



Evolution of health-related quality of life in kidney transplanted patients

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SUMMARY

Objective: We analyzed the evolution in the Health Related Quality of Life (HRQOL) during the first year following renal transplant. **Methods:** Prospective and longitudinal study carried out with 28 patients who received a primary cadaveric renal transplant. The tests applied were a structured interview and SF-36, Euroqol-5D (EQ-5D) Health Questionnaires and End-Stage Renal Disease Symptom Checklist-Transplantation Module (ESRD-SCL). **Results:** With the course of time, the renal patients improve in four areas: physical («physical functioning» and «cardiac and renal malfunction»), psychological («vitality» and «mental health»), execution of daily tasks («limitations in role in order to physical problems» and «daily tasks») and subjective perception of own state of health («current health»). **Conclusions:** The HRQOL in renal transplant patients improves with the course of time.

Key words: **Renal transplantation. Health related quality of life. Pre and post-transplantation phases.**

EVOLUCIÓN DE LA CALIDAD DE VIDA RELACIONADA CON LA SALUD EN LOS TRASPLANTADOS RENALES

RESUMEN

Objetivo: Hemos analizado la evolución de la Calidad de Vida Relacionada con la Salud (CVRS) en el primer año del trasplante renal. **Métodos:** Estudio prospectivo y longitudinal realizado con 28 pacientes que recibieron un primer trasplante renal de cadáver. Fueron evaluados en cuatro fases diferentes: en el momento de su inclusión en lista de espera para trasplante y a los tres, seis y doce meses de haber recibido el injerto. Empleamos una entrevista estructurada y los siguientes instrumentos: Cuestionario de Salud SF-36, Cuestionario de Salud Euroqol-5D (EQ-5D) y End-Stage Renal Disease Symptom Checklist-Transplantation Module (ESRD-SCL). **Resultados:** A medida que transcurre el tiempo, los trasplantados renales mejoran en cuatro áreas: física («funcionamiento físico» y «disfunción cardíaca y renal»), psicológica («vitalidad» y «salud mental»), realización de las tareas cotidianas («limitaciones en el rol por problemas físicos» y «actividades cotidianas») y percepción subjetiva de su estado de salud («salud actual»). **Conclusiones:** La CVRS en los trasplantados renales mejora a largo plazo.

Palabras clave: **Trasplante renal. Calidad de vida relacionada con la salud. Fases pre y post-trasplante.**

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INTRODUCTION

Health-related quality of life (HRQOL) is a multidimensional construct including three basic domains (physical functioning, psychological functioning, and social functioning) that may be affected by disease and/or treatment.¹⁻³ Assessing the evolution of this construct in renal transplant patients is necessary, among other reasons, to determine the effectiveness of the medical intervention, to improve the clinical decisions, to manage the physical, functional, psychological, and social aspects of the patient's course, to understand the quality of life of the main caregivers, and to plan for psychosocial and rehabilitation interventions.⁴⁻⁶

Most of the studies on this topic conclude that all renal transplant patients present an HRQOL similar to that of the general population, and better than that of patients on chronic hemodialysis.^{7,8} Regarding evolution of HRQOL after renal transplant, the investigations establishing different comparison periods after transplantation are of great interest. For instance, there are studies concluding that patients with more than 10 years after transplantation have poorer quality of life as compared with those with less than 5 years, likely due to older age and the side effects of immunosuppressive medication.⁹ Other investigations conclude that HRQOL decreases between the third and sixth months, with less intensity in transplanted patients managed with Mycophenolate Mofetil, likely related with the lower rate of acute rejection.¹⁰ Other studies consider that there is an improvement in the quality of life of transplanted patients in the short (0-6 months) and long term (37-120 months), although in the intermediate term (7-36 months) the patients experience a worsening, coming back to pre-transplantation levels. One possible explanation is that in the period immediately after transplantation the patients have a feeling of liberation from dialysis dependence, but as time goes by they have to cope with several somatic (e.g., the side effects from medication, medical complications, etc.) and social problems (e.g., return to work, social life, etc.) that may explain the quality of life worsening experienced by the patients before achieving complete adaptation to their transplant.¹¹

