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Hormonal intrauterine device in women with renal transplantation: a prospective observational study

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SUMMARY

OBJECTIVE: The main objective of this study is to evaluate the rate of continuity and satisfaction with hormonal intrauterine device in renal transplant recipients.

METHODS: This was a prospective observational study. The sample consisted of patients treated at a Family Planning Outpatient Clinic, from August 2016 to September 2021. Information on each patient's age, parity, and associated diseases as well as satisfaction with the method were analyzed. Patients were invited to participate through electronic messages, and the questionnaire included questions about acceptance of the contraceptive method.

RESULTS: A total of 40 patients were included in the study. The mean age of the renal transplant patients was 32.5 years. The mean duration of hormonal intrauterine device use was 37 months. Acceptance of the method was high, with 97.5% of patients remaining on the method for 1 year and 85% of patients using the hormonal intrauterine device at the time of the study. There were no pregnancies or renal transplant complications in the study. Regarding satisfaction with the method, the majority (77.5%) scored 10.

CONCLUSION: Patients were satisfied or very satisfied with the hormonal intrauterine device. Therefore, the continuation rate was high. Furthermore, this contraceptive method proved to be safe and effective in kidney transplant recipients. No complications, graft rejection, or graft failure were observed after intrauterine hormonal device insertion and during follow-up.

KEYWORDS: Renal transplantation. Contraception. Medicated intrauterine devices. Levonorgestrel. Satisfaction.

INTRODUCTION

Chronic kidney disease (CKD) is a severe, progressive, and terminal pathology of the organ, besides being associated with high morbidity and mortality[1]. According to national data, Brazil occupies a prominent position in the world with the absolute number of kidney transplants (among 35 countries), which is almost 6,000 renal transplants per year[2].

Women represent about 47% of organ recipients, and it is estimated that 40% of them are of childbearing age, i.e., between 18 and 49 years. The median age of patients who received transplants in recent years was 37.9 years, ranging from 23 to 55 years[2]. The degree of sexual dysfunction in women and men with CKD ranges from 20 to 80% depending on the site studied. In women, menstrual irregularity and infertility are most commonly reported.

Renal transplantation improves health outcomes and quality of life[3,4]. After transplantation, women are more likely to become pregnant due to the rapid resumption of renal and endocrine function, which improves fertility[4,5]. There is a tendency toward hormonal normalization, leading to an adequate reproductive physiology. Thus, menstruation and ovulation may return 1–2 months after transplantation, thereby increasing the risk of unplanned pregnancy[4,5].

Women are advised to wait 18–24 months before trying to conceive, as this period allows for graft stabilization, institution of immunosuppressive therapy, and completion of infection prophylaxis. This advice is valid if there are no complications and there is a desire to conceive[6-8]. Therefore, because of the short time interval between transplantation and fertility restoration, effective contraception should be discussed, counseled, and started soon after surgery or ideally before surgery[8,9]. These measures would reduce the complications and adverse events that can occur during pregnancy after renal transplantation. Other concerns include the use of antihypertensive and immunosuppressive drugs, which are often unsafe during pregnancy[10-12].

Renal transplant recipients should be counseled to use safe and highly effective methods, including long-acting reversible contraception: hormonal intrauterine device (levonorgestrel), non-hormonal intrauterine device (copper), and subdermal

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implant[9,13-15]. Although there is consensus on the need for appropriate contraceptive methods in solid organ transplant recipients, there is less evidence to support their efficacy and safety[9,14-16]. The World Health Organization (WHO) neither includes organ transplantation among its eligibility criteria nor describes guidelines for its prescription[17].

Given the importance of the issue, the growth in the population of transplanted women, and the lack of studies, we decided to evaluate the effects of the hormonal intrauterine device in renal transplant patients and their quality of life.

METHODS

This was a prospective observational study, with qualitative and quantitative approaches. The sample consisted of patients who attended the Family Planning Outpatient Clinic of Hospital São Paulo, Federal University of São Paulo, from 2016 to 2021 and who accepted the invitation to participate in the research. All kidney transplant patients with hormonal devices who accepted the invitation to the research were included, and only women who did not have knowledge of Portuguese language were excluded.

