Screening and evaluation of potential recipients and donors for living donor uterus transplantation: results from a single-center observational study

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Objective: To report our experience with the screening and selection of potential recipients and living donors of our uterus transplantation (UTx) program.
Design: Part of an observational program.
Setting: University hospital.
Patient(s): Patients with absolute uterine factor infertility (AUFI).
Intervention(s): Screening by e-mail and telephone, selection during surgical consultation, and preoperative investigations according to a multistep procedure for living donation.
Main Outcome Measure(s): Age, cause of AUFI, exclusion reasons, and preoperative workup.
Result(s): A total of 212 potential recipients expressed interest in participation. Among the 46 potential recipients and 49 directed donors were 4 potential recipients, each with 2 directed donors. Mean (range) age of potential recipients was 29.6 (19–41) years. Of the potential recipients, 39 (84.8%) had congenital AUFI and 7 (17.3%) had acquired AUFI. Ultimately, 15 potential recipients with 16 directed donors were selected for participation, with 1 potential recipient having 2 directed donors. Mean age of included potential recipients was 28.9 (22–35) years, and mean donor age was 51.3 (37–62) years. Fourteen potential recipients (93.3%) had congenital AUFI, and one potential recipient (6.7%) had undergone hysterectomy for obstetric complications.
Conclusion(s): The number of potential candidates for UTx is not inconsiderable, with congenital AUFI being the leading cause of AUFI in our cohort. However, our findings highlight that large numbers of AUFI patients need to be screened, considering our exclusion rates were >50%, owing to ABO incompatibility, unavailability of a directed donor, and self-withdrawal. Moreover, meticulous preoperative screening, including in-depth psychological assessment, is mandatory to maximize living donor safety and UTx success. (Fertil Steril® 2019;111:186–93. ©2018 by American Society for Reproductive Medicine.)

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Key Words: Donor, recipient, screening process, uterus transplantation

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The complete nonfunctionality or absence of the uterus, as a result of congenital aplasia or hysterectomy, is termed *absolute uterine factor infertility* (AUFI) (1). It affects approximately 3%–5% of all women worldwide and was until recently regarded an incurable cause of female infertility (1). In Germany, up to 15,000 women are affected by AUFI, approximately 8,000 of whom have congenital uterine aplasia, according to our own estimations based on German population statistics (2).

To overcome AUFI, human uterus transplantation (UTx) was first implemented in Sweden after extensive, systematic, animal-based research conducted over more than a decade (3). The first clinical UTx trial resulted in the first childbirth in 2014, thus providing proof of concept for this novel infertility treatment (1). Since these initial promising results from Sweden, interest in UTx has dramatically increased worldwide; to our knowledge, there have been at least 42 human UTx attempts, with the majority of trials pursuing the living-donor concept (personal communications, press releases, lectures at the 1st Congress of the International Society of Uterus Transplantation, published reports) (4–8). Whereas there were 12 UTx attempts between 2000 and 2015, the number of UTx attempts peaked at 30 during 2016/2017. Meanwhile, eight human UTx programs have been initiated around the globe. Additionally, several living-donor UTx (LD-UTx) procedures resulted in successful pregnancy and childbirth (personal communications, press releases, lectures at the 1st Congress of the International Society of Uterus Transplantation, and published reports) (2, 6).

Our team recently published the experience gained in implementing the first human LD-UTx program in Germany, which included two successful transplantations resulting in menstrual functionality and one attempt that was aborted after organ retrieval (2). Our earlier publication highlighted the need for meticulous preoperative evaluation of potential recipients and living donors (2).

On the other hand, little is known regarding the characteristics of women who seek UTx as a treatment for AUFI. Furthermore, only one research group so far has described the screening protocol developed within their UTx trial (9). As a consequence, currently no standardized evaluation protocols are available for the screening process (10). Nevertheless, these data may offer important insights into the process of screening, evaluation, and selection of recipients and donors for LD-UTx, to improve the safety of the procedure for both donors and recipients and to provide high-quality grafts for the recipients (9). Thus, the primary objective of the present analysis was to describe the characteristics of women with AUFI who were screened and evaluated for UTx at our institution. We also provide a detailed description of our screening protocol and evaluation steps.

