ORIGINAL ARTICLE

Assessment of physical performance and quality of life in kidney-transplanted patients: a cross-sectional study

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Abstract

Background: Information on physical and mental wellness in renal transplantation is limited. Therefore, we performed a cross-sectional study to evaluate and describe the different components of physical performance and quality of life (QoL) in a cohort of kidney-transplanted patients.

Methods: Physical performance and QoL were determined through the administration of validated tests and questionnaires [muscle strength, dynamometer handgrip, tactile sensitivity, visual analogue scale (VAS) for pain, Timed Up and Go (TUG) test, Fatigue Severity Scale (FSS) and the 36-item Short Form Health Survey]. The patients were divided into three groups based on time elapsed since transplantation: early (in the first 6 months), middle (from 7 to 60 months) and late (>60 months).

Results: Of 132 enrolled patients, 11 patients (8.3%) presented a severe reduction of muscle strength, 63 patients (47%) had significant bilateral impaired handgrip and tactile sensitivity was altered in 23 patients (17.4%). TUG assessment showed significant mobility limitation in 29 patients (21.9%). The FSS presented a pathological value in 50 patients (37.3%), while the mean VAS was 1.8 ± 2.7. There were no significant differences in physical performance parameters among the three patient groups. There were inverse correlations among different components of physical performance and age, comorbidity and dialysis vintage, and there was a direct correlation with renal function. During the first months after transplantation there were limitations in physical, social and emotional activities. Overall, the self-perceived physical performance was significantly lower in transplanted patients with respect to the normal reference level.

Conclusion: Kidney-transplanted patients may present different degrees of impairment in physical performance and quality of life. Systematic functional assessment is essential to identify patients needing intensive and personalized rehabilitation programmes.

Key words: kidney transplantation, physical and rehabilitation medicine, quality of life

Introduction

Chronic kidney disease (CKD) causes an early loss of physical and mental performance associated with a self-perceived poor quality of life (QoL) [1]. Disability is particularly severe in patients undergoing haemodialysis (HD) or peritoneal dialysis (PD), which results in unemployment, depression, pain, low sleep quality and increased risk for malnutrition, inflammation and anaemia [2–5]. In patients with defective physical performance, protein-energy wasting and abnormal body composition are common and lead to increased hospitalization and mortality [6]. The strong correlation between physical performance and clinical, mental and social outcomes has been the thrust to develop tools aimed at quantifying physical performance in patients on regular dialysis treatment [7–9]. However, even though the impact of CKD and HD/PD on QoL and physical performance status has been extensively studied, less is known about these factors in kidney transplanted (KT) patients.

Renal transplant is the best therapeutic expectation for uraemic patients and has been associated with a significant improvement in QoL, a reduction in pain and a general increase in functional capacities [10, 11]. Nevertheless, there is a lack of quantitative evaluation of the different components of functional performance status in KT patients and, as yet, no specific test has been designed to understand what part physical performance plays as a determinant of clinical outcomes in transplanted patients. Such information is necessary both to address selected patients to rehabilitation programmes and to evaluate cost/benefits of rehabilitation intervention.

This is why we designed this observational study to define and grade the various aspects of functioning in a population of KT patients.

Materials and methods

Study design and clinical setting

We designed a cross-sectional observational study in KT patients on regular follow-up at the Policlinico 'San Matteo' in Pavia (Italy). From March 2014 to March 2015, all patients with kidney transplants attending the outpatient Nephrology Clinic were invited to participate in the study. Patients were excluded if they did not provide informed consent or if they presented with acute infections or cardiovascular events during the last 3 months. On the date of scheduled outpatient visits, we collected demographic and clinical data, including age, sex, BMI, cause of end-stage renal disease, date of transplant, updated haemoglobin (Hb), serum creatinine, estimated glomerular filtration rate (eGFR) and current medications.

