Focus on Research

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Integrating Evidence into Clinical Practice:
An Alternative to Evidence-based Approaches

The author of this paper suggests that Evidence-based medicine (EBM) has thus far failed to adequately account for the appropriate incorporation of other potential warrants for medical decision making into clinical practice. In particular, it is suggested that EBM has struggled with the value and integration of other kinds of medical knowledge, such as those derived from clinical experience or based on pathophysiologic rationale.

The general priority given to empirical evidence derived from clinical research in all EBM approaches is not epistemically tenable. A casuistic alternative to EBM approaches will be broad in approach. This alternative recognizes that five distinct topics are potentially relevant to any clinical decision.

These are

1) Empirical evidence,
2) Experiential evidence,
3) Pathophysiologic rationale,
4) Patient goals and values, and
5) System features,

No single topic has a general priority over any other and the relative importance of a topic will depend upon the circumstances of the particular case.

The skilled clinician, it is suggested, must weigh these potentially conflicting evidentiary and non-evidentiary warrants for action, employing both practical and theoretical reasoning, in order to arrive at the best choice for an individual patient.

Reference:

Tonelli MR. **Integrating evidence into clinical practice: an alternative to evidence-based approaches.** J Eval Clin Practice 2006; 12: 248.

Reflex Effects of a Spinal Adjustment on Blood Pressure

[Platform presentation; the Association of Chiropractic Colleges' Thirteenth Annual Conference, 2006]

Compiled by Dr Adrian Wenban, BSc., B.App., Sc., M.M.Sc

Most studies concerning the effect of a chiropractic spinal adjustment on blood pressure have shown either no significant effect of the adjustment or no conclusive relationship between the level of the spinal adjustment and the nature of the blood pressure changes. An interesting paper (1), recently presented at the Association of Chiropractic Colleges' Thirteenth Annual Conference, unveiled the results of a pilot study that investigated the effect of a diversified spinal adjustment on blood pressure with respect to the region of the spine adjusted.

Participants that met the selection criteria of the study included 63 patients reporting to a private chiropractic practice in Auckland, New Zealand. The study gained ethics approval from the New Zealand College of Chiropractic Ethics Committee. Blood pressure was manually recorded from both arms in the sitting position after patients were allowed five minutes of quiet relaxation. Patients were then examined for the presence of vertebral subluxations using motion and static palpatory findings and a coin was tossed to determine the allocation of the patient to the control or experimental group for that trial. In the experimental group, an adjustment was performed in each trial based on motion and static palpation findings and the trial was then allocated to a subgroup depending on the region of the spine that was adjusted. The control group received only gentle digital pressure at the site of suspected vertebral subluxation. The subgroup sizes ranged from 36-46 trials. Blood pressure was retaken at the end of each trial by the same chiropractor who performed the adjustment or digital pressure and the initial recording.

The ‘pre’ and ‘post’ blood pressure recordings were then compared using a 2-tailed paired t-test. The experimental subgroups all showed statistically significant changes of systolic and diastolic blood pressure ($p<0.001$). The cervical and lumbosacral adjustment groups showed a decrease of both systolic and diastolic pressure, while the thoracic adjustment group showed an increase. In the control groups, the only statistically significant change following adjustment setup and gentle digital pressure was for the diastolic pressure of the cervical group, which showed a small decrease ($p=0.02$).

The authors, in discussing their results, state,

> "The results of the present study support previous assertions that a sympathetic excitatory response may occur after adjustments to the thoracic spine and a sympathetic inhibitory response after adjustments to the lumbosacral and cervical spine. It is likely that considerable integration occurs at both spinal segmental and supraspinal levels of the neuraxis as a consequence of parallel processing of primary afferent inputs. Varying degrees of activation and inhibition of both segmental and supraspinal pathways may contribute to the different blood pressure responses depending on the region that was adjusted. Clinically, it is not known how important the results of this study are as blood pressure was not monitored long-term. Experimental design should be enhanced in future studies by using a blinded examiner, considering longer term follow up and the use of a digital oscillometric sphygmomanometer to record blood pressure."

