TRANSPLANT INTERNATIONAL

Transplant International ISSN 0934-0874

ORIGINAL ARTICLE

The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation

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Keywords
ethics, experimentation, infertility, reproductive endocrinology, uterus transplantation, uterine transplant, uterine factor infertility.

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Conflicts of Interest
The authors disclose no conflict of interest.

Synopsis: Uterine transplantation is under investigation for the treatment of uterine factor infertility. Before the transplant becomes standard practice, an ethical framework should be established.

Received: 13 September 2011
Revision requested: 21 October 2011
Accepted: 15 January 2012
Published online: 23 February 2012

doi:10.1111/j.1432-2277.2012.01438.x

Summary

Absolute uterine factor infertility (UFI) refers to the refractory causes of female infertility stemming from the anatomical or physiological inability of a uterus to sustain gestation. Today, uterine factor infertility affects 3–5% of the population. Traditionally, although surrogacy and adoption have been the only viable options for females affected by this condition, the uterine transplant is currently under investigation as a potential medical alternative for women who desire to go through the experience of pregnancy. Although animal models have shown promising results, human transplantation cases have only been described in case reports and a successful transplant leading to gestation is yet to occur in humans. Notwithstanding the intricate medical and scientific complexities that a uterine transplant places on the medical minds of our time, ethical questions on this matter pose a similar, if not greater, challenge. In light of these facts, this article attempts to present the ethical issues in the context of experimentation and standard practice which surround this controversial and potentially paradigm-altering procedure; and given these, introduces ''The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation'', a set of proposed criteria required for a woman to be ethically considered a candidate for uterine transplantation.

Introduction

Reproductive Endocrinology and Infertility (REI) is a continuously expanding discipline. Numerous technological advances in assisted reproduction, accompanied by a greater understanding of the factors that underlie human infertility, have allowed more women to conceive, proceed to gestation, and give birth to genetically related offspring. Still, absolute Uterine Factor Infertility (UFI), female infertility stemming from the anatomical or physiological inability of the uterus to sustain gestation (Fig. 1), remains one of the greatest challenges for couples and infertility specialists to overcome. The overall prevalence of UFI is approximately 3–5% of the general population [1], and it remains the primary infertility factor of a considerable proportion of the infertile population [2]. Excluding afflictions of congenital origin, conditions whose complications may lead to UFI tend to develop during a female's reproductive years and may be accompanied by adverse symptoms and outcomes, such as intractable pain, substantial bleeding, and malignancy potential. As such, these cases often result in hysterectomy, a dire measure that effectively deprives a woman from the future opportunity of bearing a child.

In the current state of reproductive medicine, should the desire to have more children exist, the only alternatives for women affected by UFI are surrogacy and adop-