Laboratory parameters were measured by standard methods. Creatinine was measured by enzymatic methods and the Modification of Diet in Renal Disease (MDRD) equation was used for GFR estimation [12]. The Charlson Index (CCI) was used in assessments of comorbidity [13]. Post-induction immunosuppression included calcineurin inhibitors, mechanistic target of rapamycin inhibitors (mTORis), mycophenolate mofetil (MMF) and prednisone, tailored to patient needs in various combinations.

Patients were divided into three groups based on time elapsed since transplantation: early (in the first 6 months), middle (from 7 to 60 months) and late (>60 months).

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Foundation IRCCS Policlinico 'San Matteo' of Pavia, Italy. Written informed consent was obtained from each participant prior to enrolment in the study.

Functional tests

One of two trained assessors conducted all functional assessments using a standardized protocol. Functional assessments were performed in a quiet environment under standard conditions and included muscle strength, dynamometer handgrip strength, tactile sensitivity, visual analogue scale (VAS) for pain, Timed Up and Go (TUG) test and Fatigue Severity Scale (FSS).

Muscle strength was assessed according to the Medical Research Council (MRC) scale of the upper limbs (biceps brachii and triceps brachii) and the lower limbs (psoas major and iliacus, quadriceps, hamstrings, tibialis anterior, calves) for a total of 10 muscle groups. An overall MRC score ≥40/50 was considered indicative of good strength [14].

Handgrip strength, a measure of upper-limb muscle strength, was tested using a Jamar handgrip dynamometer, with a single maximal effort squeeze to the dynamometer grip. Handgrip strength in the dominant hand >40 kg in males and >20 kg in females was considered normal [15].

Tactile sensitivity of the upper and lower limbs was assessed by the Semmes–Weinstein monofilament test. The monofilaments were applied to the test site perpendicularly. Patients were instructed to say 'yes' each time they sensed the monofilament on their limbs. If patients failed to sense the monofilament after it was bent, the test site was considered insensate [16].

A VAS was used for pain evaluation. Values >3 were considered indicative of pain requiring pharmacological treatments [17].

The TUG test was used to evaluate functional mobility [18]. The patient was observed and timed in seconds while rising from an armchair, walking 3 m, turning, walking back and sitting down again. As previously described, longer test times (>10 s) were considered pathological and predictive of the future need for placement in a long-term care facility [19].

Finally, muscular fatigue was evaluated by a self-report questionnaire, the nine-item FSS, as previously reported. Each item was valuated with a score from 1 to 7 points (range 9–63), and a score >36 was considered pathological [20].

QoL

QoL was assessed by the Medical Outcomes Study 36-item Short Form Health Survey (SF-36), a generic instrument translated and validated in Italian patients with CKD [7]. This instrument is divided into eight dimensions: physical functioning, bodily pain, role-physical, general health, vitality, social functioning, role-emotional and mental health. The results of each scale vary from 0 to 100 (worst to best possible status). The physical and mental components, respectively, of the eight scales were combined into a physical component summary (PCS) and a mental component summary (MCS). The two summary measures were standardized to have a mean value of 50 and a standard deviation (SD) of 10 in the general population [21]. Normal QoL was defined as a score of >50 points [22].

Statistical analysis

Descriptive analyses were performed for all variables. Continuous variables were reported using mean ± SD or median and interquartile range (IQR). For categorical variables, absolute numbers and percentages were calculated. The 95% confidence intervals (CIs) were computed for the SF-36 PCS and MCS. To compare patient characteristics according to time since transplant (three groups), the Fisher exact test, general linear model or analysis of variance was used. The correlation among quantitative

variables was assessed using Spearman's rho correlation coefficient, because of the expected non-normal distribution of the questionnaires' scores and to detect non-linear relationships.

Stata 13.1 (StataCorp, College Station, TX, USA) was used for computation. A two-sided P-value <0.05 was considered statistically significant.