Reference:

1.) Beck RW, Holt K, Sexton SG. **Reflex effects of a spinal adjustment on blood pressure** [platform presentation; the Association of Chiropractic Colleges' Thirteenth Annual Conference, 2006] J Chiropr Educ: SPR 2006; 20:1.

The Availability of References and the Sponsorship of Original Research cited in Pharmaceutical Advertisements.

The primary goal of pharmaceutical advertisements is to convince physicians to prescribe the manufacturer's product. These ads often cite external documents in support of their claims, but studies have shown that these claims may be misleading, distort the reporting of scientific data or fail to provide enough information to accurately interpret the data they present.

A recently published study (1) sought to determine what materials are cited in support of claims in pharmaceutical ads and medical research articles, and whether health care professionals seeking to verify the claims could obtain these references.

The authors reviewed 438 unique ads from the 1999 issues of 10 American medical journals (*American Journal of Psychiatry*, *Annals of Emergency Medicine*, *Annals of Internal Medicine*, *Annals of Surgery*, *Hospital Practice*, *Journal of the American Medical Association*, *New England Journal of Medicine*, *Neurology*, *Obstetrics and Gynaecology* and *Paediatrics*), and a random sample of 400 references in medical research articles selected from the same journals. References were then classified as journal article, data on file, meeting abstract or presentation, book or monograph, marketing report, prescribing information, government document or Internet site. Attempts were then made to confirm or obtain each reference through library and Internet searches or by direct request from the manufacturer. The main outcome measure was the availability of the reference to a clinician. The authors also attempted to ascertain the source of funding for original research cited in the ads and the research articles.

In the 438 ads with medical claims, 126 contained no references. The remaining 312 ads contained 721 unique references. Of these ad references, 55% (396/721) cited journal articles and 19% (135/721) cited data on file. In contrast, in the sample of research article references, 88% (351/400) cited journal articles and 8% (33/400) cited books. Overall, 84% of the citations from the ads were available: 98% of journal articles, 86% of books, 71% of meeting abstracts or presentations and 20% of data-on-file references. In all, 99% of the sample of research article references were available. Importantly, 58% of the original research cited in the pharmaceutical ads was sponsored by or had an author affiliated with the product's manufacturer, as compared with 8% of the articles cited in the research articles.

It is concluded,

> "Many pharmaceutical ads contain no references for medical claims. Although references to journal articles were usually obtainable, other published sources were not as easily acquired. The majority of unpublished data-on-file references were not available, and the majority of original research cited to substantiate claims in the pharmaceutical ads was funded by or had authors affiliated with the product's manufacturer."

Reference:

1. Cooper RJ, Schriger DL. **The availability of references and the sponsorship of original research cited in pharmaceutical advertisements.** CMAJ 2005;172:487-91.

Note - The full text PDF version of this paper can be accessed at the following address - http://www.cmaj.ca/cgi/reprint/172/4/487?ijkey=aedbfc68a03cd381f8a9a40404166ec3b27f6f92

The Comparison of Two Chiropractic Techniques amongst Older Adults.

The aim of the study (1), which was conducted in the research clinic of the Parker College of Chiropractic, was to compare the clinical outcomes of 2 approaches to chiropractic care for patients with chronic musculoskeletal pain. Included were the approach most commonly used by doctors of chiropractic (diversified technique spinal manipulation) and a non-manipulative mind-body approach (Bioenergetic Synchronization Technique). This clinical experiment tested the null hypothesis that there is no clinically or statistically significant difference in effect between the 2 approaches.

Eighty-one patients (74 females; median age, 66 years) were enrolled and 78 (96%) completed the study. The primary end point was the end of a 3-week non-treatment interval after a 4-week treatment period. An intention-to-treat analysis was used; all patients who completed assessments were included whether or not they were compliant with the treatment protocol. A sample size of 55 per group was estimated to be necessary to detect a clinically significant (6-point) between-group difference in the Pain Disability Index. The primary outcome, the mean between-group difference between PDI scores at visit 1 and the exit visit, was tested with a 2-tailed t test for independent samples.

