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Re: Bouter L, Pennick V, Bombardier C. Cochrane back review group. Spine. 2003;28 : 1215-1218. - Response

Bouter, L.M.; Pennick, V.; Bombardier, C.

published in

Spine

2004

document version

Publisher's PDF, also known as Version of record

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citation for published version (APA)

Bouter, L. M., Pennick, V., & Bombardier, C. (2004). Re: Bouter L, Pennick V, Bombardier C. Cochrane back review group. Spine. 2003;28 : 1215-1218. - Response. *Spine*, 29(5), 596-596.

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Letters

To the Editor:

Re: Bouter L, Pennick V, Bombardier C. *Cochrane Back Review Group. Spine. 2003;28:1215-1218.*

I read with great interest the recent report of Bouter *et al* of the Cochrane Back Review Group (CBRG) regarding its mission, scope, and activities. I was particularly pleased to read of their recent recognition of the need to “broaden the scope” of their work.

As reported in the article, historically, the only focus of the CBRG has been on randomized controlled trials (RCTs) of low back treatment interventions. Unfortunately, these RCTs have provided minimal guidance in managing low back pain (LBP), a result that more and more are realizing will be perpetuated as long as such studies continue to focus on nonspecific LBP rather than on validated LBP subgroups.

Nonspecific, unhelpful outcomes are very much a function of studying nonspecific groups. A commonly cited analogy may help understanding: to determine the efficacy of sublingual nitroglycerin, it is best to study a subgroup with chest pain rather than studying everyone with chest pain, regardless of its source. The high efficacy of nitroglycerin for cardiac patients would be missed completely by studying only nonspecific chest pain.

This point was addressed exceptionally well by Spratt,¹ who correctly stated that any RCT intended to evaluate treatment efficacy must first establish the validity of an “assessment–diagnosis–treatment–outcome” model consisting of three important links: assessment linked to diagnosis, diagnosis linked to treatment, and finally, treatment linked to outcome. Spratt stated that none of these three links can be validated until all previous links have been established.¹

RCTs of nonspecific LBP, Pratt stated, “generally focus only on the treatment–outcome link, without carefully and explicitly establishing the assessment–diagnosis and diagnosis–treatment links.”¹ For this reason, Pratt indicated that RCTs of nonspecific LBP “are doomed because they fail to establish all three links and thus leave too many alternative explanations, or rival hypotheses, for interpreting the results.”¹ Without adopting this research model, “the results of randomized controlled trials will continue to be frustrating, meaningless, and even misleading,” resulting in “articles written in another 25 years that suggest that Nachemson’s 1976 lament,² that 85% of patients with LBP have no specific diagnosis, remains as true as it was 50 years before.” How tragic that would be!

Reports cited by Bouter *et al* of the Second Forum for Primary Care Research in Low Back Pain agree by concluding that the number 1 LBP research priority is the identification of LBP subgroups and the criteria used to differentiate them.³ Identifying these subgroups is the essence of Spratt’s¹ first two links and the foundation for designing meaningful RCTs.

Bouter *et al* reported that the CBRG has more recently recognized the importance of performing systematic reviews of “etiological, diagnostic, and prognostic studies.” The importance of such studies and reviews is characterized as providing the means to “answer the ‘Holy-Grail’-type questions,” such as which interventions are most effective for which patients and what are the most important (preventable) predictors of chronicity. Obviously, these authors acknowledge the high priority of non-RCTs focused at investigating diagnostic and prognostic factors.

As such, it is then confusing why the CBRG continues their exclusive review of RCTs that focus primarily on Spratt’s treatment–outcome link and only on nonspecific LBP. Why are its limited resources still only directed toward systematic reviews of RCTs that, if we are to believe Spratt, are “doomed,” even “misleading”¹ and will more likely detract from our progress than contribute to it? RCTs are simply the wrong study design for investigating what we are now told should be our top clinical research priority.

If the mission of the CBRG is to have a positive impact on our understanding of the clinical management of LBP, it must reconsider its funding priorities and work focus, putting RCTs of nonspecific LBP at a somewhat lower priority until RCTs of validated subgroups are available. Meanwhile, the pursuit of studies that address their “Holy-Grail” topics, *i.e.*, subgroup identification and outcome prediction, would seem a much more productive and beneficial direction for them to go at this time.

The Bouter *et al* article closes with an open invitation for volunteers to help with their work. I, for one, would be delighted to be part of their transition to include this new focus on reviewing studies investigating the reliability and validity of LBP subgroups.