Results

Patient characteristics

Of 166 possible participants, 132 [age 52.3 ± 12.4 years, 78 males (59%)] were enrolled in the study while 27 patients denied consent and 7 were excluded because of recent infection. The majority of the patients (72.7%) underwent HD before the transplantation, whereas 27.3% were on PD. Dialysis vintage, i.e. the time spent in dialysis before transplantation, was 28 (range 18–48) months.

Eighteen patients (13.6%) were diabetic and the main underlying nephropathies included glomerulonephritis, nephroangiosclerosis and hereditary disease.

The graft was implanted in the right iliac fossa in 119 patients (89.6%) and in the left iliac fossa in 13 patients (10.4%). The mean eGFR and Hb were 52.8 ± 22.1 mL/min/1.73 m^2 and 12.4 ± 1.6 g/dL, respectively.

The median time from transplantation was 53.4 months (IQR 18.2–97.3). Twenty-one patients (15.9%) were assessed within 6 months from KT transplantation (early group), 50 (37.9%) between 7 and 60 months (middle group) and 61 patients (46.2%) >60 months from transplantation (late group).

These groups did not significantly differ regarding demographic and clinical characteristics (Table 1).

Physical performance measures

All participants completed the functional assessment. Considering the totality of the evaluated patients, 103 patients (78%) had good force in all areas examined, 18 patients (13.6%) had an overall muscle strength that was slightly reduced (MRC 40–<45), and 11 (8.3%) had severely reduced muscle strength (MRC < 40).

The specific analysis of the performance of psoas major and iliacus muscle showed that 99 patients (75%) had good force for the left psoas and 95 patients (72%) for the right psoas, while no correlations were found between the side of the transplant intervention and weakness of the psoas.

Global muscle strength resulted in a significantly inverse correlation with age ($r = -0.31$ and $r = -0.29$, P < 0.005, respectively) and dialysis vintage ($r = -0.2$, P < 0.05), whereas it was directly correlated with renal function, expressed as eGFR ($r = 0.27$, P < 0.005).

Sixty-three patients (47%) had significant bilateral impaired handgrip, 29 patients (21.7%) presented monolateral impairment, and 40 subjects (31.3%) showed normal results.

Handgrip strength was directly correlated with eGFR ($r = 0.32$, P < 0.001), whereas it was inversely related to dialysis vintage ($r = -0.22$, P < 0.05).

Among patients with monolateral impairment, there was a significantly higher prevalence of subjects with a pretransplant history of HD when compared with other patients (89% versus 68%; P < 0.05).

Tactile sensitivity to four limbs was preserved in 109 patients (82.6%), while 14 patients complained of dysesthesia in the lower limbs (11.2%), 8 in the upper limbs (5.9%) and 1 (0.1%) in all four limbs. The TUG mobility assessment showed mean values of 9 ± 3.1 s and significant mobility limitations (i.e. TUG >10 s) in 29

Table 1. Clinical characteristics of the patients at the time of functional evaluation