Mean improvements in the Pain Disability Index from visit 1 to the exit visit were 6.9 points in the Bioenergetic Synchronization Technique group (n = 40) and 6.4 in the diversified technique group (n = 38); the between-groups difference was not statistically or clinically significant (95% confidence interval, -4.7 to 5.8).

For this particular group of patients, both groups demonstrated similar improvement scores on the Pain Disability Index.

Reference:

1.) Hawk C, Rupert RL, Colonvega M, Boyd J, Hall S. **Comparison of Bioenergetic synchronization technique and customary chiropractic care for older adults with chronic musculoskeletal pain.** J Manipulative Physiol Ther 2006; 29:540-9.

What is the Prevalence of Chiropractic Use among Children in South Australia?

Researchers from the School of Health Sciences, University of South Australia, Adelaide, recently had the results of a cross-sectional, population-based survey (1) published. The aim of the survey was to determine the use of complementary and alternative medicines and therapies (CAM) and common treatment modalities in children.

The survey of 2985 adult and 911 children aged 15 years or less, was conducted in South Australia during the Spring 2004. The outcome measures of interest were CAM use in children in the previous 12 months.

The authors report that overall, the 12-month prevalence of CAM use in children was 18.4% (95% confidence interval 15.9-21.0). A wide variety of CAM modalities were used by children including ingestible therapies (33%), **chiropractic (34%)** and massage (20%). Common reasons for use of CAM were to **prevent illness or to maintain health (39%)** and for musculoskeletal conditions (22%), respiratory problems (20%) and skin complaints (18%). There was little difference in the use of CAM treatment modality across child ages.

The authors concluded,

> "Approximately one in five children used CAM in the past 12 months in South Australia. Our findings further highlight the importance of increasing public awareness about the need to inform doctors and primary health-care providers of CAM use in children. Health professionals working with children should ask parents about their children's use of CAM. There is a need for further research examining the safe and judicious use of CAM in children".

Reference: 1.) Smith C, Eckert K. **Prevalence of complementary and alternative medicine and use among children in South Australia.** J Paediatr Child Health 2006; 42:538-43.

Effects of Strength Training on the Incidence and Progression of Knee Osteoarthritis

Quadriceps weakness is a risk factor for incident knee osteoarthritis (OA). While numerous studies have documented the symptomatic benefits of isometric and dynamic exercise for individuals with knee OA, no studies have investigated whether quads strengthening exercises prevent incident radiographic changes or slow the progression of knee OA.

A recently published paper (1) describes a randomized controlled trial that examines the effects of lower-extremity strength training on incidence and progression of knee OA. A total of 221 older adults (mean age 69 years) were stratified by sex, presence of radiographic knee OA, and severity of knee pain, and were randomized to strength training (ST) or range-of-motion (ROM) exercises.

Subjects exercised 3 times per week (twice at a fitness facility, once at home) for 12 weeks, followed by transition to home-based exercise after 12 months. Assessments of isokinetic lower-extremity strength and highly standardized knee radiographs were obtained at baseline and 30 months.

The authors report that subjects in both groups lost lower-extremity strength over 30 months. However, the rate of loss was slower with ST than with ROM.

Compared with ROM, ST decreased the mean rate of joint space narrowing (JSN) in osteoarthritic knees by 26% (P = not significant). However, the difference between ST and ROM groups with respect to frequency of knee OA progression in JSN consensus ratings was marginally significant (18% versus 28%; P = 0.094). In knees that were radiographically normal at baseline, JSN >0.50 mm was more common in ST than in ROM (34% versus 19%; P = 0.038). Incident JSN was unrelated to exercise adherence or changes in quadriceps strength or knee pain.

Study limitations include the absence of concurrent data on radiographic outcomes; isotonic strength measurements not blinded to treatment group; differences in the results of isotonic testing and isokinetic testing possibly due to strength specificity; and limited study power.

The authors conclude,

> "The strength training group retained more strength and exhibited less frequent progressive joint space narrowing over 30 months than the range of movement group. The increase in incident joint space narrowing >0.50 mm in strength training is unexplained and requires confirmation."