Ronald Donelson, MD, MS
Department of Orthopedic Surgery
Dartmouth-Hitchcock Medical Center
Lebanon, NH

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In Response:

We appreciate Dr. Donelson's interest in our article, and we agree with some of his comments. We also believe that evidence-based management of low back pain (LBP) would improve if it were possible to identify subgroups of patients for whom specific treatments were indicated. We agree that randomized clinical trials (RCTs) can neither identify homogeneous subgroups of patients nor lead to promising new treatments. However, this is not what RCTs are meant to do, and the same holds for systematic reviews of RCTs. The humble aim of both study designs is to assess the effectiveness of a plausible and/or widely used intervention in comparison to an alternative, among patients with a putative indication for both interventions.

When the results of an RCT or corresponding systematic review are negative, it may be because both interventions are equally (in)effective, or it may be because the study population is too heterogeneous. Of course, chance findings or a suboptimal operationalization of one or both interventions may also be an explanation of the findings. We believe that this type of information is important to inform clinical practice where many interventions are offered to patients with nonspecific LBP. The mission of the Cochrane Collaboration is to summarize the available evidence from RCTs on the effects of health care interventions, but it does not in any way claim that etiologic, diagnostic, prognostic, or clinimetric systematic reviews are unimportant. Currently, broadening the scope to include diagnostic reviews is being considered, and the Back Review Group is eager to participate in this development.

Since the publication of the Nachemson paper, cited by Donelson, there has been no shortage of articles claiming to identify clinically meaningful subgroups within the domain of nonspecific LBP. Unfortunately, however, very little progress has yet been made in the search for this "Holy Grail." Some nonbelievers even dare to suggest that the "Holy Grail" doesn't exist and that we should instead focus on the common features of a range of musculoskeletal disorders, for instance, nonspecific back, neck, and upper limb pain. The future will teach us who is right. The Back Review Group is not in the business of producing or funding the necessary new primary studies. We will continue to focus on systematic reviews of RCTs and try to broaden our scope gradually to include other types of reviews. We strongly disagree that our work is "doomed" or "misleading," although we do admit that we are unable to answer all the relevant

questions concerning LBP. However, the core business of the Cochrane Back Review Group of carefully conducting systematic reviews of RCTs has played and still plays an important role in identifying effective treatments for low back and neck pain. This work has been used by many guideline committees around the world and has proven to be useful.

L. M. Bouter, PhD

V. Pennick, RN, BScN, MHSc

C. Bombardier, MD, FRCP

Institute for Research in Extramural Medicine

VU University Medical Center

Amsterdam, The Netherlands

To the Editor:

Re: Giles LG, Muller R. Chronic spinal pain: a randomized clinical trial comparing medication, acupuncture, and spinal manipulation. Spine 2003;28:1490–502.

I read with pleasure this well-designed clinical article. This study has tremendous clinical application for both physicians and patients.

Tremendous amounts of sick leave and billions of dollars are spent annually for spinal pain with the overwhelming majority involving low back pain. As we all know, more and more patients are seeking complementary and alternative medicine approaches for various ailments, especially musculoskeletal conditions involving the neck and low back.

Treating physicians are also beginning to realize the overwhelming need and potential of alternative methods for these often chronic and debilitating conditions in our young, otherwise healthy, working population. This has led to a recent upsurge in interest in treatment alternatives for various musculoskeletal conditions with manipulation on the forefront of these alternative methods. We have seen recent articles on clinical outcomes following manipulative treatment as well as recent symposia on this subject at national integrative spine meetings such as the North American Spine Society this past October. As a spinal surgeon and chiropractor, in my nonsurgical patient population, I often incorporate spinal manipulation along with other treatment methods *via* a multidisciplinary approach into my treatment algorithm with positive results. This multidisciplinary approach to patient care is being utilized with increasing frequency across the country, and it gives me great pleasure to witness the growing partnership between the allopathic and homeopathic professions. It must be emphasized that this study incorporated the most common form of manipulation involving a high velocity, low amplitude thrust as their form of treatment, as there are other types of "spinal manipulation" techniques. Furthermore, although chiropractors perform the vast majority of spinal manipulation, they are not the only health professionals utilizing it. Future studies need to be performed with a

larger patient base and longer follow-up. Finally, and probably most importantly, I strongly feel that articles like this will help to decrease the anxiety of both health care professionals and their patients to seek manipulative treatment either alone or as an adjunct and hopefully allow a more complete array of cotreatment methods that can offer patients pain relief and a better quality of life. After all, our goal as doctors is to help alleviate pain and suffering of patients without undue harm, so interestingly enough, we have been on the same page all along.

