Medgar Evers College

Stem Cell Therapy

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Abstract

The ability to derive stem cells from embryos has generated much excitement in the medical field about the many possibilities of treatments for diseases and other medical conditions that before that major discovery were seen as impossible. This interest has not only been seen among medical professionals but in the general public as well, as this discovery provides hope where there was practically no treatment for some medical conditions.

With all this interest, however, embryonic stem cell research brings with it many challenges for bioengineers, medical scientists and those responsible for making and implementing policies and the regulating practices. The most significant source of contention is in determining what the legal and moral dimensions of the embryo are. This is crucial, as embryo stem cell research encompasses salvaging embryonic tissue from embryos, ultimately leading to the lost or destruction of such embryos. This is the reality, as the embryo that has the overall capacity to develop into a full human being has to be sacrificed for the benefit of those in need of treatments. It must also be noted that regulations that monitor stem search research globally have legitimate concerns regarding these issues surrounding ethical and moral issues.

Amidst these global concerns, there is no doubt an immense need for either biomedical scientists to find other ways to retrieve stem cells or for there to be a resolution regarding the moral and legal status of the embryo. Although the later seems less likely, this paper will attempt to present information that will demonstrate how the dire need for expanding the research around stem cells as a viable tool to be used in stem cell therapy.

Key Words: *Stem cells, embryonic stem cell research, ethical, moral and legal status of embryo, stem cell therapy*

Introduction

The age of modern medicine brought with it all the excitement and hopes that reflects the Age of Enlightenment. Since then, man has always pursued opportunities for healthier and longer lives. Such pursuit has led to the creation of new and emerging divisions or branches of medicine. One such branch is regenerative medicine, aspiring to restore organs or tissue function to individuals who many have suffered serious injuries or experiencing chronic diseases, where their own bodies' responses are not enough to provide functional use. An increase in the need for organ transplantation and an aging population is the motivating factor that is driving the search for new and alternative therapies. It is estimated that there are roughly 90,000 individuals in the United States currently on the transplant-waiting list while at the same there are many patients needing medical treatments which might be resolved by technologies that tackle regenerative medicine.[1]

There are parts of our bodies can repair themselves very well if they are damaged, but there are other parts that do not repair at all. We do not have the ability to regrow a whole leg or an arm, but amazingly, some animals can. New research in various animals that have this ability has revealed that these animals utilize various stem cell tactics enabling them to redevelop complete body parts made from several tissues. Scientist believe that an understanding of how these animals are able to regenerate adult tissues, it would provide an insight into the engineering of human tissue.[2]

In order to make the case for research and use of stem cell therapy, it is important, therefore, to look at a brief history of stem cells, gain an understanding of what stems cells are, what's their targeted use, the argument for and against what most view as imperative to enhanced quality of life for many.

Brief History of Stem Cells

Stem cells can be seen as "cellular putty" from which all body tissues are made. Growing human embryonic stem cells in a lab allowed researchers to dream of someday using these cell to repair damaged tissue or generate new organs. However, having the ability to use such cells for medical treatments and therapies have also drawn much controversy, which would be discussed later.[3]

The records will show that more than 30 years ago, in 1981, scientists found ways to obtain embryonic stem cells from early mouse embryos. The study of the dogma in mouse stem cell biology, led to the discovery of a method to obtain stem cells from human embryos and grow such in labs. They are referred to as human embryonic stem cells. It must be noted that the embryos used here were generated for reproductive reasons through in vitro fertilization techniques. Later in 1998, a scientist from the University of Wisconsin, Thompson, was able to separate cells from the inner cell mass of some early embryos and created the first embryonic stem cell lines. That same year, Johns Hopkins University scientist, Gearhart, obtained germ cells from cells in foetal gonad tissue. Pluripotent stem cell lines were then developed from those sources. Later in 1999 and 2000, scientists realized that manipulating adult mouse tissues could generate various cell types. This discovery now meant that cells from bone marrow could now produce nerve or liver cells and cells in the brain could also yield other cell types. These were exciting breakthroughs for stem cell research, which held great potential and promise of more scientific control over the variation and production of stem cells. There was another important breakthrough in 2006 when researchers were able to identify an environment that allowed some specific adult cells to be genetically "reprogrammed", assuming a "stem cell-like state".[4,5]

Political leaders and legislators around the globe have taken on the task of regulating stem cell research. Here, in the United States, laws forbid the production or creation of embryos intentionally for research. What Scientists are able to do instead is receive unused ones from fertility clinics with the consent from donors which is generally agreed on to be appropriate guidelines. Although the federal government allots billions of dollars annually towards biomedical research, some believe that it is unethical to fund stem cell research. It is therefore challenging for legislators who deem it necessary to encourage improvements in the medical field while at the same time having to uphold respect for life.