Other recently published studies show the phases through which somebody receiving a renal transplant must go: «alertness», «adaptation», and «exhaustion», that is to say, they have more negative feelings (anxiety and depression) and worse physical self-esteem during the first year («alertness»), and two years and on from transplantation («exhaustion»), with no significant differences between these two period, but with differences when both periods are compared

with the 13-24 months interval («adaptation»), during which the patients improve.¹² Following this line of thought, four possible phases are proposed during the process of adaptation to renal transplant: 1) «beginning», which is characterized by a fear to the unknown and the search for physical indicators of well-being or discomfort; 2) «awareness», a time during which the patient becomes familiar with the new physical feelings and care, and usually he/she starts thinking about his/her limitations, risks, and capabilities; 3) «thinking», during which he patient goes through an unstable period, with elaboration of new values and beliefs about the disease; and 4) «re-adaptation», during which the patient will resolve the doubts to which he/she was confronted in the past (e.g., «what can I do, or cannot do?», «What is my role within the family?», «What is my role within the social group?», etc.).¹³

From all these studies, we may conclude that after renal transplant, the patient's HRQOL is not stabilized but different phases are experienced, ones better and other worse. All of this will depend on the time periods being compared, which vary in the different investigations. Given the importance of this issue, the main objective of our investigation was to analyze the evolution of HRQOL in renal transplant patients, considering four different periods: the pre-transplantation phase (the time at which the patient is included in transplant waiting list), and three post-transplantation phases (at three, six, and twelve months from receiving the graft).

MATERIAL AND METHODS

Participants

We selected all patients consecutively receiving their first dead-donor renal transplant at the Virgen del Rocío University Hospital of Seville, during the period October of 2003 and June of 2006.

Procedure

Renal transplant patients were assessed at four different phases: at the time of inclusion in the renal transplant waiting list, and at three, six, and twelve months from receiving the graft.

In the first place, when patients were on the waiting list, and after offering them information about the study and resolve all of their doubts, they gave their written informed consent, taking into account that their participation was voluntary and that they

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could withdraw from the study whenever they wanted, without giving any explanation and without any repercussion on their medical care. In the second place, by means of a structured interview, we gathered several demographic and clinical data, which were updated at every study phase. Thirdly, at each study phase we assessed HRQOL by means of three questionnaires.

Four inclusion criteria were required among the general characteristics for selecting the subjects: 1) age 18 years and older; 2) sufficient cognitive capacity to fill out the questionnaires, that is to say, they should not have any impairment of their sensorial aptitudes or mental state preventing them from being oriented in space and time or maintain a congruent conversation; 3) being included in the renal transplant waiting list; and 4) giving their written informed consent to participate into the study. On the other hand, in order to be able to give answer to the objective planned, we only included those patients that had filled out all the questionnaires at the four investigation phases.

Instruments

Structured interview, compounded by three sets of information: 1) general data: gender, age, height, etc., 2) demographical data: income level, educational level, working status, etc., and 3) clinical data: these were asked to the physician in charge of the patient and referred to different areas such as general personal history (cigarette and alcohol consumption, arterial hypertension, dyslipidemia, diabetes, and COPD), main diagnosis (vascular, diabetes, glomerulonephritis, interstitial, polycystic renal disease, and others), data of inclusion in the waiting list, time on renal replacement therapy, date of transplantation and number of transplants, initial graft dysfunction, laboratory data (hemoglobin, serum creatinine, albumin, etc.), type of immunosuppressive therapy for the transplant (cyclosporin, azathioprine, sirolimus, etc.), and number of hospital admissions, and their duration. Some clinical data were directly obtained at the first study phase (waiting list) and others during the protocolled follow-up of the patients (at three, six, and twelve months from receiving the graft).

