



A Review of Embryo Donation to the Infertile Couples in Iran

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Abstract

Embryo donation is an assisted reproductive technology and one of the most effective ways for treating infertile couples who are not able to have children by themselves at all. Although the approval of the law on embryo donation has partially resolved the issue of transferring the embryo to infertile couples and has revolutionized the laws in Iran, has some drawbacks. This study aims to review the way of donating embryos to infertile couples in Iran. This is a narrative review study. Search for documents related to the research topic were carried out with no time limit and with the use of keywords including infertility, assisted reproductive technologies, donation, donor, recipient, embryo donation, rule, law, embryo donation law, and Iran, singly or in combination at the databases of PubMed, Scopus, Magiran, SID, Google Scholar and department of health and medical education's website, Islamic consultative assembly research center, comprehensive system of constitutional council's comments, legal and parliamentary affairs deputy of the judiciary and medical ethics and law research center. The embryo donation to infertile couples Act and its regulations were legislated by jurisprudence opinions and Islamic community conditions. Indeed, donors don't donate the formed embryo, but they agree with giving gamete and reposing it to authorized infertility treatment centers, and the embryo formed is donated to couples with a special condition. Although the embryo donation Act has some flaws that some actions should be taken to eliminate and correct, it should be acknowledged that approval of this Act and its regulations are one of the biggest measures taken in recent years in Iran. Moreover, given the legal, religious, and cultural contexts in Iran and because this kind of donation has the least legal problems, it has been able to solve many infertile couples' problems.

Key words: infertility, Assisted Reproductive Technologies, embryo donation, Iran

Introduction

Infertility is the failure of occurring pregnancy after one year of sexual intercourse without using contraceptive methods [1, 2]. It is estimated that 10-15% of couples are affected by infertility [1]. Some studies reported that one in six couples has infertility [3]. The prevalence of primary infertility in Iran is 24.9%, in other words, about one-fourth of Iranian couples experience primary infertility in their marital life [4].

Fertility is of great value in most cultures, because the ability to reproduce is an essential issue in life for most people and is considered one of the family functions [5, 6]. For these reasons, infertility is not simply a medical problem, but it is a crisis in life and a tragedy that inflicts severe

psychological trauma on the couple [6-8]. Many infertile couples experience stress, anxiety, unrest, depression, grief, frustration, guilt feeling, impaired sense of identity, feeling broken, low self-confidence, negative self-perception, sexual disorder, sexual dissatisfaction, social isolation, and decreased life quality [9-12]. To this end, parallel to increasing infertility and its adverse effects on couples, medical procedures have rapidly developed for its treatment [13] and the world has witnessed remarkable developments in reproduction since the late twentieth century, and the advent of assisted reproductive technologies (ART) has provided various solutions to the infertile couples and made it possible to treat most infertility cases [14]. These technologies

include In Vitro Fertilization (IVF), Intra-Cytoplasmic Sperm Injection (ICSI), Gamete Intra-Fallopian Transfer (GIFT), Zygote Intra-Fallopian transfer (ZIFT), Iced Embryo Transfer (ICET), and Embryo, Ovum and Embryo donation [1, 2].

Embryo donation is one of the assisted reproduction technologies provided by medical science development to infertile couples to resolve their infertility problems. This method has been one of the most effective ways of treating infertility in couples who are not able to have children anyway in recent decades. Embryo donation is done when the couples don't have the healthy sex cell (sperm or oocyte) for fertilizing and the involvement in forming their biological embryo but the woman has a healthy uterus and can complete a pregnancy [15, 16]. Therefore, the only treatment is that the embryo from an oocyte and sperm belonging to the legal couples (the donors) transfer to the aforementioned woman's uterus (the recipient) by using in vitro fertilization technology [17].

The first donation was performed by Trounson et al in 1983 in Australia, and nowadays it is commonly used in many countries. In this method, the extra embryos of infertile couples produced by in vitro fertilization are donated to the infertile couples, the applicant receives the embryo because in some cases the number of oocytes collected from a woman under infertility treatment is more than the number needed for doing a course of treatment. In this case, the extra oocytes are fertilized and then frozen and are used for the next treatment courses. In many cases, after occurring pregnancy, the couples refuse to reuse their frozen embryos and declare readiness to donate their embryos to couples with no sperms or oocytes [1, 15, 16, 18].

