Neuroradiology (2021) 63:1747–1748
https://doi.org/10.1007/s00234-021-02801-z

LETTER TO THE EDITOR

Methodological concerns of "Intra-osseous basivertebral nerve radiofrequency ablation (BVA) for the treatment of vertebrogenic chronic low back pain"

Estanislao Arana[1,2] · Francisco M. Kovacs[2,3] · Víctor González-Pérez[4] · Beatriz Asenjo[2,5]

Received: 25 August 2021 / Accepted: 30 August 2021 / Published online: 10 September 2021

Dear Editor

A recent paper focuses on "intra-osseous basivertebral nerve radiofrequency ablation" (BVA) for patients with "vertebrogenic" low back pain (LBP) [1].

We would like to point out that:

1. The authors assume that (a) disc degeneration and Modic changes (especially type I) cause chronic LBP; (b) "vertebrogenic" LBP can be suspected "on the basis of clinical examination"; (c) a single facet block at one single level suffices to identify (or rule out) facet joint as the origin of pain; (d) imaging can reveal the cause of LBP; and (e) radiofrequency denervation procedures are effective. The available evidence challenges all these assumptions [2–4].
2. This study, with no asymptomatic subjects, reports a correlation between Modic changes and LPB. However, a case–control study with both symptomatic and asymptomatic subjects ruled out this association also in Southern Europe [4].
3. The original trial on BVA, which has never been replicated, established three outcomes; two were not met, and the third one was omitted in the report [2, 5]. Nonetheless, the authors concluded that the procedure led to "sustained clinical benefits." The fact that this conclusion was published suggests inadequate peer review and lack of due editorial oversight [2].
4. The representativeness of the sample in the current study [1] is unknown; inclusion and exclusion criteria are insufficiently described and the authors dot not disclose: criteria used for suspecting "vertebrogenic" LBP, the number of patients who were screened, the number of patients who refused to sign the informed consent, and the number and reasons for other exclusions.
5. The authors show concern for the bone edema accompanying Modic 1 images, but disregard the bigger edema caused by BVA (see Fig. 1) [1].
6. Fig. 2 shows a lesion on the lower endplate of L4 detected on SPECT-CT, while MRI only detected minor disc degeneration. However, the image taken after post-radiofrequency ablation shows that the procedure was conducted in the upper (not lower) endplate. This raises concern on the accuracy of this technique [1].
7. Study conclusions are not supported by the results reported [1]. For instance:
   a. None of the study findings supports the statement: "vertebrogenic pain is one of the most frequent and frequently underestimated causes of chronic low back pain."
   b. Only 56 patients underwent BVA, no control group was established, and statistical analysis was elementary. Therefore, the influence of unspecific effects (e.g., regression to the mean, Hawthorne or placebo effects, etc.) could not be determined, and results could not be adjusted for potential confounders. As a consequence, conclusions on effectiveness are largely speculative.

✉ Estanislao Arana
aranaeext.uv.es
http://www.ivo.es

[1] Department of Radiology, Fundación Instituto Valenciano de Oncología, Prof Beltrán Báguena, 19, 46009 Valencia, Spain

[2] Spanish Back Pain Research Network, Palma de Mallorca, Spain

[3] Unidad de La Espalda Kovacs, Hospital Universitario HLA-Moncloa, Avda. Menéndez Pelayo 67, 28009 Madrid, Spain

[4] Department of Radiation Physics, Fundación Instituto Valenciano de Oncología, Valencia, Spain

[5] Department of Radiology, Hospital Universitario Regional, Málaga, Spain

c. The small sample size prevents drawing reliable conclusions on safety.

8. The current study also raises ethical concerns:

a. This study required patients aged 38–52 to undergo; the BVA procedure itself, a bone biopsy, a SPECT/CT (which implies a radiation equivalent to a natural background radiation for 3.3–4 years) and a 32-min mean duration, CT-assisted procedure (equals to 4.7 years natural radiation, approximately). They did not report effective dose. Bearing in mind the weak methods and limited practical value of this study, exposing patients to these inconveniences and levels of radiation raises ethical concerns. This begs the question; were the amount of radiological exposure, the lack of solid evidence supporting BVA, and the limited usability of results in clinical practice, due to the study design, disclosed to patients in the written informed consent?

b. Due to the invasiveness of procedures required in this study and the amount of radiation exposure, sample size should have been carefully calculated. However, sample size calculations and the corresponding assumptions are not disclosed.

Overuse of low-value care, and underuse of high-value care, has been repeatedly reported in the field of LBP [2]. Claiming unusually positive results as if they were solid evidence (i.e., "96.5%" clinical success for pain and "96.5%" for disability) [1], when in fact these figures derive from a small, very low-quality study, adds confusion and does not help researchers, clinicians, or patients. Tighter peer-review and editorial processes would protect the clinical and scientific community from misleading information.

In fact, 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 on BVA for LBP, with the only exception of high-quality studies designed to ensure clinically useful results, would be beneficial for patients, clinicians, and society.

Funding No funding was received for this study.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Not applicable as no participant was included in the study.

References

1. De Vivo AE, D'Agostino G, D'Anna G et al (2021) Intra-osseous basivertebral nerve radiofrequency ablation (BVA) for the treatment of vertebrogenic chronic low back pain. Neuroradiology 63:809–815. https://doi.org/10.1007/s00234-020-02577-8
2. Buchbinder R, Underwood M, Hartvigsen J, Maher CG (2020) The Lancet Series call to action to reduce low value care for low back pain: an update. Pain 161(Suppl 1):S57–S64. https://doi.org/10.1097/j.pain.0000000000001869
3. Maas ET, Ostelo RW, Niemisto L, Jousimaa J, Hurri H, Malmivaara A, van Tulder MW (2015) Radiofrequency denervation for chronic low back pain. Cochrane Database Syst Rev 10:CD008572. https://doi.org/10.1002/14651858.CD008572.pub2
4. Kovacs FM, Arana E, Royuela A et al (2012) Vertebral endplate changes are not associated with chronic low back pain among Southern European subjects: a case control study. AJNR Am J Neuroradiol 33:1519–1524. https://doi.org/10.3174/ajnr.A3087
5. Fischgrund JS, Rhyne A, Franke J et al (2019) Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. Int J Spine Surg 13:110–119. https://doi.org/10.1007/s00586-018-5496-1