SF-36 Health Questionnaire: we used the Spanish version (validated by J. Alonso and L. Prieto¹⁴) of the original «SF-36 Health Survey» developed by Ware and Sherbourne.¹⁵ It comprised 36 items, with several answering options each, which are grouped in eight domains: «physical functioning», «role limitations due to physical problems», «body pain», «general he-

alth», «vitality», «social functioning», «role limitations due to emotional problems», and «mental health». A score is obtained at each domain, varying from 0 (the worst health status) to 100 (the best health status). The scores of these domains are grouped in a physical compounded score (PCS) and mental compounded score (MCS).

EuroQOL 5-D (EQ): we used the Spanish version (validated by M. Rué and X. Badía¹⁶) of the original «EuroQOL» questionnaire.¹⁷ It comprises a descriptive system of the health status with five domains: «mobility», «self care», «daily living activities», «pain/discomfort», and «anxiety/depression». Each one of them comprises three items defining three severity levels: from 1 (the best quality of life) to 3 (the worst quality of life). Besides, it includes a self-evaluation of the health state or analogue visual scale, ranging from 1 (the worst possible health status) to 100 (the best possible health status).

End-Stage Renal Disease Symptom Checklist-Transplantation Module (ESRD-SCL)¹⁸: this questionnaire is in its validation phase in a multicenter prospective study within the Thematic Transplantation Investigation Network. It comprises 43 items scored following a Likert-like scale ranging from 0 (complete absence of the symptom) to 4 (very present symptom). These items are grouped in six domains assessing HRQOL in renal transplant recipients, and taking into account the effects of immunosuppressive therapy: «limitations in the physical capacity», «limitations in the cognitive capacity», «cardiac and renal dysfunction», «side effects from corticosteroids», «increased hair growth», and «transplant-associated psychological disorders». A score is obtained for each domain ranging from 0 (best HRQOL) to 4 (worst HRQOL).

RESULTS

We selected a group of 28 patients (15 men and 13 women, with mean age of 40.61 years) that consecutively received their first dead-donor renal transplant at the de Virgen del Rocío University Hospital of Seville. Eighty-two point one percent of them had a personal history of arterial hypertension and the cause of their renal disease was: glomerulonephritis (56.5%), polycystic renal disease (13.1%), interstitial nephropathy (8.7%), diabetes mellitus (4.3%), and other causes (17.4%). The average time on dialysis was 28.41 months and the average time on the transplant waiting list was 19.71 months. The mean serum creatinine value before transplantation was 8.12, decreasing to 1.76, 1.69, and 1.62 at three, six, and twelve months from transplantation, respectively.

Table I. Progression of HRQOL (SF-36) in renal transplanted patients

SF-36	Pre-transplantation phase (n = 28)	Post-transplantation phase			Sig.	Comparison between phases					
		3 months (n = 28)	6 months (n = 28)	12 months (n = 28)		Pre-3 months	Pre-6 months	Pre-12 months	3-6 months	3-12 months	6-12 months
Physical functioning	78.92	67.67	80.00	85.71	0.001**	0.112	1.000	0.613	0.012*	0.000**	0.249
Role limitations due to physical problems	37.32	39.64	55.00	58.92	0.006**	1.000	0.685	0.234	0.195	0.005**	1.000
Body pain	83.03	80.71	88.12	82.23	0.684	-	-	-	-	-	-
General health	35.89	45.17	45.71	47.14	0.167	-	-	-	-	-	-
Vitality	52.85	65.89	73.03	66.78	0.017*	0.313	0.008**	0.081	1.000	1.000	1.000
Social functioning	68.75	70.98	81.25	81.25	0.114	-	-	-	-	-	-
Role limitations due to emotional problems	65.47	75.83	69.53	69.05	0.779	-	-	-	-	-	-
Mental health	66.71	76.92	80.10	77.14	0.028*	0.209	0.021*	0.122	1.000	1.000	1.000

Note: The scores range 0-100. The higher the score the better the HRQOL, *p < 0.05, **p < 0.01.

