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Educating osteopaths to be researchers – what role should research methods and statistics have in an undergraduate curriculum?

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Abstract

Evidence-based medicine (EBM) involves using research data to enhance the diagnosis and treatment of clinical disorders. Somatic dysfunction and osteopathic manipulative treatment (OMT) are two unique aspects of osteopathy that will benefit from a greater emphasis on scientific evidence. Most evidence in osteopathy is based on expert opinions, case reports, case series, and observational studies. Only one systematic review of randomized controlled trials, involving OMT for low back pain, has been published. Although this study demonstrates the efficacy of OMT for low back pain, other clinical trials are needed to expand the evidence base in osteopathy. Undergraduate osteopathy curricula should ensure that students acquire the tools necessary to become knowledgeable consumers of the research and statistics presented in biomedical journals. Such curricula need to be supplemented with graduate training programs and research funding mechanisms to ensure that young osteopathic researchers are able to produce the research needed to practice and advance evidence-based osteopathy in the future.

Keywords

osteopathy; osteopathic medicine; osteopathic manipulative treatment (OMT); somatic dysfunction; low back pain; evidence-based medicine; evidence-based osteopathy; research methods; biostatistics

1. Research Methods 101: an overview of evidence-based osteopathy

The quest for evidence-based medicine (EBM) seemingly pervades all of modern clinical practice. The movement which started as clinical epidemiology in North America¹ and subsequently manifested itself as the Cochrane Collaboration² is now firmly entrenched in contemporary medicine. Four common applications of EBM in clinical practice involve using research studies to address the etiology, diagnosis, prognosis, and treatment of clinical disorders.³ Fundamental elements of the EBM process include: (1) finding relevant studies; (2) assessing their methodological characteristics; and (3) interpreting their results in light of the clinical question at hand. Thus, education in the trilogy of biomedical literature searching, research methods, and statistics should be a critical prerequisite for evidence-based practice in

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any health profession. This commentary will focus on the two latter components of the trilogy as applied to osteopathy.

Clinical research in osteopathy often focuses on patient-oriented studies, broadly defined as experimental and observational studies.⁴ The common types of research design that constitute patient-oriented research and, therefore, potentially contribute to evidence-based osteopathy (EBO) may be placed in the hierarchical order shown in Figure 1. This “evidence pyramid” is a useful point of departure for putting into context the evolution of osteopathic research. Historically, in various schools of medicine and health-related professions, principles and practices have flowed from founder to dedicated (and sometimes fanatical) followers, and eventually to the rank and file. Osteopathy was no different, with its founder Andrew Taylor Still, and the establishment of the American School of Osteopathy in 1892.⁵ Osteopathic education in manipulative techniques was largely handed from teacher to student following the apprenticeship model. After decades of such educational experience, both in the United States and Europe, a cadre of experts in osteopathy were developed. Their teachings and those of their followers constitute the base of the current evidence pyramid in osteopathy. Textbooks such as *Foundations for Osteopathic Medicine*⁶ are replete with examples of osteopathic manipulative treatment (OMT) techniques that are recommended by experts for treating somatic dysfunction or related clinical disorders. With the advent of open-access publishing and the related flexibility afforded by non-traditional online formats, even journals in the field of osteopathy now offer a vehicle for disseminating such OMT techniques.⁷

Moving up the evidence pyramid, case reports about individual patients and case series involving multiple patients with a given condition are also encountered in the osteopathic literature. The hallmark of such studies is that they move beyond expert opinion by providing some empirical data relating to a given clinical question. However, such data are often limited by providing no control data for comparison. For example, in the realm of diabetes, a report noted hypoglycemic symptoms following manipulation of the mid-thoracic area in a diabetic patient, with a consequent reduction in his daily insulin dosage.⁸ A viscerosomatic lesion was also identified in this report. Similarly, a series of 150 patients accumulated over a 25-year period (including unspecified non-diabetic patients) received OMT that was intended to provide pancreatic stimulation.⁹ Fasting blood glucose was initially measured, and patients then received pancreatic stimulation, consisting of raising of the second, third, fourth, and fifth ribs. Glucose was then measured 30 and 60 minutes following pancreatic stimulation. The results, although uncontrolled, showed rapid drops in blood glucose, including a hypoglycemic coma that was induced within 60 minutes of receiving pancreatic stimulation in the last case reported in this study! While such reports and expert opinions lack the methodological rigor to drive EBO recommendations, they nonetheless play an important role in the EBO process by proposing first principles in osteopathy and thereby generating hypotheses for further research using more rigorous methods.

