VU Research Portal

Low back pain – Authors' reply

Foster, Nadine E.; Underwood, Martin; Maher, Chris G.; Hartvigsen, Jan; van Tulder, Maurits; Buchbinder, Rachelle

published in

The Lancet
2018

DOI (link to publisher)

[10.1016/S0140-6736\(18\)32190-1](https://doi.org/10.1016/S0140-6736(18)32190-1)

document version

Publisher's PDF, also known as Version of record

document license

Article 25fa Dutch Copyright Act

[Link to publication in VU Research Portal](#)

citation for published version (APA)

Foster, N. E., Underwood, M., Maher, C. G., Hartvigsen, J., van Tulder, M., & Buchbinder, R. (2018). Low back pain – Authors' reply. *The Lancet*, 392(10164), 2549-2550. [https://doi.org/10.1016/S0140-6736\(18\)32190-1](https://doi.org/10.1016/S0140-6736(18)32190-1)

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal ?

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

E-mail address:

vuresearchportal.ub@vu.nl

the results of a controversial study should overrule the recommendations from a comprehensive evidence-based guideline that was based on eight randomised controlled trials.

A more balanced recommendation would have been appropriate, since withholding patients a potentially effective treatment, integrated into a multidisciplinary approach, cannot be considered as good clinical practice.

We declare no competing interests.

***Jan Van Zundert, Guy Hans, Sander van Kuijk, Koen Van Boxem, Kris Vissers**

jan.vanzundert@zol.be

Department of Anesthesiology, Critical Care and Multidisciplinary Pain Center, Ziekenhuis Oost-Limburg, 3620 Lanaken, Belgium (JVZ, KVB); Department of Anesthesiology and Pain Medicine (JVZ), Department of Clinical Epidemiology and Medical Technology Assessment (SVK), Maastricht University Medical Center, Maastricht, Netherlands; Multidisciplinary Pain Center, University Hospital Antwerp, Edegem, Belgium (GH); and Department of Pain and Palliative Medicine, Radboud University Medical Center, Nijmegen, Netherlands (KV)

- 1 Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018; **391**: 2368–83.
- 2 Bernstein IA, Malik Q, Carville S, Ward S. Low back pain and sciatica: summary of NICE guidance. *BMJ* 2017; **356**: i6748.
- 3 Pinto RZ, Maher CG, Ferreira ML, et al. Epidural corticosteroid injections in the management of sciatica: a systematic review and meta-analysis. *Ann Intern Med* 2012; **157**: 865–877.
- 4 Provenzano DA, Buvanendran A, de Leon-Casasola OA, Narouze S, Cohen SP. Interpreting the MINT randomized trials evaluating radiofrequency ablation for lumbar facet and sacroiliac joint pain: a call from ASRA for better education, study design, and performance. *Reg Anesth Pain Med* 2018; **43**: 68–71.
- 5 van Kuijk SMJ, Van Zundert J, Hans G, et al. Flawed study design and incorrect presentation of data negatively impact potentially useful interventional treatments for patients with low back pain: a critical review of JAMA's Mint study. *Pain Pract* 2018; **18**: 292–95.

Authors' reply

Christelle Nguyen and colleagues, Tim Germon and colleagues, and Kosmas I Paraskevas argue that we did not pay sufficient attention to the specific nociceptive causes of low back pain in our *Lancet* Series on low back pain. We were quite explicit that low back pain is a symptom

not a disease and can result from several different known or unknown abnormalities or diseases.¹ When it is possible to define additional specific nociceptive causes for low back pain with effective treatments then we will be able to address this major health issue, as Germon and colleagues suggest. There is insufficient evidence to support the existence of any such specific causes of low back pain beyond those we mentioned in the Series—ie, malignancy, fracture, infection, or inflammatory disorders such as ankylosing spondylitis.¹ Nguyen and colleagues draw attention to their work on intradiscal glucocorticoid injections to support their case for including discopathy as a specified nociceptive pain source. In a highly selected patient group the authors found a reduction in pain but not disability at 1 month and no long-term benefits. We agree with their conclusions, that the efficacy of glucocorticoid intradiscal injection as a possible treatment for chronic low back pain associated with active discopathy is questionable, given the lack of long-term benefit.² We agree with Paraskevas on the importance of recognising ruptured aortic aneurysm, and indeed other intra-abdominal emergencies and malignancies, as causes of acute low back pain. These conditions are, however, uncommon causes of low back pain, and poor explanations for long-term low back pain and disability.