There are many differences in the regulations regarding embryo donation in countries. Some countries allow all forms of gamete and embryo donation, some allow sperm donation but prohibit oocyte and embryo donation and some groups ban all forms of donation including sperm, oocyte, and embryo [19].

In Iran, many developments are made in the field of assisted reproduction technologies and, like other new biological and medical technologies, applying this technology has raised several challenges and questions in the religious,

jurisprudential, moral, legal, and social fields [17], because Iran is an Islamic and Shiite community and in such a community Islamic criteria and Shiite religion and jurists views are especially important for those who are looking for infertility treatment. On the other side, Islam has assigned tasks and duties for every single deed [20, 21].

Indeed, religious view of this technology is one of the main and important factors in couples' decision for using assisted reproduction technology. Embryo donation is also one of these technologies that we need the fatwa from authorities and statement of Islamic views in this area to use in this country to open the way for legislation in these fields and its practical use [20]. Of course, different religions and sects have different views in this regard. In the Jewish religion, sperm insemination from an alien man and woman in another woman's womb and also sperm insemination from a couple in another woman's womb are banned. Catholic Church inhibits transferring the semen from a couple to another woman's womb in all cases. Orthodox Church bans the insemination of two alien sperm and oocyte in addition to insemination by sperm from a non-husband man, but insemination of sperm and oocyte from a couple is allowed if it doesn't lead to excessive reproduction of sperm. From a Protestant's view, insemination of sperm and oocyte from an alien man and woman in the same or another woman's womb is allowed. In a referendum by medical study and research center and Ahl-al-Bayt Jurisprudence Assembly on artificial insemination, this is the answer: fertilizing the woman's oocyte with the semen of her husband out of the uterus and transferring it into another woman's womb is allowed and it's a kind of rental uterus. According to Islam in the Sunni school, any kind of embryo, oocyte, and sperm donation is banned and it's like mixing genes [18, 22].

In Iran, most Shiite authorities on religious matters voted for the permission of embryo donation after complete investigations and in response to the question that if the principle of embryo donation to infertile couples is permissible? After issuing the existing fatwa and permissibility of embryo donation by Shiite jurists, the way for approval of this law was opened in this country, and following that the

embryo donation to infertile couple Act was approved in the public session of the Islamic Consultative Assembly on 2003-07-03, consisting of 5 articles, and it was approved by constitutional council on 2003-07-30. In this Act, embryo donation is allowed under some terms and conditions [20, 23-26]. Certainly, people don't donate the formed embryo, but they agree with giving gamete and imposing to the authorized centers for infertility treatment, and the embryo formed is donated to couples with special conditions [27]. This Act is considerable because it has partially resolved the embryo transfer issue and made a change in Iran's law, however, it has some flaws. This study aims to review embryo donation in Iran.

Materials and Methods

The present study is a narrative review. The documents ... with no time limit and by using the keywords including infertility, embryo donation, embryo donation Act, in vitro fertilization, donor, recipient, descent, the descent of the donated embryo, jurisprudence, religious law, law, and Iran, singly or in combination at the Persian and English databases of PubMed, Scopus, Magiran, SID, Google Scholar and department of health and medical education's website, Supreme Council of the Cultural Revolution, National information base of laws and regulations, Islamic consultative assembly research center, National Portal of the Judiciary and world health organization...

The present study is a narrative review. The documents were searched with no time limit and by using the keywords including infertility, assisted infertility methods, donation, donor, recipient, embryo donation, Act, law, embryo donation Act, and Iran, singly or in combination at databases of PubMed, Scopus, Magiran, SID, Google Scholar and department of health and medical education's website, Islamic consultative assembly research center, comprehensive system of constitutional council's comments, legal and parliamentary affairs deputy of the judiciary and medical ethics and law research center. The documents related to the embryo donation Act were gathered and reviewed in Iran.

Results and Discussion

The text of the embryo donation to infertile couples Act and the executive regulations

Article 1- By this Act, all the competent specialized infertility treatment centers are allowed to transfer the embryo produced by in vitro fertilization from legal couples after written consent by the couples owning the embryo to the womb of women whose infertility has been proved after marriage and medical procedures (each one or both).