*Jeff S. Silber, MD, DC
Department of Orthopedic Surgery
Long Island Jewish Medical Center
Great Neck, New York*

In Response:

We thank Dr. Silber for his comments on our randomized clinical trial (RCT). We attempted to establish a well-designed RCT as a basis for studies on spinal pain syndromes that are costly to patients and cause tremendous suffering and hardship. We agree that incorporating spinal manipulation with other treatment methods *via* a multidisciplinary approach can have positive results. This reinforces the concept for establishing the Multidisciplinary Spinal Pain Unit (MSPU) at Townsville General Hospital (TGH) in July 1995. The Unit's Mission Statement, in part, was "to provide a multidisciplinary focus for the diagnosis and treatment of spinal pain sufferers. In addition, the Unit would collect data for research and education with respect to the clinical symptom of spinal pain. . .to lessen the human, social and economic costs of this common, poorly understood, and disabling condition." The Unit's primary intention was to determine what patient satisfaction was to such an approach and to ascertain which of three specific treatment methods may be more beneficial for chronic spinal pain sufferers, the objective being to enable patients to return to work and to live a normal life.

Cooperation between a hospital and a university, in order to combine service provision for patients and a legitimate research base, was achieved by the vision of the then Director of Medical Services at TGH and the then Vice-Chancellor of James Cook University, both of whom facilitated the establishment of Australia's first hospital-based multidisciplinary spinal pain service provision and research activity. Initial funding for staff salaries was provided by the university with the Australian Medicare system allowing Medicare rebates for medical practitioners for service provision. Subsequent funding was *via* a philanthropist, then by a 4-year funding grant from the State Government of Queensland to "enable the work of the Unit to continue."

In addition to the Unit's multidisciplinary staff (medical practitioner, chiropractor, acupuncturist, chiropractor/clinical anatomist) working as a team at TGH, the

goodwill of an orthopedic surgeon enabled the Unit to request magnetic resonance imaging (MRI) studies, when required, to ensure a thorough investigation of patients. Imaging costs, therefore, were covered under the Commonwealth of Australia Medicare system. In addition, a consultant psychiatrist, with an interest in chronic pain, and who was the catalyst in the establishment of the Unit, made it possible for any of the Unit's patients that were "at the end of their tether" due to chronic spinal pain to be fitted into his busy private practice on short notice, as did a specialist in rehabilitation medicine. These specialists had private practices outside the public hospital system but only charged the Unit's essentially impecunious patients the Medicare rebate fee, in effect subsidizing the Unit's activities.

A patient satisfaction questionnaire showed that 85.9% of patients randomly surveyed gave a very positive response.¹ This was gratifying, as most patients presented with serious and intractable spinal pain problems, usually of considerable duration. We agree with Dr. Silber that a study with a larger patient base and longer follow-up needs to be performed. When the Director of the Unit requested ongoing service provision funding of U.S. \$192,000 per year for 3 years from Queensland Health, funding was denied, which is regrettable, as it took several years of negotiation to establish the unique MSPU in an Australian hospital setting, and it provided a valuable service to many general and specialist medical practitioners and patients. Furthermore, over the Unit's 7-year period of operation, it achieved its aims and goals as stated in the Mission Statement. By denying funding, the State Government effectively dismantled the flourishing Unit, which is most unfortunate, as the period from 2000 to 2010 is the International Bone and Joint Decade. Unless governments provide long-term funds to enable multidisciplinary spinal pain units to address the huge and skyrocketing problems associated with spinal pain, they will continue to waste large amounts of taxpayer funds on a noncohesive spinal pain health care system. As Dr. Silber states, it is importance for patients to receive a complete array of cotreatment methods that can offer them pain relief and a better quality of life.

We hope that the international response to the Unit's activities will lead to greater collaboration between clinicians from different professional groups.

