BEIKE BIOTECHNOLOGY

A Clinical Summary of Stem Cell Therapy for Liver Cirrhosis From 2008 and 2009

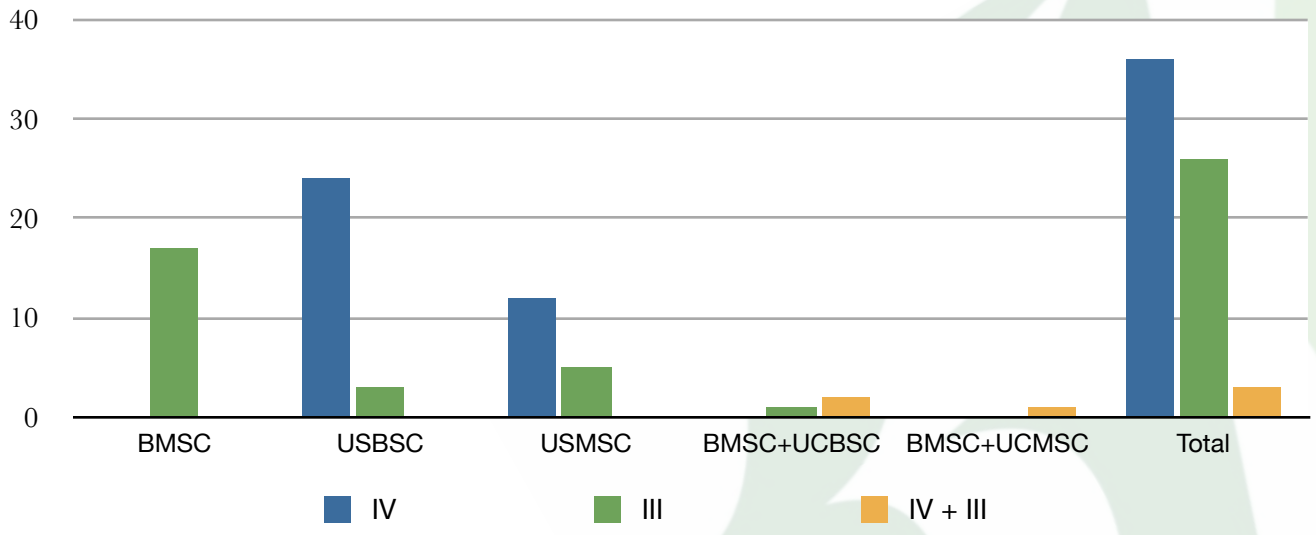
Patient Background Information

From December 2008 to November 2009, 65 patients with liver cirrhosis underwent stem cell transplantation in Beike Biotechnology's treatment and rehabilitation centers at our partner hospitals in Hainan, Shijiazhuang and Harbin. 51 men and 14 females with an average age of 47 were treated. Each patient underwent stem cell transplantation 1 to 4 times. Stem cell types and therapeutic approaches (two cell delivery ways: intravenous injection/IV and intravascular interventional injection/III) are shown in Table 1 below.

Table 1: Stem Cell Type and Therapeutic Approaches for Patients Treated by Stem Cell Therapy (BMSC=Autologous Bone Marrow-Derived Stem Cells, UCBSC=Umbilical Cord Blood-Derived Stem Cells, UC-MSC=Umbilical Cord-Derived Mesenchymal Stem Cells)

Items	BMSC	UCBSC	UC-MSC	BMSC + UCBSC	BMSC + UC-MSC	Total
IV	0	24	12	0	0	36 (55.38%)
III	17	3	5	1	0	26 (40.00%)
IV + III	0	0	0	2	1	3 (4.62%)
Total	17 (26.15%)	27 (41.54%)	17 (26.15%)	3 (4.62%)	1 (1.54%)	65 (100%)

Chart 1: Stem Cell Type and Therapeutic Approaches for Patients Treated by Stem Cell Therapy



Results

Lab Test Index

Liver and coagulation function was tested 3 days before and after treatment. The evaluation of the efficacy includes the level of serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL), albumin (ALB), prothrombin time (PT) and activated partial thromboplastin time (APTT). Below is the statistical report for the liver and coagulation function test.

