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ORIGINAL PAPER

Kidney transplantation restores sex hormone profile and improves sexual function in ESRD patients with erectile dysfunction

Hany M. El Hennawy [1], Omar Safar [2], Abdullah S. Al Faifi [1], Osama Shalkamy [2, 3], Mahmoud Z. El Madawie [2], Saad Thamer [2], Muath Almurayyi [2], Abdullah Mohammed Alqarni [4], Sami Saleh Amri [4], Ali Abdullah Hawan [4], Adel Elatreisy [3, 5]

[1] Surgery Department, Section of Transplantation, Armed Forces Hospitals Southern Region, Khamis Mushayte, 101, Saudi Arabia;
[2] Urology Department, Armed Forces Hospitals Southern Region, Khamis Mushayte, 101, Saudi Arabia;
[3] Urology Department, Faculty of Medicine, Al Azhar University, Cairo, Egypt;
[4] Laboratory Department, Armed Forces Hospitals Southern Region, Khamis Mushayte, 101, Saudi Arabia;
[5] Urology Department, King Fahd Armed Forces Hospital, Jeddah, Saudi Arabia.

Summary ***Background: Erectile dysfunction (ED) and sex hormone profile disturbances are common in ESRD patients. Objective: To assess the effect of kidney transplant (KT) and Hemodialysis/peritoneal dialysis (HD/PD) on the serum sex hormone profile and sexual functions in ESRD patients with ED. Patients and methods: A single-center, non-concurrent cohort study included a hundred ESRD patients with ED, on regular HD/PD (group A, n = 50) and after KT (group B, n = 50) at Armed Forces Hospitals Southern Region, KSA.***
Results: the mean age of patients was 47.3 ± 7.01 and 56.8 ± 9.6 years in groups A and B, respectively. The cohorts were comparable regarding patient demographics, apart from a higher incidence of comorbidities in group B. After KT the mean testosterone level was higher in Group B (13.64 ± 3.21 nmol/L Vs 10.26 ± 3.26 nmol/L, p < 0.001). Similarly, LH and prolactin levels were lower in group B than in group A (p < 0.05).
As regards sexual function, ED was reported in 92% of patients in group A compared to 42% in group B (p < 0.001). In groups A and B, mild ED was found in 48% and 14% of patients, while moderate ED was found in 16% and 8%, respectively. The mean total IIEF-15 score was 36.42 ± 9.33 and 43.87 ± 9.146 in groups A and B, respectively (p = 0.0001). Sexual desire and orgasm were significantly better in Group B.
Conclusions: Our study showed that kidney transplantation could improve erectile function and restore normal sex hormone levels in ESRD male patients with ED, with better outcomes compared to HD/PD.

KEY WORDS: Sex hormones profile; Erectile dysfunction; Kidney transplantation.

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INTRODUCTION

Hormonal disturbances such as *luteinizing hormone* (LH), *follicle-stimulating hormone* (FSH), and prolactin increase, and decreased testosterone levels are associated with *End-stage renal disease* (ESRD) (1-3). These hormonal changes may lead to sexual dysfunction, especially disorder in sexual arousal (4). In addition, low testosterone levels have been associated with an increased risk of morbidity and mortality in males with ESRD (5, 6).

Kidney transplantation (KT) has been reported to improve sexual function and sex hormone profiles (7-10). However, there are few studies concerning serum pituitary-gonadal hormones and sexual dysfunction during dialysis and post-KT in Saudi populations.

This study aimed to evaluate sex hormonal profile and sexual function status in patients with *erectile dysfunction* (ED) after two treatment modalities for ESRD, including KT and *peritoneal/hemodialysis* (PD/HD) in Southern Saudi Arabia.

PATIENTS AND METHODS

A non-concurrent cohort study included ESRD patients associated with ED after two treatment modalities, including KT and *peritoneal/hemodialysis* (PD/HD). The study was conducted at the *Armed Forces Hospitals Southern Region, KSA*, from September 2017 to January 2023. The local institutional ethical committee approved the protocol, and all enrolled patients signed an informed consent form.

