Intervertebral disc repair with autologous nucleus pulposus-derived MSCs transplantation: a controlled clinical trial by 5-year follow-up

Ruan DK, Wang CF, He Q, Zhang C, Hou LS, Li C, Bai XD, Ji W, Weng TY

Department of Orthopedic Surgery, The Sixth Medical Center of PLA General Hospital, Beijing, China
There is no conflicts among the authors
Introduction

- Loss of nucleus material
- Loss of Disc height
- Instability
- Herniation recurrent

IVDD

Biotechnology

Surgery

Cell transplantation

Tissue engineering

Genetic engineering

Factor

Department Of Orthopedic Surgery The Sixth Medical Center of PLA General Hospital
Methods

1. Subjects were 30 patients aged from 20 to 55 years

2. All patients had been diagnosed single level lumbar disc herniation and been given the discectomy

3. Nucleus pulposus cells were cultured in GMP condition

4. Trial group (15 patients): transplanted with 1ml of $5 \times 10^6$ autologous NP- MSCs at 4 weeks post-discectomy

   Control group (15 patients): No NP- MSCs transplantation

5. Long-term clinical efficacy was assessed by the VAS scores, JOR scores, ODI Index and SF-36 Index

6. X-Ray and MRI analysis
## Results

### VAS scores assessment

<table>
<thead>
<tr>
<th>Group</th>
<th>Preoperative</th>
<th>3 mons PO</th>
<th>1 yr PO</th>
<th>3 yrs PO</th>
<th>5 yrs PO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Group</strong></td>
<td>6.5 ± 0.7</td>
<td>1.8 ± 0.3</td>
<td>1.1 ± 0.2</td>
<td>1.2 ± 0.5</td>
<td>1.1 ± 0.3</td>
</tr>
<tr>
<td><strong>Control group</strong></td>
<td>6.3 ± 1.1</td>
<td>1.6 ± 0.4</td>
<td>1.0 ± 0.3</td>
<td>1.3 ± 0.3</td>
<td>1.4 ± 0.2</td>
</tr>
</tbody>
</table>

### JOR scores assessment

<table>
<thead>
<tr>
<th>Group</th>
<th>Preoperative</th>
<th>3 mons PO</th>
<th>1 yr PO</th>
<th>3 yrs PO</th>
<th>5 yrs PO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Group</strong></td>
<td>16.5 ± 1.6</td>
<td>26.2 ± 1.2</td>
<td>27.1 ± 1.0</td>
<td>27.2 ± 1.5</td>
<td>28.1 ± 2.2</td>
</tr>
<tr>
<td><strong>Control group</strong></td>
<td>16.0 ± 2.1</td>
<td>25.8 ± 1.4</td>
<td>28.2 ± 2.5</td>
<td>26.3 ± 0.8</td>
<td>27.8 ± 1.6</td>
</tr>
</tbody>
</table>
## Results

### ODI index assessment

<table>
<thead>
<tr>
<th>Group</th>
<th>Preoperative</th>
<th>3 mons PO</th>
<th>1 yr PO</th>
<th>3 yrs PO</th>
<th>5 yrs PO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Group</td>
<td>32.6 ± 4.2</td>
<td>11.8 ± 0.7</td>
<td>11.1 ± 1.0</td>
<td>10.8 ± 1.5</td>
<td>9.8 ± 1.6</td>
</tr>
<tr>
<td>Control group</td>
<td>31.8 ± 2.1</td>
<td>12.6 ± 0.6</td>
<td>11.0 ± 1.2</td>
<td>11.3 ± 0.8</td>
<td>10.7 ± 0.6</td>
</tr>
</tbody>
</table>

### SF-36 Index assessment

<table>
<thead>
<tr>
<th>Group</th>
<th>Preoperative</th>
<th>3 mons PO</th>
<th>1 yr PO</th>
<th>3 yrs PO</th>
<th>5 yrs PO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Group</td>
<td>33.6 ± 8.2</td>
<td>71.8 ± 11.7</td>
<td>73.1 ± 11.0</td>
<td>74.8 ± 11.5</td>
<td>76.8 ± 9.6</td>
</tr>
<tr>
<td>Control group</td>
<td>32.7 ± 7.1</td>
<td>68.6 ± 8.6</td>
<td>74.0 ± 12.1</td>
<td>77.3 ± 12.8</td>
<td>75.7 ± 12.1</td>
</tr>
</tbody>
</table>
During 5 years follow-up, X-ray showed that the height of intervertebral disc in two groups had no significant difference.
The MRI result indicate that the NP cell-treated disc had the higher water contents than the control disc.
During 5 years after transplantation, all functional scores at two groups, including VAS scores, JOR scores, ODI Index and SF-36 Index, had the significant improvements to pre-operation.

During 5 years follow-up, X-ray results showed that the height of intervertebral disc in two groups hadn't the significant difference.

The MRI results indicate that the cell-treated disc had the higher water contents than the control disc.

At the last follow-up, UTE series also showed the better results of cartilage end-plate structure in MSCs transplantation group.
Conclusions

- Autologous NP-MSCs transplantation showed the safety and efficacy in clinical trial by 5-year follow-up

- The findings suggest the efficacy of this treatment to slow down the further degeneration of human intervertebral discs after discectomy