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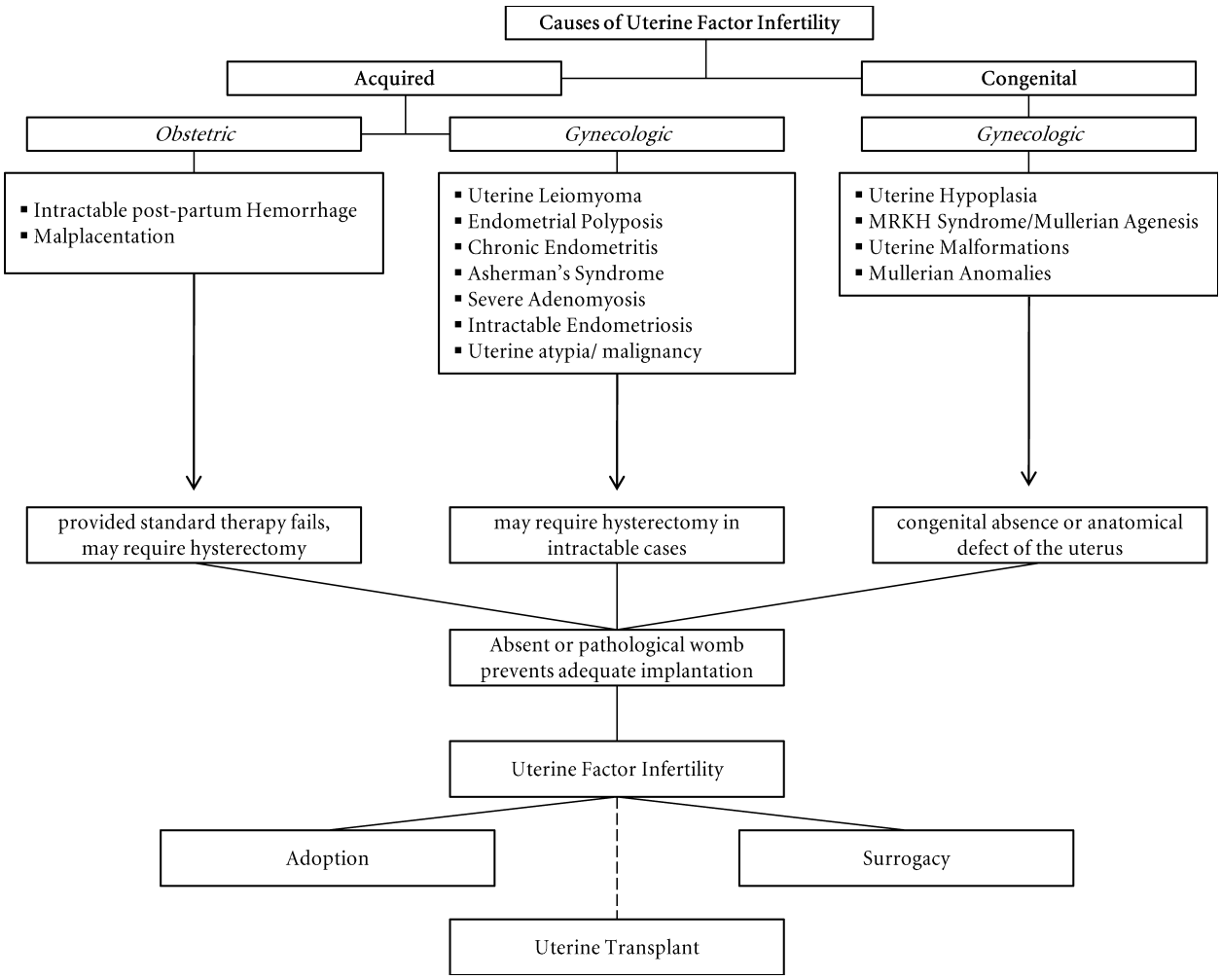

Fig. 1 Causes of uterine factor infertility.

tion, options that are not always viable given cultural, religious, legal, and personal concerns.

Despite the current state of affairs, REI research is on the cusp of soon providing a third alternative to women affected by UFI – the uterine transplant. Uterine transplantation (UTx) would allow females to receive an allogeneic uterus from a human donor to restore gestational ability in cases where the woman has a desire to undergo the experience of carrying a fetus, as well as a predilection not to seek adoption and surrogacy. Recent investigations into this new surgical solution using animal models have thus far shown promising results [3].

Notwithstanding the intricate medical and scientific complexities that UTx poses to the medical minds of our time, ethical questions on this matter arguably pose greater challenges. In light of this, this article has two objectives – first, the presentation of the ethical issues in the context of experimentation and standard practice which surround this controversial and potentially paradigm-altering procedure; and second, the introduction of ''The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation'': a set of proposed criteria required for a woman to be ethically considered a candidate for a uterine transplant.

The uterine transplant – a historical perspective

In 1966, Eraslan *et al.* [4] used female dogs to perform the first successful animal autotransplantation of the uterus. Despite multiple breakthroughs thereafter, uterine transplant research interest was lost to the onset of in-vitro fertilization in the 1970s [5]. Similar experiments did not occur until 2000, when the first human UTx was performed in Saudi Arabia on a patient whose own uterus had hemorrhaged after childbirth [6]. Ninety-nine days after the uterus was implanted, exploratory laparotomy confirmed uterine necrosis because of poor vascular reperfusion and anatomical support, leading to the prompt removal of the allograft.

