***Transplantologiya*. 2017;9(3):236-241.**

DOI:10.23873/2074-0506-2017-9-3-236-241

Evaluation of patient's life quality after simultaneous pancreas and kidney transplantation

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Received: 25 May 2017

Introduction: *the use of standardized questionnaires for assessment of patients' life quality after organ transplan-tation has not been widely used in our country.*

Purpose: *The assessment of patients' quality of life after the simultaneous pancreas & kidney transplantation using the SF-36 questionnaire.*

Material and methods: *35 patients with type I diabetes mellitus (DM1) complicated by end-stage chronic renal failure were investigated. There were 16 women (45.7%) and 19 men (54.3%). The median age was 36 [33;45] years. The patients were divided into 2 groups depending on the transplantation type: group I included the patients who underwent isolated kidney transplantation, group II included those after simultaneous kidney and pancreas transplantation. Patients' life quality was estimated using the SF-36 questionnaire.*

Results: *Patients in group II had significantly better physical functions, general health status, and vital activity.*

Conclusion: *Simultaneous pancreas & kidney transplantation considerably improves the life quality of patients with DM1.*

Keywords: Type I diabetes mellitus, quality of life, simultaneous pancreas & kidney transplantation, kidney transplantation

Zagorodnikova N.V., Storozhev R.V., Anisimov Yu.A., et al. Evaluation of patient's life quality after simultaneous pancreas and kidney transplantation. *Transplantologiya*. 2017;9(3):236–241. (In Russian). DOI:10.23873/2074-0506-2017-9-3-236-241

Introduction

Recently, a significant improvement has been seen in the results of organ transplantation thanks to many-year activities on refining the surgical technique, the implementation of modern immunosuppressive, antibacterial and antiviral drugs, the development of diagnostic and therapeutic algorithms for various surgical and immunological complications. Transplantation of the heart, lungs, and liver belongs to the category of life-saving surgery. In contrast, the kidney and(or) pancreas transplantation (PT) refers to the category of surgery that improves the quality of life (QoL). The concept of QoL has been widely used in assessing the treatment efficacy and is characterized by a number of physiological and psychoemotional parameters based on patient's subjective perception. Despite the multi-facet nature of the concept and the differences in its definitions, it reflects the impact of the disease and the effect of its treatment on the patient's physical, emotional, and social well-being [10, 11].

A large number of standardized questionnaires have been developed so far to assess the QoL. SF36 Health Status Survey is the most common general questionnaire to study QoL in population and in various somatic

diseases, which makes it possible to assess the patients' satisfaction with their level of functioning in conditions of the disease [12]. In our country, this approach has not been widely adopted, and the experience of applying the SF36 Health Status Survey is relatively small.

The purpose of this study was to evaluate the effect of simultaneous pancreas and kidney transplantaion (SPK Tx) compared to that of isolated kidney transplantation on the quality of life of patients with type 1 diabetes mellitus (DM1) with end-stage chronic kidney disease (CKD).

Material and methods

Recipients

The study included 35 patients with diabetes mellitus complicated by end-stage CKD who underwent organ transplantation in N.V. Sklifosovsky Clinical and Research Institute for Emergency Medicine in the period from June 2008 to December 2014. There were 16 women (45.7%) and 19 men (54.3%) (Table.1). The age of the patients varied from 25 to 55 years, the

Table 1. General characteristics of patients

Men, n (%)	19 (54.3%)
Women, n (%)	16 (45.7%)
Age, years	36 (33; 45)
BMI, kg/m^2	20.7 (19.4: 23.5)
Diabetes history, years	23 (20.30)
Period on renal replacement therapy, months	4 (1.5, 16)
Type of renal replacement therapy hemodialysis peritoneal dialysis	 19 (54.3%) 12 (34.3%)

median age being 36 (33; 45) years old. The mean Body Mass Index (BMI) in the patients was 20.7 (19.4:23.5) kg/m^2. The BMI made from 16 to 18.5 in 4 patients (11.4%), from 18.5 to 25 in 26 (74.3%), from 25 to 30 in 3 (8.5%); 1 patient (2.9%) had Class I obesity and another one had Class II obesity. The history of the disease by the time of transplantation had ranged from 11 to 42 years, the median was 23 (20; 30) years. Renal replacement therapy had been administered to 31 patients (88.6%), including the programmed hemodialysis in 19 patients (54.3%), and the out-patient programmed peritoneal dialysis in 12 (34.3%). The period of renal replacement therapy ranged from 1 to 109 months, the median period was 4 (1.5, 16) months. Transplantation before the initiation of renal replacement therapy by using dialysis techniques appeared feasible to be performed in 4 patients (11.4%). Among patients enrolled in the study, there were 11 (31.4%) with O (I) blood group, 13 (37.1%) with A (II) blood group, 10 (28.6%) having B (III) blood group, and 1 (2,9%) having AB (IV) blood groop.

