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REVIEW ARTICLE **OPEN ACCESS**

Controversies: Stem Cell Research

Kausar Malik*, Khadija Sabir, Naveera Shabir, Numrah Nisar,Muhammad HamzaBasit, MuhammadIdrees Khan, Hafiza Samra Ambreen, Aleena Sumrin and Halima Sadia
Lahore College for Women University, Lahore
Centre for Applied Molecular Biology Lahore
University of the Lahore, Lahore
E.mail; kausarbasit786@yahoo.com

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STEM CELLS

Stem cells are unspecialized cells in the human body that are capable of becoming specialized cells, each with new specific cell functions [1]. Under the right conditions, or given the right signals, stem cells can give rise (differentiate) to the many different cell types that make up the organism. That is, stem cells have the potential to develop into mature cells that have characteristic shapes and specialized functions, such as heart cells, skin cells, or nerve cells [2].

Stem cell biology has attracted tremendous interest recently. It is hoped that it will play a major role in the treatment of a number of incurable diseases via transplantation therapy. Several varieties of stem cells have been isolated and identified *in vivo* and *in vitro*. Very broadly they comprise of two major classes: embryonic/fetal stem cells and adult stem cells [3]. Depending on "differentiating power", SCs are divided into several groups. The cells, deriving from an early progeny of the zygote up to the eight cell stage of themorula, are defined as "totipotent", due to their ability to form an entire organism [4]. The "pluripotent" cells, such as ESCs, can generate the tissues of all embryonic germ layers, i.e. endoderm, mesoderm, and ectoderm, while "multipotent" cells, such as ASCs, are capable of yielding a more restricted subset of cell lineages. Another type of SCs classification is based on the developmental stage from which they are obtained, i.e. embryonic origin (ESCs)or postnatal derivation (ASCs) [5].

Basically, a stem cell remains uncommitted until it receives a signal to develop into a specialized cell. Stem cells have the remarkable properties of developing into a variety of cell types in the human body. They serve as a repair system by being able to divide without limit to replenish other cells. When a stem cells divides, each new cell has the potential to either remain as a stem cell or become another cell type with new special functions, such as blood cells, brain cells, etc. Some scientists wish to pursue research on embryonic/fetal stem cells because of their versatility and pluripotentiality, while others prefer to pursue research on adult stem cells because of the controversial ethical sensitivities behind embryonic/fetal stem cells [3].

STEM CELL RESEARCH

Stem cells first became a topic of widespread public attention in 2001, when President George W. Bush authorized the use of federal funds for research on existing embryonic stem cell lines, but prohibited the derivation of new ones. Since that time, struggles over the types of stem cell research that should be allowed, and the levels of funding committed to such research, have continued unabated [6].

Scientists are using stem cells to study basic processes of embryological development, including the processes that lead to genetic disease and abnormalities. They also are conducting research to see if stem cells might be used directly for therapeutic purposes. The phrase "stem cell research" can refer to research using adult stem cells, embryonic stem cells obtained from IVF embryos, or embryonic stem cells derived from clonal embryos. The derivation of stem cells from IVF or clonal embryos involves the destruction of those embryos [7].

WHAT DOES AN EMBRYO REPRESENT AND IT'S USE IN STEM CELL RESEARCH

Four stances have been formed regarding what am embryo represents and thus what its use is for stem cell research. The extremes are represented by two beliefs: an embryo is a human being or an embryo is a mass of tissue. These two extremes represent two fundamental questions of the moral status of an embryo. While there are advocates of both extremes, the general acceptance is somewhere in between both positions. In the paragraphs that follow, all four stances will be explored to aid in forming an unbiased decision on the status of the embryo:

Position 1: The embryo is a human being and must not be destroyed or used for research purposes.