Table 2: Before and after treatment blood test results (X±s)

Items	No. Patients	Before Therapy	After Therapy	*P*
ALT	55	70.38±82.74	43.95±34.80	< 0.05*
AST	44	79.80±79.43	47.45±25.14	< 0.05*
TBIL	53	114.71±145.50	82.47±115.36	< 0.05*
ALB	51	29.71±6.16	32.04±5.43	< 0.001**
PT	31	21.55±8.34	20.54±9.62	> 0.05**
APTT	32	54.50±20.61	51.89±12.98	> 0.05**

- The conclusion is drawn by rank sum test.
- The conclusion is drawn by paired T test.

In addition, the liver function indexes were also compared in patients who received different types of stem cells. It was found out that there were no significant differences in the outcomes of patients receiving umbilical cord blood-derived stem cell, umbilical cord-derived mesenchymal stem cell and autologous bone marrow stem cells (Table 3). 3 cases were not involved in the statistical analysis because they received combination treatments.

Table 3: Comparison of UCBSC, UC-MSC and BMSC

Items	UCBSC (d1)	UC-MSC (d2)	BMSC (d3)	*P*
ALT	51.41±107.15	4.78±11.90	14.57±7.93	> 0.05*
AST	52.63±86.03	14.78±25.49	25.43±24.84	> 0.05*
TBIL	74.07±145.41	0.33±18.18	31.50±51.68	> 0.05*
ALB	-3.60±5.03	-1.30±3.73	-2.90±4.34	> 0.05*

1. Rand sum test of complete random design and multiple comparisons
2. d (d1, d2, d3) = indexes before treatment − indexes after treatment. 22 cases treated by umbilical cord blood-derived stem cell, 9 cases umbilical cord-derived mesenchymal stem cell and 7 cases autologous bone marrow stem cell.
3. There were discrepancies between value of mean number and standardized difference due to different samples and efficacy.

Clinical Analysis

(1) ALT levels fluctuated in the normal range in 29 cases before and after treatment. 1 case was in normal range before treatment and out of range after treatment. ALT levels were above the

normal range in 25 cases and then decreased after treatment in 23 cases (92.0%), and among them, ALT levels decreased to within the normal range in 10 (40.0%).

(2) AST levels fluctuated in the normal range in 15 cases before and after treatment. 2 cases were in normal range before treatment and out of range after treatment. AST levels were over the normal range in 27 cases and then decreased after treatment in 26 (96.3%), and among them, AST levels decreased to within the normal range in 10 patients (37.0%).

(3) ALB levels fluctuated in the normal range in 7 cases before and after treatment. 3 cases were in normal range before treatment and out of range after treatment. ALB levels that were below the normal range in 41 cases then increased after treatment in 30 patients (73.2%), and among them, the ALB levels increased to the normal range in 10 (24.4%).

(4) TBIL levels fluctuated in the normal range in 6 cases before and after treatment. 3 cases were in normal range before treatment and of range after treatment. TBIL levels had been over the normal range in 44 cases then decreased after treatment in 30 (68.2%), and among them, the TBIL levels decreased to within the normal range in 7 patients (15.9%).

