Stem cell banking: an update on current scenario

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ABSTRACT

The emerging medical science coupled with biotechnological innovations is paving way for an exciting science – stem cell research. The researchers in the area of stem cell banking are exploiting the factual impending market worldwide. The possible clinical application of stem cells has generated great curiosity amongst medical professionals and general public. No only this, but stem cell research can be used for the treatment of widespread diseases like diabetes, Parkinson's disease, severe aplastic anemia, leukeamias, etc. The present article highlights the historical perspective about the stem cell banking along with an overview of global scenario of stem cell banking in the private and public sectors.

KEY WORDS: Biotechnological, emerging, medical, stem cell banking

INTRODUCTION

Research in the area of stem cells has offered a new valuable beneficial option to provide visualization of a potent biological health[1]. It holds a great potential to revolutionize healthcare. Big hope is invested in this field to deliver new treatments for many serious conditions for which few effective treatments currently exist[2]. Because of this, many nations have invested heavily in stem cell research. This has further given way for stem cell banks[3]. Use of stem cell technology is concomitantly increasing in the fields of regenerative medicine[4]. Through escalating attention in stem cell based therapy, the scope of stem cell banking is becoming more of a cell pharmacy[5]. The importance of stem cell banking can be understood only when their applications can be explored imperatively. The present article overviews the classification of stem cells, knowledge of stem cell banking, its global scenario along with the laws that govern the stem cell banking and a precise comparison about private and public stem cell banking.

STEM CELLS AND THEIR CLASSIFICATION

In general, the stem cells are basically unspecialized biological cells which have the ability to duplicate and produce its own blood cells, platelets, red and white blood cells through mitosis. These cells have the remarkable potential to develop into many different cell types in the body, serving as a sort of repair system for the body. The stem cells ability to differentiate or change into other types of cells in the body is a new discovery that holds tremendous potential for treating and curing some of the most common diseases such as heart diseases, cancer, etc. These cells are the chief cells responsible for producing all the mature cells in our blood and immune system[6-7]. As per 'National Guidelines for Stem Cell Research', stem cells are classified into two types, depending on the origin[8]:

- Somatic Stem Cells (SSCs)
- Embryonic Stem Cells (ESCs)

The SSCs have limited differentiation capacity and may be multipotent or unipotent, while, ESCs on the other hand are pluripotent.

Various sources of stem cells include:

- Embryonic Stem Cells.
- Fetal Stem Cells.
- Umbilical Cord Cells.
- Adult Stem Cells - Dental Pulp (Milk teeth of children between 6-12 years and wisdom teeth of adults over 30 years).

STEM CELL BANKING (SCB)

Stem Cell Banking is a procedure wherein the cells isolated from various sources are collected, stored and preserved for the future use. It's a concept of preserving the cord blood from newborn. The procedure takes about 10 to 15 minutes and it can be done both in normal and caesarean section deliveries. There are no risks or pain involved in the procedure. The cells can be cryo-frozen and kept stored for decades. Stem cell banks are progressively seen as a vital resource of biological materials for both basic and translational research[9]. These banks support transnational access to quality-controlled and ethically sourced stem cell lines from different origins and of varying grades[10]. Some of the international initiatives are also emerging in order to access harmonization and standardization processes for stem cell research and banking. These include the International Society for Stem Cell Research (ISSCR) and the International Stem Cell Banking Initiative (ISCBI). Stem cell bank itself refers to number of different levels and types of operations as well as institutions[11]. Stem cell banks range from public banks, as for instance the UK Stem Cell Bank and the Spanish National Stem Cell Bank, to institutional banks.

PERSPECTIVE

Stem cell banking has become a feasible source for transplantation since the first successful transplantation for a child with Fanconianaemia in 1988. The first related stem cell bank started at New York Blood Centre in 1992. Now nearly, 142 public

banks and additional 25 private banks are actively involved in Stem Cell banking around the world. The highest inventory of about 48,808 stem cells is with New York Blood Centre's National Cord Blood Program[12].

