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Response to the comment by Van Boxem

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We thank Van Boxem et al for their comments on our study (Curatolo et al., 2022). We agree with most of their remarks, and most of the limitations discussed by Van Boxem et al are highlighted in the discussion of our paper. Our goal was to provide information from a pragmatic rather than an explanatory approach (Loudon et al., 2015). However, their comments do not seem to consider this specific focus and value of pragmatic, real-world research.

Our study provides insight into the long-term effectiveness of epidural steroid injections (ESI) in clinical practice by gathering prospective data in over 6,000 patients, from three different health care systems, and with two-years of follow-up. Importantly, patients were recruited from primary care, which reflects a different clinical reality from specialty clinics when evaluating treatments for patients with new onset low back/leg pain.

A large randomized controlled trial with long-term follow up would address many of the legitimate questions raised by Van Boxem et al, but such a study is of doubtful feasibility. There are published data on the efficacy of ESI and even systematic reviews and meta-analyses, but none of them address whether ESIs work in real-world clinical practice and in the long-term. This question, which was the focus of our study, is different from the question implicitly posed by Van Boxem et al, namely: does ESI work after “meticulous patient selection?” Van Boxem et al found our approach to patient selection questionable. We as investigators did not constrain patient selection, but instead included all the patients actually treated with ESI, in line with our purpose of evaluating ESI use in the real world. The authors of PRECIS-2, a tool used to determine the degree to which a study is pragmatic vs. explanatory, state that “A highly pragmatic approach to eligibility criteria would be to include … anyone with the condition of interest who is likely to be a candidate for the intervention if it was being provided in usual care for this condition” (Loudon et al., 2015). Again, this goal is different from evaluating the efficacy of ESI in specific patient populations. For example, Van Boxem et al mention that ESIs “are indicated to improve pain

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and disability in patients suffering (sub-) acute radicular pain but are controversial in chronic radicular pain", and that "transforaminal ESI approach yields better outcome compared to an interlaminar approach". We do not believe that these statements are supported by solid evidence, but even if this were the case, these considerations would not reduce the value of our study, because it addressed a different question.

Regarding the follow-up time, as stated in our paper, we agree with Van Boxem et al that a short- or middle-term improvement may be valuable in a subset of patients, but this was not our study's focus. Van Boxem et al find the lack of difference between ESI and non-ESI patients at 24 months not surprising, but we are not aware of previous studies in this patient population that document lack of effectiveness at 24 months. The question of long-term effectiveness remains relevant to patients and health professionals.

In summary, we agree with Van Boxem et al that ESI may be effective in the short- or middle-term in sub-sets of patients. We acknowledge that our study design is not a substitute for a randomized controlled trial on a large patient population that would allow the analysis of predictors of outcomes, such as clinical and procedural factors. In the absence of such investigations, we believe that our study contributes to the knowledge that current practice of ESI is unlikely to provide specific long-term effects in older adults. The knowledge that older adults with a new episode of back/leg pain are likely to improve in the long-term, independent of undergoing an ESI, is of likely relevance to clinicians and patients.

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