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Letter to Editor

Landscape of Stem Cell Therapy and Research in India: Challenges and Solutions

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Sir,

Stem cell therapy and regenerative medicine is the holy grail of Modern Medicine. Though whole world is interested in this area of medicine and consider that this medicine will revolutionize modern medical practice but the progress in the field has been very slow and India is also no exception to that. There are innumerable reasons for this sluggish progress and some of them will be discussed here.

There are several dimensions in the landscape of stem cell therapy and research in our country.

1. **Regulatory and Ethical Dimension:** In new science is seen by the establishment with skepticism because there remain many unknown and unproven areas in the new science. Moreover initial evidences on the effectiveness of new management accrues slowly, initially as individual case reports, then case series and finally different types of randomized trial. This may even need initial studies of safety, efficacy, dose, etc. and some of the studies may be initially done in-vitro or in animals. The human trial may initially include hope less cases and subsequently may follow classical phases of clinical trials. All these needs proper regulatory and ethical frame works which is not too oppressive yet optimize the safety and progress (Viswanathan, 2013).[1] In India these rules and regulation are formulated by ICMR, DBT in close association with Drug Controller General of India (DCGI). There are lots which need to be done by regulatory authorities to expedite therapy and research in this area (Tiwari, 2018).[2]
2. **Institutions Engaged in Stem Cell Research and Therapy in India:** Very few Government institute and charitable hospitals as well as private companies are engaged in serious stem cell research in this country (Sharma, 2006).[3] However some basic biological work on animals and in-vitro is conducted in a handful of centers. When one looks at therapeutic application of stem cells both autologous and allogenic there are many private hospitals and centers, which are practicing this kind of therapy for diverse clinical applications like, diabetes, wound healing, neurological disorders, cardiomyopathy, myocardial infarction and myopathies, osteoarthritis, acute spinal injury to name a few (Sangwan, 2003).[4] Reports on success of these therapies are anecdotal and as patient has to bear the cost for these as yet unestablished therapies clinical trials are hampered (Viswanathan, 2013).[1] India with its huge population can become an ideal place for medical research in stem cell (Jose, 2020),[5] but due to lack of awareness and investment, its progress is slowing down. I believe the funding

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agencies must come in good numbers to give generous funding to at least gain empirical evidence on success or failure of such therapies in a multi-centric mode. If efficacious the proper indication, contraindications, sources, doses of the stem cells needs to be established. It also needs to be established whether there are any window of opportunity in terms of timing such therapy. The role of ancillary cells i.e. platelets, lymphocytes, other cells in success or failure of such a therapy also needs to be researched.

3. **Sources of Stem Cells:** There are multitudes of sources of stem cells; however most commonly autologous haemopoietic stem cells, umbilical cord blood stem cells or umbilical cord derived stem cells are extensively used. Mesenchymal Stem Cells (MSCs) can have multitude of uses and some companies have tried to produce off the shelf material (Ankrum, 2010).[6] However again details of such therapeutic approach and its scope needs to be developed in the form of guidelines when the data matures. Ownership of such kind of stem cells also has ethical and financial dimensions.
4. Few negative studies from funded research at established recognized Institutions can and have brought negative feeling on stem cell therapy and research. It is to be recognized that when there is rational for therapy and it fails we have to analyze the causes of failure, correct it and should get ready for next trials (Tiwari, 2014; Tiwari, 2018).[2,7]
5. Fear that when externally manipulated stem cells are used or embryonic or allogeneic stem cells are used, a remote possibility of future oncogenesis or mal alignment of these stem cells in tissues like heart or brain may cause life threatening arrhythmias or epilepsy. Hundreds of different trials across the globe have shown that if we don't use embryonic stem cells then this kind of therapy is reasonably safe.
6. **Lack of Multidisciplinary Approach with Stem Cell Research and Therapy:** There are needs for multidisciplinary approach for stem cell research and therapy. Apart from clinicians, who are overseeing the application of cell therapy in a particular specialty, there are needs for molecular biologists, cell biologists, cryo-biologists, flow cyto-metrists, cyto-geneticists as a team. In addition there should be good quality animal house to study application in experimental animals. All these research should be guided by good clinical and laboratory practice.
7. **Need to Develop Stem Cell Therapy Registry:** Here all the cases where stem cell has been applied as a part of therapy should be recorded in a common proforma voluntarily with follow of results. All the clinicians in our country who are using this form of therapy if they record their results in this registry voluntarily then we will have numerator and denominators as well as degrees of success and failures. In a few years this data will be so robust that we can go to funding agencies with such a data which they cannot deny.
8. We already have many cord blood banks where privately Individuals store cord and cord blood. However, we need public cord blood banks and standardization of materials stored in such banks. Without that standard therapy cannot be given.
9. Tissue engineering is developing in many countries and they are trying to develop future applications with engineered organs. In our country such institutions are needed.

In conclusion we may say that though stem cell therapy outside haemopoietic stem cell transplantations are being used by many private and corporate hospitals yet we have not accumulated data in one place to even empirically confirm the success , failure , nature of cells given and dose of cells given for different purposes. Few good researches have been published in this area. More work is needed and do that generous government funding for multi-centric disease wise studies are urgently required. The regulatory authorities need to see how they can encourage research and therapy in this very important area without compromising patient safety. Already there are indication as that in several areas of human disease this kind of therapy could be effective at least in the short run. Let us begin with them systematically with generous government funding.

Conflict of Interest

None.

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