It must be treated and protected as an individual of the human society. Supporters of position 1 believe a human embryo to be an individual whose destruction would be considered immoral and murderous. They strongly oppose ES cell research as it involves the destruction of an embryo. Their proposed solution is to use adult and umbilical cord stem cells since their medical benefits have clearly been illustrated within the last 20 years. A subsection of the supporters do not believe destroying the embryo is a form or murder, but simply immoral. Most supporters feel that the ends do not justify the means: the potential medical benefit does not justify the destruction of a human embryo [8].

In addition**,** the use of embryos that are already destroyed is acceptable since the act of killing is irreversible. No new embryos, however, may be destroyed. This status represents the current federal policy under the Bush Administration as of August 9, 2001. One problem that arises from this policy is "complicity". Working with the previously destroyed embryos is viewed as participating in the immoral act. Hence, some supporters of position 1 disagree even with President Bush's federal policy [8].

Position 2: The existence of an embryo is considered valuable but it does not share the same status as a baby or a fetus. Thus, it can be used for research purposes.

Supporters of position 2 reason that an embryo is not worthy of the rights of a baby or fetus, and therefore its existence is dulled by the rights and potential benefits for people currently alive. An embryo possesses the ability to become a human being, but it is not yet a human being. Moreover, its destruction will benefit people who are alive and suffering and therefore, it is deemed worthy for scientific research. Supporters of this stance believe that the advancement in locating cures for life-threatening diseases must not be hindered by the inability to use embryos [8]. Although adult stem cells are less controversial to work with, their existence in all cell types is unknown, and their medical applications are more restrictive. Also, further research must be conducted in inducing these cells to differentiate correctly, which would only be made possible through isolation and use of embryonic stem cells and embryonic germ cells.

Position 3: Embryos should not be created for research purposes; however, what is left of IVF procedures may be used in scientific research.

Position 3 is known as the "nothing is lost" principle. If embryos are not to be used for their intended purpose of reproduction and are to be discarded, then they may be used to aid in scientific research. No embryos, however, should be created or cloned on the grounds of research only. Most of these discarded embryos are obtained from *in vitro* fertilization clinics. Essentially, the "intention" of the embryo matters to certain ethicists. Furthermore, a couple who has finished all reproductive treatments with the clinic may issue consent to donate their embryos for research purposes (8).Ethical concerns arise in this situation: a woman must indeed give consent and must not be paid to do so.

Position 4: Embryos are a cluster of cells similar to somatic cells and thus can be used and destroyed for scientific research.

The fourth position takes a purely biological standpoint. Embryos are a cluster of undifferentiated cells that posses the *ability* to create a human being, but are not yet a human being. This specific ability makes them unique and invaluable to scientific research. Furthermore, the intent for creating an embryo is irrelevant. For this position, embryos may be used from IVF procedures or created from somatic cell nuclear transfer procedures (SCNT).Many advocates for stem cell research support the SCNT procedure since it is used to generate tissue that will restore the function of damaged organs. There is hope that this therapy will be more successful than organ transplantation since stem cells obtained from a patient may be used to create transplant tissues viewed as self by that patient's immune system.

CONTROVERSIES REGARDING STEM CELL RESEARCH

CHALLENGES FACING THERAPEUTIC STEM CELL APPLICATIONS

Experiments with mice and rats, as well as preliminary work with humans, have raised hopes about the eventual development of therapies using stem cells (9). An honest appraisal, however, suggests that many questions need to be answered before it becomes clear if stem cell–based therapies will be possible, let alone clinically practicable and affordable for average patients. According to the National Institutes for

Health (NIH), in order for embryonic stem cells to be used for therapies, scientists will have to learn how to reliably make them proliferate extensively, differentiate into the desired cell types, survive in the recipient after transplant, integrate into the surrounding tissue, function appropriately for the rest of the recipient's life, and avoid harming the recipient in any way.