Records show that United States President Bush restricted government funding to approximately 70 of human embryonic stem cell lines in 2001. While some may say that this discussion slowed down the destruction of human embryos, many more believe that the limits set back the advancement of stem cell research significantly. President Obama, on the other hand, having overturned Bush's stem cell policy in 2009, expanded the number of stem cell lines accessible to scientists. A new issue is now on the table for policy-makers, in that they now have to content with the question of whether there should be a need for different laws for pluripotent stem cells differ from those for human embryonic stem cells.[6]

The Science Behind Stem Cells

Stem cells are cells that have not yet developed the ability for a specific function or use but are capable of developing into more differentiated or various specific cell type in the body. In other words, a stem cell is like a blank slate having the ability to receive information that will

enable it to develop into a specific cell type based on the information received. A stem cell can become a cell type such as a skin cell, a muscle cell, or a nerve cell.[7] Stem cells are also considered primitive or unlearned but have the capacity to divide and develop somatic cell tissues.

Generally speaking stem cells can be placed in two categories: embryonic stem (ES) cells and adult stem cells. Embryonic stem cells from humans are referred to as Human Embryonic Stem Cells (HESC), and are derived from developing embryos. They are obtained in the very early stage of development known as the blastocyst. In order for these cells to be viable, they must be harvested within five days after fertilization. Adult stem cells are undifferentiated cells found among differentiated cells in various tissue types in the body. Scientists find embryonic stem cells more viable and gives them the advantage over adult stem cells because more readily follow the instructions as to what they are told as to what tissues they need to grow into. The best stem cell is those of the fertilized egg and are considered totipotent, as they can lead to the creation or development of all cell tissue. Embryonic stem cells that are harvested in the very early development stages using today's technology are considered pluripotent as they can give rise to the three germ layers, namely the endoderm, mesoderm or ectoderm. On the other hand, adult stem cells are considered multipotent as they have the potential to differentiate into multiple, but limited cell types.[8]

Use of Stem Cells

The main purpose of stem cells is to provide therapy or medical treatment by way of either regenerating new tissue to form complete organs or to repair damaged or injured tissue. Current procedures together with new discoveries will be able to utilize stem cells to create tissues that can

live and function to restore and repair damaged or diseased tissue and organs. Some scientists believe that the potential of stem cells as a therapy has been overstated. Assessments of the possible benefits of therapies using stem cells indicate that in the United States alone about 128 million people might be helped. The most impact would be on patients with about 5.5 million suffering from cardiovascular disorders, 25 million from autoimmune disorders and 16 million with diabetes (more than 217 million worldwide) where stem cells will produce insulin that could treat these diabetic patients. Other patients with disorders in the United States who most likely would benefit are about 10 million who suffer from osteoporosis, .3 million with severe burns and .25 million with spinal cord injuries will have neurons replaced. Some other common diseases or medical conditions that utilize stem cell therapy are strokes, Alzheimer's disease, Parkinson's disease and other neurological problems, and even generate heart muscle cells that could repair due to damage because of a heart attack. Other conditions worth mentioning are Lou Gehrig's disease, giving them the ability to move once again, lung diseases where stem cells are used to repair damage due to a number of pulmonary disorders or lung trauma due to car accidents or bullet wound or sports injury, Arthritis or degenerative joint disease where lost cartilage and shot joints are rebuilt and repaired, Sickle cell anemia where patients may receive stem cells transfusions from their own skin cells and of course easing the shortage for transplants by growing new organs because of organ failure.[9,10,11]

Challenges of Stem Cell Therapy

Biotechnological advancements and findings in stem cell science are proliferating at a precipitous pace. Still, in no other area of scientific research has the trend and scale of scientific

progress so closely monitored and influenced by "ethical consideration and formal sanctions". When stem cells were first cultured in 1998, it triggered a controversial array of issues based on religious, legal, social, and moral principles.[12] Unfortunately, with such a huge extent of data researchers may be tempted to concoct reports and conclusions as was the case in 2004 to 2005, when a Korean researcher, Hwang Woo-Suk alleged to have created human embryonic stem cell lines from unfertilised human eggs. These lines were ultimately shown to be entirely inaccurate and therefore made-up, but the buzz left the global public cynical and mistrusting of the scientific community.

