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The Stem Cell Dilemma: Ethics, Regulation and Society

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Abstract

Stem cells are undifferentiated cells capable of differentiation into more specialized cells. Stem cell therapy is one approach to regenerative medicine which seeks to give humans a new lease of life by repairing or replacing damaged tissue, and possibly reversing disease or trauma. Stem cell research has always been a morass of controversy since coming to the public's attention, with the benefits and risks of stem cell therapy placed under continuous assessment. Despite the ability of stem cell treatment to help many people, it is extremely important that the controversial and ethical issues are adequately addressed. Researchers expect that in the future stem cell treatment will be able to effectively treat a multitude of diseases and medical conditions, thus creating the potential for treatment of currently untreatable diseases or conditions. Stem cell therapy has a few contentious issues, and in particular, controversial treatments that are not clinically proven are dangerous and expose the patient to major health risks. This research paper seeks to review the promise of stem cell research in the context of ethical, scientific and political arguments

Keywords: Stem cell, Ethics, Regenerative medicine, Embryonic, Mesenchymal.

INTRODUCTION

Regenerative medicine is a branch of medicine that aims to repair, replace or regenerate damaged tissue to restore normal body function by relying extensively on advances in stem cell biology [1]. Stem cell therapy is one approach to regenerative medicine which seeks to give humans a new lease of life by repairing or replacing damaged tissue, and possibly reversing disease or trauma [1,2]. Stem cells are undifferentiated cells capable of self-renewal and differentiation into more specialized cells and have the ability to transform themselves into cells from different types of tissue [1]. Stem cells may be obtained from the umbilical cord, bone marrow, liver, adipose tissue, pancreas, skeletal muscle, dermis, and synovial membrane [3].

Based on their ability to differentiate into specialized cells, stem cells can be classified to have totipotent, pluripotent, or multipotent differentiation potential [1]. Totipotent stem cells have the ability to differentiate into both embryonic and extra embryonic tissues [2]. Pluripotent stem cells can differentiate into any of the three embryonic germ layers; the endoderm, mesoderm, or ectoderm [3]. Embryonic stem cells are pluripotent and are harvested from the inner cell mass of the pre-implantation embryo that is a few days old [3,4], and can differentiate into cells from all three germ layers and thus can differentiate into any type of cell in the body [3,5]. Multipotent stem cells including mesenchymal stem cells can differentiate into a limited number of specialized cells [4].

In the early years of stem cell transplant development, bone marrow stem cell transplants were performed with stem cells that were harvested from the adult bone marrow or stored cord blood [6,7]. A few decades later, in 1998 scientists developed techniques to extract stem cells from human embryos [7], however this was mired in moral controversy from both religious and political groups [7,8]. and initiated the on-going stem cell research debate, which has not abated, despite major advances in this field [7,8]. This research paper seeks to address the promise of stem cell research in the context of ethical, scientific and political arguments around stem cell research.

ETHICS, REGULATION AND GOVERNANCE

Stem cell research has always been a morass of controversy since coming to the public's attention in the late 1990s [6,7], with the groundbreaking first successful culturing of human stem cells from embryos being achieved in 1998, which attracted relentless ethical, scientific, and socio-political debate [5,8]. The main ethical issues confronting embryonic stem cell research is firstly, the isolation of embryonic stem cells involves the destruction of a human embryo and secondly, the transplantation of undifferentiated embryonic stem cells may result with a formation of teratomas, which are tumors that contain all three germ layers Figure 1 [5,8].

Induced pluripotent stem cell therapy has a multitude of potential applications such as gene therapy, disease modelling, cell replacement therapy and drug discovery. Embryonic stem cell research can be applied to drug toxicity effects, human development research, and cell replacement regenerative therapies [7,8]. Induced pluripotent stem cell therapy has a multitude of potential applications such as gene therapy, pathogenesis research, cell replacement therapy and drug discovery [5]. A potential complication regarding induced pluripotent stem cells therapy is genetic mutations and terratoma [5].

The benefits and risks of stem cell therapy are under continuous assessment and clinical trials have been conducted for the implantation of embryonic and other stem cell or stem cell-derived products [9,10]. The European Union released a Proposal [9] in 2022 to significantly change its regulation of cells and tissues and repeal Directive 2004/23/EC, the foundation of stem cell regulation for the last two decades [9]. The changes were aimed to address the main concerns of patient protection from avoidable risks, regulation of new therapies [10] and elucidate on how stem cell therapy could be offered to patients [10].

