

The Stem Cell Debate

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ABSTRACT

Purpose. The use of human embryos for stem cell based researches is currently high on the ethical and political agenda in many countries. Despite their immense plasticity and promising potential in regenerative and reconstructive medicine, the use of human embryonic stem cells (HESC) remains controversial because of their derivation from killing early embryos.

This paper addresses complex bio-ethical and social issues related with the instrumental use of embryos and HESC in context of state-of-the-art research on development of stem cell based transplantation therapy.

Methods. Published literature with strict inclusion and exclusion criteria was extensively reviewed through use of general and meta search engines to elucidate the applications and implications of HESC in modern medicine. A systematic meta-analysis of 95 representative articles from the year 2000-2010 was performed.

Results. Numerous studies have demonstrated that environmental, political, and societal factors are important contributors to the development of stem cell researches and policy models in any country. The therapeutic potential of HESC is indisputable but complex social and moral issues remain hopelessly intertwined beneath the pleasant facade.

Conclusions. Stem cell research is dynamic and alluring. It opens up novel therapeutic avenues to alleviate most of Man's ailments at the cellular level, in terms of organ replacement, reversing ageing and disease phenomenon and eliminating congenital or inherited disorders. Yet there are many questions and 'unknowns' in terms of crossing moral, religious and biological boundaries when it comes to matters of deciding about 'Life & death', 'Eternal life', 'Chimeras', 'A-temporal existence', 'Teratogenicity', 'Immune rejections'.... The list is long and demands some serious reflection. New insights into the effectiveness, risks and usefulness of HESC and exploring various uncontroversial alternatives may have immediate consequences for the ethical evaluation and legal standardization of the isolation of HESC. While a categorical ban on reproductive cloning is at present unjustified and premature; stem cell debates must be progressed with caution to avoid untimely political truncation of the true potential of these cells. In the end, the wisdom to choose wisely between 'responsible utilization' and 'senseless exploitation' rests with us.

Key words: Human embryonic stem cell, ethical issues.

Introduction

The ethical bedrock comprises of justice, values and equality. Ethics opens with moral values but does not close there. A lot of questions arise about virtues, risks and benefits. The most impactful event in biomedicine is the dawn of the human embryonic stem cells (HESC) era. Its isolation, culturing and identification of its numerous uses has now become the most blistering issue of this century with a legion of controversies. The culturing of HESC reckons a tremendous promise in regenerative medicine due to its remarkable abilities of multiplicity and pluripotency.

In stem cell researches, the main constrict lies in the fact that mouse models may not accurately predict the mode of action of cells in humans. Stem cell differentiation may not be as controllable in humans as in experimental animals. Sometimes, stem cells have a tendency to generate tumors.(6) Stem cell lines are predominantly divided into two major grades: Research grade stem cell lines and Clinical trial stem cell lines. Only the latter might be safe for use in clinical trials in humans. (6)

The key issue in production of HESC lies in the very source of these cells; the human embryo which is invariably destroyed/killed in the process. It seems an irony that cells with such incredible prospective for ameliorate and can draw out the lives of our babies.

Material and Method

The author conducted on extensive review of published literature on stem cells using general search engines (Google, Mozilla) and meta search engines (science direct, med line, pubmed, medscape, dog pile, Googlescholar) using the key search strategies of medical subject heading (mesh) and text word searching. Once the 'key article' was identified, authors used the 'related articles' feature and further reference list harvesting. Digital Libraries of Embase, Cochrane and National Library of Medicine were similarly searched. Scientific literature database were extensively reviewed, including Open j gate, Indian database, medical journal database and gray literature database. A total of 95 articles (original research, reviews, reports, communication etc) were searched. 58 articles met the inclusion criteria, based on context relevance regarding the applications and implications of stem cells in medicine.

Discussion

Bioethical issues

The most logical way of defining ethical norms is to develop a distinction between the acceptable and the unacceptable. Critics of stem-cell researches propose some major objections: Some accommodate that despite its applaudable ends, stem-cell research is inappropriate because it spells the destruction of human embryos; others worry that even if research on embryos itself is not wrong, it can embark on right smart to a lubricious pitch of mechanize practice.(4) The concept of embryo cultivation, cloned babies and the commercialization of human life is slowly but surely taking its final shape.

If we take into account these objections, they focus on the argument that biomedical ethics is a means but not the end; any research, however great a potential it has, is unreasonable if its achievements pay the cost of plundering cardinal human rights. This prompts us to canvass the image of the human embryo as an unborn human person who can smell, feel, dream and even enjoy some basic feelings.

The policy of storing excess embryos in frozen form to yield stem cells at a later time create the issue of donor women becoming spare targets for repeated attempts.(8) Also ,an overwhelming

number of in vitro fertilization clinics vigorously produce more and more fertilized eggs. So it has become almost a business to develop embryos, buy or sell them. Defenders of in vitro fertilization point out that embryo loss in assisted reproduction is far less frequent than in natural pregnancy, in which more than half of all fertilized eggs either fail to implant or are otherwise lost.(6) This fact highlights a further hindrance with the view that equates embryos as persons.

Social issues

There is always a question about whether this therapy will be accepted by the general public, if they know about the source. Apart from this, there are some commercial issues as well, when the embryo becomes an item of sale. The cost at which it has been purchased by the recipient and the cost at which it was sold by the donor may widely vary.(5) There is always room for scams during such embryo tradings.

