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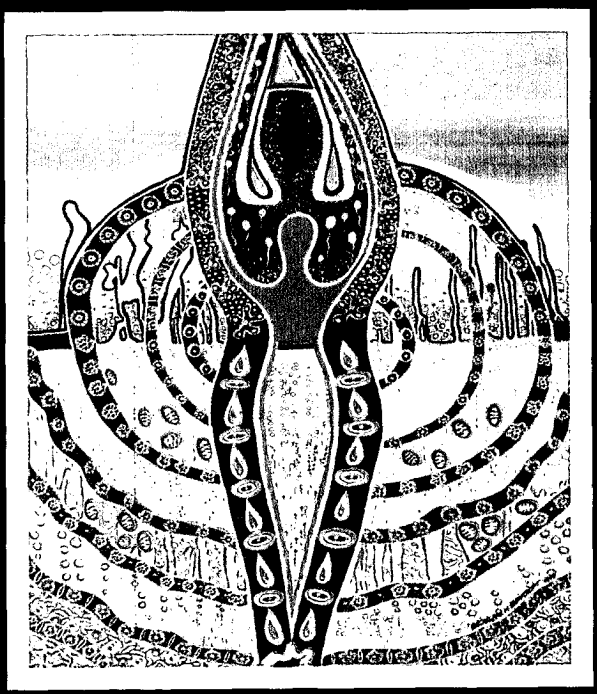

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The Donation of Supernumerary Cryopreserved Embryos to Women in Ovarian Failure Yields Excellent Pregnancy and Implantation Rates

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Summary

This study reported the outcome of an embryo donation program in which couples donated their supernumerary cryopreserved embryos to infertile couples with medical problems such as ovarian failure or azoospermia who could not obtain donor oocytes either because of availability or cost. Seventeen couples received donated embryos. The embryos had been in storage from 1.8 to 6.8 years (median 3.8 years). The clinical pregnancy rate (PR) per transfer was 47.6% (10/21) and the clinical PR per patient was 58.8%. The implantation rate was 24.3%. Cryopreserved embryos that are currently in "limbo" because their owners do not wish to pursue another pregnancy nor do they wish to destroy them can be donated to infertile women. These embryo recipients have a high rate of pregnancy.

Introduction

As a result of the ovarian hyperstimulation protocols in use in most in vitro fertilization (IVF) programs, embryos in excess of the number that can be transferred at one time are created. These embryos are cryopreserved in liquid nitrogen for replacement at a later date. Often, couples decide not to pursue another pregnancy and are faced with the decision of how to dispose of their embryos. They can opt to have them destroyed, donate

them to research, donate them to another infertile couple, or leave them in storage indefinitely. Each option is associated with its own set of ethical and legal decisions both for the patient and the clinician.

John A. Robertson, an attorney, has evaluated the ethical and legal issues in human embryo and has concluded that when appropriately performed, this procedure is an ethically and legally acceptable way for infertile couples to form families (1). More recently, the American Society for Reproductive Medicine has published guidelines for embryo donation (2). These include guidelines for the ART programs wishing to offer embryo donation as well as guidelines for the couples who wish to donate the embryos and the potential recipients.

One criterion for establishing a donor embryo program is the availability of a good cryopreservation program with good pregnancy rates (PRs) following frozen embryo transfer (ET) (2). Since our program has comparable PRs in both fresh and frozen ET, we established a donor embryo program at our center. This report describes the results of a recent series of embryo donation cycles using cryopreserved embryos that were no longer wanted by their owners.

Materials and Methods

All patients undergoing IVF at the Cooper Center for IVF are informed of the possibility that excess embryos may be generated and cryopreserved as a result of their medical treatment. They are also informed of the options for the use and disposition of these embryos. They are first encouraged to use the cryopreserved embryos themselves to help achieve their goal of a successful pregnancy. If, however, there are embryos left in storage after they achieve their objective, they are encouraged to donate their unused embryos to other infertile couples. Another option is long-term storage.

If they elect to donate their embryos to another couple, they can elect whether or not they wish to remain anonymous. They receive no compensation for their embryos. They also sign a contract relinquishing their rights to the embryos.

An anonymous list of donors is maintained with personal characteristics and medical history. Approximately 30 donors are on the list at any one time. Couples electing to enroll in the donor embryo program as recipients select a donor from this list. Once a match is made, the recipient agrees to maintain the cryopreservation costs from the time of the agreement until the ET. The recipient also pays for her own frozen ET. No other compensation or costs result from participation in this program.

All women (n=17) entering the donor embryo program from January, 1997 through August, 1998 were included in the study. The women ranged in age from 33 years to 58 years (median, 44 years) and were unable to produce an embryo of their own. All patients received hormone replace-

ment prior to ET. In some cases, down regulation with leuprolide acetate was used if the recipient still had some ovarian function. For the most part, they were treated with a graduating dose of oral estradiol until adequate endometrial development was noted sonographically (endometrial thickness at least 8mm and a trilaminar echo pattern). The embryos were cryopreserved using a simplified freezing and thawing technique (3). Assisted hatching was generally performed prior to transferring 3-day-old embryos (4).

The success of the program was measured by survival rate of cryopreserved embryos, PR per transfer and per patient.

Results

Seventeen embryo recipients underwent a total of 21 frozen ETs. Seventy-seven embryos were thawed for transfer. The embryos had been in storage from 1.8 to 6.8 years (median 3.8 years). Thirty-seven embryos were cryopreserved and thawed at the 2 pronuclear (2PN) stage, 40 were cryopreserved and thawed at the multi-cell stage. The survival rates were 91.9% for the 2PN embryos and 70% for the multi-cell embryos. On average, 3.2 embryos were transferred per cycles.

The outcomes of the donor embryo cycles are presented in Table 1. Following the first ET, there were 7 clinical pregnancies (41.2%) of which 4 had multiple gestations giving an implantation rate of 21.8% (12/55). Four of the women underwent a second ET and 3 conceived. Thus, the overall PR per transfer was 47.6% (10/21) and the implantation rate was 24.3%. The clinical PR per patient was 58.8% (10/17). The PRs was comparable for cycles in which all 2PN embryos were thawed (4/8) and all multi-cell embryos were thawed (3/6).

Table 1 - Outcome of a donor embryo program

Cryopreservation Results	
Survival rates	
Pronuclear stage	91.9%
Multi-cell embryos	70.0%
Clinical PRs	
First ET	41.2% (7/17)
Second ET	75.0% (3/4)
Per transfer	47.6% (10/21)
Per patient	58.8% (10/17)
Implantation Rates	
First ET	21.8% (12/55)
Per transfer	24.8% (17/70)

Conclusions

The program at our center was established before the guidelines published by ASRM. However, our program since its inception followed these guidelines. These data demonstrate that it is possible to set up a donor embryo donation program that abides by ethical and legal guidelines and is also clinically successful. Couples with supernumerary embryos in storage should be informed of the high potential of these embryos so that if they no longer want them, they may choose to donate them to other infertile couples seeking to achieve their same goals.

There are many advantages for a recipient to receive donated embryos: 1) they allow her to deliver the baby(ies) as opposed to adoption and 2) they are less costly and thus more attainable to those without the financial means to purchase donor oocytes. Since women who donate embryos do not receive any compensation and there are no expensive medications or retrieval procedures needed for the donor or recipient, the use of donor embryos can be a much cheaper option for women who can not afford donor oocytes. The program has advantages for the donor also, since many patients prefer to see the potential life of their embryo brought to fruitation than destroyed or left in storage.

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