Inclusion criteria

The study included all married male patients with ED associated with ESRD aged 18-60; in group A, 40 and 10 patients were on HD and PD, respectively. In group B, all patients underwent KT between September 2017 and September 2023 and had stable graft function.

Exclusion criteria

Primary hypogonadism, hemochromatosis, history of cancer treatment (chemotherapy and radiotherapy), pituitary tumors, hypopituitarism of any etiology, and inflammatory diseases such as tuberculosis and sarcoidosis. Moreover, patients having second KT, rejection within three months after transplantation, unstable postoperative graft function with serum creatinine over 20 mg/L, and sirolimus as part of the immunosuppressive regimen.

In addition, patients receiving medication or herbal compounds to restore erectile function or underwent testosterone replacement therapy.
During the pre-*kidney transplant* (KT) evaluation, 50 patients presenting with ED were selected from the urology clinic (Group A). In comparison, an additional 50 patients with ED were chosen from the dialysis unit (Group B) based on predefined inclusion and exclusion criteria.
In all transplanted patients, the kidney graft was placed extraperitoneal in the right/left iliac fossa, the renal artery was anastomosed to the common or external iliac artery, and the vein was anastomosed to the common or external iliac vein. The ureter was anastomosed to the recipient's bladder using the Lich-Gregoire technique over a double-J ureteric stent. We usually remove the ureteric stent after six weeks. Immunosuppression for all patients consisted of a triple regimen including tacrolimus, mycophenolate mofetil or mycophenolic acid, and prednisolone.
All patients were subjected to a complete medical history through medical examination and routine laboratory investigation. In addition, gonadal hormone levels (LH, FSH, free Testosterone, *prolactin* [PRL]) and the *International Index of Erectile Function* (IIEF5-15) questionnaire were assessed pretransplant and 6 months after renal transplantation. Major drugs causing ED, such as beta-blockers, alpha-blockers, spironolactone, and thiazide diuretics, were withdrawn six months before starting the study.

Measurements

Serum pituitary-gonadal hormones were measured as follows: All blood samples were drawn in the morning (7.00-9.00 a.m.) after an overnight fast (12 h). Venous blood samples of the patients with ED were collected during dialysis and 1-2 and 3-4 months postoperatively, respectively. Serum *prolactin* (PRL), *follicle-stimulating hormone* (FSH), LH, and testosterone levels were measured immediately by electrochemiluminescence immunoassay (*Elecsys System, Roche Diagnostics GmbH, Mannheim, Germany*) according to the manufacturer's instructions. All blood samples were measured in duplicate (11).
Moreover, we reported sexual activity after transplantation, sexual desire, degree of erection, satisfaction with sexual activities, frequency of sexual activities, and IIEF5-15 score for all patients.
Comparison between the study groups included patient demographics, sex hormone levels, and sexual function status.

Statistical analysis

We analyzed the data using the *Statistical Package for Social Science* (SPSS) software, version 29 (*SPSS Inc., Chicago, IL*). We presented the numeric variables as a mean and standard deviation, while categorical variables were presented as a frequency and percentage. We tested the association between nominal variables using the chi-square test. At the same time, the Student's t-test was applied to define the difference between the means of continuous variables for different groups. We used the Mann-Whitney U test to compare the ordinal variables in two groups. A paired-sample t-test was used to detect the significance level between pre-transplant and post-transplant values.