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The case of UTx is particularly unique in that the first human trial of uterine transplantation preceded the first successful animal trial that used modern immunosuppressive therapy and led to gestation [3,6]. The human trial in Saudi Arabia, although successful for 3 months, deemed the woman eligible to receive the donated uterus based only on ABO compatibility, HLA tissue matching, and negative cytotoxic antibodies in the recipient. Of the nonmedical considerations, it is said that after ''thorough evaluation'', she was found to be eligible. As no mention of specific ethical considerations is made in the report [6] and advances have since been made [3], an ethical framework should be developed before UTx becomes standard therapy.

Since then, publications have documented successful pregnancies after syngeneic uterine transplantations in the mouse, and others have developed a surgical protocol for performing successful uterine allotransplantations in the ewe, rabbit, and swine models [1]. Most recently, Ramirez *et al.* [3] performed a uterine transplant in a sheep model, which successfully carried a pregnancy to a live birth.

Despite clear advances in transplantation science, a successful human uterine transplant remains to be carried out. The FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health intends ''to provide material for consideration and debate about [...] ethical aspects of issues that impact [...] women's health'' [1]. In 2008, FIGO provided a committee report on UTx, which deemed the procedure unethical, given the lack of data on safety and efficacy [1]. As documented advances have been made since [3], ''The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation'' is an attempt to begin where FIGO left off.

Clinical foundations

The ethical context of UTx is intimately affected by key clinical questions: Is it 'surgically appropriate' to perform UTx? What medical harm could transplantation pose for the fetus? How will the biophysiological impact of UTx on fetal development be assessed? Of particular relevance is the implicit clinical consideration that unlike organs, such as the heart, liver, and kidneys, which are considered physiologically vital for life, the uterus is clinically regarded as a 'non-vital' organ [7,8]. Pursuant to this consideration, there is inherent legitimacy in approaching the topic of UTx with the same clinico-ethical framework currently shaping the transplant of other nonvital organs, such as the larynx and face [9], the increasing acceptance of which creates a precedence for the acceptance of the UTx in principle. From a clinical perspective, the increasing prevalence and acceptance of nonvital transplants has given rise to strong arguments in favor of supporting such procedures. Propounding reasons include but are not limited to our growing arboretum of solutions to the technical challenges of the associated perioperative care for these procedures, the promising research being amassed in respective surgical fields, and the shifting societal perspectives and positions on what is considered acceptable surgical risk for such procedures [10]. Hence, irrespective of the plausible psycho-emotional value a uterus may have for women in the context of parturition, there is a strong ground for acceptance of UTx on the surgical basis that the uterus is an organ amendable for transplant.

Addressing the clinical legitimacy of UTx, it is important to then consider the practical question of how requisite transplant immunosuppression would affect pregnancy and what risks post-transplantation organ management and care would pose to the developing fetus. A deep body of evidence and literature has established no statistically significant increase in the incidence of newborn malformation in the post-transplant setting of many solid organs. Reports from the National Transplantation Pregnancy Registry (NTPR) and others strongly support maintenance of immunosuppression combination therapy regimens during pregnancy [11–13]. Although malformation and development risk has been reported for certain regimens, the flexibility of available low-morbidity immunosuppression protocols used with other organ transplants suggests that UTx regimens could be formulated to minimize gestational harm [11].

Moreover, no transplanted organ nor post-transplant management care has consistently demonstrated any major morbidity risks to patients apart from the possible accepted sequelae of maintaining the patient in an immunosuppressive state [13]. There are no intrinsic pathophysiologically specific qualities to the healthy uterus which would exacerbate an immunosuppressive state or make a patient less fit in the post-transplant setting, thus it is unlikely that clinicomedical facets of UTx should confer frank morbidity risk to either the patient or fetus [14,15]. If the transplantation procedure, the care surrounding transplant and the uterus itself do not affect the post-transplant clinical course more adversely than what is observed in other transplant procedures, then we conclude that neither will the technical aspects of a UTx procedure and the subsequent requisite immunosuppression.