In order to analyze the evolution of HRQOL in renal transplanted patients, we carried out a comparison of the different domains assessed by the questionnaires used in this study at four different moments: at the time of patient inclusion in the renal transplant waiting list, and at three, six, and twelve months from receiving the renal graft. We firstly applied a variance analysis for repeated measurements, and secondly, for those domains being significant and in order to know at what temporal moments the differences occurred, we carried out post-hoc comparisons (paired comparisons between the levels of the time factor). We also adjusted by the Bonferroni's correction in order to control the error rate for both the critical levels and the confidence intervals.

As shown in Tables I, II and III, by comparing the different phases of this study, eight domains were statistically significant: «physical functioning» (p < 0.01), «role limitations due to physical problems» (p < 0.01), «vitality» (p < 0.05), «mental health» (p < 0.05), «daily living activities» (p < 0.01), «current health» (p < 0.01), «cardiac and renal dysfunction» (p < 0.01) and «side effects from corticosteroids» (p < 0.01). For all the domains but the last one, it is observed that one year after transplantation the patients experience a improvement as compared with the phase they remained on the waiting list.

For SF-36, when the pre-transplantation phase is compared with the time «six months after transplantation», we observed a significant improvement in this latter phase for the domains «vitality» (p < 0.01)

and «mental health» (p < 0.05). This same trend is observed for the variable «physical functioning» (p < 0.05) when the phases three- and six-months post-transplantation are compared, and in the variables «physical functioning» (p < 0.01) and «role limitations due to physical problems» (p < 0.01), when the phases three- and twelve-months post-transplantation are compared (table I). About the EuroQol 5-D (EQ), we should point out that there is a significant improvement during the last phase in the variable «daily living activities» (p < 0.01) when the phases three- and twelve-months post-transplantation are compared. This same evolution was observed for the domain «current health» when the pre-transplantation phase is compared with the three- and six-months post-transplantation phases (p < 0.05 and p < 0.01, respectively), the patients significantly improving in the two last temporal moments (table II). On the other hand, for the ESRD-SCL, the domain «cardiac and renal dysfunction» improves in the long term, mainly when the pre-transplantation phase is compared with the three post-transplantation phases (three- (p < 0.01), six- (p < 0.01), and twelve-months (p < 0.01)). Completely the opposite is observed with the variable «side effects from corticosteroids», in which we observe a worsening expressed by the patients as time goes by, especially when the pre-transplantation phase is compared with the three post-transplantation phases (three- (p < 0.01), six- (p < 0.01), and twelve-months (p < 0.01)) (table III).

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Table II. Progression of HRQOL (EUROQOL-5D) in renal transplant patients

EUROQOL-5D	Pre-transplantation phase (n = 28)	Post-transplantation phase			Sig.	Comparisons between phases					
		3 months (n = 28)	6 months (n = 28)	12 months (n = 28)		Pre-3 months	Pre-6 months	Pre-12 months	3-6 months	3-12 months	6-12 months
Mobility	1.00	1.07	1.00	1.04	0.382	-	-	-	-	-	-
Self care	1.04	1.04	1.04	1.00	0.409	-	-	-	-	-	-
Daily living activities	1.29	1.61	1.29	1.11	0.000**	0.103	1.000	0.576	0.103	0.000**	0.576
Pain/discomfort	1.43	1.32	1.39	1.36	0.838	-	-	-	-	-	-
Anxiety/depression	1.32	1.21	1.21	1.36	0.503	-	-	-	-	-	-
Current health	60.57	75.71	74.11	72.14	0.008**	0.020*	0.009**	0.103	1.000	1.000	1.000

Note: For the first five domains, which scores range 1-3, the higher the score the worse the HRQOL. For the last domain, which scores ranges 0-100, e higher the score the better the HRQOL, *p < 0.05, **p < 0.01.