MATERIALS AND METHODS

Ethical and Legal Aspects

Our clinical LD-UTx program received initial approval from the University of Tübingen and the Ethics Committee of the University of Tübingen. Several healthcare and ethical authorities, committees, and organizations, including the Transplantation Committee of the German Medical Association, were informed about the start of our clinical LD-UTx program, and the legally competent among them gave their approval. In accordance with the relevant provisions laid out in Section 5a of the Medical Practitioners' Act of the State of Baden-Württemberg, potential donors presented themselves to the Living Donation Committee of the State Chamber of Physicians of Baden-Württemberg, the composition and role of which are described below. All potential donors and recipients were presented to the Multidisciplinary Transplantation Board of Tübingen University Hospital (2). Similarly to other UTx programs, our team included specialists in gynecologic surgery, transplantation surgery, reproductive medicine, maternal–fetal medicine, neonatology, internal medicine, psychiatry and psychotherapy, anesthesiology, radiology, and pathology. Considering the potential occurrence of ethical challenges not previously encountered in other transplantation procedures (i.e., the non–life-saving nature of LD-UTx), it was considered essential also to involve the Institute for Ethics and History of Medicine at the University of Tübingen from the very inception of the program.

Recruitment

The applicants described in the present program independently contacted our institution by e-mail or phone. Recruitment did not involve any advertising aside from the information posted on our hospital website and presentation of the program at a single symposium, at which we provided relevant contact details (names, e-mail addresses, and phone numbers). For screening and recruitment, we divided the evaluation process into a preinclusion phase and a selection phase (Fig. 1). There were two reasons for self-withdrawal after expressing interest in program participation: potential participants either failed to respond to phone calls and e-mails or felt that UTx was not a viable option in their current life situation.

Preinclusion Phase

As shown in Figure 1, the preinclusion phase encompassed the screening and basic evaluation of potential trial

FIGURE 1

Chronological sequence of the screening procedures and development of preoperative investigations for the Tübingen uterus transplantation trial. HLA = human leucocyte antigen.

Taran. Screening for uterus transplantation. Fertil Steril 2018.

candidates by e-mail, telephone, or personal appointment (depending on candidate preference). The preinclusion assessments were carried out by a medical specialist assigned to coordinate the entire screening process. Initial, basic exclusion criteria for this phase were age ($\geq$38 years for recipients and $\geq$65 years for donors), body mass index (BMI) >30 kg/m^2, and a history of malignant disease with an uneventful follow-up of <5 years. Furthermore, the German Transplantation Act (*Transplantationsgesetz*), which covers the large legal areas such as procurement of organs from dead and living donors, requires that the living donor of a non–self-regenerating organ must be a close relative, spouse, or life partner of the recipient or evidently be in a verifiable close personal relationship with the recipient (e.g. a long-standing friend). Hence, the prerequisite for our LD-UTx program was the existence of healthy potential donors from the recipients' families (mothers, sisters, or aunts). Candidate recipients and donors initially considered suitable for participation were then assigned to the inclusion phase. Because every potential recipient was required to name a potential donor, all further evaluation steps were performed simultaneously.

Selection and Participation Phases

Also shown in Figure 1, the selection phase involved recipient and donor selection by extensive, meticulous preoperative evaluation according to a multistep approach for living UTx donation established at our center (2). This phase essentially encompassed three steps: the second appointment at the hospital, the multidisciplinary UTx conference, and consultation with the Baden-Württemberg State Chamber of Physicians' Living Donation Committee, which made the final decision on the donors' eligibility and acceptability for LD-UTx donation.