Prospective cohort studies and retrospective case-control studies are observational studies, with adequate control groups, that traditionally have been used to identify etiological risk factors and thereby help establish disease causation. For example, observational studies were useful in establishing cigarette smoking as a cause of lung cancer.^{10, 11} Although there are no diseases that are considered unique to osteopathy, somatic dysfunction is a fundamental osteopathic concept that lends itself to scientific inquiry using observational studies. If somatic dysfunction represents a precursor of disease that, if left unchecked, could progress to clinical manifestations, then observational studies are an attractive option for studying this phenomenon. Somatic dysfunction is sometimes a manifestation of disease, such as occurs in viscerosomatic reflexes. In such cases, observational studies may be adapted to determine the strength of association between a disease and its subsequent viscerosomatic manifestations. Recently, a case-control study was used to show that osteopathic palpatory abnormalities at

T11-L2 were strongly associated with diabetes, suggesting a viscerosomatic reflex possibly related to diabetic nephropathy.¹² Observational studies may also be adapted to assess the benefits of OMT in clinical situations, thereby serving as an alternative to performing experimental studies. For example, an observational study was used to assess obstetrical outcomes, such as meconium-stained amniotic fluid, preterm delivery, umbilical cord prolapse, use of forceps, and cesarean section delivery, among women who had received prenatal OMT compared with women who had not received such OMT.¹³ The study found that prenatal OMT significantly reduced the risk of meconium-stained amniotic fluid and preterm delivery.

Randomized controlled trials are experimental studies that traditionally have been considered the gold standard in establishing the efficacy of an intervention in treating or preventing a clinical disorder. For example, several randomized controlled trials of OMT for low back pain have been reported over the past three decades.^{14–20} These studies involved subjects in ambulatory settings; however, their methodological aspects varied and most had relatively small sample sizes. These trials generally tended to support the benefits of OMT for low back pain, although none individually has been credited as definitively demonstrating the efficacy of OMT. Interestingly, the trial commonly cited in support of OMT for low back pain¹⁷ had important methodological weaknesses,²¹ and found no significant differences in any of the primary outcomes between the OMT and control groups.¹⁷ In essence this trial represents a non-inferiority trial,²² in which the OMT group generally fared as well as the control group while less frequently using analgesics, muscle relaxants, and physical therapy.

Systematic reviews (often coupled with meta-analyses) of randomized controlled trials have emerged during the EBM movement to assume their position atop the evidence pyramid. The rationale for greater acceptance and use of meta-analysis in medicine is evident in two examples. First, countless lives may have been saved had published meta-analytic results involving the efficacy of thrombolytic therapy in treating acute myocardial infarction been more readily accepted by “experts” and implemented in clinical practice.²³ More recently, a meta-analytic study demonstrated that cardiovascular adverse events associated with rofecoxib should have been identified several years before the drug was ultimately withdrawn from the market.²⁴ The authors of this study questioned why the drug manufacturer and drug licensing authorities did not continuously monitor and summarize the accumulating evidence. Meta-analysis has been used successfully in osteopathy to pool the results of clinical trials of OMT for low back pain noted above to thereby demonstrate a statistically significant and clinically relevant reduction in pain.²⁵

2. Statistics and probabilistic thinking in medicine and osteopathy

Statistics have long been an important element of public health. Much of the preeminence of statistics in this field has been linked historically to the need for prevention and control of the spread of infectious diseases through human populations. Through the early 20th century, government agencies and charitable organizations were often the source of health care for many people. The provision of such health care to the masses lent itself to planning and assessment using statistical methods. During the latter half of the 20th century, the use of statistics in medicine grew as government entitlement programs were established. For example, in the United States during the 1960s, millions of people became eligible for health care through the Medicare and Medicaid health insurance plans. Thus, statistics and epidemiology often served as pillars upon which public health and government health insurance plans were based, and they helped ensure the health of millions of people.

