

A brief overview of cell therapy and its product

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Cell therapy is therapy in which cellular material is injected into a patient¹. Nowadays, various cell therapies are approved and used clinically. And many products are currently under active investigation worldwide and their market size is expected to grow rapidly in the near future. Ministry of Food and Drug Safety mentioned the global trend of stem cell therapy product in August 28, 2013 and said that market size will grow to 6.6 billion dollars in 2016 from 3.5 billion dollars last year. Global markets for stem cells by BCC Research (2012), cited by Ministry of Food and Drug Safety, predicted the global market size of stem cell therapy product would be 6.6 billion dollars in 2016 and grow 11.7% on average every year. Currently, US's stem cell therapy product occupying the biggest market share amounts to 1.3 billion dollars and Europe's is 872 million dollars. US's stem cell therapy product market is predicted to have an average annual growth rate of 11.5% (2.3 billion dollars in 2016), and Europe's is 10.9% (1.5 billion dollars in 2016). Until August 1, 2013, three stem cell therapies has acquired a sale permit for domestic use in Korea: Hearticellgram-AMI by FCB-Phamicell (the world's first stem cell therapy product), Cartistem by Medipost (the world's first allogeneous stem cell therapy product) and Cupistem by Anterogen. Besides, 24 medicines are undergoing clinical trial till January 1, 2013.

The cell therapy product treatment is different from the existing one because it is personalized, and this is valuable progress for the personalized medicine. Most of the medicine, up to now, is organic compounds or proteins to alleviate the symptom, not for ultimate cure. However, cell therapy product can be said to be the beginning of new technology confronting disease, because it is pursuing ultimate cure of disease. Cell therapy product uses cell itself as medicine, which mostly were made from patient's own tissue to have certain properties by manipulation and culture, and injected back to the patient. Therefore, cell therapy product is called personalized medicine compared to the medicine with mass

production for all.

Today two distinct categories of cell therapy are recognized¹. The first category is cell therapy in mainstream medicine. Allogenic cell therapy, human embryonic stem cell therapy, neural stem cell therapy, mesenchymal stem cell therapy and hematopoietic stem cell therapy belong to this category. This is the subject of intense research and the basis of potential therapeutic benefit². Such research, especially when it involves human embryonic material, is controversial. The second category is in alternative medicine, and perpetuates the practice of injecting animal materials in an attempt to cure disease. This practice, according to the American Cancer Society, is not backed by any medical evidence of effectiveness, and can have deadly consequences¹.

The cell therapy technologies are already started to play an important role in the practice of medicine and cell therapy is bound to become a part of medical practice. Cell therapy technologies overlap with those of gene therapy, cancer vaccines, drug delivery, tissue engineering and regenerative medicine. Methods of delivery of cell therapy product range from injections to surgical implantation using special devices. Cell therapy has applications in a large number of disorders. The most important are diseases of the nervous system and cancer. Other applications include cardiac disorders (myocardial infarction and heart failure), diabetes mellitus, diseases of bones and joints, genetic disorders, and wounds of the skin and soft tissues³.

Cell therapy product, suggesting a new paradigm of medicine, is technically very important and also very meaningful as country's growth engine in post-IT era. Korean government invested 100 billion won for research and development (R&D) in 2012. Ministry of Health and Welfare launched Global Stem Cell and Regenerative Medicine Initiative and invested 45 billion won for R&D (15 billion won in 2011: Ministry of Education and Science Technology invested 40 billion won in 2011 and 49 billion won in 2012),

and it intensely supports transitional clinical research in the field of Stem Cell and Regenerative Medicine. Besides, Ministry of Health and Welfare leads an active examination over the law and system about Stem Cell and Regenerative Medicine⁴.

There are so many problems to solve; the lack of guideline for the cell therapy product specialized clinical research procedure, establishing the effectiveness of treatment, treating side effects and so on, but cell therapy product for treating human disease is an inevitable process for biotechnology. Especially, when we try to understand more about development and differentiation through the study of stem cell as well as the biotechnology development like implementing Human Genome Project and apply to the patients by investigating the mechanism of disease, cell therapy product could suggest new revolutionary treating method which is totally different from the existing one. Nowadays, the developed countries' government and corporation are concentrating on R&D and commercializing of cell therapy product. This means that cell therapy product

has high potential and enough effective value in the market. It could be the beginning of new age for the new technology to realize the personalized medicine.

There are many obstacles to get over: regulation, safety and ethical issue and so on. However, we, oral and maxillofacial surgeons try to take a continuous interest in, research and cooperate to the development of cell therapy and cell therapy product.

References

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