Targeted Therapy of Low Back Pain Associated with de novo Degenerative Lumbar Scoliosis in the Elderly: Observation Cohort Study

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Introduction: Treatment of low back pain (LBP) with de novo degenerative lumbar scoliosis (DLS) in the elderly is the subject of much debate. However, the cause of LBP in DLS is unclear. Bone marrow edema (BME) on magnetic resonance imaging (MRI) is frequently found in the endplates at the concave side of scoliosis. We speculated that BME is strongly associated with LBP. We developed a novel minimally invasive procedure; percutaneous transpedicular intervertebral vacuum polymethylmethacrylate injection (PIPI). The rationale for this new treatment method rests on the shock-absorptive effect of medical cement to mechanical back pain. The purpose of this study was to report the 2-year outcomes of PIPI and nonoperative treatment for LBP associated with DLS in the elderly.

Methods: This observational study involved patients with DLS referred to our hospital for the treatment of LBP. DLS is defined as de novo DLS with a Cobb angle of more than 10° in the coronal plain that developed after bone maturation with no previous history of scoliosis. We defined LBP as axial pain in the area from the lower margin of the thorax to the iliac crest. In the current study, we included DLS patients aged 65 years or older and with 1) persistent LBP of more than 50 visual analogue scale (VAS; ranging from 0 to 100, with 0 denoting no pain) despite some nonoperative treatment for at least 6 months, 2) intervertebral vacuum phenomenon on coronal reconstructed computed tomography (CT), 3) BME on coronal gadolinium-contrasted T1- or T2-weighed fat-saturated images on MRI, and 5) the spinal locations of BME consistent with that of lumber tender points. We excluded patients with osteoporosis, infectious disease, tumorous conditions of the spine, a previous history of lumbar surgery, and a leg length discrepancy due to joint disease. Patients whose LBP alleviated by facet joint anesthetic injection were also excluded. Patients who were disoriented or who did not complete the screening questionnaire were ineligible. Patients chose their treatments (PIPI vs nonoperative treatment) at enrollment. The nonoperative protocol was usual care recommended to include at least, active physical therapy, education and counseling with home exercise instruction, and non-steroidal anti-inflammatory drugs or narcotic analgesic agent if tolerated. Nonoperative treatments were individualized for each patient and tracked prospectively. The study protocol was approved by the ethics committees of our institute and all patients gave written informed consent. We conducted a 2-year, prospective cohort study that included DLS patients aged 65 years or older who had significant LBP for at least 6 months. We compared the treatment effects of PIPI and nonoperative treatment for LBP. The primary outcome measures were changes from baseline in a VAS and the modified Oswestry Disability Index (ODI). As the objective changes, we measured BME score on magnetic resonance imaging. VAS, ODI and BME score analyses compared changes from baseline and percentages of patients showing improvement at each follow-up time based on treatments received. We used paired t-test, repeated measure ANOVA,
Spearman’s correlation coefficient by rank test where appropriate. Continuous variables are expressed as mean ± SD and range. Statistical significance was defined as P < 0.05. PIPI was targeted to the intervertebral vacuum space (IVS) having both of BME on MRI and tenderness on physical findings. Spine surgeons with experience of over 10 years performed this procedure. The patient was set a prone position on X-ray permeable frame under general anesthesia. With a biplane fluoroscopic guidance, a bone needle was percutaneously and transpedicularly inserted into the IVS. Before injection of medical cement, we performed vacuumography; contrast study of the IVS using a contrast media. We confirmed a correct placement of a needle tip in the IVS and measured the cavity of the IVS by the vacuumography. Medical cement of the same amount of the IVS was injected. On the next day of PIPI, a radiologist checked leakage of the medical cement with CT. Patients were required bed rest on the operative day and discharged 2 days after PIPI.

**Results:** Of the 162 patients enrolled in this study, 101 patients received PIPI and 53 received nonoperative treatment, and 8 switched from nonoperative to PIPI. At 1 month, patients who chose PIPI had greater improvement in the primary outcome measure of VAS (mean change: PIPI, -55.3 vs nonoperative treatment, -1.9; treatment effect -53.4; 95% confidence interval, -59.7 to -47.0), and ODI (mean change: PIPI, -22.7 vs nonoperative treatment, -0.6; treatment effect -22.1; 95% CI, -26.9 to -17.3). These differences were maintained at 2 years: VAS (mean change: PIPI, -52.2 vs nonoperative treatment, -4.0; treatment effect -48.2; 95% CI, -57.9 to -38.6) and ODI (mean change: PIPI, -20.7 vs nonoperative treatment, -1.0; treatment effect -19.7; 95% CI -26.6 to -12.9). There were no major complications but 1 patient (1%) had cement leakage into the foramen with no symptom. Among patients underwent PIPI, BME scores decreased (P<0.001 vs nonoperative treatment), and were correlated with the improvement of VAS and ODI (VAS: r=0.502, P<0.001, ODI: r=0.372, P<0.001). On the other hand, we found no significant changes of BME scores in the patients with nonoperative treatment.

**Discussion:** We developed a targeting therapy; PIPI for LBP associated with DLS in the elderly. LBP relief after PIPI is immediate and sustained for at least 2 years, and significantly greater than that achieved with conservative treatment, at an accepted cost. PIPI is minimally invasive surgery for LBP in health care concern of elderly people.

**Significance:** LBP relief after PIPI is immediate and sustained for at least 2 years, and is significantly greater than that achieved with nonoperative treatment.
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