Article 2- Applicant for receiving the donated embryo should be jointly set out and offered to the court by both couples and the court will issue a permit to receive the embryo if the following conditions are met:

- a) According to a valid medical certificate, the couples are not able to have children and the wife is capable of receiving the embryo.
- b) The Couple has moral competence.
- c) Neither couple should be insolvent.
- d) None of the couples should have an incurable disease.
- e) Neither couple should be addicted to drugs.
- f) The couple should have citizenship in the Islamic Republic of Iran.

Article 3- The recipient couple of the embryo and the born child have the same duty and responsibility in taking care of, education, alimony, and respect as the duties and responsibility of children and parents.

Article 4- the eligibility of the applicant couples will be checked in family courts, out of turn and without observing the civil procedures and if their eligibility is not approved, they can appeal.

Article 5- the regulation of this Act will be prepared within three months by the Ministry of Health and Medical Education in cooperation with the Ministry of Justice and will be approved by the council of ministers.

Executive regulation of embryo donation to the infertile couples

The council of ministers approved the above-mentioned executive regulation in a session on 2005/03/03 based on the joint proposal No. 69773 on 2004/07/31 from the ministry of health and medical education and the ministry of justice and according to article 5 of embryo donation to the infertile couple Act, approved in 2003, as follows:

Executive regulation of embryo donation to the infertile couples

• Chapter 1

Definitions and generalities

Article 1- in this regulation, the following words and terms are applied with detailed meanings:

a) Act: it means the Act of embryo donation to infertile couples, approved in 2003.

b) Embryo: the sperm from in vitro fertilization of legal couples, which will be from the reproductive stage to a maximum of five days. This embryo can be both fresh and frozen.

c) Embryo donation: voluntarily and free transfer of one or more embryos from the eligible couples prescribed in the law and this regulation to the authorized specialized infertility treatment centers for the applicant couples with the conditions stated in the law.

• Chapter 2

Conditions for donating and receiving embryos:

Article 2- the donor couples should have the following conditions:

a) Have a legal and religious marital relationship.

b) Have standard physical and mental health and a good IQ.

c) Not addicted to the addictive and psychotropic drugs.

d) No incurable diseases like AIDS, Hepatitis, and so on.

Note: Authorized specialized centers of infertility treatment are obliged to hold the following conditions in this article before receiving the embryo from the donors.

Article 3- Embryo donation should be done with written consent and agreement of the donors and in the authorized specialized centers of infertility treatment, by their identification and in complete confidentiality.

Article 4- The applicant couples should have the conditions prescribed in article 2 of this Act.

Article 5- The applicant to receive the donated embryo will be considered in a competent court and out of turn, without observing the civil procedure. If the court issued a sentence rejecting the applicant and not confirming the eligibility of the couple, it can be appealed.

• Chapter 3

The responsibilities and duties of the authorized specialized infertility treatment centers:

Article 6- the authorized specialized infertility treatment centers are obliged to take action in the following cases:

a) Keeping the embryos from Muslim and non-Muslim donors separately and considering the religious proportionality of the applicant couples with the donated embryo in transfer time.

b) Receiving and maintaining the final sentence of the judicial authority from the applicant.

c) Issuance of the necessary certificate and letter of introduction that confirm the physical and mental health of applicants for receiving the embryo according to the law and this regulation.

d) Receiving, maintaining, and transferring the donated embryos in a completely confidential way.

Note: the information about the donated embryos is classified as totally confidential information.

Article 7- the certificate for infertility and inability of the wife in receiving and keeping the embryo is issued after detailed medical testing and examinations for the competence of authorized specialists for infertility treatment.

• Chapter 4

the requirements for receiving, maintaining, and transferring the embryo

Article 8- each of the authorized specialized centers of infertility treatment can establish an embryo bank according to the instruction of the health and medical education ministry. This bank is responsible for receiving and transferring the embryos to infertile couples according to the provisions included in the law and this regulation.

Article 9- the transplant center of the health and medical education ministry is obliged to close supervision of receiving, maintaining, and transferring the embryo according to the instructions from the mentioned ministry.

