td>Flat</td>
<td>Everted (after stimulation)</td>
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<td>Inverted</td>
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<tr>
<td>C</td>
<td>Comfort (breast/nipple)</td>
<td>Filling</td>
<td>Soft</td>
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<td></td>
<td>Engorged</td>
<td>Reddened/small blisters or bruises</td>
<td>Nontender</td>
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<tr>
<td></td>
<td>Cracked, bleeding, large</td>
<td>Mild/moderate discomfort</td>
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</tr>
<tr>
<td></td>
<td>blisters or bruises</td>
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<tr>
<td></td>
<td>Severe discomfort</td>
<td></td>
<td></td>
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<tr>
<td>H</td>
<td>Hold (positioning)</td>
<td>Minimal assist (ie, elevate head of bed,</td>
<td>No assist from staff</td>
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<tr>
<td></td>
<td>Full assist (staff holds</td>
<td>place pillows for support)</td>
<td>Mother able to position/hold</td>
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<tr>
<td></td>
<td>infant at breast)</td>
<td>Teach one side; mother does other staff</td>
<td>infant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>holds and then mother takes over</td>
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Studyblue.com
Other Areas of Interest

- ADHD
- Neonatal Abstinence Syndrome
- Plagiocephaly +/- torticollis
- Chronic OM/sinusitis
- Constipation
- Carpal tunnel
- Scoliosis
Resources


Resources