In 2020, The U.S. Food and Drug Administration (FDA) released a regulation document "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products Minimal Manipulation and Homologous Use" to assist in regulating and classifying tissue therapy [11]. Homologous use is when tissue performs the same basic function in the recipient as in the donor, though it may be in a different location in the body [11]. Some stem cell treatments currently available may be compliant with FDA rules however they are not yet approved, though the FDA has approved the use of blood-forming cells for treating cancer or immune disorders [12,13], Similar situations have been reported in other countries, including in Europe and Asia [13]. In the United States, the Food and Drug Administration (FDA) and Institutional Review Boards (IRBs) provide guidance on the level of manipulation of tissue, and in cases where tissue is considered to have been minimally manipulated, there is no requirement for a clinical trial, and thus are not regulated or documented.as these therapies are classed as innovative medical procedures, rather than medical products requiring marketing approval [10,11]. This designation also means they are not formally considered to be research, meaning they are not subject to oversight from research ethics committees or requirements to report results [15]. According to this guidance, tissue collection, stem cell isolation and implantation could be classified as minimal manipulation, however the FDA has classified these 'many steps' as more than minimal manipulation, particularly cell purification and expansion, which involves culturing in media, and transportation between sites [14,15]. These regulations will not deter non-compliant stem cell clinics from ignoring these rules and hence regulation bodies such as the FDA have to be proactive, because without adequate regulatory monitoring, it is left to the clinician to determine if a tissue has been minimally manipulated [14,16].

The United Kingdom, the Human and Fertilisation Embryology Act (HFEA) of 1990 which legalised the in- vitro embryonic stem cell research during the 14 days after fertilisation, at which instance the primitive streak, of the embryo differentiates into the three germ layers which give rise to adult tissue: ectoderm, mesoderm and endoderm, has not manifested [17-19]. These 14 days rule ensured that beneficial embryonic research was conducted in a manner which protected the status of the unborn [18], largely resulting in liberalisation of Britain's embryonic research regime [18,19]. The isolation of mesenchymal stem cells presented an ethical dilemma in the fact that they have the ability to produce a clone of the donor resulting in countries and stakeholder organisations legislating to ban human cloning [6,17]. These developments necessitated the UK government to amend the HFEA [20,22].

In terms of policy and governance in stem cell research, the 14 days rule has been considered a success; however, with recent progress in science and medicine, there have been calls for a review of the 14 days rule [21,23]. Revision of the rule will encourage researchers and give hope to patients that the benefits of stem cell research will become available safely and responsibly in the near future [23,24]. Progressive stem cell research will require review of mitochondrial replacement techniques, gene editing techniques for embryos and the 14 days rule [29,30].

According to advocates for a time extension to 28 days, argue that the 14 days rule did not create a firm moral boundary for embryonic stem cell research but rather a practical time frame, and the embryos used for research are destroyed in 14 days and will not develop into a person [29,30]. In addressing the issue of the possibility of pain and suffering caused by research being carried out on an embryo that is more than 14 days old, extension advocates argue that no functional neural connections or sensory systems are present in the embryo [19], making it virtually impossible for the embryo to experience pain or suffering within a research period of day 1 to day 28 [19,29,30]. The period between the 14th and 28th day of embryo development is often referred to as the "black box" of human development [29,30]. Proponents of extending the 14 days period contend that an extension would give scientists the opportunity to study the developmental processes when the first primitive tissues form during the process termed gastrulation [18,19]. During gastrulation researchers can understand more about the developing nervous system without any risk of neural connections being present and gain a better understanding of the early development of organs [28,29]. Proponents further argue that an extended research window could potentially improve the safety and success rate of current *in vitro* fertilization procedures and assist clinicians determine which embryos have the best chance of pregnancy success [1,30].

However, opponents of an extension point out that any extension would be morally irreconcilable since the 14 days rule has been considered moral significant for a variety of reasons [29,30]. One of the most important considerations is that the embryo has a moral standing at the initiation of gastrulation which occurs after 14th day [26].

One of the most crucial arguments put forward is the risk of the embryo experiencing pain and suffering when research is conducted on embryos after initiation of gastrulation [27,28]. It is further argued that any proposed extension to 28 days will open an opportunity for further extensions in the time period [27,30].

The Nuffield council on bioethics emphasizes that any consideration of the extension of the 14 days period would have to be on the basis of the prospect of scientific breakthroughs that will greatly benefit humans [30].