Donors

Among donors there were 30 men (85.7%), and 5 women (14.3%). The age of donors ranged from 18 to 60 years, the median age was 29 (25; 37) years. The organs were mostly obtained from brain-dead donors (n = 29, 82.9%); the organs were retreived in the process of multi-organ harvesting.

Transplantation

The median mismatch in the donor-recipient pairs for HLA-A, HLA-B, and HLA-Dr antigens was 1 (1; 2), 2 (1; 2), and 2 (1; 2) antigens,

respectively. The median duration of donor organ preservation was 8 (6; 10) hours for a kidney allograft, and 9.8 (9; 10.5) hours for a pancreas allograft.

Immunosuppressive therapy

Patients received a three-component immunosuppressive therapy. The main component used in immunosuppressive therapy was tacrolimus in 26 patients (74.3%), or cyclosporine in 9 (25.7%). As an induction, the interleukin-2 inhibitor basiliximab was used in 31 (88.6%) patients, and polyclonal antilymphocytic antibodies in 4 (11.4%) patients.

All the recipients were divided into two groups regarding the extent and type of the surgical intervention: Group I consisted of patients who underwent an isolated kidney transplantation, Group II comprised the patients who underwent SPK Tx.

In Group I, there were 6 men (50%) and 6 women (50%). Their age varied from 25 to 51 years, the median age being 45 (35; 50) years. Their mean BMI was 21.8 (20; 24.27) kg/m^2, including no patients with BMI of 16 to 18.5, 10 (83.4%) patients with BMI in the range from 18.5 to 25, 1 patient (8.3%) with BMI in the range from 25 to 30; one patient (8.3%) had Class I obesity with BMI = 30.8. The history of the disease at the time of transplantation ranged from 18 to 42 years (the median 23 [21; 27.7] years). Eleven patients (91.7%) had received the renal replacement therapy including the programmed hemodialysis (7 patients [58.3%]), and the out-patient programmed peritoneal dialysis (4 patients [33.44%]); one patient (8.3%) underwent transplantation before the initiation of renal replacement therapy (pre-dialysis transplantation). The period of renal replacement therapy varied from 4 to 90 months (the median 10.5 [5.5, 37] months). In Group I, there were 2 patients (16.7%) with O (I) blood group, 6 (50%) with

A (II) blood group, 3 (25%) patients having B (III) blood group, and 1 (8.3%) having AB (IV) blood type.

Group II comprised 13 men (56.5%) and 10 women (43.5%). The patients' age varied from 33 to 55 years (the median age was 34 [31; 39] years). The mean BMI of patients was 20.7 (19.4, 22.4) kg/m^2, including 4 patients (17.4%) with BMI from 16 to 18.5, 16 (69.6%) having BMI from 18.5 to 25, 2 (8.7%) with BMI from 25 to 30; and 1 patient (4.3%) had Class II obesity with BMI of 36. The history of the disease by the time of transplantation had ranged from 11 to 35 years, the median was 22 (19; 30) years. Twenty patients (87%) had received the renal replacement therapy, including the programmed hemodialysis (12 patients [52%], or the out-patient programmed peritoneal dialysis (8 pateints [35%]); and 3 (13%) patients underwent a pre-dialysis transplantation. The duration of the renal replacement therapy ranged from 1 to 109 months, the median was 2 (1; 10) months. In Group II, there were 9 patients (39%) with O (I) blood group, 7 (30.5%) with A (II) blood group, 7 (30.5%) with B (III) blood group; none of the recipients in that Group had AB (IV) blood type.

Patients' characteristics for Groups I and II are presented in Table. 2.

There were no statistically significant differences between the groups in terms of gender, age, BMI, and the diabetes history at the time of transplantation. The period of renal replacement therapy received by patients of Group II was significantly shorter compared to group I.

