

BEIKE BIOTECHNOLOGY

Patient Case Study

Amyotrophic Lateral Sclerosis

Male, 51 years old, 4 treatment cycles

Background

Age: 41 years old

Sex: Male

Nationality: American

History of Condition: Patient has had muscular weakness and atrophy since 2006 and dysarthria since 2008

Treatment Schedule: Patient has received four cycles of stem cell treatments thus far. Please see the details below:

Treatment 1

Treatment Schedule: Patient received 6 umbilical cord blood-derived stem cell (UCBSC) packets by intravenous (IV) injection and lumbar puncture (LP), as per schedule below:

Number	Date	Cell Type	Delivery Method
1	June 4, 2008	UCBSC	IV
2	June 11, 2008	UCBSC	LP
3	June 16, 2008	UCBSC	LP
4	June 27, 2008	UCBSC	IV
5	June 27, 2008	UCBSC	LP
6	June 30, 2008	UCBSC	IV

Treatment 2

Treatment Schedule: Patient received 4 umbilical cord blood-derived stem cell (UCBSC) packets and 2 autologous bone marrow stem cell (BMSC) packets by intravenous (IV) injection and lumbar puncture (LP), as per schedule below:

Number	Date	Cell Type	Delivery Method
1	February 18, 2009	UCBSC	IV
2	February 20, 2009	UCBSC	LP
3	February 27, 2009	UCBSC	LP

4	March 6, 2009	BMSC	LP
5	March 9, 2009	UCBSC	IV
6	March 13, 2009	BMSC	LP

Follow up report: Patient observed improvements which began during his stay in the hospital and lasted for longer than 6 months following this treatment course. Main gain was in muscle strength and walking ability. Patient was able to walk a little faster and for a longer period of time without becoming fatigued. Speech was also improved and patient felt he had more energy.

Treatment 3

Specific Condition on Admission: Patient presented with dysarthria and dysphagia. Muscles of the tongue were atrophied and trembling. The reflection of the pharynx was weak and the limbs were hypertonic and trembling. The muscle strength in upper limbs was grade 3 and in lower limbs was grade 4.

Treatment Schedule: Patient received 7 umbilical cord-derived mesenchymal stem cell (UC-MS) packets and 1 autologous bone marrow stem cell (BMSC) packets by intravenous (IV) injection and lumbar puncture (LP), as per schedule below:

Number	Date	Cell Type	Delivery Method	Side Effects
1	March 5, 2010	UC-MS	IV	none reported
2	March 10, 2010	UC-MS	LP	none reported
3	March 15, 2010	UC-MS	IV	none reported
4	March 19, 2010	UC-MS	LP	none reported
5	March 24, 2010	UC-MS	IV	none reported
6	March 29, 2010	BMSC	LP	none reported
7	April 2, 2010	UC-MS	LP	none reported
8	April 7, 2010	UC-MS	IV	none reported

Condition on Discharge: The doctors reported that his limb strength, fine motor movement, and pronunciation had improved.

Treatment 4

Specific Condition on Admission: Muscles of the tongue were atrophied and had fasciculation and the reflection of the pharynx was weak. The muscle tension of the limbs was almost normal. The muscle strength in the proximal upper limbs was grade 3, in the distal upper limbs it was grade 2-3, and in the lower limbs was grade 4.

Treatment Schedule: Patient received 8 umbilical cord blood-derived stem cell (UCBSC) packets, given two at a time, by intravenous (IV) injection as per schedule below:

Number	Date	Cell Type	Delivery Method	Side Effects
1 and 2	February 14, 2011	UCBSC	IV	none reported
3 and 4	February 18, 2011	UCBSC	IV	none reported
5 and 6	February 23, 2011	UCBSC	IV	none reported
7 and 8	February 28, 2011	UCBSC	IV	none reported

Condition on Discharge: After stemcell treatment, the doctors reported that he had more energy, and greater muscle strength in his limbs and trunk. They also noted that he could move his tongue with greater ease and this meant he could speak more clearly. He could also sit up on his bed more easily and his gait was more forceful and stable when he was walking without support.

The below table is an excerpt taken from the patient's own assessment on the follow up form:

Symptom	Parents' Assessment of Improvement
Trunk control	Significant improvements
Balance	Small improvements
Walking	Moderate improvements
Overall strength	Moderate improvements
Limb muscle strength	Moderate improvements
Speech	Moderate improvements
Drooling	Small improvements
Writing	No improvement
Breathing	Significant improvements
Swallowing	Small improvements
Energy	Moderate improvements

Follow Up Information

Condition 3 months after treatment: Three months after treatment the patient reported that he was still doing well. Some of the major gains of the treatment had started to decrease a little but his condition was still better than what it was when he had arrived for treatment. Below are comments taken from his follow up evaluation:

"I finally had a period in my life where I could get a good night sleeps, best I've felt for 2 years, strengthening of my diaphragm made breathing easier. Frequent hiccup episodes went away and have not come back 3 months later. I got stronger in my right side, not so much in the left. No

improvement in ability to balance but more awareness of my balance means I can know if I'm going to fall and stop it. Walking much improved but still slowly and the limp has gone. 3 months after treatment my limp has returned but not as much as before treatment. Speech improvement noticed by others, I feel it is better but gets worse after I talk for a long time. Ability to swallow has improved, it was pretty good at discharge and still better at 3 months.”

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