Today clinicians often rightly claim that each patient is unique. Consequently, they argue that research findings and relevant clinical practice guidelines and recommendations, even if evidence-based, are not necessarily applicable to their patients. While there is some element

of truth to this reasoning, it downplays important similarities among patients and consequently fails to capitalize on the potential of establishing clinical gestalts. The Healthier People Health Risk Appraisal instrument, which uses statistical prediction models based on the Framingham Study and other epidemiological studies, provides a classic example of how probabilistic data may be used by clinicians to enhance the health care and counseling of individual patients.

²⁶ For example, a 44 year-old female patient indicates that she is smoker who has high blood pressure, drives over the speed limit, hasn't had a pap exam in over 3 years, eats a high fat diet, but exercises at least 3 times per week. She is 5 feet 4 inches tall, weighs 170 pounds, and estimates herself to have a medium body frame. Using such very basic health information along with the Healthier People Health Risk Appraisal and its population-based approach, the clinician would have an abundance of data, as seen in Figure 2, which could be used in the health care and counseling of this particular patient. On average, for every 1000 women with a similar constellation of historical and physical findings as this patient, 48 (4.8%) will die in the next 10 years. Although *this* particular patient will either be living (0% mortality risk) or dead (100% mortality risk) 10 years from now, these population-based data still provide a useful point of departure in counseling her. Quitting smoking would have the greatest impact on survival in women like this patient, almost twice the impact of adequately controlling her blood pressure. Yet, considering clinicians' time and societal costs allocated to treating hypertension relative to smoking cessation efforts, who would argue that clinicians (or health insurers) adequately use the population-based statistics presented in this case scenario?

A recent survey of 277 internal medicine residents in Connecticut concluded that most lacked the knowledge of statistics needed to interpret many of the results published in clinical research. ²⁷ Only 59% correctly answered a fundamental knowledge-based question about the meaning of the $P = .05$ cutpoint in hypothesis testing. Worse yet, only 12% knew how to interpret 95% confidence intervals in determining statistical significance. Years since medical school graduation was inversely related to the knowledge scores attained. The authors commented that erroneous applications of clinical research may occur when physicians are unable to detect appropriate statistical analyses and to accurately understand their results. These findings and comments are an indictment of both undergraduate and graduate medical education curricula in the realm of statistics and understanding of the medical literature.

Although a discussion of classical statistical methods per se is beyond the scope of this commentary, the clinical applications of statistical thinking should not be overlooked. Diagnosis represents one aspect of health care where many clinicians poorly understand such basic statistical concepts as sensitivity, specificity, positive predictive value, and negative predictive value of a diagnostic test. These relatively simple probabilistic building blocks are integral to applying more complex (but potentially useful) concepts in the management of individual patients. The latter concepts include pre-test likelihood, pre-test odds, likelihood ratios (LRs) of positive and negative tests, post-test odds, and post-test likelihood of disease.

Somatic dysfunction is a distinctly osteopathic diagnosis considered to be central to osteopathy. While the prevalence of somatic dysfunction in various anatomical regions has been described in a family medicine population,²⁸ it would be useful to know what risk factors may be related to such somatic dysfunctions. The case-control study of osteopathic palpatory findings in type 2 diabetes provides data to begin addressing this issue by looking at the significant results for tissue texture changes at T11-L2 on the right side.¹² The relevant findings are summarized in Table 1. In this example, simple historical information about the presence or absence of type 2 diabetes is considered the "diagnostic test." In the absence of any information about the type 2 diabetes status of a particular patient, we estimate that about 14% of patients in family medicine clinics will have this element of somatic dysfunction.²⁸ This constitutes the pre-test likelihood of somatic dysfunction (i.e., the "disease" in this example). If the patient has type 2 diabetes (i.e., "tests positive"), using the likelihood ratio for a positive test (1.85) we can

compute the post-test odds of somatic dysfunction (30%) and ultimately the post-test likelihood of somatic dysfunction (23%). Alternatively, if the patient does not have type 2 diabetes (i.e., “tests negative”), using the likelihood ratio for a negative test (0.41), the post-test odds and post-test likelihood of somatic dysfunction can each be determined to be 7%. A likelihood ratio nomogram has been developed to minimize the computations needed to determine post-test likelihood of disease,²⁹ and modified versions of this classical Bayesian approach to diagnostic testing are being developed for use in didactic settings.³⁰