SCB - MARKET ANALYSIS (INDIA)

SCB has emerged as a new opportunity for healthcare service providers in India. The market is still in its nascent stage of development and valued at more than Rs 400 Crore (US$ 70 Million) in 2013[13]. The probable market for stem cell banking in India is cherished at more than US$ 350 million at preservation level of 1% which can increase to more than US$ 1 billion at stem cell preservation level of 3% for new born babies [14].

STEM CELL BANKING – A DELIGHTFUL DILEMMA, PUBLIC VS PRIVATE BANKING

In the early 1990s, first cord blood bank was established in New York and subsequently, over 35 cord blood banks have been established in 21 countries[15]. The stem cell banks are gradually more seen as an essential resource of biological materials for both basic and translational research studies. Stem cells are a vast source of primitive hematopoietic progenitor cells available for clinical application to reconstitute the hematopoietic system and/or restore immunological functions. Researchers continue to evaluate the usefulness of stem cells in treating human diseases or disorders for purposes other than hematological disorders including heart disease, strokes, brain or spinal cord injuries and cancer [16]. Stem cell banking can be differentiated into public and private banks[12]. The public and private cord blood banking must strictly follow standardize policies and procedures. The basic differences between private and public stem cell banks are as follows:

Public Stem Cell Banking	Private Stem Cell Banking
The eligible donations of stem cells given by the donors are stored free of cost.	It's a commercial approach.
This banking type is not used exclusively for use by family and donors.	It is exclusively for family and personal use at a cost which includes initial processing and subsequent storage.
This type of banking relies on first come and first serve basis.	It relies solely for the donors.
It can be used for carrying stem cell research; however, the donors consent is needed to carry the research.	It cannot be used for research.
It benefits the general population suffering the risk of heart diseases and cancer.	It benefits the people if advised by the doctor, under special conditions (family history of people suffering from genetic disorders) and rare human leukocyte antigen (HLA) complex disorders can be benefitted through private banking.
Public banks utilize specific criteria like quality, reliability, functional capability of stem cells at different time periods.	Private banks store all collective stem cells.

STEM CELL BANKING – GLOBAL SCENARIO

A few FDA (Food and Drug Administration) approved stem cell products are making into the clinics in various parts of the world[13]. Globally, the stem cell banks are spread across 70 countries governed by 19 regulatory bodies for storage and transplantation[12]. Internationally over 300,000 stem cell samples have been stored through International Registries for future use[17]. Globally, stem cells are used to treat over 130 diseases and it is estimated that more than 500 clinical trials are being done to develop therapies using stem cells[18]. Universally among all the countries working in the area of stem cell banking, Austria, Canada and Finland are the lowest repositories for stem cell banking accounting about 0.5%, 1.0% and 1.9% respectively. While, India, Mexico, France and Belgium have nearly about 2.3%, 3.0%, 5.0 % and 5.0% respectively, followed by the highest number of stem cell banking reported in Japan (11%) and USA (27%)[19] (Fig – 1).

STEM CELL BANKING – INDIAN SCENARIO

India is emerging as a hub for SCB with greater potential for SCB research because of high birth rate and genetic diversity. According to a stem cell research promoting global organization, stem cell banking is a 100 crore business in India with an estimated annual growth of over 35% [13]. As umbilical cords are the rich source of stem cells, it's no surprise that leading stem cell banking companies are keen on shifting their stem cell bases to India[20].

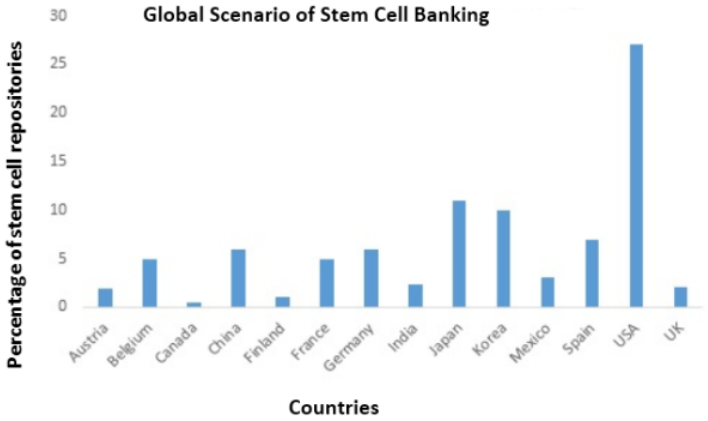

Fig.1. Global scenario of stem cell banking - India and other countries

INTERNATIONAL ARENA – GLOBAL LAWS

Over the past few years, the field of stem cell technology is witnessing maturation of the stem cell banking market making the industry very competitive. Considering the competitive expansion that is occurring within this industry, it is essential to understand the laws that govern stem cell research and banking functioning in the space and their geographical coverage. However, United States (US) remains the world leader in stem cell research and banking[21].

