A Case Study of Osteopathic Medicine’s “Catch-22”

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Presentation Objectives

- Provide background information on osteopathic research and The Osteopathic Research Center (ORC)
- Review history of high-impact publications relevant to osteopathic medicine and identify challenges for the osteopathic profession in achieving visibility via elite high-impact medical journals
- Describe the evolution of *Osteopathic Medicine and Primary Care* (OMPC) and lessons learned from its start-up, operation, and close-out
The Osteopathic Research Center

- The ORC is the leading center dedicated to osteopathic research
  - Cutting-edge basic science research on mechanisms of action of osteopathic manipulative medicine
  - Major clinical trials of osteopathic manipulative treatment funded by the National Institutes of Health to build an evidence base
  - Health services research and publications to inform governmental health policy and regulatory actions
  - Osteopathic Heritage Foundation and the National Institutes of Health have been main sponsors (~$20 million since 2002)

- Join us and support our mission to promote the osteopathic profession worldwide
  - [www.hsc.unt.edu/orc](http://www.hsc.unt.edu/orc)
“Catch-22”

There was only one catch and that was Catch-22, which specified that a concern for one’s own safety in the face of dangers that were real and immediate was the process of a rational mind. Orr was crazy and could be grounded. All he had to do was ask; and as soon as he did, he would no longer be crazy and would have to fly more missions. Orr would be crazy to fly more missions and sane if he didn’t, but if he was sane he had to fly them. If he flew them he was crazy and didn’t have to; but if he didn’t want to he was sane and had to. Yossarian was moved very deeply by the absolute simplicity of this clause of Catch-22 and let out a respectful whistle.

“That’s some catch, that Catch-22,” he observed.

“It’s the best there is,” Doc Daneeka agreed.

Joseph Heller, Catch-22, 1961
The Paradox of Osteopathy

Paradox:

“If osteopathy has become the functional equivalent of allopathy, what is the justification for its continued existence? And if there is value in therapy that is uniquely osteopathic — that is, based on osteopathic manipulation or other techniques — why should its use be limited to osteopaths?”

Additional commentary:

“At the end of the century, osteopathy continues its uneasy dance with allopathy, but only one partner is really paying attention.”
Previous High-Impact Publications on Osteopathic Medicine

Situation in 2003
Systematic Review of OMT
Low Back Pain

ES = –0.30 (–0.47 - –0.13); P = .001

Licciardone JC et al, *BMC Musculoskel Disorders* 2005;6:43
Systematic Review Conclusions: OMT Efficacy in LBP

- Pain reduction is statistically greater than expected from placebo effects (twice as great)

- Pain reduction is clinically important; comparable to NSAIDs, including COX-2 inhibitors, and may last longer

- Pain reduction persists at least through the first three months of treatment, and possibly as long as the first year
Corroborative Findings

National Ambulatory Medical Care Survey

- Analysis of patient visits for low back pain in USA, 2003-2004
  - 62 million (42 million where low back pain [LBP] was primary reason for visit)
- Multivariate analyses comparing DO and MD visits while controlling for several variables, including patient age, sex, race, ethnicity; geographic region; MSA status; LBP chronicity; and injury etiology

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Odds Ratio (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased DO use</td>
<td>0.1</td>
</tr>
<tr>
<td>Increased DO use</td>
<td>0.2</td>
</tr>
<tr>
<td>Opioid use</td>
<td>0.5</td>
</tr>
<tr>
<td>NSAID use</td>
<td>1.0</td>
</tr>
<tr>
<td>Exercise counseling</td>
<td>2.0</td>
</tr>
<tr>
<td>Chronic LBP visits</td>
<td>5.0</td>
</tr>
<tr>
<td>All LBP visits</td>
<td>10.0</td>
</tr>
</tbody>
</table>

Licciardone JC, *Osteopath Med Prim Care* 2008;2:11
Challenges in Publishing Osteopathic Research Findings

Elite High-Impact Medical Journals

- Elite high-impact medical journals (e.g., *New England Journal of Medicine*, *JAMA*, *Lancet*, *BMJ*, *Annals of Internal Medicine*) generally are not receptive to publishing “positive” osteopathic studies.

- Systematic review and meta-analysis of OMT for low back pain: “… not of sufficient interest to our audience” (2004-2005)
  - These journals routinely publish articles on other complementary and alternative (CAM) therapies.

  - Low back pain is a common condition, which experts agree should generally be managed by primary care physicians, not specialists.