	Total population	Early (≤6 months)	Middle (7–60 months)	Late (>60 months)	P-value
N	132	21	50	61	
Gender (M/F)	78/54	13/8	31/19	34/27	0.79
Age (years)	52.3 ± 12.4	55.5 ± 10.8	50 ± 11.3	53.1 ± 13.6	0.16
BMI (kg/m^2)	24.7 ± 4.8	23 ± 4	25 ± 4.1	25 ± 5.5	0.1
Time on dialysis before KT, months (IQR)	28 (18–48)	30 (24–54)	26 (20–48)	30 (16–48)	0.5
Type of dialysis, *n* (%)					
HD	96 (72.7)	13 (61.9)	37 (74)	45 (75.4)	0.48
PD	36 (27.3)	8 (38.1)	13 (26)	14 (24.6)	
Primary cause of ESRD, *n* (%)					
HTN/vascular	36 (27.3)	7 (33.3)	12 (24)	17 (27.9)	0.52
GLN	47 (35.6)	6 (28.7)	24 (48)	17 (27.9)	
Hereditary	27 (20.4)	4 (19)	7 (14)	16 (26.2)	
Other/UN	22 (16.7)	4 (19)	7 (14)	11 (18)	
Time from transplantation, months (IQR)	53.4 (18.2–97.3)	1 (0.9–2)	32 (18.2–43)	102 (81–127)	0.001
Current medications (*n*/%)					
Steroids	70 (53)	18 (85.7)	26 (52)	26 (42.6)	0.002
Calcineurin inhibitors	100 (75.8)	20 (95.2)	37 (74)	43 (70.5)	0.056
MMF	87 (65.9)	18 (85.7)	33 (66)	36 (59)	0.08
mTORi	23 (17.4)	0	9 (18)	14 (22.9)	0.03
Hb levels (g/dL)	12.5 ± 1.6	11.9 ± 1.2	12.7 ± 1.8	12.4 ± 1.6	0.09
eGFR (mL/min)	52.8 ± 22.1	46.2 ± 17.3	56.8 ± 22.3	51.9 ± 22.9	0.1
Active working people, *n* (%)	83 (63)	12 (60)	31 (62)	40 (65)	0.8
Diabetes, *n* (%)	18 (13.6)	2 (9.5)	8 (16)	8 (13.1)	0.8
Charlson Index (age-related)	3.7 ± 1.5	4.2 ± 1.5	3.5 ± 1.7	3.6 ± 1.3	0.24

Data are presented as mean ± SD unless otherwise noted. The patients were considered overall and divided according to time elapsed since transplantation.
BMI, body mass index; KT, kidney transplant; ESRD, end-stage renal disease; HTN, hypertension; GN, primary and secondary glomerulonephritis; UN, unknown aetiology; eGFR, estimated glomerular filtration rate (according to the MDRD equation).

patients (21.9%). Five subjects (3.8%) recalled having fallen at least once in the past year.

The resulting TUG scores were strictly related to age ($r = 0.5$, $P < 0.005$) and inversely correlated with muscle strength ($r = -0.5$, $P < 0.005$) and eGFR ($r = -0.17$, $P < 0.05$). Ninety-two patients (69.7%) had a VAS score ≤ 3, indicative of an insignificant presence of pain.

The area most affected by pain was the lower limbs (43.8%), followed by the lumbar spine (31.2%) and upper limbs (8.4%). The mean FSS was 31 (SD 18) with 50 patients (37.3%) presenting a clear pathological value. Finally, none of the parameters evaluating physical performance correlated with the type of pretransplant dialytic technique (HD versus PD) and time from transplantation. Consistently there were no significant differences among the three patient groups, either when considering the absolute results of the functional tests (Table 2) or after dichotomization according to normality thresholds (Figure 1).

Immunosuppressive treatment

At the time of observation the immunosuppressive treatment included steroids in 70 patients (53%), calcineurin inhibitors (cyclosporine or tacrolimus) in 100 patients (75.8%), MMF in 87 patients (65.9%) and mTORi in 23 (17.4%) patients. The immunosuppression drugs used changed according to the time from kidney transplantation. Indeed, a higher percentage of patients evalu-

Table 2. Physical performance tests in patients at the time of functional evaluation