PHASES OF STEM CELL RESEARCH

Lo and Parham [31] proposed a classification of the different ethical issues based on the four phases of stem cell research. The donation of biological material is the first phase which highlights the problem of informed and voluntary consent [31]. Research with human embryonic stem cells, is the second phase. This phase creates several ethical issues which include the creation of embryos for research purposes and the destruction of embryos for research purposes, compensating the oocyte donors financially, the medical hazards associated with the retrieval of the oocyte, and the protection of the reproductive interests of women undergoing infertility treatment [31,32] is The third phase of stem cell research is the issue of adverse legal and ethical principles which arise from the use of stem cell lines obtained from other institutions [31,32]. The use of stem cells in clinical trials is the fourth phase which encompasses both the advantages and disadvantages of the trial and; the fourth phase also highlights the ethical issue of informed and voluntary consent [31,32].

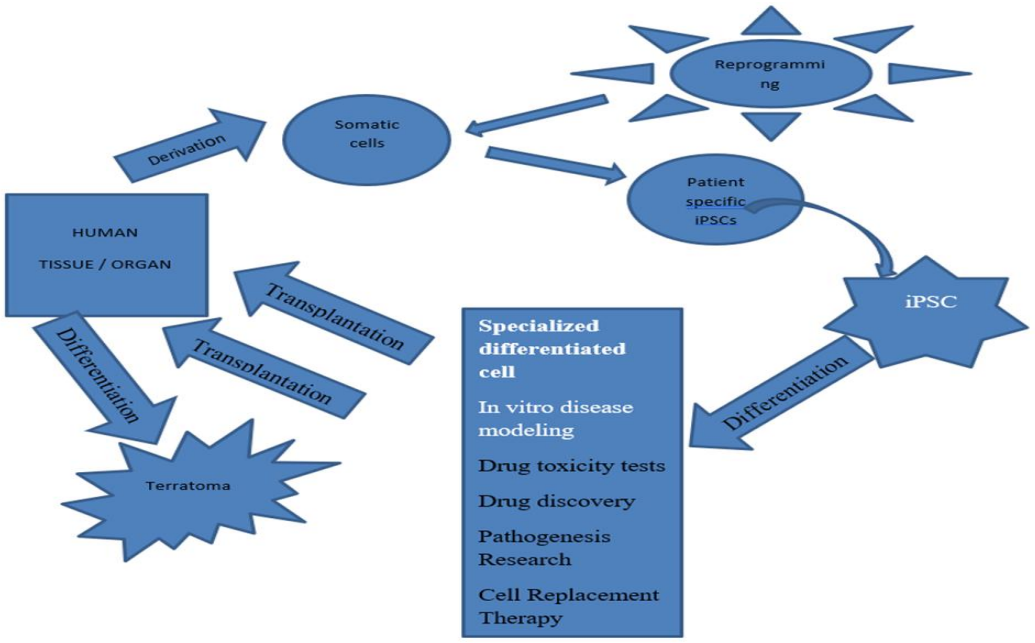

Figure 1: Schematic diagram illustrating the processes of induced pluripotent stem cell therapy. Adapted from Volarevic *et al* 2018 [5].

POTENTIAL STEM CELL APPLICATIONS

One of the clinical applications in which stem cell treatment may be applied in various scenarios is tissue engineering which is a rapidly evolving field that entails treating diseases with the body's own stem cells by repairing, replacing or augmenting diseased tissue and organs [1,20,22]. Scientists believe that conditions, such as diabetes and heart disease can be effectively treated with stem cell therapy. in the case of patients with a damaged heart, which has scarring that is considered untreatable, by transplanting stem cells into the patient's heart healthy cardiac tissue can be stimulated to grow, and subsequently the heart heals itself by regeneration [5 ,9,20]. In cases of patients with type 1 diabetes, their blood sugar levels are controlled by daily insulin injections. The transplantation of stem cells into the islets of Langerhans brings about regeneration and normalization of the insulin production by islets of Langerhans, and eliminating the need for insulin injections [5,20,24].

Stem cell banking is another area of application of stem cell research. In this situation stem cells are harvested at birth, which is a person's point of biological perfection [10], as these stem cells have original, uncorrupted DNA which is unexposed to injurious stimuli, like electromagnetic radiation, chemicals etc, and the biological software is considered uncorrupted. These stem cells captured at birth, are replicated into large number of cells which are the frozen and stored until they are needed in the future [22, 23].

