

Uterus transplantation trial: Psychological evaluation of recipients and partners during the post-transplantation year

Stina Järholm, Psy.D.,^{a,b} Liza Johannesson, M.D., Ph.D.,^a Alex Clarke, Psy.D.,^c and Mats Brännström, M.D., Ph.D.^a

^a Department of Obstetrics and Gynecology, Sahlgrenska Academy, and ^b Department of Psychology, University of Gothenburg, Göteborg, Sweden; and ^c Department of Plastic and Reconstructive Surgery, Royal Free London, National Health Service Foundation Trust, London, United Kingdom

Objective: To explore the psychology and well-being of the nine patients undergoing uterus transplantation (UTx) as part of the first clinical trial, during the first 12 months of which seven patients experienced graft survival with occasional mild rejection episodes and two patients experienced graft failure, with hysterectomy.

Design: Prospective observational study.

Setting: University hospital.

Patient(s): Nine female uterine recipients and their partners.

Intervention(s): Psychological evaluations by questionnaires focusing on quality of life, mood, relationship, and fertility quality of life were conducted at inclusion and at 3, 6, and 12 months after UTx.

Main Outcome Measure(s): Scores of four different questionnaires regarding mood, quality of life, fertility quality of life, and relationship.

Result(s): In all questionnaire domains, the recipients and their partners showed a similar pattern at baseline, and the UTx group, including both recipients and partners, scored similarly or better when compared with relevant norm groups. Among the recipients there was a reversible decline in score of physical activity and increased bodily pain at 3 months past surgery.

Conclusion(s): The results show that participants of this first UTx trial were psychologically stable both at baseline and during the first year, despite rejection episodes and possible worries about viability of graft.

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Key Words: Infertility, uterus, transplantation, psychology

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The first baby born to a woman with a uterine graft was recently announced (1), and this medical breakthrough raises hope for women worldwide with absolute uterine factor infertility. This type of infertility has for a long time remained the last major

subgroup of female infertility without available treatment, although adoption and gestational surrogacy have been options for some couples to achieve parenthood. The causes of uterine factor infertility, which affects one in 500 reproductive-age women (2, 3),

are several. There can be a lack of the uterus from birth (Mayer-Rokitansky-Küster-Hauser [MRKH] syndrome) or after hysterectomy during fertile age due to cervical cancer or emergency peripartum bleeding. The uterus can also be present but nonfunctional, owing to intrauterine adhesions or major uterine malformations.

Uterus transplantation (UTx) belongs to the group of nonvital and quality of life-enhancing types of transplantations, such as the hand and face. Unlike other quality of life-improving transplantations, UTx is the first nonpermanent type of

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Reprint requests: Stina Järholm, Psy.D., Kvinnokliniken, Blå stråket 6, s-413 45 Göteborg, Sweden (E-mail: stina.jarholm@vgregion.se).

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transplantation, since the graft can and should be removed after giving birth to a restricted number of children. This means, from a psychological aspect, that the patients are more likely to temporally and partly adjust to the new situation, knowing this is a phase of life and not a new permanent way of life.

The ethics surrounding UTx are complex and have been the focus of several publications (4, 5). The first ethical guidelines for research and development of human UTx were presented by the International Federation of Gynaecology and Obstetrics in 2009 (6). The ethics debate ranges from the potential benefits for the individual to the limits and boundaries of medical intervention, risks, the medical and psychological selection, donor and recipient relationship, and the preparation and subsequent management of patients. One major difference from other organ transplantations is that UTx involves at least four parties: the recipient, the donor, the partner of the recipient, and the potential child. The ethics and unknown parameters around a future child after UTx are similar in many ways to those surrounding the introductions of major infertility treatments such as IVF and intracytoplasmic sperm injection. We and other investigators are working to create an international registry that will follow all UTx participants and in particular the offspring. They should be followed in a detailed way by tests that explore medical, psychological, and neuropsychiatric issues.

In 2013, we initiated the world's first clinical trial of UTx, which included nine women lacking a uterus who were then transplanted with uterine grafts from live donors. The 6 and 12 months' medical outcomes for the cohort have been published (7, 8). Two uteri were removed during the initial 4 months, because of infection in one case and uterine vessel thrombosis in the other case. ETs have been initiated in the remaining seven women, and recently the first live birth was reported (1).

Psychological aspects and assessments should be addressed in all types of organ transplantation, and these factors are especially important when establishing a new type of transplantation. It is recognized that the outcome of any transplantation is highly associated with the recipient's psychological state (9, 10). Protocols for psychological assessment and evaluation of recipients already exist (11, 12) for other types of non-life-saving transplantation, such as the face and hand. The psychological questionnaires we used for the UTx couples were based on data and research in other transplantation fields but finally determined by the specific situation of UTx, which resembles and differs from other types of transplantations. The resemblances include necessity to evaluate psychological and behavioral factors such as cognition, social support, mental illness, and substance abuse (12). The facts that the transplantation affects the couple's chance of becoming parents and that the transplantation is nonpermanent are two major differences from other organ transplantations, which highlight the importance of evaluation and acknowledgment of the couple. It is important to point out that the psychological evaluation in UTx is not mainly performed to exclude participants but to identify potential risks and offer support when needed.

In the present study we describe the population entering the UTx trial, before and at set intervals of a 12-month period

after UTx, using standardized questionnaires focusing on the four domains of quality of life, mood, relationship, and fertility quality of life.

MATERIALS AND METHODS

Patients

The characteristics of the recipients and their partners are described in Table 1. They had all been in a stable relationship and had cohabitated at least 2 years before entering the trial. The medical screening tests included verification of a healthy donor with blood group compatibility, gynecological examination confirming absolute uterine factor infertility, and multiple medical, laboratory, and imaging examinations, as described in detail elsewhere (7). IVF was done before UTx to both assure fertility within the couple and to cryopreserve embryos for planned ET >12 months after transplantation, according to international transplantation recommendations (13, 14). The selection of recipients performed by the surgical team was primarily on medical grounds. The first psychological evaluation by questionnaires, defined as baseline, took place in the interval from 6 months to 1 month before the first IVF procedure. All participants were thoroughly informed that the evaluation was not mainly performed to exclude but to identify potential risks and offer support when needed.

Written informed consent to participate in a research project involving a novel transplantation procedure with unknown outcome, IVF, immunosuppression, ET, and medical and psychological evaluation for at least 2 years was obtained from all recipients and their partners. The project was

TABLE 1

Characteristics of recipients included in the UTx trial and their partners.

Characteristic	Recipients (n = 9)	Partners (n = 9)
Age (y), median (range)	33 (27–38)	35 (29–42)
Length of relationship, y		
<5	3	3
>5	6	6
Highest education		
Secondary school	3	7
University	6	2
Occupation		
Employed	8	9
Student	1	—
First or second generation immigrants	1	1
Residence		
Urban	8	8
Rural	1	1
Relation to donor		
Mother	5	
Related close family	2	
Partners close family	1	
Friend	1	
Cause of uterine agenesis		
Mayer-Rokitansky-Küster-Hauser syndrome	8	
Cervical cancer	1	

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