	Total population	Early (≤6 months)	Middle (7–60 months)	Late (>60 months)	P-value[b]
N	132	21	50	61	
MRC	47.3 ± 3.9	46.8 ± 3.5	47.5 ± 4	47.4 ± 4.1	0.74
HG (kg)	25.4 ± 9.3	24.1 ± 9.3	26.0 ± 8.9	25.3 ± 9.8	0.72
Male	29.4 ± 9.2	28.1 ± 9.1	29.2 ± 9.1	30.2 ± 9.6	0.77
Female	19.5 ± 5.7	17.6 ± 5.4	20.8 ± 5.7	19.1 ± 5.8	0.36
Tactile sensitivity[a], n (%)	109 (82)	17 (81)	42 (82)	50 (82)	0.91
VAS	1.8 ± 2.7	1.8 ± 2.8	1.4 ± 2.4	2.1 ± 2.9	0.38
TUG test (s)	9 ± 3.1	9.58 ± 3.4	9.13 ± 3.3	8.8 ± 2.8	0.50
FSS	31.4 ± 18	29.7 ± 18.6	34.6 ± 18.3	29.3 ± 17.3	0.28

The patients were considered overall and divided according to time elapsed since transplantation. Data are presented as mean ± SD unless otherwise noted.
[a]For tactile sensitivity, the percentage of normal tests is shown.
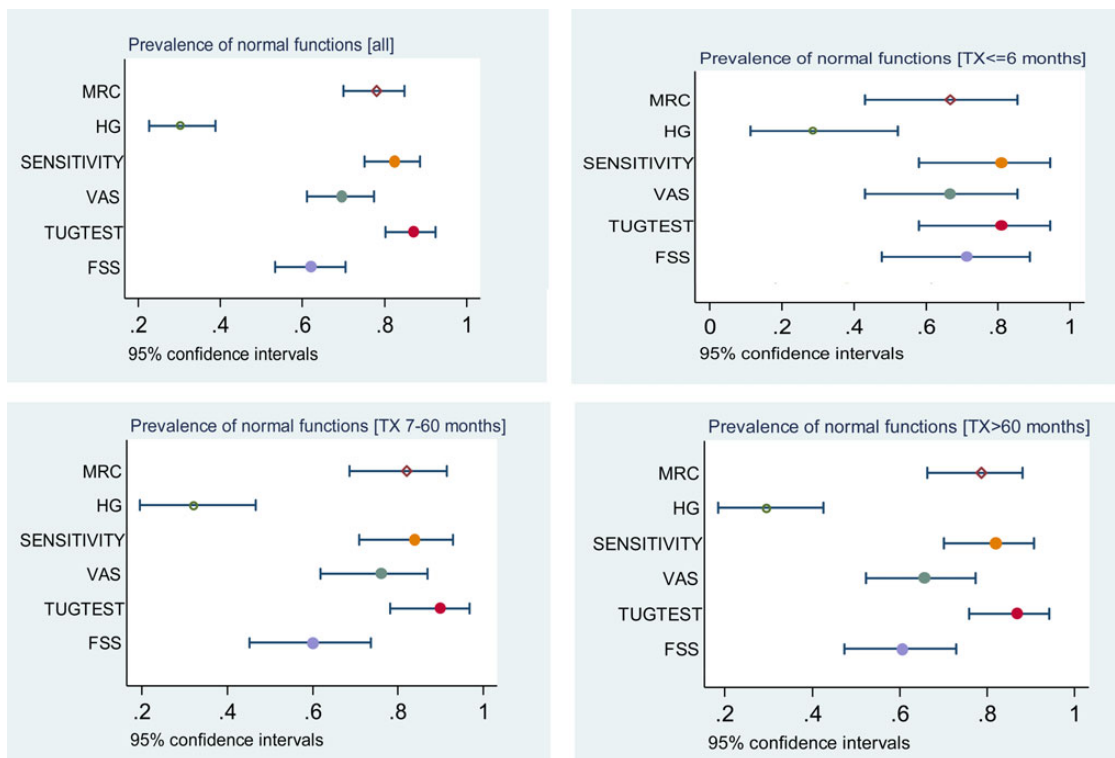[b]General linear regression model.

Fig. 1. Prevalence of normal functional (on *x*-axis) indices for the entire population (upper left panel) and according to short (upper right), middle (lower left) and long (lower right) time elapsed since transplantation. Whiskers represent 95% CI; dots represent prevalence.