Table 2. Characteristics of patients in Groups I and II

	CRAT, n = 12	SPK Tx, n = 23	Statistical significance of differences, p-value
Men, n (%)	6 (50%)	13 (43.5%)	0.64
Women, n (%)	6 (50%)	10 (56.5%)	0.64
Age, years	45 (35, 50)	34 (31; 39)	0.006
BMI, kg/m ^{2}	21.8 (20; 24.27)	20.7 (19.4, 22.4)	1.0
Diabetes history, years	23 (21; 27.5)	22 (19; 30)	0.6
Period on renal replacement therapy, months	10.5 (5.5, 37)	2 (1; 10)	0,017
Type of renal replacement therapy			
hemodialysis	7 (58.3%)	12 (52%)	0.85
peritoneal dialysis	4 (33.44%)	8 (35%)	0.95

CRAT: Cadaveric kidney allotransplantation

The QoL in the study pateints was assessed using the SF-36 Health Status Survey (SF-36) that is a 36 item questionnaire which measures QoL across eight domains:

1. Physical Functioning (PF) that reflects the ability to withstand physical exertion.

2. Physical Role Functioning (PRF) reflects role limitations in daily activities due to physical health.

3. Bodily Pain (BP) and its impact on daily activities.

4. General Health (GH) assessment reflects the patient's current health perceptions and treatment-related expectations.

5. Vitality (VT) implies general activity, vigor.

6. Social Role Functioning (SRF) characterizes the limitations in social functioning due to physical health and emotional problems.

7. Emotional role functioning (ERF) characterizes role limitations in daily activities due to emotional problems.

8. Mental Health (MH) characterizes the mood, the presence of depression, anxiety, and a general indicator of emotional well-being.

The patient's physical health is assessed by scoring the items in the domains from 1 to 4, the mental state is assessed by scoring the items in the domains from 5 to 8. The questionnaire allows each item to be scored on a scale in the range from 0 to 100, where higher scores correspond to a better QoL, and a score of 100 represents the highest level of functioning possible. The QoL was assessed in all patients at 3 years after organ transplantation.

Statistical data processing was made using the software package Statistica for Windows v. 10.0, StatSoft Inc. (USA). The Shapiro-Wilk test was used to check the normality of the distribution,. When comparing the groups by qualitative variables, the Pierson chi-square (χ^2) test was used, and the one-sided exact Fisher test was used for binary qualitative data. The Mann-Whitney test was used to compare the two groups by quantitative variables. The differences were considered statistically significant at $p<0.05$.

The study results and their discussion

The mean QoL data of the post-transplant patients assessed using the SF36 questionnaire are presented in Table. 3.

Table 3. Quality of life domains for the patients after organ transplantation

QoL	Group I	Group II	Statistical significance of differences, p
Physical Functioning	64 ± 26	85.4 ± 14	**0.011**
Physical Role Functioning	68.7 ± 44	72.9 ± 32	0.96
Bodily Pain	83.8 ± 28.8	86 ± 21.9	0.85
General Health	44 ± 25	60 ± 19	**0.05**
Vitality	54.6 ± 22.7	73 ± 14.8	**0.015**
Social Role Functioning	74 ± 30.7	82.8 ± 18.7	0.49
Emotional Role Functioning	69.4 ± 46	91.6 ± 22.5	0.18
Mental Health	63.3 ± 20.5	71 ± 19.7	0.28

When comparing the QoL data in the patients of two groups, we found that the scores in all the items (physical, role, social, and emotional functioning, bodily pain and general health perceptions, vitality and mental health) were higher in the patients who underwent SPK Tx. However, the statistically significant differences could be seen in three scored items: physical functioning, general health, and vitality.

The physical functioning in patients after SPK Tx was scored as 85.4 that corresponded to the data of practically healthy people and indicated that the patients experienced no significant limitations in physical health functioning (self-care, walking, climbing the stairs, carrying heavy objects, etc.). The patients after SPK Tx considered themselves to be full of vital activity and strength, assessed their physical health status and further treatment prospects higher than the patients after isolated kidney transplantation.

The SF36 Health Status Survey made it possible to assess the main components of the physical and mental health of the patients after organ transplantation and confirm that QoL in patients SPK Tx was significantly better than in the recipients who underwent isolated kidney transplantation. SPK Tx is a method of choice in the treatment of patients with type I diabetes mellitus complicated by end-stage diabetic nephropathy; SPK Tx facilitates the further maximum possible physical and social rehabilitation of this patient population and thereby a significant improvement in their QoL.

Conclusions

1. SF36 Health Status Survey can be used to assess the QoL of patients after isolated kidney transplantation and simultaneoous pancreas and kidney transplantation because it is the most common questionnaire for the QoL assessment in this patient population, and in various somatic diseases,as well. It helps to evaluate patient's satisfaction with the level of functioning in conditions of the disease, and fully reaches the objectives of this study.

2. The QoL of the patients who underwent simultaneous pancreas and kidney transplantation is higher than that of the patients who underwent isolated kidney transplantation as reflected by the scores assessing physical functioning, general health status, and vital activity ($p = 0.011$, $p = 0.05$ and $p = 0.015$, respectively) .

3. Simultaneous pancreas and kidney transplantation is the method of choice in the treatment of patients with type 1 diabetes mellitus complicated by end-stage diabetic nephropathy because using this technique results in their quality of life improvement.

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