Further advances in stem cell research have resulted in isolation of highly multipotent mesenchymal stem cells (MSC) from the amniotic fluid and umbilical cord tissue [23]. Mesenchymal stem cells are adult, fibroblast-like, multipotent cells usually harvested from the umbilical cord blood, adipose tissue and bone marrow [6,11]. Amniotic fluid which contains stem cells that can be harvested and stored usually in liquid nitrogen to be subsequently used to treat conditions such as congenital disabilities. These congenital disabilities are usually diagnosed with an amniocentesis and treatment can be initiated during gestation or in the future as required [24].

Another innovative stem application is in developing and testing new drugs [19,24]. New drugs are tested and developed using induced pluripotent stem cells which are differentiated and genetically "reprogrammed" using viruses [19,24]. Anti-cancer drugs can be tested by growing differentiated cells from these pluripotent stem cells can be made to mimic cancer cells or characteristic cells of other severe human conditions such as Parkinson's and auto immune disorders. Mesenchymal stem cells based therapy has shown a measure of success in ischaemic bowel disease, liver disease and cardiac disease therapy, however at times it may result in unwanted effects like differentiating into unwanted tissues such as cartilage and bone. Mesenchymal stem cells-based therapy has the ability to suppress anti tumour response and develop new blood vessels which can support tumour metastasis [5,20,24]. The development of these cells will assist researchers in better identifying the true nature of the conditions and enabling scientists to develop effective treatments [5,20,24]. Despite the scientific breakthrough of developing induced pluripotent stem cells which act as stem cells and using this in regenerative medicine [23] the emergence of IPS cells has softened but not completely nullified the stem cell debate because human ES cells are still required to be used as a measure of the "stemness" of the IPS cells [23,24].

In a study to treat cataracts using stem cell therapy researchers removed the clouded lens , the eye stem cells were regenerated to grow a new lens. This therapy has been effectively tested in animals and on a small scale in humans [1,25].

A research project to stimulate damaged teeth to self-repair using stem cell stimulating fillings has achieved considerable success [1]. This will have a huge economic and health impact as tooth decay and its treatment, which generally has a 20 -30 percent failure rate, is a very prevalent and costly problem throughout the world [1]. The researchers have developed a synthetic biomaterial capable of stimulating the regeneration of stem cells in the tooth pulp [1]. The biomaterial is placed into the tooth and hardened with ultra violet light similar to a normal dental filling procedure [1]. The stem cells differentiated and proliferated into protective dentin tissue effectively the tooth self-healed [1]. This treatment has the potential of saving teeth and eliminating the need for costly and invasive dental treatments [1].

These stem cell therapies that utilise the patient's specific organs stem cell to regenerate and repair that specific organ highlights the aspiration of stem cell therapy to treat a patient using their own stem cell tissue [1,25]. The promise of stem cell therapy is endless however there has been no scientifically and clinically proven stem cell success, and stem cell therapies are still mostly theoretical rather than evidence-based [19,22]. Further research and clinical trials are ongoing and hopefully will yield more positive outcomes that will see the initiation of stem cell therapy routinely [19,22].

CHALLENGES OF STEM CELL THERAPY

Some researchers believe that since the success in developing induced pluripotent stem cells, the hurdle of the ethical issues of using embryos

to make stem cell lines has been navigated [5,24]. However, other researchers and interest groups believe that new controversies and ethical issues emerged with the ability of IPS cells forming human organs or even eventually clone a human [5,24].

Despite the ability of stem cell treatment to help many people, it is extremely important that the controversial and ethical issues are adequately addressed [5,24] Researchers expect that in the future stem cell treatment will be able to effectively treat a multitude of diseases and medical conditions. As much as stem cell treatment may offer the potential to treat diseases or conditions for which few treatments exist, stem cell treatments that are not clinically proven are dangerous and expose the patient to major health risks [23,24]. Unscrupulous healthcare practitioner use the hype around stem cells to offer stem cell treatments that are have not been approved and neither proven to vulnerable patients that are desperately seeking cures and remedies. It is imperative to be clear about all the facts if you are considering or adopting any treatment [37, 38].

The FDA has reported that dishonest practitioners exploit research that indicates possible significant clinical potential of properly developed products, and they use this information to deceive desperate patients [39]. In the USA, the FDA also issued a warning to a stem cell clinic for marketing stem cell products without FDA approval [39] as part of a crackdown to prevent unscrupulous caregivers from being able to deceive patients and potentially harm their health [39]. Unproven stem cell therapies jeopardize the reputation of legitimate therapies which have not yet been made available commercially. This is also partially due to patients incorrectly estimate the probability of benefit or risk [40] which is referred to as misestimation [40]. These further fuels misconception about stem cell research developments with subsequent widespread political and organizational calls for tighter regulation, however this has not impeded the proliferation of private stem cell practitioners offering unproven stem cell treatments [40].