Stem cell laws are the law rules and policy governance concerning the sources, research and uses in treatment of stem cells in humans. These laws have been the source of much controversy and vary significantly by country. In 2005, the law of stem cell banking was signed by President George W Bush under 'Stem Cell Therapeutic and Research Act' to support building of 150,000 cord blood units which was reauthorized in 2010 to place new emphasis on actions such as exploring innovations on stem cell banking. The Federal Legislation Committee has authorized funding for escalating high quality and genetically diversified stem cell banking units. In United Kingdom (UK), Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC) are the funding sources for stem cell banking. The UK government has initiated 'UK Stem Cell Initiative' in 2005 with the aim of working with public and private sectors for ten-year vision for stem cell banking in the UK. Along with this initiative, in 2007 the UK government also launched UK National Stem Cell Network (UKNSCN)[22]. Coming to Canada, 'Canadian Stem Cell Network' has been launched to coordinate in improving the scope of stem cell research and banking. In Japan, Centre for Developmental Biology (CDB), launched a division of stem cell technology in order to provide full support services to the Japanese labs with an increased interest in stem cell banking[23].

LAWS TO REGULATE STEM CELL BANKING IN INDIA

In India's first move to legalize the growing business of stem cell banking, the Ministry of Health has prepared draft rules for umbilical cord blood banking and put them up for public consultation[24]. The Drug Controller General of India (DGCI) within Central Drug Standard Control Organization (CDSCO) has established guidelines for cord blood banking by amending the Drugs and Cosmetics Rules of 1945. These cord blood banking guidelines, which became effective in 2012, are applicable to cord blood units intended for autologous and allogeneic use and are designed to provide a framework for facilities to obtain a license to manufacture and distribute cord blood in India. The guidelines outline the collection, processing, testing, storage, banking and release requirements for umbilical cord blood[8]. At present, only the stem cell research that aims to create a drug requires prior approval from Drug Controller General of India (DCGI) for conducting human clinical trials [25].

STEM CELL THERAPY – CLINICAL TRIALS UNDER STUDY

According to a recent study by Trounson[26], rapid advancement in the area of stem cell clinical trials are evolving in the medical field in many new directions. The number of clinical trials involving stem cell research has grown rapidly in the last two to three years, creating new clinical avenues for developing novel drugs. Further, globally, many clinical trials are continuing to evaluate the potentiality of stem cells. Currently, clinical trials for various diseases like thalassemia, sickle cell anaemia, osteogenesisimperfecta, acute myocardial infarction, asymptomatic hyperthyroidism, sarcomas, paraplegia, ataxia, multiple sclerosis, amyotrophic lateral sclerosis, cerebrovascular disease, multiple system atrophy, motor neuron disease, etc., are in progress[27-28]. Also placenta-derived stem cells are being considered for similar uses and are in Phase III of clinical trial for critical limb ischemia[26]. To date, bone marrow is the best source for most of the clinical studies. Recently,

adipose tissue has gained clinical interest for its use in therapeutic studies[29]. Although there are many clinical trials under study, however, the positive results of the clinical research studies needs to be explored for further applications in clinical practice.

CONCLUSION

The possibilities presented by stem cells in the treatment of various diseases have created widespread excitement globally. A new trend has arisen in many developed countries, regarding the stem cell as the initial source of life or life itself. But, in the rest of the world, perspectives on the beginnings of life vary and the subject remains an unresolved issue, giving rise to contradictory narratives and policies. As these therapies are increasingly entering public health systems, there is a need for a greater visibility and awareness on stem cell related technologies. Obviously, identifying clear and transparent policies will facilitate this process and encourage more efficient research[29]. Therefore, an established stem cell bank would broaden the extent of beneficiaries by using these benefits.

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