Table 3. Different components of QoL as evaluated by the SF-36 in patients with different transplant vintage

SF-36 item	Early (≤6 months)	Middle (7–60 months)	Late (>60 months)	P-value
N	21	50	61	
PCS	41.2 ± 2.1[a] (36.8–45.6)	45.6 ± 1.1[a] (43.3–47.8)	44.1 ± 1.2[a] (41.7–46.6)	0.18
Physical functioning	58.0 ± 26.7 (45.4–70.5)	76.2 ± 23.4 (69.6–82.7)	76.3 ± 23.9 (70–82.4)	0.009[b]
Bodily pain	65.4 ± 32.7 (50–80.7)	67.8 ± 27.3 (60.1–75.5)	68.3 ± 29.3 (60.7–76)	0.9
Role-physical	40 ± 40.8 (20.8–59)	55.4 ± 41 (43.8–67)	62.5 ± 41 (51.9–73)	0.1
General health	59.4 ± 20.6 (49.7–69)	56.4 ± 19.9 (50.8–62)	52 ± 22.8 (46–57.8)	0.3
MCS	48.7 ± 1.9 (44.7–52.6)	48.8 ± 1.6 (45.5–52.1)	51.8 ± 1.2 (49.5–52.1)	0.2
Vitality	61.7 ± 21.1 (51.8–71.6)	56.6 ± 20.5 (50.9–62.4)	58.5 ± 20.3 (53.3–63.8)	0.6
Social functioning	56 ± 32.5 (40.7–71.3)	70.8 ± 22.3 (64.6–77.1)	75.2 ± 22.2 (69.4–81)	0.01[c]
Role-emotional	43.2 ± 43.3 (22.9–63.5)	62.6 ± 42 (50.8–74.4)	73.8 ± 37 (64–83.4)	0.01[c]
Mental health	68.4 ± 17.8 (60–76.7)	66.2 ± 23.6 (59.5–72.8)	71.4 ± 20.7 (66.1–76.8)	0.4

Data are presented as value (95% CI).
[a]If 95% CI excludes 50 (reference normal population) it means a significant difference from the norm.
[b]Early group versus middle and late groups.
[c]Early group versus late group.

ated within 6 months after transplantation took steroids (18/21) and calcineurin inhibitors (20/21) when compared with patients with longer transplantation times (steroids 26/61, calcineurin inhibitors 43/61; P < 0.05), probably reflecting the switch from calcineurin antagonists that occurred during the follow-up (Table 1). Statistical analysis did not show any relationship between the immunosuppressive therapies, in particular the use of steroids, and physical performance parameters both when considering the totality of patients and the three different groups.

QoL

The majority of scores obtained from the SF-36 questionnaire were >50, indicating an absence of limitations in the various items considered (Table 3). The presence of limitations in physical and social functioning, as well as in role-emotional, was significantly higher in patients evaluated within the first 6 months after transplantation when compared with patients with longer transplant age. When QoL parameters were summarized as self-perceived mental performance (expressed as MCS) and self-perceived physical performance (PCS), we found that PCS was significantly lower in KT patients with respect to the normal reference level (i.e. >50), independent of time from transplantation.

Discussion

Although physical performance is a very important determinant of health and QoL, few studies have explored this topic in KT patients [23, 24].

The point is relevant because of many factors, some of which are specific to transplants, such as infections and immunosuppressive treatment, and increase the risk for impaired physical condition, and we can miss this important determinant of clinical outcomes because we lack adequate attention and tools to detect and grade it. In this study, we assessed several aspects of physical performance in a well-defined KT population using a panel of standardized functional tests to build a preliminary description of the physical state of KT patients based on a controlled, homogeneous method of assessment. A relevant finding of our study was that, even excluding confounding complications in KT patients, the results of functional tests were very variable. Nonetheless, we found that kidney transplantation has a conservative effect on global physical performance; in particular, it is associated with low rates of pain, physical limitations and accidental falls. Also, the overall muscle strength and tactile sensitivity were preserved in ∼80% of patients. However, the upper limit of arm strength, measured as handgrip, was normal in only 30% of patients, suggesting a reduction in muscle power related with a decrease in muscle mass.