One might reasonably ask how the statistics in this diagnostic testing exercise advance osteopathy. The answer highlights both opportunities and fundamental challenges for the osteopathic profession. First, the exercise indicates that about one-quarter of patients with type 2 diabetes have the osteopathic palpatory finding of tissue texture changes at T11-L2, which is likely a viscerosomatic reflex indicative of chronic diabetics (possibly reflecting diabetic nephropathy). Thus, millions of patients with type 2 diabetes have somatic dysfunction that may be amenable to OMT. This provides an important rationale for using OMT to complement the conventional medical treatment of type 2 diabetes. In addition to treating the underlying pathology of visceral disorders, OMT of associated viscerosomatic reflexes has been advocated to reduce somatic dysfunction and interrupt the reflex arc, thereby influencing the affected viscus through somatovisceral mechanisms.³¹ However, before such OMT can be advocated in type 2 diabetes, a fundamental challenge is to close this viscerosomatic-somatovisceral loop. That is, randomized controlled trials involving complementary OMT in the treatment of type 2 diabetes are needed to demonstrate benefits in management, potentially including reduced risk of diabetic complications and improved quality of life among patients.

Osteopathic manipulative treatment is the unique approach to treating somatic dysfunction. As described above, low back pain is the clinical condition for which the most OMT evidence is available,^{14–20} including a systematic review and meta-analysis supporting the efficacy of OMT.²⁵ Overall, with regard to pain reduction, the latter study attributed an effect size of 0.30 to OMT. The effect size represents a standardized difference between treatment groups. While statistically appealing, a deficiency of such data is that most clinicians are unable to extrapolate them to the management of their patients. The following illustrates this dilemma. Twenty-five mm is the estimated standard deviation on a 100-mm visual analogue scale (VAS) for pain.³² Thus, on a 100-mm VAS for pain, OMT provides 7.5-mm (i.e., effect size $[0.30] \times$ standard deviation $[25 \text{ mm}]$) greater pain reduction than control treatments. But how beneficial is a 7.5 mm reduction in pain? This is a deceptively complex question that depends on multiple factors. An evidence-based approach may provide a way forward in this situation. Paradoxically, this requires that we “loose” information by abandoning the conventional VAS for pain (a continuous measure) in favor of a more readily interpretable measure of treatment response (a dichotomous measure). Once such a dichotomous outcome is specified, then the tools of EBM can be brought to bear, including measures for assessing the potential benefits and harms of OMT. These measures include relative risk reduction, absolute risk reduction, number needed to treat (NNT), number needed to harm (NNH), and likelihood of help vs. harm (LHH). Until the requisite studies and data are available to assess the benefits and harms of OMT using these evidence-based approaches, indirect comparisons with other accepted therapies may be used. For example, in treating pain, an effect size of 0.26 has been found for OMT vs. placebo control or active treatment,²⁵ while an effect size of 0.23 has been observed for non-steroidal anti-inflammatory drugs (including selective cyclo-oxygenase-2 inhibitors) vs. placebo control.³³

3. Osteopaths as research consumers and producers

Osteopaths should have the requisite skills in research methods and statistics to critically evaluate the relevant biomedical literature. The concepts presented above illustrate basic elements that constitute evidence-based practice (either directly involving osteopathy or

indirectly involving other aspects of medicine that may be relevant to patient care provided by osteopaths) and, therefore, should be included in the undergraduate osteopathy curriculum. Additionally, curricula in research methods and statistics should inextricably cover major sources of bias, including selection bias, information bias, and confounding. Intensive review of current journal articles, either as part of formal coursework or in journal clubs, is an essential component in the mastery of research methodology and statistics. In this way, students of osteopathy become knowledgeable consumers of the biomedical literature and will learn to apply relevant findings to their practices. The importance of such curricula is further highlighted by the World Health Organization, which recently has signaled a shift away from reliance on expert opinions and toward systematic reviews of the literature.³⁴

