



Uterus transplantation in France: for which patients?



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ABSTRACT

Objective: Uterine infertility (UI), which can be caused by a variety of congenital or acquired factors, affects several thousand women in Europe. Uterus transplantation (UTx), at the current stage of research, offers hope for these women to be both the biological mother and the carrier of their child. However, the indications of UTx still need to be defined. The main aim of the study was to describe the different etiologies of UI and other data as marital and parental status from women requesting UTx who contacted us in the framework of a UTx clinical trial. Secondly, we discussed the potential indications of UTx and their feasibility.

Study design: This is an observational study.

Results: Of a total of 139 patients with UI, 105 patients (75.5%) had uterine agenesis, making it the leading cause of UI in this sample. Among the patients with uterine agenesis, 25% had a solitary kidney and 44.7% had undergone vaginal reconstruction. Peripartum hysterectomy, hysterectomy for cancer, and hysterectomy for benign pathologies accounted for 9.4%, 7.2% and 5% of cases, respectively. Less common causes of UI included complete androgen insensitivity syndrome (2.2% of patients) and prenatal diethylstilbestrol exposure (0.7%). Approximately 14% of the women already had at least one child and 66% were in a couple living together for at least 2 years.

Conclusion: UTx is still under evaluation and further research is under way. Nulliparous patients with no major medical or surgical history and with normal ovarian function, who meet the legal criteria for medically assisted reproduction, represent the best indications for UTx at this stage of its development.

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Introduction

Uterine infertility (UI) affects several thousand women in Europe [1]. In France, the only option available to these women is

adoption, as gestational surrogacy is prohibited. Uterus transplantation (UTx), at the current stage of its development, offers hope for patients with UI to be both the biological mother and the carrier of their child [2]. To date, thirteen UTx procedures have been carried out worldwide: nine in Sweden [1,3], one in Saudi Arabia [4], one in Turkey [5] and more recently one in China (data from UTx congress, Goteborg, January 2016) and one in the US. Five successful pregnancies have ensued, all from the Swedish trial, for a success rate of 38%. According to the available data, four uteri

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had to be removed, i.e. 33% of cases: one in Saudi Arabia, one in the US and two in Sweden. These observations confirm the need to study UTX in the framework of a clinical trial.

The causes of UI are varied. Absolute UI refers to the congenital or acquired absence of a uterus, while non-absolute UI refers to a uterus which is present but non-functional. The preferred indications of UTX have yet to be defined. Among the thirteen reported cases of UTX, eleven were in patients with uterine agenesis or Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome. The other two were performed in women who had undergone hysterectomy for cervical cancer and due to postpartum hemorrhage.

The main aim of the study was to describe the different etiologies of UI and other data as marital and parental status from the contacts we made with patients requesting UTX during the screening phase of an ongoing clinical trial on UTX from brain-dead donors. Secondly, we provide an overview of UI and discussed the potential indications of UTX and their feasibility.

Patients and methods

This is a French preliminary observational study in women with UI requesting UTX. As part of the pre-inclusion phase of the ATU clinical trial (uterine allo-transplantation with brain-dead donor, clinical trial no. NCT02637674), patients with UI contacted us if they were interested in participating in our study.

The following data were collected prospectively: age, body mass index (BMI), cause of UI, marital status (married, civil union, couple living together >/<2 years, single), obstetrical history, parental status and smoking status. For patients with MRKH syndrome, the vaginal reconstruction technique (if performed) and presence of renal abnormalities were also collected.

Data were collected by email, phone, or during the information meetings. Data were recorded anonymously. Qualitative data are expressed as percentages.

The discussion of the potential indications of UTX took place with the French uterus transplantation study group (CETUF: T Gauthier, JM Ayoubi, V Lavoué, O Garbin, P Collinet, A Agostini) under the aegis of the National College of Obstetricians Gynecologists (CNGOF).

Results

A total of 139 women from all over France who were candidates for UTX contacted us. The characteristics of these patients are shown in Table 1. The mean age and mean BMI were 30.7 years (18–42) and 23.7 kg/m² (14.9–38.3), respectively. Twenty-six patients (18.7%) were active smokers.

Among the 105 MRKH patients, a third had undergone renal imaging. Eight patients (25%) had a solitary kidney and 47 patients (44.7%) had undergone vaginal reconstruction. Among the different techniques for creation of a neovagina, sigmoid colpoplasty accounted for close to 50% of cases (23 patients, 48.9%). For these 23 patients, colpoplasty with vulvar flaps, with the Vecchietti technique [6] or with the Davidoff technique [7], was performed in 10.6% (5 patients), 10.6% (5 patients) and 6.3% (3 patients). For 10 patients the surgical technique used was not known.

Among the 10 hysterectomies for cancer, four involved ovarian cancer, three cervical cancer, one bladder sarcoma and one choriocarcinoma. Five of these patients also had bilateral adnexectomy; this information was not known for the other five. The mean time between hysterectomy and the UTX trial was 8.37 years (3–23 years).

Of the 114 patients who indicated their marital status, 108 were in a couple living together and 6 were single. The relationship was considered stable in 66.1% of cases. The 14.3% of patients who already had a child either had it naturally (16 cases), through adoption (2 cases) or via a surrogate mother in another country (2 cases).

Comment

This observational study suggests that the number of potential candidates for UTX in France is not inconsiderable. MRKH syndrome was the leading cause of UI in this study, whereas acquired forms of absolute UI were only seen in a minority of patients.

However, this distribution does not reflect the prevalence pattern of UI. In fact, despite the absence of registries, it is highly likely that the prevalence of hysterectomy in women of childbearing age is higher than that of MRKH syndrome. The annual incidence of MRKH syndrome is 1 in 4500 births, or about 80 cases per year in France, although no precise figures are currently available and the reference used by the authors is old [8]. Furthermore, the number of peripartum hysterectomies is estimated at several hundred per year. French data from the PITHAGORE 6 trial indicate an incidence of hysterectomy of 5 in 10,000 deliveries, or approximately 1% of postpartum hemorrhage cases [9].

The reason why so many MRKH patients show a keen interest in UTX can be explained in several ways. First of all, these patients are all nulliparous. Secondly, UTX can help fulfill their quest for normalcy [2]. Thirdly, these are women with a rare disorder, and the prospect of UTX engenders solidarity between them [2]. Although MRKH patients are candidates for UTX, it is important to determine whether UxT can be envisioned in these cases. To date, of the thirteen cases of UTX reported worldwide, eleven concerned

Table 1
Characteristics of patients with UI.

Data of patients with UI	Total: 139 patients	Percentage
MRKH syndrome	105	75.5%
Complete androgen insensitivity	3	2.2%
DES syndrome	1	0.7%
Peripartum hysterectomy	13	9.4%
Hysterectomy for fibroids	7	5%
Hysterectomy for cancer	10	7.2%
Marital status		
Married/civil union/living together ≥2 years	92 patients	66.1%
Single/living together ≤2 years	22 patients	15.8%
Missing data	25 patients	17.9%
Parental status		
≥1 child	20 patients	14.3%
No children	96 patients	69%
Missing data	23 patients	16.5%

UI, uterine infertility; MRKH, Mayer–Rokitansky–Küster–Hauser; DES, diethylstilbestrol.

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