Appointment 1 at the Hospital

The first personal contact with potential candidate recipients and donors was through the medical specialist gynecologic surgeon coordinating the screening process. Candidates completed a detailed health history questionnaire, which they were guided through, and received comprehensive information about LD-UTx in general and the objectives of the program in particular. Recipients and donors additionally received detailed information regarding the surgical procedure, mandatory preoperative investigations, postoperative care, potential complications, and the estimated length of time until return to work and everyday activities (Supplemental Table 1, available online at www.fertstert.org). Furthermore, potential recipients received detailed information on the need for, and duration of, immunosuppressant therapy and the potential side effects of immunosuppressants (Supplemental Table 1). After the first appointment, the screening process coordinator consulted with the head of the program, a gynecologic oncologist, to ensure that the principal inclusion criteria were met and thus to establish that recipients and donors were suitable for further screening procedures, before they were scheduled for the second appointment at the hospital.

All inclusion and exclusion criteria were exclusively based on medical criteria, the experience of the Gothenburg team, the German Transplantation Act, and the relevant German laws on reproductive medicine, the prime goal being to ensure a maximum success rate of later pregnancy and delivery of a healthy child while minimizing the risk for the donor. Potential recipients with abnormal female karyotypes were therefore also excluded.

Appointments 2 and 3 at the Hospital

The second appointment at the hospital comprised an extensive, in-depth medical workup, as detailed in Supplemental Table 2 (modified from reference 9; available online at www.fertstert.org). Initially, during the first year of the screening process, the diagnostic procedures were carried out at the candidates' discretion with no defined time limits. However, considering the large number of potential candidates and to expedite the medical workup, it was condensed into three days. During this appointment the potential recipients and their partners and potential donors gave their written informed consent to participate in the trial. Potential recipients and donors underwent two psychological assessments to determine their suitability for participation and to identify and exclude candidates who were under severe psychological strain (Fig. 1). During the third appointment, potential recipients and their partners and potential donors underwent comprehensive, in-depth psychological assessments involving interviews and standardized questionnaires (Supplemental Table 2). These assessments were carried out by psychologists in an ambulatory setting.

Multidisciplinary UTx Conferences

The multidisciplinary UTx conferences were attended by transplant surgeons, gynecologic surgeons, obstetricians, anesthesiologists, intensive/critical care specialists, radiologists, psychologists, pediatricians (independent participants), internists, pathologists, and the local transplant coordinator. Every matched recipient–donor pair was presented and discussed at a multidisciplinary UTx conference. Unanimous approval by the attendees was mandatory for final program inclusion. This constituted the penultimate step before trial participation and initiation of the IVF procedure.

Consultation of the State Chamber of Physicians' Living Donation Committee

Upon UTx conference approval, all potential donors and recipients had a mandatory interview with the State Chamber of Physicians' Living Donation Committee (Fig. 1) as the last step before participation in a living-donor program. The interview constitutes an essential part of the German Transplantation Act and is essentially designed as a measure to protect the donor. Its purpose is to ascertain that organ donation is voluntary and does not involve organ trafficking. Furthermore, a close relationship between the recipient and the donor must be demonstrated, as described above. The Committee consists of at least three individuals: a physician who is not involved in the procurement and transplantation of organs and not subject to directives from a physician involved in such activities, a person qualified to hold judicial office, and a person with extensive psychological experience.

