In Response

To the Editor:

Thank you for the critical letter you sent after reading our study titled: "Long-term efficacy of percutaneous epidural neurolysis of adhesions in chronic lumbar radicular pain: 10-year follow-up of a randomized controlled trial."

You have almost described the limitation of this 10 year analysis. The most important aspects are uncontrolled confounder and concomitant therapies which occurred within the 10 years follow-up period. After 10 years, many confounders, such as progressive musculoskeletal degeneration, comorbitities, change of work load, worker's compensation, social environment, or simple change of the activity level, could have significant effects. Also, simple uncontrolled over the counter medication, physical intervention, change of biometric characteristics, such as body mass index or comorbidities (e.g., stroke or cardiac infarct), were not analyzed in this trial, but may have significant effect on outcome.

As you mentioned, spine surgery has a significant impact on the outcome. For this reason we have excluded patients who had spine surgery within the 10 years period (See Fig. 1. in the original article. Flow chart of the randomized controlled trial in accordance with the CONSORT Statement).

Initially we have tried to use the same washout periods as we defined for the primary endpoint, but ultimately most patients could not fulfill these washout phases because other factors justify the intake of pain medication, NSAIDs or other concomitant therapies and nearly all patients could not interrupt these ongoing treatments.

The second aspect described by Min Chang was the aspect of spinal stenosis. We have described the exclusion criteria of the spinal stenosis in our paper (1).

All patients suffering from spinal stenosis were excluded. This means patients with clinical signs together with radiological findings that correlated with clinical signs of spinal stenosis were not enrolled. The authors are aware of the different prognoses of spinal stenosis and disc protrusion. First, we have assumed the all patient will be affected by progressive degeneration within 10 years in the same manner for both groups . Second, the progression of a spinal stenosis in patients not suffering from spinal stenosis at the time of enrollement 10 years ago was not designed as an outcome parameter, but could be an important parameter. For more precise analysis, imaging tools like magnetic resonance imaging or computed tomography scans would be better, but this was not intended to do in the final study plan.

Patients with motor deficits was the third aspect of Min Chang. Ten years ago we designed the trial, after several expert consensus meetings, and agreed to exlude patients suffering from any motor deficits completely. The analysis of motor deficits, because of the procedure itself or because of the progression of the desease, was not part of the trial. The change of function and pain scores were defined as primary criteria. We completely agree with Dr. Chang that a long-term analysis are needed to identify variables that have an impact on this neurologic aspect in patients suffering from chronic lumbar radicular pain.

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References

1. Gerdesmeyer L, Wagenpfeil S, Birkenmaier C, et al. Percutaneous epidural lysis of adhesions in chronic lumbar radicular pain: A randomized, double-blind, placebocontrolled trial. *Pain Physician* 2013; 16:185-196.