It is profoundly important to consider that part of the ethics surrounding UTx will be irrevocably linked to our surgical scope and capacity to perform the procedure. Changes in societal perspectives on the ethical dilemmas of many procedures have shifted opinion from ensconcement in athwart views based on patient safety, social impact, and management of healthcare resources to views based on increased access, decreased cost, lower morbid-

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ity, better long-term outcomes and more effective technology [16]. Arguably, the same transition may take place with UTx.

Ethics in the context of experimentation

Moore defined the criteria for ethical analysis of surgical innovation [17]. These criteria have three components: laboratory background, field strength, and institutional stability. The first, laboratory background, mandates that the research foundation for the procedure be sound. The second, field strength, requires the adequate synthesis of knowledge and expertise from all fields related to the procedure. The last criterion, institutional stability, addresses the overall level of expertise in the institution in which the procedure is performed; this includes all clinical services, how well they function in an interdisciplinary manner, and the quality of the support services available to patients. For a UTx to be ethically acceptable, all these criteria must be satisfied transparently and through public evaluation.

Initially, UTx in humans will be carried out only in the context of research, as an innovative surgical procedure. If studies find UTx to be safe and effective in allowing women to carry and give birth to viable children, then and only then will UTx be an option for women in a context other than research. We will first discuss the problems specific to UTx in a research context, and then discuss how the ethical issues change if UTx is found to be safe and effective.

Research differs fundamentally from clinical care in that clinical care concerns itself only with the welfare of the patient, whereas research aims to aid all persons for whom the findings will benefit and inform. Therefore, if a researcher is to properly consent a woman for participation in a trial of the surgical viability of UTx, it must be done not to primarily help a particular woman carry a baby, but rather to work toward allowing the general population to one day have UTx as an option.

Informed consent is important in clinical practice; it is even more so in clinical research. This is because of the differences elucidated above. For consent to be valid, the ethicist Freedman requires that the consenting person be responsible enough to consent (i.e. competent), informed enough to make a responsible decision, and not under coercion [18]. A consenting subject must understand the potential risks and benefits of the intervention and be able to make sense of the chances of success and failure. In most clinical trials, the subject usually has a certain condition that requires treatment, and he or she must understand that one treatment is considered standard therapy with well-established statistics of risk and benefit, whereas the other treatment is in theory sound and in practice hopeful. In contrast, subjects of UTx trials will have UFI, a condition that does not require medical intervention to reduce morbidity or mortality. It is on this basis that Catsanos *et al.* consider these subjects closer to healthy research volunteers than patients turned subjects [19]. Their decision to participate in research will be socially and emotionally motivated, not medically indicated. On this basis, and on the innovative surgical nature of the proposed intervention, the informed consent of these subjects will likely be more problematic than otherwise.

A consenting subject for a UTx trial must understand the harm they may incur and the low chance of success. As human UTx has only been reported successfully once to date, subjects of early trials should have low expectations with regard to the chances of carrying and giving birth to a healthy baby. Healthy volunteers for research expect no benefit, and as was previously discussed, women in early trials should expect the same. This aspect may be especially problematic for this population. Rather than making an altruistic or a personal health-motivated decision, these women are making an emotional and social decision to attempt to carry a baby in an implanted uterus rather than to have a baby by adoption or use a surrogate, if available. Their consent must therefore be ensured to be as informed and reasonable as possible. UTx does not offer women the opportunity to *have* a baby, but rather to carry a pregnancy; this is an important distinction to understand. Subjects must also understand that should the surgery be successful, the pregnancy will not be an *ordinary* pregnancy. The uteri will not be innervated, so women will not feel fetal movements or contractions. They will require cesarean sections to deliver, and so will not experience a vaginal birth, either [19]. These distinctions will be critical to understand in a woman consenting after clinical trials have concluded, as well.