Results

Group A included 50 patients with ED on HD/PD, and Group B included 50 patients with ED who underwent living-related donor KT.
The cohorts were comparable in terms of patient demographics, including smoking history, duration of peritoneal/hemodialysis, and body mass index. Nevertheless, the prevalence of comorbidities, including diabetes mellitus, hypertension, ischemic heart disease, and dyslipidemia, was significantly higher in group B, as shown in Table 1.
The median duration of peritoneal/hemodialysis in Group A was 4 years, while the median duration of hemodialysis before KT in Group B was 2 years, with an average of (4 and 3 years), in Groups A and B, respectively Table 1.
Table 2 displays the serum sex hormone levels for the study groups at 6-month follow up after KT.. In group A, FSH, Prolactin, and LH levels were significantly higher, and serum testosterone levels were significantly lower than average range values. The mean testosterone level was 13.64 ± 3.21 nmol/L in group B compared to 10.26 ± 3.26 nmol/L in group A with a statistically significant difference (p = 0.0001). Similarly, LH and prolactin lev-

Table 1.
Demographic data of the study groups.

Parameter	Group A (Dialysis patients = 50)	Group B (KT patients, n = 50)	p-value
Total (n) patients	50	50	
Age in years, Mean ± SD	47.32 ± 7.013	56.87 ± 9.612	0.0001
DM, % (N)	22% (11)	100% (50)	0.00001
HTN, % (N)	100% (50)	100% (50)	N/A
IHD, % (N)	6% (3)	54% (27)	0.00001
Dyslipidemia, % (N)	22% (11)	72% (36)	0.00001
PVD, % (N)	0% (0)	18% (9)	0.00001
Smoking, % (N)	18% (9)	28% (14)	0.234
Neuropathy, % (N)	0% (0)	0% (0)	N/A
Psychological disease, % (N)	0% (0)	0% (0)	N/A
Cause of ESRD, % (N)			0.00001
DM	22% (11)	8% (4)	
HTN	76% (32)	28% (14)	
DM, HTN	14% (7)	64% (32)	
Mood of dialysis, % (N)			N/A
PD	20% (10)	0% (0)	
HD	80% (40)	100% (50)	
Previous Transplant	2% (n = 1)	0% (0)	N/A
Duration of peritoneal/hemodialysis before KT, median (IQR) in years	4 (4)	2 (3)	N/A
BMI, Mean ± SD	24.68 ± 1.42	24.41 ± 3.62	0.630
Follow up serum creatinine mean ± SD in µmol/L	976.96 ± 204.1	83.26 ± 19.44	0.0001

Table 2.
Comparison in Sex Hormones serum levels between the study groups.

Serum levels of sex hormones Mean ± SD	Group A (Dialysis patients = 50)	Group B (KT patients, n = 50)	p-value
Before Kidney transplant			
· Testosterone (nmol/L)	10.25 ± 3.32	10.11 ± 3.23	0.76
· LH (mIU/ml)	15.52 ± 17.56	15.87 ± 4.81	0.58
· FSH (mIU/ml)	11.08 ± 20.21	11.9 ± 12.96	0.98
· Prolactin (ng/ml)	23.98 ± 16.46	23.22 ± 1.71	0.26
6 months After Kidney transplant			
· Testosterone (nmol/L)	10.26 ± 3.26	13.64 ± 3.21	0.0001
· LH (mIU/ml)	15.49 ± 17.64	5.66 ± 4.76	0.0001
· FSH (mIU/ml)	11.11 ± 20.39	11.07 ± 13.95	0.993
· Prolactin (ng/ml)	24.12 ± 16.57	9.19 ± 1.63	0.0001

Table 3.
Degree of erectile dysfunction in the study groups.

Serum levels of sex hormones Mean ± SD	Group A (Dialysis patients = 50)	Group B (KT patients, n = 50)	p-value
No ED	4 (8%)	29 (58%)	<0.001
Mild ED	24 (48%)	7 (14%)	
Mild to moderate ED	10 (20%)	9 (18%)	
Moderate ED	8 (16%)	4 (8%)	
Sever ED	4 (8%)	1 (2%)	

Table 4.
The IIEF-15 score in transplant group before & after transplant.