Data collection was done through medical records and the database of the Family Planning Outpatient Clinic. The main objective was to select and quantify the number of renal transplant recipients who accepted the hormonal intrauterine device as a contraceptive method, thus evaluating its acceptance rate and continuity. In addition, some variables were analyzed within the group in order to characterize the population using hormonal devices, such as age, ethnicity, number of pregnancies, number of children, comorbidities, time of kidney transplantation, complications with transplantation after insertion of the method (rejection of transplantation, occurrence of comorbidities, pelvic infections, etc.), duration of method use, adverse symptoms after its insertion, continuity, and satisfaction.

Patients were invited to participate in the survey through electronic messages. The women who were interested received a free informed consent form that explained the objectives and benefits of the research. Risks associated with participating in research in a virtual environment and by electronic means, such as the limitations to ensure confidentiality and the potential risk of violation, were also mentioned.

Invited patients who agreed to participate received a questionnaire sent by electronic media, containing 16 questions about the knowledge and acceptance of the long-acting reversible contraception methods (through a score from 0 to 10), as well as the possible side effects and its continuity rate. The medical records of each patient were also analyzed.

RESULTS

A total of 290 renal transplant patients were identified in our outpatient clinic who were being monitored. Among them, we evaluated those who chose the intrauterine hormonal device as a contraceptive method, which totaled to 47 patients (16%). The other 243 (83.7%) chose injectable contraceptives, oral contraceptives, or subdermal contraceptive implants. Of the 47 women who chose an intrauterine hormonal device, 40 patients were included in the study. Among the remaining seven patients, three patients were excluded due to data entry errors, and four patients were excluded due to patient refusal, hospital follow-up, and unsuccessful telephone contact.

The age of the patients at the time of the study ranged from 17 to 48 years. The mean age of the patients in the study was 32.5 years. In this group, the majority (60%) were under the age of 35 years. Out of 40 patients surveyed, 18 (45%) identified themselves as white, 17 (42.5%) as mixed race, and 5 (12.5%) as black (Table 1). Among the patients studied, 20 (50%) reported chronic hypertension and 9 (22.5%) reported diabetes mellitus. These were the most common diseases identified in the group. No patient reported the appearance of a new pathology or worsening of comorbidities after intrauterine hormonal device insertion. Regarding obstetric history, 15 were nulliparous (38%), 12 were primiparous (30%), and 13 (33%) were multiparous. The incidence of previous miscarriage in this population was 20% (8 patients) (Table 1).

The time of renal transplantation was analyzed in months. All intrauterine hormonal devices were placed after transplantation. The mean time from transplantation to device insertion was 65 months. Among the patients, only one (2.5%) had the intrauterine hormonal device inserted less than 2 years after

Table 1. Baseline demographic characteristics of 40 patients with renal transplantation and hormonal intrauterine device.

Age (mean)	32.5 years	
	n	%
Race or ethnicity		
White	18	45
Non-white	22	55
Previous pregnancies		
0	15	38
1	12	30
≥2	13	32
Parity		
0	16	40
1	16	40
≥2	8	20

transplantation, 22 patients (55%) between 2 and 5 years after transplantation, and 17 patients (42.5%) more than 5 years after transplantation.

The mean duration of method use was 37 months. Among the 40 patients, the majority (85%) had received an intrauterine hormonal device in 2 years or more previously. Most users had remained with the intrauterine hormonal device for more than 2 years, indicating good acceptability. Out of six patients who were not using the intrauterine hormonal device at the time of data collection, three had expelled and refused reinsertion, two patients opted for removal because of colic, and one patient opted for removal because of irregular vaginal bleeding. Of the expelled intrauterine hormonal device, one was in the first month and two were after 2 years of use (Table 2).

No patient developed graft rejection or graft failure after insertion of the hormonal intrauterine device. Only two patients reported recurrent urinary tract infection as a complication, and there were no pregnancies among women using the hormonal intrauterine device. Thus, the continuation rate in the first year of use was 97.5 and 85% of patients continued to use the method up to the time of the study, demonstrating a good rate of acceptance and continuation. In terms of satisfaction, 97.5% of renal transplant patients were satisfied or very satisfied with the use of this method.