A major hurdle to the therapeutic use of embryonic stem cells extracted from IVF embryos is the expected immune rejection problem. Cells or tissues obtained from IVF embryos would likely be identified by a patient's immune system as foreign and thus rejected [6]. Several proposals have been advanced to solve or avoid this problem:

- Whenever possible, use adult stem cells taken from a patient's own body.
- Use stem cell lines that are roughly compatible with a patient's immune system, supplemented with rejection-suppressant drugs. Such lines could be maintained in carefully supervised stem cell "banks."
- Chemically or genetically modify the stem cell surfaces to avoid activating the rejection response.
- Use stem cells derived from clonal embryos created using SCNT, with the patient as the nuclear donor.

Each of these proposals has technical advantages and disadvantages.

SOURCES OF EMBRYONIC STEM CELLS:

Most embryonic stem cells currently used in research are derived from embryos that were created in the course of infertility treatments by means of *in vitro* fertilization (IVF) procedures. Many IVF embryos are not used to establish a pregnancy, and some of these "spare" IVF embryos are donated for medical research. Embryonic stem cells also can be derived from IVF embryos created specifically for research purposes. Some scientists are investigating a third source of embryonic stem cells, involving the production of embryos by means of a technique variously known as *somatic cell nuclear transfer* (SCNT), *research cloning,* or *therapeutic cloning.*

HUMANEMBRYOSFORSTEMCELLRESEARCH:

Perspectives on the morality of embryonic stem cell research are tied to beliefs about the moral status of the human embryo [6]. The variety of viewpoints about this issue fall along a spectrum:

1. Some people believe that early-stage human embryos are in no way morally equivalent to human infants, children, or adults, and that the rights or protections that are due human beings do not apply to these embryos. For people who hold this view, the use of early-stage embryos for medical research generally does not raise serious moral or ethical problems.
2. Others do not regard early-stage embryos as full human beings, yet believe that these embryos are due some level of respect. People holding this view may support the use of early-stage embryos for medical research if careful procedures are in place to ensure that the research is justified and conducted in a responsible manner. Some may support the use for research of "spare" IVF embryos that were created but not used for fertility purposes.
3. Others believe that an embryo implanted in a woman's uterus deserves absolute protection, but that embryos outside a woman's body are not capable of becoming human beings, and may be used for medical research. This is the view of some who oppose abortion but support embryonic stem cell research.
4. Others believe that personhood exists upon conception and that embryos at any stage of development deserve the full respect and protection due any other living human being. Given this view, the destructive use of embryos for medical research is tantamount to murder.

DONATING EMBRYOS:

Donating embryos for hES cell research has proven to be as controversial an issue asorgan donation. Payment for organ and tissue donation is currently illegal in the United States under the National Organ Transplantation Act (NOTA) established in 1984. Donation of organs alleviates suffering for those in need, but there are concerns of uneven distribution of organs topatients with higher financial qualifications. Similarly, women can be compensated for donating eggs for fertility treatments just as in blood and plasma donations. More importantly, there is apprehension that researchers may use research advances for financial gain and personal prestige. Unethical practices may then arise. In order to minimize such practices, several countries are considering placing bans on patents for stem cell research and on stem cell-related products. This will prevent researchers from claiming to hold a patent on a lung or heart function [8].

ETHICAL ISSUESREGARDING STEM CELL RESEARCH:

The stem cell debate involves both the ongoing and divisive controversy about the moral status of human embryos and an array of other fundamental values and beliefs. These include the healing imperative; the

role of science in democratic societies; and the appropriate balance among commitments to individual autonomy, social justice, and the common good [6].