RESULTS

Preinclusion Phase

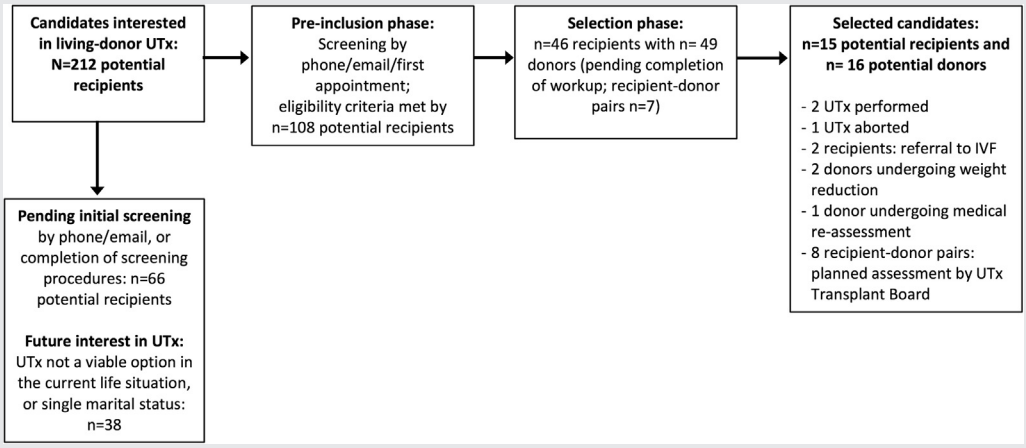
As shown in Figure 2, between March 2015 and September 2016, 212 potential recipients contacted our institution with an interest in participating in the UTx trial. Mean age (range) of interested potential recipients was 29.2 (17–53) years. The cause of AUFI was congenital AUFI/Mayer–Rokitansky–Küster–Hauser syndrome (MRKHS) in 135 women (63.6%), acquired AUFI in 56 women (26.4%), and unknown in 17 women (8.0%). In addition, there were three male-to-female transgender applicants (1.4%) and one applicant with a 46,XY disorder of sex development (0.4%). Of the 212 candidate recipients, 108 (50.9%) continued to the second step of the screening and evaluation process.

Selection Phase

Table 1 summarizes the characteristics of the 46 potential recipients with 49 directed donors who passed the initial preinclusion phase. These included four potential recipients, each with two directed donors. During the psychological assessment one potential recipient (2.1%) (psychiatric comorbidities) was excluded, and one potential donor (2.0%) withdrew (Fig. 2). Reasons for exclusion of potential recipients and donors in the preinclusion and selection phases of the Tübingen living-donor uterus transplantation program are summarized in Table 2.

Mean age (range) of potential recipients was 29.6 (19–41) years. Of the potential recipients in the trial selection phase, 39 (84.8%) had congenital AUFI, whereas 8 (17.3%) had acquired AUFI (Table 1). Furthermore, five potential recipients

FIGURE 2



Screening and selection of recipients and living donors for uterus transplantation.

Taran. Screening for uterus transplantation. Fertil Steril 2018.

(10.8%) had at least one child before applying for trial participation (Table 1). Mean age (range) of potential directed donors was 51.0 (31–67) years, and all donors had delivered at least one child.

Participation Phase

Table 1 also summarizes the characteristics of the 15 potential recipients with 16 directed donors included in the trial. One

TABLE 1

Characteristics of potential recipients and living donors included in the program selection phase and selected for program participation.

Characteristic	Recipients	Donors
Candidates included in the trial selection phase	46	49
Age (y)	29.6 (19–41)	51.0 (31–67)
Cause of AUFI		N/A
Congenital AUFI/MRKHS	39 (84.8)	
Acquired AUFI		
Hysterectomy for obstetric complications	3 (6.5)	
Hysterectomy for malignancy	2 (4.3)	
Hysterectomy for benign disease	3 (6.5)	
Prior children	5 (10.8)	49 (100)
Candidates selected for trial participation	15	16
Age (y)	28.9 (22–35)	51.3 (37–62)
BMI (kg/m^2)	21.6 (18.7–24.8)	25.2 (19.9–31.2)
Cause of AUFI		N/A
Congenital AUFI/MRKHS	14 (93.3)	
Acquired AUFI		
Hysterectomy for obstetric complications	1 (6.7)	
Race		
White	14 (93.3)	15 (94.0)
Asian	1 (6.7)	1 (6.0)
Menopausal status		
Premenopausal	15 (100)	9 (56.3)
Postmenopausal	0 (0)	7 (43.7)
History of smoking	6	5
No. of prior children, range	0–1	1–4
Marital status		
Married	6	10
Committed relationship	9	3
Divorced	0	3
Geographic origin		
Germany	13	12
United Kingdom	0	1
Switzerland	2	2
Vietnam	0	1

Note: Values are mean (range) or number (percentage). N/A = not applicable.

Taran. Screening for uterus transplantation. Fertil Steril 2018.

TABLE 2

Reasons for exclusion of potential recipients and donors in the preinclusion and selection phases of the Tübingen living-donor uterus transplantation program.