*Lynton G. F. Giles, DC, MSc, PhD
Reinhold Muller, PhD
School of Public Health and Tropical Medicine
James Cook University
Townsville, Queensland, Australia*

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To the Editor:

Re. Kleinstueck FS, Diederich CJ, Nau WH et al *Temperature and Thermal Dose Distributions During Intradiscal Electrothermal Therapy in the Cadaveric Lumbar Spine*. *Spine* 2003;28:1700–8 and the accompanying *Point of View* by Carragee EJ. *Spine* 2003;28:1709

Both the article by Kleinstueck *et al* and the point of view following it are well written and informative, and we recognize the time and effort required in such research and discussion. We would like to further the discussion regarding the position of the catheter during intradiscal electrothermal therapy (IDET), and we appreciate the opportunity this forum allows for such debate.

After assessing the temperatures and thermal dose distribution during IDET, the authors reported that temperatures were not reliably produced in clinically relevant regions, such as the posterior annulus. Our understanding from the method of this study was that the IDET catheter was placed in the nucleus or inner annulus, and in reading both discussions, a reader might assume that this is the most common final catheter position used in clinical practice. In the clinical setting, however, a more common practice is to place the catheter in the outer annular fibers. Karasek and Bogduk¹ emphasized that the catheter position at all times is buried between the lamellas of the annulus fibrosus 5 mm deep to its outer surface.

The IDET probe was developed as an improved method of delivering thermal energy to target tissue. Sluijter² utilized a standard radiofrequency needle inserted into the center of the disc.³ Saal and Saal⁴ improved the method using a catheter that could be navigated within the disc. The original idea was to be able to place catheter in outermost annular fibers where the majority of the pain fibers occur. Bilateral catheter insertions were performed when needed to completely cover the outer annulus and to improve outcomes some have recommended placing the IDET catheter within 5 mm of outer annulus.¹ We also prefer to have the catheter placed in close proximity to the majority of nerve fibers, and in fact, when there has been significant posterior annular disruption, it is difficult to navigate the catheter anywhere but the outermost annular fibers. With the catheter within 5 to 6 mm of the outer annulus, the Kleinstueck *et al* study showed that one can achieve sufficient thermal doses capable of generating complete thermal damage to the nociceptive nerve fibers. The provocation of concordant pain recorded during IDET in the O'Neil *et al* study⁵ was also based on the IDET procedure in which catheters were often placed within the outer annular fibers. Our recent study case reviews⁶ showed that 90% of the time, the catheter was within 5 mm of the outer annular fibers. In addition, we noted that outcomes were poorer and postprocedural flare-ups were longer with the recommended 90° protocol. When the catheter was located in the outermost annular fibers, outcomes actually improved with lower temperatures (<85°) and shorter than recommended total heating times (<15 minutes).

In conclusion, we agree with both Kleinstueck *et al* and Carragee's concern for recommending a more aggressive heating protocol based on the study findings, and we feel that higher temperatures, longer heating times, or both should be reserved for cases where the catheter is within the nucleus or inner annulus. When the catheter is in the outermost annular fibers, nociceptive nerve fiber destruction with less collateral tissue damage can probably be achieved at more conservative heating protocols.

Richard Derby, MD
Sang-Heon Lee, MD, PhD
Spinal Diagnostic & Treatment Center
Daly City, California

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To the Editor:

Re: Foley KT, Holly LT, Schwender JD. *Minimally invasive lumbar fusion*. *Spine* 2003;28:S26–35.

Having had the opportunity of reviewing numerous articles for *Spine* before publication, it is not comforting to see how this manuscript was published. There are two major flaws in the manuscript that I would like to outline.

1. Page S27 under the title *Evolution of Minimally Invasive Lumbar Fusion*, a brief reference to the Leu and Hauser work on percutaneous endoscopic interbody fusion is made. However, the reported outcome of this approach is not current.

The authors have failed to include Kambin's scientific presentations in the early 1990s and subsequent publications from 1995 and thereafter on percutaneous minimally invasive lumbar fusion and percutaneous insertion of pedicle screws through previously positioned cannulas on the pedicle.^{1–5}

2. Page S28, paragraph 4, the authors claim that the tubular retractor system was first developed for microdiscectomy by Foley and Smith in 1994, citing a reference that was published in 1997. It should be noted that Kambin published his work on translaminar approach to the content of the spinal canal *via* a 10 mm ID cannula as early as 1995.^{3,4} In addition, the use of a larger diameter

cannula for foraminal surgery was submitted to the U.S. Patent Office in March 1994.⁶

Parviz Kambin, MD
Department of Orthopaedic Surgery
Drexel University College of Medicine
Philadelphia, Pennsylvania

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