- ***The moral status of human embryos.*** Beliefs about the moral status of human embryos, and about the obligations that these beliefs entail, differ widely in the United States and elsewhere. Opinion polls show that most people in the United States believe that human embryos have a greater moral status than, say, an equivalent number of non-embryonic cells clumped together in a petridish, and that most also believe that abortion should belegal and available, although not necessarily on demand. Most people can imagine a range of situations in which it is acceptable for human embryos to be used for scientific research, although most also recognize the necessity of establishing limits on such use [10].
- ***The healing imperative.*** Throughout history most societies have put a strong moral and ethical value on coming to the aid of those suffering from disease and impairment and on preventing disease in the first place. To the extent that stem cell research is directed toward these ends, it commands presumptive support. But like most moral and ethical values, the healing imperative is neither absolute nor simple to apply.
- ***The role of science in society.*** The quest for knowledge was a core project of the Enlightenment and, together with values of individualism and enterprise, strongly shaped the development of modern liberal democracy. Some people would argue that the freedom to pursue scientific research is so central to human well-being that it should be understood as a foundational right, akin to the right to free speech [11]. Others would reply that no right is absolute, that knowledge has consequences, and that scientific research proceeds within rather than apart from a wider set of social values and interests, especially when the means used affects the lives or welfare of other beings [12]. On this view, democratic societies have an obligation to monitor and, when necessary, regulate the course of scientific research. These concerns have heightened in recent years as the lines between scientific research and commercial enterprise have become increasingly indistinct.
- ***Balancing individual autonomy and the common good.*** In the United States, most people place a high value on individual autonomy and rights. But most also recognize that individual choices are shaped by social forces and that these choices often have social consequences.

SOCIAL AND POLITICAL CONCERNS ABOUT STEM CELL RESEARCH:

Though much of the public debate over embryonic stem cell research has focused on differences about the acceptability of destroying human embryos in the course of research, many concerns unrelated to beliefs about the moral status of human embryos have been voiced. Such issues are often raised by people who support embryonic stem cell research but are concerned about particular aspects of the research process and about potential social and political consequences [6]. Some of these concerns apply to research using both IVF and SCNT embryos; others apply only to research using SCNT. These concerns include:

Accessible and affordable health care. Therapeutic applications of SCNT are likely to be very expensive: it has been estimated that such individualized stem cell treatments could cost at least $100,000 per patient (13). Egg retrieval alone is estimated by institutions that perform it to cost over $20,000 per procedure (14). Other health policy experts have raised concerns about whether the billions now being committed to stem cell research represent the best use of scarce health research funds [15].

Patent and ownership issues. Over the past twenty-five years, the courts have interpreted intellectual property laws to allow a wide range of patents on basic biotechnologies. Many researchers and even some venture capitalists now suggest that the proliferation of patents is interfering with basic research in fields such as stem cell therapies [16]. The Patent Office has issued more than 750 patents that mention stem cells in their abstracts, and has over a thousand more applications pending; thousands more mention stem cells in their text [17].

Consumerist eugenics and other abuses. In the absence of strong systems of regulation and oversight, stem cell and cloning technologies could be misapplied for socially unacceptable purposes [18]. The creation of clonal embryos is the necessary first step toward the creation of clonal human beings and paves the way for the creation of "designer babies," that is, children who have been genetically modified to suit parental preferences [6].

Women as egg providers. Women's eggs are the critical "raw materials" for creating embryos using SNCT. If individualized stem cell therapies are developed for common degenerative conditions such as heart disease, arthritis, and Parkinson's, millions of women's eggs would be needed to meet the therapeutic demand. The potential for the development of a market for eggs and the exploitation of economically vulnerable women is a cause for concern. The assisted reproduction industry, which is likely to serve as the major supplier of eggs for stem cell research, has been widely criticized for lax standards. If stem cell researchers create embryos using SCNT or IVF techniques, rather than using

"surplus" embryos donated from fertility clinics, they will need a supply of women's eggs. To procure such eggs, women undergo injections of hormones that first shut down and then hyper stimulate their ovaries, followed by surgical extraction of multiple eggs [19]. The drug most often used to shut down the ovaries, Lupron, can cause side effects such as severe joint pain, difficulty breathing, chest pain, depression, amnesia, hypertension, and asthma. The drugs used to hyper stimulate the ovaries can lead to Ovarian Hyper stimulation Syndrome. The syndrome can range from mild to severe; on rare occasions, it has caused deaths [20]. There has been little sustained research on the frequency of these conditions, and estimates vary widely.

