OBSTETRICS

Living uterus donation and transplantation: experience of interest and screening in a single center in the United States

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BACKGROUND: Little is known about attitudes toward uterus donation and transplantation in society and the interest of the women the treatment is aimed to assist.

OBJECTIVE: This study examined the interest of recipients and living donors in our uterus transplantation program; it describes the screening protocol we developed and the results of the screening and reports demographic data and characteristics of screened candidates.

STUDY DESIGN: Initial screening and evaluation included physical examinations by a gynecologist and a transplant surgeon; psychological evaluation; imaging (x-ray, computed tomography, ultrasound); blood tests; immunological testing; viral, bacterial, and fungal testing; drug screen; hormonal testing; Papanicolau smear; urinalysis; and electrocardiogram. For selected recipients, the process also included in vitro fertilization.

RESULTS: A total of 351 women contacted our department with interest in participating in uterus transplantation; 272 were potential recipients and 79 were potential donors. Among these women, 179 potential recipients and 62 potential donors continued the evaluation after the initial telephone screening. The mean age of the donor candidates was 40 years; all had completed their own family, and 80% were nondirected. Most recipient candidates (92%) had an anatomical lack of the uterus, and of these, 36% had a congenital malformation. The women with a congenital uterine absence were in general younger than the women in the group whose uterus had been removed (mean of 28 and 33 years, respectively). In every step of the initial screening and evaluation process, there were donor and recipient candidates that chose not to continue the process. The reasons for self-withdrawal after expressing interest were not returning phone calls or e-mails (17 donors and 76 recipients); after initial phone screening, no longer interested (1 donor and 9 recipients); in step 1, health history questionnaire not returned after 1 reminder (10 donors and 9 recipients); step 2, not right in their current life situation (2 donors and 2 recipients), and in step 3, chose another way to achieve motherhood (1 recipient). Most donor and recipient candidates (52% and 78%, respectively) could be screened out (because of self-withdrawal or transplant team's decision) during the noninvasive and cost-efficient initial screening.

CONCLUSION: Our initial experience shows a great interest in participating in a trial of uterus transplantation by both potential recipients and donors. It is the first study to show interest in nondirected donation. A sufficient but thoughtful screening process of living donors and recipients is essential and should aim both to assure donor/recipient safety and to provide good quality grafts.

Key words: donor, infertility, interest, recipient, uterus transplantation

In 2014, the first baby was delivered by a mother born without a uterus.[1] The birth was facilitated by a uterus transplantation almost 2 years prior to the delivery. While uterus transplantation is still in an experimental stage, it is a promising potential treatment for women with absolute uterine-factor infertility. Approximately 1 in 500 women are affected by absolute uterine-factor infertility[2]; based on the population, we estimate that there are about 80,000 reproductive-age women with absolute uterine-factor infertility in the United States. The many women who have no functional uterus but want to have a child are currently given only adoption or surrogacy as options.

Uterus transplantation is unique in several ways. Rather than being life saving, it enhances quality of life and is potentially life giving. It is the first temporary organ transplantation, with planned removal after childbirth. It can be performed with both living and deceased donors, although to date the birth of a child has occurred only after living-donor transplants.

The first attempt at uterus transplantation in the United States in 2016 was unfortunately unsuccessful.[3] The transplant was conducted with a deceased-donor uterus, and the graft had to be removed less than 2 weeks after the transplant. Six months after this initial uterus transplantation, we performed the first living-donor uterus transplantation in the United States.

While public attitudes toward traditional organ donation are favorable and uterus transplantation is considered a promising treatment option among health care professionals, little is known about attitudes toward uterus donation and transplantation in society and the interest of the women the treatment is aimed to assist. In this paper, we present our initial experience with the interest of potential recipients and donors for uterus transplantation, the development of a screening protocol, and the demographic data and characteristics of our screened candidates.

Materials and Methods

Our clinical uterus transplantation trial (Project 015-158) was performed at Baylor University Medical Center (Dallas, TX) and was approved by the institutional review board. The policy of the program is to present all potential uterus recipients with the possibility

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TABLE 1
Evaluation of candidates for in vitro fertilization

Type	Test
Health care professional evaluation	Physical examination
	Pelvic examination
	Psychological evaluation (including in-depth interview and standardized questionnaires[a])
Imaging	Chest x-ray
	Computed tomography, abdomen and pelvis
	Vaginal ultrasound
	Doppler ultrasound
	Transabdominal ultrasound
Blood tests	Complete blood count with differential
	Comprehensive metabolic panel
	Gamma-glutamyl transferase
	Lipid panel
	Prothrombin time/international normalized ratio
	Partial thromboplastin time
	Hemoglobin A1c
Immunological testing	ABO blood groups Rh antigens
	Human leukocyte antigens
Viral, bacterial, and fungal testing	Syphilis
	Chlamydia and gonorrhea *(Neisseria gonorrhoeae* culture)
	Herpes simplex virus 1 and 2
	Hepatitis C virus RNA by polymerase chain reaction
	Surface antigen of the hepatitis B virus
	Cytomegalovirus IgM and IgG
	Epstein-Barr virus IgM and IgG
	HIV
	Fungal screening
	Urine culture
	Rubella
	Tuberculosis (T-SPOT)
Drug screen	Serum alcohol test
	Urine drug test
Other tests	Papanicolau smear with cotesting for human papillomavirus
	Urinalysis
	Electrocardiogram

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of both living and deceased donor transplants at the time of evaluation for transplantation.

The candidates (both potential donors and recipients) independently contacted our institution. There was no advertising or recruiting for the clinical trial aside from information on the hospital web site and a local press conference to announce the start of the trial, during which contact information was provided (e-mail and phone number) as well as the listing on clinicaltrials.gov (clinical number NCT02656550).

The first contact with the potential recipient or donor was through a nurse coordinator (with >10 years of experience in women's health) assigned to the program. The candidates were informed at the initial contact about the experimental nature of the program, the worldwide experience/outcome of uterus transplantation, details of the surgery, postoperative care, and potential complications. They were also informed that participation in the uterus transplantation trial possibly could render costs for them.

The trial would cover investigations, surgery, hospital stay, medications, and follow-up visits but would not cover in vitro fertilization (IVF), travels, accommodation, or loss of income. No compensation for participating in the trial would be handed out. A basic initial screening also took place during this first contact, with exclusion criteria being age (limit of 65 years for donors and 35 years for recipients), body mass index (BMI) limit of 30 kg/m^2, medical comorbidities, and obstetric history. The candidates considered to be initially suitable and interested in participation proceeded to the first step of evaluation.

Step 1: subjective health screening

The candidates received an informed consent form for screening and a health history questionnaire. Candidates were also encouraged to send any related medical records, if present. Based on the health history questionnaires, the primary investigator (transplant surgeon)