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Research on the Application Risks of the Regulatory Mechanism of Embryonic Gene Editing Technology

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ABSTRACT

This article takes one of the technical cores - regulatory mechanisms - as the starting point to discuss the direct risks such as off target and chimerism caused by the failure or imperfection of regulatory mechanisms; And analyze the potential medical risks, gene pool changes, ethical risks, and social evolution risks that this technology may bring from the perspectives of personal level, reproductive genetics, ethical and social aspects, and ecological evolution. This article also attempts to propose specific and feasible risk prevention and regulatory measures from the perspectives of technology, evaluation standards, laws and regulations, and social supervision, in order to benefit the cautious and rational use of embryo gene editing technology.

KEYWORDS

Embryonic gene editing; Regulatory mechanism; Off-target effect; Chimerism

1. INTRODUCTION

The development of science and technology has promoted the continuous deepening of life science research. In recent years, with the rapid development of CRISPR Cas gene editing technology, people can accurately perform targeted operations in the genome. Applying this technology to human embryos has a completely new connotation and extension. In theory, gene editing during the embryonic stage can directly repair harmful mutated genes at the beginning of life. The organisms developed from this embryo not only do not suffer from this genetic disease themselves, but also pass on normal genes to the next generation, fundamentally preventing the occurrence of genetic diseases [1].

The ability to eradicate monogenic genetic diseases has made it one of the hot topics in biology and medical research. But the development of any science and technology precedes ethics and codes of conduct. The 2018 gene edited baby incident sounded the alarm for the potential serious harm of embryonic genome editing in the global scientific community and various sectors of society, and received widespread moral criticism. This also makes people ponder: can our level handle the clinical use of this technology?

In fact, embryo gene editing is far from simply using molecular scissors, it also involves a series of complex regulatory mechanisms. The quality of regulatory mechanisms directly affects the accuracy and safety of gene editing. At present, people's understanding of how gene editing tools operate in the special environment of embryonic development, the long-term effects of gene function after editing, and the potential irreversible impact on the human gene pool is still insufficient. Once control errors occur, unexpected changes can occur.

2. REGULATION MECHANISM AS THE CORE OF GENE EDITING PRECISION AND SAFETY

CRISPR/Cas9 gene editing essentially activates the inherent DNA repair mechanism of cells by inducing DNA double strand breaks at specific genomic loci, thereby completing the process of knocking out, knocking in, or correcting the target gene. How to ensure that CRISPR/Cas9 gene editing is carried out accurately and efficiently according to people's wishes depends on the design and construction of a regulatory system that can implement precise temporal and spatial regulation of the Cas protein and sgRNA editing components [2]. The regulatory system mainly includes the following parts: including the entire process from the editing tool to its function: the first stage is the delivery system's safe and effective delivery of gene editing tools (such as Cas protein encoded mRNA or protein and gRNA) to the embryonic cell nucleus.

The second step is to guide the device, which uses complementary pairing of guide RNA and target DNA sequence to guide the editor to a unique target on the genome; The third step is to edit the activity regulatory device, such as regulating the expression time and intensity of Cas protein, in order to ensure that the cleavage event occurs at the most appropriate time, such as before the replication of the embryonic genome, in order to avoid unnecessary mutations. In principle, highly specific gRNAs can specifically target a target location, and controllable editing activity can ensure the timeliness of editing and reduce the possibility of off target rate [3]. For embryos, there are even greater difficulties in control: in early embryos, cell proliferation is fast and the genome is active, and editing needs to have certain efficiency and timeliness in this process. If the response speed of regulatory measures is slow, it may cause some cells to remain unedited or the editing time to be inappropriate, leading to unexpected situations in other cells.

Therefore, a sound regulatory system is a technical prerequisite for efficient and highly specific editing, ensuring the safety of embryonic gene editing. It is a technical barrier to avoid many risks from the source and a guarantee for ultimately achieving therapeutic goals.

3. TYPES OF RISKS CAUSED BY THE FAILURE OF REGULATORY MECHANISMS IN EMBRYO GENE EDITING TECHNOLOGY

When the regulatory mechanism cannot achieve the expected precise control, embryonic gene editing will give rise to a series of technical risks, which are the direct source of subsequent deeper application risks. Off target means that Cas9 or its derivative will be cut in an incorrect position as a result of incomplete matching between gRNA and nontarget DNA. Off-target effect occurs due to insufficient specificity and accuracy of the guide part to identify and bind the target site, resulting in undesired cleavage sites: random mutation of important genes can then turn oncogenes or silence tumour-suppressing genes, jeopardizing the long-term quality of life of the edited object; Off target effects are random, they can have grave consequences, making them a key factor in determining whether or not gene-editing is safe.