DISCUSSION

After having analyzed the results, we found that renal transplant patients experience significant changes during the transplantation process, essentially in four different sets: 1) physical: «physical functioning», «side effects from corticosteroids», and «cardiac and renal dysfunction»; 2) psychological: «vitality» and «mental health»; 3) performance of daily living activities: «role limitations due to physical problems» and «daily living activities»; and 4) subjective perception of the health status: «current health.»

In all of these areas (but the variable «side effects from corticosteroids») the patients improve in the long-term when comparing the pre-transplantation phase (when the patients are on the waiting list) to the post-transplantation phase (within one year of receiving the graft). The reasons explaining why the HRQOL is worse during the phase on the waiting list include not only physical deterioration and emotional weariness due to hemodialysis, but also the feeling of loss of freedom since the patients have to be reachable 24 hours a day, the fact that it is impossible for them to estimate the time they are going to wait until being transplanted, and the high anxiety level generated by the thought of having to go into the operating room and being submitted to a high-risk surgical intervention. If we add to all these reasons the fact that after receiving the graft they will not depend on dialysis, which obliges them to commute to the hospital three or more days in the week, and they have more time to return to their daily living activities (e.g., work, studies, attention to their families, etc.), with no doubt all this has a positive impact on their physical,

psychological, and social well-being in the long-term.¹⁹

In the physical domain we observe a renal transplant-related improvement with time in «cardiac and renal dysfunction», mainly due to the disappearance of the negative effects of being on dialysis and of the renal disease itself (e.g., palpitations from high blood pressure, swollen feet, tingling on the legs, tendency for bruises, and severe thirst), but the «physical functioning» of the patients experiences a significant decrease at three months from transplantation, that is to say, just at that time the patients' health limits them to carry out vigorous efforts (such as running, lifting heavy objects, participating in strenuous sports) or moderate efforts (moving a table, vacuum cleaning, play bowling, walking for more than one hour), as well as carrying the grocery bags, climbing up the stairs, squeaking or kneeling, doing own self-care, etc. One possible explanation is that patients overdo adhering to therapeutic prescriptions, that is to say, take care of themselves in excess because they fear to do efforts that may damage their kidney and loose their graft. Besides, sometimes the patients have extremely optimistic expectancies with regards to transplantation (they expect not to have any medical or psychological complication) that immediately after receiving the transplant are not reached, especially if we take into account the «side effects from corticosteroids» (for instance, the worry about the physical look, the swollen face, the susceptibility for infections, the facial changes, etc.) that patients undergo after transplantation and that they perceive as very disturbing, even limiting the improvement derived from transplantation and altering their body image.^{20,21} Within this context, we should take into account that trans-

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Table III. Progression of HRQOL (ESRD-SCL) in renal transplant patients

ESRD-SCL	Pre-transplantation phase (n = 28)	Post-transplantation phase			Sig.	Comparisons between phases					
		3 months (n = 28)	6 months (n = 28)	12 months (n = 28)		Pre-3 months	Pre-6 months	Pre-12 months	3-6 months	3-12 months	6-12 months
Limitations in the physical capacity	0.75	0.73	0.63	0.65	0.563	-	-	-	-	-	-
Limitations of the cognitive capacity	0.61	0.70	0.57	0.75	0.135	-	-	-	-	-	-
Cardiac and renal dysfunction	1.09	0.37	0.35	0.33	0.000**	0.000**	0.000**	0.000**	1.000	1.000	1.000
Side effects from corticosteroids	0.57	1.67	1.72	1.41	0.000**	0.000**	0.000**	0.000**	1.000	1.000	0.226
Increased hair growth	0.16	0.28	0.22	0.27	0.475	-	-	-	-	-	-
Transplant-associated psychological disorders	0.94	1.05	0.90	0.98	0.626	-	-	-	-	-	-