Clearly, there is also a desire for young researchers to gain proficiency in producing the needed research in osteopathy. Both undergraduate and graduate options should be available to help develop the next generation of osteopathic researchers. In the United States, where undergraduate research is generally not required, osteopathic students may elect to undertake dual degree programs that provide varying degrees of research training (e.g., D.O.-M.S, D.O.-M.P.H., and D.O.-Ph.D. programs). Subsequently, beginning osteopathic researchers are eligible for grant funding (including associated mentoring) from government agencies such as the National Institutes of Health (NIH). For example, their K-23 mechanism funds Mentored Patient-Oriented Research Career Development Awards, which provide support for the career development of researchers who have made a commitment to focus their endeavors on patient-oriented research. This mechanism provides support for up to five years to clinically trained professionals who have the potential to develop into productive, clinical researchers. The NIH's National Center for Complementary and Alternative Medicine is an attractive target for those in osteopathy seeking such support because manipulative and body-based practices represents a major area of funding. In Europe, many students in schools of osteopathy gain valuable experience by conducting supervised research projects as part of their undergraduate curricular requirements. However, upon completing the undergraduate curriculum in osteopathy, government research training and funding opportunities for osteopaths may be more limited in Europe than in the United States. Some European osteopaths are now enrolling in a graduate program recently established by the A.T. Still University in the United States.

4. Conclusion

Undergraduate coursework in research methods and statistics is necessary to adequately prepare osteopathic students to become knowledgeable consumers of the biomedical literature. Such curricula should focus on evidence-based applications relevant to diagnosis and therapy. Somatic dysfunction and OMT are uniquely osteopathic entities that are amenable to study using EBM concepts; however, much of the fundamental research still needs to be performed. A combination of novel approaches and more traditional research training and funding programs will be needed to support the future consumers and producers of osteopathic research.

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Figure 1. Hierarchy of evidence in patient-oriented osteopathic research. RCT denotes randomized controlled trial; SR, systematic review. (Adapted from Straus, Richardson, Glasziou, and Haynes.³)

Figure 2.
Sample Healthier People Health Risk Appraisal report. (Reproduced with permission from Scariati and Williams.²⁶)

Table 1
Somatic dysfunction in type 2 diabetes.*

	Somatic dysfunction is present	Somatic dysfunction is absent	Total
History of type 2 diabetes	47	12	59
No history of type 2 diabetes	15	17	32
Total	62	29	91

Sensitivity = $a/(a + c) = 47/62 = 76\%$

Specificity = $d/(b + d) = 17/29 = 59\%$

Positive predictive value = $a/(a + b) = 47/59 = 80\%$

Negative predictive value = $d/(c + d) = 17/32 = 53\%$

LR+ = sensitivity/(100% - specificity) = $76\%/41\% = 1.85$

LR- = (100% - sensitivity)/specificity = $24\%/59\% = 0.41$

Pre-test likelihood of somatic dysfunction = $173/1199 = 14\%$

Pre-test odds of somatic dysfunction = pre-test probability/(100% - pre-test probability) = $14\%/86\% = 16\%$

Post-test odds of somatic dysfunction (+ test) = pre-tests odds $\times$ LR+ = $16\% \times 1.85 = 30\%$

Post-test odds of somatic dysfunction (- test) = pre-test odds $\times$ LR- = $16\% \times 0.41 = 7\%$

Post-test likelihood of somatic dysfunction (+ test) = post-test odds/(post-test odds + 100%) = $30\%/130\% = 23\%$

Post-test likelihood of somatic dysfunction (- test) = post test odds/(post-test odds + 100%) = $7\%/107\% = 7\%$

* Data refer type 2 diabetes as a "diagnostic test" for tissue texture changes at T11-L2 on the right side. LR denotes likelihood ratio. Pre-test likelihood of somatic dysfunction is based on Licciardone, Nelson, Glonek, Sleszynski, and Crusier.²⁸