

# Amniotic Fluid Cell Therapy to Relieve Disc-Related Low Back Pain and Its Efficacy Comparison with Long-Acting Steroid Injection

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## Abstract

*Introduction:* There are many problems in case of treatment of the patients reporting with degenerated disc with or without disc prolapse, desiccation, bulge, or compression of the adjacent nerves and its implications. Most of the patients with chronic discogenic back pain, without specific history of trauma, are on geriatric age group. In this age group, low back pain is associated with varying degree of age-induced degenerative osteoporosis, spondylosis, spondyloarthrosis, intervertebral disc prolapse, or even compression collapse apart from other problems like diabetic background, hypertension, ischemic heart disease, chronic obstructive pulmonary disorder, dyslipidemia, and hypothyroidism. MRI presentation of a typical geriatric presentation of low back pain is shown (Figs. 19.1, 19.2, and 19.3).

*Materials and methods:* 42 patients participated and randomized in two equal groups. Group A ( $N = 21$ , male 10 and female 11, mean age  $56.4 \pm 8.9$  year) was treated with 80 mg methylprednisolone in 10 mL water for injection under C-arm guidance in the operation theater (OT) after 1 % infiltration with Xylocaine at the site of maximum tenderness in the back.

Similarly, Group B ( $N = 21$ , male 12 and female 9, mean age  $59.4 \pm 6.4$  year) was also treated in the OT with similar protocol with 10 mL of freshly collected amniotic fluid from mothers undergoing hysterotomy and ligation. All the procedures passed through the donor and recipient's informed consent protocol and vetted by the institute-based ethical committee.

*Result and analysis:* Studying and comparing the clinically manifested effect of treatment, it can be easily seen that both steroid (Group A) and cell therapy (Group B) patients showed improvement of pain and distress from the pretreatment value; however, Group B scoring is much better ( $p, 0.01$ ), as seen and assessed from the value of the VAS (visual analog pain scale), WD (walking distance in meters), and HAQ (Health Assessment Questionnaire). If we see further the clinical assessment of pain relief and patient's satisfaction as seen from Table 19.3 and Graph 19.1 in case of Group A (long-acting steroid group), it was 20/21 cases in 1st month which became 12/21 in 3rd month, 6/21 in 6th month, 4/21 in 12th month, and 2/21 after 24-month follow-up. Similarly in Group B (cell therapy patients), the identical values after the 1st month were 18/21, which became 21/21 in 3rd month, 21/21 in 6th month, 14/21 in 12th month, and 12/24 after 24-month follow-up. Another globally practiced guideline for pain assessment or scoring for comparison is Oswestry low back pain disability questionnaire. Here in Table 19.4 and Graph 19.2, we have again compared the effect of treatment of Group A (steroid) and Group B (cell therapy with fresh amniotic fluid) and followed up the results of Group A and Group B treatment as per scoring by Oswestry low back pain disability questionnaire up to 24 months. Here, postinjection with long-acting steroid (Group A) suggested a mean scoring of  $9 \pm 1.2$  % SD after 3 months, which became mean  $1.9 \pm 1.2$  % SD after 6 months, mean  $39 \pm 9.2$  % SD after 9 months, mean  $39 \pm 8.2$  % SD after 12 months, mean  $41 \pm 7.2$  % SD after 18 months, and then ultimately mean  $48 \pm 12.2$  % SD after 24 months.

Similarly in case of cell therapy group (Group B), the mean scoring was  $11.7 \pm 1.6$  % SD after 3rd month follow-up, which became mean  $9.4 \pm 0.6$  % SD after 6th month, mean  $9.1 \pm 0.96$  % SD after 9th month, mean  $7.1 \pm 0.6$  % SD after 12th month, mean  $6.7 \pm 0.4$  % SD after 18th month, and ultimately mean  $4.1 \pm 0.96$  % SD after 24th month follow-up.

*Discussion and conclusion:* If we analyze the results, we can see long-acting steroid, due to its anti-inflammatory and other activities, causes some improvement of the patients; however, it is ill sustained as noted from the follow-up. But freshly collected simple amniotic fluid cell therapy has a much more sustained effect apart from the remarkable improvement, but the question remains why in long-term follow-up there is reappearance of pain in some of the victims. Is it psychosomatic aspects or a recurrent cell therapy or increasing the cell dosage that can have a more sustained effect. These are some of the questions for the future investigators in this frontline area of cellular therapy.

But from an overall point of view, regeneration can only treat the root cause of degeneration of the whole lumbosacral region. Cell therapy is the only curative approach for such a generalized multisystemic deterioration of the region, and the palliative approach of pain relief with anti-inflammatory drug including steroid is short lived and has longtime use and may lead to drug-induced problems in addition of the recurrence of the symptoms.