Chart 2: Clinical Improvement Results

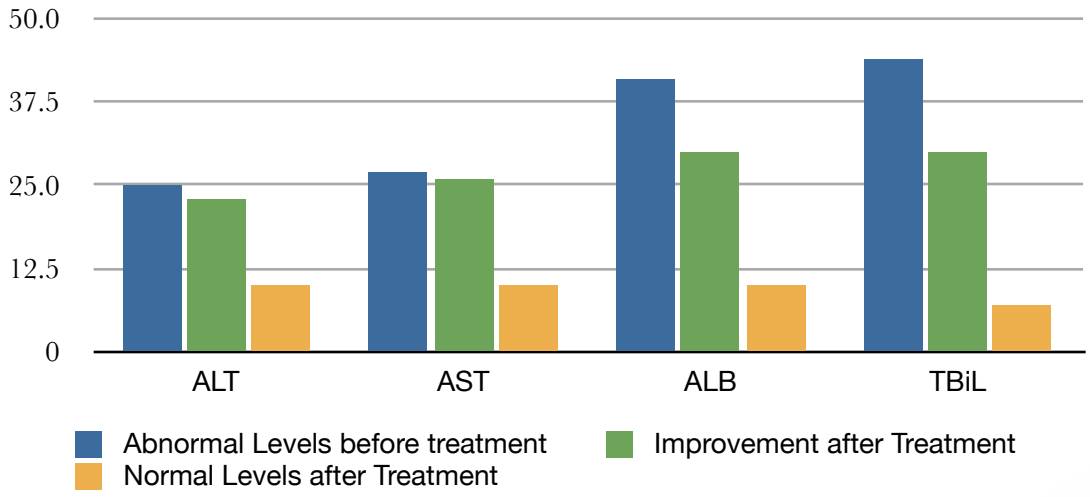
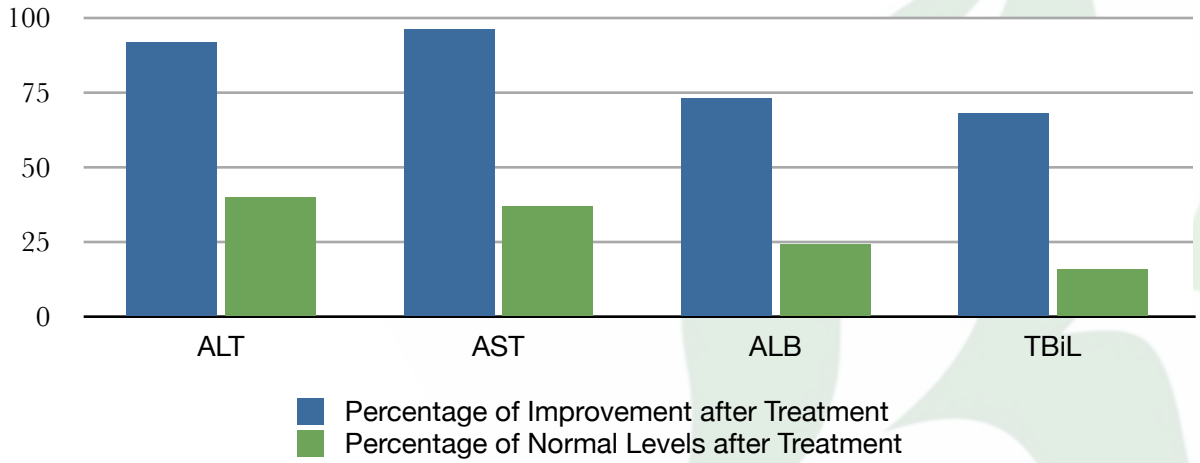


Chart 3: Clinical Improvement Percentage



Out of the 65 patients treated, 6 provided reexamination reports to us two months after the treatment. Among them, the ALB levels had increased in 5 patients and were stable within the normal range in 4 patients. The AST levels were in the normal range before and after treatment in 4 patients and were out of the normal range before treatment and in range at the 2 months time point in 2 patients. . AST levels were in the normal range in 3 patients and had improved from the baseline in the other 3 patients. One of the three abnormal patients was stable in the normal range after treatment. TBIL levels improved in 2 patients and increased in 4 patients.

Observation of Symptoms and Vital Signs

Table 4: Improvement Rate of Symptoms and Vital Signs Before and After Stem Cell Therapy

Items	No.	No. of Patients Improved	Rate
Mental status	47	46	97.87%
Complexion	28	15	53.57%
Appetite	47	43	91.49%
Jaundice	36	25	69.44%
Pleural effusion, fluid of the lung	46	24	52.17%

Conclusions

By analysis of the laboratory data before and after stem cell therapy, it was found that:

- There was a statistical significance in differences of liver function before and after stem cell therapy. The levels of ALT, AST, TBIL decreased, while the level of ALB increased.
- There was no statistical significance in the levels of PT and APTT before and after stem cell therapy.
- In regards to the stem cell sources, there was no statistical significance in the improvement of liver function of patients treated by umbilical cord blood-derived stem cell, umbilical cord-derived mesenchymal stem cell and autologus bone marrow stem cell.
- By analyzing the improvement of symptoms, the most significant improvement was mental status, followed by appetite, jaundice, complexion and pleural effusion.
- General speaking, stem cell therapy can improve the liver function of patients with liver cirrhosis. There is no different efficacy in patients who underwent the transplantation of umbilical cord blood-derived, umbilical cord-derived mesenchymal or autologus stem cells.

Note: the clinical data above is reliable and obtained from three treatment and rehabilitation centers. The clinical tests were not designed before collecting the data. The selection of patients and observation of clinical data was not based on the same standard. Therefore, this clinical summary is limited and we provide it for reference only. (Medical Department of Beike Biotechnology)

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