On the safety and efficacy of human patient stem cell transplantation therapy

Abstract

Although stem cell therapy is very promising, so far, there are insufficient clinical trials reported. Therefore, the safety and efficacy of stem cell transplantation are still not confirmed clinically. Here, we reported approximately 9,000 patient cases treated with human fetal neural stem cells, human mesenchymal stem cells and human adipose stem cells for various human diseases. By follow-up visits, the efficacies of the treatments were confirmed. These data vigorously demonstrated the safety and effectiveness of stem cell therapy for patients, and provided critical evidence for the great promises of the therapeutic applications of stem cells.

Keywords: stem cell therapy, human fetal neural stem cells, human mesenchymal stem cells, human adipose stem cells

Abbreviations: HFNSC, human fetal neural stem cell; HASC, human adipose stem cell; HMSC, human mesenchymal stem cell

Background

It had been a long-time controversy for stem cell therapy about its safety and efficacies.1–3 The main concerns included the tumor formation and immune rejection.4 So far, the main data of stem cell therapy were obtained from animal models, such as mice,5 rats6 and monkeys7 etc. Among these investigations, most of the allogenic stem cell transplantations were performed into immuno-deficient animal models to avoid the rejections of transplanted stem cells.8,9,10 These immuno-deficient animal models are currently widely used. Although these models can allow the transplanted stem cells to integrate into the hosts, the lack of normal immune system failed to vigorously evaluate their tumor formation potentials. Hence, the safety issues of stem cell therapy could not be demonstrated reliably.4 Therefore, the huge gap between laboratory investigations and clinical stem cell therapies still existed.

Statement of ethical approval

The treatments for the patients and the use of human stem cells were approved by the Ethics Committee of Interventional Hospital of Shandong Red Cross Society (Shengjiyi 2003, No.26) in compliance with Helsinki Declaration. The Ethics Committee of Interventional Hospital of Shandong Red Cross Society approved this clinical study and treatments. The participants provided their written confirmed consent to participate the clinical study and treatments. The Ethics Committee of Interventional Hospital of Shandong Red Cross Society approved this consent procedure. All the treatments for the patients included HFNSCs, HMSCs and HASCs. To date, no tumor formation was observed. The obvious effective rates of the treatments were about 40–95%, and the effectiveness rates were about 50–95%, respectively. In an astonishing patient case, the patient’s spinal cord was severely injured in a car accident, after traditional treatments, he was treated with 10 times of HFNSCs transplantation.9 Gradually, he recovered very well and even could ride motorcycle and work as an courier. Here, for the first time in the world, we reported a huge number of patients treated with different stem cells. These data demonstrated that human stem cell therapy is safe and effective. This important discovery overturned the long-existed controversies about stem cell therapy for the concerns of tumor formation and immune rejection. Based on the patient follow-up visits, the effectiveness of stem cell therapy was showed in Table 1 (this table is original for this article).
Table 1 The effective rates of the stem cell transplantation therapy for different diseases based on the patient follow-up visits.

| Kinds of diseases                        | Patient number | Stem cells | Effective rate | Obvious effect rate | Ineffective rate |
|------------------------------------------|----------------|------------|----------------|---------------------|------------------|
| Brain trauma and stroke Sequelae         | 1280           | HFNSCs     | 78%            | 65%                 | 22%              |
| Cerebral palsy                           | 1295           | HFNSCs     | 85%            | 76%                 | 15%              |
| Down’s syndrome                          | 300            | HFNSCs     | 95%            | 95%                 | 5%               |
| Cerebellar atrophy                       | 980            | HFNSCs     | 70%            | 57%                 | 30%              |
| Alzheimer disease, brain Atrophy         | 553            | HFNSCs     | 78%            | 65%                 | 22%              |
| Myasthenia gravis                        | 6              | HFNSCs     | 50%            | 40%                 | 50%              |
| Optic atrophy                            | 108            | HFNSCs     | 70%            | 65%                 | 30%              |
| Parkinson disease                        | 712            | HFNSCs     | 74%            | 70%                 | 26%              |
| Multiple system atrophy                  | 181            | HFNSCs     | 68%            | 60%                 | 32%              |
| Multiple sclerosis                       | 62             | HFNSCs     | 57%            | 45%                 | 43%              |
| Spinal cord injury                       | 1245           | HFNSCs     | 80%            | 75%                 | 20%              |
| Diabetes                                 | 944            | HMSCs + HASCs | 79% | 70% | 21% |
| Motor neuron diseases                     | 184            | HFNSCs     | 79%            | 65%                 | 21%              |
| Liver cirrhosis                          | 148            | HMSCs + HASCs | 85% | 85% | 15% |
| Chronic nephrosis                        | 126            | HMSCs + HASCs | 85% | 85% | 15% |
| Cardio-cerebral-vascular disease         | 704            | HMSCs + HFNSCs | 89% | 80% | 11% |
| Plant human patient                      | 6              | HFNSCs     | 75%            | 70%                 | 25%              |

Conclusion

Although clinical stem cell therapy for patients is very promising, the lack of vigorous animal models to assess the tumor formation and immune rejection of transplanted stem cells leads to a dilemma with controversies. Recently, a novel animal model, “Mouse Clone Model”, was proposed, yet, it still need a long time to be proved world-widely. During the past decade, we treated 8,834 patients with HFNSCs, HMSCs and HASCs. Many patients improved their physical conditions significantly. Most importantly, no tumor-formation was observed in any patients. These data vigorously proved that stem cell transplantation is safe and effective for curing different human diseases. These data of stem cell therapy for 8,834 cases provided strong evidence for the safety and efficacy of clinical stem cells therapy and laid important foundations for regenerative medicine.

Declarations

Ethical Approval and Consent to participate

Described in Statement of ethical approval section.

Consent for publication

All the participated patients were consent for the publication of this work.

Availability of supporting data

The datasets generated and/or analysed during the current study are not publicly available due to the protection of the confidential information of the participated patients but are available from the corresponding author on reasonable request.

Competing interests

The authors declare they have no competing interests.

Authors contributions

TW instructed and performed the clinical part of the work, GZ instructed and performed the experiment part of the work. Both authors discussed, wrote, read and approved the final manuscripts.

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Conflict of interest

The author declares no conflict of interest.

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