

Advances in stem cell research*

Regenerative medicine and stem cell technologies are estimated to become a US\$ 500 billion market over the next 20 years. To establish India in an advantageous position in this fast developing global stem cell market, we need to have a strategy in place. The Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT), New Delhi have plans for a national stem cell initiative to prioritize research funding, focus on clinical applications and promote 'stem cell city clusters' in India. The National Task Force on Stem Cell Research established in April 2005, is taking these plans forward. To look at the advances in stem cell research around the world, the current regulatory scene in our country and the potential of stem cells in the future, a national seminar was organized on advances in stem cell research. There were 94 participants from different institutions of India.

Stem cell research is an emerging field of interdisciplinary research with clinical implications focused on repair, replacement or regeneration of cells to salvage impaired organ function. From biological insurance, repository services, autologous and allogenic transplants, assisted devices to system solutions, the tremendous potential of stem cell research can be limited only by imagination. This can be envisioned by viewing it from three different perspectives – science, unmet medical needs and potential product and services range.

Gurunath Kilara (Gokula-Curie Cancer Centre, Bangalore) spoke on the stem cell perspective and prospects and called for a national agenda on stem cell research that can help in therapeutics. In the inaugural address, Ramananda S. Nadig (Triesta Sciences Pvt (India) Ltd, Bangalore) mentioned that the economic fundamentals of new drug development are about to be altered radically in the future.

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For example, it takes 10–12 years for a new drug discovery, whereas it takes just 3–5 years in stem cell research; the pre-launch cost of development for a new drug is US\$ 500 million against the US \$200 million in stem cell research. And the success rate of a new drug is 5–10% against 50% or better in stem cell research. According to Nadig, stem cell therapies have virtual unlimited medical and dental applications, gene to personalized and customized medicines and biomarkers for various diseases. A diseased approach to drug development will significantly reduce time and resources that are required and stem cells add impetus to alternatives. By the end of 2009, India can develop a first defined stem cell-based drug for standard therapy, just like other medicines. On similar lines, P. K. Shetty (NIAS, Bangalore) mentioned that adult stem cells have shown promising results. They are effective in tissue repair, spinal cord injury, heart damage, Parkinson's disease and autoimmune diseases. More than 45,000 people across the world are receiving adult stem cell transplant every year. Stem cell technology can reduce pharmaceutical R&D by 25% each year, with savings of up to US \$25 million in each drug market.

S. G. A. Rao (Cryo Stemcell (Kar) Pvt Ltd and Sri Raghavendra Biotechnologies Pvt Ltd, Bangalore) spoke on 'Stem cells, application and banking'. Available source of stem cells for banking are umbilical cord blood (UCB) – haematopoietic stem cell banking, umbilical cord – mesenchymal stem cells, bone marrow – haematopoietic stem cells. UCB stem cells are an easily accessible source. However, they are available only at the time of birth. Stem cells need to be banked for later autologous or allogenic use. These banks are similar to blood banks. Cord blood stem cells are collected from consenting donors and banked. These banks have large sample numbers, since human leukocyte antigen matches are difficult in small numbers. These need to be regulated more stringently compared to autologous banks.

Aparna Khanna (Embryonic Stem Cell Group, Reliance Life Sciences Pvt Ltd, Mumbai) in her keynote address spoke on 'Recent trends in embryonic stem cell

research'. At Reliance Life Sciences, the embryonic stem cell group is engaged in developing cell-based therapies to address neural, cardiac and metabolic disorders. Further, they are trying to delineate the intricate signal transduction mechanisms governing stem cell differentiation by proteomic studies. Since much of our current knowledge of the molecular expression profile of human embryonic stem (hES) cells is based on transcriptional approaches, these analyses are only partly predictive of protein expression, leaving a gap in our knowledge of the biology of these cells. Additionally, the group has also focused on identifying candidate biomarkers to predict or measure pharmacological efficacy and toxic response by employing the hES cell metabolome. Further, Khanna also envisaged the current status of embryonic stem cell research and discussed the problems being encountered, keeping abreast with the recent progress in this field. This is critical to the translation of ES cell therapy from the bench to the bedside.

Joshua Peter (Novel Foundation for Science, and Lalbhag Nursing Home, Bangalore) spoke on the role of the embryologist in embryonic research. He also described the recent developments in reprogramming somatic cells into embryonic-like stem cells by expressing a defined set of transcription factors, generating ES cells from left-over pre-implantation embryos or using somatic cell nuclear transfer. Traditionally, ES cells are derived from early embryos and involve embryo destruction, which is against ethical standards. Reprogramming adult stem cells into ES cells generates a potentially limitless source of immune-compatible cells for tissue engineering and transplantation medicine. Some important technical obstacles remain before this shows up in the clinic. But once these obstacles are overcome, the technique could ultimately aid in drug development and even therapies for injury or disease.

A. K. Dutta (ExCel Matrix Biological Devices P Ltd, Hyderabad) spoke on designing *ex vivo* organs systems. We cannot just harvest cells, culture them (2D/3D), and expect them to grow and form tissues. Cells need structural, mechanical,

chemical and electrical cues to regulate cell differentiation, proliferation, morphology and migration to develop as functional tissues. Therefore, to grow cells as three-dimensional tissues, we need to provide a tissue-like environment through a biomaterial that mimics the extracellular matrix present in the tissues. Dutta also spoke on various other developments in computer-aided tissue engineering, CAD-based anatomic reconstruction, computer-aided bio-fabrication and ECM analogue technology in tissue engineering.

In the panel discussion on 'Stem cell research', speakers expressed concern about the private stem cell banks for yet-to-be-developed therapies. Even if thera-

pies are developed, stem cells derived with today's methods and medical approaches may be inappropriate for future applications. In addition to guidelines, we need to develop a regulatory body for monitoring stem cell harvesting as well as applications in our country.

Reacting to the various queries related to government research fellowships (ICMR, CSIR and DBT), Dutta explained various government initiatives like the Small Business Innovation Research Initiative and Technopreneur Promotion Programme. He urged students to think big and aim to become entrepreneurs with these schemes. He shared his own experience of getting funds in establishing his company at Hyderabad.

Thus stem cell researchers, industry leaders, policy makers, patients, legal experts, investors and philanthropists were brought together to illuminate the critical issues and chart the future of stem cell research in the country. India is capable of leading from the front given its early success, potential and the proactive, favourable regulations of government agencies.

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