LETTER TO THE EDITOR

Investigating the Effects of Pulsed Radiofrequency on Dorsal Root Ganglion in Chronic Lumbar Radicular Pain Patients: Is It Not Important That We Ask the Right Question, the Right Way, on an Appropriate Sample of Patients?

Dear Editor,

It is interesting to read the paper by Koh et al. on the investigation of the pulsed radiofrequency (PRF) of the dorsal root ganglion (DRG) in patients of chronic lumbosacral radicular (CLR) pain [1]. It is noteworthy that the authors attempted to perform a controlled trial on a challenging topic. However, I am afraid that the study design, results, and conclusions have further “muddied the water” instead of bringing clarity to the existing evidence on the efficacy of PRF-DRG in CLR pain patients. I would like to highlight some aspects of the study, which decrease the confidence in their study results and conclusions.

The study was conducted on patients of lumbar spinal stenosis (LSS). Note that LSS is a radiological diagnosis, and the clinical diagnosis of spinal stenosis and its symptoms (leg pain) bear no relation to the extent of corresponding imaging findings of either central or foraminal stenosis. However, generally patients with central stenosis present with neurogenic claudication, whereas lateral foraminal stenosis could cause symptoms similar to radicular elements of pain [2,3]. In the study by Koh et al., it is not clear why the researchers selected only patients with LSS. More than 70% of the subjects in each group had multilevel LSS, yet more than 90% of the subjects had either PRF or transforaminal epidural steroid injections (TFESIs) at only L5. How do the researchers explain this discrepancy? The final inclusion required that subjects demonstrate pain reduction for a preliminary steroid injection for a duration of less than 6 weeks. The information in the demographic table indicates that all patients had more than two previous epidural steroid injections (ESIs). The medians (interquartile range) were indicated to be 2 (4, 9) for the PRF group and 2 (5, 9) for the control group (Table 1)—perhaps an error since the lower interquartile range should have been less than the median. If all subjects had previous ESIs, what specific information would have been gained by their final selection of TFESI requiring only < 6 weeks of pain relief? It is important, especially when one wants to assume a known treatment modality as a control group, to test another treatment modality whose primary efficacy has never been established. This is clear from the final results as well, which showed no differences between the two groups in terms of improved pain scores, Oswestry Disability Index, or analgesic requirements. The small difference in the results (apparent only in their composite primary outcome) could simply be due to differences in the study groups stemming from variable effects related to the TFESIs; small randomized studies are widely known to be fragile [4]. The small number of study subjects was not powered enough to adjust for the variability in steroid injections. Any intervention must be tested for efficacy before comparative effectiveness studies (when compared with active treatments) can be done.

The effect of PRF-DRG on CLR pain is not conclusively proven. There are no controlled studies to prove its efficacy (compared to placebo) in CLR pain. Our own attempts to obtain feasibility results in a pilot randomized control trial showed minimal effects compared to placebo [5]. In the present study [1], it is necessary to know the theoretical framework or rationale behind the use of TFESI along with PRF. Was PRF expected to enhance the steroidal effects, meaning a synergic effect? Or did the researchers hypothesize that at 3 months TFESI should not be working, and hence the effects are attributable solely to PRF? The inclusion that patients demonstrate a pain reduction for a preliminary steroid injection for a duration of less than 6 weeks (≥2 points or at least a 30% reduction in the Numeric Rating Scale score) is a single-dimension outcome. The same difference in pain measure was used to calculate the sample size, based on an earlier prospective study. But the primary outcome was a composite outcome inferring success or failure. Given this information, how can the authors state in the discussion that “we could not confirm the statistical significance of additional PRF treatment over control . . . . This limitation was caused because the primary outcome results were underpowered.” The study was underpowered for that outcome from the very beginning and the “actual outcome” for which the study was “actually powered” (pain reduction by pain scores) showed no difference. This should have led to the conclusion that PRF has no benefit at 3 months in pain scores because this was not designed as a non-inferiority study.

The loss to follow-up was significant—up to one-fourth to one-fifth of subjects in each arm were lost at 3 months. The analysis mentions that a linear mixed model was used to account for the missing secondary continuous variables. It is not clear how the “composite” categorical primary outcome variable was inferred for.
the missing patients. It is also not clear for the final analysis how many patients out of 31 were considered treatment successes at 3 months, leading to a difference of 38% in the PRF group and 9.8% in the control group. In summary, PRF-DRG in CLR pain continues to be a controversial treatment. It is incumbent upon readers, and future investigators, to clearly understand the limitations of the existing evidence.

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References