Investigators are bound by the principles of nonmaleficence and respect for persons not to propose an experimental procedure that will cause more harm than good – this is the basis for requiring that the trial meet the Moore criteria prior to beginning human trials. Investigators have more leeway in trials on healthy volunteers, as such trials are not expected to benefit and are anticipated to have potential consequences. However, the ''standard of care'' for women with UFI who wish to have a baby is to offer adoption services and surrogacy options. The principle of clinical equipoise requires trials to compare interventions such that the superior intervention between the trial arms remains unknown in advance, but rather is in a state of indeterminacy in the general clinical community [20]. Kukla *et al.* ground this principle in the established principles of justice and respect for persons [21]. No clinician would argue that UTx is potentially superior

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to adoption or surrogacy in terms of efficacy, safety, or expediency. However, as was discussed in the previous paragraph, the proper question is whether UTx is superior in allowing a woman the opportunity to *carry a pregnancy* – in this respect, UTx has potential for superiority. Finally, investigators in early human trials of UTx will be forced to decide whether they can ethically offer an option that has significant risk of harm with little potential medical benefit. Informed consent alone does not absolve investigators of their duty to minimize harm. However, the potential benefits lie in the rationale for considering UTx in the first place: there are women with UFI who have a strong emotional and social desire to carry a pregnancy. On these bases, investigators in trials of UTx can ethically admit subjects into their trials under the assumption that proper animal trials have found that the procedure is reasonably effective and safe.

Ethics in the context of standard practice

Assuming that clinical trials of UTx will be ethically carried out, and assuming that they find UTx to be safe and effective in allowing women with UFI to carry a baby, there are still ethical dilemmas to tackle. Consider the medical and psychological consequences of donating a uterus for transplant. If the donor is deceased or ''brain-dead'', someone who has perhaps given consent in advance of irreversibly losing their ability to use their body, these consequences are inconsequential. However, if the donor is a live donor, issues arise with informed consent of the donor relating to organ donation in general and specific to the donation of a uterus.

The medical community accepts many different types of transplantations as standard practice – UTx would be unique in several respects. The liver's ability to partially regenerate allows for a low rate or morbidity and mortality for donors [22]. A single kidney can be donated without much clinical significance if no harm comes to the other kidney [23]. A uterus, however, cannot be regenerated, and although the clinical significance of living without a uterus is minor, there are emotional and practical consequences to uterus donation; loss of gender identity and effects on sexuality are among the consequences described [24,25].

Organ donors in general experience not only risk to their physical health, but risk to their mental health as well; indeed, some authors suggest that the mental health risk is greater than the physical [26]. Depression, anger, disillusionment, and a sense of betrayal have been noted among kidney donors after donation [27]. Even suicides have been recorded, as the donor becomes inextricably tied to the recipient's outcome [28]. The principle of autonomy obliges others to allow persons the right to make choices for themselves; a prospective donor's decision to undertake the risks of donation must be, in general, respected. However, the principle of nonmaleficence requires the treating team to deny a prospective donor whom they believe to be at high risk of severe negative consequences. Psychological screening, follow-up, and ongoing care are critical to an ethical approach to live organ donation.

An ideal live donor would be one who is of childbearing age without a previous history uterine disease or trauma, to maximize recipient fecundity. If a woman is of childbearing age, but has repeatedly attested that she has concluded her parity, she may choose to be a uterus donor. This decision, if carried out, would be completely irreversible barring submitting herself to receiving a uterine transplant; there is therefore real risk that such a woman would regret her decision at a later date. Indeed, men who receive vasectomies are usually sure of their decision at the time, but are often grateful for the fact that vasectomies tend to be reversible should they decide to have children later on [29]. Finally, there is data suggesting that posthysterectomy, women experience a decrease in sexual satisfaction [30] and an increase in sexual dysfunction [31]. To ensure that prospective donors make informed, autonomous decisions, there is an added impetus to give a potential uterus donor both comprehensive information relating to giving up a healthy uterus and time to consider such a significant and irrevocable decision.