The score Mean ± SD	Group A (Dialysis patients = 50)	Group B (KT patients, n = 50)	p-value
IIEF5-15 (ED)	13.94 ± 3.941	17.03 ± 3.719	0.0001
IIEF 9-10 (orgasm)	4.90 ± 1.469	5.84 ± 1.369	0.001
IIEF 11-12 (sexual desire)	5.10 ± 1.62	5.81 ± 1.515	0.026
IIEF 6-8 (intercourse satisfaction)	7.42 ± 2.233	9.16 ± 2.311	0.0001
IIEF 13-14 (overall satisfaction)	5.06 ± 1.526	6.03 ± 1.581	0.002
Total IIEF-15 score	36.42 ± 9.330	43.87 ± 9.146	0.0001

els were lower in group B than in group A ($p < 0.05$). There was no significant difference in the FSH levels, as shown in Table 2.

As regards sexual function, ED was reported in 92 % of patients in group A compared to 42% in group B ($p < 0.001$). In groups A and B, mild ED was found in 48% and 14% of patients, while moderate ED was found in 16% and 8%, respectively, as detailed in Table 3.

In group A, the mean IIEF5-15 score was 18.4/30 ± 5.4 (range, 7-30), and the mean total IIEF-15 score was 46.8/75 ± 12.7 (range, 19-75). In group B, one year after successful KT, the mean IIEF5-15 score was significantly higher than group A; it was 22.3 ± 5.7 ($p < .001$). Similarly, the mean total IIEF-15 score was 55.5 ±13 ($p < .001$), as depicted in Table 4.

Sexual desire and orgasm were significantly better in Group B compared to Group A; similarly, sexual intercourse satisfaction and overall patient sexual satisfaction were significantly higher in Group B, as demonstrated in Table 4.

In group B, patients who had improved erectile function post-transplant (n = 34), mean serum testosterone level increased by 48% compared with an 18% increase in patients who reported no change in erectile function (n = 16) ($p = 0.001$).

Discussion

Erectile dysfunction is defined as the persistent incapability to attain or maintain a penile erection sufficient for satisfactory sexual activity. In end-stage renal disease, incidence is 50-70% (2).

Significant hormonal changes, such as LH, FSH, and prolactin elevation, as well as declines of testosterone and *anti-Müllerian hormone* (AMH) levels, are the most prominent effects of a decrease in kidney function levels (3, 8). Likewise, our study found similar changes in sex hormone levels in dialysis patients (Table 3).

Total testosterone was inversely associated with ED after adjusting for SHBG. Men with both low free testosterone and high SHBG had the highest ED risk (12-14). In addition, high testosterone levels independently predicted a decreased risk of ED in young men (12).

Moreover, the duration of dialysis was more than fifty months, and the FSH level was higher in subjects with longer period of dialysis than that in those dialyzed for a shorter period or not dialyzed (15).

Hyperprolactinemia commonly occurs in CKD, with a prevalence of 30-65% (16) due to declines in excretion and to increased synthesis (17). Clinical features may include ED, decreased libido, infertility, gynecomastia, and reduced skeletal mass (18). cardiovascular events in men with ED are associated with elevated plasma prolactin levels (17, 18).

In addition, the impairment of testicular function seen in advanced uremia is not reversible by maintenance hemodialysis (19). Several studies have demonstrated restoration of pituitary-gonadal axis dysfunction and improved hormonal profile, clinical sexual profile, and fertility after KT (11, 20, 21). It was found that pituitary-gonadal function was nearly restored to the normal range in most recipients about four months post-KT (3, 12). Similarly, in our study, normal sex hormone levels were restored within six months post-KT.Our study reported that serum testosterone levels were higher in the post-KT group in association with lower plasma prolactin and LH levels. There was no noticeable difference in plasma FSH levels between the two groups. These results are comparable to the findings of *Rahman et al.* (22). In agreement with several studies (23), during the serial baseline and follow-up assessments, we discovered a significant increase in testosterone levels in the post-KT ($p < 0.008$). Furthermore, serum testosterone levels were restored to the normal range 3-4 months post-KT in male recipients. Consequently, sexual activities and IIEF-15 scores improved markedly post-KT (11, 22). Similarly, our study restored total testosterone levels within six months after KT. In our study, we found that patients