Reference:

1.) Mikesky AE, Mazzuca SA, Brandt KD, Perkins SM, Damush T, Lane KA. **Effects of strength training on the incidence and progression of knee osteoarthritis.** Arthritis Rheum. 2006 Sep 29;55(5):690-699 [Epub ahead of print]

Compiled by Dr Adrian Wenban, BSc., B.App., Sc., M.M.Sc

Cochrane Reviews Compared with Industry Supported Meta-analyses of the same Drugs: Systematic Review

The objective of this systematic review was to compare the methodological quality and conclusions in Cochrane reviews with those in industry supported meta-analyses and other meta-analyses of the same drugs. Data was collected from Cochrane Database of Systematic Reviews (2003, issue 1), PubMed, and Embase. Two observers independently extracted data and used a validated scale to judge the methodological quality of the reviews.

The authors report that 175 of 1596 Cochrane reviews had a meta-analysis that compared two drugs. Twenty four meta-analyses that matched the Cochrane reviews were found: eight were industry supported, nine had undeclared support, and seven had no support or were supported by non-industry sources. On a 0-7 scale, the median quality score was 7 for Cochrane reviews and 3 for other reviews ($P < 0.01$).

Compared with industry supported reviews and reviews with undeclared support, Cochrane reviews had more often considered the potential for bias in the review—for example, by describing the method of concealment of allocation and describing excluded patients or studies. The seven industry supported reviews that had conclusions recommended the experimental drug without reservations, compared with none of the Cochrane reviews ($P = 0.02$), although the estimated treatment effect was similar on average ($z = 0.46$, $P = 0.64$).

The authors conclude,

> "Industry supported reviews of drugs should be read with caution as they were less transparent, had few reservations about methodological limitations of the included trials, and had more favourable conclusions than the corresponding Cochrane reviews."

Reference:

Jorgensen AW, Hilden J, Gotzsche PC. **Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: systematic review.** BMJ 2006 Oct 6; [Epub ahead of print]

ASRF Chiropractic Update editor's comment: The following brief commentary by Dr. Scott Haldeman relates to a case series published in the same edition of the Spine Journal. Reference - Oppenheim JS, Spitzer DE, Segal DH. **Nonvascular complications following spinal manipulation.** Spine J 2005; 5:660-6.

COMMENTARY

Scott Haldeman, DC, MD, PhD, FRCP(C)

The authors present a retrospective series of 18 cases where patients claimed to have suffered a severe nonvascular complication after spinal manipulation. These cases were gleaned from a neurosurgical practice over a period of 6 years. It is important to study adverse events and negative outcomes following any treatment, and spinal manipulation should be subject to the same scrutiny as other treatment approaches. There is no treatment for spinal pain that is free of risk, and it is important that those risks are known.

This paper will clearly appeal to surgeons who consult on cases of adverse events associated with non-surgical care, perhaps even eliciting a strong emotional response to the topic. Similar reactions are not uncommonly expressed by gastroenterologists who have to deal with the complications of nonsteroidal anti-inflammatory drugs, cardiologists who now have to deal with the recently documented vascular complications of cyclooxygenase-2 inhibitors, and neurologists who are often called in to see the disasters that can occur after surgery.

The issue here is not that the authors would have consulted on such patients but rather that so few cases could be found in what is clearly a very busy neurosurgical practice. Estimates of 60,000 chiropractors and 3,000 neurosurgeons in the United States would indicate that the referral base ratio would be 20:1. If a practice with three neurosurgeons was aware of only 18 serious adverse events from 60 chiropractors over a 6-year period, the incidence of these complications is so small that it would be the envy of any other medical or surgical spinal treatment approach.

Reference:

Haldeman S. **[Nonvascular complications following spinal manipulation] commentary**. Spine J 2005; 5:667.

Identifying Domains of Chiropractic Health Promotion and Wellness

The objective of this workshop was to promote standardization of chiropractic practice through identification of domains of health promotion and wellness appropriate for integration with usual and customary chiropractic practice.