- NAMCS 2002-2006 analysis of osteopathic physician practice patterns in relation to health care reform and needs for primary care: “… unfortunately, the only format that topic would be considered for possible publication in _____ would be a commentary” (2010)
  - The journal in question routinely publishes all types of articles on matters relating to health care reform and physician workforce issues.
A Tale of Two OMT Studies

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study A</th>
<th>Study B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Randomized controlled trial</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Funding source</td>
<td>American Osteopathic Association</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>ClinicalTrials.gov registration</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Setting</td>
<td>Health maintenance association</td>
<td>Health science center</td>
</tr>
<tr>
<td>Type of low back pain</td>
<td>Mixture of acute, subacute, and chronic (3 weeks to 6 months)</td>
<td>Chronic (3+ months)</td>
</tr>
<tr>
<td>Treatment groups</td>
<td>OMT+standard care vs standard care only</td>
<td>OMT+standard care vs sham OMT+standard care</td>
</tr>
<tr>
<td>Sample size</td>
<td>178 (no assessment of statistical power)</td>
<td>455 (80% statistical power based on previous data)</td>
</tr>
<tr>
<td>Randomization</td>
<td>Adequate</td>
<td>Adequate</td>
</tr>
<tr>
<td>Type of treatments</td>
<td>Variety of techniques individualized to each subject</td>
<td>Variety of techniques individualized to each subject</td>
</tr>
<tr>
<td>Follow-up period</td>
<td>12 Weeks</td>
<td>12 Weeks</td>
</tr>
<tr>
<td>Number of treatments</td>
<td>8 treatments over 12 weeks</td>
<td>6 treatments over 8 weeks</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Week 12</td>
<td>Weeks 1, 2, 4, 6, 8, and 12</td>
</tr>
<tr>
<td>Intention-to-treat analysis</td>
<td>No (23 drop outs not assessed)</td>
<td>Yes</td>
</tr>
<tr>
<td>Jadad quality score</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Primary outcome result</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS pain</td>
<td>NS</td>
<td>P=.003 favoring OMT</td>
</tr>
<tr>
<td>Secondary outcome results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roland-Morris</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>NS</td>
<td>P=.005 favoring OMT</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>NS</td>
<td>P&lt;.001 favoring OMT</td>
</tr>
<tr>
<td>Drug use</td>
<td>P&lt;.05 favoring OMT</td>
<td>NS</td>
</tr>
<tr>
<td>Adverse events reporting</td>
<td>No</td>
<td>Yes, none significantly or causally associated with OMT</td>
</tr>
</tbody>
</table>
Editorial Composition
March 2011

The NEW ENGLAND JOURNAL of MEDICINE

- Committee on publications
  - 10 MDs, 0 DOs
- Editors
  - 20 MDs, 0 DOs
- Editorial board
  - 15 MDs, 0 DOs
- NEJM totals
  - 45 MDs, 0 DOs

JAMA

- Editorial staff
  - 36 MDs, 0 DOs
- Editorial board
  - 21 MDs, 0 DOs
- Journal oversight committee
  - 5 MDs, 0 DOs
- JAMA totals
  - 62 MDs, 0 DOs

Combined totals: 107 MDs, 0 DOs
Osteopathic Medicine’s “Catch-22”

- Osteopathic medicine needs to provide “evidence” that its unique therapeutic approaches have value to justify its continued existence (Howell, 1999)
- Elite high-impact medical journals are not a forum for publishing the “osteopathic evidence”
- Public health policy and general perceptions are driven by the elite high-impact medical journals and their messages, as delivered by mass media
- Consequently, the established medical and public health communities (through lack of coverage by elite journals) and, by extension, the general public (through lack of mass media attention) do not acquire any of the “osteopathic evidence.” Thus, osteopathic medicine needs to provide the evidence
Challenges in Publishing Osteopathic Research Findings

Osteopathic Journals

- The only major osteopathic journal in the USA up to 2007 (*Journal of the American Osteopathic Association*) had important limitations
  - Routinely had 3+ year lag from manuscript submission to publication
  - Extensive editing of manuscripts prior to publication
  - No established impact factor to assess journal status
  - Limited readership outside the osteopathic profession

- International osteopathic journals (e.g. *International Journal of Osteopathic Medicine*)
  - Very limited circulation and impact, and not indexed in PubMed
  - International audience required focus almost exclusively on OMT (i.e., on “osteopathy”), but not other aspects of “osteopathic medicine”
Osteopathic Medicine and Primary Care

Start-Up

- Began negotiation with BioMed Central (BMC) about starting an independent journal with a focus on osteopathic medicine in 2005
- Vetting process by BMC to ensure need for journal and sustainability over time
  - Potential merger with *Chiropractic and Osteopathy* considered, but rejected by both parties
- *Osteopathic Medicine and Primary Care* (OMPC) received “green light” from BMC in 2006 and was launched in January 2007
Why Publish in OMPC?