Over-promising results. A disturbing number of scientists and other supporters of stem cell and cloning research have made highly exaggerated claims about the likelihood and imminence of treatments and cures.

Integrity in science. Concerns have been raised that stem cell research is proceeding in a manner and in an environment highly conducive to undermining the research's integrity, and that of biomedical research in general: prospects of immense financial gain; the lure of celebrity and renown; exaggerated claims of treatments and cures; competition among cities, states, and countries to develop research centers; researchers' desires to show and publish quick results; and the lack of a strong framework of regulatory oversight and control [6].

RELIGIOUS VIEWS ABOUT STEM CELL RESEARCH:

Ethical, moral, and theological perspectives on stem cell research differ widely among religious faiths, denominations, and individuals [21]. In general, there is little opposition to adult stem cell research. Opposition to embryonic stem cell research is strongest among Catholics, Evangelicals, and Mormons [22]. Protestant denominations that allow abortion tend to be supportive of embryonic stem cell research, although some, such as the United Methodist Church and most Orthodox Protestant churches, oppose SCNT. Leaders of major Reform, Conservative, and Orthodox Jewish religious bodies have tended to be supportive of embryonic stem cell research.

The majority of Islamic scholars see the use of the embryo for essential therapeutic or research purposes as being permissible if necessary on the strict condition that this process does not contradict any genuine Islamic moral rule. They emphasize that this research should always be limited to the time before ensoulment and should be restricted to the use of the extra embryos left behind by the IVF technique. It is not acceptable to deliberately produce embryos for the research purposes. In addition, seeking non-controversial sources of stem cells is most encouraged [23-24].

ALTERNATIVE SOURCE FOR EMBRYONIC STEM CELL LINES – PARTHENOTES:

To reduce some of the current ethical concerns surrounding the destruction of fertilize embryos to obtain ES cells, an alternative solution has been developed: parthenotes. Parthenogenesis is a Greek word meaning "virgin birth", hence no sperm or SCNT procedure is needed for the egg to divide and begin developing. During parthenogenesis, oocytes are activated via chemical simulation, and the eggs are incubated *in vitro* to the blastocyst stage where their ES cells can be extracted for research purposes [25]. Some female amphibians, insects, reptiles and turkeys have been known to develop via parthenogenesis and recently, researchers have succeeded in obtaining blastocycts from primates; primate parthenote blastocysts were obtained in 2002 [26] and provided ES cell lines. Human parthenote blastocysts were also obtained in 2002 [27] but provided no ES cell lines. In 2004, murine parthenote pups were obtained that developed into adult mice [28].Development of mammalian parthenotes to adults is difficult because biparental reproduction is normally needed and parent-specific epigenetic modifications in the genome occur during gametogenesis which can alter the ability of DNA from one parent to be fully viable. Hence there is an unequal expression of imprinted genes from both mother and father. Recent experiments, however, have shown the development of mouse parthenotes with expression of specific genes (*Igf2* and *H19*) that are sometimes silenced which affirms the need for paternal imprinting for parthenogenesis to occur [28].

If ES cell lines can be isolated in humans, parthenogenesis would reduce a large portion of the ethical concerns related to hES cell research [8, 25]. Since parthenotes cannot develop into people, the question that arises is whether or not the parthenotes are as morally significant as embryos [29]. The stem cell lines could be used to help other tissue-matched individuals and thereby eliminate embryo stem-cell banks [8, 25]. One ethical concern that arises, however, is whether or not it is morally acceptable to collect eggs from women's ovaries for therapeutic reasons rather than reproductive reasons. Hence, with proper terminology to describe this new process, policy makers may be able to fully appreciate and understand the full capabilities of eggs [25].

Stem cell research and its applications hold scientific and medical promise. Like other powerful technologies, they pose challenges and risks as well. If we are to realize the benefits, meet the challenges, and avoid the risks, stem cell research must be conducted under effective, accountable systems of social oversight and control, at both national and international levels.

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