Receiving a donated organ can carry colossal risks. Due to the adverse effects of immunosuppression, as well as the risks associated with organ transplant rejection, organ recipients have been documented to be at a higher risk of developing diabetes mellitus [32] and malignancies [33], among other conditions. There are psychological risks as well: the complex relationship that develops between a donor and recipient can contribute to ''shame, anxiety… and guilt over involving another healthy individual in their plight'' [26]. This is a particular concern in UTx, in which sexual and reproductive identity play a significant role. In light of this, it is even more important to safeguard the principle of anonymity of donor and recipient in cases where those involved are not friends or family or do not wish to be identified.

Some receivers of organ donations benefit from the practical advantages of having their missing organ replaced, but fail to bond emotionally with their new organ, that organ causing a failure of assimilation into the person's body identity. Organ recipients can experience a change in personal identity and subjectivity [34]. In the case of UTx, there is the added danger of potentially failing to emotionally identify with the baby born of the transplanted uterus, despite its genetic relation. These potential issues necessitate even greater counseling and psychological consultation to avoid or reduce their incidence.

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Assuming that a human uterine transplant is shown to lead to a viable gestation and is proven to be medically safe for the mother and fetus, a woman may be considered as a candidate for a uterine transplant if and only if all of the following criteria, as they pertain to three distinct groups, are met:

1. The recipient
    a. is a genetic female of reproductive age with no medical contraindications to transplantation,
    b. has documented congenital or acquired UFI which has failed all current gold standard and conservative therapy,
    c. (**c1**) has a personal or legal contraindication to surrogacy and adoption measures, or (**c2**) seeks the UTx solely as a measure to experience gestation, with an understanding of the limitations provided by the UTx in this respect,
    d. has not had her decision to undergo UTx deemed as irrational expert psychological evaluation,
    e. does not exhibit frank unsuitability for motherhood, and
    f. is responsible enough to consent, informed enough to make a responsible decision, and not under coercion.

2. The donor
    g. is a female of reproductive age with no medical contraindications to donation,
    h. (**h1**) has repeatedly attested to her conclusion of parity, or (**h2**) has signed an advanced directive for post-mortem organ donation,
    i. has no history of uterine damage or disease, and
    j. is responsible enough to consent, informed enough to make a responsible decision, and not under coercion.

3. The health care team
    k. is part of an institution that meets Moore's third criteria as it pertains to institutional stability,
    l. has provided adequate informed consent to both parties regarding risks, potential sequelae, and chances of success and failure,
    m. has no conflict of interest independently or with either party, and
    n. has the duty to preserve anonymity if the donor or recipient do not explicitly waive this right.

Fig. 2 The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation.

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As was alluded to earlier, it is critical in a physician's evaluation of the patient to assess the patient's reasons for wanting a UTx. If the reason is that the woman would like to carry a pregnancy, then UTx is a good option. If the reason is that the woman would like to simply have a child, then UTx, with its concomitant risks of surgical complications, infections, malignancies, and psychological consequences, is not a good option. If the reason is that the woman would like to feel fetal movements or contractions, or that she would like to have a vaginal delivery, then the woman may not be well informed. Consequently, given the medical, social, economical, and emotional risks of UTx, the physician must be acutely sensitive when listening to the patient's rationale for seek-

Against UTx:

Principle of non-maleficence

- requires persons to refrain from causing others harm
- opposes UTx, as UTx involves bodily and potentially psychological harm of recipients and donors
- encourages extensive research of potential risks to the donor, recipient, and fetus
- promotes stringent medical and psychological evaluation of UTx candidates prior to approval

In favour of UTx:

Principle of autonomy

- asserts the right of persons to make their own choices, and mandates that others respect these choices
- the principle of autonomy gives rise to the right to self-determination, including in the dominion of one's body
- supports UTx, as UTx performed in the context of proper informed consent respects the donor and recipient's right to govern their own bodies and reproductive potential

Equivocal regarding UTx:

Principle of beneficence:

- encourages persons to do good for others
- depends on the particular instance of UTx (the specific donor, recipient, and health care team)
    - if the Montreal Criteria are met, then the authors of this paper believe that the UTx does more good than harm
    - if the criteria are not met, then the authors believe that UTx would be unacceptably harmful

Principle of justice:

- promotes the equality of persons, the right to equal access to opportunities offered and the right to be given one's due
- requires that the participants of clinical trials be part of the population that will benefit from the research
- recommends that UTx be offered to all appropriate candidates, if it is found to be safe and effective

Fig. 3 Ethical principles and uterine transplantation.