A 12 hour workshop was convened to identify and develop domains within the broad areas of chiropractic health promotion and wellness most appropriate for chiropractic practice. Seed material was submitted to a panel of eight chiropractors with expertise in health promotion and wellness. Areas of expertise included related graduate training, instruction of health promotion and wellness classes, and experience in research and

practice associated with health promotion and wellness. Participants made presentations in pairs with critique and suggestions for additional material following each presentation.

The authors report that the domains of chiropractic health promotion and wellness identified included -

Leading health indicators
Principles of health behaviour
Screening and risk assessment
Strategies for lifestyle modification
Spinal health
Nutrition
Physical and mental fitness
Performance enhancements
Occupational health

The authors concluded,

> "Greater than 90% of chiropractors report that they perform health promotion and wellness procedures. (2) Identification and development of domains of chiropractic health promotion and wellness most appropriate to chiropractic practice can lead to increased standardization of chiropractic health promotion and wellness practices".

References:

1.) Gatterman M, Hawke C. Identifying domains of chiropractic health promotion and wellness. Proceedings of the 2006 Conference on Chiropractic Research. September 15-16, 2006, Chicago Illinois. page 65.

2.) Christensen MG. Job analysis of chiropractic. A project report, survey analysis, and summary of the practice of chiropractic in the United States. Greeley, CO. National Board of Chiropractic Examiners. 2005.

CAM Use and Information-seeking Behaviour among Medical Students, Residents & Faculty

There is significant and growing national interest in the introduction and integration of CAM instruction into allopathic medical education, in part supported by recent educational funding from the National Institutes of Health. Interestingly, rates of CAM use by US medical students were found to be higher than reported in the US general population in both 1998 and 2004.

The objective of a recently published survey (1) was to investigate and compare CAM attitudes, CAM use, and CAM information-seeking behaviours to derive priorities for CAM instruction in medical school and residency. The groups surveyed were (a) medical students, (b) medical and surgical interns at the start of their post-graduate training, and (c) faculty who teach or intend to integrate CAM into their courses or classes.

Student respondents included two medical student class cohorts (*n*= 355) at the University of California, Irvine (UCI), School of Medicine. The previously validated 10-item CAM Health Belief Questionnaire (CHBQ) was used to measure attitudes.

The final sample included 667 respondents with 53% (n=355) medical students, 39% (n=258) interns and 8% (n=54) faculty.

Faculty used a significantly higher total number of CAM modalities than either students or interns (*F*=26.18; *p*<.0005). Across the 3 groups of respondents, massage was the most frequently used modality, followed by Spirituality and herbals. The next 3 highest rates of use occurred for meditation, **chiropractic** and traditional Oriental Medicine. Students and interns were similarly likely to use meditation and **chiropractic** but their use was lower than that of faculty.

The most commonly identified resources for CAM information for all 3 respondent groups were the Internet (75 to 80%), followed by journals (40 to 70%) and books (40 to 60%). Faculty members were twice as likely to use journals as resources compared to students and interns. Of online resources used, PubMed was identified most often (75 to 85% of respondents) followed by the Cochrane Library.

The authors concluded,

> "We conducted a survey of attitudes toward CAM and CAM use that included rate of self-use of CAM modalities and information-seeking behaviours amongst medical students, interns and selected faculty attending CAM workshops. We used a previously validated measure, the CHBQ, to assess CAM attitudes. Not surprisingly, faculty members were likely to have more positive attitudes on the CHBQ compared to interns and students. They also demonstrated higher use of CAM modalities than medical students and interns. A notable result was that student attitudes toward CAM and CAM use remained stable and positive and did not deteriorate over the course of training from year 1 to 3 as might be expected from exposure to negative attitudes toward CAM during clinical training. We speculate that CAM instruction could be best directed toward increasing student knowledge of CAM modalities available in their communities and skills to access, appraise and interpret evidence on CAM use, to appropriately advise patients."

Reference:

1. Lie DA, Boker J. **Comparative survey of Complementary and Alternative Medicine (CAM) attitudes, use, and information-seeking behaviour among medical students, residents & faculty.** BMC Med Education 2006; 6:58.

Note - The PDF version of the above cross sectional/longitudinal survey can be accessed at the following web-address - http://www.biomedcentral.com/content/pdf/1472-6920-6-58.pdf

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