DISCUSSION

This study supports the safety and efficacy of the hormonal intrauterine device in renal transplant patients. A total of 40 patients were analyzed for an average period of 37 months, forming a sample to compile data and results. The most significant study about this topic was published by Juliato et al.[16] with a cohort of 23 patients, which concluded the safety of using this method in kidney transplant recipients, even when taking immunosuppressive drugs. Despite the clear need for contraception after organ transplantation, the WHO does not yet provide guidelines on the medical appropriateness of contraceptive use in solid organ transplant recipients[17].

Table 2. Time of use of the hormonal intrauterine device and adverse symptoms of 40 patients with renal transplantation and hormonal intrauterine device.

Time of use	Months	n	(%)
≤2 years		6	(15)
2–5 years		32	(80)
≥5 years		2	(5)
Mean time	37		
Expulsion		4	(10)
Reinsertion		2	(5)
Adverse symptoms			
Colic pain		5	(13)
Vaginal bleeding		3	(8)
Recurrent urinary infections		2	(5)

In 2009, the American College of Obstetricians and Gynecologists published a committee opinion endorsing and recommending the use of long-acting methods in this group. These guidelines were well-positioned in 2016 by the U.S. Centers for Disease Control and Prevention, which recognized that solid organ transplantation is a condition associated with the risk of serious adverse events in pregnancy, and stated that long-acting reversible contraception is highly effective and may be the best choice for women in these circumstances[18].

A study published by Ramhendar et al.[14] conducted a 10-year retrospective analysis of 11 renal transplant patients using an intrauterine hormonal device and proved that none of them failed the method or had any type of infection. As mentioned in the study by Dumanski et al.[4], the highest rate of clinical complications after renal transplantation occurs in the first year. Therefore, the necessity for contraception should be guided as early as possible in these patients. The ideal would be the introduction of a method even before the renal transplantation. In our study, we observed a delay in guidance and insertion of the method. Of the renal transplant patients who opted for the intrauterine hormonal device in our outpatient clinic, only one patient (2.5%) had undergone renal transplantation less than 2 years ago. The mean time between renal transplantation and hormonal intrauterine device insertion was 65 months in our study.

During the study period, 290 renal transplanted women were followed and 47 (16%) opted for the intrauterine hormonal device. The mean age of our patients was 33 years, and the majority (60%) reported having one or more children. None of them became pregnant during the study period. There was also no deterioration in renal function or graft rejection during this period. Since the first published studies of this contraceptive method, the literature has described high efficacy, tolerability, safety, and acceptance by women regardless of age or parity[19,20].

Regarding the complaints related to the method, the most common ones reported by this group of patients were colics such as abdominal pain and vaginal bleeding, as reported in the studies for general population. The only point that could be highlighted in our study is the recurrent urinary infections

that occurred after insertion of the method in two patients, with no repercussions on renal transplantation.

The satisfaction rate among users of intrauterine hormonal device is high, reaching 92.5% of patients after 6 years[21]. Our data confirmed the high satisfaction rate with 97.5% of satisfied or very satisfied. Another interesting fact is that 92.5% of them would recommend the intrauterine hormonal device to other women, which shows the good acceptance of the method. In addition, 85% of patients continued to use the method, showing a good continuation rate, with a mean time of use of 37 months.

CONCLUSION

Our study showed that renal transplant women benefited from the use of the hormonal intrauterine device because of its high efficacy and low side effects. In addition, this method was well accepted by the patients and proved to be a great option for this group in particular.

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AUTHORS' CONTRIBUTIONS

CAFG: Conceptualization, Project administration, Visualization. FCA: Data curation, Investigation, Validation, Visualization, Writing – original draft. **APO:** Data curation, Methodology, Validation, Visualization. **TENKH:** Formal Analysis, Supervision, Validation, Visualization. **EAJ:** Visualization, Writing – review & editing.

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