

## Comments on “Can Additional Facet Joint Block Improve the Clinical Outcome of Kyphoplasty for Acute Osteoporotic Vertebral Compression Fractures?”

### **TO THE EDITOR:**

A recent study conducted in China on patients with symptomatic, acute osteoporotic vertebral fractures, reports larger improvements in pain and disability in patients treated with facet joint blocks, in addition to kyphoplasty, than in those who only received kyphoplasty (1).

However, methodological and ethical concerns undermine these results:

1. No information is provided on sample size calculation, the randomization process, and the reasons behind the 12% losses to follow-up and their distribution across groups.
2. The report suggests that patients were not blinded to the treatment they received, and that statistical analysis did not adjust for potential confounders.
3. No “control” or “sham” groups were established. Therefore, the study does not provide a solid basis to hypothesize on the effect of vertebral augmentation. In fact, the highest quality evidence currently available consistently shows that vertebroplasty does not lead to better results than placebo, and is associated with significant risks including death (2,3). As compared to vertebroplasty, kyphoplasty can decrease the kyphotic wedge angle, increase vertebral body height, and reduce the risk of cement leakage (4), but does not lead to larger improvement in pain and disability (i.e., equal to placebo) (2-4).
4. Facet blocks were performed only once and at a single level, which leads to a high rate of false positives (5). Intraarticular blocks have shown not to be predictive of response to any form of treatment, and there is currently no convincing evidence on the effectiveness of denervation procedures for improving low back pain and disability (5,6). Should an effect exist, data suggest that it would be small and short lived (7). In fact, the reported differences in the evolution of pain among patients who received and did not receive facet joint blocks in addition to kyphoplasty (1), are below the threshold

for clinical relevance (8), and were only detected one month after the procedure, and not thereafter (1).

5. Cointerventions are not appropriately described, also antiinflammatories and analgesics appear to have been permitted only for patients assigned to the “kyphoplasty plus blocks” group (1). This makes it impossible to rule out the influence of cointerventions on reported outcomes, and on differences detected across groups. Additionally, it raises ethical concerns.
6. Only patients with pain attributed to vertebral fracture and lasting for up to 6 weeks with pain severity of > 6 Visual Analog Scale points, were eligible to enter the study (1). However, the report states that “supplemental calcium, ...vitamin D ..., and antiosteoporosis therapy” were administered after the operation. Whether these treatments were also administered before the operation, is undisclosed. Denial of antiosteoporotic treatment to patients with symptomatic osteoporotic vertebral fractures until they underwent the operation (i.e., up to 6 weeks later), would raise additional ethical concerns.
7. The report states that “follow-up consultations were scheduled 1 day, 3 days, 1 week, 1 month, 3 months, and 1 year post-operatively” and that “to accurately reflect the intensity of back pain and level of dysfunction, these evaluations were performed without the use of analgesics” (1). The report does not clarify whether analgesics were withheld during the entire follow-up period, or were only suspended for an undisclosed period of time before each assessment. Both these scenarios would raise additional ethical concerns.

Therefore, we believe that:

- A. The methodological concerns expressed above, should be addressed.
- B. Due to methodological shortcomings, this study is

inappropriate to support the use of kyphoplasty and facet joint blocks in the treatment of patients with symptomatic, osteoporotic vertebral fractures, outside the experimental environment.

- C. Offering kyphoplasty and facet joint blocks to patients with pain caused by osteoporotic vertebral fractures in the absence of convincing evidence on health benefits, would expose them to unjustified and avoidable health risks (2-7). Consistent results from high quality randomized controlled trials with the appropriate design, should be made available before this treatment can be considered as an option in clinical practice.
- D. Despite solid evidence supporting the need to halt spinal augmentation in clinical practice (2,3), aggressive promotion by industry and the proliferation of reports deriving from very low-quality research, have led to continued use of spinal augmentation in clinical practice. Low-quality research can mislead clinicians, harm patients and drain resources away from high quality, clinically useful

endeavors. Therefore, we think that a moratorium on studies in this field, with the only exception of high-quality studies designed to ensure clinically useful results, would be beneficial for patients, clinicians and society.

Estephanie Robles, MD  
Hospital Santo Tomás. Spanish Back Pain Research Network, Panama City, Panama

Estanislao Arana, MD, PhD  
Fundación Instituto Valenciano de Oncología  
Spanish Back Pain Research Network, Valencia, Spain

Francisco Kovacs, PhD  
Hospital Universitario Moncloa: HLA Universitario Moncloa  
Spanish Back Pain Research Network  
Madrid, Madrid, Spain  
E-mail: fmkovacs@kovacs.org

## REFERENCES

1. Li QD, Yang JS, Gong HL, et al. **Can additional facet joint block improve the clinical outcome of kyphoplasty for acute osteoporotic vertebral compression fractures?** *Pain Physician* 2021; 24:283-291.
2. Buchbinder R, Johnston RV, Rischin KJ, et al. Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. *Cochrane Database Syst Rev* 2018; 4:CD006349.
3. Buchbinder R, Busija L. Why we should stop performing vertebroplasties for osteoporotic spinal fractures. *Intern Med J* 2019; 49:1367-1371.
4. Wang B, Zhao CP, Song LX, Zhu L. Balloon kyphoplasty versus percutaneous vertebroplasty for osteoporotic vertebral compression fracture: A meta-analysis and systematic review. *J Orthop Surg Res* 2018; 13:264.
5. Perolat R, Kastler A, Nicot B et al. Facet joint syndrome: From diagnosis to interventional management. *Insights Imaging* 2018; 9:773-789.
6. Maas ET, Ostelo RW, Niemisto L, et al. Radiofrequency denervation for chronic low back pain. *Cochrane Database Syst Rev* 2015; (10):CD008572.
7. Chappell ME, Lakshman R, Trotter P, Abrahams M, Lee M. Radiofrequency denervation for chronic back pain: A systematic review and meta-analysis. *BMJ Open* 2020; 10:e035540.
8. Kovacs FM, Abreira V, Royuela A, et al. Minimal clinically important change for pain intensity and disability in patients with nonspecific low back pain. *Spine* 2007; 32:2915-2920.