



EVIDENCE / RESEARCH / SCIENCE

A Valuable New Resource: The Benefit-Harm Scale

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WHAT YOU NEED TO KNOW

- The Benefit-Harm Scale is a newly developed scale that summarizes benefits and harms of specified treatments in a simple format that is easy for doctors to understand.
- The chiropractic profession has published numerous quality studies in prestigious medical journals that support the effectiveness and safety of chiropractic care.
- In contrast, there is an absence of quality research to support the use of pharmaceuticals and spinal surgery for patients with chronic low back pain.

Whenever a doctor and patient select a treatment, they do so because they anticipate the benefits of that treatment will exceed its potential harms. Thus, it is critically important that information is available which combines the best evidence on both benefits and harms.¹¹ The wide variation in care for patients with low back pain suggests there is professional uncertainty about the optimal approach and the quality of data regarding benefits and harms.^{7, 12}

Numerous systematic reviews have provided guidance for patients with chronic low back pain.^{1-5,}

^{8-10, 13-14} Although these reviews provide data regarding the benefits of various treatments, they do not provide data about the frequency or severity of potential harms. Yet harms are easier to inflict, and can have greater and more enduring effects than benefits.

In practice, doctors and patients need to compare many treatment options. To do this, they need summary statistics for both benefits and harms. It is difficult to select the best treatment option when you do not have data for *both* factors.

Important New Research Comparing Benefits and Harms

Recently, an international, multidisciplinary research team conducted a systematic review and meta-analysis to compare the benefits and harms of common treatments for adults with nonspecific chronic low back pain without radiculopathy.

The study was published in *The Spine Journal*, the highest-rated spine science journal.⁶ The research team consisted of three PhDs, one spine surgeon, one doctor of pharmacy, and one doctor of chiropractic. The team members hail from prestigious research institutions, including the University of Sydney, University of Colorado, Weill Cornell Medical Center, Italian Scientific Spine Institute, Macquarie University, and the Institute of Evidence-Based Chiropractic.

The review investigated studies of common interventions, including nonpharmacological treatments (spinal manipulation, needle acupuncture), pharmacological treatments [skeletal muscle relaxants, opioid analgesics, gabapentinoids (gabapentin and pregabalin, systemic corticosteroids, NSAIDs, acetaminophen)], and invasive treatments (spinal surgery, spinal corticosteroid injections).

The search retrieved 17,362 records. Benefit studies were required to be high-quality, placebo-controlled, randomized clinical trials with at least 30 patients per group and a loss to follow-up of less than 20%.

The Benefit-Harm Scale

The Benefit-Harm Scale is a newly developed scale that summarizes benefits and harms of specified treatments in a simple format that is easy for doctors to understand. The benefit domain recognizes that reproducibility of clinical trial findings is important, so it values multiple trials over a single trial.

Because measuring serious adverse events is more important than including reports of mild pain that resolve quickly, the research team examined only serious adverse events.

The Findings for Benefits

This meta-analysis provided 22 summary data points. Overall, the research team found that acupuncture and manipulation were effective in reducing pain intensity. The benefits of the pharmacological and invasive interventions were uncertain due to the absence of trials meeting the eligibility criteria. It was surprising that there was no quality research for any of the pharmacological agents, corticosteroid injections or surgery.

The Findings for Harms

The harms warnings (serious adverse events) were lowest for acupuncture, spinal manipulation, NSAIDs, combination-ingredient opioids, and steroid injections; and higher for single-ingredient opioid analgesics (moderate risk) and surgery (very high risk).

Benefits And Harms Of Interventions For Chronic Low Back Pain

Treatment	Benefit Rating	Serious Harms
Spinal manipulation versus sham	★★★★★	●
Needle acupuncture versus sham	★★★★	●
Acetaminophen versus placebo	∅	∅
NSAIDs versus placebo	∅	●
Muscle relaxants versus placebo	∅	∅
Gabapentinoids versus placebo	∅	∅
Opioids (single ingredient) versus placebo	∅	●●●●
Opioids (combination ingredient) versus placebo	∅	●
Systemic corticosteroids versus placebo	∅	∅
Spinal corticosteroid injections versus sham	∅	●
Spinal surgery versus sham	∅	●●●●●●

Benefits Scale

- 7 stars ★★★★★★ = multiple placebo RCTs with overall effect size > 0.80
6 stars ★★★★★ = multiple placebo RCTs with overall effect size 0.80 - 0.50
5 stars ★★★★★ = multiple placebo RCTs with overall effect size 0.49 - 0.20
4 stars ★★★★★ = one placebo RCT with effect size > 0.80
3 stars ★★★★★ = one placebo RCT with effect size 0.80 - 0.50
2 stars ★★ = one placebo RCT with effect size 0.49 - 0.20
1 star ★ = one placebo RCT, effect size < 0.20, or effect size not statistically significant
∅ = no relevant studies/data or uncertainty {heterogeneity prevented pooling}