The poor people do not know that their aborted embryos fetch high market prices. The unknowing donor sells her embryo at very low costs but fertilization clinics sell them to potential buyers at costs reciprocal to urge. That creates a big trading gap in the embryo market. The destroying of human embryos is an intractable offence.(5) There is a significant but intangible moral difference between producing and destroying human embryos purposely to obtain stem cells and utilizing discarded or surplus human embryos from infertility clinics to cure critical disorders or diseases.

Policy models

US President George W. Bush precluded federal endowment for researches on embryonic stem-cell lines that originated after August 9, 2001; but this order did not interdict HESC research itself, nor did it call upon scientists to break off from it.(1) It just denied federal funds for such endeavors; the possibility of pursuing these projects with the aid of other funding sources remaining open.

The UK Congress averted the thin end of the wedge by an impersonate perceptible ordinance, starting with a simple forbiddance on human reproductive cloning. Advances of the approach taken by United Kingdom might also require that research embryos will not be allowed to ripen beyond 14 days and limits will be posed on the commoditization of embryos, gametes and stem cell banks. (9)

The Canadian Institutes of Health Research (CIHR) published a road map for human stem cell research. This road map demonstrates a national stem cell protocol review board, the Stem Cell Oversight Committee (SCOC), the federal granting agencies, the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC). These agencies have taken up stem cell measures that recognize that no research with human pluripotent stem cells would be endowed without prior review and approval of the SCOC. (12) The CIHR Guidelines are applicable to both the sources of pluripotent stem cells from human embryos or other tissues and to researches using HESC lines that have previously originated. They also comprise all stem cells nevertheless of their source of origin. If adult stem cells can be “reprogrammed” to become pluripotent, the CIHR guidelines would apply.

Stem cells therapies mitigate as biologics; products originating from biological sources. Biologics are enrolled in Schedule D of Canada’s Food and Drugs Act. That may also involve

blood products, cells and tissues, gene therapies, vaccines, radiopharmaceuticals and therapeutic products produced through biotechnology. (9)

Once a stem cell therapy has been permitted, biologically similar stem cell therapies might be able to abbreviate in the regulatory review if they qualify as “Subsequent Entry Biologics” (SEB). Health Canada has delivered a draft guidance accredited as “Information and Submission Requirements for Subsequent Entry Biologics (SEBs).” This docket frameworks the regulatory review process that Health Canada will use for a biologic that can be likened to another biologic that has already been countenanced for use.(9)

Patents and the stem cell

Patents illustrate a bounded property right that permits the patent holder the legitimate to exclude all others from the use or misuse of the patentable subject matter. Under the Canadian Patent Act, something must be new, useful and non-obvious to receive a patent.(3)

Non-natural discoveries are a patentable subject matter and isolated and purified stem cells are patentable as research tools. While patents on animal stem cells might be bona fide if they are non-obvious, patents on HESC are still wallowing in controversy. In Europe, applications for patents on animal stem cells and HESC have been a challenge.(2)

In May 2008, the United States Patent and Trademark Office (USPTO) established a patent for the isolation and derivation of HESC cell lines in the University of Edinburgh.(7) The same sought patent on isolation of stem cells using genetic modification had been under review by the European Patent Office (EPO) since 1999. In 2007, the Edinburgh patent was confined to non-human animal embryonic stem cells and adult stem cells.

The European Patent Convention declared that the EPO may deny patents on ethical grounds, if the monetary use of those patents is opposite of ordre public (public order) or morality. Examples are patents using human embryos for industrial or trading contemplation and patents that alter the inherited genetic identity of humans.(7)

Medical progress

HESC, skeletal myoblasts and adult bone marrow stem cells confine the infarct size. HESC are pluripotent cells that can regenerate myocardium in infarcted hearts, cause weakened heart remodeling and encourage left ventricle systolic force development.(10)

Stem cell therapies are being applied in a number of neurological disorders caused by loss of neurons and glial cells like Parkinson's disease, stroke and multiple sclerosis. Scientists have established that stem cell cultures can successfully generate neurons and glial cells which forms the basis for these treatments.(11)

As of now, stem cell therapy is well established in Leukemia and researchers anticipate a range of diverse applications in cancers, birth defects, spinal cord injuries, baldness, blindness, diabetes and various congenital syndromes. However, the teratogenic tendencies, transplant rejections and abnormal migration and unguided proliferation of transplant cells cannot be ignored.

Conclusion

The embryonic stem cell therapy has an incredible therapeutic prospective but it is not without many debatable issues. Some issues may be more or less answered but some answers only seem to generate an endless array of still more questions. Even the federal policy models for this therapy are widely heterogeneous and arriving at a standardized consensus is a tedious endeavor

at present. When we think of resource limited and developing countries where no advisory board and registries are available for such researches, the situation becomes even more of a haze. Women are susceptible targets for the hidden trading terms of commercial cell lines without any legislation fear by agents who pay nominal costs to donors. It is desirable that we channelize our research ideas on the improvement of animal stem cell lines and somatic human cell lines that may be coaxed to exhibit the perfect pluripotency of HESC. Such conscientious efforts will minimize the loss of potent human lives and prove to be more justifiable and humane.

Conflict of Interests: The authors have no conflict of interests.

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