Article 10- documents and information about the donors and recipients are only allowed to provide by observing the regulations on preserving government secrets and to the judicial authorities.

The matter of the mentioned Act is one of the assisted reproduction methods, namely embryo donation, which is authorized under the

conditions included in the law and the executive regulation. According to this Act, the recipient couples should submit their application to the court. After confirming the requirements included in this law by the donor and recipient couples, embryo donation permission is issued [28].

Embryo donation is one of the new assisted reproduction methods, which is a critical matter due to affecting the biological relationships in the family. In the Islamic Republic of Iran, most mighty jurists have allowed embryo donation to infertile couples provided that no unlawful action is committed in the formation of an embryo from the legal couples [28, 29]. Accordingly, and by votes from the jurists in 2003, the Act of embryo donation for infertile couples and its executive regulation was approved in 2004 which originated from the jurist's opinions and was proportional to the Islamic community.

One of the most important positive points of this Act is the physical, spiritual, and mental health assessment of the donor and the recipient. In this method, by descent, the father of a child is the owner of donated sperm and the mother is the owner of the donated oocyte and the owner of the womb. Legally, inheritance is not established due to lack of descent between the recipient couple and the mentioned child, but it is the duty and responsibility of the recipient couples for care, education, alimony, and respect to the child. Embryo donation Act and its executive regulation suffice to mention the generalities; therefore, it has many flaws in several contexts and needs to provide more detailed information including the conditions of donors and recipients of the donated embryo, the confidentiality of donation, the details of duties and responsibilities of donors and recipients, legal status of the donors and recipients and especially the rights of the born child through donation like descent status, inheritance, etc. and how to fulfill the mentioned child's right, how to hold the conditions included in the act and regulation, and observing the ethical standards in the donation process.

Another important point that seems to be mentioned in the executive regulations is to council with the couples (donors and recipients) and full awareness of donation operations before starting the treatment, during the treatment, and after that to prevent consequent problems [16].

Thus, given that the aforementioned act and executive regulation do not have the necessary comprehensiveness, Iran's legislator must determine many details not mentioned in the act according to the mighty jurists and considering the religious, ethical, and cultural principles of the community in embryo donation [30], so that the Islamic community of Iran has no concerns about using such treatments, in addition to correcting the ethical, legal, social, cultural and juridical flaws in the mentioned act. Indeed, since there are various opinions of jurists in this field and it has many pros and cons, thus it requires the mighty jurists to reach a consensus on these issues by holding meetings [31, 32]. Moreover, it seems that, despite the rapid growth of medical science in the field of infertility treatment, there is still a legal shortage in many modern infertility treatments which needs to inform and approve some laws in these contexts, because lack of public awareness from the juridical, legal, moral and social aspects of assisted reproduction methods can cause irreparable damages to couples and children born as a result of these methods [16].

Although the act of embryo donation has some flaws that can have a great impact on the practical application of this method in society (of course, some measures should be taken to correct and eliminate them), it should be admitted that approval of this act and its executive regulation is one of the biggest measures taken in recent years in this country, and since the matter of embryo transfer is partially resolved and made a remarkable change in the laws in Iran, and also considering to the juridical, religious and cultural contexts in Iran and because it is a kind of donation with least juridical problems [28, 32], it can pave a way for many infertile couples and resolves problems of many couples and causes to more correlation ad intimacy between family members. Considering the novelty of this phenomenon in the Iranian legal system, the above-mentioned act left unsaid many key points like inheritance and privity. Matters like whether the real parents of the child are the biological parents or the donors or the fertilizer. In addition, the role of the husband of the fertilizing woman and the inclusion or non-inclusion of his name in the identity card of the child, etc., is ambiguous and there is no text can be found on these items

among legal regulations, which its legal provisions can be inferred by appealing to the juridical generalities and the spirit of the subject matter regulations that are more compatible with the legal and moral principles and rules in one side and people's interests in human societies [33, 34].

Conclusion

Although the embryo donation Act has some flaws that some actions should be taken to eliminate and correct, it should be acknowledged that approval of this Act and its regulations are one of the biggest measures taken in recent years in Iran. Moreover, given the legal, religious, and cultural contexts in Iran and because this kind of donation has the least legal problems, it has been able to solve many infertile couples' problems.

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