When gene editing is performed on fertilized eggs or early embryos, if the editing is not timely or the editing rate is low, there may be a phenomenon where some cells are successfully edited while others are not, and even multiple different editing situations may occur. In the final developed individual, each cell contains different types of genotypes, forming a chimera. The regulatory failure here mainly refers to the lack of sufficient spatiotemporal accuracy in the regulation of editing activity, which cannot guarantee that all target alleles have been uniformly edited before embryonic cells divide into several cells.

The existence of chimeras makes it difficult to evaluate the effectiveness of editing, and cannot guarantee whether certain tissues or organs in a person have the expected genetic modifications, nor can it guarantee that reproductive cells have been successfully edited. This is an intolerable

uncertainty for reproductive system editors who wish to permanently alter the human genome. Further, loss of control may result in unexpected loss of large fragment or chromosomal aberration [4]. If CRISPRCas9 and ZFNs induce dsDNA breakage on the target site, they can not always be correctly repaired and sometimes (particularly with embryonic cells) there is a loss of large chunks of DNA from the target locus, and even chromosomal rearrangements might happen. The effects caused by such radical changes in the genome are incomparable with point mutations, which may result in a concomitant dysfunction, or expression disorder of several genes. The occurrence of these risks also indicates that the current regulatory system lacks control over the repair process after gene editing, and people's understanding of how embryonic cells respond and repair DNA damage caused by gene editing tools is not sufficient.

4. MULTI DIMENSIONAL APPLICATION RISK ANALYSIS OF EMBRYO GENE EDITING TECHNOLOGY

4.1. Individual Health Dimension: Medical Risks of Long term Unknown Gene Function

For people born through embryo gene editing, the first risk they face is medical. Although the goal of editing is to correct a specific disease causing gene, the work of the human genome is a complex network where a gene may have multiple functions and interact with many other genes. Any genetic modification made during embryonic development can disrupt this delicate balance, such as completely knocking out a gene to release its inhibitory effect on another gene, or unexpectedly affecting the splicing pattern or expression level of a gene that was originally thought to be a safe repair method.This type of effect only manifests in certain physiological states during the later stages of development and even after birth [5]. At present, the exact role that most genes continue to play throughout a person's life is not clear, so embryo gene editing is like conducting a human experiment with unknown future consequences, which may lead to health risks such as susceptibility to another disease, which are completely unpredictable and cannot be ruled out by prenatal examinations.

4.2. Reproductive Genetic Dimension: Risk of Irreversible Changes in the Human Gene Pool

The essential feature of embryonic gene editing different from somatic cell editing is that it edits germ cells or early embryos. Therefore, the edited gene information will exist with the development of the person and have the opportunity to be naturally reproduced and passed on to the next generation, which will become inheritable information embedded in the human gene pool.The danger lies in the fact that if the editing of a certain gene proves to be wrong in the future, such as a mutation that is considered pathogenic becoming a protective factor in a certain environment, or if the editing introduces a new recessive harmful mutation, the error will be permanently written into the human gene pool and continuously amplified through intergenerational inheritance. The changes in the gene pool are one-way, and once you take a wrong step, there is no turning back. Building a major decision that may affect the entire species on the basis of currently immature technology and understanding carries enormous genetic risks.

4.3. Ethical and Social Dimensions: Ethical Risks With Blurred Boundaries Between Treatment and Enhancement

The scope of using embryo gene editing technology for intervention is a very ethical and thorny issue. The most undisputed use for treating clear and severe monogenic genetic diseases is, but in fact, this use may continue to be expanded. Once genes related to complex traits such as intelligence, height, and appearance can be altered, the boundary between treatment and enhancement becomes blurred [6]. Who will determine what traits are therapeutic and what are enhancing?If gene editing technology

can be applied for enhancement, then in a society where economic and technological levels are not equal, this technology is likely to further lead to social inequality, create genetic privilege classes, and bring about new social divisions; More seriously, it will shake people's understanding of the natural value of life, technologize and instrumentalize the process of life, and challenge the equality of human dignity. The ethical consequences of such a natural transformation of human nature are fundamental.

4.4. Ecological Evolution Dimension: Evolutionary Risks of Gene Population Diffusion through Editing

If the field of vision is limited to humans themselves, the risks that the application of embryonic gene editing technology may bring also include the risk of evolution. When genetically edited individuals survive and reproduce, the edited genes they contain can spread within the population. This will bring about a human evolutionary change under artificial intervention. It is unknown whether the benefits outweigh the drawbacks or the drawbacks outweigh the benefits of an artificially modified gene over a long-term evolutionary time scale.