European union countries have adopted a 'compassionate use' program were a patient with life-threatening, debilitating or long-term illness with no approved treatment can access an trail drug outside of a clinical trial [41]. In Australia, the Therapeutic Goods Administration (TGA) has no control over autologous stem cell therapies for individual patients due to a medical practice exemption clause. This has resulted in an increase the number of private stem cell clinics in both regions [42]. Many clinics offer stem cell-based treatment for conditions ranging from minor injuries to cancer and already in 2016 there were 570 clinics offering stem cell treatments in the United States [42]. Any effort resulting in reduction of the burden of disease in developing countries is always encouraged and a study conducted in 2006, reported that a mong developing countries, only China, India and Brazil had significant stem cell research capacity [43]. Developing the stem cell capacity of developing countries will contribute significantly to the reduction in the burden of disease. However, due to the lack of adequate regulation and enforcement in developing countries patients are exploited and risk adverse health effects and long-term difficulties [43]. China has forged ahead with its embryonic stem cell research program by initiating the world's first clinical trial of treating Parkinson's disease with human embryonic stem cells [43]. Emerging countries have increased their investment in stem cell research and development projects and this is particularly evident in Australia, Singapore and Japan [44].

Practitioners of unproven stem cell treatment have traditionally been operating in low income countries where they can exploit the poor regulations and enforcement, however recently there has been an increase in these practitioners, in developed and emerging countries [26]. This exploitation may make patients financially vulnerable, have significant psychosocial consequences and deprive individuals and communities of resources that could be spent elsewhere [26]. Additionally, in some countries, the costs of adverse health effects caused by stem cell interventions are borne by public health-care systems, not by stem cell clinics or the patients [26].

The International Society for Stem Cell Research (ISSCR) [44] is an organization that seeks to promote high scientific and ethical standards. The ISSCR's guidelines [44], for the conduct of human embryonic stem cell research and guidelines for the clinical translation of stem cells have provided critical direction and support for stem cell researchers [44]. Stem cell products have to meet regulatory requirements and then pass through the clinical translation pathway to ensure optimum safety and acceptable efficacy [44]. The ISSCR's judgment allows room for innovation while keeping an equilibrium between clinical progress and scientific prudence within a realm of ongoing political and ethical debate [44].

The development of regenerative medicine through understanding stem cell therapy research is important as there are millions of individuals suffering from and succumbing to "incurable degenerative diseases of the, heart, liver nervous system, pancreas, and other organs" annually [31,33]. Similarly, stem cells can be considered as the hope for many patients who are suffering with illnesses such as Parkinson's, Huntington's diseases, and diabetes who in dire need of a cure [31,34]. The use of stem cells, presents many ethical, religious and political challenges, related to stem cells research and the rights of donors [27,34] has increased recently and many countries including the United Kingdom, United States, Japan and more recently, emerging countries have incorporated stem cell therapies in their practices necessitating increased human rights organizations and governments concerns regarding stem cell research [27,36].

CONCLUSION

Some researchers are of the opinion that we are on a the brink of a stem cell revolution and suggest that further stem cell understanding will bring about groundbreaking development in dealing with currently incurable illnesses. Despite these perceptions and reports of breakthroughs in scientific journals and media reports, there are a very low number of approved stem cell therapies. This situation has opened a window for unscrupulous practitioners to offer unapproved and unsafe stem cell treatments to desperate patients. This taints the reputation of stem cell research which is already dodged by the ethical, scientific and political controversies and thus adds to the limitation of stem cell therapies finding the transition from laboratory research concept to an administered potential cure. Thus, it is imperative that the degree of patient benefits and the nature of adverse events, of these treatments are reported.

Stem cell therapy has demonstrated the potential to treat many disorders that have no available treatments, however finding the right cells, guaranteeing patient safety, and maximizing these cells' performance still presents a major challenge.

The merits of clinically unproven remedies such as those offered by stem cell treatment are contentious, however it is not surprising that so many clinics offering stem cell treatment are available and thriving, given the fact that when it comes to healthcare, desperation can prevail, particularly when the options are limited in terms of evidence or financially.

Conflict of interest

There is no conflict of interest.

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