

## Cochrane Review of Chiropractic Interventions for LBP Misses the Mark

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As systematic as Walker, et al.'s recent Cochrane review of combined chiropractic interventions for low back pain<sup>1</sup> may seem, it cannot be disputed that it remains only a single and possibly myopic lens through which the most appropriate clinical interventions for chronic low-back pain may actually be viewed. For although the review initially identified 3,699 potentially relevant citations from a broad array of search methods, it accepted and integrated just 12 studies and excluded: (1) nonrandomized, observational, and uncontrolled studies; (2) studies whose interventions were limited to chiropractic spinal manipulative therapy; and (3) studies in which the chiropractor delivered the intervention in both study arms, since "the overall effect of the combined chiropractic interventions could not be determined from the study design."

While the authors' approach could be commended for recognizing more pragmatic trials approaching "real clinical practice," it immediately raises suspicions that this objective has been markedly compromised from the following perspectives:

### Adherence to Blinding as a Criterion of Quality

The authors' slavish adherence to blinding of patients and providers as a criterion of freedom from bias - and thus a criterion of quality - is not only diametrically opposed to the actual experiences of a patient in a clinical encounter, but also is difficult if not impossible to implement (with the possible exception of the use of drop-tables or instrumental methods of adjustment). This is simply because physical methods, rather than the taking of placebo pills are involved. The nonfeasibility of blinding the practitioner in numerous modalities of alternative medicine has been extensively discussed elsewhere<sup>2</sup> and needs to be duly noted.

### Comparative Side Effects and Relative Safety

Although Walker's study was limited to the more traditionally measured pain, disability, and global outcome scales, one has to recognize the element of safety in the real-world clinical encounter. For spinal manipulation, the occurrence of major complications, regardless of the region of the spine manipulated, has generally been shown to be less than one per million.<sup>3-4</sup> These figures pale when compared to an extensive body of literature describing as many as 10,000-20,000 fatalities produced annually by NSAID medications alone, frequently the treatment given for low back pain in medical settings.<sup>5-6</sup>

The comparison between spinal manipulation to the commonly used treatment alternatives of either direct analgesic ingestion or visits to the general practitioner should ideally be presented during the informed consent process as one of relative clarity and comprehensiveness to the patient; in one instance, there is an option with a low rate of lasting side effects, and, in the other, a treatment regimen with severe and sometimes fatal complications that are inexplicably deemed to be "acceptable."<sup>7</sup>

## Inclusion of the Cherkin Study

The assertion by Walker, et al., that their included study from Cherkin<sup>8</sup> is "free from other bias" is highly problematical in that the following criticisms can be leveled against that particular investigation: (a) The side-posture technique is only one of several alternatives available to the chiropractor and in no way represents the combined chiropractic interventions as touted in Walker, et al's title ["A Cochrane Review of Combined Chiropractic Interventions for Low-Back Pain"]; (b) The characteristics of the medical intervention are not given; (c) Patient expectations are not validated and appear to be skewed; (d) The baseline characteristics do not appear to be matched; (e) The sample size is too small to allow apparently favorable trends to emerge; (f) Patient compliance is not specified; and (g) The grounds for patient exclusion have not been specified.

Indeed, the Cherkin study has been extensively rebutted elsewhere,<sup>9-11</sup> and an evaluation from the Royal College of General Practitioners has concluded that the Cherkin study neither adds nor detracts from the evidence base regarding appropriate interventions for low-back pain.<sup>12</sup> Therefore, one cannot help but conclude that the integration of Cherkin's data into Walker's study may represent a significant liability.

## Intrinsic Deficiencies of Systematic Reviews and Meta-Analyses

Regarding their clinical relevance, the very basis of meta-analyses – and their related systematic reviews – bears further scrutiny. One report has gone so far as to compare meta-analyses to statistical alchemy due to their intrinsic nature. This report suggests that meta-analyses are responsible for: "the removal and destruction of the scientific requirements that have been so carefully developed and established during the 19th and 20th centuries. In the mixtures formed for most statistical meta-analyses, we lose or eliminate the elemental scientific requirements for reproducibility and precision for suitable extrapolation, and even sometimes for fair comparison."<sup>13</sup>

Specifically, Feinstein has raised the following deficiencies of meta-analysis, most having to do with the sloughing of important clinical information:<sup>13</sup>

- Disparate groups of patients of varying homogeneity across different studies are thrown into one analysis, often called a "mixed salad."
- The weighting of studies of different quality may be inaccurate or absent altogether.
- One needs to know about the real-world effects in the presentation and treatment of patients; in particular the severity of the illness, co-morbidities, pertinent co-therapies and clinically relevant and meaningful outcomes.
- Inconsistent statistical techniques exist pertaining to increments, effect size, correlation coefficients, and relative risk and odds ratios.
- The reference denominator may be omitted.
- The odds ratio inflates the true value of the relative risk under certain conditions.