It may lead to unpredictable reactions of pathogens in future epidemics; Or it could lead to a decrease in the adaptability of the entire human population to new ecological environments, as it has already reduced the genetic variability of the entire human population [7]. Although these effects may not manifest in the short term, in the long run, any significant artificial manipulation of human genetic resources during the long process of evolution may have unpredictable impacts, seriously affecting the survival of the human species.

5. OPTIMIZATION OF RISK PREVENTION AND REGULATORY MEASURES FOR EMBRYO GENE EDITING TECHNOLOGY

5.1. Technical Optimization of Precision and Safety of Gene Editing Tools

The most fundamental aspect is to enhance the accuracy and security of editing tools at the technical level. Improving regulatory methods is the most direct approach. For example, constructing engineering Cas protein variants with stronger specificity to minimize off target effects; Constructing more precise guide RNAs to achieve strictness in target sequence recognition; Research new transfection systems to achieve more precise temporal and spatial regulation of editing elements, such as rapid degradation after editing and narrowing the editing time window.In addition, by utilizing next-generation editing technologies based on base editing and guided editing, specific base substitutions can be achieved without the need for DNA double strand cleavage, which may fundamentally eliminate the risk of large fragment loss and chromosomal translocation caused by DSB [8]. Intensify efforts in basic scientific research and explore the repair mechanisms of genomic damage in early embryos, which will help design safer editing strategies.

5.2. Standardized Establishment of Preclinical Safety Assessment System for Embryo Editing

Therefore, before any embryo gene editing method can be applied to the human body, a comprehensive and rigorous preclinical safety evaluation protocol is required. This approach cannot simply demonstrate its editing efficiency on embryos cultured in vitro, and evaluate off target, chimeric rates, and the integrity of genomic sequences around the target site. The best experimental model should include substitutes for human embryos, such as establishing embryo models based on human stem cells, or conducting long-term observations on non-human primates and other animals closely related to humans after embryo editing, in order to evaluate the impact of editing events on individual development [9]. In addition, a corresponding evaluation mechanism should be established

to track and observe the stability and effectiveness of the edited genes in future generations, so as to comprehensively consider various factors and obtain sufficient information to determine whether the editing scheme has a high risk.

5.3. Improvement of Laws, Regulations, and Ethical Guidelines for Reproductive System Gene Editing

The scope of technology use needs to be limited by corresponding regulations and ethical norms. At present, most countries in the world adopt a cautious or even prohibited attitude towards the clinical use of human reproductive system gene editing, and restrict it through corresponding laws and policies. This is a reasonable approach. In the future, efforts should be made to promote the establishment of stricter international conventions and legal regulations, and to delineate prohibited areas for embryonic gene editing research and application.

For basic research, it is allowed to proceed under strict supervision and gradually expand scientific understanding; For clinical use, a strict prohibition stance should be maintained until its safety and effectiveness are ensured and recognized by the entire society. The discussion of technology itself should be elevated to an ethical level, touching on the boundary between treatment and enhancement, human dignity, intergenerational rights, and social equity, in order to establish value standards for legislation and public policies.

5.4. Building Social Consensus on Public Participation and Interdisciplinary Dialogue Mechanisms

The development trend of embryonic gene-editing technology should not only depend on scientists, ethicists or policy makers to decide but also concern the interests of all people and need wide social participation in order to reach a social consensus throughit is important to create adequate work platforms where experts of different disciplines (natural and social sciences,humanities, law, religion, etc.) for open and equal discussion and dialogue with the representative of public, patient organization,media, etc. Through science popularization education, enhance public understanding on the basis of principle, possible values and dangers of technology;Seeking opinion and involving public discussion would help us to know the concern and expectation from different sector of society.A decision that has been thoroughly discussed and reflects the consensus of the majority in society can provide the strongest legal basis for regulatory policies on embryo gene editing technology, and ensure that any future applications can be carried out in a transparent and accountable environment.

6. CONCLUSION

Genetic engineering, this is the greatest jump in human history which has affected our own process of living. It's like a sharp knife used to cure genetic disease or a key to open many unknown risks. This article,based on the core technical view of control principles, explains the direct risk effects of off target and chimerism induced by its loss of control. It analyses the potential impact that those risks could have to our individual health,reproductive genetics; ethical society; and ecological evolution [10]. From this, it can be seen that the current risks of gene editing of embryos are not limited to the technical field, but involve issues of medical ethics, social equity, and even the survival of the entire human species. In this regard, we should be particularly cautious in balancing the pros and cons. In the future, on the basis of continuously improving editing techniques and enhancing editing accuracy, a rigorous risk prevention system that integrates scientific argumentation, legislative supervision, and social ethics should also be established.Only in this way can we approach this technology with reverence for life and respect for humanity, and make its development direction beneficial to the entire human society.

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