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ing the procedure, and may choose to involve expert psychological evaluation if her rationale seems misguided or irrational.

A woman who uses UTx to carry a pregnancy to a successful delivery will face the responsibility of raising a child. To some extent she must therefore be socially, economically, physically, and psychologically fit to raise a child. In terms of expert evaluation for this fitness, there are two precedents to draw from, namely, the two fields that UTx relates to most, REI and transplantation medicine. REI does not as a policy exclude women from treatment for infertility for social, economic or psychological reasons, whereas transplantation medicine does, as in the case of alcoholics requiring liver transplants [35]. These authors recommend denying UTx or offering remedial support to women with frank unsuitability for parenthood, but at this point stringent evaluation of suitability for motherhood appears unwarranted and a potential encroachment on the candidate's dignity and right to reproduction.

Ethical foundations

The fundamental ethical tension in the debate on UTx is drawn between the principles of autonomy and nonmaleficence. Some would argue that the physician's duty to minimize harm prevents him or her from performing a UTx, a procedure with potential harm and no clear clinical indication. The autonomous person, others would contend, has the right to choose the risks they undertake. A woman with UFI and the opportunity and desire to receive a UTx arguably exerts an ethical obligation on others to facilitate actualization of her reproductive potential, based on the right to reproductive self-determination that springs from the principle of autonomy. In the end, the principle of beneficence compels the physician to weigh the potential psychosocial benefits of UTx to a particular candidate with the biophysical risks she will be exposed to by the procedure. The set of criteria offered by this article furnishes the physician with a framework to make this evaluation.

Given the biopsychosocial risks and consequences of UTx on the recipient, donor, and potential developing fetus, it is valuable to explicate how the desire to experience gestation is enough to justify UTx. First, UTx will only be available in a clinical setting after research finds it reasonably safe. Second, women with pre-existing medical conditions that pose dangers to them or their fetuses are allowed to use Assisted Reproductive Technology, despite the fact that their pregnancies will be higher risk. Third, other non-life saving transplantations (such as transplantations of hands, faces, or larynxes) are justified by patients' nonclinical desires. Finally, donors of other organs can subject themselves to risky surgeries and postsurgical sequelae if they so desire and are well informed. The desire to experience gestation is therefore sufficient to justify the potential negative consequences of UTx.

The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation

Based on the aforementioned ethical issues and the prediction that the human UTx will soon be proven safe and effective [36], the authors propose the creation of a set of criteria required for a woman to be ethically considered a candidate for UTx. These principles are grouped according to three distinct entities: the recipient, the donor, and the treating health care team. Collectively, these criteria are termed ''The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation'' (Fig. 2). These criteria dictate that an instance of UTx can be considered ethical only if each individual criterion is met. Hence, any situation where an individual criterion is not met should be considered an ethical contraindication to UTx.

Conclusion

The uterine transplant is a procedure that currently lies in the womb of human transplantation science. As the techniques develop and potential effects on the recipient, donor, and fetus are better understood, the human uterine transplant is likely to become a reality of our time, and perhaps one day the gold standard therapy for absolute uterine factor infertility. In this article, we explore the ethical issues and provide an essential perspective that we hope will serve clinicians and investigators interested in the matter. Indeed, ''The Montreal Criteria for the Ethical Feasibility of Uterine Transplantation'' is an attempt to foster interest in the transplant, and facilitate transition from an experimental phase to standard practice with regards to the nonmedical intricacies of the procedure.

Authorship

AL: developed the ethical sections, as well as the criteria. ME: developed the clinical foundation section and contributed to the discussion of the topic. JB: conceived the study question and developed the background and historical sections, as well as the criteria.

Funding

The authors have no funding to declare.

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