In any event, the numbers of patients needed to treat must be reported in order to observe a true difference in treatment groups, a practice often overlooked in meta-analyses. To make matters worse, a recent report involving four medical areas (cardiovascular disease, infectious disease, pediatrics and surgery) indicates that individual quality measures were not reliably associated with the strength of the treatment effect in 276 randomized controlled trials analyzed in 26 meta-analyses.<sup>14</sup> Finally, it has been convincingly shown elsewhere that biases in scoring the quality of studies – and thus their inclusion in systematic reviews such as Walker's – can produce diametrically opposed conclusions depending upon whose scoring criteria one chooses.<sup>15</sup>

## Overlooked Studies of Potential Significance

Arguments can be raised to the effect that numerous studies of potential significance have been omitted in Walker, et al.'s review. Observational studies, in particular, have been found to have improved in their validity, such that: (1) estimated combined treatment effects from observational studies reported after 1984 are either consistently larger or qualitatively different from those obtained in randomized controlled trials;<sup>16</sup> and (2) average results of observational studies were found to be "remarkably similar" to those obtained in randomized controlled trials.<sup>17-18</sup> That said, the following omitted studies - some being randomized, controlled trials - are examples of additional perspectives lacking in the Walker study:

- Although chiropractors were not exclusively factored out from osteopaths and physiotherapies in the multiple arms of the U.K. BEAM trial, they were included in a trial arm which specified a spinal manipulation *package* in which practitioners "chose from the agreed manual and *non-manual* treatment options" [italics mine], including spinal manipulation followed by exercise. In this regimen, the manipulation package compared to other regimens displayed a "moderate" benefit at three months and a "small" benefit at 12 months.<sup>19</sup>
- A comparison of two approaches to chiropractic care, one including the method most commonly used by doctors of chiropractic and which included soft-tissue treatment, heat, ultrasound and/or interferential current, as well as advice on exercise and nutrition, yielded a clinically significant improvement in the Pain Disability Index both at the end of a four-week treatment period and three weeks afterward. The patient population consisted of 81 patients ages 18 years or older with musculoskeletal pain of at least three months duration.<sup>20</sup>
- Hondras' comparison of two biomechanically distinct forms of spinal manipulation included a home exercise instruction session. Compared to a minimal medical conservative care regimen, either chiropractic intervention yielded improvements in the mean functional status 18 weeks after six weeks of treatment, ranging from 1.3-2.2 points over the medical group. Patients were at least 55 years of age and presented with nonspecific back pain of at least four weeks duration.<sup>21</sup>
- The fact remains that practice-based longitudinal studies of chiropractic patients with acute and chronic low-back pain whose pain and disability indices matched those of patients treated by conventional medical interventions showed marked improvements compared to medically treated patients up to one year following treatment.<sup>22</sup> Other studies involving chiropractic patients with chronic low-back pain with pain radiating below the knee showed the same improvements at one year compared to their medically treated cohorts.<sup>23</sup>

## Narrow Review of the Literature

Despite the fact that Walker, et al.'s study was limited to combined chiropractic interventions, it is surprising and somewhat disappointing that variances with a significant body of systematic reviews that were limited to single chiropractic manipulative procedures were not more thoroughly explored. The only such study by Assendelft<sup>24</sup> not actually appearing in a journal was cited by the authors; however, the more recent and numerous studies bearing journal publications by Bronfort,<sup>25-26</sup> Lawrence<sup>27</sup> and Dagenais<sup>28</sup> were not.

Yet in these unrecognized studies, moderate to strong evidence in support of spinal manipulation was evident. To provide further enlightenment as to why combined chiropractic interventions might have been found to be largely ineffective in Walker's study, as compared to the multiplicity of more positive clinical results in the single-intervention studies, further discussion of this apparent discrepancy should have been provided.

The prevailing operative that one carries away from the Walker, et al., study is that the authors have assiduously turned the crank of a formulaic literature review and ground through a vast body of retrieved material, collecting only a few and sometimes fatally flawed pieces of literature on which to base their conclusions. From many points of view, Walker's exercise appears to have strayed far from what is truly a clinical perspective, one in which the most clinically relevant evidence base has been argued to be no less than a tripartite construct of the best available external evidence, individual clinical expertise<sup>29</sup> and empowerment of the patient in the decision-making process.<sup>30</sup> For this reason, as well as those discussed above, the authors in their attention to certain details appear to have missed the forest for the trees and left us with a regrettably incomplete portrayal of clinical evidence in support of the chiropractic management of back pain.

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