Preinclusion phase	n
Potential recipients meeting eligibility criteria	108
Excluded eligible potential recipients	57
Reasons for exclusion	
Age ≥39 y	16
No donor available	13
Parity ≥2	7
<5 y follow-up after malignancy	4
BMI ≥30 kg/m^2	4
No ovaries	4
Low AMH in combination with azoospermia	1
Single pelvic kidney	2
Abnormal karyotype	2
Pursuit of surrogacy	2
Self-withdrawal	2
Selection phase	
Potential recipients	46
Potential donors	49
Recipient–donor pairs pending completion of workup	7
Excluded recipients	3
Reasons for exclusion	
Low AMH in combination with azoospermia	1
Severe psychiatric diagnosis	1
Severe intraabdominal adhesions	1
Excluded donors	24
Reasons for exclusion	
ABO incompatibility	9
Donor-specific HLA AB	10
BMI ≥30 kg/m^2	2
Self-withdrawal	2
Withdrawal during psychological assessment	1

Note: AMH = antimüllerian hormone; HLA = human leucocyte antigen.

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potential recipient had two potential directed donors. Respective mean ages (ranges) of the potential recipients and donors included in the trial were, respectively, 28.9 (22–35) and 51.3 (37–62) years. Fourteen potential recipients (93.3%) had congenital AUFI, and one recipient (6.7%) had undergone hysterectomy for obstetric complications. More than half (56.7%) of the potential donors were premenopausal and had delivered between one and four children before expressing interest in trial participation. All donors had completed family planning.

DISCUSSION

The successful treatment of AUFI by UTx opens up new, fascinating horizons in modern women's healthcare. Our data strengthen the evidence that the number of potential candidates for inclusion in an LD-UTx program in Europe is not inconsiderable.

Recent publications from the teams behind the first UTx in the United States also demonstrated that interest in UTx was considerable, with more than 250 potential recipients and 272 potential recipients seeking participation in UTx clinical trials (9, 11). However, whereas congenital AUFI/MRKHS was the leading cause of AUFI in potential recipients (63.6%) in our cohort, the two studies from the United States reported high percentages of recipients (64.0% and 58.0%) with acquired AUFI. In concordance with our results, a French UTx study by Huet et al. (12) reported that in their observational study 75.5% of potential recipients had congenital AUFI/MRKHS.

The observed differences between the European and the United States cohorts can be explained in several ways. First, surgical or nonsurgical neovagina creation alone does not ensure a successful psychological outcome in women diagnosed with congenital AUFI (12). Several studies reported that infertility was one of the aspects of AUFI that women with the condition found hardest to accept and that childlessness caused great emotional distress in women with MRKHS (13). Moreover, even after neovagina creation, infertility greatly influences the further well-being of women with congenital AUFI (14). Until recently, the only options for women with congenital AUFI/MRKHS to achieve motherhood were adoption or the use of gestational carriers; however, the latter is currently illegal in Germany and, in fact, the majority of countries worldwide (3, 15). Against the background of such legislation, UTx is the only option these women will have in future to conceive and carry their own child. Hence UTx is, in our opinion, a viable alternative to adoption and cross-border reproductive care involving gestational surrogacy. Thus, interest in UTx may be greater in patients with congenital AUFI living in European countries.

Second, there may be differences between the United States and European countries regarding the indication for hysterectomy in women of reproductive age with presumed benign disease. As pointed out by Arian et al. (11), the culture of hysterectomy in the United States may lead to a bias about the predominant cause of acquired AUFI. However, the distribution from the French and our own cohort of potential recipients may also not reflect the true pattern of acquired AUFI because it is highly likely that the prevalence of hysterectomy for benign disease in women of reproductive age is higher than the prevalence of MRKHS (12). Finally, the fact that our group developed and optimized a minimally invasive neovagina technique and our Department created a Center for Rare Female Genital Malformations may result in additional bias regarding the number of potential applicants for UTx seeking treatment at our institution (16).