Note: The scores range 0-4. The higher the score, the worse the HRQOL, **p < 0.01.

planted patients usually receive a lot of information about the surgical procedure and pre-surgical preparation, but little information regarding the negative effects from transplant, including the adverse effects from immunosuppressive therapy.²²

This close relationship with the physical area lies in the domain of doing the daily living activities, in which we have included, on the one hand, the domain referring to «daily living activities» and, on the other hand, the domain «role limitations due to physical problems». In the first domain, we observed that patients improve in the long run, but at three months there is a significant decrease; comparing the four phases, it is in that phase during which the patients experience more problems to carry out their daily living activities, such as work, study, doing housekeeping, family activities, or other kind of activities during their spare time. Similarly, during the second phase, although there is a progressive improvement in these domains as time goes by, the most significant difference is observed when the periods three- and twelve-months post-transplantation are compared, the patients being significantly worse at three months since because of their physical health they have to reduce the time spent or doing more difficultly work-related tasks or daily living activities, or not doing them at all. The factors implicated may be, in the first place, the high frequency at which the patients must go to the hospital after transplantation to do check-outs (once or twice a week), and in the second place, the fear to have infections since their immune system is depressed by immunosuppressants and they avoid

going out to crowded places because they fear getting sick; thus, their personal health care exceeds that prescribed by their doctor; finally, the fact that sometimes they have to get integrated in a social and working environment that many times is not the best considering their physical conditions.^{12,23}

About the psychological domain, several studies highlight that the changes transplanted patients undergo (e.g., anxiety, depression, fantasies about the donor, dissatisfaction with body image, sexual disorders, guilt feelings because of the donor's death, etc.) are the single most important cause influencing the HRQOL after a successful transplantation.^{24,25} In our study, we have particularly included two domains within the psychological area («vitality» and «mental health»), and we observed the same progression in both of them: in the long-term, the patients improve considerably, with the most remarkable differences being observed between the pre-transplantation phase and the period of 6 months post-transplantation. After the transplant, the patients particularly experience a high energy level that is expressed as the feeling of being full of life and with no exhaustion or tiredness («vitality»). Besides, they feel less and less nervous, calmer and quieter, with less discouragement and depression, overall more happy («mental health»). With no doubt, making the acquaintance of other people in the same situation, after the transplant, either through associations or at the hospital itself, contributes to this and relieves the patients since they talk about emergent problems and how to cope with them, which diminishes the patient's uncertain-

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ties before the unknown. Moreover, all the disturbing feelings and emotions that the patients had while they were on the waiting list vanish; among others, we should point out anger («why this occurred precisely to me?»), anxiety («for how long will I live if there is no donor?»), and guilt («if I were lived in another way», «If I had better taken care of myself»).²⁶ This positive progression is reflected in the subjective perception that the patients have about their own health status («current health»), which experiences a long-term improvement, the most remarkable differences being observed between the pre- and post-transplantation phases (at three and six months); the current health status at these two latter moments is fairly good, and remains stable thereafter.

As conclusions, in all the dimensions that were significant (but in the variable «side effects from corticosteroids»), the patients experience an improvement after the transplant when the pre- and post-transplantation phases are compared. In general terms, in this latter phase, there is a progressive improvement as time goes by (three, six and twelve months), reaching a point at which HRQOL stabilizes in most of the domains. That is to say, in the long term, the patients get adapted to all the circumstances derived from the transplant: they get used to the prescriptions, they get integrated in their social and working environment, they no longer fear organ rejection, and they find more support from their families since this one is also more psychologically recovered from the emotional impact imposed by the transplant (for example, fear to patient's death, worry about whether the graft works or not, etc.).²⁷

Finally, we should highlight that although as time goes by HRQOL in transplanted patients improves, therapeutic intervention programs should meet the psychological demands posed by these patients during the transplantation process in order to help them at any time to adaptively cope with this situation, in both the patients and their relatives.

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