On the other hand, lies the ethical, moral and political debate. The ethical and moral dilemma we face is the duty to avert or ease human suffering while at the same time having a duty to respect and regard human life. It, however, seems impossible in the case of embryonic stem cell research. To acquire these stem cells, the early embryo has to be destroyed. This also means damaging or destroying a possible human life. But the argument remains that this research ultimately lead to breakthroughs in the provision of new medical treatments and therapies that would relieve so many people of their suffering. The decision as to which moral principle should be given precedence is hinged to our perception of or how we view the embryo. Does it have the status of a person?[5]

In view of the development of an embryo up to 14 days, before it develops the embryonic streak, the three germ layers appear and at which time the embryos can split and develop into twins or develop into one embryo. It, therefore can be reasonably disputed that at these early phases there is in theory no ontological individuality or personality, which at this stage limits the moral value of what an embryo is.

While some hold the view that the human embryo should be seen as a human being in its embryonic phase, just as an infant is a human being in the infant stage, even though the embryo

does not have the characteristics of a person in this stage, others believe that the embryo in its early stage has not yet been implanted into the woman's womb and does not have the psychological, emotional or physical properties that we associate with being a person, since the embryo cannot be developed into a child without being transferred to a woman's uterus where it gets the external help to develop into a person, and therefore it cannot have any interests to being protected and we can use it for the benefit of patients who are indeed persons. [13]

Conclusion

This discussion clearly highlights the importance of stem cell research to provide treatments and therapies for so many who are in need of alleviating their suffering worldwide. This is an exciting time for both those in the field of biomedicine and the public on a whole. As with any other industry, when new discoveries are made, there is the tendency to take advantage of the technology or methods for the sake of power or control and also monetary gains. It is therefore imperative, that those responsible for ensuring that the venerable sick and the public at large are not taken advantage of. The hope, therefore, is that consensus is reached with time, so that all could benefit in a way that is fair to all while relying on ethical, moral and legal principles,

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Review Research Paper

Embryonic Stem Cell Research Ethical and Legal Controversies

[1]Amit M Patil

Abstract

The discovery of stem cells particularly embryonic stem cells with its possible clinical application has generated great curiosity amongst medical professionals and general public. Embryonic stem cell research has become a challenging issue for biomedical scientists, policy makers and regulatory bodies.

The key controversial issue is the determination of moral and legal status of the embryo as embryo stem cell research involves retrieving embryonic tissue from spare embryos leading to their destruction. This embryo that has the full capacity to develop into a human being is sacrificed for the benefit of others. Global regulations monitoring stem cell research are also troubled with similar ethical and moral issues associated with it. The main source of embryonic tissue is the spare or supernumerary embryos created during infertility treatment by artificial reproductive techniques (ART). Sadly, in absence of regulatory provisions to govern them, the field of ART is open for all forms of medical malpraxis bearing direct implications on embryonic stem cell research. This article is an attempt to seek clarity on the concept of embryonic stem cell research and contentious issues associated with it.

Key Words: Stem cells, embryonic stem cell research, Moral and legal status of embryo, ART, Global regulation

Introduction:

Stem cell research has offered a new viable therapeutic option for debilitating diseases, injuries and other diseased conditions. The scope of stem cell based treatment has expanded in recent years due to advances in stem cell research and technologies. Now, stem cell based treatments have been established as standard clinical care in certain disorders like use of hematopoietic stem cells in leukemia's or use of limbal stem cells in corneal disorder.

Stem cell technology is speedily increasing within the field of regenerative medicine, granting DE novo production of functional tissue and providing for brand new diagnostic and therapeutic capabilities that will surpass the risk benefit ratio of typical existing reparative treatment modalities e.g. organ transplantation, rejuvenation of tissues. [1] The hype created by this discovery and so claimed by many research scientists has made people believe that something significant is happening.

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Whatever promising future clinical application it holds, stem cell research especially embryonic stem cell research is associated with ethical, social and legal controversies.

What is so unethical about embryonic stem cell research? The major conflicting unethical issue identified with this research is extraction of embryonic stem cells by embryo destruction. The very embryo which has the capacity to become a human being is destroyed at the onset of its potentiality of becoming one of us. The current view about any clinical research is to look it from the view point of cardinal research principles of autonomy, justice, non-malfeasance and human dignity.

