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Percutaneous epidural lysis of adhesions in chronic lumbar radicular pain: a randomized, double-blind, placebo-controlled trial

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BACKGROUND
Chronic radicular pain can occur after disc pathology and failed back surgery. An evidence-based effective therapeutic option is not available nor does a gold standard exist.

OBJECTIVES
A randomized controlled trial to analyze the clinical efficacy of percutaneous epidural lysis of adhesions in chronic radicular pain.

STUDY DESIGN
Prospective randomized placebo controlled interventional trial. Power calculation based on a feasibility trial.

SETTING
Medical university centers.

METHODS
Within 4 years a total of 381 patients with chronic radicular pain lasting longer than 4 months which failed to respond to conservative treatments were screened and 90 patients were enrolled. They were randomly assigned to receive either percutaneous neurolysis or placebo with concealed allocation in permuted blocks of 4 to 8, stratified by treatment center. The primary outcome measure was the differences in percent change of Oswestry Disability Index (ODI) scores 3 months after intervention. Secondary outcome measures were difference in percent change of ODI scores and Visual Analog Scale (VAS) 6 and 12 months after intervention and success rates defined as at least 50% reduction in ODI scores and VAS scores (mean change from baseline) at 3, 6, and 12 months after treatment. Explorative, 2-sided group comparisons for baseline characteristics between active treatment and controls were done using the t-test for 2 independent samples for quantitative data and Fisher's exact test for binary data.

RESULTS
The ODI and VAS scores as well as the success rates for ODI vs VAS were significantly better 3, 6, and 12 months in the lysis group vs the control group. The ODI in the lysis group improved from 55.3 ± 11.6 to 26.4 ± 10.8 after 3 months. The placebo group improved from 55.4 ± 11.5 to 41.8 ± 14.6 ($P < 0.01$). VAS improved from 6.7 ± 1.1 to 2.9 ± 1.9 in the active group and from 6.7 ± 1.1 to 4.8 ± 2.2 ($P < 0.01$) after placebo. Twelve month follow-up shows further improvement, the differences remain significant. In multiple linear regression, forward and backward variable selection methods resulted in the same covariate model confirming the univariate result for group comparison in the primary analysis. No severe side effects occurred but minor transient neurological effects such as partial sensomotoric deficits did. One dura puncture and one catheter displacement were found.

LIMITATIONS
Specific effects of single treatment components cannot be specified because there was no imaging examination after treatment.

CONCLUSION
Based on the findings of our study as well as other studies, we believe the minimally invasive percutaneous adhesiolysis procedure should be the first choice treatment option for patients with chronic lumbosacral radicular pain who present with clinical history and findings similar to those of the patients enrolled in our study.

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