Similarly to the screening and evaluation process described by the Dallas group (9), our procedures were designed to progress from the least to the most invasive examinations so that unsuitable candidates (recipients and donors) would be detected as early as possible, to save time and costs. We also performed a psychological pretransplantation assessment as previously described (17), which primarily involved determining the suitability of the participants and ruling out individuals under severe psychological strain. Thus, all patients underwent an extensive psychological assessment, as a result of which one potential recipient (psychiatric comorbidities) and one donor (self-withdrawal) were excluded during the inclusion phase of our program. By contrast, none of the recipients or donors in the Dallas study were excluded on the basis of the psychological evaluation (9).

Several LD-UTx procedures have resulted in successful pregnancy and childbirth, rendering LD-UTx a viable option

for women with congenital or acquired AUFI. However, a series of medical and ethical challenges may yet occur that have not been fully clarified by other transplantation procedures (17–20). Nevertheless, in our opinion, UTx offers numerous advantages for women with congenital or acquired AUFI.

Our data strengthen the evidence that in Europe the number of potential candidates for inclusion in a LD-UTx program is not inconsiderable. However, the present data highlight the necessity to screen large numbers of patients with AUFI because more than 50% of potential recipients and donors were excluded for various reasons, mainly ABO incompatibility, unavailability of a directed donor, and self-withdrawal. Moreover, a meticulous preoperative screening process, including psychological assessment, is mandatory to maximize the safety of LD-UTx and the chances of a successful outcome. Further research in this field is warranted and should focus on improving the donor selection criteria, to prevent abortion of the UTx procedure, identify risk factors for graft rejection, define the waiting period before inducing pregnancy, and perfect minimally invasive organ retrieval in living-donor transplantation. Wide dissemination of screening and evaluation results will unquestionably help to improve the selection process as a whole.

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Cribado y evaluación de las potenciales receptoras y donantes para el trasplante de útero: resultados de un estudio observacional unicéntrico.

Objetivo: comunicar nuestra experiencia con el cribado y selección de posibles receptoras y donantes vivas con nuestro programa de trasplante de útero (TxU).

Diseño: parte de un programa observacional.

Entorno: hospital universitario.

Paciente(s): pacientes con infertilidad absoluta por factor uterino (IAFU).

Intervención(es): cribado por correo electrónico y teléfono, selección durante la consulta quirúrgica e investigaciones preoperatorias de acuerdo a un procedimiento de múltiples pasos para la donación en vida.

Medida(s) de resultado principal: edad, causa de AUFI, motivos de exclusión y evaluación preoperatoria.

Resultado(s): un total de 212 receptoras potenciales expresaron su interés en participar. Entre las 46 receptoras potenciales y las 49 donantes dirigidas, hubo 4 receptoras potenciales, cada una con 2 donantes dirigidas. La edad media (rango) de las posibles receptoras fue de 29.6 años (19–41). De las posibles receptoras, 39 (84.8%) tenían una IAFU congénita y 7 (17.3%) adquirida. Al final, fueron seleccionadas para participar 15 receptoras potenciales con 16 donantes dirigidas, teniendo 1 receptora potencial 2 donantes dirigidas. La edad media de las posibles receptoras incluidas fue de 28.9 años (22-35), y la edad media de la donante fue de 51.3 años (37-62). Catorce potenciales receptoras (93,3%) tenían IAFU congénita, y una potencial receptora (6,7%) había tenido una histerectomía por complicaciones obstétricas.

Conclusión(es): el número de posibles candidatas para el TxU no es despreciable, siendo la IAFU congénita la principal causa de IAFU en nuestra cohorte. Sin embargo, nuestros hallazgos resaltan que un gran número de pacientes con IAFU deben ser evaluadas, ya que nuestras tasas de exclusión fueron mayores del 50%, debido a la incompatibilidad ABO, a la falta de disponibilidad de una donante dirigida y a la autoexclusión del estudio. Además, es obligatorio realizar un meticuloso estudio preoperatorio, incluyendo una evaluación psicológica profundidad, para maximizar la seguridad de la donante viva y el éxito del TxU.