Any research which stands to violate these principles is bound to suffer from moral and ethical controversies. A research that involves embryo destruction will find it difficult to accommodate itself within these cardinal principles.

Definition and Platforms of Stem cells:

Stem cells are one of the human body's master cells with the ability to grow into any one of the body's more than 200 cell types. [2] They are unspecialized and undifferentiated cells capable of self proliferation, migration and differentiation. The distinct characteristic associated with the stem cell is their potential of

self renewal and capacity to differentiate into specialized cell. In short they are immature precursor cells with a capacity to specialize and differentiate into a mature specialized cell.

i. **Embryonic Stem cells (ESCs):** These are the first differentiation after fertilization of cells of the embryo proper. They are derived from the inner cell mass of the blastocyst, 4–5 days after fertilization. They are not totipotent, but pluripotent and capable of forming all other cells of the body.

ii. **Adult Stem Cells:** These are derived from bone marrow, peripheral blood, tissues, muscles, adipose tissues, cartilage etc.

The adult stem cells are broadly classified as hematopoietic, non-hematopoietic and organ specific stem cells.

Hematopoietic stem cells are blood forming cells derived from bone marrow. Non-hematopoietic stem cells are mesenchymal stem cells (MSCs) present in many tissues like bone marrow, blood, cartilage, fat, placenta, liver etc.

MSCs have unique characteristics of differentiating into several cell lineages such as cartilage, bone etc. They are pluripotent, non immunogenic, not patient specific and have tendency to migrate to the sites of inflammation.

iii. **Umbilical Cord Blood Stem Cells and Placental Stem Cells:** Stem cells can also be isolated from the umbilical cord blood and placenta. Cord blood is found to be rich source of stem cells. They are multi potent in nature.

Further based on their capacity to divide and differentiate they may be totipotent, pluripotent or Multipotent. Totipotent stem cells give rise to all different types of stem cells in the body including a living organism e.g. fertilized egg. Pluripotent stem cells give rise to any type of cell except those required to form a foetus. Multipotent stem cell gives rise to specific different type of cells.

Induced Pluripotent Stem Cell (IPSC):

These are adult cells that are engineered or reprogrammed to become pluripotent i.e., to behave like an embryonic stem cell. The scientific experience with induced pluripotent stem cells till date seems to be very promising. Yamanaka and then Thomson have discovered ways to reprogram somatic cells to a primordial state and then redifferentiate them to tissues of choice. [3]

It is important to note that though IPSC technology as enormous potential, it is still at its infancy, and certainly does not do away with the need for ESCs. [4]

Somatic Cell Nuclear Transplant (SCNT) – Cloning:

Known as cloning, SCNT was first demonstrated in 1997 through the creation of Dolly the sheep. [5] As it suggest, it is simply the transfer of a somatic cell nucleus into an enucleated oocyte that can give rise to a cloned zygote from which embryonic stem cells can ultimately be derived. [6]

Human Embryonic Stem Cells (HESCs) Sources:

HESCs are derived from the inner cell mass of the human blastocysts. Blastocyst is formed five days after fertilization of the egg by the sperm. It has outer shell which matures and if survives implantation becomes placental tissue and the inner cell mass becomes the tissues of the human body.

The extraction of HESCs from inner cell mass for research purpose leads to the destruction of the embryo. The major source of human embryonic stem cell tissues are the spare or supernumerary embryos created during in vitro fertilization as a part of infertility treatment. The other source is creating embryos with somatic cell nuclear transfer techniques (SCNT). The legislation of most countries including India allows use of spare or supernumerary embryos either fresh or frozen created during in-vitro fertilization.

Some countries with more liberal view have allowed creation of human embryos with SCNT as a source of embryonic tissues. The controversial issue in embryo research is concerned with which embryos are suitable and can be used for research.

There is disagreement over whether it is appropriate to create embryos solely for research purposes, and what techniques should be used to create those embryos. Many people and governments feel that an appropriate restriction on embryo research is to limit the use of embryos in research to those embryos that are surplus to infertility treatments. [7]

The Status of the Embryo- Moral, Legal, Personhood:

As mentioned earlier, the extraction of embryonic tissue for research purpose involves destruction of the embryo. So what is wrong with destroying embryo? Most of these arguments about the rightness and wrongness of embryo destruction are based on the moral status of the embryo. The moral wrongness associated with embryo destruction will not only make the research impermissible but also deny the potential benefits expected from this research.

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