Until recently, we might have agreed with Damian M Bailey and colleagues that promotion of exercise might help reduce cognitive decline in older people. However, there are now good quality prospective data to show that, although physical activity declines in the years preceding diagnosis, there is no neuroprotective effect of physical activity on cognitive function.³ Furthermore, a randomised controlled trial of exercise for people with mild to moderate dementia found exercise training had a detrimental effect on cognitive function.⁴ Although there might be many reasons to promote physical activity and exercise, the

prevention of dementia appears not to be one of them.

Jan Van Zundert and colleagues challenge our portrayal of epidural injections and radiofrequency denervation. The authors dispute our statement that epidural glucocorticoid injection for herniated disc with radiculopathy has only a small short-term effect.⁵ However, the review they cite in support of their argument actually concluded: “the available evidence suggests that epidural corticosteroid injections offer only short-term relief of leg pain and disability for patients with sciatica. The small size of the treatment effects, however, raises questions about the clinical utility of this procedure in the target population”.⁶ The authors also question our summary of the place of radiofrequency denervation for chronic low back pain. Although the National Institute for Health and Care Excellence⁷ recommended use of the treatment for patients with moderate to severe chronic low back pain who have had insufficient improvement despite comprehensive conservative management including a combined physical and psychological programme, they also listed radiofrequency denervation as one of their five future research recommendations because of the absence of conclusive evidence for effectiveness. The results of a 2015 Cochrane review⁸ examining the same research showed that there was no high-quality evidence to suggest that radiofrequency reduced pain or improved function in people with chronic low back pain. The UK National Institute for Health Research Health Technology Assessment Programme is seeking to commission a new trial in the UK comparing this procedure versus sham radiofrequency denervation. The evidence from the Dutch Mint trials suggested that radiofrequency did not provide greater benefit than an exercise programme.⁹ We acknowledge that the Mint trials have been controversial. The same level of critical appraisal also needs to be applied to previous studies

Kritchanut / StockPhoto

that appear to support use of the procedure. We therefore are of the firm, and balanced, view that radiofrequency denervation should be withheld from patients unless within the context of a high quality research trial that can reduce the uncertainty about value of the procedure.

See Online for appendix Please see appendix for authors' declaration of interests.

***Nadine E Foster, Martin Underwood, Chris G Maher, Jan Hartvigsen, Maurits van Tulder, Rachelle Buchbinder**
n.foster@keele.ac.uk

Arthritis Research UK Primary Care Centre, Research Institute for Primary Care and Health Sciences, Keele University, Staffordshire ST5 5BG, UK (NEF); Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK (MU); Sydney School of Public Health, University of Sydney, NSW, Australia (CGM); Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark (JH); Department of Health Sciences, Faculty of Science, Vrije Universiteit Amsterdam, Amsterdam, Netherlands (MvT); and Cabrini-Monash Department of Clinical Epidemiology, Cabrini Institute and Monash University, Malvern, VIC, Australia (RB)

- Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. *Lancet* 2018; **391**: 2356–67.
- Nguyen C, Boutron I, Baron G, et al. Intradiscal glucocorticoid injection for patients with chronic low back pain associated with active discopathy: a randomized trial. *Ann Intern Med* 2017; **166**: 547–56.
- Sabia S, Dugravot A, Dartigues JF, et al. Physical activity, cognitive decline, and risk of dementia: 28-year follow-up of Whitehall II cohort study. *BMJ* 2017; **357**: j2709.
- Lamb SE, Sheehan B, Atherton N, et al. Dementia and physical activity (DAPA) trial of moderate to high intensity exercise training for people with dementia: randomised controlled trial. *BMJ* 2018; **361**: k1675.
- Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018; **391**: 2368–83.
- Pinto RZ, Maher CG, Ferreira ML, et al. Epidural corticosteroid injections in the management of sciatica: a systematic review and meta-analysis. *Ann Intern Med* 2012; **157**: 865–77.
- National Institute for Health and Care Excellence. Non-specific low back pain and sciatica: management. NICE guideline: short version. November 2016. <https://www.nice.org.uk/guidance/ng59> (accessed Sept 28, 2018).
- Maas ET, Ostelo RWJG, Niemisto L, et al. Radiofrequency denervation for chronic low back pain. *Cochrane Database Syst Rev* 2015; **10**: CD008572.
- Juch JNS, Maas ET, Ostelo RWJG, et al. Effect of radiofrequency denervation on pain intensity among patients with chronic low back pain: the Mint randomized clinical trials. *JAMA* 2017; **318**: 68–81.

Discrepancies in guidelines for acute respiratory distress syndrome

In July, 2018, the Faculty of Intensive Care Medicine (FICM) and the Intensive Care Society (ICS) released their guidelines on the management of acute respiratory distress syndrome.¹ These guidelines used GRADE methodology to develop evidence based recommendations for the management of acute respiratory distress syndrome in adult patients in intensive care. Overall, the guideline provides useful guidance to stakeholders.

Our main concern with the guidelines¹ is that the evidence summaries rely on previously completed systematic reviews and meta-analyses, rather than performing an updated analysis specifically for this guideline effort. The result is that many of the recommendations are based on evidence summaries that are outdated, not entirely relevant, or do not include the most recent trial data. This greatly lowers the trustworthiness of the recommendations. For example, the evidence profile addressing corticosteroids in acute respiratory distress syndrome synthesises the results of three meta-analyses published in 2008,² 2009,³ and 2014.⁴ Two of these meta-analyses^{2,4} incorporate randomised controlled trials (RCTs) from the 1980s that investigated short-term (24–48 h) and large-dose corticosteroids (up to 120 mg/kg methylprednisolone equivalent), an intervention that is obsolete and discredited by the present pathophysiological understanding of acute respiratory distress syndrome. Using this evidence summary that was judged to be very low quality, the FICM–ICS guideline panel did not feel confident in making a recommendation for or against corticosteroids in acute respiratory distress syndrome and instead made a research recommendation.

Hospital mortality, extracted from the 2008 meta-analysis and used in

this guideline,¹ reports a pooled relative risk (RR) of 0.62 with a 95% CI of 0.23–1.26.⁴ This point estimate includes trials at both high and low risk of bias, and does not include a recent RCT of 197 patients.⁵ As part of the 2017 Society of Critical Care Medicine (SCCM) and European Society of Critical Care Medicine (ESICM) Corticosteroid Guideline Task Force, we updated the evidence summary examining the efficacy of corticosteroids in acute respiratory distress syndrome. In an updated systematic review and meta-analysis,² specifically designed to support this guideline effort, we identified nine RCTs (as compared with the five identified by the 2008 systematic review). Five of these RCTs were rated as having a low risk of bias, and subsequent meta-analysis of these five studies showed a pooled RR estimate of 0.76 (95% CI 0.58–0.99) for hospital mortality when using corticosteroids. This estimate includes only studies with low risk of bias and includes all recent trial data (up until the time of publication). The net effect, compared with the 2008 review,² is a decrease in imprecision (upper end of the CI now excludes harm), and a decrease in concerns related to risk of bias producing moderate-quality evidence of benefit with corticosteroids.

Armed with this higher-certainty evidence, and combined with our updated review that showed an increase in mechanical ventilator-free days with corticosteroids (mean difference 7.06 days fewer, 95% CI 3.19–10.93, high certainty evidence), the 2017 SCCM and ESICM guideline panel made a conditional recommendation for corticosteroids in acute respiratory distress syndrome.⁶ We suggest that the FICM and ICS consider updating their guideline development processes. Although there are time and resource implications for societies contemplating updating systematic reviews, the investment is necessary if the goal is to provide the most up-to-date and comprehensive