Harms scale

- Level 7 warning ●●●●●●● = Extremely high risk (≥ 1 in 4 patients)
Level 6 warning ●●●●●● = Very high risk (≥ 1 in 20 to < 1 in 4 patients)
Level 5 warning ●●●●● = High risk (≥ 1 in 100 to < 1 in 20 patients)
Level 4 warning ●●●● = Moderate risk (≥ 1 in 1,000 to < 1 in 100 patients)
Level 3 warning ●●● = Low risk (≥ 1 in 10,000 to < 1 in 100 patients)
Level 2 warning ●● = Very low risk (≥ 1 in 100,000 to < 1 in 10,000 patients)
Level 1 warning ● = Rare risk (< 1 in 100,000 patients)
∅ = no relevant studies/data or uncertainty (heterogeneity prevented pooling)

Source: Feise et al Spine J. 2023

Chiropractic Answers the Call

The chiropractic profession has long been criticized for lacking quality clinical research. But over the past two decades, the profession has published numerous quality studies in prestigious medical journals. The vast majority of these studies support the effectiveness and safety of chiropractic care.

In contrast, there is an absence of quality research to support the use of pharmaceuticals and spinal surgery for patients with chronic low back pain. Do those treatments have any value? Are they more harmful than beneficial? Right now, we cannot be certain, because pharma companies and surgeons have failed to provide quality research.

Until and unless we have convincing research to support the use of drugs and surgery for low back pain, doctors, patients, insurance companies and regulators need to use the utmost care in assessing treatment options, based on the best available evidence regarding safety and effectiveness.

References

1. Assendelft WJ, Morton SC, Yu EI, et al. Spinal manipulative therapy for low back pain: a meta-analysis of effectiveness relative to other therapies. *Ann Intern Med*, 2003;138:871-881.
2. Chou R, Qaseem A, Snow V, et al.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*, 2007;147:478-91.
3. Chou R, Deyo R, Friedly J, et al. Nonpharmacologic therapies for low back pain: a systematic review for an American College of Physicians clinical practice guideline. *Ann Intern Med*, 2017a;166:493-505.
4. Chou R, Deyo R, Friedly J, et al. Systemic pharmacologic therapies for low back pain: a systematic review for an American College of Physicians clinical practice guideline. *Ann Intern Med*, 2017b;166:480-492.
5. de Zoete A, de Boer MR, van Tulder MW, et al. Rational and design of an individual participant data meta-analysis of spinal manipulative therapy for chronic low back pain-a protocol. *Syst Rev*, 2017;6:21.
6. Feise RJ, Mathieson S, Kessler RS, et al. Benefits and harms of treatments for chronic non-specific low back pain without radiculopathy: systematic review and meta-analysis. *Spine J*, 2023 May;23(5):629-641.
7. Gellhorn AC, Chan L, Martin B, Friedly J. Management patterns in acute low back pain: the role of physical therapy. *Spine*, 2012;37:775-82.
8. Kamper SJ, Apeldoorn AT, Chiarotto A, et al. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: Cochrane systematic review and meta-analysis. *BMJ*, 2015;350:h444.
9. Qaseem A, Wilt TJ, McLean RM, Forciea MA; Clinical Guidelines Committee of the American College of Physicians. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline From the American College of Physicians. *Ann Intern Med*, 2017;166:514-530.
10. Scholten-Peeters GG, Thoomes E, Konings S, et al. Is manipulative therapy more effective than sham manipulation in adults : a systematic review and meta-analysis. *Chiropr Man Therap*, 2013;21:34.
11. Vandenbroucke JP, Psaty BM. Benefits and risks of drug treatments: how to combine the best evidence on benefits with the best data about adverse effects. *JAMA*, 2008;300:2417-9.
12. van der Windt DA, Dunn KM. Low back pain research - future directions. *Best Pract Res Clin Rheumatol*, 2013;27:699-708.
13. Walker BF, French SD, GrantW, Green S. Combined chiropractic interventions for low-back pain. *Cochrane Database Syst Rev*, 2010:CD005427.
14. Yeganeh M, Baradaran HR, Qorbani M, et al. The effectiveness of acupuncture, acupressure and chiropractic interventions on treatment of chronic nonspecific low back pain in Iran: a systematic review and meta-analysis. *Complement Ther Clin Pract*, 2017;27:11-18.

JULY 2023