- **Thorough, Fair Peer Review**
  - 2 referees and statistician if needed

- **Fast Publication**
  - Aim for accepted manuscripts to be published within 2–6 months following initial submission

- **Open Access**
  - No subscriptions
  - Freely available online to all using easily readable formats such as PDF and HTML

- **High Visibility**
  - High downloads
  - Press releases for selected articles with wide audience appeal

- **Immediate Inclusion in PubMed**
  - Also permanently archived in PubMed Central

- **You Retain Copyright**
  - Article may be posted on the Web
  - Article may be disseminated via reprints or electronically

- **My Biomed Central**
  - Track your manuscript through peer-review
  - Access article download statistics online after publication
OMPC Scope

› **Osteopathic Medicine**
  › Uniquely osteopathic topics
  › Osteopathic manipulative treatment
    › Mechanisms
    › Reliability of placatory findings
    › Clinical outcomes
    › Efficacy

› **Primary Care**
  › Family Medicine
  › Internal Medicine
  › Pediatrics
  › Obstetrics and Gynecology

› **Health Services/Public Health Research**
  › Relevant to osteopathic medicine
  › Relevant to primary care
Open Access Publishing: The Costs

Article Processing Charges (APCs)
- Currently, $1,300 per article paid directly to BMC
- No costs for submitting manuscripts
- APCs are payable at the time of publication to process accepted manuscripts for publication

Reasons for APCs
- Development and maintenance of peer review, publication tools
- Preparation of articles for publication in various formats
- Inclusion of articles in a number of permanent archives

Institutional Memberships
- 5 colleges of osteopathic medicine are institutional members
- Faculty, staff, and students at institutional members do not pay APCs for their accepted articles
- Institutional membership fees previously based on number of faculty and students; evolving to membership fees based on number of institutional publications
- $1,300 (£750) at publication, compared with the current $3000-5000 aggregate publisher turnover per article, which the libraries collectively pay
2009 Unofficial Impact Factors

Osteopathic Journals

The bar chart compares the impact factors of three journals: OMPC, JAOA, and IJOM, across four citation metrics: A, A-sc, R, and R-sc. The chart illustrates the relative impact of each journal in terms of citation metrics.
OMPC Operational Considerations

- Editor-in-Chief was heavily invested in day-to-day activities of the journal and received no salary
- There was no journal staff provided other than the journal production team in London, which simultaneously supported about 150-200 other open-access journals for BMC
- The intent of the journal was to widen the scope of submissions to include any primary care topics to attract authors from outside the osteopathic profession
- Editorial board primarily consists of “ambassadors” who mainly represented osteopathic organizations (15 DOs, 2 MDs), although OMPC sought more MDs to encourage submissions in the primary care field
OMPC Lessons Learned

Being Part of BioMed Central (BMC)

- Status as a BMC independent journal essentially provided instantaneous entry into the journal publishing arena, at no cost

- Advantages
  - Established publication enterprise and business model
  - Available assistance and experience in journal promotional efforts
  - Editorial production team support always available
  - Special publications (e.g., conference proceedings) were supported
  - Mechanisms were in place for advancing journal (e.g., acquiring impact factor)

- Disadvantages
  - All journal equity and goodwill accrued to BMC
  - Status of OMPC was potentially at the mercy of BMC acquisition (e.g., Springer)
  - Direct competition with other BMC journals for manuscript submissions
  - “One size fits all” model for BMC journals
  - Vulnerability to the vagaries of international monetary exchange rates and their impact on article processing charges (APCs)
OMPC Lessons Learned

Other Considerations

- Initial concerns about OMPC “going out of business”
  - Backed by substantial funding from BioMed Central and Springer
  - Permanency of PubMed Central archives

- NIH Public Access Policy
  - Should have encouraged open-access publishing

- Stigma associated with publishing in an “osteopathic” journal
  - More pervasive than originally thought and probably the biggest reason for the eventual demise of OMPC

- Article processing charges (APCs)
  - Was a significant barrier to manuscript submissions because BMC institutional memberships did not grow as expected
  - OMPC had a substantial journal fund to provide APC waivers; however, need for a waiver was generally inversely correlated to authors’ status and/or manuscript’s quality
  - Need for vigilance to screen out industry-sponsored reviews with unacceptable conflicts of interest (avoid perception of being a “throw-away journal”)

Status of Osteopathic Publishing Options in 2011

- BioMed Central has divested itself of osteopathic journals
  - OMPC no longer published, effective January 2011
  - Chiropractic & Osteopathy changed name to Chiropractic & Manual Therapies, effective January 2011
- IJOM (Elsevier) has failed in its attempt to be indexed by PubMed
- JAOA
  - Still does not have an established impact factor
  - Currently undergoing transitions
Conclusions

- The osteopathic profession needs positive articles in elite high-impact medical journals to counter its “Catch-22”
- The osteopathic profession needs a credible “second-tier” journal for research in the fields of osteopathic medicine and primary care that is ignored by, or does not meet the standards of, elite high-impact medical journals
- The growth of osteopathic medicine will be enhanced by assembling a critical mass of investigators within the osteopathic profession who conduct substantive research having relevance to osteopathic principles and practices (Men at some time are masters of their fates: The fault, dear Brutus, is not in our stars, But in ourselves, Julius Caesar 1.2.135)