with an increase in the IIEF score post-KT showed a rise in mean testosterone levels by 48% compared with an 18% increase in patients with a decrease in the IIEF score post-KT (P = 0.366). This corresponds to an increase in potency. During the serial baseline and follow-up assessments, we discovered a significant decrease in prolactin levels in the post-KT group (p 0.006) compared with the other group. Similarly, in a study by *Reinhardt et al.*, they reported that prolactin levels fell immediately post-KT and were constant until the end of follow-up (10). Our findings contradicted those of *Sikora-Grabka et al.* (24), who found that both LH and FSH levels decreased significantly during the observation period. Successful KT could improve gonadal function, but immunosuppressive medications could also impair it. It remains controversial whether KT could improve gonadal, sexual, and reproductive functions, especially in the long follow-up (11). Glucocorticoids affect gonadal function at several levels in the hypothalamic-pituitary-gonadal axis: 1) decreasing the release and synthesis of GnRH by the hypothalamus; 2) decreasing the release and synthesis of LH and FSH by the pituitary gland; 3) modulating of steroidogenesis and/or gametogenesis directly by the testis/ovary (25). Furthermore, several studies found that plasma testosterone levels were lower in FSH and LH in sirolimus-treated recipients than in non-sirolimus-treated controls, although the two groups showed no significant difference in serum prolactin levels in another study (21, 26, 27). Several studies show post-KT recipients' improvement in the IIEF score (28-30). The impact of KT on ED is controversial. Many studies show successful KT may play an essential role in ED improvement (23), (22), which aligns with the current study's findings. In our study, ED was reported in 42 % of patients after KT compared to 92 % in patients on regular HD/PD. Sexual desire and orgasm were significantly better in post-KT patients.

Furthermore, the mean total IIEF-15 score was significantly higher in the post-KT group (p < .001).

Nevertheless, other studies have suggested that ED may persist in 20%-50% of patients (31, 32). Alternatively, it may worsen in patients younger than 45 years post-KT but is unaffected in patients older than 45 years (33). The study has limitations due to its small sample size, single-center nature, and retrospective design with data recall bias. Future research could consider a prospective randomized trial.

Conclusions

Our study showed that kidney transplantation could improve erectile function and restore normal sex hormone levels in ESRD male patients with ED. We demonstrated a significantly higher serum testosterone level and lower levels of luteinizing hormone and prolactin after renal transplantation compared to regular HD/PD.

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Correspondence
Hany M. El Hennawy, MD
hennawyhany@hotmail.com
Abdullah S. Al Faifi, MD
Surgery Department, Section of Transplantation, Armed Forces Hospitals Southern Region
Khamis Mushayte, 101, Saudi Arabia

Omar Safar, MD
Mahmoud Z. El Madawie, MD
Saad Thamer, MD
Muath Almurayyi, MD
Urology Department, Armed Forces Hospitals Southern Region, Khamis Mushayte, 101, Saudi Arabia

Osama Shalkamy, MD
Urology Department, Faculty of Medicine, Al Azhar University, Cairo, Egypt
Urology Department, Armed Forces Hospitals Southern Region, Khamis Mushayte, 101, Saudi Arabia

Abdullah Mohammed Alqarni, MD
Sami Saleh Amri, MD
Ali Abdullah Hawan, MD
Laboratory Department, Armed Forces Hospitals Southern Region, Khamis Mushayte, 101, Saudi Arabia

Adel Elatreisy, MD
Urology Department, Faculty of Medicine, Al Azhar University, Cairo, Egypt
Urology Department, King Fahd Armed Forces Hospital, Jeddah, Saudi Arabia

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