Considering the relationship between physical performance and clinical variables, we found that while time from transplant did not seem to significantly influence functional parameters, the main factors associated with the results of functional tests were age, comorbidity index and time spent in dialysis. This is not surprising and may account for the differences that we found between our data and those reported in early studies on KT patients.

Indeed, the global physical performance of our patients was significantly better than that previously reported in other observational studies that demonstrated a high prevalence of functional dependence, a high annual rate of falls and significantly decreased muscle strength in elderly transplanted patients [25, 26]. These differences may be explained by considering that our patients were younger than those included in previous studies, with a significantly lower prevalence of diabetes and cardiovascular diseases, thus resulting in a low dialytic vintage and low comorbidity rate.

Moreover, it is interesting to notice that renal function at the time of evaluation was one of the most significant variables correlated with physical performance, probably reflecting the fact that patients with good graft function present a better metabolic and ionic profile, which may be associated with better muscle trophism and performance [27].

In addition, we also found that in patients with monolateral handgrip impairment, there was an elevated prevalence of a pretransplant history of HD. Therefore, it is possible that in these patients, monolateral impairment developed as a consequence of the presence of a vascular access. This finding suggests that the pretransplant dialysis technique, although not correlated with global performance status, may equally impact some features of physical performance.

Analysis of QoL revealed some other interesting issues. In fact, we found that our patients experienced major limitations in social and emotional life during the first months after transplantation, probably because of hospitalization and prophylactic restrictions (use of a face mask, frequent hand washing, avoidance of contact with animals, etc.).

Afterward, there were no differences between transplanted patients and the normal reference population, with the important exception of PCS (i.e. the self-perceived physical component derived from the SF-36), which was substantially lower in KT patients. These data might seem to contrast with the observation that MCS (i.e. the self-perceived mental wellness) in our patients

was comparable with the normal population. Actually, we think that these results reflect the way in which KT patients perceive their illness condition. Indeed, it is possible that the discrepancy between PCS and MCS might be explained by the fact that the psychological effect of freedom from dialysis evokes a feeling of mental well-being that is not suppressed by objective troubles such as intensive follow-up and the load of immunosuppressive drugs [28]. Interestingly, this phenomenon was present in all the patients we evaluated, independent of time from transplantation, indicating that the mental component constitutes a fundamental (and unexplored) aspect that should be taken into consideration in the clinical care of these patients.

On designing this study, we were aware of some methodological limitations, mainly the relatively small number of patients enrolled and the single-centre cross-sectional design, which did not permit insights into how physical performance varies over time and how it might correlate with clinical variables such as changes in steroid dosing and body weight. Moreover, we did not investigate other important determinants of physical performance status, such as physical activity and lifestyle, which are other major contributors to physical and mental wellness [29].

In conclusion, our data demonstrate that kidney transplantation presents a general conservative effect on global physical performance and QoL. Nevertheless, the finding that the distinctive components of physical function may present different degrees of impairment underlines that systematic assessment of physical performance and QoL should be provided for every KT patient. Therefore, implementation and validation of new methodologies, such as comprehensive clinical scores obtained by the use of standardized questionnaires and simple physical tests, could represent a promising approach and a new field of research [30]. This information might be of help in guiding clinical decisions, making it possible to programme preventive interventions and more extensive evaluation or to monitor the effectiveness of clinical and behavioural (i.e. lifestyle changes) interventions [31].

Conflict of interest statement

This paper is not under consideration elsewhere; none of the paper's content have been previously published in any part. There is no conflict of interest in connection with this study or any potential relationship with industry for any of the authors.

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